Service readiness for inpatient care of small and sick newborns: Improving measurement in low- and middle-income settings

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Declaration of own work

I, Sarah Moxon, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signed: Sarah Moxon .... Date: 2nd February 2020 ....

Abstract

Background: In 2018, 2.5 million newborns died; mainly from prematurity, infections, and intrapartum events. Preventing these deaths requires health systems to provide routine and emergency care at birth, and quality inpatient care for small and sick newborns. Despite high potential impact, inpatient newborn care is not consistently measured.

Methods: For this PhD, I conducted a bottleneck analysis using data from 12 national workshops regarding delivery of inpatient newborn care in low- and middle-income countries (LMIC). Using WHO guidelines, grey literature and expert consultation, I mapped the components required to deliver inpatient care and reviewed these against three health facility assessment tools. Finally, I carried out an online survey to elicit global practitioner opinions regarding levels of newborn care, paralleling those used for monitoring emergency obstetric care in LMIC.

Results: In 12 high-burden countries in sub-Saharan Africa and Asia, health financing and workforce were identified as the greatest bottlenecks to scaling up quality inpatient care, followed by community ownership. My review identified 654 components required to deliver inpatient care. These are inconsistently measured by existing health facility assessments. The 262 survey respondents agreed on 12 interventions to comprise a package of care for small and sick newborns; selected levels of care varied by clinical background and experience in LMIC.

Conclusion: Inpatient newborn care faces multiple health system challenges, particularly to ensure funding and skilled staffing. Standard facility numbers and staffing ratios by defined levels of care are important for countries to benchmark service delivery progress. Due to the large number of components required for delivering quality care, newborn "signal functions" could be selected by level of care to parallel emergency obstetric care indicators. Improved measurement of service readiness requires sustained focus on interoperability of routine measurement systems, and further research to better capture the experience of newborn inpatient care for families.

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Abbreviations

ACS	Antenatal corticosteroids
AMDD	Averting Maternal Death and Disability
ANC	Antenatal care
ARR	Annual rate of reduction
BEmOC	Basic Emergency Obstetric Care
BFHI	Baby Friendly Hospital Initiative
CEmOC	Comprehensive Emergency Obstetric Care
CD	Countdown
CHX	Chlorhexidine
COIA	Commission for Information and Accountability
CPAP	Continuous Positive Airway Pressure
CRVS	Civil registration and vital statistics
DALY	Disability Adjusted Life Years
DHS	Demographic and Health Surveys
DHIS-2	District Health Information System-2
DRC	Democratic Republic of the Congo
EMEN	Every Mother Every Newborn
ENAP	Every Newborn Action Plan
EmOC	Emergency Obstetric Care
EmONC	Emergency Obstetric and Newborn Care
EPMM	Ending Preventable Maternal Mortality
GA	Gestational age
HBB	Helping Babies Breathe
HIC	High-income countries
HFA	Health Facility Assessment
HMIS	Health management information systems
HR	Human resources
ICD	International Classification of Disease
IMCI	Integrated Management of Childhood Illnesses
IUGR	Intrauterine growth restriction
KMC	Kangaroo mother care
LBW	Low birthweight
LMIC	Low- and middle-income country
LMIS	Logistics management information system
LMP	Last menstrual period
LSHTM	London School of Hygiene and Tropical Medicine
MDSR	Maternal Death Surveillance and Response
MICS	Multiple Indicator Cluster Surveys
MMR	Maternal mortality ratio
MNCH	Maternal newborn and child health
MNH	Maternal and newborn health
MDG	Millennium Development Goals
NICU	Neonatal intensive care unit
NMR	Neonatal Mortality Rate
PMTCT	Prevention of mother to child transmission

PNC	Postnatal care
PROM	Premature rupture of membranes
PSBI	Possible serious bacterial infection
QoC	Quality of care
RDS	Respiratory distress syndrome
R-HFA	Rapid Health Facility Assessments
RMNCH	Reproductive, maternal, newborn and child health
ROP	Retinopathy of prematurity
SARA	Service availability and readiness assessments
SBA	Skilled birth attendance (previously skilled birth attendant)
SBR	Stillbirth rate
SCBU	Special care baby unit
SDG	Sustainable development goals
SGA	Small for gestational age
SoWC	State of World's Children
SPA	Service provision assessment
UHC	Universal Health Coverage
UN	United Nations
UNCoLSC	United Nations Commission on Life Saving Commodities
UNFPA	United Nations Population Fund
UN-IGME	United Nations Inter-Agency Group for Child Mortality Estimation
UNICEF	United nations international children's emergency fund
USAID	United States Agency of International Development
VR	Vital Registration
WHO	World Health Organization

Chapter 1. Introduction

In 2018, an estimated 2.5 million babies died during their first 28 days after birth[1](1). The main causes of death included direct complications of prematurity (35%), infections (23%), and intrapartum complications leading to birth injury (24%) (1-3). Most of these deaths occurred in low- and middle-income countries (LMIC). Many lives could be saved – and morbidity prevented – through a health systems approach (4), with identification of those at high risk and timely provision of quality inpatient care (5, 6).

All mothers and newborns require quality care at birth, with emergency obstetric and newborn care for those that need it. Routine newborn care (providing cleanliness, thermal care and support for breastfeeding) is essential for all babies, while timely resuscitation may additionally be required for up to 10% of babies at birth (7, 8). These packages of care are already well described in implementation guidelines and integrated into global and national monitoring systems.

Many low birth weight (LBW) newborns, which include both preterm infants, and those born small for gestational age, along with essential newborn care, will require additional support to feed and to maintain their temperature. In addition, preterm newborns face increased risks of respiratory problems, infections, and jaundice (9, 10). Even amongst those born at full term, significant numbers of newborns face complications including, systemic infections, neonatal encephalopathy, severe jaundice, and congenital disorders, with high mortality risk in the absence of care. Many of these babies will require inpatient (facility-based) care for them to survive and to minimise chances of developing future morbidities and/or long-term disability.

For this PhD, "small and sick newborns" refers to all newborn babies who are 1) preterm and/or LBW and/or 2) face life threatening illness and require inpatient care to survive. The care that small and sick newborns require is not a single intervention, but a package made up of multiple interventions, including ongoing provision of warmth, hygiene, nutrition, respiratory support, and detection and management of complications, such as infections and jaundice. Unlike other packages along the care continuum, such as emergency obstetric care and essential newborn care, inpatient care of small and sick newborns is not currently routinely defined and tracked as part of LMIC monitoring systems.

In LMIC, access and availability of quality inpatient care for small and sick newborns remains a major challenge. Providing such services requires significant health system capacity and the associated monitoring systems to identify gaps in access, availability, coverage and quality of care. For health

[1] UN-IGME updates estimates of child mortality each year. Throughout the life course of this PhD, estimated newborn deaths have reduced from 2.8 million in 2014 to 2.5 million in 2018 (the most recent estimates are from 2018). In earlier published material, earlier mortality estimates may have been used.

system planning and accountability purposes, there is a need to improve dimensions of measurement of inpatient care for small and sick newborns, starting with service readiness.

At the start of the Sustainable Development Goal (SDG) era, the WHO envisions a world where every pregnant woman and newborn receives quality care throughout pregnancy, childbirth and the postnatal period (11). These sentiments are echoed in the *Every Newborn* Action Plan (ENAP) (6) and Ending Preventable Maternal Mortality (EPMM) (12). *Every Newborn* was launched in 2014, followed by EPMM in 2015; both aim to achieve equitable and high-quality coverage of care for all women and newborns through links with other global and national plans, and measurement and accountability frameworks (6, 13). The next phase from 2016-2030 described in the Global Strategy for Women's Children's and Adolescent's health, should target multiple dimensions of quality of care to further reduce the burden of not just preventable mortality, but morbidity into the (SDG) era so that newborns not only survive, but go on to thrive (14). Such a vision cannot be achieved without a focus on the continuum of care for mothers and newborns, and importantly including inpatient care for small and sick newborns, which has to date been overlooked.

1.1 Aims and objectives

The overall aim of this PhD is to identify the challenges to delivering inpatient care in LMIC health systems, describe the health system components required to deliver inpatient care, and explore how measurement of service readiness for inpatient care can be integrated into existing maternal and newborn measurement systems. The thesis will use both a conceptual and practical approach to consider health systems and measurement frameworks and tools. Learning from this work is intended to help inform the refinement of existing measurement tools. In addition, it aims to contribute to the development of new approaches such that LMIC can systematically track readiness to deliver quality inpatient care services for small and sick newborns.

This overall aim will be addressed by five key objectives, covering two main themes;

Theme A: Delivering quality inpatient care services for small and sick newborns

This theme identifies the health system structures and challenges to delivering quality inpatient care for small and sick newborns

Theme B: Measurement of service readiness for care of small and sick newborns

This theme explores how measuring service readiness for small and sick newborn can be integrated into existing and evolving measurement systems.

Theme A

Objective 1: To describe the package of inpatient care for small and sick newborns and determine the existing health system challenges impeding scale up in 12 high burden countries by health system building block

Objective 2: To create a standardised matrix of the structural components required to deliver inpatient care for small and sick newborns

Theme B

Objective 3: To review the capacity of existing health facility assessment tools to capture service readiness for small and sick newborns

Objective 4: Carry out and analyse a global survey to elicit expert opinion on a list of newborn interventions to different levels of care to determine newborn signal functions

Theme A and B

Objective 5: To synthesis and evaluate overall findings in the context of existing and evolving measurement systems.

Table 1.1 Summary of research themes and objectives by PhD chapter

Research themes & questions	Chapter number and title		Objective	Sub-objectives	Methods	Paper
	1	**Introduction**				
		Aims and objectives of PhD thesis				
	2	**Background**		Epidemiology and existing literature		
	3	**A measurement improvement roadmap**	To provide context for the research thesis and background of the *Every Newborn* Action Plan metrics work	-Describe the systematic process used to select ENAP indicators -Assess the status of the ENAP indicators -Describe the process for the five-year measurement improvement roadmap		Count every newborn: a measurement improvement roadmap (15) BMC Pregnancy and Childbirth
Theme A: Delivering quality inpatient care services for small and sick newborns What are the structures and challenges to delivering quality inpatient care for small and sick newborns?	4	**Inpatient care of small and sick newborns and the health system**	Objective 1: To describe the package of inpatient care for small and sick newborns and determine the existing health system challenges impeding scale up in 12 high burden countries	1.1 Describe the package of inpatient care for small and sick newborns 1.2 Analyse graded health system bottlenecks 1.2 Conduct thematic analysis of qualitative data on health system challenges and solutions 1.3. Conduct a literature review of evidence for proposed solutions 1.4. Link findings to literature review	Bottleneck analysis Thematic analysis Literature review	Inpatient care for small and sick newborns: Health system bottlenecks and potential solutions (16) BMC Pregnancy and Childbirth
	5	**Service readiness structures and domains for inpatient care of**	Objective 2: Create a standardised matrix of the structural components required	2.1 Review existing global guidelines for content relevant to inpatient care for small and sick newborns	Grey literature review	

		small and sick newborns	to deliver inpatient care for small and sick newborns	2.2 Construct a standardised service readiness matrix organised by health system domain (infrastructure, equipment, drugs, providers and guidelines) 2.3 Populate the matrix with structural components relevant to inpatient care		Service readiness for inpatient care of small and sick newborns: What do we need and what can we measure now? (17) Journal of Global Health Paper published and has been split into two chapters
Theme B: Measurement of service readiness for care of small and sick newborns How can we integrate small and sick newborn service readiness measurement into existing and evolving maternal and newborn measurement systems?	**6**	**Existing tools to measure service readiness for inpatient care of small and sick newborns: What can we measure now?**	Objective 3: To review the capacity of existing health facility assessment tools to capture service readiness for small and sick newborns	3.1 Compare standardised service readiness matrix against what is currently measured by multi-country health facility survey tools (SPA, SARA, EmONC assessment) and identify gaps in measurement of the structural and process domains 3.2 Synthesise these findings to provide recommendations on how to improve measurement of service readiness for inpatient care of small and sick newborns	Review of tools	
	7	**Categorising interventions to levels of inpatient care for small and sick newborns: findings from a global survey**	Objective 4: Identify potential signal functions and levels of care for small and sick newborns to parallel existing obstetric signal functions	4.1 Carry out a global survey to elicit expert opinion on which newborn clinical services are feasible to provide at different levels of care in LMICs 4.2 Identify variation between respondent groups 4.3 Discuss findings in the context of existing EmONC signal functions and levels of care.	Analysis of global survey	Categorising interventions to levels of inpatient care for small and sick newborns: findings from a global survey (18) PLoS One
	8	**Application of overall findings to measurement of service readiness for small and sick newborns**	Objective 5: To synthesis and evaluate overall findings in the context of existing and evolving measurement systems	5.1 Synthesise the overall findings and discuss results across objectives 5.3 Discuss combined implications for newborn measurement and integration into maternal newborn measurement systems 5.4 Discuss implications of findings for policy, programmes and future research		
		Conclusions		Final interpretation of findings and implications		

1.2 Outline of thesis

This thesis is a hybrid of chapters and research papers. There are four published research papers; one presented as a background chapter and three as results chapters. One of the published papers is split over two results chapters as it addressed two distinct objectives.

This first chapter introduces the thesis, outlines the overall aim and objectives and the research questions and themes. There is no unifying methods chapter because the study design and methods used to address each objective differ. Detailed methods for each study are presented in individual chapters to avoid repetition.

Chapter 2 is the background to the research thesis. To provide context, it presents existing epidemiological data on small and sick newborns and delineates some of the terminologies and definitions used in the thesis. It describes the importance of service readiness as a prerequisite for quality of care, what we know about measuring service readiness and how it complements other areas of measurement for maternal and newborn health.

Chapter 3 presents the first of the four papers titled "Count Every Newborn: a measurement improvement roadmap" (15). The chapter provides an introductory description of how the research in this thesis fits into the broader *Every Newborn* measurement improvement roadmap by addressing an identified research need. This paper articulates the global *Every Newborn* metrics project and the details of the *Every Newborn* measurement improvement roadmap.

Chapter 4 presents the second published research paper titled "Inpatient care of small and sick newborns: a multi-country analysis of health system bottlenecks and potential solutions" (16). This paper addresses objective one of the PhD thesis. Firstly, it describes the package of inpatient care for small and sick newborns within the context of the health system. Using the WHO health system building blocks as a framework, this paper assesses the existing health system challenges impeding the scale up of inpatient care for small and sick newborns in 12 high burden countries using secondary data collected with a "bottleneck" analysis tool. This paper uses quantitative and qualitative methods to analyse the data, combined with literature review.

Chapters 5 and 6 present the third published research paper entitled "Service readiness for inpatient care of small and sick newborns: What do we need and what can we measure now?" (17) The paper is split into two chapters for this thesis as it addresses two different thesis objectives.

Chapter 5 presents the results of a grey literature review of existing international guidelines and resources on inpatient care of small and sick newborns. To address objective two of this PhD, it applies the Donabedian framework (19) as a construct to create and populate a matrix of the service readiness structural components (infrastructure, equipment, drugs, providers and guidelines) required to deliver a package of inpatient care interventions for small and sick newborns.

Chapter 6 presents part of the same published research paper (17) to address the fourth objective of this thesis. It reviews the matrix presented in chapter 5 against three multi-country health facility survey tools to determine gaps in these existing measurement tools to capture service readiness for inpatient care of small and sick newborns.

Chapter 7 presents the final published research paper titled "Categorising interventions to levels of inpatient care for small and sick newborns: Findings from a global survey"(18). It addresses the fifth objective of the thesis that identifies potential signal functions and levels of care for small and sick newborns to parallel existing obstetric signal functions. The paper presents the results of a quantitative analysis of a global survey on signal functions and levels of inpatient care for small and sick newborns. It discusses findings from the survey in the context of existing EmONC signal functions and levels of care.

Finally, Chapter 8 synthesises the main findings and discusses internal consistency of the results and their combined implications for measurement of small and sick newborn care within existing and evolving measurement systems. This chapter also discusses future policy, programme and research priorities for this topic, and puts the focus back into the context of the broader agenda for newborn health and measurement of quality of care in the SDG era.

1.3 Role of candidate in *Every Newborn* metrics project

I developed the idea for this PhD research during and following an *Every Newborn* Action Plan metrics workshop hosted by WHO in Ferney-Voltaire. The idea for the PhD research was conceived with my supervisor, Joy Lawn and co-supervisor Hannah Blencowe as part of the *Every Newborn* metrics project. Initially, I took the lead role in a task team to develop metrics for kangaroo mother care (KMC) and then began the analysis of bottleneck data on inpatient care of small and sick newborns, which led to development of the research on service readiness. Thereon, I took the lead in the CIFF funded *Every Newborn* metrics team in developing the research and technical side of the workstream on care for small and sick newborns and service readiness. All work was carried out from my base at the LSHTM with additional travel to conferences and workshops. A summary of my contribution to each research activity and element included in this thesis is provided in Appendix A.

1.4 Ethics

Permissions for the national consultations for the bottleneck analyses for chapter 4 was granted to UNICEF by national Ministries of Health; the tools were then utilised in a series of national consultations supported by the *Every Newborn* Steering Group between July 1st and December 31st, 2013. Where required, ethics for other work for this thesis was obtained from the London School of Hygiene and Tropical Medicine (LSHTM) ethics committee and is described in further detail in individual chapters.

1.5 Funding

This research was carried out as part of a full-time research fellow role at LSHTM from 2014 to 2019; most of this time was funded by Children's Investment Fund Foundation (CIFF) through a grant entitled "Transforming Newborn Measurement". Save the Children's Saving Newborn Lives Project provided funding for initial background work. The bottleneck data collection in countries was funded by the Bill & Melinda Gates Foundation through a grant to the US Fund for UNICEF (Grant ID: OPP OPP1094117). Additional funding for the bottleneck analysis was received from USAID (Grant ID GHA-G-00-07-00007) through UNICEF. Work for the service readiness matrix and some of the time for the work on the global survey were funded by Save the Children's Saving Newborn Lives programme.

Chapter 2. Background

At the end of the Millennium Development Goals (MDGs) the global health community celebrated 21 million extra lives saved between 2000-2015 (20). Survival gains were especially apparent for children, in part thanks to collective investment in immunisation and preventive disease-specific focused community programmes and reductions in deaths from HIV/AIDS, malaria, and tuberculosis (21-23). Despite a doubling of donor funding to reproductive, maternal, newborn and child health (RMNCH) programmes (24), progress for maternal and newborn survival was much slower, and newborn deaths saw the smallest proportional declines. For children aged 1-59 months, there was a 3.4% average annual rate of reduction (ARR) in mortality between 1990-2012 compared to an ARR of only 2.0% for newborns (21). Deaths in the newborn period (the first 28 days of life) emerged as nearly half (44%) of all the under-five deaths globally (20, 21, 25).

According to recent estimates, 2.5 million neonatal deaths occurred in 2018 (1); the majority (97%) of deaths were in lower-middle incomes countries with 75% of these in sub-Saharan Africa and South Asia (21). Ten countries, all LMIC, accounted for around two-thirds of all neonatal deaths globally, and three countries (India, Pakistan and Nigeria) accounted for almost half of all neonatal deaths worldwide (21). Estimates of the burden of neonatal morbidities also drew attention to 19 million newborns annually facing life-threatening conditions who require specific care and who are at high risk of long-term disabilities and poor health outcomes (21, 26). Disability following neonatal conditions is high, with rising numbers of disability in middle-income countries where rates of disability are nearly double those in high-income countries (21, 27).

The SDG era saw in a shift in global health focus beyond survival alone and towards thriving, including human capital and well-being (28). Recognition that most of the death and disability that occurs due to newborn conditions occurs in LMIC and are preventable with known intervention packages prompted international action. At the 67th World Health Assembly in 2014, the ENAP was endorsed and launched, setting targets of ≤12 neonatal deaths per 1000 live births and ≤12 stillbirths per 1000 total births by 2030 with eight specific milestones set at global and country level to 2020, many of which focused on measurement improvement (6). The *Every Newborn* impact framework (21), brought *"Every Newborn"* into the "*Every Woman, Every Child*" concept, broadening its goals to include ending preventable stillbirths and deaths for women, newborns and children, as well as improving child development and human capital.

The *Every Newborn* Action Plan together with the *Strategy for Ending Preventable Maternal Mortality* (EPMM) provide a strong investment case for women's and children's health with clear actions and goals for maternal and newborn health post-2015 (6, 12). Effective intervention packages for improving the survival and health of newborns form one component of integrated health services for reproductive, maternal, newborn, child and adolescent health (RMNCH).

2.1 Situating inpatient care of small and sick newborns within the continuum of care for reproductive, maternal, newborn and child health

The continuum of care for RMNCH, as shown in Figure 2.1, includes the main intervention packages for women and newborns during pregnancy and around the time of birth: 1) integrated pregnancy care (antenatal care) 2) quality care at birth, including emergency obstetric care and management of preterm labour (and prompt newborn resuscitation if needed) 3) essential newborn care and postnatal care for women and babies, including inpatient care for small and sick newborns. At each stage of the continuum, there is opportunity for identification of high risk and associated interventions to improve survival and longer-term outcomes (23). Inpatient care of small and sick newborns is highlighted in bold in the continuum of care shown in Figure 2.1 to situate it within the continuum of care for RMNCH.

Figure 2.1 Situating inpatient care for small and sick newborns within the continuum of care for reproductive, maternal, newborn and child health

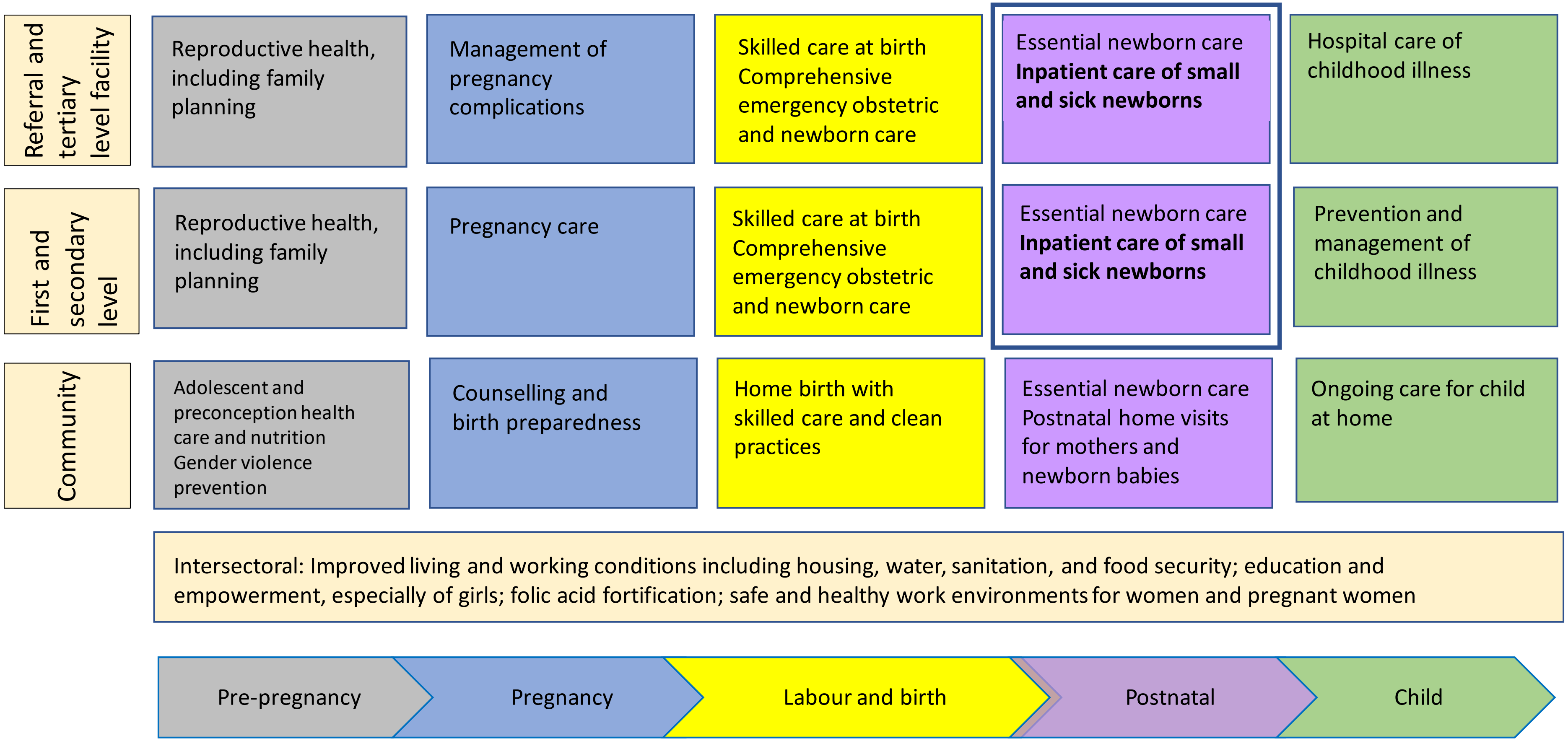


Figure adapted from Mason et al (2014): From evidence to action to deliver a healthy start for the next generation (23)

In the 2015 *Every Newborn* Lancet series, it was estimated that high coverage of currently available interventions along the continuum of care have the potential to save 3 million lives per year by 2025, which would include 162,000 women, 816,000 stillbirths, and 1.95 million newborn babies (4). Inpatient care for small and sick newborns was identified in this research as an intervention package for which high quality coverage could have some of the highest potential impact on newborn deaths, especially in LMIC where the greatest proportion and numbers of deaths occur (21, 23, 25). For example, care of small and sick newborns could avert over half a million (580,000) estimated newborn deaths per year by 2025, besides additional potential impact on disability and long-term well-being (4). Despite this, policy and health system analysis identified care of small and sick newborns as an area of the continuum of care that has been largely overlooked in LMIC health systems (23, 25, 29). Neglect of this package of care may well have been due to a widespread belief that caring for small and sick newborns is either unaffordable or unfeasible in LMIC health systems (25, 29).

In high-income settings, the speciality of neonatology exists as an independent discipline. However this is not the case in many LMIC, and small and sick newborns can be "lost" between obstetric and paediatric services (25). The assumption that general maternal and child care "trickles down" to small and sick newborns without intentional investment and focus has proved to be erroneous, as demonstrated by the most recent epidemiological evidence (21, 23, 25). Skilled nurses or midwives, as well as doctors, are critical for care of small and sick newborns and training in only essential newborn care and resuscitation is insufficient to manage the diverse needs of small and sick newborns (29-31).

The place of care for small and sick newborns also needs to be different. Labour ward care has great potential impact for women and newborns through both routine and emergency care. However, care in the labour ward alone is insufficient for small and sick newborns, who require a separate place of care. It is not sufficient for small and sick newborns to be cared for in postnatal wards or as part of general paediatrics (which is currently typical in many LMIC settings) they require a specific, dedicated space for ongoing inpatient care, usually referred to as a neonatal inpatient care ward or unit. (32).

The lack of focus and attention on inpatient care for small and sick newborns within the care continuum has been a hindrance to scale up in LMIC. Whilst packages of antenatal care, obstetric care and postnatal care have accompanying WHO global guidelines and standards, this is not the case for inpatient care of small and sick newborns. Monitoring systems and available data on the care that small and sick newborns receive are lacking, making programme planning and targeted actions to improve care challenging (15, 29).

2.2 Inpatient care for small and sick newborns: epidemiology and specific conditions

For the purpose of this PhD, "small and sick newborns" refers to all newborn babies who are 1) preterm and/or LBW and/or 2) face life threatening illness and require inpatient care to survive. For this section, the general definitions/terms, aetiology, and epidemiology of the main conditions faced by newborns requiring inpatient care are described using the most recent available estimates. None of the conditions described in this section can be tackled with provision of inpatient care alone. As emphasised in the background, reducing newborn mortality and morbidity requires a health system approach along the continuum of care. This PhD, however, is focused on the inpatient care package. I therefore describe the clinical condition and then the implications for inpatient care for each of these conditions to highlight the large burden that will only be fully addressed with newborn inpatient care.

2.2.1 Small size at birth

Low birth weight (LBW) is an umbrella term for babies born weighing less than 2500g. LBW babies may be preterm or small for gestational age, or both; the degree of overlap between the two varying by setting. Small size at birth is a major risk factor contributing to more than 80% of the neonatal deaths and increasing risk of postnatal mortality (especially infection) and poor growth in childhood (33).

2.2.1.1 Preterm

Preterm birth is defined as all births before 37 completed weeks of gestation (or fewer than 259 days since the mother's last menstruation) (34).

Risk factors for preterm birth are multi-factorial with genetic, social, environmental, and physiological factors playing a role. Preterm birth can be spontaneous, or provider induced. With spontaneous preterm birth, the cause is unknown in up to half of cases (10). Maternal factors contribute to the risk of spontaneous preterm birth including multiple pregnancies, body mass index, ethnic group, young or advanced age, exposure to stress, excessive physical work, or exposure to infections (including malaria, sexually transmitted infections or urinary tract infections) and non-communicable disease (especially pregnancy related diabetes and hypertension) (9, 35-38). Provider-initiated preterm birth for a clinical indication occurs as a result of induced labour or elective caesarean-section (10); these births vary between countries and are affected by the quality of antenatal care and contextual factors, such as rates of caesarean-sections (many for non-clinical indications) (39). Spontaneous preterm birth overall is more common in boys than girls (9).

Preterm births can be subdivided into three categories based on gestational age: late and moderate preterm (32 to <37 weeks), very preterm (28 to <32 weeks) or extremely preterm (<28 weeks) (9, 10). Identifying the gestation of a pregnancy is important to determine whether it is preterm or term, which is informative for individual antenatal, intrapartum care and postnatal newborn care, as well as for health system planning at a population level. However, accurate assessment of gestational age is challenging, especially in lower-income settings where access to first trimester ultrasound (the gold standard for gestational age assessment) is limited (40). Other approaches to gestational age assessment include dating on reported last menstrual period (LMP) or clinical assessment of the newborn at birth. The former is limited by maternal recall and variation of in length of menstrual cycle and recent use of hormonal contraception, and the latter of variable accuracy depending on provider skill and experience in using clinical assessment tools (41). A further challenge is misclassification of extremely preterm births as miscarriages, which may vary between settings dependent on perceptions viability (9). The challenges in accurately assessing gestational age often results in poor and inconsistent reporting and recording at the facility level (9). The quality of data on preterm birth, therefore, is limited by the correct identification and consistent reporting of preterm births (9).

The Global Burden of Disease study found that 3.1% (a total of 77 million) DALYs were attributed to preterm birth (21, 42). National estimates for preterm birth in 2010 were published for 184 countries showing a total of 14.9 million (12.3-18.1 million uncertainty range) preterm births, which equates to 11.1% of all livebirths (10). Estimates suggest that preterm birth rates range from about 5% of live births in European countries to up to 18% in African countries (9). Estimates show that most preterm births occur in the late and moderate preterm bracket (84%), which is important as mortality risk decreases with increasing gestational age. However, even later preterm newborns face significant risk to their health, especially in more poorly resourced settings (9). Complications of prematurity are estimated to be the single largest cause of under-five child deaths overall, and a significant cause of long-term loss of human potential globally (2).

Preterm birth greatly increases a baby's risk of mortality and morbidity due to other causes, especially neonatal infections (43) (See section 2.1.2). Being born preterm is also a major risk factor for longer-term health issues, including neurological conditions (cerebral palsy and learning difficulties), vision and hearing impairment and later non-communicable disease (2, 9). Of 13 million survivors of preterm birth in 2010, 345,000 (uncertainty range 269,000-420,000) were estimated to have moderate of severe neurodevelopmental impairment, and a further 567,400 (uncertainty range 445,000-732,000) estimated to have mild neurodevelopmental impairment (44).

South Asia and sub-Saharan Africa account for an estimated 60% of the world's preterm babies, and over three-quarters of the world's newborn deaths are due to preterm birth complications (9, 10, 27). In settings with more reliable data, trend data suggests that preterm birth rates are increasing; countries with the largest numbers of preterm births include Brazil, the United States, India, and

China. (9). Explanations for this vary between settings, with some countries seeing changing obstetric practices and behaviours: higher maternal age, increasing infertility treatments (leading to higher rates of multiple births), or increases in preterm C-sections (10). In lower-income settings apparent increases in preterm birth rates may also be explained in part by higher rates of reporting with increased awareness of the issue (9, 10). However, there is uncertainty in these national estimates due to the limitations of correctly assessing preterm births, described above.

2.2.1.2 Small for gestational age

Birthweight less than the 10th centile for gestational age gender-specific reference population are referred to as small for gestational age (SGA). SGA babies may be either constitutionally small (in the lower tail of the growth curve) or pathologically growth restricted (or a combination of both) (45).

For SGA babies, maternal stature and weight is an important factor and ethnic group and lower socioeconomic status have also been found to play a role (46). Specific risk factors for intrauterine growth restriction include maternal nutritional status, substance exposure (especially smoking) (47), as well as chronic (asthma, autoimmune) and/or maternal non-communicable disease (pre-eclampsia, hypertension) (48).

The highest rates of SGA occur in South Asia where in 2010, an estimated 45% (uncertainty range 40.0-49.7) of births were estimated to be SGA, compared to a global average of 27% (uncertainty range 24.1-30.5) (45). In South Asian settings, growth restriction accounts for a high proportion of SGA births justifying the frequent use of SGA as a proxy for growth restriction in many such settings (33, 45). SGA babies were found to have nearly twice the risk of neonatal and post neonatal mortality when compared with infants born at an appropriate size for gestational age (≥10% birth weight for gestational age) (33).

Quantifying the burden of SGA is challenging. For the 2010 estimates, US National Centre for Health Statistics data for 1991 was used (based on 313,4879 livebirths) (49). However, it is accepted that adopting a global reference population for birthweight may not be appropriate for all populations (45, 50).

2.2.1.3 Small size and implications for inpatient care

Small babies, whether premature, growth restricted, or both, carry a considerably higher risk of mortality and morbidity in the neonatal period and childhood and are especially vulnerable to hypothermia, difficulty establishing feeding, hypoglycaemia, breathing difficulties (respiratory distress), infections and jaundice. Strategies and interventions that focus on prevention to reduce the numbers of small babies are needed, especially through family planning strategies (birth spacing), treatment of infections (particularly malaria) during pregnancy (51). Nonetheless, rates of preterm births are rising in most settings (9, 10) and the cause of small size at birth is often not known (5). Direct complications of preterm birth, especially due to respiratory problems is the leading cause of death in all settings globally (2). In high income settings, the majority of the newborn deaths now occur in a sub-population of extremely preterm babies, often described as micro-preemies (<26 weeks gestation). However, in lower-income settings, the majority of preterm deaths still occur in late and moderate preterm (32- <37 weeks gestation) (10). Recent estimates show that up to half of preterm deaths could be averted through warmth, feeding support, infection prevention and treatment supported by kangaroo mother care (KMC); over 90% could be avoided with special and intensive newborn care including continuous positive airway pressure (CPAP) (4). Thus, preventing a large proportion of deaths in small babies globally is achievable but requires the provision of these known affordable interventions as part of an inpatient care package.

2.2.2 Infections

Serious bacterial infections, a major cause of newborn morbidity and mortality, include the clinical infection syndromes of sepsis, meningitis, and pneumonia (43, 52). Infections are usually described as early (within the first 3 days) or late onset (after the first 3 days until the end of the neonatal period). The former is commonly associated with vertical acquisition (during or related to birth or from the birth canal); the latter is usually acquired from external sources after birth (e.g. from the home or hospital environment) (53).

There are multiple reasons for increased vulnerability to infection in the first 28 days of life, including immaturity of the immune system, potential exposure to micro-organisms in the birth canal and risk factors during the intrapartum and postpartum period, especially in resource poor environments (54). Maternal risk factors for newborn infections include prolonged rupture of membranes, preterm labour and maternal infections. Babies born in unhygienic conditions, with low birth weight (especially preterm) and/or that are fed substances other than breastmilk are known to be at greater risk of infections (54, 55), as well as those with unhygienic substances applied to the umbilical cord area after birth (8). Boys have been found to have higher risk of serious neonatal infections than girls (43, 52).

When more advanced laboratory support is available, diagnosis of suspected infections is confirmed fully using microbiological investigations (e.g. analysis of microorganisms in blood and other body fluid and tissue) (43). Such advanced laboratory infrastructure is often lacking in lower-income settings. In addition, when babies are born outside the health facility, cases may go unrecorded. Therefore, both diagnosis and reporting of neonatal infections in LMICs is challenging, often relying on clinical algorithms which detect possible infections with greater sensitivity than specificity (56).

Serious bacterial infections account for approximately a third of the 2.5 million neonatal deaths globally (43). Serious bacterial infections in the neonatal period are an important contributor to the global burden of disease, accounting for about 3% of all DALYs, most of which are deaths (42, 52). The incidence of possible serious bacterial infection (PSBI) in 2012 was estimated at 7.6 per 100 live births (95% confidence interval 6·1–9·2%) (43, 52). In 2012 there were an estimated 6.9 million (uncertainty range 5.5-8.3 million) cases of PSBI requiring treatment (in liveborn babies ≥32 weeks gestation or ≥1500g birthweight) in sub-Saharan Africa, South Asia and Latin America; 680,000 (460,000-920,000 uncertainty range) of these were estimated to have led to neonatal deaths (43). The largest number of cases of PSBI in 2012 were estimated in South Asia at 3.5 million (uncertainty range 2.8-4.2 million), followed by sub-Saharan Africa at 2.6 million (uncertainty range 2.1-3.1 million) and then Latin America at 0.8 million (uncertainty range 0.7-1.0 million) (43). Despite higher numbers of PSBI in South Asia, it was estimated that case fatality risk in sub-Saharan Africa was higher – which may be explained by access to quality care or differing underlying causes and risk factors, such as higher preterm rates in Africa compared to Asia (43).

Data on long-term morbidity of babies with severe neonatal infection are sparse, especially for disability in survivors, and estimation of rates of impairment following neonatal sepsis and pneumonia was not possible due to lack of data (52).

2.2.2.1 Infections and implications for inpatient care

Prevention of infection is of critical importance in reducing newborn death and long-term disability and multiple strategies are needed, including maternal vaccination, hygienic care at and around the time of birth and exclusive breastfeeding (43, 57). However, with estimated incidence of 7.6 cases of PSBI per 100 live births in 2012, inpatient care is also critical to reduce the resulting burden of death and disability (57, 58). The severity of bacterial infection in the newborn period, as well as the overlap with other major risk factors for neonatal death and disability (particularly small size) means most newborns with infections cannot be treated in the community and will require a period of inpatient care. In hospital settings, WHO recommends treatment with injectable antibiotics for 7-10 days with supportive care (58). Microbiological investigations (blood culture and lumbar puncture for suspected infections) are a core component of inpatient care, alongside antibiotic stewardship and strict infection control procedures, to prevent both nosocomial infections and development of antimicrobial resistance, which are growing public health issues (53).

2.2.3 Intrapartum-related events and neonatal encephalopathy

"Birth asphyxia" is a term that was previously used to describe impaired oxygen delivery and decreased blood flow to the fetus in the perinatal period, most frequently due to events during labour (intrapartum). Clinically, "birth asphyxia" was used to describe babies that are not breathing at birth, who require resuscitation in the delivery room, or who show signs of brain injury (59). However, there are a broad range of conditions that may present with this same clinical picture, which makes the diagnosis of birth asphyxia challenging. Because of this complexity, particularly in lower-income settings, there has been a shift in terminology, from using "birth asphyxia" to "intrapartum-related" complications or events to indicate the timing and subsequent injury due to hypoxia (60, 61). The use of "intrapartum-related" events deliberately does not assume a causal relationship (60).

Neonatal encephalopathy is a disorder of brain function, which develops in infants that survive intrapartum or severe hypoxic events at birth (16, 60). The more severe cases of encephalopathy can progress to seizures, lack of consciousness and apnoea.

Risk factors for neonatal encephalopathy include primiparity, multiple births, lack of antenatal care, small or large for gestational age, induction and/or augmentation of labour and prolonged/obstructed or labour and perinatal infection (62, 63).

Based on estimates of intrapartum related events, 1.15 million (0.89-1.60 million uncertainty range) new cases of neonatal encephalopathy were associated with intrapartum related events in 2010; 96% of these were born in LMICs. An estimated 287,000 (181,000-440,000 uncertainty range) of these died (60). Of those babies that survived, 413,000 were diagnosed with neurodevelopmental impairment; 233,000 (163,000-342,000 uncertainty range) with moderate to severe neurodevelopmental impairment and 181,000 (82,000-319,000 uncertainty range) with mild neurodevelopmental impairment (60). In 2010, intrapartum-related conditions are estimated to have accounted for 50.2 million disability adjusted life years (DALYs) and 6.1 million years lived with disability (60).

2.2.3.1 Intrapartum-related events and implications for inpatient care

Quality obstetric care and effective neonatal resuscitation are of key importance in the prevention of death and disability related to intrapartum complications and subsequent injury to the brain (61). However, for those babies that survive intrapartum events and develop neonatal encephalopathy, many will go on to require inpatient care to treat symptoms (such as seizures), provide developmentally supportive care, establish feeding and minimise and manage long term sequelae. In advanced settings where neonatal intensive care is available, interventions such as brain cooling have been shown to be effective in treating neonatal encephalopathy (64), but it is still unclear how to translate these interventions to more diverse and resource limited care settings.

2.2.4 Jaundice

Neonatal jaundice, characterised by high levels of serum bilirubin, is common, occurring in up to 85% of all live births (65). Whilst most cases are physiological and resolve spontaneously, unresolved and severe cases can result in acute bilirubin encephalopathy (kernicterus) or death.

Preterm newborns and those with infections are at increased risk of jaundice, as well as those with blood group incompatibilities or genetic disorders, such as glucose-6 phosphate dehydrogenase (G6PD) deficiency (65, 66).

Quantifying the burden of severe jaundice (serum bilirubin levels >25mg/dL) is challenging, especially in LMICs where diagnosis with serum bilirubin levels is often delayed or not available (67).

Based on figures published in 2013, an estimated 481,000 newborns were affected by extremely severe jaundice in 2010 (66). More recently, a meta-analysis of studies from 2010-2017 found an incidence of severe neonatal jaundice (defined as jaundice associated with acute bilirubin encephalopathy and/or exchange transfusions and/or jaundice related death) of 667.8 (95% confidence interval 603.4-738.5) per 10,000 live births in the African region followed by 251.3 (95% confidence interval 132.0-473.2) per 10,000 live births in South East Asia; lower rates were found in Europe, Americas and Western Pacific (65).

Acute bilirubin encephalopathy is a significant cause of death and long-term disability, including cerebral palsy, deafness, language and processing disorders and motor and speech delays (68). Follow up of cases of kernicterus, estimates published in 2013 found 64,100 (uncertainty range 36,000-83,300) cases of hearing loss, 62,100 (uncertainty range 35,200-81,800) cases of developmental delay and 35,500 (uncertainty range 15,000-155,500) cases of cerebral palsy (66). The burden of impairment following kernicterus disproportionally affects LMIC, especially sub-Saharan Africa and South Asia (65, 66).

2.2.4.1 Jaundice and implications for inpatient care

Prevention, early diagnosis and inpatient care treatment can transform outcomes for babies with jaundice. This requires a combination of screening, diagnostics and treatment with phototherapy. Previous work has highlighted the critical importance of providing effective phototherapy in resource poor settings, where the burden of severe neonatal jaundice is the greatest and contribute significantly to the global burden of cerebral palsy, deafness and other auditory and language processing disorders (65). Cases of jaundice can be treated in LMIC with affordable and available diagnostic and phototherapy technologies as part of inpatient care; more extreme cases will require more intensive inpatient care, including exchange transfusions (68).

2.2.5 Congenital disorders

According to WHO, congenital disorders (also referred to as birth defects) are any potential pathological conditions arising before birth; they are either evident at birth or become manifest later in life (69). Congenital disorders are highly diverse in their aetiology and outcomes and subsequently, epidemiological data is lacking in most settings (70); they can be grouped into congenital malformations/anomalies (such as neural tube defects, orofacial clefts and congenital heart disease) chromosomal disorders (such as Down syndrome and other trisomies) and inherited disorders (such as sickle cell and thalassemia). Risk factors for congenital disorders include genetic, societal, and environmental factors (e.g. infections, toxins, teratogens).

In the absence of interventions, the birth prevalence of congenital disorders in any given population is relatively constant. Average baseline prevalence of congenital anomalies is estimated to be at least 20 per 1000 and the baseline prevalence of congenital disorders is over 37 per 1000 (69). Actual prevalence, however, varies greatly depending on both preventative and treatment interventions. For example, meta-analysis suggests folic acid food fortification could reduce incidence of neural tube defects by 46% (95% confidence interval 37-54%), with a potentially higher effect using supplementation (71) (69).

Cleft lip and palate, congenital heart anomalies, and neural tube defects account for an estimated 21.4 million DALYs. An estimated 6% of global under 5 deaths are attributed to congenital anomalies, of which 92% occur in LMICs (72).

2.2.5.1 Congenital conditions and implications for inpatient care

If a fetus is diagnosed in utero to be affected by a congenital disorder, options include treatment during pregnancy, termination of pregnancy, planning for labour and postnatal care (often involving neonatal care). The inpatient care interventions mainly centre on identification and clinical management, including supportive care for both affected child and wider family. In some congenital anomalies, including orofacial cleft, neural tube defects and congenital heart disease surgical correction can improve both survive and quality of life (73). Often surgery cannot occur in the immediate neonatal period (and/or access to surgery is limited) therefore, for clinical management many of the core inpatient care package interventions apply, such as assisted feeding (often by intragastric tube) and supportive care, which can significantly impact mortality and longer term morbidity and functioning (70).

2.3 Service readiness: a prerequisite for quality of care

A significant change observed during the MDG era was a major shift in the proportion of births that occurred in facilities with a skilled birth attendant. Rates of facility births increased from 62% globally in 2000 to 80% in 2015 (21). However, despite this shift in place of birth, maternal and newborn deaths did not decrease accordingly (74).

A frequently cited explanation for why maternal and newborn mortality did not decrease as much as hoped is that there was insufficient attention and investment in the quality of intrapartum care (4, 11, 21, 22, 75, 76). For example, in South Africa, more than 95% of births are facility-based, but NMR did not significantly shift by the close of the MDGs, most probably due to inadequate quality of care not only during pregnancy and childbirth, but during the postnatal period (77). Similarly, the evaluation of the conditional cash transfer Janani Suraksha Yojana program in India, focused on increasing skilled birth attendance, showed significant increases in facility deliveries but no change in NMR (78).

2.3.1 What is quality of care

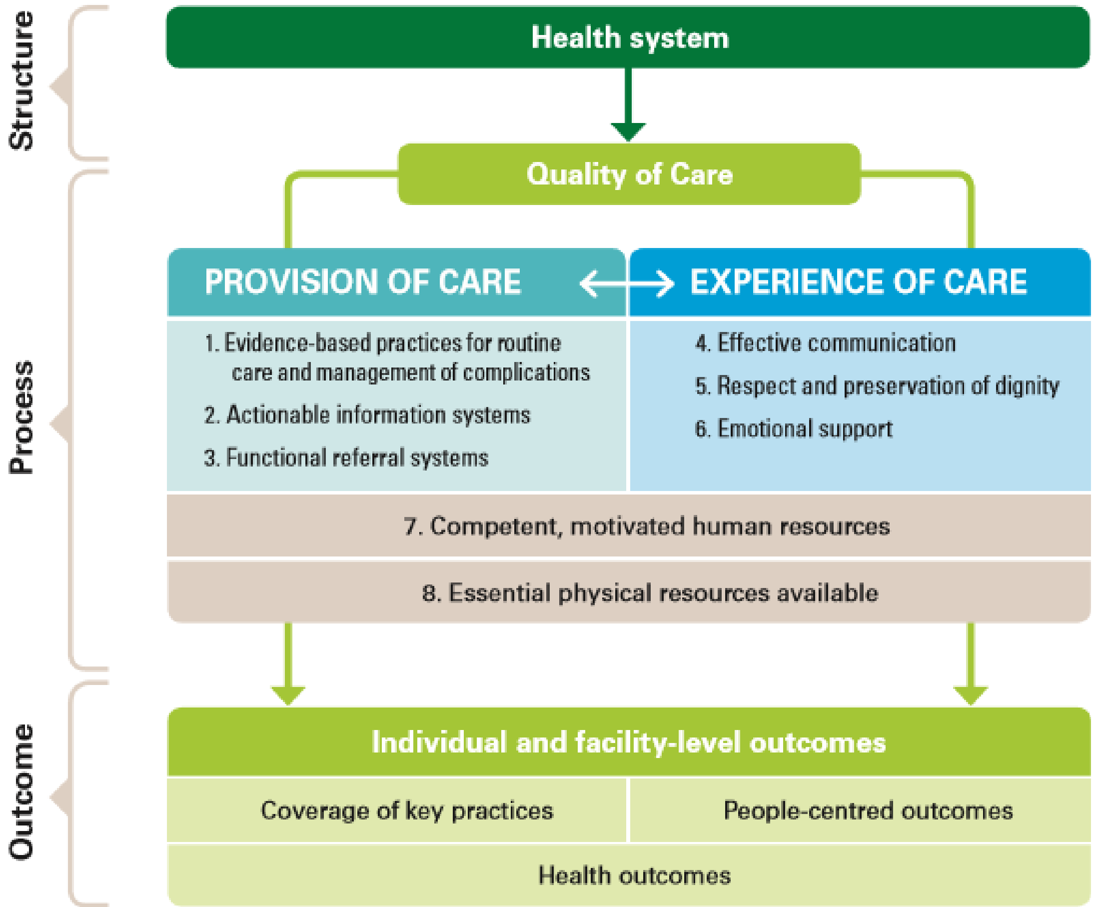
Quality of care is a multidimensional concept defined by WHO as "the extent to which health services provided to individual and patient populations improve desired health outcomes" (p 1046) (11). There is no single definition or framework for quality, but many definitions for quality healthcare are based around the Institute of Medicine's six dimensions, which call for quality healthcare to be safe, effective, patient-centred, timely, efficient and equitable (79).

Defining quality healthcare differs from definitions of quality improvement, which involves interventional experiments or changes in practice designed to test a change over time (80, 81). Many of the models or frameworks for quality improvement in healthcare are borrowed or developed from the manufacturing industry (82, 83). They are designed to help understand the factors influencing outcomes or processes in a specific context or population (81). For example, Ishikawa or fishbone diagrams are graphic tools used to display the causes of a certain effect (or identified problem) and graphically display the relationship of more distal and proximal factors and their relationship to each other (84). Deming or Plan Do Study Act (PDSA) cycles, originally developed by Deming and Shewhart for use in manufacturing, are iterative and cyclical learning approaches that encourage process and culture change by measuring and testing changes in a complex system over time (82, 85-87). Also developed in the manufacturing industry, Lean and Six Sigma have been applied in conjunction to healthcare since 1990 (82, 85). Lean focuses on waste reduction and six sigma on defect rates to reduce variability and standardise outcomes in a system (82, 85).

Fundamental in measuring and translating concepts of quality to healthcare, the Donabedian model for measuring quality of care emerged in the 1970s (19). The Donabedian framework contains three measurement domains: the structures (e.g. infrastructure, equipment, health providers) and processes (e.g. actions performed by health professionals) that lead to health outcomes (what happens to the patients). It has now been used for decades to help academics, implementation scientists and programme implementers operationalise and measure key concepts of quality in health care (19, 88-90).

As part of a global health vision for quality of care beyond the MDG era and into the SDG era, the WHO developed a new framework for quality of care for maternal and newborn health care, conceptualising both the provision and experience of care as essential components of quality care (Figure 2.2). This framework builds on both the Donabedian model and the six WHO health system building blocks (leadership and governance, financing, essential medicines, information systems, workforce, service delivery) (11) using different domains which can be targeted to assess, improve and monitor care within the context of a health system. Identifying where problems are occurring can therefore help to point to interventions to improve quality (75).

Figure 2.2 WHO framework for the quality of maternal and newborn health care



Source: Adapted from Tuncalp et al (2015) Quality of care for pregnant women and newborns – the WHO vision (11) http://apps.who.int/iris/bitstream/handle/10665/249155/9789241511216-eng.pdf?sequence=1

This thesis aims to describe the health system components required to deliver inpatient care using both the WHO health system building blocks and the Donabedian model; they provide frameworks to describe the foundations of the health system required to build quality of care relevant to newborns. Measuring service readiness requires an understanding of the needs of health systems delivering inpatient care for small and sick newborns. The Donabedian framework is a practical model for operationalising service readiness and placing it within the broader context of RMNCH and the WHO vision for quality of care. The choice of the Donabedian model alongside the health system building blocks helps ensure that findings from this thesis are relevant and aligned with WHO vision of health care quality for maternal and newborn health, and helps contextualise findings within the SDG era.

2.3.2 Importance of quality of care for small and sick newborns

It was estimated in 2014 that addressing quality of care was an immediately feasible opportunity for newborns, and that addressing the quality of care gap could save 1.325 million newborns by 2020 (4). Some of the greatest effect could be achieved through a focus on small and sick newborns, which could prevent 600,000 newborn deaths per year by 2025 (4). This is largely achievable through focus on high coverage of quality of care in facilities, particularly district and sub-district level facilities in LMIC where some of the greatest gains can be made (4).

It is not only survival that is gained through quality of care. Being born in either a low- or a middle-income country greatly influences your chance not only of survival, but long-term health and development. In high-income settings where higher quality inpatient care is almost universally available, neonatal mortality is low (<5 per 1000 live births) and few full-term babies develop complications. Furthermore, for preterm babies, 95% survive free of disability, even those born at the lower thresholds of viability (21, 27). In middle-income settings, the risk of disability in babies born between 28-32 weeks is nearly double that in high-income countries (21, 27). This is not only related to access to care; a similar pattern was observed in higher-income settings as intensive care was introduced. Specialisation of neonatal staff alongside factors such as safe use of oxygen, developmentally supportive care, and management of pain, have been instrumental in improving the quality of neonatal care in higher income settings over the last few decades, and improving long term outcomes for neonatal survivors (5, 27). In LIC, disability following neonatal illness is less common because those with severe complications (<28 weeks) still die due to lack of essential and routine care at and around the time of birth (91). The existing data shows us that as we progress into the SDG era, health programmes will require specific focus on quality and safety to avoid a similar trajectory of rising rates of preventable disability as mortality rates decrease.

2.3.2.1 Learning from retinopathy of prematurity

The example of retinopathy of prematurity (ROP) is a useful illustration of the importance of quality of inpatient care for small and sick newborns (92-95). ROP is a condition characterised by abnormal retinal vascular development, usually caused by unregulated use of high concentrations of oxygen without monitoring its effect on oxygen content of arterial blood (oxygen saturations). Oxygen is one of the most frequently used drugs to treat respiratory distress due to preterm birth in inpatient care units (96). In 2010, an estimated 184,700 preterm babies developed ROP during the neonatal period; 53,800 progressed to potentially vision impairing disease, 20,000 of whom became blind or severely visually impaired (97). ROP is now a leading cause of childhood blindness worldwide (93, 97), yet is largely preventable with well-controlled oxygen levels, use of the appropriate devices and monitoring systems. Therefore, high rates of ROP, particularly in moderate and late preterm newborns, are directly related to the quality of care that they received (97, 98). If rates of intrapartum events are considered a key marker of the quality of obstetric care, rates of ROP are a similar marker of the quality of inpatient newborn care.

The highest rates of ROP are found in middle-income settings, especially Asia, Latin America and increasing rates of ROP are seen in countries where neonatal care has been scaled up without due attention to the quality of care (95, 99). Lessons learned from the example of ROP demonstrate the need for simultaneous focus on preventing avoidable death and preventing disability through attention to quality and safety of inpatient care (27). Quality of care is the nexus between newborn survival and children thriving into adulthood. Significant gains to both survival and quality of life can be achieved through focused attention to safety and quality of care (4) and improved monitoring and data for babies requiring inpatient care. In the case of ROP, the provision of safe, monitored levels of oxygen in cases of respiratory distress during the period of neonatal inpatient care is a critical safety and quality issue with potentially long-term consequences for social and educational outcomes.

2.3.3 What is service readiness and how is it measured?

For health systems to function effectively they need a combination of inputs and processes, as well as coverage of care. As per the Donabedian quality of care framework, services are usually judged on their outcomes, but improved outcomes cannot be achieved without the key structures and processes in place (89). Assessing quality of care, therefore, requires measures of both structures and processes (19, 88, 89).

Structures are the key characteristics of the health service and its providers – the health system inputs. Planning, resource allocation and day-to-day management of healthcare requires timely information on these inputs (equipment, supplies, infrastructure and human resources) (100). Processes refer to the actions carried out on patients in a health care institution. Process indicators are important to measure, but often more challenging to measure than structural inputs (76, 101) as there is greater variability in the performance of process measures than service inputs, which are more stable (102).

Outcome measures are essential as they assess the ultimate goal of the health system but reflect multiple factors beyond the health system itself (76) making it less easy to action change at a local level.

Service readiness refers to the capacity of a health system to deliver the services offered (101). Service readiness is measured predominantly through service inputs – the equipment, supplies, infrastructure, and human resources. To ensure that services are ready, however, the structures not only need to be present, but maintained, re-stocked and updated (e.g., equipment requires maintenance, supplies require re-stocking, guidelines require updating) and staff continually trained and supervised. Therefore, elements of processes are also covered through service readiness measurement. Given the pivotal role of quality newborn care in affecting long term newborn outcomes, this PhD views the service readiness structures as a critical starting point to identify service delivery gaps and support scale up of quality care.

To be immediately actionable, service readiness data is ideally readily available at a local level. However, national health information systems in LMIC may currently have limited capacity to collect this type of data. Data are particularly lacking in settings where access to neonatal inpatient care is the lowest and where facilities are most in need of targeted efforts to strengthen services and improve the quality of care. This means that many LMIC settings rely on national surveys to supplement their health information for measures of access, availability, and quality of care, including service readiness. Intermittent surveys - such as health facility assessments - are frequently used.

There are many health facility assessment tools available, using multiple different methods and indicators to collect data. Despite the variety of health facility assessments that exist to supplement general national health information gaps, there are relatively few studies of service readiness specific to inpatient care for small and sick newborns. A recent systematic review of health facility assessments found 10 different tools covering 41 different assessment domains (103). Broadly, however, health facility assessment tools have been found to tend towards assessments of services at the primary care or community level rather than secondary level services, limiting the number that capture information on inpatient care for small and sick newborns (103).

2.3.4.1 Example of service readiness data for inpatient care of small and sick newborns

A recent study in Kenya aimed to describe the provision and access to inpatient neonatal services within Nairobi City County health care system and examined the structural capacity of facilities to provide quality of care (104). The study found that larger facilities tended to score higher on structural capacity than smaller ones. Several items were missing from inpatient care units, including blood transfusion giving sets, Vitamin K and IV drugs. Thermometers, weighing scales and suction machines were often shared between maternity or sick child services. Of 17 drugs required for small and sick newborns, a median of 88.9% (5.3-100%) were only available in stores (rather than immediately available). Pulse oximeters were only available in 24 out of 31 facilities. Incubator sharing was reported by 9 out of 31 facilities and was especially common in the larger volume public facilities. Only 12 out of 31 facilities had dedicated nursing staff for small and sick newborns with greater staff shortages on night shifts (104).

While the study is not representative of the whole country and cannot be directly extrapolated to other settings, it is reasonable to assume that other settings may face similar challenges. The Nairobi study found that half of small and sick newborns are not able to access appropriate care (104), further emphasising the need for routine monitoring systems in place that can track health system readiness and availability of services to be able to improve dimensions of quality of care and plan appropriate distribution of services (104-106).

2.4 Conclusions

For this PhD, service readiness is framed both through the lens of WHO building blocks and the Donabedian framework. These frameworks are used as foundational constructs to identify and understand domains which can be targeted to track and monitor health system readiness for small and sick newborns within the context of the health system. Measuring service readiness for inpatient care requires an understanding of the structural components that comprise the package of inpatient care, which is lacking for small and sick newborns in comparison to other packages of interventions along the continuum of care. Rather than creating a parallel system, the overall aim of this PhD is to contribute a body of work that will help to guide and improve the measurement of service readiness for inpatient care for small and sick newborns. As part of this aim, this PhD considered small and sick newborn measurement within the context of existing and evolving metrics systems.

Chapter 3: A measurement improvement roadmap

3.1 Introduction

Chapter 3 presents the first published research paper entitled "Count Every Newborn: A measurement improvement roadmap". The chapter provides a description of how the research in this thesis fits into the broader *Every Newborn* measurement improvement roadmap to address an identified research need. This paper describes the broader context of the global *Every Newborn* Action Plan (ENAP) and the *Every Newborn* metrics measurement improvement roadmap. While the focus on this paper is largely on coverage measurement rather than service readiness, this work is included as part of the background section of this PhD to show how the candidate identified the need for and shaped the subsequent project on service readiness for small and sick newborns within the *Every Newborn* measurement improvement roadmap project.

This work was published in BMC Pregnancy and Childbirth as an open access article in September 2015. See Appendix M (15) for the published version of this article and copyright. The paper was part of a supplement of nine papers on scaling up high impact interventions and improving the quality of care for mothers and newborns at and around the time of birth This is one of the crosscutting papers in the supplement focused on newborn measurement.

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SECTION A – Student Details

Student ID Number	1405761	**Title**	Ms
First Name(s)	Sarah		
Surname/Family Name	Moxon		
Thesis Title	Service readiness for inpatient care of small and sick newborns: Improving measurement in low- and middle-income countries		
Primary Supervisor	Joy Lawn		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	BMC Pregnancy and Childbirth		
When was the work published?	September 2015		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**

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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	
Please list the paper's authors in the intended authorship order:	
Stage of publication	Choose an item.

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I am the first author of this paper and I was primarily responsible for the writing. The work for this paper was conceptualised by Joy Lawn and I in discussion with the Every Newborn metrics coordination group (see Appendix A). I then worked with Joy Lawn and Harriet Ruysen to coordinate the work carried out by the coverage task teams for antenatal corticosteroids, newborn resuscitation, kangaroo mother care, neonatal infection case management, and chlorhexidine cord cleansing. I led the work for the kangaroo mother care task team with Tanya Guenther and Juan Ruiz Pelaez. I coordinated drafts of the manuscript with Harriet Ruysen to bring together inputs from the coverage task teams. I was responsible for editing content, managing inputs from co-authors and writing the final version of the manuscript with oversight from Joy Lawn and Matthews Mathai from WHO. All co-authors reviewed drafts and approved the final manuscript.

SECTION E

Student Signature	Sarah Moxon
Date	09/12/2018

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Date	09/12/2018

3.2 Abstract

The *Every Newborn* Action Plan (ENAP), launched in 2014, aims to end preventable newborn deaths and stillbirths, with national targets of $\leq$12 neonatal deaths per 1000 live births and $\leq$12 stillbirths per 1000 total births by 2030. This requires ambitious improvement of the data on care at birth and of small and sick newborns, particularly to track coverage, quality and equity.

In a multistage process, a matrix of 70 indicators were assessed by the *Every Newborn* steering group. Indicators were graded based on their availability and importance to ENAP, resulting in 10 core and 10 additional indicators. A consultation process was undertaken to assess the status of each ENAP core indicator definition, data availability and measurement feasibility. Coverage indicators for the specific ENAP treatment interventions were assigned task teams and given priority as they were identified as requiring the most technical work. Consultations were held throughout.

ENAP published 10 core indicators plus 10 additional indicators. Three core impact indicators (neonatal mortality rate, maternal mortality ratio, stillbirth rate) are well defined, with future efforts needed to focus on improving data quantity and quality. Three core indicators on coverage of care for all mothers and newborns (intrapartum/skilled birth attendance, early postnatal care, essential newborn care) have defined contact points, but gaps exist in measuring content and quality of the interventions. Four core (antenatal corticosteroids, neonatal resuscitation, treatment of serious neonatal infections, kangaroo mother care) and one additional coverage indicator for newborns at risk or with complications (chlorhexidine cord cleansing) lack indicator definitions or data, especially for denominators (population in need). To address these gaps, feasible coverage indicator definitions are presented for validity testing. Measurable process indicators to help monitor health service readiness are also presented. A major measurement gap exists to monitor care of small and sick babies, yet signal functions could be tracked similarly to emergency obstetric care.

The ENAP Measurement Improvement Roadmap (2015-2020) outlines tools to be developed (e.g., improved birth and death registration, audit, and minimum perinatal dataset) and actions to test, validate and institutionalise proposed coverage indicators. The roadmap presents a unique opportunity to strengthen routine health information systems, crosslinking these data with civil registration and vital statistics and population-based surveys. Real measurement change requires intentional transfer of leadership to countries with the greatest disease burden and will be achieved by working with centres of excellence and existing networks.

3.3 Background in the paper

The close of the Millennium Development Goals (MDGs), with a halving of maternal mortality and under five child deaths, demonstrates that global targets are linked to national and global accountability and can drive change. Under-five deaths due to HIV/AIDS, malaria and measles (among others), have seen the greatest proportional declines (107). Where indicators for high impact, evidence-based interventions are carefully tracked, previous analysis has demonstrated that coverage tends to improve, largely due to focused policy attention, investment and informed planning, leading to better population health outcomes (25). Interventions for child health and causes of child death have had more programmatic data (coverage and process), collected more frequently, at a more granular level (e.g. district level, by various equity analyses groups), than for newborn health, where the data is of poorer quantity and quality, and has been collected with less frequency (21).

As the MDGs transition to the Sustainable Development Goals (SDGs), there remains an unfinished agenda for 2.7 million neonatal deaths, for whom progress has been much slower than progress towards reducing the overall under 5 mortality rate. An estimated 2.6 million stillbirths were not counted at all in the MDGs (108). Well-functioning civil registration and vital statistics (CRVS) systems generate policy, ensure access to services and are associated with better health outcomes worldwide (109); counting births and deaths, especially the deaths around the time of birth, lies at the heart of post-2015 health monitoring, accountability and action (21). Tracking vital events and measuring coverage is also central to developing national health management information systems (HMIS), such as in the Measurement and Accountability for Results in Health (MA4Health) Roadmap (110), which aims to increase investment in national data systems and data use.

The *Every Newborn* Action Plan (ENAP) (6) is a global multi-partner movement to end preventable maternal and newborn deaths and stillbirths. Through a series of consultations, multiple stakeholders (governments, United Nations (UN) agencies, donors, business communities, professional associations, academic and research institutions, global initiatives and civil society members) developed an impact framework and an action and measurement agenda for integration within national newborn health plans (21, 23).

To reach 2030 national targets for neonatal mortality and stillbirth rates of ≤12 per 1000 births, high and equitable coverage of the evidence-based interventions identified by ENAP is needed (4). ENAP prioritises achieving universal coverage of these interventions particularly during childbirth and the first week of life. Yet many of these interventions are not systematically measured. One of the five

ENAP strategic objectives – to count every newborn (and birth) – underlines the need for improved data and accountability. The ENAP milestones, linked to a World Health Assembly resolution [7], have a particular focus on inputs required prior to 2020 and more than half refer to improving metrics for targeting and driving change (Figure 3.1). One such milestone is to develop a monitoring framework building on the Commission on Information and Accountability (COIA) for Women's and Children's Health (111) to track global progress post 2015 and align with country priorities and objectives.

Figure 3.1 *Every Newborn* Action Plan Measurement Improvement Roadmap: the arc of change

In support of Health Measurement and Accountability post-2015: A Common Roadmap WHO (2015) (110).
ENAP: Every Newborn Action Plan; WHO: World Health Organization.

The principal focus of this paper is based on the ENAP milestone to define and improve priority coverage indicators, as this was where the largest measurement gaps were identified. Many newborn care interventions lack standard indicator definitions and are not routinely monitored at national or global level, especially in low and middle-income countries (LMIC). We define a coverage indicator as a population-level metric that measures the number of individuals that receive an intervention or service (numerator) out of a total population that should receive the intervention or service (the denominator). For the numerator, indicators rely on clear technical definitions of the service or intervention. Where there is difficulty capturing the population in need (the denominator) particularly for specific treatment interventions, some indicators (such as the caesarean-section rate) use total live births as the denominator to give a proxy. In such cases, where the aim is not for 100% coverage, the rate is then benchmarked against a target threshold.

The coverage indicators prioritised by the Commission for Information and Accountability (COIA) mainly reflect contact points along the continuum of care, notably antenatal care, skilled birth attendance and postnatal care. Such coverage indicators capture contact with the health system or delivery of a specific intervention, but not always detailed, accurate information on the content or quality of the care delivered (112), although antenatal care now has a detailed content module within the Demographic and Health Survey (DHS) (113). In high-burden countries the main current data source is through household surveys. The most commonly employed household surveys are the United States Agency for International Development (USAID)-supported DHS (114) and the United Nations International Children's Fund (UNICEF)-supported Multiple Indicator Cluster Survey (MICS) (115). However, coverage of many maternal and newborn interventions cannot feasibly and/or accurately be collected through household surveys.

For health information collected through household surveys, the data quality usually depends on the validity of the mother's report, often up to two to five years after the intervention occurred. There is evidence suggesting that maternal recall of events that occurred during labour is poor (113), especially if there were complications. In addition, how the question is asked can affect the accuracy of the response. For surveys, large sample sizes are needed to generate sufficient statistical power to assess social and demographic factors. Bryce et al (116) described some of the limitations of household surveys for measuring coverage of interventions, including the time, cost and limited validity (sensitivity and specificity) of many of the indicators.

Health facility assessments (HFAs) are frequently used to complement HMIS, facility-based logistics and service delivery information systems. These provide information on staffing, equipment availability, spatial organisation, data collection capacity, and service readiness. A number of standardised HFA tools exist, the most commonly employed being the Service Availability and Readiness Assessment (SARA) (101), Service Provision Assessments (SPA) (117) and the Emergency Obstetric Care (EmOC) needs assessments (118). These allow health systems to report on a sample of facilities that provide a certain service or have health workers trained in specific skills but are not routine reporting mechanisms. In addition, the WHO Health Access/Action International database has data on medication availability. Service availability and quality indicators provide complementary metrics to population coverage which can be used to ensure that services achieve adequate coverage and give due attention to the availability of care, and the readiness of facilities to deliver the safe and quality care that is fundamental to the *Every Newborn* movement.

Since coverage of evidence-based care for mothers and newborns is often unknown, or data may be old or not locally available, this is a major "bottleneck", impeding scale up of high-impact, evidence-based interventions for newborns. Such data have been critical in accelerating progress in the implementation and scale-up of immunisation and HIV programmes through increased policy attention, focused investment of resources and accountability (116). Such data are crucial for informed planning, driving programme improvement and targeting underserved populations to reduce inequities.

3.3.1 Objectives of the paper

The objectives of this paper are to:

1. Describe the systematic process used to select *Every Newborn* action plan indicators and present the core and additional indicators.
2. Assess the status (technical definitions and data availability) of the *Every Newborn* action plan coverage indicators and identify actions needed to improve these for measurement at scale, particularly for coverage of the treatment interventions.
3. Identify priorities for testing validity and feasibility, in order to institutionalise these metrics within large scale data collection platforms and outline a five-year measurement improvement roadmap.

3.4 Methods

3.4.1 Selecting the core *Every Newborn* action plan and additional indicators

A multi-stage process was carried out to identify a list of potential indicators and then prioritise a short list. This process involved a working group appointed by the ENAP management team who compiled a comprehensive list of indicators, drawing on existing databases such as COIA(111), UNICEF's State of the World's Children (SoWC) (119), Countdown to 2015 (120) and other World Health Organization (WHO) statistics and reports. Standardised, nationally representative survey tools currently in use (MICS, DHS, SPA, SARA and EmOC surveys) were considered as sources of data. In addition, possible indicators relating to common causes of neonatal death were included. This resulted in a matrix of over 70 relevant indicators measuring impact (mortality and morbidity), outcome (coverage of care for all babies and coverage of treatment interventions), outputs (service quality, availability, demand, and the enabling environment) and inputs (human resources, essential medicines and supplies) (see Appendix B). The current status of definitions, measurability and data availability were reviewed for each of the proposed indicators.

A systematic scoring process was applied to prioritise core indicators that could track the main focus of the action plan, particularly on quality of care at birth and the five strategic objectives. Each indicator was graded by its importance to the ENAP focus (A to C) and by current data availability (1 to 3). A grade of A was given to indicators of highest relevance and match to the ENAP focus and a score of 1 was given to indicators with a common and consistent definition already measured in existing data sources. Scoring was completed by an expert working group and decided via group consensus with priority given to indicators in terms of their relevance to the ENAP focus, rather than data availability.

Given the principle of accelerating impact, a decision was taken to focus on a shorter list of important indicators and ensure those would be made measurable, rather than to just select those that were already measurable. Hence, indicators were prioritised first based on their importance to the ENAP focus (category A) and then on data availability. Indicators in Category A ranged from those with definitions and existing data (availability 1) to those without standard definitions and existing data (availability 2 or 3). The latter were identified as having priority measurement gaps that needed to be addressed with a specific program of work.

3.4.2 Assessing the status of the *Every Newborn* action plan coverage indicators and identify priorities to improve measurement at scale

For each of five high impact interventions identified with the greatest measurement gap (red box in Figure 3.2), a Task Team was established. These included antenatal corticosteroids (ACS), newborn resuscitation, Kangaroo Mother Care (KMC), case management of serious neonatal infection and chlorhexidine cord cleansing. The Task Teams sought to represent both the maternal and newborn health communities and reflect multiple stakeholders, e.g. non-governmental organisations, UN organisations, professional associations, and research institutions; ensuring representation from LMIC. With the support of the *Every Newborn* metrics coordination group, Task Teams carried out a consultation process to define indicators based on a technical definition, suggest feasible indicators that can be measured now through existing data collection platforms, and outline research priorities to test validity and feasibility for these coverage metrics for each area, including data collection tools.

Figure 3.2 *Every Newborn* core and additional indicators

Current Status		Core ENAP Indicators	Additional indicators
Definitions clear but quantity and consistency of data lacking	***Impact***	1. Maternal mortality ratio 2. Stillbirth rate 3. Neonatal mortality rate	Intrapartum stillbirth rate Low birth weight rate Preterm birth rate Small for gestational age **Neonatal morbidity rates** **Disability after neonatal conditions**
Contact point definitions clear but data on content of care are lacking	***Coverage:*** **Care for All Mothers and Newborns**	4. Skilled attendant at birth 5. Early postnatal care for mothers and babies 6. Essential newborn care (tracer is early breastfeeding)	Antenatal Care Exclusive breastfeeding up to 6 months
Gaps in coverage definitions, and requiring validation and feasibility testing for HMIS use	***Coverage:*** **Care for newborns at risk or with complications (specific treatment interventions)**	**7. Antenatal corticosteroid use** **8. Neonatal resuscitation** **9. Kangaroo mother care** **10. Treatment of severe neonatal infections**	Caesarean section rate **Chlorhexidine cord cleansing**
	Input: **Service Delivery Packages for Quality of Care**	Emergency Obstetric Care **Care of Small and Sick Newborns** **Every Mother Every Newborn Quality Initiative with measurable norms and standards**	
	Input: **Counting**	Birth Registration	Death registration, cause of death

Shaded= Not currently routinely tracked at global level.
Bold red= Indicator requiring additional testing to inform consistent measurement.
Indicators to be disaggregated by equity such as urban/rural, income and education.
Adapted from WHO and UNICEF, Every Newborn Action Plan. WHO, 2014. www.everynewborn.org and Mason *et al*. Lancet 2014(23).

WHO hosted a consultation at a meeting in Geneva, December 2014 to review the work of the Task Teams, and also gain inputs on the other core indicators. This meeting developed a draft plan to deliver on the ENAP metrics milestones including discussion on the specific actions needed to improve coverage indicators. Plans for improving measurement tools and tracking systems were also discussed; for example, perinatal audit tools, neonatal care registers and Civil Registration and Vital

Statistic (CRVS) improvements. The draft plan was then advanced by those at the meeting and through wider consultation.

The priorities for testing validity and feasibility to institutionalise these metrics within large scale data collection platforms and the measurement improvement roadmap (***Objective 3***) are discussed in detail in the discussion section of this paper.

3.5 Results

3.5.1 Grading of *Every Newborn* action plan core and additional indicators

Following the process described above, ENAP listed 10 core indicators (Figure 3.2). For the three impact indicators that already have agreed definitions (Figure 3.3), the priority is for improved quality and quantity of data. There is increasing consensus on the need to invest in CRVS and linked facility-based tracking to improve reliability of impact indicators (21, 42, 108).

The principal focus of this paper is on the coverage indicators, where the largest metrics gaps were identified. The coverage indicators fall into two groups: key contact points for care for all mothers and newborns (Figure 3.4), and specific treatment interventions (mainly for care for newborns at risk or with complications) (Figure 3.5 and Figure 3.6). For essential newborn care, early initiation of breastfeeding was identified as a tracer indicator, with exclusive breastfeeding up to 6 months as an additional indicator. Chlorhexidine cord cleansing was also added to the improvement agenda, given the gaps in coverage data.

Figure 3.3 *Every Newborn* core indicators regarding impact, with definitions and data sources

Core			Numerator	Denominator*	Data sources	Definition source
IMPACT	1	Maternal mortality ratio	Number of maternal deaths per year during pregnancy and childbirth or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy. Defined as a death from any cause related to or aggravated by pregnancy or its management (excluding accidental or incidental causes).	Per 100,000 live births	CRVS and registries (when high coverage and quality) or surveys or facility/HMIS and/or estimation modelling	ICD10. For more details see WHO/UNFPA/UNICEF estimates 2014 (121)
	2	**Stillbirth rate**	For International Comparison: Number of babies per year with no signs of life born weighing at least 1000 grams or after 28 weeks gestation (ICD10 also recommends the inclusion of fetal deaths ≥22 weeks or ≥500g).	Per 1,000 total (live and stillborn) births		ICD10**. See Lancet Stillbirth series 2011 Lawn et al for details of variations (122)
	3	Neonatal mortality rate	Number of live born infants per year dying before 28 completed days of age.	Per 1,000 live births		ICD10. See Lancet Every newborn for discussion of reporting of definitions (21)

Shaded= Not currently routinely tracked at global level.
Bold= indicator requiring additional evaluation for consistent measurement.
*The time period will normally be calculated per year.
**ICD assumes weight and gestational age are equivalent, which they are not (see Stillbirth series Lawn *et al.* 2011).

Figure 3.4. ***Every Newborn*** **core indicators regarding coverage of care for all mothers and newborns, with definitions and data sources**

<table>
<tr><th colspan="3">Core</th><th>Numerator</th><th>Denominator</th><th>Data sources</th></tr>
<tr><td rowspan="5">COVERAGE:
Care for all mothers and newborns</td><td>4</td><td>Intrapartum care tracked by the contact point of skilled attendant at birth</td><td>Number of women aged 15-49 years who were attended by skilled health personnel during their most recent live birth [MICS - 2 years preceding the survey]
Number of live births assisted by a skilled provider (doctor, nurse midwife, and auxiliary nurse/midwife) [DHS - 5 years preceding the survey]</td><td>Total number of women aged 15-49 years with a live birth in the two years prior to the survey [MICS] or all live births within the last 5 years [DHS]</td><td rowspan="5">Household surveys (e.g. DHS, MICS) or National facility data/Health management information system or district health information software</td></tr>
<tr><td rowspan="2">5</td><td rowspan="2">Early postnatal care contact for mothers and babies</td><td>Woman:
Number of women aged 15-49 years who received a health check within 2 days after delivery for the most recent live birth [DHS & MICS - 2 years preceding the survey]</td><td>Woman:
Total number of women 15-49 years with a live birth in the last 2 years [DHS & MICS]</td></tr>
<tr><td>Newborn:
Number of last live birth with a postnatal health check in the first 2 days after birth [DHS & MICS- 2 years preceding the survey]</td><td>Newborn:
Total number of last live births in the last 2 years [DHS & MICS]</td></tr>
<tr><td rowspan="2">6</td><td>Essential Newborn Care with Early Initiation of breastfeeding as Tracer indicator</td><td>Number of live born infants (born in the 2 years preceding the survey) who are breastfed within first hour after birth [DHS, MICS]</td><td>Total number of last live born infants [DHS & MICS]</td></tr>
<tr><td>Exclusive breastfeeding to 6 months</td><td>Number of living children (born in the 2 years preceding the survey) under 6 months of age who are exclusively breastfed [MICS] (MICS allows oral rehydration solution, vitamins, mineral supplements and medicines)

Number of babies 0-5 months who are exclusively breastfed [DHS]
(Both MICS and DHS questions focus on feeding behaviours within the last 24 hours from the time of survey)</td><td>Total number of living infants under 6 months of age [DHS & MICS]</td></tr>
</table>

Figure 3.5. ***Every Newborn*** **core indicators regarding coverage of care for newborns at risk or with complications, with definitions and data sources**

<table>
<tr><th colspan="3">Core</th><th>Numerator</th><th>Denominator (options to be tested and compared especially when target population for coverage is challenging to measure)</th><th>DATA SOURCES</th></tr>
<tr><td rowspan="5">COVERAGE:
Care for newborns at risk or with complications</td><td rowspan="2">7</td><td rowspan="2">Antenatal corticosteroids (ACS) use</td><td>Process Indicator:
The number countries with ACS on the essential drug list for the purpose of fetal lung maturation [As collected in the United Nations commodities commission data system & reported in Countdown]</td><td>Number of countries with Essential Medicine List policy data</td><td rowspan="5">Facility based: National facility-based data or facility survey (SARA, SPA etc.), potential in HMIS (initial focus of data collection in facilities WHO guidelines for these are mainly for facility treatment but for countries with major national scale up of community provision e.g. of severe neonatal infection case management, additional community tracking will be required.

Household surveys: These treatment interventions are unlikely to be measurable in Household surveys based on sample size, and challenges with defining denominators especially for parental recognition and also in knowing or recalling details of numerator (e.g.</td></tr>
<tr><td>Coverage indicator (needs validation):
All women giving birth in facility who are <34 completed weeks and received one dose of ACS for being at risk of preterm birth (later testing focus on splitting by gestational age)</td><td>a) Live births in the facility
b) Total births in the facility (including stillbirths)
c) Estimated births (live or total)
d) Target population for coverage:
i.e. live births in facility by gestational age in weeks, notably GA <34 weeks as target population for coverage</td></tr>
<tr><td rowspan="2">8</td><td rowspan="2">Newborn Resuscitation</td><td>Process indicator:
Number of facilities with a functional neonatal bag and two masks (size 0 and size 1) in the labour and delivery service area [as defined in WHO QoC report and collected in SPA & SARA facility assessment tools]</td><td>Total number of facilities with inpatient maternity services that are assessed</td></tr>
<tr><td>Coverage indicator (needs validation):
Number of newborns who were not breathing spontaneously/crying at birth for whom resuscitation actions (stimulation and/or bag and mask) were initiated</td><td>a) Live births in the facility
b) Total births in the facility (including stillbirths)
c) Estimated births (live or total)
d) Target population for coverage:
i.e. total births in the facility not breathing spontaneously/crying but excluding macerated stillbirths (i.e. including fresh stillbirths as a surrogate of intrapartum stillbirths)</td></tr>
<tr><td>9</td><td>Kangaroo Mother Care (KMC)</td><td>Process indicator:
Number of facilities in which a space is identified for KMC & where staff have received KMC training (< 2 years)</td><td>Total number of facilities with inpatient maternity services that are assessed</td></tr>
</table>

			Coverage indicator (needs validation work): Number of newborns initiated on facility based KMC	a) Live births in the facility b) Total births in the facility (including stillbirths) c) Estimated births (live or total) d) Target population for coverage: i.e. total number of newborns with birthweight <2000g as target population for coverage or <2500g	ACS injection vs. Oxytocin injection). KMC and treatment of neonatal infections may be feasible with further testing and sample size calculations.
	10	***Treatment of Severe Neonatal Infection***	Process Indicator: Number of facilities in which gentamicin is available at suitable peripheral level for treatment of severe neonatal infection [WHO QOC, collected by SPA and SARA]	Number of facilities assessed	
			Coverage indicator (needs validation work): Number of newborns that received at least one dose of antibiotic injection for PSBI in the facility	a) Live births in the facility b) Total births in the facility (including stillbirths) c) Estimated births (live or total) d) Target population for coverage: -newborns diagnosed with Possible Serious Bacterial Infection (PSBI) as target population for coverage	

Blue coloured cells= not currently tracked and collated by United Nations.
Bold italics= indicator needing further work to ensure availability of consistent data in routine information systems.
All coverage indicators to be tracked in such a way that they can be broken down to assess equity- e.g. urban or rural, regional, wealth quintile.

Figure 3.6 *Every Newborn* core indicators regarding coverage of complications and extra care (specific treatment indicators), with definitions and data sources

<table>
<tr><th colspan="2">Core</th><th>Numerator</th><th>Denominator (Options to be tested and compared especially when target population for coverage is challenging to measure)</th><th>DATA SOURCES</th></tr>
<tr><td rowspan="3">COVERAGE: Care for newborns at risk or with complications (specific treatment interventions)</td><td rowspan="2">Chlorhexidine (CHX) cord cleansing</td><td>Process Indicator:
The number countries with CHX on the essential drug list for the purpose of cord cleansing [As collected in the United Nations (UN) commodities commission data system & reported in Countdown]</td><td>Countries with Essential Medicine List policy data</td><td>As collected in the UN Commodities Commission & reported in Countdown to 2015</td></tr>
<tr><td>Coverage indicator (needs validation work):
Number of newborns that received at least one dose of CHX (7.1%) to the cord on the first day after birth (within 24 hours of birth)</td><td>Live births in surveyed population
(or live births at home depending on national policy/data available)</td><td>Potential to collect in household surveys (e.g. DHS, MICS)</td></tr>
<tr><td>Caesarean Section Rate</td><td>Number of women ages 15-49 with a live birth in the X years preceding survey delivered by caesarean section [Countdown, 2015]</td><td>Women ages 15-49 with a live birth
(also to evaluate option of per total births in facility per year (i.e. including stillbirths, macerated and fresh) given high rate of C-section amongst women with a stillbirth)</td><td>National facility-based data, or facility survey, HMIS, or household surveys</td></tr>
<tr><td rowspan="3">QUALITY: Service delivery packages for quality care</td><td>Emergency Obstetric care (EmOC)</td><td>Number of facilities in area providing basic or comprehensive EmOC [Monitoring EmOC handbook, 2009]</td><td>Population of area by 500000 [Monitoring EmOC handbook, 2009]
(note recent recommendation to shift to denominator based on births not population)</td><td>Facility based survey, or potentially from national facility-based data / HMIS</td></tr>
<tr><td>Care of small and sick newborns</td><td>Definitions and measurement approach to be determined
(Similar approach to EmOC)</td><td>Population to be defined
(according to births)</td><td rowspan="2">Facility based survey, or potentially from national facility-based data / HMIS</td></tr>
<tr><td>Every Mother Every Newborn</td><td colspan="2">Other norms and standards to be defined
(e.g. criteria related to structure, such as Water and Sanitation)</td></tr>
</table>

Blue coloured cells= not currently tracked and collated by United Nations.
Bold italics= indicator needing further work to ensure availability of consistent data in routine information systems.
Red= service delivery package for which norms and standards will be defined and tracked.
All coverage indicators to be tracked in such a way that they can be broken down to assess equity- e.g. urban or rural, regional, wealth quintile.

3.5.2 Status of *Every Newborn* action plan coverage indicators, and priorities to improve measurement at scale

For each coverage indicator, we describe technical definitions, current data availability, improvements needed and steps to be taken.

3.5.3 Coverage measurement of care of all mothers and newborns

3.5.3.1 Intrapartum care

Technical definition of package

A package of support and healthcare around the time of birth integral to maintaining perinatal and maternal safety along the continuum of care (123) (124). Skilled birth attendance (SBA) is used as the contact point indicator to monitor coverage of this care.

Indicator to track contact point

A skilled birth attendant is described by the WHO as an accredited health professional (such as a midwife, doctor or nurse) educated and trained to proficiency in the skills needed to manage normal (uncomplicated) pregnancies, childbirth and the immediate postnatal period and in the identification, management and referral of complications in women and newborns (125).

Current data availability

SBA data are available mostly from DHS, MICS, and are reported in many UN documents and by the Countdown to 2015/2030 report (http://countdown2030.org/), which charts country progress towards meeting MDG goals and targets. However, no robust time series has been published for all countries for the MDG era to date, although SBA was the main indicator under MDG5 for maternal health. Of 75 countries participating in Countdown, all but 15 provide equity analysis in relation to the coverage of SBA (120) (countries who do not report equity compared with SBA coverage are: Angola, Botswana, Brazil, China, Djibouti, Equatorial Guinea, Eritrea, Korea, Mexico, Myanmar, Papua New Guinea, Solomon Islands, South Sudan, Sudan and Turkmenistan). These suggest SBA coverage has the widest equity gap for any contact point along the COIA continuum of care indicators (120). SPA also has a new optional observational module for labour and delivery care that has been applied in Kenya, Malawi and Bangladesh developed by the Maternal and Child Health Integrated Program (MCHIP) that provides supplementary data for assessment of quality of care.

What can we do to improve the data?

While WHO's definition of a SBA has a defined list of core midwifery skills (118), measurement of SBA is challenged by the variety of cadres included in the definition and the lack of consistency in training, skills and core functions across countries (126). Besides doctors, nurses and midwifes, there are several other country specific cadres of auxiliary midwifes, medical assistants and other health professionals that are included in the SBA category in many countries; these may also be subject to change over time, or across survey programmes. Current work towards standardising the professional remit of SBAs and foster more universal accountability mechanisms are being carried out by WHO, UNICEF and UNFPA and expert consultations will be held in late 2015 to discuss operational definitions and develop measurement guidance for survey programmes.

In addition, SBA is an indicator of contact with the health system and does not provide information on the content or quality of care making it an incomplete and misleading proxy for quality of care at birth (113); additional information about equipment, provider skills, referral availability, content of care and other measures of quality are also required. Process indicators on facility readiness are collected by SPA, SARA and EmOC needs assessments (Figure 4) though the range of data collected varies between surveys and there is limited focus on newborn care. Current DHS and MICS survey tools do not collect extensive data on the content of care at time of birth (113); therefore, increasing the capacity and availability of routine facility level data is a priority for improvement.

3.5.3.2. Early postnatal care

Technical definition of package

A package of healthcare provided to women and their newborn either at the facility or during consultation at home. For women who deliver at a health facility, WHO recommendations support inpatient care for at least 24 hours, and/or provision of care as early as possible and at least within 24 hours for women and newborns who are born at home (127).

Indicator to track contact point

Early postnatal care is defined as a contact provided to a woman and her newborn during the 2 days (48 hours) following birth (whether in a facility or at home) (see Figure 4) and excludes immediate postpartum care (114).

Current data availability

The early postnatal care contact point is measured in household surveys as two separate indicators (a postnatal health check for the newborn and a postnatal health check for the mother) tracking coverage of a first postnatal contact within 2 days of delivery. The questions used to derive this indicator have changed significantly over time and have been different between the DHS and MICS (115), however Phase 7 of DHS (114) now includes questions allowing computation of a comparable postnatal care indicator.

What can we do to improve the data?

Postnatal care is a package of services for women and babies, therefore, data on content and quality are required in addition to tracking the contact point. One critical question is to ensure the data can distinguish between intrapartum and postnatal care (128). In both DHS and MICS, this is being attempted through the use of question prompts to better describe the content of the postnatal check and recent revision of the DHS core questionnaire includes a question on the content of PNC checks. Supplementary data pertaining to the content of care, provider skill and other quality control measures is urgently required; a move away from intermittent survey-based data collection towards sustainable HMIS is essential in ensuring that effective management mechanisms can be facilitated and can support routine quality of care tracking.

3.5.3.3 Essential newborn care

Technical definition of package

Preventive and supportive care required for all newborns including: warmth, cleanliness, breastfeeding, cord and eye-care, Vitamin K and immunisations (129-131).

Indicator to track care

Due to the strong evidence of a reduction in newborn mortality and morbidity with early initiation of breastfeeding, especially through decreased rates of infection (132-134), early initiation of breastfeeding was prioritised as a tracer indicator for essential newborn care, with exclusive breastfeeding at 6 months as a further marker (Figure 4). Indicators of other components such as skin-to-skin care, may also be possible, and are recalled accurately by mothers (113). However, these data are not currently widely available, and further testing is required to ensure that routine skin-to-skin can be accurately distinguished from KMC by survey respondents.

The WHO recommends the early initiation of breastfeeding within one hour of birth (135) and then exclusive breastfeeding for the first 6 months of life (136). To support this, babies should be placed skin to skin with their mothers immediately following birth and offered help to breastfeed when needed (137).

Current data availability

MICS, DHS and other national household surveys collect data measuring coverage of the early initiation of breastfeeding (107, 138) and it is reported in Countdown and State of World's Children (SoWC) (120). Both MICS and DHS contain measurement questions focusing on feeding behaviours within the last 24 hours from the time of survey. This approach allows for more accurate recall of the behaviour, however, does not capture breastfeeding practises across the infant time period and, therefore, the results may not reflect breastfeeding practises over time.

What can we do to improve the data?

A recent validation study reported that the early initiation of breastfeeding indicator had high sensitivity (0.82) but poor specificity (0.25), using a household survey instrument (113). Although the instrument used in the study posed a slightly different question than what is in DHS, this suggests a need for further testing and validation. Additional research to determine the impact of other essential newborn care practices would enable more informed and targeted behaviour change and associated measurement approaches.

3.5.3.4 Antenatal corticosteroids

Technical definition of intervention

Currently, antenatal corticosteroid therapy (ACS) (24mg of intramuscular dexamethasone or betamethasone in divided doses over 24 hours) is recommended by WHO for all mothers at risk of imminent preterm birth (delivery before 34 completed weeks of gestation) when the mother is in a facility where accurate gestational age can be obtained, where there is no clinical evidence of maternal infection, and there are adequate levels of maternity care and special newborn care available (139) (WHO guidelines are currently being revised). These guidelines reflect changes after the Antenatal Corticosteroids Trial (ACT) which evaluated prescription of ACS at lower levels of the health system, with approximately half of births being a home, and found a risk of adverse outcomes especially amongst births after 34 completed weeks of gestation (140). This trial underlines the importance of measuring gestational age, and better tracking of coverage and outcomes.

Current coverage data availability

Coverage data on provision of ACS for neonatal admissions are routinely collected within most high-income countries (HIC), but are not consistently part of HMIS or standardised facility surveys. Since the intervention is used in health facilities (140), improved facility level data are a priority for capturing ACS coverage. Household surveys are unlikely to be a useful source for this information, as mothers may not accurately report ACS (with difficulties to differentiate between ACS and other drugs given at the time of labour). In addition, data may have low statistical power given the relatively small numbers in the population who receive ACS for fetal lung maturation (113).

Process indicator to track now

In many LMICs, where HMIS does not capture ACS coverage, a commodities-based process indicator can be measured for tracking in the short term; SARA and SPA includes the availability of dexamethasone within their facility checklist. WHO Health Access/Action International database also collect data on availability of dexamethasone and betamethasone in their existing pharmacy and facility audits (141). However, a denominator of all health facilities may not be fully accurate as not all facilities would meet WHO criteria for safe provision of ACS (see definition above), including provision of appropriate maternal and newborn care (107) (142). Countdown reports the number of countries whose national policy recommends antenatal corticosteroids for preterm labour (107). While this indicator is distal to coverage, it is available and helpful in tracking changes in policy context (Figure 5).

What can we do to improve the data?

It is challenging to define a precise indicator that can capture both eligible women who should receive ACS and measure ACS provision. Recent evidence suggests use of ACS may be associated with a risk of adverse outcomes for babies whose gestational age is ≥34 completed weeks (140). A major challenge is defining the denominator of eligible mothers presenting in labour <34 weeks. In LMICs, the recall of LMP is often poor or inaccurate in settings with low rates of literacy and antenatal care. Access to ultrasonography is low and mothers frequently present for ANC late in pregnancy, when ultrasound dating is inaccurate. Thus, improved assessment of gestational age before and/or after birth, and documentation of gestational age in medical records, is an urgent priority in all settings irrespective of resource availability, along with improved tracking of safety and non-fatal outcomes. Studies are needed to validate different and feasible methods of ascertaining gestational age compared to accurate gestational age dating (early ultrasonography) in LMIC. Furthermore, methods require validation in different regions and in settings with high rates of fetal growth restriction.

Thus, present capacity within most LMIC may only extend to crude coverage of ACS (e.g. all mothers who received 1 dose) and will not differentiate between those who received ACS before (true positives), or after (false positives) 34 weeks completed gestation. To capture such information, existing datasets from high- or middle-income countries may be analysed to facilitate the development and testing of a more refined indicator. Improved gestational age assessment and documentation is needed in all settings irrespective of resource availability, along with improved tracking of safety and non-fatal outcomes.

Observation of facility births in a number of countries would allow for testing and validation of a number of options for the denominator (Figure 5). The measurement improvement roadmap aims to assess whether using these denominators is feasible in routine HMIS, and the extent to which proposed options for testing yield useful programmatic tracking information.

As with many of the treatment intervention coverage indicators, the option of using all live births as a denominator will not give accurate population-representative treatment coverage in settings where reporting in HMIS is poor, such as settings with low facility births or a large private sector. In such contexts it may be worth considering estimated births within a facility catchment area as denominator, which is more challenging where populations are not well-defined or birth cohorts are uncertain. A denominator that is not restricted to the population in need, will require definition of target coverage levels. For ACS this target benchmark could potentially be defined by the recent estimates of national preterm birth rate (<34 weeks), which was shown to vary from around 4% to 18% globally (9).

3.5.3.5 Neonatal resuscitation

Technical definition of intervention

Basic neonatal resuscitation describes assessment and actions for every newborn at the time of birth, to assist in establishing breathing and circulation (143); it should be practised on all non-macerated newborns not breathing spontaneously following immediate drying in accordance with current WHO guidelines (144). Effective and safe resuscitation of these babies is highly time-sensitive and should be initiated within the first minute after birth. The actions include additional stimulation and positive pressure ventilation with bag and mask if clinically indicated following stimulation (145). The intervention definition does not include advanced resuscitation measures such as intubation and/or medications.

Current coverage data availability

National coverage data are not currently available on neonatal resuscitation and the intervention lacks a standard measurable indicator. As with ACS, there are several known and suspected limitations of using household surveys to measure neonatal resuscitation coverage, including the likely inability of mothers to report accurately as they may not understand or know if their newborn was resuscitated at birth, and small numbers resulting in low statistical power (113, 146).

Process indicator to measure now

Data on the availability of a functional newborn size bag and mask in the delivery area of a health facility offering maternity services may be utilised as a service readiness indicator for neonatal resuscitation, as these data are easy to document and already available now for many countries (see Figure 5) (101, 117, 118). SPA and SARA capture the availability of at least one neonatal size bag and mask in the labour and delivery ward (SARA captures two sizes of masks) and neonatal resuscitation was added to the UN EmOC signal functions in 2009 with data collected as part of standard EmOC needs assessments supported by UNICEF. Since a neonatal-size bag and mask is on the UN essential commodities list, this equipment is also increasingly tracked in logistics management information systems (LMIS). This indicator has strong negative predictive value (a labour ward with no bag and mask cannot ensure adequate resuscitation when needed) and was recommended by the WHO consultation on quality of care (147). However, the presence of resuscitation equipment does not equate to appropriate and timely use of the neonatal bag and mask, and not all newborns who do not breathe at birth require positive pressure ventilation. Many newborns may respond to stimulation alone, and there is evidence demonstrating that the provision of resuscitation training is associated with a reduction in bag and mask use (148). Supplementary information regarding the presence of staff who have received newborn resuscitation training in the last two years is collected as part of the SARA and SPA surveys; however, these data may be difficult to compare depending on question framing (101, 117).

What can we do to improve the data?

One of the major challenges in capturing precise neonatal resuscitation coverage is the identification and accurate measurement of a denominator that reliably captures babies requiring resuscitation to establish breathing after birth. As with other treatment indicators, accurate identification of the target population depends on correct diagnosis and classification of the individuals in need by health care providers. Accurate classification of babies needing resuscitation is challenging in all settings due to variable diagnostic skills and experience of individual providers (7, 146). Independent of provider competence, this would likely be difficult data to collect in routine systems; we can speculate that it is unlikely that any healthcare worker would record a case where a baby required resuscitation but did not receive it. As with ACS, the measurement improvement roadmap outlines the priority denominators for testing and the validation of observed compared with reported resuscitation practises. Appearance, Pulse, Grimace, Activity, Respiration (APGAR) scores were intended to assess the condition of the newborn after birth but are not useful for measuring of resuscitation for monitoring purposes as they are not reported until 1 minute of life, after the time within which resuscitation should be initiated. In addition, APGAR scores may not be predictive of outcome unless the score is very low at 5 minutes, and in busy labour wards the scores are often recorded after the event, if at all.

There are further challenges associated with defining a numerator to track neonatal resuscitation coverage accurately and feasibly. An important principle in effective and safe neonatal resuscitation is careful assessment and stimulation of the newborn who does not start breathing spontaneously after routine drying, and only using bag and mask if needed in order to reduce inappropriate use of positive pressure ventilation (145, 149, 150). However, bag and mask use may be easier to recall and validate than distinguishing stimulation actions, such as back rubbing, from routine drying and wrapping. A study in Sweden found that neonatal resuscitation documentation was inadequate for reliable evaluation (151); documentation of resuscitation is unlikely to be more adequate in LMICs. Several countries such as Bangladesh, Nepal, and Tanzania, propose testing collection of routine information on newborn resuscitation by action step. Further analysis of such efforts is likely to be useful.

Proposed testing includes comparison of health worker documentation of newborn resuscitation actions in facility records with observed or video recorded resuscitation care; some of this may be possible using existing videos from Nepal or birth records from Bangladesh. New work to observe births in health facilities across a number of countries would allow testing of the resuscitation denominator options (Figure 3.4) in line with the other treatment indicators, including various case definitions of babies who do not breathe at birth, or do not breathe after stimulation. A simpler denominator for resuscitation based on live births would require defined target levels. According to estimates (based on limited observational data) approximately 6-10% of newborns may require some assistance to begin breathing at birth (7, 152).

3.6.3.6 Kangaroo mother care

Technical definition of intervention

A method of caring for LBW newborns (mostly preterm) is direct and continuous skin-to-skin contact, in the kangaroo position, with their mother (or guardian), with support for early and exclusive breastmilk feeding. The current evidence to achieve mortality reductions is KMC for clinically-stable newborns, weighing less than 2000g, initiated in a facility (153). WHO guidelines support that the infant is cared for in the kangaroo position for the equivalent number weeks it would have taken for the infant to reach full term (or as long as the baby will tolerate the position) accompanied with appropriate follow up after discharge (154).

Current coverage data availability

Limited data on KMC are available from facility-based surveys and HMIS for several countries, including Malawi, Dominican Republic, and El Salvador. Some middle-income countries, especially in Latin America, have detailed program data on KMC received, but there is no existing standardised coverage indicator definition. There may be differences between the level of facility in which KMC can be safely provided or initiated and the eligibility criteria for KMC, which creates difficulties in comparing data between settings. Measurement of KMC is not currently carried out by routine household survey platforms.

Process indicator to measure now

Given the immediate challenges for capturing coverage, a service-readiness indicator is proposed: the number of facilities in which a space is identified for KMC and where at least one staff member has received KMC training (SPA measures within the last 2 years) (see Figure 3.5). This measure is similar to that defined in a recent consultation by WHO on improving measurement on the quality of maternal, newborn and child health care in facilities (147) and is consistent with current SARA and SPA facility assessment tools (101, 117).

What can we do to improve the data?

It is possible to measure the number of newborns initiated on facility based KMC in a number of settings through HMIS or hospital admission records (e.g. El Salvador, Dominican Republic, Malawi, Tanzania). However, measuring a denominator of <2000g is challenging given that nearly half of all newborns globally are not weighed at birth. Where birthweight is recorded, there is a known tendency for digit preference and heaping, especially at 2500g and 2000g (155). The denominator could be measured as a rate per 100 or per 1000 live births, avoiding the difficulties of including weight in the numerator and identifying babies in need for the denominator. However, this doesn't measure whether babies were truly eligible or benefitted from KMC. Since KMC is an intervention that benefits predominantly preterm infants, the proportion of live births that could benefit from KMC will vary between settings (4 to 18%); identical rates may correspond to a different unmet need for KMC (9).

Efforts to improve birthweight recording and gestational age assessment are integral to the scale-up and measurement of more precise indicators for KMC. Existing datasets from countries with established KMC programmes and accurate assessment of gestational age and birthweight should be used for testing the denominators and proposed numerator (Figure 3.5). Linked to the measurement improvement roadmap, developing and validating questions for household surveys is also important if the practice is widespread enough to ensure a sufficient sample size. Recent work in Colombia has shown that women can accurately and reliably recall KMC, even decades later (156).

To develop the service readiness indicator, both the WHO quality of care report and the KMC Acceleration Group propose a measure of "operational" KMC (147), although this would need further work to identify and test its specific components. The operational indicator could be based on available "tracers"; for example, SPA currently collects data on allocated KMC space, infant weighing scales, thermometer, and whether staff has received training. Other items (feeding cups, NG tubes, job aids) or improvements to the questions on training and space could be added where more detailed assessments are being carried out. In Colombia, a manual of minimum, desirable and optimal standards for KMC has been developed (157), which could be adapted for different settings.

3.5.3.7 Treatment of neonatal infection

Technical definition of intervention

The provision of antibiotics to newborns admitted for inpatient care with PSBI, in accordance with current WHO treatment guidelines (158, 159) and diagnostic algorithms (160). Case management can also be considered by levels of care: administration of oral antibiotics only, injectable antibiotics only, or full case management of neonatal infection (potentially second line antibiotic therapy, IV fluids, oxygen therapy, other supportive measures) (161). Recent trials of Simplified Antibiotic Therapy show that, where referral is not possible, treatment with the simpler regimes by lower level workers is feasible (162).

Current coverage data availability

Most LMICs do not collect or aggregate the number of newborns treated for PSBI in HMIS. Household surveys, including DHS and MICS, do not collect data on newborns treated for PSBI because these would likely be unreliable (given recall issues measuring incidence of pneumonia in children under five years) (163). This contrasts with HIC settings where HMIS data is routinely maintained with additional data points specific to monitoring antibiotic resistance.

Process indicator to measure now

Given challenges in measuring coverage of serious neonatal infection, a process indicator is proposed: the proportion of facilities in which gentamicin is available (at a suitable peripheral level) for treatment of serious neonatal infection (147). This is collected by both the SPA, SARA facility assessment tools (101, 117) and the WHO health action/access international database (141). However, as with resuscitation, the presence of the antibiotic in the facility does not directly measure correct use of antibiotics to treat newborns for PSBI or guarantee that the antibiotic is available in paediatric doses (164).

What can we do to improve the data?

The number of newborns treated with at least one dose of injectable antibiotic at a facility is proposed for validation and feasibility testing against a number of denominator options, including total live births, the number of newborns presenting with illness, or the number of newborns diagnosed with pSBI. As treatment regimens may vary between settings, the measurement improvement roadmap aims to assess multiple options for a numerator and explore the validity, feasibility and utility of using HMIS to collect this data. For measurement of the dose of any antibiotic, more details would be required at program and/or facility level (rather than from the coverage indicator); notably, which antibiotic(s) were used and whether the course was completed. It will be necessary to determine appropriate use of antibiotics, as over treatment may increase anti-microbial drug resistance. Routine, national systems are required to track all injectable antibiotic doses given, and those not given, with associated clinical outcomes. A recent review found that within facility based audits, the availability of data on neonatal specific formulations (lower concentration gentamicin, procaine benzylpenicillin) was scarce (164) and therefore, more data is needed regarding the availability of neonatal formulations and specific requirements for administration to newborns. At first level facilities, testing of the new WHO module on “where referral is not possible” with new simplified antibiotic regimens (165) will be possible in five countries (Democratic Republic of Congo, Bangladesh, Pakistan, Ethiopia and Nigeria). Process and quality indicators should also be improved at the facility level, for example, gentamicin has a narrow therapeutic index and is associated with toxicity risks (158); therefore, monitoring its safe administration at program or facility level is an important marker of quality care. Specific data on neonatal administration of medicines (formulations, concentrations) could also help monitor safety and quality of care in facilities. In addition, where direct patient observations are carried out (as with SPA for the treatment of suspected pneumonia), this could be extended to the treatment of serious neonatal infection in facilities to ensure health worker compliance with integrated management of childhood illnesses (IMCI) guidelines (159).

3.5.3.8 Chlorhexidine cord cleansing

Technical definition of intervention

Chlorhexidine (CHX) cord cleansing is the routine application of topical chlorhexidine digluconate 7.1% (solution or gel, delivering 4%) to the cord stump within the first 24 hours of life. The WHO currently recommends this intervention in settings with an NMR >30 per 1000 or for homebirths (166) (167).

Current coverage data availability

The recommended routine administration of CHX cord cleansing is a recent policy development (127). Data are not collected by most HMIS or as part of standardised household survey tools. Both SPA and SARA track the availability of CHX used for general disinfection in their commodity checklists (101, 117). Monitoring use of 7.1% CHX for cord cleansing requires documentation of the presence of the specific concentration of CHX (7.1% formulation rather than any type of CHX product). Because of country-specific variations in policy for routine cord cleansing, documenting availability of 7.1% CHX in a health facility will only be of use in settings where programs that use chlorhexidine for umbilical cord cleansing exist.

Process indicator to measure now

Given the current challenges in measuring coverage, the inclusion of CHX 7.1% (solution or gel) within national essential drug lists for the purpose of cord cleansing has been identified as an interim process indicator (Figure 3.6). These data are collected by the RMNCH Trust (formerly UN Commodities Commission) and are reported by Countdown (107). As with ACS, this indicator is distal and is not a measure of coverage; however, it is an important enabling condition, data are currently available, and it would facilitate tracking of policy changes in the coming years.

What can we do to improve the data?

Household surveys can be used to measure CHX coverage, as carried out in Nepal (168), *The number of newborns who had chlorhexidine applied to the cord stump within the first day of birth* can be evaluated against a denominator of live births in the survey population. DHS has incorporated an optional five question CHX module for countries with a national CHX for umbilical cord cleansing programme as part of its newborn module. In countries where CHX has been introduced at scale (e.g. Nepal, Bangladesh, and Nigeria), the CHX technical working group is recommending adding a follow-up probe question specifically asking about CHX use.

Refinement of both the numerator and denominator with rigorous assessment of sensitivity and validity will be beneficial. Showing the respondent a picture of the locally marketed CHX during a household interview might assist with recall, improve validity and will be tested as part of the measurement improvement roadmap. Due to variations in national policy on use of CHX within facilities, further testing is required to assess the sensitivity and specificity of household survey questions on CHX cord cleansing following birth within a facility, where cord cleansing may have occurred away from the mother or performed in her absence. Further validation will be undertaken to compare observed CHX use with reported practice. Depending on findings, longer-term efforts towards institutionalising CHX coverage questions within routine household survey platforms would be essential to achieve consistent coverage data.

3.6 Discussion

The *Every Newborn* movement is committed to supporting countries to reach a target of $\leq$12 neonatal deaths and stillbirths per 1000 births by 2030, also closely linked to ending preventable maternal deaths (6). The ENAP metrics process has highlighted major gaps and lack of tracking for newborn interventions at all levels of the health management information system. To date, insufficient technical work and investment has been dedicated to strengthening national data systems and to rigorous testing of coverage data. Both validation and feasibility testing using standard research protocols for rigorous testing are needed. The multistage ENAP metrics process identified 10 core indicators and a set of 10 additional indicators (Figure 3.2). Of the core ENAP indicators, five newborn-specific interventions are high impact and central to ENAP, yet coverage information is not collected through existing measurement platforms with comparable data. Our findings highlight the priority actions required to improve ENAP indicators, especially coverage, and detail the technical and research priorities that will enable countries to collect and use the data in health sector review processes (Figure 3.1); these findings are informing a roadmap to address measurement deficits by 2020.

3.6.1 Measurement improvement roadmap

The ENAP measurement improvement roadmap aims to build on existing national and global metrics work, particularly linking to maternal health metrics, whilst identifying and addressing key measurement gaps for the focus around care at birth and care of small and sick newborns (Figure 3.7). Through this process the measurement improvement roadmap aims to intentionally transfer data collection, management and analysis skills at a country level (Figure 3.8).

Figure 3.7. Measurement improvement roadmap for coverage indicators (including care of small and sick newborns)

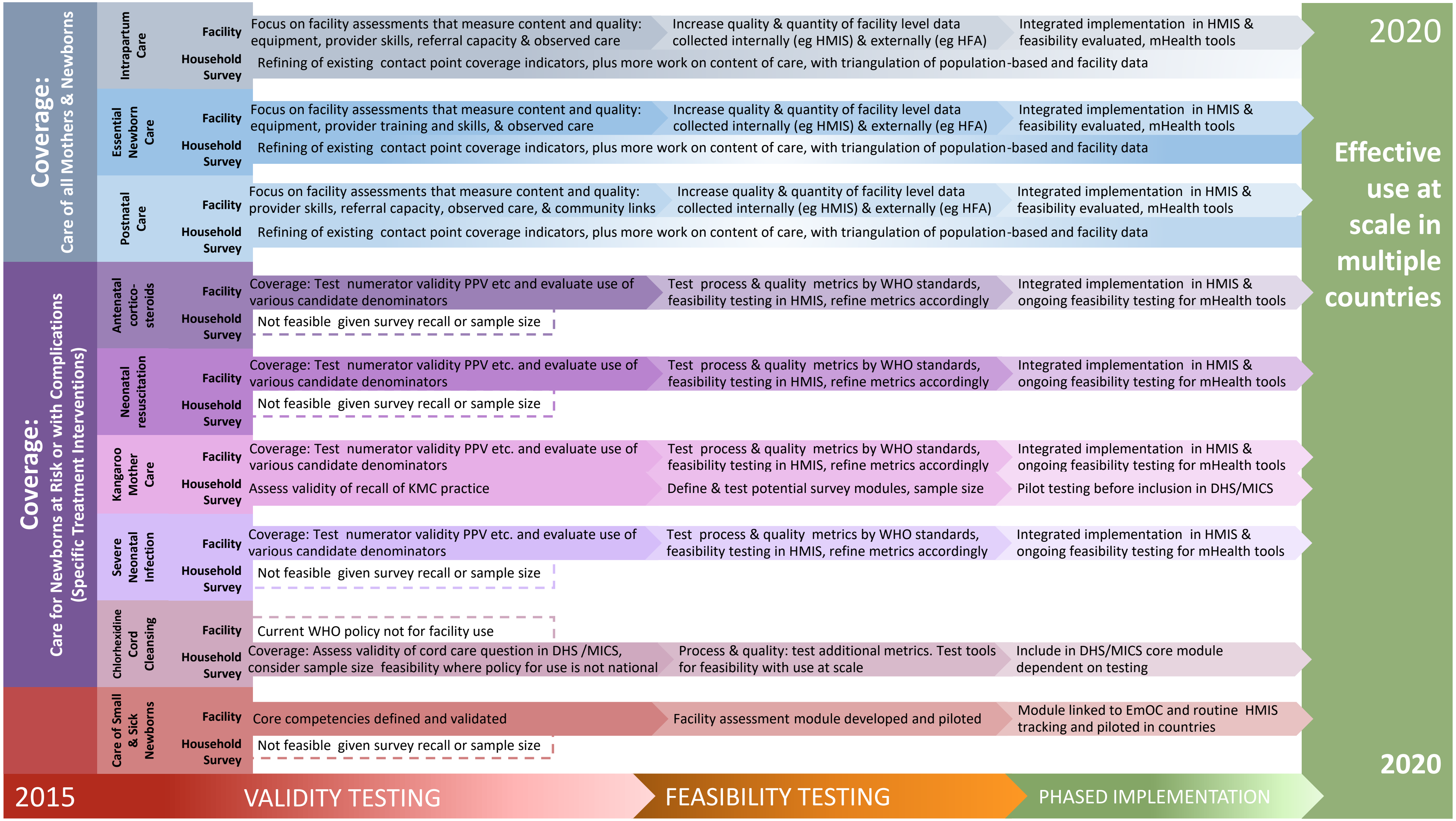

Figure 3.8. *Every Newborn* Measurement Improvement Roadmap

What is the Every Newborn Action Plan measurement improvement roadmap?

Given the world's commitment to end preventable maternal, newborn, child deaths and stillbirths, the *Every Newborn* Action Plan (ENAP) measurement improvement roadmap is a five-year plan to improve, institutionalise and use ENAP metrics in programmes by the year 2020, to track and drive reduction of neonatal mortality and stillbirths to ≤12 per 1000 by 2030. This Roadmap is in support of the Measurement and Accountability for Health (MA4Health) Roadmap (110) to increase investment in national health management information systems. Strong national data systems that count births and deaths, and track coverage of interventions, are fundamental to influence policy, improve quality and delivery of equitable services for a healthy start in life.

How has it been developed?

During the development of ENAP, a systematic process listed 10 core indicators. In the implementation phase, ENAP metrics work is led by a coordination group with representation from multiple partners co-chaired by World Health Organization (WHO), and London School of Hygiene & Tropical Medicine (LSHTM), working with task teams linked to existing technical working groups (e.g. Newborn Indicator Technical Working Group, United Nations Commission on life saving commodities (UNCoLSC) technical working groups). The work involved technical mapping of indicators, and measurement gaps and questions. Following a WHO Technical meeting in Geneva, December 2014, the measurement improvement roadmap was refined through a consultation process between January and May 2015.

What will this result in?

The output is a multi-partner, 5-year ambitious plan to validate and institutionalise these metrics in national data collection platforms and global metrics architecture including accountability mechanisms. This will result in improved measurement of coverage, quality and equity as well as impact through the development, refinement and/or the improvement of the following tools, and approaches to cross link data at these three levels including use of innovative mHealth platforms:

Civil and vital statistics

- Birth certificates and increased coverage and quality of data, e.g. for birth weight.
- Death certificates with improved perinatal data capture and International Classification of Disease (ICD) codes.

Facility and HMIS

- Perinatal mortality audit (linked to maternal audit, and death surveillance and response).
- Minimum perinatal dataset with health management information systems (HMIS) collation for highly prioritised data points, possible in Demographic and Health information systems 2 (DHIS2).
- Tracking of validated coverage indicators for quality of care at birth and care of small and sick newborns, (e.g. antenatal corticosteroids, resuscitation, kangaroo mother care, and treatment of neonatal infections).
- Health facility assessment tools (with standardised process and quality indicators).

Population based surveillance and surveys (Demographic and Health information systems/Multiple Indicator Cluster Surveys)

- Mortality capture including recall, misclassification of stillbirth/neonatal death and pregnancy versus live birth
- Verbal autopsy for stillbirths and neonatal deaths, with optional social autopsy
- Improved tools for assessing birthweight, birth size and gestational age.

Which partners?

To achieve institutionalisation, and intentionally shift technical leadership to high burden settings, the measurement improvement roadmap is linked to existing networks and country centres of excellence to ensure testing and use in many contexts. The process depends on national governments and multiple partners.

NETWORK 1: For mortality data INDEPTH Network with more than 50 sites in Asia and Africa:

- Population based pregnancy surveillance of birth, stillbirths and neonatal deaths
- Opportunities to advance validation of pregnancy history modules, improved low birth weight assessment and verbal autopsy tools.

NETWORK 2: For "Beyond Newborn Survival" data the All India Institute of Medical Sciences (AIIMS), the WHO collaborating centre for training and research in newborn care is well placed to be the institutional focus for:

- Designing a simplified follow up schedule for at risk newborns, by varying levels of care, to screen for disability, retinopathy of prematurity (ROP) and to improve child developments,
- Validate and test the feasibility of a minimum linked dataset for follow up.

COUNTRY HUBS FOR TESTING: The validation work will start with a few countries with opportunities to then expand to other countries

- Validation and feasibility testing for facility-based coverage data
- Linked tools such as perinatal audit, minimum perinatal dataset, and simplified gestational age assessment.

3.6.1.1 Impact indicators

Impact indicators are fundamental to tracking progress for *Every Newborn*. Without impact data we cannot accurately measure progress towards goals to end preventable maternal and newborn deaths and stillbirths. Child mortality data have seen the most significant improvement progress over the last decade (169). For example, the UN Inter-agency Group for Child Mortality Estimation (UN-IGME) report more than tripling input data, mostly through surveys.

ENAP milestones by 2020 include a number of tools to link facility-based minimum perinatal datasets with CRVS to increase birth/death registration (170) and birthweight capture, and in settings with a high proportion of home births, links to intermittent surveys or population surveillance may also be possible (Figure 3.1). Some countries are now implementing maternal death surveillance and response (171) and have begun to count maternal deaths in real time. A few countries are also incorporating perinatal death audits, which represents a key opportunity to expand use and quality of perinatal audit data (172). A major focus is needed for inclusion of stillbirth rates in reporting and accountability mechanisms, and especially increasing data on intrapartum stillbirths. Further opportunities have been identified in increasing the coverage and quality of CRVS and verbal autopsy to improve cause of death estimates for maternal, neonatal and stillbirths (173, 174). Substantial work is required on the additional indicators measuring newborn morbidity, disability and child development, which are critical to validate and institutionalise particularly as countries scale up neonatal intensive care services (Figure 3.7).

Improving measurement of gestational age is essential given that prematurity is the leading cause of newborn deaths and deaths in children under five (10). Preterm birth is also a major risk factor for deaths from infections and other morbidities (175). Gestational age is an essential part of clinical targeting of interventions to reduce morbidity and mortality and can be measured both during pregnancy (using methods ranging from the dating of LMP to using more resource intensive ultrasound scans) to clinical assessments of the newborn. The skill sets needed for the measurement approaches that are currently available are different. Estimating gestational age using first trimester ultrasound and the date of LMP is standard in most HIC, but these methods are not available for most women in LMIC. LMP recall is often poor or inaccurate in settings with low literacy. Universal access to ultrasonography is unlikely to be available to large numbers of women in LMIC in the shorter term, and/or mothers who present late in pregnancy, when ultrasound dating is inaccurate (+/- 3 weeks). Current work is looking at the potential for simplified tools for more accurate assessment of gestational age (176), including simplified clinical tools, and surrogate anthropometric measures that could be used by community health workers(177-179). Validation of new methods in cohorts with early accurate ultrasonography dating is a critical need. Feasible and innovative approaches need to be validated in different regions, populations and settings, across which their performance may vary.

3.6.1.2 Coverage indicators

The next five years demands an ambitious and systematic process for data improvement (through effective partnership) to address the gaps in newborn coverage indicators. Shared goals across the maternal and newborn health (MNH) community will facilitate metrics testing and help institutionalise capacity for systems to collect and use these data (Figure 1). In the short term, desk-based testing and validation of indicator definitions using existing datasets (from LMIC) is required. Additionally, these indicators need to be field-tested in a range of settings. The research process for validation of indicators involves collecting empirical data through direct observations of care in a facility and directly comparing this data with both health worker reports and maternal recall of events. Relatively large numbers of direct observations may be needed to ensure sufficient sample power for estimating sensitivity and specificity of the indicators using appropriate statistical tests. Initial testing sites have been identified as part of the measurement improvement roadmap (Figure 8). Once finalised, testing protocols will be made available to facilitate wide-scale testing across many different settings to yield comparable results. Where indicator definitions already exist and are being collected at scale, there is potential to increase the quantity, quality and frequency of the data (Figure 4). Crosscutting work on increasing the availability, quality, and accuracy of birth weight and gestational age assessment (both in pregnancy and the neonatal period) is needed and will support the development of more precise indicators. It is anticipated that findings from these studies will inform refinements to the proposed indicators before institutionalisation into existing systems (Figure 7).

Household surveys remain the primary data collection method to estimate coverage of contacts with the health system. The Population Council is carrying out ongoing work to assess the validity of current indicators measuring SBA (180). Such work provides invaluable evidence on the validity of maternal recall of interventions at the time of birth, with MICS using two-year recall and DHS now using the last birth within two years for some maternal and newborn indicators (although collects data for a five-year retrospective period). Even where recall achieves higher specificity (such as location of birth or Caesarean-section), their infrequent cycles (currently averaging 5 years) and high cost (181) make population level surveys less sensitive for annual programme planning and timely decision-making (182). Previous efforts to improve measurement of many interventions have focused predominantly on household surveys (183) (128) (113), including recent validation studies from the Improving Coverage Measurement Group. Many of the challenges of measuring the treatment of pneumonia in children through household surveys, especially in identifying the true population of children with pneumonia for the denominator (163), are also applicable to measuring coverage of treatment of neonatal infections and other specific treatment interventions.

The sample size required to generate point estimates of coverage of newborn interventions with sufficient precision through household surveys is often too high; even more so when attempting to consider equity and analyse by socioeconomic and demographic factors. For CHX cord cleansing in settings where policy is provision for all live births (127), data collection through a household survey such as DHS could be feasible. Other treatment indicators address subsets of newborns, and therefore, sample sizes and recall issues may make household surveys very challenging for coverage measurement. For measurement of treatment indicators, the results of the ENAP metrics process suggest a shift away from household surveys towards a focus on facility-based data collection tools where these interventions can be more feasibly and accurately measured, and a range of denominators tested for use (Figure 3.9).

Figure 3.9. Large scale data collection platforms for coverage and process indicators

Indicator (For full indicator definitions, numerators and denominators see Table 1-3 and web appendix)	Household Surveys		Routine health information systems	Health Facility Assessments		
	DHS	MICS	HMIS	SPA	SARA	EmOC
Care for all mothers and newborn babies						
Skilled birth attendant at birth (SBA)	✓	✓	✓	✓	✓	✓
Essential Newborn Care (immediate breastfeeding as tracer)	✓	✓				
Early postnatal care – for mother and baby	✓	✓				
Early and Exclusive breastfeeding	✓	✓				
Care for newborns at risk or with complications (specific treatment interventions)						
Antenatal corticosteroid (ACS)	X	X	*	✓	✓	*
Newborn resuscitation	X	X	*	✓	✓	*
Kangaroo Mother Care (KMC)	*	*	*	*	*	*
Management of severe neonatal infection	X	X	*	✓	✓	*
Chlorhexidine (where recommended)	*	*		✓	*	

✓ Already collected

* Feasible to collect

X=Not likely to be feasible to collect (due to recall of numerator, denominator identification challenges, sample size issues)

DHS: Demographic and Health Surveys, MICS: Multiple Indicator Cluster Surveys, HMIS: health management information systems, SPA: Service performance assessments, SARA: Service Availability and Readiness Assessments, EmOC: Emergency Obstetric Care.

For most of the treatment interventions, KMC, ACS, and currently most neonatal resuscitation and serious neonatal infection case management, policy recommendations are focused largely on facility-based initiation or administration. This has meant that preliminary task team work has focused predominately on facility platforms (with the exception of CHX). Combined testing in a number of facilities of the range of treatment interventions would enable more efficient testing of a range of numerators and denominators for each intervention using the same datasets and help to harmonise and align indicators with national and facility-level needs.

Where there is no denominator

Task teams found denominators the most technically challenging issue for measurement of intervention indicators and have identified a list of denominator options for testing wherever possible. Where detailed datasets are available with complete and accurate birthweight and gestational age data (for example in higher or middle-income settings), these will be analysed to test and compare the simplified per 100 or per 1000 live births denominator to a more precise indicator option to ascertain correlation between risk and the more precise indicator and sensitivity to change over time.

In view of contextual variation, such as varying preterm birth rates, or PSBI in different countries, there may be a need to define thresholds or upper and lower limits for indicator values. The proportion of C-section deliveries, for example, has been roughly benchmarked against a threshold of 5-15% in order to highlight where there is an unmet need (less than 5%) or to identify an excess number of C-sections (more than 15%) within a population (184-186); this threshold is not without controversy. Learning from such processes is important to set realistic, useful ranges for countries to monitor whether interventions are reaching a sufficient number of newborns within safe limits.

Health management information systems

Work towards sustainable, real-time, locally owned and used systems underlines the need for strengthening national HMIS (182). HMIS refers to health information collected and routinely reported from health facilities and districts (often from government or public sector facilities only) and are an ideal platform to influence as they are present in most settings, relatively inexpensive (compared with large scale representative household surveys) and largely driven by national decision makers. Electronic platforms are evolving to support data collection, management, analysis and report generation, linking to other systems including logistics management (rather than external agencies). The emphasis for strengthening HMIS needs to fall on improving the validity of HMIS indicators and increasing the use of this data for improving programme performance at the ground level. Many settings are now using District Health Information Systems 2 (DHIS2) (187). DHIS 2 software has a field-tested flexible data model with data entry forms for indicators and the ability to support data collection, management and analysis, including generating reports to monitor indicator trends over time and produce maps to visualise subnational variations for identification of inequities. There is potential for newborn treatment indicators (particularly KMC, ACS) to be included in HMIS/ LMIS, SPAs and other facility audits along with the supplies and equipment for ACS, neonatal resuscitation and PSBI treatment in settings where they do not already exist.

Before recommending inclusion of indicators into any national data collection system, indicators will need testing for validity and then for feasibility and usefulness, as per the steps of the measurement improvement plan (see Figure 1 and Figure 7). Given the ongoing tension between demand for more information for decision making, versus the need to be parsimonious with the number of indicators to avoid overburdening frontline workers and information systems, prioritisation of the ENAP treatment indicators for inclusion in these systems should be country specific and consider relevance to national policy and health system needs. Overloading an HMIS system with data can limit its usefulness and negatively affect data quality. In addition to validity testing, consideration of national data needs, existing levels of facility, infrastructure, resources and technical capacity is essential before introducing new indicators into a national HMIS. Furthermore, data from HMIS may be more limited in settings where a large proportion of births take place in the community (e.g. Ethiopia), or where there is a large private sector (e.g. India).

3.6.1.3 Input and process data for tracking content and quality of care

Given the challenges in measuring coverage for several of the treatment interventions, appropriate process indicators were identified that can be measured immediately. For the purpose of this discussion, “process” data refers to any measurement of the presence of specific elements needed to deliver an intervention, such as supportive policy, trained staff, commodities, documentation or infrastructure. Process data are not a replacement for coverage data but ensure a standardised proxy can be used immediately. These data can be measured through a variety of platforms, including HMIS, routine audits and/or facility-based supervision checklists. Additionally, periodic or intermittent health facility assessments, such as SPA (117) and service readiness assessments, such as SARA (101) and EmOC needs assessments (118) monitor input and process indicators. As many of the indicators (impact and coverage) measured through household surveys require relatively long periods of time to see significant change following policy adjustments, facility level programmatic data is essential for measurement of more proximate factors in the facility that are more amenable to change in the shorter term. Furthermore, facility surveys can provide external validation for self-reported data, such as those emerging from HMIS. Harmonisation of core modules for HFAs should include the priority ENAP process indicators to maximise their use and allow for comparison between surveys (Figure 3.9). However, the use of periodic health facility assessments is expensive and does not replace routine supervision or programme monitoring.

Some task teams proposed indicators regarding existence of supporting policy at national level as a key measure of process. For example, the task teams for both ACS and CHX proposed a measure of the number of countries with ACS or CHX respectively on the essential drug list since their addition is recent (2013)(139), data are collected in the RMNCH Trust data system and reported in Countdown (Figures 3.5 and 3.6). Given that these interventions are at an earlier point in policy to programme change, these may be useful trackers for now but as programme implementation accelerates, the process indicator should be shifted to more proximal readiness indicators and coverage.

The ENAP measurement improvement roadmap, in partnership with other tracking data harmonisation efforts, aims to test both simple and composite readiness indicators for newborn interventions, considering the presence of essential commodities, trained staff, and space.

Care of small and sick babies

There is a major gap in the definition of standards for the care of small and sick newborns; the provision of quality inpatient care for small and sick babies could have a significant impact on neonatal deaths (123). The UN EmOC indicators are based on process indicators referred to as “signal functions” for basic and comprehensive emergency obstetric care (118); currently only one signal function specifically relates to newborn care, but does not fully represent all interventions needed for emergency newborn care. New research supports the addition of signal functions specific to newborn care and strongly recommends that these indicators should be updated (188). Specific challenges and details on the levels of care are explained in greater detail elsewhere in the series (16) and ENAP recommends an ongoing process with the UN to define indicators for newborn care intervention packages by levels of care.

As a milestone in ENAP and reiterated in EPMM, addressing quality of care at birth is critical; the Every Mother, Every Newborn (EMEN) Initiative is part of this process as discussed in another paper (189).

3.6.2 Challenges and opportunities going forward

Integrating maternal health and broader roadmaps for improving metrics

It is essential to unite maternal and neonatal health communities towards a common metrics agenda with a convergence of global efforts to end preventable mortality and coordinated support to countries to assess progress meeting targets set within the SDGs, ENAP and the EPMM movement. These functions are the remit of the WHO, other UN agencies and academic partners, and can be aligned through the creation of an over-arching MNH reference group. This remit will also aim to link existing work and relevant convening groups, including those working on wider metrics systems change.

Intentional development of leadership to assess, improve and use data

In order to institutionalise the proposed metrics, there is a need to build leadership skills to assess and use data in high burden settings (Figure 3.8). These include INDEPTH Network's Maternal and Newborn Working Group, which aims to improve population-based metrics, especially pregnancy tracking, mortality, cause of death and social autopsy, birthweight and gestational age. INDEPTH is a network of currently 52 health and demographic surveillance sites (HDSS) in twenty countries where a total population of 3.8 million people are tracked each year. The Maternal and Newborn Working Group is building the capacity of member sites to use standardised tools and to make data regularly available to the public. The All India Institute of Medical Sciences/WHO Collaborating Centre for Newborn Care is well placed to develop a simplified database for follow up of at risk neonates, track and minimise disability outcomes and maximise child development, especially preterm, for example preventing blindness from retinopathy of prematurity (97, 190). ENAP is identifying provisional country hubs for testing of proposed indicator numerators and denominators initially linked to focus countries for EMEN.

3.7 Conclusion

Major gaps have been identified in the measurement of core ENAP indicators to track the progress towards targets to end preventable deaths for women, stillbirths, newborns and children; key messages and action points are summarised in Figure 10. The quality and quantity of impact data must be improved, but coverage indicators need the most urgent work. Content and quality of care is the current priority for the three contact point indicators. For the treatment indicators, preliminary work to identify measurable denominators is required in preparation for the quality improvement agenda. The findings of this work underline the need for increasing prioritisation for strengthening and improving routine facility-based data, CRVS and national HMIS. This paper has laid out a systematic, yet ambitious testing agenda – the ENAP Measurement Improvement Roadmap – to move towards use of these indicators at scale, which must be combined with an intentional transfer of technical leadership, especially to countries with the greatest disease burden. The strengthening of institutional capability to collect, analyse and convert data into action is essential. By 2020, the aim is to institutionalise the proposed metrics at scale across all countries. A roadmap that focuses on counting births, deaths and improves tracking of coverage and equity is central to support countries to build a strong national data system that can be used to inform policy and focus investment and resources towards quality service delivery for every newborn to have the chance of a healthy start in life (110).

Figure 3.10 Key messages for measurement improvement

Key messages

Every Newborn Action Plan published 10 core indicators with selected additional indicators following a systematic, multi-stage consultation process to assess 70 indicator options.

- The ***impact indicators*** – neonatal mortality rate, stillbirth rate and maternal mortality ratio – have clear definitions, but there are gaps in data quantity and quality.

- The ***coverage indicators for care of all mothers and newborns*** – intrapartum/skilled birth attendance, early postnatal care and essential newborn care – are based on clearly defined contact points, but still have major gaps in measuring package content and quality.

- The ***coverage indicators for care for newborns at risk or with complications (specific treatment interventions)*** - antenatal corticosteroids, neonatal resuscitation, treatment of severe neonatal infection and kangaroo mother care, and an additional indicator, chlorhexidine cord cleansing - lack clear indicator definitions. Data on these treatment interventions is not currently tracked in routine systems or existing data collection platforms. Measurement of the denominator for these treatment intervention indicators is especially challenging.

Key action points

The *Every Newborn* Metrics group has devised the Measurement Improvement Roadmap in order to track progress of *ENAP* milestones so that every country can reach a target of ≤12 neonatal deaths and stillbirths per 1000 births by 2030. This involves:

- Development of measurement tools (perinatal death certificates, audit tools, minimum perinatal dataset, gestational age and birthweight metrics improvements), including a focus on strengthening routine health information systems, linking to CRVS and population-based surveys.

- An ambitious plan to test validity of the *Every Newborn* coverage indicators, in selected facilities/settings, and feasibility of including in facility based HMIS, considering a range of options for denominators.

- Intentional transfer of leadership for measurement, especially in those countries with the greatest disease burden, with links to existing networks (e.g. INDEPTH) for testing, validation and institutionalisation of the proposed coverage indicators.

THEME A: Delivering quality inpatient care services for small and sick newborns

Chapter 4. Inpatient care of small and sick newborns: a multi-country analysis of health system bottlenecks and potential solutions

4.1 Introduction

The paper presented in this chapter aims to address the first objective of this PhD and describes the package of inpatient care for small and sick newborns. Using the WHO health system building blocks as a framework, this paper assesses the existing health system challenges impeding the scale up of inpatient care for small and sick newborns in 12 high burden countries using secondary data collected with a "bottleneck" analysis tool.

This paper was published in BMC Pregnancy and Childbirth in September 2015 as an open access article (16). See Appendix N for the published version of this article and copyright. The paper was part of a supplement of in-depth analyses, which focused on the specific challenges to scaling up high impact interventions and improving the quality of care for mothers and newborns around the time of birth. The nine papers in the series consist of one overview paper, six intervention package specific papers and two crosscutting papers. This is the 7th paper in the series focused specifically on inpatient care of small and sick newborns.

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Student ID Number	1405761	**Title**	Ms
First Name(s)	Sarah		
Surname/Family Name	Moxon		
Thesis Title	Service readiness for inpatient care of small and sick newborns: Improving measurement in low- and middle-income countries		
Primary Supervisor	Joy Lawn		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	BMC Pregnancy and Childbirth		
When was the work published?	September 2015		
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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I am the first author on this paper. I was responsible for designing and undertaking the analysis (secondary analysis of bottleneck data on small and sick newborn care) and writing the paper. Hannah Blencowe, the senior author of this paper, supported this work in an advisory capacity and helped to review drafts of the paper along with Joy Lawn. Kim Dickson with the Every Newborn action plan and UNICEF teams (including Aline Simen-Kapeu) were responsible for the development of the bottleneck analysis tool development, country consultation process. Aline Simen-Kapeu provided contributions to the data analysis in this paper. All named authors reviewed and approved the final manuscript.

SECTION E

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Date	06/12/2018

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Date	06/12/2018

4.2 Abstract

Preterm birth is the leading cause of child death worldwide. Small and sick newborns require timely, high-quality inpatient care to survive. This includes provision of warmth, feeding support, safe oxygen therapy and effective phototherapy with prevention and treatment of infections. Inpatient care for newborns requires dedicated ward space, staffed by health workers with specialist training and skills. Many of the estimated 2.8 million newborns that die every year do not have access to such specialised care.

The bottleneck analysis tool was applied in 12 countries in Africa and Asia as part of the *Every Newborn* Action Plan process. Country workshops involved technical experts to complete the survey tool, which is designed to synthesise and grade health system "bottlenecks" (or factors that hinder the scale up) of maternal-newborn intervention packages. For this paper, we used quantitative and qualitative methods to analyse the bottleneck data, and combined these with literature review, to present priority bottlenecks and actions relevant to different health system building blocks for inpatient care of small and sick newborns.

Inpatient care of small and sick newborns is an intervention package highlighted by all country workshop participants as having critical health system challenges. Health system building blocks with the highest graded (significant or major) bottlenecks were health workforce (10 out of 12 countries) and health financing (10 out of 12 countries), followed by community ownership and partnership (9 out of 12 countries). Priority actions based on solution themes for these bottlenecks are discussed.

Whilst major bottlenecks to the scale-up of quality inpatient newborn care are present, effective solutions exist. For all countries included, there is a critical need for a neonatal nursing cadre. Small and sick newborns require increased, sustained funding with specific insurance schemes to cover inpatient care and avoid catastrophic out-of-pocket payments. Core competencies, by level of care, should be defined for monitoring of newborn inpatient care, as with emergency obstetric care. Rather than fatalism that small and sick newborns will die, community interventions need to create demand for accessible, high-quality, family-centred inpatient care, including kangaroo mother care, so that every newborn can survive and thrive.

4.3 Background to the paper

Severely sick newborns, including those with infections, severe intrapartum insults, severe jaundice or those who are too small to maintain their body temperature or to breathe or to feed actively, will require inpatient care to survive. This paper forms part of a series on high quality maternal and newborn care and examines bottlenecks and solutions specific to the provision of newborn inpatient care for small and sick babies.

The first 28 days of life is a vulnerable time for newborns, with an estimated 2.8 million babies dying during the first month of life worldwide in 2013 (191). The main causes of death include direct complications of prematurity (36%), intrapartum events (previously called birth asphyxia) (23%), and infections (23%) (21, 45). Nearly three-quarters of all neonatal deaths occur in the first week of life (21). The highest risk of death or serious morbidity occurs among the 10 million born at term with low birth weight (<2500g) (33) and the 15 million born preterm (before 37 completed weeks of gestation) each year (9). Many lives could be saved, and morbidity prevented, through a combined health systems approach (4) along the continuum of care, with identification of those at high risk and timely provision of quality inpatient and supportive care (5). Strengthening of existing facility-based systems for the care of vulnerable newborns is the most effective approach for saving newborn lives (192) and is central to achieving the goals of the *Every Newborn* Action Plan (ENAP) (6).

Figure 4.1. Inpatient care of small and sick babies, showing health system requirements by level of care

Tertiary

Neonatal Intensive Care
For babies including ventilation

Place	• A special ward that includes neonatal care facilities • Incubators, resuscitaires • Space for kangaroo mother care* and supporting breastfeeding
People	• Nurses with specialised neonatal skills • High nurse-newborn ratio e.g. 1:1 in the UK • At least one doctor with specialised neonatal training
Equipment and commodities	In addition to special care equipment and commodities (see below) • Availability of Continuous Positive Airway Pressure, Intermittent Positive Pressure ventilation and monitoring equipment • Surfactant therapy for extremely premature newborns, if appropriate
Support system	• 24 hour laboratory support • Transport and safe referral if needed • Space for mother and family to stay close to their baby

Secondary

Special Care
For small & sick newborns

Place	• A specific room or specially allocated corner of a warm facility, with specific areas for resuscitation, stabilisation and space for kangaroo mother care* • Incubators/resuscitaires overhead heaters
People	• Specialised nursing and midwifery staff • High nurse/midwife to newborn ratio e.g. 1:4 in United Kingdom
Equipment and commodities	• Feeding support with **nasogastric tubes** and **Intravenous fluids** • Infection prevention and management, including antibiotics • Some access to **oxygen provision (with pulse oximetry),** and effective phototherapy for jaundice case management
Support system	• Space and support for mothers including place to express breast milk

Primary

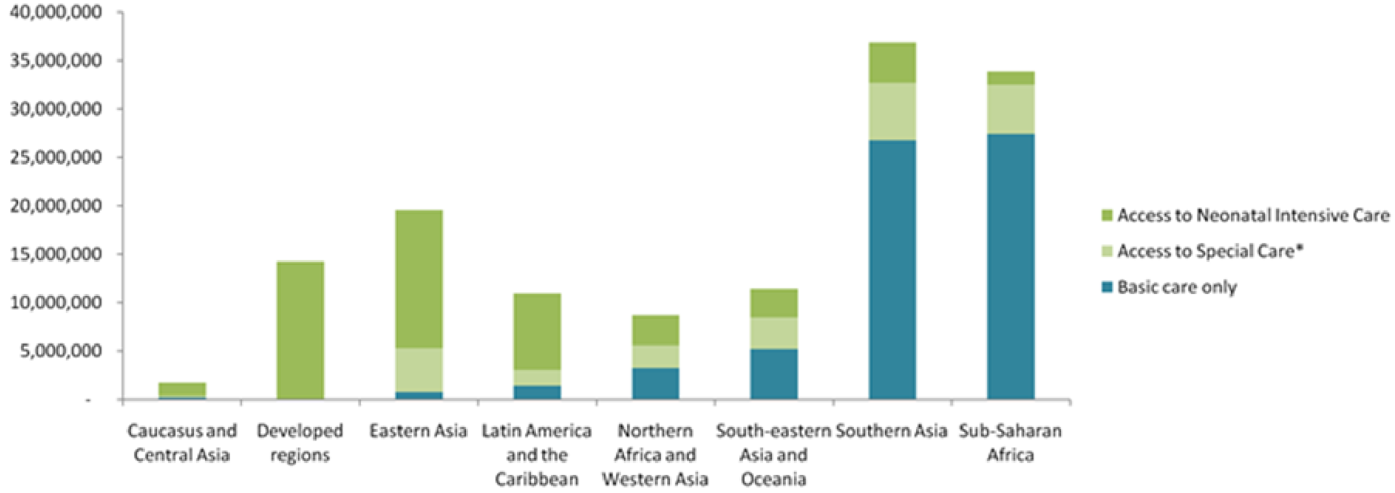
Basic Care*
For all newborns

Place	• Basic facility or home birth with skilled attendance
People	• Midwifery and nursing staff
Equipment and commodities	• No specialised equipment (apart from bag and mask for resuscitation when required).
Support system	• Warmth, cleanliness and breastfeeding support

Red text signifies tracer indicator for bottleneck tool analysis.
*See Vesel et al (2015)(193) Kangaroo mother care, Enweronu-Laryea et al (2015)(8) Basic newborn care and resuscitation, and Simen-Kapeu et al (2015)(58) neonatal sepsis.

Inpatient care is usually delivered across three levels (Figure 4.1) and refers to the facility-based care of newborns focused on both treatment and prevention of infection and further complications. Prevention includes protection from hypothermia (ensuring warmth) and hospital-acquired infection, as well as the provision of adequate nutrition (often with nasogastric or cup feeding), with the overall goal of establishing exclusive breastfeeding where possible. Treatment, where available, centres on the management of common neonatal conditions including respiratory distress syndrome (RDS), neonatal infections, hyperbilirubinaemia, feeding difficulties (5) and the prevention and treatment of retinopathy of prematurity (ROP)(97). Advanced treatment for other important conditions, such as necrotising enterocololitis (NEC), patent ductus arteriosis (PDA), correctable congenital anomalies and broncho-pulmonary dysplasia (BPD) may also be undertaken. Basic newborn care (providing cleanliness, warmth and support for breastfeeding) is essential for all babies, including timely resuscitation for up to 10% of babies that may require resuscitation at birth (7) and is covered elsewhere in this series (8). Inpatient care for small or sick babies includes two cornerstone components: KMC and sepsis case management, which are also considered elsewhere in this series (58, 193). While in a well-functioning health system all three levels of care will be available (Figure 4.1), many small babies can be managed without provision of any higher level neonatal intensive care and can be looked after in special care units (5). Currently, however, over three quarters of babies born in sub-Saharan Africa and Southern Asia could not access special care if they were to require it (Figure 4.2).

Figure 4.2. Estimated coverage of neonatal care by region of the world and level of care



*By Special Care Baby Unit, this is the highest level of care available (i.e. no Neonatal Intensive Care).

Data source: Adapted from Beyond Newborn Survival: The Global Burden of Disease due to Neonatal Morbidity. Estimates of neonatal morbidities and disabilities at regional and global levels for 2010: introduction, methods overview, and relevant findings from the Global Burden of Disease study. Pediatric Research; December 2013, Volume 74, (Supplement 1)(42).

High quality inpatient care for sick neonates includes careful monitoring by trained health professionals with a sound understanding of the physiological and psychosocial needs of the small or sick newborn baby and their families. A recent DELPHI exercise estimated that optimal supportive care in a hospital Special Care Baby Unit (SCBU) could avert 70% of neonatal deaths due to preterm birth complications, and that 90% could be averted with availability of hospital Neonatal Intensive Care Units (NICUs) (4). Whilst coverage of these inpatient care packages is near universal in high-income settings, both the coverage and the quality of care available in middle-and low-income settings are highly variable (42). The provision of high-quality nursing and inpatient medical care of small and sick newborns not only saves lives but could also help to facilitate more rapid discharges from health facilities, leading to better short and long-term morbidity outcomes for these babies, including reduction of BPD and ROP. This need is reflected by the current burden of long-term disability in survivors following preterm birth being greatest in middle income countries, particularly where coverage of inpatient neonatal care has expanded without due attention to the quality of care provided (97).

Inadequate care in facilities can be caused by a number of constraints usually related to health worker shortages and poorly equipped facilities, compounded by a lack of specific knowledge and competencies in dealing with small and sick newborns amongst existing clinicians and nursing staff (29). Facility-based neonatal care frequently remains under-prioritised and under-funded in many parts of the world, particularly in LMIC. Few standardised indicators exist to measure quality of newborn care in facilities and challenges remain to improve the metrics and core competencies (15). Inadequacies in supplies and safe use of medicines and equipment (including effective phototherapy and case management for sick neonates) are common problems despite the fact that evidence-based interventions exist that can be delivered in resource-constrained environments (194).

The vision of providing quality care to sick newborns is part of a wider global movement – the UN Secretary General Global Strategy in 2010 (195) called for innovative approaches to provide quality care for mothers and newborns, using coordinated research and the formulation of accountability mechanisms through the Commission on Information and Accountability for Women's and Children's Health (COIA). Published in 2014, The Lancet Every Newborn Series (http://www.thelancet.com/series/everynewborn) demonstrated the progress that has been made, even in challenged settings, and outlined the urgent steps still needed to improve newborn survival. The Lancet papers proposed a package of integrated quality interventions (29, 189) – the Every Mother, Every Newborn (EMEN) initiative - that have been outlined in the ENAP alongside specific actions and ambitious targets for newborn survival (6). This paper aims to interrogate country-level data on "bottlenecks" to quality care and to draw out innovative solutions, in order to aid the formulation of country led health plans and strengthen the capacity of health systems to respond to the needs of small and sick newborns.

4.3.1 Objectives of the paper

The objectives of this paper are to:

- Use a 12-country analysis to explore health system bottlenecks affecting the scale-up of inpatient supportive care for small and sick newborns
- Present the solutions to overcome the most significant bottlenecks including learning from the 12-country analyses, literature review and programme experience
- To discuss policy and programmatic implications and propose priority actions for programme scale up.

4.4 Methods

This study used quantitative and qualitative research methods to collect information, assess health system bottlenecks and identify solutions to scale up of maternal and newborn care interventions in 12 countries: Afghanistan, Cameroon, Democratic Republic of Congo (DRC), Kenya, Malawi, Nigeria, Uganda, Bangladesh, India, Nepal, Pakistan and Vietnam.

4.4.1 Data collection

The maternal–newborn bottleneck analysis tool was developed to assist countries in the identification of bottlenecks to the scale up and provision of nine maternal and newborn health interventions across the seven health system building blocks as described previously (29, 189). The tool was utilised during a series of national consultations supported by the global *Every Newborn* Steering Group between July 1st and December 31st, 2013. The workshops for each country included participants from national ministries of health, UN agencies, the private sector, non-governmental organisations (NGOs), professional bodies, academia, bilateral agencies and other stakeholders. For each workshop, a facilitator oriented on the tool coordinated the process and guided groups to reach consensus on the specific bottlenecks for each health system building block. This paper, seventh in the series, focuses on the provision of inpatient care of small and sick newborns.

Tracer interventions were defined for each package to focus the workshop discussion. For the purpose of this bottleneck analysis, three interventions required for the treatment of common neonatal conditions were included as tracer items for the package of inpatient care: safe oxygen administration, intragastric tube feeding (IGTF) and the provision of intravenous (IV) fluids (Figure 4.3). Oxygen therapy is a mainstay treatment for small and sick babies, with respiratory compromise commonly seen in RDS (following preterm birth, neonatal pneumonia and neonatal sepsis) and respiratory failure being an important mechanism in most neonatal deaths (21). Developmental immaturity of the preterm newborn (especially those born before 34 weeks gestation), or severe illness in a more mature neonate, may limit their ability to coordinate sucking and swallowing required for successful exclusive breastfeeding. In these instances, intragastric feeding is a commonly used low-tech intervention to deliver nutrition, using expressed breast milk where possible. In addition, many of the most small and sick newborns will require administration of IV fluids to prevent dehydration as a result of insensible water loss, and to manage the delicate fluid, electrolyte and glucose balance, especially in the first days after birth (196).

Figure 4.3 Definitions of tracer indicators for inpatient care of small and sick newborn bottleneck analysis tool

Safe oxygen administration
Involves the use of an appropriate delivery mechanism with adequate monitoring to ensure that babies maintain appropriate oxygen levels. Common interfaces used are nasal prongs/cannula, head box, Continuous Positive Airway Pressure (CPAP) or in a small proportion of the most severe cases, mechanical ventilation. All babies require the monitoring of oxygen levels using pulse oximetry to ensure optimum and safe levels of oxygen are delivered to maximise survival and minimise potential damage (97, 197). There has been substantial debate around the optimal oxygenation levels for sick neonates. Hyperoxia may lead to brain injury and in premature neonates can lead to retinopathy of prematurity (ROP). The highest risk of ROP is in neonates born at <32 weeks, however ROP can occur in sick neonates born at up to 36 weeks gestational age where inadequate attention is given to safe oxygen delivery (198). Conversely, hypoxemia can lead to brain injury, renal failure, pulmonary hypertension and necrotising enterocolitis (NEC). As targeting lower O_2 saturation levels (85-90%) decreases risk of ROP, but increases the risk of mortality, current recommendation is to target levels 90-95% - especially in very premature infants (199). Finally, oxygen administration relies on safe mechanisms for storage (including consideration of fire risk) and containers for its delivery (oxygen concentrators or blenders).
Intragastric feeding
Refers to the administration of milk feeds through a small plastic tube (196). The tube should be passed by a trained individual, usually a nurse, through the nose (naso-gastric) or mouth (oro-gastric) (collectively referred to as intragastric) directly into the stomach. For many infants, particularly very small and sick newborns, it will be undesirable to commence enteral feeds at the full volume needed to meet their nutritional needs. The immature gut and renal systems may have limited capacity to tolerate milk feeds and balance electrolytes – particularly sodium. Where full enteral feeding is not tolerated, intravenous fluids or total parenteral nutrition (TPN) may be considered, in settings where these are available.
Safe administration of IV fluids
Intravenous fluids are most commonly administered through venous cannulae inserted by trained medical or nursing staff. They require careful monitoring of the insertion site for signs of infection, as well as meticulous monitoring of fluid intake and output, including serum electrolytes, urine output and daily records of weight(196). Intravenous fluids should be administered with caution, complemented by enteral milk feeds where feasible. They should be discontinued as soon as possible as they do not provide adequate nutrition and small and sick infants are at high risk of NEC, broncho-pulmonary dysplasia and exacerbation of respiratory or cardiac illness through fluid overload.

Safe implementation and monitoring of these interventions can be challenging, especially in low-resource settings. The list of tracers is not exhaustive and other important interventions, notably, effective phototherapy for the treatment of hyperbilirubinemia (Figure 4.4), basic newborn care and resuscitation (8), KMC (193) and management of neonatal infections (58) are covered by other sections of the bottleneck analysis tool.

Figure 4.4 Overcoming bottlenecks for the management of neonatal jaundice: diagnostics and devices

Neonatal hyperbilirubinaemia is common, whilst most mild cases resolve spontaneously, failure to recognise and institute timely effective treatment for potentially severe disease can lead to bilirubin induced brain damage (kernicterus) and neonatal death. A systems-based approach is crucial to prevent adverse outcomes (200). This will require innovative strategies and affordable technologies to bridge the existing social and access barriers in micro and macro-health environment (66) which may include:

Improved identification and management of underlying causes: Rh haemolytic disease is an important established preventable cause of kernicterus, point-of-care Rh blood typing, minimally at the time of birth with unfettered targeted access to Rh immunoprophylaxis is critical for prevention. There is need for a panel of bilirubin tests for haemolysis and glucose-6-phoshate dehydrogenase deficiency.

Overcoming Barriers to diagnosis: Icterometry is a low cost, simple, effective diagnostic tool. Coupled with jaundice education as part of postnatal care delivered by rural health-care workers it improved care-seeking and a reduced bilirubin levels in a Vietnamese cluster-randomized study (201). In a community birthing facility in Brazil Screening, using an Ingram icterometer or transcutaneous bilirubin during the first day after birth, with promotion of breastfeeding and timely use of phototherapy was associated with very low (0.82%) readmission rates with none requiring exchange transfusions (202).

Overcoming Intervention Barriers: Effective phototherapy implies its use as a “drug” at specific blue light wavelengths, emission spectrum in a precise (narrow) bandwidth to up to 80% of an infant’s body surface. The efficacy of longer-lasting LED lights that meet clinical and engineering expectations have been demonstrated in low- and middle-income settings (67, 203). These devices are also the most affordable and effective for at least one year of continuous use and are poised for implementation at both primary and secondary birthing facilities.

Plans and Challenges are not just limited to development of novel screening and prevention technologies, improving access to healthcare, or monitoring global benchmarks of unacceptable neonatal morbidities. These need to be embedded in healthcare systems that are accountable to the newborn and their family.

4.4.2 Data analysis methods

Data received from each country were analysed and the graded health system building blocks were converted into heat maps (Figures 4.5 and 4.6). Bottlenecks for each health system building block were graded using one of the following options: not a bottleneck (=1), minor bottleneck (=2), significant bottleneck (=3), or very major bottleneck (=4) (Figure 4.5). We first present the number of countries from which workshops participants categorised health system bottlenecks as significant or very major, by mortality contexts (Neonatal Mortality Rate (NMR) <30 deaths per 1000 live births and NMR ≥30 deaths per 1000 live births) and region (countries in Africa and countries in Asia) (Figure 4.4). We then developed a second heat map showing the specific grading of health system bottlenecks for each country (Figure 4.6).

Context specific solutions to overcome challenges to scaling up inpatient care identified in all countries were categorised into thematic areas and then linked to the specific bottlenecks in the results section (Appendix D, Appendix E). We undertook a literature review to identify further case studies and evidence-based solutions for each defined thematic area (Appendix G). For more detailed analysis of the steps taken to analyse the intervention specific bottlenecks, please refer to the overview paper (189).

4.5 Results

Our analysis identified bottlenecks across seven health system building blocks relating to the inpatient supportive care of small and sick newborns. Twelve countries submitted their responses to the inpatient care of small and sick newborns bottleneck tool. Afghanistan, Cameroon, Democratic Republic of Congo (DRC), Kenya, Malawi, Nigeria, Uganda, Bangladesh, Nepal and Vietnam returned national level responses. Pakistan provided subnational data from all provinces, Gilgit-Baltisan, Azad Jammu and Kashmir, excluding two tribal territories. India returned subnational data from three states: Andhra Pradesh, Odisha and Rajasthan (Appendix F).

DRC did not provide a grade for health service delivery and community ownership and partnership; and Malawi did not provide a grade for health information systems. In these cases, the country was removed from the sample for the quantitative grading of that building block, but included for all other building blocks; their examples of described bottlenecks were still included in the analysis and presented in the results. Afghanistan listed their bottlenecks and completed rating for all building blocks but did not propose any solutions.

The solution themes are summarised by health system building block in Table 4.1. Care of small and sick newborns is a newborn intervention area highlighted by all country workshop participants as a major challenge to health systems, especially when considered in comparison with other intervention areas studied in the workshop. Grading according to the number of countries that reported very major or significant health system bottlenecks for inpatient supportive care for small and sick newborns is shown in Figure 4.5. Overall, the health systems building blocks with the most frequently reported very major or significant bottlenecks were health financing (10 out of 12 countries), health workforce (10 out of 12 countries), followed by community participation (9 out of 11 countries), suggesting these may be priority areas within which to tackle barriers to the scale up of inpatient care for small and sick newborns. As expected, building blocks were rated more poorly in countries with higher NMR. African countries reported a higher number of major and significant bottlenecks, but Afghanistan had the highest level of very major bottlenecks and Malawi had the lowest graded bottlenecks, as shown in Figure 4.6.

Table 4.1 Summary of solution themes and proposed actions for inpatient care for small and sick newborns

Health system building blocks	Solution Themes	Proposed actions
Leadership and Governance	*Advocacy and political will* *Improve organisation structures* *Review and disseminate guidelines*	• Active involvement of national advocates (professional bodies, academic, policy makers) for care of sick newborns • Increase number of special care units and spaces in facilities for newborns • Develop national policies and guidelines for referral systems, organisational standards for sick newborn care
Health Financing	*Budget allocation* *Innovative funding and removal of user fees*	• Increase and sustain funding for sick newborns, earmark funds within facilities caring for newborns • Expand existing maternal health schemes (end-user incentives, insurance schemes, voucher schemes) to cover inpatient care of newborns • Long term vision and health systems approach towards universal coverage for healthcare
Health Workforce	*Recruitment and Retention* *Competency based training* *Task shifting*	• Develop neonatal nursing cadre with agreed standards and benchmarks • Strategies to incentivise neonatal health workers • Develop job descriptions, appropriate remuneration and career development pathways for health workers caring for newborns • Scale up of simplified, skilled based training programmes on infection prevention, feeding, provision of warmth and family centred care for newborns • Maximising existing resources, including nurses, lower level health workers and communities
Essential Medical Products and Technologies	*Essential medical list* *Logistic system strengthening and forecasting*	• Update and implement the essential medical list to include oxygen • Inclusion of neonatal equipment and drugs in logistics systems • Strengthen oxygen systems at national and local level
Health Service Delivery	*Increase service delivery and rationalise service distribution* *Quality improvement and assurance* *Improve working conditions*	• Special care baby units (or dedicated area) in every district hospital • Decentralisation of inpatient neonatal care, stable babies cared for in KMC units • Develop and harmonise quality assurance tools and carry out quality assessment of neonatal units • Provide supportive supervision and mentoring • Improve remuneration and incentives (see also, health workforce), working hours, food provision and facilities to stay

Health Information System	*Strengthening and integration of HMIS* *Development of indicator definitions, reporting systems, tools and Scale up audits and registers*	• Integrate newborn indicators into national health information systems • Define and harmonise newborn indicators, especially care of sick newborns • Regular mortality audits in all special care and neonatal intensive care units.
Community Ownership and Participation	*Accessibility of information and community awareness* *Improve care seeking and linkages* *Male involvement*	• Sensitisation on importance of newborn inpatient care and entitlements to care • Use of community volunteers, local champions and leaders • Develop local transportation solutions for families, improve patient experience in facilities and develop family-centred guidelines • Male role models in the community, inclusive policies and frameworks in facilities • Education on maternal and newborn health targeted at men

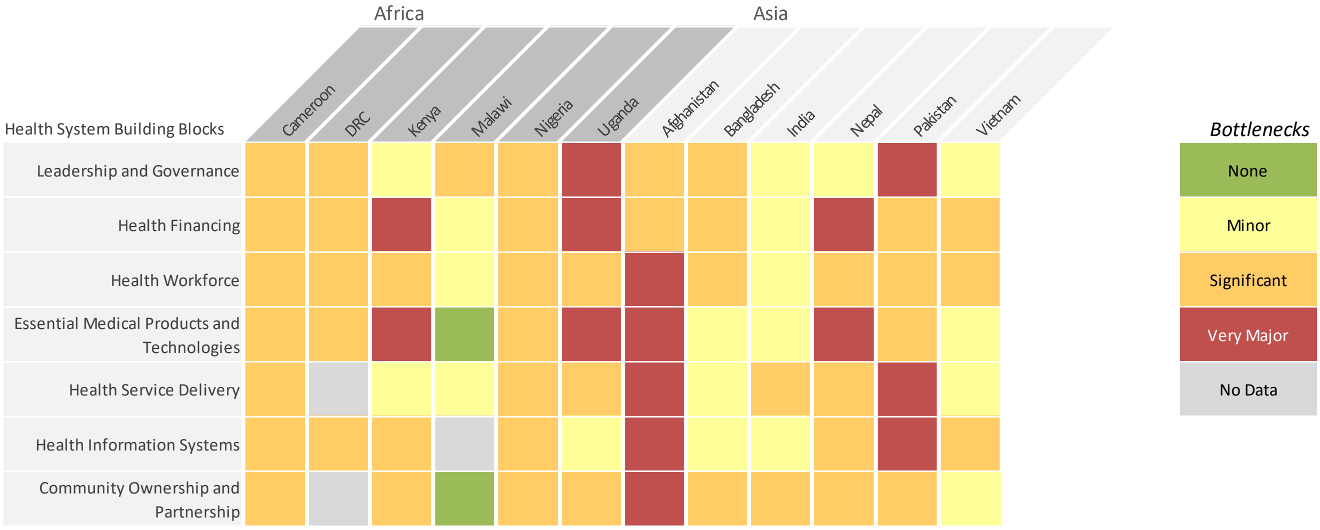
Figure 4.5 Very major or significant health system bottlenecks for inpatient care of small and sick newborns

	All 12 countries	Countries with NMR < 30 deaths per 1000 livebirths*	Countries with NMR ≥30 deaths per 1000 livebirths**	Countries in Asia	Countries in Africa
Leadership and Governance	8 out of 12	4 out of 7	4 out of 5	3 out of 6	5 out of 6
Health Financing	10 out of 12	6 out of 7	4 out of 5	5 out of 6	5 out of 6
Health workforce	10 out of 12	6 out of 7	4 out of 5	5 out of 6	5 out of 6
Essential medical products and technologies	8 out of 12	4 out of 7	4 out of 5	3 out of 6	5 out of 6
Health Service Delivery	7 out of 11	3 out of 7	4 out of 4	4 out of 6	3 out of 5
Health information System	8 out of 11	4 out of 6	4 out of 5	4 out of 6	4 out of 5
Community Ownership and Partnership	9 out of 11	5 out of 7	4 out of 4	5 out of 6	4 out of 5

% of Countries Citing Significant or Major Bottlenecks	
	≥75%
	25-74%
	<25%

NMR: Neonatal Mortality Rate
*Cameroon, Kenya, Malawi, Uganda, Bangladesh, Nepal, Vietnam. **Democratic Republic of Congo, Nigeria, Afghanistan, India, Pakistan. See additional file 2 for more details.

Figure 4.6 Individual country grading of health system bottlenecks for inpatient care of small and sick newborns



A

<table>
<tr><th></th><th colspan="14">Health System Building Blocks</th></tr>
<tr><th></th><th colspan="2">Leadership and Governance</th><th colspan="2">Health Financing</th><th colspan="2">Health Workforce</th><th colspan="2">Essential Medical Products & Technologies</th><th colspan="2">Health Service Delivery</th><th colspan="2">Health Information Systems</th><th colspan="2">Community Ownership & Partnership</th></tr>
<tr><td>None</td><td colspan="2">0</td><td colspan="2">0</td><td colspan="2">0</td><td colspan="2">1</td><td colspan="2">0</td><td colspan="2">0</td><td colspan="2">1</td></tr>
<tr><td>Minor</td><td colspan="2">4</td><td colspan="2">2</td><td colspan="2">2</td><td colspan="2">3</td><td colspan="2">4</td><td colspan="2">3</td><td colspan="2">1</td></tr>
<tr><td>Significant</td><td>6</td><td rowspan="2">8</td><td>7</td><td rowspan="2">9</td><td>9</td><td rowspan="2">10</td><td>4</td><td rowspan="2">8</td><td>5</td><td rowspan="2">7</td><td>6</td><td rowspan="2">8</td><td>8</td><td rowspan="2">9</td></tr>
<tr><td>Very Major</td><td>2</td><td>2</td><td>1</td><td>4</td><td>2</td><td>2</td><td>1</td></tr>
<tr><td>No Data</td><td colspan="2">-</td><td colspan="2">-</td><td colspan="2">-</td><td colspan="2">-</td><td colspan="2">1</td><td colspan="2">1</td><td colspan="2">1</td></tr>
</table>

B

Part A: Heat map showing individual country grading of health system bottlenecks for inpatient care of small and sick newborns
Part B: Table showing total number of countries grading significant or major for calculating priority building blocks
DRC: Democratic Republic of the Congo.

4.5.1 Leadership and governance bottlenecks and solutions

The first building block, leadership and governance, was considered to have very major or significant bottlenecks across 5 of the African countries, and 3 of the Asian countries (Figure 4.5). Countries in both regions commonly identified a lack of national level advocates (including policy makers, key individuals within professional bodies, academics and national institutions) for advancement of quality care for newborns. At the governance level, country workshop participants highlighted lack of supportive policies for care of small and sick babies. Specifically, workshop participants noted that their existing policies were not inclusive of the key supportive and organisational policies for newborn care, such as well-defined, rational referral systems, discharge criteria and standardised levels of care at the district and peripheral level. Policy documents in circulation amongst senior officials were not always disseminated to the managers at lower levels of the health service and did not always incorporate guidelines with important components of special care for newborns, such as supportive policies, guidelines for breastfeeding and family-centred care (Appendix D).

Solutions proposed by country teams centred on the need for targeted advocacy and political will. They focused on improving the organisational and supportive structures for sick newborns at the policy and governance level and building local champions. Country workshop teams proposed reviewing the existing organisational policies and guidelines at a central level and ensuring these were disseminated to all levels of the health system (Appendix E).

4.5.2 Health financing bottlenecks and solutions

Health financing bottlenecks were frequently graded as needing significant work for inpatient care of newborns – 10 out of all 12 country teams (Figure 4.5) graded it as very major or significant, with only Malawi and India perceiving there to be only minor bottlenecks (Figure 4.6). Revenue collection for newborn health, and competing calls for financing of other areas of healthcare, was clearly viewed as a barrier, and insufficient earmarked funds at the facility was impeding their ability to provide quality care to sick newborns. Participants specifically described a lack of designated funding for laboratory support and to purchase supplies such as blood components, antibiotics and other equipment for newborns, such as oxygen cylinders. The most frequently described health financing challenges pertain to prohibitive user-fees and insurance policies that do not cover inpatient care of newborns showing that families are frequently put at risk of severe financial hardship in the event of a baby being born small or sick (Appendix D).

Country workshop participants proposed solutions including the need to increase amount of earmarked funding available for sick newborns and the need to mobilise and advocate for increased funding at the health system level. Participants also proposed more innovative funding mechanisms in order to remove the prohibitive user fees placed on care of sick newborns, either through more comprehensive health insurance, community-based finance or mutual health schemes (Appendix E).

4.5.3 Health workforce bottlenecks and solutions

Almost all countries identified the lack of trained personnel in neonatal care in quantity and quality (knowledge, training, skills) and 10 out of 12 graded these bottlenecks as significant (Figure 4.5), with

Afghanistan grading their bottlenecks as very major (Figure 4.6). Poor supervision and the need for specialist and refresher training in neonatal skills were overarching challenges. Countries described difficulties recruiting specialist staff to work in remote areas and staffing disparities between urban and rural areas; 8 countries specified that problems in the health workforce stemmed from the lack of competency-based training and refresher training for the health workforce managing small babies, especially at the lower levels of the health system. Regarding task shifting, some countries noted that often only physicians are authorised to carry out tasks that could be performed by lower level health workers, such as prescribing oxygen or antibiotics. Other countries indicated that job descriptions were not clear in roles and responsibilities for those providing care to sick newborns, which is particularly relevant for neonatal nurses. Country workshop participants underlined that the motivation for neonatal nurses and other professionals to provide high quality care to sick babies was low (Appendix D) and that incentives and remuneration were insufficient, leading to poor health worker attitudes, ineffective communication and poor compliance with infection control procedures.

Participants recognised that to remove health workforce bottlenecks, detailed health worker mapping of those caring for sick newborns was needed to identify the resources available and where tasks could be rapidly shifted to make more rational use of the existing workforce. Workshop participants also proposed improving working conditions, motivation and skills through more structured pre-service and in-service training and more appropriate remuneration for neonatal skills, including rewarding those prepared to work in rural areas (Appendix E).

4.5.4 Essential medical products and technologies bottlenecks and solutions

The provision of essential medical projects and technologies was graded as having very major bottlenecks by a third of all country workshop participants (Figure 4.5). The Essential Medicine List (EML) was a commonly described bottleneck; participants noted that the EML lacked the commodities required for special care of newborns, such as oxygen and IV fluids and was not implemented at the national level. Many participants described general stock-outs of neonatal equipment, especially cannulas and drugs (specifically antibiotics) and lack of availability of specialist equipment, such as continuous positive airway pressure (CPAP) and portable radiographs. Participants reported that weak and inaccurate information systems underpinned this problem, limiting the ability of facilities to forecast the demand for oxygen, fluids and the maintenance supplies needed for provision of quality inpatient supportive care (Appendix D).

Solutions to the essential medical products and technology bottlenecks started with a need to update the EML to reflect the essential commodities needed for sick newborns (oxygen, antibiotic and IV fluids). Following this, workshop participants recognised a need for improving and building logistics management capacity to support the health system to manage inventories and prevent stock-outs (Appendix E).

4.5.5 Health service delivery bottlenecks and solutions

Service delivery was described as a challenge in all the countries with higher mortality contexts (Figure 4.5). Workshop participants described the limited number of facilities available to provide any type of services or inpatient care for sick or low birth weight babies, particularly at lower levels of the system. Poor enabling environments, undersized and outdated buildings, and lack of resource capacity for both delivery of care and provision of family-centred supportive care for babies in the public sector were commonly described. Five countries highlighted the limited space in health facilities for the special care of sick newborns. This included potential space for mothers to stay with their baby or lack of nurseries or side rooms for sick babies. Other country workshop teams described quality improvement as a major challenge due to inadequate monitoring or lack of quality improvement tools, poor mentoring and supervision, and poor implementation of clinical guidance and cot-side care plans for all staff caring for newborns (Appendix D).

Country workshop participants recognised that the number of facilities or, at least, dedicated spaces for sick newborns needed to be increased and that service delivery needed to be rationalised. In alignment with the health workforce bottlenecks, teams suggested that quality assurance tools, quality improvement strategies (including care protocols), and improved mentorship and supervision for those delivering care to newborns could help to improve service delivery (Appendix E).

4.5.6 Health information system bottlenecks and solutions

The lack of health information and standardised, well-defined indicators to measure interventions for sick newborns is a central issue being tackled within the ENAP (6). Most participants from higher mortality contexts graded it as a significant or very major bottleneck to the provision of quality care in facilities (Figure 4.5). Specific barriers to quality improvement in facilities included the absence of effective mortality audits in facilities, lack of both coverage and process indicators and registers on sick newborns with the existing data were not well managed. In other settings, participants recognised the need for strengthening and integration of newborn facility-based care indicators into their national HMIS (Appendix D).

Country workshop participants stated a need for clear definitions for indicators and harmonising these indicators such that national HMIS can be strengthened and include select indicators for sick newborns. This would require improved measurement tools, reporting systems and use of appropriate software. Participants highlighted a need for capacity building within health information to support the appropriate disaggregation, dissemination and reporting of sick newborn data. Teams also suggested scaling up regular mortality audits for neonatal units (Appendix E).

4.5.7 Community ownership and partnership bottlenecks and solutions

The community ownership and partnership building block were graded as having significant or very major bottlenecks in three-quarters of countries (Figure 4.5). Malawi was the only country for which workshop participants graded this building block as having no bottlenecks (Figure 4.6). Workshop participants specified a wide range of issues largely related to a lack of general information and awareness in communities about sick babies. Limited knowledge of the treatment processes and the severity of newborn illness, including poor awareness of the civil rights of babies born sick or low birth weight to access care, were highlighted. There were several access related problems reported, including poor referral and transport systems and inability to access facilities either due to cost or availability. For mothers in the community, participants described the lack of female decision-making power, loss of wages due to caring for a sick newborn and lack of privacy in facilities. Lack of involvement of men was mentioned by six countries partially related to poor awareness and engagement of the wider community on issues related to sick newborns (Appendix D).

Solutions for community ownership were wide-ranging but were themed around improving the accessibility of information for carers and the services for small and sick newborns. Participants suggested a need for greater community awareness of the needs for sick and small newborns in order to improve demand, compliance and patient experience; specifically, encouraging male involvement and increased participation of the community in processes to improve family centred care in facilities (through development of materials, tapping into community groups and developing mutual health type schemes) (Appendix E).

4.6 Discussion

This paper has presented an analysis and synthesis of bottlenecks and solutions for one of six key intervention packages to reduce neonatal mortality worldwide reviewed in this series of papers; inpatient care for small and sick newborns. Previous analysis of the bottleneck data showed that amongst all intervention packages explored, inpatient care has some of the highest graded bottlenecks hindering scale-up (29), with very major or significant bottlenecks being reported across all health systems building blocks. Whilst inpatient care for the small and sick newborn forms part of the overall care along the continuum from pre-pregnancy to childhood, these findings are timely and this issue is new on the global agenda. Complications from preterm birth are now the leading cause of death in children under five (191). Previous experience from high income settings has shown that initial provision of low-tech supportive inpatient care and case management, followed by full high-tech neonatal intensive care, has played an important role in reducing overall neonatal mortality (5); therefore, in order to further reduce the burden of death due to prematurity, strategies to provide comprehensive, high quality inpatient care for small and sick newborns must be developed.

The methodology used in the bottleneck analyses employed a unique consultative and participatory approach to bring together a wide range of partners and players in newborn health. Rather than the top down approach employed by many research initiatives, this data collection and analysis methodology focused on eliciting information from ground-level field implementation, as perceived by stakeholders and experts in 12 countries with the highest burden of neonatal mortality. This has helped the data to capture context-specific challenges and has enabled participants to share their experiences and work together to identify innovative solutions. The grading process encouraged the workshop participants to reach consensus on the perceived challenges and generate a quantitative measure of the perceived bottlenecks to delivering care to this vulnerable sub-population. Rather than reporting on systematic reviews or results from randomised trials, this paper aims to facilitate programmatic learning through the South-to-South exchange. This paper has brought together a wide range of programmatic experience and technical expertise in neonatal care from across the globe to inform programme managers and policy makers in multiple settings facing a range of health system challenges in delivering high quality, facility-based care to small and sick newborns.

Health systems seek to ensure that individuals in need of care receive high quality health services without the risk of financial catastrophe. This analysis identified three priority health systems building blocks with substantial barriers to implementation of facility-based care for small and sick newborns: health workforce and health financing followed by community ownership and partnership. Solution themes, including examples from literature review and programme learning, are discussed in detail below.

4.6.1 Health workforce priority actions

A worldwide nursing shortage exists in both high and low resource settings (30, 204). For small and sick newborns this is not simply a shortage of qualified individuals; there is a critical human resource gap for a neonatal nursing cadre, with almost no neonatal nursing training programmes outside of HIC (Figure 4.7). Neonatal nurses are the backbone of newborn inpatient care, as both providers of frontline care to the newborns and their families, but also through extended roles such as the advanced neonatal nurse practitioners (ANNPs) (23, 205). To improve neonatal outcomes, particularly in those countries which account for the highest newborn death and morbidity rates, nurses need to be recruited and offered specialised training in how to care for small and sick newborns and be provided with ongoing resources to enable them to give consistent high-quality care. There are other factors at institutional and country level including inadequate allocation of resources for a health workforce, inadequate workforce planning, poor retention strategies, ineffective use of existing nursing staff, and poor working conditions (29, 206).

Figure 4.7 Neonatal nursing as part of national human resource planning

Nurses caring for small and sick newborns are in a unique position to improve their chance of survival and ability to thrive. Despite the vital role for nurses in the care of a sick newborn, neonatal nursing is not an internationally recognised cadre.

What is a neonatal nurse?

The role of a neonatal nurse includes the provision of care for newborn infants born with a variety of problems ranging from prematurity, birth defects, infection, and surgical problems within an individualised, developmentally supportive and family-centred framework (http://www.nann.org). However, even across high income countries, there is no agreed definition for neonatal nurses, but it is a viewed as a highly skilled nursing speciality that requires years of hand-on experience and is usually attached to specific academic and clinical training schemes.

Health workforce planning. How many neonatal nurses do we need?

Currently, there is a global shortage of neonatal nurses (30). The survival of premature infants in facilities has been linked to the number of qualified neonatal nurses working per shift (207) and very sick or extremely premature newborns require higher staff to patient ratios than other areas of paediatric care. Intensive care newborns often require one-on-one care and special care babies require a ratio of approximately 1 to 4 (204). There are a lack of international standards on the number of nurses needed or defined staffing ratios and benchmarks. There are a small number of countries that provide specialised academic and formal training for nurses, most of which are high-income countries. As nurses constitute the largest component of the health care system, it is imperative that planning for neonatal nursing skills is incorporated into wider human resource and health workforce plans. International health workforce market analysis is needed to examine the impact of migration and retention of nursing workforce. Where neonatal nurses are trained, resources should also be directed to motivate retention including valuing their role, recognising ongoing training needs and protect them from rotation out into other sub-specialities (208). Individual countries can work towards improving quality and efficiency of care by more strategic and intentional delegation at the local and country levels. There is a need to review the efficiency of current workforce support at the local and country levels and review the current delivery of care.

Qualifications

Training in skills specific to the needs of the newborn is required, with corresponding accreditation. Accreditation is important to provide recognition and to promote increased responsibility as well as to assist with staff retention through increased job satisfaction, potentially higher salaries and the prevention of nursing staff rotation, which is common in many low- and middle-income settings.

The development of special neonatal certificates, training courses and advanced neonatal nurse practitioners (ANNP) has gained traction, especially in high income settings, but not without challenges. For example, ANNPs have been shown to be effective, but some programmes report the sentiment that ANNPs feel they are substituting junior doctors rather than being valued as an alternative approach to high quality service provision for newborns (209), leading to low morale. In low- and middle-income countries, at the district

and community level, education and training of nurses working with newborn infants within community-hospital-community network systems with integration of community healthcare workers, and in some settings, use of volunteers is possible (30). Other options include organisation or co-ordination of overseas programs involving visits by experienced trained neonatal nurses to low resource settings to provide mentoring, education, and sharing of information with the ultimate goal of building in country capacity. All institutions can increase the basic quality and speciality of neonatal nursing programmes. These strategies require financial and political support and a shared vision for neonatal nursing and care between professional institutions. Better data capture on neonates in facilities, including follow up data, is urgently needed so that standards of practice and quality of care can be carefully evaluated (209). Extraction information on the nursing workforce is essential to describe who, where, and how neonatal nurses work (noting that many nurses are not permitted to provide such data without government or institutional approval). Further research is needed to examine neonatal nursing education and distribution of the workforce in relationship to neonatal outcomes. There is a global need to establish an international competency-based standards for neonatal nursing supported by appropriate regulatory processes and mechanisms (30) that support this vital cadre to improve neonatal survival and outcomes.

ANNP: Advanced Neonatal Nurse Practitioner

4.6.1.1 Skills-based/competency-based training

Almost all countries in the workshop highlighted the lack of skills-based training programmes for health workers caring for small and sick babies. Qualitative work on the barriers to nurse education for those caring for sick newborns has found that educational programmes focusing on neonatal skills are often inconsistent, poorly structured, or may require long, off-site training courses making them inaccessible for large numbers of lower level hospitals or SCBUs (31). Survive and Thrive is a private and public partnership with the American Academy of Pediatrics and has developed educational programmes focused on newborns. Essential Care for Small Babies (ECSB) (210) is to be released in early 2015 and addresses skills such as nasogastric feeding and prevention of infection and skin-to-skin care through a cooperative learning approach[2]. Learning techniques used by ECSB are skills-based and focused on small group work, using simulation methodology and role-play to practice technical and communication skills. Knowledge is tested through multiple-choice questions and Observed Structured Clinical Evaluations (OSCEs). Such pre-service and in-service training programmes are available and could be scaled-up within health worker training, even in lower resourced settings, as they do not rely on electricity supplies (being flip-chart based) and make use of low-cost simulation models. Well-designed programmes focused on neonatal clinical skills have been shown to be

[2] See the end of chapter for additional content on ECSB and simulation based training.

effective and improve health provider knowledge and practice (211), but will require supervision systems and regular refresher training to sustain and update skills (212).

4.6.1.2 Task shifting

The WHO's recommendations on optimising the roles of health workers aim to address critical health workforce shortages that slow progress towards the health-related MDGs (213). A more rational distribution of tasks and responsibilities among cadres of health workers can significantly improve both access and cost-effectiveness – for example, by training and enabling 'mid-level' and 'lay' health workers to perform specific interventions otherwise provided only by cadres with longer (and sometimes more specialised) training. These recommendations are intended for health policy-makers, managers and other stakeholders at a regional, national and international level. WHO hopes that countries will adapt and implement them to meet local needs. The recommendations were developed through a formal, structured process including a thorough review of available evidence. Specific examples that have been taken up include nursing auxiliaries or health care assistants supporting and maintaining KMC. In Malawi, ward attendants have been involved in supporting KMC and health surveillance assistants have been trained to promote facility-based care for sick newborns (214-216). ECSB training incorporates sharing tasks with mothers, when appropriate, for basic skills such as nasogastric feeding and providing basic care to a small baby looked after in a facility (217).

4.6.1.3 Recruitment and retention

Once health workers have the skills needed to care for small and sick babies, recruitment and retention strategies are needed to supervise and motivate, which is especially important for rural and hard to reach postings. Innovative recruitment and retention strategies have been implemented with success in some settings. Thailand has historically used a bonding system to improve recruitment of health workers for rural areas. Newly qualified health professionals, including doctors and cadres of nurses are required to spend a mandatory time period in rural postings. On completion, professional qualifications can be upgraded. Evidence suggests this has led to a substantial increase in the numbers of trained professionals in rural areas and is partially responsible for the impressive health gains in Thailand in the last 25 years (218, 219).

In addition to task shifting there are other immediate, interim strategies that can be put in place. These could include improving conditions for the workforce through incentives (220) (financial, educational or other), relieving staff of other duties, improving daily working conditions (break areas, food vouchers, accommodation on-site or nearby) (221) and improving job satisfaction through structured supervision and mentoring efforts (212). Non-rotation of staff out of neonatal care is an important strategy to prevent neonatal staff being shifted annually within the hospital from department to department or into other specialties (Figure 4.7).

4.6.2 Health financing priority actions

4.6.2.1.Budget allocation

Whilst the health financing issues faced by many low-income countries (LIC) are due to the lack of financial resources for health and development overall, and are not unique to the newborn (222), those newborns requiring inpatient care are at greater risk due to their need for specialised facility-based care. Newborns are relatively neglected in official development assistance (25) and specialised, intensive care is often perceived as prohibitively expensive. A strong economic case, including the relative burden of newborn mortality globally, and the argument for prevention of long-term morbidities, is required to advocate for the earmarking of funds specifically for developing and sustaining high quality inpatient newborn care. The issue of health financing is explored in greater detail in paper 1 of this series (189).

4.6.2.2. Innovative funding and removal of user fees

The birth of a small or a sick baby can be financially catastrophic for families. Shifting from a reliance on out-of-pocket payment to prepayment and risk pooling is a critical part of the health financing transition that most countries go through as they get richer (223). Limited risk pooling means that insurance and depth of coverage is a common problem for families. Removal of user fees in the public sector is a first step, but has associated risks and challenges and must be replaced by alternative health financing mechanisms that could include: social health insurance, community based health insurance and government supply side financing (224). The success of these schemes is dependent on the context within the countries where they are implemented. Rwanda's community financing scheme is backed by compulsory government payments into the scheme and stringent pooling of donor funds (225). Provision of coverage for inpatient newborn care within insurance schemes or voucher and incentive systems is a neglected area, with often only delivery and basic newborn care being covered. Attention to successful schemes that already exist in countries could partially ameliorate the risk of financing catastrophe for families when a baby is born small or sick, rather than introducing new schemes for sick newborns that may further fragment health financing systems. Sick newborn care is frequently not covered by maternity packages or maternal health financing schemes (e.g. Nepal vouchers scheme), yet has potentially large expenses associated with it. Schemes using prospective case-based systems for inpatient care – as in Kyrgyzstan (218) could be adapted to give higher priority to newborn inpatient and special care. Further implementation research is needed for innovative funding mechanisms to identify factors that may facilitate their success and provide recommendations for their implementation in different settings.

4.6.3 Community ownership and partnership priority actions

Whilst reported bottlenecks to high quality inpatient newborn care are similar across regions, individual communities differ in their geographical and socio-cultural structures and available resources. Enabling maximum effect through tailor-made solutions for a given community will require empowering solutions from a grassroots level.

4.6.3.1 Community awareness

Lack of demand for quality newborn inpatient care may reflect the fatalistic assumption that all small and sick babies will die (23). Across settings, country teams highlighted the lack of awareness in communities about sick newborns, the treatment processes and their civil rights to access health services. Most country teams reported a lack of awareness of the severity of newborn illness and knowledge that timely, high quality care can save newborn lives. In some contexts, such as India, there are specific care-seeking barriers for newborn girls. The workshops participants' perceptions strongly suggest there is a lack of strategic, targeted health education on newborn health across settings and that sensitisation and local community education efforts are needed to reduce fatalism and increase care-seeking and demand. Mobilisation of communities using women's community groups has been shown to have a positive effect on a range of maternal and newborn health outcomes, including the potential to reduce neonatal mortality in a number of settings (226-228). There is a clear role for community volunteers, local role models and community leaders to raise awareness on issues surrounding newborn health and the care of sick newborns.

4.6.3.2 Improve care seeking and transport linkages

Qualitative study of the local barriers and solutions for care-seeking in child health in Kenya, Nigeria and Niger highlighted important factors on perceived awareness and the subsequent demand for care (229). Lack of trust in health services, perceptions that treatment is ineffective and experience of poor quality of care were perceived as important in reducing demand for care. Health services that are out-of-stock, negative experiences with health workers, or poor communication between staff and families, especially mothers, may be detrimental to the care of the newborn. Facilities may need to focus on community strategies to improve the patient experience in facilities, especially for mothers. It is critical for the mother to spend time with the sick newborn wherever possible, therefore, local hospital policy guidelines that encourage family-centred care and take into account the local and cultural family structure are vital for mothers to be able to participate in the care of their newborns.

Local transport systems are needed to facilitate access between the community and facility, especially when newborns are in the facility for long periods of time. Within the facility, involving mothers in care, in addition to the necessary support for breastfeeding and expressing milk, can play an important part in empowering mothers and securing the linkages between the family and inpatient care (215).

4.6.3.3 Male involvement

Half of the countries in the workshop specifically reported that there was a lack of male involvement in the care of sick newborns. Individual, family, community, societal and policy factors are previously identified barriers to male involvement during pregnancy and birth (230). Qualitative research suggests men often lament their lack of involvement or understanding of MNH issues (230, 231) – an area that is often seen as dominated exclusively by females. Empirical research confirms that for pregnancies that are wanted and where men are more educated, men are more likely to be involved in maternity-related care (232). The care of sick newborns is no different and tackling barriers to male involvement is an issue that spans the care continuum from family planning to the care of a sick newborn in a facility. Men often control family finances or have a stronger influence on decision-making. Women may be removed from their usual schedules when their newborn is sick, leading to potential for neglect of other commitments (whether work or household related) and, therefore, may need additional support. Use of male role models in the community may help to facilitate this transition away from MNH being viewed as an exclusively female domain. Using lessons learned from Prevention of Mother To Child Transmission (PMTCT) research (231), interventions to increase male involvement in newborn care include addressing hospital policies and staff attitudes in facilities to allow for culturally sensitive, inclusive policies for men and families, such as special visiting hours and supporting fathers to participate in KMC (193).

4.6.4 Other priority actions

As highlighted in the analysis, very major or significant bottlenecks were reported across all building blocks. Solution themes for three of these building blocks have been discussed in detail above and more details on the country-specific bottlenecks for each health system building block are available in Appendix E. A few other bottlenecks described were especially relevant to inpatient care. For example, India and Pakistan stressed the shortfall in supply of oxygen due to demand and supply gaps. Improving oxygen systems within health facilities is key to enable widespread availability when required. Oxygen cylinders are still commonly used in many facilities in low and middle-income settings, however they are expensive, require filling up regularly and are difficult to transport. Where power supplies are reliable, oxygen concentrators can provide a consistent and inexpensive source of oxygen. In view of the emerging epidemic of ROP (97), the use of oxygen in any setting should be carefully monitored using pulse oximetry and safe delivery mechanisms to ensure optimum and safe saturation levels (97, 197), as described in Figure 4.3. The safe and systematic use of oxygen, as with all drugs, needs to involve training and supervision of nurses, doctors, technicians, and administrators (96) and appropriate documentation is needed. Commonly prescribed antibiotics for small and sick newborns, such as gentamicin, which has potentially adverse effects related to dosage and interval (233) need particular attention to safety, especially where therapeutic drug monitoring is not possible (234). A number of country teams highlighted newborn inpatient care health information bottlenecks. A recent assessment of facility-based neonatal care in Kenya highlighted how poor data were potentially undermining the quality of practice (235), especially affecting the assessment of gestational age and symptoms of severe illness. At a national level, efforts are needed to strengthen the HMIS and to develop basic indicator definitions for monitoring inpatient care with core competencies and standards for small and sick newborns by levels of care (15). At the facility level, there is a clear need for improved documentation, registration and incorporating the use of regular mortality audits (172).

4.7 Limitations

The data generated from the workshop came from the subjective and consensus views of participating national stakeholders, including government representatives and experts. The quality and amount of information extracted from these workshops varied depending on the level of knowledge of participants about health system issues and facilitation. In addition, bottlenecks were reported as perceived bottlenecks relative to the other health system building blocks under exploration. There may be instances where known health system challenges or deficits based on robust quantitative data may be in conflict with the perceived bottleneck grading. This may be due to the method of grading relative to other health system building blocks, or that participants place higher subjective value on other areas of their health system. An additional explanation is that groups' may view certain building block areas as easier challenges to overcome based on their knowledge of their setting and expertise in the specific newborn intervention being discussed. The tool is comprehensive and detailed, which is one of its strengths. However, it also may have caused some *workshop fatigue*, particularly towards the end of the workshop where teams discussed and recorded solutions. For example, for the inpatient care questionnaires, Afghanistan completed the bottleneck portion of the questionnaires, but did not submit any solutions. The analysis focused only on three tracer items: safe oxygen, IGTF and the provision of IV fluids. Other specific components of inpatient neonatal care may have different bottlenecks and solutions, for example, identification of and effective phototherapy for neonatal hyperbilirubinemia (67) (Figure 4.4).

4.8 Future agenda

Improving inpatient newborn care will require a health systems approach and some countries are recognising this need. For example, the securing of political, professional and financial commitment in India has led to substantial increases in provision of quality inpatient newborn care (Figure 4.8). Previously, particularly in low-income settings, much investment has occurred in delivering public health and community-based interventions to improve newborn outcomes. This has led to important gains in outcomes, especially in settings with the highest neonatal mortality rates. However, as seen historically in high income countries, to reduce neonatal mortality further, attention is first required on improved supportive case management (which for the smallest and sickest newborns will require inpatient care) and then should be followed by the introduction and scale-up of neonatal intensive care (5).

Figure 4.8 India's health systems approach to improving inpatient care for small and sick newborns

Rationale

India, with an annual birth cohort of 26 million, accounts for highest number of stillbirths and neonatal deaths in the world. The neonatal mortality rate (NMR) of India in 2014 was 28 per 1000 live births, which means 748,000 newborns die each year (191). The NMR in rural areas (33 per 1000 live births) in 2014 was twice that in urban areas (16 per 1000 live births) (236). The Government of India, through the launch of the National Rural Health Mission in 2005, has made significant efforts to promote institutional deliveries by providing conditional cash transfer under Janani Suraksha Yojna (JSY)* and provision of free transport and care for pregnant women to reduce out of pocket expenses under Janani Shish Suraksha Karyakram (JSSK)**. These efforts contributed to an increase to 73% institutional births in 2009 (237). Despite this progress, suboptimal quality of care during birth alongside a lack of specialised care for small and sick newborns remains a major challenge to newborn survival.

Approach taken

India has focused on strengthening facility-based newborn care through the establishment of special newborn care units (SNCUs) at district level and newborn stabilisation units (NBSUs) at block level. These are linked with home visits and referrals by 0.9 million Accredited Social Health Activist (ASHA) workers focusing on both home deliveries and community follow up of both newborns delivered in hospitals and those discharged from SNCUs. The National Health Mission budget for state and districts has a separate budget line for facility based newborn care with earmarked resources for facility-based care, including operational costs, human resources, drugs and provision for record keeping and data management. To address the access barriers and reduce out of pocket expenses, free health care for pregnant women and infants, including diagnostics, treatment and drugs, has been made an entitlement. In order to attract and retain workforce, states like Madhya Pradesh have successfully used walk-in interviews, performance-based incentives, difficult area allowances, enforcement of service bonds and flexibility in place of posting based on individual preference.

Innovations: Education of health care professionals with evidence-based guidelines, using standardised tools, on-site job aids and skill building is a daunting task for such a large and diverse country. WHO Collaborating Centre at All India Institute of Medical Science (AIIMS) has designed smart phones as an innovative point of care tool for management of sick newborns and e-learning as a distance learning strategy for continuing education. To aid the implementation of corrective actions for sick newborns, a real time online data monitoring system has been developed by UNICEF and will be scaled-up nationally to monitor performance of all SNCUs and tracking after discharge till one year. A national cell has been established to support capacity building, monitor data quality and to interpret data for policy and programmatic use.

Looking Beyond survival Rashtriya Bal Suraksha Karyakram (RBSK)*** programme aims at identifying birth defects, disabilities and developmental delays with both community and facility screening, and provision of early intervention clinics at district level.

Results

All these efforts have resulted in operationalisation of 575 SNCUs and 1810 NBSUs, with states like Madhya Pradesh, Rajasthan, Andhra Pradesh, Tamil Nadu and Orissa achieving near universal coverage of SNCUs following prescribed standards at district level. However, there are still issues of inadequate human resources in these states with slower progress in Chattisgarh, Jharkhand, Bihar and Uttar Pradesh. The monitoring system currently has 13 states with 350 SNCUs inputting online data and more than 650,000 newborns are registered in the national database. The current inpatient mortality in existing SNCUs was 10%

in 2013-14 (238). Whilst this is not due to health system changes alone, the NMR of India, which had been stagnant at 37 per 1000 from 2004 to 2006, has shown a 17% decline during 2008 to 2012 (236).

Future directions

There is a need is to accelerate coverage in states where progress is slow, and to focus on quality of care and improving long-term outcomes once scale-up has been achieved. To achieve this, the system needs to reduce the case load in SNCUs by expediting establishment of kangaroo mother care wards for care of stable preterm babies, address high mortality due to respiratory distress by up scaling coverage of antenatal steroids, use of continuous positive airway pressure (CPAP) across all SNCUs and continue to develop innovative approaches and tools for capacity building of the health workforce, including implementation research to evaluate progress. In view of high load of preterm and sick babies with risk factors for ROP, the provision of ROP screening and treatment needs to be implemented. The scale–up of the real-time data system for online monitoring will be completed by mid-2015 for the whole country making it the largest database for small and sick newborns globally. All these issues have been emphasised under the India Newborn Action Plan (INAP)(239), which has set target for a single digit NMR by 2030. This will be achievable only with sustained work towards good coverage of quality interventions for newborns, including those that are small and sick.

*Janani Suraksha Yojna (JSY): a conditional cash transfer to promote institutional delivery); **Janani Shishu Suraksha Karyakram (JSSK): reducing out of pocket expenses by making free health care an entitlement; ***Rashtriya Bal Suraksha Karyakram (RBSK): looks at developmental delays and disabilities, birth defects and deficiencies, covering age group of 0-18 years of age. Other abbreviations: AIIMS: All India Institute of Medical Science; ASHA: Accredited Social Health Activist; CPAP: Continuous Positive Airway Pressure; India Newborn Action Plan (INAP); NMR: Neonatal Mortality Rate; NBSU: Newborn Stabilisation Units; ROP: Retinopathy of Prematurity; SNCU: Special Newborn Care Unit; UNICEF: United Nations International Children's Emergency Fund; WHO: World Health Organization.

Specific areas for action have been highlighted above, with many of these bottlenecks being critical to address to enable provision of quality inpatient newborn care (Figure 4.9). Interdisciplinary linkages and a focus on better quality data will help identify areas for improvement so that teams delivering care to small and sick newborns can plan and implement changes. Ongoing data monitoring helps the team recognise their improvement and identify specific areas to focus on in the future, so that the exercise is an ongoing cycle. The EMEN package (29) will be crucial to this process.

4.9 Conclusions

Whilst major bottlenecks to the scale-up of quality inpatient newborn care are present, in many cases, effective solutions exist. Currently, there is a large grass roots commitment to improving care around the time of birth to end preventable maternal and newborn deaths and stillbirths, and to improve health outcomes as part of the ENAP (6). Improving availability and quality of inpatient newborn care has been identified as an important area to achieve the aims of this plan, providing potential for political, professional, and financial support to develop and scale-up solutions to these bottlenecks. We must build on this momentum, using knowledge of what works to ensure action, so that every small and sick newborn baby has access to timely, high quality and family-centred inpatient care as required to survive and thrive.

Figure 4.9 Key messages and action points for inpatient care of small and sick newborns

Key messages

- Each year, there are an estimated 15 million preterm newborns, many of which do not have access to inpatient care when needed. Inpatient care for small and sick newborns includes the provision of warmth, feeding support, safe oxygen therapy and effective phototherapy, with prevention and treatment of infections. This requires dedicated ward space, staffed by health workers with specialist training and skills.

- Bottlenecks to the scale up of inpatient care are reported across all health system building blocks; countries that graded their bottlenecks most severely were Uganda, Afghanistan, Nepal and Pakistan.

- The health system bottlenecks graded highest by the 12 countries in the analysis were within health workforce and health financing, followed by community ownership and partnership.

Key action points

- Current health workforce effectiveness for inpatient newborn care could be improved through skills-based training for health workers, considering the potential for task shifting. There is a critical human resource gap for a neonatal nurse cadre, with almost no training programmes outside high income countries; this links to the current policy investment for midwives.

- Rather than catastrophic out of pocket payments, addressing health financing bottlenecks for newborn inpatient care requires specific, planned and sustained funding at a national level. Small and sick newborns need appropriate insurance covering their care, similar to the mechanisms for emergency obstetric care.

- Addressing community bottlenecks will require a shift in attitude away from the fatalistic assumption that all small newborns will die, towards increased awareness and demand for quality inpatient care. This should be accessible and family centred, using local resources, involving mothers through kangaroo mother care and long-term follow up for the vulnerable survivors.

Continued from footnote 2.

ECSB is not the only package of this type that focuses on simulation-based medical education. Simulation-based medical education has a long history; it was originally used in the military and aviation fields and then introduced to healthcare initially for training in trauma management before being adapted for obstetrics and care around the time of birth (240). Randomised controlled trials have shown simulation-based training to be superior to didactic and routine undergraduate training, particularly through encouraging teamwork and communication and helping students learn a more systematic approach to managing emergencies(240-243). Drawing on behavioural theory, studies also show it helps skill acquisition, performance and maintenance(243).

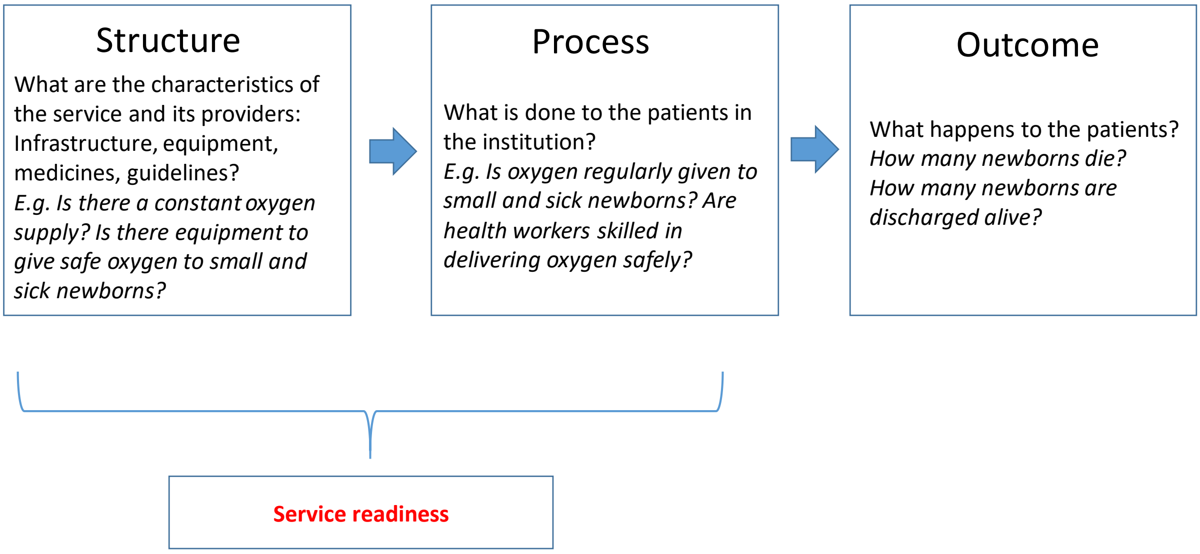
ECSB was used as an example in this chapter due to its explicit focus on small and sick newborns, its simulation-based approach as a training programme and its paediatric rather than obstetric, focus(210). There are, however, numerous emergency obstetric care training programmes using skills and drills or simulation based approaches with newborn components and that have been used with success in a wide variety of LMIC settings. The Centre for Maternal and Newborn Health at Liverpool School of Tropical Medicine (CMNH-LSTM) EmONC training covers major areas of EmONC and causes of newborn death, including newborn resuscitation, treatment of newborn hypoglycaemia, hypothermia and infection(243). It is designed using low trainer to trainee ratios and incorporates simulation and interactive learning to encourage communication and teamwork. Other important examples of such training programmes include Essential Steps in Managing of Obstetric emergencies (ESMOE)(240) and PRONTO(241), however, both of these programmes are more focused on time of birth than specific care of small and sick newborns. The Pacific Emergency Maternal and Neonatal training manual contains sections on newborn resuscitation, preterm birth and newborn infection(244). Overall, such training programmes have been shown to result in significant improvements in healthcare provider competence and improvements in clinical skills(242). There is, however, an identified need for more rigorous operational research in this field looking at how such programmes are best scaled up, and whether they result in improved outcomes for mothers and babies(243). In addition, many obstetric training programmes may benefit from adding sections on care of small and sick newborns as additional modules for health providers caring for women and babies at and around the time of birth.

Chapter 5. Service readiness structures and domains for inpatient care interventions for small and sick newborns

5.1 Introduction

Delivery of interventions to small and sick newborns requires health facilities that are prepared, which is termed as "service readiness". The underpinning principle to service readiness is based on traditional quality of care frameworks, such as that conceived by Donabedian (Figure 5.1). The framework refers to the structures (the necessary infrastructure, equipment, drugs, health providers and guidelines); and some of the processes (actions performed by health professionals with requisite training and skills) that are needed to provide a package of care (88, 89).

Figure 5.1. Service readiness as part of the Donabedian Framework



*Adapted from the Donabedian model for evaluating the quality of medical care (19, 88, 89)

According to the Donabedian framework, when all of the components of the structural domain are in place, it allows for improvements in clinical processes, which in turn lead to improvements in patient outcomes (19, 88, 89). To achieve service readiness, the structures not only need to be present, but maintained, re-stocked and updated (e.g., equipment requires maintenance, supplies require re-stocking, guidelines require updating) and staff continually trained and supervised. To deliver a quality package of care, therefore, requires strong health systems with the capacity to monitor and track service readiness and react appropriately to service needs (101, 245).

Using a process described in Table 5.1, I adapted a list of evidence-based newborn interventions (8, 16, 193, 246). All newborn interventions were included for this exercise, including essential newborn care, based on the rationale that small and sick newborns will require these basic interventions in addition to inpatient care (16, 246).

Table 5.1. Expert focus group on small and sick newborn care interventions

Expert focus group on inpatient care interventions

In April 2016, I convened a group of 14 newborn care technical experts at an *Every Newborn* metrics workshop for a focus group on the interventions and levels of inpatient care for small and sick newborns. Participants were purposively selected to represent different high and low mortality country contexts (Bangladesh, Colombia, India, Malawi, Nigeria, Peru, South Africa, Tanzania, United Kingdom and USA) and types of expertise (nurses, midwives, neonatologists, researchers and monitoring and evaluation specialists). The aim was to identify a shortlist of the key interventions for inpatient care of small and sick newborns to inform further discussion on newborn signal functions (see chapter 4 and chapter 7). The focus group discussion was structured on:

- What are the inpatient newborn care interventions?
- Which interventions should be provided at each health system level?

Prior to the workshop, the participants were given background information on the purpose of the session and background reading, including: https://bmcpregnancychildbirth.biomedcentral.com/articles/supplements/volume-15-supplement-2 . Acting as facilitator, I gave a short presentation to clarify the problem, and explain the purpose and structure of the discussion so that the group understood the task for discussion.

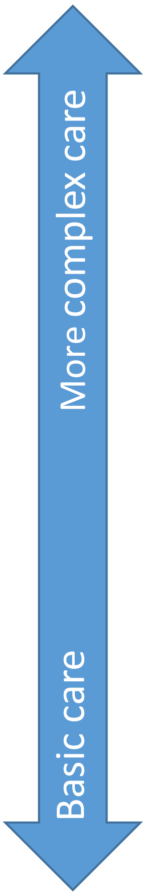
Focus group process

The focus group involved a two-hour discussion carefully facilitated to give each participant time to voice opinions and experience. Detailed notes were collected throughout the discussion by a named rapporteur (see appendix H). In the early stage of the discussion, participants found it was necessary to delineate inpatient care from routine and emergency care that occurs in the labour and delivery room. Participants agreed that routine care for all newborns should be available at all facilities where births occur and requires:

- Thermal protection/warmth
- Essential care for all newborns (draying, skin-to-skin, delayed cord clamping, hygienic cord care, Vitamin K and vaccinations)
- Early initiation and support for exclusive breastfeeding
- Neonatal resuscitation
- Prevention of mother to child transmission for HIV positive mothers.

The remainder of the discussion was focused on the inpatient care interventions. At the end of the session, each group participant was given the option to vote for up to (but no more than) eight inpatient care interventions split these between different levels as participants deemed appropriate. Votes were cast at the end of the session using colour coded markers on a wall chart to disseminate results. The wall chart results on inpatient care interventions for small and sick newborns and the extensive list discussed by the group are summarised appendix H. The final list of interventions is shown in Figure 5.2.

Figure 5.2 Evidence-based newborn care interventions from routine care for all newborns to complex inpatient care for small and sick newborns



- Treatment and screening for retinopathy of prematurity
- Blood transfusion
- Mechanical/assisted ventilation, including intubation
- Continuous positive airway pressure (CPAP)
- Specialised follow up of high-risk infant*

- Kangaroo mother care
- Assisted feeding (including cup feeding, nasogastric feeding)
- Safe administration of oxygen
- Antibiotics for neonatal infection
- Intravenous fluids
- Management of hypoglycaemia
- Effective phototherapy
- Seizure management

- Essential newborn care (drying, skin-to-skin contact of the newborn with the mother, delayed cord clamping, hygienic cord care, Vitamin K, eye care and vaccinations)
- Thermal protection
- Early initiation and support for exclusive breastfeeding
- Neonatal resuscitation
- Prevention of mother to child transmission of HIV

*Specialised follow up of high-risk infants did not have specific structural requirements, therefore, is included on the list of interventions, but not on the final matrix. There are additional evidence-based interventions for newborns that should also be included in the antenatal period – antenatal corticosteroids and antibiotics for preterm premature rupture of membranes – and additional follow-up processes that would fall outside of inpatient newborn care and be linked to paediatric services.

As described in chapter 2, Bhutta and colleagues estimated that high coverage of currently available interventions along the continuum of care have the potential to save 3 million lives per year by 2025 (4). Inpatient care for small and sick newborns is an intervention package for which high quality coverage could have some of the highest potential impact on newborn deaths, especially in LMIC where the greatest proportion and numbers of deaths occur (21, 23, 25). Despite this, there are currently no set WHO standards or guidelines for the inpatient care for small and sick newborn package. This means that to understand the specific structures needed to deliver quality inpatient care, multiple sources of information need to be consulted. As shown in chapter 4, lack of standardised guidance and monitoring tools were highlighted as hindering service delivery for inpatient care for small and sick newborns. In view of this, the objectives of this chapter are to:

- Construct a standardised service readiness matrix organised by the health system structural domain (infrastructure, equipment, drugs, providers, and guidelines)

- Review existing global guidelines for content relevant to inpatient care for small and sick newborns
- Populate the matrix with structural components relevant to inpatient care

5.2 Methods

5.2.1 Review existing global guidelines for content relevant to inpatient care for small and sick newborns

I searched for existing published guidelines for all the newborn interventions, including relevant newborn and paediatric guidelines available on the WHO website. AS the WHO website does not have an advanced search function, all relevant maternal, newborn and child health guidelines were accessed, hand-searched, and relevant guidelines downloaded. Where no WHO guideline existed, I consulted relevant resources developed by UNICEF and other partners, including resources from international professional associations, such as the American Academy of Paediatrics and Royal College of Paediatrics and Child Health.

Based on the journey of the small and sick newborn from birth to inpatient care unit, I organised the matrix by six areas: 1) labour and delivery room 2) place of care for small and sick newborns 3) pharmacy/medicines, 4) human resources/providers, 5) laboratory & blood bank and 6) transport service. I organised interventions by whether they occur in the labour and delivery room or the neonatal unit (or both). Human resources and pharmacy were allocated as a separate area given that providers and drugs will be needed in multiple places of care. Given that most of the guidelines reviewed included information or guidance on referral systems and the associated structural components, I included transport system as a separate “area”. Specialised follow up was considered a part of paediatric services, therefore, was not given a specific area of the matrix (as this would involve adding an entire paediatric section). Finally, given the wide variation in laboratory systems, I separated the laboratory and blood bank by capacity to perform certain tests and actions, rather than an itemised list of components or equipment.

5.2.1.1 Populate the matrix with structural components relevant to inpatient care

Following structuring of the matrix and selection of the resources, I was then able to populate the matrix with the specific components required to deliver the interventions for small and sick newborns. During the process of the guideline review, where items or structural requirements were mentioned in the guideline, these were marked on the relevant section the matrix. Clinical knowledge was applied when different terminologies were used to ascertain the most neutral and appropriate term for each of the structural items so that the list could be used in multiple settings. The matrix was then reviewed and checked by several practicing clinicians (including neonatologists, paediatricians, and nurses) with experience in Nigeria, India, Ghana and Malawi, United Kingdom, United States.

5.3 Results

For this chapter, I reviewed 23 resource materials; see Table 5.2 for a list of the guidelines and resources used for this review. To ensure consistency with existing tools and other areas of care, I also reviewed the interagency list of medical devices for essential interventions for RMNCH (247), a master list created for newborn health in humanitarian settings by the Inter-Agency Working Group on Reproductive Health in Crises (IWAG), UNICEF and Save the Children (248) and the latest version of the WHO model essential drugs list (249).

On the final matrix, I mapped a total of 654 service readiness items for inpatient care of small and sick newborns to provide the inpatient care interventions. This included a total 167 structural items in the labour and delivery room and 266 in the place for small and sick newborn care (or neonatal unit). I listed a total of 33 different potential providers, 114 essential newborn drugs and medicines. Within the specific "areas" of the matrix, where equipment items recurred (e.g., components required for more than one intervention such as linen, gauze, swabs, weighing scale) I included these under general items for either the labour and delivery room or place of care for small and sick newborns. The final matrix is available in Appendix I.

Table 5.2 Resource materials and guidelines reviewed for newborn interventions

Essential newborn care, thermal protection, early initiation and support for exclusive breastfeeding	WHO essential newborn care course	2010
	WHO early essential newborn care: Clinical practice pocket guide	2014
	Essential care for every baby	2015
	WHO Integrated management of pregnancy and childbirth: Pregnancy, Childbirth, Postpartum and Newborn Care: A guide for essential practice	2015
	UNICEF: Baby Friendly Hospital Initiative (BFHI)	2012
	WHO Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health	2015
Neonatal resuscitation	WHO guidelines on basic newborn resuscitation	2012
	Helping Babies Breathe Resources	2017
	WHO guidelines on managing complications in pregnancy and childbirth	2007
	WHO guidelines on managing newborn problems: a guide for doctors, nurses and midwives	2003
Prevention of mother to child transmission of HIV	WHO guideline update on HIV and infant feeding	2016
	WHO guidelines on antiretroviral drugs for treating pregnant women and preventing HIV infection in infants	2010
	Médecins sans Frontières: Neonatal Care Guidelines	2016
Kangaroo mother care for premature babies, including follow up, alternative feeding (including cup feeding and nasogastric feeding)	Essential care for small babies	2015
	WHO kangaroo mother care: A practical guide	2003
	WHO guidelines on optimal feeding of low birth-weight infants in low- and middle-income countries	2011
	UNHCR operational guidelines on improving newborn health in refugee operations	2014
	UNICEF toolkit for setting up special care newborn units, stabilisation units and newborn care corners	No date
	WHO recommendations on interventions to improve preterm birth outcomes	
Injectable antibiotics for neonatal infections, hypoglycaemia management, effective phototherapy, seizure management, administration of oxygen	WHO pocket book of hospital care for children	2013
	Save the children, UNICEF: Newborn care charts	2009
*Treatment and screening for Retinopathy of prematurity**	Guidelines on screening and treatment for retinopathy of prematurity (UK and India)	2008
Blood transfusion, Mechanical ventilation and continuous positive airway pressure (CPAP)	WHO pocket book of hospital care for children	2013

*No current WHO guidelines available; recent guidelines recommended by ROP experts from India and UK selected for review

5.4 Discussion

To the best of my knowledge, this is the first time that service readiness for inpatient care of small and sick newborns has been delineated and mapped by structural component. By mapping this information in a practical and usable matrix it can be used as a blueprint by implementers for programme planning or monitoring purposes; for example, to develop management checklists, budget templates or stock inventories. The matrix can be flexible depending on the needs of the service and the interventions or packages of care they intend to provide; those providing a limited service may only have the capacity to provide a selection of newborn interventions, such as resuscitation, assisted feeding and KMC. Overall, the matrix clearly defines the structures required for inpatient care as distinct to this package of care, rather than as a sub-set of obstetric or paediatric services.

5.4.1 Strengths and limitations

The facilitation of the focus group described in the introduction encouraged participants to account for the views that they held and covered different viewpoints in a short space of time. The process of the discussion was helpful for the researcher and participants alike to understand the complexity of the topic and to consider viewpoints from diverse contexts. The time-constraints and voting process also brought pragmatism and help to bring levels of consensus in a short timeframe. Interventions that were discussed and debated, but not included in the final list included: total parenteral nutrition (which formed an important part of the discussion but was not voted onto the final shortlist); surfactant therapy (which many felt was prohibitively expensive for many contexts); and head cooling (which participants expressed concerns about the feasibility and lack of evidence base for efficacy in LMIC contexts). As with any focus group approach, there may be some contamination of viewpoints and more vociferous participants may have influenced or shaped final views and voting choices (250). Time limitations meant that much time was focused on the interventions, with less time for discussion on the justification for levels of care or a wider consultation process.

The matrix is limited by the availability of relevant, up-to-date guidelines that are currently published and available for the review for the specific interventions outlined in Figure 5.2. As can be seen in Table 5.2, some of the resources used are now over a decade old and require updating. As these guidelines are revised, the matrix will require updating.

The matrix was particularly challenging to populate for the more complex interventions, which had fewer available, detailed guidelines and paediatric guidelines had to be used: for example, the WHO pocket book of hospital care for children (158) covers areas of sick newborn care, but does not provide the level of granularity and detail that would be required for more complex care. In some cases, for example, retinopathy of prematurity where there were no available global guidelines, recent guidelines recommended by experts were selected for review. However, the guidelines may be more context specific and may have certain equipment or items that is differently named or used in different settings. For specialised follow up of high-risk infants, I could not delineate the structural requirements without adding a full paediatric section, which exceeded the scope of this exercise, which was focused on care for small and sick newborns at and around the time of birth. However, the intervention remains on the list for consistency with other areas of the thesis and its importance in linking to paediatric services and ongoing care.

Finally, with the growing problem of nosocomial infection and antimicrobial resistance, improved antibiotic stewardship is reliant on accurate diagnostics and availability of microbiological investigations. Further investigation of the minimum laboratory structural requirements for inpatient care of small and sick newborns will be critical but exceeded the scope of this guideline review.

5.5 Conclusions

Mapping the health system structures required for delivering inpatient care and delineating these by health system domains allowed for the creation of a practical and usable matrix for small and sick newborn care. The matrix, which mapped 654 service readiness items for inpatient care of small and sick newborns, can be used by implementers for programme planning, depending on the needs of their health system and the interventions or packages of care they intend to provide at their service. For this PhD, the matrix quantifies and delineates the structural needs for inpatient care, which is a prerequisite for exploring measurement of service readiness needs. The matrix, however, is limited by the current availability of global guidelines for newborn care. Up to date WHO standards of care for inpatient care of small and sick newborns are urgently needed to inform service delivery and successful scale up of quality care and should be linked to other services along the continuum of care.

THEME B: Measurement of service readiness for care of small and sick newborns

Photo credit: Getty images/Save the Children

Chapter 6. Existing tools to measure service readiness for inpatient care of small and sick newborns: what can we measure now?

6.1 Introduction

This chapter presents the results of a review of health facility assessment tools which was carried out to address the fourth objective of this thesis to determine gaps in existing measurement tools to capture service readiness for inpatient care of small and sick newborns.

This chapter and the matrix described in chapter 5 (and Appendix I) were written as a research paper entitled "Service readiness for inpatient care of small and sick newborns: What do we need and what can we measure now?"(17), which was published in Journal of Global Health as an open access article in June 2018. For the purpose of this PhD, I divided the paper into two chapters for this thesis as it addresses two different thesis objectives. This part of the paper takes the matrix described and presented in chapter 5 and reviews this against three multi-country health facility survey tools to determine gaps in existing measurement tools to capture service readiness for inpatient care of small and sick newborns.

See Appendix O for the published version of this article. See http://www.jogh.org/contributors.htm for terms of open access publication agreement.

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SECTION A – Student Details

Student ID Number	1405761	**Title**	Ms
First Name(s)	Sarah		
Surname/Family Name	Moxon		
Thesis Title	Service readiness for inpatient care of small and sick newborns: Improving measurement in low- and middle-income countries		
Primary Supervisor	Joy Lawn		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	Journal of Global Health		
When was the work published?	June 2018		
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For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I am the first author on this paper and responsible for the writing of this paper. I conceptualised the work for this paper alongside Tanya Guenther with advisory and conceptual support from Joy Lawn. I was responsible for the design and collation of the matrix (chapter 5), carrying out the review of the tools (chapter 6), leading the writing process, coordination of paper draft and design of the figures and tables. Tanya Guenther and Joy Lawn reviewed early drafts of the manuscript. Co-authors verified the review of the tools. Oona Campbell and Joy Lawn provided advisory support for final drafts of the paper. All named authors reviewed drafts of the paper and approved the final manuscript.

SECTION E

Student Signature	Sarah Moxon
Date	05/12/2018

Supervisor Signature	Joy Lawn
Date	05/12/2018

6.2 Abstract

Each year an estimated 2.5 million newborns die, mainly from complications of prematurity, neonatal infections, and intrapartum events. Reducing these deaths requires high coverage of good quality care at birth, and inpatient care for small and sick newborns. In LMIC, standardised measurement of the readiness of facilities to provide emergency obstetric care has improved tracking of readiness to provide care at birth in recent years. However, the focus has been mainly on obstetric care; service readiness for providing inpatient care of small and sick newborns is still not consistently measured or tracked.

We reviewed existing international guidelines and resources to create a matrix of the structural characteristics (infrastructure, equipment, drugs, providers and guidelines) for service readiness to deliver a package of inpatient care interventions for small and sick newborns[3]. To identify gaps in existing measurement systems, we reviewed three multi-country health facility survey tools (the Service Availability and Readiness Assessment, the Service Provision Assessment and the Emergency Obstetric and Newborn Care Assessment) against our service readiness matrix.

For service readiness to provide inpatient care for small and sick newborns, our matrix detailed over 600 structural characteristics. Our review of the SPA, the SARA and the EmONC assessment tools identified several measurement omissions to capture information on key intervention areas, such as thermoregulation, feeding and respiratory support, treatment of specific complications (seizures, jaundice), and screening and follow up services, as well as specialised staff and service infrastructure.

Our review delineates the required inputs to ensure readiness to provide inpatient care for small and sick newborns[2]. Based on these findings, we detail where questions need to be added to existing tools and describe how measurement systems can be adapted to reflect small and sick newborn interventions. Such work can inform investments in health system to end preventable newborn death and disability as part of the *Every Newborn* Action Plan.

[3] Refer to chapter 5

6.3 Introduction to paper

The first 28 days of life, the newborn period, represents the time of highest risk in the human lifecycle. In 2016, an estimated 2.6 million newborns died (2), mainly of complications of prematurity (35%), infections (23%), and intrapartum complications leading to birth injury (24%) (2, 3). Preventing deaths from these causes requires a combined health systems approach along the continuum of care (4). This approach should deliver routine newborn care for all babies (cleanliness, thermal care and support for breastfeeding), newborn resuscitation and PMTCT for all babies who need it (7, 8); and timely provision of quality inpatient care for babies born small and sick (5, 16).

Many LBW newborns, especially preterm infants, and those born small for gestational age, require support to feed and maintain their temperature. In addition, preterm newborns face increased risks of respiratory problems, infections and jaundice (16). Even amongst those born at full term, significant numbers of newborns suffer from systemic infections, neonatal encephalopathy, pathological jaundice and congenital abnormalities, with high mortality risk in the absence of care (16). "Small and sick newborns", therefore, includes all those babies who require inpatient (facility-based) care to survive. The care that small and sick newborns require is not an individual intervention, but a package made up of multiple interventions. Previous work has discussed the specific evidence-based interventions that comprise this package of care (4, 16, 246).

Evidence from *The Lancet* Every Newborn Series (21) informed the design of the *Every Newborn* Action Plan, a multi-partner initiative launched in 2014, backed by a World Health Assembly Resolution. *Every Newborn* aims to end preventable newborn deaths and stillbirths, with national targets of ≤12 neonatal deaths per 1000 live births and ≤12 stillbirths per 1000 total births by 2030 (6). To achieve these targets, *Every Newborn* partners acknowledge a need to improve the measurement of care at birth, and to better track coverage, quality, and equity of care for small and sick newborns around the time of birth (15). A dedicated sub-group – *Every Newborn* metrics - focuses on improving the measurement of interventions (15), and has a work stream focused on service readiness for inpatient care of small and sick newborns (246).

Currently, national and facility-based health information systems in LMIC collect few data on service readiness for small and sick newborns (15, 21, 172), in contrast with child health programmes, notably immunisation, HIV and malaria (251). Data are sparse in sub-Saharan Africa and parts of Asia where access to care for small and sick newborns is the lowest, and where many facilities need targeted efforts to strengthen services (15, 16).

Data from functional routine national HMIS and logistics management systems (LMIS) are able, in principle, to capture service readiness in a sustainable way, but the content and quality of data in national HMIS are variable in practice. This means many LMIC depend on periodic evaluations, such as nationally representative facility surveys or censuses, as a key source of health information to monitor the readiness of the health system to provide facility-based care (15, 113, 116). These surveys or censuses are referred to as health facility assessments.

The most common health facility assessment tools are the DHS Programme's SPA (117), the WHO SARA (101), and the EmONC assessments, currently managed by Averting Maternal Death and Disability (AMDD) (118) in collaboration with UNFPA. The content of these tools with regards to service readiness specifically for inpatient care of small and sick newborns has not previously been systematically evaluated.

Our overall aim was to review the current health facility assessment tools' ability to capture service readiness for inpatient care of small and sick newborns.

The specific objectives of this article are to:

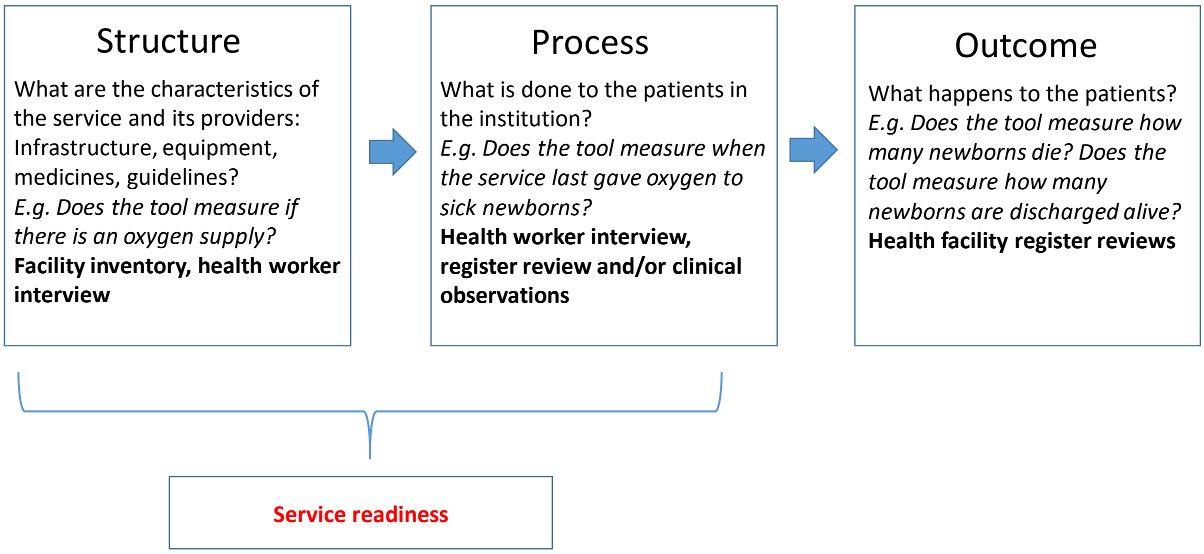
- Compare the components of a standardised matrix (chapter 5, Appendix I) against what is currently measured by widely used multi-country health facility survey tools (SPA, SARA, EmONC assessment) and identify gaps in measurement of the structural and process domains.
- Synthesise these findings to provide recommendations on how to improve measurement of service readiness for inpatient care of small and sick newborns.

6.4 Methods

6.4.1 Comparing the components of this standardised matrix against widely used multi-country health facility survey tools (SPA, SARA, EmONC assessment) and identifying gaps in measurement of structural and process domains

We applied the Donabedian framework (19, 88, 89) as a construct to review health facility assessment tools for small and sick newborns (Figure 6.1).

Figure 6.1 The Donabedian Framework as a construct to review health facility assessment tools



*Adapted from the Donabedian model for evaluating the quality of medical care (19, 88, 89)

We obtained the latest versions of the SARA (version 2.2, revision July 2015) (101) and the SPA (revised 2012) (117) from their websites. The EmONC assessment tool was being revised at the time of the study and we obtained the version undergoing field-testing from AMDD in July 2016.

We reviewed the SARA core questionnaire tool, the SPA health facility inventory and health worker interview, and the latest versions of the relevant modules from the EmONC assessment, (Module 1: Identification of facility and infrastructure; Module 2: Human Resources; Module 3: Essential drugs, equipment and supplies; Module 5: EmONC interventions; and Module 7: Provider knowledge and competency for maternal & newborn care).

We compared the content of each of the tools to the structural components in our matrix. To identify gaps in structural components we checked:

• Does the tool measure the infrastructure, equipment, drugs, health providers and/or guidelines needed to provide the interventions?

Many of the tools are also designed to also measure aspects of the process domain in the service readiness framework (Figure 6.1). Therefore, measurement of regular practice or training was considered as a proxy measurement of the process domain for service readiness (as it looks at what is regularly done to patients in the institution). For each of the 18 interventions included in the package of care (Figure 5.2), we also checked:

• Does the tool measure whether staff are given any training to provide the intervention?

• Does the tool measure if the intervention is regularly performed?

The first author (SM), completed the review of each tool. The review of the health facility assessment tools was verified by a representative of the lead agency for the EmONC assessment and the SPA to ensure the findings were consistent with the most recent versions of the tool.

6.5 Results

6.5.1 Comparison of the components of the standardised matrix against widely used multi-country health facility survey tools (SPA, SARA, EmONC assessment) and identification of gaps in measurement of structural and process domains

The SPA, the SARA and the EmONC assessment tools are summarised in Table 6.1. All three tools have different purposes, are measured at different intervals, and have different approaches to measurement and sampling.

Table 6.2 and Table 6.3 summarise the review of the interventions showing the structures and processes currently measured by the SPA, the SARA and the EmONC survey tools, and highlighting gaps in measurement of structural and process domains.

Table 6.1. Summary of three multi-country health facility assessment tools: Service Provision Assessment, Service Availability and Readiness Assessment and Emergency Obstetric and Newborn Care Assessment

	Service Provision Assessments (SPA)	**Service Availability and Readiness Assessment (SARA)**	**Emergency Obstetric and Newborn Care (EmONC) Assessment**
Purpose of tool	For comprehensive monitoring of a country's formal health care system; monitors the overall availability of different facility-based health services in a country and their readiness to provide those services	For assessing readiness of facilities using a standard set of indicators that cover all main health programmes. Only designed to assess service readiness (not performance or client perspectives)	For monitoring and assessment of the availability, use and quality of routine and emergency obstetric and newborn care in the formal health system.
Organisation(s)	The Demographic and Health Survey (DHS) Program, United States Agency for International Development (USAID)	World Health Organization (WHO), USAID	Averting Maternal Death & Disability (AMDD), United Nations Population Fund (UNFPA), United Nations Children's Fund (UNICEF), WHO.
Sample	Sample survey or census of formal sector health facilities designed to provide nationally representative results by facility type, managing authority, and geographic region.	Sample survey or census of at least 150 public and private facilities	Census of hospitals and census or sample of lower-level delivery sites (public and private facilities). Sample may be random, or selection may be restricted lower-level facilities that meet a specific volume of deliveries.
Modules	Facility inventory, exit interviews (antenatal care, family planning, sick child), clinical observations (antenatal care, family planning, sick child), health worker provider interviews	Facility inventory, health worker interview	Facility inventory, human resources, essential drugs, equipment and supplies, facility case summary, Emergency Obstetric Care (EmOC) signal functions, provider knowledge for maternal and some newborn care & chart reviews.
Numerator for indicators	Number of facilities ready to provide MNCH, family planning, HIV/AIDS, STIs, Malaria, Tuberculosis, basic surgery, non-communicable diseases services.	Proportion of health facilities, number of core medical professionals, proportion of facilities offering a defined service and the density and distribution of the facilities	Number of facilities providing EmOC, number of facilities providing each EmOC signal functions by level of care.
Denominator for indicators*	All formal facilities	All facilities, per 10,000 population	All surveyed facilities by level of care; availability of EmOC is measured per 500,000 population or 20,000 births*
Timeframe	15-18 months to complete fieldwork and report	Variable, but shorter than SPA or EmONC	12-18 months to complete field work and report
Frequency	4-5 yearly intervals	Designed to be repeated annually	4-5 yearly intervals

*(note discussion ongoing on whether denominator should measure births or population); expected number of births is the denominator for several other indicators – institutional birth rate, caesarean-section rate, met need for emergency obstetric care.

Table 6.2 A summary of the Service Provision Assessment (SPA), Service Availability and Readiness Assessment (SARA) and Emergency Obstetric and Newborn Care (EmONC) assessment tool's capacity to measure domains of service readiness for newborn interventions in the labour and delivery room

Intervention and components of structural domain	**Health facility assessment tool**		
	SPA	**SARA**	**EmONC**
Immediate/essential newborn care:			
Infrastructure	Y	Y	Y
Equipment & drugs	Y	Y	Y
Guidelines		Y	Y
Training	Y	Y	Y
Routine practice	Y	Y	Y
Thermal protection:			
Infrastructure	Y	Y	Y
Equipment & drugs			
Guidelines	Y	Y	Y
Training	Y		
Routine practice	Y		Y
Immediate and exclusive breastfeeding:			
Infrastructure			
Equipment & drugs			Y
Guidelines	Y		Y
Training	Y	Y	Y
Routine practice	Y	Y	Y
Resuscitation with bag and mask:			
Infrastructure	Y	Y	Y
Equipment & drugs	Y	Y	Y
Guidelines	Y	Y	Y
Training	Y	Y	Y
Routine practice	Y	Y	Y
PMTCT if HIV-positive mother:†			
Infrastructure	Y	Y	Y
Equipment & drugs	Y	Y	Y
Guidelines	Y	Y	Y
Training	Y	Y	Y
Routine practice	Y	Y	Y

EmONC – Emergency Obstetric and Newborn Care, SPA – Service Provision Assessment, SARA – Service Availability and Readiness Assessment
*Y – measured by the tool. †May only be applicable in settings with high HIV prevalence.

Table 6.3 A summary of the Service Provision Assessment (SPA), Service Availability and Readiness Assessment (SARA) and Emergency Obstetric and Newborn Care (EmONC) tool's capacity to measure domains of service readiness for interventions in the newborn inpatient care unit

Intervention and components of structural domain	Health facility assessment tool		
	SPA	SARA	EmONC
Kangaroo mother care (KMC) including follow up:			
Infrastructure			
Equipment & drugs			
Guidelines			Y
Training	Y		Y
Routine practice	Y	Y	Y
Alternative feeding if baby unable to breastfeed (cup feeding and nasogastric feeding):			
Infrastructure			
Equipment & drugs			
Guidelines			
Training			
Routine practice			Y
Safe administration of oxygen (including equipment for resuscitation):			
Infrastructure	Y	Y	Y
Equipment & drugs			Y
Guidelines			Y
Training			Y
Routine practice			Y
Intravenous fluids and management of hypoglycaemia:			
Infrastructure			
Equipment & drugs			Y
Guidelines			Y
Training	Y		Y
Routine practice		Y	Y
Injectable antibiotics for neonatal infection:			
Infrastructure	Y	Y	Y
Equipment & drugs	Y	Y	Y
Guidelines	Y	Y	Y
Training	Y		Y
Routine practice		Y	Y
Effective phototherapy:			
Infrastructure			
Equipment & drugs			

Guidelines			
Training			
Routine practice			
Seizure management:			
Infrastructure	Y	Y	Y
Equipment & drugs	Y	Y	Y
Guidelines			
Training			
Routine practice			
Continuous positive airway pressure and assisted/mechanical ventilation:			
Infrastructure	Y	Y	Y
Equipment & drugs			
Guidelines			
Training			
Routine practice			
Blood transfusion for newborns:			
Infrastructure	Y	Y	Y
Equipment & drugs			
Guidelines			
Training			
Routine practice			
Treatment and screening for retinopathy of prematurity:			
Infrastructure			
Equipment & drugs			
Guidelines			
Training			
Routine practice			

EmONC – Emergency Obstetric and Newborn Care, SPA – Service Provision Assessment, SARA – Service Availability and Readiness Assessment
*Y – measured by the tool.

Table 6.4 shows an example minimum drug list for inpatient care of small and sick newborns showing rationale for use in newborns and what is measured by the SPA, SARA and EmONC assessment tools.

Table 6.4 Example minimum drug list for inpatient care of small and sick newborns showing rationale for use in newborns and summary of the SPA, SARA, EmONC tools and essential medicine list*

Drug name	SPA	SARA	EmONC	EML	Drug description/use
Antibiotics					
Amoxicillin (oral suspension)	Y	Y	Y	Y	Penicillin antibacterial for neonatal infections
Amoxicillin (injection)			Y	Y	Penicillin antibacterial for serious neonatal infections
Amikacin (IV or IM)				Y	Aminoglycoside antibacterial; alternative treatment of ophthalmia neonatorum
Ampicillin (IV or IM)	Y	Y	Y	Y	Penicillin antibacterial for serious neonatal infections
Ampicillin (oral)					Penicillin antibacterial for neonatal infections
Azithromycin (oral)	Y	Y		Y	Penicillin antibacterial for P-PROM (maternal use)
Benzathine benzylpenicillin (benzathine penicillin G) (IM)	Y	Y		Y	Penicillin antibacterial for treatment of congenital syphilis
Benzylpenicillin (Penicillin G) (IV or IM)	Y		Y	Y	Penicillin antibacterial for serious neonatal infections
Cefalexin (oral suspension)				Y	First generation cephalosporin used in newborns for skin and soft tissue infections
Cefotaxime (IV or IM)			Y	Y	First generation cephalosporin with broad spectrum for treatment of serious neonatal infections
Ceftriaxone (IV or IM)	Y	Y	Y		Third generation cephalosporin for neonatal infections, genital gonococcal and/or chlamydial infection
Ciprofloxacin (injection)				Y	Second generation fluoroquinolone antibacterial sometimes used as second line treatment
Ciprofloxacin (oral)	Y	Y		Y	Second generation fluoroquinolone antibacterial for treatment of bacterial diarrhoea
Clindamycin (IV)			Y	Y	Lincosamide antibacterial, second line treatment (e.g., streptococcal or soft tissue infections)
Co-amoxiclav (oral suspension)			Y		Penicillin antibacterial can be used where no IV access

Co-amoxiclav (injection)					Penicillin antibacterial used for neonatal skin infections
Cotrimoxazole (oral)	Y	Y			Combined antibiotic for prophylactic treatment of HIV
Erythromycin (oral)	Y		Y	Y	Penicillin antibacterial for P-PROM (maternal use)
Flucloxacillin (IV/IM) (cloxacillin)			Y	Y	Penicillin antibacterial treatment for neonatal sepsis
Flucloxacillin (oral)			Y	Y	Penicillin antibacterial. Can be used in newborns as follow on from intravenous flucloxacillin
Gentamicin (IM or IV)	Y	Y	Y	Y	Aminoglycoside antibacterial used for treatment of neonatal sepsis
Isoniazid (oral)	Y	Y		Y	Antituberculous antibacterial used occasionally for congenital TB
Kanamycin				Y	Aminoglycoside antibacterial; alternative to gentamicin
Metronidazole (IV)	Y	Y	Y	Y	Antiprotozoal antibacterial used for neonatal meningitis and/or anaerobic bacterial infections
Metronidazole (oral)	Y	Y		Y	Antiprotozoal antibacterial used for neonatal meningitis and/or anaerobic bacterial infections
Procaine benzylpenicillin (IM)		Y	Y	Y	Penicillin antibacterial used for congenital syphilis
Tetracycline 1% eye ointment	Y	Y	Y	Y	Prophylactic topical antibiotic used to prevent bacterial (e.g., chlamydial, gonococcal) neonatal conjunctivitis
Anticonvulsants:					
Diazepam (oral/NG)				Y	Sedative, anticonvulsant, muscle relaxant mostly used for neonatal tetanus
Diazepam emulsion (IV)	Y	Y	Y	Y	Sedative, anticonvulsant, muscle relaxant used for neonatal tetanus
Midazolam (oral solution)				Y	Sedative, anticonvulsant used for seizures
Paraldehyde (rectal)					Anticonvulsant for seizures
Phenobarbital (IV or IM)		Y	Y	Y	First line anticonvulsant for tonic clonic and partial seizures
Phenobarbital (oral)		Y		Y	First line anticonvulsant for tonic clonic and partial seizures
Phenytoin (IV)			Y	Y	Anticonvulsant for tonic clonic and partial seizures
Emergency drugs:					
Adrenaline/epinephrine (IV)	Y	Y	Y	Y	Sympathomimetic for cardiopulmonary arrest used for advanced neonatal resuscitation
Aminophylline			Y		Bronchodilator used to prevent apnoeic attacks in premature newborns

Atropine (injection)		Y	Y	Y	Parasympatholytic, antispasmodic used for intubation
Calcium gluconate (injection)	Y	Y	Y	Y	Used for hypercalcaemic seizures and hyperkalaemia
Hydrocortisone (injection)	Y		Y	Y	Steroidal anti-inflammatory used for hypotension or severe broncho-pulmonary dysplasia
Magnesium sulphate (IV)	Y	Y	Y	Y	Inorganic salt compound Maternal use in preterm labour, protective against cerebral palsy
Naloxone (IV)			Y	Y	Specific opioid antagonist for respiratory depression in newborns
Analgesics:					
Ibuprofen (IV)				Y	Analgesic sometimes used in newborns for closing patent ductus arteriosus
Morphine (IV)	Y	Y		Y	Centrally acting opioid analgesic for severe pain, sedation and intubation
Morphine (oral)		Y	Y	Y	Used for severe pain
Paracetamol (oral)	Y	Y	Y	Y	Analgesic for minor pain
Paracetamol (suppository)				Y	Analgesic for minor pain
Paracetamol (injection)					Analgesic for minor pain. Also used for newborns for closing patent ductus arteriosus.
Corticosteroids:					
Betamethasone (IM)	Y	Y	Y		Not used in newborns; used in mothers with threatened preterm labour <34 weeks gestation for fetal lung maturation
Dexamethasone (IM)	Y	Y	Y	Y	Not used in newborns; used in mothers with threatened preterm labour <34 weeks gestation for fetal lung maturation
IV fluids:					
Calcium gluconate 10%	Y	Y		Y	Supplement used to treat calcium deficiency. Dependent on programme context - careful monitoring required
Dextrose 10% with normal saline	Y		Y	Y	Solution used for maintenance fluid therapy
Dextrose/glucose 5%	Y	Y	Y	Y	Solution used as vehicle for administration of IV drugs
Dextrose/glucose 10%		Y	Y	Y	Solution for treatment of hypoglycaemia and maintenance fluid therapy on first day of life for sick babies who cannot feed
Potassium chloride (KCl) 7.5%, 10%, 15%				Y	Solution only to be used in contexts where monitoring of potassium levels is available.
Sodium bicarbonate				Y	Solution used to dissolve artesunate

Sodium chloride 0.9%	Y	Y	Y	Y	Solution used as a vehicle for administration of IV/parenteral drugs, fluid replacement and flushing IV lines
Ringer’s lactate	Y	Y	Y	Y	Compound solution for severe dehydration/hypovolaemia can be added to dextrose/glucose for a mix
Water for injection					Sterile water for mixing drugs
Anti-malarials:					
Artesunate (IV or IM)	Y	Y		Y	First line treatment for neonatal malaria
Artesunate (rectal)	Y	Y		Y	Neonatal malaria treatment if IV/IM access not available
Arthemeter (IM)				Y	Second line treatment for neonatal malaria
Artemisinin-based combined therapy (oral)	Y	Y	Y	Y	Second line anti-malarial treatment followed by ACT
Antiretrovirals (may vary depending on national HIV guidelines):					
Azidothymidine/Zidovudine (AZT) (oral)	Y	Y	Y	Y	Antiretroviral
Lamivudine	Y	Y	Y	Y	Antiretroviral
Nevirapine (NVP) (oral)	Y	Y	Y	Y	Antiretroviral
Other drugs:					
Aciclovir (IV)				Y	Antiviral used for herpes and encephalitis
Acyclovir 3% topical eye ointment				Y	Antiviral active against herpes virus used to prevent neonatal herpes keratitis in babies born to mother with genital herpes
Anti-Rho (D) immune globulin (injection) *****			Y		To prevent Rhesus disease (haemolytic disease of the newborn) given to mothers
Caffeine citrate (oral)				Y	Preventive treatment for apnoea
Caffeine citrate (IV)				Y	Oral preferred over IV
Chlorhexidine digluconate 7.1% gel (delivering 4% chlorhexidine)	Y		Y	Y	topical treatment of omphalitis
Domperidone					Anti-reflux drug for gastro-oesophageal reflux
Ethambutamol (oral)	Y	Y		Y	First line oral anti-tuberculous drug
Ferrous fumarate (oral)	Y		Y	Y	Oral suspension used for preterm neonates to prevent iron deficiency

Folic acid	Y	Y	Y	Y	Oral suspension used for folate supplementation
Fluconazole (IV)				Y	Antifungal drug used in newborns over 1 week
Fluconazole (oral)	Y	Y	Y	Y	Antifungal drug
Furosemide (IV)		Y		Y	Diuretic used for chronic lung disease, oedema in advanced settings
Furosemide (oral)	Y		Y	Y	Diuretic
Glycerin chip					Suppository used in newborns to stimulate stooling
Hepatitis B immune globulin (HBIG)					Treatment of Hepatitis B in neonates
Human milk fortifier					Fortifier adds protein, calories and micronutrients to expressed breastmilk for LBW babies
Insecticide treated bed nets (in malaria endemic areas)	Y	Y	Y		For mothers' beds in KMC ward and for discharge home
Lidocaine solution	Y	Y	Y	Y	Local anaesthetic
Miconazole cream (or equivalent e.g., gentian violet)	Y			Y	Topical antifungal for candida dermatitis used for nappy area
Multivitamin					Containing zinc, vitamin A etc.
Nystatin (oral solution)	Y		Y	Y	Topical antifungal for oropharyngeal candidiasis used prophylactically with antibiotic treatment
Nystatin cream				Y	Topical antifungal
Omeprazole (IV)	Y			Y	Acid blocker for gastro-oesophageal reflux
Omeprazole (oral)	Y			Y	Acid blocker for gastro-oesophageal reflux
Oral rehydration solution	Y	Y	Y	Y	Powder to mix with drinking water for oral rehydration; breastmilk feeding should be encouraged
Oxygen supply				Y	Medical inhalation gas for treatment of respiratory distress
Phosphate and calcium supplements					Supplementation
Potassium Chloride (1mmol/ml) (oral)				Y	Powder solution for maintenance oral potassium replacement
Pyridoxine (oral)				Y	Preventive therapy for tuberculosis
Pyrazinamide (oral)	Y	Y		Y	First line oral anti-tuberculous drug

Ranitidine (IV)				Y	Antacid drug for gastro-oesophageal reflux
Ranitidine (oral)				Y	Antacid drug for gastro-oesophageal reflux
Rifampicin (oral)	Y	Y		Y	First line oral anti-tuberculous drug
Sucrose 30% (oral)					Non-pharmacological pain management for minor procedures (e.g., cannulation)
Tetanus immunoglobulin (HTIG) (IM)			Y	Y	Anti-tetanus immunoglobulin for treatment of neonatal tetanus
Vitamin B6 (pyridoxine) (IV or IM)					Vitamin for B6 deficiency
Vitamin D					Supplementation.
Vitamin K1 (Phytomenadione) (IM or IV)			Y	Y	Vitamin and anti-haemorrhagic for prophylactic treatment of haemorrhagic disease of the newborn
Water based lubricant					For inserting suppositories and/or other procedures.
Zinc oxide cream					Topical for nappy/diaper rash
Vaccines:					
BCG vaccine	Y	Y	Y	Y	Prevention of TB
Diphtheria	Y	Y		Y	Prevention of diphtheria
Pertussis vaccine	Y	Y		Y	Prevention of pertussis
Haemophilus influenzae type b (Hib) vaccine	Y	Y		Y	Prevention of haemophilus influenzae type B
Hepatitis B vaccine	Y	Y		Y	Prevention of hepatitis B in countries where perinatal infection is common, as per vaccination schedule
Oral poliomyelitis vaccine	Y	Y	Y	Y	Prevention of poliomyelitis
Tetanus toxoid	Y	Y	Y	Y	Prevention of tetanus in wound management, prevention of maternal and neonatal tetanus in pregnant women

EmONC – Emergency Obstetric and Newborn Care, SPA – Service Provision Assessment, SARA – Service Availability and Readiness Assessment, EML – Essential Medicines List, IM – intramuscular, IV – intravenous

*Y – measured by the tool.

For ease of presentation, and to avoid repetition, we summarise the findings from the review in this section by structural and process domains.

6.5.2 Gaps in structural domain

6.5.2.1 Infrastructure

All three tools measured elements of general health facility infrastructure, such as electricity supply, means of communication, referral and transport and availability of water, toilets/latrines and waste disposal.

All tools measure availability of a table or surface for performing resuscitation. Some infrastructural requirements to support essential newborn care both in the labour and delivery room and the postnatal ward, such as space, privacy (screens) for mother to express breastmilk and infrastructure for storage of breastmilk (and whether there is consistent power supply for refrigeration) were not measured by any of the tools. All tools collect details on infrastructure to provide PMTCT.

The SPA measured space for mothers to provide KMC in its facility inventory, but only the EmONC assessment asked about space allocation for sick newborn care or a special care unit (e.g. infrastructure to provide services beyond KMC, such as assisted feeding, thermal protection, fluids and/or oxygen support). As oxygen is a crosscutting infrastructural component needed for several interventions outside of newborn health, all tools measured availability of an oxygen source. However, none of the tools measured the newborn-specific infrastructure that would be needed for safe oxygen therapy for newborns. Continuity of electricity and oxygen is especially important for facilities offering care for small and sick newborns who may be dependent on consistent oxygen source and/or electric equipment. None of the tools measured service readiness infrastructure for screening services (for example, developmental milestones, hearing and vision) or follow-up for high-risk infants.

None of the tools measured advanced infrastructure for intensive care for very small and sick newborns, such as that required for mechanical ventilation, newborn blood and/or exchange transfusion, and specialist laboratory infrastructure beyond that needed for obstetric, and some paediatric and adult services.

6.5.2.2 Equipment

All tools measured provision of basic equipment for neonatal resuscitation, including smaller-sized face masks and resuscitation bag in the labour and delivery room. None of the tools measured whether resuscitation equipment was available in the room where small and sick newborns are cared for to ensure safety and continuity of care.

Simpler interventions for small newborns, such as assisted feeding (plastic feeding cups and small sized nasogastric tubes) were only measured by the EmONC assessment, and hats or caps (including small sizes) are not consistently measured among the tools.

Phototherapy equipment needed to treat neonatal jaundice was only measured by the EmONC assessment (fluorescent tubes and icterometry). Lower cost phototherapy technologies, such as LED phototherapy devices were not included in any of the tools.

Although the infrastructure for oxygen was measured, most likely for paediatric and adult services, safe delivery of oxygen to newborns requires significant additional equipment items, such as newborn pulse oximetry, neonatal nasal prongs, oxygen-air blenders, low-flow metres and humidifiers, which were not captured by the tools.

Higher level respiratory support for newborns, such as CPAP ventilation, was not measured by any of the tools. Our matrix shows that for safe delivery of CPAP, beyond the drivers themselves, facilities would require critical emergency equipment in case of pneumothorax such as transilluminators, chest tubes and valves.

Intubation equipment (e.g., laryngoscopes blades in small sizes) were measured by the EmONC assessment, but other critical components to support a ventilated newborn were not measured, including the ventilator machine.

6.5.2.3 Drugs

The EmONC assessment tool had the most extensive list of drugs and medicines for newborns detailing 106 medicines and drugs for mothers and newborns, but very few of these are specified for newborns. There were several notable omissions of medicines for care at birth within the SPA and SARA, such as vitamin K (SPA only asks whether it is routinely administered).

All three tools measured antibiotic drugs for treating small and sick newborn infections (amoxicillin oral and injection, ampicillin injection and gentamicin injection as a minimum). However, inventories did not seek to specify whether the antibiotic was available in the injectable form, with the appropriate concentrations and diluents (usually water for injection, sodium chloride 0.9% and glucose 5%), or the availability of smaller intravenous cannulas/catheters and syringe drivers. The tools measured standard intravenous fluid preparations, but only EmONC included glucose 10%, which is most frequently used for neonates. For seizure management, only the EmONC tool measured the first- and second-line treatments (intravenous phenobarbitone and phenytoin).

Several drugs that might be used for advanced level care, such as procedural sedation and pain relief, were not currently included in any of the tools.

In Table 6.4 we present an example drug list for inpatient care of small and sick newborns indicating which drugs are measured by each tool and whether these are on the most recent WHO model essential medicines list(252). This includes the commodities needed for retinopathy of prematurity screening and treatment, such as dilating and anaesthetic eye drops, which are not currently included in existing tools.

6.5.2.4 Health providers

There were several notable gaps in measurement of specialist newborn staff. Only the EmONC tool measured specialist staff cadres for newborns (e.g., neonatologist) and none of the tools measured specialist neonatal nurses. Allied staff and support staff (e.g., social workers, speech therapist) were not measured. None of the tools measured ophthalmologists or related professions that are needed in settings where newborns may require screening and treatment for retinopathy of prematurity, or biomedical engineers for equipment maintenance.

6.5.2.5 Guidelines

The table of guidelines used for the matrix and review is shown in chapter 5 (Table 5.2). There were notable gaps in available guidelines for some of the more complex interventions and the specialist diagnostics needed for continuous positive airway pressure, blood transfusion, exchange transfusion, ventilation, and treatment and screening of retinopathy of prematurity.

6.5.3 Gaps in process domain

Measurement of regular practice or training of health staff in specific interventions was considered as a proxy measurement for the process domain for service readiness as it looks at what is regularly done to patients in the institution.

6.5.3.1 Measurement of regular practice

All the tools relied on direct health worker reports, the register, or chart reviews to measure whether select interventions were regularly provided for small and sick newborns.

The SPA looked at whether a limited number of interventions relevant to newborns (neonatal resuscitation and corticosteroids for preterm labour) were ever practiced and practiced in the last 3 months. The SPA also included a series of questions on essential care for newborns, but none on inpatient care for small and sick newborns, other than if KMC was practiced in the facility.

The SARA asked whether a limited number of functions were provided in the last 12 months: antibiotics for preterm or prolonged premature rupture of membranes, antenatal corticosteroids, neonatal resuscitation, KMC, and injectable antibiotics.

The EmONC assessment had the most detailed list of newborn interventions (newborn resuscitation, antenatal corticosteroids, antibiotics for preterm premature rupture of membranes, antibiotics for neonatal infections, KMC, administration of oxygen and administration of IV fluids).

The EmONC tool included specific knowledge questions on small and sick newborn care, including a few interventions, such as resuscitation, oxygen therapy and infections.

Table 6.5 summarises the approaches used by each of the tools to capture regular practice and training.

The synthesis of these findings to provide recommendations on improving these measurements is provided in the discussion section.

Table 6.5 The approach used by Service Provision Assessment (SPA), Service Availability and Readiness Assessment (SARA) and Emergency Obstetric and Newborn Care (EmONC) tools to measure regular practice and training for interventions included in the tools

	SPA		SARA		EmONC	
	Regular practice	***Training***	***Regular practice***	***Training***	***Regular practice***	***Training***
Essential newborn care	Routinely practiced	Training in last 24 months	Routinely carried out	Training in last 24 months	Performed in last 3 months	Ever received training
Thermal protection		Training in last 24 months			*As part of essential newborn care*	*As part of essential newborn care*
Early initiation and support for exclusive breastfeeding	Routinely practiced	Training in last 24 months	Routinely carried out	Training in last 24 months	*As part of essential newborn care*	*As part of essential newborn care*
Neonatal resuscitation with bag and mask	Ever practiced, practiced in last 3 months	Training in last 24 months	Practiced in last 12 months	Training in last 24 months	Performed in last 3 months	Ever received training
Prevention of mother to child transmission of HIV	Routinely practiced	Training in last 24 months	Service is offered	Training in last 24 months	ARVs given to newborns in the last 3 months	Ever received training
Kangaroo mother care	Ever practiced	Training in last 24 months	Practiced in last 12 months		Performed in the last 3 months	Ever received training
Assisted feeding (cup feeding and nasogastric feeding)					Performed in last 3 months	
Safe administration of oxygen					Performed in last 3 months	
Injectable antibiotics for neonatal infection		Training in last 24 months	Practiced in last 12 months		Performed in last 3 months	Ever received training
Intravenous fluids		Training in last 24 months			Performed in last 3 months	

6.6 Discussion

Our review of three health facility assessment tools identified measurement gaps for almost all newborn interventions, even for the more basic interventions, such as thermoregulation and feeding. The most significant measurement gaps are for more complex interventions, which are currently not captured by any of the tools in our review. We found many commonalities among these tools, but also highlighted important differences that show how they have evolved with important, but distinct purposes, and different measurement approaches (103). The size and cost of these assessments already limits the frequency of carrying out these surveys; adding a long list of indicators for small and sick newborn care would compound this challenge (253). To improve the existing tools, we found that a number of indicators for basic service readiness could be harmonised, and some proxy indicators of service readiness for more complex care could potentially be added. As with other more complex areas of care, monitoring all the structures and processes for small and sick newborns will likely require a facility-based monitoring system (254-256).

Used in tandem with the matrix in the previous chapter (Appendix I), this work is a step towards developing a more general facility-based monitoring system or core module. Following validation, such a tool could be adapted for different settings as has been done in India (254-256).

The following sections provide a synthesis of findings and recommendations for improving the widely used tools for measurement of small and sick newborn care.

6.6.1 Harmonisation of existing health facility assessment tools

6.6.1.1 Indicators

The interventions that are best represented by the existing tools are those that have been promoted as vertical programmes, such as neonatal resuscitation (which is a core indicator for obstetric and newborn care assessments), essential newborn care (for all babies) and PMTCT. The measurement approach and indicators for many of the more basic newborn interventions would benefit from more standardisation between tools. As a minimum, this should include service readiness indicators for essential newborn care (including service readiness for drying, skin to skin contact, cord clamping and initiation of breastfeeding), neonatal resuscitation and KMC (253).

All of the existing tools have some questions on KMC, but for monitoring of operational KMC (253), the facility inventories require adaptations to incorporate more of the items needed for KMC including the equipment for feeding support, antibiotics and amenities for mothers to stay in the facility (15, 193, 257). Whilst listing the items needed for antenatal care exceeded the scope of this exercise, these should be considered in future tools, such as availability of antenatal corticosteroids for threatened preterm labour, antibiotics for preterm rupture of membranes (per WHO guidelines) as a minimum (258).

Measurement of training and skills for newborn interventions could be harmonised between tools such that these indicators are comparable between different surveys (see Table 6.5).

6.6.1.2 Crosscutting service readiness needs

Health providers, especially midwives and specialist nurses, play a critical role in neonatal care (5, 16, 30, 208, 259). Specially trained neonatal nurses may not be available in all health facilities, but previous studies show it is important to monitor who, if anyone, cares for newborns in the absence of specialised staff (16). Recent studies in higher income settings, where neonatal nursing is a specialist cadre, show that reducing the nurse-to-patient ratio in neonatal units increases in-hospital mortality (207, 259). As a minimum, all health facility assessment survey tools could include questions on staff rotation policies to ensure specialist staff are not regularly being rotated to other areas of care (16), however this is currently only included in the EmONC tool. Other allied and supportive professionals may be a necessary addition to the list of staff cadres, such as biomedical engineers for maintaining equipment and nursing support staff. For all health facility assessment tools, the capacity and readiness of a facility to provide referral to facilities that can provide more complex care for small and sick is a critical indicator of service readiness. The difficulty and inconsistency in measurement of provider skills and training also illustrates the need for further research into human resource tracking, and work to set benchmarks for staffing ratios for neonatal care (16).

Infection prevention and control is essential for all areas of the facility with newborns particularly vulnerable, and most of the newborn deaths from infections occurring in small babies. The current tools have several general water and sanitation indicators, which should be harmonised across tools to ensure that the basic soap, running water and safe and effective antiseptics are available in labour and delivery and neonatal care areas. A standard indicator that measures whether the newborn space is separate from the paediatric ward, and for whether there is a system for inborn and out born babies could be a potential proxy indicator for service readiness.

6.6.2 Measuring more complex inpatient care for small and sick newborns

Small and sick babies, especially those born preterm, are at higher risk of multiple childhood morbidities (including visual, hearing and neuro-developmental), with increasing gradient of adverse developmental outcomes by lower gestational age of survivors (44, 97). These newborns often require more complex interventions, such as respiratory support (oxygen, continuous positive airway pressure), treatment of specific complications (feeding, seizures, jaundice), and screening and follow up services (16). Many of these interventions carry a risk of harm when not performed with safe equipment or by trained staff. This is illustrated in middle-income settings, where we have seen an increase in impairments in survivors of neonatal care, especially where complex care has been scaled up without due attention to service readiness needs (44, 97).

The existing tools do not capture the large number of items required to deliver complex interventions safely, which would require a facility-based monitoring register or module that also includes process and outcome data (morbidity and mortality) (260). Such modules have been developed in higher- and middle-income settings (256, 260-262), but are not standardised routine systems. Further research into adaptations of existing tools is an important next step.

Clinical care charts and protocols are essential for quality and safety of neonatal care that requires complex calculations of drug concentrations and specific diluents, dosages, and delivery mode for newborns. In addition to service readiness needs, the risks of certain interventions can be mitigated by ensuring clinical record keeping, which is known to be sub-standard in many settings (263). Standardised observation charts for monitoring of vital signs (e.g., hourly or three-hourly), fluid input and output, feeding method and volume, and monitoring medications and laboratory tests (e.g., serum bilirubin and exchange transfusion thresholds) could support facilities, alongside up to date standardised evidence-based guidelines, a list of which is included in the documentation section of the matrix (Appendix I).

6.6.3 Implications and next steps for monitoring service readiness for inpatient care of small and sick newborns

Amongst existing partners and initiatives, there is widespread recognition of the need to harmonise monitoring systems for maternal and newborn care. The existing EmOC signal functions do not represent the full set of facility-based interventions for mothers and newborns, and small and sick newborns are especially neglected. Given the large number of service readiness requirements for small and sick newborn care, a short list of signal functions for monitoring purposes is a potential solution. Work has been done on this previously by Gabrysch and colleagues (188) and a global survey led by *Every Newborn* partners, alongside a technical group led by AMDD and UNFPA are currently working on linking this to the emergency obstetric care indicators, with plans to finalise recommendations for newborn signal functions 2019-2021.

Periodic evaluation, using health facility surveys, is currently necessary, but ultimately the goal should be to incorporate such assessments into functional and sustainable routine national systems. These should operate independent of donor funding and project mandates. The current health facility assessment tools are costly and time-consuming. Lighter assessments that can be carried out more frequently are also required, and need more research (264). Even in HIC, not all national facilities feed information into one database for national monitoring of inpatient care of small and sick newborns. LMIC which have not moved to electronic information systems have an advantage in that they can leap-frog the situation of having fragmented and discrepant electronic data collection forms which differ from facility to facility or region to region. Exploration of the potential use of DHIS-2 platforms for facility-based monitoring of service readiness is being carried out as part of the *Every Newborn* measurement improvement roadmap (246). This work supports the growing interest in use of routine health management information systems to monitor aspects of service delivery in facilities (15), and of LMIS to track logistics and supplies.

6.7 Conclusions

Tracking of service readiness to provide inpatient care of small and sick newborns is needed to gain the required policy attention, accountability and investment that is critical to end preventable newborn deaths and improve child development. This is reflected in the Global Strategy for Women, Children and Adolescents, the WHO Quality of Care Framework, and is supported by the *Every Newborn* metrics working group. The existing health facility assessments do not generate comparable data and have very limited assessment of more complex care for small and sick newborns. Indicators in existing tools can be harmonised, but the size and cost of these assessments limits their frequency. Developing a core list of harmonised indicators for use in routine health information system could help address this gap. Improvements in these monitoring systems are urgently needed to inform efforts to improve quality of care and investments in health systems scale-up, to end preventable newborn death and disability, alongside work to end preventable maternal deaths and stillbirths.

Chapter 7. Categorising interventions to levels of inpatient care for small and sick newborns: Findings from a global survey

7.1 Introduction

The paper presented in this chapter entitled "Categorising interventions to levels of inpatient care for small and sick newborns: Findings from a global survey" addresses the fifth objective of the thesis that identifies potential signal functions and levels of care for small and sick newborns. The paper presents the results of a quantitative analysis of a survey of global practitioners on signal functions and levels of inpatient care for small and sick newborns. It discusses findings from the survey in the context of existing EmONC signal functions and levels of care. This paper was published in PloS one in July 2019 as an open access article (18).

See Appendix P for the published version of this article.

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Student ID Number	1405761	**Title**	Ms
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Thesis Title	Service readiness for inpatient care of small and sick newborns: Improving measurement in low- and middle-income countries		
Primary Supervisor	Joy Lawn		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

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For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I am the first author on this paper and responsible for the writing. I conceptualised this work with advisory support from Hannah Blencowe and Joy Lawn, in consultation with relevant stakeholders. I was responsible for designing the survey, dissemination of the survey, the analysis and writing process, coordination of the paper drafts and the figures and tables. John Bradley provided support in an advisory capacity for the analysis. Hannah Blencowe, Joy Lawn, Louise-Tina Day, Patricia Bailey reviewed early drafts of the manuscript and provided inputs on the analysis and interpretation. All named authors reviewed drafts of the paper.

SECTION E

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7.2 Abstract

In 2017, 2.5 million newborns died, mainly from prematurity, infections, and intrapartum events. Preventing these deaths requires health systems to provide routine and emergency care at birth, and quality inpatient care for small and sick newborns. Defined levels of emergency obstetric care (EmOC) and standardised measurement of “signal functions” has improved tracking of maternal care in low- and middle-income countries (LMICs). Levels of newborn care, particularly for small and sick newborns, and associated signal functions are still not consistently defined or tracked.

Between November 2016-November 2017, we conducted an online survey of professionals working in maternal and newborn health. We asked respondents to categorise 18 clinical care interventions that could act as potential signal functions for small and sick newborns to 3 levels of care they thought were appropriate for health systems in LMICs to provide: “routine care at birth”, “special care” and “intensive care”. We calculated the percentage of respondents that classified each intervention at each level of care and stratified responses to look at variation by respondent characteristics.

Six interventions were classified to specific levels by more than 50% of respondents as “routine care at birth,” three interventions as “special care” and one as “intensive care”. Eight interventions were borderline between these care levels. Responses were more consistent for interventions with relevant WHO clinical care guidelines while more variation in respondents’ classification was observed in complex interventions that lack standards or guidelines. Respondents with experience in lower-income settings were more likely to assign a higher level of care for more complex interventions.

Results were consistent with known challenges of scaling up inpatient care in lower-income settings and underline the importance of comprehensive guidelines and standards for inpatient care. Further work is needed to develop a shortlist of newborn signal functions aligned with emergency obstetric care levels to track universal health coverage for mothers and their newborns.

7.3 Introduction to paper

Each year an estimated 2.5 million newborns die in the 28 days after birth (265). The main causes of death are direct complications of prematurity (35%), infections (23%), and intrapartum complications leading to birth injury (24%) (3). Most of these deaths occur in low- and middle-income countries (LMICs). Many lives could be saved – and morbidity prevented – through a health systems approach along the continuum of care (4). Such an approach requires delivery of quality packages of care including routine and emergency care for mothers and newborns at birth, and inpatient care for small and sick newborns (4, 23).

In addition to routine essential newborn care, many low birth weight (LBW) newborns, including both preterm infants, and those born small for gestational age, require additional support to feed and to maintain their temperature (16, 33). Preterm newborns face increased risks of respiratory problems, infections, and jaundice (9). Even amongst those born at full term, significant numbers of newborns face complications including, systemic infections, neonatal encephalopathy, severe jaundice, and congenital disorders, with high mortality risk in the absence of quality care (16, 21). Many of these small and sick babies will require inpatient care for them to survive and minimise chances of developing future morbidities and/or long-term disability (27, 42, 44, 60, 97). Access to appropriate level and quality care remains challenging, especially for mothers and newborns experiencing complications, and notably in LMICs (4, 16, 266).

Based on evidence from higher income settings, a rational approach to organising and delivering quality services is through an integrated network of facilities providing increasing levels of care, referred to as regionalisation of care (267-269). Managing mothers and newborns experiencing complications by more skilled staff working in specialised, better equipped facilities than in lower level facilities or those staffed solely by generalists allows for an efficient use of resources, and is an effective strategy to improve access to care for complications (266, 267, 269). Higher levels of care build on the capabilities of lower level(s) with the additional infrastructure, equipment, supplies and health providers to manage more complex levels of care (17, 267). For such an approach to work, synergy in institutional capabilities for mother and newborns is needed with a functional communication and referral system (91, 267, 270). Levels of care need to be clearly defined with accompanying monitoring systems to identify issues in availability, access and quality of care for services (15, 17, 268). Defined levels of maternal and newborn care are common in high-income settings (267, 268, 270-272), but there is a need for such a delineation for newborns in LMICs (16).

In LMICs, maternal care has been categorised by United Nations (UN) agencies at two levels referred to as basic emergency obstetric care (BEmOC) or comprehensive emergency obstetric care (CEmOC)

(118). These levels of care act as a proxy measure of the availability of the human resources, infrastructure, equipment, and supplies needed to provide specific services. This delineation allows Ministries of Health and technical partners to manage and monitor emergency obstetric care services in LMICs through "signal functions", a core list of life-saving services that have been used to assess the provision of emergency obstetric care at either a basic or comprehensive levels (118, 188, 273). Currently, there are seven signal functions assessed for BEmOC and two additional CEmOC signal functions; they mostly address the obstetric complications that lead to maternal death and disability, including post-partum haemorrhage, infections and hypertensive disorders (118).

Throughout this article, we will refer to the "Emergency Obstetric Care (EmOC) signal functions" in recognition of the fact that these were primarily designed from an obstetric perspective and do not represent the full spectrum of interventions required for emergency newborn care. More recently, the newborn has been more intentionally included and the term Emergency Obstetric and Newborn Care (EmONC) has emerged, a change that has been welcomed by maternal and newborn health experts, policy makers and programme implementers. We will use the term EmONC whenever we are referring to programmes, policies or indicators that were designed with a view to include both obstetric and newborn care and/or when we refer to the health facility assessments (EmONC assessments) that have been carried out with a view to looking at both maternal and newborn health services.

For small and sick newborn care in LMICs, one newborn-specific signal function, newborn resuscitation with bag and mask, was added to the core list of BEmOC signal functions nearly a decade ago (118). However, despite the addition of a resuscitation indicator, the signal functions do not accurately represent the full package of interventions needed by the mother-baby dyad, most notably care for small and sick newborns (15, 188, 266). This gap was highlighted by Gabrysch and colleagues in 2012, who proposed a new set of signal functions for routine and emergency maternal and newborn care following a systematic review of newborn survival literature and a consultation with 39 experts (188). Gabrysch and colleagues proposed additional signal functions for routine and emergency care for mothers and newborns, however, this work has yet to lead to the formal definition and adoption of levels of care and accompanying newborn signal functions. Furthermore, this work did not focus intentionally on the levels of care needed for those babies born small and sick.

Since 2012, there has been a significant increase in epidemiological data for newborns (21), including better estimates of mortality, morbidity and outcomes beyond survival (9, 27, 274). The global *Every Newborn* Action Plan, launched in 2015, called for increased focus on the programmatic and monitoring needs of newborns in order to end preventable maternal, newborn death, disability and stillbirth (6, 13, 15). *Every Newborn* highlighted the need to improve the quality care for small and sick newborns and develop accompanying monitoring systems (15, 21). During the past years increasingly efforts are being made by the global health community to tackle the specific health problems of small and sick newborn babies though investment in quality neonatal care. This article builds on this platform and the previous work to develop levels of care and associated signal functions (188) for small and sick newborns, in particular. The specific aim of this article is to describe the findings of an online global survey undertaken to categorise a list of newborn interventions, potential newborn signal functions, to different levels of care.

7.4 Methods

7.4.1 Study design and population

We designed an online survey to collect opinions from individuals working in maternal and newborn health, including clinicians with neonatal and obstetric and experience (midwives, nurses and doctors), researchers and programme managers or governmental officials (e.g. Ministry of Health). Whilst LMIC health services for small and sick newborns was the focus, the survey was not limited to respondents based in LMICs.

7.4.2 Questionnaire

We developed an online questionnaire to collect respondent characteristics (profession, current country/region of practice/employment, experience (geography, length, private/public) and type of experience (e.g. clinician, research etc.).

We generated a list of 18 newborn services or interventions based on WHO guidelines, previous work on the subject (188) and specific work carried out as part of the *Every Newborn* process (4, 8, 16, 29, 189, 193), including an expert focus group at an *Every Newborn* workshop where participants discussed interventions for small and sick newborns and voted on a shortlist (246). Interventions for the shortlist were prioritised based on potential contributions to mortality reduction and LMIC health system feasibility (4, 29).

In the questionnaire, we asked respondents to assign the 18 interventions to one of 3 levels of care appropriate for health systems in LMICs to provide: “routine care at birth”, “special care”, “intensive care” as well as a classification category for services that would not be appropriate as a signal function. Routine care at birth was included based on the rationale that all newborns (including those born small and sick) will require these interventions before they are admitted to inpatient care. To avoid biasing respondents, the questionnaire generated the list of interventions/services in random order for each respondent.

The levels of care were described in the questionnaire as follows:

- Routine care at birth: This should be available at all facilities and for all babies including those that need inpatient care because they are small and sick newborns.
- Special care: this service is part of inpatient care for small and sick newborns. In many settings, this is referred to as special care or level 2 care (268). These inpatient care signal functions are interventions for small and sick newborn that should be provided in addition to routine care at birth.
- Intensive care: This service is part of inpatient care for very small and sick newborns. In most settings this will only be available at the highest level of hospital. In many settings, this level is referred to as neonatal intensive care (NICU), or level 3 care (268). These services are for very small and sick newborns in addition to all the services provided at the special care level.

We piloted the questionnaire for face validity among a group of four experienced public health colleagues (not part of the study team) who pre-tested and provided feedback on the question flow and wording. We then refined the wording of questionnaire based on this pilot. We translated the final version into French and Spanish, using native speakers with clinical or programmatic experience in maternal and newborn health. The final version of the questionnaire is available at http://doi.org/10.17037/DATA.00000902.

7.4.3 Recruitment

The survey was accessible online for 12 months from November 2016-November 2017 in English, Spanish and French via the online platform Survey Monkey (www.surveymonkey.co.uk). Respondents could only complete the survey after giving informed consent. Respondents were given the option to exit the survey at any point. This study was granted ethical approval by the Research Ethics Committee of the London School of Hygiene &Tropical Medicine (reference number 11922).

Given that no sampling frame for this population exists, it was not possible to achieve a probability sample. Therefore, we employed a multi-faceted approach to recruit participants with diverse experience in maternal newborn health from a variety of settings, especially LMICs. We made the survey available on a wide range of professional networks, including Healthy Newborn Network https://www.healthynewbornnetwork.org/ and CHIFA http://www.hifa.org/forums/chifa-child-health-and-rights to reach both professionals working in international organisations and health professionals working on the ground. These platforms were used with the aim of recruiting a wide range of both clinicians (including nurses, midwives, doctors and allied professionals) and programme professionals with a breadth of experience. We encouraged snowball sampling by suggesting that respondents share the survey widely amongst colleagues. In addition, we promoted the survey at international conferences on newborn health: http://inkmc.net/index.php/11th-workshop-and-congress and midwifery https://www.internationalmidwives.org/events/triennial-congress/toronto-2017/.

7.4.4 Statistical analyses

We calculated descriptive statistics for the respondents, including background characteristics and respondent experience. We categorised respondent experience by age group (18-34, 35-54, 55-74, 75 years or older), experience in LMIC and/or high income countries (HICs), clinical and non-clinical experience, regional base (using World Bank regions https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups) and experience in the public and the private sector.

For each signal function:

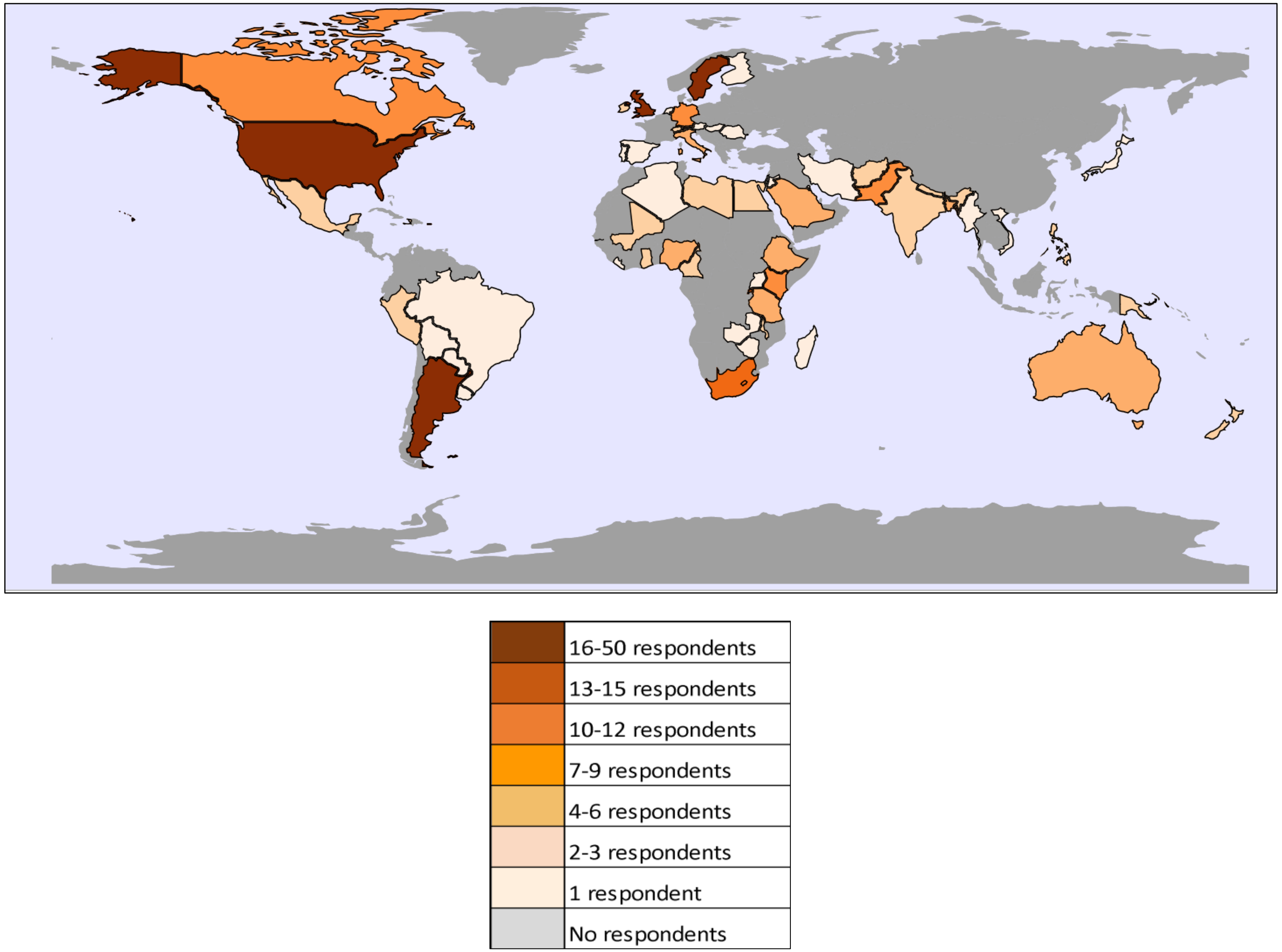
- We calculated the percentage of respondents that classified each intervention at each level of care
- We stratified responses by respondent characteristics and looked at variation for each signal function and respondent group using chi-squared tests to identify significant differences between respondent groups and selected level of care.

7.5 Results

7.5.1 Respondent characteristics

A total of 372 individuals accessed the survey, of which 110 (29.6%) were excluded as they did not answer any questions relating to interventions and levels of care. The final sample included 262 respondents from 61 countries and 7 regions of the world (Figure 7.1). Data summary tables are available at http://doi.org/10.17037/DATA.00000902

Figure 7.1 Frequency of responses to global survey on levels of inpatient care by country

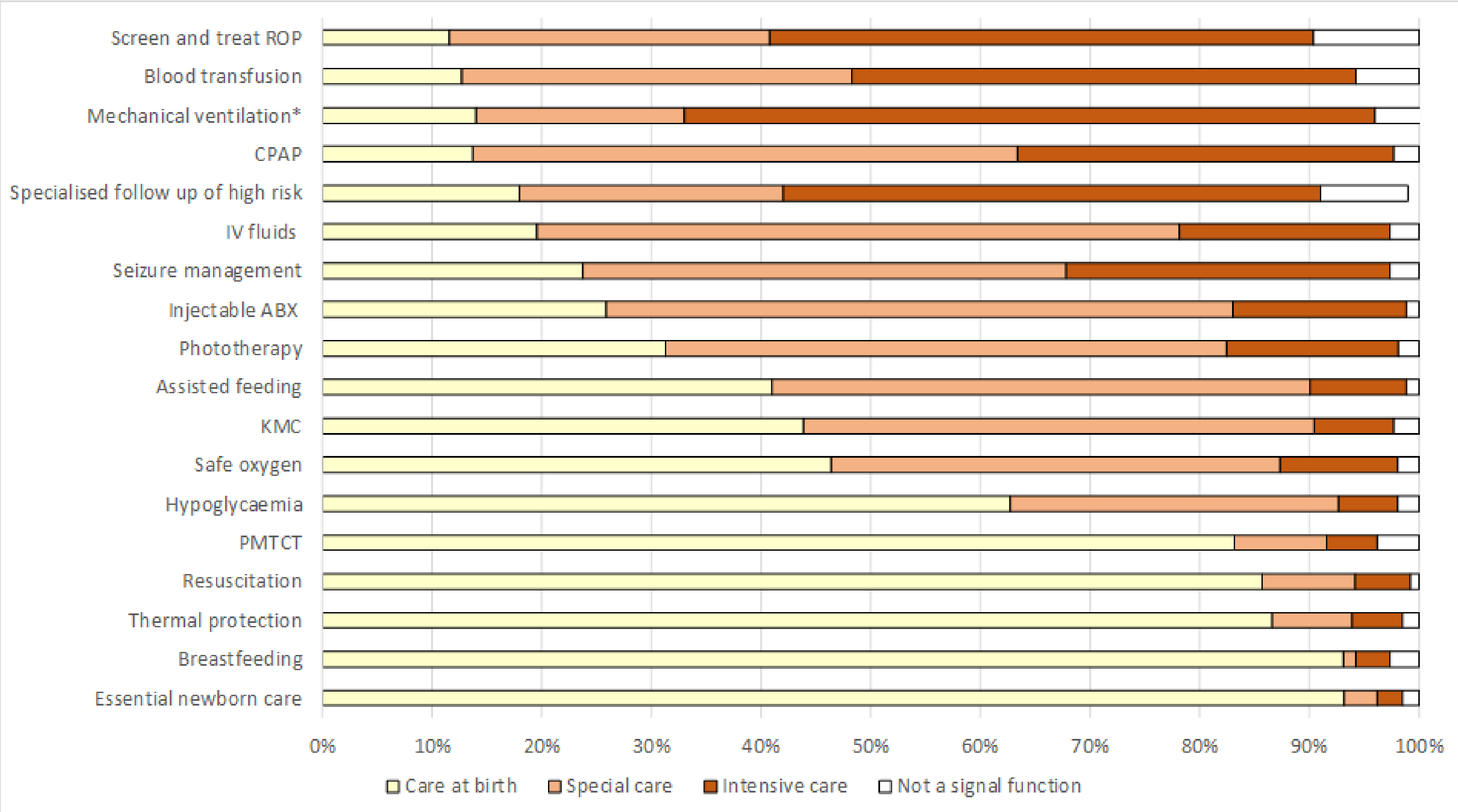


Respondent experience of working in maternal and newborn health ranged from 1-49 years with a median of 19 years. The largest percentage of respondents was based in Europe and Central Asia (31%) and the smallest percentage of respondents was based in the Middle East and North Africa (5%); thereon 14% based in North America, 11% based in Latin America & Caribbean, 8% were based in South Asia, and 7% East Asia & Pacific. Over half of respondents (52%) had previous experience working in both HICs and LMICs, 13% of respondents had experience from only a high-income country and 35% only LMIC experience. The majority of respondents were trained clinicians (75%). Of these the majority were doctors (71%) followed by nurses (25%), midwives (2%) and allied health professionals (2%). Almost all clinicians had experience working in the public sector; 65% with public sector experience only, 30% with a mix of private and public-sector experience and 6% with only private sector experience.

7.5.2 Levels of care

For the list of interventions selected as potential signal functions and the percentage of respondents that categorised these at each level of care see Figure 7.2.

Figure 7.2 Bar graph showing list of interventions and percent of respondents for each level of care (n=262)



PMTCT=Prevention of mother to child transmission of HIV, KMC=Kangaroo mother care, ABX=antibiotics, IV=intravenous, CPAP=Continuous positive airway pressure, ROP=retinopathy of prematurity*Only intervention classified by >50% of respondents as "intensive care".

In the following sections, we present the results by levels of care; a service was described under a specific level of care when it was selected at that level by >50% of respondents. This threshold was defined as an iterative process, based on exploration of the data.

7.5.2.1 Routine care at birth

Six services were selected by >50% of respondents as "routine care at birth". Prevention of mother to child transmission of HIV (PMTCT) (83%), basic neonatal resuscitation (86%), thermal protection (87%), immediate and exclusive breastfeeding (93%), and essential newborn care (93%) were all classified by over 80% of respondents as routine care at birth. Prevention and treatment of hypoglycaemia was selected by over 60% of respondents at this level.

Other than for prevention and treatment of hypoglycaemia, we found no significant variation by respondent characteristics of the six interventions that were classified as routine care at birth. Classification of hypoglycaemia by clinicians and non-clinicians did vary significantly: 70% of clinicians classified this as care at birth compared with only 44% of non-clinicians ($p<0.01$). Neonatal resuscitation, the only intervention in the list that is an existing EmOC signal function, was the option with the lowest number of responses identifying it as "not a potential signal function" (1%) .

7.5.2.2 Special care

Three services were selected by >50% of respondents as "special care": Intravenous (IV) fluids (59%), injectable antibiotics (57%) and phototherapy (51%). Respondents with only experience in LMICs, were significantly more likely to classify IV fluids at a higher level of care compared with those with experience in a high-income setting ($p<0.05$). For injectable antibiotics, respondents based in high burden settings, such as South Asia, were more likely to classify this option at higher levels of care whereas Latin American respondents were more likely to classify it at a lower level ($p<0.05$). For phototherapy, there was some variation between non-clinician and clinician respondents. Non-clinicians were more likely to classify phototherapy at either "special care" or "intensive care" than clinicians; 28% of non-clinicians categorised this as "intensive care" compared with only 12% of clinicians ($p<0.05$). A larger percentage of respondents with experience in the private sector classified phototherapy as "routine care at birth" (63%) than respondents with public (35%) or those with mixed public-private experience (27%) ($p<0.05$).

7.5.2.3 Intensive care

Mechanical ventilation was the only intervention classified by >50% of respondents as a service for "intensive care". Respondents with experience in LMICs were more likely to classify mechanical ventilation as "intensive care" than respondents who had not worked in LMICs (66% vs. 41% respectively) ($p<0.05$).

7.5.2.4 Interventions/services without clear categorisation (borderline)

Borderline "routine care at birth"/"special care" refers to interventions not meeting the >50% threshold for any level of care but categorised by close to 50% of respondents as "routine care at birth" or "special care". Three interventions were classified as borderline "routine care at birth"/"special care": safe oxygen therapy (46%/41%), KMC (44%/47%) and assisted feeding (41%/49%), respectively.

For oxygen and assisted feeding, experience of working in LMICs, regional and experience working in the public and private sector were significantly associated with variation. Those with LMIC experience or from higher burden settings were more likely to classify these interventions at higher levels of care.

For KMC, there was no significant variation between levels of care and respondent characteristics.

Borderline "special care"/"intensive care" refers to interventions not meeting the >50% threshold for any level of care but categorised by close to 50% of respondents as "special care" or "intensive care".

Five interventions were classified as borderline "special care"/"intensive care": specialised follow up of high risk (41%/49%), continuous positive airway pressure (CPAP) (50%/34%), seizure management (44%/30%),blood transfusion (36%/46%) and retinopathy of prematurity (ROP) (29%/50%).

For management of seizures, blood transfusion and CPAP, clinicians were significantly more likely to classify these interventions as special care while non-clinicians were more likely to classify them as intensive care ($p<0.05$).

For blood transfusion, CPAP and screening and treatment of ROP, experience in a LMIC was significantly associated with variation in the selected levels of care. Those with experience in LMICs were significantly more likely to classify these interventions as "intensive care" and while those with only experience in a high-income country more likely to classify them as "special care" ($p<0.05$). For example, 71% of respondents with only HIC experience classified CPAP as "special care" compared to only 33% of respondents with only LMIC experience; respondents with only LMIC experience were significantly more likely to classify it as "intensive care" (49%) (p=<0.05). For ROP, 16% of those who had only worked in LMICs responded that ROP was not a signal function compared to no respondents with only HIC experience and 7% of respondents with experience in both LMICs and HICs ($p<0.05$). For specialised follow up of high risk, there was no significant variation in respondent characteristics between levels of care selected.

7.6 Discussion

This article presents results from a global survey of 262 respondents from 61 countries to classify 18 newborn care interventions, into 3 levels of care. Applying the >50% threshold to 18 potential signal functions, 10 of these clearly aligned to specific levels of care: six for "routine care at birth", three for "special care" and one for "intensive care". The remaining eight signal functions did not meet the >50% threshold for a specific level of care. Previous work has encouraged the development of routine and emergency newborn signal functions (188), but levels of newborn care have not yet been well-defined for LMICs, particularly for small and sick newborns. This work contributes new insights into levels of neonatal care in LMICs as a step towards formally defined newborn care levels that could be aligned with EmOC.

7.6.1 Interpretation of categorisation of levels of inpatient care for small and sick newborns from global survey

7.6.1.1. Consistency with existing guidelines

Out of the interventions that were clearly classified as "routine care at birth" by more than 80% of respondents, four have existing WHO guidelines (PMTCT (83%) (275), neonatal resuscitation (86%) (144), immediate and exclusive breastfeeding (93%) (276), and essential newborn care (93%) (277)). These interventions also had little variation among respondents. For more complex interventions that do not have specific WHO guidelines, level of care classification was less clear and there was greater respondent variation. This may be related to individual respondents applying existing classification systems within countries where they had worked. For example, in many settings the capacity to provide neonatal mechanical ventilation is the defining feature of an intensive care unit (278), as it requires more complex health system capacity (17). The wording of the intervention as injectable antibiotics may have led to ambiguity with respondents by differentiating intravenous from intramuscular antibiotics. Some respondents may have perceived that intravenous infusions of antibiotics for treatment of infection may require special care capacity in contrast to intramuscular antibiotics that WHO recommends as feasible at low levels of the health system (57).

7.6.1.2 Low- and middle-income experience

Overall, experience in LMIC was most frequently associated with variation in response as was the case with oxygen, assisted feeding, blood transfusion, continuous positive airway pressure (CPAP) and screening and treatment for ROP. There was a clear pattern for respondents with experience in lower income settings or those based in LMIC to classify interventions more cautiously (not classifying them as interventions for lower levels of care). That respondents with LMIC experience were more comfortable assigning a higher level of care for certain interventions may reflect the respondents' perceptions of feasibility of introducing or scaling up interventions such as CPAP (279-281). It may also be indicative of a lack of experience delivering those interventions and/or the challenges of scaling up inpatient care in these settings. Experience in the private sector may have driven a more optimistic perception about interventions that could be provided at lower levels of care, as was the case with phototherapy, despite the increase in availability of low-cost phototherapy devices that can safely be used in LMIC (16, 68).

7.6.1.3 Clinical experience and knowledge of interventions

For more complex interventions, non-clinicians may not have been familiar with nomenclature or have had less knowledge of the clinical significance or the potential feasibility of these interventions. This may explain some of the variation in responses for hypoglycaemia, treatment of seizures and phototherapy. For example. clinicians may be more likely than non-clinicians to recognise the significance of seizures in the neonatal period and the frequency of intrapartum injury in LMIC settings. The majority of respondents were clinicians that had worked in a LMIC (197/262); very few non-clinicians who had worked only in HICs (2/262) responded to the survey. However, arguably programmatic or clinical experience in LMICs was a motivating factor to respond to the survey, which related directly to LMIC health programmes and was advertised through forums relevant to these professional groups.

7.6.1.4 Transitional interventions

There is marked variation health system requirements between different levels of care. For example, facilities may be able to provide high quality routine care at birth, but lack the infrastructure, equipment and human resources to provide special care. Perceptions of the potential harm that can be caused by certain interventions if not provided in a safe, enabling environment may have influenced respondents. The perception is justified by epidemiological data showing long term consequences of poor-quality neonatal care, a pattern that has been seen in countries where there has been rapid scale up without sufficient attention to safety and monitoring systems (27, 95). For example, countries in Asia and Latin America are seeing an epidemic of childhood blindness caused by unregulated use of oxygen in neonatal units, as well as poor screening and follow up services for survivors of neonatal care (97).

One interpretation of the results of this survey for potential signal functions that lacked clear classification may be to consider them as “transitional”. This would refer to interventions or services that bridge the nexus between two defined levels of care. This approach allows facilities that are developing inpatient care capacity at either the special care or intensive care level to go through a transitional phase whereby interventions are added in a stepwise manner before moving up to the next level of care. Facilities offering newborn care would need to offer all service category requirements at lower levels of the hierarchy before adding transitional interventions linked to higher levels (282). For example, facilities offering routine care at birth may begin a transitional phase to building special care capacity by adding interventions such as oxygen and assisted feeding (starting with cup feeding of expressed breastmilk) in addition to or as part of stabilisation and referral. The progressive or stepwise introduction of such interventions will also be influenced by context; hospitals with larger catchment areas may need to cover a wider range of services than smaller ones. To move to the next level, all transitional interventions would need to be available and provided to a minimum standard (17).

In practice the introduction of transitional interventions would require policy and implementation discussions and further operational research, as settings differ widely (91). Much of the existing evidence and guidance on neonatal care pertains from high income countries (267, 268, 270, 272, 282), with the majority of implementation studies from LMICs being hospital level only with few from a health systems perspective (283). Further research is needed to document and develop quality evidence from LMICs on the organisation of neonatal care.

7.6.2 Next steps: Aligning levels of inpatient newborn care with routine and emergency obstetric care measurement

Agreed levels of care are urgently needed for newborns, but further work is needed to align these with existing EmOC levels and determine an appropriate integrated and dynamic approach for monitoring. Figure 7.3 shows how the results of the survey could potentially align with the existing emergency obstetric care signal functions and levels of care. Critically, this figure places the mother and newborn together at the centre of the care.

Figure 7.3 Interventions and levels of inpatient care for small and sick newborns aligned with Emergency Obstetric Care (EmOC) signal functions and levels of care

Comprehensive emergency obstetric care (CEmOC)
- Perform blood transfusion
- Perform surgery (e.g. caesarean section)

Basic emergency obstetric care (BEmOC)
- Administer parenteral antibiotics
- Administer uterotonic drugs (e.g. oxytocin)
- Administer parenteral anticonvulsants (e.g. magnesium sulphate)
- Manually remove the placenta
- Remove retained products (e.g. manual vacuum extraction, dilation and curettage)
- Perform assisted vaginal delivery

Routine and essential care at birth

Intensive newborn care
- Mechanical ventilation

Transitional interventions to intensive care
- Screening and treatment of retinopathy of prematurity
- CPAP
- Specialised follow up of high risk
- Seizure management
- Blood and exchange transfusion

Special newborn care
- Phototherapy
- IV fluids
- Injectable antibiotics

Transitional interventions to special care
- Safe oxygen therapy
- Kangaroo mother care
- Assisted feeding
- (IM antibiotics as per WHO guideline)

Basic emergency newborn care
- Neonatal resuscitation
- PMTCT

Routine and essential newborn care
- Essential newborn care, thermal care
- Breastfeeding

Green=existing signal function
Grey=transitional interventions
PMTCT=Prevention of mother to child transmission of HIV, IV=intravenous, IM=intramuscular, CPAP=continuous positive airway pressure.

Interventions in green are those which are existing signal functions. Starting from the bottom of the figure, routine and preventive care interventions reduce the need for emergency and inpatient care by preventing complications and there is a strong argument for their inclusion in the list of signal functions. The special care level may align with existing comprehensive signal functions as these are interventions that are only likely to be feasible to provide at a first level referral facility or regional hospital that has the capacity to have a dedicated newborn inpatient care ward and staff. A higher level, intensive care will likely only be available at a very small number of CEmOC facilities (e.g. central hospitals). Intensive care would less likely to be part of the existing EmOC framework that does not currently cover an intensive level of care for women with severe obstetric complications. These findings are also consistent with previous work that promotes the inclusion of routine and preventive care signal functions for EmOC monitoring (188). However, one might argue that by including preventive, routine care and inpatient care measures, the framework ceases to be an "emergency framework" and becomes a framework for interventions for intrapartum and postnatal care.

Further discussion and consensus to formulate measurable newborn signal functions from this list of interventions will be needed. As currently presented, the list of interventions are potential signal functions not yet validated by being shown to link to improved outcomes, although each of these interventions does have evidence of impact (4, 16). As part of further formative research, piloting and testing the measurement of a selection of these interventions in existing LMIC inpatient care facilities would be important. Qualitative work may be needed to look at the use of a selection of signal functions at the country and facility level in different settings. In addition, these would need to be used alongside complementary indicators that could be used for newborn care that reflect access, utilization and quality dimensions, aligned with the WHO quality of care framework (11). The availability and density of facilities capable of providing both routine, emergency obstetric and small and sick newborn care as well as the proportion of population at a defined travel time from such facilities are useful health system tools for planning and monitoring the supply-side towards ensuring sufficient services for both maternal and newborn care. Such guidance has been lacking for small and sick newborn care, which faces major gaps in availability of and access to facilities.

This work is timely, as a revision of the EmONC monitoring handbook and associated indicators is planned. Such a revision is intended to build on lessons learned from implementation and better reflect the needs of the mother-baby dyad, including routine maternal and newborn care and inpatient care for small and sick newborns. This work contributes part of the formative work for this wider revision.

7.6.3 Limitations

Since health system contexts in LMICs differ, we used an online approach to collect a wide range of opinions from different settings and professional backgrounds. However, a number of limitations of this approach must be noted. Firstly, our sample was not fully representative of all regions. Whilst the sample was geographically diverse, selection bias is a limitation and opinions of those who could not or did not access the survey due to limited internet connection, language or access issues is unknown. For example, few middle-income countries in sub-Saharan Africa were represented in the sample. The findings may also be biased by the larger frequency of respondents from Europe and the Americas, although the majority of respondents reported experience in LMIC settings even if currently based in higher-income settings. Secondly, survey fatigue may have occurred, although the list of interventions appeared in random order to avoid biasing results through respondent attrition. Survey fatigue may partially explain the number of individuals that accessed the survey but did not complete any information on newborn interventions. There may also have been a number that accessed it and realised they did not have the background knowledge to be able to answer the questions on the interventions. Several factors may have influenced the classification of inpatient care interventions, including knowledge of the intervention, perception of the importance of the intervention (e.g. its potential impact on mortality and morbidity) and perceived feasibility. This may have resulted in a conflict between perceived feasibility (can do) and perceived need (should do) and respondents may have been strongly influenced by their own personal clinical or contextual programmatic experiences. Finally, for ease of interpretation, a threshold of >50% was used to classify interventions into different levels. This was pragmatic, but entirely arbitrary threshold and the findings would be slightly different if other thresholds were applied.

This work was focused on inpatient care for small and sick newborns that occurs in the postnatal period. It does not discuss community interventions or interventions that benefit newborns but are delivered in the antenatal period. The use of antenatal corticosteroids for mothers with threatened preterm labour (139) and antibiotics for preterm premature rupture of membranes (P-PROM) (284) are two interventions for small and sick newborns that have an evidence base, but that do not naturally fit into the inpatient newborn care package due to the timing in the peripartum period.

7.7 Conclusions

This article has shown how practitioners categorised 18 newborn interventions that could act as potential signal functions to different levels of care, including routine care at birth and inpatient care for small and sick newborns. Findings were consistent with existing clinical guidelines and previous work on the subject, but also provided new insights on how newborn care programmes, including more complex interventions for small and sick newborns, could be organised and monitored. Future research should focus on refining the list to a small selection of measurable signal functions and testing of these potential signal functions in existing inpatient care units. Further work is needed to align these newborn signal functions to the existing obstetric care levels to create a dynamic and integrated framework for maternal and newborn care. Working towards universal health coverage, future adaptations, including improvements to indicators of service availability, access and quality, should reflect the needs of health programmes for both mothers and their newborns.

Chapter 8. Application of overall findings to measurement of service readiness for small and sick newborns

The overall aim of this PhD has been to contribute a body of work that will help to guide and improve the measurement of service readiness for inpatient care for small and sick newborns – a package along the continuum of care that has been neglected to date in LMIC. Measuring service readiness, requires an understanding of the needs of health systems delivering inpatient care for small and sick newborns. For the first theme, using the lens of both health system building blocks and the Donabedian framework, I mapped the health system structures and identified the challenges to scaling up inpatient care for small and sick newborn in LMIC health systems. The second theme drew on the findings from the first theme to explore how measurement of service readiness for inpatient care of small and sick newborns can be integrated within existing metrics systems. The PhD, therefore, has been iterative; the first theme of this PhD serves to inform the second theme. In this discussion chapter, I first synthesise the findings by theme and outline the implications for measuring care of small and sick newborns in LMIC. Finally, I return to the quality of care framework to contextualise my findings within the SDG era and make recommendations for policy, programmes, and future research.

8.1 Synthesis of overall findings by theme

In the introduction and background, I described how the first 28 days of life, the newborn period, represents the time of highest risk in the human lifecycle. In 2016, an estimated 2.5 million newborns died, mainly of complications of prematurity (35%), infections (23%), and intrapartum complications leading to birth injury (24%) (2). Many newborns facing life-threatening conditions also go on to develop long-disabilities or poorer health outcomes. Preventing newborn mortality and morbidity requires a health systems approach along the continuum of care (4, 21). Health systems need to be able to deliver routine newborn care for all babies (cleanliness, thermal care and support for breastfeeding), with additional care for babies according to need (newborn resuscitation and PMTCT), and timely provision of quality inpatient care for babies born small and sick (23).

The introduction and background section conclude that high quality coverage at scale of inpatient care for small and sick newborns could have some of the highest potential impact on newborns deaths of all the packages of care along the care continuum for mothers and newborns. For example, a recent analysis using the lives saved tool estimated that inpatient care of small and sick newborns could avert over half a million (580,000) newborn deaths per year by 2025, which does not include the potential impact on long-term well-being and disability (4). This is especially relevant to LMIC, where the burden of death and disability is the greatest. Despite this, the package of inpatient care for small and sick newborns has been poorly defined in LMIC settings compared to other packages of care along the care continuum. Policy analysis has shown a lack of investment and targeted efforts for wider scale-up (25). There are also known deficiencies in the quality of care for small and sick newborns (16). However, these quality issues are difficult to address without data on the structures and processes of care that these vulnerable babies receive (15). Given the pivotal role of quality newborn care in affecting long term newborn outcomes, this PhD viewed defining the structures and health system challenges as a critical starting point to understanding how measurement of inpatient care can effectively be improved. This could help to identify service delivery gaps and support wider scale up of quality inpatient care for small and sick newborns.

8.1.1. Theme A: Delivering quality inpatient care services for small and sick newborns

Theme A has two distinct objectives (Table 1.1). Firstly, to describe the health system challenges to delivering quality inpatient care. Secondly, to delineate and map the structural components required to deliver small and sick newborn care.

8.1.1.1 Health system challenges to scaling up inpatient care for small and sick newborns

In chapter 4, I analysed bottleneck data collected using a structured tool to explore challenges to scaling up inpatient care for small and sick newborns in 12 high-burden settings challenges across the health system. The analysis explored and summarised quantitative and qualitative data from national stakeholder workshops on perceived challenges to scaling up inpatient care based on 3 tracer items (nasogastric feeding, IV fluids and oxygen). Looking at these elements of inpatient care through the lens of health system building blocks, findings showed that for these countries, inpatient care was an intervention package which faces major challenges. Based on the area of health system with the highest graded bottlenecks, stakeholders perceived health financing and the health workforce to be the most significant challenges (Figure 4.5).

8.1.1.1.1 Health financing

Data in chapter 4 showed how more than three quarters (10 out of 12) countries graded health financing as a major or significant bottleneck to scaling up inpatient care for small and sick newborns (Figure 4.5). Country stakeholder team specifically highlighted lack of earmarked funds in national RMNCH plans for inpatient newborn care. Thematic analysis of the qualitative data collected in these workshops shows links between the financing issues, bottlenecks in essential medical products and service delivery, with the perception that the lack of specific funds often resulted in general lack of infrastructure (not enough buildings or dedicated spaces for inpatient care) and poorly maintained supplies due to inaccurate forecasting, procurement and distribution (e.g. issues with supply chain management and maintenance of supplies).

In chapter 4, data also showed the lack of insurance policies for small and sick newborn care, often resulting in user-fees imposed on families of small and sick newborns (e.g. to purchase drugs and pay out of pocket for clinical services). Combined, the health financing bottlenecks, suggest that health financing barriers affected access to small and sick newborn care in two ways: precluding the availability of care (physical presence of well-equipped facilities) and affordability (the ability of service users to pay) (76). For services to have effective coverage, they need to be both ready and available to the users (in the case of sick newborns – their families) and for which high burden countries perceive this to be a major challenge. Standardised clinical and service provision guidelines, as well as mechanisms for tracking and accountability were missing for governments and programme planners to be able to identify and priority service gaps for targeting of scarce resources.

8.1.1.1.2 Health workforce

As shown in chapter 2 and 4, providing inpatient care for small and sick newborns requires continuous services, 24 hours a day, 7 days a week, from a multidisciplinary team of trained healthcare providers (especially doctors and nurses) with specialised skills in caring for small and sick newborns. The analysis of bottleneck data showed that health workforce was graded as a significant system gap in providing quality inpatient care of small and sick newborns; 10 out of 12 countries identified the health workforce as a major or significant bottleneck to the scaling up of inpatient care. Within this bottleneck, the two main thematic areas that were identified by country teams, were safe-staffing levels (sufficient numbers of staff) and competency-based and/or specialised training with appropriate supervision. According to the Donabedian's quality of care framework, discussed in the background and chapter 5, both structure and process are needed to improve overall outcomes. Sufficient numbers of staff (structure) and training and supervision (elements of process) were both described as bottlenecks to quality of care. For the former, the staff to patient (number of nurses to small and sick newborn inpatient) are not yet defined nor benchmarked to guide scale up of the package of care (285). The UK recommends nurse-to-patient ratios of 1:1 in neonatal intensive care, and between 1:2 - 1:4 in special care (204, 272, 278); ratios which are almost certainly not feasible in LIC settings. In existing guidelines from India, ratios vary from 1:3 -1:4, which is used as a basis for administrative and resource planning to improve care of small and sick newborns. However, it is common for reported staff ratios to be 1:20 or higher in some LMIC facilities (104) yet, there is no consensus nor WHO recommendation on what these ratios should be in LMIC. A number of challenges identified related to recruitment, retention and staff organisation often leading to low morale and lack of opportunities for career progression.

8.1.1.1.3 Community ownership and partnership

Data from my analysis in chapter 4 also showed that community ownership and partnership presented significant challenges for inpatient care of small and sick newborns with 9 of 11 countries (missing data for one country) grading this health system building block as major or significant. A cycle of lack of community awareness and care seeking paired with lack of knowledge of rights to access care were described by stakeholders. These issues may be compounded by negative experiences in the facility (including lack of attention to the needs of families during the inpatient care process) and experiences of poor quality of care. This links to previous literature that has identified a culture of fatalism (assumption that all small and sick newborns will die) as a barrier to care seeking and demand for quality services (23, 229).

8.1.1.2 Health system structures for delivering inpatient care for small and sick newborns

8.1.1.2.1 The interventions

Figure 2.1 situates inpatient care of small and sick newborns within the continuum of care for maternal and newborn health. In order to define structural requirements, it is necessary to define the inpatient care package (what interventions it entails and what it does not). This PhD drew on several processes to identify which interventions comprise the inpatient care package.

For chapter 4, the analysis of bottlenecks was based on 3 tracer items: feeding support (intragastric feeding), intravenous fluids and safe oxygen. These tracer items were selected at the time that the bottleneck tool was designed (a priori to this PhD) to represent the common challenges to implementing the package, to stimulate and focus discussion, and to facilitate the identification of bottlenecks that hinder the scale up of quality inpatient care (29, 189). The tracer interventions are described in detail in chapter 4, Figure 4.3. The inpatient care package, however, is clearly broader than 3 tracer interventions. In chapter 4, the omission of phototherapy as a potential tracer was discussed (Figure 4.4).

To further explore the package of inpatient care for small and sick newborns in LMIC, I conducted an expert focus group (described in chapter 5) to help develop a shortlist of 18 evidence-based interventions. This was then extended to a global survey to categorise interventions to levels of inpatient care for small and sick newborns, which is described in chapter 7. Apart from chapter 4, remaining work in this thesis was based on these newborn interventions.

The challenge of identifying and justifying the selected interventions persisted throughout this PhD and involved a compromise between known, published evidence (covered in literature review in chapters 2 and 4 and expert discussion, including expert focus group and a global survey). From both the expert focus group (chapter 5) and the global survey (chapter 7), this PhD showed that consensus on the interventions comprising the package is not easy to obtain. There are context specific issues that relate both to health system capabilities (e.g. with surfactant, CPAP or blood transfusion) and culture of care (e.g. KMC). With respect to health system capabilities, the global survey (chapter 7) showed significant variation in how respondents classified interventions between those with experience in LMIC and those with only HIC. This finding reflects the known challenges to delivering care that were identified in chapter 4. Context specific culture issues also affect the perception of interventions in different settings, as can be seen with KMC, which another study of health system challenges found to have greater challenges in Asian than African countries (29). The delivery of inpatient care for small and sick newborns in LMIC needs to be viewed carefully from the perspective, culture and health system capabilities in LMIC rather than a “drag and drop” approach from HIC. Defining the inpatient care package, therefore, required prioritisation of core, high impact interventions that could feasibly be introduced in less developed health systems (282).

8.1.1.2.2 The structural components/health system inputs

In chapter 5, the grey literature review resulted in a matrix of 654 structural components, to deliver 18 interventions. Of these, 114 were medicine and drugs. As shown in chapter 6, 22 of these were not included in the essential medicines list. The matrix in chapter 5 provides a starting point to defining the structural components of inpatient care for small and sick newborns. However, it is limited by the 18 interventions that were selected and the lack of standard guidelines available for review for more complex newborn interventions.

In view of the identified health system challenges highlighted in chapter 4, the findings in chapter 5 were intended as a practical and feasible way to provide countries with a structured checklist from which to start planning inpatient care services. Such a checklist can be adapted and used for multiple purposes, including development of inventories for health facility surveys and tools, checklists for management of stock, as well as development of logistics and human resource management systems. Items on the matrix were reviewed by multiple clinicians from LMIC, including nurses, paediatricians, neonatologists, and obstetricians to ensure that the suggested inputs were practical for a broad range of LMIC health systems. For the laboratory service readiness requirements, I was only able to delineate the minimal requirements of the tests that the laboratory, such as biochemistry, haematology (including blood bank) and microbiology should be able to perform as well as what facilities should be able to perform for blood grouping, screening and storage. Laboratory readiness, closely related to antibiotic stewardship, has an especially important role in tackling the growing public health problems with antimicrobial resistance e.g. to ensure cultures are available for antibiotic prescribers (53, 286). Testing of the tool alongside implementation research to look at specific issues related to laboratory readiness will be important for future research in this area. As part of laboratory readiness, consideration of the health system needs for safe neonatal blood transfusion will also be needed. In chapter 5, I also summarised the basic structural needs for referral and transport. Given the critical role of referral systems (chapter 7) in supporting a regional system of care for maternal and newborn health, this is also an area that requires significant further research.

8.1.1.2.3 Levels of care

In chapter 4, I described how inpatient care has been traditional defined by 3 levels (Figure 4.1), broadly referred to as "routine care at birth", "special care" and "intensive care". According to stakeholders in the analysis in chapter 4, the organisation of inpatient newborn services was a major health system concern. There is a lack of quality evidence from LMIC on how to organise neonatal care and much of the existing evidence and guidance pertains from high income countries (267, 268, 270, 272, 282).

The argument for providing stratified levels of maternal and newborn services has a long history and is strongly influenced by the 1976 March of Dimes (https://www.marchofdimes.org/) report "*Towards improving the outcome of pregnancy*"(271). This report first described the concept of regionalised maternal-newborn care based on evidence of more favourable outcomes and cost effectiveness. Later on in 2004, Paul and colleagues (91) argued against regionalisation of care in LMIC, suggesting that such an organisation works for developed, well-funded health systems, but is less relevant for LMIC. A more recent systematic review published in 2011 aimed to assess whether the existing evidence from interventional studies provides robust evidence on the effectiveness of regionalisation for improving maternal and newborn outcomes. This review found limited evidence from well-designed studies (e.g. a lack of controlled trials or studies that applied interrupted time series analyses) and very little evidence from LMIC. Also, multiple confounding factors, including socioeconomic changes and developments in clinical medicine, are difficult to extrapolate from the observed association with improved outcomes in HIC. In LMIC, where equivalent progression may not have occurred, the review concluded that regionalisation of care as an approach is not fully supported by the current evidence base (270).

One of the arguments against regionalised neonatal care is based on mortality rates. Earlier work (2004), argued that settings with high neonatal mortality (NMR >15 per 1000 live births) can achieve substantial mortality reductions by focusing on community interventions, antenatal care and essential newborn care (91). At the time of this publication, focus on these areas of care could achieve substantial mortality reductions; partly because a larger number of births occurred at home where babies were not resuscitated and/or parents may not have sought care for those born small and sick. In the SDG era, quality antenatal care remains critical for the health and growth of the baby in-utero and for identifying high risk cases and maternal complications. Obstetric and routine care at birth are essential to reduce cases of neonatal encephalopathy and newborn infections. However, even with quality antenatal care and high quality obstetric and care at birth, a certain proportion of newborns will still require inpatient care (e.g. those born preterm or that develop infections or jaundice). As the place of birth has increasingly shifted from community to the hospital, inpatient care is required as part of the continuum of care to ensure those small and sick newborns in hospitals are able to access quality inpatient care should they require it. To reach the targets for the SDGs and *Every Newborn* Action Plan of ≤12 neonatal deaths per 1000 live births by 2030, inpatient care for small and sick newborns, is necessary to achieve the ambitious mortality reductions as part of universal healthcare (UHC). Subsequently, organisation of care needs to reflect this need through provision of a feasible, safe and affordable inpatient care package. Meanwhile, further research and robust evidence is needed on organisation of maternal and newborn care in LMIC.

Implementation of inpatient care need not be at the expense of routine and essential newborn care at birth. Core components of this care – provision of warmth, support for breastmilk feeding and prevention of infection – are core to small and sick newborn care due to the enhanced vulnerability to hypothermia, poor growth and infections (5, 16, 282). To reflect this, I included routine newborn care interventions throughout the work in this thesis. Similarly, introducing “intensive care” should not be at the cost of “special care” services. A study in Uganda that implemented lower levels of small and sick newborn care through a staged approach found that without quality implementation of routine and special care levels, adding more specialist, high technology care may be futile (282). However, their study showed that focused attention on the lower levels of care had a significant impact on neonatal deaths (282). While this study may not be widely generalisable, this is supported by estimates published in 2014 that provision of quality special care for small and sick newborns could avert 70% of newborn deaths without provision of intensive care (4).

An additional important finding relates to the private sector. My analysis of the global survey in chapter 7 found that there was significant variation between perceptions of service feasibility for different levels of care between those that had experience in the public and private sectors. Those with only experience in the private sector more likely to categorise complex interventions at lower levels of care. This may be explained by a level of “optimism” in the private sector due to greater access to resources and/or smaller caseloads. For example, findings from a study in Kenya showed that services in Nairobi were disproportionately distributed between public and private sector despite more private sector facilities offering neonatal inpatient care; four public facilities out of 33 facilities in total accounted for 71% of neonatal admissions (105). Ensuring service readiness and quality of care within the private sector within the context of a broader health system is an important challenge that has not been covered in detail in this PhD and has specific implications for measurement, tracking, and accountability mechanisms.

8.1.1.2.4 Transitional interventions

As shown in the background, chapters 4 and 7, there is marked variation in health system requirements between different levels of care. From findings in both chapters 5 and 7, I found that certain interventions represented a significant jump in health system service readiness requirements. Many district level facilities may be able to provide safe oxygen therapy to newborns (including monitoring with pulse oximetry), but not be able to provide CPAP or mechanical ventilation due to lack of trained staff, equipment and infrastructure.

In chapter 7, I discussed “transitional interventions”, as a potential strategy for organising delivery of inpatient care across different levels. The transition refers to interventions or services that bridge the nexus between two defined levels of care. This approach allows facilities that are developing inpatient care capacity at either the special care or intensive care level to go through a transitional phase whereby interventions are added in a stepwise manner before moving up to the next level of care. As levels are defined by the services they provide, it was decided that services allocated to each category must represent a realistic minimum and transitional interventions represent those that can be added to this minimum before graduating to the next level. Thus, newborn units should meet all service category requirements at lower levels of the hierarchy before adding transitional interventions linked to higher levels (282). For example, facilities offering routine care at birth may begin a transitional phase to building special care capacity by starting KMC, intragastric feeding and oxygen before adding intravenous fluids and phototherapy treatment.

Such systems have been developed in LMIC settings; for example, India has newborn stabilisation units that focus on management and stabilisation of sick newborns prior to referral to special newborn care unit at the sub-district and district level (256). The concept of transitional interventions, therefore, whilst still providing overall guidance on the capabilities and service readiness requirements for a special care unit and an intensive care unit should allow individual countries to develop more granular categories and context-specific recommendations.

8.1.2 Theme B: How can measurement of small and sick newborn service readiness be integrated within existing and evolving maternal and newborn measurement systems?

Theme A focused on the structures required and the challenges to delivering inpatient care for small and sick newborns within health systems. Theme B described in this section of the chapter builds on theme A to explore how measurement of small and sick newborn service readiness can be integrated into measurement systems.

As described in the background section, planning, resource allocation and day-to-day management for care of small and sick newborns requires timely information from routine health information systems in order to track the delivery of quality health care services and related support systems that include equipment, and supplies, infrastructure and human resources (100). For inpatient care, information is needed to help ensure commodities are available (service readiness) to enable quality service delivery to small and sick newborns.

8.1.2.1 Health facility assessments

Whilst health facility assessments are only a small part of broader routine health information, I have focused a significant part of the work in this PhD on health facility assessment tools. This is justified by the fact that service readiness information specific to small and sick newborns found in routine health information systems is still limited. As covered in chapters 3, 5 and 6, health facility assessment surveys may be one of the only sources of national level information on facility readiness to provide small and sick newborn care.

In chapter 6, as one approach to measurement of small and sick newborn care within existing maternal and newborn measurement, I reviewed three multi-country health facility assessment tools that cover areas of MNH services, the SPA, the SARA and the EmONC assessment tools. The review showed that there are commonalities between the tools, but the histories of these tools are different, and they serve distinct purposes and have different approaches to measurements. Overall, my review showed that the existing health facility assessments do not always generate comparable data and have very limited assessment of more complex care for small and sick newborns. Training and skills of providers are especially variable (Table 6.5). Indicators in existing tools can be harmonised, but the size and cost of these assessments limits their frequency.

Findings from chapter 6 are consistent with a literature review that carried out a comparative analysis of different tools that are currently used to assess the service delivery capability of different health facility assessment tools used in LMIC (103). The review found methodological inconsistencies between health facility assessment tools and showed that health facility assessment tools were often designed with an emphasis on vertical, disease oriented programmes, which limited their ability to capture broader health system approaches needed to provide packages of care, as is the case with inpatient care of small and sick newborns (16). Furthermore, existing health facility assessment tools tend towards assessment of care at the primary care level. This is pragmatic for capturing population level data without prohibitively large sample sizes to power the study.

Revisions of the health facility assessments are generally planned on a regular basis. Findings from this thesis can serve to inform these revisions and ensure harmonisation with other tools, as well as addition of minimal content to the health facility inventories, such that some of the needs of small and sick newborns are covered within the boundaries of the overall objectives of the individual tools.

Findings from chapter 6 showed that of the all the health facility assessment tools reviewed, the EmONC assessment contained the most detailed content on small and sick newborns.

8.1.2.2 EmONC signal functions and indicators

For obstetric care, EmOC has been defined by two levels of care - "basic" and "comprehensive" - with associated signal functions (which are a list of core lifesaving services) and indicators that have helped advocate for staff and equipment, link to accountability and identify and track programmes progress. The levels of care and signal functions have remained static for nearly two decades except in 2009 when one newborn care indicator/signal function was added: newborn resuscitation with bag and mask. As covered in the background and chapter 7, it has long been recognised that these nine signal functions do not reflect the full spectrum of interventions needed by the mother-baby dyad, most notably ongoing inpatient care for small and sick newborns. As discussed in the background and chapter 4, unlike obstetric care, LMIC are often introducing neonatal care units without standardised guidance on the structures required or levels of care (4, 16, 29, 282).

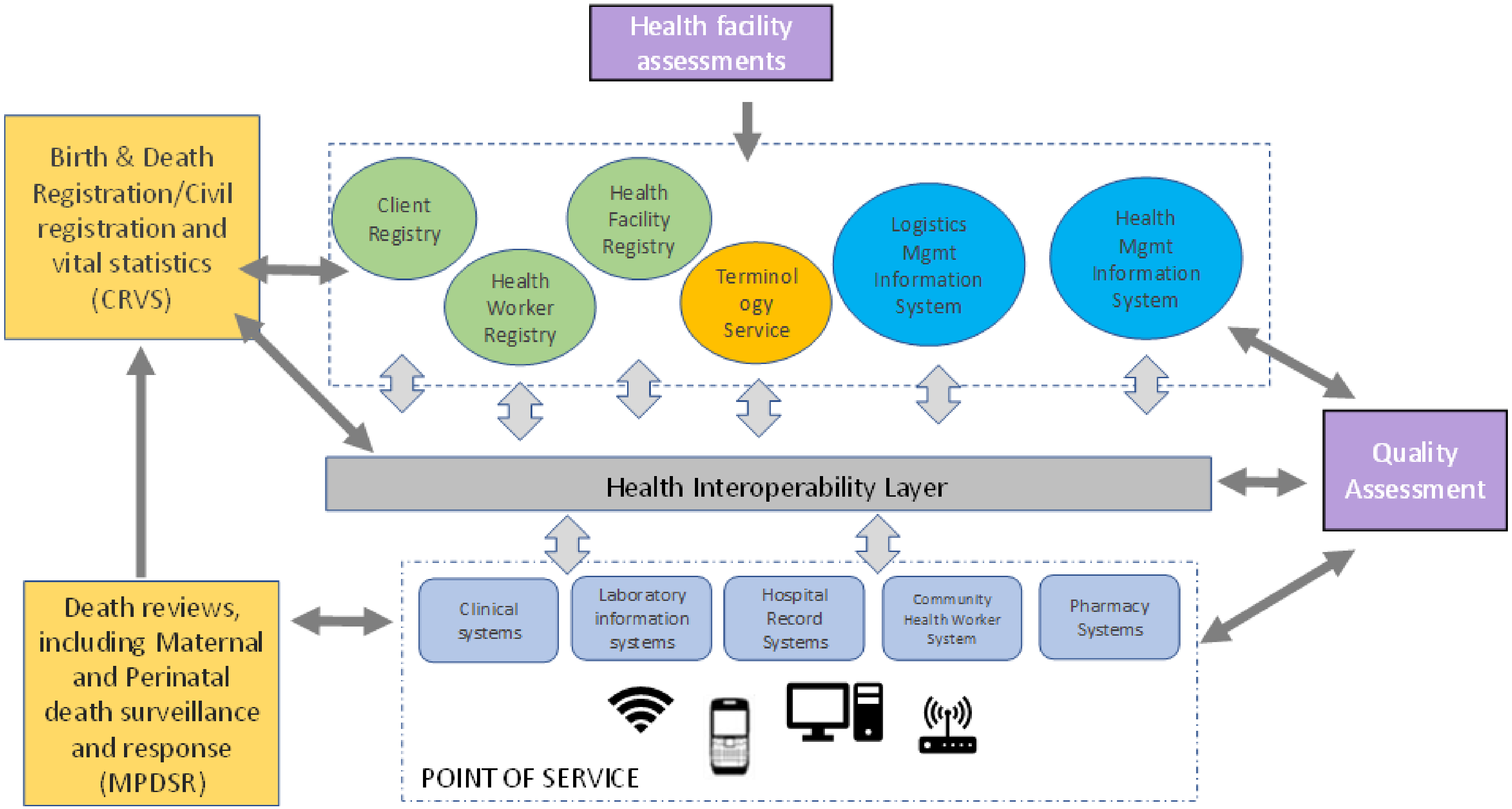
In 2012, Gabrysch and colleagues (188) proposed a set of signal functions to expand emergency newborn care and add functions for routine care for mothers and babies, including general infrastructure. Subsequently, significant newborn content has been added to the EmONC assessment tool, although there are many gaps and the content has not yet been associated with agreed newborn signal functions (16). In chapter 7, through a global survey, I aimed to explore which inpatient care interventions for newborns could be signal functions for different levels of care with in a broader stratified system for mothers and newborns. By integrating these interventions into existing EmOC measurement tools it would allow for a structured inclusion of the respective infrastructure, equipment and human resources to identify gaps, track progress and ensure accountability as part of the maternal-newborn programmes. The defined levels of care for EmOC support the system well beyond health facility assessment measurement; evidence suggests routine tracking can drive change at the implementation level and overall organisation of care (264, 287, 288). With an integrated maternal and newborn approach, managers at national and sub-national levels would therefore be able to more continuously assess the functionality of all facilities providing maternal and newborn care, as is done in some countries within a BEmONC and CEmONC network (264).

8.2. Implications of findings: Moving beyond surveys towards routine data systems for inpatient care of small and sick newborns

Throughout this thesis, my findings emphasise the importance of moving beyond surveys alone towards sustainable routine health information system that are nationally managed and respond to national and locally identified programme needs. In chapter 3, I discussed the challenge of measuring coverage of small and sick newborn interventions through household surveys and described how health facility assessments can fill an important measurement gap on service readiness for facility-based care that cannot be covered by household surveys. The health facility assessment tools explored in later chapters of this PhD are generic tools applied in multiple settings. As data systems transition from dependence on surveys towards routine information systems, the hope is that useful content and indicators within health facility assessment will increasingly harmonise with those in routine health information systems with the latter subsuming the role of the former as they develop in capability.

Health data come from a variety of sources, including population-based sources, censuses, civil registration and vital statistics, surveys, such as health facility assessments, facility records and individual patient records. Figure 8.1 shows the wider health information system and where components of service readiness measurement may enter this system.

Figure 8.1 Data entering the health information system with a functional health interoperability layer



Source. Adapted from Open HIE (289) by Landry (SEARO) and Thorell, L and D Jackson (UNICEF)

To improve measurement for small and sick newborns within the context of a wider routine health information system, there is a need to understand how the system is organised and how various components intersect with each other to influence health information system performance (290). In the current climate, with so many indicators and targets, data systems are expanding to capture, store, manage and transmit information on the heath and the activities of the health system. Service readiness, which does not fit into any one vertical system, but requires multiple sources of data collection (100). Acknowledging the wider context in which health systems operate, and the different people engaged in the data process, is critical to understanding mechanisms and actions which can improve measurement across different health sectors. There is a large body of literature on strengthening and improving routine health information systems, largely spurred by health system strengthening efforts (291-293). Frameworks, such as the Performance of Routine Information Systems (PRISM) framework (100, 290, 294) and the human, organization and technology-fit (HOT-fit) (295), have emerged to support routine health information systems to improve their overall performance. Improving the use of heath information is increasingly seen to be integral to scaling of up the delivery of quality health care systems (296). Such frameworks stress the importance of human and organisational factors, as well as technology, to improve overall performance and achieve the requisite impact on health (100, 296).

Increasingly, literature on health information stresses the need to shift the debate away from the superiority of one data source over another and focus on improving and harmonising the existing routine data systems (100, 289, 290). An important feature of figure 8.1 is the reference to the interoperability layer at the centre of the figure. An interoperability layer receives information (or "transactions") from a variety of systems and coordinates interactions between the different components of the health information system. It's existence provides a common core functionality to simplify the data exchange between systems (289). i.e. its main function is to enable disparate health information systems to share information more easily. Interoperability layers vary greatly in functionality between different countries. However, for service delivery of complex packages of care, such as inpatient care of small and sick newborns, such interoperability will be critical for effective measurement and subsequent performance of health information systems.

In figure 8.1 the blue circles highlight health management information systems and logistics management systems – these are still underdeveloped in many settings and reviewing the available data on small and sick newborns available in different LMIC settings exceeded the scope of this PhD. However, as these systems develop, this thesis has contributed concrete recommendations to help harmonise and standardise the priority content for small and sick newborn care with the intent that this be included as part of the overall RMNCH package of care. DHIS-2 is an open source, web-based

HMIS platform (187) that is now used at national scale by 46 LMIC as the national HMIS, often replacing paper-based systems or aggregating and reporting from paper-based systems (297). Web-based systems, such as DHIS-2 have facilitated the ability to collect more accurate and efficient data capture needed to inform planning and decision-making and availability of routine data for decision making (298). Such systems can also facilitate incorporation of the private sector into the national information system (297), which is critical for monitoring of the overall health system. Exploration of the feasibility of DHIS-2 platforms for facility-based monitoring of newborn care as part of the EN-BIRTH study within the ENAP metrics project is being carried out alongside this work (299).

Some countries are also developing the capacity of their human resource information systems. In DRC, the ministry of health put in place an electronic human resource information system (HRIS) for use at multiple levels of the system (300). The system facilitates health workforce tracking, management, deployment and health worker mapping and has aided the ministry of health to understand and use data to reallocate health workers and limited financial resources to where they are most needed. It has also helped to reduce paperwork at the facility level and to reduce the problem of ghost workers (individuals who are listed on payroll, but do not show up for work). While the system needs to improve its interoperability to further reduce transactions, the creation of a human resource information system has allowed the ministry of health to manage a workforce more effectively (300). Such examples show how technology can be used to reduce complexity of procedures at the facility level and reduce reliance on external and periodic monitoring systems for service readiness, such as health facility assessment surveys (296).

Even in HIC, it is rare for all inpatient care facilities to feed information into one database and it is acknowledged that there is still limited capacity to share standardised data across neonatal care facilities (301). Databases and networks, such as the Vermont Oxford Network (https://public.vtoxford.org/) have been developed and widely used to monitor the delivery of neonatal intensive and special care services in higher-income settings. The Vermont Oxford Network is voluntary quality and safety collaborative (with paid membership) that maintains a database including information about the care and outcomes of infants treated at member institutions. For example, in the US, the Vermont Oxford Network contains 578 hospitals representing approximately 65% of all neonatal intensive care units (302). Such a network has reporting forms and manuals on service characteristics that could potentially be adapted and simplified to work for wider reporting in LMIC to work in tandem with existing routine information system. Some LMICs are also reporting in the Vermont Oxford Network, largely for research purpose. However, the manuals and forms are not open source nor available free of charge. Therefore, it may not be a feasible option beyond special studies or donor-driven research programmes. Furthermore, voluntary and paid membership to the data network raises questions over the representative nature of the data for the functionality of a national system.

The concept of a national network or module for monitoring small and sick newborn care has the potential to be developed specifically for LMIC, as has been done in India, where UNICEF has developed a real time online data monitoring system for newborn special care units (Figure 4.7). The system records vital information on service delivery, as well as data on antenatal, labour room, inpatient care and post discharge follow up. It provides data on both service readiness, treatment and outcomes for newborn inpatients and has helped health workers, as well as policy makers and programme managers to target resources and initiate HR related actions. It is supported by a national cell that builds capacity in data management, monitoring and interpretation of data for policy and programmatic use. In addition, India has well established guidelines and toolkits for standardised infrastructure, human resources and services at different levels of care (16, 254-256). Currently scaled-up in 28 out of 29 states, covering 84% of the SNCUs (661 out of 792 SNCUs) and with 2.7 million newborns enrolled (303). The system model has been adapted and will be adapted for other settings e.g. Malawi. It is important, however, that as these systems are shared and developed for other settings that they are designed to link with other routine information systems. LMICs which have not moved to electronic information systems may have an advantage in that they can leap-frog the situation of having fragmented and discrepant electronic data collection forms which differ from facility to facility or region to region. To move beyond health facility assessment surveys as the main source of information on small and sick newborn care towards routine data systems it is important not to focus on individual systems, but broader overall interoperability.

8.3 Limitations

Specific limitations to each of the objectives have been noted in the relevant chapters. The main overall limitation of this PhD is the reliance on background information (literature review) and professional opinion (expert focus group and a global survey) to define the interventions that comprise the package of inpatient care for small and sick newborns. Information from expert and stakeholder opinion is usually ranked lowest on the evidence pyramid (with experimental design and meta-analysis at the top) (304). The evidence used for this PhD, therefore, is likely to have been influenced by beliefs and opinions, as well as context-specific politics and cultural issues. This is discussed in more detail in the relevant chapters. I acknowledge that had different interventions been selected, some of the findings of this PhD may have been different. Exploration of other interventions for small and sick newborns (which extends beyond the 18 interventions included) could be both valuable and important for future scale up efforts and measurement.

Another limitation of this PhD was the focus on the organisational and technical aspects of measurement (the tools and the health systems) without full exploration of the critical human and behavioural factors (100, 295). The collection and use of much of service readiness data is the responsibility of health workers who often have a priority, primarily, to deliver clinical care. Measurement of care for small and sick newborns, therefore, requires an understanding of the behaviour of health workers responsible for data collection and use (305). Originally, as an additional objective of this PhD, I had planned to collect qualitative data in Malawi as a case study for measurement of care of small and sick newborns. The work aimed to use qualitative methods to identify barriers and enablers to recording and use of service readiness data for care of small and sick newborns in Malawi. The objective was ultimately not feasible in the timeline for this PhD (the full research protocol is available in appendix L), but it is important to acknowledge the added value that a greater understanding of the many challenges faced by those recording and using data at different levels of the health system.

Finally, service readiness itself is a limited measure of quality of care. The Donabedian model of structure-process-outcome allows for measurement of quality by assuming a linear relationship between these three domains. However, there is a difficulty in establishing the exact relationship between these domains and how they interact. Structural inputs are viewed as the necessary foundations for quality of care but are insufficient to describe the content of care delivery or its effects (76). Strictly delineating structures and processes and which of these processes pertain to service readiness was a challenge and could arguably include process measures to a larger or lesser extent. The next and final section on recommendations for policy, programmes and future research also consider how service readiness will continue to evolve in changing shape of quality of care measurement.

8.4 Recommendations for policy, programmes, and future research

Service readiness refers to the capacity of a health system to deliver the services offered (101). Given the critical role of the quality of newborn care in impacting long term outcomes, this PhD has framed service readiness measurement as a starting point to identify service delivery gaps and support scale up of quality care for small and sick newborns. For this final section, I return to the WHO quality of care framework and situate findings from this PHD within this broader SDG era vision to provide recommendations for policy, programme and future research.

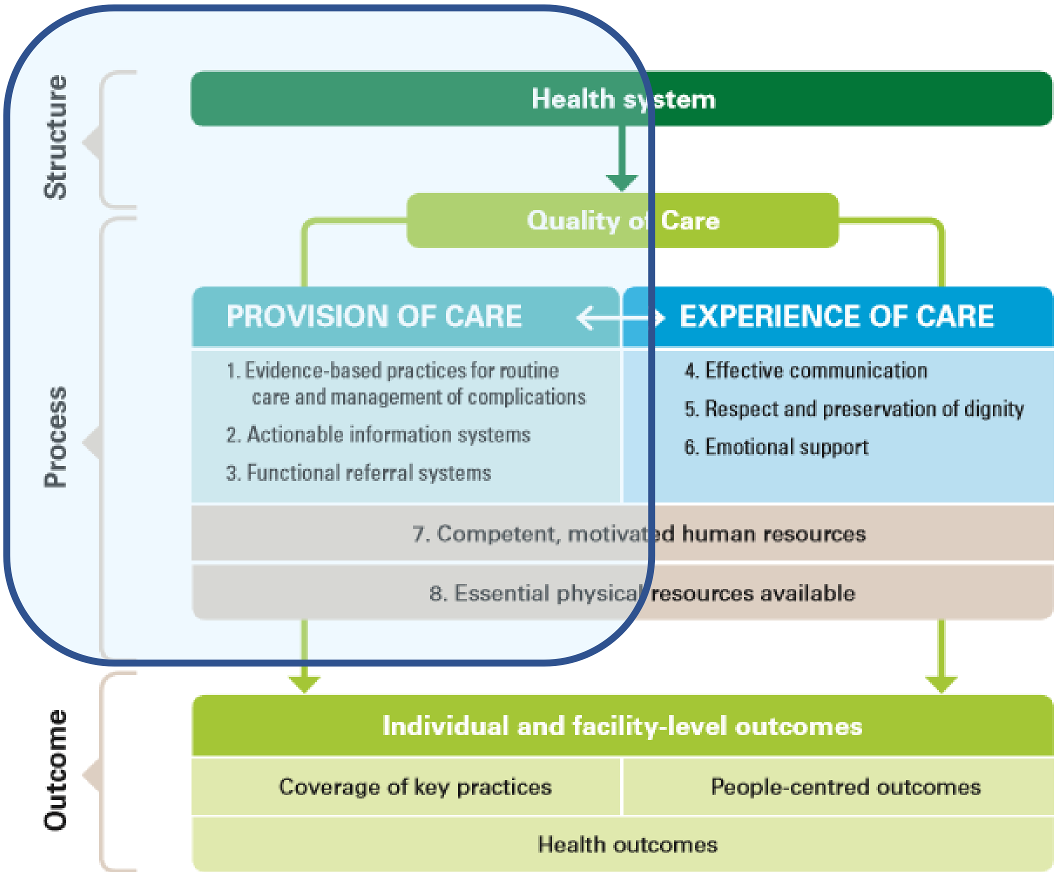
8.4.1 The WHO quality of care framework

In the background section I framed service readiness as a prerequisite for quality of care. Mirroring the conceptual frameworks applied for this PhD, the WHO framework for quality of care for maternal and newborn health care, builds on both the Donabedian model and the six WHO health system building blocks (leadership and governance, financing, essential medicines, information systems, workforce, service delivery) (11). The WHO framework outlines both dimensions of "experience of care" and "provision of care" which can be targeted to assess, improve, and monitor care within the context of a health system.

Achieving UHC, including quality essential service coverage and financial protection for all, is target 3.8 of the SDGs. According to WHO, UHC means that all people can obtain the health services they need without suffering financial hardship (22, 306). National governments and policy makers need to develop a shared vision in tandem with stakeholders and specify the standard provision and experience of care that people can expect for health services to provide (297). Therefore, incorporating the tenets of the WHO quality framework into country-led initiatives also serves to support attainment of wider goals of universal health coverage and the SDGs.

In Figure 8.2, I show the areas of the WHO framework that are explored within this PhD. These are mainly centred around the provision of care dimension of the framework starting with the health system building blocks as a foundation. Measurement of service readiness is therefore viewed as a mechanism for identifying areas of health system weakness in provision of inpatient care that can be targeted to improve of quality of care. On the other side of the WHO framework, the experience of care incorporates dignity and respect, effective communication, and emotional support. Providing these components of quality care for small and sick newborns in practice requires providing care that is family-centred care (11, 307, 308). Both dimensions of the framework are underpinned by competent human resources and essential physical resources.

Figure 8.2 WHO framework for the quality of maternal and newborn health care highlighting focus areas of this PhD



8.4.2 Is service readiness measurement sufficient?

Empirical data increasingly shows health system input measures to be weakly related to the quality of care received and poorly correlated with patient outcomes (76, 102, 297). Pragmatically, however, health systems cannot deliver quality of care without the structural inputs in place. For example, an inpatient care unit cannot treat respiratory distress in small and sick newborns, nor prevent disability associated with unregulated oxygen use, without safe, oxygen systems (including pulse oximetry). Measuring the essential physical resources (service readiness inputs), therefore, is a critical starting point for quality of care measurement. The presence of the physical resources (structures) needs to be accompanied by application of evidence-based practices by a competent health providers (processes). Thus, aspects of process are also included in this PhD, including discussion of staff competency, evidence-based guidelines and standards of care, and organisation of care.

In a rapidly evolving measurement field, nuanced measures of quality of care are also needed for developing health systems to capture the broad dimensions of health and well-being laid out in the SDG era. As shown in figure 8.2, the experience of care, including effective communication, respect and preservation of dignity and emotional support are increasingly viewed as playing a critical role in influencing and affecting individual and facility level outcomes, as per the WHO framework. For this reason, future policy and research for improving measurement for small and sick newborns needs to focus not only on the service provision inputs and processes, but the experience of care to ensure that the quality services are delivered. Service readiness as a measurement construct, therefore, may also need to adapt and evolve. This evolution will require dynamic metrics that build on the foundations of health system readiness and capture domains such as experience of care, as well as other health system processes, such as safety, organisation of care, coordination and integration with other areas of the continuum of care (297, 309).

According to the global health commission on high quality health systems in the SDG era, future measurement of quality of care needs to be focused on two critical areas: accountability and action (102, 297). For accountability, measurement needs to show progress against benchmarks and for actions and provide answers to the specific questions about the functionality of the health system. Service readiness measures are critical to identify areas of health system weakness for targeting inputs, but do not necessarily promote full accountability for high quality health systems. To capture more nuanced constructs, measures need to shift towards assessing the performance of the system and ensure that this incorporates aspects of integration, safety, and experience of care (including trust and confidence in the health system). More recently, this has been referred to in the literature as system competence (297). Building on service readiness and developing these measures towards dimensions of system competence, therefore, may be the logical progression for improving service readiness measurement, incorporating broader concepts of the fabric of the health system overall.

Table 8.1 summarises the recommendations for policy, programmes and future research. In this table, I have showed how the different recommendations laid out in this section link to specific findings within the thematic areas of this PhD. For theme A, delivery of quality inpatient care services, I have focused on the priority health system bottlenecks identified in chapter 4 as sub-themes to highlight the priority areas of the health system that require targeting. For theme B, measurement of service readiness, I have prioritised two sub-themes – health facility assessments and routine data systems, which have been the main measurement focus of this PhD. Overall, the hope is for a shift whereby routine information systems take over the service readiness inputs, and health facility assessment tools are used to capture and measure more complex measures of process that may be less feasible for routine information systems.

Table 8.1 Improving measurement of service readiness; summary of recommendations for policy, programmes and future implementation research

<table>
<tr><th colspan="2">Thematic areas</th><th>Policy and programmes</th><th>Future research themes (focused on implementation)</th></tr>
<tr><td rowspan="4">Theme A: Delivering quality inpatient care services for small and sick newborns</td><td>Priority sub-themes</td><td>Develop norms and standards for programme planning and benchmarking</td><td rowspan="4">• Evaluate benchmarks of facility and workforce capabilities and numbers (e.g. by cot numbers and staff-patient ratios)
• Evaluate integration, organisation and levels of care, referral systems
• Evaluate cost of care

Test and evaluate minimum service standards (including safety) for:
• Medicines and equipment
• Infection control
• Laboratory
• Family-centred care</td></tr>
<tr><td>Health financing</td><td>• set minimum numbers of inpatient care facilities (including cot numbers) by national population or birth rates, stratified by defined levels of care, including minimum service standards</td></tr>
<tr><td>Health workforce</td><td>• Set number and capability of health workers by defined levels of care</td></tr>
<tr><td>Community ownership and partnership</td><td>• Develop norms and standards for family-centred care by defined levels of care</td></tr>
<tr><td rowspan="7">Theme B: Measurement of service readiness for care of small and sick newborns</td><td>Priority sub-themes</td><td>Enable country-led routine data systems</td><td rowspan="7">• Test/validate signal functions in operational neonatal units
• Test/validate population denominators for estimating and tracking service need (effective coverage of services)
• Evaluate service readiness data quality, including interoperability of measurement systems
• Explore determinants of measurement recording and use
• Explore approaches to better measure experience of care</td></tr>
<tr><td rowspan="3">Health facility Assessment tools</td><td>• Harmonise newborn service readiness content in existing health facility assessment tools</td></tr>
<tr><td>• Integrate newborn signal functions for future maternal-newborn health facility assessment tools and incorporate service readiness measures in routine systems</td></tr>
<tr><td>• Develop health facility assessment tools and surveys to incorporate measures of system competence and process measures that cannot be captured easily in routine systems e.g. experience of care</td></tr>
<tr><td rowspan="3">Country-led routine health information data systems</td><td>• Strengthen and invest in logistics management systems and add small and sick newborn service readiness equipment and medicine items</td></tr>
<tr><td>• Strengthen and invest in health worker registries, linking to pay role</td></tr>
<tr><td>• Shift to electronic health management information systems for measures of service readiness</td></tr>
</table>

8.4.3 Develop norms and standards for programme planning and benchmarking

Working towards UHC, national governments and policy makers need to develop a shared vision in tandem with stakeholders of the care that people can expect for health services to provide. With the forthcoming WHO guidelines and standards for inpatient care of small and sick newborns planned for release in 2020-2021, there is a critical window of opportunity to spur national governments and policy makers to formulate corresponding national recommendations on standards for programmes implementing small and sick newborn care. These are dependent on numerous factors, including budget, demographic factors and health system structure (297), as well as linked to national and global standards for routine and emergency maternity and paediatric care.

As a minimum, these norms, and standards for care of small and sick newborns would include:

- the recommended minimum numbers of inpatient care facilities (specified by numbers of neonatal cots/bed spaces) by national population or birth rates, including minimum service standards for medicines and equipment, infection control and laboratory stratified by defined levels of care
- the recommended safe staffing numbers, including nurse (and/or midwifery) and physician ratios to small and sick inpatients, stratified by defined levels of care and accompanying capabilities/competencies. Where possible, accompanying allied health worker ratios can also be included
- Minimum standards for family centred care, stratified by defined levels of care.

8.4.3.1 Facility and workforce capabilities and numbers

For national planning for UHC, standard minimum safe staff-patient ratios are needed for small and sick newborn care to ensure that sufficient health workers, especially skilled midwives and nurses, are available to provide the hands-on care needed at the facility level. Every level of neonatal care should delineate the expected level of care with the accompanying standards and guidelines (282). Geographical availability of facilities alone may overstate health system performance (297), therefore, it is not just numbers of health facilities and health workers that are critical but defining actual capabilities (102). Work in this PhD has begun to delineate and describe the different levels of care and structural inputs and how they align with an existing maternal health EmOC framework. However, the attainment of high quality inpatient care for small and sick newborns will depend not only the availability of adequate numbers of health workers, but on their distribution, quality and performance (266, 306). In tandem with functional information systems on service readiness, such recommendations will provide an urgently needed mechanism for national and local benchmarking and accountability purposes (102, 297).

Greater numbers of health workers caring for small and sick newborns only becomes a stronger health workforce when there is sufficient and targeted funding to secure the correct investment in competencies and skills' development over the longer term (310). Competency-based training programmes have been shown to improve knowledge and skills of health providers, but ongoing mentorship is also needed (211, 212, 283, 311). A clear definition of the package of inpatient care would allow for specific interventions to be prioritised in training and ongoing skills-based training to maintain and supervise the development of specialist nurses. e.g. competency to provide NG feeding, IV fluids and oxygen as well as for other interventions (e.g. jaundice). There is a strong case for nurses with specialist skills in neonatal care, working towards a global cadre of neonatal nurses (Figure 4.6) (30). Pre-service training needs to be a central focus, and dimensions of respectful care, communication and ethics specific to care of newborns, as well as clinical and technical skills, included as part of health worker training specific to care for small and sick newborns (297).

Health financing and workforce issues are not entirely separate and investing in the health workforce, particularly in Africa and Asia, has potential for maximising the investment returns through improving the quality of care for small and sick newborns with resultant gains in human capital (306). Investment in the health workforce can also create demand and generate funding for needed jobs through enabling macroeconomic frameworks that create additional fiscal space (189, 312).

8.4.3.2 Organisation and levels of inpatient care for small and sick newborns

Historically, research and policy efforts have been more targeted towards vertical programme efforts for small and sick newborns focused on individual conditions such as prematurity, neonatal infections, or specific interventions, such as KMC. For more competent health systems that can care for small and sick newborns, a shift is needed to include the small and sick newborn package as part of broader health system strengthening systems for RMNCH. Overall, quality related implementation research remains overwhelmingly from HIC (297) and there remains a dearth of quality implementation research on small and sick newborns in LMIC (270). Future implementation research in LMIC is needed to understand what works for health systems delivering inpatient care and at what cost.

An important research question is to explore the minimum package of inpatient care required to achieve optimal newborn outcomes. Addressing such a question would require significant resources and complex evaluation design, such interrupted time series analyses, given that randomisation is unlikely to be feasible or ethical (313). Separating the effects of different interventions within the inpatient care package is methodologically challenging, especially as many of the small and sick newborns requiring inpatient care, by nature, have multiple co-morbidities (314). Lack of existing routine data on hospital capabilities will further complicate such studies, as has been found in studies from high income settings, which has limited the ability of researchers to relate study findings to other systems and/or translate it into practical recommendations (315). Where randomised controlled trials and interrupted time series analyses are not affordable or feasible in all settings for evaluating effective organisation and delivery of care, documenting the process of implementation can provide valuable lessons. Much of the existing evidence is provided from single centres or initiatives (micro-level) rather than multi-centre or district level to demonstrate meso or macro level coordination of care (283, 297). The absence of information on the potential cost implications of newer interventions and of approaches to organising and delivering inpatient care for small and sick newborns in LMIC to allow for more pragmatic and informed decision making in countries (297).

Referral and transport systems are often a missing link in the organisation of a national system for maternal and newborn health and is critical for a competent system. Whilst referral for obstetric complications is challenging, transport and referral of small and sick newborns is even more inherently risky and complex (266). Small and sick newborns can die in minutes without the correct stabilisation and cannot be transferred and referred in the same manner as larger children or adult patients. As countries invest in referral systems to achieve UHC, it is critical to document the process and provide successful models of referral systems for newborns as examples to settings struggling with referral challenges.

As innovative and novel devices become available for inpatient care for small and sick newborns (including point of care diagnostics and devices for respiratory support, phototherapy), research into quality and safety is needed. Other important areas for implementation research highlighted through this PhD are laboratory readiness for inpatient care of small and sick newborns linked to infection control and antibiotic stewardship.

8.4.3.3 Family-centred care

Families are critically concerned with the health of their newborns, for whom negative outcomes may have devastating social, emotional and financial consequences. Meanwhile newborns are dependent on their families (especially their mothers) as a source of nutrition, warmth and immune factors, as well as emotional nurturing (5, 16, 26). Family-centred care approaches not only have benefits for newborns (such as breastfeeding, growth and development), but can positively influence parents' mental health, as well as confidence and trust in the health system caring for their newborn (26, 276, 308, 316). The needs of families as part of inpatient care for small and sick newborns are often neglected in programmes. Families often suffer from a lack of very basic items, such as food and facilities to wash baby clothes. They also lack emotional support for dealing with caring for a small and sick newborn, as well as their own physical and mental health and support for their families caring for other children at home whilst their newborns are inpatients (16, 317). Negative experiences of care can influence confidence in the health system and are a known deterrent to uptake of services (318), including attendance at follow up appointments (297). For competent health systems that families will trust, national governments need to define what standards of family-centred care they are able provide, engage families in this process and ensure that the health system values, culture and leadership are supportive of family-centred care. Further research to understand the role and experience of mothers (and indeed the wider family) in delivering quality inpatient care unit is needed, especially for LMIC.

8.4.4 Enable country-led routine data systems

One of the overall aims of the SDG era is for all countries to own their data systems and to define their data needs. For accountability and action for care of small and sick newborns, measurement for specific countries will need to show results against benchmarks and be possible to disaggregate for sub-populations and levels of care. Health facility assessments and surveys needs to move away from measures that can otherwise be collected by real-time routine information systems and instead focus on measures of tenets of quality that may be more difficult to capture through routine systems, such as experience of care. In order to weave improvements in measurement of into the fabric of the health systems, more attention is needed to the performance of the routine information systems.

8.4.4.1 Explore determinants of measurement and use and evaluate service readiness data quality, including interoperability of measurement systems

Content of surveys and indicator definitions are just the tip of iceberg and it is the complex system of national data collection that makes the content and indicators meaningful and useful (305). More work is needed to explore the quality of routine data on newborns and the behavioural factors that are integral to the overall performance of the health information system for measuring care of small and sick newborns. Do the routine data collection system provide the data that health workers caring for small and sick newborns want and need? If indicators are irrelevant, data collection forms are complex, and computer software is not user-friendly, it will affect the confidence level of those collecting and using the data and data will not be used effectively for action (100, 298). Health information systems (whether paper or electronic) are of little use without the capacity of workers to collect them. For competent health systems, it is critical for there to be a net gain to the individual worker from actioning the data (305). Better understanding of the feedback loops and where the data gaps exist from the perspective of those organising, delivering and receiving care is needed. Caution is needed in embracing untested electronic and web-based technologies, such as DHIS-2, without evidence of its functionality and feasibility in practice (305). Application of tools, such as the PRISM tool (100), which have been validated and tested in multiple LMIC settings are available for this purpose and can be applied as part of wider health system strengthening efforts to understand the performance of health information systems (290). Whilst this recommendation is applicable to all areas of the RMNCH continuum of care and health system strengthening efforts, care of small and sick newborns is especially relevant given its current measurement gap, potential impact and the potentially large number of structural items that need to be measured to ensure readiness, safety and coordination of care. Service readiness information is only useful to health systems when used in tandem with information on effective coverage, quality processes and overall health outcomes and therefore needs to be looked at in tandem with HMIS, CRVS and audit systems (Figure 8.1) to ensure that health systems are fully accountable to the users and that data can be used for action (106, 172).

8.4.4.2 Test/validate signal functions in operational neonatal unit and explore population denominators for estimating and tracking service need

A revision of the EmONC measurement implementation manual and associated signal functions and indicators is set for 2020-2022 (118). This is an important opportunity to align the measurement needs of mothers and newborns. Work within this PhD has the potential to contribute to this revision process and proposes a potential list of newborn interventions that could act as signal functions allocated to different levels of care, aligned with the EmOC signal functions (see Figure 7.3). Before such measures are incorporated in routine systems, further work is needed to refine this list to measurable signal functions and to test feasibility of measurement of these signal functions in existing inpatient care units. A critical step is operationalising these signal functions against feasible and measurable population denominators to capture effective coverage of services. EmONC assessments, to calculate service need, have mostly used numbers of facilities with a certain level of readiness for a population of 500,000, set against a benchmark of five facilities (118). Research has shown that tracking the numbers of basic and comprehensive facilities per 20,000 births (rather than population size) is consistent across settings with different fertility rates and is a better predictor of mortality (188, 319). Exploring different denominator options is needed to measure effective coverage of services for small and sick newborns.

8.4.4.4 Explore approaches to measure experience of inpatient care of small and sick newborns

The provision of respectful, dignified care is included as an equal tenet of quality in the WHO quality of care framework, paralleling the provision of more traditional health service inputs (318). Respectful maternity care is an area with a growing body of research and related policy. Increased awareness of the problem of disrespect and abuse has highlighted the need for valid measures to document and quantify the issue. However, even with more clear definitions of disrespect and abuse (320) and the emergence of tools to measure the experience of respectful care (321), the prevalence and frequency of such experiences is poorly known for mothers, even less is known for newborns, especially when small and sick. To explore approaches to measure the experience of care for small and sick newborns and their families, lessons will need to be shared from paediatric and disability disciplines, as well as the respectful maternal care agenda. Documenting and studying how communication, ethics and respectful care can be incorporated into pre- and in-service training for health workers is needed. Tools to measure the experience of care (e.g. through combinations of exit interviews with families, bedside pain assessments, and observation of care) require testing in different contexts. Positive user experience is a critical marker of health system trust (297) and in the case of small and sick newborns, we are reliant on communication with the families of these vulnerable patients to build confidence in the health system.

8.4 Conclusions

Inpatient care for small and sick newborns is a complex intervention package with multiple health system challenges that need to be addressed to reduce the estimated 2.5 million newborn deaths that occur each year. High quality inpatient care is critical to both prevent deaths and minimise disability in vulnerable small and sick survivors. The package of care for small and sick newborns lacks standards and benchmarks for countries to track against, which are foundational to ensure safety and target actions to improve the quality of care at different health system levels. Competency and capacity of sufficient numbers of specially trained health workers is fundamental to ensure that service readiness inputs are delivered at high quality. This PhD has contributed to knowledge on how to improve measurement of service readiness for small and sick newborns in view of evolving measurement systems and transitions in data sources and technology. Investment in improving routine measurement systems and their interoperability as part of health system strengthening is required to track service readiness. Future work needs to develop understanding of families' experiences of inpatient care to ensure trust and subsequently to improve the availability, demand and use of high-quality health services for small and sick newborns.

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Appendix A: Summary of role of the candidate in the relevant research activities

Objective of PhD	Component (or paper if relevant)	Activity	Responsibility	Additional input
Background	Preparatory work for Every Newborn Action Plan metrics workshop and measurement improvement roadmap	Antenatal corticosteroids task team background work	Fernando Althabe, Josh Vogel, Joy Lawn and Every Newborn metrics coordination group*	Pierre Barker, Elizabeth McClure, Alfred Osoti, Robert Pattinson, Joel Segre, Jeffrey Smith, William Stone, Linda Wright
		Resuscitation task team background work	Barbara Rawlins, Susan Niermeyer and Every Newborn metrics coordination group*	Gbenga Ashola, Mary Drake, Pablo Duran, Shivaprasad Ghoudar, Ajay Khera, Susan Niermeyer, PK Prabhakar, Abiy Seifu Estefanos, Victoria Shaba and Severin Von Xylander and Linda Wright
		Kangaroo mother care task team background work	**Sarah Moxon,** Tanya Guenther, Juan Gabriel Ruiz Pelaez and Every Newborn metrics coordination group*	Kate Kerber, Socorro De Leon-Mendoza, Rachel Makunde, Goldy Mazia and Bina Valsangkar
		Neonatal infections task team	Deborah Sitrin, Steve Wall, Hannah Blencowe and Every Newborn metrics coordination group*	Ebunoluwa Adejuyigbe, Abdullah Baqui, Harry Campbell and Brendan Wackenreuter
		Chlorhexidine task team	Patricia Coffey, Troy Jabobs and Every Newborn metrics coordination group*	Neal Brandes, Luke Mullany and Beth Yeager
	A measurement improvement roadmap paper	Conceptualisation of paper	Joy Lawn, **Sarah Moxon**	
		Review and input to early drafts	Joy Lawn, **Sarah Moxon,** Hannah Blencowe	*Every newborn* metrics coordination group*
		Coordination of drafts and finalisation of paper	**Sarah Moxon,** Harriet Ruysen, Joy Lawn	*Every newborn* metrics coordination group*
		Reviews of drafts and approval of the final manuscript	**Sarah Moxon,** Joy Lawn, Harriet Ruysen, Matthews Mathai,	*Every newborn* metrics coordination group*, Kate Kerber, Niall Conroy, Metin Gülmezoglu, Joshua Vogel, Barbara Rawlins, Rubayet Sayed, Kathleen Hill, Donna Vivio, Shamin Qazi, Deborah Sitrin, Anna Seale, Steve Wall, Troy

				Jacobs, Juan Gabriel Ruiz Peláez, Tanya Guenther, Patricia Coffey, Penny Dawson, Tanya Marchant, Peter Waiswa, Ashok Deorari, Christabel Enweronu-Laryea, Shams El-Arifeen, Anne CC Lee
Objective 1	Inpatient care of small and sick newborns and the health system	Overall bottleneck tool development	Kim Dickson, Aline Simen-Kapeu, Joy Lawn, Severin von Xylander	UNICEF team
		Overall country consultation process	Kim Dickson , Aline Simen-Kapeu	UNICEF team
		Analysis of quantitative and qualitative bottleneck data on small and sick newborns	**Sarah Moxon,** Aline Simen-Kapeu	Hannah Blencowe, Joy Lawn
		Conceptualisation of paper	**Sarah Moxon**, Joy Lawn, Hannah Blencowe	Kim Dickson, Aline Simen-Kapeu
		Literature review	**Sarah Moxon**	
		Writing and overall coordination of paper drafts	**Sarah Moxon**	Hannah Blencowe, Joy Lawn
		Figures and tables	**Sarah Moxon,** Fiorella Bianchi, Helen Owen, Hannah Blencowe	Hannah Blencowe, Joy Lawn
		Text box on neonatal nursing	**Sarah Moxon,** Karen New, Carole Kenner	
		Text box on India's health system approach	**Sarah Moxon,** Gagan Gupta, Ashok Deorari	Rakesh Kumar
		Text box on jaundice	**Sarah Moxon,** Vinod Bhutani, Hannah Blencowe	
		Reviews of drafts and approval of final manuscript	**Sarah Moxon,** Joy Lawn, Kim Dickson, Aline Simen-Kapeu, Gagan Gupta, Ashok Deorari, Nalini Singhal, Karen New, Carole Kenner, Vinod Bhutani,	

			Rakesh Kumar, Elizabeth Molyneux, Hannah Blencowe	
Objective 2	Service readiness structures and domains for inpatient care of small and sick newborns	Every Newborn facility-based testing design workshop in-depth focus group on small and sick newborns	**Sarah Moxon**	Lara Vaz, Juan Dewez, Ehsan Rahman, Queen Dube, Nalini Singhal, Anne-Marie Bergh, Michel Brun, Mary Azayo, Steve Wall, Rubayet Sayet, Indira Narayanan, Al Ayede and Goldy Mazia, Georgia Gore-Langton, Oona Campbell, Matthews Mathai, Ashok Deorari
		Grey literature review	**Sarah Moxon**	
		Design, conceptualisation and construction of matrix	**Sarah Moxon**	
		Review of clinical content of matrix	**Sarah Moxon**	Susan Niermeyer, Neal Russell, Christabel Enweronu-Laryea, Olukemi Oluwatoyin, Ezeanosike Obumneme, Nana Okai Brako, Kojo Ahor-Essel, Maud Essabah Fandoh, Afua Antiwiwaa Ofori, Sasha Wilson, Pavani Ram
Objective 3	Existing tools to measure service readiness	Review of existing tools	**Sarah Moxon**	Tanya Guenther, Bina Valsangkar, Wenjuan Wang, Rebecca Winter, Liliana Carvajal-Aguirre, Patricia Bailey
	Service readiness for care of small and sick newborns paper	Conceptualisation of paper	**Sarah Moxon,** Joy Lawn, Tanya Guenther	
		Writing process	**Sarah Moxon**	Joy Lawn
		Coordination of paper drafts	**Sarah Moxon**	
		Figures and tables	**Sarah Moxon**	Victoria Ponce-Hardy, Sarindi Aryasinghe
		Final drafts of paper	**Sarah Moxon,** Oona Campbell, Joy Lawn, Tanya Guenther	
		Reviews of drafts and approval of final manuscript	**Sarah Moxon,** Tanya Guenther, Sabine Gabrysch, Christabel Enweronu-Laryea, Pavani Ram, Susan Niermeyer, Kate Kerber, Cally Tann, Neal Russell, Lily Kak, Patricia Bailey, Sasha Wilson, Wenjuan	

			Wang, Rebecca Winter, Liliana Carvajal-Aguirre, Hannah Blencowe, Oona Campbell, Joy Lawn	
Objective 4	Global survey	Survey design	**Sarah Moxon,** Joy Lawn, Hannah Blencowe	Francesca Cavallaro, John Bradley, Patricia Bailey, Sabine Gabrysch
		Ethics approval and amendments	**Sarah Moxon**	Anthony Costello, Olive Cocoman, Helen Louise Taylor, Theresa Diaz, John Bradley, Joy Lawn
		Piloting of tools	**Sarah Moxon**	
		Launch of survey	**Sarah Moxon**	Helen Louise Taylor, Nabila Zaka, Lara Vaz, Tanya Guenther, Olive Cocoman
		Dissemination of survey	**Sarah Moxon**	Conference organisers for international conference on kangaroo mother care, Neil Packenham Walsh and CHIFA team
		Analysis of data	**Sarah Moxon,** John Bradley	Francesca Cavallaro
		Conceptualisation of paper	**Sarah Moxon,** Hannah Blencowe, Joy Lawn	Louise Tina Day
	Global survey paper	Writing process	**Sarah Moxon**	
		Figures and tables	**Sarah Moxon**	
		Reviews of drafts and approval of final manuscript	**Sarah Moxon**	All author team
Objective 5	Discussion	Conceptualisation and writing	**Sarah Moxon**	Review by Hannah Blencowe and Joy Lawn

Appendix B: Listing of relevant indicators according to level of the impact framework (from impact down to inputs)

Using the ranking of A/B/C and 1/2/3 to list top priorities for urgent data improvement- see in purple and pink shading

Indicators requiring further definition in red

		ACCOUNTABILITY REPORTING		GRADING		
Level in Impact framework	**Indicator**	**Data available by equity strata**	**Reported in COIA/Countdown or other regular accountability mechanism**	**Relevance to ENAP grading**	**Availability of data grading**	
IMPACT	Maternal Mortality Ratio	some countries depending	COIA and CD	A	1	
IMPACT	Neonatal Mortality Rate	Yes	COIA tracks % of U5MR that is NMR.	A	1	
IMPACT	Low birth weight rate	no	CD and Nutrition Plan Goals	A	1	
COVERAGE OUTCOMES	Skilled attendant at birth	Yes	COIA and CD	A	1	
COVERAGE OUTCOMES	Caesarean section rate	Yes	Yes	A	1	
COVERAGE OUTCOMES	Early initiation of breast feeding	Yes	Yes	A	1	
IMPACT	Stillbirth Rate	Countries with VR	CD	A	2	TOP PRIORITY MEASUREMENT GAPS ACCORDING TO THE RANKING
IMPACT	Intrapartum/ Fresh Stillbirth Rate	no	nowhere, not tracked by UN	A	2	
IMPACT	Preterm birth rate	Countries with registry data	no	A	2	
IMPACT	Small for gestational age	no	no	A	2	
COVERAGE OUTCOMES	Essential newborn care	No	No	A	2	
COVERAGE OUTCOMES	Early postnatal care for babies	Yes	Yes	A	2	
COVERAGE OUTCOMES	Early postnatal care for mothers	Yes	Yes	A	2	
QUALITY OUTCOMES	Birth companion of choice and skilled attendant at birth	No	Not yet	A	2	
QUALITY OUTCOMES	"MotherBaby" high quality care package at birth	No	Not yet	A	2	
IMPACT	Neonatal morbidities eg PSBI,		no	A	3	
IMPACT	Long term disability after neonatal conditions eg after preterm birth		no	A	3	
COVERAGE OUTCOMES	Newborn resuscitation	No	No	A	3	
COVERAGE OUTCOMES	Antenatal corticosteroid use	No	No	A	3	
COVERAGE OUTCOMES	Kangaroo mother care	No	No	A	3	
COVERAGE OUTCOMES	Use of chlorhexidine cord cleansing	No	No	A	3	
COVERAGE OUTCOMES	Treatment of neonatal sepsis	No	No	A	3	

COVERAGE OUTCOMES	Exclusive breastfeeding <6 months	Yes	Yes	B	1	
QUALITY OUTCOMES	Proportion of women and newborns who stay in facility at least 6 hours after giving birth	No	No	B	1	
INPUTS Health Workforce	Density of midwives	No	Yes	B	1	
INPUTS Health Workforce	Density of doctors	No	Yes	B	1	
INPUTS Commodities and technologies	Proportion of health facilities with availability of soap, running water or alcohol based rub in labour and	No	No	B	1	
INPUTS Commodities and technologies	Proportion of health facilities with maternity services that have functional bag & masks (2 neonatal mask sizes) in the	No	No	B	1	
INPUTS Health Information Systems	Birth weight recorded	Yes	No	B	1	
INPUTS Legislative	All countries have adopted legislation on maternity			B	1	
INPUTS Legislative	All countries have adopted legislation in order to			B	1	
INPUTS Health Systems Financing	ODA mentioning newborn		CD and now added to CD profiles and will be tracked annually	B	1	
INPUTS Health Systems	Do they have an RMNCH costed plan		CD (and will be trying to get more detail re	B	1	
OUTPUTS Health service quality	Health facilities offering maternity services that have BFHI certification and recertification not older than	No	Not yet	B	2	**NEXT PRIOIRTY MEASUREMENT GAPS ACCORDING TO RANKING**
OUTPUTS Health service quality	Health facilities where Kangaroo Mother Care services are operational	No	No	B	2	
OUTPUTS Health service quality	Health facilities offering comprehensive obstetric emergency care	No	CD	B	2	
OUTPUTS Demand for care	Care seeking for newborn danger signs	No	No	B	2	
OUTPUTS Demand for care	Women's group participation	No	No	B	2	
INPUTS Commodities and technologies	Proportion of health facilities with safe uninterrupted oxygen supply in the childbirth, neonatal and	No	No	B	2	
INPUTS Commodities and technologies	Proportion of health facilities that without no stock outs of essential life savings medicines	No	No	B	2	

INPUTS Health Information Systems	Facility neonatal mortality rate disaggregated by birth weight: >4000 g, 2500-3999 g, 2000-2499 g, 1500-1999 g, < 1500 g	No	No	B	2	
INPUTS Health Information Systems	Maternal, stillbirth and neonatal death reviews (audit)	No	No	B	2	
INPUTS Health Information Systems	Is the core set of indicators for assessing maternal and newborn health incorporated into the health information systems			B	2	
INPUTS Leadership and	Proportion of countries with the highest burden of newborn mortality that have sharpened their national			B	2	
INPUTS Leadership and governance	Proportion of countries that have included the 13 life-saving commodities prioritized by the Commission on Life-saving Commodities for Women's and Children's Health in their essential medicine and commodities list		CD (just added to CD profile policy indicators)	B	2	
INPUTS Leadership and governance	Proportion of countries that have updated national policies and guidelines for the continuum of care of reproductive, maternal, newborn and child health in line with most recent evidence-based guidelines			B	2	
INPUTS Leadership and governance	Proportion of countries that have adopted standards of quality of maternal and newborn care in their national strategies and action plans for RMNCH			B	2	
INPUTS Leadership and governance	Proportion of countries that have assessed their health workforce and developed human resource development and retention plans to increase access to quality maternal and newborn care at community, primary and referral health care levels			B	2	

INPUTS Leadership and governance	Proportion of countries that have authorized health workers at appropriate levels to administer life-saving interventions and commodities			B	2	
INPUTS Leadership and governance	Proportion of countries that have taken steps to harness community participation and supported local champions and existing community structures to take action for maternal and newborn health			B	2	
INPUTS Leadership and governance	Proportion of countries that have taken significant steps to establish a system for birth and death registration including neonatal causes of death			B	2	
INPUTS Leadership and governance	Proportion of acute humanitarian emergency responses including newborn kits in their service delivery			B	2	
INPUTS Accountability and data for action	Proportion of countries with a high burden of neonatal deaths have conducted a population-based survey to assess progress in coverage of essential interventions for maternal and newborn health			B	2	
INPUTS Accountability and data for action	Proportion of countries with a high burden of neonatal deaths have conducted a health facility service availability and readiness assessment to assess indicators of quality of maternal and newborn care			B	2	
INPUTS Health Systems Financing	Proportion of countries with information on national and donor expenditures for reproductive, maternal, newborn and child health, disaggregated by sources		2	B	2	
INPUTS Health Systems Financing	Country commitments to Every Women Every Child		iERG and PMNCH and others	B	2	
INPUTS Health Workforce	Density of community health workers for newborn care	No	No	B	3	
INPUTS Communities behaviour change	National BCC strategy that included key newborn care messages eg recognition of danger signs, bfing, warmth, cleanliness			B	3	

INPUTS Leadership and governance	Proportion of countries where local health providers and private sector actors have been incentivized to increase production, distribution and appropriate promotion of life-saving commodities for women's and children's health			B	3	
INPUTS Leadership and governance	Proportion of countries that have developed and are implementing national e-health strategies including specifics on how this benefits maternal and newborn health			B	3	
IMPACT	Total Fertility Rate	Yes	CD	C	1	
COVERAGE OUTCOMES	Demand for family planning satisfied	Yes	COIA and CD	C	1	
COVERAGE OUTCOMES	Antenatal Care Coverage (one or more visits)	Yes	CD	C	1	
COVERAGE OUTCOMES	Antenatal Care Coverage (four or more visits)	Yes	COIA and CD	C	1	
COVERAGE OUTCOMES	Intermittent preventive treatment for malaria in pregnancy	Yes	CD	C	1	
COVERAGE OUTCOMES	Prevention of mother-to-child transmission of HIV	Yes	COIA and CD	C	1	
COVERAGE OUTCOMES	Neonatal tetanus protection	Yes	CD	C	1	
INPUTS Legislative	All countries have adopted legislation on maternal death notification within 24 hours			C	1	

Appendix C: Bottleneck tool questionnaire for inpatient care of small and sick newborns

TOOL TO SUPPORT COUNTRIES TO IDENTIFY BOTTLENECKS AND SOLUTIONS TO SCALE-UP NEWBORN CARE

Intervention 9: ***INPATIENT SUPPORTIVE CARE FOR SICK AND SMALL NEWBORNS***

Focus on IV fluids, feeding support and safe oxygen

Severely sick newborns with severe infections or who are too small to maintain their body temperature, to breath or to feed actively need full supportive in-patient care. This includes a number of interventions, including regular monitoring and assessments by health workers. As tracers for full supportive care, however, the following interventions have been identified: provision of IV fluids, intragastric tube feeding (IGTF), and safe oxygen administration.

1. Leadership and governance
1.1 Explain if full supportive in-patient care for severely sick newborns been identified as a priority intervention to avert preventable newborn deaths in the national RMNCH plan/strategy (specify the name of the documents). If so, does the plan/strategy include specific actions for in-patient supportive care for severely sick and small newborns?
1.2 Explain if there are national standard treatment guidelines or clinical protocols covering full supportive care for severely sick and small newborns after delivery. (Specify name of the guidelines/clinical protocol document and year of publication). – Describe whether they address the most common potentially lethal conditions requiring in-patient care, i.e. severe infections (e.g. sepsis/meningitis) and complications of prematurity. – Describe whether they address the need for feeding support for severely sick newborns, including intragastric tube feeding? Do they promote family –centered care? – Explain whether all recommendations are regularly updated and in line with current best practices (e.g. latest WHO guidelines).
1.3 At what level of care is inpatient care for sick and small/LBW babies recommended? – First referral level (e.g. district hospital)? – Second referral level (e.g. with specialized care available)? – Tertiary level?
1.4 Describe whether all relevant policies or regulations are aligned with the recommendations for inpatient care for sick and small/LBW babies. For example: – Explain how/whether health facilities are organized and equipped for appropriate inpatient care and monitoring for sick and small/LBW babies in line with national guidelines. – Explain how health facilities maintain hygiene standards to ensure quality care for sick and small/LBW newborns. – Describe whether there is a cadre of health personnel authorized and trained to perform extra care for sick and small/LBW newborns. Explain whether health workers who assess and manage these newborns provide adequate extra support for feeding (including exclusive breastfeeding) and warmth? (More details in section on human resources).

Please provide a summary of key bottlenecks.
After responding to the questions above, please make an overall assessment of whether leadership and governance mechanisms in place for inpatient care for sick and small/LBW newborns are: ☐ **Good** *(not a bottleneck to scale up)* ☐ **Need some improvements** *(minor bottleneck to scale up)* ☐ **Need major improvements** *(significant bottleneck to scale up)* ☐ **Inadequate** *(very major bottleneck to scale up)*
2. Health financing
2.1 Describe any specific financing issues related to the implementation of inpatient care services for sick and small/LBW newborns at all recommended level of care. For example: • *At the national level:* ○ Explain whether there are sufficient funds in centralized procurement and distribution systems to procure and distribute necessary equipment (IV fluids and safe oxygen) at all recommended levels of care to continuously provide inpatient care to sick and small/LBW babies at all health facilities where they are required. • *At the district or facility level:* ○ Explain whether there are sufficient funds in decentralized procurement and distribution systems, to procure and distribute necessary equipment (IV fluids and safe oxygen) at all recommended levels of care to continuously provide inpatient care to sick and small/LBW babies at all health facilities where they are required.
2.2 Describe any financial barriers that prevent sick and small/LBW newborns from receiving appropriate care at the health facility. For example: – Describe barriers to care-seeking for all sick and small/LBW newborns as a result of out-of-pocket payments. . – Explain whether user fees represent a barrier to admission of sick newborns and if the costs related to extra care for small/LBW babies are an issue for the clients who need it (e.g. fees for a neonatologist). – Do patients/families need to purchase drugs to benefit from this service?
2.3 Describe other financial barriers to the expansion of newborn health services for inpatient care of sick and small/LBW newborns in all recommended health facilities.
Please provide a summary of key bottlenecks.
After responding to the questions above, please make an overall assessment of whether health financing for inpatient care for sick and small/LBW newborns is: ☐ **Good** *(not a bottleneck to scale up)* ☐ **Needs some improvements** *(minor bottleneck to scale up)* ☐ **Needs major improvements** *(significant bottleneck to scale up)* ☐ **Inadequate** *(very major bottleneck to scale up)*
3. Health workforce

3.1 Explain whether there are sufficient numbers of competent health care workers who can provide inpatient care for sick and small/LBW babies, at each level of care, where this intervention should be implemented. Issues may include:

- There are insufficient health workers to provide full supportive newborn care in the health facilities.
- There might be sufficient numbers of trained health care workers, but they do not have the necessary competencies to provide full supportive care.
- How is the distribution of skilled personnel trained to provide extra care for sick and small newborns between rural and urban populations? Is there an HR strategy to expand BNC to all newborns living in remote areas through community health workers?
- Are there policies in place to insure monitoring and handling of sick/small babies by competent staff around the clock?

3.2 What cadre of health care workers are authorized and skilled to provide extra newborn care to sick and small/LBW babies with: (please, check for each of these intervention)

IV fluids ***Oxygen*** ***IGT feeding***

- Nurses
- Midwives
- Auxiliary midwives
- Physicians/Clinicians
- Other cadre (please specify all): ……….

3.3 What cadre of health care workers are authorized to prescribe and/or administer *IV fluids* to sick and small newborns?

- Midwives ☐Administer only ☐Prescribe and administer ☐ Prescribe only
- Auxiliary midwives: ☐Administer only ☐Prescribe and administer ☐ Prescribe only
- Nurses: ☐Administer only ☐Prescribe and administer ☐ Prescribe only
- Physicians/clinicians ☐Administer only ☐Prescribe and administer ☐ Prescribe only
- Other cadre (please specify all): ……… ☐Administer only ☐Prescribe and administer ☐ Prescribe only

What cadre of health care workers are authorized to prescribe and/or administer *oxygen* to sick and small newborns?

- Midwives ☐Administer only ☐Prescribe and administer ☐ Prescribe only
- Auxiliary midwives: ☐Administer only ☐Prescribe and administer ☐ Prescribe only
- Nurses: ☐Administer only ☐Prescribe and administer ☐ Prescribe only
- Physicians/clinicians ☐Administer only ☐Prescribe and administer ☐ Prescribe only
- Other cadre (please specify all): ……… ☐Administer only ☐Prescribe and administer ☐ Prescribe only

What cadre of health care workers are authorized to prescribe and/or administer *IGT feeding* to sick and small newborns?

- Midwives ☐Administer only ☐Prescribe and administer ☐ Prescribe only
- Auxiliary midwives: ☐Administer only ☐Prescribe and administer ☐ Prescribe only

• Nurses: ☐Administer only ☐Prescribe and administer ☐ Prescribe only • Physicians/clinicians ☐Administer only ☐Prescribe and administer ☐ Prescribe only • Other cadre (please specify all): ……… ☐Administer only ☐Prescribe and administer ☐ Prescribe only
3. 4 Explain whether there are job descriptions and job aids for health workers at all levels of care, which reflect their role in assessing, caring for, and monitoring sick and small/LBW newborn babies at the health facility.
3.5 Are there competency-based training programmes through which the respective cadre of health care workers acquire the necessary knowledge and skills to provide *IV fluids*? • Nurses ☐Pre-service training ☐ In-service training • Midwives ☐Pre-service training ☐ In-service training • Auxiliary midwives ☐Pre-service training ☐ In-service training • Auxiliary nurses ☐Pre-service training ☐ In-service training • Clinical officers ☐Pre-service training ☐ In-service training • Physicians/clinicians ☐Pre-service training ☐ In-service training • Other cadre: …………. ☐Pre-service training ☐ In-service training Are there competency-based training programmes through which the respective cadre of health care workers acquire the necessary knowledge and skills to provide *oxygen*? • Nurses ☐Pre-service training ☐ In-service training • Midwives ☐Pre-service training ☐ In-service training • Auxiliary midwives ☐Pre-service training ☐ In-service training • Auxiliary nurses ☐Pre-service training ☐ In-service training • Clinical officers ☐Pre-service training ☐ In-service training • Physicians/clinicians ☐Pre-service training ☐ In-service training • Other cadre: …………. ☐Pre-service training ☐ In-service training Are there competency-based training programmes through which the respective cadre of health care workers acquire the necessary knowledge and skills to provide *IGT feeding*? • Nurses ☐Pre-service training ☐ In-service training • Midwives ☐Pre-service training ☐ In-service training • Auxiliary midwives ☐Pre-service training ☐ In-service training • Auxiliary nurses ☐Pre-service training ☐ In-service training • Clinical officers ☐Pre-service training ☐ In-service training • Physicians/clinicians ☐Pre-service training ☐ In-service training • Other cadre: …………. ☐Pre-service training ☐ In-service training
Please provide a summary of key bottlenecks.
After responding to the questions above, please make an overall assessment of whether health workforce mechanisms in place for inpatient care for sick and small/LBW newborns are: ☐ **Good** *(not a bottleneck to scale up)* ☐ **Need some improvements** *(minor bottleneck to scale up)* ☐ **Need major improvements** *(significant bottleneck to scale up)* ☐ **Inadequate** *(very major bottleneck to scale up)***Good**
4. Essential medical products and technologies

4.1 Are the following appropriate IV fluids included in the National Essential Medicines List (NEML) for the indication of management of sick and small newborns? ☐ 10% Glucose ☐ 0.45 NaCl/5% glucose ☐ 0.18% NaCl/4% glucose
4.2 Explain if oxygen is included in the National Essential Medicines List (NEML) for the indication of the management of sick and small newborns and if all necessary equipment for safe oxygen therapy is included in the national essential commodities list (i.e. oxygen concentrators, blenders, tubes and nasal prongs).
4.3 Explain whether sufficient medical products (branded or generic), that can be used for treatment of sick and small/LBW newborns, are licensed.
4.4 Explain if there are functional national or local systems in place to accurate forecasting and distribution of IV fluids and oxygen for the management of sick and small/LBW newborns in health facilities.
4.5 Describe and explain the reasons for stock-outs of IV fluids and oxygen at national and sub-national levels in the last twelve months, if any.
Please provide a summary of key bottlenecks.
After responding to the questions above, please make an overall assessment of whether procurement and management systems in place for inpatient care for sick and small/LBW newborns are: ☐ **Good** *(not a bottleneck to scale up)* ☐ **Need some improvements** *(minor bottleneck to scale up)* ☐ **Need major improvements** *(significant bottleneck to scale up)* ☐ **Inadequate** *(very major bottleneck to scale up)*
5. Health service delivery
5.1 Explain whether the organization of newborn care services within health facilities allows for full supportive care of sick and small/LBW newborns. – Are there a limited number of health facilities that provide extra care for sick and small/LBW babies? What is the balance between urban and rural/remote areas? – Is the service available on a daily basis? – Is there a clearly defined supportive environment in place for extra support for feeding methods, extra support for warmth to sick and small/LBW babies? – Is there a public-private partnership that enhances delivery of newborn health care services?
5.2 Describe the systems in place to promote the adherence to national standard and clinical protocols on inpatient/extra care for sick and small/newborns (see section 1.2 on leadership and governance for relevant guidelines). For example: – Describe quality improvement mechanisms in place with standardized tools such as check lists for quality of inpatient care for sick and small/LBW babies.

– Explain specific efforts made by public and private (for-profit) health care facilities to promote and ensure quality basic newborn care. – Explain whether districts or health facilities conduct periodic reviews to ensure the provision of quality inpatient care for sick and small newborns. – Describe guidelines available and used by staff to improve the quality of inpatient care services for newborns.
5.3 Describe other barriers to the delivery of basic newborn health care services that need to be addressed. For example: – Lack of information on clients' needs for improved performance – Health care workers' attitudes – Does the country provide family-centered care for mothers and newborns?
Please provide a summary of key bottlenecks.
After responding to the questions above, please make an overall assessment of whether health service delivery in place for full supportive care for sick and small/LBW newborns is: ☐ **Good** *(not a bottleneck to scale up)* ☐ **Needs some improvements** *(minor bottleneck to scale up)* ☐ **Needs major improvements** *(significant bottleneck to scale up)* ☐ **Inadequate** *(very major bottleneck to scale up)*
6. Health information systems
6.1 Explain whether there is information available on extra newborn care coverage for sick and small newborns. For example: – What are the indicators used to track the sick or small/LBW newborns that received extra care (number of newborns hospitalized?) or to record the weight of small/LBW babies assessed? Please specify the reference document for the indicators used, including publication dates and the page.
6.2 Explain whether the findings observed during inpatient care for sick and small/LBW newborns are included in standard clinical records or checklists.
6.3 Explain whether the critical review of appropriate inpatient care for sick and small/LBW babies is included in protocols for clinical audits and perinatal death reviews.
Please provide a summary of key bottlenecks.
After responding to the questions above, please make an overall assessment of whether health information systems in place to assess and monitor full supportive care for sick and small/LBW newborns are: ☐ **Good** *(not a bottleneck to scale up)* ☐ **Need some improvements** *(minor bottleneck to scale up)* ☐ **Need major improvements** *(significant bottleneck to scale up)* ☐ **Inadequate** *(very major bottleneck to scale up)*
7. Community ownership and participation
7.1 Explain whether sick and small/LBW babies in need of extra neonatal care can use the services at all levels of care. For example: – Explain whether care seeking is limited by socio-cultural barriers (misconceptions, beliefs, seclusion of newborns, etc.), lack of male involvement or long distance to health facilities.

– Describe strategies in place to facilitate the use of inpatient neonatal care services by sick and small/LBW newborns living in rural and remote areas. – Describe the referral mechanisms in place between the community and health facilities organized to facilitate timely referral and access to care for all newborns.
7.2 Describe specific efforts to increase the awareness of the general public, adolescent girls, pregnant women and young couples of the benefits of (1) timely recognition of a newborn with LBW or with signs of illness and (2) timely care seeking to a health facility. For example: – Is information on the benefits of timely recognition of signs of illness and referral to an appropriate provider available in the appropriate local language? – Do women and the general public know about that information? – Are there IEC materials available in the appropriate local language? – What is the level of male involvement to facilitate care seeking for sick and small/LBW newborns?
7.2 Describe other challenges faced by women that limit the use of inpatient neonatal care services.
Please provide a summary of key bottlenecks.
After responding to the questions above, please make an overall assessment of whether community ownership and participation to increase full supportive care for sick and small/LBW newborns is: ☐ **Good** *(not a bottleneck to scale up)* ☐ **Needs some improvements** *(minor bottleneck to scale up)* ☐ **Needs major improvements** *(significant bottleneck to scale up)* ☐ **Inadequate** *(very major bottleneck to scale up)*

IDENTIFICATION OF SOLUTIONS TO ADDRESS THE CHALLENGES
Please add sheets as appropriate

Intervention 9: ***INPATIENT SUPPORTIVE CARE FOR SICK AND SMALL NEWBORNS - Focus on IV fluids, feeding support, and safe oxygen***		
Summary of key bottlenecks *by order of priority*		Strategies and solutions to address identified challenges and bottlenecks
Building block	*Priority bottlenecks*	
Leadership and Governance		
Health Finance		
Health Workforce		
Essential Medical products and Technologies		
Health Service Delivery		
Health Information Systems		
Community Ownership and Participation		

Appendix D: Bottlenecks for inpatient care of small and sick newborns

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
Leadership and Governance	Governance	Poor governance leading to increasing the cost of care	✓											
	Policy/strategy	No state level uniform policy for relevant supportive policies, like discharge policy (medical colleges vs District level & peripheral SNCUs)									A			
		Strategy is available but not prioritized										✓		
		No standard plan/policy for care of sick babies											A,G	
		Only physicians authorized for prescribing the drugs. ANMs skilled to provide only oxygen but not to prescribe									O,A	✓	A	
		Management of sick newborns is not part of BPHS/EPHS package so service delivery does not exists	✓						✓					
	Guidelines / standards	No guidelines or recommendations					✓					✓	A, K, P	

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
Leadership and Governance		There is a WHO Guideline on inpatient care but not well circulated					✓							
		Feeding is not emphasized in the standard treatment guidelines at district level				✓								
		Guidelines do not promote family-centered care			✓									
		Dissemination of guidelines is limited to senior officials, especially in tertiary care hospitals and does not reach the service providers at lower levels									A			
		Guidelines in place but not in practice (e.g. do not stay for 48 hours). Following the guidelines varies from institution to institution due to technical limitations									O			
	Protocol	Non-adherence to and lack of standard, clinical protocols for treatment of sick newborns and lack of adherence putting further							✓				A, G, K, P	

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
Leadership and Governance		burden upon institution and parents												
	Public-private partnership	Lack of clear public-private partnership	✓								O			
	Awareness	Lack of awareness	✓											
Health Financing	**Funding**	Competing needs for available funds			✓									
		Insufficient / lack of funds for distribution of necessary equipment and services (e.g. for lab support and blood components)	✓			✓					O		A, G, K	
		Availability of funds - not allocated for inpatient care for sick and small newborns at all recommended levels of care							✓	✓			K	
		Problems in funds disbursement at district / lower level and fund flow from national and state level									O, A			
		Low state subsidy		✓										

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
Health Financing	Insurance	Almost no insurance companies and lack of coverage of certain medicines for treatment of preterm newborns at certain levels		✓										✓
	Financial barriers to care	Government cannot promote adequate medicine due to financial barriers											A, P	
		LBW babies need treatment, but financial problems are barriers to treat them											B	
		Hospital acquired infection requires costly antibiotics											A	
	Out-of-pocket expenses / user fees	No grants to families to pay for care	✓											
		User fees - patient having to purchase drugs and out of pocket payment			✓		✓				A	✓	K	✓
	Awareness	Clients and service providers not aware of free entitlements and available funds									O			

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
Health Workforce	**Number, distribution and role of health workers**	Lack of trained personnel in neonatal care in quantity and quality (knowledge, training and skills), particularly at lower levels	✓	✓	✓	✓				✓	A		A, G, K, P	
		Disparity in the distribution of personnel (urban vs. rural)	✓	✓			✓				O		P	
Health Workforce		Selection and posting of trainees (inappropriate selections and post-training deployment)									O			
		No integrated care for sick newborns by community workers		✓										
	Supervision	Lack of supportive supervision	✓	✓			✓			✓	O			
	Accountability	No accountability											G	
	Incentives and motivation	No providers' incentive scheme (e.g. lack of encouragement for task-shifting) leading to lack of motivation		✓			✓					✓		
	Training	No/inadequate competency-based training/CME in care of small and sick babies (particularly at lower levels) including pre-and in-service and refresher training		✓			✓		✓		O, A	✓	A, G	

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
	Guidelines and instructions	Job descriptions available but not known/clear to all	✓								O			
		No job chart available on the specific mentioned areas									A			
Essential Medical Products and Technologies	**Lack of supplies and equipment**	General stock-outs / lack of supplies and equipment / inadequate supply		✓		✓			✓	✓	O, A		A, G, P	✓
		Electronic weighing machine not available in all units									O			
		0.45 NaCl/5% glucose not available									A			
		Shortfall in supply of oxygen due to demand and supply gap and non-availability									A		A, G	
		NICU in tertiary care and teaching hospitals in capital city has only ventilator support with oxygen											A	
	Essential Medical List (EML)	No oxygen in the list of essential features	✓											

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
Essential Medical Products and Technologies		All equipment required for oxygen are not included in the LNME (other than those included in the kit but not for continuity and many children)		✓										
		Fluids not on list											P	
	Policy	The essential medicine list policy is available but not fully implemented					✓				A			
		No national policy of supplies											G	
	Procurement and supply management	Poor and inaccurate forecasting, procurement, distribution and supply management (e.g. not available at all levels, no system in place to forecast demand for oxygen and IV fluids, issues with supply chain management and maintenance of supplies)			✓		✓			✓	O, A	✓	B, K	✓
Health Service Delivery	Service availability / capacity of services	Some facilities have limited availability of services (e.g. services for caring for low birth weight / small babies)	✓	✓						✓	A		B	✓

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
Health Service Delivery		Side labs with special newborn care units not functioning optimally			✓									
		Limited number of facilities providing inpatient care for severely sick and small newborns (particularly at lower levels)			✓								K, P	
		Skewed distribution of Health facilities between rural and urban					✓							
		No professional postnatal care system												✓
		Many available building plans are outdated for recommended inpatient care of sick and small baby			✓									
		National scale-up of inpatient care for supportive care for sick and small/LBW yet to be done beyond selected hospitals supported by projects								✓				

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
Health Service Delivery		No nursery and proper management of LBW babies											B	
	Referrals	Referrals are not as per the guidelines									O			
	Space	Limited space				✓					O		A	✓
		No space for mothers of inpatient newborns to stay when their babies are admitted to facilities										✓		
	Quality improvement	Poor adherence to existing guidelines/ recommendations/ protocols and no strategies in place for improvement	✓				✓					✓		
		Lack of guidelines to improve the quality of services	✓											
		No standardized quality tools and consequent performance reviews				✓								
		Quality of care at facilities is a major issue / inadequate								✓	O			
		Inadequate monitoring, quality assurance, maintenance and					✓			✓			K	

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
Health Service Delivery		improvement mechanisms (including performance improvements)												
		Lack of mechanism to ensure the guideline are properly applied and adhered to												
		Mentoring / supervision guidelines not in place									A			
		Service quality is different between levels of care												✓
	Health worker attitudes	Poor health worker attitudes toward care of newborns			✓						A, O			
	Communication	Ineffective communication (with clients and between community and facility)									A			
	Supportive environment	No family-centred, supportive care for the mother and newborn		✓										✓
		Facilities lack supportive environment (e.g. for feeding)			✓						O			

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
		Non-compliance with hygiene standards in the majority of structures			✓									
Health Information System	**Tools for information system**	Neonatal registers not developed			✓									
		Records not being maintained uniformly at both higher and lower level facilities									A			
Health Information System	**Indicators**	No harmonization of information on outcomes of hospital care in the registers	✓											
		HMIS for inpatient supportive care for sick and small newborn is not yet functioning in all facilities or captures relevant information								✓			G	✓
		Few indicators on newborns / no definition of indicators on sick newborns, only deaths		✓										✓
		Lack of tracking of referrals and treatment									O			

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
Health Information System		Lack of information on management system for sick newborns or LBW management										✓	B, K	
	Use and dissemination of information	Poor dissemination and utilization of health information materials					✓							
		SNCU software in place but not analysed regularly									O			
	Quality improvement tools	No extension sheets review of neonatal deaths		✓										
		Standardized tools such as check lists for quality of inpatient care needs review to ensure optimal inpatient newborn care and proper dissemination					✓							
	Quality improvement assessment system	Absence/poor coverage of clinical audits and perinatal deaths listed	✓	✓		✓			✓	✓	O		A, B, P	

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
		No regular reviews on mortality and performance at hospital level and at district level									A		A	✓
		Technical information needed for treatment is not properly filled out												✓
		Data not disaggregated into specific neonatal causes			✓									
Community Ownership and Partnership	**Promotion / communication**	Communication materials only in French		✓										
		No communication strategy in place										✓		
		Lack of information on newborn care												✓
Community Ownership and Partnership	**Awareness**	Lack of community awareness (e.g. of treatment process, care-seeking, available care and rights)	✓	✓					✓	✓	O		K, G	
		No specific efforts to increase the awareness of the general public, adolescent girls, pregnant women and young couples of the					✓						B	

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
Community Ownership and Partnership		benefits of timely recognition of signs and early health seeking for sick newborns												
	Care-seeking and referral	Females have limited mobility (and say in decision-making) and males may not be available all the time that care should be sought							✓		A			
		Poor health seeking behaviour in community									A			
		Poor referral system and linkages between facility and community									A		B	
	Barriers / challenges faced by mothers	Socio-cultural barriers	✓		✓						A			
		Delay in recognition of danger signs and prompt referral									A			
		Transport available but not utilized									O			
		Illiteracy		✓										
		Loss of wages									O			
		Privacy												

Healthy System Building Block	Category	Bottlenecks	Africa						Asia					
			Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda	Afghanistan	Bangladesh	India	Nepal	Pakistan	Vietnam
											O			
		Communities suffer due to increasing costs of IV funds, antibiotics and other cost incurred											G	
		Lack of social security system for poor											G	
	Access	Inability to / limited access to services at all levels	✓						✓					
	Community involvement and mobilization	Poor involvement of men	✓	✓	✓		✓				✓			✓
		Poor engagement of community		✓									A,K, P	✓
		Successful community mobilization models not available / limited community mobilization									✓ O		S	

Appendix E: Solutions for inpatient care for small and sick newborns

Inpatient Care for Sick and Small Newborns						
Health System Building Block	Africa					
	Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda
Leadership and Governance	• Revise the IMCI module will take better account of the newborn	• Strengthening of structures in equipment and organization of hospital care for small children / with low birth weight as recommended • Capacity building of staff in extra care to sick newborns and small / low birth weight • Extension of hygiene standards to the level of structures	• Building and reorganisation of facilities • Review the guideline/strategies and include medical social guidelines	• No solutions proposed	• Create enabling environment with targeted advocacy • Promote effective Coordination at all levels of care • Making guidelines widely available in Primary, secondary and tertiary facilities • Strengthening the quality assurance teams to monitor and supervise • Full dissemination of all relevant guidelines • PAN / NISONM to support the process	• No solutions proposed

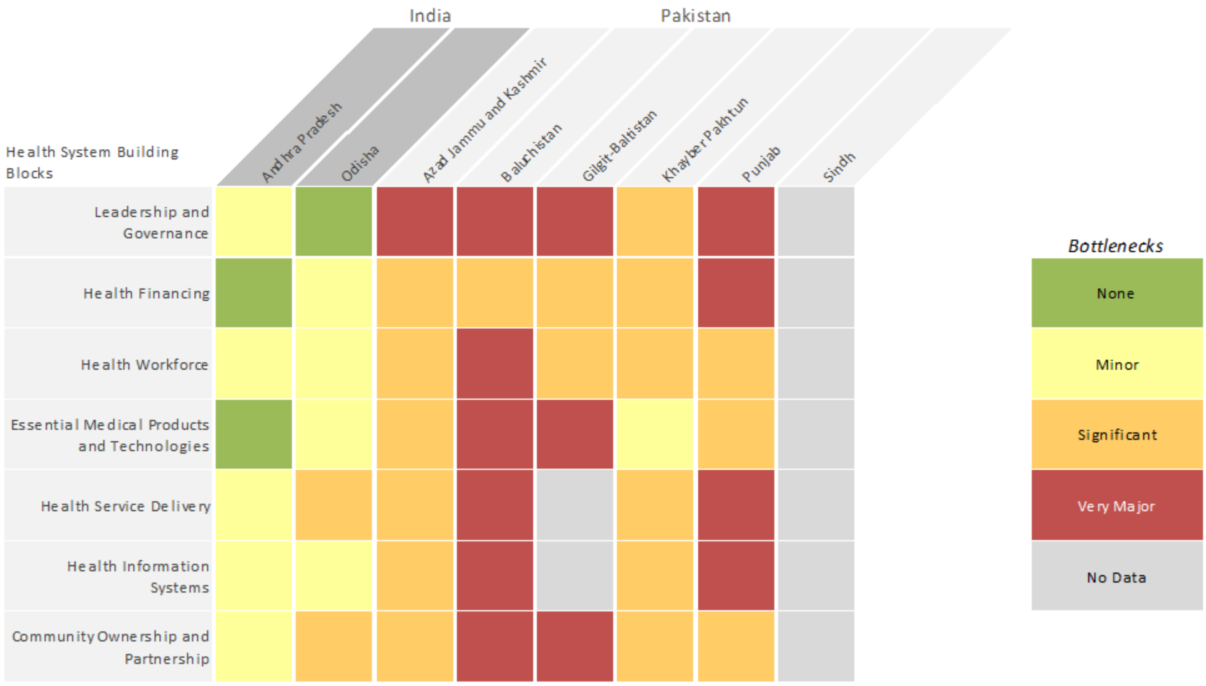
Inpatient Care for Sick and Small Newborns						
Health System Building Block	**Africa**					
	Cameroon	**DRC**	**Kenya**	**Malawi**	**Nigeria**	**Uganda**
Health Financing	• Advocacy for the mobilization of funds for the care of the newborn	• Advocacy to increase government subsidy • Creation and expansion of mutual health	• Increase resource mobilisation and prioritise needs • Alternative funding mechanism	• No solutions proposed	• Health insurance for out of pocket payment with emphasis on community based health insurance • Strengthen logistics management system (appropriate forecasting, quantification based on periodic needs assessment)	• No solutions proposed
Health Workforce	• Initial and continuing training of health personnel in the care of the newborn	• Integration of competency-based training at the initial training • Policy affection balanced staff	• Recruitment and redistribution • Scale up the in-service training and update pre-service training	• No solutions proposed	• Mapping of health worker • Remuneration and Motivation for rural posting	• No solutions proposed

Inpatient Care for Sick and Small Newborns						
Health System Building Block	Africa					
	Cameroon	DRC	Kenya	Malawi	Nigeria	Uganda
		• Capacity building of staff • Extension of the FBR			• Fast track the implementation of task shifting policy • Strengthen / support periodic competence based training (mandatory CMEs of categories of health workers)	
Essential Medical Products and Technologies	• Plea to include oxygen on the essential drug list • Equipping health facilities with oxygen extractors • Improve inventory management	• Update the LNME • Advocacy for increased funding and strengthening of SNAME	• Capacity building of personnel and streamline the procurement	• No solutions proposed	• Implementation of essential medicine policy to ensure enlisted commodities and medicines are available and accessible at service delivery points • Strengthening of logistic management systems	• No solutions proposed

Inpatient Care for Sick and Small Newborns						
Health System Building Block	**Africa**					
	Cameroon	**DRC**	**Kenya**	**Malawi**	**Nigeria**	**Uganda**
					• Ensure Abuja declaration of 15% allocation for health budget	
Health Service Delivery	• See above	• Extension of therapeutic protocols • Advocate for funds supervision • FBR	• Update recommended government building plans • Increase the number of health facilities	• No solutions proposed	• Decentralization of in- patient neonatal care: Sick but Not critically ill newborns can be managed at primary health and community settings (home based care) • Mother friendly neonatal in - patient facilities should be encouraged	• No solutions proposed
Health Information System	• See above	• Definition of indicators for newborn patients and their	• Develop neonatal registers • Ensure data is disaggregated	• No solutions proposed	• Support dissemination and utilization of health information materials	• No solutions proposed

Inpatient Care for Sick and Small Newborns						
Health System Building Block	**Africa**					
	Cameroon	**DRC**	**Kenya**	**Malawi**	**Nigeria**	**Uganda**
		integration in the NHIS • Extension sheets reviewing neonatal deaths • Extension and auditing of perinatal deaths				
Community Ownership and Partnership	• No solutions proposed	• Translation of MNCH communication materials in local languages • Increased awareness for men's involvement • Creation and expansion of mutual health • Implementation of OAC for women's literacy	• Health promotion • Community involvement	• No solutions proposed	• Promotion of Male involvement in newborn care including KMC • Increase the public enlightenment on sick newborn signs and importance of early health seeking for the sick newborn	• No solutions proposed

Appendix F: Subnational grading of bottlenecks for inpatient care of small and sick newborns



Appendix G: Literature search strategy for bottlenecks paper on inpatient care of small and sick newborns

For the background section, we used the following search terms in Pub Med. Limits were applied and only relevant articles were retrieved.

Newborn

(neonat* OR newborn* OR new-born* OR infant, newborn/ OR infant, low birth weight/ OR infant, small for gestational age/ OR infant, very low birth weight/ OR infant, extremely low birth weight/ OR infant, premature/ OR infant, extremely premature/)

AND

Oxygen

(Oxygen therapy OR o2 therapy OR continuous positive airway pressure OR CPAP or nasal prong or nasal cannula* OR head box or (oxygen or o2))

AND

Enteral/intragastric feeding

(Nasogastric feed* OR orogastric feed* OR oro-gastric feed* OR naso-gastric feed* OR enteral feed* OR enteral nutrition OR gavage feed*)

AND

IV fluids

(Maintenance fluid* OR IV fluid* OR intravenous fluid* OR supplemental fluid* OR infusion*)

For the discussion section we searched the following terms in pub med and google. Only relevant articles were retrieved.

Health Financing

(Health) AND (financial access OR financial barrier OR out-of-pocket payment OR user fees OR conditional cash transfers OR cash benefits OR performance based incentives OR voucher OR reimbursement of transport costs)

Budget allocation

Innovative funding

Social health insurance

Universal health insurance

Community based insurance

National health insurance

Health workforce

(Heath worker OR staff) AND (pre-service training OR in-service training OR recruitment OR recognition of midwifery staff OR task-shifting OR training OR performance incentive OR retention OR contracting out OR increase in availability OR skill mix OR remuneration OR salaries)

Community health workers

Task shifting

Skills based training

Neonatal nursing

Competency based training

Community:

(Health) AND (information education communication OR community mobilization OR utilization OR sensitization OR male involvement)

(Health) AND (education) AND (leaders OR women)

Community awareness

Linkages

Care-seeking

Women's group

Male involvement

Behavior change communication (BCC)

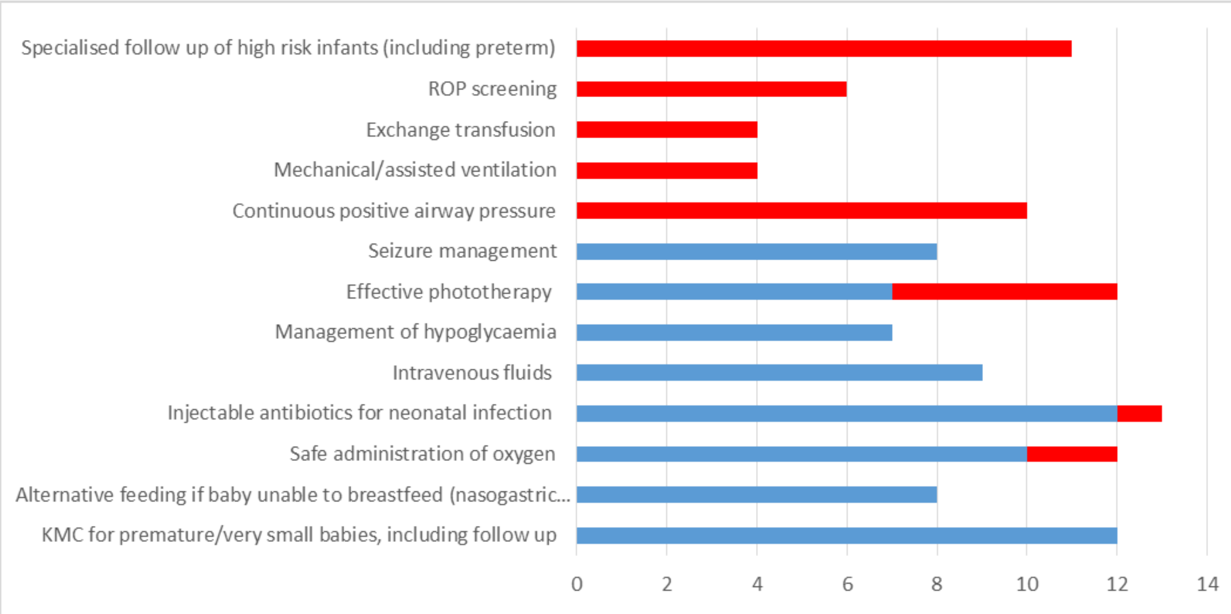
Community and facility linkages

Community engagement

Appendix H: Summary of notes from expert focus group on levels of inpatient care for small and sick newborns

Intervention	Comments/discussion
Thermal care	Almost universal consensus that thermal care should be available and emphasised at all levels. For inpatient care combination of warmed cots, KMC, incubator will need to be considered.
PPROM	All agreed that this is important to emphasise as a maternal intervention, but was not focus of discussion due to the timing of the intervention (before birth).
Antenatal corticosteroids	All agreed that this is important to emphasise as a maternal intervention, but was not focus of discussion due to the timing of the care (before birth).
Alternative feeding if baby unable to breastfeed (cup feeding and nasogastric tube feeding)	The original signal function only included cup feeding, but the group agreed that nasogastric feeding should be included as part of the signal function.
Safe oxygen therapy	Long discussion on safe oxygen and the need for the signal function to outline pulse oximetry, blenders and humidifiers and consistent O2 supply. Point made that need to stress importance of safe administration, just because a facility have O2 does not mean the facility is safe and ready to provide oxygen for newborns.
Management of hypoglycaemia	Particularly focused on glucose measurement etc.
Intravenous fluids	Safety and laboratory support.
Effective phototherapy	Management of bilirubin levels.
Intravenous antibiotics for the treatment of newborn infections	Sepsis management with infection treatment (IV) – challenges exist for IV antibiotics for week long courses/ two weeks and will need to be able to finish the course.
Kangaroo mother care, including follow up	Important that the signal function captures the facility readiness to provide follow up structures as well as the inpatient components of KMC
Management of seizures	Eg. phenobarbitone and associated care
Total parenteral nutrition (TPN)	General agreement that this should not be a signal function but formed important part of the discussion.
Continuous positive airway pressure (CPAP)	Many felt that although CPAP is becoming increasingly available, there was still a need for caution on scaling up without due attention to safety.
Mechanical ventilation	Require significant associated support and potential for long term damage means safety is critical.
Surfactant therapy	Concerns this was prohibitively expensive for many settings.
Retinopathy of prematurity (ROP) screening	Few settings able to do this, but would be important for higher level facilities to build into their care of preterm given the importance of ROP as a cause of preventable blindness.
Bronchopulmonary dysplasia screening	This was mentioned but most felt not feasible or realistic as a signal function.
Head ultrasound	Mentioned but not discussed in detail.
Exchange transfusion	Many noted that CEmOC facilities can do blood transfusion but this should not be automatically assumed that these same facilities can carry out transfusions for newborns.
Haemodialysis	This was mentioned but most felt not feasible or realistic as a signal function.
Cooling	Group participants felt evidence for this strong, but still a relatively new intervention in higher income settings.
Mechanical ventilation	Many felt very few facilities will be able to do this in many low income settings
Specialised follow up of the small and sick newborn	The group emphasised the importance of this component of offering inpatient care and that services need to think about how to build this into their facility based care as part of their service readiness.

Final list of interventions for inaptient care of small and sick newborns showing number of votes by level of care



Red for interventions that were classified as more complex.

Appendix I: Matrix of structural components for inpatient care of small and sick newborns

For excel version available online see online supplementary document available from: http://www.jogh.org/documents/issue201801/jogh-08-010702.htm

Labour and Delivery Room		
Infrastructure	**Equipment**	Drugs
	General newborn equipment	
Access to drinking water (for staff and patients)	Back up generator 25-50 KVA capacity (may be shared with other units)	See specific drugs list
Access to first stage labour room and postnatal room	Blood pressure apparatus (sphygmomanometer)	
Area for newborn resucitation	Blood pressure accessories including neonatal sized blood pressure cuff (sizes 1-5)	
Clean storage space for supplies (linen and general equipment)	Blood sugar glucose dipsticks	
Communication infrastructure (telephone, internet or radio access (may be shared with other units))	Bowls (preferably polypropylene)	
Consistent, uninterrupted 24 hour stabilised power supply	Computer (may be shared with other units)	
Dedicated space for labour and delivery only	Cot/bassinet/bayonets on castors	
Fan or air conditioning	Delivery beds (for mothers)	
Health management information system (shared with other units)	Delivery packs	
Heating arrangements	Doppler	
Lighting to ensure good illumination day and night	Dressing trolley (or equivalent)	
Consistent oxygen source/supply	Dressing trays/procedure trays (or equivalent) (sterile and non-sterile)	
Midwives station/charting or staff work area	Emergency trolley (or equivalent)	
Sufficient infrastructure for privacy for mothers, including curtains	Endotracheal tubes	
Toilet or latrine for patients and visitors	Episiotomy scissors	
Toilet or latrine for staff	Fetal stethoscope	
Water supply (uninterrupted) (for hand washing, cleaning etc.)	Flashlight/torch with spare batteries	
Waiting area for visitors/family	Forceps (large and medium)	
24 hour service availability	Gauze	
	Gauze bandages	
	Glucometer with test strips	
	Heel lancet	
	Infusion stands	
	Infusion kits	
	IV cannula 22G, 24G, (25G, 28G rarely used)	
	Kidney bowls (polypropylene, stainless steel) 825ml	
	Magills forceps	
	Manual vacuum extractor	
	Measuring tape (preferably vinyl coated)	
	Mucus extractor	
	Nasogastric feeding tubes 3.5-10 with caps	
	Oxygen tubing	
	Paediatric infusion set (60 drops per ml burette)	
	Partograph	
	Recharger for batteries	
	Refridgerator (for drugs etc)	
	Scissors	
	Speculum	
	Sterile gauze	
	Sterile needles (19-26 gauge) or butterfly set (23-25 gauge)	
	Sterile syringes (small sizes 0.5, 1ml, 2ml, 5ml, 10ml, 20ml)	
	Sterile tissue forceps	
	Sterile drapes	
	Stethoscope (neonatal)	
	Suction pump (portable, electrical with accessories)	
	Suction pump (manual, non-electric power dependent)	
	Suture set (needle and materials)	
	Swabs and/or cotton wool balls	
	Vital sign monitors (NIBP, HR, SpO2, ECG,, RR, Temp) with accessories	
	Wall clock/timer with second hand	
	Weighing scales for newborns (preferably with 5-10g increments)	

Infection Prevention and Control		
Access to laundry facilities	Alcohol-based hand rub	
Areas for hand washing	Antiseptics (e.g. chlorhexidine 7%, ethanol, povidone-iodine, chlorhexidine gluconate 4% gel, aqueous chlorhexidine 0.05% and 0.2%).	
Area for cleaning and disinfecting supplies and equipment	Autoclave (or equivalent sterilisation equipment can be shared with other units)	
Autoclave room or sterilization space (can be shared with other units)	Contaminated waste bin (leak proof)	
Hand washing stations/sinks	Decontamination container	
Incinerator (eg. burn in incinerator, off-site incineration can be shared with other units)	Disinfectant solutions (e.g. chlorine bleach)	
Sterilisation space (eg.space for dry heat, steam, electric boiler or steamer or non-electrics with cover for boiling and steaming & drum and stand) (can be shared with other units)	Eye shields	
Storage space for soiled utility	Gloves (disposable)	
Ventilation	Gloves (sterile)	
	Gloves (elbow length heavy duty)	
	Gloves (heavy duty rubber or latex utility gloves)	
	Hand drying options (paper towels or appropriate hand dryers)	
	Iodine	
	Instrument sterilizer	
	Mayo stand (or equivalent) on castors	
	Nail brushes or sticks	
	Non-sterile protective clothing (e.g. plastic aprons)	
	Pictorial hand washing instructions	
	Regular trash/waste bin	
	Receptacle for soiled linen	
	Sharps containers (puncture proof)	
	Sluice	
	Soap for handwashing	
	Surgical masks, drapes and cap and boots for procedures	
	Umbilical vein catheters sizes 3.5 and 5 (where expertise available)	
Essential Newborn Care		
As per general and infection control infrastructure for labour and delivery room	As per general equipment and infection control items for labour and delivery room	See specific drugs list for eye ointment and Vitamin K
	Clean blankets, towels and linen (for drying baby)	
	Disposable diapers/nappies	
	Newborn hats/caps (including preterm sizes)	
	Newborn mittens, socks	
	Sterile scissors and/or sterile blade to cut cord	
	Umbilical cord clamp (sterile ligatures or clamp of Barr) or cord ties/sterile thread	
Immediate and Exclusive Breastmilk Feeding		
As per general and infection control infrastructure for labour and delivery room	As per general equipment and infection control items for labour and delivery room	
Expression space/expressing room and storage for expressed breastmilk (see also sick newborn space)	Educational information on breastfeeding for mothers (e.g. written and pictoral information, support classes or groups, posters)	
Space/allowance for patient privacy for mothers		
Neonatal Resuscitation		
As per general and infection control infrastructure for labour and delivery room and essential newborn care	As per general equipment and infection control items for labour and delivery room and essential newborn care	
Newborn emergency space for resuscitaire/newborn resuscitation	Airway suction apparatus (suction bulb manual, mechanical or electrical)	
	Bag self inflating (neonatal size, ideally with filter)	
	Neonatal sized face masks (size 0-1)	
	Nasal prongs 1mm and 2mm (if nasal prongs not available use nasal catheter (8-F and 6-F sizes)	
	Neonatal sized pulse oximetry probes/sensors for oxygen saturations	
	Mucus extractor	
	Oxygen humidifiers	
	Oxygen low flow device	
	Oxygen flow splitter for newborn	
	Oxygen tubing	
	Resuscitation mannequin (for practice)	
	Resuscitaire (with heat source)	
	Suction catheters size 5, 8, 10, 12 & 14 (sterile disposable)	
	Pulse oximeter	
	T-piece resuscitator (only where expertise available)	
	Wall charts/action sequences for neonatal resuscitation (e.g. HBB flowchart)	

PMTCT		
As per general and infection control infrastructure for labour and delivery room	As per general equipment and infection control items for labour and delivery room and essential newborn care	See specific essential drugs table, protocols may vary between settings
See laboratory section - access to infrastructure for HIV testing equipment and screening for congenital TB		
Documentation for newborn unit		
GUIDELINES AND/OR PROTOCOLS for the following:		
CEmOC and BEmOC guidelines		
Classification of breathing difficulty and SpO2 thresholds		
Cleaning of instruments and equipment		
Essential newborn care guidelines		
Infection prevention and control guidelines for the labour and delivery unit and standard precautions		
Management of pregnancy and childbirth (Integrated management of pregnancy and Childbirth - IMPAC)		
Management of pregnancy and newborn complications		
Newborn resuscitation guidelines		
National immunisation schedule		
PMTCT guidelines, including vaccination schedule		
Referral and transfer to neonatal unit		
Standards on immediate and exclusive breastfeeding		
Use of radiant warmers		
CHECKLISTS		
Cleaning schedule and/or daily cleaning checklist		
Drug inventory		
FOR EACH NEWBORN		
APGAR		
Birth certification papers		
Newborn screen filter cards (per national protocol)		
General birth records/notes (ongoing medical care)		
Health insurance form (if relevant)		
Immunisation cards/weight cards		
ID labels		
Laboratory request forms		
Referral forms (if needed)		
GENERAL REGISTERS/LOG BOOKS		
Birth registration (or access to)		
Cause of death certificates		
Death/mortuary register		
General register for labour and delivery ward		
Newborn death stillbirth audit		
Referral register		
Postpartum ward register		
PMTCT labour and delivery register		
Guidelines protocols on vaccination schedule for HIV exposed infants		

Place for Small and Sick Newborn Care		
Infrastructure	**Equipment**	**Drugs**
General for neonatal unit (service availability 24/7)		
24 service availability	Adhesive strapping for peripheral lines (or IV film dressing)	See drugs list
Access to drinking water (for staff and patients)	Baby nappies/diapers napkins	
Area for preparing IV drugs and fluids	Back up generator 25-50 KVA capacity	
Clean storage space for supplies (linen, diapers, clinical supplies and general equipment)	Blood collection tubes (appropriate small size) e.g. vacuum tubes serum and EDTA 3ml and 6ml	
Communication infrastructure (telephone, internet or radio access (may be shared with other units))	Blood collection tube holders	
Consistent, uninterrupted 24 hour stabilised power supply	Blood collection vacuum tube needles 22G	
Dedicated space/room or building (only for small and sick newborns)	Blood pressure apparatus (sphygmomanometer)	
Dedicated workspace for doctor on duty	Blood pressure accessories including neonatal sized blood pressure cuff (sizes 1-5)	
Examination space or area for treatment/stabilisation (allowing for good lighting, warm, with facilities for resuscitaiton and patient privacy)	Blood pressure transducer (for central arterial lines)	
Fan or air conditioning with air filters (to prevent risk of airborne infection)	Bowls (polypropylene)	
Food provision for mothers that are rooming-in/providing KMC (access to)	IV cannula 22G, 24G, 25G 28G	
Health management information system	Capillary sample tubes (glass collection tubes)	
Heating arrangements	Comfortable chairs for mothers	
Lighting to ensure good illumination day and night	Comfortable chairs for staff	
Nurses station/charting or staff work area	Communication equipment (e.g. radio, telephone)	
Rooming in facility with chairs and beds for mothers (see kangaroo mother care)	Computer (for electronic records or data system may be shared with other unit)	
Toilet or latrine for staff	Clean blankets, towels and linen including survival blankets	
Toilet or latrine for patients and visitors	Cots/bayonets for newborns	
Water supply (uninterrupted) (for hand washing, cleaning etc.)	Cot and incubator mattresses	
Waiting area for visitors/family with educational materials/parent information	Dressing trolley (or equivalent)	
	Dressing trays/procedure trays	
	Emergency trolley (or equivalent)	
	Examination lights mobile - 220-12V	
	Flashlight/torch with spare batteries	
	Gauze, swabs, cotton wool	
	Gauze bandages	
	Heated mattresses (e.g. for hot cots)	
	Identification bands	
	Incubators	
	Infantometer, plexi, 105cm	
	Intra-osseous needle (or 22G needles)	
	Kidney bowls (polypropylene, stainless steel) 825ml	
	Long line packs (for percutaneously inserted central lines)	
	Lumbar puncture needles (or 23G needles)	
	Measuring tape (preferably vinyl coated)	
	Mucus extractor	
	Newborn hats/caps (including preterm sizes)	
	Newborn mittens, socks	
	Padded boards and/or splints for neonates and preterm	
	Room thermometer	
	Radiant warmer, fixed height, with trolley, drawers and O2 bottles	
	Recharger for batteries	
	Refridgerator (for drugs etc.)	
	Sample collection tubes (pus, cerebrospinal fluid)	

	Scissors	
	Soft gauze torniquet (or rubber band for scalp vein)	
	Spacer	
	Spatula	
	Sterile equipment stand/dressing tray	
	Sterile gauze	
	Sterile tissue forceps	
	Sterile (low flow) lancet for heel pricks	
	Sterile blades/scissors	
	Stethoscope (neonatal)	
	Suction catheters size 5, 8, 10, 12 & 14 (sterile disposable)	
	Suction pump (portable, electrical with accessories)	
	Suction pump (manual, non-electric power dependent)	
	Suture set	
	Thermometers (preferable digital for newborns that measure 32°C-43°C - must measure below 35.5°C degrees)	
	Umbilical vein catheters sizes 3.5 and 5 (where expertise available)	
	Urinary catheter sizes 5-8	
	Urine bags (paediatric)	
	Urine dipsticks (Multistix)	
	Vital sign monitors (NIBP, HR, SpO2, ECG, RR, Temp) with accessories	
	Wall clock/timer with second hand	
	Weighing scales for newborns (preferably with 5-10g increments)	
	X-ray system (preferably mobile for chest x-ray e.g. for pnuemothorax) (may be shared with other units)	
	X-ray viewer (negatoscope) (may be shared with other units)	
	CT scanner (may be shared with other units)	
	Echocardiography	
	Electrocardiagram (ECG) recorder, portable, with accessories (may be shared with other units)	
	MRI (unlikely to be available in most settings. If available, may be shared with other units)	
	Ultrasound scanner (portable) with appropriate probes (e.g. for cranial ultrasound) (not available in all settings and	
Infection Prevention and Control for the Neonatal Unit		
Access to laundry facilities	Alcohol-based hand rub	
Areas for hand washing	Antiseptics (e.g. chlorhexidine 7%, ethanol, povidone-iodine, chlorhexidine gluconate 4% gel, aqueous chlorhexidine 0.05% and 0.2%).	
Area for cleaning and disinfecting supplies and equipment	Autoclave (or equivalent sterilisation equipment) (may be shared with other units)	
Autoclave room or sterilization space (may be shared with other units)	Contaminated waste bin (leak proof)	
Hand washing stations/sinks	Decontamination container	
Hand drying towels (single use)	Disinfectant solutions (e.g. chlorine bleach)	
Incinerator (e.g. burn in incinerator, off-site incineration) (may be shared with other units)	Gloves (sterile)	
Sterilisation space (e.g. space for dry heat, steam, electric boiler or steamer or non-electrics with cover for boiling and steaming & drum and stand) (can be shared with other units)	Gloves (regular/disposable)	
Storage space for soiled utility	Gloves (heavy duty rubber or latex utility)	
Ventilation	Instrument sterilizer	
	Mayo stand (or equivalent) on casters	
	Nail brushes or sticks	
	Non-sterile protective clothing (e.g. plastic aprons)	
	Pictorial hand washing instructions	
	Regular trash/waste bin	
	Receptacle for soiled linen and diapers	
	Sharps containers (puncture proof)	
	Sluice (may be shared with other units)	
	Soap for handwashing	
	Surgical masks, drapes, gowns and cap for procedures	

Neonatal Resuscitation on neonatal unit		
As per general and infection control infrastructure for small and sick newborn space	As per general and infection control equipment for small and sick newborn space	
See oxygen adminstration for other items	Bag and mask self inflating (neonatal size, ideally with filter)	
	Oropharyngeal airway/guedel airway	
	Neonatal sized face masks (size 0-1)	
	See oxygen adminstration for other items	
Kangaroo Mother Care (KMC) including follow up		
As per general and infection control infrastructure for small and sick newborn space	As per general and infection control equipment for small and sick newborn space	See drugs list for supplements, vitamins etc.
Dedicated, separate room or space for mothers to room in (KMC room/ward)	Beds for mothers (lateral position) with curtains for privacy	
Private washing areas and toilet for mothers	Cabinets for mothers	
Food provision for mothers/area for preparation of food	Caps/hats for small babies	
Sufficient space for mothers to store personal items, comfortable chairs and privacy	Comfortable chairs for mothers	
	Insecticide treated bednets for KMC mothers (in malaria endemic areas)	
Alternative feeding if baby unable to breastfeeding (cup & nasogastric feeding)		
As per general and infection control infrastructure for small and sick newborn space	As per general and infection control equipment for small and sick newborn space	See drugs list for supplements, vitamins etc.
Area or room for breastmilk expression	Adhesive tape/strapping for NG tubes	
Milk room/area for preparing milk feeds and storage of expressed breastmilk	Bottles, teats, dummies (as appropriate for feeding guidelines)	
	Breast pumps (battery powered)	
	Breastmilk subsitute (only for babies with mothers unable to express mik)	
	Collection containers (for expressed breastmilk)	
	Feeding cups and spoons/paladai/feeding syringes	
	Lithmus paper/testing strips (or equivalent)	
	Nasogastric feeding tubes 3.5-10 with caps	
	Educational information on breastfeeding for mothers (e.g. written and pictoral information, posters)	
	Refrigerator and freezer (for milk storage only)	
	Sterile feeding syringes (2.5ml, 5ml, 10ml)	
	Stethoscope	
	Utensils and containers for preparing milk feeds especially graduated measuring jug/cup	
Safe administration of oxygen (including equipment for resuscitation)		
As per general and infection control infrastructure for small and sick newborn space	As per general and infection control equipment for small and sick newborn space	See drugs list
Consistent oxygen source/supply (e.g. oxygen concentrators)	Apnoea monitor	
	Bag and mask self inflating (neonatal size, ideally with filter)	
	Head box (optional)	
	Mucus extractor	
	Nasal prongs 1mm and 2mm (if nasal prongs not available use nasal catheter (8-F and 6-F sizes)	
	Neonatal sized face masks (size 0-1)	
	Neonatal sized pulse oximetry probes/sensors	
	Oxygen blenders	
	Oxygen humidifiers	
	Oxygen low flow device	
	Oxygen flow splitter for newborn	
	Oxygen tubing	
	Pulse oximeters (bedside)	
	Resuscitation mannequin (for training and practice)	
	Suction bulbs	
	Suction catheters size 5, 8, 10, 12 & 14ch	
	Suction pump (portable, electrical with accessories)	
	Suction pump (manual, non-electric power dependent)	

Intravenous fluids and management of hypoglycaemia		
As per general and infection control infrastructure for small and sick newborn space	As per general and infection control equipment for small and sick newborn space	See drugs section for specific IV fluid preparation
See laboratory section	Butterfly sets (22-25 gauge)	
Separate area/clean space for preparing IV fluids (can be the same area as for preparation of IV drugs)	Glucometer	
	IV tubing/infusion set (neonatal giving set) with burette 100-150ml, sterile, single use	
	IV infusion stands on castors	
	Sterile needes (19-26 gauge) or butterfly set (23-25 gauge)	
	Sterile syringes (small sizes 0.5, 1ml, 2ml, 5ml, 10ml, 20ml)	
	Stopcocks 2 or 3 way	
	Syringe driver/syringe pumps 10, 20, 50ml (single phase)	
	Rapid blood sugar testing strips/paper reagent strips or equivalent	
Injectable antibiotics for neonatal infection		
As per general and infection control infrastructure for small and sick newborn space	As per general and infection control infrastructure for small and sick newborn space	See drugs section for specific antibiotics, including gentamicin, ampicillin and fluids for dilution
Lab infrastructure for septic screening (blood culture, Full blood count, C-Reative Protein) (see lab)	See general equipment and specific equipment for IV fluids	
Separate area/clean space for preparing IV drugs (can be the same as area for IV fluids)		
Effective Phototherapy		
As per general and infection control infrastructure for small and sick newborn space	As per general and infection control equipment for small and sick newborn space	
See laboratory section for bilirubin levels (or trancutaneous bilirubinometer on ward)	Eye patches/eye shields for baby	
	Exchange transfusion sets	
	Icterometer	
	Irradiance meter/spectro-radiometer	
	Phototherapy lamps/units with fluorsecent tubes (high intensity) or LED phototherapy	
	Spare fluorescent tubes	
	Trancutaneous bilirubinometer	
	White linen for babies on phototherapy for cot and to cover unit	
Seizure Management		
As per general and infection control infrastructure for small and sick newborn space	As per general and infection control equipment for small and sick newborn space	See drugs section for emergency drugs including phenobarbital
See laboratory section		
Continuous Positive Airway Pressure and Assisted/Mechanical Breathing		
As per general and infection control infrastructure for small and sick newborn space	As per general and infection control equipment and safe oxygen therapy equipment for small and sick newborn spac	See drugs section
See laboratory section	CO2 detector	
	Chest drain set	
	CPAP driver system (standard or bubble CPAP) with accessories (may vary dependent on CPAP system used)	
	Distilled water	
	Drainage tubing and under water seal drainage bottle plus accessories	
	Endotracheal tubes (disposable cuffed or uncuffed), sizes 2.0, 2.5, 3.0 and 3.5	
	Endotracheal tube introducers	
	Infant laryngoscope set with spare bulb and batteries	
	Infant laryngoscope (0,1 blades)	
	Large forceps (e.g spencer wells)	
	Laryngoscope light bulb (spare)	
	Oxygen air blenders	
	Pump suction, portable, bottle with accessories	
	Nasogastic suction tubes 3.5, 5, 8, 10	
	Respirator/ventilators plus accessories	
	Portable patient monitors	
	Transilluminators	

Blood Transfusion for Newborns		
Blood bank (see lab and blood bank for specifics)	Neonatal blood transfusion set	See essential drugs list
	4-way stopcock for umbilical venous line	
	Exchange transfusion sets	
	Portable monitors	
Treatment and screening for retinopathy of prematurity		
As per general and infection control infrastructure for small and sick newborn space	As per general and infection control equipment and safe oxygen therapy equipment for small and sick newborn spac	Dilating eye drops (tropicamide 0.5% + phenylepherine 2.5%)
Opthalmology service (does not need to be 24 hour)	Indirect opthalmoscope (with small pupil adjustments) x1 per neonatal unit	Local aneasthetic eye drops (proparacaine 0.5%)
	Condensing lenses 20D and 28D for indirect opthalmoscope	Artifical tear drops - for lubrication during procedure
	Neonatal lid speculums (Alfonso)	Antibiotic drops (moxifloxacin/betadine) - at end of procedure
	Scleral depressors (Schoket/wire vectis)	
	Solution for corneal wetting (e.g. Ringer's lactate)	
	Newborn pulse oximter	
	Laser (can be shared between more than one facility/service)	
	Portable diode/green laser with indirect delivery system (can be shared between more than one facility)	
	Laser goggles	

Documentation		
GUIDELINES AND/OR PROTOCOLS for the following:		
Admission guidelines		
Blood transfusion and exchange transfusion procedural guidelines		
Classification of breathing difficulty and SpO2 thresholds and protocols for oxygen therapy and monitoring		
Cleaning of instruments and equipment		
Discharge and follow up		
Disease specific treatment guidelines (e.g. malaria, tetanus, hepatitis, Zika)		
Drug doses, dilutions and preparations for the neonatal unit		
Gestational age assessment		
IMNCI		
Inborn and outborn infants		
Infant feeding for the neonatal unit, including enteral feeding volumes by weight and age, IV fluid volumes		
Infection prevention and control for the neonatal unit		
Kangaroo mother care		
Management of gastric residuals		
Management of newborn convulsions and spasms		
Medication formulary (with neonatal doses) or prescribing guideline		
Neonatal practical procedure guideline or advanced neonatal guidelines		
National immunisation schedule		
Parental/family visitation and access		
Referral		
Thermal protection, including bathing		
Treatment of HIV on the neonatal unit and vaccination schedule for HIV exposed infants		
Treatment thresholds for phototherapy and exchange transfusion		
Use of incubators and radiant warmers		
Visitation		
Use of phototherapy units (eg. positioning of phototherapy lamps, baby etc.)		
CHECKLISTS and JOB AIDS		
Cleaning schedule and/or daily cleaning checklist		
Discharge checklist		
Drug inventory		
Emergency trolley checklist		
Fluid volumes and medications		
Follow up		
Prescription charts		
DOCUMENTATION FOR EACH INPATIENT		
Discharge forms		
Fluid balance and feeding chart (fluid input and output)		
General clinical records/notes (ongoing medical care)		
Growth chart (weight, length, head circumference) (premature and infant charts)		
Health insurance form (if relevant)		
ID labels for inpatients		
Lab request forms		
Observations charts for recording of vital signs		
Prescription chart		
Referral forms (if needed)		
Tetanus observation charts		
Transfusion surveillance/vital signs document (for blood transfusions)		
GENERAL REGISTERS/LOG BOOKS		
Birth registration		
Cause of death certificates		
Civil Vital registration system		
Death/mortuary register		
Discharge register		
Kangaroo mother care register		
Newborn care unit register		
Newborn death stillbirth audit		
Referral register		
Reporting forms for adverse events (including blood transfusion reaction reporting)		
Vaccination record/register		

Referral Service		
Infrastructure	**Equipment**	**Drugs**
Vehicle maintainance infrastructure (or access to)	Adhesive tape	IV fluids
Communication for transport vehicle (e.g. radio)	Antiseptic solution	Drugs/medicine (any medicine newborn is taking if receiving a dose during trip)
Fuel source/system	Blankets/linens	Expressed breastmilk (if baby is able to feed or, preferably, mother with newborn)
	Butterfly set or cannula	
	Cotton wool balls and /or guaze	
	Diapers/napkins	
	Fuel for transport vehicle	
	Gastric tubes (size 5, 6, 7, 8)	
	Gloves	
	Hats, socks, mittens (for baby)	
	IV infusion set	
	Resuscitation bag and mask	
	Portable suction apparatus	
	Pulse oximetry	
	Oxygen cylinder with flow metre	
	Oxygen cylinder (portable)	
	Nasal prongs/and or nasal catheter	
	Source of warmth	
	Stethoscope	
	Sterile needes (19-26 gauge) or butterfly set (23-25 gauge)	
	Sterile syringes (small sizes 0.5, 1ml, 2ml, 5ml, 10ml, 20ml)	
	Torch with extra batteries and bulb	
	Thermometer	
	Transport incubator(s)	
	Transport vehicle (type may vary by context)	
	Wraps or cloths for kangaroo position	
Documentation		
GUIDELINES/PROTOCOLS		
Referral guidelines		
Distance to nearest intensive care and special care unit and contact number of centre with advanced care		
DOCUMENTATION		
Detailed documents with patient notes (drugs and other treatment given before transport)		

Human Resources

Provider

NUMBERS OF EACH PROVIDER NOT PROVIDED HERE BUT STAFF RATIOS SHOULD BE ESTABLISHED BASED ON NATIONAL GUIDELINES BY PATIENT CASELOAD. JOB DESCRIPTIONS SHOULD BE AVAILABLE FOR ALL STAFF.

Administration staff	Lactation counsellor/infant feeding coordinator	Pediatrician
Anesthetist	Midwifery professional (eg enrolled midwife, degree, diploma)	Pharmacist
Biomedical engineer	Nursing professsional	Pharmacy technicians/assistants
Cleaners	Neonatal nurse (or nursing/midwifery professionals with specialist training in sick newborn care)	Porters
Community health worker (or equivalent)	Neonatalogist	Psychologist
Driver (transport vehicle)	Nutritionist	Physiotherapist
General medical doctor	Obs/gyne doctor	Radiographer
Health officer/Clinical officer (may be context specific)	Other nursing professionals (e.g. enrolled nurse), nursing assistants or auxillaries	Security staff
Health information technologist/data manager	Other anesthetics staff (e.g. nurse anasthetist, diploma etc.)	Social worker
Lab scientist	Opthalmologist	Speech therapist (or equivalent)
Lab technician	Pathologist	Surgeon

Medicines/drugs

Infrastructure		
Pharmacy service availability 24/7		
Supply management system		
Refridgeration for vaccination		
Refridgeration for other drugs/medicines		
Safe drug storage conditions (protection from moisture, heat, infestation)		
Drug inventory (also in health information section)		
Antiretrovirals (may vary depending on national HIV guidelines)	**Anticonvulsants**	**Emergency Drugs**
Azidothymidine/Zidovudine (AZT) (oral)	Diazepam (oral/NG)	Adrenaline/epinephrine (IV)
Lamivudine	Diazepam emulsion (IV)	Aminophylline
Nevirapine (NVP) (oral)	Midazolam (oral solution)	Atropine (injection)
	Paraldehyde (rectal)	Calcium gluconate 10% (injection)
	Phenobarbital (IV or IM)	Hydrocortisone (injection)
	Phenobarbital (oral)	Magnesium sulphate (IV)
	Phenytoin (IV)	Naloxone (IV)
Analgesics	**Corticosteroids**	**IV Fluids**
Ibuprofen (IV)	Betamethasone (IM)*	Calcium gluconate 10%
Morphine (IV)	Dexamethasone (IM)*	Dextrose 10% with normal saline
Morphine (oral)		Dextrose/glucose 5%
Paracetamol (oral)		Dextrose/glucose 10%
Paracetamol (suppository)		Potassium chloride (KCL) 7.5%, 10%, 15%
Paracetamol (injection)		Sodium bicarbonate
		Sodium chloride 0.9%
		Ringer's lactate
		Water for injection
Anti-malarials	**Vaccines**	
Artesunate (IV or IM)	BCG vaccine	
Artesunate (rectal)	Diptheria	
Arthemeter (IM)	Pertussis vaccine	
Artemisinin-based combined therapy (oral)	Haemophilus influenzae type b (Hib) vaccine	
	Hepatitis B vaccine	
	Oral poliomyelitis vaccine	

Antibiotics	Other drugs	
Amoxicillin (oral suspension)	Aciclovir (IV)	Phosphate and calcium supplements
Amoxicillin (injection)	Acyclovir 3% topical eye ointment	Potassium chloride (1mmol/ml) (oral)
Amikacin	Anti-Rho (D) immune globulin (injection)	Pyridoxine (oral)
Ampicillin (IV or IM)	Caffeine citrate (oral)	Ranitidine (IV)
Ampicillin (oral)	Caffeine citrate (IV)	Ranitidine (oral)
Azithromycin (oral)	Chlorhexidine digluconate 7.1% gel (delivering 4% chlorhexidine)	Rifampicin
Benzathine benzylpenicillin (IM)	Domperidone	Pyrazinamide
Benzylpenicillin (Penicillin G) (IV or IM)	Ethambutol	Sucrose 30% (oral)
Cefalexin (oral suspension)	Ferrous fumerate (oral syrup)	Surfactant (not likely to be available in many settings due to cost)
Cefotaxime (IV or IM)	Folic acid	Tetanus immunoglobulin (HTIG) (IM)
Ceftriaxone (IV or IM)	Fluconazole (IV)	Vitamin B6 (pyridoxine) (IV or IM)
Ciprofloxacin (injection)	Fluconazole (oral)	Vitamin D
Ciprofloxacin (oral)	Furosemide (IV)	Vitamin K1 (Phytomenadione) (IM or IV)
Clindamycin (IV)	Furosemide (oral)	Water based lubricant
Co-amoxiclav (oral suspension)	Glycerin chip	Zinc oxide cream
Co-amoxiclav (injection)	Hepatitis B immune globulin (HBIG)	
Cotrimoxazole (oral)	Human milk fortifier	
Erythromycin (oral)	Insecticide treated bed nets (in malaria endemic areas)	
Flucloxacillin (IV/IM) (cloxacillin)	Lidocaine solution	
Flucloxacillin (oral)	Miconazole cream (or equivalent e.g. gentian violet)	
Gentamicin (IM or IV)	Multivitamin	
Isoniazid (oral)	Nystatin (oral solution)	
Kanamycin	Nystatin cream	
Metronidazole (IV)	Omeprazole (IV)	
Metronidazole (oral)	Omeprazole (oral)	
Penicillin G Procaine (IM only)	Oral rehydration solution	
Procaine benzylpenicillin (IM)	Oxygen supply	
Tetracycline 1% eye ointment		

Laboratories and Blood Bank		
Biochemistry should be able to perform:	**Haemotology should be able to perform:**	**Microbiology should be able to perform:**
Blood glucose (e.g. glucometer and test strips)	Blood typing and cross matching	Culture and sensitivity on samples of blood, pus, cerebrospinal fluid and urine
C-reactive protein (CRP)	Coagulation profile	Cerebrospinal cell count
Electrolytes (urea, sodium, potassium, calcium, magnesium and creatinine)	Coombs test	Gram staining
Serum bilirubin (or transcutaneous bilirubinometers as cheaper alternative)	Full blood count (FBC)/Full blood examination (FBE)	Stool analysis
Cerebrospinal fluid analysis (glucose and protein)	Haemaglobin (e.g. haemacue, haemoglobin colour scale refill kit/starter kit) and or haematocrit testing	
Liver function testing		
Blood gas analysis		
Urine dipstick for urinalysis that measure: pH, proteins, glucose, ketones, blood nitrates, leucocytes		
Glucose 6-phosphate deyrogenase (G6PD) screening		
STI Testing including	**Other important tests:**	
Chlamydia testing	TB testing (tuberculin skin testing, access to Ziehl-Neilsen staining and ideally GeneXpert)	
Enzyme immuno assay (EIA), gonnorhea Ag, kit	Malaria testing (preferabily blood film microscopy as more reliable option than rapid diagnostic tests for neonatal	
Hepatitis B surface antigen (HbsAg)	Glucose 6-phosphate deyrogenase (G6PD) screening	
HIV testing kit	Thyroid function tests	
Syphilis testing		
Blood bank should have facilities to perform:		
Blood typing and cross matching		
Coombs test		
Storage of fresh whole blood, including type 0, Rh-negative blood, packed cells and fresh frozen plasma		
Blood screening for HIV, Hep B, Hep C, Syphilis and malaria		
Blood transfusion guidelines for neonates		

Appendix J: Ethics approval for global survey on levels of inpatient care for small and sick newborns

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LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Observational / Interventions Research Ethics Committee

Ms Sarah Moxon
Research Fellow
Department of Infectious Disease Epidemiology (IDE)
Epidemiology and Population Health (EPH)
LSHTM

16 November 2016

Dear Sarah

Study Title: Defining signal functions for inpatient care for small and sick newborns: A global survey

LSHTM Ethics Ref: 11922

Thank you for responding to the Observational Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Investigator CV	CV Joy Lawn june 2016	30/06/2016	June 2016
Investigator CV	CV_LSHTM_Sarah Moxon_2016	17/08/2016	recent
Protocol / Proposal	Proposal_Defining signal functions for inpatient care of small and sick newborns_FINAL	30/09/2016	final
Protocol / Proposal	Signal functions survey_FINAL_30thSept2017	30/09/2016	draft
Investigator CV	CV_John_Bradley_2page	30/09/2016	current
Investigator CV	HLT WHO cv long	30/09/2016	current
Investigator CV	Olive CocomanCurriculum VitaeSeptember2016	30/09/2016	current
Information Sheet	Participant Information Sheet_FINAL_30thSept2017	30/09/2016	draft
Information Sheet	Example consent form_FINAL_30thSept2017	30/09/2016	draft
Advertisements	Example recruitment email_FINAL_30thSept2017	30/09/2016	draft
Covering Letter	Ethics_signal functions_responses	31/10/2016	1
Investigator CV	TheresaDiazMD_CV_2016	31/10/2016	1
Information Sheet	Example consent form_FINAL_31stOct_2016	31/10/2016	2
Information Sheet	Participant Information Sheet_FINAL_31stOctober2016	31/10/2016	2
Protocol / Proposal	Proposal_Defining signal functions for inpatient care of small and sick newborns_FINAL	31/10/2016	2

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

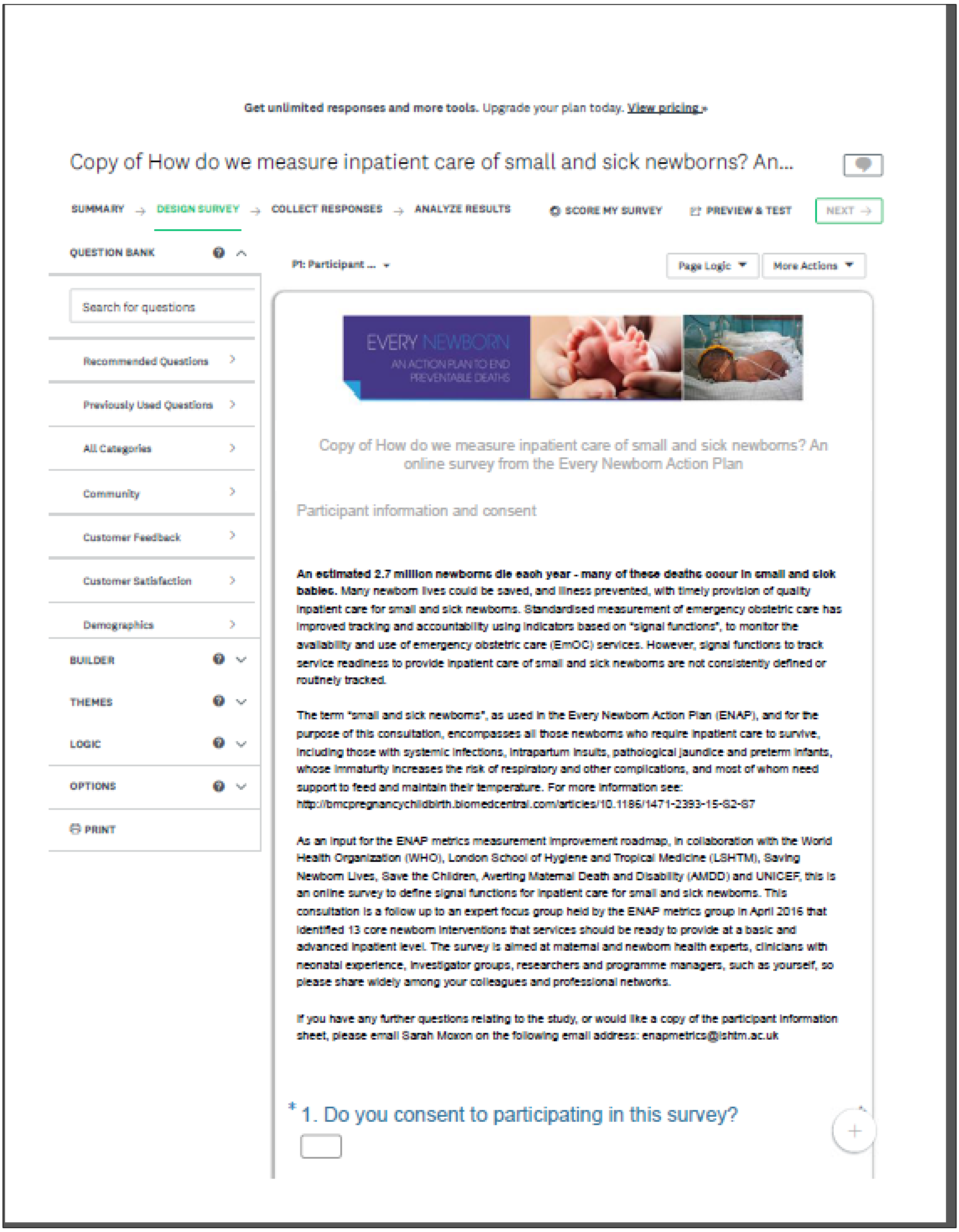
Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Appendix K: Questionnaire for global survey on levels of inpatient care for small and sick newborns



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Background details

* 2. What is your gender?

- Female
- Male
- Other (please specify)

* 3. What is your age?

- 18 to 24
- 25 to 34
- 35 to 44

◯ 45 to 54

◯ 55 to 64

◯ 65 to 74

◯ 75 or older

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About your occupation

* 4. Which of the following best describes your occupation? If you have more than one role, please select all that apply.

☐ Programme management

☐ Research

☐ Technical assistance

- [ ] Clinician (nursing)
- [ ] Clinician (midwifery)
- [ ] Clinician (medical doctor)
- [ ] Allied health professional
- [ ] Charity employee
- [ ] Non-governmental organisation employee

Other (please specify)

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About your experience

* 5. In what country do you currently work?
(If you work in multiple countries, indicate the country in

which you are based)

* 6. How many years have you worked in maternal and newborn health?

0 — more than 50

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* 7. Do have experience in low- and middle- income settings?

- ◯ Yes, all of my experience is in low- and middle-income settings
- ◯ Yes, I have a mix of experience of working in low- and middle-income settings and higher-income settings
- ◯ No, I have only worked in higher-income settings

8. For clinicians only - what type(s) of health facility have you worked in?

- ☐ Public hospital
- ☐ Private hospital
- ☐ NGO or field hospital
- ☐ Public health centre
- ☐ Private health centre

Other (please specify)

9. For clinicians only - in which countries have you practiced clinically?

Afghanistan	◯
Albania	◯
Algeria	◯
Andorra	◯
Angola	◯
Antigua and Barbuda	◯
Argentina	◯
Armenia	◯
Australia	◯
Austria	◯
Azerbaijan	◯

Bahamas

Bahrain

Bangladesh

Barbados

Belarus

Belgium

Belize

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Benin

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Bhutan

Bolivia (Plurinational State of)

Bosnia and Herzegovina

Botswana

Brazil

Brunei Darussalam

Bulgaria

Burkina Faso

Burundi

Cabo Verde

Cambodia

Cameroon

Canada

Central African Republic

Chad

Chile

China

Colombia

Comoros

Congo

Costa Rica

Côte D'Ivoire

Croatia

Cuba

Cyprus

Czech Republic

Democratic People's Republic of Korea

Democratic Republic of the Congo

Denmark
Djibouti
Dominica
Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Estonia
Ethiopia
Fiji
Finland
France
Gabon
Gambia
Georgia
Germany
Ghana
Greece
Grenada
Guatemala
Guinea
Guinea Bissau
Guyana
Haiti
Holy See
Honduras
Hungary
Iceland
India
Indonesia
Iran (Islamic Republic of)
Iraq
Ireland
Israel
Italy
Jamaica

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Japan
Jordan
Kazakhstan
Kenya
Kiribati
Kuwait
Kyrgyzstan
Lao People's Democratic Republic
Latvia
Lebanon
Lesotho
Liberia
Libya
Liechtenstein
Lithuania
Luxembourg
Madagascar
Malawi
Malaysia
Maldives
Mali
Malta
Marshall Islands
Mauritania
Mauritius
Mexico
Micronesia (Federated States of)
Monaco
Mongolia
Montenegro
Morocco
Mozambique
Myanmar
Namibia
Nauru
Nepal
Netherlands

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New Zealand
Nicaragua
Niger
Nigeria
Norway
Oman
Pakistan
Palau
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Poland
Portugal
Qatar
Republic of Korea
Republic of Moldova
Romania
Russian Federation
Rwanda
Saint Kitts and Nevis
Saint Lucia
Saint Vincent and the Grenadines
Samoa
San Marino
Sao Tome and Principe
Saudi Arabia
Senegal
Serbia
Seychelles
Sierra Leone
Singapore
Slovakia
Slovenia
Solomon Islands
Somalia

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South Africa
South Sudan
Spain
Sri Lanka
State of Palestine
Sudan
Suriname
Swaziland
Sweden
Switzerland
Syrian Arab Republic
Tajikistan
Thailand
The former Yugoslav Republic of Macedonia
Timor-Leste
Togo
Tonga
Trinidad and Tobago
Tunisia
Turkey
Turkmenistan
Tuvalu
Uganda
Ukraine
United Arab Emirates
United Kingdom of Great Britain and Northern Ireland
United Republic of Tanzania
United States of America
Uruguay
Uzbekistan
Vanuatu
Venezuela (Bolivarian Republic of)
Viet Nam
Yemen

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Zambia ○

Zimbabwe ○

Other (please specify)

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Copy of How do we measure inpatient care of small and sick newborns? An online survey from the Every Newborn Action Plan

Selecting signal functions for inpatient care of small and sick newborns

Signal functions should be considered as a core list of life-saving facility level services that are aimed at averting the main complications that lead to newborn death and disability.

Care at birth: This is not part of inpatient care for small and sick newborns, but should be available for all babies at birth at all facilities where births take place.

Basic inpatient care for small and sick newborns: This service is part of inpatient care for small and sick newborns. This is similar to what is referred to as special care, or level 2 care, in many higher-income settings. Basic inpatient care signal functions are interventions for small and sick newborns in addition to care provided for all babies at birth.

Comprehensive inpatient care for small and sick newborns: This service is part of comprehensive inpatient care for extremely small and sick newborns. In most settings this will only be available at the highest level of hospitals or facilities. This is similar to what is referred to as neonatal intensive care (NICU), or level 3 care, in many higher-income settings. Comprehensive inpatient care signal functions are interventions for extremely small and sick newborns in addition to all services provided at the basic inpatient care level.

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* 10. Below are a list of signal fur facilities. For each signal function, please indicate whether you think it is an appropriate signal function for
- Care at birth (available for all newborns)
- Basic inpatient care (for small and sick newborns)
- Comprehensive inpatient care (for extremely small and sick newborns) only
- Not a newborn care signal function at all

	Care for all newborns	Basic inpatient care	Comprehensive inpatient care	Not a signal function
Thermal protection	○	○	○	○

Comments

	Care for all newborns	Basic inpatient care	Comprehensive inpatient care	Not a signal function
Essential newborn care (immediate and thorough drying, placing the baby skin to skin, delayed cord clamping, hygienic cord care)	○	○	○	○

Comments

	Care for all newborns	Basic inpatient care	Comprehensive inpatient care	Not a signal function
Immediate and exclusive breastfeeding	○	○	○	○

Comments

	Care for all newborns	Basic inpatient care	Comprehensive inpatient care	Not a signal function
Resuscitation for newborns not breathing spontaneously at birth	○	○	○	○

Comments

	Care for all newborns	Basic inpatient care	Comprehensive inpatient care	Not a signal function
Prevention of mother to child transmission for babies of HIV positive mothers	○	○	○	○

	Care for all newborns	Basic inpatient care	Comprehensive inpatient care	Not a signal function
Comments				
Kangaroo mother care for premature/small babies, including follow-up	○	○	○	○
Comments				
Alternative feeding if baby unable to breastfeed (cup feeding and/or nasogastric tube feeding)	○	○	○	○
Comments				
Safe administration of oxygen	○	○	○	○
Comments				
Intravenous antibiotics for neonatal infection	○	○	○	○
Comments				
Intravenous fluids	○	○	○	○
Comments				
Prevention and management of hypoglycaemia	○	○	○	○
Comments				
Effective phototherapy	○	○	○	○
Comments				
Seizure management	○	○	○	○
Comments				
Continuous positive airway pressure (CPAP)	○	○	○	○

	Care for all newborns	Basic inpatient care	Comprehensive inpatient care	Not a signal function
Comments				
Mechanical/assisted ventilation, including intubation	◯	◯	◯	◯
Comments				
Neonatal blood transfusion	◯	◯		
Comments				
Screening and treatment for retinopathy of prematurity	◯	◯	◯	◯
Comments				
Specialised clinical follow up of high risk infants	◯	◯	◯	◯
Comments				

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Other signal functions for inpatient care of

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Do you think there are other signal functions for inpatient care of small and sick newborns that should be measured?

11. What other signal functions do you think should be considered for basic inpatient care of small and sick newborns?

12. What other signal functions do you think should be considered for comprehensive care of extremely small and sick newborns?

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Further contact with the ENAP metrics research team

There is a chance that we may want to follow up some participants on specific details or invite you to participate in a further consultation. If you would prefer not to be contacted and remain anonymous, you do not have to fill in this section.

* 13. Would you like to be contacted again by the ENAP metrics research team?

- ◯ No, I do not want to be contacted.
- ◯ Yes, I would be happy for the ENAP metrics research team to contact me again.

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Contact details

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14. What is your first name?

15. What is your last name?

16. At what email address would you like to be contacted?

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See how easy it is to create a survey.

NEW PAGE

Appendix L: Research protocol for Malawi mixed methods approach to assessing measurement of care for small and sick newborns in Malawi

A mixed methods approach to assessing measurement of care for small and sick newborns in Malawi

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

REACH Trust

Save the Children.

Study proposal

v. February 2018

Principle investigator team

Primary researcher:
Sarah Moxon (London School of Hygiene and Tropical Medicine (LSHTM))

Co-investigators:
Ireen Namakhoma (Reach Trust, Malawi)
Hastings Banda (Reach Trust, Malawi)

I - ABSTRACT

Of the 2.6 million newborns deaths globally each year, an estimated 18,000 of these deaths occur in Malawi. The main causes are prematurity complications, intrapartum hypoxia and neonatal infections. Preventing these deaths requires quality neonatal inpatient care for babies that are born small and sick. In Malawi, there is limited availability of neonatal inpatient care facilities and facility-based care for small and sick newborns is not consistently measured and tracked. The aim of this research is to assess approaches to measurement of care for small and sick newborns, using quantitative and qualitative methods.

We will use data from a register review from maternity hospitals collected in 2014 as part of a national Emergency Obstetric and Newborn Care (EmONC) assessment and compare this with HMIS (DHIS-2) data from 28 facilities from the same period. We will look at data agreement for select maternal and newborn indicators between the EmONC assessment and DHIS-2 data. Through the quantitative analysis, we will use Bland Altman approach to plot the difference of paired variables versus their average to look at data agreement between the two sources. Where there are significant differences, we will use linear regression to identify potential factors associated with these discrepancies.

We will then use qualitative approaches, including data flow assessment combined with in-depth interviews with data handlers in 8-10 randomly selected hospitals. Through the data flow assessment and in-depth interviews, we will map the data journey from the neonatal care unit to the ministry of health, and gain understanding of the perceptions regarding this data recording and data use process. We will then hold a national level workshop with data stakeholders to explore potential strategies to improve data recording and use. We will use a prefigured thematic analysis (applying an established framework) to analyse the combined data. We will identify organisation, technical and environmental barriers and facilitators, and potential strategies to improve data collection and use.

The learning and implications from this work will inform the refinement of existing measurement tools in Malawi, and contribute to the wider global learning and development of new approaches to measure service readiness for inpatient care for small and sick newborns.

II - BACKGROUND

The first 28 days of life - the newborn period - is the riskiest time in the human lifecycle. In 2016, an estimated 2.6 million babies died during the first month of life globally (1). The main causes of death are direct complications of prematurity (35%), intrapartum events (previously called birth asphyxia) (24%), and infections (23%) (1). Direct complications of preterm birth are now the leading cause of child death worldwide. Many lives could be saved, and morbidity prevented, through a combined health systems approach along the continuum of care, with timely provision of quality inpatient care for small and sick newborns (2). Core components of this care include the provision of warmth, feeding support, safe oxygen therapy and effective phototherapy, including kangaroo mother care as a cornerstone of care for preterm and low birth weight newborns (3, 4). Such care needs to be delivered by health workers with specialist training and skills in a facility with a dedicated ward space equipped to prevent and treat infections. Globally, many newborns do not have access to such care if they were to require it (see Figure 1) (3).

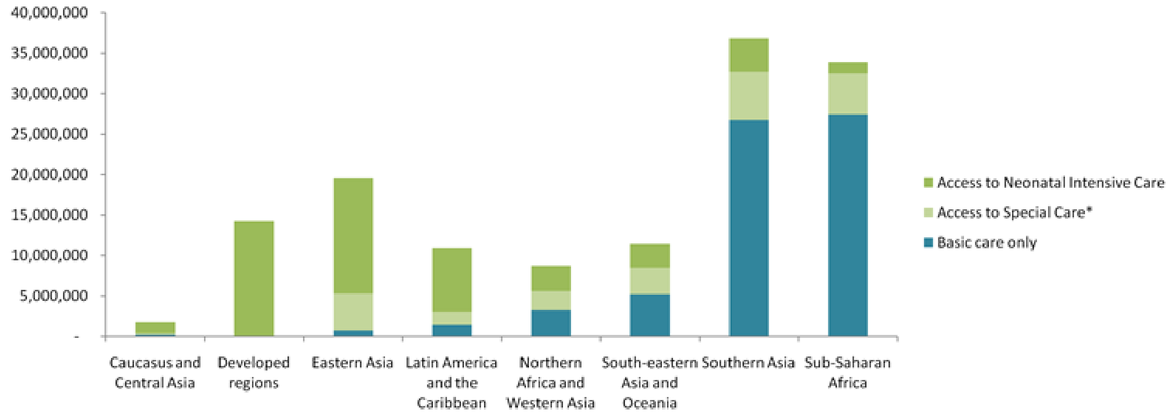


Figure 1. Estimated coverage of neonatal care by region of the world and level of care (from Moxon *et al*, 2015 Inpatient care of small and sick newborns BMC Pregnancy & Childbirth)

Malawi and the *Every Newborn* Action Plan

Malawi is a low-income country that faces numerous health system challenges, including unevenly distributed and poorly resourced health facilities, a lack of trained health workers and a high birth rate. The neonatal mortality rate is 22 per 1000 live births (5). In addition to this, Malawi has the highest preterm birth rate in the world, estimated at 18% of live births (6). Each year an estimated 18,000 of the 2.6 million global newborn deaths occur in Malawi, a significant number of the total global burden.

The Malawi Newborn Action Plan (7) was developed in response to the global Every Newborn Action Plan (8, 9), a multi-partner initiative launched in 2014 with the overall goal of ending preventable newborn deaths and stillbirths by 2030. *Every Newborn* has a specific stream of work on improving measurement, which is co-chaired by LSHTM and the World Health Organisation (*Every Newborn* metrics). Strengthening of existing facility-based systems for the care of vulnerable newborns is the most effective approach for saving newborn lives and is central to achieving *Every Newborn* goals (10). One of the five global *Every Newborn* strategic objectives – to count every newborn (and birth) – underlines the need for improved data and accountability (9, 11). The global *Every Newborn* milestones, linked to a World Health Assembly resolution, have a particular focus on inputs required prior to 2020 and more than half refer to improving metrics for targeting and driving change (8, 9).

The Malawi *Every Newborn* plan focuses on identifying what actions are necessary for newborns to realise their right to survival and well-being and harmonise actions for newborns with other country plans, such as the Safe Motherhood Initiative and Integrated Maternal and Newborn Health plan. Despite numerous challenges, Malawi has made significant efforts to implement initiatives in response to the problems of both maternal and newborn morbidity and mortality. This includes exemplary efforts to institutionalise high impact interventions for small and sick newborns, most notably, their focus on facility based kangaroo mother care (KMC) (12), resuscitation training for health workers though the Helping Babies Breathe (HBB) initiative (13) and development of newborn care protocols. Through implementation of the Malawi *Every Newborn* Action Plan, the intention is to support and track progress to reach national and global targets, including the Family Planning 2020 Initiative and the Global Sustainable Development goals for 2030.

As Malawi began to develop their monitoring strategy for their national newborn plan, increasing attention has been paid to facility level data and data on small and sick newborns. In 2013, the Central Monitoring and Evaluation Division (CMED) of the MOH rolled out the District Health Information System 2 (DHIS2) platform nationally. By 2014 all districts were reporting data for the main HMIS monthly reports, including data on maternity, delivery and newborn care (kangaroo mother care, helping babies breathe, etc). While reporting rates are generally high (>90%) for the standard forms supported by CMED, there are notable gaps in reporting, particularly among the high volume central hospitals, which often do not report. However, as of 2015, CMED and partners have been working to address these reporting gaps and reporting rates by central hospitals are improving.

For countries that are fast developing their newborn health programmes, such as Malawi, *Every Newborn* recognises a unique opportunity to learn from their experience. One approach to learn from Malawi is to consider the existing data system and use both quantitative and qualitative methods to explore data quality and identify data barriers and enablers within the system for improving the data on care for small and sick newborns. Through this process, *Every Newborn* aims to provide learning for newborn health data and programmes globally.

III - JUSTIFICATION

The aims of this project are closely aligned to support Malawi to achieve the goals of their national newborn action plan, especially focused on service delivery and health information systems for small and sick newborns. The learning from this work will inform the refinement of existing measurement tools, and contribute to wider global learning for *Every Newborn* and development of tools and approaches to measure care for small and sick newborns.

The Malawi newborn plan identified specific challenges within the national health information systems, such as ineffective data use, and limited newborn indicators in the routine health management information system. The plan also identified a lack of accountability systems in maternity facilities and limited availability of quality newborn care services, especially for small and sick newborn care.

IV - LITERATURE REVIEW

Existing tools to measure service readiness for inpatient care of small and sick newborns

Delivery of interventions to small and sick newborns requires facilities that are prepared, which is termed as "service readiness". Service readiness refers to the structures (the necessary infrastructure, equipment, drugs and guidelines); and processes (services performed by health professionals with requisite training and skills) that are needed to provide a package of care (14, 15). This requires strong health systems with the capacity to monitor and track service readiness and react appropriately to service needs.

In most low and many middle-income countries (LMIC), there are still very little routine data available on care for sick newborns, especially on service readiness, and the structures that support the care that small and sick newborns receive (11). The data are particularly lacking in settings where access to neonatal special or intensive care is the lowest and where facilities are most in need of targeted efforts to strengthen services and improve the quality of care.

Information on care for small and sick newborns may be collected through multiple systems within a wider health information system (see Figure 2). Notes on clinical care are often found in the hospital admission or care records, but these data are not reported in national health information systems. Human resource databases, financing and logistics managements systems are operational to a different extent in many settings. Most low and middle-income settings still rely on national surveys to supplement information on service readiness and coverage of interventions and on the processes and content of facility-based care. Surveys, notably health facility assessments, are frequently used to capture information on service readiness, and are best suited to measure the number of facilities that are prepared to provide components of the service such as sufficient number of trained staff, equipment availability, spatial organisation and service delivery information.

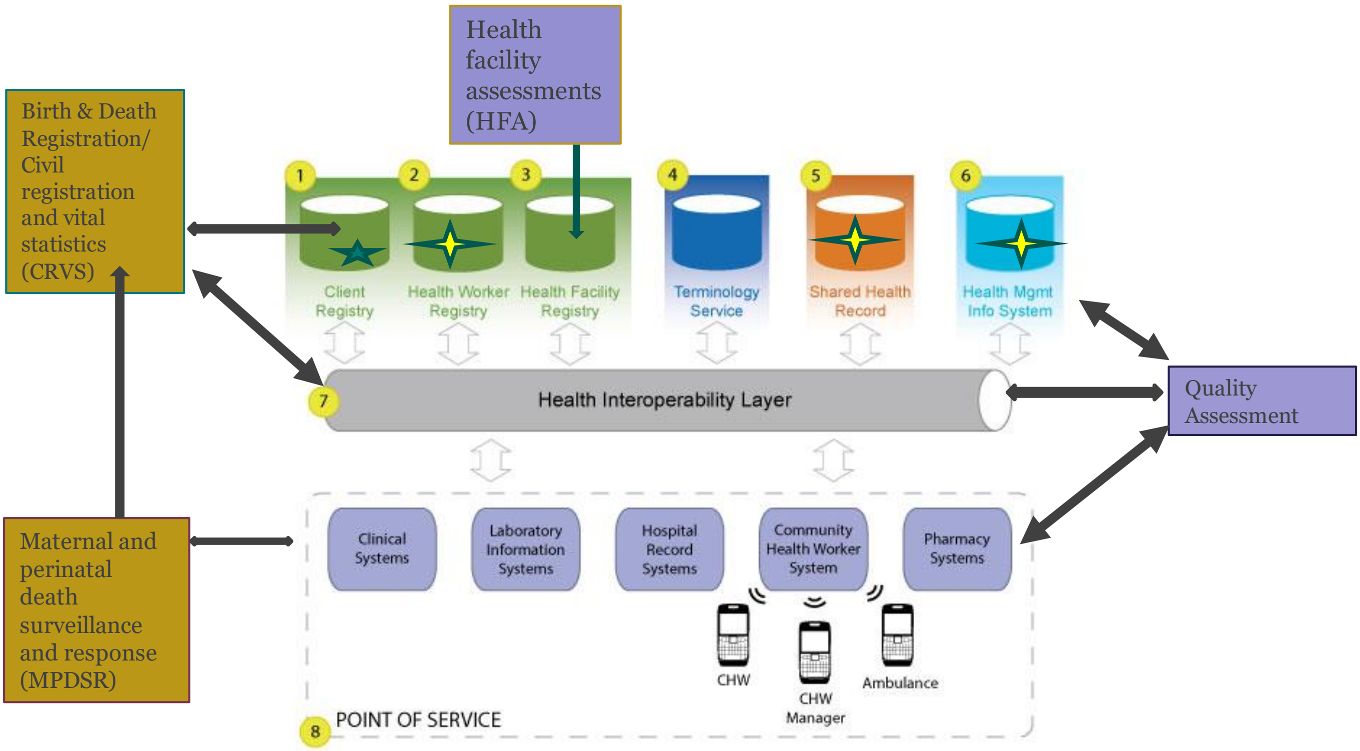


Figure 2. Figure showing a comprehensive routine health information system and the interaction of different components of the system

A number of standardised health facility assessment tools exist to measure service readiness, the most commonly employed being the World Health Organisation Service Availability and Readiness Assessments (SARA)(16), the DHS programme Service Provision Assessments (SPA) (17) and the Averting Maternal Death and Disability (AMDD) Emergency Obstetric and Newborn Care (EmONC) assessments (18). These allow health systems to report on a sample of facilities that provide a certain service or have health workers trained in specific skills, but are not routine reporting mechanisms. A recent review of the health facility assessment tools, identified EmONC as having the most comprehensive content on newborn care (19).

Emergency obstetric and newborn care surveys

The Emergency Obstetric and Newborn care (EmONC) needs assessments surveys are detailed assessments of service readiness for women and newborns at and around the time of birth. They are based on a core list of life-saving services, or 'signal functions', that define a health facility's capacity to treat obstetric emergencies at either a basic or a comprehensive level known as basic emergency obstetric care (BEmOC) and comprehensive emergency obstetric care (CEmOC). More recently, additional newborn content has been added to the surveys, which have been piloted in Malawi (2015) and Ethiopia (2016) (19). There are 10 modules in the EmONC assessment. Module 4 of the EmONC assessment contains a register review and facility case summary, which reviews service statistics on deliveries, interventions and outcomes.

It is often argued that surveys, such as health facility assessments, yield better quality information than routine information systems and generate more objective data with less bias (20). However, there are still relatively few countries where regular EmONC assessments have been carried out. EmONC, and other health facility assessment surveys, are run by external agencies and therefore are resource intensive and costly. Access to the data that is generated can be complex and time consuming. As more content is added to these surveys, the cost of carrying out the surveys increases.

Health management information systems

Health management information systems (HMIS) are a more sustainable form of health information and are relatively inexpensive compared with health facility assessments. Further, they are largely driven by national decision makers meaning there is real potential to streamline and improve the existing data and its quality. HMIS provide routine information for health managers to monitor and track progress of key health indicators. Such systems have the potential to also link to the management information for other associated support services (Figure 2). However, in low and middle-income countries, HMIS systems are often struggling to balance national data demands with their limited resources. Other systems, such as logistics management, human resource databases are also functional to different extents and their interoperability is often limited.

In Malawi, there is a functional LMIS and human resource database (IHRIS) alongside the HMIS, but it is not always possible for these systems to communicate between each other due to different management structures.

Improving routine measurement of service readiness for inpatient care of small and sick newborns

There is a large body of literature on strengthening and improving routine health information systems, largely spurred by health system strengthening efforts(21-23). Good quality health information supports health systems to improve accountability, and ensure evidence based decision making at local, district and national levels (11, 20, 24, 25). A number of authors have indicated a need to shift the debate away from the superiority of one data source over another and focus on improving the existing routine data systems and their interoperability (20, 24). As a result, tools and frameworks have emerged to support health systems, rather than specific disease programmes, to strengthen country capacity for health information production and use, such as the Health Metrics Network Framework (26) and later the Roadmap for Health Measurement and Accountability (27). Work identified by the *Every Newborn* metrics group also identified a wide-spread need to strengthen HMIS in low income settings, especially to build national capacity for the use of HMIS data for improving programme performance, and to improve the quality of the data (11, 28).

The challenges that are faced by routine information system management, such as country led DHIS-2, is partly related to the number of different people engaged from the point of data recording down to handling and data use. Highly complex data collection forms can then result in inaccurate transfer of data from patient records and high data errors (20). And the complexity of the systems – often which do not communicate or speak the same language in order for interoperability between different systems. Measurement challenges are also created by different tools, data collection mechanisms, indicators that are difficult to measure or lack of the indicators needed at the point of planning and level of health system. There are also issues with who collects the data and the frequency of data collection. Such complex challenges have been well articulated by the Performance of Routine Information System Management (PRISM) framework that separates these into technical factors (e.g. complexity of forms), organization factors (e.g. training and supervision) and behavioural factors (e.g. level of knowledge and/or confidence of data handlers) (Figure 3).

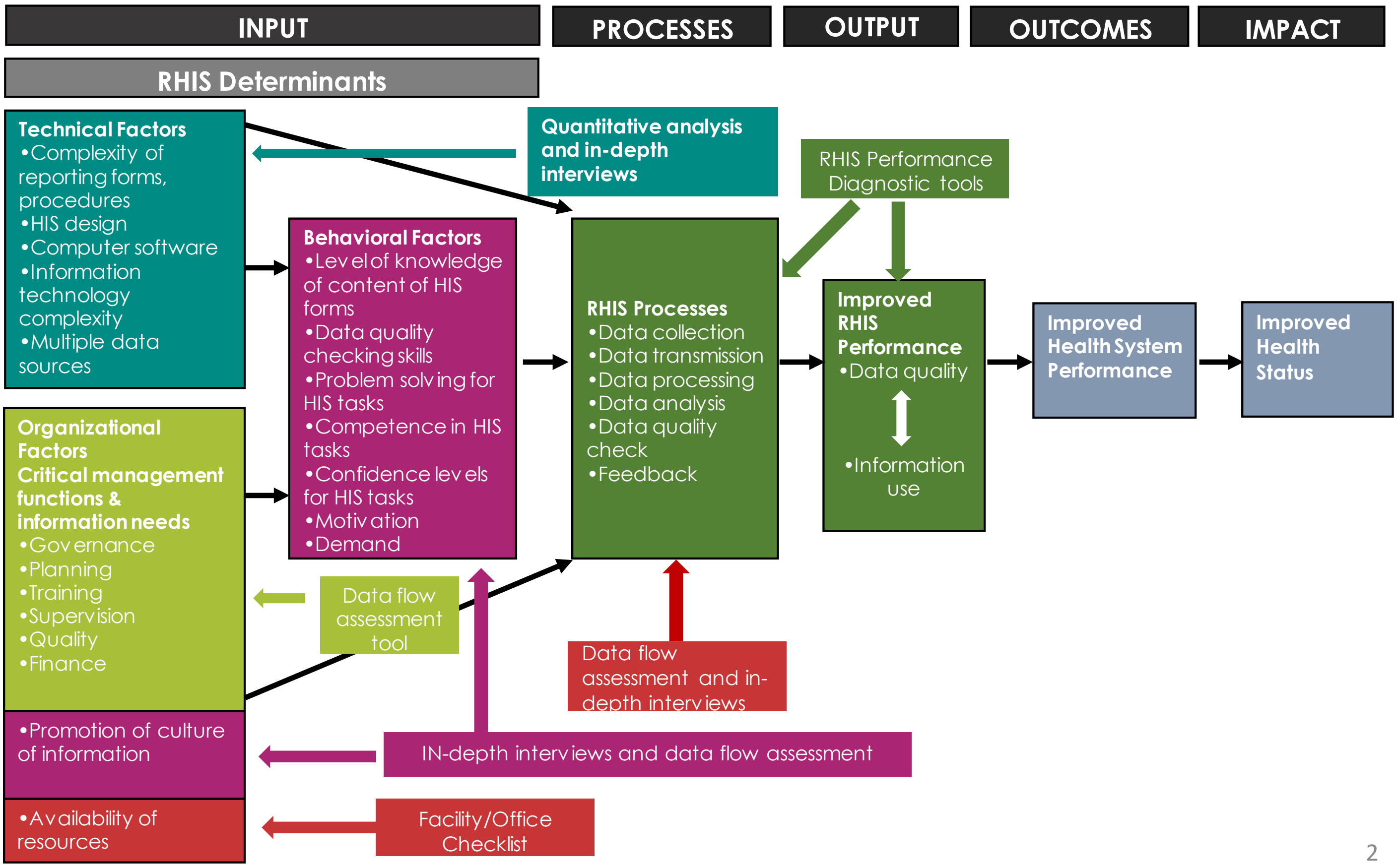


Figure 3. Applying the PRISM (Performance of routine information system management) framework to identify barriers and enablers to data collection and use for service readiness data for small and sick newborns adapted from: https://www.measureevaluation.org/resources/publications/ja-09-99

Acknowledging the wider context in which health systems operate, and the different people engaged in the data process, is critical to understanding mechanisms and actions which can improve the recording and use of the data (29).

V – OBJECTIVES

Our overall aim is to evaluate and improve approaches for routine measurement of service readiness for inpatient care of small and sick newborns in Malawi to inform global *Every Newborn* metrics and use in other countries.

Malawi uses District Health Information System 2 (DHIS 2) as their HMIS platform (30) and a national EmONC assessment was completed in Malawi in 2015.

Objective 1*: To analyse selected maternal and newborn indicators comparing Malawi district health information system (HMIS) data with a national health facility assessment for EmONC (2013-2014)*

- Compare the different estimates of select maternal and newborn indicators from District Health Information System – 2 (DHIS-2) and the EmONC health facility assessment register review from the same time period (2013-2014)
- Identify missing data, under or over reporting, bias and variation for selected maternal and newborn indicators between the two data platforms
- Explore quantitative factors associated with discrepancies using linear regression.

Objective 2: *To identify barriers and enablers to recording and use of service readiness data for care of small and sick newborns in Malawi*

- Randomly select 2-4 hospitals from each of the 3 regions in Malawi
- Carry out a data flow assessment to explore the data processes for service readiness data for care of small and sick newborns
- Using in-depth interviews with data handlers, explore the perceived barriers and facilitators to data recording and use for monitoring service readiness for small and sick newborns
- Through consensus building workshop
    - explore data that could potentially be added or removed from existing tools based on perceived relevance, completeness, timeliness, and accuracy
    - explore other potential sources of data and indicators needed to measure service readiness (infrastructure, equipment, drugs, providers) for inpatient care of small and sick newborns

VI – METHODOLOGY

Type of study

This is a mixed methods observational study involving secondary quantitative analysis of existing data sources (*objective 1*), data flow assessment, in-depth interviews with data handlers and a consensus building workshop with national stakeholders (*objective 2*).

Place of study

Place of study for *objective 1:* The secondary data analysis will compare the different estimates of select maternal and newborn indicators from DHIS-2 and the EmONC health facility assessment register review from the same time period (2013-2014). As part of an EmONC health facility assessment, a register review was carried out for events between September 2013 and August 2014. Support for the data collection came from UNFPA, in-country experts and Averting Maternal Death and Disability (AMDD). The sample included a census of all maternity hospitals in Malawi (hospitals that did not offer maternal and newborn health services were not included). DHIS-2 data for the same time period was collated and reported by local data clerks and programme focal points at the facility and district level. In 2013-2014 28 facilities in Malawi were reporting maternal and newborn health indicators into the DHIS-2 system. This gives us 28 facilities with data that can be compared between the DHIS-2 and the EmONC assessment.

All quantitative data is anonymised and was collected in Malawi through the Ministry of Health.

Place of study for objective 2:

In order to select the hospitals, we created a sampling frame of all of the hospitals with DHIS-2 data from the relevant time period and then generated a random number list for North, Central and

Southern regions of Malawi. We then selected the lowest numbers from each region, including one central hospital.

For each selected hospital, we have sought permission from the respective District Health Officer. The list of selected hospitals and subsequent permissions is as follows:

Region	Hospital	Permission from DHO
Northern region	Chitipa District Hospital	
	Karonga Distrcit Hospital	
	Rumphi District Hospital	
Central region	Kamuzu Central Hospital	
	Mchinji District Hospital	
	Ntchtisi District Hospital	
	Salima District Hospital	
Southern region	Chiradzulu District Hospital	
	Machinga District Hospital	
	Nsanje District Hospital	

Data flow assessments will be carried out at the hospital site using a structured tool. In-depth interviews with health facility staff will also be carried out at the health facility (to minimise disruption to clinical staff).

Study period

The secondary analysis for *objective 1* will be conductedMarch-May 2018. For *objective 2*, the data flow assessment, in-depth interviews and national workshop will be carried out in May-June 2018. We will conduct the analysis of the qualitative data June-September 2018 (See section VII for Gantt chart).

Sample size

For *objective 1*, the data analysis involves a secondary analysis of data from 28 maternity hospitals that were reporting DHIS-2 data between September 2013-August 2014.

For *objective 2*,a random sample of 6-8 hospitals has been selected for data flow assessment and in-depth interviews with data staff During the data flow assessment, we will purposively select 2-4 data handlers (such as clinicians, nurses and data clerks) in each facility who document, record, or use hospital level information on services for small and sick newborns. This type of sampling is consistently used in qualitative research to identify informants and interviewees with specific expertise or experiences (23). The number of in-depth interviews is chosen based on previous similar studies of this type (31, 32) and per recommendations from Green and Thorogood (33). Should this number be deemed insufficient to meet the study objectives, additional interviews may be arranged. We will also use snowball sampling to identify further individuals at the hospital level, if needed.

Data Collection

Objective 1 is a secondary analysis, there will not be any new data collection for this objective.

For *objective 2*, we will begin qualitative data collection in May 2018 starting with observation of the data flow process followed by in-depth interviews using semi-structured interview guides (see example data flow assessment and in-depth interview guide in tools). The two senior researchers, IN and SM, will carry out the data flow assessments and in-depth interviews with support from an experienced research assistant from REACH Trust.

The REACH Trust team has wide experience collecting qualitative data in Malawi and is familiar with the Malawi health system.

Before data collection, a two-day training workshop will be conducted for the study team to familiarise well with the study tools and on ethical issues around the study.

Informed written consent will be sought from hospital managers before observing data flow and then individual informed consent will be obtained from each participant before any in-depth interviews. Study participants will be informed that participation in the study is voluntary and that they are free to withdraw at any point during the interviews. All data will be collected in English.

A national level workshop with policy makers and key staff from the ministry of health or programme management level that use or require data for planning purposes will be held following initial analyses from the secondary data analysis, the data flow assessment and the in-depth interviews to consolidate information and probe any further themes for discussion (See Figure 4). Per diems, refreshments and transport will be provided for the workshop participants. Participants in the workshop will include representatives from the Reproductive Health Department, CMED, Planning department, and implementing partners.

Data analysis

For objective 1, the quantitative analysis will be carried out by the principle investigator at LSHTM in collaboration with the advisory group (including AMDD, Saving Newborn Lives, Malawi, REACH Trust) following appropriate ethical approval.

Data from the EmONC health facility assessment was double entered into CSPro 5.0 by the data collection teams. The cleaned data files will be exported to STATA for analysis by the principle investigator. Data from September 2013-2014 will be extracted from the DHIS-2 system and exported to STATA for analysis. The relevant reports from DHIS-2 data sources are: a) the maternity monthly report; b) the monthly HMIS form.

The quantitative data sources will be analysed for data completeness and range. Since the data are based on the same original source, the two samples are not independent, and appropriate statistical methods considering the paired nature of the data are necessary for this analysis. For each indicator value the ratio and difference between EmONC health facility assessment rates and DHIS-2 will calculated by facility, district and national. Paired t-tests will be used to examine differences between the aggregate rates obtained with both data sources to calculate a p-value. Bland Altman plots will be used to examine agreement between the data collection platforms. This is achieved by plotting the differences (or ratios) between the two platforms against their average.
Where discrepancies are found, further analysis will be undertaken to explore potential facility level variables that explain the discrepancy (For example: rural/urban, facility level and type, health sector, staffing and caseload) using linear regression.

The following comparable data points have been identified from the EmONC health facility assessment and the DHIS-2:

Maternal
Spontaneous vertex deliveries
Breech deliveries
Deliveries with vacuum extraction
C-section deliveries
Laparotomy for known and unknown ruptured uterus
Total deliveries
Newborn

Low birthweight (LBW) babies (<2.5kg)
Fresh stillbirths
Macerated stillbirths
Neonatal deaths
Referrals
Referrals out of the facility due to obstetric indications
Referrals out of the facility due to newborn complications
Kangaroo mother care
LBW babies initiated on facility based KMC
LBW babies on KMC discharged alive
LBW babies on KMC who died before discharge

For objective 2, in-depth interviews will be recorded. Following completion of data collection, we will transcribe data. All names of those participating in the qualitative analysis will be removed from the scripts and replaced with pseudonyms. We will then carry out prefigured thematic analysis applying the PRISM framework (Figure 3) (20, 24), to identify the organisational, technical and behavioural barriers and enablers to data recording and use for small and sick newborns in Malawi. Qualitative data analysis will be conducted using Nvivo software.

The prefigured thematic analysis of the qualitative data will follow the five steps proposed by Green and Thorogood applying the PRISM framework (Figure 3) (33):

- Familiarisation – listing important ideas and recurrent themes by listening to the tapes and reviewing the transcripts.

- Pre-figured thematic analysis – identifying the principal and relevant themes by which data can be examined within the PRISM framework. This will help to develop a coding scheme. New sub-themes will emerge from the focus groups and combined with themes identified from the quantitative analysis.

- Indexing – the transcripts will be annotated applying the thematic framework to all of the data using numerical codes.

- Charting – create summaries distilling the sub-themes within the framework

- Mapping and interpretation – using the charts to find links between the themes with the purpose of providing explanation for the findings.

Two team members will carry out coding and analysis to ensure rigour and consistency.

VII – DISSEMINATION OF RESULTS

Initial findings from both objectives will be shared with policy makers and key staff from the ministry of health or programme management level at the national workshop to ensure national engagement in the data analysis process.

Results from *objectives 1 and 2* will be written up in report format with detailed context specific recommendations to develop and improve measurement on service readiness for care of small and sick newborns and recommendations for the Malawi DHIS-2 and future EmONC surveys and/or other health facility assessments including:

- Summary of results from both analyses
- Recommendations on indicators that can be added and removed from existing data modules in both the DHIS-2 and emergency obstetric and newborn care (EmOC) surveys in Malawi
- Recommendations on other potential sources of data (including at the facility level), tools, and indicators needed to measure service readiness (infrastructure, equipment, drugs, providers) for care of small and sick newborns.

These consolidated findings will then be shared again with Ministry of Health and other key stakeholders and partners following completion and write-up of results. The potential for extending the DHIS-2 and health facility comparative analysis to other country settings will also be explored. The combined findings of objective 1 and 2 may also be written up as a publication.

VIII – ETHICAL CONSIDERATIONS

Data collection for both quantitative data sources to be used in *objective 1* was overseen by the Malawian National Ministry of Health. The Ministry of Health in Malawi uses DHIS-2 as their health management information system and regular quality check are built into the system. The Malawi EmONC Health Facility Assessment was carried out by the Malawi Ministry of Health and Malawi government with technical support from various development partners, notably Averting Maternal Death and Disability (AMDD), Saving Newborn Lives - Save the Children, United Nations Family Planning Association (UNFPA), United Nations Children's Emergency Fund (UNICEF) and United States Agency for International Development (USAID). The Ministry of Health and the Government of Malawi, as the overseers of the assessment, assured that the data collection process followed ethical principles. The data collectors were trained on the principles of confidentiality. No person's name was recorded on any of the modules except that of the data collector. Permission was requested from in-charge of facilities to visit the facility and interview members of staff. Team leaders carried with them letters of introduction from the Ministry of Health. The facility in-charges' responses and those of members of staff were always respected. Providers who were interviewed for module 7 provided oral consent.

For *objective 2*, The qualitative research approach will take into account the local context, power relationships between different participants and the position of the researchers, as well as local cultural and professional norms, in the data collection phase and in interpretation of results (33). Informed written consent will be sought from hospital managers (see example letter to hospital managers, and informed consent for hospital managers) before observing data flow and then individual informed consent (see informed consent forms) will be obtained from each participant before any in-depth interviews.

All names of those participating in the qualitative analysis will be removed from the scripts and replaced with pseudonyms. In cases where participant's do not want the name of another person disclosed, the name will be replaced with a pseudonym and/or tag that typifies that person's role (e.g. data technician). In cases where participant's do not want the name of a facility or a geographic location disclosed, the facility name will be replaced with a meaningful descriptive term that typifies the facility type or location (eg. private maternity hospital).

The Principle Investigator will be responsible for the data and only members of the research technical team will have access to the data. Data collection and data analysis processes will follow LSHTM Guidelines on Good Research Practice. Data will be stored in a password encrypted file on a backed-up server, in compliance with the LSHTM Information Security Policy. Local copies will be stored securely on an encrypted drive held in a locked drawer. Data will be retained following

LSHTM records retention and disposal schedule.:
http://intra.lshtm.ac.uk/infoman/records/retention.html

This study has been presented to the national Safe Motherhood Committee who support the study, and a copy of the protocol shared with the Committee prior to submission the National Health Sciences Research Committee (NHSRC). Ethical approval for this study has already been obtained from the London School of Hygiene and Tropical medicine (approval letter included as part of this proposal: LSHTM ethics ref: 10668). The research will not commence in Malawi until ethics approval has been granted by the NHSRC in Malawi and correct permissions obtained from the Ministry of Health.

IX – PERSONNEL AND INSTITUTIONS

Principle Investigator

Sarah Moxon is a Research Fellow and PhD Candidate within the Maternal, Adolescent, Reproductive and Child Health (MARCH) Centre at the London School of Hygiene and Tropical Medicine (LSHTM). Sarah's work is focused on improving the quality of care for small and sick newborns, strengthening health systems and developing the associated metrics for monitoring maternal and newborns health programmes. Sarah has a background in neonatal nursing and has a Masters in Public Health. She has worked in research, monitoring and evaluation of health systems in low and middle-income settings since 2008.

Co-Investigators

Ireen Namakhoma is a senior social scientist focusing on the development of practical recommendations to promote equity in access to health care for the poor. Her primary interest is in the implementation of qualitative and quantitative research activities to promote equitable access to health services in Malawi.

Hastings Banda is a Senior Clinical Researcher and the Acting Executive Director with REACH Trust. He has a Masters in Community Health from Liverpool School of Tropical Medicine and has attended courses in epidemiology, statistics and research methodologies. Hastings leads REACH Trust's Clinical Research Team, developing the clinical research portfolio for the Trust as well as managing relevant research projects and all clinical staff.

Advisory group for research

Dyson Likomwa (USAID Malawi)
Tanya Guenther (Saving Newborn Lives, DC)
Kondwani Chavula (Saving Newborn Lives, Malawi)
Tanya Marchant (LSHTM)
Patricia Bailey (Averting Maternal Death and Disability)
Loveday Penn-Kekana (LSHTM)
John Bradley (LSHTM)
Joy Lawn (LSHTM co-chair for Every Newborn metrics and Principle Investigator for CIFF grant)

Tanya Guenther works as an Advisor, Monitoring and Evaluation and HMIS for Save the Children, with a focus on newborn and child health. She will provide technical support for the study design, implementation and data analysis, working closely with counterparts in SC Malawi.

Lara Vaz is the Senior Advisor, Monitoring and Evaluation for Saving Newborn Lives, Save the Children with expertise in qualitative research. She will provide technical oversight for the study implementation, analysis and dissemination.

Dyson Likomwa is a monitoring and evaluation technical officer for USAID in Malawi. He will provide technical inputs into the study design and support analysis and reporting.

Patricia Bailey, is a Senior Scientist at FHI 360 and a Senior Technical Advisor to the Averting Maternal Death & Disability (AMDD) program at Columbia University's Mailman School of Public Health. She will provide technical guidance on the Emergency Obstetric and Newborn Care assessment.

John Bradley is a lecturer in statistics at the LSHTM and will provide guidance on statistical analysis.

Loveday Penn-Kekana is a medical anthropologist and lecturer at LSHTM and has extensive experience using a range of methods such as participant observation, in-depth interviews, reflective diaries and focus groups, and expertise working in mixed method research projects on maternal health and health systems.

Dr Tanya Marchant, a Senior Lecturer in epidemiology at LSHTM, will provide guidance on research design and analysis.

Professor Joy Lawn is a global expert in perinatal epidemiology, the Director of the Maternal, Adolescent, Reproductive and Child Health Centre (MARCH) at the LSHTM, and co-chairs the global Every Newborn Action Plan metrics group.

Curriculum Vitae of all the members of the technical team are included in annex B.

London School of Hygiene and Tropical Medicine

The London School of Hygiene &Tropical Medicine is the co-chair of the ENAP metrics working group alongside the WHO. LSHTM a world-leading centre for research and postgraduate education in public and global health. The LSHTM mission is to improve health and health equity in the UK and worldwide; working in partnership to achieve excellence in public and global health research, education, and translation of knowledge into policy and practice. http://www.lshtm.ac.uk

REACH Trust

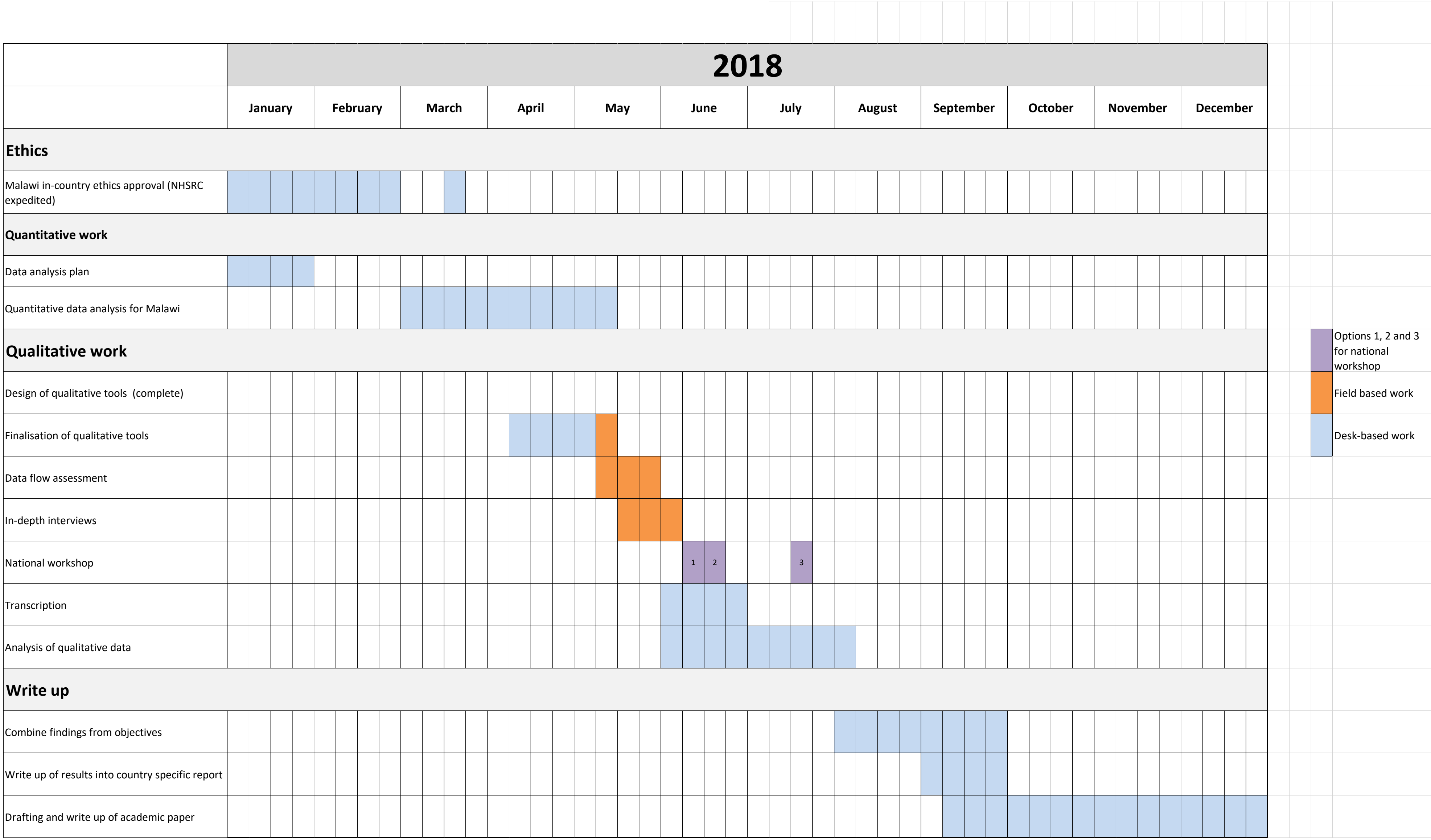
The Reach Trust is a centre of excellence for multidisciplinary health research that generates evidence; advocates for the development of inclusive health policies; and practices in promoting equity in access to health care, mostly for the vulnerable, poor and marginalized populations in Malawi.

Saving Newborn Lives, Save the Children

Save the Children's Saving Newborn Lives program is funded by the Bill and Melinda Gates Foundation and seeks to reduce global neonatal mortality by working in partnership with countries to develop packages of effective, evidence-based newborn care interventions and to implement these innovations at scale. http://www.savethechildren.org/site/c.8rKLIXMGIpI4E/b.6234299/ Saving Newborn Lives has supported the Reproductive Health Department and Central Monitoring and Evaluation Division in Malawi for a number of years helping to integrate newborn indicators and providing ongoing support for data quality assessments, data analysis and dashboard development.

X – WORKPLAN

Study Gantt chart



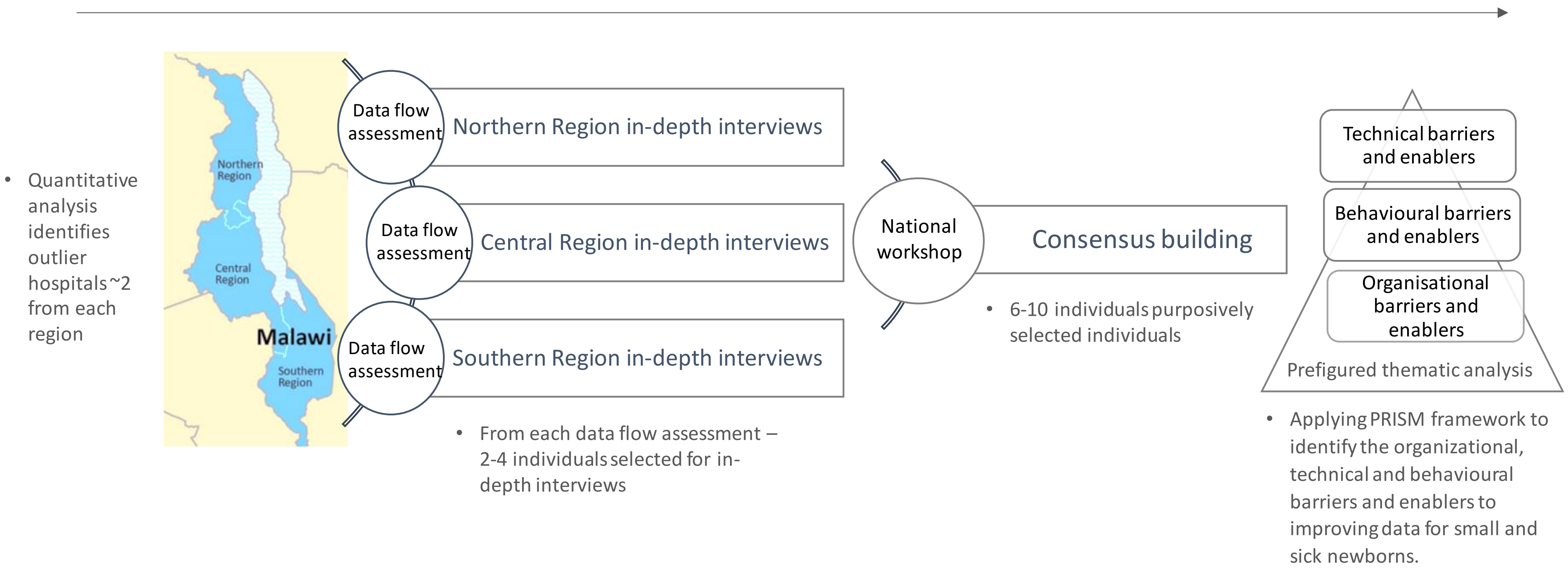


Figure 4. Flow diagram for qualitative data collection (objective 2) including data flow assessments, in-depth interviews and consensus building workshop

XI – BUDGET

	Unit	Cost	Totals
Data collection			
Vehicle hire	18	60000	1,080,000
Fuels costs	672.05	825	554,441
Per diems and accommodation (3 people for 18 days	54	25000	1,350,000
Airtime and internet	18	2000	36,000
Lunch/Snack for interviewees	30	2000	60,000
SUBTOTAL			**3,080,441**
National Focus Group			
(Venue- REACH/MOH MNH Conference)	20	78200	1,564,000
Transport refund for national focus group	5	5000	25,000
Accomodation for national focus group	5	25000	125,000
Tea and lunch for national focus group	20	8000	160,000
SUBTOTAL			**1,874,000**
General items			
Printing and stationery	1	200000	200,000
Recorders??	2	100000	200,000
			400,000
NHSRC fees	1	110000	110,000
NHSRC 10% of the budget	1	500000	500,000
			610,000
SUBTOTAL			**2,020,000**
SUBTOTAL			**6,974,441**
SUBTOTAL in dollars			**9,686.72**

Budget justification

The time for Sarah Moxon is funded by a grant from Children's Investment Fund Foundation (CIFF) to LSHTM for *Every Newborn* metrics research. Sarah's time until October 2017 is also co funded by Save the Children's Saving Newborn Lives project. The qualitative work described in this proposal will be funded by the CIFF grant at LSHTM. Other partners such as USAID, AMDD and LSHTM academics are part of the work but funded through other means. All costs for data collection will be covered by Children's Investment Fund Foundation (CIFF) and are already included in grant *for Every Newborn* Action Plan metrics to the London School of Hygiene and Tropical Medicine.

Personnel (technical team)

Time for the REACH Trust team will be covered by the CIFF grant at LSHTM through an existing agreement. Other partners such as USAID, AMDD and LSHTM academics are part of the work but funded through other means.

Travel and accommodation

Travel and accommodation for Sarah Moxon is covered by the CIFF grant at LSHTM.

Logistics

All equipment for the analysis and data collection will be provided by the London School of Hygiene and Tropical Medicine. The Principle Investigator will use her own computer (lap top) for data analysis.

Other materials and cost

An administration fee of 10% has been added as per the NHSRC ethics guidelines.

XII – BIBLIOGRAPHY/REFERENCES

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XIII - LSHTM ETHICS APPROVAL

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LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Observational / Interventions Research Ethics Committee

Ms Sarah Moxon

Research Fellow

Department of Infectious Disease Epidemiology (IDE)

Epidemiology and Population Health (EPH)

LSHTM

7 March 2017

Dear Sarah

Study Title: Evaluating approaches to measurement of service readiness for inpatient care of small and sick newborns

LSHTM Ethics Ref: 10668

Thank you for responding to the Observational Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant. **Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Investigator CV	CV Joy Lawn june 2016	01/12/2016	1
Investigator CV	CV_John_Bradley_2page	01/12/2016	1
Investigator CV	CV_LSHTM_Sarah Moxon_2016	01/12/2016	1
Information Sheet	Example consent form_FINAL_1stDecember2016	01/12/2016	1

Information Sheet	Participant information sheets	01/12/2016 1
Advertisements	Example recruitment email	01/12/2016 1
Investigator CV	Tanya Marchant 2page CV_Dec16	01/12/2016 1
Protocol / Proposal	Proposal_Malawi_service readiness data for care of small and sick newborns)_FINALdec2016	15/12/2016 1
Protocol / Proposal	Example topic guides for qualitative interviews	15/12/2016 1
Information Sheet	Example consent form_v2_Feb2017	28/02/2017 2
Covering Letter	Response research committee	28/02/2017 1
Information Sheet	Participant information sheet_v2_Feb2017	28/02/2017 2

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

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The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

[redacted]

Professor John DH Porter

Chair

ethics@lshtm.ac.uk http://www.lshtm.ac.uk/ethics/

Improving health worldwide

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Appendix M: PDF of published paper and licensing agreement: Count Every Newborn; a measurement improvement roadmap for coverage data

Moxon et al. BMC Pregnancy and Childbirth 2015, 15(Suppl 2):S8
http://www.biomedcentral.com/1471-2393/15/S2/S8

BMC Pregnancy & Childbirth

RESEARCH Open Access

Count every newborn; a measurement improvement roadmap for coverage data

Sarah G Moxon[1,2,3], Harriet Ruysen[1,2], Kate J Kerber[3], Agbessi Amouzou[4], Suzanne Fournier[5], John Grove[6], Allisyn C Moran[7], Lara ME Vaz[3], Hannah Blencowe[1,2,3], Niall Conroy[1,8], A Metin Gülmezoglu[9], Joshua P Vogel[9], Barbara Rawlins[10], Rubayet Sayed[11], Kathleen Hill[12], Donna Vivio[13], Shamim A Qazi[14], Deborah Sitrin[3], Anna C Seale[15], Steve Wall[3], Troy Jacobs[13], Juan Gabriel Ruiz Peláez[16,17,18], Tanya Guenther[3], Patricia S Coffey[19], Penny Dawson[20], Tanya Marchant[1,21], Peter Waiswa[22,23], Ashok Deorari[24], Christabel Enweronu-Laryea[25], Shams El Arifeen[26], Anne CC Lee[27], Matthews Mathai[14], Joy E Lawn[1,2,3*]

Abstract

Background: The *Every Newborn* Action Plan (ENAP), launched in 2014, aims to end preventable newborn deaths and stillbirths, with national targets of ≤12 neonatal deaths per 1000 live births and ≤12 stillbirths per 1000 total births by 2030. This requires ambitious improvement of the data on care at birth and of small and sick newborns, particularly to track coverage, quality and equity.

Methods: In a multistage process, a matrix of 70 indicators were assessed by the *Every Newborn* steering group. Indicators were graded based on their availability and importance to ENAP, resulting in 10 core and 10 additional indicators. A consultation process was undertaken to assess the status of each ENAP core indicator definition, data availability and measurement feasibility. Coverage indicators for the specific ENAP treatment interventions were assigned task teams and given priority as they were identified as requiring the most technical work. Consultations were held throughout.

Results: *ENAP* published 10 core indicators plus 10 additional indicators. Three core impact indicators (neonatal mortality rate, maternal mortality ratio, stillbirth rate) are well defined, with future efforts needed to focus on improving data quantity and quality. Three core indicators on coverage of care for all mothers and newborns (intrapartum/skilled birth attendance, early postnatal care, essential newborn care) have defined contact points, but gaps exist in measuring content and quality of the interventions. Four core (antenatal corticosteroids, neonatal resuscitation, treatment of serious neonatal infections, kangaroo mother care) and one additional coverage indicator for newborns at risk or with complications (chlorhexidine cord cleansing) lack indicator definitions or data, especially for denominators (population in need). To address these gaps, feasible coverage indicator definitions are presented for validity testing. Measurable process indicators to help monitor health service readiness are also presented. A major measurement gap exists to monitor care of small and sick babies, yet signal functions could be tracked similarly to emergency obstetric care.

Conclusions: The ENAP Measurement Improvement Roadmap (2015-2020) outlines tools to be developed (e.g., improved birth and death registration, audit, and minimum perinatal dataset) and actions to test, validate and institutionalise proposed coverage indicators. The roadmap presents a unique opportunity to strengthen routine health information systems, crosslinking these data with civil registration and vital statistics and population-based surveys. Real measurement change requires intentional transfer of leadership to countries with the greatest disease burden and will be achieved by working with centres of excellence and existing networks.

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Full list of author information is available at the end of the article

Background

The close of the Millennium Development Goals (MDGs), with a halving of maternal mortality and under five child deaths, demonstrates that global targets are linked to national and global accountability and can drive change. Under-five deaths due to HIV/AIDS, malaria and measles (among others), have seen the greatest proportional declines [1]. Where indicators for high impact, evidence-based interventions are carefully tracked, previous analysis has demonstrated that coverage tends to improve, largely due to focused policy attention, investment and informed planning, leading to better population health outcomes [2]. Interventions for child health and causes of child death have had more programmatic data (coverage and process), collected more frequently, at a more granular level (e.g. district level, by various equity analyses groups), than for newborn health, where the data is of poorer quantity and quality, and has been collected with less frequency [3].

As the MDGs transition to the Sustainable Development Goals (SDGs), there remains an unfinished agenda for 2.7 million neonatal deaths, for whom progress has been much slower than progress towards reducing the overall under 5 mortality rate. An estimated 2.6 million stillbirths were not counted at all in the MDGs[4]. Well-functioning civil registration and vital statistics (CRVS) systems generate policy, ensure access to services and are associated with better health outcomes worldwide [5]; counting births and deaths, especially the deaths around the time of birth, lies at the heart of post-2015 health monitoring, accountability and action [3]. Tracking vital events and measuring coverage is also central to developing national health management information systems (HMIS), such as in the Measurement and Accountability for Results in Health (MA4Health) Roadmap [6], which aims to increase investment in national data systems and data use.

The *Every Newborn* Action Plan (ENAP) [7] is a global multi-partner movement to end preventable maternal and newborn deaths and stillbirths. Through a series of consultations, multiple stakeholders (governments, United Nations (UN) agencies, donors, business communities, professional associations, academic and research institutions, global initiatives and civil society members) developed an impact framework and an action and measurement agenda for integration within national newborn health plans [3,8].

To reach 2030 national targets for neonatal mortality and stillbirth rates of ≤12 per 1000 births, high and equitable coverage of the evidence-based interventions identified by ENAP is needed [9]. ENAP prioritises achieving universal coverage of these interventions particularly during childbirth and the first week of life. Yet many of these interventions are not systematically measured. One of the five ENAP strategic objectives - to count every newborn (and birth) - underlines the need for improved data and accountability. The ENAP milestones, linked to a World Health Assembly resolution [7], have a particular focus on inputs required prior to 2020 and more than half refer to improving metrics for targeting and driving change (Figure 1). One such milestone is to develop a monitoring framework building on the Commission on Information and Accountability (COIA) for Women's and Children's Health [10] to track global progress post 2015 and align with country priorities and objectives.

The principal focus of this paper is based on the ENAP milestone to define and improve priority coverage indicators, as this was where the largest measurement gaps were identified. Many newborn care interventions lack standard indicator definitions and are not routinely monitored at national or global level, especially in low and middle-income countries (LMIC). We define a coverage indicator as a population-level metric that measures the number of individuals that receive an intervention or service (numerator) out of a total population that should receive the intervention or service (the denominator). For the numerator, indicators rely on clear technical definitions of the service or intervention. Where there is difficulty capturing the population in need (the denominator) particularly for specific treatment interventions, some indicators (such as the caesarean-section rate) use total live births as the denominator to give a proxy. In such cases, where the aim is not for 100% coverage, the rate is then benchmarked against a target threshold.

The coverage indicators prioritised by the Commission for Information and Accountability (COIA) mainly reflect contact points along the continuum of care, notably antenatal care, skilled birth attendance and postnatal care. Such coverage indicators capture contact with the health system or delivery of a specific intervention, but not always detailed, accurate information on the content or quality of the care delivered [11], although antenatal care now has a detailed content module within the Demographic and Health Survey (DHS) [12]. In high-burden countries the main current data source is through household surveys. The most commonly employed household surveys are the United States Agency for International Development (USAID)-supported DHS [13] and the United Nations International Children's Fund (UNICEF)-supported Multiple Indicator Cluster Survey (MICS) [14]. However, coverage of many maternal and newborn interventions cannot feasibly and/or accurately be collected through household surveys.

For health information collected through household surveys, the data quality usually depends on the validity of the mother's report, often up to two to five years after the intervention occurred. There is evidence suggesting that maternal recall of events that occurred during labour is poor [12], especially if there were complications. In

Figure 1 ***Every Newborn*** **Action Plan (ENAP) Measurement Improvement Roadmap: the arc of change**. In support of Health Measurement and Accountability post-2015: A Common Roadmap WHO (2015) [6]. ENAP: Every Newborn Action Plan; WHO: World Health Organization.

addition, how the question is asked can affect the accuracy of the response. For surveys, large sample sizes are needed to generate sufficient statistical power to assess social and demographic factors. Bryce et al: [15] described some of the limitations of household surveys for measuring coverage of interventions, including the time, cost and limited validity (sensitivity and specificity) of many of the indicators.

Health facility assessments (HFAs) are frequently used to complement HMIS, facility-based logistics and service delivery information systems. These provide information on staffing, equipment availability, spatial organisation, data collection capacity, and service readiness. A number of standardised HFA tools exist, the most commonly employed being the Service Availability and Readiness Assessment (SARA) [16], Service Provision Assessments (SPA) [17] and the Emergency Obstetric Care (EmOC) needs assessments [18]. These allow health systems to report on a sample of facilities that provide a certain service or have health workers trained in specific skills, but are not routine reporting mechanisms. In addition, the WHO Health Access/Action International database has data on medication availability. Service availability and quality indicators provide complementary metrics to population coverage which can be used to ensure that services achieve adequate coverage and give due attention to the availability of care, and the readiness of facilities to deliver the safe and quality care that is fundamental to the *Every Newborn* movement.

Since coverage of evidence-based care for mothers and newborns is often unknown, or data may be old or not locally available, this is a major "bottleneck", impeding scale up of high-impact, evidence-based interventions for newborns. Such data have been critical in accelerating progress in the implementation and scale-up of immunisation and HIV programmes through increased policy attention, focused investment of resources and better accountability structures [15]. Such data are critical for informed planning, driving programme improvement and targeting underserved populations to reduce inequities.

The objectives of this paper are to:

1. Describe the systematic process used to select ENAP indicators and present the core and additional indicators.
2. Assess the status (technical definitions and data availability) of the ENAP coverage indicators and identify actions needed to improve these for measurement at scale, particularly for coverage of the treatment interventions.
3. Identify priorities for testing validity and feasibility, in order to institutionalise these metrics within large scale data collection platforms and outline a five-year measurement improvement roadmap.

Methods

Objective 1: systematically grade to select the ENAP core and additional indicators

A multi-stage process was carried out to identify a list of potential indicators and then prioritise a short list. This process involved a working group appointed by the ENAP management team who compiled a comprehensive list of indicators, drawing on existing databases such as COIA [10], UNICEF's State of the World's Children (SoWC) [19], Countdown to 2015 [20] and other World Health Organization (WHO) statistics and reports. Standardised, nationally representative survey tools currently in use (MICS, DHS, SPA, SARA and EmOC surveys) were considered as sources of data. In addition, possible indicators relating to common causes of neonatal death were included. This resulted in a matrix of over 70 relevant indicators measuring impact (mortality and morbidity), outcome (coverage of care for all babies and coverage of treatment interventions), outputs (service quality, availability, demand, and the enabling environment) and inputs (human resources, essential medicines and supplies) (see Additional file 1). The current status of definitions, measurability and data availability were reviewed for each of the proposed indicators.

A systematic scoring process was applied to prioritise core indicators that could track the main focus of the action plan, particularly on quality of care at birth and the five strategic objectives. Each indicator was graded by its importance to the ENAP focus (A to C) and by current data availability (1 to 3). A grade of A was given to indicators of highest relevance and match to the ENAP focus and a score of 1 was given to indicators with a common and consistent definition already measured in existing data sources. Scoring was completed by an expert working group and decided via group consensus with priority given to indicators in terms of their relevance to the ENAP focus, rather than data availability.

Given the principle of accelerating impact, a decision was taken to focus on a shorter list of important indicators and ensure those would be made measureable, rather than to just select those that were already measureable. Hence, indicators were prioritised first based on their importance to the ENAP focus (category A) and then on data availability. Indicators in Category A ranged from those with definitions and existing data (availability 1) to those without standard definitions and existing data (availability 2 or 3). The latter were identified as having priority measurement gaps that needed to be addressed with a specific program of work.

Objective 2: assess status of ENAP coverage indicators and identify priorities to improve measurement at scale

For each of five high impact interventions identified with the greatest measurement gap (red box in Figure 2), a Task Team was established. These included antenatal corticosteroids (ACS), newborn resuscitation, Kangaroo Mother Care (KMC), case management of serious neonatal infection and chlorhexidine cord cleansing. The Task Teams sought to represent both the maternal and newborn health communities and reflect multiple stakeholders, e.g. non-governmental organisations, UN organisations, professional associations, and research institutions; ensuring representation from LMIC. With the support of the ENAP metrics coordination group, Task Teams carried out a consultation process to define indicators based on a technical definition, suggest feasible indicators that can be measured now through existing data collection platforms, and outline research priorities to test validity and feasibility for these coverage metrics for each area, including data collection tools.

WHO hosted a consultation at a meeting in Geneva, December 2014 to review the work of the Task Teams, and also gain inputs on the other core indicators. This meeting developed a draft plan to deliver on the ENAP metrics milestones, including discussion on the specific actions needed to improve coverage indicators. Plans for improving measurement tools and tracking systems were also discussed; for example, perinatal audit tools, neonatal care registers and Civil Registration and Vital Statistic (CRVS) improvements. The draft plan was then advanced by those at the meeting and through wider consultation.

The priorities for testing validity and feasibility to institutionalise these metrics within large scale data collection platforms and the measurement improvement roadmap (***Objective 3***) are discussed in detail in the discussion section of this paper.

Results

Objective 1: systematically grade to select the ENAP core and additional indicators

Following the process described above, ENAP listed 10 core indicators (Figure 2). For the three impact

Current Status		Core ENAP Indicators	Additional indicators
Definitions clear but quantity and consistency of data lacking	*Impact*	1. Maternal mortality ratio 2. Stillbirth rate 3. Neonatal mortality rate	Intrapartum stillbirth rate Low birth weight rate Preterm birth rate Small for gestational age **Neonatal morbidity rates** **Disability after neonatal conditions**
Contact point definitions clear but data on content of care are lacking	*Coverage:* Care for All Mothers and Newborns	4. Skilled attendant at birth 5. Early postnatal care for mothers and babies 6. Essential newborn care (tracer is early breastfeeding)	Antenatal Care Exclusive breastfeeding up to 6 months
Gaps in coverage definitions, and requiring validation and feasibility testing for HMIS use	*Coverage:* Care for newborns at risk or with complications (specific treatment interventions)	**7. Antenatal corticosteroid use** **8. Neonatal resuscitation** **9. Kangaroo mother care** **10. Treatment of severe neonatal infections**	Caesarean section rate **Chlorhexidine cord cleansing**
	Input: Service Delivery Packages for Quality of Care	Emergency Obstetric Care **Care of Small and Sick Newborns** **Every Mother Every Newborn Quality Initiative with measurable norms and standards**	
	Input: Counting	Birth Registration	Death registration, cause of death

Figure 2 ***Every Newborn*** **Action Plan (ENAP) core and additional indicators**. Shaded= Not currently routinely tracked at global level. Bold red= Indicator requiring additional testing to inform consistent measurement. Indicators to be disaggregated by equity such as urban/rural, income and education. Adapted from WHO and UNICEF, Every Newborn Action Plan. WHO, 2014. http://www.everynewborn.org/ and Mason *et al*: Lancet 2014.

indicators that already have agreed definitions (Figure 3), the priority is for improved quality and quantity of data. There is increasing consensus on the need to invest in CRVS and linked facility-based tracking to improve reliability of impact indicators [3,4,21].

The principal focus of this paper is on the coverage indicators, where the largest metrics gaps were identified. The coverage indicators fall into two groups: key contact points for care for all mothers and newborns (Figure 4), and specific treatment interventions (mainly for care for newborns at risk or with complications) (Figure 5 and 6). For essential newborn care, early initiation of breastfeeding was identified as a tracer indicator, with exclusive breastfeeding up to 6 months as an additional indicator. Chlorhexidine cord cleansing was also added to the improvement agenda, given the gaps in coverage data.

Objective 2: assess status of ENAP coverage indicators, and identify priorities to improve measurement at scale

For each coverage indicator, we describe technical definitions, current data availability, improvements needed and steps to be taken.

Coverage: care of all mothers and newborns (contact points)

Intrapartum care

Technical definition of package

A package of support and healthcare around the time of birth integral to maintaining perinatal and maternal safety along the continuum of care [9,22]. Skilled birth attendance is used as the contact point indicator to monitor coverage of this care.

Indicator to track contact point

A skilled birth attendant (SBA) is described by the WHO as an accredited health professional (such as a midwife, doctor or nurse) educated and trained to proficiency in the skills needed to manage normal (uncomplicated) pregnancies, childbirth and the immediate postnatal period and in the identification, management and referral of complications in women and newborns [23].

Current data availability

SBA data are available mostly from DHS, MICS, and are reported in many UN documents and by the Countdown to 2015 report series, which charts country progress towards meeting MDG goals and targets. However, no robust time series has been published for all countries for the MDG era to date, although SBA was the main indicator under MDG5 for maternal health. Of 75 countries participating in Countdown, all but 15 provide equity analysis in relation to the coverage of SBA [20] (countries who do not report equity compared with SBA coverage are: Angola, Botswana, Brazil, China, Djibouti, Equatorial Guinea, Eritrea, Korea, Mexico, Myanmar, Papua New Guinea, Solomon Islands, South Sudan, Sudan and Turkmenistan). These suggest SBA coverage has the widest equity gap for any contact point along the COIA continuum of care indicators [20]. SPA also has a new optional observational module for labour and delivery care that has been applied in Kenya, Malawi and Bangladesh developed by the Maternal and Child Health

Core			Numerator	Denominator*	Data sources	Definition source
IMPACT	1	Maternal mortality ratio	Number of maternal deaths per year during pregnancy and childbirth or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy. Defined as a death from any cause related to or aggravated by pregnancy or its management (excluding accidental or incidental causes).	Per 100,000 live births	CRVS and registries (when high coverage and quality) or surveys or facility/HMIS and/or estimation modelling	ICD10. For more details see WHO/UNFPA/UNICEF estimates 2014 [94]
	2	**Stillbirth rate**	For International Comparison: Number of babies per year with no signs of life born weighing at least 1000 grams or after 28 weeks gestation (ICD10 also recommends the inclusion of fetal deaths ≥22 weeks or ≥500g).	Per 1,000 total (live and stillborn) births		ICD10**. See Lancet Stillbirth series 2011 Lawn et al for details of variations [95]
	3	Neonatal mortality rate	Number of live born infants per year dying before 28 completed days of age.	Per 1,000 live births		ICD10. See Lancet Every newborn for discussion of reporting of definitions [3]

Figure 3 ***Every Newborn*** **Action Plan (ENAP) core indicators regarding impact, with definitions and data sources**. Shaded= Not currently routinely tracked at global level. Bold= indicator requiring additional evaluation for consistent measurement. *The time period will normally be calculated per year. **ICD assumes weight and gestational age are equivalent, which they are not (see Stillbirth series Lawn *et al*: 2011). ICD: International Classification of Disease; UNFPA: United Nations Population Fund; UNICEF: United Nations International Children's Emergency Fund; WHO: World Health Organization.

Integrated Program (MCHIP) that provides supplementary data for assessment of quality of care.

What can we do to improve the data?

While WHO's definition of a SBA has a defined list of core midwifery skills [18], measurement of SBA is challenged by the variety of cadres included in the definition and the lack of consistency in training, skills and core functions across countries [24]. Besides doctors, nurses and midwifes, there are several other country specific cadres of auxiliary midwifes, medical assistants and other health professionals that are included in the SBA category in many countries; these may also be subject to

Core			Numerator	Denominator	Data sources
COVERAGE: Care for all mothers and newborns	4	**Intrapartum care tracked by the contact point of skilled attendant at birth**	Number of women aged 15-49 years who were attended by skilled health personnel during their most recent live birth [MICS - 2 years preceding the survey] Number of live births assisted by a skilled provider (doctor, nurse midwife, and auxiliary nurse/midwife) [DHS - 5 years preceding the survey]	Total number of women aged 15-49 years with a live birth in the two years prior to the survey [MICS] or all live births within the last 5 years [DHS]	Household surveys (e.g. DHS, MICS) or National facility data/Health management information system or district health information software
	5	**Early postnatal care contact for mothers and babies**	Woman: Number of women aged 15-49 years who received a health check within 2 days after delivery for the most recent live birth [DHS & MICS - 2 years preceding the survey]	Woman: Total number of women 15-49 years with a live birth in the last 2 years [DHS & MICS]	
			Newborn: Number of last live birth with a postnatal health check in the first 2 days after birth [DHS & MICS- 2 years preceding the survey]	Newborn: Total number of last live births in the last 2 years [DHS & MICS]	
	6	**Essential Newborn Care with Early Initiation of breastfeeding as Tracer indicator**	Number of live born infants (born in the 2 years preceding the survey) who are breastfed within first hour after birth [DHS, MICS]	Total number of last live born infants [DHS & MICS]	
		Exclusive breastfeeding to 6 months	Number of living children (born in the 2 years preceding the survey) under 6 months of age who are exclusively breastfed [MICS] (MICS allows oral rehydration solution, vitamins, mineral supplements and medicines) Number of babies 0-5 months who are exclusively breastfed [DHS] (Both MICS and DHS questions focus on feeding behaviours within the last 24 hours from the time of survey)	Total number of living infants under 6 months of age [DHS & MICS]	

Figure 4 ***Every Newborn*** **Action Plan (ENAP) core indicators regarding coverage of care for all mothers and newborns, with definitions and data sources**. DHS: Demographic and Health Survey; MICS: Multiple Indicator Cluster Survey.

Core			Numerator	Denominator (options to be tested and compared especially when target population for coverage is challenging to measure)	DATA SOURCES
COVERAGE: Care for newborns at risk or with complications	7	***Antenatal corticosteroids (ACS) use***	Process Indicator: The number countries with ACS on the essential drug list for the purpose of fetal lung maturation [As collected in the United Nations commodities commission data system & reported in Countdown]	Number of countries with Essential Medicine List policy data	***Facility based:*** National facility based data or facility survey (SARA, SPA etc.), potential in HMIS (initial focus of data collection in facilities WHO guidelines for these are mainly for facility treatment but for countries with major national scale up of community provision e.g. of severe neonatal infection case management, additional community tracking will be required. ***Household surveys:*** These treatment interventions are unlikely to be measureable in Household surveys based on sample size, and challenges with defining denominators especially for parental recognition and also in knowing or recalling details of numerator (e.g. ACS injection vs. Oxytocin injection). KMC and treatment of neonatal infections may be feasible with further testing and sample size calculations.
			Coverage indicator (needs validation): All women giving birth in facility who are <34 completed weeks and received one dose of ACS for being at risk of preterm birth (later testing focus on splitting by gestational age)	a) Live births in the facility b) Total births in the facility (including stillbirths) c) Estimated births (live or total) d) Target population for coverage: i.e. live births in facility by gestational age in weeks, notably GA <34 weeks as target population for coverage	
	8	***Newborn Resuscitation***	Process indicator: Number of facilities with a functional neonatal bag and two masks (size 0 and size 1) in the labour and delivery service area [as defined in WHO QoC report and collected in SPA & SARA facility assessment tools]	Total number of facilities with inpatient maternity services that are assessed	
			Coverage indicator (needs validation): Number of newborns who were not breathing spontaneously/crying at birth for whom resuscitation actions (stimulation and/or bag and mask) were initiated	a) Live births in the facility b) Total births in the facility (including stillbirths) c) Estimated births (live or total) d) Target population for coverage: i.e. total births in the facility not breathing spontaneously/crying but excluding macerated stillbirths (i.e. including fresh stillbirths as a surrogate of intrapartum stillbirths)	
	9	***Kangaroo Mother Care (KMC)***	Process indicator: Number of facilities in which a space is identified for KMC & where staff have received KMC training (< 2 years)	Total number of facilities with inpatient maternity services that are assessed	
			Coverage indicator (needs validation work): Number of newborns initiated on facility based KMC	a) Live births in the facility b) Total births in the facility (including stillbirths) c) Estimated births (live or total) d) Target population for coverage: i.e. total number of newborns with birthweight <2000g as target population for coverage or <2500g	
	10	***Treatment of Severe Neonatal Infection***	Process Indicator: Number of facilities in which gentamicin is available at suitable peripheral level for treatment of severe neonatal infection [WHO QOC, collected by SPA and SARA]	Number of facilities assessed	
			Coverage indicator (needs validation work): Number of newborns that received at least one dose of antibiotic injection for PSBI in the facility	a) Live births in the facility b) Total births in the facility (including stillbirths) c) Estimated births (live or total) d) Target population for coverage: -newborns diagnosed with Possible Serious Bacterial Infection (PSBI) as target population for coverage	

Figure 5 Every Newborn Action Plan (ENAP) core indicators regarding coverage of care for newborns at risk or with complications, with definitions and data sources. Blue coloured cells= not currently tracked and collated by United Nations. Bold italics= indicator needing further work to ensure availability of consistent data in routine information systems. All coverage indicators to be tracked in such a way that they can be broken down to assess equity- e.g. urban or rural, regional, wealth quintile. ACS: antenatal corticosteroids; GA: gestational age; HMIS: Health Management Information System; KMC: kangaroo mother care; QoC: quality of care; SARA: Service Availability and Readiness Assessments; SPA: Service Provision Assessments; WHO: World Health Organization.

change over time, or across survey programmes. Current work towards standardising the professional remit of SBAs and foster more universal accountability mechanisms are being carried out by WHO, UNICEF and UNFPA. Expert consultations will be held in late 2015 to discuss operational definitions and develop measurement guidance for survey programmes.

In addition, SBA is an indicator of contact with the health system and does not provide information on the content or quality of care making it an incomplete and misleading proxy for quality of care at birth [12]; additional information about equipment, provider skills, referral availability, content of care and other measures of quality are also required. Process indicators on facility readiness are collected by SPA, SARA and EmOC needs assessments (Figure 4) though the range of data collected varies between surveys and there is limited focus on newborn care. Current DHS and MICS survey tools do not collect extensive data on the content of care at time of birth [12]; therefore, increasing the capacity and availability of routine facility level data is a priority for improvement.

Early postnatal care

Technical definition of package

A package of healthcare provided to women and their newborn either at the facility or during consultation at home. For women who deliver at a health facility, WHO recommendations support inpatient care for at least 24 hours, and/or provision of care as early as possible and

Core		Numerator	Denominator (Options to be tested and compared especially when target population for coverage is challenging to measure)	DATA SOURCES
COVERAGE: Care for newborns at risk or with complications (specific treatment interventions)	***Chlorhexidine (CHX) cord cleansing***	Process Indicator: The number countries with CHX on the essential drug list for the purpose of cord cleansing [As collected in the United Nations (UN) commodities commission data system & reported in Countdown]	Countries with Essential Medicine List policy data	As collected in the UN Commodities Commission & reported in Countdown to 2015
		Coverage indicator (needs validation work): Number of newborns that received at least one dose of CHX (7.1%) to the cord on the first day after birth (within 24 hours of birth)	Live births in surveyed population (or live births at home depending on national policy/data available)	Potential to collect in household surveys (e.g. DHS, MICS)
	Caesarean Section Rate	Number of women ages 15-49 with a live birth in the X years preceding survey delivered by caesarean section [Countdown, 2015]	Women ages 15-49 with a live birth (also to evaluate option of per total births in facility per year (i.e. including stillbirths, macerated and fresh) given high rate of C-section amongst women with a stillbirth)	National facility based data, or facility survey, HMIS, or household surveys
QUALITY: Service delivery packages for quality care	Emergency Obstetric care (EmOC)	Number of facilities in area providing basic or comprehensive EmOC [Monitoring EmOC handbook, 2009]	Population of area by 500000 [Monitoring EmOC handbook, 2009] (note recent recommendation to shift to denominator based on births not population)	Facility based survey, or potentially from national facility based data / HMIS
	Care of small and sick newborns	Definitions and measurement approach to be determined (Similar approach to EmOC)	Population to be defined (according to births)	Facility based survey, or potentially from national facility based data / HMIS
	Every Mother Every Newborn	Other norms and standards to be defined (e.g. criteria related to structure, such as Water and Sanitation)		

Figure 6 ***Every Newborn*** **Action Plan (ENAP) core indicators regarding coverage of complications and extra care (specific treatment indicators), with definitions and data sources**. Blue coloured cells= not currently tracked and collated by United Nations. Bold italics= indicator needing further work to ensure availability of consistent data in routine information systems. Red= service delivery package for which norms and standards will be defined and tracked. All coverage indicators to be tracked in such a way that they can be broken down to assess equity- e.g. urban or rural, regional, wealth quintile. CHX: chlorhexidine; DHS: Demographic and Health survey; EmOC: emergency Obstetric Care; HMIS: Health Management Information System; MICS: Multiple Indicator Cluster Survey; UN: United Nations.

at least within 24 hours for women and newborns who are born at home [25].

Indicator to track contact point

Early postnatal care is defined as a contact provided to a woman and her newborn during the 2 days (48 hours) following birth (whether in a facility or at home) (see Figure 4) and excludes immediate postpartum care [13].

Current data availability

The early postnatal care contact point is measured in household surveys as two separate indicators (a postnatal health check for the newborn and a postnatal health check for the mother) tracking coverage of a first postnatal contact within 2 days of delivery. The questions used to derive this indicator have changed significantly over time and have been different between the DHS and MICS [14], however Phase 7 of DHS [13] now includes questions allowing computation of a comparable postnatal care indicator.

What can we do to improve the data?

Postnatal care is a package of services for women and babies, therefore, data on content and quality are required in addition to tracking the contact point. One critical question is to ensure the data can distinguish between intrapartum and postnatal care [26]. In both DHS and MICS, this is being attempted through the use of question prompts to better describe the content of the postnatal check and recent revision of the DHS core questionnaire includes a question on the content of PNC checks. Supplementary data pertaining to the content of care, provider skill and other quality control measures is urgently required; a move away from intermittent survey based data collection towards sustainable HMIS is essential in ensuring that effective management mechanisms can be facilitated and support routine quality of care tracking.

Essential newborn care

Technical definition of package

Preventive and supportive care required for all newborns including: warmth, cleanliness, breastfeeding, cord and eye-care, Vitamin K and immunisations [27-29].

Indicator to track care

Due to the strong evidence of a reduction in newborn mortality and morbidity with early initiation of breastfeeding, especially through decreased rates of infection [30-32], early initiation of breastfeeding was prioritised as a tracer indicator for essential newborn care, with exclusive breastfeeding at 6 months as a further marker (Figure 4). Indicators of other components such as skin-to-skin care, may also be possible, and are recalled accurately by mothers

[12]. However, these data are not currently widely available, and further testing is required to ensure that routine skin-to-skin can be accurately distinguished from KMC by survey respondents.

The WHO recommends the early initiation of breastfeeding within one hour of birth [33] and then exclusive breastfeeding for the first 6 months of life [34]. To support this, babies should be placed skin to skin with their mothers immediately following birth and offered help to breastfeed when needed [35].

Current data availability

MICS, DHS and other national household surveys collect data measuring coverage of the early initiation of breastfeeding [1,36] and it is reported in Countdown and SoWC [20]. Both MICS and DHS contain measurement questions focusing on feeding behaviours within the last 24 hours from the time of survey. This approach allows for more accurate recall of the behaviour, however, does not capture breastfeeding practises across the infant time period and, therefore, the results may not reflect breastfeeding practises over time.

What can we do to improve the data?

A recent validation study reported that the early initiation of breastfeeding indicator had high sensitivity (0.82) but poor specificity (0.25), using a household survey instrument [12]. Although the instrument used in the study posed a slightly different question than what is in DHS, this suggests a need for further testing and validation. Additional research to determine the impact of other essential newborn care practices would enable more informed and targeted behaviour change and associated measurement approaches.

Coverage: care for newborns at risk or with complications (specific treatment interventions)

Antenatal corticosteroids

Technical definition of intervention

Currently, antenatal corticosteroid therapy (ACS) (24 mg of intramuscular dexamethasone or betamethasone in divided doses over 24 hours) is recommended by WHO for all mothers at risk of imminent preterm birth (delivery before 34 completed weeks of gestation) when the mother is in a facility where accurate gestational age can be obtained, where there is no clinical evidence of maternal infection, and there are adequate levels of maternity care and special newborn care available [37] (WHO guidelines are currently being revised). These guidelines reflect changes after the Antenatal Corticosteroids Trial (ACT) which evaluated prescription of ACS at lower levels of the health system, with approximately half of births occurring at home, and found a risk of adverse outcomes especially amongst births after 34 completed weeks of gestation [38]. This trial underlines the importance of measuring gestational age, and better tracking of coverage and outcomes.

Current coverage data availability

Coverage data on provision of ACS for neonatal admissions are routinely collected within most high income countries (HIC), but are not consistently part of HMIS or standardised facility surveys. Since the intervention is used in health facilities [38], improved facility level data are a priority for capturing ACS coverage. Household surveys are unlikely to be a useful source for this information, as mothers may not accurately report ACS (with difficulties to differentiate between ACS and other drugs given at the time of labour). In addition, data may have low statistical power given the relatively small numbers in the population who receive ACS for fetal lung maturation [12].

Process indicator to track now

In many LMICs, where HMIS does not capture ACS coverage, a commodities-based process indicator can be measured for tracking in the short term; SARA and SPA includes the availability of dexamethasone within their facility checklist. WHO Health Access/Action International database also collect data on availability of dexamethasone and betamethasone in their existing pharmacy and facility audits [39]. However, a denominator of all health facilities may not be fully accurate as not all facilities would meet WHO criteria for safe provision of ACS (see definition above), including provision of appropriate maternal and newborn care [1,40]. Countdown reports the number of countries whose national policy recommends antenatal corticosteroids for preterm labour [1]. While this indicator is distal to coverage, it is available and helpful in tracking changes in policy context (Figure 5).

What can we do to improve the data?

It is challenging to define a precise indicator that can capture both eligible women who should receive ACS and measure ACS provision. Recent evidence suggests use of ACS may be associated with a risk of adverse outcomes for babies whose gestational age is ≥34 completed weeks [38]. A major challenge is defining the denominator of eligible mothers presenting in labour <34 weeks. In LMICs, the recall of last menstrual period (LMP) is often poor or inaccurate in settings with low rates of literacy and antenatal care. Access to ultrasonography is low and mothers frequently present for ANC late in pregnancy, when ultrasound dating is inaccurate. Thus improved assessment of gestational age before and/or after birth, and documentation of gestational age in medical records, is an urgent priority in all settings irrespective of resource availability, along with improved tracking of safety and non-fatal outcomes. Studies are needed to validate different and feasible methods of ascertaining gestational age compared to accurate gestational age dating (early ultrasonography) in LMIC. Furthermore, methods require validation in different regions and in settings with high rates of fetal growth restriction.

Thus, present capacity within most LMICs may only extend to crude coverage of ACS (e.g. all mothers who received 1 dose) and will not differentiate between those who received ACS before (true positives), or after (false positives) 34 weeks completed gestation. To capture such information, existing datasets from high or middle income countries may be analysed to facilitate the development and testing of a more refined indicator. Improved gestational age assessment and documentation is needed in all settings irrespective of resource availability, along with improved tracking of safety and non-fatal outcomes.

Observation of facility births in a number of countries would allow for testing and validation of a number of options for the denominator (Figure 5). The measurement improvement roadmap aims to assess whether using these denominators is feasible in routine HMIS, and the extent to which proposed options for testing yield useful programmatic tracking information.

As with many of the treatment intervention coverage indicators, the option of using all live births as a denominator will not give accurate population-representative treatment coverage in settings where reporting in HMIS is poor, such as settings with low facility births or a large private sector. In such contexts it may be worth considering estimated births within a facility catchment area as denominator, which is more challenging where populations are not well defined or birth cohorts are uncertain. A denominator that is not restricted to the population in need, will require definition of target coverage levels. For ACS this target benchmark could potentially be defined by the recent estimates of national preterm birth rate (<34 weeks), which was shown to vary from around 4% to 18% globally [41].

Neonatal resuscitation

Technical definition of intervention

Basic neonatal resuscitation describes assessment and actions for every newborn at the time of birth, to assist in establishing breathing and circulation [42]; it should be practised on all non-macerated newborns not breathing spontaneously following immediate drying in accordance with current WHO guidelines [43]. Effective and safe resuscitation of these babies is highly time-sensitive and should be initiated within the first minute after birth. The actions include additional stimulation and positive pressure ventilation with bag and mask if clinically indicated following stimulation [44]. The intervention definition does not include advanced resuscitation measures such as intubation and/or medications.

Current coverage data availability

National coverage data are not currently available on neonatal resuscitation and the intervention lacks a standard measurable indicator. As with ACS, there are several known and suspected limitations of using household surveys to measure neonatal resuscitation coverage, including the likely inability of mothers to report accurately as they may not understand or know if their newborn was resuscitated at birth, and small numbers resulting in low statistical power [12,45].

Process indicator to measure now

Data on the availability of a functional newborn size bag and mask in the delivery area of a health facility offering maternity services may be utilised as a service readiness indicator for neonatal resuscitation, as these data are easy to document and already available now for many countries (see Figure 5) [16-18]. SPA and SARA capture the availability of at least one neonatal size bag and mask in the labour and delivery ward (SARA captures two sizes of masks) and neonatal resuscitation was added to the UN EmOC signal functions in 2009 with data collected as part of standard EmOC needs assessments supported by UNICEF. Since a neonatal-size bag and mask is on the UN essential commodities list, this equipment is also increasingly tracked in logistics management information systems (LMIS). This indicator has strong negative predictive value (a labour ward with no bag and mask cannot ensure adequate resuscitation when needed) and was recommended by the WHO consultation on quality of care [46]. However, the presence of resuscitation equipment does not equate to appropriate and timely use of the neonatal bag and mask, and not all newborns who do not breathe at birth require positive pressure ventilation. Many newborns may respond to stimulation alone, and there is evidence demonstrating that the provision of resuscitation training is associated with a reduction in bag and mask use [47]. Supplementary information regarding the presence of staff who have received newborn resuscitation training in the last two years is collected as part of the SARA and SPA surveys; however, these data may be difficult to compare depending on question framing [16,17].

What can we do to improve the data?

One of the major challenges in capturing precise neonatal resuscitation coverage is the identification and accurate measurement of a denominator that reliably captures babies requiring resuscitation to establish breathing after birth. As with other treatment indicators, accurate identification of the target population depends on correct diagnosis and classification of the individuals in need by health care providers. Accurate classification of babies needing resuscitation is challenging in all settings due to variable diagnostic skills and experience of individual providers [45,48]. Independent of provider competence, this would likely be difficult data to collect in routine systems; we can speculate that it is unlikely that any healthcare worker would record a case where a baby required resuscitation but did not receive it. As with ACS, the measurement improvement roadmap outlines the priority denominators for testing and the validation of observed compared with reported resuscitation practises. Appearance, Pulse, Grimace, Activity, Respiration (APGAR) scores were intended to assess the condition of the newborn after birth, but are not useful for measuring of resuscitation for monitoring purposes as they are not reported until 1 minute of life, after the time within which resuscitation should be initiated. In addition, APGAR scores may not be predictive of outcome unless the score is very low at 5 minutes, and in busy labour wards the scores are often recorded after the event, if at all.

There are further challenges associated with defining a numerator to accurately and feasibly track neonatal resuscitation coverage. An important principle in effective and safe neonatal resuscitation is careful assessment and stimulation of the newborn who does not start breathing spontaneously after routine drying, and only using bag and mask if needed in order to reduce inappropriate use of positive pressure ventilation [44,49,50]. However, bag and mask use may be easier to recall and validate than distinguishing stimulation actions, such as back rubbing, from routine drying and wrapping. A study in Sweden found that neonatal resuscitation documentation was inadequate for reliable evaluation [51]; documentation of resuscitation is unlikely to be more adequate in LMICs. Several countries such as Bangladesh, Nepal and Tanzania, propose testing collection of routine information on newborn resuscitation by action step. Further analysis of such efforts is likely to be useful.

Proposed testing includes comparison of health worker documentation of newborn resuscitation actions in facility records with observed or video recorded resuscitation care; some of this may be possible using existing videos from Nepal or birth records from Bangladesh. New work to observe births in health facilities across a number of countries would allow testing of the resuscitation denominator options (Figure 5) in line with the other treatment indicators, including various case definitions of babies who do not breathe at birth, or do not breathe after stimulation. A simpler denominator for resuscitation based on live births would require defined target levels. According to estimates (based on limited observational data) approximately 6-10% of newborns may require some assistance to begin breathing at birth [48,52].

Kangaroo mother care

Technical definition of intervention

A method of caring for low birthweight newborns (mostly preterm) in direct and continuous skin-to-skin contact, in the kangaroo position, with their mother (or guardian), with support for early and exclusive breastmilk feeding. The current evidence to achieve mortality reductions supports KMC for clinically-stable newborns, weighing less than 2000 g, initiated in a facility [53]. WHO guidelines support that the infant is cared for in the kangaroo position for the equivalent number weeks it would have taken for the infant to reach full term (or as long as the baby will tolerate the position) accompanied with appropriate follow up after discharge [54].

Current coverage data availability

Limited data on KMC are available from facility-based surveys and HMIS for several countries, including Malawi, Dominican Republic, and El Salvador. Some middle-income countries, especially in Latin America, have detailed program data on KMC received, but there is no existing standardised coverage indicator definition. There may be differences between the level of facility in which KMC can be safely provided or initiated and the eligibility criteria for KMC, which creates difficulties in comparing data between settings. Measurement of KMC is not currently carried out by routine household survey platforms.

Process indicator to measure now

Given the immediate challenges for capturing coverage, a service-readiness indicator is proposed: the number of facilities in which a space is identified for KMC and where at least one staff member has received KMC training (SPA measures within the last 2 years) (see Figure 5). This measure is similar to that defined in a recent consultation by WHO on improving measurement on the quality of maternal, newborn and child health care in facilities [46] and is consistent with current SARA and SPA facility assessment tools [16,17].

What can we do to improve the data?

It is possible to measure the number of newborns initiated on facility based KMC in a number of settings through HMIS or hospital admission records (e.g. El Salvador, Dominican Republic, Malawi, Tanzania). However, measuring a denominator of <2000 g is challenging given that nearly half of all newborns globally are not weighed at birth. Where birthweight is recorded, there is a known tendency for digit preference and heaping, especially at 2500 g and 2000 g [55]. The denominator could be measured as a rate per 100 or per 1000 live births, avoiding the difficulties of including weight in the numerator and identifying babies in need for the denominator. However, this doesn't measure whether babies were truly eligible or benefitted from KMC. Since KMC is an intervention that benefits predominantly preterm infants, the proportion of live births that could benefit from KMC will vary between settings (4 to 18%); identical rates may correspond to a different unmet need for KMC [41].

Efforts to improve birthweight recording and gestational age assessment are integral to the scale-up and measurement of more precise indicators for KMC.

Existing datasets from countries with established KMC programmes and accurate assessment of gestational age and birthweight should be used for testing the denominators and proposed numerators (Figure 5). Linked to the measurement improvement roadmap, developing and validating questions for household surveys is also important if the practice is widespread enough to ensure a sufficient sample size. Recent work in Colombia has shown that women can accurately and reliably recall KMC, even decades later [56].

To develop the service readiness indicator, both the WHO quality of care report and the KMC Acceleration Group propose a measure of "operational" KMC [46], although this would need further work to identify and test its specific components. The operational indicator could be based on available "tracers"; for example, SPA currently collects data on allocated KMC space, infant weighing scales, thermometer, and whether staff has received training. Other items (feeding cups, NG tubes, job aids) or improvements to the questions on training and space could be added where more detailed assessments are being carried out. In Colombia, a manual of minimum, desirable and optimal standards for KMC has been developed [57], which could be adapted for different settings.

Treatment of neonatal infection

Technical definition of intervention

The provision of antibiotics to newborns admitted for inpatient care with possible serious bacterial infection (pSBI), in accordance with current WHO treatment guidelines [58,59] and diagnostic algorithms [60]. Case management can also be considered by levels of care: administration of oral antibiotics only, injectable antibiotics only, or full case management of neonatal infection (potentially second line antibiotic therapy, IV fluids, oxygen therapy, other supportive measures) [61]. Recent trials of Simplified Antibiotic Therapy show that, where referral is not possible, treatment with the simpler regimes by lower level workers is feasible [62].

Current coverage data availability

Most LMICs do not collect or aggregate the number of newborns treated for pSBI in HMIS. Household surveys, including DHS and MICS, do not collect data on newborns treated for pSBI because these would likely be unreliable (given recall issues measuring incidence of pneumonia in children under five years) [63]. This contrasts with HIC settings where HMIS data is routinely maintained with additional data points specific to monitoring antibiotic resistance.

Process indicator to measure now

Given challenges in measuring coverage of treatment of serious neonatal infection, a process indicator is proposed: the proportion of facilities in which gentamicin is available (at a suitable peripheral level) for treatment of serious neonatal infection [46]. This is collected by both the SPA, SARA facility assessment tools [16,17] and the WHO health action/access international database [39]. However, as with resuscitation, the presence of the antibiotic in the facility does not directly measure correct use of antibiotics to treat newborns for pSBI or guarantee that the antibiotic is available in paediatric doses [64].

What can we do to improve the data?

The number of newborns treated with at least one dose of injectable antibiotic at a facility is proposed for validation and feasibility testing against a number of denominator options, including total live births, the number of newborns presenting with illness, or the number of newborns diagnosed with pSBI (Figure 5). As treatment regimens may vary between settings, the measurement improvement roadmap aims to assess multiple options for a numerator and explore the validity, feasibility and utility of using HMIS to collect this data. For measurement of the dose of any antibiotic, more details would be required at program and/or facility level (rather than from the coverage indicator); notably, which antibiotic(s) were used and whether the course was completed. It will be necessary to determine appropriate use of antibiotics, as over treatment may increase anti-microbial drug resistance. Routine, national systems are required to track all injectable antibiotic doses given, and those not given, with associated clinical outcomes. A recent review found that within facility based audits, the availability of data on neonatal specific formulations (lower concentration gentamicin, procaine benzylpenicillin) was scarce [64] and therefore, more data is needed regarding the availability of neonatal formulations and specific requirements for administration to newborns. At first level facilities, testing of the new WHO module on "where referral is not possible" with new simplified antibiotic regimens [65] will be possible in five countries (Democratic Republic of Congo, Bangladesh, Pakistan, Ethiopia and Nigeria). Process and quality indicators should also be improved at the facility level, for example, gentamicin has a narrow therapeutic index and is associated with toxicity risks [58]; therefore, monitoring its safe administration at program or facility level is an important marker of quality care. Specific data on neonatal administration of medicines (formulations, concentrations) could also help monitor safety and quality of care in facilities. In addition, where direct patient observations are carried out (as with SPA for the treatment of suspected pneumonia), this could be extended to the treatment of serious neonatal infection in facilities to ensure health worker compliance with IMCI guidelines [59].

Chlorhexidine cord cleansing

Technical definition of intervention

Chlorhexidine (CHX) cord cleansing is the routine application of topical chlorhexidine digluconate 7.1%

(solution or gel, delivering 4%) to the cord stump within the first 24 hours of life. The WHO currently recommends this intervention in settings with an NMR >30:1000 or for homebirths [66,67].

Current coverage data availability

The recommended routine administration of chlorhexidine cord cleansing is a recent policy development [25]. Data are not collected by most HMIS or as part of standardised household survey tools. Both SPA and SARA track the availability of chlorhexidine used for general disinfection in their commodity checklists [16,17]. Monitoring use of 7.1% chlorhexidine for cord cleansing requires documentation of the presence of the specific concentration of chlorhexidine (7.1% formulation rather than any type of chlorhexidine product). Because of country-specific variations in policy for routine cord cleansing, documenting availability of 7.1% chlorhexidine in a health facility will only be of use in settings where programs that use chlorhexidine for umbilical cord cleansing exist.

Process indicator to measure now

Given the current challenges in measuring coverage, the inclusion of chlorhexidine 7.1% (solution or gel) within national essential drug lists for the purpose of cord cleansing has been identified as an interim process indicator (Figure 6). These data are collected by the RMNCH Trust (formerly UN Commodities Commission) and are reported by Countdown [20]. As with ACS, this indicator is distal and is not a measure of coverage; however, it is an important enabling condition, data are currently available, and it would facilitate tracking of policy changes in the coming years.

What can we do to improve the data?

Household surveys can be used to measure chlorhexidine coverage, as carried out in Nepal [68], *The number of newborns who had chlorhexidine applied to the cord stump within the first day of birth* can be evaluated against a denominator of live births in the survey population. DHS has incorporated an optional five question chlorhexidine module for countries with a national chlorhexidine for umbilical cord cleansing programme as part of its newborn module. In countries where chlorhexidine has been introduced at scale (e.g. Nepal, Bangladesh and Nigeria), the chlorhexidine technical working group is recommending adding a follow-up probe question specifically asking about chlorhexidine use.

Refinement of both the numerator and denominator with rigorous assessment of sensitivity and validity will be beneficial. Showing the respondent a picture of the locally marketed chlorhexidine during a household interview might assist with recall, improve validity and will be tested as part of the measurement improvement roadmap. Due to variations in national policy on use of chlorhexidine within facilities, further testing is required to assess the sensitivity and specificity of household survey questions on chlorhexidine cord cleansing following birth within a facility, where cord cleansing may have occurred away from the mother, or performed in her absence. Further validation will be undertaken to compare observed chlorhexidine use with reported practice. Depending on findings, longer-term efforts towards institutionalising chlorhexidine coverage questions within routine household survey platforms would be essential to achieve consistent coverage data.

Discussion

The *Every Newborn* movement is committed to supporting countries to reach a target of ≤12 neonatal deaths and stillbirths per 1000 births by 2030, also closely linked to ending preventable maternal deaths [7]. The ENAP metrics process has highlighted major gaps and lack of tracking for newborn interventions at all levels of the health management information system. To date, insufficient technical work and investment has been dedicated to strengthening national data systems and to rigorous testing of coverage data. Both validation and feasibility testing using standard research protocols for rigorous testing are needed. The multistage ENAP metrics process identified 10 core indicators and a set of 10 additional indicators (Figure 2). Of the core ENAP indicators, five newborn-specific interventions are high impact and central to ENAP, yet coverage information is not collected through existing measurement platforms with comparable data. Our findings highlight the priority actions required to improve ENAP indicators, especially coverage, and detail the technical and research priorities that will enable countries to collect and use the data in health sector review processes (Figure 1); these findings are informing a roadmap to address measurement deficits by 2020.

Measurement improvement roadmap

The ENAP measurement improvement roadmap aims to build on existing national and global metrics work, particularly linking to maternal health metrics, whilst identifying and addressing key measurement gaps for the focus around care at birth and care of small and sick newborns (Figure 7). Through this process the measurement improvement roadmap aims to intentionally transfer data collection, management and analysis skills at a country level (Figure 8).

Impact indicators

Impact indicators are fundamental to tracking progress for *Every Newborn*. Without impact data we cannot accurately measure progress towards goals to end preventable maternal and newborn deaths and stillbirths. Child mortality data have seen the most significant improvement progress over the last decade [69]. For example, the UN

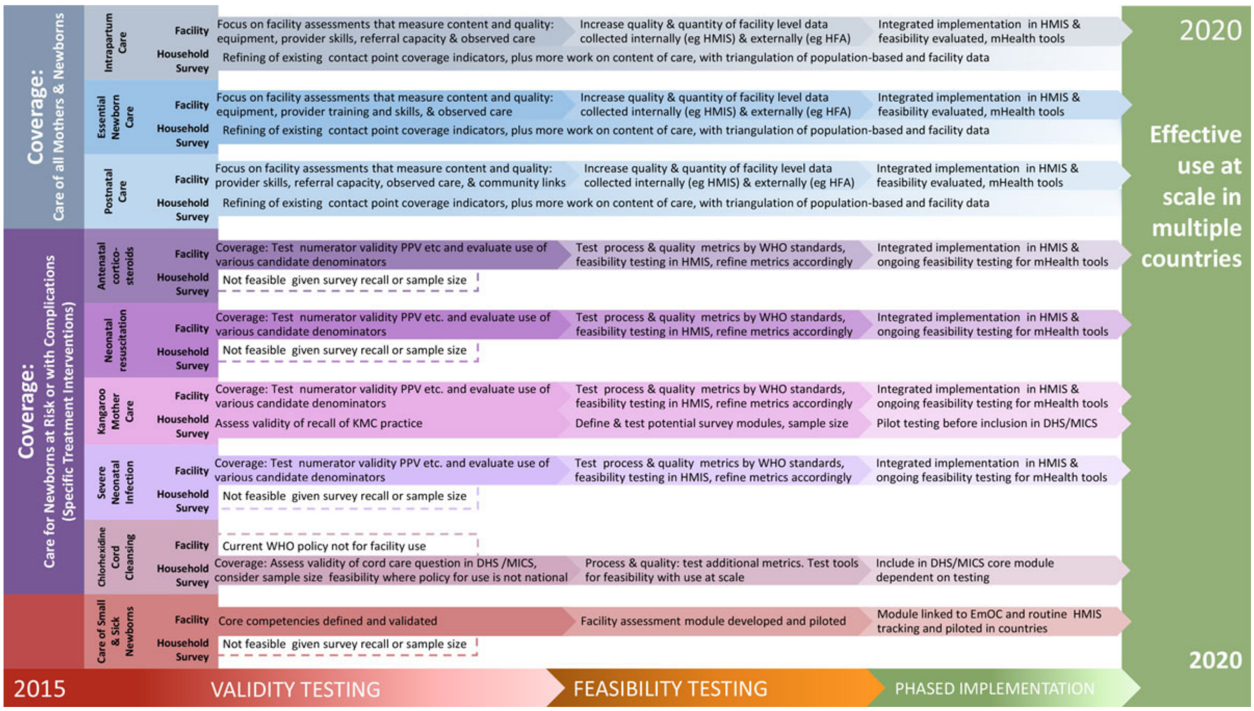

Figure 7 Measurement improvement roadmap for coverage indicators (including care of small and sick newborns). DHS: Demographic and Health Survey, HFA: Health Facility Assessment, HMIS: Health Management Information System, MICS: Multiple Indicator Cluster Survey, PPV: positive predictive value, WHO: World Health Organization.

Inter-agency Group for Child Mortality Estimation report more than tripling input data, mostly through surveys.

ENAP milestones by 2020 include a number of tools to link facility-based minimum perinatal datasets with CRVS to increase birth/death registration [70] and birthweight capture, and in settings with a high proportion of home births, links to intermittent surveys or population surveillance may also be possible (Figure 1). Some countries are now implementing maternal death surveillance and response [71] and have begun to count maternal deaths in real time. A few countries are also incorporating perinatal death audits, which represents a key opportunity to expand use and quality of perinatal audit data [72]. A major focus is needed for inclusion of stillbirth rates in reporting and accountability mechanisms, and especially increasing data on intrapartum stillbirths. Further opportunities have been identified in increasing the coverage and quality of CRVS and verbal autopsy to improve cause of death estimates for maternal, neonatal and stillbirths [73,74]. Substantial work is required on the additional indicators measuring newborn morbidity, disability and child development, which are critical to validate and institutionalise particularly as countries scale up neonatal intensive care services (Figure 7).

Improving measurement of gestational age is essential given that prematurity is the leading cause of newborn deaths and deaths in children under five [75]. Preterm birth is also a major risk factor for deaths from infections and other morbidities [76]. Gestational age is an essential part of clinical targeting of interventions to reduce morbidity and mortality and can be measured both during pregnancy (using methods ranging from the dating of LMP to using more resource intensive ultrasound scans) to clinical assessments of the newborn. The skill sets needed for the measurement approaches that are currently available are different. Estimating gestational age using first trimester ultrasound and the date of last menstrual period is standard in most HIC, but these methods are not available for most women in LMIC. LMP recall is often poor or inaccurate in settings with low literacy. Universal access to ultrasonography is unlikely to be available to large numbers of women in LMIC in the shorter term, and/or mothers who present late in pregnancy, when ultrasound dating is inaccurate (+/- 3 weeks). Current work is looking at the potential for simplified tools for more accurate assessment of gestational age [77], including simplified clinical tools, and surrogate anthropometric measures that could be used by community health workers [78-80]. Validation of new methods in cohorts with early accurate ultrasonography dating is a critical need. Feasible and innovative approaches need to be validated in different regions, populations and settings, across which their performance may vary.

What is the Every Newborn Action Plan measurement improvement roadmap?

Given the world's commitment to end preventable maternal, newborn, child deaths and stillbirths, the Every Newborn Action Plan (ENAP) measurement improvement roadmap is a five year plan to improve, institutionalise and use ENAP metrics in programmes by the year 2020, to track and drive reduction of neonatal mortality and stillbirths to ≤12 per 1000 by 2030. This Roadmap is in support of the Measurement and Accountability for Health (MA4Health) Roadmap [6] to increase investment in national health management information systems. Strong national data systems that count births and deaths, and track coverage of interventions, are fundamental to influence policy, improve quality and delivery of equitable services for a healthy start in life.

How has it been developed?

During the development of ENAP, a systematic process listed 10 core indicators. In the implementation phase, ENAP metrics work is led by a coordination group with representation from multiple partners co-chaired by World Health Organization (WHO), and London School of Hygiene & Tropical Medicine (LSHTM), working with task teams linked to existing technical working groups (e.g. Newborn Indicator Technical Working Group, United Nations Commission on life saving commodities (UNCoLSC) technical working groups). The work involved technical mapping of indicators, and measurement gaps and questions. Following a WHO Technical meeting in Geneva, December 2014, the measurement improvement roadmap was refined through a consultation process between January and May 2015.

What will this result in?

The output is a multi-partner, 5-year ambitious plan to validate and institutionalise these metrics in national data collection platforms and global metrics architecture including accountability mechanisms. This will result in improved measurement of coverage, quality and equity as well as impact through the development, refinement and/or the improvement of the following tools, and approaches to cross link data at these three levels including use of innovative mHealth platforms:

Civil and vital statistics

- Birth certificates and increased coverage and quality of data, e.g. for birth weight.
- Death certificates with improved perinatal data capture and International Classification of Disease (ICD) codes.

Facility and HMIS

- Perinatal mortality audit (linked to maternal audit, and death surveillance and response).
- Minimum perinatal dataset with health management information systems (HMIS) collation for highly prioritised data points, possible in Demographic and Health information systems 2 (DHIS2).
- Tracking of validated coverage indicators for quality of care at birth and care of small and sick newborns, (e.g. antenatal corticosteroids, resuscitation, kangaroo mother care, and treatment of neonatal infections).
- Health facility assessment tools (with standardised process and quality indicators).

Population based surveillance and surveys (Demographic and Health information systems/Multiple Indicator Cluster Surveys)

- Mortality capture including recall, misclassification of stillbirth/neonatal death and pregnancy versus live birth
- Verbal autopsy for stillbirths and neonatal deaths, with optional social autopsy
- Improved tools for assessing birthweight, birth size and gestational age.

Which partners?

To achieve institutionalisation, and intentionally shift technical leadership to high burden settings, the measurement improvement roadmap is linked to existing networks and country centres of excellence to ensure testing and use in many contexts. The process depends on national governments and multiple partners.

NETWORK 1: For mortality data INDEPTH Network with more than 50 sites in Asia and Africa:

- Population based pregnancy surveillance of birth, stillbirths and neonatal deaths
- Opportunities to advance validation of pregnancy history modules, improved low birth weight assessment and verbal autopsy tools.

NETWORK 2: For "Beyond Newborn Survival" data the All India Institute of Medical Sciences (AIIMS), the WHO collaborating centre for training and research in newborn care is well placed to be the institutional focus for:

- Designing a simplified follow up schedule for at risk newborns, by varying levels of care, to screen for disability, retinopathy of prematurity (ROP) and to improve child developments,
- Validate and test the feasibility of a minimum linked dataset for follow up.

COUNTRY HUBS FOR TESTING: The validation work will start with a few countries with opportunities to then expand to other countries

- Validation and feasibility testing for facility based coverage data
- Linked tools such as perinatal audit, minimum perinatal dataset, and simplified gestational age assessment.

Figure 8 ***Every Newborn*** **Action Plan (ENAP) Measurement Improvement Roadmap**. ENAP: Every Newborn Action Plan; HMIS: Health Management Information System; WHO: World Health Organization.

Coverage indicators

The next five years demands an ambitious and systematic process for data improvement (through effective partnership) to address the gaps in newborn coverage indicators. Shared goals across the MNH community will facilitate metrics testing and help institutionalise capacity for systems to collect and use these data (Figure 1). In the short term, desk-based testing and validation of indicator definitions using existing datasets (from LMIC) is required. Additionally, these indicators need to be field-tested in a range of settings. The research process for validation of indicators involves collecting empirical data through direct observations of care in a facility and directly comparing this data with both health worker reports and maternal recall of events. Relatively large numbers of direct observations may be needed to ensure sufficient sample power for estimating sensitivity and specificity of the indicators using appropriate statistical tests. Initial testing sites have been identified as part of the measurement improvement roadmap (Figure 8). Once finalised, testing protocols will be made available to facilitate wide-scale testing across many different settings to yield comparable results. Where indicator definitions already exist and are being collected at scale, there is potential to increase the quantity, quality and frequency of the data (Figure 4). Crosscutting work on increasing the availability, quality, and accuracy of birth weight and gestational age assessment (both in pregnancy and the neonatal period) is needed and will support the development of more precise indicators. It is anticipated that findings from these studies will inform refinements to the proposed indicators before institutionalisation into existing systems (Figure 7).

Household surveys for tracking coverage

Household surveys remain the primary data collection method to estimate coverage of contacts with the health system. The Population Council is carrying out ongoing work to assess the validity of current indicators measuring skilled attendance at birth [81]. Such work provides invaluable evidence on the validity of maternal recall of interventions at the time of birth, with MICS using two year recall and DHS now using the last birth within two years for some maternal and newborn indicators (although collects data for a five year retrospective period). Even where recall achieves higher specificity (such as location of birth or Caesarean-section), their infrequent cycles (currently averaging 5 years) and high cost [82]) make population level surveys less sensitive for annual programme planning and timely decision-making [83]. Previous efforts to improve measurement of many interventions have focused predominantly on household surveys [12,26,84], including recent validation studies from the Improving Coverage Measurement Group. Many of the challenges of measuring the treatment of pneumonia in children through household surveys, especially in identifying the true population of children with pneumonia for the denominator [58], are also applicable to measuring coverage of treatment of neonatal infections and other specific treatment interventions.

The sample size required to generate point estimates of coverage of newborn interventions with sufficient precision through household surveys is often too high; even more so when attempting to consider equity, and analyse by socioeconomic and demographic factors. For chlorhexidine cord cleansing in settings where policy is provision for all live births [25], data collection through a household survey such as DHS could be feasible. Other treatment indicators address subsets of newborns, and therefore, sample sizes and recall issues may make household surveys very challenging for coverage measurement. For measurement of treatment indicators, the results of the ENAP metrics process suggest a shift away from household surveys towards a focus on facility based data collection tools where these interventions can be more feasibly and accurately measured, and a range of denominators tested for use (Figure 9).

Facility data for tracking coverage

For most of the treatment interventions, KMC, ACS, and currently most neonatal resuscitation and serious neonatal infection case management, policy recommendations are focused largely on facility-based initiation or administration. This has meant that preliminary task team work has focused predominately on facility platforms (with the exception of Chlorhexidine). Combined testing in a number of facilities of the range of treatment interventions would enable more efficient testing of a range of numerators and denominators for each intervention using the same datasets, and help to harmonise and align indicators with national and facility-level needs.

Where there is no denominator

Task teams found denominators the most technically challenging issue for measurement of intervention indicators and have identified a list of denominator options for testing wherever possible. Where detailed datasets are available with complete and accurate birthweight and gestational age data (for example in higher or middle income settings), these will be analysed to test and compare the simplified per 100 or per 1000 live births denominator to a more precise indicator option to ascertain correlation between risk and the more precise indicator, and sensitivity to change over time.

In view of contextual variation, such as varying preterm birth rates, or pSBI in different countries, there may be a need to define thresholds or upper and lower limits for indicator values. The proportion of C-section deliveries, for example, has been roughly benchmarked against a threshold of 5-15% in order to highlight where there is an unmet need (less than 5%) or to identify an excess number of C-sections (more than 15%) within a population [85-87]; this threshold is not without controversy. Learning from such processes is important to set realistic, useful ranges for countries to monitor whether interventions are reaching a sufficient number of newborns within safe limits.

Indicator (For full indicator definitions, numerators and denominators see Table 1-3 and web appendix)	**Household Surveys**		**Routine health information systems**	**Health Facility Assessments**		
	DHS	MICS	HMIS	SPA	SARA	EmOC
Care for all mothers and newborn babies						
Skilled birth attendant at birth	✓	✓	✓	✓	✓	✓
Essential Newborn Care (immediate breastfeeding as tracer)	✓	✓				
Early postnatal care – for mother and baby	✓	✓				
Early and Exclusive breastfeeding	✓	✓				
Care for newborns at risk or with complications (specific treatment interventions)						
Antenatal corticosteroid (ACS)	X	X	*	✓	✓	*
Newborn resuscitation	X	X	*	✓	✓	*
Kangaroo Mother Care	*	*	*	*	*	*
Management of severe neonatal infection	X	X	*	✓	✓	*
Chlorhexidine (where recommended)	*	*		✓	*	

Figure 9 Large scale data collection platforms for coverage and process indicators. ✓ Already collected. * Feasible to collect. X=Not likely to be feasible to collect (due to recall of numerator, denominator identification challenges, sample size issues). DHS: Demographic and Health Surveys, MICS: Multiple Indicator Cluster Surveys, HMIS: health management information systems, SPA: Service performance assessments, SARA: Service Availability and Readiness Assessments, EmOC: Emergency Obstetric Care.

Health management information systems

Work towards sustainable, real-time, locally owned and used systems underlines the need for strengthening national HMIS [83]. HMIS refers to health information collected and routinely reported from health facilities and districts (often from government or public sector facilities only) and are an ideal platform to influence as they are present in most settings, relatively inexpensive (compared with large scale representative household surveys) and largely driven by national decision makers. Electronic platforms are evolving to support data collection, management, analysis and report generation, linking to other systems including logistics management (rather than external agencies). The emphasis for strengthening HMIS needs to fall on improving the validity of HMIS indicators and increasing the use of this data for improving programme performance at the ground level. Many settings are now using District Health Information Systems 2 (DHIS 2)[88]. DHIS 2 software has a field-tested flexible data model with data entry forms for indicators and the ability to support data collection, management and analysis, including generating reports to monitor indicator trends over time and produce maps to visualise subnational variations for identification of inequities. There is potential for newborn treatment indicators (particularly KMC, ACS) to be included in HMIS/ LMIS, SPAs and other facility audits along with the supplies and equipment for ACS, neonatal resuscitation and pSBI treatment in settings where they do not already exist.

Before recommending inclusion of indicators into any national data collection system, indicators will need testing for validity and then for feasibility and usefulness, as per the steps of the measurement improvement plan (see Figure 1 and 7). Given the ongoing tension between demand for more information for decision making, versus the need to be parsimonious with the number of indicators to avoid overburdening frontline workers and information systems, prioritisation of the ENAP treatment indicators for inclusion in these systems should be country specific and consider relevance to national policy and health system needs. Overloading an HMIS system with data can limit its usefulness and negatively affect data quality. In addition to validity testing, consideration of national data needs, existing levels of facility, infrastructure, resources and technical capacity is essential before introducing new indicators into a national HMIS. Furthermore, data from HMIS may be more limited in settings where a large proportion of births take place in the community (e.g. Ethiopia), or where there is a large private sector (e.g. India).

Input and process data for tracking content and quality of care

Given the challenges in measuring coverage for several of the treatment interventions, appropriate process indicators were identified that can be measured immediately. For the purpose of this discussion, "process" data refers to any measurement of the presence of specific elements needed to deliver an intervention, such as supportive policy, trained staff, commodities, documentation or infrastructure. Process data are not a replacement for coverage data, but ensure a standardised proxy can be used immediately. These data can be measured through a variety of platforms, including HMIS, routine audits and/or facility based supervision checklists. Additionally, periodic or intermittent health facility assessments, such as SPA [17] and service readiness assessments, such as SARA [16] and EmOC needs assessments [15] monitor process indicators. As many of the indicators (impact and coverage) measured through household surveys require relatively long periods of time to see significant change following policy adjustments, facility level programmatic data is essential for measurement of more proximate factors in the facility that are more amenable to change in the shorter term. Furthermore, facility surveys can provide external validation for self-reported data, such as those emerging from HMIS. Harmonisation of core modules for HFAs should include the priority ENAP process indicators to maximise their use and allow for comparison between surveys (Figure 9). However, the use of periodic health facility assessments is expensive and does not replace routine supervision or programme monitoring.

Some task teams proposed indicators regarding existence of supporting policy at national level as a key measure of process. For example, the task teams for both ACS and CHX proposed a measure of the number of countries with ACS or CHX respectively on the essential drug list since their addition is recent (2013) [37]; data are collected in the RMNCH Trust data system and reported in Countdown (Figures 5 and 6). Given that these interventions are at an earlier point in policy to programme change, these may be useful trackers for now but as programme implementation accelerates, the process indicator should be shifted to more proximal readiness indicators and coverage.

The ENAP measurement improvement roadmap, in partnership with other tracking data harmonisation efforts, aims to test both simple and composite readiness indicators for newborn interventions, considering the presence of essential commodities, trained staff, and space.

Care of small and sick babies

There is a major gap in the definition of standards for the care of small and sick newborns; the provision of quality inpatient care for small and sick babies could have a significant impact on neonatal deaths [9]. The UN EmOC indicators are based on process indicators referred to as "signal functions" for basic and comprehensive emergency obstetric care [18]; currently only one signal function specifically relates to newborn care, but does not fully represent all interventions needed for emergency newborn care. New research supports the addition of signal functions specific to newborn care and strongly recommends that these indicators should be updated [89]. Specific challenges and details on the levels of care are explained in greater detail elsewhere in the series [90] and ENAP recommends an ongoing process with the UN to define indicators for newborn care intervention packages by levels of care.

As a milestone from ENAP linked to EPMM, addressing quality of care at birth is critical; the Every Mother, Every Newborn (EMEN) Initiative is part of this process as discussed in paper 1 of this supplement [91].

Challenges and opportunities going forward

Integrating maternal health and broader roadmaps for improving metrics

It is essential to unite maternal and neonatal health communities towards a common metrics agenda with a convergence of global efforts to end preventable mortality and coordinated support to countries to assess progress meeting targets set within the SDGs, ENAP and the ending preventable maternal mortality movement (EPMM). These functions are the remit of the WHO, other UN agencies and academic partners, and can be aligned through the creation of an over-arching MNH reference group. This remit will also aim to link existing work and relevant convening groups, including those working on wider metrics systems change.

Intentional development of leadership to assess, improve and use data

In order to institutionalise the proposed metrics, there is a need to build leadership skills to assess and use data in high burden settings (Figure 8). These include INDEPTH Network's Maternal and Newborn Working Group, which aims to improve population-based metrics, especially pregnancy tracking, mortality, cause of death and social autopsy, birthweight and gestational age. INDEPTH is a network of currently 52 health and demographic surveillance sites (HDSS) in twenty countries where a total population of 3.8 million people are tracked each year. The Maternal and Newborn Working Group is building the capacity of member sites to use standardised tools and to make data regularly available to the public. The All India Institute of Medical Sciences/WHO Collaborating Centre for Newborn Care is well placed to develop a simplified database for follow up of at risk neonates, track and minimise disability outcomes and maximise child development, especially preterm, for example preventing blindness from retinopathy of prematurity [92,93]. ENAP is identifying provisional country hubs for testing of proposed indicator numerators and denominators initially linked to focus countries for EMEN.

Conclusions

Major gaps have been identified in the measurement of core ENAP indicators to track the progress towards targets to end preventable deaths for women, stillbirths, newborns and children; key messages and action points are summarised in Figure 10. The quality and quantity of impact data must be improved, but coverage indicators need the most urgent work. Content and quality of care is the current priority for the three contact point indicators. For the treatment indicators, preliminary work to identify measurable denominators is required in preparation for the quality improvement agenda. The findings of this work underline the need for increasing prioritisation for strengthening and improving routine facility based

Key messages

The *Every Newborn* Action Plan (ENAP)

ENAP published 10 core indicators with selected additional indicators following a systematic, multi-stage consultation process to assess 70 indicator options.

- The ***impact indicators*** – neonatal mortality rate, stillbirth rate and maternal mortality ratio – have clear definitions, but there are gaps in data quantity and quality.
- The ***coverage indicators for care of all mothers and newborns*** – intrapartum/skilled birth attendance, early postnatal care and essential newborn care – are based on clearly defined contact points, but still have major gaps in measuring package content and quality.
- The ***coverage indicators for care for newborns at risk or with complications (specific treatment interventions)*** - antenatal corticosteroids, neonatal resuscitation, treatment of severe neonatal infection and kangaroo mother care, and an additional indicator, chlorhexidine cord cleansing - lack clear indicator definitions. Data on these treatment interventions is not currently tracked in routine systems or existing data collection platforms. Measurement of the denominator for these treatment intervention indicators is especially challenging.

Key action points

The *Every Newborn* Metrics group has devised the Measurement Improvement Roadmap in order to track progress of *ENAP* milestones so that every country can reach a target of ≤12 neonatal deaths and stillbirths per 1000 births by 2030. This involves:

- Development of measurement tools (perinatal death certificates, audit tools, minimum perinatal dataset, gestational age and birthweight metrics improvements), including a focus on strengthening routine health information systems, linking to CRVS and population based surveys.
- An ambitious plan to test validity of the ENAP coverage indicators, in selected facilities/settings, and feasibility of including in facility based HMIS, considering a range of options for denominators.
- Intentional transfer of leadership for measurement, especially in those countries with the greatest disease burden, with links to existing networks (e.g. INDEPTH) for testing, validation and institutionalisation of the proposed coverage indicators.

Figure 10 Key messages and action points. ENAP: Every Newborn Action Plan; HMIS: health management information systems.

data, CRVS and national HMIS. This paper has laid out a systematic, yet ambitious testing agenda - the ENAP Measurement Improvement Roadmap - to move towards use of these indicators at scale, which must be combined with an intentional transfer of technical leadership, especially to countries with the greatest disease burden. The strengthening of institutional capability to collect, analyse and convert data into action is essential. By 2020, the aim is to institutionalise the proposed metrics at scale across all countries. A roadmap that focuses on counting births, deaths and improves tracking of coverage and equity is central to support countries to build a strong national data system that can be used to inform policy and focus investment and resources towards quality service delivery for every newborn to have the chance of a healthy start in life [6].

Additional material

Additional file 1: Listing of relevant indicators according to level of the impact framework (from impact down to inputs).

List of abbreviations

ANC: antenatal care; ACS: Antenatal Corticosteroids; BFI: Baby Friendly Initiative; CD: Countdown to 2015; COIA: Commission on Information and Accountability; CHX: Chlorhexidine; CRVS: Civil Registration and Vital Statistics; DHS: Demographic and Health Survey; DHIS2: District Health Information Software 2; EMEN: Every Mother Every Newborn; EmOC: Emergency Obstetric Care; ENAP: Every Newborn Action Plan; HBB: Helping Babies Breathe; HFA: Health Facility Assessment; HIC: high income countries; HMIS: Health Management Information System; ICD: International Classification of Disease; KMC: Kangaroo Mother Care; LMIC: Low and middle income countries; LMIS: logistics management information system; LMP: last menstrual period; LSHTM: London School of Hygiene and Tropical Medicine; MCHIP: Maternal and child health integrated program; MDSR: Maternal Death Surveillance and Response; MICS: Multiple Indicator Cluster Survey; MMR: maternal mortality ratio; MNCH: maternal newborn and child health; NMR: neonatal mortality rate; PNC: postnatal care; pSBI: potential severe bacterial infection; QoC: quality of care; R-HFA: Rapid Health Facility Assessments; ROP: Retinopathy of Prematurity; RMNCH: Reproductive, Maternal, Newborn and Child Health; SARA: Service Availability and Readiness Assessments; SBA: Skilled Birth Attendant; SBR: Stillbirth rate; SGA: small for gestational age; SoWC: State of the World's Children; SPA: Service Provision Assessments; UN: United Nations; UNCoLSC: United Nations Commission on Life Saving Commodities; UNICEF: United Nations International Children's Emergency Fund; UN-IGME: United Nations inter agency group for child mortality estimation; UNFPA: United nations Population Fund; USAID: United States Agency for International Development; VR: vital registration; WHO: World Health Organization.

Competing interests

All authors declare they have no competing interests. The content of this article is the view and responsibility of the authors alone and does not necessarily reflect the policy or views of any of the organisations listed, including: the World Health Organization, USAID or the United States Government.

Authors' contributions

JEL and SGM conceptualised the paper coordinated the drafts with HR-F and MM. The ENAP Metrics coordination group (JEL, MM, AA, SF. JG, ACM, LMEV) all reviewed and input starting from early drafts. The Coverage Task teams for antenatal corticosteroids (ACS), kangaroo mother care (KMC), newborn resuscitation, severe neonatal infection case management, and chlorhexidine (CHX) cord cleansing all worked on their indicator and specific sections. All authors reviewed drafts and approved the final manuscript.

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Inpatient care of small and sick newborns: a multi-country analysis of health system bottlenecks and potential solutions

Sarah G Moxon[1,2,3*], Joy E Lawn[1,2,3], Kim E Dickson[4], Aline Simen-Kapeu[4], Gagan Gupta[5], Ashok Deorari[6], Nalini Singhal[7], Karen New[8], Carole Kenner[9], Vinod Bhutani[10], Rakesh Kumar[11], Elizabeth Molyneux[12], Hannah Blencowe[1,2,3*]

Abstract

Background: Preterm birth is the leading cause of child death worldwide. Small and sick newborns require timely, high-quality inpatient care to survive. This includes provision of warmth, feeding support, safe oxygen therapy and effective phototherapy with prevention and treatment of infections. Inpatient care for newborns requires dedicated ward space, staffed by health workers with specialist training and skills. Many of the estimated 2.8 million newborns that die every year do not have access to such specialised care.

Methods: The bottleneck analysis tool was applied in 12 countries in Africa and Asia as part of the *Every Newborn* Action Plan process. Country workshops involved technical experts to complete the survey tool, which is designed to synthesise and grade health system "bottlenecks" (or factors that hinder the scale up) of maternal-newborn intervention packages. For this paper, we used quantitative and qualitative methods to analyse the bottleneck data, and combined these with literature review, to present priority bottlenecks and actions relevant to different health system building blocks for inpatient care of small and sick newborns.

Results: Inpatient care of small and sick newborns is an intervention package highlighted by all country workshop participants as having critical health system challenges. Health system building blocks with the highest graded (significant or major) bottlenecks were health workforce (10 out of 12 countries) and health financing (10 out of 12 countries), followed by community ownership and partnership (9 out of 12 countries). Priority actions based on solution themes for these bottlenecks are discussed.

Conclusions: Whilst major bottlenecks to the scale-up of quality inpatient newborn care are present, effective solutions exist. For all countries included, there is a critical need for a neonatal nursing cadre. Small and sick newborns require increased, sustained funding with specific insurance schemes to cover inpatient care and avoid catastrophic out-of-pocket payments. Core competencies, by level of care, should be defined for monitoring of newborn inpatient care, as with emergency obstetric care. Rather than fatalism that small and sick newborns will die, community interventions need to create demand for accessible, high-quality, family-centred inpatient care, including kangaroo mother care, so that every newborn can survive and thrive.

Background

Severely sick newborns, including those with infections, severe intrapartum insults, severe jaundice or those who are too small to maintain their body temperature or to breathe or to feed actively, will require inpatient care to survive. This paper forms part of a series on high quality maternal and newborn care and examines bottlenecks and solutions specific to the provision of newborn inpatient care for small and sick babies.

The first 28 days of life is a vulnerable time for newborns, with an estimated 2.8 million babies dying during the first month of life worldwide in 2013 [1]. The main causes of death include direct complications of prematurity (36%), intrapartum events (previously called birth

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asphyxia) (23%), and infections (23%) [2,3]. Nearly three-quarters of all neonatal deaths occur in the first week of life [3]. The highest risk of death or serious morbidity occurs among the 10 million born at term with low birth weight (<2500 g) [4] and the 15 million born preterm (before 37 completed weeks of gestation) each year [5]. Many lives could be saved, and morbidity prevented, through a combined health systems approach [6] along the continuum of care, with identification of those at high risk and timely provision of quality inpatient and supportive care [7]. Strengthening of existing facility-based systems for the care of vulnerable newborns is the most effective approach for saving newborn lives [8] and is central to achieving the goals of the *Every Newborn* Action Plan (ENAP) [9].

Inpatient care is usually delivered across three levels (Figure 1) and refers to the facility-based care of newborns focused on both treatment and prevention of infection and further complications. Prevention includes protection from hypothermia (ensuring warmth) and hospital acquired infection, as well as the provision of adequate nutrition (often with nasogastric or cup feeding), with the overall goal of establishing exclusive breastfeeding where possible. Treatment, where available, centres on the management of common neonatal conditions including respiratory distress syndrome (RDS), neonatal infections, hyperbilirubinaemia, feeding difficulties [7] and the prevention and treatment of retinopathy of prematurity (ROP) [10]. Advanced treatment for other important conditions, such as necrotising enterocololitis (NEC), patent ductus arteriosis (PDA), correctable congenital anomalies and broncho-pulmonary dysplasia (BPD) may also be undertaken. Basic newborn care (providing cleanliness, warmth and support for breastfeeding) is essential for all babies, including timely resuscitation for up to 10% of babies that may require resuscitation at birth [11] and is covered elsewhere in this series [12]. Inpatient care for small or sick babies includes two cornerstone components: Kangaroo Mother Care (KMC) and sepsis case management, which are also considered elsewhere in this series [13,14]. While in a well-functioning health system all three levels of care will be available (Figure 1), many small babies can be managed without provision of any higher level neonatal intensive care and can be looked after in special care units [7]. Currently, however, over three quarters of babies born in Sub-Saharan Africa and Southern Asia cannot access special care if they were to require it (Figure 2).

High quality inpatient care for sick neonates includes careful monitoring by trained health professionals with a sound understanding of the physiological and psychosocial needs of the small or sick newborn baby and their families. A recent DELPHI exercise estimated that optimal supportive care in a hospital Special Care Baby Unit (SCBU) could avert 70% of neonatal deaths due to preterm birth complications, and that 90% could be averted with availability of hospital Neonatal Intensive Care Units (NICUs) [6]. Whilst coverage of these inpatient care packages are near universal in high-income settings, both the coverage and the quality of care available in middle-and low-income settings are highly variable [15]. The provision of high quality nursing and inpatient medical care of small and sick newborns not only saves lives, but could also help to facilitate more rapid discharges from health facilities, leading to better short and long-term morbidity outcomes for these babies, including reduction of BPD and ROP. This need is reflected by the current burden of long term disability in survivors following preterm birth being greatest in middle income countries, particularly where coverage of inpatient neonatal care has expanded without due attention to the quality of care provided [10].

Inadequate care in facilities can be caused by a number of constraints usually related to health worker shortages and poorly equipped facilities, compounded by a lack of specific knowledge and competencies in dealing with small and sick newborns amongst existing clinicians and nursing staff [9,16]. Facility-based neonatal care frequently remains under-prioritised and under-funded in many parts of the world, particularly in low and middle income countries (LMIC). Few standardised indicators exist to measure quality of newborn care in facilities and challenges remain to improve the metrics and core competencies [17]. Inadequacies in supplies and safe use of medicines and equipment (including effective phototherapy and case management for sick neonates) are common problems despite the fact that evidence-based interventions exist that can be delivered in resource-constrained environments [18].

The vision of providing quality care to sick newborns is part of a wider global movement - the United Nations (UN) Secretary General Global Strategy in 2010 [19] called for innovative approaches to provide quality care for mothers and newborns, using coordinated research and the formulation of accountability mechanisms through the Commission on Information and Accountability for Women's and Children's Health (COIA). Published in 2014, The Lancet Every Newborn Series (http://www.thelancet.com/series/everynewborn) demonstrated the progress that has been made, even in challenged settings, and outlined the urgent steps still needed to improve newborn survival. The Lancet papers proposed a package of integrated quality interventions [16,20] - the Every Mother, Every Newborn (EMEN) initiative - that have been outlined in the Every Newborn Action Plan (ENAP) alongside specific actions and ambitious targets for newborn survival [9]. This paper aims to interrogate country-level data on "bottlenecks" to quality care and to

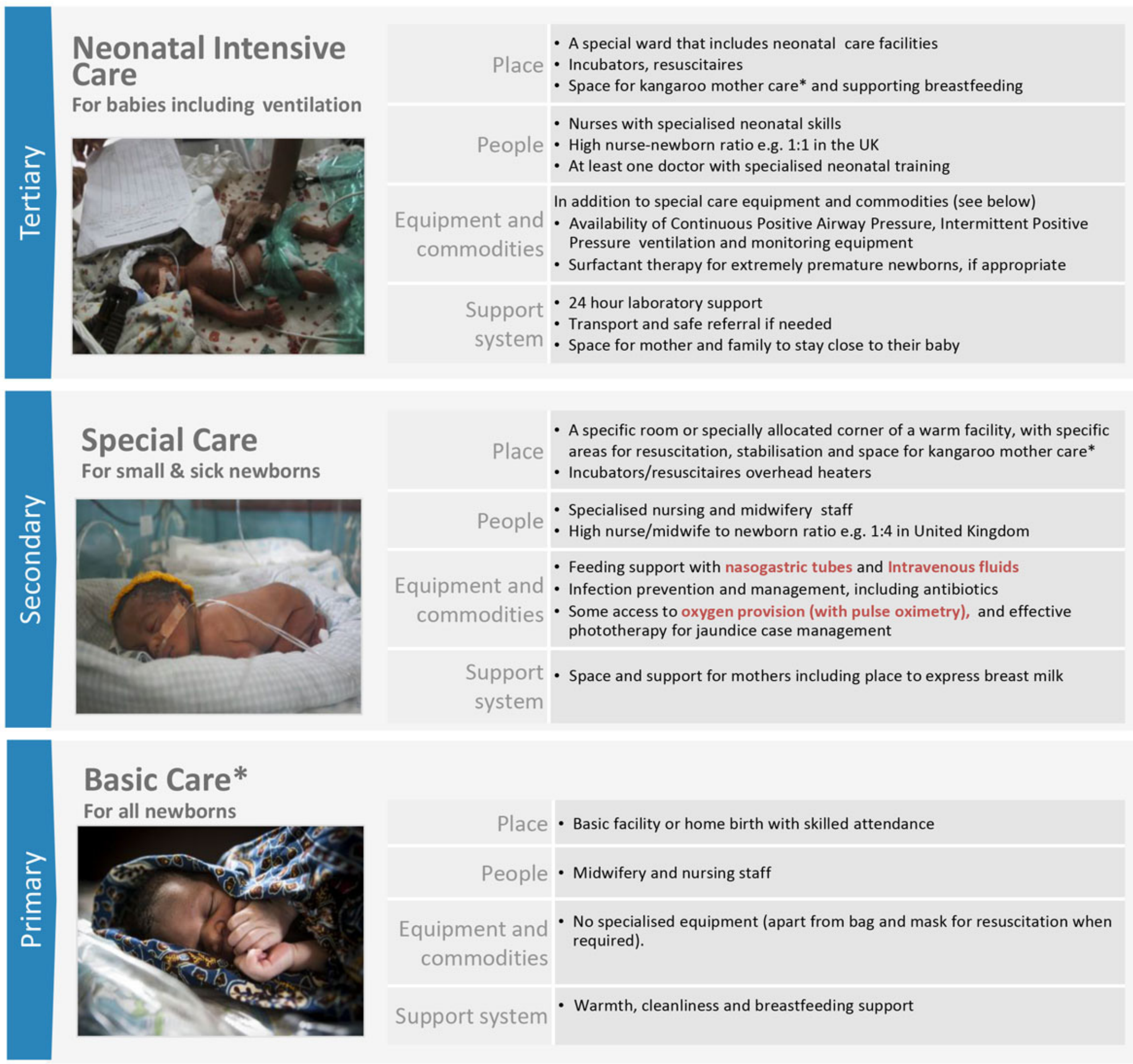


Figure 1 Inpatient care of small and sick babies, showing health system requirements by level of care. Red text signifies tracer indicator for bottleneck tool analysis. *See Vesel et al (2015) Kangaroo mother care, Enweronu-Laryea et al (2015) Basic newborn care and resuscitation, and Simen-Kapeu et al (2015) neonatal sepsis. Neonatal intensive care image source: Getty images/Save the Children. Special care for small and sick newborns image source: Ian Hurley/Save the Children. Basic care for all newborns image source: Jonathan Hyams/Save the Children.

draw out innovative solutions, in order to aid the formulation of country led health plans and strengthen the capacity of health systems to respond to the needs of small and sick newborns.

Objectives of this paper are to:

1. Use a 12-country analysis to explore health system bottlenecks affecting the scale up of inpatient supportive care for small and sick newborns
2. Present the solutions to overcome the most significant bottlenecks including learning from the 12-country analyses, literature review and programme experience
3. To discuss policy and programmatic implications and propose priority actions for programme scale up.

Methods

This study used quantitative and qualitative research methods to collect information, assess health system bottlenecks and identify solutions to scale up of maternal and newborn care interventions in 12 countries:

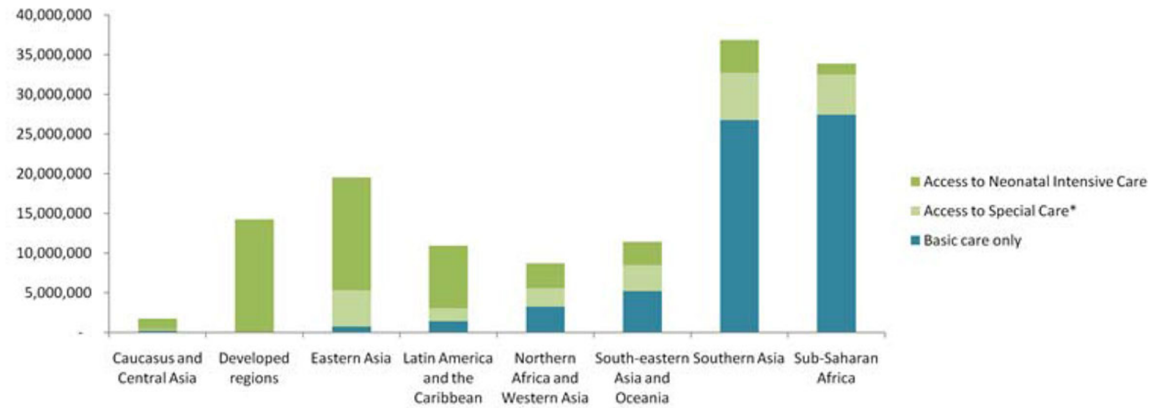


Figure 2 Estimated coverage of neonatal care by region of the world and level of care. *By Special Care Baby Unit, this is the highest level of care available (i.e. no Neonatal Intensive Care). Data source: Adapted from Beyond Newborn Survival: The Global Burden of Disease due to Neonatal Morbidity. Estimates of neonatal morbidities and disabilities at regional and global levels for 2010: introduction, methods overview, and relevant findings from the Global Burden of Disease study. Pediatric Research; December 2013, Volume 74, (Supplement 1).

Afghanistan, Cameroon, Democratic Republic of Congo (DRC), Kenya, Malawi, Nigeria, Uganda, Bangladesh, India, Nepal, Pakistan and Vietnam.

Data collection

The maternal-newborn bottleneck analysis tool (additional file 1) was developed to assist countries in the identification of bottlenecks to the scale up and provision of nine maternal and newborn health interventions across the seven health system building blocks as described previously [16,20]. The tool was utilised during a series of national consultations supported by the global *Every Newborn* Steering Group between July 1st and December 31^{st,} 2013. The workshops for each country included participants from national ministries of health, UN agencies, the private sector, non-governmental organisations (NGOs), professional bodies, academia, bilateral agencies and other stakeholders. For each workshop, a facilitator oriented on the tool coordinated the process and guided groups to reach consensus on the specific bottlenecks for each health system building block. This paper, seventh in the series, focuses on the provision of inpatient care of small and sick newborns.

Tracer interventions were defined for each package to focus the workshop discussion. For the purpose of this bottleneck analysis, three interventions required for the treatment of common neonatal conditions were included as tracer items for the package of inpatient care: safe oxygen administration, intragastric tube feeding (IGTF) and the provision of intravenous (IV) fluids (Figure 3). Oxygen therapy is a mainstay treatment for small and sick babies, with respiratory compromise commonly seen in RDS (following preterm birth, neonatal pneumonia and neonatal sepsis) and respiratory failure being an important mechanism in most neonatal deaths [3]. Developmental immaturity of the preterm newborn (especially those born before 34 weeks gestation), or severe illness in a more mature neonate, may limit their ability to coordinate sucking and swallowing required for successful exclusive breastfeeding. In these instances, intragastric feeding is a commonly used low-tech intervention to deliver nutrition, using expressed breast milk where possible. In addition, many of the most small and sick newborns will require administration of IV fluids to prevent dehydration as a result of insensible water loss, and to manage the delicate fluid, electrolyte and glucose balance, especially in the first days after birth [21,22].

Safe implementation and monitoring of these interventions can be challenging, especially in low-resource settings. The list of tracers is not exhaustive and other important interventions, notably, effective phototherapy for the treatment of hyperbilirubinaemia (Figure S2, additional file 2), basic newborn care and resuscitation [12], KMC [13] and management of neonatal sepsis [14] are covered by other sections of the bottleneck analysis tool.

Data analysis methods

Data received from each country were analysed and the graded health system building blocks were converted into heat maps (Figures 4 and 5). Bottlenecks for each health system building block were graded using one of the following options: not a bottleneck (=1), minor bottleneck (=2), significant bottleneck (=3), or **very** major bottleneck (=4) (Figure 5). We first present the number of countries from which workshops participants categorised health system bottlenecks as significant or very

Safe oxygen administration

Involves the use of an appropriate delivery mechanism with adequate monitoring to ensure that babies maintain appropriate oxygen levels. Common interfaces used are nasal prongs/cannula, head box, Continous Postive Airway Pressure (CPAP) or in a small proportion of the most severe cases, mechanical ventilation. All babies require the monitoring of oxygen levels using pulse oximetry to ensure optimum and safe levels of oxygen are delivered to maximise survival and minimise potential damage [54, 55]. There has been substantial debate around the optimal oxygenation levels for sick neonates. Hyperoxia may lead to brain injury and in premature neonates can lead to retinopathy of prematurity (ROP). The highest risk of ROP is in neonates born at <32 weeks, however ROP can occur in sick neonates born at up to 36 weeks gestational age where inadequate attention is given to safe oxygen delivery[62]. Conversely, hypoxemia can lead to brain injury, renal failure, pulmonary hypertension and necrotising enterocolitis (NEC). As targeting lower O2 saturation levels (85-90%) decreases risk of ROP, but increases the risk of mortality, current recommendation is to target levels 90-95% - especially in very premature infants[63]. Finally, oxygen administration relies on safe mechanisms for storage (including consideration of fire risk) and containers for its delivery (oxygen concentrators or blenders).

Intragastric feeding

Refers to the administration of milk feeds through a small plastic tube[64]. The tube should be passed by a trained individual, usually a nurse, through the nose (naso-gastric) or mouth (oro-gastric) directly into the stomach. For many infants, particularly very small and sick newborns, it will be undesirable to commence enteral feeds at the full volume needed to meet their nutritional needs. The immature gut and renal systems may have limited capacity to tolerate milk feeds and balance electrolytes – particularly sodium. Where full enteral feeding is not tolerated, intravenous fluids or total parenteral nutrition (TPN) may be considered, in settings where these are available.

Safe administration of IV fluids

Intravenous fluids are most commonly administered through venous cannulae inserted by trained medical or nursing staff. They require careful monitoring of the insertion site for signs of infection, as well as meticulous monitoring of fluid intake and output, including serum electrolytes, urine output and daily records of weight [21, 65]. Intravenous fluids should be administered with caution, complemented by enteral milk feeds where feasible. They should be discontinued as soon as possible as they do not provide adequate nutrition and small and sick infants are at high risk of NEC, broncho-pulmonary dysplasia and exacerbation of respiratory or cardiac illness through fluid overload [22, 65].

Figure 3 Definitions of tracer indicators for inpatient care of small and sick newborn bottleneck analysis tool. For more details see the complete bottleneck analysis in the additional file 2.

major, by mortality contexts (Neonatal Mortality Rate (NMR) <30 deaths per 1000 live births and NMR ≥30 deaths per 1000 live births) and region (countries in Africa and countries in Asia) (Figure 4). We then developed a second heat map showing the specific grading of health system bottlenecks for each country (Figure 5).

Context specific solutions to overcome challenges to scaling up inpatient care identified in all countries were categorised into thematic areas and then linked to the specific bottlenecks in the results section (Table 1/ Table S1, additional file 2). We undertook a literature review to identify further case studies and evidence-based solutions for each defined thematic area (Additional file 2). For more detailed analysis of the steps taken to analyse the intervention specific bottlenecks, please refer to the overview paper [20].

Results

Our analysis identified bottlenecks across seven health system building blocks relating to the inpatient supportive care of small and sick newborns. Twelve countries submitted their responses to the inpatient care of small and sick newborns bottleneck tool. Afghanistan, Cameroon, Democratic Republic of Congo (DRC), Kenya, Malawi, Nigeria, Uganda, Bangladesh, Nepal and Vietnam returned national level responses. Pakistan provided subnational data from all provinces, Gilgit-Baltisan, Azad Jammu and Kashmir, excluding two tribal territories. India returned subnational data from three states: Andhra Pradesh, Odisha and Rajasthan.

DRC did not provide a grade for health service delivery and community ownership and partnership; and Malawi did not provide a grade for health information systems. In these cases the country was removed from the sample for the quantitative grading of that building block, but included for all other building blocks; their examples of described bottlenecks were still included in the analysis and presented in the results. Afghanistan listed their bottlenecks and completed rating for all building blocks, but did not propose any solutions.

The solution themes are summarised by health system building block in Table 1 (with more details in additional file 2). Care of small and sick newborns is a newborn intervention area highlighted by all country workshop

	All 12 countries	Countries with NMR <30 deaths per 1000 livebirths*	Countries with NMR ≥30 deaths per 1000 livebirths**	Countries in Asia	Countries in Africa
Leadership and Governance	8 out of 12	4 out of 7	4 out of 5	3 out of 6	5 out of 6
Health Financing	10 out of 12	6 out of 7	4 out of 5	5 out of 6	5 out of 6
Health workforce	10 out of 12	6 out of 7	4 out of 5	5 out of 6	5 out of 6
Essential medical products and technologies	8 out of 12	4 out of 7	4 out of 5	3 out of 6	5 out of 6
Health Service Delivery	7 out of 11	3 out of 7	4 out of 4	4 out of 6	3 out of 5
Health information System	8 out of 11	4 out of 6	4 out of 5	4 out of 6	4 out of 5
Community Ownership and Partnership	9 out of 11	5 out of 7	4 out of 4	5 out of 6	4 out of 5

% of Countries Citing Significant or Major Bottlenecks
≥75%
25-74%
<25%

Figure 4 Very major or significant health system bottlenecks for inpatient care of small and sick newborns. NMR: Neonatal Mortality Rate. *Cameroon, Kenya, Malawi, Uganda, Bangladesh, Nepal, Vietnam. **Democratic Republic of Congo, Nigeria, Afghanistan, India, Pakistan. See additional file 2 for more details.

participants as a major challenge to health systems, especially when considered in comparison with other intervention areas studied in the workshop. Grading according to the number of countries that reported very major or significant health system bottlenecks for inpatient supportive care for small and sick newborns is shown in Figure 4. Overall, the health systems building blocks with the most frequently reported very major or significant bottlenecks were health financing (10 out of 12 countries), health workforce (10 out of 12 countries), followed by community participation (9 out of 11 countries), suggesting these may be priority areas within which to tackle barriers to the scale up of inpatient care for small and sick newborns. As expected, building blocks were rated more poorly in countries with higher NMR. African countries reported a higher number of major and significant bottlenecks, but Afghanistan had the highest level of very major bottlenecks and Malawi had the lowest graded bottlenecks, as shown in Figure 5.

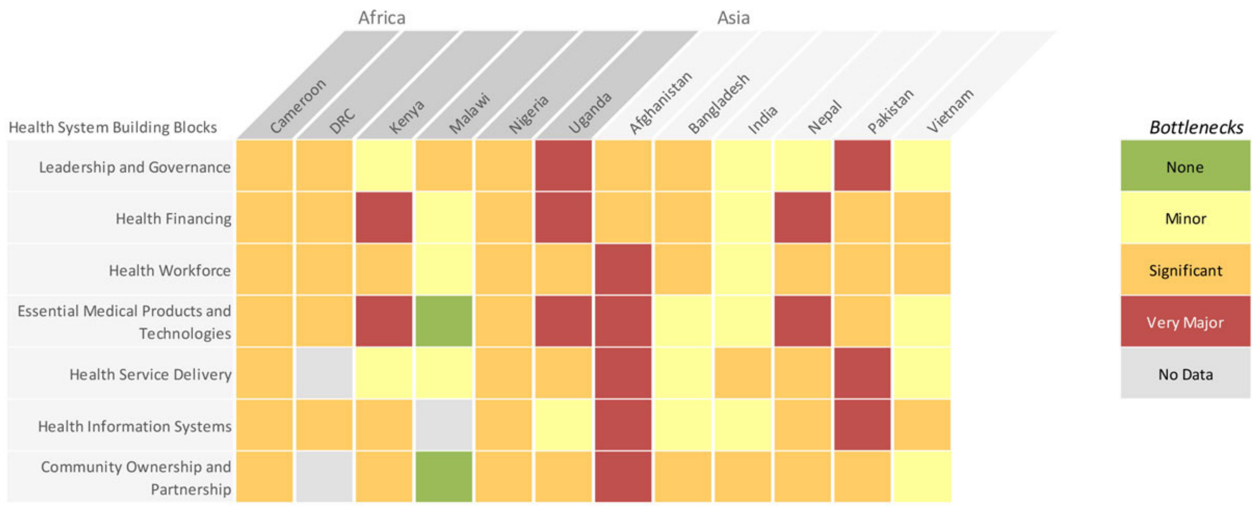
Leadership and governance bottlenecks and solutions

The first building block, leadership and governance, was considered to have very major or significant bottlenecks across 5 of the African countries, and 3 of the Asian countries (Figure 4). Countries in both regions commonly identified a lack of national level advocates (including policy makers, key individuals within professional bodies, academics and national institutions) for advancement of quality care for newborns. At the governance level, country workshop participants highlighted lack of supportive policies for care of small and sick babies. Specifically, workshop participants noted that their existing policies were not inclusive of the key supportive and organisational policies for newborn care, such as well-defined, rational referral systems, discharge criteria and standardised levels of care at the district and peripheral level. Policy documents in circulation amongst senior officials were not always disseminated to the managers at lower levels of the health service and did not always incorporate guidelines with important components of special care for newborns, such as supportive policies, guidelines for breastfeeding and family centred care (Table 1/ Table S1, additional file 2).

Solutions proposed by country teams centred on the need for targeted advocacy and political will. They focused on improving the organisational and supportive structures for sick newborns at the policy and governance level and building local champions. Country workshop teams proposed reviewing the existing organisational policies and guidelines at a central level and ensuring these were disseminated to all levels of the health system (Table 1/ Table S2, additional file 2).

Health financing bottlenecks and solutions

Health Financing bottlenecks were frequently graded as needing significant work for inpatient care of newborns - 10 out of all 12 country teams (Figure 4) graded it as very major or significant, with only Malawi and India perceiving there to be only minor bottlenecks (Figure 5).



A

Health System Building Blocks

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<tr><td>Very Major</td><td>2</td><td>2</td><td>1</td><td>4</td><td>2</td><td>2</td><td>1</td></tr>
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B

Figure 5 Individual country grading of health system bottlenecks for inpatient care of small and sick newborns. Part A: Heat map showing individual country grading of health system bottlenecks for inpatient care of small and sick newborns. Part B: Table showing total number of countries grading significant or major for calculating priority building blocks. DRC: Democratic Republic of the Congo.

Revenue collection for newborn health, and competing calls for financing of other areas of healthcare, was clearly viewed as a barrier, and insufficient earmarked funds at the facility was impeding their ability to provide quality care to sick newborns. Participants specifically described a lack of designated funding for laboratory support and to purchase supplies such as blood components, antibiotics and other equipment for newborns, such as oxygen cylinders. The most frequently described health financing challenges pertain to prohibitive user-fees and insurance policies that do not cover inpatient care of newborns showing that families are frequently put at risk of severe financial hardship in the event of a baby being born small or sick (Table 1/ Table S1, additional file 2).

Country workshop participants proposed solutions including the need to increase amount of earmarked funding available for sick newborns and the need to mobilise and advocate for increased funding at the health system level. Participants also proposed more innovative funding mechanisms in order to remove the prohibitive user fees placed on care of sick newborns, either through more comprehensive health insurance, community-based finance or mutual health schemes (Table 1/ Table S2, additional file 2).

Health workforce bottlenecks and solutions

Almost all countries identified the lack of trained personnel in neonatal care in quantity and quality (knowledge, training, skills) and 10 out of 12 graded these bottlenecks as significant (Figure 4), with Afghanistan grading their bottlenecks as very major (Figure 5). Poor supervision and the need for specialist and refresher training in

Table 1. Summary of solution themes and proposed actions for inpatient care for small and sick newborns

Health system building blocks	Solution Themes	Proposed actions
Leadership and Governance	*Advocacy and political will* *Improve organisation structures* *Review and disseminate guidelines*	• Active involvement of national advocates (professional bodies, academic, policy makers) for care of sick newborns • Increase number of special care units and spaces in facilities for newborns • Develop national policies and guidelines for referral systems, organisational standards for sick newborn care
Health Financing	*Budget allocation* *Innovative funding and removal of user fees*	• Increase and sustain funding for sick newborns, earmark funds within facilities caring for newborns • Expand existing maternal health schemes (end-user incentives, insurance schemes, voucher schemes) to cover inpatient care of newborns • Long term vision and health systems approach towards universal coverage for healthcare
Health Workforce	*Recruitment and Retention* *Competency based training* *Task shifting*	• Develop neonatal nursing cadre with agreed standards and benchmarks • Strategies to incentivise neonatal health workers • Develop job descriptions, appropriate remuneration and career development pathways for health workers caring for newborns • Scale up of simplified, skilled based training programmes on infection prevention, feeding, provision of warmth and family centred care for newborns • Maximising existing resources, including nurses, lower level health workers and communities
Essential Medical Products and Technologies	*Essential medical list* *Logistic system strengthening and forecasting*	• Update and implement the essential medical list to include oxygen • Inclusion of neonatal equipment and drugs in logistics systems • Strengthen oxygen systems at national and local level
Health Service Delivery	*Increase service delivery and rationalise service distribution* *Quality improvement and assurance* *Improve working conditions*	• Special care baby units (or dedicated area) in every district hospital • Decentralisation of inpatient neonatal care, stable babies cared for in KMC units • Develop and harmonise quality assurance tools and carry out quality assessment of neonatal units • Provide supportive supervision and mentoring • Improve remuneration and incentives (see also, health workforce), working hours, food provision and facilities to stay
Health Information System	*Strengthening and integration of HMIS* *Development of indicator definitions, reporting systems, tools and Scale up audits and registers*	• Integrate newborn indicators into national health information systems • Define and harmonise newborn indicators, especially care of sick newborns • Regular mortality audits in all special care and neonatal intensive care units.
Community Ownership and Participation	*Accessibility of information and community awareness* *Improve care seeking and linkages* *Male involvement*	• Sensitisation on importance of newborn inpatient care and entitlements to care • Use of community volunteers, local champions and leaders • Develop local transportation solutions for families, improve patient experience in facilities and develop family-centred guidelines • Male role models in the community, inclusive policies and frameworks in facilities • Education on maternal and newborn health targeted at men

neonatal skills were overarching challenges. Countries described difficulties recruiting specialist staff to work in remote areas and staffing disparities between urban and rural areas; 8 countries specified that problems in the health workforce stemmed from the lack of competency-based training and refresher training for the health workforce managing small babies, especially at the lower levels of the health system. Regarding task shifting, some countries noted that often only physicians are authorised to carry out tasks that could be performed by lower level health workers, such as prescribing oxygen or antibiotics. Other countries indicated that job descriptions were not clear in roles and responsibilities for those providing care to sick newborns, which is particularly relevant for neonatal nurses. Country workshop participants underlined that the motivation for neonatal nurses and other professionals to provide high quality care to sick babies was low (Table 1/ Table S1, additional file 2) and that incentives and remuneration were insufficient, leading to poor health worker attitudes, ineffective communication and poor compliance with infection control procedures.

Participants recognised that to remove health workforce bottlenecks, detailed health worker mapping of those caring for sick newborns was needed to identify the resources available and where tasks could be rapidly shifted to make more rational use of the existing workforce. Workshop participants also proposed improving working conditions, motivation and skills through more structured pre-service and in-service training and more appropriate remuneration for neonatal skills, including rewarding those prepared to work in rural areas (Table 1/ Table S2, additional file 2).

Essential medical products and technologies bottlenecks and solutions

The provision of essential medical projects and technologies was graded as having very major bottlenecks by a third of all country workshop participants (Figure 4). The Essential Medicine List (EML) was a commonly described bottleneck; participants noted that the EML lacked the commodities required for special care of newborns, such as oxygen and IV fluids and was not implemented at the national level. Many participants described general stock-outs of neonatal equipment, especially cannulas and drugs (specifically antibiotics) and lack of availability of specialist equipment, such as continuous positive airway pressure (CPAP) and portable radiographs. Participants reported that weak and inaccurate information systems underpinned this problem, limiting the ability of facilities to forecast the demand for oxygen, fluids and the maintenance supplies needed for provision of quality inpatient supportive care (Table 1/ Table S1, additional file 2).

Solutions to the essential medical products and technology bottlenecks started with a need to update the EML to reflect the essential commodities needed for sick newborns (oxygen, antibiotic and IV fluids). Following this, workshop participants recognised a need for improving and building logistics management capacity to support the health system to manage inventories and prevent stock-outs (Table 1/ Table S2, additional file 2).

Health service delivery bottlenecks and solutions

Service delivery was described as a challenge in all the countries with higher mortality contexts (Figure 4). Workshop participants described the limited number of facilities available to provide any type of services or inpatient care for sick or low birth weight babies, particularly at lower levels of the system. Poor enabling environments, undersized and outdated buildings, and lack of resource capacity for both delivery of care and provision of family-centred supportive care for babies in the public sector were commonly described. Five countries highlighted the limited space in health facilities for the special care of sick newborns. This included potential space for mothers to stay with their baby or lack of nurseries or side rooms for sick babies. Other country workshop teams described quality improvement as a major challenge due to inadequate monitoring or lack of quality improvement tools, poor mentoring and supervision, and poor implementation of clinical guidance and cot-side care plans for all staff caring for newborns (Table 1/ Table S1, additional file 2).

Country workshop participants recognised that the number of facilities or, at least, dedicated spaces for sick newborns needed to be increased and that service delivery needed to be rationalised. In alignment with the health workforce bottlenecks, teams suggested that quality assurance tools, quality improvement strategies (including care protocols), and improved mentorship and supervision for those delivering care to newborns could help to improve service delivery (Table 1/ Table S2, additional file 2).

Health information system bottlenecks and solutions

The lack of health information and standardised, well-defined indicators to measure interventions for sick newborns is a central issue being tackled within the ENAP [9]. Most participants from higher mortality contexts graded it as a significant or very major bottleneck to the provision of quality care in facilities (Figure 5). Specific barriers to quality improvement in facilities included the absence of effective mortality audits in facilities, lack of both coverage and process indicators and registers on sick newborns with the existing data were not well managed. In other settings, participants recognised the need for strengthening and integration of newborn facility-based care indicators into their national HMIS (Table 1/ Table S1, additional file 2).

Country workshop participants stated a need for clear definitions for indicators and harmonising these indicators such that national Health Management Information Systems (HMIS) can be strengthened and include select indicators for sick newborns. This would require improved measurement tools, reporting systems and use of appropriate software. Participants highlighted a need for capacity building within health information to support the appropriate disaggregation, dissemination and reporting of sick newborn data. Teams also suggested scaling up regular mortality audits for neonatal units (Table 1/ Table S2 and S3, additional file 2).

Community ownership and partnership bottlenecks and solutions

The community ownership and partnership building block was graded as having significant or very major bottlenecks in three-quarters of countries (Figure 4). Malawi was the only country for which workshop participants graded this building block as having no bottlenecks (Figure 5). Workshop participants specified a wide ranges of issues largely related to a lack of general information and awareness in communities about sick babies. Limited knowledge of the treatment processes and the severity of newborn illness, including poor awareness of the civil rights of babies born sick or low birth weight to access care, were highlighted. There were a number of access related problems reported, including poor referral and transport systems and inability to access facilities either due to cost or availability. For mothers in the community, participants described the lack of female decision-making power, loss of wages due to caring for a sick newborn and lack of privacy in facilities (Table 1). Lack of involvement of men was mentioned by six countries partially related to poor awareness and engagement of the wider community on issues related to sick newborns (Table 1/ Table S3, additional file 2).

Solutions for community ownership were wide-ranging, but were themed around improving the accessibility of information for carers and the services for small and sick newborns. Participants suggested a need for greater community awareness of the needs for sick and small newborns in order to improve demand, compliance and patient experience; specifically, encouraging male involvement and increased participation of the community in processes to improve family centred care in facilities (through development of materials, tapping into community groups and developing mutual health type schemes) (Table 1/ Table S2, additional file 2).

Discussion

This paper has presented an analysis and synthesis of bottlenecks and solutions for one of six key intervention packages to reduce neonatal mortality worldwide reviewed in this series of papers; inpatient care for small and sick newborns. Previous analysis of the bottleneck data showed that amongst all intervention packages explored, inpatient care has some of the highest graded bottlenecks hindering scale-up [16], with very major or significant bottlenecks being reported across all health systems building blocks. Whilst inpatient care for the small and sick newborn forms part of the overall care along the continuum from pre-pregnancy to childhood, these findings are timely and this issue is new on the global agenda. Complications from preterm birth are now the leading cause of death in children under five [1]. Previous experience from high income settings has shown that initial provision of low-tech supportive inpatient care and case management, followed by full high-tech neonatal intensive care, has played an important role in reducing overall neonatal mortality [23]; therefore, in order to further reduce the burden of death due to prematurity, strategies to provide comprehensive, high quality inpatient care for small and sick newborns must be developed.

The methodology used in the bottleneck analyses employed a unique consultative and participatory approach to bring together a wide range of partners and players in newborn health. Rather than the top down approach employed by many research initiatives, this data collection and analysis methodology focused on eliciting information from ground-level field implementation, as perceived by stakeholders and experts in 12 countries with the highest burden of neonatal mortality. This has helped the data to capture context specific challenges and has enabled participants to share their experiences and work together to identify innovative solutions. The grading process encouraged the workshop participants to reach consensus on the perceived challenges and generate a quantitative measure of the perceived bottlenecks to delivering care to this vulnerable sub-population. Rather than reporting on systematic reviews or results from randomised trials, this paper aims to facilitate programmatic learning through the South-to-South exchange. This paper has brought together a wide range of programmatic experience and technical expertise in neonatal care from across the globe to inform programme managers and policy makers in multiple settings facing a range of health system challenges in delivering high quality, facility-based care to small and sick newborns.

Health systems seek to ensure that individuals in need of care receive high quality health services without the risk of financial catastrophe. This analysis identified three priority health systems building blocks with substantial barriers to implementation of facility-based care for small and sick newborns: health workforce and health financing followed by community ownership and partnership. Solution themes, including examples from literature review and programme learning, are discussed in detail below.

Health workforce priority actions

A worldwide nursing shortage exists in both high and low resource settings [24,25]. For small and sick newborns this is not simply a shortage of qualified individuals; there is a critical human resource gap for a neonatal nursing cadre, with almost no neonatal nursing training programmes outside of high income countries (Figure 6). Neonatal nurses are the backbone of newborn inpatient care, as both providers of frontline care to the newborns and their families, but also through extended roles such as the advanced neonatal nurse practitioners (ANNPs) [26,27]. To improve neonatal outcomes, particularly in those countries which account for the highest newborn death and morbidity rates, nurses need to be recruited and offered specialised training in how to care for small and sick newborns, and be provided with ongoing resources to enable them to give consistent high quality care. There are other factors at institutional and country level including inadequate allocation of resources for a health workforce, inadequate workforce planning, poor retention strategies, ineffective use of existing nursing staff, and poor working conditions [16,28].

Skills-based/competency based training

Almost all countries in the workshop highlighted the lack of skills-based training programmes for health

Nurses caring for small and sick newborns are in a unique position to improve their chance of survival and ability to thrive. Despite the vital role for nurses in the care of a sick newborn, neonatal nursing is not an internationally recognised cadre.

What is a neonatal nurse?

The role of a neonatal nurse includes the provision of care for newborn infants born with a variety of problems ranging from prematurity, birth defects, infection, and surgical problems within an individualised, developmentally supportive and family-centred framework (http://www.nann.org). However, even across high income countries, there is no agreed definition for neonatal nurses, but it is a viewed as a highly skilled nursing speciality that requires years of hand-on experience and is usually attached to specific academic and clinical training schemes.

Health workforce planning. How many neonatal nurses do we need?

Currently, there is a global shortage of neonatal nurses [24]. The survival of premature infants in facilities has been linked to the number of qualified neonatal nurses working per shift [66] and very sick or extremely premature newborns require higher staff to patient ratios than other areas of paediatric care. Intensive care newborns often require one-on-one care and special care babies require a ratio of approximately 1 to 4[25]. There are a lack of international standards on the number of nurses needed or defined staffing ratios and benchmarks. There are a small number of countries that provide specialised academic and formal training for nurses, most of which are high-income countries. As nurses constitute the largest component of the health care system, it is imperative that planning for neonatal nursing skills is incorporated into wider human resource and health workforce plans. International health workforce market analysis is needed to examine the impact of migration and retention of nursing workforce. Where neonatal nurses are trained, resources should also be directed to motivate retention including valuing their role, recognising ongoing training needs and protect them from rotation out into other sub-specialities [67]. Individual countries can work towards improving quality and efficiency of care by more strategic and intentional delegation at the local and country levels. There is a need to review the efficiency of current workforce support at the local and country levels and review the current delivery of care.

Qualifications

Training in skills specific to the needs of the newborn is required, with corresponding accreditation. Accreditation is important to provide recognition and to promote increased responsibility as well as to assist with staff retention through increased job satisfaction, potentially higher salaries and the prevention of nursing staff rotation, which is common in many low and middle income settings.

The development of special neonatal certificates, training courses and advanced neonatal nurse practitioners (ANNP) has gained traction, especially in high income settings, but not without challenges. For example, ANNPs have been shown to be effective, but some programmes report the sentiment that ANNPs feel they are substituting junior doctors rather than being valued as an alternative approach to high quality service provision for newborns [68], leading to low morale. In low and middle income countries, at the district and community level, education and training of nurses working with newborn infants within community-hospital-community network systems with integration of community healthcare workers, and in some settings, use of volunteers is possible [69]. Other options include organisation or co-ordination of overseas programs involving visits by experienced trained neonatal nurses to low resource settings to provide mentoring, education, and sharing of information with the ultimate goal of building in country capacity.

All institutions can increase the basic quality and speciality of neonatal nursing programmes. These strategies require financial and political support and a shared vision for neonatal nursing and care between professional institutions. Better data capture on neonates in facilities, including follow up data, is urgently needed so that standards of practice and quality of care can be carefully evaluated [68]. Extraction information on the nursing workforce is essential to describe who, where, and how neonatal nurses work (noting that many nurses are not permitted to provide such data without government or institutional approval). Further research is needed to examine neonatal nursing education and distribution of the workforce in relationship to neonatal outcomes. There is a global need to establish an international competency based standards for neonatal nursing supported by appropriate regulatory processes and mechanisms [24] that support this vital cadre to improve neonatal survival and outcomes.

Figure 6 Neonatal nursing as part of national human resource planning. ANNP: Advanced Neonatal Nurse Practitioner.

workers caring for small and sick babies. Qualitative work on the barriers to nurse education for those caring for sick newborns has found that educational programmes focusing on neonatal skills are often inconsistent, poorly structured, or may require long, off-site training courses making them inaccessible for large numbers of lower level hospitals or SCBUs [29]. Survive and Thrive is a private and public partnership with the American Academy of Pediatrics and has developed educational programmes focused on newborns. Essential Care of the Small Baby (ECSB) [30] is to be released in early 2015 and addresses skills such as nasogastric feeding and prevention of infection and skin-to-skin care through a cooperative learning approach. Learning techniques used by ECSB are skills-based and focused on small group work, using simulation methodology and role-play to practice technical and communication skills. Knowledge is tested through multiple-choice questions and Observed Structured Clinical Evaluations (OSCEs). Such pre-service and in-service training programmes are available and could be scaled-up within health worker training, even in lower resourced settings, as they do not rely on electricity supplies (being flip-chart based) and make use of low-cost simulation models. Well-designed programmes focused on neonatal clinical skills have been shown to be effective and improve health provider knowledge and practice [31], but will require supervision systems and regular refresher training to sustain and update skills [32].

Task shifting

The World Health Organization (WHO)'s recommendations on optimising the roles of health workers aim to address critical health workforce shortages that slow progress towards the health-related Millennium Development Goals [33]. A more rational distribution of tasks and responsibilities among cadres of health workers can significantly improve both access and cost-effectiveness - for example, by training and enabling 'mid-level' and 'lay' health workers to perform specific interventions otherwise provided only by cadres with longer (and sometimes more specialised) training. These recommendations are intended for health policy-makers, managers and other stakeholders at a regional, national and international level. WHO hopes that countries will adapt and implement them to meet local needs. The recommendations were developed through a formal, structured process including a thorough review of available evidence. Specific examples that have been taken up include nursing auxiliaries or health care assistants supporting and maintaining KMC [33]. In Malawi, ward attendants have been involved in supporting KMC [34] and health surveillance assistants have been trained to promote facility-based care for sick newborns [35]. ECSB training incorporates task shifting to mothers, when appropriate, for basic skills such as nasogastric feeding and providing basic care to a small baby looked after in a facility [30].

Recruitment and retention

Once health workers have the skills needed to care for small and sick babies, recruitment and retention strategies are needed to supervise and motivate, which is especially important for rural and hard to reach postings. Innovative recruitment and retention strategies have been implemented with success in some settings. Thailand has historically used a bonding system to improve recruitment of health workers for rural areas. Newly qualified health professionals, including doctors and cadres of nurses are required to spend a mandatory time period in rural postings. On completion, professional qualifications can be upgraded. Evidence suggests this has led to a substantial increase in the numbers of trained professionals in rural areas and is partially responsible for the impressive health gains in Thailand in the last 25 years [36,37].

In addition to task shifting there are other immediate, interim strategies that can be put in place. These could include improving conditions for the workforce through incentives [38] (financial, educational or other), relieving staff of other duties, improving daily working conditions (break areas, food vouchers, accommodation on-site or nearby) [39] and improving job satisfaction through structured supervision and mentoring efforts [32]. Non-rotation of staff out of neonatal care is an important strategy to prevent neonatal staff being shifted annually within the hospital from department to department or into other specialties (Figure 6).

Health financing priority actions

Budget allocation

Whilst the health financing issues faced by many low-income countries are due to the lack of financial resources for health and development overall, and are not unique to the newborn [40], those newborns requiring inpatient care are at greater risk due to their need for specialised facility-based care. Newborns are relatively neglected in official development assistance [41] and specialised, intensive care is often perceived as prohibitively expensive. A strong economic case, including the relative burden of newborn mortality globally, and the argument for prevention of long-term morbidities, is required to advocate for the earmarking of funds specifically for developing and sustaining high quality inpatient newborn care. The issue of health financing is explored in greater detail in paper 1 of this series [20].

Innovative funding and removal of user fees

The birth of a small or a sick baby can be financially catastrophic for families. Shifting from a reliance on out-of-pocket payment to prepayment and risk pooling is a critical part of the health financing transition that most countries go through as they get richer [42]. Limited risk pooling means that insurance and depth of coverage is a common problem for families. Removal of user fees in the public sector is a first step, but has associated risks and challenges and must be replaced by alternative health financing mechanisms that could include: social health insurance, community based health insurance and government supply side financing [43]. The success of these schemes is dependent on the context within the countries where they are implemented. Rwanda's community financing scheme is backed by compulsory government payments into the scheme and stringent pooling of donor funds [44]. Provision of coverage for inpatient newborn care within insurance schemes or voucher and incentive systems is a neglected area, with often only delivery and basic newborn care being covered. Attention to successful schemes that already exist in countries could partially ameliorate the risk of financing catastrophe for families when a baby is born small or sick, rather than introducing new schemes for sick newborns that may further fragment health financing systems. Sick newborn care is frequently not covered by maternity packages or maternal health financing schemes (e.g. Nepal vouchers scheme), yet has potentially large expenses associated with it. Schemes using prospective case-based systems for inpatient care - as in Kyrgyzstan [36] could be adapted to give higher priority to newborn inpatient and special care. Further implementation research is needed for innovative funding mechanisms to identify factors that may facilitate their success and provide recommendations for their implementation in different settings.

Community ownership and partnership priority actions

Whilst reported bottlenecks to high quality inpatient newborn care are similar across regions, individual communities differ in their geographical and socio-cultural structures and available resources. Enabling maximum effect through tailor-made solutions for a given community will require empowering solutions from a grassroots level.

Community awareness

Lack of demand for quality newborn inpatient care may reflect the fatalistic assumption that all small and sick babies will die [27]. Across settings, country teams highlighted the lack of awareness in communities about sick newborns, the treatment processes and their civil rights to access health services. Most country teams reported a lack of awareness of the severity of newborn illness and knowledge that timely, high quality care can save newborn lives. In some contexts, such as India, there are specific care-seeking barriers for newborn girls. The workshops participants' perceptions strongly suggest there is a lack of strategic, targeted health education on newborn health across settings and that sensitisation and local community education efforts are needed to reduce fatalism and increase care-seeking and demand. Mobilisation of communities using women's community groups has been shown to have a positive effect on a range of maternal and newborn health outcomes, including the potential to reduce neonatal mortality in a number of settings [45-47]. There is a clear role for community volunteers, local role models and community leaders to raise awareness on issues surrounding newborn health and the care of sick newborns.

Improve care seeking and transport linkages

Qualitative study of the local barriers and solutions for care-seeking in child health in Kenya, Nigeria and Niger highlighted important factors on perceived awareness and the subsequent demand for care [48]. Lack of trust in health services, perceptions that treatment is ineffective and experience of poor quality of care were perceived as important in reducing demand for care. Health services that are out-of-stock, negative experiences with health workers, or poor communication between staff and families, especially mothers, may be detrimental to the care of the newborn. Facilities may need to focus on community strategies to improve the patient experience in facilities, especially for mothers. It is critical for the mother to spend time with the sick newborn wherever possible, therefore, local hospital policy guidelines that encourage family-centred care and take into account the local and cultural family structure are vital for mothers to be able to participate in the care of their newborns. Local transport systems are needed to facilitate access between the community and facility, especially when newborns are in the facility for long periods of time. Within the facility, task shifting to mothers, in addition to the necessary support for breastfeeding and expressing milk, can play an important part in empowering mothers and securing the linkages between the family and inpatient care [49,50].

Male involvement

Half of the countries in the workshop specifically reported that there was a lack of male involvement in the care of sick newborns. Individual, family, community, societal and policy factors are previously identified barriers to male involvement during pregnancy and birth [51]. Qualitative research suggests men often lament their lack of involvement or understanding of maternal and newborn health issues [48] - an area that is often seen as dominated exclusively by females. Empirical research confirms that for pregnancies that are wanted and where men are more educated, men are more likely to be involved in maternity related care [52]. The care of sick newborns is no different and tackling barriers to male involvement is an issue that spans the care continuum from family planning to the care of a sick newborn in a facility. Men often control family finances or have a stronger influence on decision-making. Women may be removed from their usual schedules when their newborn is sick, leading to potential for neglecting other commitments (whether work or household related) and, therefore, may need additional support. Use of male role models in the community may help to facilitate this transition away from maternal and newborn health being viewed as an exclusively female domain. Using lessons learned from Prevention of Mother To Child Transmission (PMTCT) research [53], interventions to increase male involvement in newborn care include addressing hospital policies and staff attitudes in facilities to allow for culturally sensitive, inclusive policies for men and families, such as special visiting hours and supporting fathers to participate in KMC [13].

Other priority actions

As highlighted in the analysis, very major or significant bottlenecks were reported across all building blocks. Solution themes for three of these building blocks have been discussed in detail above and more details on the country-specific bottlenecks for each health system building block are available in the additional file 2. A few other bottlenecks described were especially relevant to inpatient care. For example, India and Pakistan stressed the shortfall in supply of oxygen due to demand and supply gaps. Improving oxygen systems within health facilities is key to enable widespread availability when required. Oxygen cylinders are still commonly used in many facilities in low and middle-income settings, however they are expensive, require filling up regularly and are difficult to transport. Where power supplies are reliable, oxygen concentrators can provide a consistent and inexpensive source of oxygen. In view of the emerging epidemic of ROP [10], the use of oxygen in any setting should be carefully monitored using pulse oximetry and safe delivery mechanisms to ensure optimum and safe saturation levels [54,55], as described in Figure 3. The safe and systematic use of oxygen, as with all drugs, needs to involve training and supervision of nurses, doctors, technicians and administrators [56] and appropriate documentation is needed. Commonly prescribed antibiotics for small and sick newborns, such as gentamicin, which has potentially adverse effects related to dosage and interval [57] need particular attention to safety, especially where therapeutic drug monitoring is not possible [58]. A number of country teams highlighted newborn inpatient care health information bottlenecks. A recent assessment of facility-based neonatal care in Kenya highlighted how poor data were potentially undermining the quality of practice [59], especially affecting the assessment of gestational age and symptoms of severe illness. At a national level, efforts are needed to strengthen the HMIS and to develop basic indicator definitions for monitoring inpatient care with core competencies and standards for small and sick newborns by levels of care [17]. At the facility level, there is a clear need for improved documentation, registration and incorporating the use of regular mortality audits [60].

Limitations

The data generated from the workshop came from the subjective and consensus views of participating national stakeholders, including government representatives and experts. The quality and amount of information extracted from these workshops varied depending on the level of knowledge of participants about health system issues and facilitation. In addition, bottlenecks were reported as perceived bottlenecks relative to the other health system building blocks under exploration. There may be instances where known health system challenges or deficits based on robust quantitative data may be in conflict with the perceived bottleneck grading. This may be due to the method of grading relative to other health system building blocks, or that participants place higher subjective value on other areas of their health system. An additional explanation is that groups' may view certain building block areas as easier challenges to overcome based on their knowledge of their setting and expertise in the specific newborn intervention being discussed. The tool is comprehensive and detailed, which is one of its strengths. However, it also may have caused some *workshop fatigue*, particularly towards the end of the workshop where teams discussed and recorded solutions. For example, for the inpatient care questionnaires, Afghanistan completed the bottleneck portion of the questionnaires, but did not submit any solutions. The analysis focused only on three tracer items: safe oxygen, IGTF and the provision of IV fluids. Other specific components of inpatient neonatal care may have different bottlenecks and solutions, for example, identification of and effective phototherapy for neonatal hyperbilirubinaemia [61] (Figure S2, additional file 2).

Future agenda

Improving inpatient newborn care will require a health systems approach and some countries are recognising this need. For example, the securing of political, professional and financial commitment in India has led to substantial increases in provision of quality inpatient newborn care (Figure 7). Previously, particularly in low-income settings, much investment has occurred in delivering public health and community-based interventions to improve newborn outcomes. This has led to important gains in outcomes, especially in settings with the highest neonatal mortality rates. However, as seen historically in high income countries, to reduce neonatal mortality further, attention is first required on improved supportive case management (which for the smallest and sickest newborns will require inpatient care) and then should be followed by the introduction and scale-up of neonatal intensive care [62].

Specific areas for action have been highlighted above, with many of these bottlenecks being critical to address to enable provision of quality inpatient newborn care (Figure 8). Interdisciplinary linkages and a focus on better quality data will help identify areas for improvement so that teams delivering care to small and sick newborns

Rationale

India, with an annual birth cohort of 26 million, accounts for highest number of stillbirths and neonatal deaths in the world. The current neonatal mortality rate (NMR) of India is 28 per 1000 live births, which means 748,000 newborns die each year [1]. The NMR in rural areas (33 per 1000 live births) is twice that in urban areas (16 per 1000 live births) [70]. The Government of India, through the launch of the National Rural Health Mission in 2005, has made significant efforts to promote institutional deliveries by providing conditional cash transfer under Janani Suraksha Yojna (JSY)* and provision of free transport and care for pregnant women to reduce out of pocket expenses under Janani Shish Suraksha Karyakram (JSSK)**. These efforts contributed to an increase to 73% institutional births in 2009[71]. Despite this progress, suboptimal quality of care during birth alongside a lack of specialised care for small and sick newborns remains a major challenge to newborn survival.

Approach taken

India has focused on strengthening facility-based newborn care through the establishment of special newborn care units (SNCUs) at district level and newborn stabilisation units (NBSUs) at block level. These are linked with home visits and referrals by 0.9 million Accredited Social Health Activist (ASHA) workers focusing on both home deliveries and community follow up of both newborns delivered in hospitals and those discharged from SNCUs. The National Health Mission budget for state and districts has a separate budget line for facility based newborn care with earmarked resources for facility-based care, including operational costs, human resources, drugs and provision for record keeping and data management. To address the access barriers and reduce out of pocket expenses, free health care for pregnant women and infants, including diagnostics, treatment and drugs, has been made an entitlement. In order to attract and retain workforce, states like Madhya Pradesh have successfully used walk-in interviews, performance based incentives, difficult area allowances, enforcement of service bonds and flexibility in place of posting based on individual preference.

Innovations: Education of health care professionals with evidence-based guidelines, using standardised tools, on-site job aids and skill building is a daunting task for such a large and diverse country. WHO Collaborating Centre at All India Institute of Medical Science (AIIMS) has designed smart phones as an innovative point of care tool for management of sick newborns and e-learning as a distance learning strategy for continuing education. To aid the implementation of corrective actions for sick newborns, a real time online data monitoring system has been developed by UNICEF and will be scaled-up nationally to monitor performance of all SNCUs and tracking after discharge till one year. A national cell has been established to support capacity building, monitor data quality and to interpret data for policy and programmatic use.

Looking Beyond survival Rashtriya Bal Suraksha Karyakram (RBSK)*** programme aims at identifying birth defects, disabilities and developmental delays with both community and facility screening, and provision of early intervention clinics at district level.

Results

All these efforts have resulted in operationalisation of 575 SNCUs and 1810 NBSUs, with states like Madhya Pradesh, Rajasthan, Andhra Pradesh, Tamil Nadu and Orissa achieving near universal coverage of SNCUs following prescribed standards at district level. However, there are still issues of inadequate human resources in these states with slower progress in Chattisgarh, Jharkhand, Bihar and Uttar Pradesh. The monitoring system currently has 13 states with 350 SNCUs inputting online data and more than 650,000 newborns are registered in the national database. The current inpatient mortality in existing SNCUs was 10% in 2013-14[72]. Whilst this is not due to health system changes alone, the NMR of India, which had been stagnant at 37 per 1000 from 2004 to 2006, has shown a 17% decline during 2008 to 2012[70].

Future directions

There is a need is to accelerate coverage in states where progress is slow, and to focus on quality of care and improving long-term outcomes once scale-up has been achieved. To achieve this, the system needs to reduce the case load in SNCUs by expediting establishment of kangaroo mother care wards for care of stable preterm babies, address high mortality due to respiratory distress by up scaling coverage of antenatal steroids, use of continuous positive airway pressure (CPAP) across all SNCUs and continue to develop innovative approaches and tools for capacity building of the health workforce, including implementation research to evaluate progress. In view of high load of preterm and sick babies with risk factors for ROP, the provision of ROP screening and treatment needs to be implemented. The scale–up of the real-time data system for online monitoring will be completed by mid-2015 for the whole country making it the largest database for small and sick newborns globally. All these issues have been emphasised under the India Newborn Action Plan (INAP)[73], which has set target for a single digit NMR by 2030. This will be achievable only with sustained work towards good coverage of quality interventions for newborns, including those that are small and sick.

Figure 7 India's health systems approach to improving inpatient care for small and sick newborns. *Janani Suraksha Yojna (JSY): a conditional cash transfer to promote institutional delivery); **Janani Shishu Suraksha Karyakram (JSSK): reducing out of pocket expenses by making free health care an entitlement; ***Rashtriya Bal Suraksha Karyakram (RBSK): looks at developmental delays and disabilities, birth defects and deficiencies, covering age group of 0-18 years of age. Other abbreviations: AIIMS: All India Institute of Medical Science; ASHA: Accredited Social Health Activist; CPAP: Continuous Positive Airway Pressure; India Newborn Action Plan (INAP); NMR: Neonatal Mortality Rate; NBSU: Newborn Stabilisation Units; ROP: Retinopathy of Prematurity; SNCU: Special Newborn Care Unit; UNICEF: United Nations International Children's Emergency Fund; WHO: World Health Organization.

Key messages

- Each year, there are an estimated 15 million preterm newborns, many of which do not have access to inpatient care when needed. Inpatient care for small and sick newborns includes the provision of warmth, feeding support, safe oxygen therapy and effective phototherapy, with prevention and treatment of infections. This requires dedicated ward space, staffed by health workers with specialist training and skills.
- Bottlenecks to the scale up of inpatient care are reported across all health system building blocks; countries that graded their bottlenecks most severely were Uganda, Afghanistan, Nepal and Pakistan.
- The health system bottlenecks graded highest by the 12 countries in the analysis were within health workforce and health financing, followed by community ownership and partnership.

Key action points

- Current health workforce effectiveness for inpatient newborn care could be improved through skills-based training for health workers, considering the potential for task shifting. There is a critical human resource gap for a neonatal nurse cadre, with almost no training programmes outside high income countries; this links to the current policy investment for midwives.
- Rather than catastrophic out of pocket payments, addressing health financing bottlenecks for newborn inpatient care requires specific, planned and sustained funding at a national level. Small and sick newborns need appropriate insurance covering their care, similar to the mechanisms for emergency obstetric care.
- Addressing community bottlenecks will require a shift in attitude away from the fatalistic assumption that all small newborns will die, towards increased awareness and demand for quality inpatient care. This should be accessible and family centred, using local resources, involving mothers through kangaroo mother care and long-term follow up for the vulnerable survivors.

Figure 8 Key messages and action points for inpatient care of small and sick newborns.

can plan and implement changes. Ongoing data monitoring helps the team recognise their improvement and identify specific areas to focus on in the future, so that the exercise is an ongoing cycle. The EMEN package [16] will be crucial to this process.

Conclusions

Whilst major bottlenecks to the scale-up of quality inpatient newborn care are present, in many cases, effective solutions exist. Currently, there is a large grass roots commitment to improving care around the time of birth to end preventable maternal and newborn deaths and stillbirths, and to improve healthy outcomes as part of the ENAP [9]. Improving availability and quality of inpatient newborn care has been identified as an important area to achieve the aims of this plan, providing potential for political, professional and financial support to develop and scale-up solutions to these bottlenecks. We must build on this momentum, using knowledge of what works to ensure action, so that every small and sick newborn baby has access to timely, high quality and family-centred inpatient care as required to survive and thrive.

Additional material

Additional file 1: Bottleneck tool questionnaire.

Additional file 2: Supplementary tables, figures and literature search strategy.

List of abbreviations

ANNP: Advanced Neonatal Nurse Practitioner; BPD: Broncho-Pulmonary Dysplasia; COIA: Commission on Information and Accountability; CPAP: Continuous Positive Airway Pressure; DRC: Democratic Republic of Congo; ECSB: Essential Care of the Sick Baby; EMEN: Every Mother, Every Newborn; EML: Essential Medicines List; ENAP: Every Newborn Action Plan; HIC: High income countries; IGTF: Intra Gastric Tube Feeding; IV: Intra-Venous; JSSK: Janani Shishu Suraksha Karyakram; KMC: Kangaroo Mother Care; LBW: Low birth weight; LIC: Low income countries; LMIC: Low and Middle Income Countries; NBSU: Newborn Stabilization Unit; NEC: Necrotising Enterocolitis; NICU: Neonatal Intensive Care Unit; NMR: Neonatal Mortality Rate; NGO: Non-Governmental Organisation; OSCE: Observed Structured Clinical Evaluation; PDA: Patent Ductus Arteriosus; PMTCT: Prevention of Mother to Child Transmission (PMTCT); ROP: Retinopathy of Prematurity; RDS: Respiratory Distress Syndrome; SCBU: Special Care Baby Unit; SNCU: Special Newborn Care Unit; UN: United Nations; UNICEF: United Nations International Children Emergency Fund; WHO: World Health Organization.

Competing interests

The authors have not declared competing interests. The assessment of bottlenecks expressed during consultations reflects the perception of the

technical experts and may not be national policy. The authors alone are responsible for the views expressed in this article and they do not necessarily represent the decisions, policy or views of the organisations listed, including WHO.

Authors' contributions
SGM was responsible for the analysis and writing process with HB and JEL who oversaw the analysis, writing and reviews of the paper drafts. KED along with the ENAP & UNICEF teams, were responsible for the overall coordination of the bottleneck analysis tool development, country consultation process, and reviews of the paper drafts. AS-K was responsible for the tool development and substantial contributions to the data analysis. All named authors contributed sections of text and approved the final manuscript.

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Inpatient care of small and sick newborns: A multi-country analysis of health system bottlenecks and potential solutions (1471-2105-X-S2-7)

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Appendix O: PDF of published paper: Service readiness for inpatient care of small and sick newborns: what do we need and what can we measure now?

Electronic supplementary material:
The online version of this article contains supplementary material.

journal of global health

RESEARCH THEME 3: KANGAROO MOTHER CARE

Service readiness for inpatient care of small and sick newborns: what do we need and what can we measure now?

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Background Each year an estimated 2.6 million newborns die, mainly from complications of prematurity, neonatal infections, and intrapartum events. Reducing these deaths requires high coverage of good quality care at birth, and inpatient care for small and sick newborns. In low- and middle-income countries, standardised measurement of the readiness of facilities to provide emergency obstetric care has improved tracking of readiness to provide care at birth in recent years. However, the focus has been mainly on obstetric care; service readiness for providing inpatient care of small and sick newborns is still not consistently measured or tracked.

Methods We reviewed existing international guidelines and resources to create a matrix of the structural characteristics (infrastructure, equipment, drugs, providers and guidelines) for service readiness to deliver a package of inpatient care interventions for small and sick newborns. To identify gaps in existing measurement systems, we reviewed three multi-country health facility survey tools (the Service Availability and Readiness Assessment, the Service Provision Assessment and the Emergency Obstetric and Newborn Care Assessment) against our service readiness matrix.

Findings For service readiness to provide inpatient care for small and sick newborns, our matrix detailed over 600 structural characteristics. Our review of the SPA, the SARA and the EmONC assessment tools identified several measurement omissions to capture information on key intervention areas, such as thermoregulation, feeding and respiratory support, treatment of specific complications (seizures, jaundice), and screening and follow up services, as well as specialised staff and service infrastructure.

Conclusions Our review delineates the required inputs to ensure readiness to provide inpatient care for small and sick newborns. Based on these findings, we detail where questions need to be added to existing tools and describe how measurement systems can be adapted to reflect small and sick newborns interventions. Such work can inform investments in health systems to end preventable newborn death and disability as part of the *Every Newborn* Action Plan.

The first 28 days of life, the newborn period, represents the time of highest risk in the human lifecycle. In 2016, an estimated 2.6 million newborns died [1], mainly of complications of prematurity (35%), infections (23%), and intrapartum complications leading to birth injury (24%) [1,2]. Preventing deaths from these causes requires a combined health systems approach [3] along the continuum of care. This approach should deliver routine newborn care for all babies (cleanliness, thermal care and support for breastfeeding), newborn resuscitation and prevention of mother to child transmission of HIV (PMTCT) for all babies who need it [4,5]; and timely provision of quality inpatient care for babies born small and sick [6,7].

Many low birth weight newborns, especially preterm infants, and those born small for gestational age, require support to feed and maintain their temperature. In addition, preterm newborns face increased risks of respiratory problems, infections and jaundice [8]. Even amongst those born at full term, significant numbers of newborns suffer from systemic infections, neonatal encephalopathy, pathological jaundice and congenital abnormalities, with high mortality risk in the absence of care [8]. "Small and sick newborns", therefore, includes all those babies who require inpatient (facility-based) care to survive. The care that small and sick newborns require is not an individual intervention, but a package made up of multiple interventions. Previous work has discussed the specific evidence-based interventions that comprise this package of care [3,8,9], which are displayed in **Figure 1**.

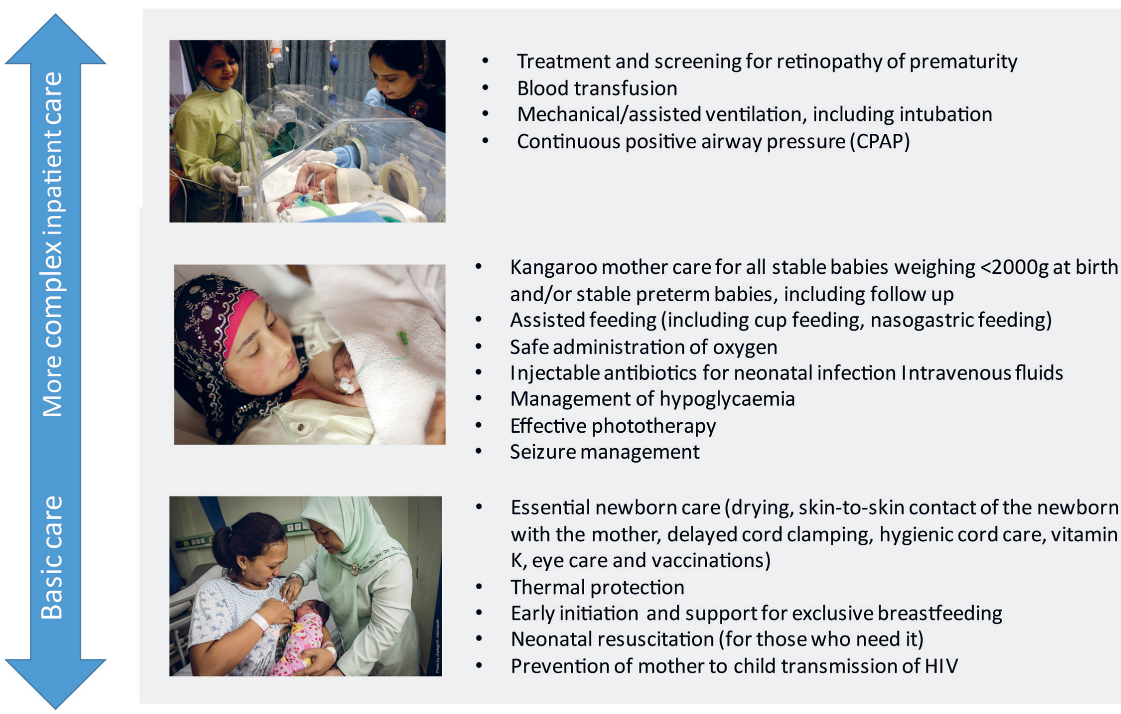

Figure 1. Evidence-based newborn care interventions from basic to complex care. There are additional evidence-based interventions for newborns that should be included in the antenatal period – antenatal corticosteroids and antibiotics for preterm premature rupture of membranes – and follow-up processes that would fall outside of the newborn period and be linked to paediatric services. Figure adapted from [8]. Photo credit (from top to bottom) Ayesha Vellani/Save the Children, ©EFCNI, JHPIEGO.

Delivery of interventions to small and sick newborns requires health facilities that are prepared, which is termed as "service readiness". The underpinning principle to service readiness is based on traditional quality of care frameworks, such as that conceived by Donabedian (**Figure 2**). The framework refers to the structures (the necessary infrastructure, equipment, drugs, health providers and guidelines); and processes (actions performed by health professionals with requisite training and skills) that are needed to provide a package of care [8]. When all of the components of the structural domain are in place, it allows for improvements in clinical processes, which in turn lead to improvements in patient outcomes [10-12].

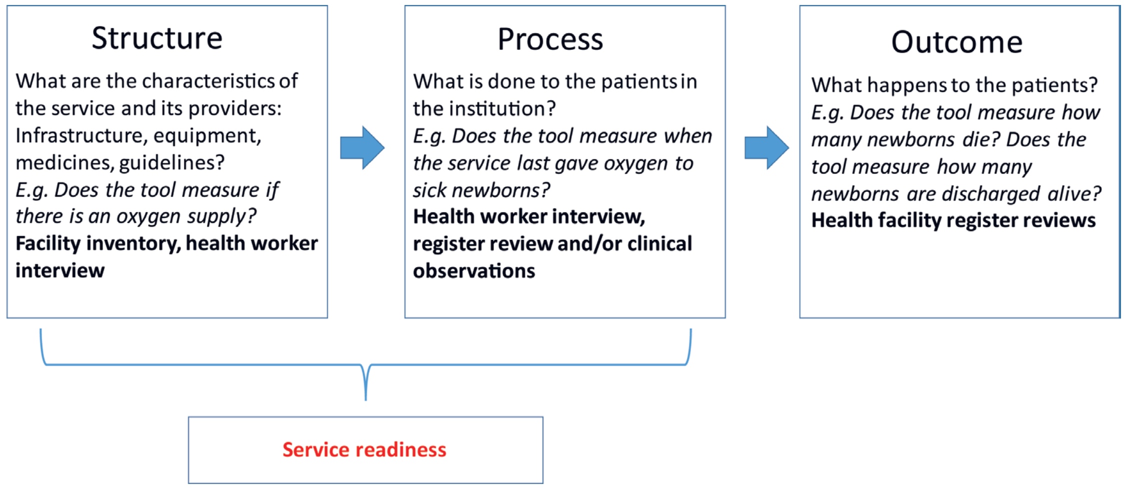

Figure 2. The Donabedian framework applied as a construct to map health facility assessment tools.

To achieve service readiness, the structures not only need to be present, but maintained, re-stocked and updated (eg, equipment requires maintenance, supplies require re-stocking, guidelines require updating) and staff continually trained and supervised. To deliver a quality package of care, therefore, requires strong health systems with the capacity to monitor and track service readiness and react appropriately to service needs.

Evidence from *The Lancet* Every Newborn Series [13] informed the design of the *Every Newborn* Action Plan, a multi-partner initiative launched in 2014, backed by a World Health Assembly Resolution. *Every Newborn* aims to end preventable newborn deaths and stillbirths, with national targets of ≤12 neonatal deaths per 1000 live births and ≤12 stillbirths per 1000 total births by 2030 [7]. To achieve these targets, *Every Newborn* partners acknowledge a need to improve the measurement of care at birth, and to better track coverage, quality, and equity of care for small and sick newborns around the time of birth [14]. A dedicated sub-group – *Every Newborn* metrics - focuses on improving the measurement of interventions [14], and has a work stream focused on service readiness for inpatient care of small and sick newborns [9].

Currently, national and facility-based health information systems in low- and middle-income countries collect few data on service readiness for small and sick newborns [13-15], in contrast with child health programmes, notably immunisation, HIV and malaria [16]. Data are sparse in sub-Saharan Africa and parts of Asia where access to care for small and sick newborns is the lowest, and where many facilities need targeted efforts to strengthen services [8,14].

Data from functional routine national health management information systems (HMIS) and logistics management systems (LMIS) are able, in principle, to capture service readiness in a sustainable way, but the content and quality of data in national HMIS are variable in practice. This means many low- and middle-income countries depend on periodic evaluations, such as nationally representative facility surveys or censuses, as a key source of health information to monitor the readiness of the health system to provide facility-based care [14,17,18]. These surveys or censuses are referred to as health facility assessments.

The most common health facility assessment tools are the Demographic and Health Survey Programme's Service Provision Assessment (SPA), the WHO Service Availability and Readiness Assessment (SARA) [19,20], and the EmONC assessments, currently managed by Averting Maternal Death and Disability (AMDD) [21] in collaboration with UNFPA [22]. The content of these tools with regards to service readiness specifically for inpatient care of small and sick newborns has not previously been systematically evaluated.

Our overall aim was to review the current health facility assessment tools' ability to capture service readiness for inpatient care of small and sick newborns.

The specific objectives of this article are to:

1. Create a standardised matrix of the structural components (infrastructure, equipment, drugs, providers and guidelines) required to deliver inpatient care for small and sick newborns.
2. Compare the components of this standardised matrix against what is currently measured by widely used multi-country health facility survey tools (SPA, SARA, EmONC assessment) and identify gaps in measurement of the structural and process domains.
3. Synthesise these findings to provide recommendations on how to improve measurement of service readiness for inpatient care of small and sick newborns.

METHODS

Conceptual framework for service readiness

We applied the Donabedian framework [10,11] as a construct to map service readiness for small and sick newborns (**Figure 2**).

For the first objective, we mapped the structural domain of the framework and identified the infrastructure, equipment, drugs, health providers and guidelines required to deliver inpatient care for small and sick newborns. The second domain in the framework (process) links structures and outcomes, and is dealt with in objective 2.

Objective 1: Create a standardised matrix of structural components

Development of matrix of service readiness requirements for inpatient care of small and sick newborns

We listed a total of 17 newborn interventions based on work done previously as part of the *Every Newborn* metrics process [5,8,23] (**Figure 1**). All newborn interventions were included for this exercise, including essential newborn care, based on the rationale that small and sick newborns will require these basic interventions in addition to inpatient care [8,9].

We organised the matrix by six areas: 1) labour and delivery room 2) place of care for small and sick newborns 3) pharmacy/medicines, 4) human resources/providers, 5) laboratory & blood bank and 6) referral service. We organised interventions by whether they occur in the labour and delivery room or the neonatal unit (or both). Human resources and pharmacy were allocated as a separate area given that providers and drugs will be needed in multiple places of care. Given that most of the guidelines reviewed included information or guidance on referral systems and the associated structural components, we included referral system as a separate "area". Finally, given the wide variation in laboratory systems, we separated the laboratory and blood bank by capacity to perform certain tests and actions, rather than an itemised list of components or equipment.

We searched for existing published guidelines for all the newborn interventions, including relevant newborn and paediatric guidelines available on the WHO website. Where no WHO guideline existed, we consulted relevant resources developed by UNICEF and other partners, including resources from international professional associations, such as the American Academy of Paediatrics and Royal College of Paediatrics and Child Health. To ensure consistency with other areas of care, we also reviewed the inter-agency list of medical devices for essential interventions for reproductive, maternal, newborn, and child health [24], a master list created for newborn health in humanitarian settings by the Inter-Agency Working Group on Reproductive Health in Crises (IWAG), UNICEF and Save the Children [25] and the latest version of the WHO model essential drugs list [26]. See **Table 1** for a list of the guidelines and resources used for this review.

Within each area of the matrix, where equipment items recurred (eg, components required for more than one intervention such as linen, gauze, swabs, weighing scale) we included these under general items for either the labour and delivery room or place of care for small and sick newborns. We were then able to populate the matrix with the specific components required to deliver the interventions for small and sick newborns.

Table 1. Resource materials and guidelines reviewed for newborn interventions

Intervention	Resource material or guideline	Year published
Essential newborn care, thermal protection, early initiation and support for exclusive breastfeeding	WHO essential newborn care course	2010
	WHO early essential newborn care: Clinical practice pocket guide	2014
	Essential care for every baby	2015
	WHO Integrated management of pregnancy and childbirth: Pregnancy, Childbirth, Postpartum and Newborn Care: A guide for essential practice	2015
	UNICEF: Baby Friendly Hospital Initiative (BFHI)	2012
	WHO Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health	2015
Neonatal resuscitation	WHO guidelines on basic newborn resuscitation	2012
	Helping Babies Breathe Resources	2017
	WHO guidelines on managing complications in pregnancy and childbirth	2007
	WHO guidelines on managing newborn problems: a guide for doctors, nurses and midwives	2003
Prevention of mother to child transmission of HIV	WHO guideline update on HIV and infant feeding	2016
	WHO guidelines on antiretroviral drugs for treating pregnant women and preventing HIV infection in infants	2010
	Médecins sans Frontières: Neonatal Care Guidelines	2016
Kangaroo mother care for premature babies, including follow up, alternative feeding (cup feeding and nasogastric feeding)	Essential care for small babies	2015
	WHO kangaroo mother care: A practical guide	2003
	WHO guidelines on optimal feeding of low birth-weight infants in low- and middle-income countries	2011
	UNHCR operational guidelines on improving newborn health in refugee operations	2014
	UNICEF toolkit for setting up special care newborn units, stabilisation units and newborn care corners	2015
	WHO recommendations on interventions to improve preterm birth outcomes	
Injectable antibiotics for neonatal infections, hypoglycaemia management, effective phototherapy, seizure management, administration of oxygen	WHO pocket book of hospital care for children	2013
	Save the Children, UNICEF: Newborn care charts	2009
Treatment and screening for retinopathy of prematurity*	Guidelines on screening and treatment for retinopathy of prematurity (UK and India)	2008
Blood transfusion, Mechanical ventilation and continuous positive airway pressure (CPAP)	WHO pocket book of hospital care for children	2013

*No current WHO guidelines available; recent guidelines recommended by ROP experts from India and UK selected for review.

Objective 2: Compare the components of this standardised matrix against widely used multi-country health facility survey tools (SPA, SARA, EmONC assessment) and identify gaps in measurement of structural and process domains

We obtained the latest versions of the SARA (version 2.2, revision July 2015) [20] and the SPA (revised 2012) [27] from their websites. The EmONC assessment tool was being revised at the time of the study and we obtained the version undergoing field-testing from AMDD in July 2016.

We reviewed the SARA core questionnaire tool, the SPA health facility inventory and health worker interview, and the latest versions of the relevant modules from the EmONC assessment, (Module 1: Identification of facility and infrastructure; Module 2: Human Resources; Module 3: Essential drugs, equipment and supplies; Module 5: EmONC interventions; and Module 7: Provider knowledge and competency for maternal & newborn care).

We compared the content of each of the tools to the structural components in our matrix. To identify gaps in structural components we checked:

- Does the tool measure the infrastructure, equipment, drugs, health providers and/or guidelines needed to provide the interventions?

Many of the tools are designed to also measure aspects of the process domain in the service readiness framework (**Figure 2**). Therefore, measurement of regular practice or training was considered as a proxy measurement of the process domain for service readiness (as it looks at what is regularly done to patients in the institution). For each of the 17 interventions included in the package of care (**Figure 1**), we also checked:

- Does the tool measure whether staff are given any training to provide the intervention?
- Does the tool measure if the intervention is regularly performed?

The first author (SM), conceptualised the matrix and completed the review of each tool. The matrix was then verified for completeness by practicing neonatologists and nurses with experience in neonatal care in Ghana, Nigeria and co-author practicing neonatal clinicians with experience in India, Malawi, Uganda, United Kingdom and United States.

The review of the health facility assessment tools was verified by a representative of the lead agency for the EmONC assessment and the SPA to ensure the findings were consistent with the most recent versions of the tool.

RESULTS

Objective 1: Create a standardised matrix of structural components

We mapped a total of 654 service readiness items for inpatient care of small and sick newborns to provide 17 interventions. This included a total 167 structural items in the labour and delivery room and 266 in the place for small and sick newborn care (or neonatal unit). We listed a total of 33 different potential providers, 114 essential newborn drugs and medicines. A summary list of the international resource materials and guidelines available for care of small and sick newborns used for this objective is included in **Table 1**. The essential drug list is shown in **Table 2**. The complete matrix is available in the supplementary material (Table S1 in **Online Supplementary Document**).

Table 2. Example minimum drug list for inpatient care of small and sick newborns showing rationale for use in newborns and summary of the Service Provision Assessment (SPA), Service Availability and Readiness Assessment (SARA) and Emergency Obstetric and Newborn Care (EmONC) Assessment tools and Essential Medicines list*

Drug name	SPA	SARA	EmONC	EML	Drug description/use
Antibiotics:					
Amoxicillin (oral suspension)	Y	Y	Y	Y	Penicillin antibacterial for neonatal infections
Amoxicillin (injection)			Y	Y	Penicillin antibacterial for serious neonatal infections
Amikacin (IV or IM)				Y	Aminoglycoside antibacterial; alternative treatment of opthalmia neonatorum
Ampicillin (IV or IM)	Y	Y	Y	Y	Penicillin antibacterial for serious neonatal infections
Ampicillin (oral)					Penicillin antibacterial for neonatal infections
Azithromycin (oral)	Y	Y		Y	Macrolide antibacterial for P-PROM (maternal use)
Benzathine benzylpenicillin (benzathine penicillin G) (IM)	Y	Y		Y	Penicillin antibacterial for treatment of congenital syphilis
Benzylpenicillin (Penicillin G) (IV or IM)	Y		Y	Y	Penicillin antibacterial for serious neonatal infections
Cefalexin (oral suspension)				Y	First generation cephalosporin used in newborns for skin and soft tissue infections
Cefotaxime (IV or IM)			Y	Y	First generation cephalosporin with broad spectrum for treatment of serious neonatal infections
Ceftriaxone (IV or IM)	Y	Y	Y		Third generation cephalosporin for neonatal infections, genital gonococcal and/or chlamydial infection
Ciprofloxacin (injection)				Y	Second generation fluoroquinolone antibacterial sometimes used as second line treatment
Ciprofloxacin (oral)	Y	Y		Y	Second generation fluoroquinolone antibacterial for treatment of bacterial diarrhoea
Clindamycin (IV)			Y	Y	Lincosamide antibacterial, second line treatment (eg, streptococcal or soft tissue infections)
Co-amoxiclav (oral suspension)			Y		Penicillin antibacterial, can be used where no IV access
Co-amoxiclav (injection)					Penicillin antibacterial used for neonatal skin infections
Cotrimoxazole (oral)	Y	Y			Combined antibacterial for prophylactic treatment of HIV
Erythromycin (oral)	Y		Y	Y	Macrolide antibacterial for P-PROM (maternal use)
Flucloxacillin (IV/IM) (cloxacillin)			Y	Y	Penicillin antibacterial treatment for neonatal sepsis

Table 2. Continued

Drug name	SPA	SARA	EmONC	EML	Drug description/use
Flucloxacillin (oral)			Y	Y	Penicillin antibacterial. Can be used in newborns as follow on from intravenous flucloxacillin
Gentamicin (IM or IV)	Y	Y	Y	Y	Aminoglycoside antibacterial used for treatment of neonatal sepsis
Isoniazid (oral)	Y	Y		Y	Antituberculous antibacterial used occasionally for congenital TB
Kanamycin				Y	Aminoglycoside antibacterial; alternative to gentamicin
Metronidazole (IV)	Y	Y	Y	Y	Antiprotozoal antibacterial used for neonatal meningitis and/or anaerobic bacterial infections
Metronidazole (oral)	Y	Y		Y	Antiprotozoal antibacterial used for neonatal meningitis and/or anaerobic bacterial infections
Procaine benzylpenicillin (IM)		Y	Y	Y	Penicillin antibacterial used for congenital syphilis
Tetracycline 1% eye ointment	Y	Y	Y	Y	Prophylactic topical antibiotic used to prevent bacterial (eg, chlamydial, gonococcal) neonatal conjunctivitis
Anticonvulsants:					
Diazepam (oral/NG)				Y	Sedative, anticonvulsant, muscle relaxant mostly used for neonatal tetanus
Diazepam emulsion (IV)	Y	Y	Y	Y	Sedative, anticonvulsant, muscle relaxant, used for neonatal tetanus
Midazolam (oral solution)				Y	Sedative, anticonvulsant used for seizures
Paraldehyde (rectal)					Anticonvulsant for seizures
Phenobarbital (IV or IM)		Y	Y	Y	First line anticonvulsant for tonic clonic and partial seizures
Phenobarbital (oral)		Y		Y	First line anticonvulsant for tonic clonic and partial seizures
Phenytoin (IV)			Y	Y	Anticonvulsant for tonic clonic and partial seizures
Emergency drugs:					
Adrenaline/epinephrine (IV)	Y	Y	Y	Y	Sympathomimetic for cardiopulmonary arrest used for advanced neonatal resuscitation
Aminophylline			Y		Methylzanthine used to prevent apnoeic attacks in premature newborns
Atropine (injection)		Y	Y	Y	Parasympatholytic, antispasmodic used for intubation
Calcium gluconate (injection)	Y	Y	Y	Y	Used for hypocalcaemic seizures and hyperkalaemia
Hydrocortisone (injection)	Y		Y	Y	Steroidal anti-inflammatory used for hypotension or severe broncho-pulmonary dysplasia
Magnesium sulphate (IV)	Y	Y	Y	Y	Inorganic salt compound, maternal use in preterm labour, protective against cerebral palsy
Naloxone (IV)			Y	Y	Specific opioid antagonist for respiratory depression in newborns
Analgesics:					
Ibuprofen (IV)				Y	Analgesic sometimes used in newborns for closing patent ductus arteriosus
Morphine (IV)	Y	Y		Y	Centrally acting opioid analgesic for severe pain, sedation and intubation
Morphine (oral)		Y	Y	Y	Used for severe pain
Paracetamol (oral)	Y	Y	Y	Y	Analgesic for minor pain
Paracetamol (suppository)				Y	Analgesic for minor pain
Paracetamol (injection)					Analgesic for minor pain. Also used for newborns for closing patent ductus arteriosus.
Corticosteroids:					
Betamethasone (IM)	Y	Y	Y		Not used in newborns; used in mothers with threatened preterm labour <34 weeks gestation for fetal lung maturation
Dexamethasone (IM)	Y	Y	Y	Y	Not used in newborns; used in mothers with threatened preterm labour <34 weeks gestation for fetal lung maturation
IV fluids:					
Calcium gluconate 10%	Y	Y		Y	Supplement used to treat calcium deficiency. Dependent on programme context – careful monitoring required
Dextrose 10% with normal saline	Y		Y	Y	Solution used for maintainance fluid therapy
Dextrose/glucose 5%	Y	Y	Y	Y	Solution used as vehicle for administration of IV drugs
Dextrose/glucose 10%		Y	Y	Y	Solution for treatment of hypoglycaemia and maintenance fluid therapy on first day of life for sick babies who cannot feed
Potassium chloride (KCl) 7.5%, 10%, 15%				Y	Solution only to be used in contexts where monitoring of potassium levels is available.
Sodium bicarbonate				Y	Solution used to dissolve artesunate
Sodium chloride 0.9%	Y	Y	Y	Y	Solution used as a vehicle for administration of IV/parenteral drugs, fluid replacement and flushing IV lines
Ringer's lactate	Y	Y	Y	Y	Compound solution for severe dehydration/hypovolaemia can be added to dextrose/glucose for a mix
Water for injection					Sterile water for mixing drugs

Table 2. Continued

Drug name	SPA	SARA	EmONC	EML	Drug description/use
Anti-malarials:					
Artesunate (IV or IM)	Y	Y		Y	First line treatment for neonatal malaria
Artesunate (rectal)	Y	Y		Y	Neonatal malaria treatment if IV/IM access not available
Arthemeter (IM)				Y	Second line treatment for neonatal malaria
Artemisinin-based combined therapy (oral)	Y	Y	Y	Y	Second line anti-malarial treatment followed by ACT
Antiretrovirals (may vary depending on national HIV guidelines):					
Azidothymidine/Zidovudine (AZT) (oral)	Y	Y	Y	Y	Antiretroviral
Lamivudine	Y	Y	Y	Y	Antiretroviral
Nevirapine (NVP) (oral)	Y	Y	Y	Y	Antiretroviral
Other drugs:					
Aciclovir (IV)				Y	Antiviral used for herpes
Acyclovir 3% topical eye ointment				Y	Antiviral active against herpes virus used to prevent neonatal herpes keratitis in babies born to mother with genital herpes
Anti-Rho (D) immune globulin (injection) *			Y		To prevent Rhesus disease (haemolytic disease of the newborn), given to mothers
Caffeine citrate (oral)				Y	Preventive treatment for apnoea
Caffeine citrate (IV)				Y	Preventive treatment for apnoea, oral preferred over IV
Chlorhexidine digluconate 7.1% gel (delivering 4% chlorhexidine)	Y		Y	Y	Topical treatment of omphalitis
Domperidone					Anti-reflux drug for gastro-oesophageal reflux
Ethambutamol (oral)	Y	Y		Y	First line oral anti-tuberculolous drug
Ferrous fumerate (oral)	Y		Y	Y	Oral suspension used for preterm neonates to prevent iron deficiency
Folic acid	Y	Y	Y	Y	Oral suspension used for folate supplementation
Fluconazole (IV)				Y	Antifungal drug used in newborns over 1 week
Fluconazole (oral)	Y	Y	Y	Y	Antifungal drug
Furosemide (IV)		Y		Y	Diuretic used for chronic lung disease, oedema in advanced settings
Furosemide (oral)	Y		Y	Y	Diuretic
Glycerin chip					Suppository used in newborns to stimulate stooling
Hepatitis B immune globulin (HBIG)					Treatment of Hepatitis B in neonates
Human milk fortifier					Fortifier, adds protein, calories and micronutrients to expressed breastmilk for LBW babies
Insecticxide treated bed nets (in malaria endemic areas)	Y	Y	Y		For mother's beds in KMC ward and for discharge home
Lidocaine solution	Y	Y	Y	Y	Local anaesthetic
Miconazole cream (or equivalent eg, gentian violet)	Y			Y	Topical antifungal for candida dermatitis used for nappy area
Multivitamin					Containing zinc, vitamin A etc.
Nystatin (oral solution)	Y		Y	Y	Topical antifungal for oropharyngeal candidiasis used prophylactically with antibiotic treatment
Nystatin cream				Y	Topical antifungal
Omeprazole (IV)	Y			Y	Acid blocker for gastro-oesophageal reflux
Omeprazole (oral)	Y			Y	Acid blocker for gastro-oesophageal reflux
Oral rehydration solution	Y	Y	Y	Y	Powder to mix with drinking water for oral rehydration; breastmilk feeding should be encouraged
Oxygen supply				Y	Medical inhalation gas for treatment of respiratory distress
Phosphate and calcium supplements					Supplementation
Potassium Chloride (1mmol/ml) (oral)				Y	Powder solution for maintainance oral potassium replacement
Pyridoxine (oral)				Y	Preventive therapy for tuberculosis
Pyrazinamide (oral)	Y	Y		Y	First line oral anti-tuberculolous drug
Ranitidine (IV)				Y	Antacid drug for gastro-oesophageal reflux
Ranitidine (oral)				Y	Antacid drug for gastro-oesophageal reflux
Rifampicin (oral)	Y	Y		Y	First line oral anti-tuberculolous drug
Sucrose 30% (oral)					Non-pharmacological pain management for minor procedures (eg, cannulation)
Tetanus immunoglobulin (HTIG) (IM)			Y	Y	Anti-tetanus immunoglobulin for treatment of neonatal tetanus
Vitamin B6 (pyridoxine) (IV or IM)					Vitamin for B6 deficiency
Vitamin D					Supplementation.
Vitamin K1 (Phytomenadione) (IM or IV)			Y	Y	Vitamin and anti-haemorrhagic for prophylactic treatment of haemorrhagic disease of the newborn

Table 2. Continued

Drug name	SPA	SARA	EmONC	EML	Drug description/use
Water based lubricant					For inserting suppositories and/or other procedures.
Zinc oxide cream					Topical for nappy/diaper rash
Vaccines:					
BCG vaccine	Y	Y	Y	Y	Prevention of TB
Diptheria	Y	Y		Y	Prevention of diptheria
Pertussis vaccine	Y	Y		Y	Prevention of pertussis
Haemophilus influenzae type b (Hib) vaccine	Y	Y		Y	Prevention of haemophilis influenzae type B
Hepatitis B vaccine	Y	Y		Y	Prevention of hepatitis B in countries where perinatal infection is common, as per vaccination schedule
Oral poliomyelitis vaccine	Y	Y	Y	Y	Prevention of poliomyelitis
Tetanus toxoid	Y	Y	Y	Y	Prevention of tetanus in wound management, prevention of maternal and neonatal tetanus in pregnant women

EmONC – Emergency Obstetric and Newborn Care, SPA – Service Provision Assessment, SARA – Service Availability and Readiness Assessment, EML – Essential Medicines List, IM – intramuscular, IV – intravenous, NG – nasogastric
*Y – measured by the tool.

Objective 2: Compare the components of this standardised matrix against widely used multi-country health facility survey tools (SPA, SARA, EmONC assessment) and identify gaps in measurement of structural and process domains

The SPA, the SARA and the EmONC assessment tools are summarised in Table 3. All three tools have different purposes, are measured at different intervals, and have different approaches to measurement and sampling.

Table 3. Summary of three multi-country health facility assessment tools: Service Provision Assessment (SPA), Service Availability and Readiness Assessment and Emergency Obstetric and Newborn Care (EmONC) Assessment

	Service Provision Assessments (SPA)	Service Availability and Readiness Assessment (SARA)	Emergency Obstetric and Newborn Care (EmONC) Assessment
Purpose of tool	For comprehensive monitoring of a country's formal health care system; monitors the overall availability of different facility-based health services in a country and their readiness to provide those services	For assessing readiness of facilities using a standard set of indicators that cover all main health programmes. Only designed to assess service readiness (not performance or client perspectives)	For monitoring and assessment of the availability, use and quality of routine and emergency obstetric and newborn care in the formal health system.
Organisation(s)	The Demographic and Health Survey (DHS) Program, United States Agency for International Development (USAID)	World Health Organization (WHO), USAID	Averting Maternal Death & Disability (AMDD), United Nations Population Fund (UNFPA), United Nations Children's Fund (UNICEF), WHO.
Sample	Sample survey or census of formal sector health facilities designed to provide nationally representative results by facility type, managing authority, and geographic region.	Sample survey or census of at least 150 public and private facilities	Census of hospitals and census or sample of lower-level delivery sites (public and private facilities). Sample may be random or selection may be restricted to lower-level facilities that meet a specific volume of deliveries.
Modules	Facility inventory, exit interviews (antenatal care, family planning, sick child), clinical observations (antenatal care, family planning, sick child), health worker provider interviews	Facility inventory, health worker interview	Facility inventory, human resources, essential drugs, equipment and supplies, facility case summary, Emergency Obstetric Care (EmOC) signal functions, provider knowledge for maternal and some newborn care & chart reviews.
Numerator for indicator	Number of facilities ready to provide MNCH, family planning, HIV/AIDS, STIs, Malaria, Tuberculosis, basic surgery, non-communicable diseases services.	Proportion of health facilities, number of core medical professionals, proportion of facilities offering a defined service and the density and distribution of the facilities	Number of facilities providing EmOC, number of facilities providing each EmOC signal functions by level of care.
Denominator for indicator*	All formal facilities	All facilities, per 10 000 population	All surveyed facilities by level of care; availability of EmOC is measured per 500 000 population or 20 000 births*
Timeframe	15-18 months to complete fieldwork and report	Variable, but shorter than SPA or EmONC	12-18 months to complete field work and report
Frequency	4-5 yearly intervals	Designed to be repeated annually	4-5 yearly intervals

*Discussion is ongoing on whether denominator should measure births or population); expected number of births is the denominator for several other indicators – institutional birth rate, caesarean-section rate, met need for emergency obstetric care.

Table 4. A summary of the Service Provision Assessment (SPA), Service Availability and Readiness Assessment (SARA) and Emergency Obstetric and Newborn Care (EmONC) assessment tools' capacity to measure structural and process domains of service readiness for newborn interventions in the labour and delivery room

Intervention and components of structural domain	Health facility assessment tool		
	SPA	SARA	EmONC
Immediate/essential newborn care:			
Infrastructure	Y	Y	Y
Equipment & drugs	Y	Y	Y
Guidelines		Y	Y
Training	Y	Y	Y
Routine practice	Y	Y	Y
Thermal protection:			
Infrastructure	Y	Y	Y
Equipment & drugs			
Guidelines	Y	Y	Y
Training	Y		
Routine practice	Y		Y
Immediate and exclusive breastfeeding:			
Infrastructure			
Equipment & drugs			Y
Guidelines	Y		Y
Training	Y	Y	Y
Routine practice	Y	Y	Y
Resuscitation with bag and mask:			
Infrastructure	Y	Y	Y
Equipment & drugs	Y	Y	Y
Guidelines	Y	Y	Y
Training	Y	Y	Y
Routine practice	Y	Y	Y
PMTCT if HIV-positive mother:†			
Infrastructure	Y	Y	Y
Equipment & drugs	Y	Y	Y
Guidelines	Y	Y	Y
Training	Y	Y	Y
Routine practice	Y	Y	Y

EmONC – Emergency Obstetric and Newborn Care, SPA – Service Provision Assessment, SARA – Service Availability and Readiness Assessment
*Y – measured by the tool.
†May only be applicable in settings with high HIV prevalence.

Table 4 and Table 5 summarise the mapping of the interventions showing the structures and processes currently measured by the SPA, the SARA and the EmONC survey tools, and highlighting gaps in measurement of structural and process domains.

For ease of presentation, and to avoid repetition, we summarise the findings from the review in this section by structural and process domains.

Comparison of the matrix against health facility assessment tools and identification of gaps in measurement of the structural domain

Infrastructure

All three tools measured elements of general health facility infrastructure, such as electricity supply, means of communication, referral and transport and availability of water, toilets/latrines and waste disposal.

All tools measure availability of a table or surface for performing resuscitation. However, infrastructural requirements to support essential newborn care both in the labour and delivery room and the postnatal ward, such as space, privacy (screens) for mother to express breastmilk and infrastructure for storage of breastmilk (and whether there is consistent power supply for refrigeration) were not measured by any of the tools. All tools collect details on infrastructure to provide PMTCT.

The SPA measured space for mothers to provide kangaroo mother care (KMC) in its facility inventory, but only the EmONC assessment asked about space allocation for sick newborn care or a special care unit (eg, infrastructure to provide services beyond KMC, such as assisted feeding, thermal protection, fluids and/or oxygen support). As oxygen is a crosscutting infrastructural component needed for several interventions outside of newborn health, all tools measured availability of an oxygen source. However, none of the tools measured the newborn-specific infrastructure that would be needed for safe oxygen therapy. Continuity of electricity and oxygen is especially important for facilities offering care for small and sick newborns who may be dependent on consistent oxygen source and/or electric equipment. None of the tools measured service readiness infrastructure for screening services (for example, developmental milestones, hearing and vision) or follow-up for high-risk infants.

Table 5. A summary of the Service Provision Assessment (SPA), Service Availability and Readiness Assessment (SARA) and Emergency Obstetric and Newborn Care (EmONC) tools' capacity to measure structural and process domain of service readiness for interventions in the newborn inpatient care unit

Intervention and components of structural domain	Health facility assessment tool		
	SPA	SARA	EmONC
Kangaroo mother care (KMC) including follow up:			
Infrastructure			
Equipment & drugs			
Guidelines			Y

Table 5. Continued

Intervention and components of structural domain	Health facility assessment tool		
	SPA	SARA	EmONC
Training	Y		Y
Routine practice	Y	Y	Y
Alternative feeding if baby unable to breastfeed (cup feeding and nasogastric feeding):			
Infrastructure			
Equipment & drugs			
Guidelines			
Training			
Routine practice			Y
Safe administration of oxygen (including equipment for resuscitation):			
Infrastructure	Y	Y	Y
Equipment & drugs			Y
Guidelines			Y
Training			Y
Routine practice			Y
Intravenous fluids and management of hypoglycaemia:			
Infrastructure			
Equipment & drugs			Y
Guidelines			Y
Training	Y		Y
Routine practice		Y	Y
Injectable antibiotics for neonatal infection:			
Infrastructure	Y	Y	Y
Equipment & drugs	Y	Y	Y
Guidelines	Y	Y	Y
Training	Y		Y
Routine practice		Y	Y
Effective phototherapy:			
Infrastructure			
Equipment & drugs			
Guidelines			
Training			
Routine practice			
Seizure management:			
Infrastructure	Y	Y	Y
Equipment & drugs	Y	Y	Y
Guidelines			
Training			
Routine practice			
Continuous positive airway pressure and assisted/mechanical ventilation:			
Infrastructure	Y	Y	Y
Equipment & drugs			
Guidelines			
Training			
Routine practice			
Blood transfusion for newborns:			
Infrastructure	Y	Y	Y
Equipment & drugs			
Guidelines			
Training			
Routine practice			
Treatment and screening for retinopathy of prematurity:			
Infrastructure			
Equipment & drugs			
Guidelines			
Training			
Routine practice			

EmONC – Emergency Obstetric and Newborn Care, SPA – Service Provision Assessment, SARA – Service Availability and Readiness Assessment
*Y – measured by the tool.

None of the tools measured advanced infrastructure for intensive care for very small and sick newborns, such as that required for mechanical ventilation, newborn blood and/or exchange transfusion, and specialist laboratory infrastructure beyond that needed for obstetric, and some paediatric and adult services.

Equipment

All tools measured provision of basic equipment for neonatal resuscitation, including smaller-sized face masks and resuscitation bag in the labour and delivery room. None of the tools measured whether resuscitation equipment was available in the room where small and sick newborns are cared for to ensure safety and continuity of care.

Simpler interventions for small newborns, such as assisted feeding (plastic feeding cups and small sized nasogastric tubes) were only measured by the EmONC assessment, and hats or caps (including small sizes) are not consistently measured among the tools.

Phototherapy equipment needed to treat neonatal jaundice was only measured by the EmONC assessment (fluorescent tubes and icterometry). Lower cost phototherapy technologies, such as LED phototherapy devices were not included in any of the tools.

Although the infrastructure for oxygen was measured, most likely for paediatric and adult services, safe delivery of oxygen to newborns requires significant additional equipment items, such as newborn pulse oximetry, neonatal nasal prongs, oxygen-air blenders, low-flow metres and humidifiers, which were not captured by the tools.

Higher level respiratory support for newborns, such as Continuous Positive Airway Pressure (CPAP) ventilation, was not measured by any of the tools. Our matrix shows that for safe delivery of CPAP, beyond the drivers themselves, facilities would require critical emergency equipment in case of pneumothorax such as transilluminators, chest tubes and valves.

Intubation equipment (eg, laryngoscopes blades in small sizes) were measured by the EmONC assessment, but other critical components to support a ventilated newborn were not measured, including the ventilator machine.

Drugs

The EmONC assessment tool had the most extensive list of drugs and medicines for newborns detailing 106 medicines and drugs for mothers and newborns, but very few of these are specified for newborns. There were several notable omissions of medicines for care at birth within the SPA and SARA, such as vitamin K (SPA only asks whether it is routinely administered).

All three tools measured antibiotic drugs for treating small and sick newborn infections (amoxicillin oral and injection, ampicillin injection and gentamicin injection as a minimum). However, inventories did not specify whether the antibiotic was available in the injectable form, with the appropriate concentrations and diluents (usually water for injection, sodium chloride 0.9% and glucose 5%), or the availability of smaller intravenous cannulas/catheters and syringe drivers. The tools measured standard intravenous fluid preparations, but only EmONC included glucose 10%, which is most frequently used for neonates. For seizure management, only the EmONC tool measured the first and second line treatments (intravenous phenobarbitone and phenytoin).

Several drugs that might be used for advanced level care, such as procedural sedation and pain relief, were not currently included in any of the tools.

In **Table 2** we present an example drug list for inpatient care of small and sick newborns indicating which drugs are measured by each tool and whether these are on the most recent WHO model essential medicines list [26]. This includes the commodities needed for retinopathy of prematurity screening and treatment, such as dilating and anaesthetic eye drops, which are not currently included in existing tools.

Health providers

There were several notable gaps in measurement of specialist newborn staff. Only the EmONC tool measured specialist staff cadres for newborns (eg, neonatologist) and none of the tools measured specialist neonatal nurses. Allied staff and support staff (eg, social workers, speech therapist) were not measured. None of the tools measured ophthalmologists or related professions that are needed in settings where newborns may require screening and treatment for retinopathy of prematurity, or biomedical engineers for equipment maintenance.

Guidelines

Table 1 shows all the guidelines and educational resources used for this review. Some resources cover a number of different interventions. However, there were notable gaps in available guidelines for more complex interventions, such as continuous positive airway pressure, blood transfusion, exchange transfusion, ventilation, and treatment and screening of retinopathy of prematurity.

Identification of gaps in measurement of the process domain to capture service readiness to care for small and sick newborns for each intervention

Measurement of regular practice or training of health staff in specific interventions was considered as a proxy measurement for the process domain for service readiness as it looks at what is regularly done to patients in the institution.

Regular practice

All the tools relied on direct health worker reports, the register, or chart reviews to measure whether select interventions were regularly provided for small and sick newborns.

The SPA looked at whether a limited number of interventions relevant to newborns (neonatal resuscitation and corticosteroids for preterm labour) were ever practiced and practiced in the last 3 months. The SPA also included a series of questions on essential care for newborns, but none on inpatient care for small and sick newborns, other than if KMC was practiced in the facility.

The SARA asked whether a limited number of functions were provided in the last 12 months: antibiotics for preterm or prolonged premature rupture of membranes, antenatal corticosteroids, neonatal resuscitation, KMC, and injectable antibiotics.

The EmONC assessment had the most detailed list of newborn interventions for which questions on regular or recent practice were asked (newborn resuscitation, antenatal corticosteroids, antibiotics for preterm premature rupture of membranes, antibiotics for neonatal infections, KMC, administration of oxygen and administration of IV fluids).

The EmONC tool included specific knowledge questions on small and sick newborn care, including a few interventions, such as resuscitation, oxygen therapy and infections.

Table 6 summarises the approaches used by each of the tools to capture regular practice and training.

Table 6. The approach used by Service Provision Assessment (SPA), Service Availability and Readiness Assessment (SARA) and Emergency Obstetric and Newborn Care (EmONC) assessment to measure regular practice and training

	SPA		SARA		EmONC	
	Regular practice	Training	Regular practice	Training	Regular practice	Training
Essential newborn care	Routinely practiced	Training in last 24 months	Routinely carried out	Training in last 24 months	Performed in last 3 months	Ever received training
Thermal protection		Training in last 24 months			As part of essential newborn care	As part of essential newborn care
Early initiation and support for exclusive breastfeeding	Routinely practiced	Training in last 24 months	Routinely carried out	Training in last 24 months	As part of essential newborn care	As part of essential newborn care
Neonatal resuscitation with bag and mask	Ever practiced, practiced in last 3 months	Training in last 24 months	Practiced in last 12 months	Training in last 24 months	Performed in last 3 months	Ever received training
Prevention of mother to child transmission of HIV	Routinely practiced	Training in last 24 months	Service is offered	Training in last 24 months	ARVs given to newborns in the last 3 months	Ever received training
Kangaroo mother care	Ever practiced	Training in last 24 months	Practiced in last 12 months		Performed in the last 3 months	Ever received training
Assisted feeding (cup feeding and nasogastric feeding)					Performed in last 3 months	
Safe administration of oxygen					Performed in last 3 months	
Injectable antibiotics for neonatal infection		Training in last 24 months	Practiced in last 12 months		Performed in last 3 months	Ever received training
Intravenous fluid		Training in last 24 months			Performed in last 3 months	

EmONC – Emergency Obstetric and Newborn Care, SPA – Service Provision Assessment, SARA – Service Availability and Readiness Assessment

The synthesis of these findings to provide recommendations on improving these measurements is provided in the Discussion section.

DISCUSSION

We have mapped the service readiness requirements for inpatient newborn care, detailing a total of 654 structural components to deliver 17 newborn interventions. Our review of three health facility assessment tools identified measurement gaps for almost all newborn interventions, even for the more basic interventions, such as thermoregulation and feeding. The most significant measurement gaps are for more complex interventions, which are currently not captured by any of the tools in our review. We found many commonalities among these tools, but also highlighted important differences that show how they have evolved with important, but distinct purposes, and different measurement approaches [9]. The size and cost of these assessments already limits the frequency of carrying out these surveys; adding a long list of indicators for small and sick newborn care would compound this challenge [28]. To improve the existing tools, we found that a number of indicators for basic service readiness could be harmonised, and some proxy indicators of service readiness for more complex care could potentially be added. As with other more complex areas of care, monitoring all the structures and processes for small and sick newborns will likely require a facility-based monitoring system [29-31].

The existing, up-to-date care guidelines for inpatient care for small and sick newborns are mainly split between obstetric care and paediatric care (**Table 2**) [32-35]. To the best of our knowledge, this is the first time that service readiness for small and sick newborn care has been delineated and mapped by structural component. The resulting matrix can be used by implementers for programme planning, depending on the needs of their health system and the interventions or packages of care they intend to provide at their service (Table S1 in **Online Supplementary Document**). It is a step towards developing a more general facility based monitoring system or core module. Following validation, such a tool could be adapted for different settings as has been done in India [29].

The following sections provide a synthesis of findings and recommendations for improving the widely used tools for measurement of small and sick newborn care.

Harmonisation of existing health facility assessment tools

Indicators

The interventions that are best represented by the existing tools are those that have been promoted as vertical programmes, such as neonatal resuscitation (which is a core indicator for obstetric and newborn care assessments), essential newborn care (for all babies) and PMTCT. The measurement approach and indicators for many of the more basic newborn interventions would benefit from more standardisation between tools. As a minimum, this should include service readiness indicators for essential newborn care (including service readiness for drying, skin-to-skin contact, cord clamping, vitamin K and initiation of breastfeeding), neonatal resuscitation and kangaroo mother care [28].

All of the existing tools have some questions on KMC, but for monitoring of operational KMC [28], the facility inventories require adaptations to incorporate more of the items needed for KMC [23] including the equipment for feeding support, antibiotics and amenities for mothers to stay in the facility [14]. Whilst listing the items needed for antenatal care exceeded the scope of this exercise, these should be considered in future tools, such as availability of antenatal corticosteroids for threatened preterm labour and antibiotics for preterm rupture of membranes (per WHO guidelines) as a minimum.

Measurement of training and skills for newborn interventions could be harmonised between tools such that these indicators are comparable between different surveys (see **Table 4**).

Crosscutting service readiness needs

Health providers, especially midwives and specialist nurses, play a critical role in neonatal care [6,8,36-38]. Specially trained neonatal nurses may not be available in all health facilities, but previous studies show it is important to monitor who, if anyone, cares for newborns in the absence of specialised staff [8]. Recent studies in higher income settings, where neonatal nursing is a specialist cadre, show that reducing the nurse-to-patient ratio in neonatal units increases in-hospital mortality [39,40]. As a minimum, all health facility assessment survey tools could include questions on staff rotation policies to ensure specialist staff are not regularly being rotated to other areas of care [8], such a question is currently only included in the EmONC tool. Other allied and supportive professionals may be a necessary addition to the list of staff cadres, such as biomedical engineers for maintaining equipment and nursing support staff. For all health facility assessment tools, the capacity and readiness of a facility to provide referral to facilities that can provide more complex care for small and sick is a critical indicator of service readiness. The difficulty and inconsistency in measurement of provider skills and training also illustrates the need for further research into human resource tracking, and work to set benchmarks for staffing ratios for neonatal care [8].

Infection prevention and control is essential for all areas of the facility, with newborns particularly vulnerable, and most of the newborn deaths from infections occurring in small babies. The current tools have several general water and sanitation indicators, which should be harmonised across tools to ensure that the basic soap, running water and safe and effective antiseptics are available in labour and delivery and neonatal care areas. A standard indicator that measures whether the newborn space is separate from the paediatric ward, and for whether there is a system for inborn and out born babies could be a potential proxy indicator for service readiness.

Measuring more complex inpatient care for small and sick newborns

Small and sick babies, especially those born preterm, are at higher risk of multiple childhood morbidities (including visual, hearing and neuro-developmental), with increasing gradient of adverse developmental outcomes by lower gestational age of survivors [41,42]. These newborns often require more complex interventions, such as respiratory support (oxygen, continuous positive airway pressure), treatment of specific complications (feeding, seizures, jaundice), and screening and follow up services (**Figure 1**) [8,43-47]. Many of these interventions carry a risk of harm when not performed with safe equipment or by trained staff. This is illustrated in middle-income settings, where we have seen an increase in impairments among survivors of neonatal care, especially where complex care has been scaled up without due attention to service readiness and quality of care [41,42,48].

The existing tools do not capture the large number of items required to deliver complex interventions safely, which would require a facility based monitoring register that also includes process and outcome data (morbidity and mortality) [49]. Such registers have been developed in higher- and middle-income settings [29,49], but are not standardised routine systems. Further research into adaptations of existing tools is an important next step.

Clinical care charts and protocols are essential for quality and safety of neonatal care that requires complex calculations of drug concentrations and specific diluents, dosages, and delivery modes for newborns. In addition to service readiness, the risks of certain interventions can be mitigated by ensuring clinical record keeping, which is known to be sub-standard in many settings [50]. Standardised observation charts for monitoring of vital signs (eg, hourly or three-hourly), fluid input and output, feeding method and volume, and monitoring medications and laboratory tests (eg, serum bilirubin and exchange transfusion thresholds) could support facilities, alongside up-to-date standardised evidence-based guidelines, a list of which is included in the documentation section of our matrix.

Implications and next steps for monitoring service readiness for inpatient care of small and sick newborns

Amongst existing partners and initiatives, there is widespread recognition of the need to harmonise monitoring systems for perinatal care. The existing EmOC signal functions do not represent the full set of facility-based interventions for mothers and newborns, and small and sick newborns are especially neglected. Given the large number of service readiness requirements for small and sick newborn care, a short list of signal functions for monitoring purposes is a potential solution. Previous work by Gabrysch and colleagues has recommended improvements to these tools [51]. Currently, a global survey led by *Every Newborn* partners, alongside a technical group led by AMDD and UNFPA are working on linking this to the emergency obstetric care indicators, with plans to finalise recommendations for newborn signal functions in 2018-2019 [9].

Periodic evaluation, using health facility surveys, is currently necessary, but ultimately the goal should be to incorporate such assessments into functional and sustainable routine national systems. These should operate independent of donor funding and project mandates. The current health facility assessment tools are costly and time-consuming. Lighter assessments that can be carried out more frequently are also required, and need more research [52]. Even in high-income countries, not all national facilities feed information into one database for national monitoring of inpatient care of small and sick newborns. Low- and middle-income countries that have not moved to electronic information systems have an advantage in that they can leap-frog the situation of having fragmented and discrepant electronic data collection forms which differ from facility to facility or region to region. Exploration of the potential use of DHIS-2 platforms for facility-based monitoring is being carried out as part of the *Every Newborn* metrics work on small and sick newborns [9]. This work supports the growing interest in use of routine health management information systems to monitor aspects of service delivery in facilities [14], and of logistic management information systems (LMIS) to track logistics and supplies.

CONCLUSIONS

Tracking of service readiness to provide inpatient care of small and sick newborns is needed to gain the required policy attention, accountability and investment that is critical to end preventable newborn deaths, and improve child development. This is reflected in the Global Strategy for Women, Children and Adolescents, the WHO Quality of Care Framework, and is supported by the *Every Newborn* metrics working group. The existing health facility assessments do not generate comparable data, and have very limited assessment of more complex care for small and sick newborns. Indicators in existing tools can be harmonised, but the size and cost of these assessments limits their frequency. Developing a core list of harmonised indicators for use in routine health information systems could help address this gap. Improvements in these monitoring systems are urgently needed to inform efforts to improve quality of care and investments in health systems scale-up, to end preventable newborn death and disability, alongside work to end preventable maternal deaths and stillbirths.

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Appendix P: PDF of published paper: Categorising interventions to levels of inpatient care for small and sick newborns: Findings from a global survey

RESEARCH ARTICLE

Categorising interventions to levels of inpatient care for small and sick newborns: Findings from a global survey

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Abstract

Background

In 2017, 2.5 million newborns died, mainly from prematurity, infections, and intrapartum events. Preventing these deaths requires health systems to provide routine and emergency care at birth, and quality inpatient care for small and sick newborns. Defined levels of emergency obstetric care (EmOC) and standardised measurement of "signal functions" has improved tracking of maternal care in low- and middle-income countries (LMICs). Levels of newborn care, particularly for small and sick newborns, and associated signal functions are still not consistently defined or tracked.

Methods

Between November 2016-November 2017, we conducted an online survey of professionals working in maternal and newborn health. We asked respondents to categorise 18 clinical care interventions that could act as potential signal functions for small and sick newborns to 3 levels of care they thought were appropriate for health systems in LMICs to provide: "routine care at birth", "special care" and "intensive care". We calculated the percentage of respondents that classified each intervention at each level of care and stratified responses to look at variation by respondent characteristics.

Results

Six interventions were classified to specific levels by more than 50% of respondents as "routine care at birth," three interventions as "special care" and one as "intensive care". Eight interventions were borderline between these care levels. Responses were more consistent for interventions with relevant WHO clinical care guidelines while more variation in

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respondents' classification was observed in complex interventions that lack standards or guidelines. Respondents with experience in lower-income settings were more likely to assign a higher level of care for more complex interventions.

Conclusions

Results were consistent with known challenges of scaling up inpatient care in lower-income settings and underline the importance of comprehensive guidelines and standards for inpatient care. Further work is needed to develop a shortlist of newborn signal functions aligned with emergency obstetric care levels to track universal health coverage for mothers and their newborns.

Introduction

Each year an estimated 2.5 million newborns die in the 28 days after birth [1]. The main causes of death are direct complications of prematurity (35%), infections (23%), and intrapartum complications leading to birth injury (24%) [2]. Most of these deaths occur in low- and middle-income countries (LMICs) [3]. Many lives could be saved—and morbidity prevented—through a health systems approach along the continuum of care [4]. Such an approach requires delivery of quality packages of care including routine and emergency care for mothers and newborns at birth, and inpatient care for small and sick newborns [4, 5].

In addition to routine essential newborn care, many low birth weight (LBW) newborns, including both preterm infants, and those born small for gestational age, require additional support to feed and to maintain their temperature [6, 7]. Preterm newborns face increased risks of respiratory problems, infections, and jaundice [8]. Even amongst those born at full term, significant numbers of newborns face complications including, systemic infections, neonatal encephalopathy, severe jaundice, and congenital disorders, with high mortality risk in the absence of quality care [3, 7]. Many of these small and sick babies will require inpatient care for them to survive and minimise chances of developing future morbidities and/or long-term disability [9–13]. Access to appropriate level and quality care remains challenging, especially for mothers and newborns experiencing complications, and notably in LMICs [4, 7, 14].

Based on evidence from higher income settings, a rational approach to organising and delivering quality services is through an integrated network of facilities providing increasing levels of care, referred to as regionalisation of care [15–17]. Managing mothers and newborns experiencing complications by more skilled staff working in specialised, better equipped facilities than in lower level facilities or those staffed solely by generalists allows for an efficient use of resources, and is an effective strategy to improve access to care for complications [14, 15, 17]. Higher levels of care build on the capabilities of lower level(s) with the additional infrastructure, equipment, supplies and health providers to manage more complex levels of care [15, 18]. For such an approach to work, synergy in institutional capabilities for mother and newborns is needed with a functional communication and referral system [15, 19, 20]. Levels of care need to be clearly defined with accompanying monitoring systems to identify issues in availability, access and quality of care for services [16, 18, 21]. Defined levels of maternal and newborn care are common in high-income settings [15, 16, 20, 22, 23], but there is a need for such a delineation for newborns in LMICs [7].

In LMICs, maternal care has been categorised by United Nations (UN) agencies at two levels referred to as basic emergency obstetric care (BEmOC) or comprehensive emergency obstetric care (CEmOC) [24]. These levels of care act as a proxy measure of the availability of the human resources, infrastructure, equipment, and supplies needed to provide specific services. This delineation allows Ministries of Health and technical partners to manage and monitor emergency obstetric care services in LMICs through "signal functions", a core list of life-saving services that have been used to assess the provision of emergency obstetric care at either a basic or comprehensive levels [24–26]. Currently, there are seven signal functions assessed for BEmOC and two additional CEmOC signal functions; they mostly address the obstetric complications that lead to maternal death and disability, including post-partum haemorrhage, infections and hypertensive disorders [24].

Throughout this article, we will refer to the "Emergency Obstetric Care (EmOC) signal functions" in recognition of the fact that these were primarily designed from an obstetric perspective and do not represent the full spectrum of interventions required for emergency newborn care. More recently, the newborn has been more intentionally included and the term Emergency Obstetric and Newborn Care (EmONC) has emerged, a change that has been welcomed by maternal and newborn health experts, policy makers and programme implementers. We will use the term EmONC whenever we are referring to programmes, policies or indicators that were designed with a view to include both obstetric and newborn care and/or when we refer to the health facility assessments (EmONC assessments) that have been carried out with a view to looking at both maternal and newborn health services.

For small and sick newborn care in LMICs, one newborn-specific signal function, newborn resuscitation with bag and mask, was added to the core list of BEmOC signal functions nearly a decade ago [24]. However, despite the addition of a resuscitation indicator, the signal functions do not accurately represent the full package of interventions needed by the mother-baby dyad, most notably care for small and sick newborns [14, 21, 26]. This gap was highlighted by Gabrysch and colleagues in 2012, who proposed a new set of signal functions for routine and emergency maternal and newborn care following a systematic review of newborn survival literature and a consultation with 39 experts [26]. Gabrysch and colleagues proposed additional signal functions for routine and emergency care for mothers and newborns, however, this work has yet to lead to the formal definition and adoption of levels of care and accompanying newborn signal functions. Furthermore, this work did not focus intentionally on the levels of care needed for those babies born small and sick.

Since 2012, there has been a significant increase in epidemiological data for newborns [3], including better estimates of mortality, morbidity and outcomes beyond survival [8, 13, 27]. The global *Every Newborn* Action Plan, launched in 2015, called for increased focus on the programmatic and monitoring needs of newborns in order to end preventable maternal, newborn death, disability and stillbirth [21, 28, 29]. *Every Newborn* highlighted the need to improve the quality care for small and sick newborns and develop accompanying monitoring systems [3, 21]. During the past years increasingly efforts are being made by the global health community to tackle the specific health problems of small and sick newborn babies though investment in quality neonatal care. This article builds on this platform and the previous work to develop levels of care and associated signal functions [26] for small and sick newborns, in particular. The specific aim of this article is to describe the findings of an online global survey undertaken to categorise a list of newborn interventions, potential newborn signal functions, to different levels of care.

Methods

Study design and population

We designed an online survey to collect opinions from professionals working in maternal and newborn health, including clinicians with neonatal and obstetric experience (midwives, nurses and doctors), researchers and programme managers or governmental officials (e.g. Ministry of Health). Whilst LMIC health services for small and sick newborns was the focus, the survey was not limited to respondents based in LMICs.

Questionnaire

We developed an online questionnaire to collect respondent characteristics (profession, current country/region of practice/employment, experience (geography, length, private/public) and type of experience (e.g. clinician, research, etc.).

We generated a list of 18 newborn services or interventions based on WHO guidelines, previous work on the subject [26] and specific work carried out as part of the *Every Newborn* process [4, 7, 30–33], including an expert focus group at an *Every Newborn* workshop where participants discussed interventions for small and sick newborns and voted on a shortlist [34]. Interventions for the shortlist were prioritised based on potential contributions to mortality reduction and LMIC health system feasibility [4, 32].

In the questionnaire, we asked respondents to assign the 18 interventions to one of 3 levels of care appropriate for health systems in LMICs to provide: “routine care at birth”, “special care”, “intensive inpatient care” as well as a classification category for services that would not be appropriate as a signal function. Routine care at birth was included based on the rationale that all newborns (including those born small and sick) will require these interventions before they are admitted to inpatient care. To avoid biasing respondents, the questionnaire generated the list of interventions/services in random order for each respondent.

The levels of inpatient care were described in the questionnaire as follows:

- Routine care at birth: This should be available at all facilities and for all babies including those that need inpatient care because they are small and sick newborns.
- Special care: this service is part of inpatient care for small and sick newborns. In many settings, this is referred to as special newborn care or level 2 care [16]. These inpatient care signal functions are interventions for small and sick newborns that should be provided in addition to routine care at birth.
- Intensive care: This service is part of inpatient care for very small and sick newborns. In most settings this will only be available at the highest level of a referral hospital. In many settings, this level is referred to as neonatal intensive care (NICU), or level 3 care [16]. These services are for very small and sick newborns in addition to all the services provided at the special care level.

We piloted the questionnaire for face validity among a group of 4 experienced public health colleagues (not part of the study team) who pre-tested and provided feedback on the question flow and wording. We then refined the wording of questionnaire based on this pilot. We translated the final version into French and Spanish, using native speakers with clinical or programmatic experience in maternal and newborn health. The final version of the questionnaire is available at http://doi.org/10.17037/DATA.00000902.

Recruitment

The survey was accessible online for 12 months from November 2016-November 2017 in English, Spanish and French via the online platform Survey Monkey (www.surveymonkey.co.uk). Respondents could only complete the survey after giving informed consent. Respondents were given the option to exit the survey at any point. This study was granted ethical approval by the Research Ethics Committee of the London School of Hygiene &Tropical Medicine (reference number 11922).

Given that no sampling frame for this population exists, it was not possible to achieve a probability sample. Therefore, we employed a multi-faceted approach to recruit participants with diverse experience in maternal newborn health from a variety of settings, especially LMICs. We made the survey available on a wide range of professional networks, including Healthy Newborn Network https://www.healthynewbornnetwork.org/ and CHIFA http://www.hifa.org/forums/chifa-child-health-and-rights to reach both professionals working in international organisations and health professionals working on the ground. These platforms were used with the aim of recruiting a wide range of both clinicians (including nurses, midwives, doctors and allied professionals) and programme professionals with a breadth of experience. We encouraged snowball sampling by suggesting that respondents share the survey widely amongst colleagues. In addition, we promoted the survey at international conferences on newborn health: http://inkmc.net/index.php/11th-workshop-and-congress and midwifery https://www.internationalmidwives.org/events/triennial-congress/toronto-2017/.

Statistical analyses

We calculated descriptive statistics for the respondents, including background characteristics and respondent experience. We categorised respondent experience by age group (18–34, 35–54, 55–74, 75 years or older), experience in LMICs and/or high income countries (HICs), clinical and non-clinical experience, regional base (using World Bank regions https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups) and experience in the public and the private sector.

For each signal function:

- We calculated the percentage of respondents that classified each intervention at each level of care
- We stratified responses by respondent characteristics and looked at variation for each signal function and respondent group using chi-squared tests to identify significant differences between respondent groups and selected level of care.

Results

Respondent characteristics

A total of 372 individuals accessed the online survey, of which 110 (29.6%) were excluded as after registering they did not answer any questions relating to interventions and levels of care. The final sample included 262 respondents from 61 countries and 7 regions of the world (Fig 1). Data summary tables are available at http://doi.org/10.17037/DATA.00000902.

Levels of care

For the list of interventions selected as potential signal functions and the percentage of respondents that categorised these at each level of care see Fig 2.

In the following sections, we present the results by levels of care; a service was described under a specific level of care when it was selected at that level by >50% of respondents. This threshold was defined as an iterative process, based on exploration of the data.

Routine care at birth. Six services were selected by >50% of respondents as "routine care at birth". Prevention of mother to child transmission of HIV (PMTCT) (83%), basic neonatal resuscitation (86%), thermal protection (87%), immediate and exclusive breastfeeding (93%),

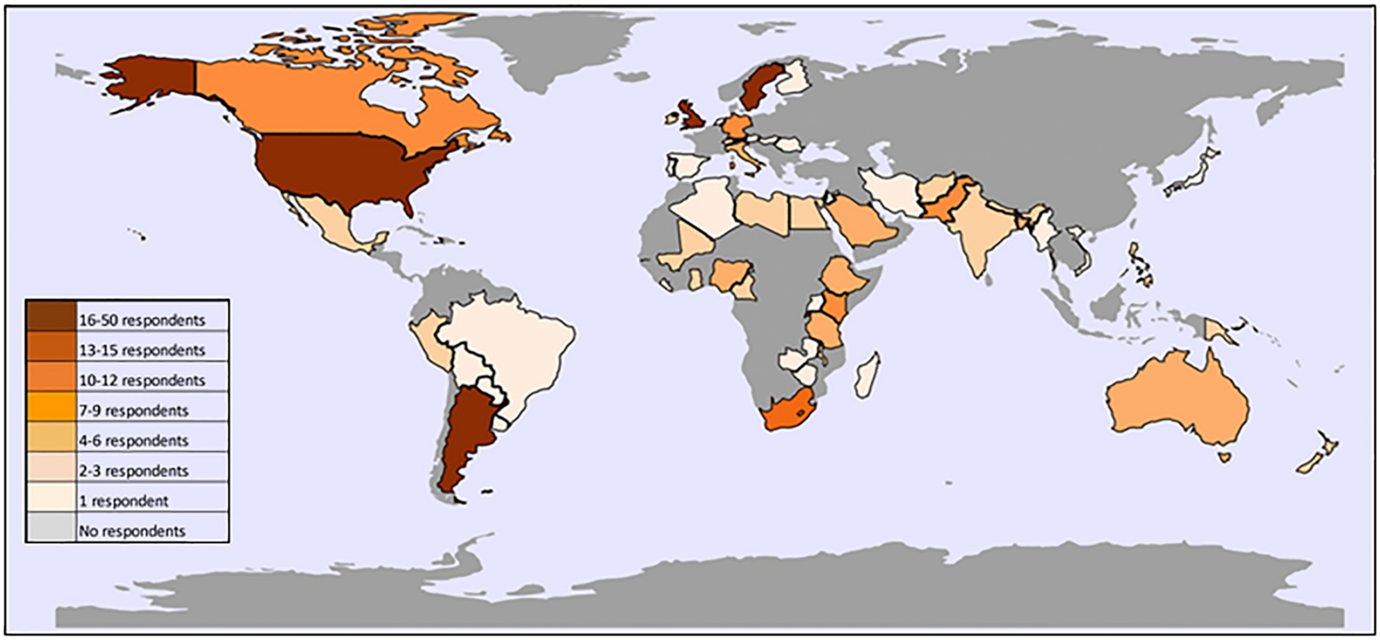

Fig 1. Frequency of responses to global survey on levels of inpatient care by country. Respondent experience of working in maternal and newborn health ranged from 1–49 years with a median of 19 years. The largest percentage of respondents was based in Europe and Central Asia (31%) and the smallest percentage of respondents was based in the Middle East and North Africa (5%); thereon 14% based in North America, 11% based in Latin America & Caribbean, 8% were based in South Asia, and 7% East Asia & Pacific. Over half of respondents (52%) had previous experience working in both HICs and LMICs, 13% of respondents had experience from only a high-income country and 35% only LMIC experience. The majority of respondents were trained clinicians (75%). Of these the majority were doctors (71%) followed by nurses (25%), midwives (2%) and allied health professionals (2%). Almost all clinicians had experience working in the public sector; 65% with public sector experience only, 30% with a mix of private and public-sector experience and 6% with only private sector experience.

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and essential newborn care (93%) were all classified by over 80% of respondents as routine care at birth. Prevention and treatment of hypoglycaemia was selected by over 60% of respondents at this level.

Other than for prevention and treatment of hypoglycaemia, we found no significant variation by respondent characteristics of the six interventions that were classified as routine care at birth. Classification of hypoglycaemia by clinicians and non-clinicians did vary significantly: 70% of clinicians classified this as care at birth compared with only 44% of non-clinicians ($p<0.01$). Neonatal resuscitation, the only intervention in the list that is an existing EmOC signal function, was the option with the lowest number of responses identifying it as "not a potential signal function" (1%).

Special care. Three services were selected by >50% of respondents as "special care": Intravenous (IV) fluids (59%), injectable antibiotics (57%) and phototherapy (51%). Respondents with only experience in LMICs, were significantly more likely to classify IV fluids at a higher level of care compared with those with experience in a high-income setting ($p<0.05$). For injectable antibiotics, respondents based in high burden settings, such as South Asia, were more likely to classify this option at higher levels of care whereas Latin American respondents were more likely to classify it at a lower level ($p<0.05$). For phototherapy, there was some variation between non-clinicians and clinician respondents. Non-clinicians were more likely to classify phototherapy at either "special care" or "intensive care" than clinicians; 28% of non-clinicians categorised this as "intensive care" compared with only 12% of clinicians ($p<0.05$). A larger percentage of respondents with experience in the private sector classified phototherapy as "routine care at birth" (63%) than respondents with public (35%) or those with mixed public-private experience (27%) ($p<0.05$).

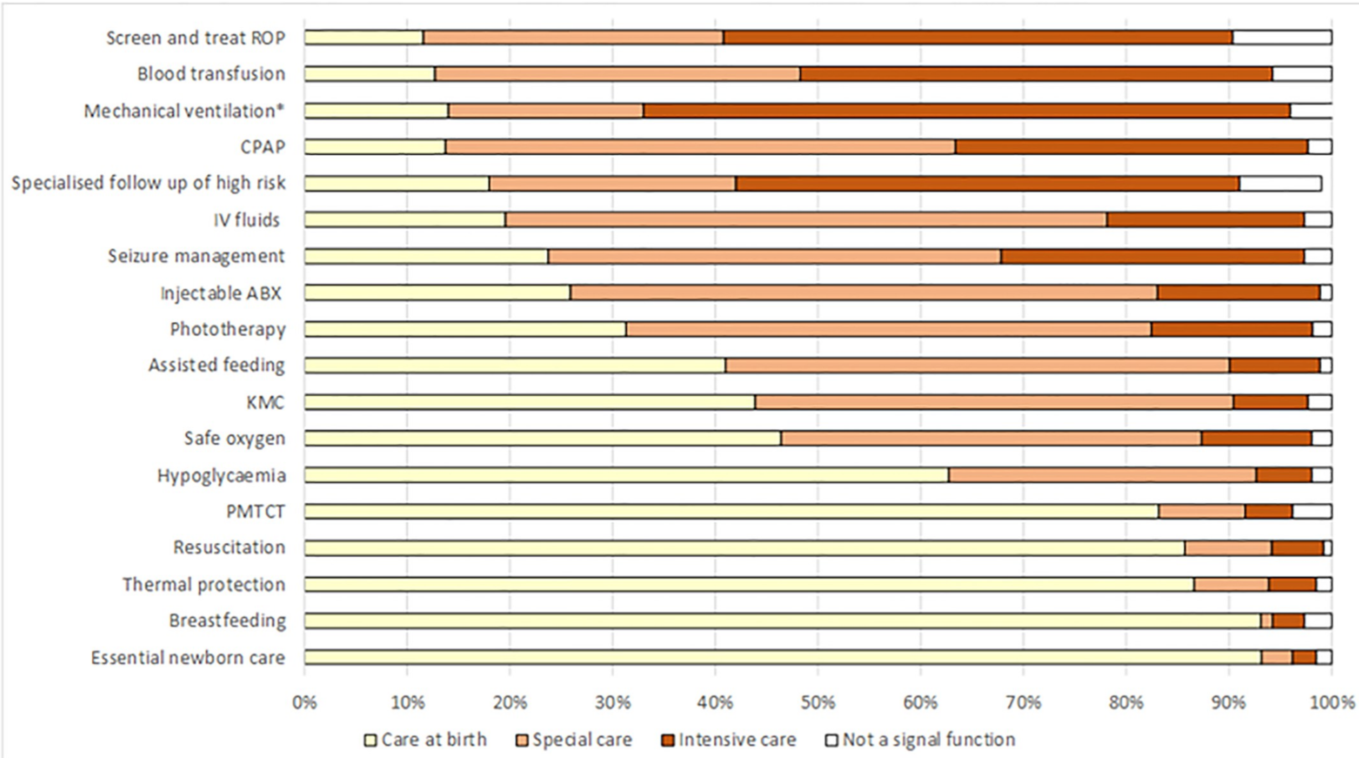

Fig 2. Bar graph showing list of interventions and percent of respondents for each level of care (n = 262). PMTCT = Prevention of mother to child transmission of HIV, KMC = Kangaroo mother care, ABX = antibiotics, IV = intravenous, CPAP = Continuous positive airway pressure, ROP = retinopathy of prematurity. *Only intervention classified by >50% of respondents as "intensive care".

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Intensive care. Mechanical ventilation was the only intervention classified by >50% of respondents as a service for "intensive care". Respondents with experience in LMICs were more likely to classify mechanical ventilation as "intensive care" than respondents who had not worked in LMICs (66% vs. 41% respectively) ($p<0.05$).

Interventions/Services without clear categorisation (borderline). *Borderline "routine care at birth"/ "special care" refers to interventions not meeting the >50% threshold for any level of care but categorised by close to 50% of respondents as "routine care at birth" or"special care".* Three interventions were classified as borderline "routine care at birth"/ "special care": safe oxygen therapy (46%/41%), KMC (44%/47%) and assisted feeding (41%/49%), respectively.

For oxygen and assisted feeding, experience of working in LMICs, regional and experience working in the public and private sector were significantly associated with variation. Those with LMIC experience or from higher burden settings were more likely to classify these interventions at higher levels of care.

For KMC, there was no significant variation between levels of care and respondent characteristics.

Borderline "special care"/ "intensive care" refers to interventions not meeting the >50% threshold for any level of care but categorised by close to 50% of respondents as "special care" or "intensive care".

Five interventions were classified as borderline "special care"/ "intensive care": specialised follow up of high risk (41%/49%), continuous positive airway pressure (CPAP) (50%/34%), seizure management (44%/30%), blood transfusion (36%/46%) and retinopathy of prematurity (ROP) (29%/50%).

For management of seizures, blood transfusion and CPAP, clinicians were significantly more likely to classify these interventions as special care while non-clinicians were more likely to classify them as intensive care ($p<0.05$).

For blood transfusion, CPAP and screening and treatment of ROP, experience in a LMIC was significantly associated with variation in the selected levels of care. Those with experience in LMICs were significantly more likely to classify these interventions as "intensive care" and while those with only experience in a high-income country more likely to classify them as "special care" ($p<0.05$). For example, 71% of respondents with only HIC experience classified CPAP as "special care" compared to only 33% of respondents with only LMIC experience; respondents with only LMIC experience were significantly more likely to classify it as "intensive care" (49%) ($p = <0.05$). For ROP, 16% of those who had only worked in LMICs responded that ROP was not a signal function compared to no respondents with only HIC experience and 7% of respondents with experience in both LMICs and HICs ($p<0.05$).

For specialised follow up of high risk, there was no significant variation in respondent characteristics for the between levels of care selected.

Discussion

This article presents results from a global survey of 262 respondents from 61 countries to classify 18 newborn care interventions, into 3 levels of care. Applying the >50% threshold to 18 potential signal functions, 10 of these clearly aligned to specific levels of care: six for routine care at birth, three for special care and one for intensive care. The remaining eight signal functions did not meet the >50% threshold for a specific level of care. Previous work has encouraged the development of routine and emergency newborn signal functions [26], but levels of newborn care have not yet been well-defined for LMICs, particularly for small and sick newborns. This work contributes new insights into levels of neonatal care in LMICs as a step towards formally defined newborn care levels that could be aligned with EmOC.

Interpretation of categorisation of levels of inpatient care for small and sick newborns from global survey

Consistency with existing guidelines. Out of the interventions that were clearly classified as "routine care at birth" by more than 80% of respondents, four have existing WHO guidelines (PMTCT (83%)[35], neonatal resuscitation (86%)[36], immediate and exclusive breastfeeding (93%)[37], and essential newborn care (93%) [38]). These interventions showed little variation among respondents. For more complex interventions that do not have specific WHO guidelines, level of care classification was less clear and there was greater respondent variation. This may be related to individual respondents applying existing classification systems within countries where they had worked. For example, in many settings the capacity to provide neonatal mechanical ventilation is the defining feature of an intensive care unit [39], as it requires more complex health system capacity [18]. The wording of the intervention as injectable antibiotics may have led to ambiguity with respondents by differentiating intravenous from intramuscular antibiotics. Some respondents may have perceived that intravenous infusions of antibiotics for treatment of infection may require special care capacity in contrast to intramuscular antibiotics that WHO recommends as feasible at low levels of the health system [40].

Low- and middle-income experience. Overall, experience in LMICs was most frequently associated with variation in response as was the case with oxygen, assisted feeding, blood transfusion, continuous positive airway pressure (CPAP) and screening and treatment for ROP. There was a clear pattern for respondents with experience in lower income settings or those based in LMICs to classify interventions more cautiously (at a higher level of care e.g. intensive care rather than special care). That respondents with LMIC experience were more comfortable assigning a higher level of care for certain interventions may reflect the respondents' perceptions of feasibility of introducing or scaling up interventions such as CPAP [41–43]. It may also be indicative of a lack of experience delivering those interventions and/or the challenges of scaling up inpatient care in these settings. Experience in the private sector may have driven a more optimistic perception about interventions that could be provided at lower levels of care, as was the case with phototherapy, despite the increase in availability of low-cost phototherapy devices that can safely be used in LMICs [7, 44].

Clinical experience and knowledge of interventions. For more complex interventions, non-clinicians may not have been familiar with nomenclature, or have had less knowledge of the clinical significance or the potential feasibility of these interventions. This may explain some of the variation in responses for hypoglycaemia, treatment of seizures and phototherapy. For example, clinicians may be more likely than non-clinicians to recognise the significance of seizures in the neonatal period and the frequency of intrapartum injury in LMIC settings. The majority of respondents were clinicians who had worked in a LMIC (197/262); very few non-clinicians who had worked only in HICs (2/262) responded to the survey. However, arguably programmatic or clinical experience in LMICs was a motivating factor to respond to the survey, which related directly to LMIC health programmes and was advertised through forums relevant to these professional groups.

Transitional interventions. There is marked variation in the health system requirements between different levels of care. For example, facilities may be able to provide high quality routine care at birth, but lack the infrastructure, equipment and human resources to provide special care. Perceptions of the potential harm that can be caused by certain interventions if not provided in a safe, enabling environment may have influenced respondents. The perception is justified by epidemiological data showing long term consequences of poor-quality neonatal care, a pattern that has been seen in countries where there has been rapid scale up without sufficient attention to safety and monitoring systems [13, 45]. For example, countries in Asia and Latin America are seeing an epidemic of childhood blindness caused by unregulated use of oxygen in neonatal units, as well as poor screening and follow up services for survivors of neonatal care [11].

One interpretation of the results of this survey for potential signal functions that lacked clear classification may be to consider them as "transitional". This would refer to interventions or services that bridge the nexus between two defined levels of care. This approach allows facilities that are developing inpatient care capacity at either the special care or intensive care level to go through a transitional phase whereby interventions are added in a stepwise manner before moving up to the next level of care. Facilities offering newborn care would need to offer all service category requirements at lower levels of the hierarchy before adding transitional interventions linked to higher levels [46]. For example, facilities offering routine care at birth may begin a transitional phase to building special care capacity by adding interventions such as oxygen and assisted feeding (starting with cup feeding of expressed breastmilk) in addition to or as part of stabilisation and referral. The progressive or stepwise introduction of such interventions will also be influenced by context; hospitals with larger catchment areas may need to cover a wider range of services than smaller ones. To move to the next level, all transitional interventions would need to be available and provided to a minimum standard [18].

In practice the introduction of transitional interventions would require policy and implementation discussions and further operational research, as settings differ widely [19]. Much of the existing evidence and guidance on neonatal care pertains from high income countries [15, 16, 20, 23, 46], with the majority of implementation studies from LMICs being hospital level

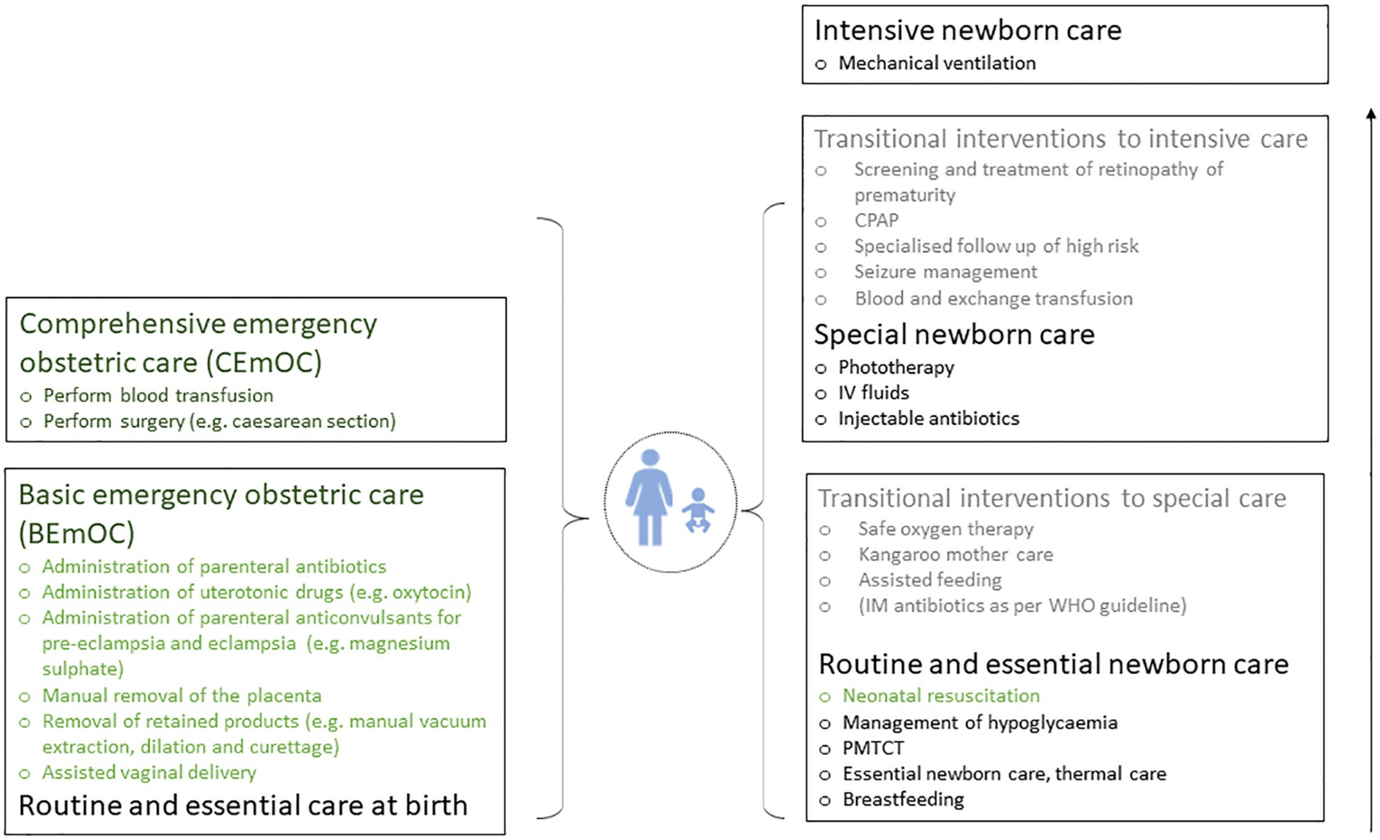

Fig 3. Interventions and levels of inpatient care for small and sick newborns aligned with Emergency Obstetric Care (EmOC) signal functions and levels of care. Green = existing signal function. Grey = transitional interventions. PMTCT = Prevention of mother to child transmission of HIV, IV = intravenous, IM = intramuscular, CPAP = continuous positive airway pressure.

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only with few from a health systems perspective [47]. Further research is needed to document and develop quality evidence from LMICs on the organisation of neonatal care.

Next steps: Aligning levels of inpatient newborn care with routine and emergency obstetric care measurement

Agreed levels of care are urgently needed for newborns, but further work is needed to align these with existing EmOC levels and determine an appropriate integrated and dynamic approach for monitoring. Fig 3 shows how the results of the survey could potentially align with the existing emergency obstetric care signal functions and levels of care. Critically, this figure places the mother and newborn together at the centre of the care.

Interventions in green are those which are existing signal functions. Starting from the bottom of the figure, routine and preventive care interventions reduce the need for emergency and inpatient care by preventing complications and there is a strong argument for their inclusion in the list of signal functions. The special care level may align with existing comprehensive signal functions as these are interventions that are only likely to be feasible to provide at a first level referral facility or regional hospital that has the capacity to have a dedicated newborn inpatient care ward and staff. A higher level, intensive care will likely only be available at a very small number of CEmOC facilities (e.g. central hospitals). Intensive care would less likely to be part of the existing EmOC framework that does not currently cover an intensive level of care for women with severe obstetric complications. These findings are also consistent with previous work that promotes the inclusion of routine and preventive care signal functions for EmoC monitoring [26]. However, one might argue that by including preventive, routine care and inpatient care measures, the framework ceases to be an "emergency framework" and becomes a framework for interventions for intrapartum and postnatal care.

Further discussion and consensus to formulate measurable newborn signal functions from this list of interventions will be needed. As currently presented, the list of interventions are potential signal functions not yet validated by being shown to link to improved outcomes, although each of these interventions does have evidence of impact [4, 7]. As part of further formative research, piloting and testing the measurement of a selection of these interventions in existing LMIC inpatient care facilities would be important. Qualitative work may be needed to look at the use of a selection of signal functions at the country and facility level in different settings. In addition, these would need to be used alongside complementary indicators that could be used for newborn care that reflect access, utilization and quality dimensions, aligned with the WHO quality of care framework [48]. The availability and density of facilities capable of providing both routine, emergency obstetric and small and sick newborn care as well as the proportion of population at a defined travel time from such facilities are useful health system tools for planning and monitoring the supply-side towards ensuring sufficient services for both maternal and newborn care. Such guidance has been lacking for small and sick newborn care, which faces major gaps in availability of and access to facilities.

This work is timely, as a revision of the EmONC monitoring handbook and associated indicators is planned. Such a revision is intended to build on lessons learned from implementation and better reflect the needs of the mother-baby dyad, including routine maternal and newborn care and inpatient care for small and sick newborns. This work contributes part of the formative work for this wider revision.

Limitations

Since health system contexts in LMICs differ, we used an online approach to collect a wide range of opinions from different settings and professional backgrounds. However, a number of limitations of this approach must be noted. Firstly, our sample was not fully representative of all regions. Whilst the sample was geographically diverse, selection bias is a limitation and opinions of those who could not or did not access the survey due to limited internet connection, language or access issues is unknown. For example, few middle-income countries in sub-Saharan Africa were represented in the sample. The findings may also be biased by the larger frequency of respondents from Europe and the Americas, although the majority of respondents reported experience in LMIC settings even if currently based in higher-income settings. Secondly, survey fatigue may have occurred, although the list of interventions appeared in random order to avoid biasing results through respondent attrition. Survey fatigue may partially explain the number of individuals that accessed the survey but did not complete any information on newborn interventions. There may also have been a number that accessed it and realised they did not have the background knowledge to be able to answer the questions on the interventions. Several factors may have influenced the classification of inpatient care interventions, including knowledge of the intervention, perception of the importance of the intervention (e.g. its potential impact on mortality and morbidity) and perceived feasibility. This may have resulted in a conflict between perceived feasibility (can do) and perceived need (should do) and respondents may have been strongly influenced by their own personal clinical or contextual programmatic experiences. Finally, for ease of interpretation, a threshold of >50% was used to classify interventions into different levels. This was pragmatic, but entirely arbitrary threshold and the findings would be slightly different if other thresholds were applied.

This work was focused on inpatient care for small and sick newborns that occurs in the postnatal period. It does not discuss community interventions or interventions that benefit newborns but are delivered in the antenatal period. The use of antenatal corticosteroids for mothers with threatened preterm labour [49] and antibiotics for preterm premature rupture of membranes (P-PROM) [50] are two interventions for small and sick newborns that have an evidence base, but that do not naturally fit into the inpatient newborn care package due to the timing in the peripartum period.

Conclusions

This article has shown how practitioners categorised 18 newborn interventions that could act as potential signal functions to different levels of care, including routine care at birth and inpatient care for small and sick newborns. Findings were consistent with existing clinical guidelines and previous work on the subject, but also provided new insights on how newborn care programmes, including more complex interventions for small and sick newborns, could be organised and monitored. Future research should focus on refining the list to a small selection of measurable signal functions and testing of these potential signal functions in existing inpatient care units. Further work is needed to align these newborn signal functions to the existing obstetric care levels to create a dynamic and integrated framework for maternal and newborn care. Working towards universal health coverage, future adaptations, including improvements to indicators of service availability, access and quality, should reflect the needs of health programmes for both mothers and their newborns.

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