Birth attendants' hand hygiene in maternity wards in low-resource settings: levels and determinants

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STATEMENT OF OWN WORK

I, Giorgia Gon, confirm 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: ………………………………….. Date:……………………………………

ABSTRACT

Rationale: High levels of preventable infection still occur among mother and newborns. This burden is concentrated in low and middle-income countries (LMICs) where increasing numbers of women attend facilities for childbirth. Poor quality of care contributes to this burden. Birth attendants' hand hygiene in healthcare facilities is a key infection prevention opportunity.

Objectives and methods: To assess existing evidence on birth attendants' hand hygiene compliance in LMIC facilities by systematically reviewing the literature. To describe the enabling environment for hand hygiene in Zanzibar maternity wards (Tanzania) using a mixed-methods cross-sectional survey. To develop a tool to capture the complex patterns of hand hygiene performed by birth attendants using time-&-motion methods. To assess the compliance of Zanzibar birth attendants to hand rubbing/washing, avoiding recontamination and glove use before aseptic procedures using time-&-motion methods and descriptive statistics. To assess the determinants of Zanzibar birth attendants' hand rubbing/washing and of avoiding recontamination before aseptic procedures using time-&-motion, a survey, and analytical methods.

Findings: We found only nine studies – often with poor methods and definitions – that quantitatively examine birth attendants' hand hygiene in LMICs facilities; amongst the three with better definitions and sample sizes, compliance ranged from 1-28%. The HANDS at birth tool was developed using time-&-motion software, which allowed all birth attendants' actions to be captured and operationalised. Only 9.6% of Zanzibar birth attendants hand rubbed/washed, donned gloves and avoided recontamination before aseptic procedures. Half of the time when rubbing/washing or glove donning was performed, hands were recontaminated. Analysis of determinants found rubbing/washing was associated with lower workload (Adjusted Odds Ratio= 29.39), and availability of single-use drying material (AOR=2.9). Avoiding glove recontamination was associated with less time elapsed since glove donning (AOR=4.49).

Conclusion: Further research should examine the extent to which failure to avoid recontamination contributes to poor hand hygiene and what effective behaviour change strategies could tackle it.

ACKNOWLEDGEMENTS

I am very grateful for the support of my family and friends. For those really near me that have supported me every day, often anticipating my needs before I was aware of them. For those further away, they are key cornerstones of my being and provide continuity to my life through space and time. Infinite gratitude also goes to those are not around anymore and that gave me unconditional love from the first day, who would have been the proudest and whom I aspire to remember in my actions every day.

The thesis would not be possible without my supervisors who supported me for the last four years with patience, wisdom and guidance, out of a sheer willingness to help me grow as a researcher, well beyond their interest in the topic per se. I am incredible grateful for all the time they devoted to me; I could not have wished for a more supportive duo.

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ACRONYMS AND ABBREVIATIONS

CI – Confidence Interval

CFU – Colony-forming Unit

CONSORT – Consolidated Standards of Reporting Trials

DEFF – Design Effect

ECDC – European Centre for Disease Prevention and Control

5MHH – Five Moments for Hand Hygiene

GG – Giorgia Gon

HAIs – Healthcare Associated Infections

HANDS – Hand-hygiene of Attendants for Newborn Deliveries and Survival

HAPA – Health Action Process Approach

HH – Hand Hygiene

HICs – High Income Countries

IBM – Integrated Behavioural Model

IPC – Infection Prevention and Control

ICC – Intra-cluster Correlation

LMICs – Low and Middle Income Countries

NHS – National Healthy System

MoH – Ministry of Health

MOOSE – Meta-analyses Of Observational Studies in Epidemiology

OR – Odds Ratio

SBA – Skilled Birth Attendant

STAMP – Suggested Time and Motion Procedures

STROBE – Strengthening the Reporting of Observational studies in Epidemiology

TDF – Theoretical Domains Framework

WASH – Water, Sanitation and Hygiene

WHO – World Health Organisation

WOMBAT – Work Observation Method By Activity Timing

PREFACE

This thesis is structured as a “Research Paper” style thesis as per the London School of Hygiene and Tropical Medicine regulations. The thesis includes five objectives that are addressed in five different chapters. Each of these five result chapters includes a preamble with a detailed description of the role of the candidate. Publication details and co-author contributions are included in the cover sheets for each manuscript.

1. BACKGROUND

1.1. The burden of healthcare associated infections at birth: the case for hand hygiene

Globally, infection contributes to at least 9% of maternal deaths[1] and 16% of neonatal deaths[2] and the vast majority of this burden is concentrated in low and middle income countries (LMICs). Clean delivery is essential to prevent maternal and newborn infection contracted at the time of birth.[3] In turn, cleanliness of birth attendants' hands is fundamental to ensure a clean delivery, especially when hands are in direct contact with entry sites for potential pathogens, but also to ensure cleanliness of other procedures. For example, a clean cord-cut requires clean blades and cord clamps, but hands also need to be clean; otherwise, they might contaminate the cord-cutting instruments.

The link between hand hygiene and maternal genital tract sepsis in healthcare facilities was established by Gordon and Semmelweiss over two centuries ago, and more recent evidence exists on the association between hand hygiene and healthcare associated infections (HAIs) in infants.[4–6] In LMICs, an estimated 15.5% of patients contract HAIs, whereas the European Centre for Disease Prevention and Control (ECDC) estimates that 6% of patients in Europe contracted at least one HAIs in acute care settings in 2012.[7,8] Infection among newborns born in hospitals in LMICs are estimated to be 3-20 times higher than in high-income countries (HICs).[9]

HAIs pose a high burden for individuals in terms of immediate health impact and longer-term disability. There is also a large cost incurred by the health system – Europe, for example, spends an estimated €13–24 billion on HAIs annually.[10] Furthermore, there is a moral burden in that the healthcare system is meant to improve health, not cause harm.

The importance of tackling HAIs is increasingly recognized, and hand hygiene is now considered a core solution, especially given the rising concerns posed by antimicrobial resistance in LMICs.[11] The World Health Organization (WHO) World Alliance for Patient Safety launched the first Global Patient Safety Challenge – "Clean Care is Safer Care" – in 2005, aiming to improve hand hygiene in healthcare settings.[10] Alongside these international efforts, national hand hygiene campaigns have been launched successfully in England and Wales, Germany and Belgium in the European context.[12] At least eighteen LMICs have joined the campaign since 2005.[13]

The campaign deployed in England and Wales, which preceded the WHO one, included provision of bedside alcohol-based antiseptic handrub, ward posters, patient empowerment materials, audit and feedback, and guidance to secure institutional engagement.[12] These are also now core components of the WHO "Clean Care is Safer Care" Campaign. The campaign in England and Wales tripled the procurement of alcohol-based handrub. Procurement was associated with lower levels of MRSA bacteremia and C. difficile infections.[14] In the African context, the WHO campaign was successfully implemented in Mali where hand hygiene behaviour improved substantially.[15]

Research and routine implementation efforts suggest that hand hygiene is a cost-effective way to prevent HAIs, yet ensuring or increasing compliance to hand hygiene in healthcare settings has not been straightforward.[10,16–18] A WHO review of observed hand hygiene compliance reports baseline rates from 5% to 89%.[10] The systematic review by Erasmus et al. estimates a median compliance of 40% in HICs (range: 4% - 100%), with hand hygiene technique and duration also being generally substandard.[16] Less is known about the hand hygiene compliance in LMICs, particularly in maternity wards; this is a current **gap**.[15,19–21] Unpublished research by the Soapbox Collaborative in one maternity unit in India and one in the Gambia found average hand hygiene compliance at 22% and 17% respectively (personal communication).[22]

At every delivery, a birth attendant is ideally required to rub/wash her or his hands at least six times.[23] With an average 380,000 deliveries per day worldwide,[24] the vast majority of which are in low-resource settings and about half of which are in healthcare facilities,[25] this translates into approximately 1.1 million hand hygiene actions that are required per day among facility birth attendants globally. Hence, hand hygiene during labour and delivery represents an infection prevention opportunity that the public health community ought to get right.

1.2. Definition and measurement of hand hygiene in healthcare facilities

This next section covers the definition of hand hygiene, including the actions involved in it, the rationale for focusing on hand hygiene before clean/aseptic procedures, and the way that hand hygiene is measured in healthcare facilities.

1.2.1. The act of hand rubbing/washing

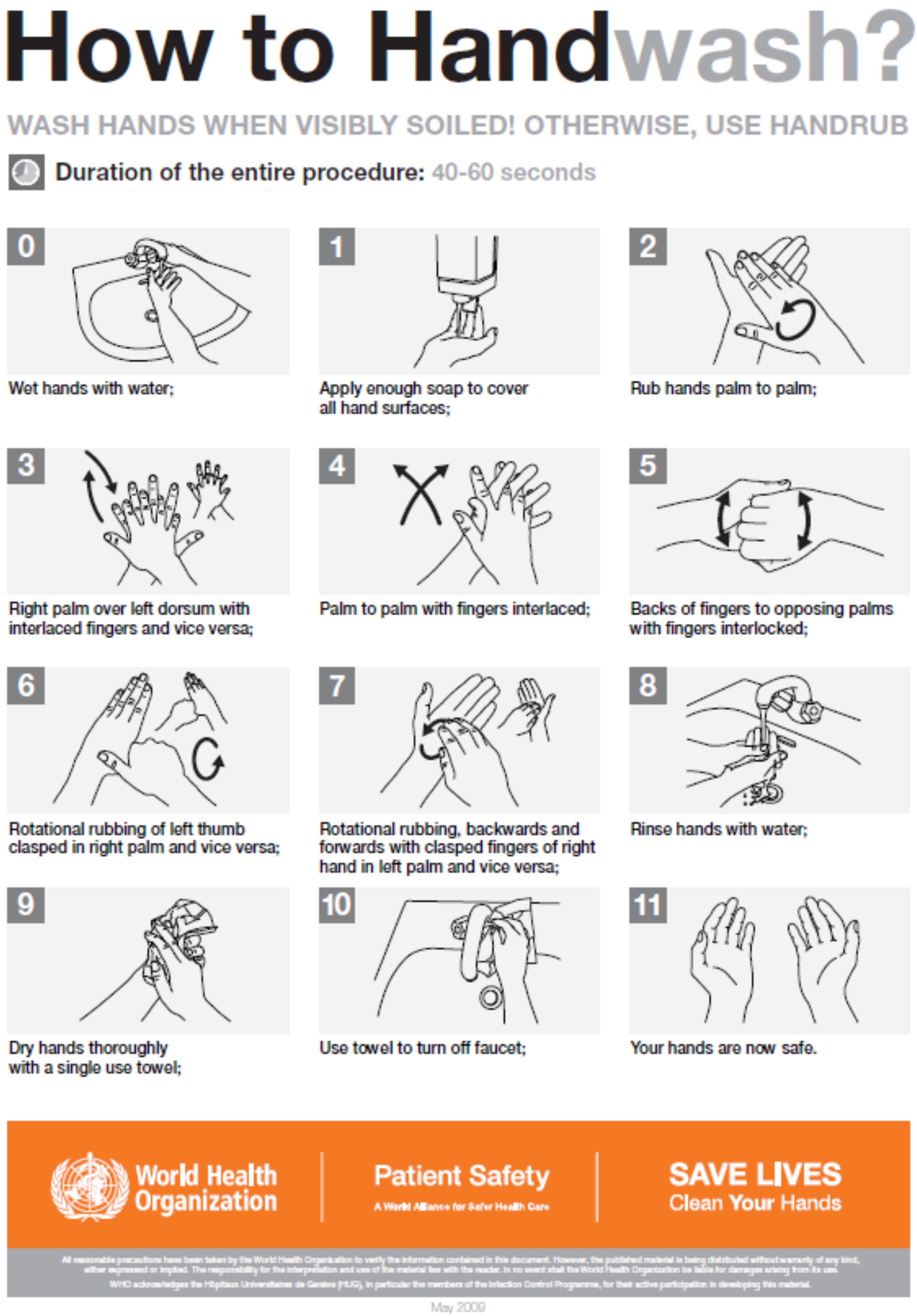
The *WHO Guidelines on Hand Hygiene in Health Care* recommends that healthcare workers clean their hands via **hand rubbing** with alcohol-based antiseptic handrub or via **washing hands** with plain or antimicrobial soap and water. Handwashing is recommended when hands are visibly dirty or soiled with body fluids, after urination or defecation, or when sporo-forming pathogens are suspected or proven.[10] Otherwise, hand rubbing is recommended. Hand rubbing is preferred over hand washing with soap and water, because a) it can be applied on hands effectively in significantly less time (guidelines below), b) it is not linked to a specific sink location (e.g., it can be applied while walking), c) it does not require the use of drying material, and d) it can lead to a more effective hand disinfection.[26,27]

According to WHO international recommendations, the act of hand washing requires a certain technique and duration, summarized in Figure 1.1. Steps 0 and 1 involve applying the product. The technique, explained in steps 2-7, is identical for hand rubbing and hand washing; steps 8-11 involve rinsing hands and drying them appropriately after washing. The overall duration for these steps should 40-60 seconds for washing with soap. Wet hands are easily contaminated and can spread organisms.[10] Therefore appropriate drying of hands after handwashing with single-use cloth or paper towels is required.[10] Sharing or re-using towels without appropriate decontamination is not recommended to avoid the transmission of potential pathogens to hands. Drying material is unnecessary when handrub is used; however handrub is not always available in LMICs.[28]

Hand rubbing follows many, but not all of the same steps. Step 1 is first, but involves applying the antiseptic handrub, followed by steps 2-7. For hand rubbing, step 8 is the last one – this indicates that hands are safe when dry. The overall duration of handrubbing should be 20-30 seconds. Avoiding long or artificial fingernails and jewellery are recommended for both hand rubbing/washing. Local guidelines at the country, regional or facility levels can differ from these international standards.

Figure 1.1 - Hand hygiene technique for handwashing with soap and water

Reprinted with permission from the Clean Care is Safer Care website[29]



1.2.2. Hand hygiene opportunities: focusing on aseptic procedures

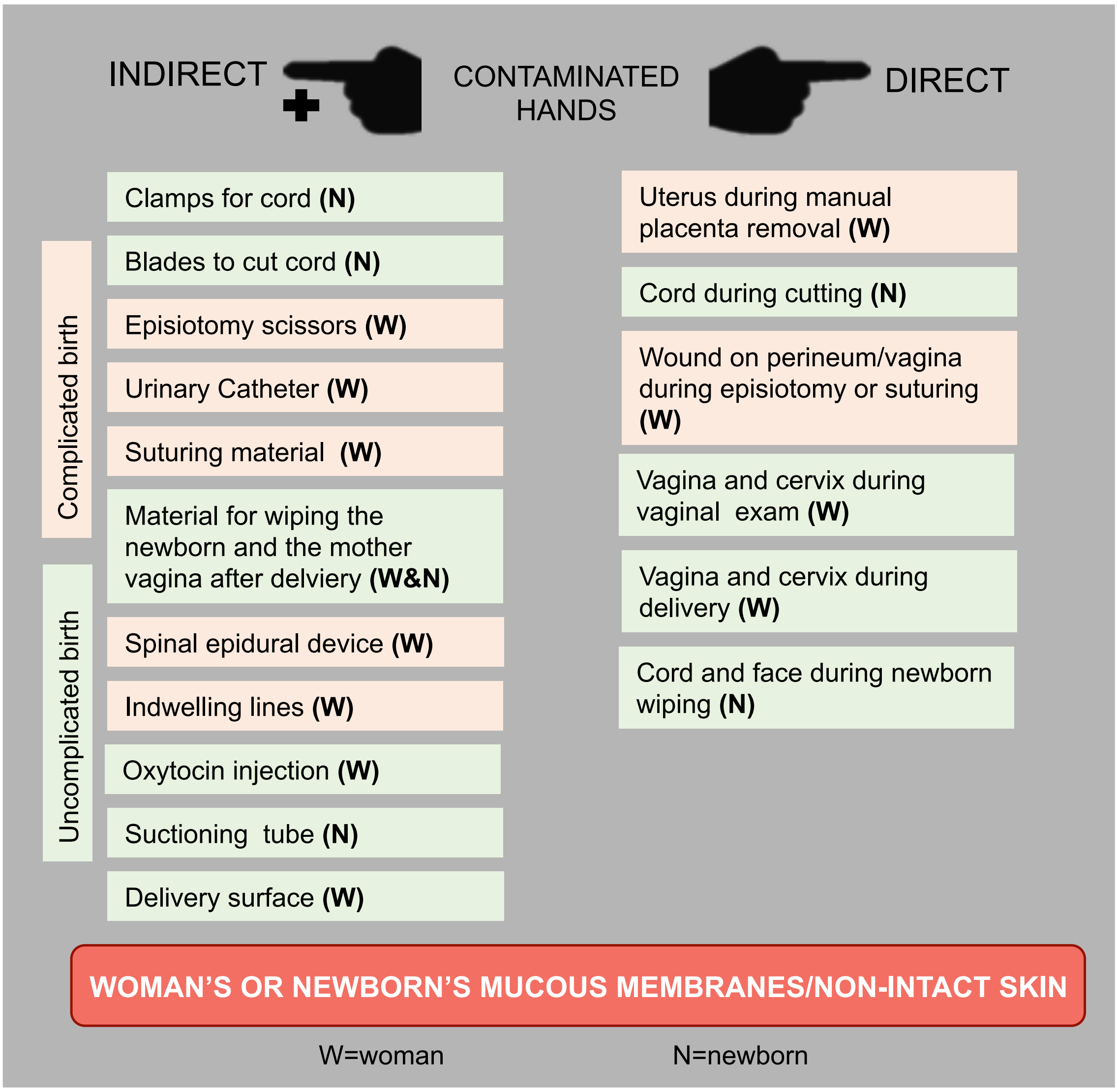
Hand rubbing/washing should occur at five "key moments" called hand hygiene opportunities:[10]

1) before touching a patient,
2) before a clean or aseptic procedure,
3) after body fluid exposure,
4) after touching a patient, and
5) after touching a patient's surroundings.

This thesis focuses on "moment 2", the opportunities before clean or aseptic procedures (termed "aseptic procedures" for simplicity) because they are particularly critical to infection prevention. Indeed, aseptic procedures are defined by contact with mucous membrane/non-intact skin site, and thus pose a higher risk of pathogens cross-transmission compared to contact with a patient's intact skin (for example, during "moment 1", a "before touching a patient" opportunity).

If a birth attendant's hands are contaminated, they can in turn contaminate a woman's or newborn's mucous membranes or non-intact skin (e.g. the vagina, cervix, open wounds, or cord after cutting) directly or indirectly (Figure 1.2). Direct transmission occurs when the attendant's hands (gloved or ungloved) touch these vulnerable sites. Indirect transmission is when hands contaminate a surface or an instrument (vehicles) that in turn engage with the vulnerable sites, such as when a blade cuts the cord or scissors are used for an episiotomy.[30]

Figure 1.2 - Direct and indirect routes from contaminated hands (or gloves) to woman's or newborn's mucous membranes or non-intact skin

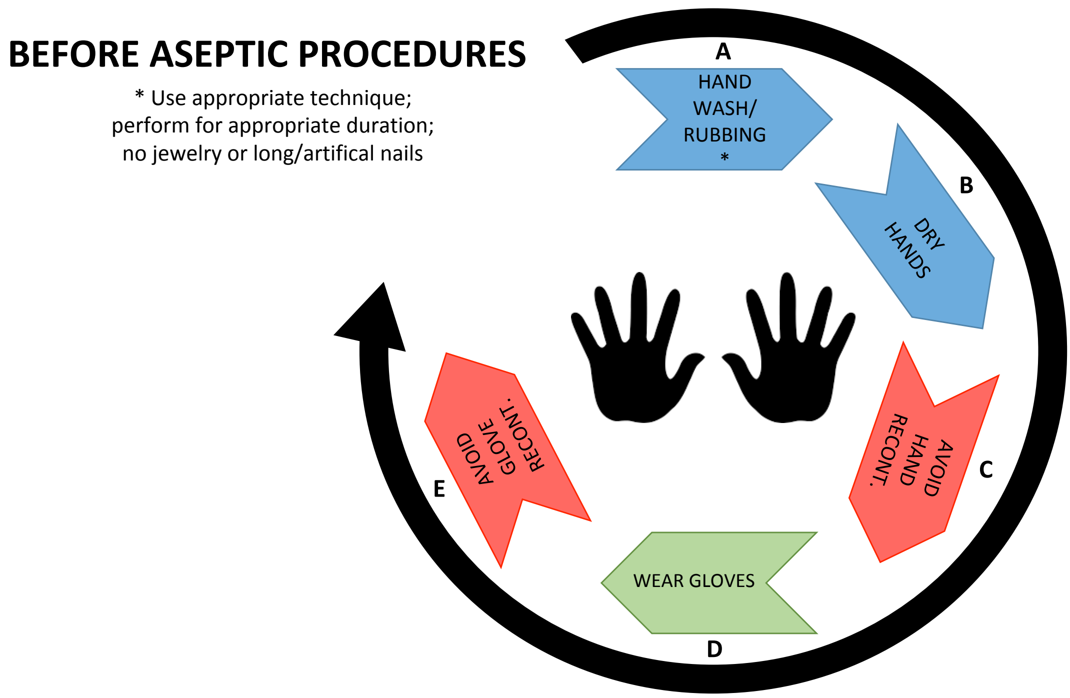


Infection, and even sepsis, can develop when contaminated hands or instruments touch women's or newborns' vulnerable sites.[31] Hands can carry exogenous bacteria – introduced to the patient from the external world – or endogenous bacteria – that normally reside in the patient; both can lead to sepsis. Adequate hand hygiene should prevent both, because hands should contact vulnerable sites only when clean or after touching clean or sterile sites. One exception is that hand hygiene cannot prevent pathogens being transmitted during vaginal examination when the hands pick up bacteria in the lower genital tract and transport them into the chorioamnion. Little is known about the relative contribution of different pathogen transmission routes of maternal and newborn infection contracted during birth in LMICs.[32,33]

1.2.3. The appropriate steps before aseptic procedures

The steps outlined so far, in Figure 1.1, only comprise a small component of the overall WHO hand hygiene guidelines before aseptic procedures. Specifically, all of those actions fall within two steps: (A) the act of hand rubbing/washing and (B) appropriate drying. The other aspects are (C), avoiding hand recontamination, (D) wearing at least one glove (the need for one glove or a pair of gloves depends on the procedure to be undertaken), and (E) avoiding recontamination of gloves until the procedure of interest is complete.[10] These are summarized in Figure 1.3.

Figure 1.3 – Steps before aseptic procedures



Gloves should be worn immediately before the aseptic procedure opportunity in the sequences described above (Figure 1.3). Afterwards, gloves should be removed.[10] Hand hygiene is also necessary after gloves are removed because gloves can become significantly contaminated with bacterial cultures as shown in an early study by Pittet et al.[34] and because some bacteria can go through latex gloves or contaminate healthcare workers hands through back-spray when they remove such gloves.[35] However, this thesis does not focus on this type of hand hygiene opportunity i.e. hand rubbing/washing after glove removal. Evidence suggest that healthcare workers tend to perform less hand hygiene when using gloves, perhaps due to the false belief that gloves are a secure barrier to cross-transmission.[35] The WHO guidelines on

Pregnancy, Childbirth, Postpartum and Newborn Care suggest single-use sterile or highly disinfected gloves be worn for all aseptic procedures: vaginal examination, delivery, cord-cut, repair of episiotomy or tear, and blood drawing.[36] The WHO hand hygiene guidelines stress that using gloves does not remove the requirement to hand rub/wash.[10]

Between having performed hand rubbing/washing and the aseptic procedure, healthcare workers should avoid recontaminating their hands or gloves i.e. avoid contact with any surface that may lead to pathogens being transmitted to the hands or gloves. The longer the contact with these surfaces, the higher the likelihood of hand/glove contamination.[10,34] The ability to perform procedures during delivery without recontaminating one's hands depends heavily on how easy it is to access the necessary instruments (e.g. blades). Ideally, instruments should be prepared on a sterile field near the delivery bed, ensuring that the equipment does not need to be collected from various places with the concomitant increase in the likelihood of recontamination.

1.2.4. Measuring hand hygiene in healthcare facilities

Data on hand hygiene in healthcare facilities are commonly collected by self-reporting, observation, or by using a proxy via the amount of rub/soap used. Observation, either directly by an observer or via video monitoring is preferred to self-report because healthcare workers tend to over-estimate their compliance and report expected practices. Observation also has limitations as it is subject to observer bias (for reasons that we describe in section 1.2.5), selection bias (since observation usually is limited in time and observations sessions are not always picked at random and so may not represent the 24/7 period, the type of activity, the patient and the provider), and the Hawthorne effect.[16,37] Video monitoring may introduce less Hawthorne effect after a period of habituation, but it also poses ethical dilemmas since it records individuals, especially patients. The extent to which the Hawthorne effect influences behaviour is controversial in the literature; there is some evidence it may only come into effect 10-20 minutes after the observation started.[14,16,26,38,39] Quantifying the amount of alcohol rub/soap used or electronic monitoring of alcohol rub dispensers have also been used to capture hand hygiene.[16,26,38–40] These alternatives, based on product quantities, are cheaper and easier than direct observation but they remain proxies for compliance; indeed usually the number of hand hygiene opportunities is estimated based on assumptions around patient interactions, rather than observed actions; in addition they cannot be linked to individuals' hand hygiene behaviour.[16]

Erasmus et al. in 2010 reviewed 96 articles on hand hygiene in healthcare facilities in HICs and found that only a few used previously tested tools to measure compliance.[16] Since then, the WHO Observation Form, published in 2009, has provided a relatively simple and standardized way to measure hand hygiene through observation.[41] This has been widely used for both research and implementation purposes all over the world. For this reason, in this thesis I compare my research tool to the WHO Observation Form.

However, the WHO Observation Form serves infection prevention practitioners, meaning that it needs to be simple and is therefore restricted in the range of behaviours it captures. Specifically, the WHO Observation Form does not cover aspects of glove use (except if the opportunity was missed) or avoiding recontamination, behaviours that are valuable for understanding the complex patterns of healthcare workers' practices. Other available hand hygiene tools suffer from similar shortcomings.[42] In addition, the WHO Observation Form, in its current form, does not include a dedicated space for registering an individual's reference number across opportunities or observations sessions. This means it provides only an aggregate-level measure at the cadre or higher group level, and cannot track individual-level behaviour nor individual-level variation in hand hygiene compliance within facilities. Finally, the WHO Observation Form' standard operating procedures (the instructions for using the tool) can be considered sparse. This is in contrast, for example, with another tool, the Hygiene Observation Form, which has detailed standard operating procedures, and 298 hand hygiene opportunities and behaviours individually assessed for inter-observer reliability.[43] The Hygiene Observation Tool however, is not as widely used as the Observation Form.

In the WHO Observation Form, the data collector registers whether the person observed carried out hand rubbing, or hand washing at each opportunity, or whether the opportunity was missed. If hand rubbing/washing is ticked, it means that the healthcare worker was observed hand rubbing or washing, **but also implicitly that they avoided hand or glove recontamination**. Opportunities could be missed either because no hand rubbing/washing was performed, or the person observed rubbed/washed but subsequently also touched surfaces beyond the patient zone (defined below), thereby potentially recontaminating her hands. In the WHO

Observation Form, this would lead a to a new hand hygiene opportunity. It would be important to separately monitor whether the failure to comply to hand hygiene guidelines is due to the lack of hand rubbing or washing, or due to recontamination in order to design meaningful behaviour change strategies. Indeed, the determinants behind failing to reach the sink or the handrub bottle are likely to differ from those driving the touching of potentially contaminating surfaces before a procedure. Isolating avoiding recontamination as a positive standalone action to be undertaken by healthcare workers could be important for improving hand hygiene compliance overall. A current **gap** is the availability of a tool that can monitor both behaviours, hand rubbing/washing and avoiding recontamination, in particular in the context of labour and delivery.

In this thesis, I use the term hand hygiene or hand hygiene compliance to include hand rubbing/washing AND avoiding recontamination together, unless specified otherwise.

1.2.5. Operationalizing the hand hygiene compliance indicator

Hand rubbing/washing compliance is most commonly reported as the percentage of hand hygiene opportunities (denominator) with which healthcare workers' comply to hand rubbing/washing (numerator).[44] Hand hygiene opportunities are those patient-attendant interactions, previously described in Section 1.2.2. A compliance of 20% translates into healthcare workers washing/rubbing hands in two out of ten opportunities. The WHO provides a strong framework for defining hand hygiene, but studies have operationalized compliance in various ways. Some focus on the simple act of hand rubbing/washing for their numerator (i.e. whether the act was performed or not), while others include elements of technique and duration (i.e. hand rubbing/washing was performed only if appropriate duration and technique were used).

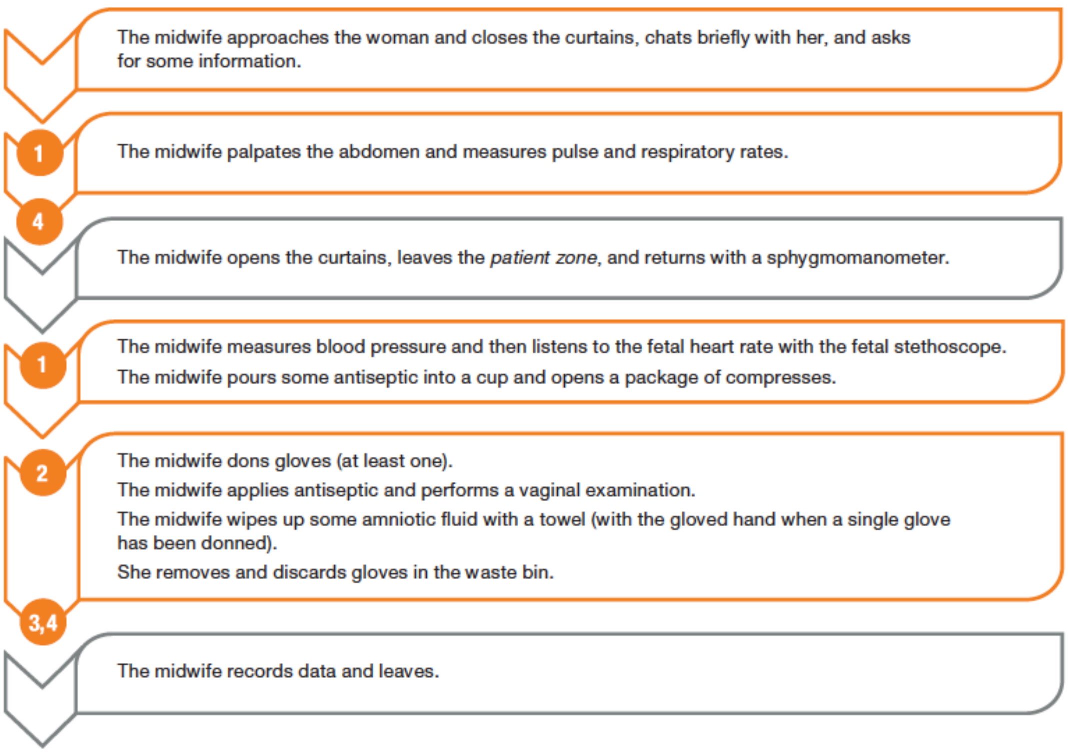
A more difficult aspect of operationalizing hand hygiene compliance is defining the denominator: how to identify the boundaries of hand hygiene opportunities. Hor et al. provides a useful ethnography of the concept of boundaries in hand hygiene and infection prevention in Australia, including the perception of certain surfaces potentially leading to cross-transmission or not.[45] More specifically, two concepts are needed to define a hand hygiene opportunity: the **systematic flow of patient contacts** allowed within a single hand hygiene opportunity, and the **patient zone**. By a systematic flow they mean the procedures or actions of interest that define the start of hand hygiene opportunity, as well as the sequence of these procedures still being considered as *one* opportunity for hand hygiene.[23] In this thesis, I will term this a '**delivery flow'**. The WHO guidelines *Hand Hygiene in Outpatient Care and Home-based care and Long-term care* specify, for example, that during childbirth the birth attendant can deliver the baby, clamp and cut the cord, and manually remove the placenta (these are all aseptic procedures) all within a single hand hygiene opportunity, because they are part of the same delivery flow.[23] However, when the birth attendant proceeds to check the woman's vital signs following an aseptic procedure, a new hand hygiene opportunity arises because there is a risk of blood or other body fluid exposure and hands must be clean before undertaking the new task even on the same patient.

Figure 1.4, taken from the WHO guidelines *Hand Hygiene in Outpatient Care and Home-based care and Long-term care,* describes a typical flow during labour and delivery and when hand hygiene is recommended. Although this is a good starting point, the figure does not include complications, and it has a standardised definition of patient zone.

Figure 1.4 – Hand hygiene recommendations during labour (A) and delivery (B).

Reprinted from the Hand Hygiene in Outpatient Care and Home-based care and Long-term care, pages 51-52. World Health Organisation. Copyright: WHO (2012)

DURING LABOUR (A)



DURING DELIVERY (B)

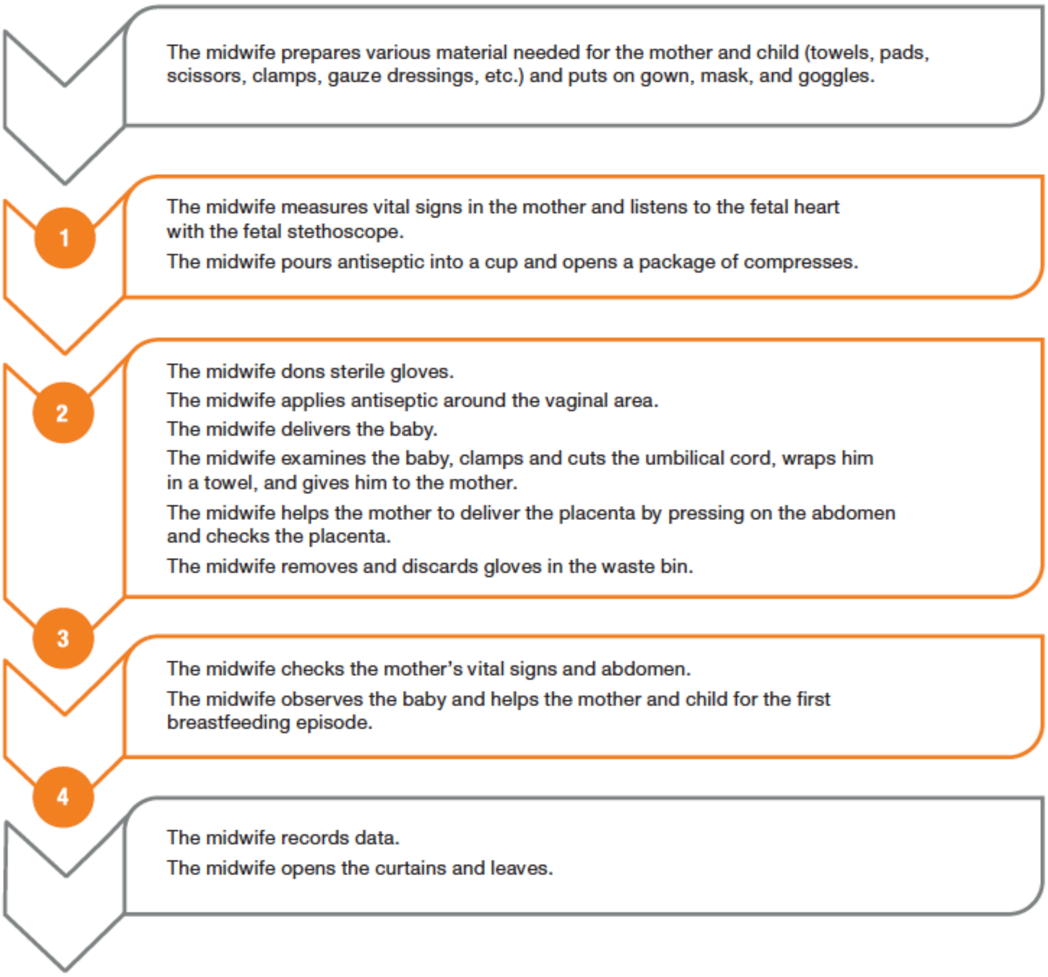


Table 5.1 in this thesis details the delivery flow definition (including complications) that I used for my research – the aseptic procedures listed in Table 5.1 are:

- Wiping the vagina
- Vaginal examination
- Artificial rupture of membranes
- Episiotomy
- Catching the baby (delivering the baby)
- Cord cutting and clamping
- Cord traction
- Manual removal of placenta
- Post-delivery vaginal examination
- Suturing of the perineum
- Wiping baby clean
- Urinary catheter insertion or removal

The **patient zone** includes the patient (in this thesis, this is the labouring woman) and some surfaces and items that are temporarily and exclusively dedicated to her, limiting the risk of transmitting pathogenic organisms.[41] During a delivery flow, a birth attendant can undertake hand actions within the patient zone without leading to a new opportunity. Many elements define what comes under the patient zone:

a) the extent of environmental hygiene in the patient area is very important – this in turn is dictated by hospital routine practices including cleaning practices (is the patient zone cleaned after each patient? Are surfaces microbiologically clean?);

b) the status of equipment (e.g. decontamination and sterilization practices; the source of sheets/pads used under the woman's perineum during birth);

c) the management of patients flow and potentially crowding. With regards to the latter, Salmon et al. revisited the concept of patient zone for the overcrowded environments that typify higher-level facilities in LMICs using a case study from Vietnam. They argue that since patients often shared beds, there was already cross-transmission between them. Thus, they suggest that for certain opportunities e.g. "before touching a patient", hand hygiene is unnecessary between patients sharing the same bed.[46]

A current **gap** is the availability of a tool where all birth attendants' actions are recorded without the need for the data collectors to judge whether the actions they observe fit the definitions of systematic flow and patient zone and thus what constitutes a new hand hygiene opportunity.

Defining when a new hand hygiene opportunity arises is particularly difficult during labour and delivery as further explained below. Observers must deal with a transition from observing one patient (the mother) to two (the mother and the newborn), the amount, type and location of body fluids can rapidly change, and in low resource settings, one healthcare worker may attend many mothers simultaneously. Also, the duration phases during labour is often unpredictable, and the time between hand rubbing/washing and delivery of the newborn may be lengthy, during which the observer needs to pay close attention to assess if any actions occur that lead to a new hand hygiene opportunity. Time-&-motion methods can overcome some of these challenges. Observers are able to record all healthcare workers' actions without having to decide which comprise a new hand hygiene opportunity. Instead, opportunities are defined during data analysis. Time-&-motion methods are now at the forefront of healthcare observation[47] and are increasingly used, though seldom in LMICs.

1.3. Behavioural determinants of healthcare workers hand hygiene

To identify the levers for change, we need to understand the determinants of health care workers' hand hygiene. Previous studies stress the importance of investigating both the contextual and individual determinants.[10,48] Contextual factors include workload,[10,16,49,50] and the availability of necessary materials such as soap and water.[10,16,50] Individual factors include staff professional background[10,16,48] and psychological constructs like knowledge,[10,16] healthcare workers' attitudes,[10,16,50,51] control beliefs,[10,52] as well as the role of social influence and the normative environment.[10,48,50,53]

A current **gap** is that there do not appear to be published studies looking at the specific determinants of avoiding recontamination, separately from those of hand rubbing/washing.

Interventions aimed at improving hand hygiene in healthcare settings call for context-specific information on the determinants to be targeted.[10,18,54] This requires good quality formative research prior to intervention design. The importance of the context resides in the elements of the environment (culture and infrastructure). For example, the availability of water and soap and alcohol based handrub is likely to be more of an issue in LMICs than HICs. In addition, the specific type of care under investigation which is the process of labour and delivery in this thesis, is another context specific element.

Labour wards may differ from other types of wards in a health care facility in several specific ways. These features, aforementioned, include:

- dealing with transition from having one patient (the labouring woman) to two (woman and newborn);
- the variety, amount and type of body fluids, that can rapidly escalate;
- the mixture of uncomplicated and complicated deliveries, that translates into varying timings of labour and delivery;
- the unpredictability of volume of birth at any one time, meaning that one birth attendant may need to attend several mothers simultaneously in the context of under-staffed, poorly resourced facilities in LMICs.

These characteristics make the labour ward more like emergency wards than other hospital departments. A research **gap** is that quality studies of hand hygiene and its determinants in LMICs for the context of the labour ward have not been complied and systematically reviewed.

1.3.1. An approach grounded in behavioural theory

Two main ideas underpin this research. First, that “improving hand hygiene implies behaviour change”.[18] The need for behavioural approaches to understand hand hygiene in healthcare facilities has been advocated for, and this is what I use in my thesis.[16,38,55] Modifying healthcare workers’ hand hygiene is complex – the last twenty years of research and implementation have only managed to engineer a mixed degree of sustained success.[17,38,56]

As described for labour and delivery above, hand hygiene is a dynamic behaviour strongly influenced by frequent distractions, complex actions between tasks. It competes with concomitant multiple priorities necessary during patient care. This places strain on healthcare attention, memory, and task prioritisation, which makes it harder to identify when hand hygiene is needed.[57]

Evidence from systematic reviews on interventions aimed at increasing healthcare workers’ hand hygiene suggest that training and knowledge is insufficient to achieve sustained hand hygiene behaviour change and that multimodal interventions are more successful than single component interventions.[10,17,18,44,58,59] Huis et al. found that the greater the range behavioural determinants targeted, the greater the effect of the intervention.[18] Most interventions they reviewed focused on knowledge, awareness, action control and environmental constraints. Although, the more successful intervention strategies also targeted social influence, attitude, self-efficacy, and intention.[18] A study by Fuller et al. used the Theoretical Domains Framework to enquire in real time why healthcare workers did not comply with hand hygiene guidelines. Across 207 self-reported explanations, the main reason for noncompliance in the “Memory/Attention/Decision Making behaviour” domain; the second reason was “Knowledge”.[57] These findings suggest that interventions should target both automatic associative learning, and conscious decision-making; these findings support those systematic reviews suggesting that interventions should be multimodal, rather than focus on a single behaviour change technique.[57,60]

It is now recognized that inadequate attention to theory has compounded the difficulties in designing effective interventions. Increasingly, behaviour change frameworks that incorporate multiple theories or determinants have been used to design interventions to change healthcare workers practices on hand hygiene and beyond.[60–65] Examples are: the Integrated Behavioural Model (IBM), the Theoretical Domains Framework (TDF) and Health Action Approach (HAPA).[57,66,67] In my thesis, I employ the widely-used Integrated Behavioural Model (IBM)[66] as the organizing framework, because it integrates individual and contextual behavioural determinants from multiple theories in one comprehensive model. In addition, I used this over other models because my research team had in depth knowledge of using this model and hence I could learn from more senior team members. The IBM states that there are five determinants directly influencing behaviour, including environmental constraints, knowledge and skills, habit, salience, and most importantly: intention.[66] In turn, intention is determined by attitude, perceived norms and personal agency.[66]

The second idea within the thesis is that developing more effective interventions for increasing hand hygiene requires an understanding of context-specific factors associated with compliance.[18,54] In my research this refers to the type of facility unit, namely the labour ward described above, and the setting, Zanzibar. A recent systematic review of behavioural interventions targeted at changing healthcare workers practices provides some evidence that tailoring interventions to individuals and their context, increases the effectiveness of such interventions.[68] Indeed, recent cluster randomized trials that use these tailored behavioural approaches, including personalized feedback and individualized action planning alongside the multimodal approach of the WHO Hand Hygiene strategy, reported success and absolute increases of 10-18%.[38,40,54]

1.4. The country context: United Republic of Tanzania

Despite improvements in its maternal and newborn indicators in the last 15 years,[69] Tanzania still has a Maternal Mortality Ratio of 398 per 100 000 live births (2015 estimates), and a Neonatal Mortality Rate of 22 per 1000 live births (2016 estimates).[70] These rates are similar to other Sub-Sahara African countries, which is the world region with the greatest burden of maternal and newborns deaths.[2,24] The proportion of institutional deliveries in Tanzania increased by a third in the two decades 1996-2016, from 46.5% to 62.5%.[71] Simultaneously, nationally representative surveys and individuals studies confirm low quality of care at birth within facilities.[72–74] According to the World Bank, Tanzania spends about 6% of its GDP on health, in line with other low income countries.[75] One study reported that 15% of Tanzania patients develop healthcare associated infections, also in line with average estimates for LMICs.[76]

Infection prevention practices are sub-optimal;[77] even basic access to key resources for hand hygiene such as running water are scarce in Tanzania labour wards – less than half of institutional births have access to reliable supplies of running water.[78] This is comparable to other low-income countries in the East African region,[78] and derives from an analysis I conducted (outside the scope of this PhD) which is available in Appendix I (page 251).

Four of the five results chapters of this thesis specifically focus on Zanzibar. Zanzibar is an autonomous region of Tanzania comprised of two islands: Unguja and Pemba. The population across the two islands is about 1.3 million and the predominant religion is Islam. Although the GDP per capita in Zanzibar in 2016 was slightly lower than the rest of mainland Tanzania ($823 vs. $881),[79] Zanzibar has slightly higher provision of infection control equipment for delivery services compared to the national average.[77] Along with the country's efforts to improved water, sanitation and hygiene in healthcare facilities, the independent Ministry of Health of Zanzibar has also committed to these efforts.

1.5. Aim and objectives

Considering the gaps in research described above, the aim of my thesis is to synthesize existing evidence and generate new evidence on the levels and determinants of hand hygiene compliance before aseptic procedures, among birth attendants in healthcare facilities in LMICs, with a focus on Zanzibar. Ultimately, this work should inform interventions to increase hand hygiene compliance of birth attendants in Zanzibar and similar contexts.

This thesis is structured around the following objectives and their respective manuscripts. These are to:

1. systematically review the existing evidence on birth attendants' hand hygiene compliance in facilities in LMICs (Manuscript 1);
2. describe the enabling environment for hand hygiene in Zanzibar maternity wards (Tanzania) using a mixed-methods cross-sectional survey (Manuscript 2);
3. develop a tool to capture the complex patterns and multiple behaviours involved in hand hygiene performed by birth attendants (Manuscript 3);

4. assess compliance of Zanzibar birth attendants to hand rubbing/washing, avoiding recontamination and glove use before aseptic procedures using time-&-motion methods (Manuscript 4); and
5. assess the determinants of Zanzibar birth attendants' hand rubbing/washing and of avoiding glove recontamination before aseptic procedures using time-&-motion methods and behavioural science tools (Manuscript 5).

1.6. Funding

The work presented in this thesis was funded as follows:

WaterAid UK funded the cross-sectional study of enabling factors of hygiene practices during birth across 37 maternity wards in Zanzibar (Principle Investigator: Wendy J. Graham).

The Medical Research Council UK (Grant number: MR/N015975/1) funded the in-depth study of hand hygiene of birth attendants under the Public Health Intervention Development scheme (Principle Investigator: Wendy J. Graham). I was co-investigator and played a substantial role in applying for the research grant and managing it.

The Soapbox Collaborative, a UK charity dedicated to improving hygiene at birth in facilities LMICs, paid my salary when not covered by the aforementioned grants, as well as my part time staff-PhD fees over the entire course of the PhD.

2. BIRTH ATTENDANTS' HAND HYGIENE COMPLIANCE IN HEALTHCARE FACILITIES IN LOW AND MIDDLE INCOME COUNTRIES: A SYSTEMATIC REVIEW (PHD OBJECTIVE 1)

2.1. Preamble

This manuscript aims to investigate the available evidence on levels and determinants of hand hygiene compliance, and on existing interventions aimed at improving the hand hygiene of birth attendants in facilities in LMICs for Objective 1 of the PhD.

To achieve this aim I conducted a systematic review of the literature on the hand hygiene compliance of birth attendants in facilities in low and middle-income countries. I conceptualized and designed the review with advice from Oona Campbell. I developed the search strategy, designed the extraction tools, screened titles and abstracts, selected the full texts, and conducted the primary extraction from the full texts. The second author, Mícheál de Barra, independently screened titles and abstracts, selected full texts, and double-checked the data I extracted from the full texts. I wrote the first draft and led on the revisions suggested by the co-authors.

Two of the studies included in this review are before-and-after studies evaluating the effectiveness of an intervention. These studies have been evaluated against the ORION checklist. This assessment is available in Additional File 3 (page 84) of this manuscript.

The manuscript is formatted according with the BMC Health Services Research journal requirements.

2.2. Coversheet

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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Giorgia Gon
Principal Supervisor	Oona Campbell
Thesis Title	Birth attendants' hands hygiene in maternity wards in low resource settings: levels and drivers

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?			
When was the work published?			
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?*	Choose an item.	Was the work subject to academic peer review?	Choose an item.

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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	BMC Health Services Research
Please list the paper's authors in the intended authorship order:	Giorgia Gon, Mícheál de Barra, Stephen Nash, Oona M. Campbell
Stage of publication	**Not yet submitted**

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 developed the search strategy and extraction tools, screened articles, conducted the extraction, wrote the first version of the manuscript and led on the revisions suggested by co-authors. Details in chapter's preamble.

Student Signature: [redacted] **Date:** 24/10/2018

Supervisor Signature: [redacted] **Date:** 24 Oct 2018

2.3. Manuscript 1 – Birth attendants' hand hygiene compliance in healthcare facilities in low and middle income countries: a systematic review

Giorgia Gon[1], Mícheál de Barra[2], Stephen Nash[1], Oona M.R. Campbell[1]

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2.3.1. Abstract

Background With an increasing number of women delivering in healthcare facilities in Low and Middle Income Countries (LMICs), healthcare workers' hand hygiene compliance on labour wards is pivotal to preventing infections. Currently there are no estimates of how often birth attendants comply with hand hygiene, or of the factors influencing compliance in healthcare facilities in LMICs.

Methods We conducted a systematic review to investigate the a) level of compliance, b) determinants of compliance and c) interventions to improve hand hygiene during labour and delivery among birth attendants in healthcare facilities of LMICs. We also aimed to assess the quality of the included studies and to report the intra-cluster correlation for studies conducted in multiple facilities.

Results We obtained 526 results across four databases and reviewed 59 full texts. Of these, nine met our inclusion criteria. Overall, the quality of the included studies was particularly compromised by poorly described sampling methods and definitions. Hand hygiene compliance varied substantially across studies from 0% to 100%; however, the heterogeneity in definitions of hand hygiene did not allow us to combine or compare these meaningfully. The three studies with larger sample sizes and clearer definitions estimated compliance, including before aseptic procedures opportunities, to be low (range: 1%-28%). Two studies used pre-post designs to test multi-component interventions. The interventions differed but both were successful at improving hand hygiene compliance. No studies reported an intra-cluster correlation coefficient.

Conclusions Hand hygiene compliance was low for studies with larger sample sizes and clear definitions. This poses a substantial challenge to infection prevention during birth in LMICs facilities. We also found that the quality of many studies was suboptimal. Future studies of hand hygiene compliance on the labour ward should be designed with better sampling frames, assess inter-observer agreement, use measures to improve the quality of data collection, and report their hand hygiene definitions clearly.

2.3.2. Introduction

Globally, infection contributes to at least 9% of maternal deaths[1] and 16% of neonatal deaths,[2] the vast majority of this burden concentrates in low and middle income countries (LMICs). Hand hygiene during birth has been long recognised as a key infection prevention opportunity.[4,5] With an increasing number of women delivering in healthcare facilities in LMICs,[73] appropriate hand hygiene compliance of healthcare workers on the labour wards is pivotal to preventing infections.

Several systematic reviews have been published on the compliance, determinants and intervention to improve healthcare workers hand hygiene across the facility environment;[16,17,20,58,59] only two of these reviews include studies from low resource healthcare facilities, none of which provide estimates for the labour ward.[17,20] Erasmus et al. report a median hand hygiene compliance of 40% for studies from high-income countries;[16] the other, more recent, reviews focus on evaluating existing interventions and do not report summary estimates of compliance, but there is value in collating estimates from observational studies too.

Currently there are no estimates of how often birth attendants comply with hand hygiene, or of the factors influencing their compliance in healthcare facilities in LMICs. Hand hygiene compliance in LMICs may differ in levels and determinants compared to those in high-income countries (HICs), where most published evidence is. For example, there are cultural and contextual elements around the process of labour and delivery that might influence hand hygiene compliance of healthcare workers such as unpredictable workloads, unreliable water supplies, or the concept of pollution and purity around delivery – important among healthcare workers in India and Bangladesh.[78,80] Finally, detailed estimates on compliance in LMICs and their determinants are useful to inform whether interventions are needed, and how to tailor them.

The aim of this paper is to systematically review the literature from LMICs to:

1. Estimate birth attendants' hand hygiene compliance during labour and delivery in healthcare facilities
2. Assess the quality of the studies reporting these estimates
3. Investigate what factors influence hand hygiene compliance
4. Estimate the effectiveness of interventions aimed at increasing hand hygiene compliance
5. Estimate intra-cluster correlation for hand hygiene compliance

2.3.3. Methods

The search was conducted on the 24th of April 2018 EMBASE, MEDLINE, CINHAL and the WHO regional databases, updating an earlier search on the 27th of January 2016. We used a comprehensive set of search terms based on previous systematic reviews[17,18,81] and consulted the London School of Hygiene and Tropical Medicine librarian. The search themes included hand hygiene and maternity ward terms with international spelling variations, and it was restricted to LMICs. Additional File 1 details the strategy. Peer reviewed articles were eligible for inclusion, while abstracts and conference proceeding were not. All texts were reviewed using Endnote X7. No protocol was registered for this review.

Duplicates were removed, and titles and abstracts screened by two reviewers for any mention of hand hygiene compliance in labour wards. Two reviewers independently applied the inclusion criteria to the selected full texts. Any discrepancy was resolved through discussion. Once full texts were selected, one author screened references to search for other relevant studies that might be eligible for inclusion. The inclusion criteria were:

- Studies with either of the following estimates for the specific group of healthcare workers attending labour and delivery or working on the labour ward:
    - A measure of frequency for hand hygiene compliance (observed or other objective method; self-reports were not included)
    - OR an effect size (odds ratio, rate ratio, risk ratio) of factors driving hand hygiene (observed or other objective method; self-reports were not included)
- LMICs based studies
- Peer-reviewed studies
- Intervention or observational studies
- Quantitative studies
- Studies in any language

Data extraction was done by one author and checked by another. The data extraction form included study type, intervention details, country, urban-rural location, type of healthcare facility, staff cadre, facility ward specification, availability of hand hygiene infrastructure (soap, water, handrub), sample size, sample selection, analysis methods, measurement tools, and the effect size of hand hygiene determinants. We extracted the estimates of hand hygiene compliance by healthcare workers before aseptic procedures (or compliance estimates which were likely to include before aseptic procedure opportunities) for a) types of patient-attendant interactions that could occur during labour and delivery, or b) healthcare workers working in the labour ward. We specifically focused on estimates reflecting hand hygiene opportunities before aseptic procedures or including these because these are the most pivotal to infection prevention. For each estimate we extracted the hand hygiene definition, the numerator, denominator, the percentage compliance estimates, the number of staff or women observed, the staff cadre, the number of facilities, and the intervention stage details underpinning the individual estimate. We calculated the percentage compliance for each included study where this was possible. We contacted the corresponding author (or if this was not published, the first or senior author whose email we found via their department or on *researchgate)* when it was not clear from the paper whether a) their observation included procedures around labour and vaginal delivery; or b) when the hand hygiene definition was unclear.

Key measures of bias and quality were included in the data extraction. For randomised controlled trials we intended to use the CONSORT guidelines to assess quality. For observational studies, we assessed quality using eight items adapted from the STROBE guidelines'[82] methods section (as recommended by Sanderson and colleagues),[83] to the specific context of observing hand hygiene in healthcare settings. Items included assessing 1) sampling methods, 2) quality of data collection, 3) description of the data collectors background, 4) whether inter-observer agreement was estimated, 5) the definition of hand hygiene compliance, 6) details of the tool used for observation, 7) whether study aims were concealed from the study participants and 8) whether the statistical procedures were described. Items were scored *positively* or *negatively*, except for items 1, 3 and 6 where we added an extra option of *partially met* when only one of two criteria was met, and item 7 which could also be scored as *unclear*.

Intra-cluster correlation (ICC) accounts for the relatedness of data by comparing the variance within clusters with the variance between clusters; it is useful for designing and analysing observational and intervention studies. To obtain the ICC for hand hygiene compliance of the included studies comparing the variation in compliance between and within facilities, we also contacted the authors of studies with multiple facilities (clusters) to ask for:

- Either, the following single measures:
    - The standard deviation exhibiting how the cluster means vary from the population mean from cluster to cluster σ_b (between-cluster variation)

- The standard deviation exhibiting how individual values vary from their cluster mean from individual to individual σ_w (within-cluster variation). Individuals are birth attendants in our review.

- Or, the overall estimated ICC (ρ) = $\rho = \sigma_b^2 / (\sigma_b^2 + \sigma_w^2)$

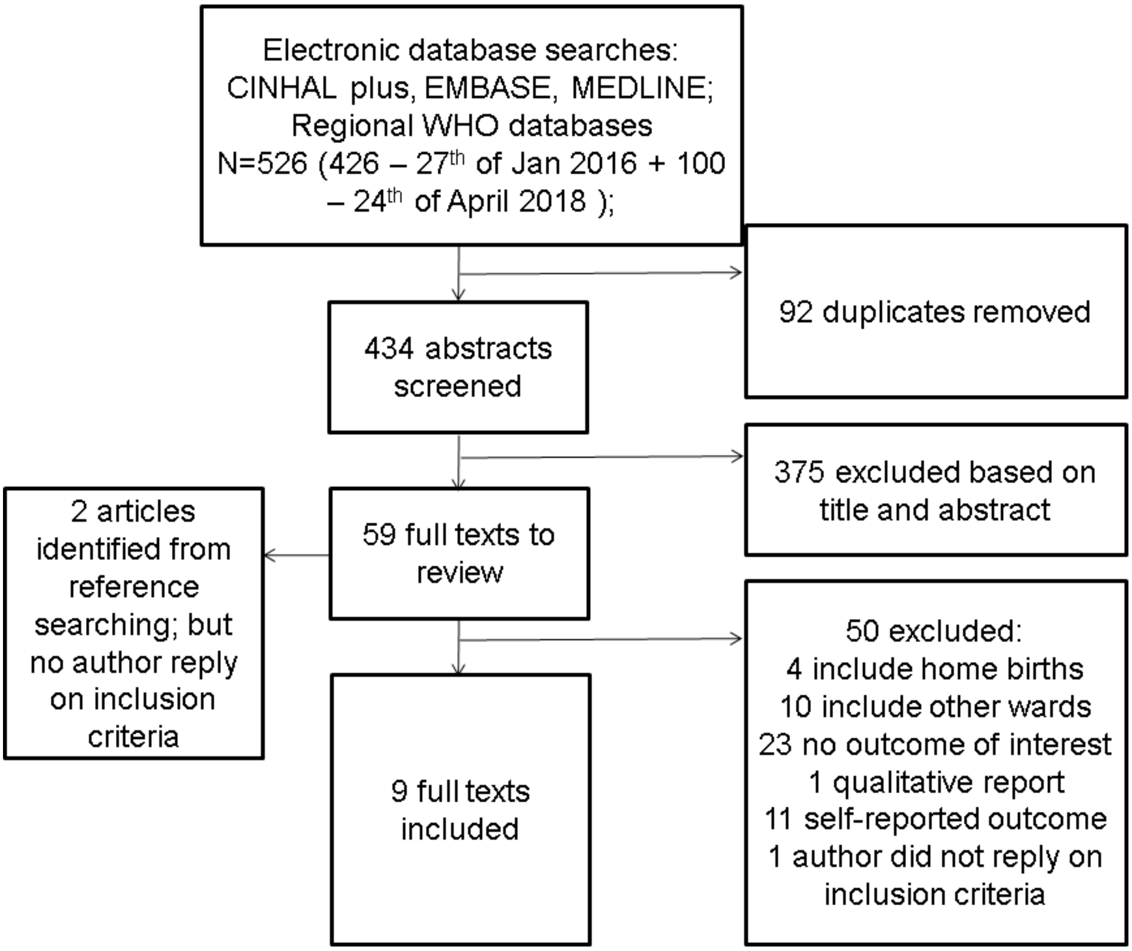
We aimed to conduct pooled analysis of the estimates by hand hygiene compliance estimated using similar outcome definitions, measurement tools or investigating similar interventions, unless there are differences in setting or risk of bias; where studies did not use similar outcomes, measurement tools or investigate similar interventions, estimates were described.

We followed the PRISMA guidelines for systematic reviews to report our methods and findings (see Additional File 2).[84]

2.3.4. Results

After removing duplicates, we obtained 526 results across the four databases and reviewed 59 full texts (Figure 2.1). We ultimately included nine studies that met our inclusion criteria. The reasons for excluding the fifty studies are in (Figure 2.1), with the most common being that the study did not report on the outcome of interest, i.e. hand hygiene of healthcare workers during labour or delivery, or in the labour ward. In three articles (two of which were identified via reference searching), it was unclear whether labour and delivery were being studied, and the author of the paper did not reply to enquiry, so these papers were not included.[85]

Figure 2.1 – Systematic search flow diagram



Of the nine included studies, four were in Sub-Saharan Africa (Nigeria, Zimbabwe and two in Ghana), two were in Iran, and three in South-East Asia (India, Thai-Myanmar border and Vietnam) – see Table 2.1. The studies were published between 1993 and 2018, with seven being published after 2008. Four studies were conducted in a single facility. Three of the nine studies did not report any information on hand hygiene infrastructure (Table 2.1); one study discussed how inconvenient the sink location was; one study selected the hospital based on it generally having supplies to provide good quality of maternal care; three studies reported on the general availability of supplies (two positively and one negatively), but it is unclear what elements of hand hygiene infrastructure were surveyed if any. Only one study reported specifically on the availability of hand hygiene infrastructure; needed supplies were present, except for handrub (Table 2.1).

Table 2.1 – Study characteristics

	Asp (2011)[86]	**Changaee (2014)**[87]	**Cronin (1993)**[88]	**Danda (2015)**[89]	**Hoogenboom (2015)**[90]	**Yawson (2013)**[91]	**Phan (2018)**[92]	**Simbar (2008)**[93]	**Spector (2012)**[94]
Country; site	Nigeria; Lagos	Iran; Lorestan	Ghana; North & South Birim Districts	Zimbabwe	Thai-Myanmar border; Mae La refugee camp	Ghana; Accra	Vietnam; Ho Chi Minh City	Iran; Kurdistan	India; Karnataka
Study design	Cross-sectional	Cross-sectional	Cross-sectional	Cross-sectional	Cross-sectional	Cross-sectional	Pre-post multi-component intervention	Cross-sectional	Pre-post multi-component intervention
Facility type	1 secondary and 1 tertiary maternity care facility	9 public hospitals	1 public hospital, 6 public health posts, 5 private maternity homes	2 University of Zimbabwe Central Hospitals i.e. National referral hospitals	Shoklo Malaria Research Unit Clinic	Korle-Bu Teaching Hospital (tertiary healthcare facility)	Hung Vuong University Hospital	Be-Sat Hospital of Sanandaj and Hafte-Teer Hospital of Beejar	Sub-district level hospital (basic emergency obstetric care and C-sections)
Unit/ward	Maternity ward	Unclear. Presumably labour ward	Unclear. Presumably labour ward	Labour & postnatal ward	Birth centre	Emergency Room and Labour ward	Delivery suite	Labour & delivery wards	Unclear. Presumably labour ward
Effect size	None	None	None	None	None	None	None	None	None
Intervention	None	None	None	None	None	None	Yes; educational intervention	None	Yes; testing checklist
Health professionals involved	Midwives	Unclear. Midwives are mentioned in the discussion	Midwives, midwives' assistants and lay women trained by midwives	Midwives	Literate skilled birth attendants resident in the camp and trained by the clinic (not previously	Doctors and nurses	All healthcare workers in the delivery suite. Across all departments in the study they capture doctors,	Unclear	Any healthcare worker* (nurses & obstetricians) who cared for women and newborns

					trained in midwifery)		nurses, midwives and technicians*		from admission for childbirth to discharge
Type of patient-attendant interactions	52 women during delivery and immediate postpartum	200 (low risk) pregnant women**	18 vaginal deliveries and 22 neonatal cord-care events	20 observations in the labour and 17 in the postnatal wards	20 births	Unclear	All types of hand hygiene opportunity in the delivery suite	96 women with low risk pregnancies**	405 vaginal examinations at admission and 388 deliveries
Observation period	May 2010	Unclear	2 Months. August - September 1991	May to June 2014	6 weeks. Nov-Dec 2008	3 weeks. September 2011	August 2014-May 2015	Throughout 2006	Baseline: Jul-Sept 2010; Endline: Sept.-Dec 2010
Data collectors	Unclear	Unclear	Project director and co-director (a Ghanaian nurse)	3 midwives researchers. 2 working at the study institution. 1 just left the study institution	2 Dutch midwifery students (4^{th} year)	6 nurses specifically trained in infection control	6 infection control staff trained in direct observation. Unclear if worked in study institute	Unclear. "Researcher"	Student nurses previously unknown to hospital staff with no clinical responsibility
Tool used for observation	Checklist developed for study. Based on protocol by Christensson et al. (2001)[95]	Checklist developed for study. Content validity assessed	Checklist created for study using criteria from e.g. the WHO Global Programme on AIDS, 1989	Checklist for labour ward developed for study	Checklist developed for study, drawing on WHO Safe Motherhood Needs Assessment v1.1 2001	Modified version of the WHO form for hand hygiene direct observation, 2010	Checklist using the WHO Guidelines on Hand Hygiene in Health Care, 2009. Observation checklist content	Tool developed for study based mainly on WHO's protocol of normal birth, 1997& 2006a	WHO Safe Childbirth Checklist presumed to have been used

							validity reviewed by MoH and University staff		
Study aim disclosed to participants	Unclear. Non participant observation	Unclear	Participants not told when observation would take place or what practices were observed	Observers were "inside participants" assisting midwives in their work. Checklist was filled after procedures in private	Unclear	Unclear. Health workers in these service centres were not aware of being observed	Unclear. Healthcare workers were aware of the observation period	Study aims were explained to the participants, midwives	Nature of the intervention, which included awareness practices included in the WHO Safe Birth Checklist (e.g. hand hygiene), presumably clear to participants
Sampling	Unclear	Non-random quota sampling used to recruit 200 women. 10-30 selected in different stages of labour in each hospital. Sample size calculations justified.	Observation took place when the project staff visited a facility at a time when a woman was in labour. All midwives on duty when observation took place were included. Occasionally	All midwives at the time of the observation were included in the study. Not clear how facility visits for observation were scheduled	Unclear	Observation in times & locations with high care density. Each centre was observed at a different time of day for 2 days between 8AM-5PM. Not clear how they selected which healthcare	Unclear	Women's selection – quota sampling (1 in 3 women) proportionally divided between morning, evening and night shifts. Not clear if all women received the full set of	Observation took place 24-h for a minimum of 6 days weekly; unobserved days were random. Observation was carried out at admission, from start of pushing to 1 hour after

		Unclear how different stages of labour or women and timing of visits were selected	called by facility when delivery expected. Not clear how facility visits for observation were scheduled			worker to observe		observations	birth, discharge. Unclear how women were selected each stage
Water/Soap/ handrub availability	Unclear. Sinks were not located in convenient locations	None	Unclear. Only reported missing items. Water, soap, handrub were not mentioned as missing	Unclear. They report broadly that basic supplies were often unavailable (not clear is specific to hand hygiene supplies)	Unclear. All essential equipment for standard antenatal care, and essential care of obstetric complications was present.	Resources observed once. Water, soap and single-use towel for drying available on labour ward. Handrub not available	None	None	Unclear. Hospitals selected based on general availability of supplies

* Unclear if all mentioned cadres were observed during labour and delivery

** Unclear whether hand hygiene was observed for all of these.

Quality of primary studies

All studies used observation as their primary method of data collection. The methods were described in most articles only partially. The lowest ranked quality indicators were 1) sampling, 2) methods to enhance data quality during data collection, 3) measurement of inter-observer agreement, and 4) the level of description of the hand hygiene compliance definition used (Figure 2.2).

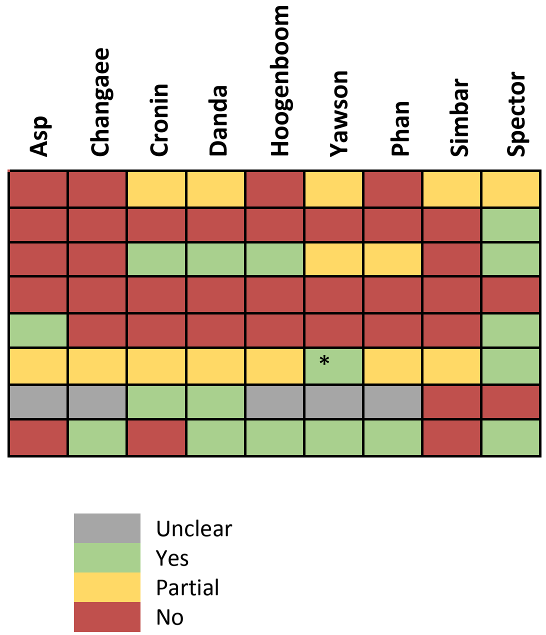
<u>Sampling</u> We required two aspects of the sampling methods to be described: a) how the unit of observation (e.g. woman, procedure or healthcare worker) was sampled and b) how the facility visits were scheduled. None of the articles described both aspects sufficiently; four articles did not describe them at all. As detailed in Table 2.1, it was often unclear how different women or healthcare workers were selected for observation for specific procedures/stages of labour.

<u>Quality during data collection</u> Only Spector et al.[94] described the procedures adopted to ensure a better quality of data collection, including for example, on-site reviews of all observation forms within 72 hours by the local study coordinator, and in-built data management checks confirming the data collected were logical.

<u>Inter-observer agreement</u> Even though no studies reported inter-observer agreement estimates, Spector et al.[94] attempted to examine agreement between observers – specifically, they reported that periodic assessments were used to confirm that data collectors achieved 100% concordance on a sample of three observations. Yawson and Hesse only report that different pairs of technical personnel visited the unit each day in order to limit intra-observer bias.[91]

Figure 2.2 – Quality assessment

1. Was sampling of the unit of observation described? How a) the unit was sampled; b) facility visits were scheduled
2. Were any measures to check or enhance the quality of data collection described?
3. a) Were the professional background of observers described? & b) Did they worked in the study facilities?
4. Was the agreement between observers estimated (justifiable only if study clearly used 1 observer)?
5. Was the definition of hand hygiene compliance reported clearly?
6. Was the tool used for data collection a) described and b) available?
7. Did the authors attempt to conceal the study aim from the participants?
8. Were statistical procedure described?



*Modified version of the tool is not available

Definition of outcome Hand hygiene compliance was not defined clearly in most studies. Each definition is reported in detail in Table 2.2. Often studies did not report specifically whether soap use was necessary to achieve adequate hand washing, or if other aspects of hand hygiene such as appropriate technique or duration were assessed. Yawson and Hesse, and Phan et al. mentioned that they followed the hand hygiene guidelines by the World Health Organisation (WHO) but it was not clear which aspects of the guidelines they included. Danda et al. and Hoogenboom et al. chose a poor definition of hand hygiene compliance because their denominator referred to whole individuals or group of individuals rather than specific patient-healthcare worker interactions (e.g. *hand washed at least once* or *at least one birth attendant washed hands*). In Changaee et al., it was not clear how they calculated their estimate of *desirable* hand washing.

Another aspect of the definition is the type of hand hygiene opportunity (when hand hygiene should occur). The WHO hand hygiene guidelines refer to five key hand hygiene opportunities: before clean/clean procedures, after exposure to body fluids, before touching the patient, after touching the patient, after touching the patient's surrounding. Studies did not always report what the type of contact (before vs. after; contact with intact skin i.e. "touching a patient" or non-intact/mucous membrane i.e. clean/aseptic procedures) or what procedures during labour or delivery were captured. Yawson and Hesse, and Simbar et al were contacted for further information on their hand hygiene definition, but did not reply.[91,93]

Table 2.2 – Compliance estimates before aseptic procedures during labour or delivery

	Asp (2011)[86]	**Changaee (2014)**[87]	**Cronin (1993)**[88]	**Danda (2015)**[89]	**Hoogenboom (2015)**[90]	**Yawson (2013)**[91]	**Phan (2018)**[92]	**Simbar (2008)**[93]	**Spector (2012)**[94]
1st Estimate									
Outcome definition	Hand washing with soap or hand disinfection	Unclear. Desirable hand washing. Estimated % was compliance with desirable status defined as 68-100% score. Unclear if soap necessary	Number of midwives who hand scrubbed with Dettol or soap and water	Whether each midwife washed her hands at least once. Unclear if with soap	Hand washing of at least one of the birth attendant present. Unclear if with soap	Hand hygiene compliance based on WHO guidelines 2009 (% of times performed hand hygiene of all observed moments when required). Presumably, soap& water or handrub necessary	Hand hygiene compliance is the ratio of the number of performed actions to the number of opportunities. Followed WHO guidelines 2009. Presumably, soap & water or handrub necessary	Hand washing; Unclear if with soap	Hands washed with clean water and soap, and clean gloves worn for admission vaginal examination. Proportion of each birth practice successfully delivered
Opportunity type	Before contact with patient during delivery	Second stage of labour; unclear if before or after what type of contact	Before delivery	Before procedures in the labour and postnatal ward	Before or after delivery	Before aseptic/clean procedures in the labour and emergency room	5 types of WHO hand hygiene opportunities in the delivery suite e.g. before patient contact	Second stage of labour; unclear if before or after what type of contact	Before vaginal examination
Numerator	1	Unclear	0	14	15	31*	142	Unclear	5.3*
Denominator	52	Unclear	18	37	20	116	507	Unclear	405

Compliance %	1.9%*	11.5%	0%*	37.8%*	75.0%*	27.0%	28.0%*	<20.0%**	1.3%
N individuals	52 women	200 women	18 women	37 midwives	20 women	Unclear	Unclear	96 women	Unclear
N facilities	2	9	Unclear	2	1	1	1	2	1
Cadre/ intervention	NA	NA	NA	NA	NA	Doctors	Before the intervention	NA	Before the intervention
2nd Estimate									
Outcome definition			Hands were washed; unclear if with soap	Whether each midwife never washed her hand. Unclear if with soap		As above			As above
Opportunity type			Before wound care for episiotomy and vaginal tears	Before procedures in the labour and postnatal ward		Before aseptic/clean procedures in the labour and emergency room			Before delivery
Numerator			4	23		4*			41*
Denominator			4	37		18			388
Compliance %			100%*	62.2%*		21.2%			10.6%*
N individuals			4 women	37 midwives		Unclear			Unclear
N facilities			Unclear	2		1			1
Cadre/ intervention			NA	NA		Nurses			Before the intervention

3rd Estimate									
Outcome definition			Hands were washed; unclear if with soap						
Opportunity type			Cord care; unclear if before/after						
Numerator			9						
Denominator			22						
Compliance %			40.9%*						
N individuals			22 newborns						
N facilities			Unclear						
Cadre/ intervention			NA						

*Estimates imputed by systematic review author

** Less than 20% was considered a level that is “not acceptable”. No exact estimate provided – estimated from Figure 1 of Simbar et al.

Hand hygiene compliance estimates during labour and delivery

We extracted estimates that were clearly for aseptic procedures, and estimates for which this was not clear or where aseptic procedures were not the exclusive focus. Definitions across the studies were extremely heterogeneous and hence we did not combine their estimates; compliance estimates varied from 0% to 100%. Spector et al. reported a baseline compliance of 1.3% before vaginal examinations during admission and 10.6% before deliveries. Simbar et al.[93] and Changaee et al.[87] reported on compliance during second stage of labour, although it was unclear whether compliance was before or after interaction with the patient or which type of interaction i.e. aseptic procedure, touching the patient. Simbar et al.[93] reported a compliance level below 20.0%, which they describe as unacceptable. We could not interpret the estimate by Chanagaee et al.[87] because of their unclear definition. Asp et al. report a compliance of 1.9% before contact with patient during delivery or immediate postpartum; it is unclear if this includes aseptic procedures or not.[86] Hoogenboom et al.[90] found that in 75.0% of deliveries, either before or after the delivery, at least one birth attendant present hand washed. Danda et al.[89] reported compliance before procedures (not clear what type) across the labour and postnatal wards – here, 37.8% of midwives washed their hands at least once and 62.2% never washed their hands. Yawson and Hesse[91] reported hand hygiene compliance before aseptic procedures across both the labour and emergency room (we assumed that the emergency room was primarily dedicated to pregnant women); among doctors, compliance was 26.7%, whereas among nurses it was 22.2%. Phan et al.[92] reported the baseline compliance to be 28% across five types of WHO hand hygiene opportunities (before patient contact, before aseptic task etc.) observed in the delivery suite. Finally, Cronin et al.[88] reported that the midwives scrub hands in none of the 18 deliveries they observed (currently this practice is not necessary before delivery); however, all used either water and soap, or Dettol to perform hand hygiene. All the four observations of wound care in this study were preceded by hand washing (100%) but only 40.9% of the cord-care observations (not clear if before or after cord care).

Table 2.3 describes the estimates extracted from the smallest to the largest, as well as whether we considered their sample size adequate, their definition sufficiently good and whether the authors provided isolated estimates specifically for opportunities before aseptic procedures during labour and delivery. Three studies with better definitions and larger sample sizes are those by Yawson and Hesse,[91] Phan et al. and Spector et al.[94] Only Spector et al.[94] met fully all three criteria.

Table 2.3 – Compliance estimates summarised

% Compliance	Author		Sample size	Definition	Specific estimate before aseptic proc. during labour and delivery
0	Cronin[88]	Before delivery	Small	Suboptimal	No
1.3	Spector[94]	Before vaginal exam.	Adequate	Good	Yes
1.9	Asp[86]	Before contact	Adequate	Suboptimal	No
10.6	Spector[94]	Before delivery	Adequate	Good	Yes
11.5	Changaee[87]	II stage of labour	Adequate	Suboptimal	No
<20	Simbar[93]	II stage of labour	Adequate	Suboptimal	No
21.2	Yawson[91]	Before aseptic (doct.)	Adequate	Satisfactory	Unclear*
27.0	Yawson[91]	Before aseptic (nurs.)	Adequate	Satisfactory	Unclear*
28.0	Phan[92]	All 5 types of opp.	Adequate	Satisfactory	No
37.8	Danda[89]**	Before procedures	Small	Suboptimal	No
40.9	Cronin[88]	During cord care	Small	Suboptimal	Yes
62.2	Danda[89]	Before procedures	Small	Suboptimal	No
75.0	Hoogenboom[90]	During delivery	Small	Suboptimal	No
100	Cronin[88]	Before wound care	Small	Satisfactory	Yes

* Emergency room may not only cater for labouring women

This refers to a *negative* compliance, **% of midwifes who never washed their hands

Technique and duration of hand hygiene, and avoiding hand recontamination

Only two studies[88,91] reported on aspects of hand hygiene quality such as technique and duration. Cronin et al. reported qualitatively that hand washings were generally not timed (not within the expected duration). Yawson and Hesse reported that on the labour ward, 50% or more of staff used soap and running water for hand washing, and dried hands with clean single use towels. Less than 50% washed hands for 40-60 seconds, or cleaned hands with alcohol handrub, or performed the appropriate handwashing technique.[91]

Only Cronin et al.[88] discuss qualitatively the concept of avoiding hand or glove recontamination before a procedure. They mention that

> "*frequent breaks in technique included … the midwife's gloved hands touching the patient's bed, leg, abdomen, and perineal pad before the delivery*."[88]

Interventions, effect size for hand hygiene determinants and ICC

Two studies developed and evaluated interventions to increase hand hygiene compliance. Both studies relied on a pre-post intervention design, without randomization or control wards. Both studies reported on interventions including several intervention components. Spector et al. tested a four-components childbirth safety program based on the WHO Safe Childbirth Checklist.[94] After the intervention, hand hygiene compliance increased respectively from 1.3% to 97.8% before vaginal examination during admission and from 10.6% to 99.5% before delivery. The checklist included prompts on elements of hand hygiene; therefore, the healthcare workers were not blinded to the aim of the intervention.

Phan et al.[92] tested an educational program on hand hygiene provided to healthcare workers over two 3 hours sessions. The educational model used experiential learning and incorporated novel techniques of learning that allowed for consideration of past hand hygiene experiences. 52 out of 53 healthcare staff in the delivery suite participated in the intervention. The intervention improved hand hygiene overall in the selected wards, but the effect was largest in the delivery suite increasing from 28% to 61.8% across all five types of WHO hand hygiene opportunities.[92] The improvement was sustained over a period of six months of post intervention follow-up. Given the nature of the intervention, we assumed that participants were not blinded to the aim of the intervention.

Only one author, Asp et al.,[86] responded when asked information on the ICC. The study collected information on 52 hand hygiene opportunities across two facilities. However, as they only observed hand washing once it was not possible to obtain a reliable estimate of the ICC.

No studies looked quantitatively at the association between potential determinants and hand hygiene compliance (measured via observation or other objective method).

2.3.5. Discussion

We performed a systematic review of published studies reporting estimates of birth attendants' hand hygiene compliance conducted in healthcare facilities in LMICs. We found nine studies that met our inclusion criteria. Hand hygiene compliance estimates were extremely diverse, ranging from 0 to 100%; the heterogeneity in definitions of hand hygiene did not allow us to combine or compare these meaningfully. Three studies (Danda et al., Cronin et al., Hoogenboom et al.) reported higher compliance but also had a very small sample, or used an individual level or group level definition for the denominator rather than the number of patient-attendant interactions (hand hygiene opportunities) as recommended by the WHO hand hygiene guidelines.[88–90] The three studies[91,92,94] with larger sample sizes and clearer definitions suggest compliance to hand hygiene before aseptic procedures to be low, between 1.3% and 28.0%. Of these, the estimates by Phan et al. (28.0%) included opportunities besides just before aseptic procedures; whereas, for the estimates by Yawson et al. (21.2% and 27.0%) we are not completely sure whether they are exclusive to the process of labour and delivery. Only Spector et al. provide estimates for opportunities before aseptic procedures specifically specific to labour and delivery: 1.3% before vaginal examination on admission and 10.6% before delivery. Overall, the quality of the included studies was particularly compromised by poorly described sampling methods and definitions.

The studies included were published in the last 16 years and spanned seven countries between Sub-Saharan Africa, South East Asia and the Middle East. Half of the studies only included one facility, limiting their generalizability. The supplies of key hand hygiene infrastructure were poorly described, except in one study. The quality of the studies included was generally poor with a high risk of bias. The weakest aspect of the studies was their description of the sampling strategy, as most studies did not describe how the unit of observation was sampled (whether women, healthcare workers or specific procedures). Also, the reported definitions of hand hygiene were often incomplete. For most studies it was unclear whether the use of soap was a necessary condition to achieve hand washing compliance. In addition, the type of hand hygiene opportunity was often poorly described i.e. before or after the interaction with the patient; aseptic procedures vs. contact with the patient intact skin. Finally, in two studies the denominator did not rely on patient-worker interactions but on the overall performance of an individual or a group. This finding of poor methods in conducting and reporting of observational studies on hand hygiene and more broadly of healthcare workers was reported elsewhere.[9616]

Beyond the basic aspect of quality required for any observational study and described by the STROBE guidelines,[82] future studies focusing on hand hygiene during labour and delivery should design and report the following more clearly:

a) what sampling strategy was used to observe either workers, women, or patient-worker interactions; and how facilities visits were scheduled;

b) the methods used to ensure the quality of data collection in the study e.g. data monitoring
c) the inter-observer agreement where multiple observers are employed;
d) the definition of hand hygiene following the WHO hand hygiene guidelines[10] (i.e. soap necessary for hand washing; which type of hand hygiene opportunity e.g. before vs. after, touching intact skin vs. aseptic procedure; denominator based on patient-worker interactions rather than individual or group level performance);

Our findings of low birth attendants' hand hygiene compliance are consistent with other systematic reviews or multi-country studies in LMICs of hand hygiene among healthcare workers more generally, which report compliance estimates ranging from 22% to 35% during non intervention periods.[19,21] Similarly to these studies, our estimates point to a slight lower compliance in LMICs compared to high-income settings. With approximately 140 million women delivering worldwide, most of which are in LMICs and at least half of which occur in healthcare facilities where quality of care is suboptimal, these low estimates of hand hygiene compliance during labour/delivery are worrisome.[24,25,73] If correct, these estimates pose a substantial risk to infection prevention during birth in LMICs where both mothers and newborns are still largely affected by infection.[1,2,97]

None of the included studies reported any effect size for the association between potential hand hygiene determinants. Two studies[91,94] investigated the effect of two different interventions on hand hygiene, a checklist on quality of care at birth and an education program. Both were successful in increasing substantially the hand hygiene compliance during labour/delivery. Given the nature of their study design – pre-post intervention without a control ward, and with study participants who are no blinded – and the fact that they only operated in one facility each, these interventions tell us more about the feasibility of these interventions in these specific contexts compared to anything conclusive about their scope for improving hand hygiene more widely in LMICs. A follow-up trial of the WHO Safe Birth Checklist, which was not picked up by our search because it did not mention hand hygiene terms in the title or abstract, provides further evidence of low hand hygiene compliance before delivery during the 12 months intervention follow up at 12% (from 35% during the 2 month follow up) in the intervention arm and less than 1% in the control arm (% stayed the same as during the 2 month follow up); this study also suggest the limited scope of the intervention to achieve sustained hand hygiene change.[98] Finally, we could only comment on the variance between and within facilities from one study because no other authors replied to our request for this additional data.

Our systematic review covered four separate databases, has a clearly reported search strategy adapted from previous systematic reviews on the topic, did not pose any restrictions based on language, and used independent double screening and article selection. A potential weakness is that our search might have missed articles which included hand hygiene in the broader framework of quality of care during birth or infection prevention and control and which did not mention hand hygiene in their title or abstract, such as the Safe Birth Checklist trial.[98] We did not assess publication bias, but this would be more of an issue for intervention studies that found negative results for example than for observational studies reporting on compliance estimates. Finally, the set of health care facilities included in this systematic review is unlikely to represent health care facilities across LMICs. Without random sampling from the reference population of health care facilities (which none of the included studied did), estimates of hand hygiene may be subject to selection bias stemming from researchers non-random decisions about which facilities to study. For example, researchers may be more likely to sample from higher volume facilities where deliveries are frequent than to sample from lower volume facilities. Studies suggest that higher volume facilities are better equipped for attending deliveries, but they maybe more prone to crowding which in turn makes hand hygiene more challenging.[72]

In conclusion, we found nine articles reporting the hand hygiene compliance of healthcare workers during labour and delivery in LMICs. Compliance including before aseptic procedures opportunities for studies with larger sample sizes and clear definitions was low, ranging between 1-28%. This is an opportunity for infection prevention reduction during birth in LMICs facilities since effective interventions in this area are likely to reduce infection rate among mothers and newborns. We also found that the quality of many studies was suboptimal. In particular, future studies of hand hygiene compliance during the labour ward should be designed with better sampling frame, assess inter-observer agreement, use measures to improve quality of data collection and report their hand hygiene definitions clearly.

2.3.6. Declarations

Ethics approval and Consent to participate

Not applicable

Consent for publication

Not applicable

Availability of data and materials

All data generated or analysed during this study are included in this published article

Competing interests

The authors declare that they have no competing interests.

Funding

The Soapbox Collaborative contributed by funding the corresponding author.

Authors' contribution

Conceived and designed the study: GG OC
Analysed the data: GG first reviewer, MDB second reviewer
Wrote the paper: GG MDB SN OC
Data interpretation: GG MDB SN OC

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2.3.7. Additional Files

Additional File 1 - Systematic review search strategy

EMBASE

1. Handwashing/
2. (hand antisepsis or handwash$ or hand wash$ or hand disinfection or hand hygiene or surgical scrub$).tw.
3. exp Hand/
4. exp Sterilization/
5. 1 or 2
6. 3 and 4
7. 5 or 6
8. exp maternity ward/
9. (maternit* or gynaecology* or gynecolog* or labour or labor or birth* or deliver* or obstetric* or childbirth* or intrapartum).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
10. 8 or 9
11. 7 and 10
12. Limit to Low and Middle Income Countries (LMICs – see full list below)
13. 11 and 12

MEDLINE

1. Handwashing/
2. (hand antisepsis or handwash$ or hand wash$ or hand disinfection or hand hygiene or surgical scrub$).tw.
3. exp Hand/
4. exp Sterilization/
5. 1 or 2
6. 3 and 4
7. 5 or 6
8. exp Hospitals, Maternity/
9. (maternity* or gynaecolog* or gynecolog* or labour or labor or deliver* or birth* or obstetric* or childbirth* or intrapartum).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
10. 8 or 9
11. 7 and 10
12. Limit to LMICs (see full list below)
13. 11 and 12

CINHAL Plus

1. (MH* "Handwashing+")
2. (hand antisepsis or handwash* or hand
   wash* or hand disinfection or hand hygiene

   or surgical scrub*)
3. 1 or 2
4. Hand*
5. Sterilization*
6. 4 and 5
7. 3 or 6

8. (MH "Delivery Rooms+")
9. Maternity* or gynaecolog* or gynecolog* or labour or labor or deliver* or birth* or obstetric* or childbirth or intrapartum
10. 8 or 9
11. 10 and 7
12. **Limiters** – Mexico and South America, Asia, Africa, Middle East

WHO regional databases

(hand antiseps* handwash* OR hand hygiene OR hand wash* OR hand disinfection OR surgical scrub OR hand sterilization) AND (Maternit* or gynaecolog* or gynecolog* or labour or labor or deliver* or birth* or obstetric* or childbirth* or intrapart*)

LMICs country search strategy (developed by the London School of Hygiene and Tropical Medicine librarian)

EMBASE

1. developing country/
2. low income country/
3. middle income country/
4. ((developing or less* developed or under developed or underdeveloped or middle income or low* income or underserved or under served or deprived or poor*) adj (economy or economies)).ti,ab.
5. ((developing or less* developed or under developed or underdeveloped or middle income or low* income or underserved or under served or deprived or poor*) adj (countr* or nation? or population? or world)).ti,ab.
6. (low* adj (gdp or gnp or gross domestic or gross national)).ti,ab.
7. (low adj3 middle adj3 countr*).ti,ab.
8. (lmic or lmics or third world or lami countr*).ti,ab.
9. transitional countr*.ti,ab.
10. global south.ti,ab.
11. "Africa south of the Sahara"/
12. ("africa south of the sahara" or sub-saharan africa or central africa or eastern africa or southern africa or western africa).ti,ab.
13. Botswana/
14. (Botswana or Bechuanaland or Kalahari).ti,ab.
15. Equatorial Guinea/
16. (Equatorial Guinea or Spanish Guinea).ti,ab.
17. Gabon/
18. (Gabon or Gabonese Republic).ti,ab.
19. Mauritius/

20. (Mauritius or Agalega Islands).ti,ab.
21. Namibia/
22. Namibia.ti,ab.
23. South Africa/
24. South Africa.ti,ab.
25. Angola/
26. angola.ti,ab.
27. Cameroon/
28. Cameroon.ti,ab.
29. Cape Verde/
30. (Cape Verde or Cabo Verde).ti,ab.
31. Congo/
32. (congo not ((democratic republic adj3 congo) or congo red or crimean-congo)).ti,ab.
33. Cote d'Ivoire/
34. (Cote d'Ivoire or Ivory Coast).ti,ab.
35. Ghana/
36. (Ghana or Gold Coast).ti,ab.
37. Kenya/
38. kenya.mp.
39. Lesotho/
40. (Lesotho or Basutoland).ti,ab.
41. Mauritania/
42. Mauritania.ti,ab.
43. Nigeria/
44. Nigeria.ti,ab.
45. "Sao Tome and Principe"/
46. (sao tome adj2 principe).ti,ab.
47. Sudan/
48. (Sudan not south sudan).ti,ab.
49. Swaziland/
50. Swaziland.ti,ab.
51. Zambia/
52. (Zambia or Northern Rhodesia).ti,ab.
53. Benin/
54. (Benin or Dahomey).ti,ab.
55. Burkina Faso/
56. (Burkina Faso or Burkina Fasso or Upper Volta).ti,ab.

57. Burundi/
58. Burundi.ti,ab.
59. Central African Republic/
60. (Central African Republic or Ubangi-Shari).ti,ab.
61. Chad/
62. Chad.ti,ab.
63. Comoros/
64. (Comoros or Comoro Islands or Mayotte or Iles Comores).ti,ab.
65. "Democratic Republic Congo"/
66. ((democratic republic adj2 congo) or belgian congo or zaire).ti,ab.
67. Eritrea/
68. Eritrea.ti,ab.
69. Ethiopia/
70. Ethiopia.ti,ab.
71. Gambia/
72. Gambia.ti,ab.
73. Guinea/
74. (Guinea not (New Guinea or Guinea Pig* or Guinea Fowl)).ti,ab.
75. Guinea-Bissau/
76. (Guinea-Bissau or Portuguese Guinea).ti,ab.
77. Liberia/
78. Liberia.ti,ab.
79. Madagascar/
80. (Madagascar or Malagasy Republic).ti,ab.
81. Malawi/
82. (Malawi or Nyasaland).ti,ab.
83. Mali/
84. Mali.ti,ab.
85. Mozambique/
86. (Mozambique or Mocambique or Portuguese East Africa).ti,ab.
87. Niger/
88. (Niger not (Aspergillus or Peptococcus or Schizothorax or Cruciferae or Gobius or Lasius or Agelastes or Melanosuchus or radish or Parastromateus or Orius or Apergillus or Parastromateus or Stomoxys)).ti,ab.
89. Rwanda/
90. (Rwanda or Ruanda).ti,ab.
91. Senegal/

92. senegal.ti,ab.
93. Sierra Leone/
94. Sierra Leone.mp.
95. exp Somalia/
96. Somalia.ti,ab.
97. South Sudan/
98. south sudan.ti,ab.
99. Tanzania/
100. (Tanzania or Tanganyika or Zanzibar).ti,ab.
101. Togo/
102. (Togo or Togolese Republic).ti,ab.
103. Uganda/
104. Uganda.ti,ab.
105. Zimbabwe/
106. (Zimbabwe or Rhodesia).ti,ab.
107. Maldives/
108. Maldives.ti,ab.
109. Algeria/
110. Algeria.ti,ab.
111. Iran/
112. Iran.ti,ab.
113. exp Iraq/
114. Iraq.ti,ab.
115. Jordan/
116. Jordan.ti,ab.
117. Lebanon/
118. Lebanon.ti,ab.
119. Libyan Arab Jamahiriya/
120. Libya.ti,ab.
121. Argentina/
122. Argentina.ti,ab.
123. Belize/
124. Belize.ti,ab.
125. exp Brazil/
126. Brazil.ti,ab.
127. Colombia/
128. Colombia.ti,ab.

129. Costa Rica/
130. Costa Rica.ti,ab.
131. Cuba/
132. Cuba.ti,ab.
133. Dominica/
134. Dominica.ti,ab.
135. Dominican Republic/
136. Dominican Republic.ti,ab.
137. Ecuador/
138. Ecuador.ti,ab.
139. Grenada/
140. Grenada.ti,ab.
141. Guyana/
142. Guyana.mp.
143. Jamaica/
144. Jamaica.ti,ab.
145. Mexico/
146. Mexico.ti,ab.
147. exp Panama/
148. Panama.ti,ab.
149. Paraguay/
150. Paraguay.mp.
151. Peru/
152. Peru.ti,ab.
153. Saint Lucia/
154. (St Lucia or Saint Lucia).ti,ab.
155. "Saint Vincent and the Grenadines"/
156. Grenadines.ti,ab.
157. Suriname/
158. Suriname.ti,ab.
159. Venezuela/
160. Venezuela.ti,ab.
161. Albania/
162. Albania.ti,ab.
163. Azerbaijan/
164. Azerbaijan.ti,ab.
165. Belarus/

166. (belarus or byelarus or belorussia).ti,ab.
167. exp "Bosnia and Herzegovina"/
168. (bosnia or herzegovina).ti,ab.
169. Bulgaria/
170. Bulgaria.ti,ab.
171. Croatia/
172. croatia.ti,ab.
173. Kazakhstan/
174. (Kazakhstan or kazakh).ti,ab.
175. "Macedonia (Republic)"/
176. Macedonia.ti,ab.
177. "Montenegro (republic)"/
178. Montenegro.ti,ab.
179. Romania/
180. Romania.ti,ab.
181. exp Russian Federation/
182. USSR/
183. (Russia or Russian Federation or USSR or Union of Soviet Socialist Republics or Soviet Union).mp.
184. exp Serbia/
185. serbia.ti,ab.
186. "Turkey (republic)"/
187. turkey.ti,ab. not animal/
188. Turkmenistan/
189. Turkmenistan.ti,ab.
190. Yugoslavia/
191. yugoslavia.ti,ab.
192. exp Samoan Islands/
193. american samoa.ti,ab.
194. exp China/
195. china.ti,ab.
196. Fiji/
197. fiji.ti,ab.
198. Malaysia/
199. malaysia.ti,ab.
200. Marshall Islands/
201. marshall islands.ti,ab.

202. Nauru/

203. nauru.ti,ab.

204. ("independent state of samoa" or (samoa not american samoa) or western samoa or navigator islands or samoan islands).ti,ab.

205. Thailand/

206. Thailand.ti,ab.

207. Tonga/

208. tonga.ti,ab.

209. Tuvalu/

210. Tuvalu.ti,ab.

211. Bangladesh/

212. Bangladesh.ti,ab.

213. Bhutan/

214. Bhutan.ti,ab.

215. exp India/

216. India.ti,ab.

217. exp Pakistan/

218. Pakistan.ti,ab.

219. Sri Lanka/

220. Sri Lanka.ti,ab.

221. Djibouti/

222. (Djibouti or French Somaliland).ti,ab.

223. Egypt/

224. Egypt.ti,ab.

225. Jordan/

226. Jordan.ti,ab.

227. Morocco/

228. Morocco.ti,ab.

229. Syrian Arab Republic/

230. (Syria or Syrian Arab Republic).ti,ab.

231. Tunisia/

232. tunisia.mp.

233. Palestine/

234. Gaza.ti,ab.

235. Yemen/

236. Yemen.ti,ab.

237. Bolivia/

238. Bolivia.ti,ab.
239. El Salvador/
240. El Salvador.ti,ab.
241. Guatemala/
242. Guatemala.ti,ab.
243. Honduras/
244. Honduras.ti,ab.
245. Nicaragua/
246. Nicaragua.ti,ab.
247. Armenia/
248. Armenia.ti,ab.
249. "Georgia (Republic)"/
250. Kosovo/
251. Kosovo.ti,ab.
252. Kyrgyzstan/
253. (kyrgyzstan or kyrgyz republic or kirghizia or kirghiz).ti,ab.
254. Moldova/
255. Moldova.ti,ab.
256. Tajikistan/
257. tajikistan.ti,ab.
258. exp Ukraine/
259. Ukraine.ti,ab.
260. Uzbekistan/
261. Uzbekistan.ti,ab.
262. Cambodia/
263. cambodia.ti,ab.
264. exp Indonesia/
265. indonesia.ti,ab.
266. Kiribati/
267. Kiribati.ti,ab.
268. Laos/
269. (laos or (lao adj1 democratic republic)).ti,ab.
270. "Marshall Islands"/
271. "Federated States of Micronesia"/
272. (marshall island* or caroline island* or ellice island* or gilbert island* or johnston island* or mariana island* or micronesia or pacific island*).ti,ab.
273. Mongolia/

274. mongolia.ti,ab.
275. Myanmar/
276. (myanmar or burma).ti,ab.
277. Papua New Guinea/
278. Papua New Guinea.ti,ab.
279. Philippines/
280. Philippines.ti,ab.
281. Timor-Leste/
282. Timor-Leste.ti,ab.
283. Vanuatu/
284. Vanuatu.ti,ab.
285. Viet Nam/
286. (Viet Nam or vietnam).ti,ab.
287. Afghanistan/
288. Afghanistan.ti,ab.
289. Nepal/
290. Nepal.ti,ab.
291. Haiti/
292. Haiti.ti,ab.
293. "North Korea"/
294. (north korea or (democratic people* republic adj2 korea)).ti,ab.
295. or/12-305 [ALL LMICs]
296. 11 and 306

MEDLINE

1. ((developing or less* developed or under developed or underdeveloped or middle income or low* income or underserved or under served or deprived or poor*) adj (economy or economies)).ti,ab.
2. ((developing or less* developed or under developed or underdeveloped or middle income or low* income or underserved or under served or deprived or poor*) adj (countr* or nation? or population? or world)).ti,ab.
3. (low* adj (gdp or gnp or gross domestic or gross national)).ti,ab.
4. (low adj3 middle adj3 countr*).ti,ab.
5. (lmic or lmics or third world or lami countr*).ti,ab.
6. transitional countr*.ti,ab.
7. global south.ti,ab.
8. Developing Countries/

9. "africa south of the sahara"/ or africa, central/ or africa, eastern/ or africa, southern/ or africa, western/
10. ("africa south of the sahara" or sub-saharan africa or central africa or eastern africa or southern africa or western africa).ti,ab.
11. "Democratic People's Republic of Korea"/
12. (north korea or (democratic people* republic adj2 korea)).ti,ab.
13. Cambodia/
14. cambodia.ti,ab.
15. Indonesia/
16. indonesia.ti,ab.
17. Micronesia/
18. Kiribati.ti,ab.
19. Laos/
20. (laos or (lao adj1 democratic republic)).ti,ab.
21. (marshall island* or caroline island* or ellice island* or gilbert island* or johnston island* or mariana island* or micronesia or pacific island*).ti,ab.
22. Mongolia/
23. mongolia.ti,ab.
24. Myanmar/
25. (myanmar or burma).ti,ab.
26. Papua New Guinea/
27. Papua New Guinea.ti,ab.
28. Philippines/
29. Philippines.ti,ab.
30. Timor-Leste/
31. Timor-Leste.ti,ab.
32. Vanuatu/
33. Vanuatu.ti,ab.
34. Vietnam/
35. (Viet Nam or Vietnam).ti,ab.
36. American Samoa/
37. american samoa.ti,ab.
38. exp China/
39. china.ti,ab.
40. Fiji/
41. fiji.ti,ab.
42. Malaysia/

43. malaysia.ti,ab.
44. marshall islands.ti,ab.
45. nauru.ti,ab.
46. samoa/
47. "independent state of samoa"/
48. ("independent state of samoa" or (samoa not american samoa) or western samoa or navigator islands or samoan islands).ti,ab.
49. Thailand/
50. Thailand.ti,ab.
51. Tonga/
52. tonga.ti,ab.
53. Tuvalu.ti,ab.
54. Armenia/
55. Armenia.ti,ab.
56. "Georgia (Republic)"/
57. Kosovo/
58. Kosovo.ti,ab.
59. Kyrgyzstan/
60. (kyrgyzstan or kyrgyz republic or kirghizia or kirghiz).ti,ab.
61. Moldova/
62. Moldova.ti,ab.
63. Tajikistan/
64. tajikistan.ti,ab.
65. Ukraine/
66. Ukraine.ti,ab.
67. Uzbekistan/
68. Uzbekistan.ti,ab.
69. Albania/
70. Albania.ti,ab.
71. Azerbaijan/
72. Azerbaijan.ti,ab.
73. "Republic of Belarus"/
74. (belarus or byelarus or belorussia).ti,ab.
75. Bosnia-Herzegovina/
76. (bosnia or herzegovina).ti,ab.
77. Bulgaria/
78. Bulgaria.ti,ab.

79. Croatia/
80. croatia.ti,ab.
81. Kazakhstan/
82. (Kazakhstan or kazakh).ti,ab.
83. "Macedonia (Republic)"/
84. Macedonia.ti,ab.
85. Montenegro/
86. Montenegro.ti,ab.
87. Romania/
88. Romania.ti,ab.
89. exp Russia/
90. USSR/
91. (Russia or Russian Federation or USSR or Union of Soviet Socialist Republics or Soviet Union).mp.
92. Serbia/
93. serbia.ti,ab.
94. Turkey/
95. turkey.ti,ab. not animal/
96. Turkmenistan/
97. Turkmenistan.ti,ab.
98. Yugoslavia/
99. yugoslavia.ti,ab.
100. Haiti/
101. Haiti.ti,ab.
102. Bolivia/
103. Bolivia.ti,ab.
104. El Salvador/
105. El Salvador.ti,ab.
106. Guatemala/
107. Guatemala.ti,ab.
108. Honduras/
109. Honduras.ti,ab.
110. Nicaragua/
111. Nicaragua.ti,ab.
112. Argentina/
113. Argentina.ti,ab.
114. Belize/

115. Belize.ti,ab.
116. Brazil/
117. Brazil.ti,ab.
118. Colombia/
119. Colombia.ti,ab.
120. Costa Rica/
121. Costa Rica.ti,ab.
122. Cuba/
123. Cuba.ti,ab.
124. Dominica/
125. Dominica.ti,ab.
126. Dominican Republic/
127. Dominican Republic.ti,ab.
128. Ecuador/
129. Ecuador.ti,ab.
130. Grenada/
131. Grenada.ti,ab.
132. Guyana/
133. Guyana.mp.
134. Jamaica/
135. Jamaica.ti,ab.
136. Mexico/
137. Mexico.ti,ab.
138. exp Panama/
139. Panama.ti,ab.
140. Paraguay/
141. Paraguay.mp.
142. Peru/
143. Peru.ti,ab.
144. Saint Lucia/
145. (St Lucia or Saint Lucia).ti,ab.
146. "Saint Vincent and the Grenadines"/
147. Grenadines.ti,ab.
148. Suriname/
149. Suriname.ti,ab.
150. Venezuela/
151. Venezuela.ti,ab.

152. Djibouti/
153. (Djibouti or French Somaliland).ti,ab.
154. Egypt/
155. Egypt.ti,ab.
156. Jordan/
157. Jordan.ti,ab.
158. Morocco/
159. Morocco.ti,ab.
160. Syria/
161. (Syria or Syrian Arab Republic).ti,ab.
162. Tunisia/
163. tunisia.mp.
164. Gaza.ti,ab.
165. Yemen/
166. Yemen.ti,ab.
167. Algeria/
168. Algeria.ti,ab.
169. Iran/
170. Iran.ti,ab.
171. Iraq/
172. Iraq.ti,ab.
173. Jordan/
174. Jordan.ti,ab.
175. Lebanon/
176. Lebanon.ti,ab.
177. Libya/
178. Libya.ti,ab.
179. Afghanistan/
180. Afghanistan.ti,ab.
181. Nepal/
182. Nepal.ti,ab.
183. Bangladesh/
184. Bangladesh.ti,ab.
185. Bhutan/
186. Bhutan.ti,ab.
187. exp India/
188. India.ti,ab.

189. Pakistan/
190. Pakistan.ti,ab.
191. Sri Lanka/
192. Sri Lanka.ti,ab.
193. Indian Ocean Islands/
194. Maldives.ti,ab.
195. Benin/
196. (Benin or Dahomey).ti,ab.
197. Burkina Faso/
198. (Burkina Faso or Burkina Fasso or Upper Volta).ti,ab.
199. Burundi/
200. Burundi.ti,ab.
201. Central African Republic/
202. (Central African Republic or Ubangi-Shari).ti,ab.
203. Chad/
204. Chad.ti,ab.
205. Comoros/
206. (Comoros or Comoro Islands or Mayotte or Iles Comores).ti,ab.
207. "Democratic Republic of the Congo"/
208. ((democratic republic adj2 congo) or belgian congo or zaire).ti,ab.
209. Eritrea/
210. Eritrea.ti,ab.
211. Ethiopia/
212. Ethiopia.ti,ab.
213. Gambia/
214. Gambia.ti,ab.
215. Guinea/
216. (Guinea not (New Guinea or Guinea Pig* or Guinea Fowl)).ti,ab.
217. Guinea-Bissau/
218. (Guinea-Bissau or Portuguese Guinea).ti,ab.
219. Liberia/
220. Liberia.ti,ab.
221. Madagascar/
222. (Madagascar or Malagasy Republic).ti,ab.
223. Malawi/
224. (Malawi or Nyasaland).ti,ab.
225. Mali/

226. Mali.ti,ab.
227. Mozambique/
228. (Mozambique or Mocambique or Portuguese East Africa).ti,ab.
229. Niger/
230. (Niger not (Aspergillus or Peptococcus or Schizothorax or Cruciferae or Gobius or Lasius or Agelastes or Melanosuchus or radish or Parastromateus or Orius or Apergillus or Parastromateus or Stomoxys)).ti,ab.
231. Rwanda/
232. (Rwanda or Ruanda).ti,ab.
233. Senegal/
234. senegal.ti,ab.
235. Sierra Leone/
236. Sierra Leone.mp.
237. Somalia/
238. Somalia.ti,ab.
239. South Sudan/
240. south sudan.ti,ab.
241. Tanzania/
242. (Tanzania or Tanganyika or Zanzibar).ti,ab.
243. Togo/
244. (Togo or Togolese Republic).ti,ab.
245. Uganda/
246. Uganda.ti,ab.
247. Zimbabwe/
248. (Zimbabwe or Rhodesia).ti,ab.
249. Angola/
250. angola.ti,ab.
251. Cameroon/
252. Cameroon.ti,ab.
253. Cape Verde/
254. (Cape Verde or Cabo Verde).ti,ab.
255. Congo/
256. (congo not ((democratic republic adj3 congo) or congo red or crimean-congo)).ti,ab.
257. Cote d'Ivoire/
258. (Cote d'Ivoire or Ivory Coast).ti,ab.
259. Ghana/

260. (Ghana or Gold Coast).ti,ab.
261. Kenya/
262. kenya.mp.
263. Lesotho/
264. (Lesotho or Basutoland).ti,ab.
265. Mauritania/
266. Mauritania.ti,ab.
267. Nigeria/
268. Nigeria.ti,ab.
269. Atlantic Islands/
270. (sao tome adj2 principe).ti,ab.
271. Sudan/
272. (Sudan not south sudan).ti,ab.
273. Swaziland/
274. Swaziland.ti,ab.
275. Zambia/
276. (Zambia or Northern Rhodesia).ti,ab.
277. Botswana/
278. (Botswana or Bechuanaland or Kalahari).ti,ab.
279. Equatorial Guinea/
280. (Equatorial Guinea or Spanish Guinea).ti,ab.
281. Gabon/
282. (Gabon or Gabonese Republic).ti,ab.
283. Mauritius/
284. (Mauritius or Agalega Islands).ti,ab.
285. Namibia/
286. Namibia.ti,ab.
287. South Africa/
288. South Africa.ti,ab.
289. or/1-288 [ALL LMIC]

Additional File 2 – PRISMA checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Page 37
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	Page 38
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Page 39
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Page 39, last paragraph
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Page 40, I paragraph.
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Page 40, II paragraph.
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	Page 40, I paragraph. Page 41, I paragraph.
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Additional File I

Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	Pages 40-41. Methods section
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	Pages 40 last paragraph; Page 41
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Page 40, last paragraph. Page 41
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	Page 41, II paragraph. Page 42, II paragraph
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Page 42, II paragraph
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Page 42, II paragraph

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	NA Page 59, II paragraph.
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	NA

RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Figure 2.1; Page 42, last paragraph.
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Table 2.1
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Table 2.1; Figure 2.2
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Page 54, 55, 56 (Results section) Tables 2.2 and 2.3
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	NA
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	NA
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	Page 56, last paragraph (continues on page 57).
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	Page 57, II paragraph. Page 58, last

			paragraph. Page 59, II paragraph.
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	Page 59, last paragraph.
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Page 60

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: **www.prisma-statement.org**.

Additional File 3 – ORION checklist

Original checklist for abstract revision available from https://www.ucl.ac.uk/antimicrobial-resistance/sites/antimicrobial-resistance/files/checklist_abstracts.pdf

Author	**Spector et al (2012)**[94]	
Title	1. Clear statement that this is an intervention study or an outbreak report	Intervention as it states that it pilots the WHO safe childbirth checklist program
Background	2. Rationale for study with clear hypothesis for intervention studies or objective for outbreak reports	Rationale and explicit hypotheses
Methods	3. Clear statement of intervention study design or case definition for outbreak report	Described as a pre-post intervention study (no controls mentioned) Two time points assessed
	4. Brief description of setting, participants, and intervention or outbreak control measures with start and stop dates	Setting, participants and intervention clear Start and stop dates stated
	5. Clearly defined outcomes and denominators at regular intervals, not as totals for each phase (can be in results)	Clearly defined outcomes
	6. Statistical analysis accounts for any dependencies in the data (can be in results instead)	Not accounted for
	7. Which potential biases or confounders were considered, recorded or adjusted for (can be in results instead)	Potential biases considered. Confounders not assessed
	8. Where relevant: details of culture, typing, environmental sampling, and risk factors for	Not mentioned

	acquisition, root cause analysis or organisational risk assessment	
Results	9. For the main outcomes: estimated effect size & its precision (usually using 95% C.I.) (A graphical summary is often appropriate for dependent data -such as most time series).	Proportion compliance reported for period before, and one after the intervention with precision estimates too. Not graphical representation
Conclusions	10. For intervention studies: consider in relation to original hypothesis, accounting for potential confounders & biases. For outbreak reports: consider clinical significance of observations and hypothesis to explain them.	Original hypothesis addressed

Author	**Phan et al. 2018**[92]	
Title	1. Clear statement that this is an intervention study or an outbreak report	Intervention is clearly stated i.e. an education program to improve hand hygiene
Background	2. Rationale for study with clear hypothesis for intervention studies or objective for outbreak reports	Rationale is clear Direction of intervention effect is not explicit in the hypothesis
Methods	3. Clear statement of intervention study design or case definition for outbreak report	Design not explicitly reported. It reports that compliance was monitored monthly for six months following the intervention
	4. Brief description of setting, participants, and intervention or outbreak control measures with start and stop dates	Setting and participants described. Description of the intervention limited. No dates available

	5. Clearly defined outcomes and denominators at regular intervals, not as totals for each phase (can be in results)	Clearly defined outcomes. More details could be added on type of opportunities observed.
	6. Statistical analysis accounts for any dependencies in the data (can be in results instead)	Not accounted for
	7. Which potential biases or confounders were considered, recorded or adjusted for (can be in results instead)	Not considered
	8. Where relevant: details of culture, typing, environmental sampling, and risk factors for acquisition, root cause analysis or organisational risk assessment	Not mentioned
Results	9. For the main outcomes: estimated effect size & its precision (usually using 95% C.I.) (A graphical summary is often appropriate for dependent data -such as most time series).	Proportion compliance reported for period before, and one after the intervention with precision estimates too. Graphical summary available
Conclusions	10. For intervention studies: consider in relation to original hypothesis, accounting for potential confounders & biases. For outbreak reports: consider clinical significance of observations and hypothesis to explain them.	Considered original hypothesis. Not consideration of limitations

3. ENVIRONMENTAL DETERMINANTS REQUIRED TO SUPPORT HAND HYGIENE IN ZANZIBAR MATERNITY UNITS (PHD OBJECTIVE 2)

3.1. Preamble

We conducted a mixed-methods cross-sectional study to assess the enabling factors of key clean practices necessary at birth: clean hands, clean cord cutting and clean delivery surface. This research was developed with the aim of providing the Zanzibar MoH with an in-depth picture of the state of hygiene in maternity wards, so as to inform action. This manuscript aims at describing the context (availability of infrastructure, policies and procedures, training and staffing levels) that should enable the performance of hand hygiene amongst birth attendants for Objective 2 of this PhD. The manuscript is however broader than that and covers the context that enables other clean practices necessary at birth.

I participated in the study design, adapted the tools and planned the data collection for this study prior to the start of the PhD with oversight from Wendy Graham, one of my PhD advisory members and senior author of this manuscript. Even though I participated in conceptualizing the objectives and tool development for the microbiology and qualitative sections of this manuscript, I did not have a leading role in finalising the tools and carrying out the primary analysis of the data that these tools generated. Wendy Graham also secured the funding for this project. The project was a research partnership between the London School of Hygiene and Tropical Medicine, The Soapbox Collaborative, the Public Health Laboratory-Ivo de Carneri Foundation, WaterAid, and the Ministry of Health of Zanzibar. During the PhD I conceptualized the analysis framework, which combines the WHO “clean” framework and the WHO Infection Prevention and Control Core Components. In addition, I analysed the data and wrote the first draft of this manuscript; I also led on the revisions from co-authors and reviewers for publication.

The WHO cleans framework refers a list of important clean birth practices (for example clean hands), which was presented by the World Health Organization (WHO). We investigated four out of the six *cleans*: clean hands, clean cord (clamping and cutting), and a clean birth surface. The clean perineum of the mother at birth was excluded because of the weak evidence base for this clean and the postpartum skincare of the newborn was excluded because we were focused on intrapartum care for data collection.

The manuscript is formatted in accordance with the Health Policy and Planning requirements. As the manuscript is already published, a copy of the PDF version is available in Appendix II (A) (page 271) along with the ethics approvals in Appendix III (page 332).

To add to the already published paper, I provide the following tools: walk-through and semi-structured interviews respectively in Appendices II (B) (page 282) and II (C) (page 304). In addition, the STROBE checklist relevant to this chapter is in Appendix II (D) (page 329).

I presented this work in a poster presentation at the following conferences:

- 6th Infection Control Africa network Congress 2016. 25-28th of September 2016. Johannesburg, South Africa. "Actionable information: unpacking the determinants of hand, cord and birth-surface hygiene in Zanzibar maternity units." Giorgia Gon, Catriona Towriss, Catherine Kahabuka, Said M. Ali, Siti M. Ali, Ali O. Ali, Sue Cavill, Mohammed Dahoma, Haji S. Haji, Ibrahim Kabole, Emma Morrison, Rukaiya M. Said, Amour Tajo, Yael Velleman, Susannah Woodd, Wendy J. Graham
- Fourth global symposium on health system research. 14-18th November 2016. . "Actionable information: unpacking the determinants of hand, cord and birth-surface hygiene in Zanzibar maternity units." Giorgia Gon, Catriona Towriss, Catherine Kahabuka, Said M. Ali, Siti M. Ali, Ali O. Ali, Sue Cavill, Mohammed Dahoma, Haji S. Haji, Ibrahim Kabole, Emma Morrison, Rukaiya M. Said, Amour Tajo, Yael Velleman, Susannah Woodd, Wendy J. Graham

3.2. Cover sheet

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
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E: registry@lshtm.ac.uk

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PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Giorgia Gon
Principal Supervisor	Oona Campbell
Thesis Title	Birth attendants' hands hygiene in maternity wards in low resource settings: levels and drivers

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?	Health Policy and Planning		
When was the work published?	12/07/2017		
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**

**If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.*

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)	During the PhD I conceptualized the analysis framework. In addition, I analyzed the data and wrote the first draft of this manuscript; I also led on the revisions from co-authors and reviewers for publication. Details in chapter's preamble.

Improving health worldwide **www.lshtm.ac.uk**

Student Signature: [redacted] **Date:** 24/10/2018

Supervisor Signature: [redacted] **Date:** 24 Oct 2018

3.3. Copyright agreement

Journal: Health Policy and Planning
DOI: 10.1093/heapol/czx081
Title: Unpacking the enabling factors for hand, cord and birth-surface hygiene in Zanzibar maternity units

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3.4. Manuscript 2 – Unpacking the enabling factors for hand, cord and birth-surface hygiene in Zanzibar maternity units

Gon G[1,2], Ali SM[3], Towriss C[4], Kahabuka C[5], Ali AO[6], Cavill S[7], Dahoma M[6], Faulkner S[8], Haji HS[3], Kabole I[9], Morrison E[2], Said RM[6], Tajo A[3], Velleman Y[10], Woodd SL[1,2], Graham AWJ[1,2].

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6. The Ministry of Health of the Revolutionary Government of Zanzibar, Maternal and Child Health Office, Ministry of Health Zanzibar, PO Box 236, Zanzibar, Tanzania
7. WaterAid, 27 Cranbrook Drive, Maidenhead, Berkshire
8. The University of Sheffield, 2 Sudan Avenue, Brackley, Northamptonshire NN13 6LE, UK
9. WaterAid, PO Box 33579, Dar Es Salaam, Tanzania
10. WaterAid, 47-49 Durham Street, London SE11 5JD, UK

Corresponding author: Giorgia.gon@lshtm.ac.uk

3.4.1. Abstract

Background: Recent national surveys in The United Republic of Tanzania have revealed poor standards of hygiene at birth in facilities. As more women opt for institutional delivery, improving basic hygiene becomes an essential part of preventative strategies for reducing puerperal and newborn sepsis. Our collaborative research in Zanzibar provides an in-depth picture of the state of hygiene on maternity wards to inform action.

Methods: Hygiene was assessed in 2014 across all 37 facilities with a maternity unit in Zanzibar. We used a mixed methods approach, including structured and semi-structured interviews, and environmental microbiology. Data were analysed according to the WHO "cleans" framework, focusing on the fundamental practices for prevention of newborn and maternal sepsis. For each "clean" we explored the following enabling factors: knowledge, infrastructure (including equipment), staffing levels, and policies. Composite indices were constructed for the enabling factors of the "cleans" from the quantitative data: clean hands, cord cutting, and birth surface. Results from the qualitative tools were used to complement this information.

Results: Only 49% of facilities had the *infrastructural* requirements to enable *clean hands,* with the availability of constant running water particularly lacking. Less than half (46%) of facilities met the *knowledge* requirements for ensuring a *clean delivery surface*; 6 out of 7 facilities had birthing surfaces that tested positive for multiple potential pathogens. Almost two thirds of facilities met the *infrastructure (equipment) requirement* for *clean cord*; however, disposable cord clamps being frequently out of stock, often resulted in the use of non-sterile thread made of fabric.

Conclusion: This mixed methods approach, and the analytical framework based on the WHO "cleans" and the enabling factors, yielded practical information of direct relevance to action at local and ministerial levels. The same approach could be applied to collect and analyse data on infection prevention from maternity units in other contexts.

3.4.2. Introduction

Worldwide estimates indicate 2.6 million possible cases of severe bacterial infections among newborns in 2012 across Sub Saharan Africa alone [99]. Additionally, puerperal sepsis is estimated to occur in 4% of live births [100]. Gordon, Semmelweiss, and Wendell-Holmes established the link between puerperal sepsis and poor hygiene at birth over two centuries ago [4,5,101], and it has been estimated that a clean birth in a facility could prevent 38% of newborn tetanus mortality [3].

A list of important clean birth practices (for example clean hands), was presented by the World Health Organization (WHO) in the *cleans* framework [3]. For the clean practices to be carried out, the necessary enabling environment needs to be in place. This falls under the broader umbrella of infection prevention and control practices (IPC). The new WHO guidelines on IPC in facilities identified core components required to improve IPC practices and ultimately reduce healthcare associated infections [102], for example ensuring access to the relevant infrastructure such as safe water and sanitation [10] or sterilization of key equipment.

There are few data on the performance of the clean practices around birth or on the status of the enabling environment necessary for the clean practices, apart from some emerging efforts on water and sanitation, including by the Joint Monitoring Program for Water Supply and Sanitation [103]. The need to develop indicators and to incorporate water and sanitation and hygiene (WASH) in routine health monitoring systems was recently emphasized in the *Call to Action* paper on WASH and maternal and newborn health and the WHO report on the issue [104,105].

We have two aims in this paper. The first is to illustrate how the WHO cleans framework and a framework of enabling factors from the WHO IPC guidelines were used to produce actionable information to enable the Zanzibar Ministry of Health (MoH) to identify priorities to improve hygiene in their maternity units. The second is to present the main assessment findings, which examined the enabling factors of key *clean* practices, including hands, cord and birth surface hygiene, in maternity units in Zanzibar. The data were collected during an assessment across maternity units in Zanzibar, commissioned by the MoH in 2013 to inform a quality improvement process for maternity wards.

The Revolutionary Government of Zanzibar is a semi-autonomous region of Tanzania; it is home to a population of about 1.3 million people spread over two main and several small islands, and has an independent MoH. As in mainland Tanzania, only 50% of births in Zanzibar occur in facilities, and great efforts in the last decade have reduced the maternal mortality ratio from 473 per 100 000 live births in 2006 to a ratio of 310 in 2013 [106]. A modest increase in facility births in Tanzania, from 43.5% to 50.1%, between 1999 and 2010,[71], along with the aim of the government to encourage all women to deliver in facilities, emphasizes the importance of making hygiene in maternity units a priority, and the opportunity this provides to prevent infections. Recent publications highlight the poor WASH environment where women give birth in The United Republic of Tanzania, both in facilities and at home [107,108]. Only 24% of delivery rooms have basic improved water and sanitation standards across a representative sample of facilities in Tanzania [108].

3.4.3. Methods

Our first aim was to produce actionable information, meaning information that a) is organized by the WHO *clean* practices necessary to reduce maternal and newborn infection acquired at the time of delivery; b) clearly identifies the behavioural factors from the WHO IPC guidelines that enable these clean practices and that can be addressed through MoH interventions; and c) allows the root causes of the IPC gaps to be identified, using a mixed methods approach. We investigated four out of the six *cleans*: clean hands, clean cord (clamping and cutting), and a clean birth surface. The clean perineum of the mother at birth was excluded because of the weak evidence base for this clean [3] and the postpartum skincare of the newborn was excluded because we were focused on intrapartum care for data collection

The WHO IPC guidelines for facilities identified eight core components.[102] We collected data in Zanzibar that allowed us to investigate four of these components that we refer to as behavioural factors in relation each of the four cleans we chose to investigate.

These enabling factors and their definition in this paper are:

1. Knowledge & training (from WHO core component number 3) – what it is necessary to know to practice relevant IPC behaviour, including awareness of key practices and levels of training.

2. Infrastructure (from WHO core component number 8) – the availability, access and maintenance of the infrastructure (e.g. water supply) and equipment required to perform the cleans.
3. Staffing levels (from WHO core component number 7) – the presence of an adequate number of staff responsible for the relevant clean practice; health orderlies to clean the delivery surface; and skilled birth attendants (SBAs) for performing clean hands and clean cord. If no SBA is present, it is possible that the delivery will be carried out by an unqualified member of staff without any formal training on these cleans. In Zanzibar, the following cadres, who have between 2 and 8 years of professional training, are considered qualified to assist a birth: Nurse midwife, Public Health Nurse B, Maternal and Child Health Aid, Clinical officers, Assistant Medical Officers, Medical officers, and Obstetricians.
4. Policies (from WHO core component number 2) – whether there are existing policies, guidelines or other indications (e.g. through posters) to prescribe the clean practice of interest. Information on policies was collected for all cleans except cord care.

Data collection tools using a mixed methods approach

Three tool sets were used during the assessment: 1) a structured facility questionnaire, administered to the maternity in-charge or equivalent at the time of the interview in all facilities providing delivery services (N=37), 2) a *walkthrough* tool set (described below), and 3) semi-structured interviews conducted in a purposively selected sample of facilities in Zanzibar (N=7). The seven facilities were selected by the Zanzibar MoH to represent the variation in facility type, volume of deliveries, location and levels of service quality. The tools described below were based on the WASH & CLEAN toolkit, adapted with the collaboration of key MoH stakeholders and administered in Swahili. The toolkit, previously used in India, Bangladesh and the Gambia, was developed by the Soapbox Collaborative from existing tools from international organizations to assess IPC on maternity units and is publically available online [80]. The facility questionnaire was initially piloted in five facilities, and the walkthrough tools and the semi-structured interviews were piloted in four.

The tools were administered between 19 May and 10 September 2014. We conducted 26 semi-structured interviews with healthcare staff including in-charges (7), care providers in the maternity (7), orderlies (7) and maintenance staff (5) present in the facility at the time of the visit. One member per cadre per facility was invited to be interviewed. Staff selection was based on who was available at the time. The facility questionnaire and the semi-structured interviews focused on guidelines, training and infrastructure for IPC, WASH and solid waste management; barriers to maintaining good practice; and the actions needed to overcome them. Qualitative interviews were also conducted with 20 women attending vaccination services for their newborns at the seven facilities, who had delivered within the past eight weeks. The team aimed to interview a minimum of two women at each facility visited; one who delivered at the facility under assessment and one who delivered at home but who was living around the facility catchment area. The first woman presenting in the relevant facilities during the assessment period who consented to participate in the study was interviewed. These interviews sought to capture women's perception of an appropriate delivery environment, and their experiences during their most recent childbirth, particularly in relation to hygiene at the delivery unit. Interviews were conducted in Swahili and were tape recorded.

Two types of data were collected with the walkthrough tool set: a) observations recorded in the walkthrough checklist, noting the availability and conditions of specific areas and equipment (e.g. labour ward room, toilets and cleaning equipment); and b) microbiological samples taken using swabs of high-risk hand touch sites such as bedside lockers, delivery beds, cleaning equipment, and of water used for hand washing in the maternity unit. See Supplementary File 1 for more details on the water sampling and microbiological swabs.

Constructing indices for the enabling factors of the four cleans

For each *clean* we built a composite index, using the facility questionnaire data (N=37), that aimed to be represent each of the four enabling factors investigated: *knowledge & training*, *infrastructure, staffing levels* and *policies.* The choice of index components was informed by published IPC international guidelines for each topic [105,109,110]. This allowed us to standardise the analysis of the *cleans'* enabling factors with relevant data from the facility questionnaire.

Table 3.1 describes the information used to build these indices. For the *knowledge & training* index, we used questions that explored the topics discussed during IPC training received in the past year and questions around maternal and newborn care practices. With regards to the latter, interviewees were asked about their care practices but discussion with our data collectors led us to believe that their answers reflect knowledge of expected practices rather than actual staff behaviour and thus are best considered a proxy for knowledge. We aimed to interview the maternity in-charge or equivalent in each facility; this information therefore represents their knowledge. For the *infrastructure* index, we used questions on the availability of, and access to key infrastructure and equipment in the maternity unit.

Table 3.1 – Indices' components by clean and for each enabling factor

Enabling factor	Clean hands	Clean cord	Clean birthing surface
Knowledge & training	Wash hands during the WHO key moments of hand hygiene (no data on hand washing before aseptic procedures, so this was not included)	Frequency of use of sterile clamps or ties	Delivery room cleaned at least once a day
	AND	AND	AND
	Training on hand hygiene received in the last year	Training on infection prevention and control received in the last year	Training for non-medical staff received in the last year
Infrastructure	a) Soap available in the maternity unit	a) Disposable or sterile clamps available in the maternity unit	a) Bleach or bleaching powder currently available
	AND	AND	AND
	b) Disposable gloves available in the maternity unit	b) Disposable or sterile blades available in the maternity unit	b) Delivery bed available and functional
	AND	AND	AND
	c) Water is improved and available (24h availability, AND functional sink AND available AND piped water supply is not interrupted more than once a week)	c) If reusable equipment is used, any sterilization method (i.e. products for High-level Chemical Disinfection, autoclaves, autoclave, dry heat sterilizer or boilers) available and functional	c) Water is improved and available (24h availability, AND functional sink AND available AND piped water supply is not interrupted more than once a week)
Staffing levels	At least one SBA present during the morning and night shift prior to the survey	At least one SBA present during the morning and night shift prior to the survey	At least one orderly present during the morning shift prior to the survey
Policies or posters on	Hand washing	*Not applicable as we did not collect this information*	Decontamination of areas contaminated with body fluids

For the *policies* determinant, we present data on whether policies or posters of key protocols i.e. IPC, hand hygiene and decontamination of areas soiled by blood and other body fluids were available in the maternity unit. For *human resources*, at least one skilled SBA should be present in the maternity during the morning and night shifts;

this ensures that someone formally trained in IPC is available on site capable of cleaning their hands adequately at appropriate times and capable of performing clean cord care. Since it was unusual in Zanzibar, especially in small facilities, that orderlies were allocated to night shifts, for clean birth surface the variable we referred to was whether an orderly was present on the previous morning shift.

The indices were all binary, with facilities either meeting all the conditions prescribed by the index or not. Similar composite indices have been used previously to describe key markers of the quality of maternal healthcare facilities [73,111]. The key assumption was that the components chosen to construct the indices were fundamental for performing the *cleans*.

Analysis

The variety of tools used produced quantitative, qualitative and microbiological data. Results from all three tool sets were organised thematically using the frameworks discussed: the WHO cleans and the enabling factors.

The water analysis, using conventional pour plate and membrane filtration techniques, focused on the total bacterial count in the water samples, as well as looking at the presence of *Enterococcus* and fecal coliforms – standard indicators for assessing water quality [112]. Swabs collected from surfaces were directly inoculated onto selective media and screened using standard biochemical techniques to identify and characterize potential pathogens. The analysis of the microbiology swab data focused first on whether *Staphylococcus aureus* (*S. aureus*), one of the most common pathogens linked to healthcare associated infections [7], was present at the touch site. Opportunistic pathogens such as *S. aureus* are frequently shed by patients and staff in healthcare environments and can persist on surfaces for months on dry surfaces, posing a significant transmission risk to new patients admitted to the facility – thus, we used this as an indicator for cleanliness [113]. The second indicator examined was whether multiple pathogenic organisms were identified on the touch site. Two or more such pathogens found on a hand touch site indicate a lack of effective cleaning or long durations between cleans. For more details see Supplementary File 1.

We began our analysis of the qualitative materials with word-for-word transcriptions of the audio files in their original language. Transcripts were later translated into English and analysed manually using a qualitative *content analysis* method to extract manifest and latent content from the interviews [114]. We used an inductive process for analysis whereby all codes and themes were derived from data. No software was used, a research assistant coded the data manually and the senior qualitative researcher reviewed the codes to check their quality (all codes are available on request).

Using facility questionnaire responses, indices representing each of the four enabling factors were constructed for each *clean* and described by facility type. In our dataset, we distinguished between three types of facilities: with an operating theatre or without, and those which the MoH had not deemed appropriate to perform deliveries because they lacked key equipment and infrastructure. Since facility questionnaire data came from all facilities providing maternity services in Zanzibar, no survey weights were applied. The walkthrough checklist data produced counts of the infrastructure and equipment available, cleaned, and according to state of repair. Data were double entered into EpiData v3.1 and analysed using STATA v13 SE.

Ethics approval and consent to participate

We obtained ethical approval from the Zanzibar Medical Research and Ethics Committee and the Observational/Interventions Research Ethics Committee at the London School of Hygiene and Tropical Medicine for this study. The women interviewed gave their individual consent, while the MoH granted permission to interview healthcare staff, and collect and analyze microbiology samples in the facilities.

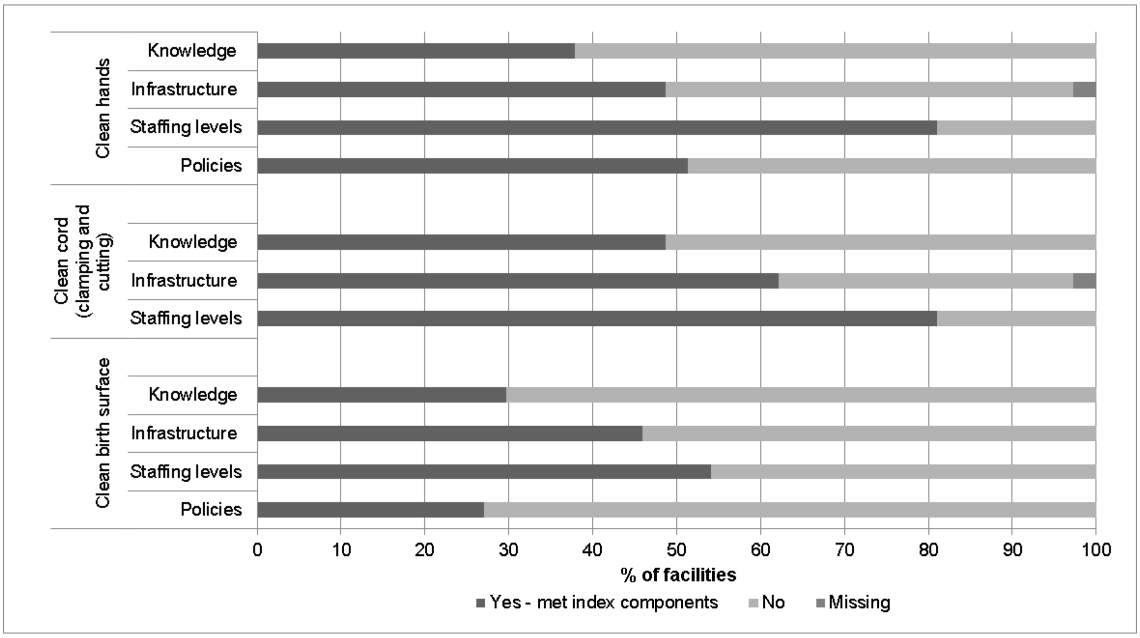
<u>Women who gave birth recently</u> - Respondents were informed about the purpose of the survey before the start of the interview, informed that their participation was voluntary, and that all information provided was confidential and would be de-identified. The respondent's consent, if obtained, was in written form.

<u>Facility data</u> - Prior to commencing the facilities questionnaire, an official letter was sent by the MoH to all facilities to inform them of the study aims and that the information collected might be used by the MoH or other organisations seeking to improve the planning and delivery of health services, and that the identity of the facility would be anonymised. For each of the seven facilities selected for the semi-structured interviews and the walkthrough this information was also provided in person by the enumerator to the facility in-charge, the maternity in-charge and the orderlies in-charge.

3.4.4. Results

Of the 37 facilities providing childbirth services in Zanzibar, eight had an operating theatre, 24 did not, and five were considered by the MoH to be too poorly equipped to perform deliveries because of lack of water and delivery equipment. 84% of facility births across the 37 facilities surveyed took place at one of the eight facilities with an operating theatre (data not shown). The enabling factors' indices for each of the *cleans* were met by only 50% or fewer of the 37 facilities, with two exceptions: the infrastructure index for clean cord and the proportion of facilities with an SBA present in the morning and night shift before the survey, as described further below (Figure 3.1).

Figure 3.1 – Percentage of facilities meeting all components per enabling factor index by clean (Knowledge stands for knowledge and training)



Clean hands

Coverage of knowledge & training around clean hands was 38%, with 14 facilities out of the total of 37 meeting all the knowledge & training conditions (Table 3.2 and Figure 3.1). The weakest knowledge & training index component was knowledge around when to wash hands and, in particular, many respondents did not know they were supposed to wash hands "after touching the environment around the patient." In 70% of facilities, staff reported having had training on hand hygiene, and this was confirmed by the qualitative interviews. Almost all care providers with which we conducted qualitative interviews could explain the hand hygiene process correctly (N=26).

Table 3.2 – Proportion* of facilities meeting the enabling factors' indices by clean and facility type (data source: facility questionnaire)

Variable	Facilities with an operating theatre N=8 n (%)	Facilities without an operating theatre N=24 n (%)	Facilities deemed inappropriate for deliveries N=5 n (%)	Total facilities N=37 n (%)
Clean hands				
Knowledge & Training				
Yes	4 (50)	9 (38)	1 (20)	14 (38)
No	4 (50)	15 (63)	4 (80)	23 (62)
Missing	0	0	0	0
Infrastructure				
Yes	7 (88)	9 (38)	2 (40)	18 (49)
No	1 (12)	15 (63)	2 (40)	18 (49)
Missing	0	0	1 (20)	1 (3)
Staffing levels				
Yes	8 (100)	21 (88)	1 (20)	30 (81)
No	0	3 (13)	4 (80)	7 (19)
Missing	0	0	0	0
Policies				
Yes	6 (75)	12 (50)	1 (20)	19 (51)
No	2 (25)	12 (50)	4 (80)	18 (49)
Missing	0	0	0	0
Clean cord				
Knowledge & Training				
Yes	6 (75)	11 (46)	1 (20)	18 (49)
No	2 (25)	13 (54)	4 (80)	19 (51)
Missing	0	0	0	0
Infrastructure				
Yes	6 (75)	14 (58)	3 (60)	23 (62)
No	2 (25)	10 (42)	1 (20)	13 (35)
Missing	0	0	1 (20)	1 (3)
Staffing levels				
Yes	8 (100)	21 (88)	1 (20)	30 (81)
No	0	3 (13)	4 (80)	7 (19)
Missing	0	0	0	0
Clean birth surface				
Knowledge & Training				
Yes	5 (63)	4 (17)	2 (40)	11 (30)
No	3 (38)	20 (83)	3 (60)	26 (70)
Missing	0	0	0	0
Infrastructure				
Yes	6 (75)	9 (38)	2 (40)	17 (46)
No	2 (25)	15 (63)	3 (60)	20 (54)
Missing	0	0	0	0
Staffing levels				
Yes	8 (100)	11 (46)	1 (20)	20 (54)
No	0	13 (54)	4 (80)	17 (46)
Missing	0	0	0	0
Policies				
Yes	5 (63)	5 (21)	0	10 (27)

	No	3 (38)	19 (79)	5 (100)	27 (73)
	Missing	*0*	*0*	*0*	*0*

* The proportion was approximated to the nearest decimal; hence, variables options might not add up

The facility questionnaire (N=37) showed 18 facilities (49%) met all the infrastructure conditions for hand washing (Table 3.2 and Figure 3.1). The availability of a functional sink (i.e. a sink which can accommodate running water flowing from a tap) and whether running water is available 24 hours a day were the main gaps in facilities' hand washing infrastructure. Of the 22 hand-washing stations (including buckets and sinks) across 7 facilities surveyed in the walkthrough checklist, 15 had water available. When water was not available, facilities use stored water. Due to logistical difficulties in accessing the storage containers, we were only able to take samples from two water storage containers at two of the 7 facilities: a plastic bucket and a larger plastic container. Both showed high levels of contamination; their total bacterial count was over 300 CFU/ml, and one sample had a high presence of *enterococcus* (100 CFU/ml). We also took samples from water sources routinely used for hand washing, and 21% of these (N=102) had a total bacterial count of over 100 CUF/ml (See details on the water analysis results in Supplementary File 1). Indeed, 73% of the facilities surveyed reported water testing is never done in the facility, and the rest did not know this information.

The qualitative interview analysis (N=26) emphasized that water availability was a major challenge. A common substitute for the lack of piped water was to store water in buckets. At two facilities out of seven, staff reported having to carry water in buckets from water storage tanks outside the facility, due to blockages in pipes. Maintaining a sufficient water supply was an issue, particularly at night when institutional availability of water is less reliable and those in charge of maintenance are not on shift.

In 12% of the facilities without an operating theatre (N=24), there was no SBA during the morning and night shift prior to the survey (Table 3.2); whereas, all facilities with an operating theatre had at least one SBA present. Staffing shortages and high caseloads were frequently mentioned during qualitative interviews as reasons for poor IPC.

The facility questionnaire (N=37) data showed that policies or posters about hand washing were available in 51% of facilities (Table 3.2); this proportion was 75% for facilities with an operating theatre. The walkthrough revealed that only three of the seven maternity wards observed had a poster on hand hygiene displayed in the maternity area.

Clean cord

From the facility questionnaire (N=37), 18 facilities (49%) met the knowledge & training conditions and 23 facilities (62%) met the basic infrastructure conditions for a clean cord (Figure 3.1). All facilities reported routinely using disposable blades and cord clamps, but these were not always available; 89% of facilities had sterile blades available, but only 68% had both sterile cord clamps and sterile blades (data not shown). One facility reported commonly using reusable cord clamps but also reported having no functioning sterilization or high level disinfection equipment.

Walkthrough data showed similar results: all seven facilities had access to either reusable or disposable cord cutting equipment. The walkthrough supplemented the questionnaire findings by showing whether equipment for cord care was decontaminated (if reusable) and stored safely. Similar to the facility questionnaire results, access to cord clamps was lower than for blades. Qualitative interviewees at five of the seven facilities reported creating self-made cord ties from the rim of sterile gloves or pieces of string, ideally soaked in alcohol solution. Potential failure in carrying out this procedure makes strings less safe and practical than disposable sterile clamps.

The staffing levels for clean cord care were measured in the same way as for clean hands as reported above. We did not collect specific information on policies around clean cord.

Clean birth surface

All the basic conditions for knowledge and training index around a clean birth surface were met by 11 out of 37 facilities (30%) (Table 3.2 and Figure 3.1). A weak component of index was the lack of training for non-medical staff, including orderlies, who are responsible for cleaning the bed surface.

The walkthrough checklist results confirm these findings. Microbiological samples revealed that in six of the seven facilities where swabs were taken, the maternity beds were highly contaminated with multiple organisms, especially around the perineal area. Sixty percent of mops and mop bucket swab sites tested positive for multiple microbiological organisms. Multiple organisms were further identified on six out of eight surface cleaning cloths. It was a common finding that most mops were stored inside buckets filled with mopping fluid for most of the day.

The infrastructure index suggests that only 17 out of 37 facilities (46%) met the basic requirements for a clean birth surface (Table 3.2), with the weakest index component being the same as for clean hands: consistent availability of water (Figure 3.1). The facility questionnaire (N=37) found that all but two facilities surveyed had at least one functional delivery bed available (data not shown). The results from the walkthrough checklist found that in both the maternity and delivery rooms, most beds (21/26) across the seven facilities surveyed were covered in cleanable materials and/or a mackintosh (data not shown).

Across all seven facilities where qualitative interviews (N=26) were conducted, staff complained about a shortage of orderlies. In line with these findings, the facility questionnaire (N=37) revealed that only 54% of facilities had an orderly present in the maternity unit on the morning before the survey (Table 3.2). The shortage of orderlies was further aggravated by the fact that most of the orderlies interviewed also performed healthcare related tasks such as antenatal care, wound dressing, prescribing medications and assisting deliveries, which significantly reduced the time they spent on cleaning activities.

Of the facilities without an operating theatre, only 21% had policies or posters on the decontamination of areas contaminated with body fluids (Table 3.2). The proportion was higher for those facilities with an operating theatre, 63%.

3.4.5. Discussion

We provided an illustrative analysis of IPC information collected in maternity units in a low-income country to assist in developing a quality improvement strategy both at the local facility and the MoH levels. Our results are actionable for three main reasons: the use of a clear framework, the WHO IPC guidelines, made up of four enabling factors amenable to change; the use of mixed methods to unpack the complex picture behind the infection prevention gaps; and the focus on and relevance to the key interventions necessary to reduce maternal and newborn infection embedded in the WHO clean practices: making sure that during labour and delivery the hands of the birth attendants, the birth surface and the cord clamping and cutting are all clean.

Using the WHO IPC guidelines framework we could organise our results so that the MoH could identify the weakest enabling factors of the necessary clean practices and the type of intervention needed –e.g. infrastructure vs. training. For example: the weakest index component for clean birth surface was the knowledge of health orderlies and their lack of training on decontamination of areas exposed to body fluids. The theme of knowledge in itself helped narrow down the potential for action to an educational intervention involving specific roles in the MoH, such as district level supervisors and the local institute for nursing training.

To produce data on IPC gaps that can be actioned by the Ministry of Health required a mixed-methods approach to data collection and analysis. Our mixed methods approach provided a comprehensive and useful description of key enabling factors of the relevant clean practices in maternity units, with different methods suited to different items of information. For example, the facility questionnaire revealed that water is often unavailable on the labour ward. With this information alone we did not know whether delivery was practiced in the absence of running water or how the problem was overcome. Through semi-structured interviews, we learned that staff perform deliveries without running water, and that standing water buckets are used as an alternative to non-functioning sinks. Although very limited in number, the standing water buckets we sampled were highly contaminated; as found elsewhere, inappropriate water storage leads to contamination [115,116]. The triangulation of data strengthened our conclusions, and avoided some of the assumptions inherent in the interpretation quantitative results. The mixed methods approach allowed us to understand the complex picture behind the IPC weaknesses we found and to provide potential intervention targets to the ministerial audience.

Our approach to producing actionable information is unable to recommend which of the enabling factors will have a sustainable and wider benefit; indeed, it probably draws attention towards shorter-term solutions such as infrastructure and training that are quick wins for any MoH, compared to longer-term structural changes. Yet, our approach still highlights these wider structural gaps – such as the lack of sufficient staff and policy gaps.

Although no agreed definition for *actionable information* exists in global health, other research using this terminology refers to information presented in a way that makes evidence-based programming more accessible, using for example the visual display of data [117]. This was also our intent and fits into the current wider attempt in public health to ensure that evidence feeds into action by using condition specific frameworks and platforms [118,119]. Using a clear and simple approach to identify actionable information was an important ingredient for the project's endorsement and support from the MoH; yet translating that information into action would not have been possible without a participatory workshop that included all key stakeholders. We describe how we engaged with the key stakeholders in a participatory workshop and how the information presented was then translated into action in Supplementary File 2.

An important limitation to our actionable information approach is that we looked at proxies of the enabling factors rather than actual practices. Ideally, both should be done, but time and financial limitations meant that we could not observe practices. We would also have liked to explore more enabling factors, but the type of data we collected did not permit this. In particular, the tools we used did not collect information on social norms and individuals' motivation – key areas for explaining behaviour [66].

The results show that overall facilities' performance across all enabling factors for each of the *cleans* was poor. Each enabling factors' index was met by, at best, half of facilities, apart from two factors met by a higher proportion. However, even these better performing indices are of concern. Only 81% of facilities had SBAs present in the morning and night shift before the survey; a finding supported by the low presence of skilled personnel in maternity wards in Eastern African shown by a recent multi-country study [72]. Indeed, this index should be at 100% as facilities providing maternity care should run with 24h services. In this context, in the absence of an SBA, deliveries are occasionally performed by health orderlies. Across virtually all indices, facilities with an operating theatre performed better, in terms of knowledge, infrastructure, availability of staffing and policies, compared to smaller facilities providing basic obstetric care. This is consistent with other studies showing that larger facilities generally tend to score better in terms of some markers of quality of care [73].

Other key findings included firstly, the substantial lack of a reliable and constant water supply, with half of facilities operating without basic water infrastructure. This is consistent with research on water availability in facilities in low and middle income countries [120] and specifically in maternities in Tanzania [78,108]. A recent review [121] of water quality in LMICs found very few studies based in health facilities, highlighting the importance of our data in this field. They proposed a score to assess the quality of water sampling and analysis. Applying their system, our study met 10 out of 13 quality criteria, which is above the interquartile range of the 319 studies in their review [121].

Another key finding was the poor knowledge & training and practice of health orderlies in cleaning the birth surface – from the walkthrough exercise we found that six of the seven maternity units swabbed had beds with *S. aureus*, representing a lack of effective or frequent cleaning. A very recent study in paediatric wards with poor cleaning practices in South Africa also found *S. aureus* on their surfaces [122]. A study from India which includes the maternity unit environment, found that 10% of patient care equipment was contaminated with some kind of pathogen [123]. In addition, the facility questionnaire reported that 37% of facilities cleaned the delivery room less than once a day on average and their non-medical staff were un-trained. The high levels of pathogens present on the cleaning equipment may explain the high level of microbiological contamination found on the beds. Overall cleaning in healthcare facilities is a poorly-monitored and an under-researched area in spite of being vital to effective IPC and the reduction of healthcare associated infection. Simple solutions like fluorescent gel and UV markers can promote local engagement and training of cleaners [122].

We have confidence in our results given the consistency across the different tools used and because indices were constructed using data from all maternity units across Zanzibar. Moreover, our findings were consistent with the views on the status of IPC in maternities expressed by workshop participants including the MoH. Results of the enabling factors' indices, should, however, be interpreted cautiously, especially for knowledge & training of staff which was based on the response of only one person at each facility. Having said this, as we aimed to interview the maternity in-charge, or equivalent at the time, at each facility, we expect the results are fairly representative of the maternity unit personnel. If anything, our choice of interviewee may overestimate the average knowledge of the personnel in the maternity unit. With regards to the staffing indices, having at least one SBA or health orderly available does not guarantee clean practice – but their presence would increase the likelihood of the 'clean' being performed. As mentioned earlier, in the absence of an SBA, deliveries are occasionally performed by health orderlies with no formal training in delivering a baby including relevant aspects of IPC.

These data may be influenced by observer bias because the data collectors were MoH employees for all tools except the semi-structured interviews. However, two things minimise this issue: first, data collectors were sensitised repeatedly about the fact that data were collected mainly for local improvement purposes and needed to be accurate for this to be possible. In addition, we emphasised that data would be anonymised, so there should be no repercussions for interviewees, facilities, or interviewers. Second, the walkthrough tool set and the semi-structured interviews at each of the seven facilities were closely supervised by an independent senior qualitative scientist. The results from these tools were consistent with the facility questionnaire results, providing further evidence that observer bias might not have influenced our results significantly.

Quantitative analysis of environmental samples was not possible due to limited laboratory capacity, although 30% of the swabs yielded levels of growth too high for quantification. Indeed, this was the first time, the Pemba Health Laboratory carried out environmental sampling and analysis. Not many healthcare laboratories in low-income settings have exposure to environmental sampling and therefore greater advocacy, training and support for laboratories would lead to standardisation of swabbing techniques, sample culturing and reporting.

A further limitation is that information on the availability of electricity which is key to performing a clean delivery, especially at night, was not collected [124]. From the 2014 Service Provision Assessment of healthcare facilities, we know that 77% of facilities have regular electricity in Zanzibar [77]. Other information related to infection prevention during birth was collected, such as on waste disposal, and availability of malaria bed nets, however, this is not presented as it does not directly relate to our outcome framework.

We present a simple approach to analysing IPC data from maternity units to facilitate and prompt action. Using our approach, the Zanzibar MoH was able to readily prioritise and follow-up on the findings presented here by organising for the first time a formal training for health orderlies on cleaning practices, and by improving the infrastructure of sinks in the maternity wards. Observation of the actual clean practices would significantly improve our approach but could be prone to a non-trivial Hawthorne effect. Using this approach in other settings/countries could provide key evidence for governments to improve maternity units, and so contribute to the prevention of newborn and puerperal sepsis.

3.4.6. Declarations

Ethics approval and consent to participate

We obtained ethical approval from the Zanzibar Medical Research and Ethics Committee and the Observational/Interventions Research Ethics Committee at the London School of Hygiene and Tropical Medicine for this study. The women interviewed gave their individual consent, while the MoH granted permission to interview healthcare staff, take pictures and collect and analyze microbiology samples in the facilities.

Women who gave birth recently - Respondents were informed about the purpose of the survey before the start of the interview, informed that their participation was voluntary, and that all information provided was confidential and would be de-identified. The respondent's consent, if obtained, was in written form.

Facilities data - Prior to commencing the facilities questionnaire, an official letter was sent by the MoH to all facilities to inform them of the study aims and that the information collected might be used by the MoH or other organisations seeking to improve the planning and delivery of health services, and that the identity of the facility would be anonymised. This information was also provided in person by the enumerator for each of the seven facilities selected for the semi-structured interviews and the walkthrough. In these cases the enumerators visited the facilities consulting with the in-charge, the maternity in-charge and the orderlies in-charge.

Consent for publication

Not applicable

Availability of data and material

The data that support the findings of this study are kept by the Ministry of Health of Zanzibar but restrictions apply to the availability of these data, which were used under license for the current study, because some of the data may allow to breach anonymity of the facilities and individuals involved and so are not publicly available. Data may be obtained from the authors upon request and with permission of Ministry of Health of Zanzibar.

Competing interests

The authors declare that they have no competing interests

Funding

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WaterAid funded the work of a social scientist and the Soapbox Collaborative funded the epidemiologist to undertake tool adaptation, data collection and analysis.

Authors' contributions

GG analysed the survey data, analysed the data across the different data streams, and drafted the manuscript. SMA managed the fieldwork for this project and the final workshop organization. CT analysed the walkthrough data and CK collected and analysed the qualitative data. GG, CT, CK, SMA, SC, HSH, IK, AT, RS, YV, SW and WJG worked together to conceptualise the paper. All authors read and approved the final manuscript.

Prior publication policy

Results were presented at the Zanzibar Ministry of Health in November 2014. In addition, posters with selected results were presented via mean of a conference poster at the 6th Infection Control Africa Network Congress in September 2016, and at the Global Symposium on Health System Research in Vancouver, November 2016.

3.4.7. Additional Files

Supplementary File 1

<u>Surfaces and water sampling</u>
Trained personnel supervised surface and water sample collection and laboratory technicians at an accredited laboratory analyzed samples according to local standard operating and quality control procedures.

Swab samples from selected surface areas were collected by the data collection team during facility walkthroughs. To take surface swabs the data collection team soaked the tip of a sterile swab with sterile phosphate buffered saline. The selected area was swiped using the dampened swab (for flat surfaces a sterile template –(10x10cm) was used, for irregular surfaces e.g. door handles & taps, the entire surface area was swabbed). Swabs were taken by applying even pressure and rotating the swab for 30 seconds at each selected area. The swabs were transferred aseptically into the transport media and were labelled with the corresponding unique photograph number. Samples were placed in a cool box (at 4 - 8◦C) and transported to the laboratory for analysis.

Water samples (500 ml volumes) were collected from all available water sources (both improved and unimproved) in maternity units for each of the seven facilities, according to standard operating procedures. An assessment was made regarding the environmental condition of each water source (for example, signs of leakage, standard of cleanliness). When samples were collected from a tap; the tap was sanitized with 70% alcohol and water flushed through for 60 seconds prior to sample collection. Samples from water storage containers were collected using sterile cups and then transferred to sterile glass bottles. Water samples were transported to the laboratory within two hours of collection and were stored between 2 °C – 10 °C for the duration. Samples were processed upon arrival at the laboratory. No chemicals were used t to neutralize residual disinfectants potentially present in water samples; 30% of facilities reported that water was untreated and a further 8% of facilities were unaware of treatment.

<u>Microbiological analysis</u>
Water Samples
Using conventional pour plate and membrane filtration techniques, analysis of water samples focused on total bacterial count, and the presence of *Enterococcus* and fecal coliforms respectively, as standard indicators used to assess water quality. Only single

water samples were analyzed – no duplicates were collected. Neither pH, nor turbidity testing was carried out.

Surface Samples

The analysis of the environmental swab data focused on two standard indicators of microbiological cleanliness. First, whether or not the swab site had *Staphylococcus aureus* (*S. aureus*) present. Opportunistic pathogens such as *S. aureus* are frequently shed by patients and staff in health care environments and can persist on surfaces for days, posing a significant transmission risk for new patients admitted to the facility. *Staphylococcus* isolates were presented as either coagulase-positive or coagulase-negative. *S. aureus* is coagulase-positive and is regarded as the most medically significant species of the genus; as such it is one of the most common pathogens linked to healthcare associated infections. We therefore focused on the presence or absence of *S. aureus* as an indicator of cleanliness. At the time of swab collection and analysis, the laboratory lacked the capacity to screen for antibiotic resistance. The second indicator examined was the presence or absence of multiple pathogenic organisms on the swab site. Further to *S. aureus*, each opportunistic pathogen poses a clinical risk, some to a greater extent than others. If two or more such pathogens are found on a hand-touch site it indicates a lack of effective cleaning or long durations between cleans.

Table 3.3 – Water analysis results - frequency of different CFU levels of bacteria, enterococcus and faecal coliform in hand-washing water

	0	1-10	11-100	101-300	300+	TOTAL
B.Count	0	0	13	17	4	34
E	11	10	13	0	0	34
F.C	26	8	0	0	0	34
TOTAL	37	18	26	17	4	102

Supplementary File 2

We describe here how we engaged key stakeholders in a participatory workshop, which enabled us to translate this information into action. The findings were presented on the first day of a three-day participatory workshop held in November 2014 with the MoH and the project partners and relevant stakeholders such as the Zanzibar College of Health Sciences, Jhpiego and the Zanzibar Water Authority. The workshop was used to a) finalise priorities among the findings and b) develop action plans to tackle those agreed priorities. A debrief between the key workshop organisers identified the following key features to be the main reason for the success of the workshop: first, an action-oriented focus was a priority from the beginning of the project. Well established participatory quality improvement exercises were used to prioritise and develop action plans; these were the “fish bone exercise” and “plan, do, study and act” cycles respectively[125,126]. Second, ahead of the workshop, a smaller workshop with a few key stakeholders was held in October 2014, to gather feedback on the way information should be presented to the group. From this initial meeting, it was decided to use pictures, microbiology findings and text as the informational channels. Graphs were not used prominently. Third, a good range of key decision makers at national, district and facility level; and representing both the government and the key partners, were engaged in the process to ensure ownership and collaboration at all levels.

The priorities identified during the workshop were a lack of good practices and training for health orderlies and the limited availability of functional sinks on the maternity units. The workshop participants agreed on the following action plans for 2015-2016:

- **Training for all health orderlies on waste management, cleaning techniques and cleaning and maintaining equipment.** The training curriculum for this was developed by the Zanzibar MoH and 30 orderlies were trained. Currently the training curriculum is being rolled out in Tanzania mainland.
- **Ensure that at least one functional sink is available in each maternity unit.** In collaboration with WaterAid Tanzania, the Zanzibar MoH developed a staggered implementation plan to accomplish this across nine facilities where no functional sink was available.

4. USING TIME-&-MOTION METHODS TO MONITOR COMPLIANCE WITH HAND HYGIENE GUIDELINES AMONG BIRTH ATTENDANTS: EXPERIENCE FROM A LOW RESOURCE SETTING (PHD OBJECTIVE 3)

4.1. Preamble

In light of the poor enabling environment for hand hygiene in Zanzibar in Manuscript 2, we wanted to further investigate the levels of hand hygiene in this context. We used the results of the systematic review described in Manuscript 1 to improve our study design. This paper addresses the feasibility of using time-&-motion methods to monitor hand hygiene, based on our experience in labour wards in Zanzibar, Tanzania. These methods have been rarely used in low-resource settings, or for monitoring hand hygiene behaviour. We developed the HANDS at birth tool to observe the complex patterns of hand hygiene behaviour for Objective 3 of the PhD.

My upgrading examiner and currently one my Advisory members, Robert Aunger, suggested collecting data based on birth attendants' actions rather than using an *a priori* hand hygiene opportunity schema such as the one used by the WHO Observation Form. I conceptualized and designed the *HANDS at birth tool*, as well as led on the various tool revisions. The steps in the development of this tool, as well as who participated in this, are explained in detail in the Manuscript. I piloted the tool, recruited data collectors and trained them, planned and organized data collection with the support of the local principal investigator, Said M. Ali and advice from one my advisory members, Wendy J. Graham. During the data collection, I monitored the data and gave feedback to the data collectors. Finally, I cleaned and analysed the data and structured the manuscript with advice from my supervisors, Oona Campbell and Stephen Nash. I wrote the first version of the manuscript and I was responsible for all the revisions suggested by co-authors. The STROBE checklist relevant to chapter and the following chapter is in Appendix IV (page 335).

The manuscript is formatted in accordance with the Pilot and Feasibility Studies Journal requirements where it has been submitted.

4.2. Cover sheet

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SECTION A – Student Details

Student	Giorgia Gon
Principal Supervisor	Oona Campbell
Thesis Title	Birth attendants' hands hygiene in maternity wards in low resource settings: levels and drivers

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?			
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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Pilot and Feasibility Studies
Please list the paper's authors in the intended authorship order:	Giorgia Gon, Said M. Ali, Robert Aunger, Oona M. Campbell, Mícheál de Barra, Marijn de Bruin4 Mohammed Juma, Stephen Nash, Amour Tajo , Johanna Westbrook, Susannah Woodd, Wendy J. Graham
Stage of publication	**Submitted**

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 conceptualized, designed and piloted the HANDS at birth tool with advice from the co-authors. I analyzed the data with advice from my supervisors. I wrote the first version of the manuscript and led on all the co-authors' revisions. Details in chapter's preamble.

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Student Signature: [redacted] **Date:** 24/10/2018

Supervisor Signature: [redacted] **Date:** 24 Oct 2018

4.3. Manuscript 3 – Using time-&-motion methods to monitor compliance with hand hygiene guidelines among birth attendants: experience from a low resource setting

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4.3.1. Abstract

Background: Birth attendants' hand hygiene during labour and delivery is a key infection prevention opportunity for mothers and newborns. However, there is limited good quality evidence on hand hygiene compliance in low resource labour wards. Time-&-motion methods permit the recording of all healthcare workers' actions without the need for observers to make *a priori* judgements on when a new HH opportunity arises. Therefore, we developed the "HANDS at birth" tool to observe the complex patterns of birth attendants' hand hygiene and its determinants and glove use.

Methods: To develop the tool we used available guidelines, unstructured observation, and iterative refinement based on consultation with collaborators and pilot results. The "HANDS at birth" tool was implemented using the WOMBAT software (Work Observation Method By Activity Timing) that supports the collection of multi-dimensional time-&-motion data. We also describe the tool performance in relation to inter-observer agreement and convergent validity, and the implications of the data structure for data analysis.

Results: Tool elements comprise a list of hand actions, plus context-relevant information. Hand actions were either procedures relevant during labour and delivery; hand hygiene or glove actions; or another type of touch. During the field implementation, the tool was used for continuous observation, wherein the external observer maintains attention on the birth attendant. Inter-observer agreement was good respectively at 0.9 for two data collector pairs, and 0.7 for the third pair. Estimated levels of hand hygiene compliance were similar across observers. Hand hygiene compliance was higher in the presence of water, lower workload and previous training– showing convergent validity.

Conclusions: This is one of very few time-&-motion studies to deploy a computerised system in a low resource health care facilities. Advantages of using time-&-motion methods to capture hand hygiene include simpler training and less observer bias in assessing hand hygiene compliance, and the ability to monitor multiple behaviours. Future studies should explore the use of this tool in labour wards in other contexts.

4.3.2. Background

Multiple methods exist to measure hand hygiene (HH) compliance in healthcare settings, but observation of behaviours is considered to be the gold standard [37]. Observation can be done by an observer or by video recording. A recent validation study suggests that both capture similar numbers of HH opportunities – moments when healthcare workers ought to practice handrub or handwash;[127] however, video recording poses substantial ethical issues, which often make it difficult to use, particularly in a process such as childbirth when women may be vulnerable and undressed.

The World Health Organisation (WHO) HH Observation Form is an excellent, widely-used tool for directly observing.[41] However, due to its aim and scope, it does not allow more complex patterns of behaviour to be captured. For example, it does not distinguish whether the failure to comply is because hand rubbing/washing wasn't attempted or because hands were recontaminated after initial washing.[128] Avoiding hand/glove recontamination is implicit in the WHO tool's HH definition because touching a surface with the risk of germ transmission creates a new HH opportunity. It also does not aim to capture the use or "misuse" of gloves.[129] Finally, it requires the observers to judge when a new HH opportunity arises, thereby reducing the consistency of data collection by multiple observers.

Defining when a new HH opportunity arises is particularly difficult during labour and delivery, where observers must deal with a transition from observing one patient (the mother) to two (mother and newborn), where the amount, type and location of body fluids can rapidly change, and where, in the context of low resource settings, one healthcare worker may attend many mothers simultaneously. With often an unpredictable duration phases during labour, the time between hand rubbing/washing and delivery of the newborn may be lengthy, during which the observer needs to pay close attention to assess if any actions occur that lead to a new HH opportunity. Time-&-motion methods can overcome some of these challenges. These methods are now at the forefront of healthcare observation[47] and are increasingly used, but seldom in LMICs. Observers are able to record all healthcare workers' actions without having to decide which comprise a new HH opportunity. Instead, this is defined during data analysis.

The HANDS study (Hand-hygiene of Attendants for Newborn Deliveries and Survival) was a mixed-methods research project conducted in the 10 highest volume maternity wards in Zanzibar between November 2015 and April 2017.[128] The aim was to explore compliance to HH guidelines and identify factors that explain compliance. Hand hygiene during labour and delivery is a key infection prevention opportunity for mothers and newborns;[3,4] however, there is limited good quality evidence on HH compliance from low resource labour wards.[89,91,93,94,130] Therefore, we developed the *HANDS at birth* tool to observe the complex patterns of birth attendants' HH and glove use at three levels: (i) the opportunity, (ii) the individual and (iii) the facility, using a time-&-motion design. WOMBAT,[131,132] a software package that allows the collection of multi-dimensional work tasks, was used to develop and collect data with the *HANDS at birth* tool. This is one of the few time-&-motion studies of healthcare workers, conducted using a software that automatically records time, to be carried out in a low resource setting.[133,134]

This manuscript is aimed at researchers and practitioners who want to measure the compliance to HH guidelines thoroughly during labour and delivery, particularly in low resource settings. It 1) explains how we designed the data collection tool, 2) describes the tool format and its elements, 3) characterizes its implementation components, 4) investigates the tool's performance, and 5) outlines the implications for data analysis.

4.3.3. Methods and Results

Development methodology

We developed the *HANDS at birth* data collection tool between March and October 2016 using an existing systematic process for tool development[94]. This included use of available guidelines, unstructured observation, and iterative refinement based on consultation with collaborators and pilot results.

<u>Guidelines' review & semi-structured observation</u>

We consulted the World Health Organisation (WHO) Hand Hygiene Technical Reference Manual, and the WHO guidelines on Pregnancy and Childbirth and on Hand Hygiene in Outpatient and Home-based Care and Long-term Care Facilities.[23,36,41] We also conducted eleven semi-structured observation sessions in four labour wards in Zanzibar during which either a delivery or a vaginal examination occurred. All birth attendants' actions were recorded, together with the time at which they happened, and their location. Using this information, we created a list of procedures (what we also call 'key attendant-patient interactions') relevant to labour and delivery and other hand actions that can occur before and after each of these procedures.

Iterative Collaborator consultation

The project was conducted as a partnership between the Public Health Laboratory-Ivo de Carneri, the University of Aberdeen, the London School of Hygiene and Tropical Medicine and the Ministry of Health (MoH) of Zanzibar; we sought feedback on the tool from all project members. Additionally, a three-hour in-depth consultation was carried out with two clinically trained members of the team (one General Practitioner and one midwife) who provided additional feedback.

A three-step pilot & training

We conducted three two-day pilots. Two data collectors conducted the first pilot in a labour ward on Pemba Island, Zanzibar in June 2016 using a very early version of the *HANDS at birth* tool. One data collector conducted the second pilot in August 2016 in a labour ward in London using the tool, incorporated into WOMBAT v2 software on a tablet. Finally, one data collector conducted the third pilot in September 2016 in the same facility on Pemba Island using the tool with WOMBAT. Feedback was collected and incorporated to improve the tool at each stage.

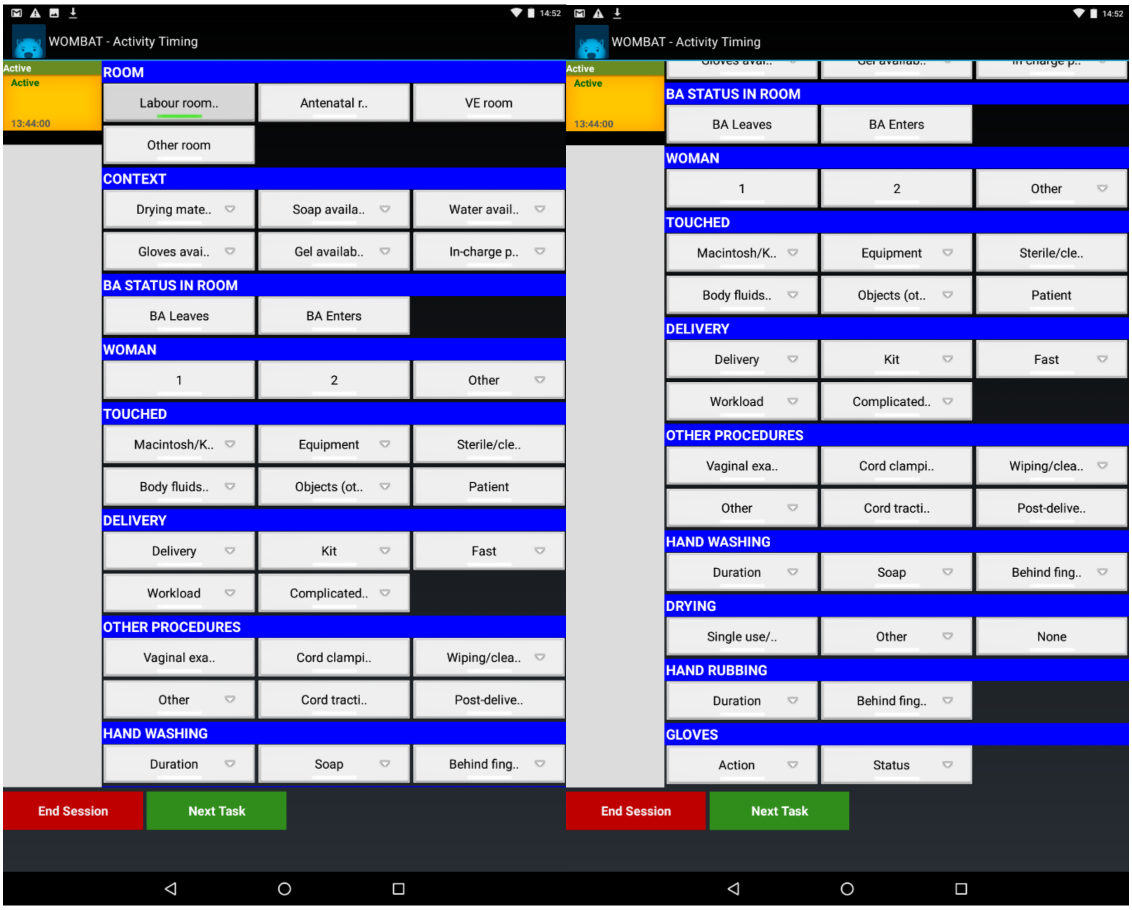
Training the observers to use the tool took three days in the classroom using role-play (e.g., staged observation) and presentations. Each observer also practiced with the tool in the labour ward for three hours under supervision by the trainer (GG). The trainer also carried out two hours of observation simultaneously with each observer and provided relevant feedback. During training minor refinements were made to the tool.

Tool format and elements

Following Lopetegui and colleagues' classification,[47] our type of time-&-motion study uses continuous observation, where the external observer maintains attention on one subject: in our case, the birth attendant. When a subject performs an action, this triggers the observer to record the action. Continuous observation was chosen because timing of procedures, in particular delivery itself, is unpredictable, and using alternative methods, such as short observation sessions at fixed or random intervals, could have missed many HH opportunities. Hence, observers were asked to remain in the labour room the whole of their allocated shift (about 7 hours for morning/afternoon shifts, and 10 hours for night shifts) and to start recording observations whenever a patient-attendant interaction began.

The tool, available in Additional File 1, includes a list of hand actions, and context relevant information (see Figure 4.1). The hand actions listed were exhaustive (meaning that the list did not leave any possible actions out) and mutually exclusive (meaning that no two actions could occur simultaneously as these are hand actions). We did not design a tool that aimed to capture multi-tasking or interruptions because we did not want to add to the burden on the observers.

Figure 4.1– HANDS at birth tool as it appears on the tablet during data collection



Note: Image on the left is the first page you see when logging into the tool. When you scroll down the page you can see the remaining categories (in the right hand image): “drying”, “handrubbing”, and “gloves”. BA refers to Birth Attendant. Full tool content is in Additional File 1.

Hand actions were either procedures relevant during labour and delivery (e.g. vaginal examination; see Table 4.1), HH or glove actions, or other types of touches (e.g. touching a pen or equipment). Observers recorded when an attendant left the room where observation was being undertaken (when observation was suspended) and when the attendant re-entered.

The tool also captured information on the context, such as availability of key infrastructure/ staffing (e.g. water or the presence of the nurse in-charge) and which woman was being attended (first, second, third etc. since the beginning of the observation session). This allowed us to assess whether birth attendants performed HH between patients. Observers entered this context-related information at the beginning of the observation session and updated it only if the situation changed. Many of the recorded actions required further details to be entered. For example, when a delivery was observed, the observer also recorded whether the delivery occurred rapidly (within five minutes of the woman walking into the labour room), whether there were complications, whether the observer birth attendant had an assistant, and whether a pre-made delivery kit was used. The observers collected contextual information and details of certain actions as we intended to use these as potential determinants of HH in the analysis.

Table 4.1– Relevant procedures during birth

1. Measuring vital signs
2. Wiping the vagina
3. Vaginal examination
4. Artificial rupture of membranes
5. Episiotomy
6. Catching the baby (delivery)
7. Cord cutting and clamping
8. Cord traction
9. Post-delivery examination of the vagina
10. Wiping the baby clean after birth
11. Supporting breastfeeding
12. Manual removal of placenta
13. Suturing
14. Suctioning baby's nose/mouth
15. Using bag and mask on the baby
16. Catheter's insertion or removal
17. Insertion or removal of IV lines
18. Adjusting IV fluids or changing IV bag

Tool implementation

The following section characterises how we used the tool to collect data and provides considerations for using it in future studies. We used the guidance provided by Zheng et al.[135] for reporting time-&-motion studies, and include their full STAMP checklist information in Additional File 2.

<u>Sample size calculations</u>
The data collection timeframe was based on the expected number of deliveries in the targeted facilities. We estimated the latter using the formula for estimating a proportion from a cross-sectional survey with α =0.05 and 80% power. We used a design effect (DEFF) of 2 based on a survey by Rowe et al.[136]. To estimate a hand rubbing/washing

compliance of 10% with an absolute precision of +/– 3%, we needed 768 HH opportunities. We estimated the length of observation needed to collect this number, and in practice these data were collected during 336 observation sessions ranging from 13 minutes to 6 hours 45 minutes, with a median time of 1 hour and 41 minutes.[128] As described in Gon et al 2018[128] we collected information on 876 HH opportunities before aseptic procedures (*before aseptic procedures* is one of the five types of hand hygiene opportunity prescribed by the WHO[41]).

Planning and logistics of data collection

To obtain representative data on deliveries across all shifts (morning, afternoon and night); three observers, one per shift, conducted observations that covered 24h a day. They observed for a total of 130 hours in the morning, 153 hours in the afternoon and 205 hours in the night. Each observer had their own tablet for data collection. Each facility was visited for a mode of six consecutive days (range: 5-14 days) between the 17th of September and 31st of December 2016. The order in which we visited the facilities was chosen based on logistics considerations. We arranged for additional days of observation in one facility with a high volume of staff to allow all staff to be observed and in three facilities with low volume of deliveries to capture a sufficient number of procedures.

We consulted the ward rosters to allocate individual attendants to the observers. Each attendant had a unique identifier that the observer had to record in WOMBAT when observing them. Observers were allocated to shifts based on the following principles: a) the same observer should observe the same attendant so that she gets accustomed to the same person being on the ward; b) the initial attendant/observer pairs at each facility were assigned at random (unless specific concerns were raised – for example, some flexibility on choice of types of shifts was allowed to cater for observers' needs); c) ideally observation days should be planned during changes in shift pattern, to allow observation of the same attendants working on different types of shifts. The need to observe the same attendant across different shifts using the same observer increased the fieldwork duration and therefore had to be counter-balanced by the need to remain within our budget.

The observers

Observers were all trained nurse-midwives working in managerial roles. Two of them worked in the study facilities but not in the labour wards. The third observer worked in district level management. Their previous knowledge and understanding of the labour process was vital to the success of our project.

Study participants
All birth attendants present during the observation period who were involved in the childbirth procedures outlined in Table 4.1, were eligible for observation. We observed a total of 104 birth attendants across the 10 facilities. Each attendant was observed between one to nine observation sessions.[128] In each observation session they observed only one attendant, but during the session attendants could care for multiple women and carry out many procedures. Attendants in our study were all women, 90% were professionally trained, and 10% were health orderlies/non-professionals.
The attendants' responsibilities were usually allocated during the shift itself. We encouraged observers to listen at staff meetings to learn which attendant was most likely to perform the childbirth procedures outlined in Table 4.1 to decide whom to spend time observing. Observers were instructed to observe each allocated birth attendant roughly equally in each facility.

How to observe
We trained the observers to enter only one action at a time to facilitate the data input process. We were specifically interested in the attendants' actions; the sequence of these actions and the length of time between them; rather than the duration of each action per se. An action was selected and entered immediately – we do not have details on when the action ended; but since the actions are mutually exclusive we know when an action replaced another one.

When to observe
As described above, the start of data entry was triggered by a relevant patient-attendant interaction (Table 4.1); it was expected that observers would be continuously present in the ward due to the unpredictable nature of birth. Observers were encouraged to take breaks when there were no women in labour or with women very early stages of labour, and to have their break in locations where they could see if an emergency admission occurred to avoid missing delivery events. We also encouraged breaks if the observer's concentration level was low.

We instructed observers to end a session when a major procedure ended and no further patient activities were in sight, when the observer wanted to take a break, when there was the opportunity to start observing another birth attendant (whom so far was observed for less time), or when the birth attendants would leave the room to perform duties elsewhere.

Where to observe
Observers would usually sit in the labour room. If no deliveries were happening, we asked observers to observe vaginal examinations in other rooms, such as the antenatal ward or examination room.

Consent
Written consent was gathered from women in the antenatal ward prior to observation; alternatively women were asked for verbal consent once in the labour ward and followed up for written consent in the postnatal ward before discharge.[128] Women were told no demographic information was collected on them and the only recorded observations were regarding birth attendants' behaviour. Permission to observe the attendants was obtained by the Ministry of Health and verbal consent obtained by the observers when they first visited the facility.[128]

Attendants were told the observation was about the quality of care at birth, not on HH specifically, to conceal the study's focus and reduce the Hawthorne effect. In all but the one facility where piloting took place, the focus of the study (HH practices) is likely to have been well concealed from the birth attendants being observed. The pilot facility had the highest compliance to hand rubbing/washing before aseptic procedures. Compliance was 10% higher than the second-best facility, and seven times higher than the worst one.

For ethical reasons, observers were trained to notify health workers and the field manager if they observed a potentially harmful condition or practice.

Quality during data collection
To ensure quality of data collection, we held regular meetings with collectors over the telephone and onsite; set up and frequently communicated via a WhatsApp group; held Skype calls at the end of observations in each facility; and monitored monthly the data uploaded. These communication channels enabled rapid feedback, questions to be answered, and maintenance of morale during long periods of observation. Drivers ensured observers arrived at sites on time. Finally, we are confident that the data is unlikely to be manufactured because it would take as much time to manufacture time-stamped data as to create it from actual observation because the time stamp of each entry is recorded.

Tool performance

Inter-observer (interrater) agreement
To report on inter-observer agreement procedures and findings we followed the recommendations by Lopetegui et al. for time-and-motion studies an consulted the WOMBAT guidelines.[132,137,138] Whilst piloting the tool, the trainer carried out two hours of simultaneous observation between the trainer (GG) and each of the observers. From this, we verified the extent of agreement between GG and each of the three observers on the basis of 28, 29 and 36 opportunities for hand washing/rubbing, glove wearing and touch events. The exercise was also used to provide feedback to the observers.

During the first month of data collection, we also assessed inter-observer agreement, whereby a pair of observers was allocated two of the same shifts in the busiest facility and asked to observe the same attendants. Observers were asked to perform this independently, avoiding communication or looking at each other's tablet, but they were not blinded – meaning that they probably knew we were going to check the data and hence some form of communication might have still occurred. Two pairs carried out this exercise for one morning and one afternoon shift each, the other pair for two-night shifts. Two pairs observed three birth attendants, and the third pair observed four.
We calculated kappa statistics based on either 49 or 50 hand rubbing/washing, hand recontamination or glove behaviours per pair of observers. We ensured, through visual inspection of the data, that the behaviours compared were the same between observers by checking the reported time and sequence of actions. The kappa statistic calculated for pairs of observers was good for two out of three pairs at 0.93 and 0.90, but was below the optimal level of 0.85 for one of the pairs, at 0.73.[132] In addition, we are also confident that discrepancies between observers were minimal because in our final dataset we showed that hand rubbing/washing compliance before aseptic procedures did not vary substantially by observer as described in Gon et al 2018.[128]

Convergent validity
We assessed the degree to which two measures of constructs that theoretically should be related, are in fact related (convergent validity) by showing whether hand rubbing/washing before aseptic procedures compliance varies in the expected direction by contextual characteristics. Using the methods described in Gon et al 2018,[128] we descriptively show that higher compliance was present when the necessary equipment (water & soap, or gel) was available, when fewer women were attended in the same observation session (i.e. a lower workload was expected to be associated with better

HH), and when attendants had received HH refresher training in the previous year (Table 4.2).

Table 4.2 – Hand rubbing/washing compliance by availability of equipment, number of women attended and training received.

Necessary hand hygiene equipment (water & soap, or gel)	**Opportunities % (n) N=779**	**Rubbed/washed % (n) N= 190**
No	6.2 (48)	10.4 (5)
Yes	90.4 (704)	25.1 (177)
Missing	1.7 (13)	23.1 (3)
Inconsistent information	1.8 (14)	35.7 (5)
Maximum number of women attended in an observation session		
1	69.5 (541)	27.0 (146)
2	25.2 (196)	19.9 (39)
3	4.6 (36)	11.1 (4)
Missing	0.77 (6)	16.7 (1)
Hand hygiene refresher training in the past 12 months		
No	44.5 (347)	21.3 (74)
Yes	55.5 (432)	26.9 (116)

<u>Implications for data analysis and interpretation</u>
In Additional File 3 we describe in detail the areas for data cleaning, analysis and interpretation that need to be considered. Of note, some data items that relied on observer subjectivity (e.g. duration of hand washing) and some variables (e.g. variables describing the context) that require more stringent training than others.

<u>Data structure</u>
A strength of WOMBAT is that when each action is recorded, the time of that action is automatically logged. Our final dataset was a list of 7893 time-ordered entries. The data could be uploaded as soon as internet access is available, and data were immediately accessible, for example in *csv* format through the WOMBAT portal from any computer. Additional File 4 shows what the data look like when after being downloaded from the WOMBAT portal; the table only shows a sample of the available variables. Variables that describe actions appear in a binary format with 1 if the action was ticked and 0 if it was not. These data were coded to derive HH opportunities and to calculate compliance. First, each HH opportunity needed to be identified within each observation session– further explained below. Second, for HH opportunities *before* aseptic procedures or touchng the patient, the sequence of actions preceding the

opportunity needed to be examined for hand rubbing/washing actions, glove use and actions that may lead to a new HH opportunity. Whereas, for HH opportunities *after* exposure to body fluids or touching the patient or the patient's surrounding, the actions following the opportunity needed to be examined. We used STATA to analyse these data. Once definitions were agreed, preparing and cleaning the data took approximately two weeks, and the analysis another two weeks.

Time stamps

We used WOMBAT's time stamp information in two ways. First, to check the plausibility of certain actions being linked; for example, a hand rubbing/washing action could not be linked to a procedure conducted 10 hours before or after it. Second, to calculate the length of time between hand rubbing/washing and the HH opportunity to determine whether time would predict the likelihood of hand recontamination occurring.

A priori definitions required

To estimate HH compliance, the following definitions were operationalised: the *systematic flow* of patient contacts allowed within a given HH opportunity and the *patient zone*. By a *systematic flow* – which we termed a 'delivery flow'[128] – it is meant the procedures or actions of interest that defined the start of a HH opportunity, as well as the sequence of these procedures which occurred without a break and were considered as *one* opportunity for HH.[23] For example, in a given delivery flow, a vaginal examination could be followed by the delivery of the baby, but not by touching a patient's shoulder.

During a delivery flow, a birth attendant could undertake hand actions within the *patient zone* without the need for a new HH opportunity to arise. In this study, the patient zone was defined as encompassing a woman's perineal area and thighs, any clean or sterile equipment being used, and the newborn as it was caught and wiped. A break in the delivery flow, indicating a new HH opportunity, arose if an activity occurred that was outside the patient zone e.g. inserting an IV line, touching the patient beyond the zone, or leaving the room. [128]

Details on the definitions used in our study are reported in Gon et al 2018.[128] Potentially, a separate software could be programmed to automatically analyse this type of data in the future allowing for definitions to be applied from the outset.

Context specific adaptations
To classify what surfaces we should include in the patient zone we used previous formative research[139] on the microbiological load of the labour surfaces in Zanzibar, as well as unstructured observation of labour wards conducted within the HANDS project. For example, we excluded the delivery bed and trolley from the patient zone because previous work found that these surfaces were often contaminated with potential pathogens.[128] Other important information to consider include the details of the cloth or plastic sheet used under the woman's body during birth, the cleaning routines of the wards, the type of water available, the delivery equipment preparation, and the local HH guidelines against which to measure hand washing/rubbing duration and technique. It is not clear that all projects will have the capacity to gather this level of contextual information. However, capturing the real workflows in this context was our aim.

Ideally all definitions should be clear at the start of a project; however, during data collection the project may accrue context-specific information on the surfaces or the attendants' workflows which should be used to update the definitions. To illustrate this, we present in Additional File 5 the number of HH opportunities and hand rubbing/washing compliance results for four different patient zone definitions.

4.3.4. Discussion

We developed the *HANDS at birth* tool to capture the complex HH and glove behaviours of birth attendants using state of the art methods: a time-and-motion study using a computerised system (WOMBAT). This has been rarely used to measure HH, or in low resource settings.[47,133,134,140,141] Our time-and-motion study allowed us to accomplish the following which would have not been possible with the WHO HH Observation Form: a) to look at whether birth attendants comply with the complete sequence of behaviours prescribed by the WHO guidelines[10], b) to look at each behaviour individually, and c) to look at different behaviour sequences.[128] Additionally, our method reduced the risk of observer bias because data collection coded a series of individual actions rather than relying on observer judgement that a new HH opportunity had occurred; hence opportunities were identified retrospectively in a standardised way.[142] Indeed, hand rubbing/washing compliance was similar between observers in our study as reported in Gon et al 2018.[128] Beyond HH, the *HANDS at birth* tool allowed investigation of other behaviour sequences and workflows.

Because we were interested in individual determinants of HH behaviour, we observed only one birth attendant at any one time, whereas, the WHO HH Observation Form audit tool is designed to observe multiple healthcare workers simultaneously, and hence more HH opportunities can be collected in the same observation session. Importantly, the *HANDS at birth* tool is not intended to substitute for the WHO HH Observation Form; the two serve very different purposes. The former is aimed at research and the latter at infection prevention practitioners. Another limitation of our tool, and how we used it, is that it requires data cleaning and data management post observation. For example, even though misclassification was minimal, multiple actions were recorded by mistake at the same time. In addition, a couple of variables relied on observer subjectivity – for example whether a delivery happened very fast after the woman's admission in the labour room. The structure of data implies that data management is needed to create HH opportunities and HH compliance results. Finally, the cost of the software and hardware needs to be considered especially for deployment in LMICs. Our WOMBAT software licence was approximately £2500, but could cover multiple research projects and three years of use. Free packages like Open Data Kit could be considered for the same purpose, however Open Data Kit is less user friendly for the purpose of time-&-motion studies. In addition, we bought three tablets for approximately £400.

We are aware of one other study that uses time-and-motion methods to report HH of healthcare workers in the context of an Intensive Care Unit in the United States of America.[141] The study's aims differed from ours including determining the number of contacts between patients and healthcare workers, as well as how long these take, and estimating HH compliance specifically before entering a room and after exiting a room. The paper did not detail information on the tool format or content. In comparison, the *HANDS at birth* tool allows for a more exhaustive list of actions to be recorded, including beyond the patient-attendant interactions; it also allows one to look at all HH opportunities not just the ones related to exiting or entering the room.

In conclusion, we report the process of developing a research tool to capture the complexity of HH and glove behaviour during labour and delivery, including the tool elements, field implementation, tool performance and implications for analysis. We used a computerised system that was feasible to use in low resource facilities. Advantages of this tool include simpler training and less observer bias in assessing HH compliance (compared to the WHO HH Observation Form), and the ability to monitor multiple behaviours. The data it produced also showed good reliability and convergent validity. Future studies should explore the use of this research tool in labour wards in other contexts.

4.3.5. Declarations

Ethics approval and Consent to participate

The project was approved by the Zanzibar Medical Research and Ethics Committee, the London School of Hygiene and Tropical Medicine Research Ethics Committee, and the Research Ethics Committee at the University of Aberdeen. Either written consent was gathered from women in the antenatal ward prior to observation; or women were asked their verbal consent once in the labour ward and their written consent gathered in the postnatal ward before discharge. Women were made aware that no demographic information was collected on them and the only recorded observations were regarding birth attendant behaviour. Consent for the attendants was gained by the Ministry of Health and asked verbally by the observers when they first visited the facility.

Attendants were told that the observation was about the overall quality of care of the birth, not on hand hygiene specifically, to conceal the focus of the study and reduce the Hawthorne effect.

For ethical reasons, observers were trained to notify health workers and the field manager if they observed a potentially harmful condition or practice.

Consent for publication

Not applicable

Availability of data and materials

The dataset generated during the current study are available in the London School of Hygiene and Tropical Medicine Data Compass repository, https://doi.org/10.17037/DATA.00000778

Competing interests

The authors declare that they have no competing interests.

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Authors' contribution

Conceived and designed the study: GG SW RA M de Bruin M de Barra WJG SMA

Analysed the data: GG

Wrote the paper: GG SW RA M de Bruin M de Barra WJG SMA, OC, MJ, AT, SN, JW

Data interpretation: GG SW RA M de Bruin M de Barra WJG SMA, OC, MJ, SN, JW

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4.3.6. Additional Files

Additional File 1 - HANDS at birth tool

Room (room where you are sitting)
- Labour room
- Antenatal rom
- Vaginal Examination (VE) room
- Other room

Context (availability of equipment and in-charge presence)
- Drying materials available
  - None
  - Single use
- Soap available
  - None
  - At the sink
  - Not near the sink
- Water available
  - None
  - Basin pour
  - Tap in room
  - Tap in next room
- Gloves available
  - None
  - In the room
- Alcohol handrub available
  - None
  - In the room
- In Charge
  - Yes
  - No

Birth Attendant (BA) status in room
- BA leaves
- BA enters

Woman
- 1
- 2
- other
  - 3
  - 4
  - 5
  - 6
  - 7
  - 8
  - 9
  - 10
  - 11
  - 12

Touched

- Mackintonsh/kanga (bed cover)
    - With body fluids
    - Clean
    - Not clean
    - Don't know
- Equipment (for delivery)
    - Sterile
    - With body fluids
    - After de-contamination up to sterilization (any)
    - Don't know
- Other sterile/clean (E.g. cotton swabs)
- Body fluids contaminated objects
    - Carry away placenta
    - Cloth for cleaning the bed
    - Other
- Objects (other)
  - Register, paper or pen
  - Bag
  - Bin
  - Patient bed
  - Trolley
  - Tap
  - Phone
  - Mop or other cleaning material
  - Gloves pack
  - Own body
  - Other (unclean)
- Patient (woman or baby) (everything but inside legs and perineal area)

Delivery

- Delivery
    - Normal
    - Vacuum

- Kit
    - Pre-made or collected prior to delivery
    - Passed by colleague
    - Made along the way
    - Not seen

- Fast
  - Yes
  - No

- Workload
    - Working alone
    - 1 assistant
    - 2+ assistants

- Complicated (if you suspect the woman is having a complication, unless it is obvious confirm with BA first)
    - No complications
    - Breech delivery: comes out with the buttocks or feet

    - Prolonged labour: ask Birth Attendant: 12h for primagravida, and 8h for multipara
    - Haemorrhage (antenatal): excessive blood loss (>500ml); confirm with Birth Attendant
    - Pre-eclampsia/Eclampsia: ask Birth attendant A: high blood pressure, (>140/90 on 2 occasions or >160/110) plus either 1+ protein on urine dip or cerebral/visual disturbance e.g. severe headache/reduced conscious level/blurred vision; or seizure attributable to pre-eclampsia confirm with BA
    - Baby floppy and blue
    - Premature rupture of membrane: Ask the BA
    - Induction/augmentation: process to induce/speed up labour using drugs
    - Other: e.g. fever
    - Not able to determine

Other procedures

- Vaginal examination
- Cord clamping and cutting
- Wiping/cleaning vagina
    - Clean material
    - Unclean material
    - Not seen
- Other
    - Catheter
    - MROP (manual removal of placenta)
    - Suturing
    - Intravenous (iv) fluids (insertion or removal)
    - Intravenous blood line (insertion or removal)
    - Breaking amniotic membranes
    - Nasal suction (newborn)
    - Episiotomy
    - Newborn resuscitation - bag and mask
    - Changing IV bag
    - Adjusting IV line
    - Vital signs
    - Supporting breastfeeding
    - Injection
    - Wiping baby
- Cord traction
- Post delivery exam (checking for tears)

Hand washing

- Duration
    - 1-9 seconds
    - 10+ seconds
    - Not seen
- Soap
    - Yes
    - No
    - Not seen
- Behind fingers
    - Yes
    - No
    - Not seen

Drying

- Single use
- Other
  - Re-usable
  - Own gown
  - Air
  - Other
  - Not seen
- None

Hand rubbing

- Duration
  - 1-9sec
  - 10+
  - Not seen
- Behind fingers
  - Yes
  - No
  - Not seen

Gloves

- Action
  - Add
  - Remove
- Status
  - One hand
  - Both hands
  - Bear hands

Additional File 2 – Reporting the study characteristics using STAMP (Suggested Time and Motion Procedures)[135]

Area and element	Ref Code	Description
Intervention	INT.1-INT.3	Not applicable. This was an observational study with no interventions conducted.
Empirical setting		
Institution type	ES.1	The 10 healthcare facilities with highest volume of deliveries ranging from 75-930 in Pemba and Unguja islands, Zanzibar, Tanzania. Eight of these facilities had an operating theatre.
Care area	ES.2	Data collectors were observing any healthcare worker involved in the delivery process, hence they would usually be sitting in the labour room. If no deliveries were in sight, we asked data collectors to observe vaginal examinations in other rooms where they were conducted e.g. the antenatal ward or examination room
Locale	ES.3	Urban (6 facilities) and Rural (3 facilities may be considered rural; 1 is definitely rural)
Research design		
Protocol	RD.1	Observational study
Duration	RD.2	3.5 months (September to December 2016)
Shift distribution	RD.3	130 hours in the morning, 153 hours in the afternoon and 205 hours in the night
Observation hours	RD.4	489:25:45 (hh:mm:ss)
Task category		
Definition and classification	TC.1	See Appendix A for definitions of tasks that included all birth attendants hand actions: procedures i.e. patient-attendant interactions (e.g. a vaginal examination), hand hygiene or glove actions (hand rubbing/washing, drying, glove use etc.) or some other touch (e.g. touching a pen or touching equipment).
Acknowledgement of prior work	TC.2	We used the World Health Organisation (WHO) Hand Hygiene Technical Reference Manual, the WHO guidelines on Pregnancy and Childbirth and on Hand Hygiene in Outpatient and Home-based Care and Long-term Care Facilities[23,36,41] to a) list the procedures (what we also call key attendant-patient interactions) that can occur during labour and delivery; and b) list all any other hand actions birth attendants can undertake before and after each of these procedures.
New development	TC.3	Not applicable as previous work described above.
Observer		
Size of field team	OBS.1	Three data collectors
Training	OBS.2	Training for this tool involved three days in the classroom using role-play (e.g. staged observation) and presentations. Each data collector also had a chance to practice the tool for three hours in the labour ward whilst being supervised by the trainer. In addition, the trainer carried out two hours of simultaneous observation with each of the data collector and provided relevant

		feedback. Role-play in the classroom, and exercises in the labour wards during the training also helped to add minor refinements to the tool.
Background	OBS.3	Data collectors (observers) were trained nurse midwifes working in managerial roles. Two of these data collectors worked in two of the study facilities but not in their labour wards. The third data collector worked at the district level management. Their previous knowledge and understanding of the process of labour was vital for the success of our project.
Inter-observer uniformity	OBS.4	Details of the inter-observer agreement are in the main manuscript. The kappa statistic calculated for pairs of data collectors was good for two out of three pairs at 0.93 and 0.90, but was below the optimal level of 85% for one of the pairs, at 0.73.[132]
Continuity	OBS.5	Not applicable. The three data collectors were the same throughout the study and each participated in observation in each of the 10 facilities.
Assignment	OBS	We consulted the ward rosters to allocate individual health workers to the observers that was important because each birth attendant had a unique identifier that observers needed to input into WOMBAT when observing them. Shift allocation to data collectors was based on the following principles: a) as much as possible the same observer should be observing the same birth attendant so that she gets accustomed to the same person being on the ward; b) the initial birth attendant/data collector pairs at each facility were assigned at random (unless specific concerns were raised – for example some flexibility on choice of types of shifts i.e. morning, evening or night was allowed to cater for data collectors personal needs); c) ideally observation days should be planned during changes in shift pattern) to allow observation of the same birth attendants working on different types of shifts. The need to observe the same birth attendant across different shifts using the same observer had implications for the fieldwork duration and therefore had to be counter-balanced by our budget. Because the allocation of responsibilities across birth attendants during a shift were usually decided during the shift itself, we encouraged observers to listen in to staff meetings on a daily basis to be aware of this allocation. This meant that an observer knew which birth attendant was most likely to perform the procedures outlined above (Table 4.1) that day and was able to decide whom to spend more time observing, also based on whom she observed the previous days. Indeed, observers were instructed that the aim was to observe each birth attendant roughly equally in each facility.
Subject		
Size	SUB.1	104 birth attendants were observed.
Recruitment and	SUB.2	Data collectors were trained to observe all the allocated

randomisation		birth attendants that were involved in vaginal examinations and assisting deliveries.
Continuity	SUB.3	Not applicable. This study did not have multiple study phases.
Background	SUB.4	Birth attendants in our study were all women; 90% were professionally trained, and 10% were health orderlies/non-professionals.
Data recording		
Multitasking	DR.1	The hand actions were exhaustive (meaning that the list did not leave any possible actions out) and mutually exclusive (meaning that no two actions could occur simultaneously as these are hand actions). We did not design a tool that aimed to capture multi-tasking or interruptions because we did not want to add to the burden of the data collectors.
Non observed periods	DR.2	We instructed observers to end a session when a major procedure was naturally over and no further patient activities were in sight, when the observer wanted to take a break, when there was the opportunity to start observing another birth attendant, or when the birth attendants would leave the room to perform other duties elsewhere.
Between task transitions	DR.3	Not applicable. No multiple tasks allowed.
Collection tool		WOMBAT
Data analysis		
Definition of key measures		The study aimed to capture hand hygiene compliance. All definitions required are highlighted in the manuscript and in Gon et al. 2018.[128]
Analytical methods		STATA was used to analyse the data. We used descriptive statistics as well as logistic regression models accounting for individual level clustering (birth attendant level). Procedures are described in Gon et al. 2018.[128]
Ancillary data		
Interruption	AD.1	Not applicable. Interruptions were not recorded.
Interaction	AD.2	The aim was to record all hand actions. Interpersonal communication was not recorded. We have information on whether the birth attendant touched her phone. No computers were available in the location of the observation in this study.
Location	AD.3	Data collectors were observing any healthcare worker involved in the delivery process, hence they would usually be sitting in the labour room. If no deliveries were in sight, we asked data collectors to observe vaginal examinations in other rooms where they were conducted e.g. the antenatal ward or examination room

Additional File 3 – Tool items with specific implications for data cleaning, analysis and interpretation

Items that required data cleaning and consistency checks

The following is a list of data entry errors that we found in our dataset and required data cleaning:

1. We performed consistency checks on actions subcategories that were mutually exclusive – for example, if on the same entry it was coded that drying hands was carried out with single-use material and at the same time no drying was performed, we could not tell the correct response and the entry was recoded as "inconsistent information". 'Inconsistent information' was not used in the analysis.
2. In a few cases, data collectors reported an action and its sub-categories in successive separate entries, against the training instructions. For example, they would report a delivery, press enter, and then provide the detail of the delivery e.g. type of delivery kits used or availability of an assistant, in one or multiple successive entries. Hence we cleaned this data by allowing for the entry on the sub-categories of an action to appear on the same line of entry as the action of interest.
3. In a few cases, multiple actions of different types were found on the same line of data entry for example a birth attendant touched a surface and at the same time that she assisted a delivery. Since we cannot make an assumption of which of the two actions happened first we prioritised hand actions and procedures meaning that some information was lost. This was minimal because the number of multiple actions entered simultaneously was small (37/7893.) Given the way we used the WOMBAT software, unless the data collector pressed enter after each action it was possible to record two actions simultaneously. Visual inspection of the data and conversation with data collectors suggests that data collectors, if they made a mistake, would sometimes repeat the recording of a certain action with the corrected information – we do not know however how often this was done as we do not have video recording of the true situation to verify the counterfactuals. During the training we could have had more practical exercises on how to revise the last action recorded to minimise this issue.
4. During cleaning, we also checked candidate data errors against field notes where possible. For example, one woman appeared to have triplets from the data. Since triplets are rare, we checked this information against the field notes and a triplet was indeed reported on the same day of the observation via the WhatsApp group.
5. There were a few instances when the reported unavailability of a context-related item was contradicted by the performance of an action requiring that item. There

were 14 instances when the data collector recorded unavailability of water but hand washing was performed. There were 10 occasions each when soap or alcohol hand gel were reported as not available but were also observed to be used. In these cases, we kept the observed behaviour and changed the availability of the item to "available" because behaviour was monitored more constantly than the item availability. This questions further the reliability of the context-related data. It is important to note that we could check if the use of an item corresponded to its availability, but we could not check the opposite – if an item was not used e.g. if hand washing without soap was recorded, does it mean that soap was really there?

Items that are more affected by observer subjectivity

Two types of information relied on observer subjectivity: whether a delivery happened very fast after the woman entered the labour room and the duration of hand washing or rubbing. Neither item was timed –they were based on the data collectors' judgement. As per the training, a delivery was considered to be fast if the delivery of the baby occurred within 5 minutes of the woman entering the labour ward. Two out of the three data collectors reported 70% of the deliveries they observed as "fast". One data collector (the one showing the highest qualitative agreement with the trainer) only recorded 20% of the deliveries observed as "fast". This suggests that this indicator might have not been interpreted the same across all data collectors; we might have overestimated the frequency of "fast" deliveries occurred in our sample. Among the times when hand washing or rubbing occurred, the three observers reported that the duration of hand washing or rubbing was more than 10 seconds in 8% (observer 1), 13% (observer 2) and 28% (observer 3) of these instances.[128]

Because of the way we trained data collectors to use WOMBAT – i.e. focusing on tasks rather their duration – and because the nature of hand hygiene behaviours which occur fast, we could not establish a simple way of timing the duration of hand washing or the delivery. Using a stopwatch or changing the way we used WOMBAT appeared too cumbersome for this group of data collectors and would have exacerbated observer biases. Some of the features of WOMBAT – such as its ability to capture task duration could be exploited in future uses of this tool.

Items that required stringent training

The variables describing the context, for example the availability of water, need updating when the environment changes compared to the status quo recorded at the beginning of the sessions. We have reason to think that sometimes data collectors forgot to update at least some of this context. For example, from data inspection and conversations with data collectors, it became evident half way through data collection that two of three of data collectors did not always remember to update the information on whether the in-charge was present. In addition, information on the index number of the woman being attended could be improved: in five observations sessions we did not have any index number recorded at all indicating that this information was perhaps poorly recorded across the study. If there was no index number recorded, or the number did not change during a session, during data analysis we assumed that the same woman was being assisted across a session. More tailored training could improve the data collection on these variables; or perhaps the use of a different software that reminds at regular intervals to update these variables.

Additional File 4 – example of raw data output (includes only a sample of available variables)

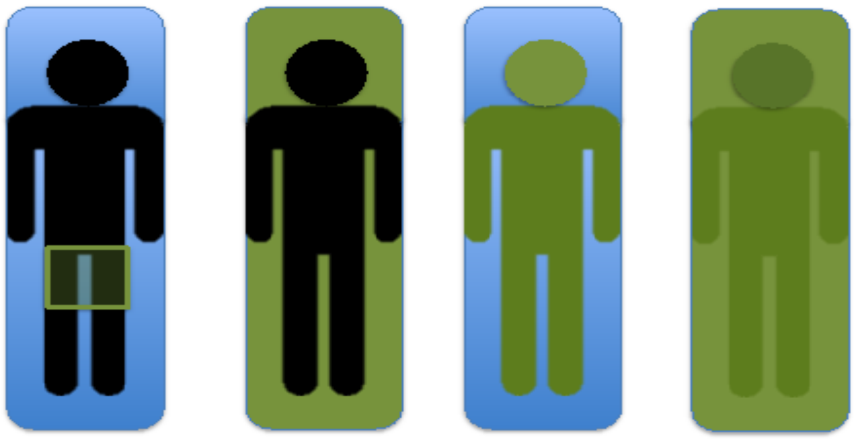
session date	session id	participant id	session start	session end	[Hand washing-Duration] 1-9sec	[Hand washing-Duration] 10+	[Hand washing-Duration] Not seen	[Hand washing-Soap] Yes	[Hand washing-Soap] Not	[Hand washing-Soap] Not seen	Drying	Drying (subcategories)	
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	Other	Air	
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	1	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	1	0	0	0	1	0	0		0
21/09/2016	7	4	19:59:06	20:47:07	0	0	0	0	0	0	Other	Air	

Additional File 5 - Changing the definition of patient zone

As discussed in the main body of this manuscript (under the “context specific adaptations” section), the definition of patient zone can be tailored for different contexts. For example, they can be based on local cleaning practices or other infection prevention practices, such as the use of re-usable macintoshes, or the degree of microbiological cleanliness of key surfaces e.g. delivery bed. Below we present four different patient zone scenarios as examples.

Using the methods described in Gon et al. 2018[128] we calculate the compliance to hand washing/rubbing based on the following patient zone definition: the mother‘s perineum and thighs, newborn and any other clean or neutral hand actions. To show how our tool performs with a different definition of the patient zone, we calculated the number of HH opportunities and the hand rubbing/washing compliance for an additional three patient zone scenarios describes in Figure 4.2 below. Based on these results, the hand rubbing/washing compliance did not substantially change as the patient zone widened, although it increased slightly; whereas the number of HH opportunities decreased as hypothesized (since the wider the zone, the less opportunities for touches outside the zone).

Figure 4.2 – Patient zone scenarios, number of opportunities and compliance (green highlights the zone)



Patient zone 1	Patient zone 2	Patient zone 3	Patient zone 4	
Mother's perineum and thighs, newborn + clean or neutral hand actions	Zone 1 + unclean mackintosh + patient bed	Zone1 + patient	Zone 1 + Zone 2 + Zone 3	**Definition of patient zone**
781	729	717	640	**Number of opportunities**
24.6 (21.6-27.8)	26.2 (23.0-29.6)	27.8 (23.7-30.2)	29.8 (26.3-33.6)	**Compliance to washing/rubbing %(Confidence interval)**

5. HAND WASHING, GLOVE USE AND AVOIDING RECONTAMINATION BEFORE ASEPTIC PROCEDURES AT BIRTH: A MULTI-CENTRE TIME-&-MOTION STUDY CONDUCTED IN ZANZIBAR (PHD OBJECTIVE 4)

5.1. Preamble

Most studies reporting on hand hygiene compliance before aseptic procedures do not describe each of the expected behaviour involved (hand rubbing/washing, avoiding recontamination and donning gloves), or their sequence. Using the study design described in Manuscript 3, in this manuscript we aimed: to estimate the compliance of birth attendants' to hand rubbing or washing, avoiding recontamination and glove donning before aseptic procedures across Zanzibar labour wards; to describe what sequence of behaviours they undertake more often against the WHO Hand Hygiene Guidelines; and estimate the extent to which the failure to avoid recontamination contributes to poor hand hygiene.

This manuscript presents the analysis of the dataset for which I described in detail my contribution in Manuscript 3. I conceptualized the analysis and the graphical outputs with advice from my supervisor, Oona Campbell and one my advisory members Marijn de Bruin. I conducted the analysis with statistical advice from my supervisor Stephen Nash. I wrote the first draft of the manuscript and I led the revisions from the co-authors and the reviewers.

The manuscript is formatted in accordance with the American Journal of Infection Control requirements. As the manuscript is already published, a copy of the PDF version is available in Appendix V (A) (page 338) along with the ethics approvals in Appendix V (B-D) (page 348).

I presented this work in a presentation format at the following conference:

- European Health Psychology Society Conference. 29th of August-2nd of September 2017. Padova, Italy.

I presented this work in a poster presentation at the following conferences:

- International Consortium for Prevention & Infection Control Conference. 20th-23rd of June 2017. Geneva, Switzerland.

- Global Women's Research Society Conference. 18th-20th of June 2018. Cambridge, UK.

5.2. Cover sheet

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PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Giorgia Gon
Principal Supervisor	Oona Campbell
Thesis Title	Birth attendants' hands hygiene in maternity wards in low resource settings: levels and drivers

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?	American Journal of Infection Control		
When was the work published?	4/10/2018		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
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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 conceptualized the analysis and the graphical outputs with advice from my main supervisor, and one my advisory members. I conducted the analysis and wrote the first draft of the manuscript and I led the revisions from the co-authors and the reviewers. Details in chapter's preamble.

Student Signature: [redacted] **Date:** 24/10/2018

Supervisor Signature: [redacted] **Date:** 24 Oct 2018

5.3. Copyright agreement

5.4. Manuscript 4 – Hand washing, glove use and avoiding recontamination before aseptic procedures at birth: a multi-centre time-&-motion study conducted in Zanzibar

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5.4.1. Abstract

Background: Our primary objective was to assess hand hygiene (HH) compliance before aseptic procedures among birth attendants in the10 highest-volume facilities in Zanzibar. We also examined the extent to which recontamination contributes to poor HH; recording exact recontamination occurrences is not possible using the existing World Health Organisation HH audit tool.

Methods In this time-&-motion study, three trained coders used the WOMBATv2 software to record the hand actions of all birth attendants present in the study sites. The percentage compliance and 95% confidence intervals for individual behaviours (hand washing/rubbing, avoiding recontamination and glove use) and for behavioural sequences during labour and delivery were calculated.

Results We observed 104 birth attendants and 781 HH opportunities before aseptic procedures. Compliance with hand rubbing/washing was 24.6% (CI:21.6-27.8). Only 9.6% (CI:7.6-11.9) of birth attendants also donned gloves and avoided recontamination. Half of the time when rubbing/washing or glove donning was performed, hands were recontaminated prior to the aseptic procedure.

Conclusions In this study, HH compliance by birth attendants before aseptic procedures was poor. To our knowledge this is the first study in a low-to middle-income country to show the large contribution to poor HH compliance from hand and glove recontamination before the procedure. Recontamination is an important driver of infection risk from poor HH and should be understood for the purposes of improvement and therefore included in HH monitoring and interventions.

5.4.2. Introduction

Healthcare associated infections (HAIs) in low and middle-income countries (LMICs) affect an estimated 15% of patients; three times more than in Europe.[7] For mothers and newborns in LMICs, where infection is already a leading cause of death,[1,2] the risk of HAIs could escalate with increasing healthcare facility newborn deliveries as well as substandard infection prevention standards.[73]

Hand hygiene (HH) is deemed the single most important behaviour for preventing HAIs.[17] Historical evidence suggests the importance of HH in reducing maternal infections in European hospitals and recent studies support its value for newborns in LMICs.[3] The World Health Organization (WHO) recommends five moments for hand hygiene (5MHH) during patient care.[10] Among these, Moment 2 – HH before clean/aseptic tasks when there is potential contact with patient's mucous membranes or non-intact skin – is considered the most significant for preventing bacterial transmission to patients including the bloodstream that could result in infection. During birth, this primarily occurs before and during a vaginal examination or delivery, and related procedures.

Before these aseptic procedures, the WHO guidelines require attendants to hand rub or wash, avoid recontaminating their hands, don gloves and avoid recontaminating those gloves before starting the procedure.[10] The current WHO HH Observation Form does not distinguish whether the failure to comply with the 5MHH stems from not hand rubbing/washing or from, for example, subsequently touching potentially unclean surfaces,[10] thus negating the initial hand washing/rubbing action. Although successful multimodal interventions exist to improve HH, they require in-depth understanding of the context and achieve only variable long-term success.[10,17,56,59] Determining whether birth attendants comply with any of the steps in the prescribed behavioural sequence and more specifically within the workflow in our context – Zanzibar, a region of Tanzania – is important to inform successful improvement interventions.

Therefore, our study therefore aimed to examine the complex workflow in relation to hand hygiene and glove use undertaken by birth attendants in multiple high-volume labour wards in Zanzibar. Our specific research questions were:

1. What is the compliance with hand rubbing/washing (and then avoiding hand recontamination) and donning gloves (and then avoiding glove recontamination)?

2. Is variability of these behaviours primarily greater *between* birth attendants or *within* birth attendants across different HH opportunities?
3. To what extent does failure to avoid recontamination (as opposed to not hand rubbing/washing before a procedure) contribute to poor HH?
4. What behaviour sequences do birth attendants undertake most often before aseptic procedures when compared to the behaviour sequence prescribed by the WHO guidelines?

5.4.3. Methods

Context

This study is part of the larger HANDS project (Hand-hygiene of Attendants for Newborn Deliveries and Survival): a mixed-methods study investigating drivers of birth attendant HH. HANDS ran between November 2015 and April 2017 in the 10 highest-volume labour wards in Zanzibar, with average monthly delivery volumes ranging from 75 to 930 (Appendix A, available from https://doi.org/10.17037/DATA.00000778). The project was a partnership between the London School of Hygiene and Tropical Medicine, the University of Aberdeen and the Public Health Laboratory of Pemba. Previous work in eight of these maternity wards found the majority had policies and basic infrastructure to perform HH but only 50% received HH training in the previous year.[139]

Study design and data collection

Within HANDS, we conducted a time-&-motion study wherein three observers recorded the hand actions (e.g. procedures and hand touches on surfaces) of birth attendants 24 hours per day (one data collector per 8-hour shift – morning, evening and night), for a mode of 6 days (range: 5-14 days) per labour ward. Results are reported using the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.[82] All observers were trained midwives. Birth attendants were all staff involved in assisting deliveries, irrespective of cadre, including midwifes and orderlies. Details of the tool, training and data collection protocols can be requested from the authors.

To estimate a HH compliance of 10% with an absolute precision of +/– 3%, 768 HH opportunities were required. For the sample size calculation, we used the formula for estimating a proportion from a cross-sectional survey, with $\alpha = 0.05$ and a design effect of 2 based on a survey in Benin of facility quality indicators.[136] Using the reported number of deliveries in the 10 study facilities overall, we calculated the length of observation required to achieve this sample size.

Data were collected via tablets, pre-coded using WOMBATv2 software (© Centre for Health Systems and Safety Research, Macquarie University, Sidney, New South Wales).[132,135] An observation session began when an attendant started assisting a a woman in labour. All observed hand actions were recorded as they occurred, and the time of each was automatically logged. A set of mutually exclusive actions was pre-coded and used specifically in this study. One attendant was observed per observation session, but multiple patients or procedures could be included. Multiple observation sessions were usually captured in one shift. To minimise the Hawthorne effect, attendants in all facilities but the one where the pilot occurred were told that the observation was about overall quality of care, not specifically HH.[129]

We trained on and piloted the observation tool over two-weeks following the WHO guidelines.[10,41] During the first month of data collection we also assessed inter-observer agreement between pairs of data collectors (on 49 or 50 behaviours for each pair) and calculated kappa statistics. We provided tailored feedback to the data collectors based on these results.

Ethics

The project was approved by the Zanzibar Medical Research and Ethics Committee and the London School of Hygiene and Tropical Medicine Research Ethics Committee. Consent was obtained from women (patients) either in writing in the antenatal ward prior to observation, or verbally in the labour ward, with written consent obtained before discharge. Women were informed that the person being observed was the birth attendant, and that no information would be collected on them. Consent to observe the birth attendants was granted by the Ministry of Health Zanzibar and obtained verbally from the birth attendants when the data collectors first visited the facility. All observed healthcare worker information was anonymised.

Definitions

<u>HH opportunity</u>

HH compliance is calculated as the number of times HH was performed, divided by the number of opportunities when HH ought to occur. The opportunities in this study were procedures at birth that ought to be aseptic (listed in Table 5.1). We termed a ‘delivery flow' as any sequence of these procedures occurring one after the other without a break and considered as *one* opportunity for HH. We defined these opportunities using available guidelines[23,36,41], unstructured observations in four of the study wards, and expert consultation. This aimed to capture realistic workflows within our setting and accurately observe HH according to WHO recommendations.

Table 5.1 – List of aseptic procedures during a 'delivery flow'

Aseptic procedures
Wiping the vagina
Vaginal examination
Artificial rupture of membranes
Episiotomy
Catching the baby (delivering the baby)
Cord cutting and clamping
Cord traction
Manual removal of placenta*
Post-delivery vaginal examination
Suturing of the perineum*
Wiping baby clean
Urinary catheter insertion or removal

*We allowed manual removal of placenta or suturing to be considered within the 'delivery flow' when these occurred before or after a vaginal examination, post-delivery examination, or vaginal wiping; or when manual removal of the placenta occurred after cord traction.

During a 'delivery flow', a birth attendant was permitted to undertake hand actions within the *patient zone*, defined for this study as the woman's perineal area and thighs, any clean or sterile equipment being used and the newborn as it was caught and wiped (Table 5.2). The patient zone included the patient and some surfaces and items that were temporarily and exclusively dedicated to her, limiting the risk of transmitting pathogenic organisms.[23] We excluded the delivery bed and trolley from the patient zone because previous work in Zanzibar found that these surfaces were often contaminated with bacteria.[139] A break in the 'delivery flow', indicating a new HH opportunity, arose if an activity occurred that was not exclusive to the patient zone e.g. inserting an intravenous line, touching the patient beyond the zone, or leaving the room.

Table 5.2 – Types of hand actions that did NOT indicate a new opportunity for HH

Hand Actions
Touching the patient thighs or perineal area, and the newborn after birth
Touching her own (the attendant's) body*
Touching a clean** delivery surface – cloth or macintosh
Touching equipment contaminated only with the woman's own body fluids during the procedure
Touching other sterile or clean material e.g. cotton swabs, drying material already available in the area for patient care***
Performing an injection (oxytocin) or supporting breastfeeding
Carrying the placenta to be disposed i.e. 'dragging' the patient zone
Removing or adding gloves, or rinsing hands with water **** as per WHO recommendations

*Unconscious touches e.g. touching briefly her own face are allowed by the WHO guidelines[10]. During the training we did not differentiate between this type of unconscious gesture and a longer behaviour e.g. standing with hands on hips for minutes. This recommendation assumes overall cleanliness and health of the birth attendant. These "permitted touches" did not include the birth attendant's clothes or gown.

**Usually a delivery surface was a large rectangular sheet of cloth or plastic (also called macintosh) brought by the woman from her own household. The surface was presumed to be clean, provided it was not contaminated e.g. with a woman's faeces or after falling on the floor. When the observer could not see what happened to the sheet, it was presumed to be clean

***If these items were collected outside the patient zone, they were also allowed as long as the birth attendant did not touch any other surface whilst collecting these items. Any other hand touch was recorded as a separate action, and would indicate a new opportunity.

****We allowed for the donning or removal of gloves, and rinsing hands with water only during the 'delivery flow' (after the first procedure) without indicating a new HH opportunity. This is because the WHO Guidelines for Pregnancy and Childbirth suggest that birth attendants should change their gloves before cord cutting and clamping, without needing HH, or that they should wash their gloved hands [36] while this is not a recommendation within the WHO HH Guidelines.

Hand rubbing/washing, glove use and recontamination

Before a 'delivery flow', a birth attendant should perform four behaviours sequentially, defined in our study as follows:[10]

1) Rub hands with alcohol-based handrub or wash hands with soap and water (soap use was presumed if the observer could not see the action).
2) Avoid hand recontamination after rubbing/washing until gloves are donned (or until the procedure if gloves are not worn).
3) Don at least one glove.
4) Avoid glove recontamination before starting the 'delivery flow'.

We defined recontamination of hands or gloves, as any touch on potentially contaminated surfaces within the workflow; this included touching an unclean delivery surface (e.g. a sheet that was in contact with the floor or with the woman's faeces), unclean hand-drying material (e.g. re-usable material), the woman and newborn outside the defined patient zone, the woman's bed, trolley, unclean objects used during HH (e.g. the sink tap or the bin) and *other* unclean surfaces, unless classified as outside the workflow (a full list of activities outside the workflow is shown in Appendix B available from https://doi.org/10.17037/DATA.00000778). These touches were distinguished from a deliberate new activity outside the workflow that would lead to a new HH opportunity as per the 5MHH (e.g. leaving the room or measuring blood pressure after completion of the aseptic procedure; see Appendix B available from https://doi.org/10.17037/DATA.00000778).

Where none of the four behaviours was implemented, we described the suboptimal glove related behaviours practiced instead.

Data cleaning and analyses

One author cleaned and checked the data for consistency. When multiple actions were recorded simultaneously we used the actions related to the hygiene behaviours and procedures of interest above other actions (e.g. leaving the room) leading to some loss of information. When contradictory information was reported about the same action (e.g. if observers recorded that both that soap was used and that they did not see soap being used), we coded the data as *inconsistent information*. For software interruptions during data collection, we followed the WOMBAT guidelines to clean time data.[132] We censored opportunities with insufficient information on hand rubbing/washing, glove use and recontamination because they occurred too close to the start of a time-&-motion observation session.

We estimated percentage compliance (behaviour performed over number of opportunities) and 95% confidence intervals for the entire recommended behaviour sequence (Behaviours 1-4), for partial completion of the sequence, and for each of the four hygiene behaviours individually. Behaviours 2 and 4 (avoid hand and glove recontamination) were, respectively, contingent on hand rubbing/washing (behaviour 1) and donning gloves (behaviour 3) (see Appendix C for numerators and denominators for each combination available from https://doi.org/10.17037/DATA.00000778).

We calculated frequency of adequate rubbing/washing technique (right palm over left dorsum with interlaced fingers and *vice versa*[41]) and duration (≥10s, following the Zanzibar infection prevention guidelines). We also described surfaces touched during hand/glove recontamination. Finally, we described within- and between-individual variation for the four behaviours using bar charts and intracluster correlation coefficients (ICC), restricted to attendants with ≥5 opportunities. The ICC is a measure of the relatedness of data. It accounts for this relatedness by comparing the variance within clusters with the variance between clusters.[143] The ICC was calculated on the log odds scale from univariate logistic regression models accounting for individual level clustering at the birth attendant level. GG coded all outcomes and SW checked the coding. Analyses were performed using STATA v14 (© Copyright 1996–2018 StataCorp LLC, College Station, TX).

Data sharing

Anonymised data at the opportunity level are available in Appendix F available from https://doi.org/10.17037/DATA.00000778.

5.4.4. Results

Dataset

We observed a total of 7893 hand actions (including procedures, touches and HH). After cleaning, the final results present the actions of 104 birth attendants across 10 facilities with 4 to 18 attendants per facility. These data were collected during 336 observation sessions ranging from 13 minutes to 6 hours 45 minutes, with a median time of 1 hour and 41 minutes. Each attendant was observed between 1-9 times (observation sessions). The kappa statistic calculated for pairs of data collectors was good for 2 of 3 pairs at 0.93 and 0.90, but was below the optimal level of 0.85 for one of the pairs, at 0.73.[132] Tailored feedback was provided to data collectors based on these results.

HH opportunities

There were 914 HH opportunities, of which 127 (13.9%) were censored because they occurred too close to the start of the observation period. Six HH opportunities were dropped because they had inconsistent information on HH. Our final dataset contains 781 HH opportunities.

Compliance levels

Birth attendants hand rubbed/washed in 24.6% (95% CI: 21.6-27.8; 192/781) of opportunities and 6.3% (12/192) of these instances were hand rubbing. Compliance with hand rubbing/washing did not vary much by observer or by shift – the CIs overlap (Appendix D available from https://doi.org/10.17037/DATA.00000778). Hand rubbing/washing was performed with adequate technique 30.7% (59/192) of the time and 14.6% (160/192) of the time lasted ≥10seconds (Appendix E available from https://doi.org/10.17037/DATA.00000778). Birth attendants avoided hand recontamination after rubbing/washing in 68.8% (95% CI: 61.7-75.2; 132/192) of opportunities.

In 63.0% (95% CI: 59.5-66.4, 492/781) of opportunities, attendants added at least one glove before the procedure (with or without prior hand washing/rubbing). Of these, 61.8% (95% CI: 57.3-66.1, 304/492) avoided glove recontamination. Overall, birth attendants risked recontaminating their hands or gloves in 45.3% (95% CI: 40.9-49.8; 227/501) of the opportunities when rubbing/washing or glove-donning occurred.

Consider now the actions that led to failures in avoiding glove or hand recontamination (Table 5.3). On average, 1.3 unclean touches occurred after hand washing/rubbing (standard deviation [SD]= 0.7, range 1-4) and the most commonly touched surfaces were the glove packs and unclean hand-drying material. On average, there were 1.5 unclean touches occurred after adding gloves (s.d.= 0.5, range 1-7) and the most commonly touched surfaces were the patient outside the defined patient zone and unclean delivery surfaces.

Table 5.3 – Surfaces touched risking recontamination after hand rubbing/washing or glove use

Type of surface touched	**After hand rubbing/washing**	**After adding gloves**
	% (n) N*=78	**% (n) N*=275**
Gloves pack	47.4 (37)	0
Unclean material when drying hands	20.5 (16)	0
Other unclean touches	16.7 (13)	16.4 (45)
Patient touched in areas which are **not** within the defined zone (i.e. the pelvis and thighs, or the newborn)	9.0 (7)	56.0 (154)
Personal bag	5.1 (4)	2.2 (6)
Unclean delivery surface (cloth or macintosh)	1.3 (1)	20.0 (55)
Patient bed	0	5.1 (14)
Waste bin	0	0.4 (1)

*Overall number of touches performed when birth attendants did not avoid hand or glove recontamination. These touches are spread across 60 opportunities when birth attendants did not avoid hand recontamination; whilst these touches are spread across 187 opportunities when birth attendants did not avoid glove recontamination.

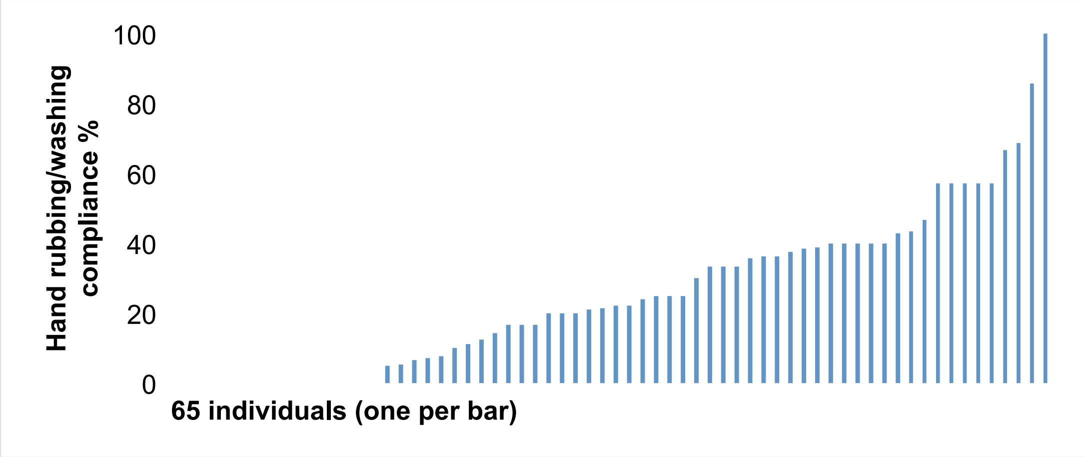
Between-person and within-person variability

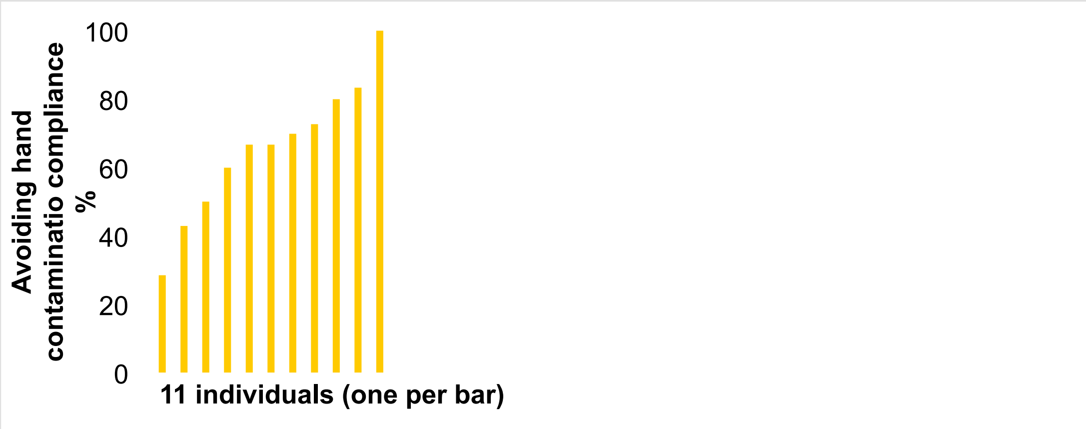
The 65 individuals with ≥5 HH opportunities contributed to the individual-level analyses of hand rubbing/washing (behaviour 1) and glove donning (behaviour 3) (Figure 5.1). However, recontamination could only be examined among 11 individuals who rubbed/washed and 44 individuals who donned gloves ≥5 times.

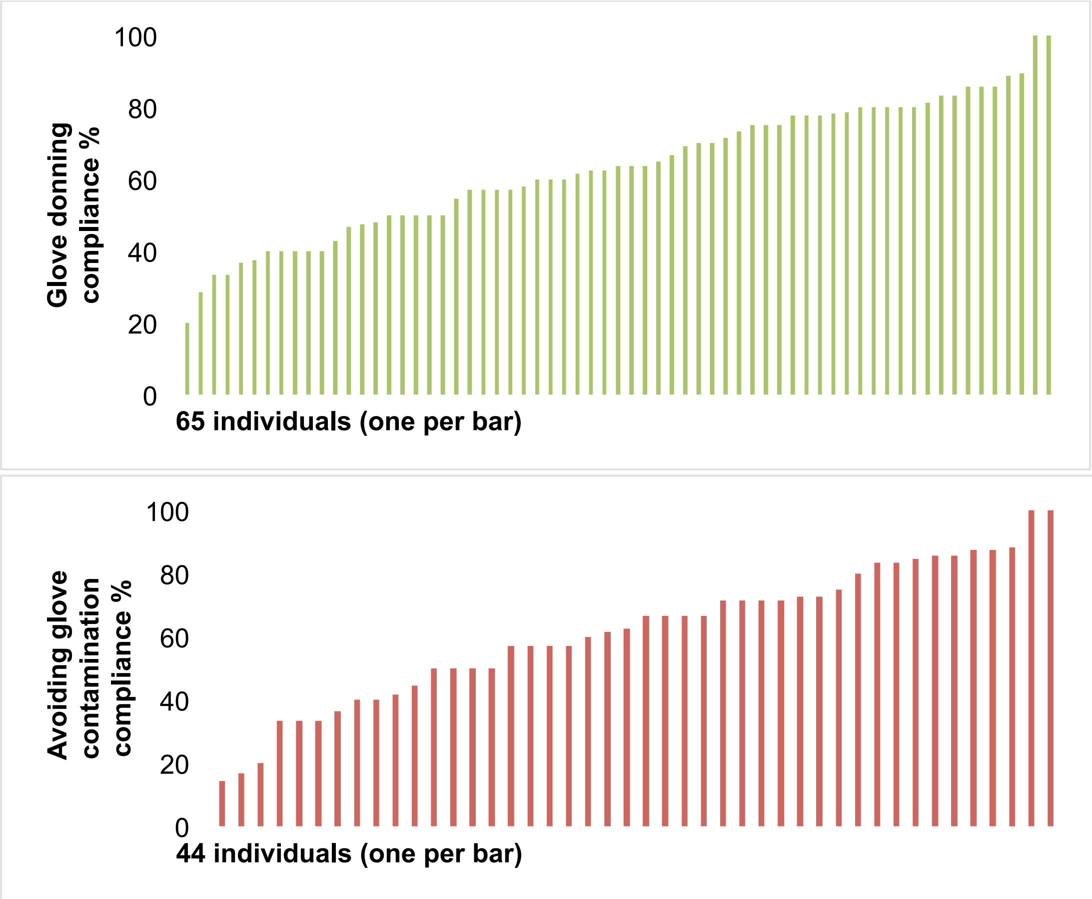
Fifteen attendants never rubbed/washed, one had 100% compliance, and the rest ranged between 5% and 85.7% compliance. The ICC indicates that most of the variation was within (72%; 95% CI:0.57-0.84) rather than between individuals (28%; CI 0.16-0.43). One attendant always avoided hand recontamination. The rest ranged between 28.6% and 83.3%. Most of the variation was within individuals, rather than between individuals (10%; 95% CI: 0.01-0.59%).

Two individuals always added new gloves before an aseptic procedure. The rest ranged between 20.0% and 89.5%. Almost all of the variation lies within individuals (96%; 95% CI:0.86-0.99) rather than between individuals (4%; 95% CI:0.01-0.14). After glove donning, two individuals always avoided recontamination. The rest ranged between 14.3% and 88.2%. Only 8% (CI:0.03-0.22) of the variation was between individuals and most of the variation was within individuals (92%; 95% CI:0.78-0.97). All ICC analyses were also carried out with all 104 individuals and yielded remarkably similar results.

Figure 5.1 – Distribution of individuals' compliance for hand rubbing/washing, glove use and recontamination







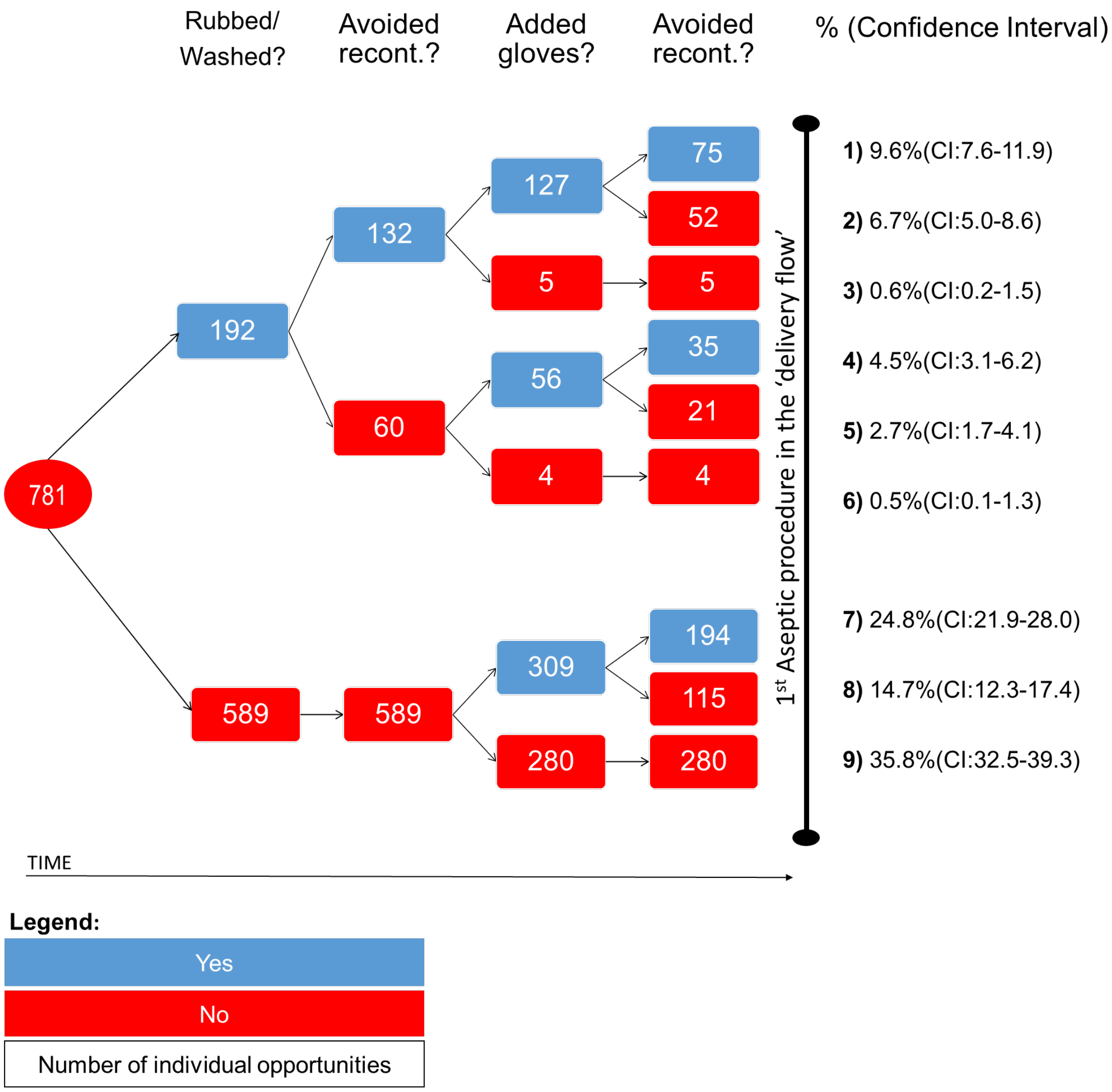
Note on Figure 5.1: Only individual with more than five opportunities were included in each of these graphs.

Behaviour sequences

Figure 5.2 presents the specific behaviour sequences of birth attendants. Sequence 1, the WHO recommendation, was followed in only 9.6% (95% CI:7.6-11.9) of opportunities. The most common practice, Sequence 9, was to perform none of the four behaviours (35.8%; 95% CI:32.5-39.3), followed by donning gloves without hand rubbing/washing and avoiding glove recontamination (24.8%; 95% CI:21.9-28.0) or not avoiding recontamination (14.7%; 95% CI:12.3-17.4); (Appendix F available from https://doi.org/10.17037/DATA.00000778).

In most opportunities in sequence 9 (55.0%; 95% CI:49.0-61.0, 154/280) attendants wore gloves used in a previous delivery flow. Other patterns are described in Appendix G, available from https://doi.org/10.17037/DATA.00000778.

Figure 5.2 - Behaviour sequences for 781 hand hygiene opportunities*



Note on Figure 5.2: This Figure describes the 781 opportunities available in the dataset. For each opportunity it outlines whether each of the four behaviours was performed. *Percentages refer to the number of opportunities in the last column e.g. in the first sequence: 9.6% refers to 75/781.

5.4.5. Discussion

In this time-&-motion study of 104 birth attendants across the 10 highest-volume labour wards in Zanzibar, we observed 781 HH opportunities before aseptic procedures. Compliance with hand rubbing/washing occurred in a quarter of opportunities; but in only 9.6% of opportunities attendants also donned gloves and avoided hand and glove recontamination before the procedure in accordance with WHO guidelines.[41] Half the time attendants either rubbed/washed hands or donned gloves they subsequently touched unclean surfaces with thus potentially recontaminating their hands, contributing substantially to poor HH compliance. The variation in behaviour was much larger within individuals than between, suggesting that these behaviours are not habitual.

Our findings of poor compliance are similar to those of other studies from LMICs. Low HH compliance (21%) before aseptic procedures was recently reported in a Nigerian hospital.[130] In Indian labour wards, compliance before delivery was 10.6%.[94] A study from Iran reported similar levels during the second stage of labour.[93] A study of one labour ward in Ghana reported compliance ranging between 21% and 27% before aseptic procedures.[91] In Zimbabwe one study found that 62% of midwives never washed hands before procedures.[89]. HH definitions vary in these studies making direct comparison with our results challenging. However, all studies highlight extremely poor HH behaviour.

Although, for most opportunities birth attendants did not rub/wash hands, in two-thirds of opportunities they did wear at least one new glove for the procedure. In the remaining one third, birth attendants adopted suboptimal glove-use behaviours that are not recommended[10] but may imply an attempt at placing a barrier between the birth attendant's hands and the patient. The most common was to attend different patients and procedures using the same gloves, consistent with other studies on the misuse of gloves.[129,144]

Although delineation between patient zones to address recontamination was studied in Vietnam,[46] to our knowledge, ours is the first study that sought to quantify the contribution of avoiding recontamination to HH compliance. Our findings are supported by studies in the United Kingdom and Australia where healthcare workers were observed to touch privacy curtains between HH or glove donning and patient care.[129,145] In a study based in Ghana, Cronin et al. describe qualitatively how birth attendants' gloved hands were observed touching the patient bed before the delivery.[88] Loftus et al. demonstrated microbiological recontamination of hands at the point of care despite high levels of self-reported HH compliance, indicating the relevance of recontamination in infection transmission.[146] Recontamination may be an indication that there is a lack of understanding of the definition of the WHO 5MHH in its attempt to direct an approach to HH action at times when recontamination risk within or between patients has been established. Future versions of the WHO HH Observation Form could add a recontamination option for the "missed" HH opportunities (when compliance was not met); which allow for recontamination to be monitored for both implementation and research purposes.

The contribution of avoiding recontamination to overall HH compliance in our study calls for further research, to investigate its importance in other contexts, its drivers, and its direct contribution to HAIs.[10] Acknowledging the avoidance of recontamination as a distinct behaviour and incorporating its measurement into existing tools for observing compliance, such as the WHO HH audit tool, would help quantify this problem and inform interventions to tackle it.

Our analyses revealed that variation in behaviour was much larger within individuals than between, suggesting that varying factors such as availability of materials and workload may be more important drivers than individual psychological determinants and that behaviour change strategies need to be tailored to actual practices and contexts.[18,48] It is important to note that these findings were generated in settings with limited resources; hence, in settings with more stable resources practices may be more habitual. Future studies could further investigate this.

We monitored healthcare workers behaviour using state-of-the-art time-and-motion methods, that have rarely been employed in low-resource settings.[47] This allowed us to investigate compliance with the complete sequence prescribed by the WHO guidelines on HH, as well as each individual behaviour and behaviour sequence. It also reduced the risk of observer bias because HH opportunities were identified retrospectively in a standardised way rather than relying on observer judgement.

Our study has some potential limitations. A residual Hawthorne effect may have caused over-estimation of compliance, despite blinding attendants to the study purpose in all but one facility. The 13% of opportunities with incomplete hand hygiene and glove information might not be random, as they may have occurred when procedures were rushed and HH more difficult – leading us to over-estimate compliance.[147] In 5/336 observation sessions we did not have data on attendance of new patients and assumed the same woman was attended throughout, potentially underestimating opportunities for HH and overestimating compliance.

In conclusion, in this time-&-motion study of hand hygiene and glove practices in the 10 highest-volume labour wards in Zanzibar, we found, as did previous studies, low compliance with the WHO HH guidelines. The major addition of this study is that it revealed the potential effect of recontamination, after initial washing/rubbing and donning gloves, on infection risk and the importance of including this as a separate item in HH measures. Additionally, variability in this behaviour seems to primarily reside primarily within the individuals across opportunities. Reducing the threat of HAIs in mothers and newborns calls for further research into drivers of recontamination and effective behaviour change strategies to tackle it.

5.4.6. Conflict of interest and acknowledgements

We declare no potential conflict of interests.

The project was funded by the Medical Research Council – PHIND scheme. Award number MR/N015975/1. The Soapbox Collaborative also contributed by funding staff involved in this project. The writing up of this paper provided part of the background needed for the CLEAN Study funded by the UK Joint Global Health Trials (Wellcome, MRC, DFID and DOH) Award number: MR/R019274/1.

We thank the Ministry of Health of Zanzibar for their participation and engagement in the study. A special thanks to Rukaiya M Said, Mwanafatima Ali Mohammed, Bijuma Mkubwa Abdallah, and Asya Hati Vuai who collected all the data. We also thank Marina Daniele for participating in the consultation exercise aimed at refining the definition of opportunity. Finally, we thank Daniel Powell and David Macleod for the support in data management.

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5.4.7. Additional Files

All appendices are available from https://doi.org/10.17037/DATA.00000778

Appendix A – Facilities description

Facility	**Island**	**Average reported number of deliveries per month**
Referral Hospital	Unguja	930
Maternity Hospital	Unguja	519
Cottage Hospital	Unguja	200
Cottage Hospital	Unguja	98
Private Hospital	Unguja	75
Primary Healthcare Unit	Unguja	75
District Hospital	Pemba	263
District Hospital	Pemba	200
District Hospital	Pemba	180
Cottage Hospital	Pemba	100

Appendix B – Actions that indicated a new hand hygiene opportunity & were outside of the workflow

Actions indicating a new hand hygiene opportunity and were outside of the workflow
Equipment undergoing decontamination
Object or material with body fluids *other* than that listed already listed in this table (i.e. placenta dish, equipment, macintosh, cloth for cleaning) or those listed in Table 2 in the manuscript
Attending another patient
Procedures not within the delivery flow • Adjusting IV fluids or changing IV bag • Insertion or removal of IV lines • Measuring vital signs • Manual removal of placenta* • Suturing* • Suctioning baby's nose/mouth • Using bag and mask on the baby
Other activities i.e. using: • Mop or other cleaning material • Cloth for cleaning the bed • Register, pen • Phone • Entering or leaving the room

*With exceptions stated in the manuscript

Appendix C – Numerator and denominator definitions for each outcome combination reported in the methods

(1-9 also follow the same number of Figure 5.2 in the main text)

Numerator	Denominator
1. Hand rubbed/washed, avoided hand recontamination, donned gloves, avoided glove recontamination	All opportunities
78	781
2. Hand rubbed/washed, avoided hand recontamination, donned gloves, and did **not** avoid glove recontamination	All opportunities
58	781
3. Hand rubbed/washed, avoided recontamination and did **not** donned gloves	All opportunities
5	781
4. Hand rubbed/washed, did **not** avoid recontamination, donned gloves and avoided glove recontamination	
35	781
5. Hand rubbed/washed, did **not** hand avoid recontamination and did **not** don gloves	All opportunities
4	781
6. Hand rubbed/washed, did **not** avoid hand recontamination, donned gloves and did **not** avoid glove recontamination	All opportunities
21	781
7. Did **not** hand rubbed/washed, donned gloves, and avoided glove recontamination	All opportunities
194	781
8. Did **not** hand rubbed/washed, donned gloves, and did **not** avoided glove recontamination	All opportunities
115	781
9. Did **not** perform either hand washing or glove donning	All opportunities
280	781
10. Gloves donned from a previous procedure	All opportunities where hand washing and gloves donning were not done
154	280
11. Gloves donned but a new deliberate activity that indicated a new opportunity was undertaken	All opportunities where hand washing and gloves donning were not done
43	280
12. Gloves were worn in layers in a previous procedure, the outer	All opportunities where hand washing and gloves donning were not done

layer was discarded for the procedure of interest	
34	280
13. Bare hands	All opportunities where hand washing and gloves donning were not done
41	280
14. Did not avoid glove or hand recontamination or both (after either washing/rubbing or glove donning)	All opportunities where washing/rubbing or donning gloves was done
227	501
15. Hand rubbing/washing	All opportunities
192	781
16. Avoiding hand recontamination	All opportunities where hand washing/rubbing was performed
132	192
17. Donning at least one glove	All opportunities
492	781
18. Avoiding glove recontamination	All opportunities where gloves were donned
304	492

Appendix D – Hand hygiene compliance by observer and shift

Variable	Number of observations	% hand rubbing/washing compliance	Lower 95% CI	Upper 95%CI
Shift type				
Morning	228	25.4%	19.9%	31.6%
Afternoon	256	26.2%	20.9%	32.0%
Night	297	22.6%	17.9%	27.7%
Observer				
A	234	18.4%	13.6%	23.9%
B	298	25.5%	20.7%	30.8%
C	249	29.3%	23.7%	35.4%

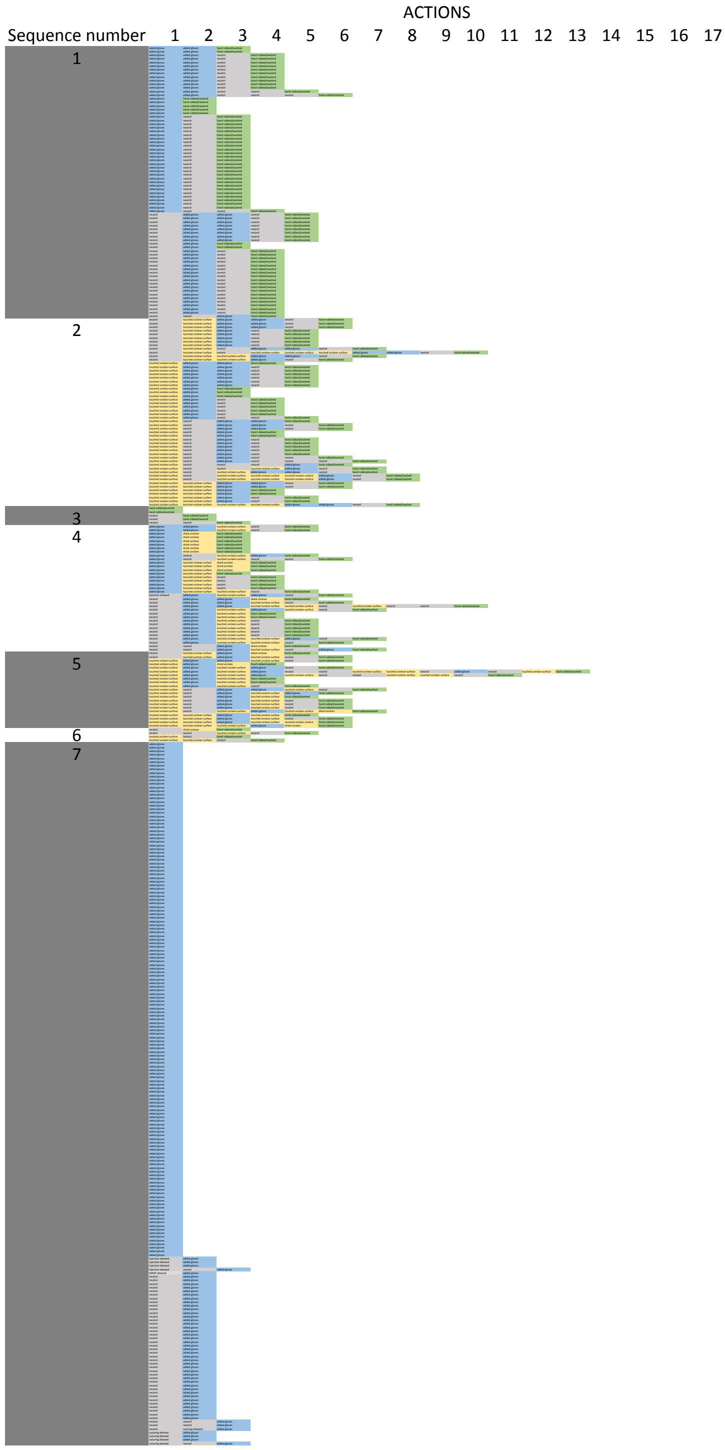
Appendix E – Duration and technique of hand rubbing/washing

	Appropriate technique	**HH lasted ≥10s**
	% (n) **N=192**	**% (n)** **N=192**
Yes	30.7 (59)	14.6 (28)
No	53.7 (103)	83.3 (160)
Not observed	14.6 (28)	2.1 (4)
Missing	1.0 (2)	0

Appendix F – Sequence of actions preceding the first aseptic procedure in the "delivery flow"

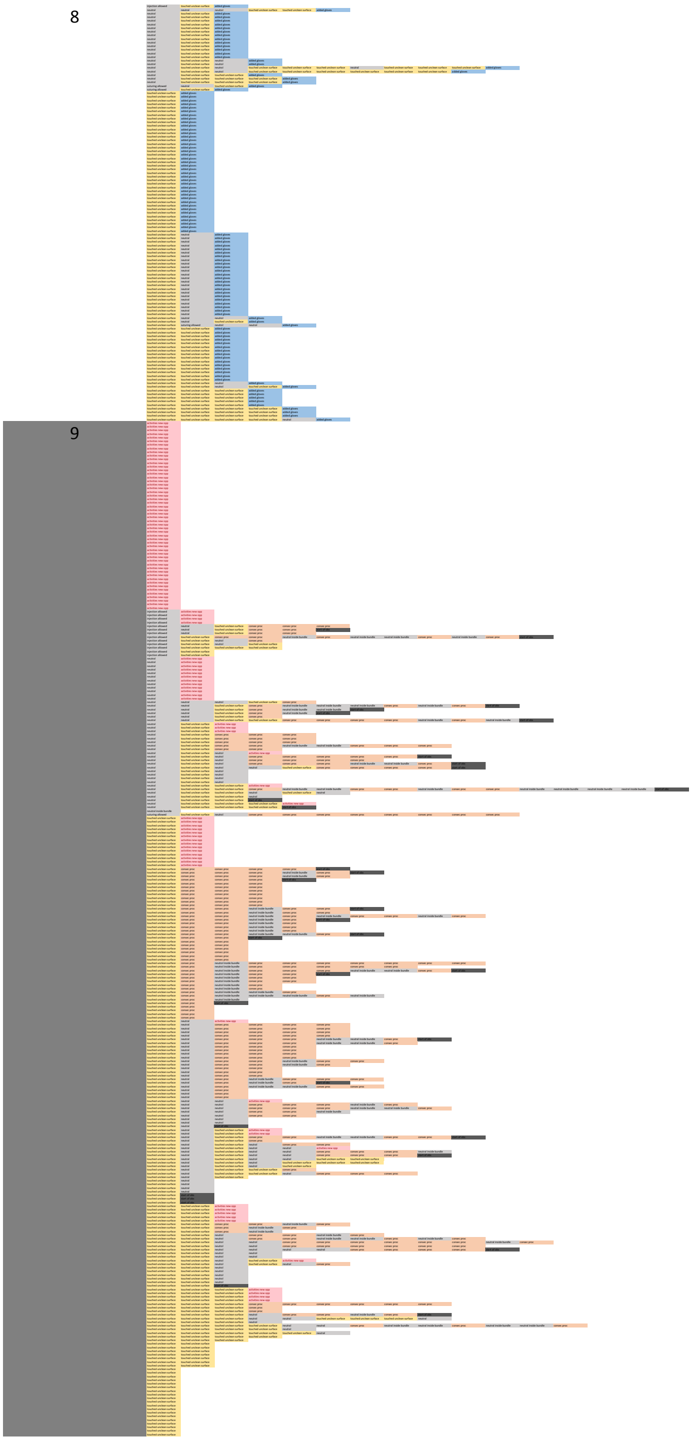
LEGEND

f	Activity that indicated a new opportunity
	Patient zone - activities that did not indicate a new opportunity
	Touched unclean surfaces
	Consececutive procedure in the delivery flow
	Action close to start of observation
	Gloves added
	Hand rubbed/washed



8

9



Appendix G –Patterns of glove behaviour under sequence 9 (from Figure 5.2 in manuscript)

We analysed the 280 opportunities in sequence 9 (Figure 5.2) in depth in relation to glove use. In 55.0% (CI:49.0-61.0) of these opportunities, attendants had gloves on from a previous delivery flow. In 15.4% (CI:11.3-20.1) of opportunities, attendants had previously donned gloves but then performed activities that constituted a new opportunity, such as leaving the room or taking blood pressure. A similar proportion had bare hands at the time of the procedure (14.6%; CI:10.7-19.3). Finally, in 12.1% (CI:8.6-16.6) of opportunities, attendants were wearing multiple layers of gloves, they took off the top layer which was used in a previous aseptic procedure, and used the second layer for the procedure of interest. For 2.9% of the opportunities we had insufficient information because the procedures of interest were too close to the start of the observation session.

6. BEHAVIOURAL DETERMINANTS OF HAND WASHING AND GLOVE RECONTAMINATION BEFORE ASEPTIC PROCEDURES AT BIRTH: A TIME-&-MOTION STUDY AND SURVEY IN ZANZIBAR LABOUR WARDS (PHD OBJECTIVE 5)

6.1. Preamble

In the previous chapter, we used to time-&-motion methods to estimate the levels of hand hygiene compliance of birth attendants in Zanzibar. In this manuscript, we combine this data with a cross-sectional survey with which we collect information on the hand hygiene determinants. We investigated the determinants of two behaviours: hand rubbing/washing and avoiding glove recontamination. To our knowledge, this study is the first to examine and compare the modifiable determinants of hand washing versus glove recontamination.

I conceptualized the study design and the tools with advice from two of my advisory members: Wendy J. Graham and Marijn de Bruin; I describe in detail my contribution to the time-&-motion dataset under Objective 3 of the thesis. In manuscript 5, I also present the results of the cross-sectional survey carried out that I designed, piloted and organized data collection for with support from one of my advisory members, Marijn de Bruin, the Tanzania principal investigator, Said M. Ali, and one of the co-authors of the manuscript, Michael de Barra. I conceptualized the analysis with advice from my supervisors and one of my advisory members Marijn de Bruin. Sandra Virgo conducted the cleaning and the operationalization of the survey variables (demographics, psychological constructs) with advice from me and one of my advisory members, Marijn de Bruin. I conducted the cleaning and variable operationalization of the time-&-motion dataset. I conducted all analyses with statistical advice from my supervisor Stephen Nash. I wrote the first draft of the manuscript and led the revisions from the co-authors.

The manuscript is formatted in accordance with the American Journal of Infection Control requirements.

6.2. Cover sheet

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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Giorgia Gon
Principal Supervisor	Oona Campbell
Thesis Title	Birth attendants' hands hygiene in maternity wards in low resource settings: levels and drivers

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?			
When was the work published?			
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?*	Choose an item.	Was the work subject to academic peer review?	Choose an item.

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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	American Journal of Infection Control
Please list the paper's authors in the intended authorship order:	Giorgia Gon, Sandra Virgo, Mícheál de Barra, Said M. Ali, Oona M. Campbell, Wendy J. Graham, Stephen Nash, Susannah Woodd, Marijn de Bruin
Stage of publication	**Not yet submitted**

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 conceptualised the study design and the tools with advice from my advisory members. I planned the data collection, and monitored the data. I conducted the analysis with advice from my supervisors. I wrote the first draft of the manuscript and led on the revisions from the co-authors. Details in chapter's preamble.

Student Signature: [redacted] **Date:** 24/10/2018

Supervisor Signature: [redacted] **Date:** 24 Oct 2018

6.3. Manuscript 5 – Behavioural determinants of hand washing and glove recontamination before aseptic procedures at birth: A time-&-motion study and survey in Zanzibar labour wards

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6.3.1. Abstract

Background: Recent research called for distinguishing whether the failure to comply to hand hygiene guidelines stemmed from omitting to rub or wash hands, or consequent recontamination of hands or gloves before a procedure. If the determinants of these behaviours are different, interventions may need to be as well. This study is the first to examine and compare the modifiable determinants of hand washing/rubbing versus glove recontamination.

Methods: Across the 10 highest volume labour wards in Zanzibar, 103 birth attendants were observed using time-&-motion methods, and interviewed using a cross-sectional survey. The latter included questions on attitudinal, normative and control beliefs. We used mixed-effect multivariable logistic regressions (accounting for clustering at the birth attendant level) to investigate the independent association of candidate determinants with two outcomes: hand rubbing/washing, and avoiding glove recontamination.

Results: After controlling for confounders, we found that that availability of single-use drying material (OR:2.9; CI: 1.58-5.14), higher workload (OR:29.4; CI:12.9- 67.0), more knowledge (OR:1.89;CI: 1.02-3.49) were associated with hand rubbing/washing, and a perceived sanctioning environment (OR:1.20; CI: 0.98-1.46) showed a tendency to do so. Only the length of time elapsed since donning gloves (OR:4.5; CI:2.5-8.0) was associated with avoiding glove recontamination.

Discussion: Multiple environmental and personal determinants of behaviour were identified for hand washing/rubbing, but only time elapsed was reliably associated with avoiding recontamination. Hence, this study suggests that determinants for both behaviours are different in this context, but future studies should investigate whether this is applicable to other wards and countries. If our findings yield true in future studies, this suggests that the two behaviours may require different interventions.

6.3.2. Background

Hand hygiene of birth attendants is a key infection prevention act for both mothers and newborns worldwide.[3,4,148] Indeed, hand hygiene is considered the single most important intervention to reduce healthcare-associated infections (HAIs).[149] These affect 15% of patients in low and middle-income countries (LMICs)[7], including Tanzania which is our study context,[76] nearly three times higher than in Europe.[8] In low-resource settings, newborns are 3-20 times more likely to develop infections compared to their European counterparts;[9] one study suggests that 4% of mothers contract puerperal sepsis in Tanzania.[148] Together with rapidly-growing numbers of women delivering in healthcare facilities in Tanzania,[71] overcrowding and unpredictable staffing levels and resources are frequent,[74] and the need for adequate infection prevention is paramount.

Inadequate hand hygiene (HH) compliance amongst healthcare personnel is common[10,16] and is usually summarized as a single behaviour. However, in our previous work in Zanzibar (Tanzania), we identified the need to distinguish whether the failure to comply with the hand hygiene guidelines stemmed from omitting to rub/wash hands, or the process of subsequently avoiding recontamination of hands/gloves before a procedure. This distinction cannot be made using the current WHO HH Observation Form;[41] yet, because these different behaviours may have different determinants, it is potentially important to study them separately in order to develop optimally effective interventions.

Previous studies have stressed the importance of investigating both the contextual and individual determinants of healthcare workers' hand hygiene.[10,48] The contextual factors include workload[10,16,49,50], staff professional background [10,16,48], availability of the necessary materials such as soap and water.[10,16] The individual factors include constructs like knowledge[10,56], and healthcare workers' attitudinal[10,48,50,51], normative [10,48,50,53], and control beliefs.[10,52] Various social cognitive theories include these individual factors, although context is usually described in very general terms (e.g. barriers and facilitators). In this study, we employ the widely-used Integrated Behavioural Model (IBM)[66] as the organizing framework, because it integrates individual and contextual behavioural determinants from multiple theories in one comprehensive model. In addition, we used this over other models because our research team had in-depth knowledge of IBM. The importance of using behavioural theory to guide research and implementation in this area has been highlighted.[10,18,54]

The IBM states that there are five determinants directly influencing behaviour: environmental constraints, knowledge and skills, habit, salience, and most importantly, intention.[66] In turn, intention is determined by attitude, perceived norms and personal agency. Valid alternatives to this model are the Theoretical Domains Framework (TDF) and the Health Action Process Approach (HAPA). The TDF consists of 14 theoretical domains (e.g. knowledge and social influence), derived from a wide range of behaviour change theories relevant to the implementation of evidence-based practice.[150] The findings from using the TDF can be directly aligned to behaviour change techniques to design an intervention in a very user friendly way. The TDF can also be used to study and improve the implementation. Being a more confined model, the HAPA describes compliance on a staged continuum from developing motivation for a given behaviour o planning, implementation and habituation of the behaviour.[54,67] Thus, it qualities as a stage theory of behaviour, allowing those applying it to differentiate healthcare workers in terms of their hand hygiene experience and behavioural stage.

To our knowledge no prior studies quantitatively examined the determinants of recontamination. Therefore, our aim was to investigate the independent association between individual and contextual determinants with hand rubbing/washing, and separately with avoiding glove recontamination (preceded or not by hand rubbing/washing); as well as compare these. We focused on determinants that were likely to be modifiable.

6.3.3. Methods

HANDS was a mixed-methods study that ran between November 2015 and April 2017 in the 10 highest-volume labour wards in Zanzibar (which we selected according to the reported volume across all the 37 facilities providing maternity services), with average monthly deliveries of 75 to 930. The project was a partnership between the University of Aberdeen, The London School of Hygiene and Tropical Medicine, and the Public Health Laboratory-Ivo De Carneri. Previous work in eight of these maternity wards found the majority had policies and basic material and infrastructure to perform HH but only 50% had received HH training in the previous year.[139]

Study design and instruments

Within HANDS, between September and December 2016, we used time-&-motion methods and a cross-sectional survey to capture the HH behaviour and its determinants amongst 103 birth attendants. For the time-&-motion component, three observers (trained midwives) used an observation tool to record hand actions (e.g. procedures, hand touches on surfaces) of birth attendants 24 hours per day, for a mode of 6 days (range: 5-14 days) in each of the 10 labour wards. They also collected information on the availability of key materials for hand hygiene (e.g. water) and on the presence of the ward in-charge during each observation session. Data were collected via tablets, and the observation tool was pre-coded using WOMBATv2 software.[132,135] More details on the use of this tool including piloting, training, data cleaning are described in Gon et al 2018.[128] We calculated several sample size scenarios for a cross-sectional design using EpiInfo v7 by varying the ratio of unexposed to exposed, the percentage of outcome in the unexposed group, and the effect size. For example, we had 80% power to capture an effect size of 2 (or above) when the distribution of the outcome in the unexposed was 10% (or above) and the ratio of unexposed to exposed ratio was 5:1 (Appendix A).

For the survey, the same data collectors administered a questionnaire, lasting about 45 minutes, to all birth attendants observed at each facility. Generally, the questionnaire was administered shortly (1-19 days) after observation in each facility, with one exception where it was 3 months later. The questionnaire was administered after the observation in order to conceal the specific study objectives from the birth attendants during the observation period. To further reduce the risk that the observational study biased survey responses,[49] we aimed for a birth attendant to not be interviewed by the data collector who observed them. For 7/103 birth attendants this was not possible because all three data collectors had observed the participant.

The questionnaire (available in Appendix B) included questions on the socio-demographic characteristics of the respondents and on psychological constructs stipulated by the Integrated Behavioural model.[66] The psychological constructs were asked for two outcomes separately (hand rubbing/washing and avoiding glove recontamination) specifically for the scenario of preparing for a delivery, which is a key infection prevention moment. Questionnaire items were also informed by the findings of earlier qualitative work within HANDS (manuscript under preparation – see thesis' Appendix VI – page 362), via a literature review, drawing on existing questionnaires and approaches as detailed below.[51,66,151–153] The questionnaire was administered in Swahili.

The questionnaire was piloted twice, respectively administering it to three and nine birth attendants, and revised accordingly. Pilot testing suggested a two-stage approach for eliciting responses about the psychological constructs (e.g. 1. do you agree or disagree? 2. Do you agree/disagree a little or a lot?) was understood best. Even though we tried to keep the number of items and responses options consistent across outcomes and constructs, the pilot results suggested some questions and response options did not work within our context (for example, answers were at ceiling). Therefore the number of items or response options differ for different constructs in the final version of the questionnaire. The training for this tool was done over two days.

In developing the psychological constructs that we measured using multiple items with Likert-like responses, we excluded two items that were intended to be reverse-scored but whose eventual distribution indicated that they had not been understood that way (details in Table 6.7 of Appendix C). We used Cronbach's alpha to investigate reliability of the constructs. Individual items were removed if this increased Cronbach's alpha by a substantial amount (details in Table 6.7 of Appendix C). Due to item removal, the final scales have a variable number of items. Sets of items with low internal reliability (alpha <0.6) were not used. These were, from Table 6.1, instrumental attitudes for both outcomes, and experiential attitudes for hand rubbing/washing. Items were combined to make a summative rating scale by calculating the mean score across all of them. Details of how we measured each construct and their internal reliability are available in Appendix C. Below we describe in more details the relevant questionnaire variables.

Table 6.1 - Reliability of psychological constructs measured with Likert-like response scales

Construct	Number of items	Cronbach's alpha
Outcome 1 (hand rubbing/washing)		
Instrumental attitudes	**5**	0.27*
Experiential attitudes	**4**	0.31*
Self-efficacy	**4**	0.68
Habit	**3**	0.71
Outcome 2 (avoiding glove recontamination)		
Instrumental attitudes	**3**	0.13*
Experiential attitudes	**2**	0.77
Self-efficacy	**3**	0.76
Habit	**3**	0.71

*Not used due to low internal reliability

Variables and their operationalization

From the variables collected during observation and the questionnaire we selected, *a priori*, candidate modifiable determinants for hand rubbing/washing and for avoiding glove recontamination (listed in Table 6.5 of Appendix C). A variable was subsequently excluded if a) it did not have a sufficient distribution within the sample (e.g. availability of gloves); b) it only related to a sub-group of HH opportunities for which the sample size was too small (i.e. whether the delivery equipment was collected or organized in a delivery set). Details of exclusion of separate variables can be found in Table 6.6 of Appendix C. The following section focuses on the variables that we used for analysis in this paper.

<u>Variables collected during observation</u>

Outcomes

We investigated determinants of two outcomes: whether birth attendants complied to hand rubbing/washing (outcome 1) and avoiding glove recontamination outcome (preceded or not by hand rubbing/washing) 2) before aseptic procedures during birth. In the latter, we included both opportunities where birth attendants did and did not hand rub/wash prior to donning gloves because the relevant set of individual determinants for this outcome collected with the questionnaire referred to avoiding glove recontamination in general. Compliance is achieved when hand rubbing/washing or avoiding recontamination after glove donning is performed when this should occur. The denominator is called a HH opportunity e.g. when the hand hygiene behaviour is expected to happen. These outcomes were operationalised using WHO guidelines[10,23,36] and are described in Gon et al.[128]

Contextual modifiable determinants

We constructed a proxy for workload, which was defined as the number of procedures conducted per minute in the interval between the start of the observation session and the opportunity of interest. Workload was categorised into five quintiles. The availability of single-use drying material was also collected during each observation session (categorised as binary). We also constructed a categorical variable measuring the time elapsed since donning gloves (less than a minute, between 1 and 2 minutes, between 2 and 3 minutes, more than 3 minutes).

Candidate confounders

For the relationship between each modifiable determinant and the outcome of interest, we drew a conceptual diagram, based on our reasoning and existing literature, to guide our selection of candidate confounders. From the observation tool we included: the presence of the in-charge (yes or no), and whether water & soap or handrub were available (which we refer to as necessary material).

<u>Variables collected with the questionnaire</u>

Individual modifiable determinants

Training

A binary variable indicated whether the birth attendant received or not a refresher training that included the topic of hand hygiene in the last year.

Attitudes

People's attitudes are comprised of beliefs about the outcomes or consequences of hand hygiene (instrumental attitudes), and experiential attitudes – the emotional or affective responses of healthcare workers when engaging in hand hygiene;[66] both have previously been found to be associated with hand hygiene.[10,48,50,51] The experiential attitudes scale for hand rubbing/washing was not used due to its low internal validity (Table 6.1). We measured experiential attitudes for avoiding recontamination with three items (questions) using a 3-point scale (no, yes a little, yes a lot). One item was removed to improve internal reliability. An example of an item asked was: "When you briefly touch the register, pen, or phone after putting on gloves, do you feel your hands are too dirty to conduct a delivery?" Experiential attitudes for avoiding recontamination did not show a continuous distribution. Hence, it was recoded into a binary variable indicating whether a respondent answered "yes a lot" to two items, in contrast to any other mixed response. Although we measured instrumental beliefs using Likert-like responses, this construct showed poor internal reliability for both outcomes and was not used (Table 6.1). Instead, we used a measure of instrumental beliefs which relied on a scenario asking participants to list all possible causes of umbilical cord infection in a one-week old baby and noting any mention of hand hygiene (binary: mention HH, or not). The use of the scenario was tried during the qualitative phase of the project and worked well among participants.

Norms and sanctioning

Norms and social influence can drive hand hygiene.[10,48,50,154] Norms were assessed using methods developed by Bicchieri et al [152] and entailed asking the respondents about the number, out of 10, of a) colleagues and b) Zanzibar maternity managers they believed to be always hand rubbing/washing or avoiding recontamination before delivery – empirical expectations (referred by the IBM as descriptive norms). We also measured normative expectations (referred by the IBM as injunctive norms) in a similar way but responses were at ceiling and we could not use this construct.

Sanctioning is an important component of normative expectations.[152] During the qualitative phase of HANDS we found that sanctioning in our context takes the shape of gentle reminders. To measure the frequency of such reminders in facilities, we asked birth attendants whether, in the past month, they reminded anyone about hand rubbing/washing; whether they were reminded; whether they heard a manager reminding anyone; whether they heard a colleague reminding anyone. Each question was scored 0 (reminders absent) or 1 (present), and summed to create a variable with a range of 0-4.

Self-efficacy

Self-efficacy is determined by one's degree of confidence in the ability to perform the behaviour in the face of constraints and obstacles.[66] The broader umbrella of personal agency (which also includes perceived control) has been found to be associated with hand hygiene.[10,52] Self-efficacy was measured with four items for hand rubbing/washing and three items for avoiding recontamination respectively using a 3-point scale (very sure, a little sure, not sure). An example is: "How sure are you that you will (can) wash hands before every delivery when water is not flowing from the sink? Self-efficacy was rescaled to a 10-point distribution for easier interpretation.

Habit

Experience performing hand hygiene might make it habitual, an automatic response.[155] We measured habit with four items drawing from the proposed habit index by Gardner et al.[153] Responses were measured on a 3-point scale (no, yes usually, yes always). One item was removed as it improved internal reliability of the scale. An example is: "Do you avoid touching unsterile objects before a delivery without thinking?" Habit was rescaled to a 10-point distribution for easier interpretation.

Knowledge

Lack of knowledge of guidelines/protocols that prescribe the behaviour has been associated with poor HH compliance.[10] Knowledge of hand rubbing/washing was assessed using demonstration of both hand washing technique (four aspects of the technique were observed e.g. covering the palm and thumbs)[10] and duration (measured as the attendant's ability to demonstrate the appropriate rubbing/washing for 10 seconds or more following the Zanzibar infection prevention guidelines). We could not include both variables because of the small sample size in our dataset; we chose to include duration.

Knowledge around avoiding glove recontamination was measured using one item on a 4-point scale (agree a lot, agree a little, disagree a little, disagree a lot). The item asked whether one could pick up germs from touching the delivery surface. It categorized into a binary outcome (agree vs. disagree). We did not use the second knowledge item about glove recontamination, as we were unsure it was correctly interpreted.

Candidate confounders

From the questionnaire, we selected: the type of professional background (e.g. senior nurse, nurse midwife), the time since their last formal training (no training, 1-3 years, 4-7 years, 8 and above), and years served in that specific maternity ward (continuous variable).

Analysis

For the two outcomes, we investigated their association with the same types of modifiable determinants aforementioned with the following exceptions. For avoiding recontamination, we did not consider the availability of single-use drying material, which was not relevant to avoiding recontamination, and knowledge of contamination which had a limited distribution in our sample as describe above (Table 6.4). For hand rubbing/washing, we did not consider the time elapsed since donning gloves, which was not relevant, or experiential attitudes because the scale had low internal reliability (Table 6.1).

All variables were cleaned and checked for inconsistencies. All analyses were carried out at the level of the hand hygiene opportunity. We used cross-tabulations to describe the distribution of variables in our sample overall and by facility. Crude associations between each independent variable and the relevant outcome were calculated using bivariate mixed-effect logistic regression models that accounted for clustering within birth attendants. We then built two separate explanatory mixed-effect logistic regression models (with individual birth attendants as a random effect), one for hand rubbing/washing (Model 1) and one for avoiding glove recontamination (Model 2), to assess which modifiable determinants were independently associated with each of the two outcomes. Model convergence was checked by increasing the number of quadrature points.[156]

To construct Model 1 and Model 2, we initially included modifiable determinants postulated above in the following order: a) contextual variables, b) knowledge and habit, c) attitudinal, normative and control beliefs, and d) other, i.e. received refresher training. We then included all candidate confounders in a stepwise fashion. Potential collinearity between the confounders and the modifiable determinants was assessed by change in the standard error and the mean least square. For variables hypothesized to have a continuous relationship with the outcome, we performed a test for departure from linearity (eventually workload and time since donning gloves were included as categorical variables). Psychological constructs measured as continuous variables were all included as linear terms *a priori*. Finally, we performed two sensitivity analyses. One assessed the effect on Model 1 of excluding data from the pilot facility; the second assessed the effect on both models of using a different definition of workload (i.e. the number of procedures in the fifteen minutes preceding the index procedure).

All analyses were carried out in STATA v15 SE.

Ethics approval

The project was approved by the Zanzibar Medical Research and Ethics Committee, the London School of Hygiene and Tropical Medicine Research Ethics Committee and the Research Ethics Committee at the University of Aberdeen. Consent was obtained from women (patients) either in writing in the antenatal ward prior to observation, or verbally in the labour ward, with written consent obtained before discharge. Women were informed that we would not collect information on them, rather that the person being observed was the birth attendant. Consent to observe the birth attendants was granted by the Ministry of Health and obtained verbally from the birth attendants when data collectors first visited the facility. All healthcare worker information was anonymised. Written consent to administer the questionnaire was obtained from birth attendants directly.

Data sharing

Anonymised outcome data at the opportunity level is available from https://doi.org/10.17037/DATA.00000778. Information on individual level variables is not publicly available because the small sample size may compromise the anonymity of this data. Part of this data can be requested directly from the manuscript authors.

6.3.4. Results

Descriptive

In total 103 birth attendants were observed and interviewed. We observed 779 HH opportunities before aseptic procedures. For 490 of these opportunities we could also examine glove recontamination. Rubbing/washing compliance was 24.4% (CI: 21.4-27.6, N=779), whilst compliance with avoiding recontamination after donning gloves was 62.0% (CI: 58.0-66.4, N=490). Rubbing/washing compliance did not vary by region (Pemba: 29.6%, N=152; Unguja: 23.1%, N=627) or shift (morning: 24.8%, N=226; afternoon: 26.2%, N=256; night: 22.6% N=297). Similarly, avoiding glove recontamination compliance did not vary by region (Pemba: 61.2%, N=85; Unguja: 62.2%: N=405) or shift (morning: 66.9%, N=151; afternoon: 60.4%, N=164; night: 59.4%, N=175).

Rubbing/washing compliance varied by facility, whilst avoiding glove recontamination did not (Figure 6.1). The intracluster correlation coefficient (ICC) for hand rubbing/washing was 12% (CI: 4.8%-29.4%) meaning that 12% of the variance lay between facilities, compared to 88% within facilities. The ICC for avoiding glove recontamination was lower, at 0.8% (CI: 0%-19.2%). The distribution of certain categorical modifiable determinants was limited in few institutions (see Table 6.2). For example, availability of single-use drying material and knowledge of hand rubbing/washing showed no variation in three facilities.

Figure 6.1 - Compliance by facility

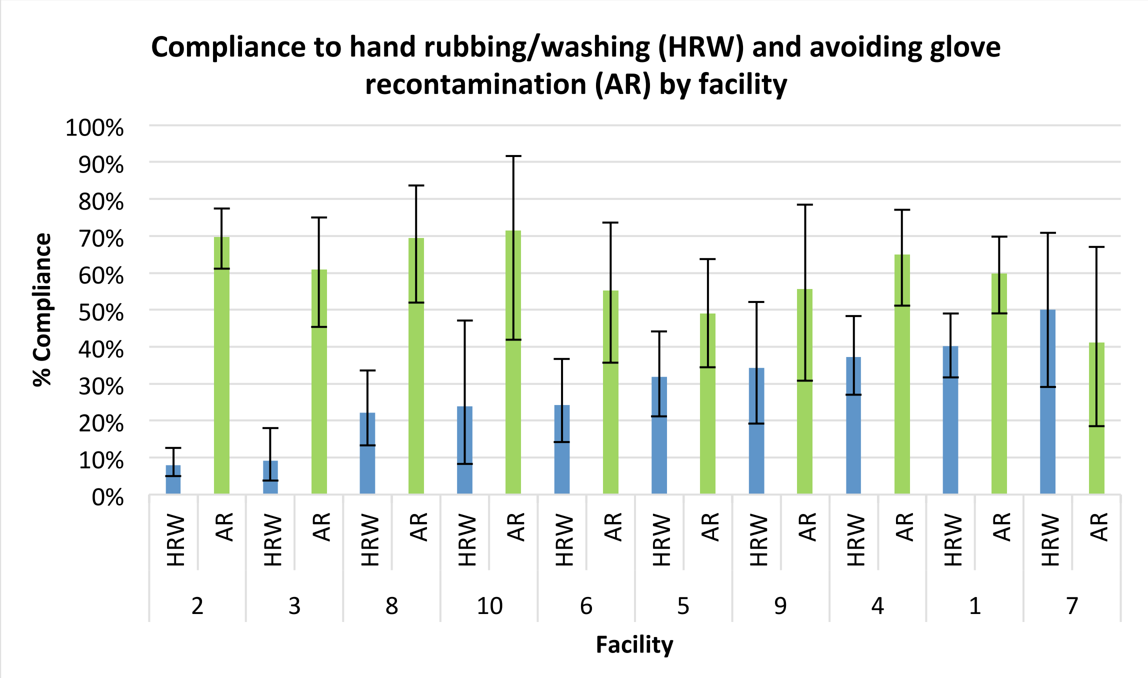

Table 6.2 - Distribution of the categorical modifiable variables by facility for each of our two datasets: A) hand rubbing/washing dataset (N=779) and B) avoiding glove recontamination (N=449)

Categorical modifiable determinants	**Facility % (n)**									
A) HAND RUBBING/ WASHING	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
N=779*										
Workload (lowest category)	19.7 (26)	11.9 (24)	21.1 (15)	15.1 (13)	24.6 (17)	24.2 (15)	54.8 (13)	19.4 (14)	25.7 (9)	38.1 (8)
Drying material (not available)	21.2 (28)	99.0 (200)	100 (76)	68.6 (59)	7.3 (5)	100 (62)	100 (24)	98.6 (71)	16 (45.7)	76.2 (16)
Knowledge (duration - >10 seconds)	94.7 (125)	34.2 (69)	35.5 (27)	44.2 (38)	36.2 (25)	66.1 (41)	100 (24)	52.8 (38)	54.3 (19)	0 (0)
Instrumental beliefs (mentions hand hygiene)	47.0 (62)	55.5 (112)	36.8 (28)	37.2 (32)	42 (60.8)	80.7 (50)	70.8 (17)	81.9 (59)	31.4 (11)	81.0 (17)
Refresher training (yes)	78.0 (103)	64.4 (130)	382 (29)	24.4 (21)	17.4 (12)	71.0 (44)	41.6 (10)	77.8 (56)	34.3 (12)	71.4 (15)

Categorical modifiable determinants	Facility % (n)									
B) AVOIDING GLOVE RECONTAMINATION	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
N=490**										
Time since donning gloves (less than one minute)	67.4 (62)	59.9 (79)	47.8 (22)	54.4 (31)	49.0 (24)	62.1 (18)	47.1 (8)	69.4 (25)	77.8 (25)	35.7 (5)
Workload (lowest category)	28.3 (26)	15.9 (21)	26.1 (19)	21.1 (12)	34.7 (17)	37.9 (11)	64.7 (11)	33.3 (12)	50.0 (9)	50.0 (7)
Experiential attitudes (always yes a lot)	97.8 (90)	65.9 (87)	82.6 (38)	80.7 (46)	87.8 (43)	27.6 (8)	100 (17)	75.0 (27)	83.3 (15)	42.9 (6)
Instrumental beliefs (mentions hand hygiene)	52.2 (48)	58.3 (77)	36.9 (17)	43.9 (25)	57.1 (28)	72.4 (21)	70.6 (12)	86.1 (31)	38.9 (7)	92.9 (13)
Refresher training (yes)	77.2 (71)	64.4 (85)	39.1 (18)	26.3 (15)	12.2 (6)	65.5 (19)	35.3 (6)	80.6 (29)	38.9 (7)	78.6 (11)

*Sample refers to data available for the hand rubbing/washing outcome

**Sample refers to data available for avoiding glove recontamination

This and the following paragraphs describe the distribution of different candidate modifiable determinants by relevant outcome. As Table 6.3 indicates, compliance with hand rubbing/washing was higher when workload was lower, single-use drying material was present, when birth attendants demonstrated knowledge of the appropriate hand hygiene duration, when they reported hand rubbing/washing to be a habitual behaviour, when they linked poor hand hygiene with negative patient outcomes (instrumental beliefs), when they believed more of their colleagues or managers rubbed/washed hands (descriptive norms), when they reported more sanctioning, and when they had received refresher training on hand hygiene in the past 12 months. Self-efficacy was not associated with hand rubbing/washing. From Table 6.3, only three variables had missing values or values with inconsistent information (<4%).

Table 6.3 – Descriptive characteristics of the sample and adjusted odds (Model 1) ratio for the association between each modifiable determinant and hand rubbing/washing

Variable name	Opportunities % (n) or Mean (s.d.) N=779	Rubbed/ washed % (n) or Mean (s.d.) N= 190	Adjusted odds ratio* (95% CI) N=751**	LRT p-value
MAIN DETERMINANTS				
Workload* **				
Highest	20.0 (156)	7.1 (11)	1	<0.0001
High	20.0 (156)	12.8 (20)	1.63 (0.67-3.92)	
Medium	20.0 (156)	25.6 (40)	4.29 (1.90-9.72)	
Low	20.0 (156)	14.7 (23)	2.22 (0.94-5.24)	
Lowest	19.9 (155)	61.9 (96)	29.39 (12.90-67.00)	
Availability of single use drying material				
No	71.5 (557)	19.9 (111)	1	0.0009
Yes	26.7 (208)	36.5 (76)	2.85 (1.58-5.14)	
Missing	1.7 (13)	23.1 (3)	-	
Inconsistent info	0.1 (1)	0	-	
Knowledge (duration)				
Less than 10 seconds	47.8 (373)	18.0 (67)	1	0.0457
10 seconds or more	52.1 (406)	30.3 (123)	1.89 (1.02-3.49)	
Habit° (1-10)	6.12 (2.50)	6.56 (2.40)	1.09 (0.96-1.24)	0.1716
Instrumental beliefs				
Does not mention HH	44.8 (349)	21.8 (76)	1	0.8066
Mentions HH	55.2 (430)	26.5 (114)	1.09 (0.55-2.14)	
Self-efficacy° (1-10)	4.9 (3.2)	4.9 (3.1)	0.94 (0.83-1.07)	0.3628
Descriptive norms (colleagues)° (1-10)	5.7 (1.8)	5.9 (1.7)	1.07(0.86-1.32)	0.5309
Descriptive norms (managers)° (1-10)	6.7 (2.3)	6.9 (2.4)	0.95 (0.82-1.11)	0.5646
Sanctioning (reminders)° (0-4)	2.5 (1.59)	2.9 (1.41)	1.20 (0.98-1.46)	0.0736
Hand hygiene refresher training in the past 12 months				
No	44.5 (347)	21.3 (74)	1	0.2390
Yes	55.5 (432)	26.9 (116)	1.43 (0.79-2.59)	
CONFOUNDERS				
Necessary material (water & soap, or gel)				
No	6.2 (48)	10.4 (5)	1	0.6798
Yes	90.4 (704)	25.1 (177)	1.28 (0.40-412)	

Missing	1.7 (13)	23.1 (3)		
Inconsistent info	1.8 (14)	35.7 (5)		
Presence of the in charge				
No	90.9 (708)	23.7 (168)	1	0.3655
Yes	7.5 (58)	32.8 (19)	1.54 (0.61-3.93)	
Missing	1.7 (13)	23.1 (3)	-	
Professional background				
Senior Nurse	4.8 (37)	16.2 (6)	1	0.1344
Nurse Midwife	48.7 (379)	23.0 (87)	0.91 (0.21-4.03)	
Public Health Nurse B	10.7 (83)	31.3 (36)	3.17 (0.63-15.87)	
Orderly	9.9 (77)	15.6 (12)	1.89 (0.38-9.50)	
Other nurse or nurse assistant	26.1 (203)	29.1 (59)	1.16 (0.23-5.91)	
Years since formal training				
8 and over	21.7(169)	22.5 (38)	1	0.0083
4-7	19.3150)	17.3 (26)	1.50 (0.49-4.58)	
1-3	15.0 (117)	24.8 (29)	4.07 (1.50-11.09)	
No training	9.9 (77)	15.6(12)	- ****	
Years working in this specific maternity°	3.7 (5.2)	3.4 (4.6)	0.99 (0.92-1.06)	0.7102

*Each odds ratio was adjusted for all other variables in the table

**28 observations with missing or inconsistent information (variables: in charge, drying material and necessary material) were not included in the model. Model 1 includes overall 182 events

***Workload was constructed as the number of procedures per minute: 0.3590-1.7647 (highest); 0.2010-0.3589 (high); 0.1129-0.2009 (medium); 0.0502-0.1128 (low); 0-0.0501 (lowest)

****The last category "no training" was omitted because of collinearity with the variable professional background. *No training* in this variable and orderlies in the *professional background* variable were perfectly matched.

°Variables included in the model as linear terms. Reported OR for these variables refers to the effect of one unit increase in the risk factor.

Avoiding glove recontamination occurred more frequently when less time elapsed between donning gloves and the index procedure, and when workload was higher (Table 6.4). The higher the workload, the shorter the time from donning gloves to the index procedure. Counter intuitively, avoiding glove recontamination also occurred more with lower experiential and instrumental attitudes, and when birth attendants had not received refresher training in the last 12 months. Self-efficacy, habit, descriptive norms and sanctioning were not associated with avoiding glove recontamination. From Table 6.4, only the variable indicating the presence of the in charge had missing values (1%).

Table 6.4 – Descriptive characteristics of the sample, and adjusted odds (Model 2) ratio for the association between each modifiable determinant and avoiding glove recontamination

Variable name	Opportunities % (n) or Mean (s.d.) N=490	Clean % (n) or Mean (s.d.) N= 304	Adjusted odds* ratio (95% CI) N=485**	LRT p-value
MODIFIABLE DETERMINANTS				
Time since donning gloves				
3 or more minutes	16.9 (83)	39.8 (33)	1	<0.0001
2-3 minutes	8.0 (39)	35.9 (14)	0.75 (0.33-1.85)	
1-2 minutes	16.3 (80)	53.8 (43)	1.54 (0.77-3.09)	
Less than a minute	58.8 (288)	74.3 (214)	4.49 (2.51-8.04)	
Workload* **				
Lowest	28.2 (138)	55.1 (76)	1	0.4694
Low	227 (111)	60.4 (67)	1.29 (0.72-2.34)	Test for trend= 0.0641
Medium	19.4 (95)	65.3 (62)	1.42 (0.75-2.69)	
High	17.8 (87)	65.5 (57)	1.64 (0.84-3.23)	
Highest	12.0 (59)	71.2 (42)	1.87 (0.87-4.04)	
Habit° (1-10)	6.6 (2.5)	6.6 (2.9)	0.99 (0.89-1.10)	0.8005
Experiential attitudes				
Mixed responses	23.1 (113)	65.5 (74)	1	0.6505
Always responded yes a lot	76.9 (377)	61.0 (230)	1.18 (0.57-2.45)	
Instrumental beliefs				
Does not mention HH	56.9 (279)	67.4 (188)	1	0.1670
Mentions HH	43.1 (211)	55.0 (116)	1.52 (0.83-2.78)	
Self-efficacy° (1-10)	4.9 (3.2)	4.9 (3.1)	1.02 (0.94-1.11)	0.6993
Descriptive norms (colleagues)° (1-10)	6.0 (2.0)	5.9 (2.1)	1.06 (0.86-1.23)	0.5551
Descriptive norms (managers)° (1-10)	6.9(2.4)	6.8 (2.5)	0.90 (0.76-1.05)	0.1731
Sanctioning (reminders)° (0-4)	2.6 (1.6)	2.6 (1.6)	1.03 (0.87-1.23)	0.7831
Hand hygiene refresher training in the past 12 months				
No	54.5 (267)	64.0 (171)	1	0.6245
Yes	45.5 (223)	59.6 (133)	1.16 (0.65-2.05)	

CONFOUNDERS				
Knowledge (touching delivery surface one can pick up germs)				
Agree	95.7 (469)	61.2 (287)	1	0.8171
Disagree	4.3 (21)	81.0 (17)	1.22 (0.23-6.53)	
Presence of the in charge				
No	90.8 (445)	62.0 (276)	1	0.4205
Yes	8.2 (40)	67.5 (27)	1.44 (0.59-3.56)	
Missing	1.0 (5)	20.0 (1)		
Professional background				
Senior Nurse	3.9 (19)	68.4 (13)	1	0.2252
Nurse Midwife	52.7 (258)	59.7 (154)	0.39 (0.10-.1.68)	
Public Health Nurse B	9.8 (48)	58.3 (28)	0.71 (0.15-3.38)	
Orderly	6.7 (33)	51.5 (17)	0.35 (0.08-1.68)	
Other nurse or nurse assistant	26.9 (132)	69.7 (92)	0.67 (0.13-3.39)	
Years since formal training				
8 and over	20.0 (98)	64.3 (63)	1	0.3938
4-7	22.2 (109)	66.1 (72)	0.82 (0.32-2.10)	
1-3	51.0 (250)	60.8 (152)	1.40 (0.53-3.74)	
No training	6.7 (33)	51.5 (17)	- ****	
Years working in this specific maternity°	3.5 (4.2)	3.24 (3.6)	0.94 (0.87-1.02)	0.1082

*Each odds ratio was adjusted for all the other variables in the table

**5 observations with missing or inconsistent information (variables: in charge) were not included from model. Model 2 includes overall 303 events

***Workload was constructed as the number of procedures per minute: 0.3590-1.7647 (highest); 0.2010-0.3589 (high); 0.1129-0.2009 (medium); 0.0502-0.1128 (low); 0-0.0501 (Lowest)

****The last category "no training" was omitted because of collinearity with the variable professional background. *No training* in this variable and orderlies in the *professional background* variable were perfectly matching.

°Variables included in the model as linear terms. Reported OR for these variables refers to one unit increase in the risk factor.

Analytical models

After adjusting for candidate confounders and all other modifiable determinants in Model 1 (Table 6.3), higher workload (p-value<0.0001) and the availability of single use drying material (p-value=0.0009) were associated with hand rubbing/washing. When workload was the lowest, the odds of rubbing/washing were 29.4 times higher (CI:12.9-67.0) than when workload was highest. When single use drying material was available, the odds of rubbing/washing were 2.9 times higher (CI: 1.58-5.14) compared to when it was unavailable. We also found weak strength of evidence that having more knowledge (p-value=0.0457) and more perceived sanctioning (p-value=0.0736) were associated with rubbing/washing. There was no evidence that other candidate modifiable determinants were associated with rubbing/washing.

After adjusting for candidate confounders and the other candidate modifiable determinants in Model 2 (Table 6.4), the time elapsed since donning gloves until the index procedure was associated with avoiding glove recontamination (p-value<0.0001). When less than a minute elapsed, the odds of avoiding glove recontamination were nearly five times higher compared to when the time elapsed was 3 or more minutes (OR: 4.5 (CI: 2.5-8.0). Other candidate modifiable determinants did not appear to be associated with avoiding glove recontamination.

Collinearity was not important in either Model 1 or 2. Our results did not substantially change when we ran the sensitivity analyses (results in Appendix D).

6.3.5. Discussion

In our study across the 10 highest volume facilities in Zanzibar, 103 birth attendants were observed using time-&-motion methods, and interviewed using a cross-sectional survey. Rubbing/washing compliance was 24.4% (CI: 21.4-27.6) and avoiding glove recontamination was 62.0% (CI: 58.0- 66.4). We found that availability of single-use drying material, lower workload, demonstrated knowledge and higher perceived sanctioning were determinants associated with more hand rubbing/washing. By contrast, less time elapsed since donning gloves until the procedure was the only factor associated higher odds of avoiding glove recontamination. The two outcomes appear to have different determinants in this context i.e. high volume labour wards in Zanzibar; this finding should be explored in future studies in other countries and in the wider healthcare environment as it may suggest the need for different behaviour change strategies required for the two behaviours.

We now consider the possible mechanisms behind the associations we found. The availability of hand hygiene material such as water, soap and drying material to ensure hand hygiene is of course necessary[16,56] – yet the role of drying material is not often investigated; this is likely to be a more prominent issue in low resource facilities with less research in this area. The importance of single-use drying material was emphasized by Yawson and Hesse in the obstetric/gynaecological units in Ghana,[91] since without these, healthcare workers need to air dry which can take several minutes. In environments like labour wards, with unpredictable volumes of patients and needs, spending several minutes drying hands after every hand rubbing/washing opportunity – meaning dozens of times a day in busy wards – is a substantial burden on healthcare workers. Our data collectors reported observing birth attendants adopt tactics to overcome this issue, for example, using the inside of the glove packs, or bringing tissues from home to dry their hands on.

More knowledge[10] or higher workload[10,16,49,50,56] are associated with hand hygiene compliance in the literature, and we also see these determinants independently associated with hand rubbing/washing in our study. These results are consistent with our earlier qualitative work within HANDS (manuscript under preparation – see thesis Appendix VI). In HH studies, workload is often measured as the number of opportunities preceding the one of interest.[48,49] We believe our measure, based on the number of procedures (since the observation start) is a stronger measure as it includes all procedures performed, not just the ones that lead to a HH opportunity. The issue remains that for different opportunities, we had varying lengths of time of observation preceding the opportunity. An observation started with a patient-attendant interaction and hence opportunities closer to the start of observation may have yielded a higher workload as an artefact of our measurement process. We performed sensitivity analyses using a workload variable only based on the previous fifteen minutes of observation, which yielded virtually the same results, giving us confidence that the selected measure of workload did not bias our findings in a significant way. Capturing workload this way was possible because we used time-&-motion methods to observe HH behaviour where all actions were recorded, not just opportunities. A potential key intervention areas is ensuring the availability of gel – very poorly available in this context but successful at improving hand rubbing/washing and healthcare associated infections in other contexts.[14,15,17,157] Handrub would at once reduce the problems posed by the unavailability of drying material and could reduce workload as less time is required to handrub than to handwash.

Although other studies have investigated the role of perceived normative beliefs on hand hygiene,[48,154,158] the specific role of a sanctioning environment has rarely been investigated. Our findings on sanctioning, that took the form of reminders in our context, suggest that when birth attendants perceived reminders around hand hygiene to be used more frequently in their environment, they were more likely to hand rub/wash. However, the statistical evidence underpinning this association is weak (p=0.07) and should be interpreted with caution; in addition reminders may not have been uniformly interpreted by the respondents as sanctioning; some may have interpreted them as a form of supportive supervision or more broadly feedback, which other studies have found to be associated with HH.[56] We could not investigate the role of injunctive norms, because the vast majority of respondents reported very high normative expectations, perhaps due to social desirability. These findings, also consistent with our qualitative findings for this project (manuscript under preparation – see thesis Appendix VI), suggest that social influence may play a larger role in Zanzibar maternity units than we have been able to demonstrate in this study. The importance of social influence, in the form of institutional engagement, has been highlighted in several large-scale HH interventions.[10,14,26]

The less time elapsed since donning gloves until the index aseptic procedure, the higher the odds of avoiding glove recontamination. The change in odds was substantial for each minute added between donning gloves and the procedure. This finding is plausible, in that the longer one keeps gloves on, the greater the chances of touching surfaces that can cause recontamination. This finding should be explored in future studies in the wider healthcare environment. Stressing the importance of donning gloves as close to the point of care as possible may be a useful strategy to prevent glove recontamination. In our dataset, no other variables were associated with avoiding glove recontamination. This is the first attempt to measure determinants of avoiding glove recontamination; it may be that the questions we used to assess the constructs for avoiding glove recontamination were not appropriate. In addition, the use of Likert-like scales is not very common in Zanzibar healthcare workers and may have led to non-differential measurement error; this in turn may have diluted our results towards the null hypothesis; this applies to both our outcomes. Alternatively, our findings may genuinely reflect the lack of strong beliefs or awareness underpinning this behaviour which, compared to hand rubbing/washing, is less emphasized as much in training or supervision in our context. Future studies should investigate the determinants of the two outcomes (hand rubbing/washing and avoiding glove recontamination) separately to assess whether determinants across them differ consistently. In this study we only investigated the determinants of glove recontamination (preceded or not by hand rubbing/washing), but ideally future enquiries could also look into recontamination of the bare hands after hand rubbing/washing (before glove donning).

Residual confounding is a limitation in this study. We were unable to account for the potential confounding effect of each facility itself (which includes infrastructural but also managerial aspects), because the number of facilities (N=10) was too small for a random effect in our model. Additionally, because the distribution of several other key determinants was entirely dependent on the facility, using a fixed effect would have prevented us from investigating key modifiable determinants. In order to investigate further the role of facility, we carried out a detailed spatial and qualitative analysis that is not presented here (manuscript under preparation – see thesis Appendix VI). A second limitation is that we could also not account for delivery-specific variables, such as the use of delivery sets or obstetric complications, because these were rare exposures. Therefore, we cannot rule out the extent to which these modify the effect of workload. Third, two particular sources of bias may have influenced our findings: Hawthorne effect for the observation tool and social desirability bias for the questionnaire. We tried to minimize the Hawthorne effect which is common in HH studies – by which we mean the potential alteration of the birth attendants' behaviour as a consequence of being observed[147,159] – for example, by concealing the specific aim of our study from the participants and running a sensitivity analysis removing the one facility that was aware of our study aim. With regards to social desirability in the questionnaire, which cannot be ruled out, the wide distribution of responses observed across the psychological constructs (except for injunctive norms) suggest the effect may be modest.

In conclusion, this multicentre time-&-motion study combined with a cross-sectional survey, found that availability of single-use drying material, workload, knowledge were associated with hand rubbing/washing. For determinants of avoiding glove recontamination, only the time elapsed since glove donning was associated; suggesting different determinants underpin the two outcomes investigated. Future studies should further investigate the determinants of avoiding recontamination (both hand and glove), and whether they differ from those driving hand rubbing/washing, in the wider healthcare environment and other countries to develop tailored behaviour change strategies.

6.3.6. Conflict of interest and acknowledgements

We declare no potential conflict of interests.
The project was funded by the Medical Research Council – PHIND scheme. Award number MR/N015975/1. The Soapbox Collaborative also contributed by funding staff involved in this project. The writing up of this paper provided part of the background needed for the CLEAN Study funded by the UK Joint Global Health Trials (Wellcome, MRC, DFID and DOH) Award number: MR/R019274/1.
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6.3.7. Additional Files

Appendix A – Sample size scenarios

Sample size scenarios were calculated in EpiInfo v7 using the Fleiss' formula with continuity correction. Cells shaded fit within our sample size.

Number of opportunities for 5:1 unexposed to exposed ratio

5:1	**Effect size**							
% of outcome in Unexposed	**1.1**	**1.3**	**1.5**	**1.8**	**2**	**2.5**	**3**	**5**
3%	191567	23213	9036	3920	2672	1365	864	309
5%	112504	13617	5294	2291	1559	794	501	176
10%	59820	6420	2487	1071	725	365	227	75
15%	33450	4020	1552	663	447	222	136	41
40%	8745	1022	381	153	98	∞	∞	∞

*Power at 80% and confidence intervals at 95%

Number of opportunities for 2:1 unexposed to exposed ratio

2:1	**Effect size**							
% of outcome in Unexposed	**1.1**	**1.3**	**1.5**	**1.8**	**2**	**2.5**	**3**	**5**
3%	120483	14771	5810	2555	1755	912	587	216
5%	70758	8660	3402	1493	1023	530	339	123
10%	33450	4079	1595	695	474	243	153	53
15%	21018	2552	993	429	291	147	92	29
40%	5478	642	240	96	62	∞	∞	∞

*Power at 80% and confidence intervals at 95%

Number of opportunities for 1:1 unexposed to exposed ratio

1:1	**Effect size**							
% of outcome in Unexposed	**1.1**	**1.3**	**1.5**	**1.8**	**2**	**2.5**	**3**	**5**
3%	107756	13350	5298	2356	1628	856	556	210
5%	63364	7824	3100	1374	938	496	320	118
10%	29900	4190	1452	144	438	226	155	50
15%	18780	3002	902	110	268	136	84	26
40%	4878	574	214	86	56	∞	∞	∞

*Power at 80% and confidence intervals at 95%

Appendix B – Questionnaire

Birth Attendant Questionnaire

Introduction

I am ______________________________ from ______________________

Purpose of the study

- To assess how well hand washing is done in maternity units and at home.
- To understand when and why health care staff wash their hands when helping during child birth.
- To design a programme to improve hand washing by health care staff.

This project is in partnership with the Ministry of Health and your co-operation is very important to ensure its success and ultimately improve infection prevention practices in Zanzibar. All birth attendants across 10 high volume hospitals in Unguja and Pemba will be asked to participate.

Conditions for participation

We would like you to take part in one interview. We will ask you questions about your experience of supervising or working in a maternity unit or caring for your newborn baby. The interview will take 30 to 45 minutes.

Risk or Discomfort

We may ask questions that you feel shy to answer or you do not want to answer. If this happens, you can refuse to answer or you can end the interview. You may find taking part in the interview is tiring. To minimize this, we will use a short structured questionnaire

Cost/Compensation

Taking part in this study will not cost you anything. You will not be paid but you will be compensated for your time.

Contact person for further questions or complaints

You can ask the interviewer any questions and raise any concerns. If they cannot help they will pass the question onto a senior member of the team. You may contact directly: Dr Said Ali, Director Public Health Laboratory, P.O.BOX 122 Wawi, Chake Chake, Pemba. Tele/Fax +255 24 2452003

Confidentiality

All information will be kept strictly confidential. Your name and any identifying information will be removed from publications so it will not be possible to link the responses to any particular person or setting. If you are not comfortable with any findings being shared, we will not publish them in order to protect your identity. Identifiable information will not be shared with your colleagues of facility managers

Voluntary participation

Taking part in the interview is voluntary and you are free to withdraw at any time. If you decide that you do not want to take part we will respect your decision. There will be no complaint or punishment.

Permission to continue

"Do you have any questions for me?"

If informant has any questions, record questions and your response here:

I, ____________________ (name of the respondent) have read and understood this text, understand what is expected of me and all my questions have been answered. I understand that I can withdraw at any time without giving any reason and this will not affect my work or any health services entitled to me. I freely accept to participate in this study.

________________________ ________________________ **Date**: ____________

Respondent's name *Signature (thumbprint)*

________________________ ________________________ **Date**: ____________

Interviewer's name *Signature*

Now we are going to start the interview. Feel free to ask any clarification and questions. If you do not understand a question, do not hesitate to ask.

Respondent Information			
R1	Respondent code (ID)		
R2A	Interviewer code (ID)		
R2B	Facility code (ID)		
R3	Date **Write the date in NUMBERS for day month year (DDMMYYYY)**	DATE MONTH YEAR	
R4	Time **Write the start time using the 24 hour clock format e.g. 0815**		
R5A	What is your title?	(1) Senior Nurse	
		(2) Nurse Midwife	
		(3) Public Health Nurse B (PHNB)	
		(4) Maternal and Child Health Aid (MCHA)	
		(5) Orderly	
		(6) Clinical officer	
		(7) Gynaecologist	
		(8) Assistant Medical Officer	
		(88)Other (Please specify)	
R5B	Are you the maternity in charge?	(1) Yes	
		(2) No	
R6	How long is your service at this maternity ward (yrs/months)?:	**Years** **Months**	
R7	How many years of service since completing your latest formal training for this position?	**If no training, put 99**	

R8	How old are you?		
R9	To become a birth attendant, how many years in total did you spend in formal training?	**If no training, put 99**	
Household characteristic			
R10A	How many household members are 18-years old or younger?		
R10B	Are all household members aged 6 to 18 currently students?	(1) Yes	
		(2) No	
		(3) No members ages 6 to 18	
R10C	What is the main building material used for the walls of the main building of your house?	(1) Baked bricks	
		(2) Poles and mud, grass, sun-dried bricks, or other	
		(3) Stones, cement bricks, or timber	
R10D	What is the main fuel used for cooking?	(1) Firewood, solar, gas (biogas), or wood residuals,	
		(2) Charcoal, paraffin, gas (industrial), electricity, generator/private source, or other	
R10E	Does your household have any televisions?	(1) Yes	
		(2) No	
R10F	Does your household have any radios, cassette/tape recorders, or hi-fi systems?	(1) Yes	
		(2) No	
R10G	Does your household have any lanterns?	(1) Yes	
		(2) No	
R10H	Does your household have any tables?	(1) Yes	
		(2) No	
R10I	In the last 12 months, has your nuclear family cultivated any crops? Does your nuclear family own cattle?	(1) No crops, and no cattle	
		(2) No crops, and yes cattle	
		(3) Yes crops, but no cattle	
		(4) Yes crops, and yes cattle	
R10J	What is the main building material used for the roof of the main building?	(1) Leaves (makuti), or other	
		(2) Iron sheets (tin)/asbestos, concrete, tiles	

Training and supervision			
F1	Think about the last two weeks - how much time during a day does the maternity in charge spend in the delivery room?	(1) Less than half an hour	
		(2) Between 30 minutes and 2 hours	
		(3) More	
F2	If there is an emergency during labour/delivery, who do you usually contact?	(1) The maternity in-charge	
		(2) Another colleague or birth attendant	
		(3) Doctor on call	
		(4) Other (please specify)	
3	Did you receive any refresher training including hand hygiene in the past 12	(1) Yes	
		(2) No	

	months?		
F4	Did you attend any supportive supervision session in the past three months?	(1) Yes	
		(2) No	
I1B	A mother brings her 1 week old baby to the pediatric ward with a high fever. You examine the baby and discover the umbilical cord is infected – it is red and discharging pus. List all the possible causes that might have caused the infection *Instructions: Encourage the respondent to identify as many sources as possible and to be* ***as specific as possible***	(1) Mentions hand hygiene of birth attendant	
		2) Does not mention hand hygiene of birth attendant	

Please remember that there are no good or bad answers, just the answers that best describe how you think and feel about these issues. The topic will be hand hygiene during delivery. When I ask you about hand hygiene I mean hand washing with water and soap or handrubbing with the appropriate duration and technique, drying.

Experiential attitudes				
		No	Yes – A little	Yes – A lot
		(1)	(2)	(3)
	I am going to ask you some questions. Let's start with one easy to practice:			
A1	Do you feel **hungry** before lunch?			
A2	Do your hands feel **dry** when you wash your hands repeatedly? *Note for interviewers: repeatedly means you have washed your hands 40 times across 10 women in labour*			
A3	Do you feel like a **good nurse** when you wash your hands before a delivery?			
A4	Do you feel **anxious** (wasi wasi) when you do **not** wash your hands before a delivery?			
A5	Do you feel **uncomfortable** when you put on gloves with wet hands?			
A6	**In a situation when you are working alone and there are multiple women to assist.** Do you feel **like you are wasting time/have insufficient time (kupoteza muda wako)** when you wash yours hands before a delivery?			

Instrumental attitudes					
I1A	Among newborns born in healthcare facilities, some newborns develop an infection within 1 week from birth. Where do you think infections com from?	Home (1)	Facility (2)	Similar for both (3)	
	I am going to read you some statements, and I will ask you if you agree with them or not	Agree a lot	Agree a little	Disagree a little	Disagree a lot
		(1)	(2)	(3)	(4)
I2	Before a delivery, if a nurse forgets to wash her hands, **she will get an infection**. Do you agree or disagree? A little or a lot?				
I3	Before a delivery, washing your hands will prevent the **newborn** from developing a serious infection. Do you agree or disagree? A little or a lot?				
I4	A newborn does not develop and infection if the birth attendant wears gloves but forgets to hand wash. Do you agree or disagree? A little or a lot?				
I5	You are wearing **two layers** of gloves at the same time. After having assisted a delivery, **you have taken the top layer off** and you immediately perform another delivery. In this situation, your hands will cause the newborn an infection. Do you agree or disagree? A little or a lot?				

Perceived control/Self-efficacy				
	In some situations, nurses find it difficult to wash their hands with soap before a delivery. I am going to ask you questions about your ability to perform hand washing in difficult situations			
		Very sure	A little sure	Not sure
		(1)	(2)	(3)
C1	How sure are you that you will (can) wash hands before **every** delivery when **water is not flowing** from the sink?			
C2	How sure are you that you will (can) wash hands before **every** delivery when **there is no disposable drying material**?			
C3	How sure are you that you will (can) wash hands before **every** delivery when **there is no birth attendant available to assist you** during delivery?			
C4	How sure are you that you will (can) wash hands before **every** delivery **when a mother is rushed** into the ward just before delivery, and you can see the **newborn's head on the perineum**?			

Social Influence and social norms				
		No	Yes usually	Yes always
		(1)	(2)	(3)
N1A	Do you think **you should** (napasso) wash your hands before a delivery?			
N2A	*[We recently asked 10 birth attendants in Zanzibar that previous question]* Out of these10, how many birth attendants thought **they should always** wash hands before a delivery?			
N3A	Think about birth attendants in Zanzibar. Out of 10, how many do you think do **always wash** hands before a delivery?			
N3B	Think about **in-charge(s)** in Zanzibar. Out of 10, how many do you think do **always wash** hands before a delivery?			
N1B	In a situation when you are working alone with multiple women to assist. Do you think **it is OK to not** wash your hands before a delivery in this circumstance?	Never OK	Not usually	OK to not wash
		(1)	(2)	(3)
N2B	*[We recently asked 10 birth attendants in Zanzibar that previous question]* Out of these10, how many birth attendants thought **it is never OK to** wash hands when they are working alone and assisting multiple women?			
N4A	In the past month, have **you** reminded anyone to wash hands?	(1) Yes		
		(2) No		
		(3) Don't remember		
N4B	In the past month, has **anyone** reminded you to wash hands?	(1) Yes		
		(2) No		
		(3) Don't remember		
N4C	In the past month In the past month have you seen or heard that **the ward manager** reminded anyone to wash hands?	(1) Yes		
		(2) No		
		(3) Don't remember		
N4D	In the past month has **any of your colleagues** reminded anyone to wash hands?	(1) Yes		
		(2) No		

		(3) Don't remember	

Habit				
Sometimes at work things come automatically and sometimes you have to remind yourself		No	Yes, usually	Yes, always
		(1)	(2)	(3)
H1	Do you wash your hands before a delivery **without thinking**?			
H2	Do you start hand washing before a delivery **without even realising** you are doing it?			
H3A	Do you ever have to **remind yourself** to hand wash before a delivery?			
	"Sometimes if people do things again and again, it becomes automatic and we don't need to think about it anymore. For example, when I first start fasting, I needed to consciously remember to not eat, but after a few days, I did it automatically without even thinking. Do you understand?"			
H3B	In a situation when you are working alone with multiple women to assist. Do you **automatically** wash hands before a delivery?			

Intention				
"Remember, there are no "good" or "bad" answers - we would like you to answer honestly. You personal answers will not be shared with anyone"		No	Yes, usually	Yes, always
		(1)	(2)	(3)
S1	Do you intend to wash your hands before every delivery?			
S2	Do you expect to wash your hands before every delivery when you are working alone?			
S3	Do you plan to wash your hands before a delivery when the birth is very fast (woman rushed into the labour room and the head is on perineum)?			

Knowledge					
	I am going to read you some statements, and I will ask you if you agree with them or not	Agree a lot	Agree a little	Disagree a little	Disagree a lot
		(1)	(2)	(3)	(4)
K1	Before a delivery, rubbing hands with hand gel is **not as effective** as water and soap at disinfecting. Do you agree or disagree? A little or a lot?				

K2	When yours hands touch very briefly the **trolley**, they **cannot** pick up germs. Do you agree or disagree? A little or a lot?				
K3	When your hands touch very briefly the **Macintosh or kanga**, they **can** pick up germs. Do you agree or disagree? A little or a lot?				

K4	Hand gel dries off in	(1) Less than 10 seconds	
		(2) between 10 and 20 seconds	
		(3) between 20 and 60 seconds	
K5 K6	Please demonstrate the appropriate hand washing technique and duration	Record if she shows: ☐ Behind fingers ☐ Thumbs ☐ Interlocking fingers (nail-fingers in Swahili) ☐ Palm Duration in seconds: 1) Less than 10 2) 10+	
K7	Which one takes longer: hand washing or hand rubbing?	(1) Hand washing	
		(2) Hand rubbing	
		(3) Don't know	

Take a couple minutes break

Sometimes birth attendants touch unsterile objects like the register or the phone before a delivery. I want to ask you some questions about this.

Experiential attitudes		No	Yes - A little	Yes - A lot
		(1)	(2)	(3)
A7	When you briefly touch the **register, pen, or phone** after putting on gloves, do you feel your hands are too dirty to conduct a delivery?			
A8	In a situation when you are working alone with multiple women to assist. Do you feel **anxious** when you briefly touch a **register, pen, or phone** after putting on gloves to conduct a delivery?			
A9	Do you feel **proud of completing things** (kufanikisha) when you avoid touching unsterile objects before conducting a delivery?			

Instrumental attitudes					
	I am going to read you some statements, and I will ask you if you agree with them or not	Agree a lot	Agree a little	Disagree a little	Disagree a lot
		(1)	(2)	(3)	(4)
I6	Touching a **register, pen, or phone** just before cord-cutting will cause an infection to the newborn. Do you agree or disagree? A little or a lot?				

I7	Avoiding touching a **kanga or Macintosh** before touching a woman's vagina will prevent her a serious infection. Do you agree or disagree? A little or a lot?				
I8	My hands are gloved and I am ready to perform a delivery. If I wash my hands again every time I touch a Macintosh or kanga I do not get any work done.				
I9	If I touch a **pen or phone or register** before touching a woman's vagina, I will get reprimanded.				

Perceived control/Self-efficacy				
		Very sure	A little sure	Not sure
	BEFORE A DELIVERY	(1)	(2)	(3)
C5	How sure are you that you will (can) avoid touching unsterile objects **when the delivery equipment is in various places**?			
C6	How sure are you that you will (can) avoid touching unsterile objects **when you are working alone**?			
C7	How sure are you that you will (can) avoid touching unsterile objects **when you are responsible for assisting multiple women at second stage labour**?			

Social Influence and social norms				
		Never touch	Not usually	OK to touch
		(1)	(2)	(3)
N5A	Do you think you **can** touch unsterile objects just after putting on gloves for a delivery?			
N6A	*We recently asked 10 birth attendants in Zanzibar the previous question*. Out of these10, how many birth attendants thought **they should never** touch unsterile objects after putting on gloves for a delivery?			
N7A	Think about birth attendants in Zanzibar. Out of 10, how many **never touch** unsterile objects after putting on gloves for a delivery?			
N7B	Think about **in-charge(s)** in Zanzibar. Out of 10, how many **never touch** unsterile objects after putting on gloves for a delivery?			
N5B	**In a situation when you are working alone with multiple women to assist.** Do you think **it is OK** to touch unsterile objects just after putting on gloves for a delivery in this circumstance?	Never OK	Not usually	OK to touch
		(1)	(2)	(3)

N6B	*We recently asked 10 birth attendants in Zanzibar the previous question*. Out of these10, how many birth attendants thought **they should never** touch unsterile objects after putting on gloves for a delivery, when they are **working alone and they are assisting multiple women**?	
N8A	In the past month have **you** reminded anyone to not touch unsterile objects after putting gloves on for a delivery?	(1) Yes (2) No (3) Don't remember
N8B	In the past month has **anyone** reminded you to not touch unsterile objects after you put your gloves on before a delivery?	(1) Yes (2) No (3) Don't remember
N9A	In the past month have you seen or heard that **the maternity in-charge** reminded anyone not to touch unsterile objects?	(1) Yes (2) No (3) Don't remember
N9B	In the past month has **any of your colleagues reminded** anyone to not touching unsterile objects?	(1) Yes (2) No (3) Don't remember

Habit		No	Yes, usually (most of the	Yes, always (all the times)
Sometimes at work things come automatically and sometimes you have to remind yourself		(1)	(2)	(3)
H4	Do you avoid touching unsterile objects before a delivery **without thinking**?			
H5	Do you avoid touching unsterile objects before a delivery **without realising** it?			
H6	Do you need to **remind yourself** to avoid touching unsterile objects before a delivery?			
	"Sometimes if people do things again and again, it becomes automatic and we don't need to think about it anymore. For example, when I first started fasting, I needed to consciously remember to not eat, but after a few days, I did it automatically without even thinking. Do you understand?"			
H7	**In a situation when you are working alone with multiple women to assist.** Do you **automatically** avoid touching unsterile objects before a delivery?			

Intention				
"Remember, there are no "good" or "bad" answers - we would like you to answer honestly. You personal answers will not be shared with anyone"		No	Yes, usually	Yes, always
		(1)	(2)	(3)
S4	Do you intend to avoid touching unsterile objects before a delivery?			
S5	Do you expect to avoid touching unsterile objects before a delivery when you are working alone?			
S6	Do you plan to avoid touching unsterile objects before a delivery when the birth is very fast (woman rushed into the labour ward and head is on perineum)?			

THE END	
Do you have any comments or questions after completing this questionnaire?	

Thank you for your participation in this study and for completing this questionnaire!

QUESTIONS FOR INTERVIEWER		
Q1	Is there any reason for you to believe that the respondent did not understand the answer categories? [If yes, explain what caused you to think this]	(1) Yes Why?
		(2) No

Appendix C - Selection of modifiable factors

Table 6.5 – List of modifiable exposures

Variable	**Questionnaire reference/Observation tool**	**How it was measured**
Both outcomes		
1. Attended supportive supervision in the last 3 months	Questionnaire – F4	Categorical response options
2. Hand hygiene refresher training in the past 12 months	Questionnaire – F3	Categorical response options
3. Instrumental beliefs (scenario)	Questionnaire – I1B	Binary response option
4. Delivery equipment type used	Observation – collected at the time of delivery	Categorical response options
5. Workload (number of procedures per minute)	Observation – procedures collected throughout observation as they happen	Composite variable described in manuscript methods section
6. Presence of the in charge	Observation – collected at the beginning of every observation session; updates after it changes	Categorical response options
Outcome 1		
1. Availability of single-use drying material	Observation – collected at the beginning of every observation session; updates after it changes	Categorical response options
2. Availability of gloves	Observation – collected at the beginning of every observation session; updates after it changes	Categorical response options
3. Necessary hand hygiene equipment	Observation – collected at the beginning of every observation session; updates after it changes	Composite variable made of three individual items with categorical response options: availability of water & soap, or gel. Described in manuscript methods section
4. Knowledge – technique demonstration	Questionnaire – K5	Number of all technique items when demonstrating handwashing
5. Knowledge – duration demonstration	Questionnaire – K6	Binary response option
6. Habit	Questionnaire – H1, H2, H3A, H3B	Likert scale response
7. Self-efficacy	Questionnaire – C1, C2, C3, C4	Likert scale response
8. Experiential attitudes	Questionnaire – A2, A3, A4, A5, A6	Likert scale response
9. Instrumental attitudes	Questionnaire – I2, I3, I4, I5	Likert scale response
10. Injunctive norms	Questionnaire – N1A, N2A,	N1A – Likert scale

	N1B, N2B	N2A – Response out of 10
11. Descriptive norms	Questionnaire – N3A, N3B	Response out of 10
12. Sanctioning (reminders)	Questionnaire – N4A, N3B, N4C, N4D	Composite variable made of N4A, N3B, N4C, N4D Individual items have categorical response options. Described in manuscript methods section
Outcome 2		
1. Time since donning gloves	Observation – automatically logged time once actions are recorded	Continuous variable described in manuscript methods section
2. Knowledge	Questionnaire – K2, K3	Likert scale response
3. Habit	Questionnaire – H4, H5, H6, H7	Likert scale response
4. Self-efficacy	Questionnaire – C5, C6, C7	Likert scale response
5. Experiential attitudes	Questionnaire – A7, A8, A9	Likert scale response
6. Instrumental attitudes	Questionnaire – I6, I7, I8 and I9	Likert scale response
7. Injunctive norms	Questionnaire – N5A, N6A, N5B, N6B	N5A– Likert scale N6A– Response out of 10
8. Descriptive norms	Questionnaire – N7A, N7B	Out of 10 response
9. Sanctioning (reminders)	Questionnaire – N8A, N8B, N9A, N9B	Composite variable made of N8A, N8B, N9A, N9B Individual items have categorical response options.

Table 6.6 - Excluded variables (as modifiable variables) and reason for exclusion

Variable	Reason for exclusion
Both outcomes	
Attended supportive supervision in the last 3 months	Limited distribution in sample 93.2% (n=726) did not attend supervision
Delivery equipment type used	Only related to delivery variable. Insufficient deliveries (N=170) in the dataset
Presence of in-charge	Limited distribution in sample; in 90.8% (n=708) in-charge was not present.
Outcome 1	
Availability of gloves	Limited distribution in sample; 96.5% (752) had gloves
Necessary hand hygiene equipment	Limited distribution in sample; 90.4% (704) had the necessary equipment
Knowledge – technique demonstration	Knowledge – duration was chosen instead.
Injunctive norms	N1A - Limited distribution in sample; 85% responded *always*.
	N2A - Limited distribution in sample; 85% responded *10/10 colleagues*
Outcome 2	
Knowledge	K2 – Concerns about the interpretation of this question. K3 seemed a better choice.
	K3 – Limited distribution in sample; 95.7% agreed with statement

Injunctive norms	N5A - Limited distribution in sample; 93% responded *never*
	N6A - Limited distribution in sample - 58% responded *10/10 colleagues*

Table 6.7 – Psychological constructs construction; excluded variables based on internal reliability or direction of association

Construct	Reason for exclusion of particular item	Scale Cronbach's alpha	If scale could not be constructed, what was the reason?
Outcome 1			
Self-efficacy	No items excluded	0.68	Not applicable
Experiential attitudes	A3 had poor spread	0.31	Low internal reliability, possibly due to formulation of items. Dropping individual items would have lowered Alpha even further. Although items A2, A5, A6 intended as reverse-scored, lack of inverse correlation indicated that A5 had not been understood as reverse-scored.
Instrumental attitudes		0.27	Low internal reliability. I4 only was intended to be scored in the opposite direction from the other three items, but in fact I3 scores also had inverse correlations with I2 and I5. Dropping I3 would not increase overall Alpha sufficiently (only achieving 0.31).
Habit	Excluded H3A, as its intended reverse scoring did not work.	0.71	Not applicable
Outcome 2			
Experiential attitudes	A9 was excluded as it had poor spread. Its removal increased the alpha from an initial 0.58.	0.77 for scale with A7 and A8 alone.	Not applicable
Instrumental attitudes	Not applicable	0.13	Low internal reliability. Removing any of the items would not have improved the result substantially.
Self-efficacy	Not applicable	0.76	Not applicable
Habit	Removed item H6, as the intended reverse scoring did	0.71	Not applicable

	not work.		

Appendix D – Sensitivity analyses

Table 6.8 – Sensitivity 1 – Remove pilot facility from Model 1

Variable name	**Adjusted odds ratio* (95% CI) N=727****
Workload***	
Highest	1
High	1.42 (0.58-3.48)
Medium	4.20 (1.85-9.52)
Low	1.94 (0.80-4.67)
Lowest	31.10(13.44-71.99)
Availability of single use drying material	
No	1
Yes	3.19 (1.76-5.78)
Knowledge (duration)	
Less than 10 seconds	1
10 seconds or more	1.71(0.90-3.25)
Habit°	1.09 (0.96-1.24)
Instrumental beliefs	
Does not mention HH	1
Mentions HH	1.26 (0.64-2.48)
Perceived control°	0.94 (0.83-1.07)
Descriptive norms (colleagues)°	1.11(0.89-1.39)
Descriptive norms (managers)°	0.94 (0.80-1.10)
Sanctioning (reminders)°	1.18 (0.97-1.45)
Hand hygiene refresher training in the past 12 months	
No	1
Yes	1.72 (0.93-3.18)

*Each odds ratio is adjusted for all other variables in the table

**Compared to Model 1 in the manuscript, 24 observations were not included from model because they belong to the pilot facility which has 12 events.

***Workload was constructed as the number of procedures per minute: 0.3590-1.7647 (highest); 0.2010-0.3589 (high); 0.1129-0.2009 (medium); 0.0502-0.1128 (low); 0-0.0501 (lowest)

°Variables included in the model as linear terms. Reported OR for these variables refers to one unit increase.

Table 6.9 – Sensitivity Model 1 and 2 with a different measure of workload (i.e. the number of procedures in the fifteen minutes proceeding the index procedure)

Hand rubbing/washing (Model 1)	
Variable name	**Adjusted odds ratio* (95% CI) N=629****
Workload (procedures number in 15 minutes preceding the index procedure)	
2 or more	1
1	9.00 (3.18-25.47)
0	21.7 (8.31-56.44)
Availability of single use drying material	
No	1
Yes	1.77 (0.93-0.23)
Knowledge (duration)	
Less than 10 seconds	1
10 seconds or more	2.17 (1.15-4.12)
Habit°	1.08 (0.94-1.23)
Instrumental beliefs	
Does not mention HH	1
Mentions HH	1.23 (0.62-2.59)
Perceived control°	0.95 (0.83-1.09)
Descriptive norms (colleagues)°	1.17(0.93-1.45)
Descriptive norms (managers)°	0.91 (0.76-1.06)
Sanctioning (reminders)°	1.17 (0.96-1.42)
Hand hygiene refresher training in the past 12 months	
No	1
Yes	1.79 (0.96-3.37)

*Each odds ratio is adjusted for all other variables in the table

**Compared to Model 1 in the manuscript, 122 observations were not included in the model because they did not have a period of 15 minutes preceding them.

°Variables included in the model as linear terms. Reported OR for these variables refers to one unit increase.

Avoiding glove recontamination (Model 2)	
Variable name	**Adjusted odds* ratio (95% CI) N=386****
Time since donning gloves	
3 or more minutes	1
2-3 minutes	0.76 (0.30-1.90)
1-2 minutes	1.30 (0.60-2.80)
Less than a minute	4.84 (2.52-9.29)
Workload (procedures number in 15 minutes preceding the index procedure)	
2 or more	1
1	1.70 (0.72-4.04)
0	0.95 (0.45-2.02)
Habit°	1.02 (0.91-1.15)
Experiential attitudes	
Mixed responses	1
Always responded yes a lot	0.99 (0.46-2.16)
Instrumental beliefs	
Does not mention HH	1
Mentions HH	1.18 (0.61-2.28)
Perceived control°	0.97 (0.86-1.10)
Descriptive norms (colleagues)°	1.01 (0.82-1.23)
Descriptive norms (managers)°	0.88 (0.74-1.05)
Sanctioning (reminders)°	0.99 (0.82-1.19)
Hand hygiene refresher training in the past 12 months	
No	1
Yes	1.08 (0.57-2.02)

*Each odds ratio is adjusted for all other variables in the table

**Compared to Model 2 in the manuscript, 99 observations were not included here because they did not have a period 15 minutes preceding them.

°Variables included in the model as linear terms. Reported OR for these variables refers to one unit increase.

7. DISCUSSION

The overall aim of this thesis was to synthesize existing evidence and generate new evidence on the levels and determinants of hand hygiene before aseptic procedures among birth attendants in LMICs, with a focus on labour wards in Zanzibar, Tanzania.

This discussion chapter is divided into seven sections including a summary of the findings; strengths; limitations; a comparison with previous studies; mechanisms; implications; and a conclusion.

7.1. Summary of findings

In this thesis, I conducted a systematic review (Objective 1) of hand hygiene compliance before aseptic procedures among birth attendants in LMICs. We found nine studies, of which only three had a large sample size and a clear definition. Their estimates of compliance ranged between 1% and 28%.[91,92,94] The systematic review also found multiple flaws across the primary studies reviewed, including poor reporting of the sampling strategy for observation and of the measures adopted to ensure quality of data collection, lack of clear definitions of hand hygiene compliance, and the lack of reporting of the inter-observer agreement. Finally, the designs, especially the lack of a sampling frame to select the facilities, limited the studies' generalizability to facilities in the same district or country.

To describe the context within which birth attendants are expected to comply to hand hygiene in Zanzibar (Objective 2), I analysed mixed-methods data from a cross-sectional study of 37 maternity wards. We found that overall less than half of facilities met the infrastructure, knowledge, and policy levels thought to be necessary to enable hand hygiene. Among higher-level facilities, the most substantial gap was in the knowledge index. Our finding of a poor enabling environment for hand hygiene warranted further research into the levels and determinants of hand hygiene compliance in this context.

With the aim of minimizing observer judgement and measuring the constituent behaviours involved in hand hygiene compliance before aseptic procedure during labour and delivery (Objective 3), we developed a tool (the HANDS at birth tool) based on time-&-motion methods. We found that the application of this tool was feasible in a low resource setting, where these methods have been seldom used before; we also found that the tool performed well in terms of inter-observer agreement.

To assess the level of hand hygiene compliance among Zanzibar birth attendants (Objective 4), we used this time-&-motion tool across the 10 highest volume facilities. We found low compliance, 10%, to the WHO hand hygiene guidelines before aseptic procedures. In addition, half of the time when rubbing/washing or glove donning was performed, hands were recontaminated prior to the aseptic procedure. In this same study, we also captured information about contextual and individual determinants of hand rubbing/washing and glove recontamination in pursuit of my final objective (Objective 5). We found multiple determinants of behaviour (workload, availability of single use-drying material, knowledge and sanctioning environment) for hand washing/rubbing, but only time elapsed was associated with avoiding recontamination.

7.2. Strengths

7.2.1. Sampling strategy and generalizability

For the cross-sectional survey (Manuscript 2) and the time-&-motion study (Manuscript 3 and 4), we used sampling strategies that allowed for our results to reflect the context of Zanzibar. During the cross-sectional survey we surveyed all 37 maternity units providing delivery services (our reference population). For our time-&-motion we chose from this exhaustive list of facilities the 10 with the highest reported volume of births. Our results thus capture high-volume facilities in this region of Tanzania. Eight of these facilities have an operating theatre and are comparable to other secondary and tertiary-level facilities in Eastern Africa. Across LMICs, facilities providing a broader range of maternity services (e.g. including C-sections) are usually higher volume, better staffed and equipped;[73] this was also shown in Manuscript 2 describing the context of Zanzibar. Although the low levels of compliance found in this thesis cannot be generalised to low-level facilities in LMICs (where workload, skilled staffing levels and the availability of infrastructure and equipment are all likely to be much lower), our results are likely representative of the majority of women delivering in facilities in Zanzibar – 90% of facility births happen in the 10 facilities we selected for our study. Similarly, in Tanzania and Kenya, most women who deliver in an institution deliver in a secondary or tertiary level facility.[73,160] Therefore, our results might provide some insights into the experience of the majority of women delivering in facilities in Eastern Africa.

Another strength was how we sampled the hand hygiene opportunities observed. Observation was carried out 24h a day for at least five days in each facility – most studies of hand hygiene do not carry out 24/7 observation, and observation is rarely carried out at night. The sequence in which we visited each facility was based on logistics considerations, whereas the start of an observation session was based on specific birth attendants-patient interactions.

7.2.2. Time-&-motion methods

We developed the *HANDS at birth* tool to capture the complex hand hygiene behaviours of birth attendants using state of the art methods: a time-and-motion study using a computerised system (WOMBAT). This has been rarely used to measure HH, or in low resource settings.[47,133,134,140,141] Our time-and-motion study allowed us to accomplish three objectives which would have not been possible with the widely used WHO HH Observation Form: a) to look at compliance with the complete sequence of behaviours prescribed by the WHO guidelines[10], b) to look at each behaviour individually, and c) to look at different behaviour sequences.[128] Additionally, our method is likely to have minimised the risk of observer bias because data collection coded a series of individual actions rather than relying on observer judgement that a new HH opportunity had occurred; opportunities were identified during the analysis in a standardised way.[142] Indeed, hand rubbing/washing compliance was similar between observers.[128] Beyond HH, the use of time and motion methods allowed investigation of other behaviour sequences and workflows.

7.2.3. Behavioural sciences tools

From the outset, we consciously aimed to integrate behavioural sciences tools into our research to better understand the behavior of hand hygiene among birth attendants and its determinants. The use of a clear behavioural framework allowed us to investigate a wide range of psychological constructs, and also to find the best way to measure these different constructs in our context spanning from Likert scales to the use of vignettes (e.g. Bicchieri et al for norms[152], Gardner et al. for habit[153]). Adopting a behavioural approach was also the foundation for using time-&-motion methods, in that we wanted to better understand behavior within the wider workflows.

7.3. Limitations

7.3.1. Sample size

A limited sample size prevented us from further exploring the determinants underpinning hand rubbing/washing and avoiding glove recontamination. First, we could not explore other potentially important contextual determinants, such as use of birth kits or complications during birth, which may lead to residual confounding. Second, a limited sample size in terms of the number of facilities (n=10), limited our ability to explore the role of the normative environment in more depth.

7.3.2. Hawthorne effect

A residual Hawthorne effect may have caused over-estimation of compliance, despite blinding attendants to the study purpose in all but one facility and despite recording all actions not just hand hygiene. However, this is likely to have been minimal because in the pilot facility, aware of our aim, we still found substantially suboptimal levels of hand rubbing/washing compliance (compliance ranged between 8% and 50% across the 10 facilities).

7.3.3. Behavioural model

We chose the IBM as the overarching framework to guide the questionnaire development described in Manuscript 5. This is a widely used model for a wide of range of behaviours including hand hygiene.[49,66] Alternatively, we could have used the TDF which relies on a wider range of behavioural theories, where the study results can be directly aligned with behavior change techniques in a more user-friendly way compared to the IBM. The TDF has been recently use to understand infection prevention behavior in the UK.[57,150]

7.4. Comparison with previous studies

In Zanzibar, in only 10% of opportunities did birth attendants fully complied with the WHO hand hygiene guidelines before aseptic procedure. These results are similar to the results found from one hospital in India by Spector et al. where the baseline compliance levels specifically before delivery was 10.6%, and before vaginal examination was 1.3% – these aseptic procedures were also the main focus of the observation in our study.[94] Amongst studies included in the systematic review, Spector et al. scored the highest on our quality indicators, and also was the only one from which we could isolate estimates of compliance exclusive to aseptic procedures during labour and delivery.

These findings of low compliance are consistent with other well-conducted multi-country studies of healthcare workers in LMICs, although not specific to the labour ward. A multi-country study in the Mediterranean region found that compliance during higher-risk patient interactions (including before aseptic opportunities) was 35%.[21] A study in Costa Rica, Mali and Pakistan found the hand hygiene compliance across all five WHO opportunity types to be 22% during the baseline period.[19] We are not aware of reviews of hand hygiene compliance during labour and delivery from high-income countries. Among the 96 studies reviewed by Erasmus at al.,[16] none provide specific estimates for the labour ward.

Although the generalizability of the importance of recontamination is limited to the context of Zanzibar birth attendants our findings are supported by qualitative studies in the UK and Australia, where healthcare workers were observed to touch privacy curtains between hand hygiene or glove donning and patient care.[129,145] Loftus and colleagues demonstrated microbiological recontamination of hands at the point of care, despite high levels of self-reported hand hygiene compliance, indicating the relevance of recontamination in infection transmission.[146] From the systematic review, we only found one study by Cronin et al., based in Ghana, describing recontamination qualitatively – birth attendants' gloved hands were observed touching the patient bed before the delivery.[88]

We cannot compare our findings on the determinants of hand rubbing/washing with those found in other LMICs labour wards, as none of the articles we included in the systematic review investigated such determinants. To our knowledge there is no other published literature on comparing the determinants of hand rubbing/washing and avoiding glove recontamination.

7.5. Mechanisms

The following section discussed the potential mechanisms behind two of our findings: the importance of recontamination and the different drivers underpinning hand rubbing/washing and glove recontamination.

7.5.1. Recontamination

Deciding if touching a certain surface led to recontamination, and thus whether hand rubbing/washing needs to be repeated, is not always simple, and may explain why recontamination plays such a substantial role in low compliance to the WHO HH guidelines. It may be relatively easy to establish when a new hand hygiene opportunity arises during a hospital round for example, when contacts between the doctor and the patients involve intact skin only. Here, as the doctor approaches the patient zone, hand rubbing/washing is clearly needed from one bed to the next. By contrast, birth attendants experience a hectic environment during labour and delivery, where it may not be straightforward to decide whether touching a specific surface could lead to pathogen transmission. The birth attendant faces a mixture of uncomplicated and complicated deliveries which translate into varying timings of labour and delivery, and the need for different procedures. This may involve rapidly collecting equipment from outside the patient area. There are unpredictable volumes of birth at any one time, meaning that one healthcare worker may need to attend several mothers simultaneously in the context of under-staffed facilities in LMICs. Finally, the birth attendant is dealing with the transition from one patient to dealing with two (mother and newborn), during which the variety, amount, and type of body fluids can rapidly escalate. Even as a research team, we found it challenging to assess when a new opportunity arose during labour using the WHO Observation Form that we used in the early stages of the HANDS study.

The hypothesis that birth attendants might not be clear on which surfaces lead to a new hand hygiene opportunity resonates across multiple findings. First, in Manuscript 4, we found that the most commonly touched surfaces leading to recontamination in Zanzibar were the gloves pack (after hand rubbing/washing), and the patient outside the patient zone (after glove donning). The weakest aspect of knowledge on the indications for hand hygiene was Moment 5, which refers to whether birth attendants should wash their hands after touching the patient's surroundings. Different personnel are likely to have different understanding of what is safe or unsafe to touch. Hor et al. provide a useful ethnography of the concept of boundaries in hand hygiene and infection prevention in Australia, including the perception of certain surfaces potentially leading to cross-transmission or not.[45] The basic knowledge of which surfaces could lead to pathogen transmission or not is of course important, but probably more important is a healthcare worker's belief that touching certain surfaces can pose a serious risk to their patient and how this is weighed against other priorities, which may be more urgent than taking the time to rub/wash. As we describe in Appendix VI (page 362), birth attendants are conscious of this prioritization exercise, stating that if a woman arrives in the labour ward fully dilated, they will prioritise attending her rather than performing adequate hand hygiene. Smiddy et al. in a systematic review of qualitative studies on hand hygiene discusses this process of prioritization, the implicit hierarchy of tasks, that healthcare workers have to juggle with.[50]

7.5.2. Different determinants

Comparing the factors underpinning hand rubbing/washing and avoiding glove recontamination, we found that these seem to differ (Manuscript 5). None of the variables that explained hand rubbing/washing variation, explained variation in avoiding recontamination. This is a plausible finding because the two behaviours entail very different component actions: hand rubbing/washing implies reaching the sink or the handrub bottle, application of the product, and a certain technique whereas avoiding recontamination only implies avoiding touching particular surfaces until the interaction with the patient or procedure. Moreover, since these components are similar across most healthcare environments, it is plausible to think that the difference in determinants will hold in other healthcare contexts. While this is only one study in a specific context, limiting its generalizability, it is nonetheless an interesting finding.

Overall, for both behaviours (hand rubbing/washing and avoiding recontamination), individual level factors, such as demographic characteristics and psychological attitudes, were less important in explaining the variation in hand hygiene compliance than contextual determinants (e.g. workload and time elapsed since donning gloves). With the conditions of labour varying so dramatically between each patient, the key role of contextual variables is not surprising; especially in a resource-limited context such as Zanzibar, which is persistently under-staffed and often lacks good management and organization. Indeed, in Manuscript 4 we described how the majority of the variation in these two behaviours was due to within-person variation rather than between-persons. Future investigation could explore this within-person variation by asking staff why they did not comply to the guidelines right after the expected behaviour was not performed, especially enquiring on their perceived control beliefs. A recent study by Fuller et al. has successfully carried out an analogous study.[57] We initially aimed to pursue a similar design but it would have revealed the study aim, putting the main objective (i.e. assessing levels of compliance reliably) at risk of bias.

7.6. Implications

7.6.1. Clinical and policy implications

I have two main recommendations targeted at public health practitioners in the context of Zanzibar, but also more generally to services to improve hand hygiene among birth attendants within LMICs:

1) Adapt the existing hand hygiene intervention approaches to the context of the labour and delivery ward.
2) Introduce handrub and educational interventions aimed at changing beliefs about handrub in Zanzibar labour wards.

1) Existing successful hand hygiene intervention strategies should be adapted by considering the specific universal features of labour and delivery. Low hand hygiene compliance during labour and delivery in LMICs was a key finding that is particularly important given the increasing number of women giving birth in facilities in LMICs.[73] The WHO has developed the Multimodal Hand Hygiene Improvement Strategy which has demonstrated moderate success in changing hand hygiene behaviour in various contexts.[17,59] The Ministry of Health of Zanzibar should sign up to this global initiative, following the lead of other low resource countries.

The WHO strategy is made of five building blocks: system change, training and education, evaluation and feedback, reminders in the workplace, and institutional safety climate. My findings highlight how two of these building blocks need particular attention when adapted to the context of labour and delivery: system change, and training and education. System change means ensuring that all necessary infrastructure and equipment is in place for healthcare workers to practice hand hygiene. As described in the Background chapter and in Manuscript 3, working in the labour ward is defined by characteristics such an unpredictable volume of patients, and a mixture of complicated and uncomplicated cases. Therefore, easily accessible material for hand washing and hand rubbing is essential in this setting. The efficient arrangement of hand hygiene material should be also thought through within the wider set of equipment needed for delivery; this would assist birth attendants to better manage the unpredictable nature of births. Small scale studies report on the importance of the physical environment in the birth setting in high-income countries.[161,162] The convenience of sink location and handrub was also shown to support hand hygiene behaviour.[163,164] Training and education is another essential building block of the WHO strategy. As summarised above, recognising when a new opportunity arises in the context of labour and delivery is not trivial and this should be considered when training birth attendants on hand hygiene. Finally, global efforts and programs to improve the wider quality of care for mothers and newborns in facilities in LMICs already exist, and it is crucial that these hand hygiene interventions are not run in silos, and work within these other parallel efforts.[165,166]

2) The Ministry of Health of Zanzibar should consider making handrub available in the labour wards and training birth attendants to use it. In Zanzibar, we found that lower workload and availability of drying material were key determinants of hand rubbing/washing. Handrub availability has previously been found to increase hand hygiene compliance and reduce HAIs including in the African context.[14,15,17,157] Handrub can simultaneously reduce workload as it takes half the time as washing with soap, and drying material is not required. As a result, in one facility on Unguja island in April 2017, we piloted the introduction of handrub. In addition, the pilot also included an educational component that explained how and when to use handrub, and a demonstration race between two nurses to show that hand rubbing is faster than hand washing with soap. Another component of the education, in the form of a video, aimed at changing instrumental beliefs around the use of handrub. The latter was done because from the questionnaire described in Manuscript 5, we learned that almost half of birth attendants agreed with the statement that handrub was not as effective as water and soap. The feasibility of this intervention was assessed by observing 144 hand hygiene opportunities (using the WHO Observation Form) for two weeks after the intervention was administered. Three-quarters of all hand hygiene actions were done using handrub (rather than water and soap). Currently we are seeking funding to evaluate the impact of this intervention. We received an expression of interest from a local company which produces alcohol (a key component of handrub) from sugar cane to start producing handrub locally, along with an expression of interest from the Ministry of Health of Zanzibar to buy 18 months of supply for three large facilities. Local production has been successfully tried in other African contexts.[28]

7.6.2. Research and monitoring implications

I have three main recommendations targeted at future research and monitoring efforts in this field:

1) Use time-&-motion methods to research hand hygiene.

2) Improve the design and reporting of studies investigating hand hygiene of birth attendants in facilities in LMICs.
3) Further investigate the levels of hand and glove recontamination and their determinants.

1) The use of time-&-motion methods should be considered in future studies of hand hygiene. These methods minimize observer bias when collecting new hand hygiene data because they do not require observers to make a judgment of what constitutes a new opportunity at the time of the observation. Capturing multiple behaviours and their sequence (recontamination events, as well as the use and *misuse* of glove) was another advantage compared to the WHO Observation Form. In addition, because we captured all the procedures performed by birth attendants using time-&-motion methods, we were able to construct a measure of workload that was not based just on the sheer number of hand hygiene opportunities, but used all observed procedures.

If WOMBAT can be linked to a statistical program that automatically analyses its output, it could be used in routine monitoring to provide individually tailored feedback and action planning to healthcare workers. These have been proven to have sustained success in improving hand hygiene in recent randomised trials in the UK.[38,40,167]

2) Future studies should design and report various aspects of study quality more clearly. This recommendation stems from the low quality of the studies we included in our systematic review. Future studies should use internationally recognised definitions of hand hygiene, measure inter-observer agreement, include a representative sample of facilities, select a random sample of hand hygiene opportunities for observation, include measures to ensure quality data collection, and attempt to blind participants from the purpose of the observation.

3) The extent to which recontamination contributes to low compliance is a novel finding which should be explored in future studies in other countries and in the wider healthcare environment – for example in Accidents and Emergency departments, which are also characterised by unpredictable workload and a mixture of complicated and less complicated cases. Recontamination should also be investigated for Moment 1 – hand hygiene before touching a patient, as for this type of opportunity avoiding recontamination is also an implicit condition when categorising hand hygiene compliance using the WHO Observation Form. If our findings are replicated, routine measurement of avoiding recontamination by practitioners is recommended. Currently

the WHO Observation Form does not allow the observer to distinguish whether the failure to comply to the WHO hand hygiene guidelines is due to a lack of hand rubbing/washing or due to hand or glove recontamination after initial hand rubbing/washing.

Future studies should also explore the specific determinants of avoiding recontamination (both hands and gloves). Recontamination appears to be a distinct behaviour compared to handrubbing/washing, and as such it may have different determinants – as we showed in Zanzibar. Interventions that work to increase hand rubbing/washing may not necessarily reduce the determinants of recontamination. Beyond the efficient organisation of wards discussed above, potential intervention areas that could be tested include providing training on the importance of donning gloves as close to the point of care as possible. Another potential area that could be tested in healthcare workers training is to explicitly discuss which surfaces should be included in the patient zone and which may be reservoirs for pathogens.

7.7. Conclusions

Using a systematic review, we found only nine studies that quantitatively examine birth attendants' hand hygiene in LMICs facilities; amongst the three with better definitions and sample sizes, compliance ranged from 1-28%. Using time-&-motion methods, we found that 10% of Zanzibar birth attendants hand rubbed/washed, donned gloves and avoided recontamination before aseptic procedures. Half of the time when rubbing/washing or glove donning was performed, hands were recontaminated. Analysis of behavioural determinants found that in Zanzibar rubbing/washing was associated with lower workload, availability of single-use drying material and knowledge; whereas, avoiding glove recontamination was associated with less time elapsed since glove donning. The public health implications are that hand hygiene should be improved in maternity wards in LMICs, given the increasing number of women giving birth in facilities[73], and that Zanzibar should implement the WHO Multimodal Hand Hygiene Improvement Strategy with widespread availability of alcohol-based handrub, and key educational and system components adapted to the maternity settings. Future research includes further development of the time-&-motion methodology to facilitate its use into clinical practice, clinical governance frameworks, and performance feedback interventions. Further exploration of hand and glove recontamination and their determinants is required to assess whether this finding is replicated in other wards and countries and to tailor existing interventions to include this behaviour.

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9. APPENDICES

9.1. Appendix I –WASH analysis paper mentioned in the Background chapter

RESEARCH ARTICLE

Who Delivers without Water? A Multi Country Analysis of Water and Sanitation in the Childbirth Environment

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Abstract

Background and Objectives

Hygiene during childbirth is essential to the health of mothers and newborns, irrespective of where birth takes place. This paper investigates the status of water and sanitation in both the home and facility childbirth environments, and for whom and where this is a more significant problem.

Methods

We used three datasets: a global dataset, with information on the home environment from 58 countries, and two datasets for each of four countries in Eastern Africa: a healthcare facility dataset, and a dataset that incorporated information on facilities and the home environment to create a comprehensive description of birth environments in those countries. We constructed indices of improved water, and improved water and sanitation combined (WATSAN), for the home and healthcare facilities. The Joint Monitoring Program was used to construct indices for household; we tailored them to the facility context–household and facility indices include different components. We described what proportion of women delivered in an environment with improved WATSAN. For those women who delivered at home, we calculated what proportion had improved WATSAN by socio-economic status, education and rural-urban status.

Results

Among women delivering at home (58 countries), coverage of improved WATSAN by region varied from 9% to 53%. Fewer than 15% of women who delivered at home in Sub-Saharan Africa, had access to water and sanitation infrastructure (range 0.1% to 37%). This was worse among the poorest, the less educated and those living in rural areas. In Eastern Africa, where we looked at both the home and facility childbirth environment, a third of women delivered in an environment with improved water in Uganda and Rwanda; whereas, 18% of women in Kenya and 7% in Tanzania delivered with improved water and sanitation.

Competing Interests: The authors have declared that no competing interests exist.

Across the four countries, less than half of the facility deliveries had improved water, or improved water and sanitation in the childbirth environment.

Conclusions

Access to water and sanitation during childbirth is poor across low and middle-income countries. Even when women travel to health facilities for childbirth, they are not guaranteed access to basic WATSAN infrastructure. These indicators should be measured routinely in order to inform improvements.

Background

Hygiene at the time of birth is important to the health of mothers and newborns, irrespective of whether childbirth takes place at home or in a facility. Existing studies link neonatal sepsis and maternal mortality to poor access to water and sanitation (WATSAN)–essential for hygiene practices, in both environments.[1–4] Moreover, historical evidence strongly links maternal mortality and hygiene at birth in facilities.[5–7] Birth-related infections cause the death of many mothers and babies. Infection contributes to at least 9% of maternal deaths, and 680 000 neonatal deaths annually; these are concentrated in low and middle-income countries (LMICs) and are likely to be underestimates.[8,9] Indeed, the rate of newborn infections among babies born in hospitals is 3–20 higher in LMICs compared with high-income countries;[10] and expert opinion suggests that about 27% of these could be reduced with a clean delivery, whether at home or in health facilities.[11] Beyond childbirth, access to WATSAN in the home has broader implications for the health of newborns and mothers, and across the life cycle.[12]

A clean delivery requires: clean hands of the birth attendant, clean perineum, clean birth surface, clean cord preparation and cutting, and appropriate newborn postpartum skin care; [11] these 'six cleans' cannot be achieved without good access to WATSAN. Access to WATSAN in both the facility and home environment is generally very low across LMICs. A recent WHO report found that 38% of healthcare facilities across 54 countries did not have access to basic water sources and 19% to basic sanitation infrastructure.[13] The absence of water, sanitation and hygiene (WASH) services jeopardises birth attendants' ability to carry out hygiene and relevant infection prevention and control practices, whether at home or in a facility. In 2015, 663 million people still lacked improved drinking water sources, and 2.4 billion people lacked improved sanitation facilities at home.[14] Hence, the new Sustainable Development Goals (SGD) recently reaffirmed access to WATSAN as a key global priority (SGD 6).[15]

While two recent studies describe the situation for WATSAN birth environment in Tanzania,[16,17] there is little research to understand the global reality. Even scarcer is information on how coverage of WATSAN at birth varies among and within countries. The Tanzania by Benova and colleagues found that women in the poorest quintiles bear a double burden: they are more likely to give birth at home and the proportion of home deliveries in a WATSAN-safe environment is at, or below 3% for all but the richest quintile. [16] The UNICEF Joint Monitoring Program (JMP) describes the status of home water and sanitation for the general population; however, the socio-economic distribution of women giving birth differs from the general population in that women giving birth are usually younger and poorer, and thus they are more likely to have worse water and sanitation than the general populations. Hence, it is important to investigate specifically the WATSAN home environment for births.

In this paper, we investigated the status of WATSAN in childbirth environments in low and middle-income countries to understand who delivers with access to basic WATSAN infrastructure. First, we described the home WATSAN environment among those who delivered at home by country, region, and women's socio-demographic characteristics. We focused on world regions and countries where the proportion of home deliveries is higher. Second, we examined the WATSAN environment in health facilities in four countries in Eastern Africa: Kenya, Rwanda, Tanzania and Uganda, by facility type, delivery volume and managing authority; we chose these countries because Eastern Africa has substantial weaknesses in home and facility WATSAN and because of data availability. Third, for each of these four countries, we compiled home and facility results to describe what proportion of women delivered with access to basic WATSAN by country and by subnational region.

Methods

To describe the water and sanitation status of home and facility childbirth environment, we relied on three distinct datasets created with publically available data: a global dataset, with information on the home environment among women who delivered at home from 58 countries, and two datasets for each of the four countries in Eastern Africa. These were the 'healthcare facility' dataset and the 'Eastern Africa combined dataset', which incorporates information on facilities, the home environment and a woman's birth location to create a comprehensive description of birth environments in those countries. Where we used information on the home environment, we restricted the study sample to women who had had a live birth in their own household in the two years preceding the survey to allow for comparability between data sources. The childbirth experience represents each woman's most recent birth.

Global dataset

Data source and variables definition. To assess WATSAN in the home, we used publicly available datasets for LMICs from Demographic and Health Surveys (DHS)[18] and Multiple Indicator Cluster Surveys (MICS).[19] The dataset included 58 national surveys, the most recent available for each country carried out since 2000, with available information on the place of delivery, water source and sanitation infrastructure (Table A in S1 Table). We only analysed world regions with data from at least five countries where more than 100 women delivered at home; our intent was to produce estimates representative of those regions where the proportion of women delivering at home is substantial. We classified the five regions that fulfilled this criterion using the UNICEF regions: West and Central Africa, Eastern and Southern Africa, East Asia and Pacific, South Asia, Middle East and North Africa. We included 91%, 77%, 22%, 87%, 30% of countries from each region respectively (Table B, in S1 Table). Countries within each selected region with fewer than 100 women who delivered at home were excluded due to sample size concerns.

These datasets are generally representative of all women of reproductive age, usually 15–49 years for DHS and 15–44 for MICS–except those restricted to include only ever-married women. Both survey types contain detailed information about women's most recent live birth. Our sample only includes women who had their most recent birth in their own home because only for those we could estimate their likely WATSAN environment at the time of delivery.

We constructed a variable to characterise the home WATSAN environment. An 'improved WATSAN environment' was one where both the drinking water source and sanitation access were improved in terms of infrastructure (improved water includes piped into dwelling, borehole etc.; improved sanitation includes flush toilet, septic tank etc.) according to the WHO/UNICEF Joint Monitoring Program (JMP) definition for households.[14] Examples of unimproved water infrastructure include an unprotected spring or dug well. Unimproved sanitation includes all sanitation infrastructures that are shared with other households, and infrastructure such as bucket or a pit latrine without a slab–even though not shared.

Socio-economic position was assessed using asset-based household indices, maternal education and rural/urban residence that were available from DHS and MICS datasets. Asset-based indices were derived using principal component analyses from variables representing household assets.[20] The first component was grouped into five quintiles (Qs) of households. Urban or rural residence was already defined in the datasets; this is done by MICSs/DHSs on a country basis, according to local census bureaus. Maternal education was classified as no education, any primary, and any secondary or higher. For Kenya, information on maternal education was not comparable to the other surveys (Table A in S1 Table); analysis with this variable was thus, not carried out for Kenya.

Analysis. Taking into account the sampling strategy using individual sample weights and clustering, we estimated the coverage of WATSAN among women who delivered at home for each country, each world region, and by three socio-demographic indicators: wealth index, maternal education and urban or rural residence. Regional values were estimated using the crude means and medians of all the countries in that region. Means and medians were not weighted by each country's population size. To assess wealth-related inequalities in access to WATSAN we calculated the difference (absolute inequality) and the ratio (relative inequality) of Q5 (richest) and Q1 (poorest) WATSAN values.

Eastern Africa

Data source and variable definitions—the healthcare dataset. WATSAN in healthcare facilities was investigated in Kenya, Tanzania, Uganda and Rwanda. These countries each had a recent Service Provision Assessment survey (SPA)–these are nationally representative surveys of health care facilities–[18] and a DHS in a similar timeframe (S2 Table). Moreover, they all belong to the Eastern and Southern Africa region, which has substantial weaknesses in home and facility WATSAN [13,14]. We based our analysis on a restricted sample of facilities providing routine delivery services.

The categorisation of facility types differed between countries. Using the SPA country reports we examined facility levels and functions across the countries to classify facilities into three main categories: hospitals, health centres and dispensaries (S3 Table); and by managing authority (private or public).

We created two main indices, which differed from the components used in the home index. The first was for improved WATER in the facility, which includes a measure for improved water source in the facility and running water–either piped or bucket with tap–in the delivery room; the second was for improved WATSAN, which includes the WATER index and information on sanitation (Fig 1).

The facility WATER index required stricter criteria for water than the home index because healthcare facilities can receive very large volumes of deliveries and thus water needs to be constantly available at the point of care. In addition, water is also more vital for environmental cleaning in a setting where the volume of ill patients increases the risk of contamination. There is no international standard definition for water, for sanitation or their combination for health facilities. We based our indices on the WHO report[13] and the classification proposed by Benova et al [16] with a slight modification explained in the next paragraph, and added a criterion of having a continuous water supply (no time of the year with a routine shortage of water), a necessary condition for improved WATER, and hence WATSAN. At community level, the criterion of continuous supply is effective in reducing diarrhoeal disease [21]–plausibly because

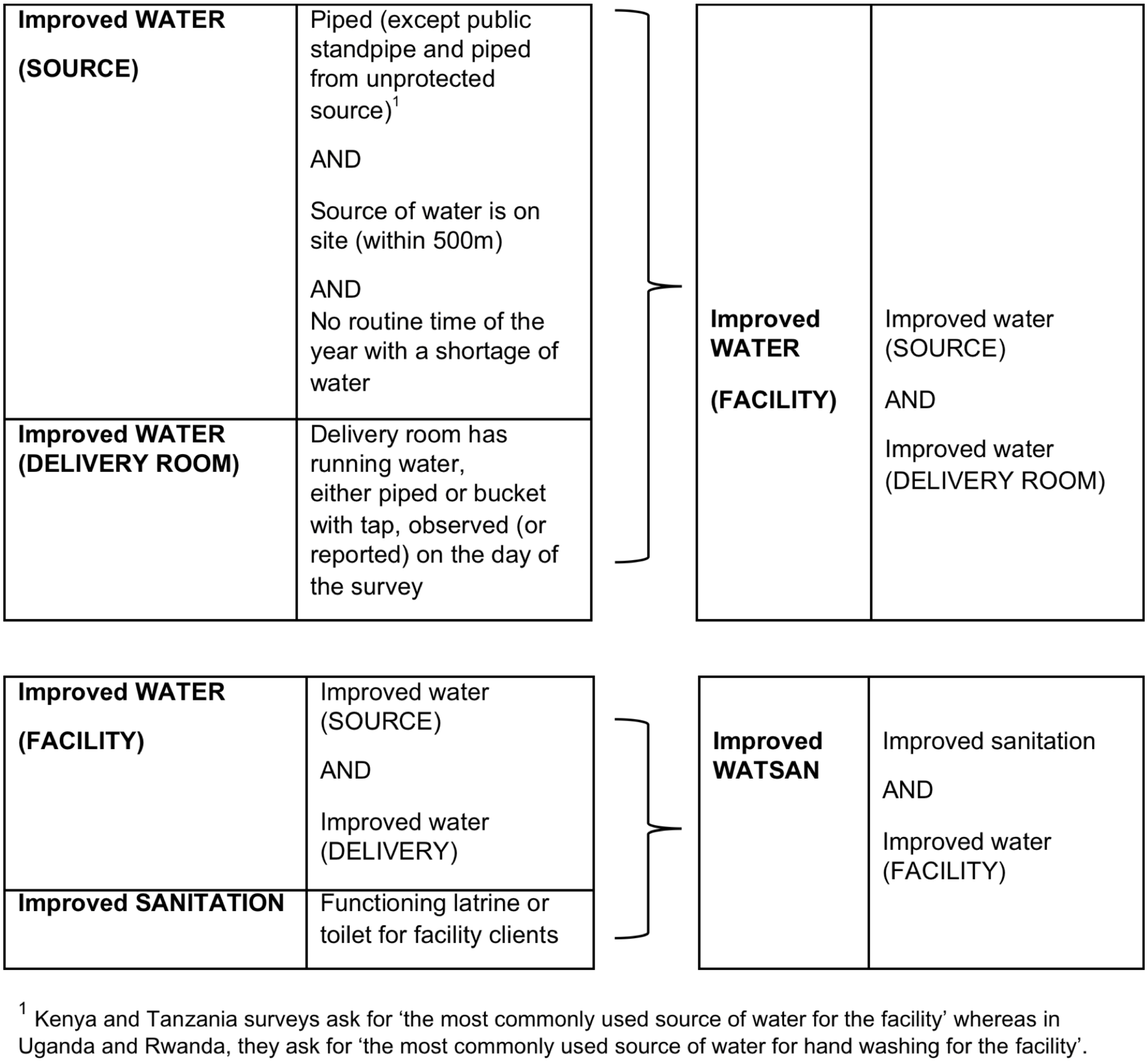

Fig 1. Facility WATER and WATSAN indices.

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it allows people to use water for infection prevention behaviours, such as washing hands, environmental cleaning, and the higher quality and quantity of drinking-water. These behaviours are also fundamental during labour and delivery for maternal and newborn sepsis prevention, and justify the additional criterion.

The slight modification was that we reasoned that the main water source should be exclusive to the facility to avoid delays in access. Therefore unlike the JMP, WHO and Benova et al definitions, we considered those facilities where the water source was a 'public tap/standpipe' (Rwanda: 8%, Kenya: 1%, Uganda: 1%) to be 'unimproved'. Also, we considered 'piped water' as 'improved', if it was from an 'unknown' source, because the information on the water source was provided by a healthcare worker who may have had little knowledge on this; it was classified as 'unimproved' if the respondent specifically chose the option 'piped from an unprotected source' (Tanzania: 3%).

The criteria for SANITATION we used also differed from the home criteria. No country collected information about latrines/toilets located in the maternity, which would have been our ideal measure, especially in larger facilities. In Kenya and Tanzania, we used information about the availability of functional general facility latrines/toilets; functionality was not available for the home SANITATION definition. Information on the type of toilet in facilities, used in the JMP definition for home SANITATION was not available for facilities. We only examined WATER in Uganda and Rwanda because they did not have sanitation data for three-quarters of facilities performing deliveries in Rwanda and one-quarter in Uganda.

Data source and variable definitions—the combined dataset. We used data from four DHS surveys, restricting the sample to women who delivered either in their own home or in a facility of a known type. Those who delivered in *other* locations (4% to 10% across the four countries) were not included because we did not have information on their likely WATSAN environment at the time of delivery (see details on this *other* category in S4 Table).

To allow for comparability between SPA and DHS, we created a 'place of delivery' variable (described in S4 Table). We used the same variable for improved WATER and WATSAN in the home as that described for the global dataset. Women in the DHS who delivered in their own home were allocated home WATSAN (Tanzania and Kenya) or WATER (Uganda and Rwanda) values. Women in the DHS who delivered in a facility were allocated the average of improved facility WATER or WATSAN for their region, calculated from the SPA within the "healthcare dataset" (details of this method in S1 File). Previous work on linking DHS and SPA datasets without using GPS coordinates suggested linking the two at a level at which the surveys were representative; hence we used this method too.[22] For Tanzania and Uganda, we recoded regions to allow comparability between the SPA and DHS (S5 Table).

Analysis—Eastern Africa. When analysing both datasets we accounted for the sampling frame (sample weights, clustering and stratification) using the *svyset* commands. In addition, for the SPA analysis only, we created an additional set of weights—*delivery (volume) weights;* these accounted for the proportion of deliveries carried out by each facility compared with the total number of facility deliveries for that country (S2 File). Our intention was to present the proportion of facility deliveries that occur in an improved WATER or WATSAN environment at country level. Information on the number of deliveries, used to produce the weighting by number of delivery was missing to a different extent in in each country, but never exceeded 8%. We ran complete case series analyses.

Using the healthcare dataset, we carried out descriptive statistics to calculate the proportion of facilities or facility deliveries with improved WATSAN or WATER, by country, facility type and managing authority. Using the Eastern Africa dataset, we estimated what proportion of women delivered with improved WATER and improved WATSAN, nationally and by subnational region. We analysed all three datasets in Stata/SEv.14, using publicly available data.

Ethical procedures and approvals

For both the SPAs and the DHSs, the Institutional Review Board (IRB) of the country where the survey takes place ensures that the survey complies with the country regulations. Whereas, ICF International IRB ensures it complies with the U.S. Department of Health and Human Services regulations for the protection of human subjects. For more information please refer to: http://dhsprogram.com/What-We-Do/Protecting-the-Privacy-of-DHS-Survey-Respondents.cfm.

For the DHS surveys, typically the written informed consent is read by the interviewer and includes the purpose of the study, that the participation is voluntary and data would be confidential and anonymised. The respondent can decline or accept verbally to consent and this is recorded on the survey tool using the interviewer signature.

Ethics for the MICS surveys is responsibility of the body and country who conducts it. Guidance for conducting MICS survey suggests that the survey must abide the laws of the country and apply for local ethics approval, that all information should be confidential, that respondents should given their full approval to the request of consent verbally unless written consent is required by the country where the survey takes place. In addition, useful feedback is expected to be given to participants and their community; for example, mothers should be advised when their children's vaccinations are overdue.

Across the four SPAs for Kenya, Tanzania, Uganda, and Rwanda, informed consent was verbally obtained from the facility in-charge, and from all respondents for the facility, and recorded by the interviewer on the survey tool using the interviewer signature. Consent from respondents involved explaining them about the purpose of the study, that no patient names would be reviewed, recorded or shared, that they might refuse to answer any question and that they can stop the interview at any time, and that facility names would be anonymised. Respondents were also told that the information about their facility may be used by their Ministry of Health or organizations supporting the facility, or researchers for planning service improvement or further studies of health services.

Our secondary analyses of these anonymised datasets were approved by the Observational/Interventions Research Ethics Committee at the London School of Hygiene and Tropical Medicine. The sources of data are available for DHSs and SPAs at www.measuredhs.com and for MICSs at http://mics.unicef.org/.

Results

Global Analysis

The sample size of women delivering at home, weighted by the sample characteristics, is available for each country is in S6 Table and ranges from 101 to 28979. The proportion of missing responses for home WATSAN was less than 2% across all 58 surveys. Table 1 shows that the average proportion of women delivering at home varies greatly by region, with the highest being in East Asia and Pacific (53%) and the lowest in Middle East and North Africa (28%).

Among women who delivered at home, regional coverage of improved WATSAN in the home varied between 9% in West and Central Africa to 53% in Middle East and North Africa (Table 1). Within regions, variation was also striking–for example within the Middle East and North Africa, the mean improved WATSAN in Sudan was 14%, whereas in Egypt it was 87% (S6 Table). Improved WATSAN coverage by country is given in S6 Table.

Table 1. Mean and median proportion of women delivering at home and improved home WATSAN among women who delivered at home, by world region *(DHS and MICS data)*.

World region	Number of countries	Proportion of women who delivered at home		Coverage of improved WATSAN among women who delivered at home	
		Mean	Median	Mean	Median
Eastern & Southern Africa	17	32.6	32.1	13.3	9.3
West & Central Africa	22	33.9	30.8	9.1	6.7
Middle East & North Africa	6	28.3	26.3	52.5	52.6
South Asia	7	48.4	51.4	34.0	27.3
East Asia & Pacific	6	53.0	54.4	24.0	24.8

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Fig 2 shows the coverage of home improved WATSAN for wealth quintiles by region. We observed a monotonic pattern in the coverage of improved WATSAN that increased with higher wealth quintiles across all the regions investigated. Eastern and Southern Africa, and West and Central Africa showed the lowest coverage (less than 50%) of improved home WATSAN across all quintiles. Middle East and North Africa, and West and Central Africa showed substantial inequalities: in the former, the poorest lagged behind; in the latter the richest were substantially better off. Distribution of improved WATSAN coverage by education and rural/urban area respectively produced similar findings to those stratified by wealth index (S1 and S2 Figs).

In terms of absolute inequality, calculated as the difference in percentage points (pp) between the women in the richest and poorest quintiles for improved home WATSAN, was lowest in Eastern and Southern Africa (24pp) (Table 2). Higher absolute inequality was seen in South Asia and the Pacific, in the Middle East and North Africa and in East Asia and Pacific (respectively at 61pp, 55pp and 58pp). Fig 2 shows absolute inequalities visually; longer lines between Q1 (poorest) and Q5 (richest) represent larger absolute inequalities. In terms of relative inequality, calculated as the ratio of improved home WATSAN between the richest and poorest quintiles, it was lower (i.e. lower relative inequality) in Middle East and North Africa with 2.7. The highest ratio of 18.5 was in West and Central Africa (Table 2).

Fig 2 shows, especially in the poorer regions (Eastern and Southern Africa, West and Central Africa, South Asia, and East Asia and Pacific), that while coverage of WATSAN increases

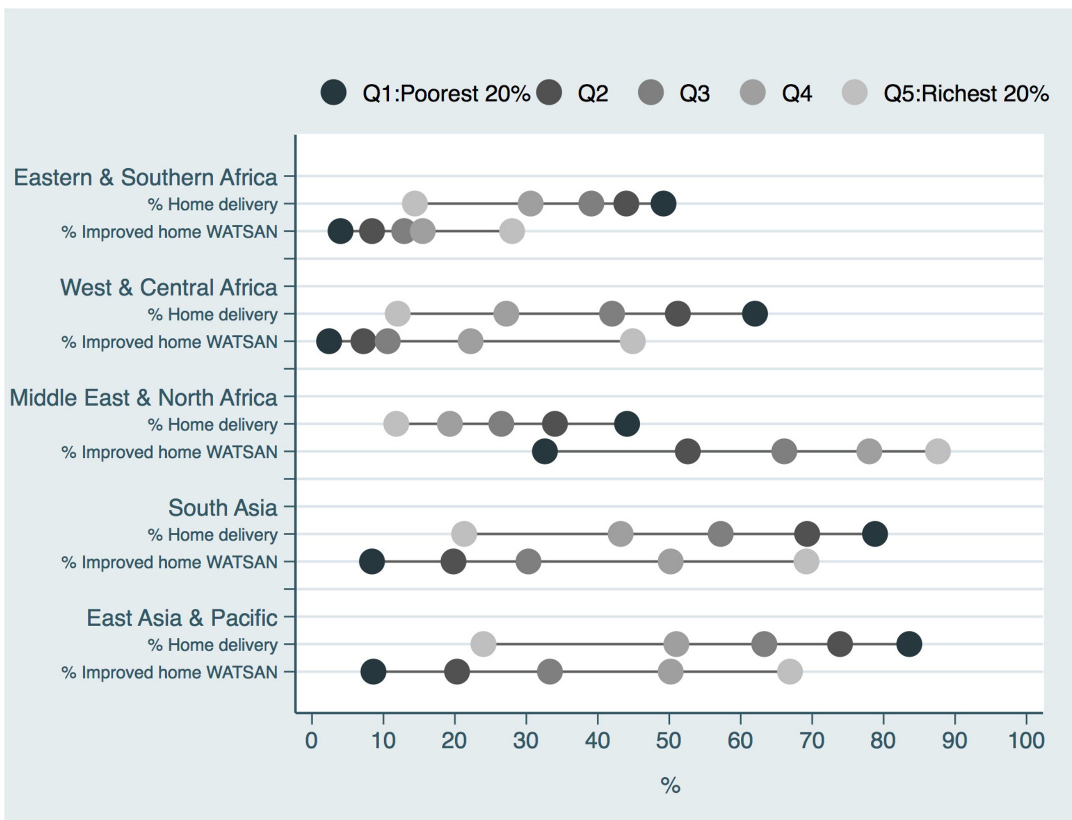

Fig 2. Proportion of home births and coverage of improved WATSAN among women who delivered at home, by wealth quintile and world region *(DHS and MICS data)*.

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Table 2. Mean and median coverage of improved WATSAN by wealth quintile, and absolute and relative inequalities between the lowest and the highest wealth quintile by world region (*DHS and MICS data)*.

World region	Wealth quintile	Proportion of women with home improved WATSAN	Absolute inequality	Relative inequality
			(Q5-Q1)	(Q5/Q1)
Eastern & Southern Africa	Poorest	4.0		
	Poorer	8.4	24.0	7.0
	Middle	12.9		
	Richer	15.5		
	Richest	28.0		
West & Central Africa	Poorest	2.4		
	Poorer	7.2	42.5	18.5
	Middle	10.6		
	Richer	22.2		
	Richest	44.9		
Middle East and North Africa	Poorest	32.6		
	Poorer	52.6	55.0	2.7
	Middle	66.1		
	Richer	78.0		
	Richest	87.6		
South Asia	Poorest	8.4		
	Poorer	19.8	60.8	8.2
	Middle	30.3		
	Richer	50.2		
	Richest	69.2		
East Asia & Pacific	Poorest	8.6		
	Poorer	20.3	58.3	7.7
	Middle	33.3		
	Richer	50.2		
	Richest	66.9		

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with increasing wealth, for home deliveries, the sequence of dots is reversed as the proportion of home deliveries decreases with wealth. This is what we refer to as the double burden of poverty; poorer women are more likely to deliver at home and have worse WATSAN compared to their richer counterparts. In West and Central Africa, those in the poorest quintile were five times more likely to deliver in their own home, and were 18 times less likely to have improved home WATSAN coverage. The double burden of poverty was less striking in the wealthier Middle East and North Africa.

Eastern Africa: Kenya, Tanzania, Uganda, Rwanda

Overall in the four countries investigated, the percentage of missing data was low (up to 6%) for the SPA datasets and even lower in the DHS (0.1% or less) (Table 3). All results presented were weighted by the sample weights provided in the datasets unless specified.

From Table 3, about half of the women delivered their most recent birth in the home in Tanzania (45%) and Kenya (52%) compared with a third in Uganda (34%,) and 20% in Rwanda. In Tanzania and Kenya, about a quarter of women delivered in hospitals, a higher proportion than in Uganda and Rwanda. Less than 10% of women delivered in health centres in Kenya and Tanzania, but the proportion is higher in Uganda (32%) and Rwanda (61%). With the exception of Tanzania at 17%, 3% or fewer women delivered in dispensaries.

Table 3. Distribution of births by place of delivery and by country *(DHS data)*.

Place of delivery	KENYA	TANZANIA	UGANDA	RWANDA
	% (CI)	% (CI)	% (CI)	% (CI)
Own home	51.5% (47.4%-55.5%)	45.4% (42.3%-48.5%)	33.7% (30.7%-36.8%)	19.6% (17.9%-21.5%)
Hospital	24.4% (21.9%-27.2%)	28.0% (25.6%-30.6%)	19.0% (16.9%-21.3%)	18.6% (17.1%-20.3%)
Health centres	8.3% (6.7%-10.3%)	9.4% (7.9%-11.2%)	32.2% (29.5%-35.0%)	60.8% (58.7%-62.8%)
Dispensaries	3.2% (2.3%-4.4%)	17.1% (14.9%-19.5%)		0.9% (0.6%-1.4%)
Private facilities	6.9% (5.6%-8.4%)		15.1% (13.0%-17.3%)	
Mission facilities	5.7% (4.4%-7.3%)			

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Fig 3 shows the coverage of improved WATSAN (A) and WATER (B) for the childbirth environment, combining information for home and healthcare facility deliveries. In most regions in Uganda and Rwanda, between 20% and 40% of women delivered in an improved WATER environment. There appeared to be more regional variation in Uganda (11% in the Central region and 75% in Kampala) compared with Rwanda. Improved WATSAN for the childbirth environment fell within the range 10–20% in most regions across Kenya and Tanzania. There was higher regional variation in Kenya (6% in Nyanza, and 51% in Central region) compared with Tanzania. Nationally, about 30% of women delivered in an environment with improved WATER in Uganda (33%) and Rwanda (30%); whereas, 18% of women in Kenya and 7% in Tanzania delivered with improved WATSAN.

The unweighted proportion of facilities providing normal delivery services in each country was 30% (207 facilities) in Kenya, 74% (454) in Tanzania, 54% (265) in Uganda, and 76% (407) in Rwanda respectively (S3 File).

The proportion of facilities with improved WATSAN (A) and WATER (B) was below 30% for all countries (Fig 4). Yet when weighted by the volume of facility deliveries, coverage appears higher, although still below 50%, for both improved WATSAN (A) and WATER (B) across all countries. This was because more deliveries occurred in higher-level facilities where there was better WATSAN. Results in Fig 4, we restricted the analysis to those facilities that have information on delivery number to ensure comparability between those weighted by the number of deliveries and those using the standard sample weights.

Overall, over 90% of facilities in Tanzania (90%) and Kenya (99%) had improved SANITATION, so the WATSAN index could mostly be explained by the lack of improved WATER at facility level. For all four countries, improved WATER coverage was brought down by WATER source indicators, rather than the delivery room indicator (S7 Table). Across the countries about half of facilities experienced water shortages and everywhere, expect Rwanda at 37%, a similar or higher proportion did not have a piped water supply. Having a water source further than 500m from a facility was more common in Rwanda (27%) and Tanzania (40%).

Fig 5 shows private facilities held the highest proportion, just above 50%, of improved facility WATSAN in both Tanzania (health centres) and Kenya (hospitals). Those with the lowest proportions were public dispensaries (below 10%) followed by private dispensaries (below 20%). The pattern of results was similar for improved facility WATER–with the exception of Rwanda were public hospitals score the highest coverage of improved WATER (Fig 6).

Discussion

The descriptive analyses of the three cross-sectional datasets shows that women who delivered at home, particularly in Sub-Saharan Africa, had poor access to WATSAN infrastructure and

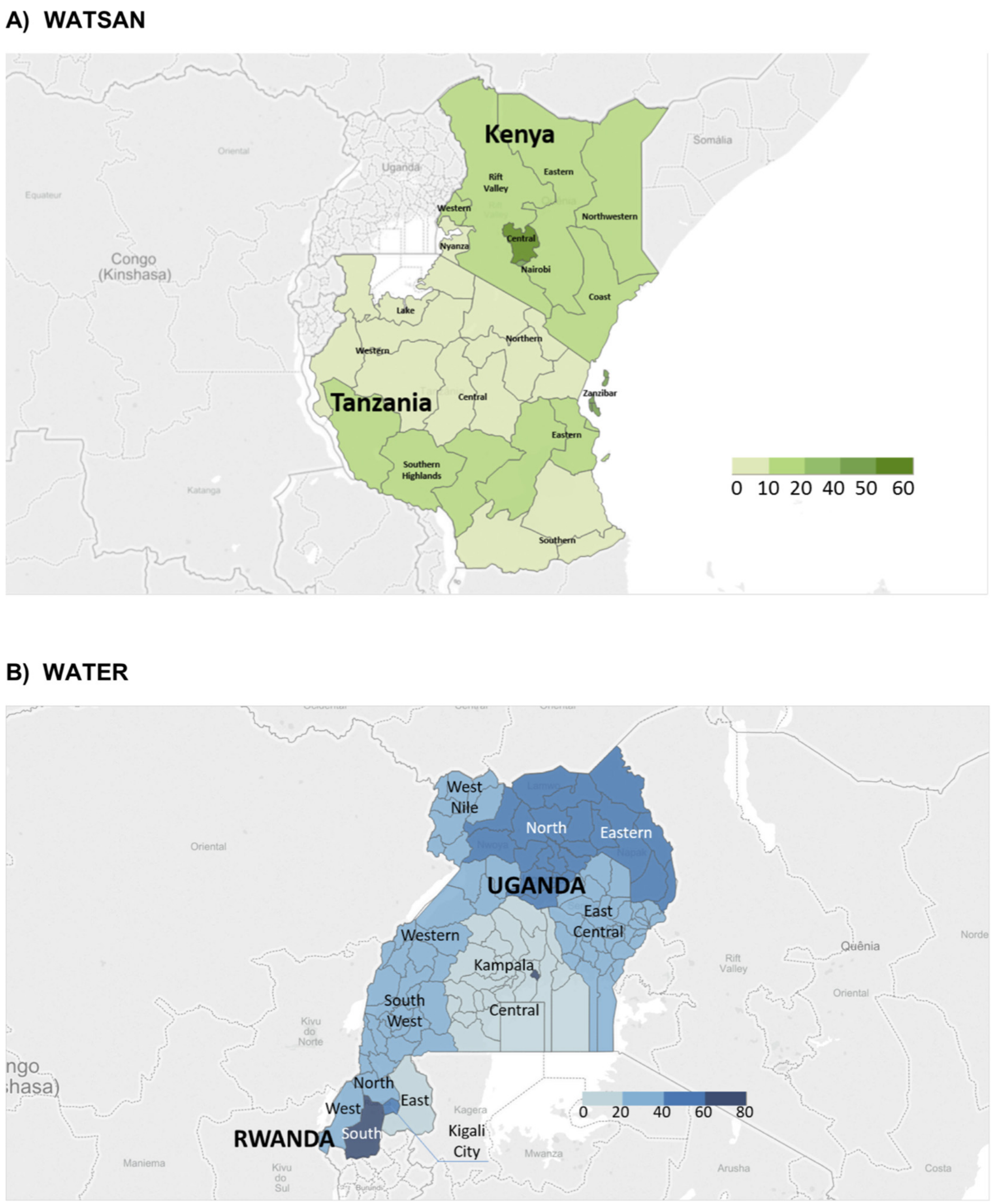

Fig 3. Proportion of improved WATER and WATSAN among women who delivery in either a facility or at home, by country and region *(SPA and DHS data)*.

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that this was worse among the poorest, the less educated and those living in rural areas. In Eastern Africa, both home and facility childbirth environments had very poor access to WATER or WATSAN.

As far as we are aware, our results are the first attempt to describe the WATSAN status of childbirth environments across low and middle-income countries, in both facility and home. We used 58 nationally representative surveys for the home analysis, covering five of the UNICEF world regions. Our results are representative of countries in these regions with at least 100

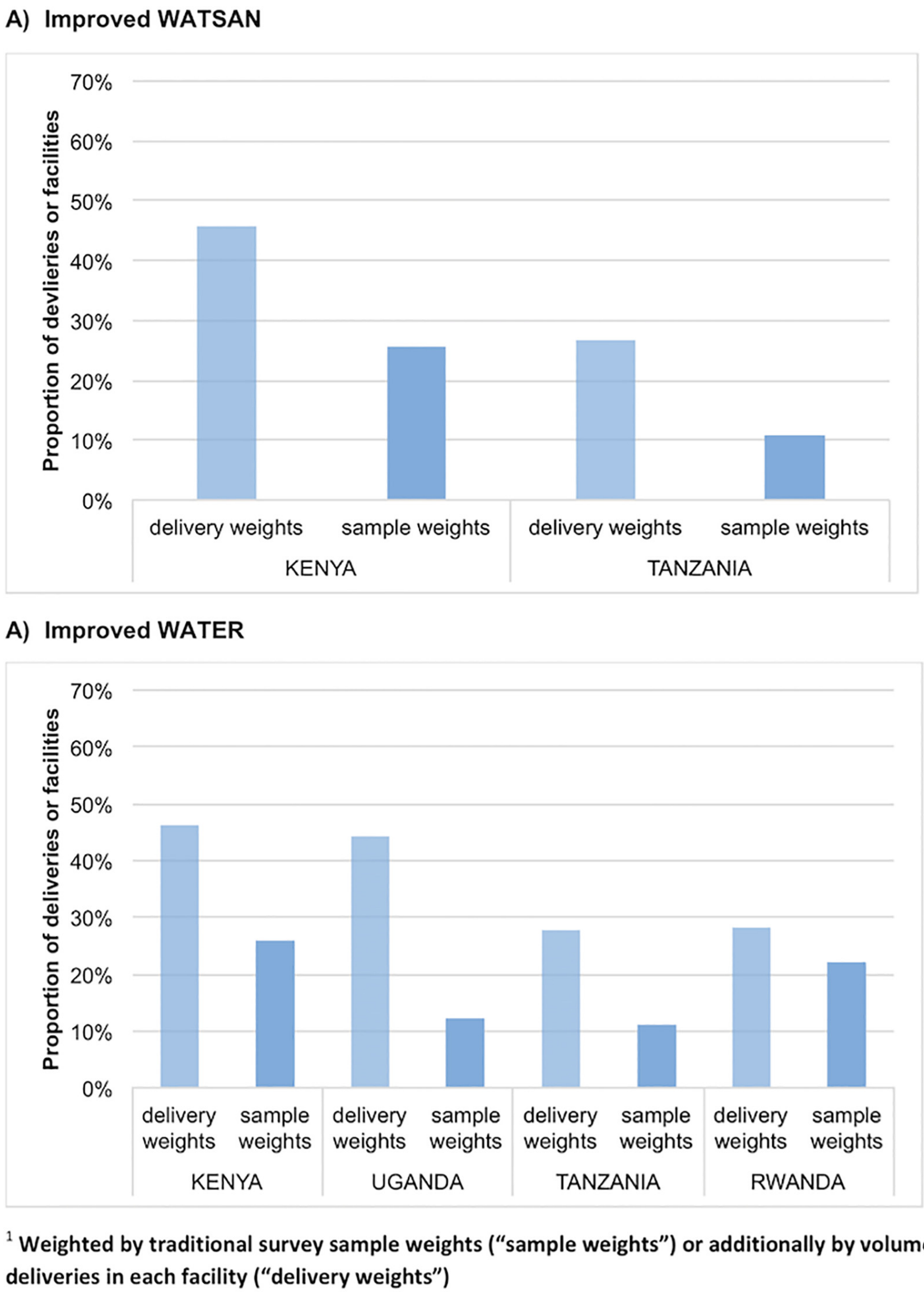

Fig 4. Proportion of facilities or facility deliveries with improved WATSAN or improved WATER, by country and by weighting methods (weighted by traditional survey sample weights "sample weights", or additionally by volume of deliveries in each facility "delivery weights")[1]. (SPA data).

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women delivering at home. Across countries in both the global and Eastern Africa datasets, our results are representative of 90% of deliveries–including women who delivered in their own home or in a facility of a known type.

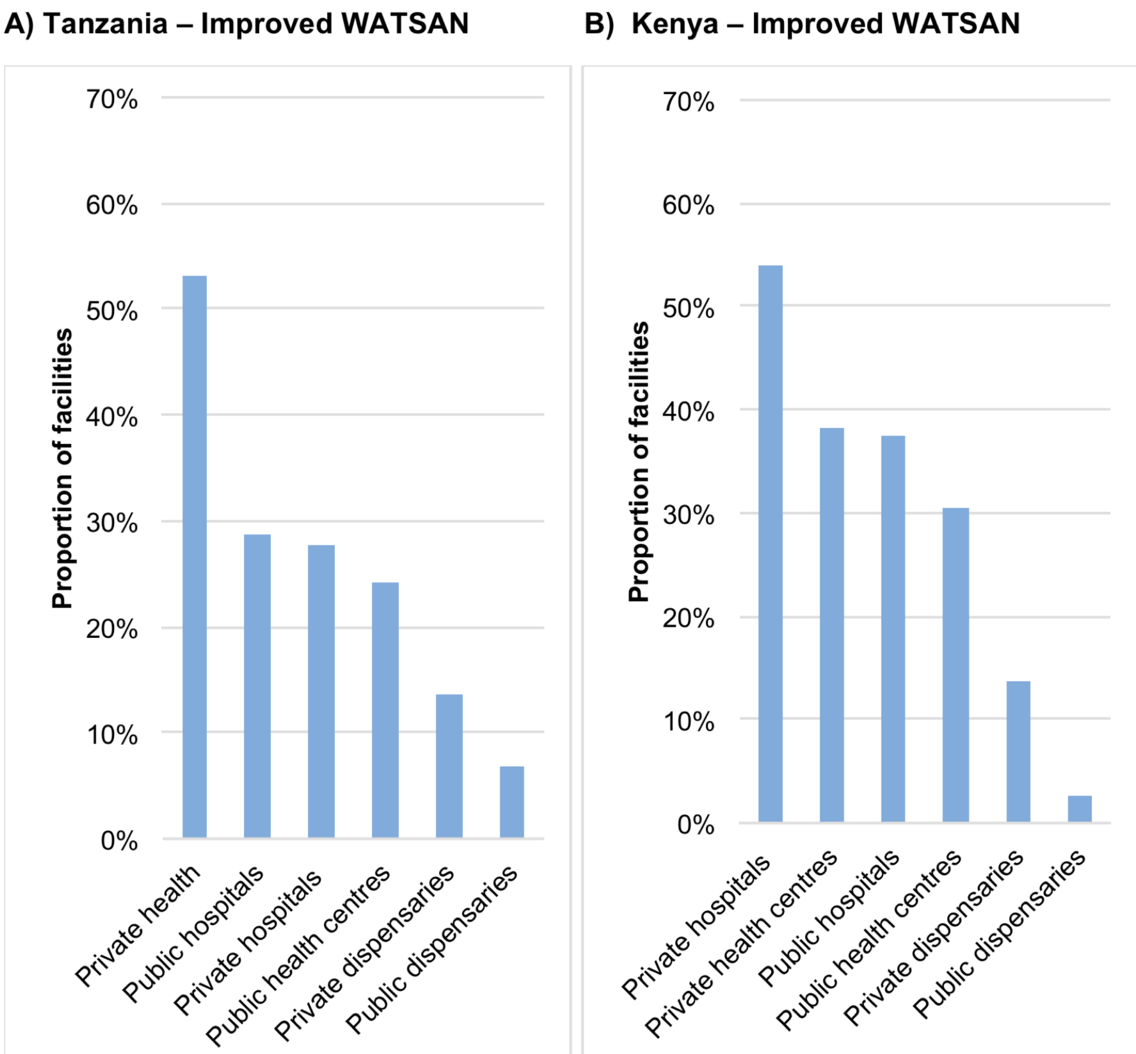

Fig 5. Proportion of facilities with improved WATSAN by facility type and managing authority A) Tanzania and B) Kenya, using sample weights. *(SPA data)*.

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Consistent with similar analyses describing the home WATSAN environment across the world, [14] we found that West and Central Africa, and Eastern and Southern Africa had the lowest coverage of improved home WATSAN, less than 15%). The regional estimates we present are generally lower than those presented by the UNICEF/JMP for the general population; this is most likely to be explained by the socio-economic distribution of women giving birth at home differing from the general population by being younger and poorer. As reported for other coverage indicators in other studies, for virtually every region, we observed a monotonic pattern in the coverage of improved home WATSAN with higher coverage among those women in the richer quintiles, having higher levels of education and living in urban areas.[23, 24] Although the number of countries per world region can be small, we chose to present the results of the global analysis using means rather than median–although both are in our table (Table 1). They yielded similar estimates, but the interpretation of means tends to be accessible to a wider audience, compared to medians.

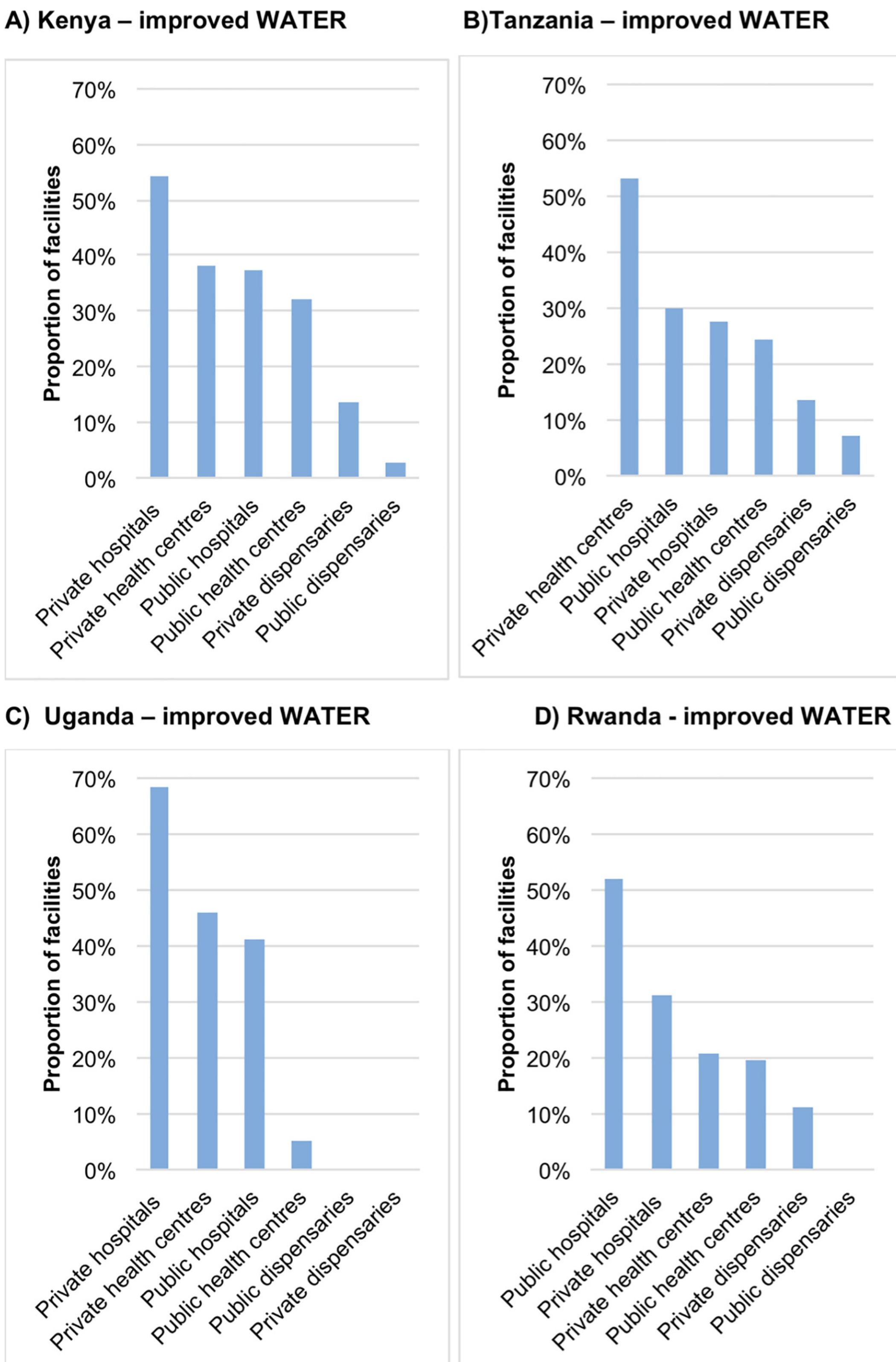

Fig 6. Proportion of facilities with improved WATER by facility type and managing authority: A) Kenya and B) Tanzania, C) Uganda and D) Rwanda, using sample weights. *(SPA data)*.

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Relative inequalities in wealth–the degree of disparity between the poorest and richest quintile–were highest in West and Central Africa. Consistent with an analogous analysis for Tanzania, [16] we observed that poorer women tended to deliver at home and have worse home WATSAN across all regions compared with those in richer quintiles. This double burden of poverty (i.e. associated with both more home deliveries and worse WATSAN conditions) was more evident across the lowest-income regions: West and Central Africa, Eastern and Southern Africa, South Asia, and East Asia and Pacific. The wealth asset-based index we used to investigate socio-economic differentials was available in the dataset and included water and sanitation variables. We do not believe this biased the results because most country wealth indices included over 30 other assets.[25]

A more in-depth analysis of Eastern Africa, allowed us to investigate WATSAN coverage in both home and facility environments. Overall, about a third of women in Uganda and Rwanda delivered in an environment with improved WATER; whereas, 18% of women in Kenya and 7% in Tanzania delivered with improved WATSAN. From our analysis we found that within each country there was substantial regional variation; this is consistent with similar work on the topic.[13,16]

To estimate regional coverage of improved WATSAN and WATER across the four countries we linked SPA and DHS surveys, initially not designed for this purpose, at the level, the region, at which they were both representative, as recommended by others.[22] We are confident in our results because we tried two distinct methods to obtain them and both yielded similar findings.

Across healthcare facilities providing maternity services in the Eastern Africa dataset, coverage of WATER or WATSAN was below 30%, similar but lower than the 41% described by the WHO report for five countries using SPA (i.e. Haiti, Kenya, Namibia, Rwanda and Tanzania). Unlike the WHO WATER indicator, our indicator also included whether the delivery room had running water (either piped water, or a bucket with a tap).[13] An internationally agreed indicator to monitor access to WATSAN in maternity rooms does not exist yet[13]; the rationale for our proposed definition is detailed in the methods and should be considered when interpreting our results. When we accounted for the volume of deliveries occurring in each facility, the picture was more positive because higher-level facilities, such as health centres and hospitals, with the highest volume of deliveries, and had better WATSAN infrastructure. Private facilities, mostly hospitals, had the highest proportion of improved facility WATER and WATSAN coverage (above 50%). Only Rwanda had the highest WATSAN coverage amongst public hospitals. This may be related to the government's recent focus to provide higher and equitable access to delivery services.[26,27] The lowest coverage, as expected, was among public dispensaries, followed by private dispensaries. Yet results for these different levels of facility types should be interpreted with caution. Classification varies greatly between countries and it is plausible that some dispensaries in one country might provide similar services to a health centre in another; likewise, a health centre in one country might be considered a hospital in another. We relied on individual countries' classifications for this analysis. In addition, governments are less likely to have accurate information on private facilities, especially smaller ones, than on public ones. Smaller and less well-known facilities are likely to have to have worse WATSAN; hence it is likely that the picture for private facilities is better than the reality. This might bias the results against public facilities.

Our analyses attempted to unpack those elements of the WATER and WATSAN indices' components that contributed more substantially to low coverage across the four East African countries. Most of the low WATSAN coverage was explained by the lack of improved WATER, compared with SANITATION. This should be interpreted in the light of the fact that we postulated four different conditions for the water index to be met; while prescribing only one condition for SANITATION. Among the WATER index components, the most frequently not met were not having access to piped water and experiencing routine seasonal water shortages. Motivation of managers, at the hospital and ministry levels, to fix such issues timely, is a fundamental part to solving water shortage; however currently the SPAs do not include this information.

Our analyses rely on the assumption that women who delivered in their own home had a similar level of WATSAN infrastructure in their home at the time of delivery to that they reported when interviewed. By restricting our analyses to births in the two years prior to the survey, we believe that misclassification of improved WATSAN from this was minimal. Another assumption was that general environment latrines/toilets in healthcare facilities in Kenya and Tanzania are accessible to women in the maternity areas. Ideally we would have information on latrines/toilets specific to the maternity area, but this information was not available.

Misclassification of WATSAN had the greatest scope to limit our results. We have assumed that respondents of both the household and facility surveys were able to report information on their WATSAN type accurately. This was an issue particularly for the question around the water source in healthcare facilities, on which an average healthcare worker might report. To minimize potential bias, we considered water improved if piped from either an improved or unknown source. Another cause of uncertainty was whether respondents interpreted the question on water source as the water type at the original source, or when it reaches the facility–for example, if dug well water was piped into the facility grounds, then it is unclear what the appropriate response would be. Limited by data availability in the datasets, we only had information on the type of infrastructure, access and reliability, not on *cleanliness*. Ideally we would have had information on whether the water stored in bucket had a lid, on microbiological data on the quality of the water.[28] Information on whether the household or facility performed water filtering and treatment would also be important.[21] With regards to sanitation, ideally we would have information on the type of toilet or latrine available in the facility, access to toilets in the maternity and the cleanliness of the toilets. Finally, because additional necessary items to perform hygiene at birth, e.g. soap, were available in the SPAs but not consistently in all DHSs and MICSs, we decided not to measure availability of soap in these analyses. Ideally, however, all future DHS/MICS surveys would capture this information.

Too many women across the world and in particular in West and Central Africa, and Eastern and Southern Africa deliver at home without access to basic WATSAN. This has major implications for maternal and newborn health and survival. Inequality of access was striking across and within countries. Within the Eastern African region, we found that even among facility deliveries, less than half were in a childbirth environment with access to basic WATSAN. Access to WATSAN during childbirth should be routinely monitored in facilities across more countries. An agreed definition of WATSAN in maternities would enhance standardised monitoring, just as the JMP did for home WATSAN.[13,14] Targeted investments in facilities can guarantee essential resources for practicing infection prevention during childbirth, ensure an enabling environment for hygiene and ultimately reduce healthcare associated infections. [13,29–31]

Supporting Information

S1 Fig. Mean coverage of WATSAN among those who delivered at home, by maternal education and world region.
(TIFF)

S2 Fig. Mean coverage of WATSAN among those who delivered at home, by rural/urban and world region.
(TIFF)

S1 File. Linking SPA and DHS.
(PDF)

S2 File. Delivery weights.
(PDF)

S3 File. Distribution of facilities by type and country.
(PDF)

S1 Table. Data Availability: A) data availability according to country (most recent survey since 2000) and B) number of countries included in the analyses according to world region.
(PDF)

S2 Table. Data sources for Eastern Africa analysis.
(PDF)

S3 Table. Facility type classification.
(PDF)

S4 Table. Classification of the place of delivery variable for the Eastern African dataset
(PDF)

S5 Table. Regions re-classification.
(PDF)

S6 Table. Improved home water, sanitation and WATSAN among women who delivered at home by country.
(PDF)

S7 Table. Unpacking the WATER index: percentage of facilities (calculated using sample weights) with or without each of the binary WATER index components.
(PDF)

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Author Contributions

Conceived and designed the experiments: GG OC MR LB WG AB.

Analyzed the data: GG MR.

Wrote the paper: GG MR OC AB LB SW WG.

Data interpretation: GG MR OC AB SW WG.

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9.2. Appendix II (A) – PDF version of Manuscript 2

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Original Article

OXFORD

Unpacking the enabling factors for hand, cord and birth-surface hygiene in Zanzibar maternity units

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Abstract

Recent national surveys in The United Republic of Tanzania have revealed poor standards of hygiene at birth in facilities. As more women opt for institutional delivery, improving basic hygiene becomes an essential part of preventative strategies for reducing puerperal and newborn sepsis. Our collaborative research in Zanzibar provides an in-depth picture of the state of hygiene on maternity wards to inform action. Hygiene was assessed in 2014 across all 37 facilities with a maternity unit in Zanzibar. We used a mixed methods approach, including structured and semi-structured interviews, and environmental microbiology. Data were analysed according to the WHO 'cleans' framework, focusing on the fundamental practices for prevention of newborn and maternal sepsis. For each 'clean' we explored the following enabling factors: knowledge, infrastructure (including equipment), staffing levels and policies. Composite indices were constructed for the enabling factors of the 'cleans' from the quantitative data: clean hands, cord cutting, and birth surface. Results from the qualitative tools were used to complement this information.

Only 49% of facilities had the 'infrastructural' requirements to enable 'clean hands', with the availability of constant running water particularly lacking. Less than half (46%) of facilities met the 'knowledge' requirements for ensuring a 'clean delivery surface'; six out of seven facilities had birthing surfaces that tested positive for multiple potential pathogens. Almost two thirds of facilities met the 'infrastructure (equipment) requirement' for 'clean cord'; however, disposable cord clamps being frequently out of stock, often resulted in the use of non-sterile thread made of fabric. This mixed methods approach, and the analytical framework based on the WHO 'cleans' and the enabling factors, yielded practical information of direct relevance to action at local and ministerial levels. The same approach could be applied to collect and analyse data on infection prevention from maternity units in other contexts.

Keywords: Maternal and child health, prevention, health care, health behaviour, water

Key Messages

- In the context of maternity units in Zanzibar, we found substantial gaps in coverage of key determinants of infection prevention practices essential at the time of birth. In particular areas for further improvement include knowledge and training, and infrastructure.
- This is the first study based on an analytical approach using both mixed methods and a combination of two sets of WHO guidelines: (i) WHO 'cleans' necessary to ensure a clean birth; and (ii) WHO guidelines on the determinants of infection prevention practices. This novel approach yielded information of direct relevance to action at both local and ministerial levels, which we refer to as 'actionable information'.
- This study's analytical approach is applicable to other contexts when collecting and analysing data on infection, prevention and control from maternity units.

Introduction

Worldwide estimates indicate 2.6 million possible cases of severe bacterial infections among newborns in 2012 across Sub Saharan Africa alone (Seale *et al.* 2014). Additionally, puerperal sepsis is estimated to occur in 4% of live births (AbouZahr 2003). Gordon, Semmelweiss, and Wendell-Holmes established the link between puerperal sepsis and poor hygiene at birth over two centuries ago (Gordon, 1795; Semmelweis, 1983; Gould, 2010), and it has been estimated that a clean birth in a facility could prevent 38% of newborn tetanus mortality (Blencowe *et al.* 2011).

A list of important clean birth practices (for example clean hands), was presented by the World Health Organization (WHO) in the 'cleans' framework (Blencowe *et al.* 2011). For the clean practices to be carried out, the necessary enabling environment needs to be in place. This falls under the broader umbrella of infection prevention and control practices (IPC). The new WHO guidelines on IPC in facilities identified core components required to improve IPC practices and ultimately reduce healthcare associated infections (WHO 2016), e.g. ensuring access to the relevant infrastructure such as safe water and sanitation (WHO 2009) or sterilization of key equipment.

There are few data on the performance of the clean practices around birth or on the status of the enabling environment necessary for the clean practices, apart from some emerging efforts on water and sanitation, including by the Joint Monitoring Program for Water Supply and Sanitation (WHO and UNICEF 2016). The need to develop indicators and to incorporate water and sanitation and hygiene (WASH) in routine health monitoring systems was recently emphasized in the *Call to Action* paper on WASH and maternal and newborn health and the WHO report on the issue (Velleman *et al.* 2014; WHO 2015).

We have two aims in this article. The first is to illustrate how the WHO cleans framework and a framework of enabling factors from the WHO IPC guidelines were used to produce actionable information to enable the Zanzibar Ministry of Health (MoH) to identify priorities to improve hygiene in their maternity units. The second is to present the main assessment findings, which examined the enabling factors of key 'clean' practices, including hands, cord and birth surface hygiene, in maternity units in Zanzibar. The data were collected during an assessment across maternity units in Zanzibar, commissioned by the MoH in 2013 to inform a quality improvement process for maternity wards.

The Revolutionary Government of Zanzibar is a semi-autonomous region of Tanzania; it is home to a population of about 1.3 million people spread over two main and several small islands, and has an independent MoH. As in mainland Tanzania, only 50% of births in Zanzibar occur in facilities, and great efforts in the last decade have reduced the maternal mortality ratio from 473 per 100 000 live births in 2006 to a ratio of 310 in 2013 (Zanzibar Annual Health Bulletin - 8th publication 2014). A modest increase in facility births in Tanzania, from 43.5 to 50.1%, between 1999 and 2010,(ICF International), along with the aim of the government to encourage all women to deliver in facilities, emphasizes the importance of making hygiene in maternity units a priority, and the opportunity this provides to prevent infections. Recent publications highlight the poor WASH environment where women give birth in The United Republic of Tanzania, both in facilities and at home (Shamba *et al.* 2013; Benova *et al.* 2014). Only 24% of delivery rooms have basic improved water and sanitation standards across a representative sample of facilities in Tanzania (Benova *et al.* 2014).

Methods

Our first aim was to produce actionable information, meaning information that (1) is organized by the WHO 'clean' practices necessary to reduce maternal and newborn infection acquired at the time of delivery; (2) clearly identifies the behavioural factors from the WHO IPC guidelines that enable these clean practices and that can be addressed through MoH interventions; and (3) allows the root causes of the IPC gaps to be identified, using a mixed methods approach. We investigated four out of the six 'cleans': clean hands, clean cord (clamping and cutting), and a clean birth surface. The clean perineum of the mother at birth was excluded because of the weak evidence base for this clean (Blencowe *et al.* 2011) and the postpartum skincare of the newborn was excluded because we were focused on intrapartum care for data collection

The WHO IPC guidelines for facilities identified eight core components.(WHO 2016) We collected data in Zanzibar that allowed us to investigate four of these components that we refer to as behavioural factors in relation each of the four cleans we chose to investigate.

These enabling factors and their definition in this paper are:

a. Knowledge and training (from WHO core component number 3)—what it is necessary to know to practice relevant IPC behaviour, including awareness of key practices and levels of training.
b. Infrastructure (from WHO core component number 8)—the availability, access and maintenance of the infrastructure (e.g. water supply) and equipment required to perform the cleans.
c. Staffing levels (from WHO core component number 7)—the presence of an adequate number of staff responsible for the relevant clean practice; health orderlies to clean the delivery surface; and skilled birth attendants (SBAs) for performing clean hands and clean cord. If no SBA is present, it is possible that the delivery will be carried out by an unqualified member of staff without any formal training on these cleans. In Zanzibar, the following cadres, who have between 2 and 8 years of professional training, are considered qualified to assist a birth: Nurse midwife, Public Health Nurse B, Maternal and Child Health Aid, Clinical officers, Assistant Medical Officers, Medical officers, and Obstetricians.
d. Policies (from WHO core component number 2)—whether there are existing policies, guidelines or other indications (e.g. through posters) to prescribe the clean practice of interest. Information on policies was collected for all cleans except cord care.

Data collection tools using a mixed methods approach

Three tool sets were used during the assessment: (1) a structured facility questionnaire, administered to the maternity in-charge or equivalent at the time of the interview in all facilities providing delivery services ($n = 37$), (2) a 'walkthrough' tool set (described below) and (3) semi-structured interviews conducted in a purposively selected sample of facilities in Zanzibar ($n = 7$). The seven facilities were selected by the Zanzibar MoH to represent the variation in facility type, volume of deliveries, location and levels of service quality. The tools described below were based on the WASH & CLEAN toolkit, adapted with the collaboration of key MoH stakeholders and administered in Swahili. The toolkit, previously used in India, Bangladesh and the Gambia, was developed by the Soapbox Collaborative from existing tools from international organizations to assess IPC on maternity units and is publically available online (Cross *et al.* 2016). The facility questionnaire was initially piloted in five facilities, and the walkthrough tools and the semi-structured interviews were piloted in four.

The tools were administered between 19 May and 10 September 2014. We conducted 26 semi-structured interviews with healthcare staff including in-charges (7), care providers in the maternity (7), orderlies (7) and maintenance staff (5) present in the facility at the time of the visit. One member per cadre per facility was invited to be interviewed. Staff selection was based on who was available at the time. The facility questionnaire and the semi-structured interviews focused on guidelines, training and infrastructure for IPC, WASH and solid waste management; barriers to maintaining good practice; and the actions needed to overcome them. Qualitative interviews were also conducted with 20 women attending vaccination services for their newborns at the seven facilities, who had delivered within the past 8 weeks. The team aimed to interview a minimum of two women at each facility visited; one who delivered at the facility under assessment and one who delivered at home but who was living around the facility catchment area. The first woman presenting in the relevant facilities during the assessment period who consented to participate in the study was interviewed. These interviews sought to capture women's perception of an appropriate delivery environment, and their experiences during their most recent childbirth, particularly in relation to hygiene at the delivery unit. Interviews were conducted in Swahili and were tape recorded.

Two types of data were collected with the walkthrough tool set: (1) observations recorded in the walkthrough checklist, noting the availability and conditions of specific areas and equipment (e.g. labour ward room, toilets and cleaning equipment); and (2) microbiological samples taken using swabs of high-risk hand touch sites such as bedside lockers, delivery beds, cleaning equipment, and of water used for hand washing in the maternity unit. See Supplementary Material S1 for more details on the water sampling and microbiological swabs.

Constructing indices for the enabling factors of the four 'cleans'

For each 'clean' we built a composite index, using the facility questionnaire data ($n = 37$), that aimed to be represent each of the four enabling factors investigated: 'knowledge and training, infrastructure, staffing levels' and 'policies'. The choice of index components was informed by published IPC international guidelines for each topic (EngenderHealth 2003, 2011; WHO 2015). This allowed us to standardise the analysis of the 'cleans'' enabling factors with relevant data from the facility questionnaire.

Table 1 describes the information used to build these indices. For the 'knowledge and training' index, we used questions that explored the topics discussed during IPC training received in the past year and questions around maternal and newborn care practices. With regards to the latter, interviewees were asked about their care practices but discussion with our data collectors led us to believe that their answers reflect knowledge of expected practices rather than actual staff behaviour and thus are best considered a proxy for knowledge. We aimed to interview the maternity in-charge or equivalent in each facility; this information therefore represents their knowledge. For the 'infrastructure' index, we used questions on the availability of, and access to key infrastructure and equipment in the maternity unit.

For the 'policies' determinant, we present data on whether policies or posters of key protocols i.e. IPC, hand hygiene and decontamination of areas soiled by blood and other body fluids were available in the maternity unit. For 'human resources', at least one skilled SBA should be present in the maternity during the morning and night shifts; this ensures that someone formally trained in IPC is available on site capable of cleaning their hands adequately at appropriate times and capable of performing clean cord care. Since it was unusual in Zanzibar, especially in small facilities, that orderlies were allocated to night shifts, for clean birth surface the variable we referred to was whether an orderly was present on the previous morning shift.

The indices were all binary, with facilities either meeting all the conditions prescribed by the index or not. Similar composite indices have been used previously to describe key markers of the quality of maternal healthcare facilities (Nesbitt *et al.* 2013; Campbell *et al.* 2016). The key assumption was that the components chosen to construct the indices were fundamental for performing the 'cleans'.

Analysis

The variety of tools used produced quantitative, qualitative and microbiological data. Results from all three tool sets were organised

Table 1. Indices' components by 'clean' and for each enabling factor

Enabling factor	Clean hands	Clean cord	Clean birthing surface
Knowledge and training	Wash hands during the WHO key moments of hand hygiene (no data on hand washing before aseptic procedures, so this was not included)	Frequency of use of sterile clamps or ties	Delivery room cleaned at least once a day
	AND	AND	AND
	Training on hand hygiene received in the last year	Training on IPC received in the last year	Training for non-medical staff received in the last year
Infrastructure	(1) Soap available in the maternity unit	(1) Disposable or sterile clamps available in the maternity unit	(1) Bleach or bleaching powder currently available
	AND	AND	AND
	(2) Disposable gloves available in the maternity unit	(2) Disposable or sterile blades available in the maternity unit	(2) Delivery bed available and functional
	AND	AND	AND
	(3) Water is improved and available (24h availability, AND functional sink AND available AND piped water supply is not interrupted more than once a week)	(3) If reusable equipment is used, any sterilization method (i.e. products for High-level Chemical Disinfection, autoclaves, autoclave, dry heat sterilizer or boilers) available and functional	(3) Water is improved and available (24 h availability, AND functional sink AND available AND piped water supply is not interrupted more than once a week)
Staffing levels	At least one SBA present during the morning and night shift prior to the survey	At least one SBA present during the morning and night shift prior to the survey	At least one orderly present during the morning shift prior to the survey
Policies or posters on	Hand washing	'Not applicable as we did not collect this information'	Decontamination of areas contaminated with body fluids

thematically using the frameworks discussed: the WHO cleans and the enabling factors.

The water analysis, using conventional pour plate and membrane filtration techniques, focused on the total bacterial count in the water samples, as well as looking at the presence of *Enterococcus* and fecal coliforms—standard indicators for assessing water quality (Ashbolt *et al.* 2001). Swabs collected from surfaces were directly inoculated onto selective media and screened using standard biochemical techniques to identify and characterize potential pathogens. The analysis of the microbiology swab data focused first on whether *Staphylococcus aureus* (*S. aureus*), one of the most common pathogens linked to healthcare associated infections (Allegranzi *et al.* 2011), was present at the touch site. Opportunistic pathogens such as *S. aureus* are frequently shed by patients and staff in healthcare environments and can persist on surfaces for months on dry surfaces, posing a significant transmission risk to new patients admitted to the facility—thus, we used this as an indicator for cleanliness (Kramer *et al.* 2006). The second indicator examined was whether multiple pathogenic organisms were identified on the touch site. Two or more such pathogens found on a hand touch site indicate a lack of effective cleaning or long durations between cleans. For more details see Supplementary Material S1.

We began our analysis of the qualitative materials with word-for-word transcriptions of the audio files in their original language. Transcripts were later translated into English and analysed manually using a qualitative 'content analysis' method to extract manifest and latent content from the interviews (Vaismoradi *et al.* 2013). We used an inductive process for analysis whereby all codes and themes were derived from data. No software was used, a research assistant coded the data manually and the senior qualitative researcher reviewed the codes to check their quality (all codes are available on request).

Using facility questionnaire responses, indices representing each of the four enabling factors were constructed for each 'clean' and described by facility type. In our dataset, we distinguished between three types of facilities: with an operating theatre or without, and those which the MoH had not deemed appropriate to perform deliveries because they lacked key equipment and infrastructure. Since facility questionnaire data came from all facilities providing maternity services in Zanzibar, no survey weights were applied. The walkthrough checklist data produced counts of the infrastructure and equipment available, cleaned, and according to state of repair. Data were double entered into EpiData v3.1 and analysed using STATA v13 SE.

Ethics approval and consent to participate

We obtained ethical approval from the Zanzibar Medical Research and Ethics Committee and the Observational/Interventions Research Ethics Committee at the London School of Hygiene and Tropical Medicine for this study. The women interviewed gave their individual consent, while the MoH granted permission to interview healthcare staff, and collect and analyse microbiology samples in the facilities.

Women who gave birth recently—respondents were informed about the purpose of the survey before the start of the interview, informed that their participation was voluntary, and that all information provided was confidential and would be de-identified. The respondent's consent, if obtained, was in written form.

Facility data—prior to commencing the facilities questionnaire, an official letter was sent by the MoH to all facilities to inform them of the study aims and that the information collected might be used by the MoH or other organizations seeking to improve the planning and delivery of health services, and that the identity of the facility would be anonymized. For each of the seven facilities selected for the semi-structured interviews and the walkthrough this information was also provided in person by the enumerator to the facility in-charge, the maternity in-charge and the orderlies in-charge.

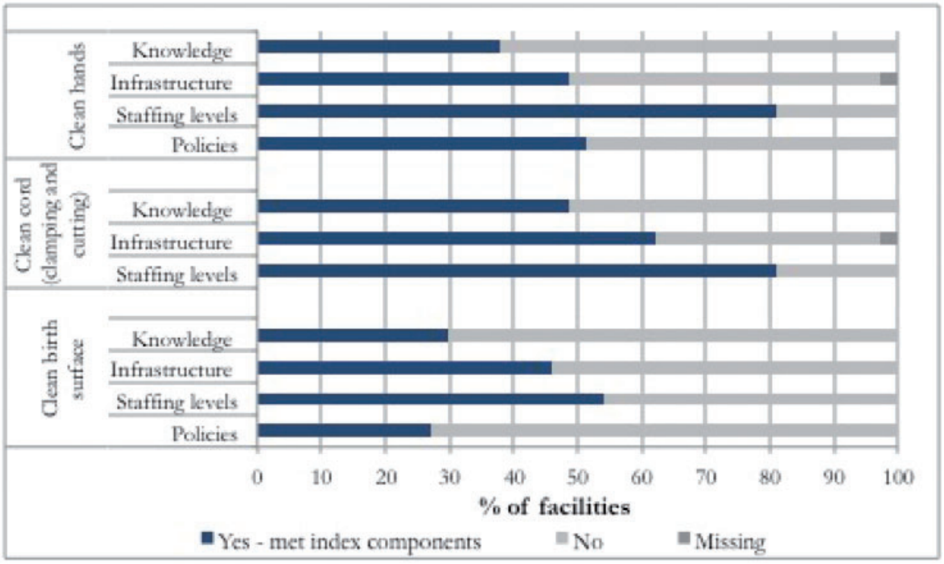

Figure 1. Percentage of facilities meeting all components per enabling factor index by clean (Knowledge stands for knowledge & training)

Results

Of the 37 facilities providing childbirth services in Zanzibar, eight had an operating theatre, 24 did not, and five were considered by the MoH to be too poorly equipped to perform deliveries because of lack of water and delivery equipment. 84% of facility births across the 37 facilities surveyed took place at one of the eight facilities with an operating theatre (data not shown). The enabling factors' indices for each of the 'cleans' were met by only 50% or fewer of the 37 facilities, with two exceptions: the infrastructure index for clean cord and the proportion of facilities with an SBA present in the morning and night shift before the survey, as described further below (Figure 1).

Clean hands

Coverage of knowledge and training around clean hands was 38%, with 14 facilities out of the total of 37 meeting all the knowledge and training conditions (Table 2 and Figure 1). The weakest knowledge and training index component was knowledge around when to wash hands and, in particular, many respondents did not know they were supposed to wash hands 'after touching the environment around the patient'. In 70% of facilities, staff reported having had training on hand hygiene, and this was confirmed by the qualitative interviews. Almost all care providers with which we conducted qualitative interviews could explain the hand hygiene process correctly ($n = 26$).

The facility questionnaire ($n = 37$) showed 18 facilities (49%) met all the infrastructure conditions for hand washing (Table 2 and Figure 1). The availability of a functional sink (i.e. a sink which can accommodate running water flowing from a tap) and whether running water is available 24 h a day were the main gaps in facilities' hand washing infrastructure. Of the 22 hand-washing stations (including buckets and sinks) across 7 facilities surveyed in the walkthrough checklist, 15 had water available. When water was not available, facilities use stored water. Due to logistical difficulties in accessing the storage containers, we were only able to take samples from two water storage containers at two of the seven facilities: a plastic bucket and a larger plastic container. Both showed high levels of contamination; their total bacterial count was over 300 CFU/ml, and one sample had a high presence of *Enterococcus* (100 CFU/ml). We also took samples from water sources routinely used for hand washing, and 21% of these ($n = 102$) had a total bacterial count of over 100 CUF/ml (See details on the water analysis results in Supplementary Material S1). Indeed, 73% of the facilities surveyed reported water testing is never done in the facility, and the rest did not know this information.

The qualitative interview analysis ($n = 26$) emphasized that water availability was a major challenge. A common substitute for the lack of piped water was to store water in buckets. At two facilities out of seven, staff reported having to carry water in buckets from water storage tanks outside the facility, due to blockages in pipes. Maintaining a sufficient water supply was an issue, particularly at night when institutional availability of water is less reliable and those in charge of maintenance are not on shift.

In 12% of the facilities without an operating theatre ($n = 24$), there was no SBA during the morning and night shift prior to the survey (Table 2); whereas, all facilities with an operating theatre had at least one SBA present. Staffing shortages and high caseloads were frequently mentioned during qualitative interviews as reasons for poor IPC.

The facility questionnaire ($n = 37$) data showed that policies or posters about hand washing were available in 51% of facilities (Table 2); this proportion was 75% for facilities with an operating theatre. The walkthrough revealed that only three of the seven maternity wards observed had a poster on hand hygiene displayed in the maternity area.

Clean cord

From the facility questionnaire ($n = 37$), 18 facilities (49%) met the knowledge and training conditions and 23 facilities (62%) met the basic infrastructure conditions for a clean cord (Figure 1). All facilities reported routinely using disposable blades and cord clamps, but these were not always available; 89% of facilities had sterile blades available, but only 68% had both sterile cord clamps and sterile blades (data not shown). One facility reported commonly using reusable cord clamps but also reported having no functioning sterilization or high level disinfection equipment.

Walkthrough data showed similar results: all seven facilities had access to either reusable or disposable cord cutting equipment.

Table 2. Proportion[a] of facilities meeting the enabling factors' indices by 'clean' and facility type (data source: facility questionnaire)

Variable	Facilities with an operating theatre ($n = 8$) n (%)	Facilities without an operating theatre ($n = 24$) n (%)	Facilities deemed inappropriate for deliveries ($n = 5$) n (%)	Total facilities ($n = 37$) n (%)
Clean hands				
Knowledge and Training				
Yes	4 (50)	9 (38)	1 (20)	14 (38)
No	4 (50)	15 (63)	4 (80)	23 (62)
Missing	0	0	0	0
Infrastructure				
Yes	7 (88)	9 (38)	2 (40)	18 (49)
No	1 (12)	15 (63)	2 (40)	18 (49)
Missing	0	0	1 (20)	1 (3)
Staffing levels				
Yes	8 (100)	21 (88)	1 (20)	30 (81)
No	0	3 (13)	4 (80)	7 (19)
Missing	0	0	0	0
Policies				
Yes	6 (75)	12 (50)	1 (20)	19 (51)
No	2 (25)	12 (50)	4 (80)	18 (49)
Missing	0	0	0	0
Clean cord				
Knowledge and Training				
Yes	6 (75)	11 (46)	1 (20)	18 (49)
No	2 (25)	13 (54)	4 (80)	19 (51)
Missing	0	0	0	0
Infrastructure				
Yes	6 (75)	14 (58)	3 (60)	23 (62)
No	2 (25)	10 (42)	1 (20)	13 (35)
Missing	0	0	1 (20)	1 (3)
Staffing levels				
Yes	8 (100)	21 (88)	1 (20)	30 (81)
No	0	3 (13)	4 (80)	7 (19)
Missing	0	0	0	0
Clean birth surface				
Knowledge and Training				
Yes	5 (63)	4 (17)	2 (40)	11 (30)
No	3 (38)	20 (83)	3 (60)	26 (70)
Missing	0	0	0	0
Infrastructure				
Yes	6 (75)	9 (38)	2 (40)	17 (46)
No	2 (25)	15 (63)	3 (60)	20 (54)
Missing	0	0	0	0
Staffing levels				
Yes	8 (100)	11 (46)	1 (20)	20 (54)
No	0	13 (54)	4 (80)	17 (46)
Missing	0	0	0	0
Policies				
Yes	5 (63)	5 (21)	0	10 (27)
No	3 (38)	19 (79)	5 (100)	27 (73)
Missing	0	0	0	0

[a]The proportion was approximated to the nearest decimal; hence, variables options might not add up.

The walkthrough supplemented the questionnaire findings by showing whether equipment for cord care was decontaminated (if reusable) and stored safely. Similar to the facility questionnaire results, access to cord clamps was lower than for blades. Qualitative interviewees at five of the seven facilities reported creating self-made cord ties from the rim of sterile gloves or pieces of string, ideally soaked in alcohol solution. Potential failure in carrying out this procedure makes strings less safe and practical than disposable sterile clamps.

The staffing levels for clean cord care were measured in the same way as for clean hands as reported above. We did not collect specific information on policies around clean cord.

Clean birth surface

All the basic conditions for knowledge and training index around a clean birth surface were met by 11 out of 37 facilities (30%) (Table 2 and Figure 1). A weak component of index was the lack of training for non-medical staff, including orderlies, who are responsible for cleaning the bed surface.

The walkthrough checklist results confirm these findings. Microbiological samples revealed that in six of the seven facilities where swabs were taken, the maternity beds were highly contaminated with multiple organisms, especially around the perineal area. Sixty percent of mops and mop bucket swab sites tested positive for multiple microbiological organisms. Multiple organisms were further identified on six out of eight surface cleaning cloths. It was a common finding that most mops were stored inside buckets filled with mopping fluid for most of the day.

The infrastructure index suggests that only 17 out of 37 facilities (46%) met the basic requirements for a clean birth surface (Table 2), with the weakest index component being the same as for clean hands: consistent availability of water (Figure 1). The facility questionnaire ($n = 37$) found that all but two facilities surveyed had at least one functional delivery bed available (data not shown). The results from the walkthrough checklist found that in both the maternity and delivery rooms, most beds (21/26) across the seven facilities surveyed were covered in cleanable materials and/or a mackintosh (data not shown).

Across all seven facilities where qualitative interviews ($n = 26$) were conducted, staff complained about a shortage of orderlies. In line with these findings, the facility questionnaire ($n = 37$) revealed that only 54% of facilities had an orderly present in the maternity unit on the morning before the survey (Table 2). The shortage of orderlies was further aggravated by the fact that most of the orderlies interviewed also performed healthcare related tasks such as antenatal care, wound dressing, prescribing medications and assisting deliveries, which significantly reduced the time they spent on cleaning activities.

Of the facilities without an operating theatre, only 21% had policies or posters on the decontamination of areas contaminated with body fluids (Table 2). The proportion was higher for those facilities with an operating theatre, 63%.

Discussion

We provided an illustrative analysis of IPC information collected in maternity units in a low-income country to assist in developing a quality improvement strategy both at the local facility and the MoH levels. Our results are actionable for three main reasons: the use of a clear framework, the WHO IPC guidelines, made up of four enabling factors amenable to change; the use of mixed methods to unpack the complex picture behind the infection prevention gaps; and the focus on and relevance to the key interventions necessary to reduce maternal and newborn infection embedded in the WHO clean practices: making sure that during labour and delivery the hands of the birth attendants, the birth surface and the cord clamping and cutting are all clean.

Using the WHO IPC guidelines framework we could organise our results so that the MoH could identify the weakest enabling factors of the necessary clean practices and the type of intervention needed—e.g. infrastructure vs training. For example: the weakest index component for clean birth surface was the knowledge of health orderlies and their lack of training on decontamination of areas exposed to body fluids. The theme of knowledge in itself helped narrow down the potential for action to an educational intervention involving specific roles in the MoH, such as district level supervisors and the local institute for nursing training.

To produce data on IPC gaps that can be actioned by the MoH required a mixed-methods approach to data collection and analysis. Our mixed methods approach provided a comprehensive and useful description of key enabling factors of the relevant clean practices in maternity units, with different methods suited to different items of information. For example, the facility questionnaire revealed that water is often unavailable on the labour ward. With this information alone we did not know whether delivery was practiced in the absence of running water or how the problem was overcome. Through semi-structured interviews, we learned that staff perform deliveries without running water, and that standing water buckets are used as an alternative to non-functioning sinks. Although very limited in number, the standing water buckets we sampled were highly contaminated; as found elsewhere, inappropriate water storage leads to contamination (Shields *et al.*; Wright *et al.* 2004). The triangulation of data strengthened our conclusions, and avoided some of the assumptions inherent in the interpretation quantitative results. The mixed methods approach allowed us to understand the complex picture behind the IPC weaknesses we found and to provide potential intervention targets to the ministerial audience.

Our approach to producing actionable information is unable to recommend which of the enabling factors will have a sustainable and wider benefit; indeed, it probably draws attention towards shorter-term solutions such as infrastructure and training that are quick wins for any MoH, compared to longer-term structural changes. Yet, our approach still highlights these wider structural gaps—such as the lack of sufficient staff and policy gaps.

Although no agreed definition for 'actionable information' exists in global health, other research using this terminology refers to information presented in a way that makes evidence-based programming more accessible, using for example the visual display of data (Makulec and Morgan 2015). This was also our intent and fits into the current wider attempt in public health to ensure that evidence feeds into action by using condition specific frameworks and platforms (Evidence for Action); Swinburn *et al.* 2005). Using a clear and simple approach to identify actionable information was an important ingredient for the project's endorsement and support from the MoH; yet translating that information into action would not have been possible without a participatory workshop that included all key stakeholders. We describe how we engaged with the key stakeholders in a participatory workshop and how the information presented was then translated into action in Supplementary Material S2.

An important limitation to our actionable information approach is that we looked at proxies of the enabling factors rather than actual practices. Ideally, both should be done, but time and financial limitations meant that we could not observe practices. We would also have liked to explore more enabling factors, but the type of data we collected did not permit this. In particular, the tools we used did not collect information on social norms and individuals' motivation—key areas for explaining behaviour (Montano and Kasprzyk 2008).

The results show that overall facilities' performance across all enabling factors for each of the 'cleans' was poor. Each enabling factors' index was met by, at best, half of facilities, apart from two factors met by a higher proportion. However, even these better performing indices are of concern. Only 81% of facilities had SBAs present in the morning and night shift before the survey; a finding supported by the low presence of skilled personnel in maternity wards in Eastern African shown by a recent multi-country study (Kruk *et al.* 2016). Indeed, this index should be at 100% as facilities providing maternity care should run with 24 h services. In this context, in the absence of an SBA, deliveries are occasionally performed by health orderlies. Across virtually all indices, facilities with an operating theatre performed better, in terms of knowledge, infrastructure, availability of staffing and policies, compared with smaller facilities providing basic obstetric care. This is consistent with other studies showing that larger facilities generally tend to score better in terms of some markers of quality of care (Campbell *et al.* 2016).

Other key findings included first, the substantial lack of a reliable and constant water supply, with half of facilities operating without basic water infrastructure. This is consistent with research on water availability in facilities in low- and middle-income countries (LMICs) (Chawla *et al.* 2016) and specifically in maternities in Tanzania (Benova *et al.* 2014; Gon *et al.* 2016). A recent review (Bain *et al.* 2014) of water quality in LMICs found very few studies based in health facilities, highlighting the importance of our data in this field. They proposed a score to assess the quality of water sampling and analysis. Applying their system, our study met 10 out of 13 quality criteria, which is above the interquartile range of the 319 studies in their review (Bain *et al.* 2014).

Another key finding was the poor knowledge and training and practice of health orderlies in cleaning the birth surface—from the walkthrough exercise we found that six of the seven maternity units swabbed had beds with *S. aureus*, representing a lack of effective or frequent cleaning. A very recent study in paediatric wards with poor cleaning practices in South Africa also found *S. aureus* on their surfaces (Dramowski *et al.* 2016). A study from India which includes the maternity unit environment, found that 10% of patient care equipment was contaminated with some kind of pathogen (Dadhich *et al.* 2014). In addition, the facility questionnaire reported that 37% of facilities cleaned the delivery room less than once a day on average and their non-medical staff were un-trained. The high levels of pathogens present on the cleaning equipment may explain the high level of microbiological contamination found on the beds. Overall cleaning in healthcare facilities is a poorly monitored and an under-researched area in spite of being vital to effective IPC and the reduction of healthcare associated infection. Simple solutions like fluorescent gel and UV markers can promote local engagement and training of cleaners (Dramowski *et al.* 2016).

We have confidence in our results given the consistency across the different tools used and because indices were constructed using data from all maternity units across Zanzibar. Moreover, our findings were consistent with the views on the status of IPC in maternities expressed by workshop participants including the MoH. Results of the enabling factors' indices, should, however, be interpreted cautiously, especially for knowledge and training of staff which was based on the response of only one person at each facility. Having said this, as we aimed to interview the maternity in-charge, or equivalent at the time, at each facility, we expect the results are fairly representative of the maternity unit personnel. If anything, our choice of interviewee may overestimate the average knowledge of the personnel in the maternity unit. With regards to the staffing indices, having at least one SBA or health orderly available does not guarantee clean practice – but their presence would increase the likelihood of the 'clean' being performed. As mentioned earlier, in the absence of an SBA, deliveries are occasionally performed by health orderlies with no formal training in delivering a baby including relevant aspects of IPC.

These data may be influenced by observer bias because the data collectors were MoH employees for all tools except the semi-structured interviews. However, two things minimise this issue: first, data collectors were sensitised repeatedly about the fact that data were collected mainly for local improvement purposes and needed to be accurate for this to be possible. In addition, we emphasised that data would be anonymized, so there should be no repercussions for interviewees, facilities, or interviewers. Second, the walkthrough tool set and the semi-structured interviews at each of the seven facilities were closely supervised by an independent senior qualitative scientist. The results from these tools were consistent with the facility questionnaire results, providing further evidence that observer bias might not have influenced our results significantly.

Quantitative analysis of environmental samples was not possible due to limited laboratory capacity, although 30% of the swabs yielded levels of growth too high for quantification. Indeed, this was the first time, the Pemba Health Laboratory carried out environmental sampling and analysis. Not many healthcare laboratories in low-income settings have exposure to environmental sampling and therefore greater advocacy, training and support for laboratories would lead to standardization of swabbing techniques, sample culturing and reporting.

A further limitation is that information on the availability of electricity which is key to performing a clean delivery, especially at night, was not collected (Adams *et al.* 2008). From the 2014 Service Provision Assessment of healthcare facilities, we know that 77% of facilities have regular electricity in Zanzibar (Tanzania Service Provision Assessment Survey 2014-2015, 2016). Other information related to infection prevention during birth was collected, such as on waste disposal, and availability of malaria bed nets; however, this is not presented as it does not directly relate to our outcome framework.

We present a simple approach to analysing IPC data from maternity units to facilitate and prompt action. Using our approach, the Zanzibar MoH was able to readily prioritise and follow-up on the findings presented here by organising for the first time a formal training for health orderlies on cleaning practices, and by improving the infrastructure of sinks in the maternity wards. Observation of the actual clean practices would significantly improve our approach but could be prone to a non-trivial Hawthorne effect. Using this approach in other settings/countries could provide key evidence for governments to improve maternity units, and so contribute to the prevention of newborn and puerperal sepsis.

Supplementary Data

Supplementary data are available at *HEAPOL* online

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9.3. Appendix II (B) – Walkthrough Checklist

Tool 2 - WALKTHROUGH CHECKLIST

DATE (DDMMYY)**:**

START TIME:

DATA COLLECTOR CODE:

FACILITY CODE:

TOOL CODE

2	**1**

I. MATERNITY WARD ENVIRONMENT (ANTINATAL AND POSTNATAL WARD)

A. ANTE/POST-NATAL WARD – GENERAL AREA & HAND WASHING					
Take several photos of the ante/post-natal ward – record each photo on the Photo Record Sheet					
Topic	**Question**	**Yes**	**No**	**N/A**	**Comments**
1. THE FLOOR IS	a. Visibly clean **[It is free from build-up of residue/dirt]**				
	b. Free from clutter **[Unnecessary or unused equipment or furniture *is not in the way*]**				
	c. Free from foul or stale odours				
2. ALL STOCK AND EQUIPMENT ARE **[Appropriate items e.g. BP machine]**	a. Stored above floor level				
3. DRINKING WATER (I.E. POTABLE WATER)	a. Drinking water for staff available				
	b. Drinking water for clients available				
4. ILLUSTRATED HAND HYGIENE POSTERS ARE	a. Displayed at every hand washing point				
	b. Displayed in general maternity unit areas				
	c. All posters are in good state of repair **[They can be read and the information is complete]**				
HAND WASHING FACILITY 1 (worst)					
5. HAND WASHING FACILITY IN THE ANTE/POST NATAL WARD	a. Available at a sink with a connected tap				
	b. Available at a bucket with a tap				
	C. Standing water in a bucket				
	d. Other arrangement (please specify in comments box)				

FOR STAFF IS (tick all that apply):					
6. NEAR OR AT THE HAND WASHING FACILITY FOR STAFF	a. Water is currently available **[Turn the tap on! Is the water running? is water in the bucket? Write in comments box]**				
	b. Soap, or suitable alternative, is available				
	c. There is disposable material on which to dry hands **[Note material in Comments box]**				
7. HAND WASHING FACILITY FOR STAFF ARE	a. Accessible **[Not blocked by furniture or equipment]**				
	b. Located near the client bed space				
	c. Visibly Clean [**It is free from build-up of residue/dirt**]				
	d. Free from items that are not needed for hand washing				
8. TAP MECHANISM IS **[e.g. hand operated, elbow operated, foot operated]**	a. Visibly clean [**It is free from build-up of residue/dirt**]				
	b. Free from visible signs of damage **[NOT dripping; tap is NOT loosely fitted]**				
	c. Functioning **[Tap can be turned to allow the water to flow]**				
HAND WASHING FACILITY 2 (best)					
9. HAND WASHING FACILITIES IN THE POST/ANTE NATAL WARD FOR STAFF IS (tick all that apply):	a. Available at a sink with a connected tap				
	b. Available at a bowl with a water canister				
	c. Available as standing water in a bucket				
	d. Other arrangement **[Please specify in Comments box]**				
10. NEAR OR AT THE HAND WASHING FACILITY FOR STAFF	a. Water is currently available **[Turn the tap on! Is the water running?; is water in the bucket?]**				
	b. Soap, or suitable alternative, is available				
	c. There is disposable material on which to dry hands **[Note material in Comments box]**				
11. HAND WASHING FACILITY FOR STAFF ARE	a. Accessible **[Not blocked by furniture or equipment]**				
	b. Located near the client bed space				
	c. Visibly Clean [**It is free from build-up of residue/dirt**]				
	d. Free from items that are not needed for hand washing				
12. TAP MECHANISM **[e.g. hand**	a. Visibly clean [**It is free from build-up of residue/dirt**]				
	b. Free from visible signs of damage **[dripping; tap is loosely fitted]**				

operated, elbow operated, foot operated]	c. Functioning **[Tap can be turn to allow for the water to flow]**				
13. IF THERE IS NO FUNCTIONING HAND WASHING FACILITY IN THE ANTE/ POSTNATAL WARD, HOW FAR TO THE ONE BEING USED?	**Is the nearest hand washing station is within 20 seconds away from the anti/post-natal ward (if there are none in the maternity area)?**				
14. OTHER ASPECTS OF THE AREA OBSERVED DURING THE INSPECTION	**Record here any other areas not mentioned above:**				

B. ANTE/POST NATAL WARD - BEDS					
Take several photos evidencing the state of the clients beds – record each photo on the Photo Record Sheet					
Topic	**Question**	**Yes**	**No**	**N/A**	**Comments**
BED NUMBER 1 (worst)					
15. BED FRAME IS	a. Visibly clean **[It is free from build-up of residue/dirt]**				
	b. Free from visible signs of damage, rust (at or above the client level), rips or cracks				
16. FIXED MATTRESS COVER IS **[e.g. rubber mackintosh]**	a. Visibly clean **[It is free from build-up of residue/dirt]**				
	b. Intact, free from signs of damage, rips or cracks				
	c. Easily cleaned, waterproof material				
17. HARD AND HORIZONTAL SURFACE NEXT TO THE CLIENT IS **[Beside the client's bed e.g. chair or table]**	a. Visibly clean **[It is free from build-up of residue/dirt; check edges and corners are free from dust and girt]**				
	b. Free from visible signs of damage, rips or cracks				
	c. Washable and impervious to moisture				
BED NUMBER 2 (best)					
18. BED FRAME IS	a. Visibly clean **[It is free from build-up of residue/dirt]**				
	b. Free from visible signs of damage, rust (at or above the client level), rips or cracks				
19. FIXED MATTRESS	a. Visibly clean				

COVER IS **[e.g. rubber mackintosh]**	**[It is free from build-up of residue/dirt]**				
	b. Intact, free from signs of damage, rips or cracks				
	c. Easily cleaned, waterproof material				
20. HARD AND HORIZONTAL SURFACE NEXT TO THE CLIENT IS **[Beside the client's bed e.g. stool or table]**	a. Visibly clean, free from build-up of residue/dirt **[Check edges and corners are free from dust and girt]**				
	b. Free from visible signs of damage, rips or cracks				
	c. Washable and impervious to moisture				
21. OTHER ASPECTS OF THE AREA OBSERVED DURING THE INSPECTION	Record here any other areas not mentioned above:				

C. ANTE/POST-NATAL WARD / DELIVERY UNIT TOILETS - CLEANLINESS & STATE OF REPAIR OF					
Take several photos evidencing the state of the delivery unit toilets – record each photo on the Photo Record Sheet					
Topic	**Question**	**Yes**	**No**	**N/A**	**Comments**
TOILET 1 FOR CLIENTS (worst)					
22. IN THE CLIENT TOILET AREA OF THE DELIVERY UNIT:	a. The floor is visibly clean **[It is free from build-up of residue/dirt; Check edges & corners are free from & grit]**				
	b. Free from clutter **[Unnecessary or unused equipment or furniture *is not in the way*]**				
	c. Free from foul or stale odours				
	d. Easily Accessible **[No more than 30 metres from the maternity]**				
	e. Toilet door handles (both going in and going out) are visibly clean **[It is free from build-up of residue/dirt; Check edges & corners are free from dirt & grit]**				
23. THE TOILET HAS	a. Functioning flush mechanism **[Flush the toilet and see if the flush works]**				
	b. Anal cleansing material **[e.g. water available]**				
	c. Toilet seat (or equivalent) which is visibly clean **[It is free from build-up of residue/dirt; Check edges & corners are free from dirt & grit]**				
HAND WASHING FACILITY 1 – CORRESPONDING TO TOILET 1					
24. HAND WASHING FACILITIY FOR	a. Available at a sink with a connected tap				

CLIENT IS	b. Available at a bowl with a water canister				
	c. Available as standing water in a bucket				
	d. Other arrangement **[Please specify in Comments box]**				
25. NEAR OR AT THE HAND WASHING FACILITY FOR CLIENTS	a. Water is currently available **[Turn the tap on! Is the water running?; is water in the bucket?]**				
	b. Soap, or suitable alternative, is available				
	c. There is disposable material on which to dry hands **[Note material in Comments box]**				
26. HAND WASHING FACILITY FOR CLIENTS ARE	a. Accessible **[Not blocked by furniture or equipment]**				
	b. Located near toilet				
	c. Visibly Clean **[It is free from build-up of residue/dirt**]				
	d. Free from items that are not needed for hand washing				
27. TAP MECHANISM IS **[e.g. hand operated, elbow operated, foot operated]**	a. Visibly clean [**It is free from build-up of residue/dirt**]				
	b. Free from visible signs of damage **[Not Dripping; tap is Not loosely fitted]**				
	c. Functioning **[Tap can be turn to allow for the water to flow]**				
TOILET 2 FOR CLIENTS (best)					
28. IN THE CLIENT TOILET AREA OF THE DELIVERY UNIT:	a. The floor is visibly clean **[It is free from build-up of residue/dirt; Check edges & corners are free from grit]**				
	b. Free from clutter **[Unnecessary or unused equipment or furniture *is in the way*]**				
	c. Free from foul or stale odours				
	d. Easily Accessible **[No more than 30 metres from the maternity]**				
	e. Toilet door handles (both going in and going out) are visibly clean **[It is free from build-up of residue/dirt; Check edges & corners are free from dirt & grit]**				
29. THE TOILET HAS	a. Functioning flush mechanism **[Flush the toilet and see if the flush works]**				
	b. Anal cleansing material **[e.g. water available]**				
	c. Toilet seat (or equivalent) which is visibly clean **[It is free from build-up of residue/dirt; Check edges & corners are free from dirt & grit]**				
HAND WASHING FACILITY 2 – CORRESPONDING TO TOILET 2					
30. HAND WASHING FACILITY FOR	a. Available at a sink with a connected tap				

CLIENTS IS **[Please comment if there is only 1 hand washing facility for both toilets]**	b. Available at a bucket with a tap				
	c. Standing water in a bucket				
	d. Other arrangement [Please specify in Comments box e.g. Standing water in a bucket]				
31. NEAR OR AT THE HAND WASHING FACILITY FOR CLIENTS	a. Water is currently available **[Turn the tap on! Is the water running?; is water in the bucket?]**				
	b. Soap, or suitable alternative, is available				
	c. There is disposable material on which to dry hands **[Note material in Comments box]**				
32. HAND WASHING FACILITY FOR CLIENTS ARE	a. Accessible **[Not blocked by furniture or equipment]**				
	b. Located near the toilet				
	c. Visibly Clean **[It is free from build-up of residue/dirt**]				
	d. Free from items that are not needed for hand washing				
33. TAP MECHANISM IS **[e.g. hand operated, elbow operated, foot operated]**	a. Visibly clean **[It is free from build-up of residue/dirt**]				
	b. Free from visible signs of damage **[Dripping; tap is loosely fitted]**				
	c. Functioning **[Tap can be turn to allow for the water to flow]**				
TOILET 3 FOR STAFF					
34. IN THE STAFF TOILET AREA:	a. The floor is visibly clean **[It is free from build-up of residue/dirt; Check edges & corners are free from grit]**				
	b. Free from clutter **[Unnecessary or unused equipment or furniture *is in the way*]**				
	c. Free from foul or stale odours				
	d. Easily Accessible **[No more than 30 metres from the maternity]**				
	e. Toilet door handles (both going in and going out) are visibly clean **[It is free from build-up of residue/dirt; Check edges & corners are free from & grit]**				
35. THE TOILET HAS	a. Functioning flush mechanism **[Flush the toilet and see if the flush works]**				
	b. Anal cleansing material **[e.g. water available]**				
	c. Toilet seat (or equivalent) which is visibly clean **[It is free from build-up of residue/dirt; Check edges & corners are free from & grit]**				
HAND WASHING FACILITY 3 – CORRESPONDING TO TOILET 3 If not dedicated hand washing station after toilet use for staff say NA					
36. HAND WASHING FACILITY FOR	a. Available at a sink with a connected tap				

STAFF IS	b. Available at a bowl with a water canister				
	c. Standing water in a bucket				
	d. Other arrangement (**Please specify in Comments box)**				
37. NEAR OR AT THE HAND WASHING FACILITY FOR STAFF	a. Water is currently available **[Turn the tap on! Is the water running?; is water in the bucket?]**				
	b. Soap, or suitable alternative, is available				
	c. There is disposable material on which to dry hands **[Note material in Comments box]**				
38. HAND WASHING FACILITY FOR STAFF ARE	a. Accessible **[Not blocked by furniture or equipment]**				
	b. Located near the toilet				
	c. Visibly Clean **[It is free from build-up of residue/dirt**]				
	d. Free from items that are not needed for hand washing				
39. TAP MECHANISM IS **[Comments box, e.g. hand operated, elbow operated, foot operated]**	a. Visibly clean [**It is free from build-up of residue/dirt**]				
	b. Free from visible signs of damage **[Dripping; tap is loosely fitted]**				
	c. Functioning **[Tap can be turn to allow for the water to flow]**				
40. OTHER ASPECTS OF THE AREA OBSERVED DURING THE INSPECTION	Record here any other areas not mentioned in the above:				

II. DELIVERY UNIT (WARD) ENVIRONMENT

D. DELIVERY UNIT – GENERAL AREA & HAND WASHING					
Take several photos evidencing the state of the labour/delivery room – record each photo on the Photo Record Sheet					
41. THE FLOOR IS	a. Visibly clean **[It is free from build-up of residue/dirt]**				
	b. Free from clutter **[Unnecessary or unused equipment or furniture *is in the way*]**				
	c. Free from foul or stale odours				
42. ALL STOCK AND EQUIPMENT ARE **[Appropriate items i.e. gauzes, thermometer, blades, IV, needles, syringes, fetoscope]**	a. Stored above floor level				
	b. Stored correctly, neat & tidy, sterile single use items in original packaging **[No overflow of items, organised]**				
	c. Storage is sufficient for stock				
43. MAIN EQUIPMENT TROLLEY IS	a. Visibly clean **[It is free from build-up of residue/dirt & dust free]**				
	b. Free from visible signs of damage, rips or cracks				
	c. Free from broken or unnecessary equipment				
HAND WASHING FACILITY 1 (worst)					
44. HAND WASHING FACILITIES FOR STAFF ARE	a. Available at a sink with a connected tap				
	b. Available at a bowl with a water canister				
	c. Standing water in a bucket				
	d. Other arrangement **[Please specify in Comments box e.g. Standing water in a bucket]**				
45. NEAR OR AT THE HAND WASHING FACILITY FOR STAFF	a. Water is currently available **[Turn the tap on! Is the water running? is water in the bucket?]**				
	b. Soap, or suitable alternative, is available				
	c. There is disposable material on which to dry hands **[Note material in Comments box]**				
46. HAND WASHING FACILITIES FOR	a. Accessible **[Not blocked by furniture or equipment]**				
	b. Located near the client bed space				

STAFF ARE	c. Visibly Clean [**It is free from build-up of residue/dirt**]				
	d. Free from items that are not needed for hand washing				
47. TAP MECHANISM IS **[Comments box, e.g. hand operated, elbow operated, foot operated]**	a. Visibly clean [**It is free from build-up of residue/dirt**]				
	b. Free from visible signs of damage **[Dripping; tap is loosely fitted]**				
	c. Functioning **[Tap can be turn to allow for the water to flow]**				
HAND WASHING FACILITY 2 (best)					
48. HAND WASHING FACILITIES FOR STAFF IS	a. Available at a sink with a connected tap				
	b. Available at a bowl with a water canister				
	c. Standing water in a bucket				
	d. Other arrangement **[Please specify in Comments box e.g. Standing water in a bucket]**				
49. NEAR OR AT THE HAND WASHING FACILITY FOR STAFF	a. Water is currently available **[Turn the tap on! Is the water running?; is water in the bucket?]**				
	b. Soap, or suitable alternative, is available				
	c. There is disposable material on which to dry hands **[Note material in Comments box]**				
50. HAND WASHING FACILITY FOR STAFF ARE	a. Accessible **[Not blocked by furniture or equipment]**				
	b. Located near the client bed space				
	c. Visibly Clean [**It is free from build-up of residue/dirt**]				
	d. Free from items that are not needed for hand washing				
51. TAP MECHANISM **[Comments box, e.g. hand operated, elbow operated, foot operated]**	a. Visibly clean [**It is free from build-up of residue/dirt**]				
	b. Free from visible signs of damage **[Dripping; tap is loosely fitted]**				
	c. Functioning **[Tap can be turned to allow for the water to flow]**				
52. IF THERE IS NOT HAND WASHING FACILITY IN THE DELIVERY UNIT, HOW FAR IS THE NEAREST?	**Is the nearest hand washing station more than 20 seconds away (if there are none in the delivery unit)?**				
53. A DEDICATED DEEP SINK FOR WASHING USED EQUIPMENT IS **[if there is not dedicated sink please, report in Comment box what**	a. Visibly clean				
	b. Free from visible signs of damage, cracks, fitted correctly				
	c. Water is currently available **[Turn the tap on! Is the water running? Is water in the bucket?]**				

is used instead for washing used equipment]					
BED 1 (worst)					
54. BED FRAME IS	a. Visibly clean **[It is free from build-up of residue/dirt]**				
	b. Free from visible signs of damage, rust (at or above the client level) rips or cracks				
55. FIXED MATTRESS COVER FOR BED IS **[e.g. rubber mackintosh]**	a. Visibly clean **[It is free from build-up of residue/dirt]**				
	b. Intact, free from signs of damage, rips or cracks				
	c. Easily cleaned, waterproof material				
56. HARD AND HORIZONTAL SURFACE NEXT TO THE CLIENT ARE **[Beside the client's bed]**	a. Visibly clean, free from build-up of residue/dirt **[Check edges and corners are free from grit]**				
	b. Free from visible signs of rust at or above the client level				
	c. Washable and impervious to moisture				
BED 2 (best)					
57. BED FRAME IS	a. Visibly clean **[It is free from build-up of residue/dirt]**				
	b. Free from visible signs of damage, rust (at or above the client level) rips or cracks				
58. FIXED MATTRESS COVER FOR BED IS **[e.g. rubber mackintosh]**	a. Visibly clean **[It is free from build-up of residue/dirt]**				
	b. Intact, free from signs of damage, rips or cracks				
	c. Easily cleaned, waterproof material				
59. HARD AND HORIZONTAL SURFACE NEXT TO THE CLIENT ARE **[Beside the client's bed]**	a. Visibly clean, free from build-up of residue/dirt **[Check edges and corners are free from girt]**				
	b. Free from visible signs of rust at or above the client level				
	c. Washable and impervious to moisture				
60. OTHER ASPECTS OF THE AREA OBSERVED DURING THE INSPECTION	Record here any other areas not mentioned in the above:				

E. DELIVERY UNIT - AVAILABILITY OF BARRIER CLOTHING					
Take several photos evidencing the state of the storage of barrier clothing – record each photo on the Photo Record She					
Topic	**Question**	**Yes**	**No**	**N/A**	**Comments**
61. PLASTIC HEAVY DUTY APRON 1 IS (worst)	a. Available in the delivery unit				

[Please comment on the material of the apron if not made of plastic; if the apron is disposable please specify this in the Comment box]	b. Stored away from contamination risk **[Not near the delivery bed; not on the floor; hanged appropriately]**				
	c. Visibly clean **[It is free from build-up of residue/dirt]**				
62. PLASTIC HEAVY DUTY APRON 2 IS (best) **[Please comment on the material of the apron if not made of plastic; if the apron is disposable please specify this in the Comment box]**	a. Close to point of care				
	b. Stored away from contamination risk **[Not near the delivery bed; not on the floor; hanged appropriately]**				
	c. Visibly clean **[It is free from build-up of residue/dirt]**				
63. STERILE GLOVES ARE	a. Close to the point of care **[Within the delivery unit]**				
	b. Stored away from contamination risk **[Should be in their package; not on the floor; not overflowing; away from the delivery bed]**				
64. OTHER ASPECTS OF THE AREA OBSERVED DURING THE INSPECTION	Record here any other areas not mentioned above:				

F. DELIVERY UNIT - WASTE STORAGE & DISPOSAL					
Take several photos evidencing the state of waste disposal – record each photo on the Photo Record Sheet					
Topic	**Question**	**Yes**	**No**	**N/A**	**Comments**
65. WASTE SEGREGATED IN TO FOUR DIFFERENT BINS ACCORDING TO THEIR CATEGORY: SHARPS (NEEDLES, ETC.); NON-SHARPS **SOLID** INFECTIOUS WASTE (DRESSINGS, GLOVES, ETC ETC.); NON-SHARPS **WET**	a. Waste segregated & disposed of into 4 different waste containers				
	b. They are colour coded according to their waste category				

INFECTIOUS WASTE (PLACENTAS ETC.); NON-SHARPS NON-INFECTIOUS WASTE (PAPER) **[If there is an alternative segregation of waste please describe this in the Comments box]**					
66. WASTE CONTAINER FOR NON-SHARPS INFECTIOUS WASTE IS **[Solid or wet infectious waste]** **[If more than 1 pick 1]**	a. Available				
	b. Visibly clean, including lid & pedal **[It is free from build-up of residue/dirt]**				
	c. Intact, free from signs of damage, rips or cracks				
	d. Lid available				
	e. Foot pedal opens lid				
	f. Less than 2/3 full				
67. A SHARPS CONTAINER IS	a. Available				
	b. Visibly clean **[It is free from build-up of residue/dirt]**				
	c. Intact, free from signs of damage, rips or cracks				
	d. Containers are less than 2/3 full				
	e. Close to the delivery bed				
68. OTHER ASPECTS OF THE WASTE STORAGE & DISPOSAL OBSERVED DURING THE INSPECTION	Record here any other issues regarding waste containers not mentioned above:				

G. DELIVERY UNIT - CLEANING AND DECONTAMINATION OF EQUIPMENT					
69. Decontamination bucket is **[If more than 1 bucket, pick 1]**	a. Available in the delivery area or near it **[e.g. sluice room – but should not be further than a room next to the delivery]**				
	b. Labelled				
	c. Visibly clean **[It is free from build-up of residue/dirt]**				
	d. Chlorine was put today **[Ask/Observe]**				
	e. Lid available				
70. Rinsing bucket **[If a dedicated is used instead please, specify this in the Comments box; if an**	a. Available next to the decontamination bucket				
	b. Labelled				
	c. Water has been changed today				
	d. Visibly clean **[It is free from build-up of residue/dirt]**				

alternative method is used please specify this method] [If more than rinsing 1 bucket, pick 1]	e. Free from signs of damage				
71. Brush/scrub to clean the re-usable equipment	Visibly clean **[It is free from build-up of residue/dirt]**				
	Free from signs of damage **[For the purpose of removing dirt and stains from equipment i.e. synthetic fibre is free from significant damage]**				
	Brush store face upward				

H. DELIVERY UNIT - CLEAN CORD CUTTING					
72. Reusable scissors/Blades for cutting the cord are	Available in the delivery area or near it **[e.g. sluice room – but should not be further than a room next to the delivery]**				
	Stored appropriately **[n a drum with a lid or in sterile delivery pack]**				
	Visibly clean and free from rust **[free from build-up of residue/dirt]**				
	Kept decontaminated before use **[Ask/observe how sterile field is set up and sterility maintained from where it is stored to where is used]**				
73. Disposable scissors or blades for cutting the cord are	Available in the delivery area or near it **[e.g. sluice room – but should not be further than a room next to the delivery]**				
	Stored in sterile packet **[Ask/observe]**				
	Kept dry [Not near a wet surface]				

I. DELIVERY UNIT - CORD CLAMPS					
74. Reusable Cord clamps are	Available in the delivery area or near it **[e.g. sluice room – but should not be further than a room next to the delivery]**				
	Stored appropriately **[n a drum with a lid or in sterile delivery pack]**				
	Visibly clean and free from rust **[free from build-up of residue/dirt]**				
	Kept decontaminated before use **[Ask/observe how sterile field is set up and sterility maintained from where it is stored to where is used]**				
75. Disposable cord clamps	Available in the delivery area or near it **[e.g. sluice room – but should not be further than a room next to the delivery]**				
	Stored in sterile packet **[Ask/observe]**				
	Kept dry [Not near a wet surface]				

J. DELIVERY UNIT - BIRTHING SURFACE					
76. Material used on delivery bed for delivery is **[e.g. mackintosh, katenge, kanga or other cloth – specify in comments the type]** **[If deliver straight on the bed/mattress specify in comments box]**	In facility **[If women bring their own please specify this in the Comments box and describe what type of material they bring]**				
	Re-usable				
	Washable material				
	Visibly clean **[It is free from build-up of residue/dirt; if not available on bed ask/observe the one to be used in the next delivery]**				

III. AVAILABILITY, STORAGE OF DELIVERY UNIT CLEANING MATERIALS

K. STORAGE AREA					
Take several photos evidencing the state of the cleaning equipment storage room & equipment – record each photo on the Photo Record Sheet					
Topic	**Question**	**Yes**	**No**	**N/A**	**Comments**
77. THE STORAGE AREA IS	a. Designated area				
	b. Area is visibly clean **[It is free from build-up of residue/dirt]**				
	c. Free from clutter **[Unnecessary or unused equipment or furniture *is in the way*]**				
Topic	**Question**	**Number or Litres (if none put 00)**			**Comments**
78. ARE THE FOLLOWING CLEANING ITEMS AND PROTECTIVE EQUIPMENT AVAILABLE AND USABLE (i.e. functioning for their purpose)?	a. Mops				
	b. Buckets				
	d. Bleach				
	e. Disinfectant				
	g. Soap or equivalent to clean the floor				
	h. Waste bags				
	j. Brushes				
	k. Dust pans				
	l. Heavy duty gloves				
	m. Heavy duty aprons				
	n. Thick soled shoes/boots				
Topic	**Question**	**Yes**	**No**	**N/A**	**Comments**
MOP 1 (worst)					

79. MOP IS	a. Free from visible signs of damage,				
	b. Stored appropriately **[Mop head not touching the floor; not in the bucket]**				
	c. Mop heads washed appropriately or disposable **[Ask/Observe]**				
	d. Colour coded for use				
	e. Strands **[If not please, comment whether is it a cloth or specify what else]**				
MOP 2 (best)					
80. THE MOP IS:	a. Free from visible signs of damage, rips or cracks				
	b. Stored appropriately **[Not touching the floor; not in the bucket]**				
	c. Mop heads washed appropriately or disposable **[Ask/Observe]**				
	d. Colour coded for use				
	e. Strands **[If not please, comment whether is it a cloth or specify what else]**				
MOP BUCKET 1 (worst)					
81. MOP BUCKET IS	a. Visibly clean, **[Check inside the bucket; check inside edges; It is free from build-up of residue/dirt]**				
	b. Free from visible signs of damage, rips or cracks				
	c. Stored inverted & dry **[Large buckets may be stored upright but must be dry)**				
	d. Colour coded for use				
MOP BUCKET 2 (best)					
82. MOP BUCKET IS	a. Visibly clean, **[Remove & check inside the backer; check inside edges; It**				

	is free from build-up of residue/dirt]				
	b. Free from visible signs of damage, rips or cracks				
	c. Stored inverted & dry **[Large buckets may be stored upright but must be dry)**				
	d. Colour coded for use				
83. CLEANING CLOTH/RAG 1 (worst) (USED FOR WIPING SURFACES)	a. Stored appropriately **[Not touching the floor; not in the bucket]**				
	b. Washed appropriately or disposable **[Ask/Observe]**				
	c. Dried appropriately **[Ask/Observe]**				
84. CLEANING CLOTH/RAG 2 (best) (USED FOR WIPING SURFACES)	a. Stored appropriately **[Not touching the floor; not in the bucket**				
	b. Washed appropriately or disposable **[Ask/Observe]**				
	c. Dried appropriately **[Ask/Observe]**				
85. CLEANING MATERIALS FOR TOILETS	a. Disinfectant available				
	b. Dedicated mop for toilet cleaning **[Please specify if the same mop is used to clean both the toilet floor and the actual toilet]**				
	c. Other cleaning material used which is dedicated to the toilet **[Specify the material and number of items in Comments box]**				
86. OTHER ASPECTS OF THE AREA OBSERVED DURING THE INSPECTION	Record here any other areas not mentioned above:				

IV. DISPOSAL PITS AND INCINERATOR

L. DISPOSAL AREA					
Take several photos evidencing the state of the main waste pit, rubbish in and around it, the incinerator and any fence/protection around the area – record each photo on the Photo Record Sheet					
Topic	**Question**	**Yes**	**No**	**N/A**	**Comments**
87. WASTE DISPOSAL IN THE FACILITY GROUNDS IS **(if waste is disposed off-site indicate in comments box)**	a. Designated area				
	b. Area protected by fence				
88. THE INFECTIOUS WASTE PIT HAS	a. Pit has a cover				
	b. No waste lying around the pit				
	c. Waste has been burned				
89. THE NON-INFECTIOUS WASTE PIT HAS	a. Pit has a cover				
	b. No waste lying around the pit				
	c. Waste has been burned				
90. AN INCINERATOR FOR SHARPS IS	a. Incinerator available				
	b. Incinerator functioning				
	c. Traces of waste/sharps that have been burned are evident				

V. DOCUMENT AVAILABILITY

The following section of the Walkthrough Checklist refers to the facility documents (e.g. policies and protocols) relevant to infection prevention and control. Please enter a tick in the relevant column corresponding to the appropriate document:

DA = Document available
DARA = Document available & shown to the enumerators for verification
UNAV = Document exists but is unavailable (provide reason for unavailability in Comments column)
DNE = Document does not exist
PS= Posters
PP= Policies or protocols

If possible please take a picture of the documents marked with *

Please list relevant documents not included in the table provided on the next page

FACILITY DOCUMENT	DA	DARA	UN AV	DNE	PS	PP	N/A	Comments
91. .Facility Organogram – including contractual staff								
92. Policy documents related to:								
a. Procurement of cleaning material								
b. Infection control and cleaning*								
c. Waste disposal								
d. Training of staff for infection control*								
e. Promotion of cleaning staff								
f. Contracting cleaning services								
93. Hospital budget for cleaning and infection control*								
94. Minutes of infection control committee meetings								
95. Registers for swabs collected from the operating theatre & delivery unit*								
96. Register for fumigation of the delivery unit								
97. Documentation of post-delivery infections/readmission for infections*								
98. Protocols for cleaning and infection control*								
99. Protocols for antibiotic use								
100. Protocols for replacement of cleaning material								

101. Please provide details of any other relevant documents

102. Please provide details of any other observations made during the walk-through not captured above or any other comments you would like to include

END TIME: | | | | |

9.4. Appendix II (C) – Semi-structured interview guides

MODULE 1 – MANAGERS INTERVIEW

WASH & CLEAN Module 1: Interview Questions
with **Facility In-charge (or acting In-charge)**

Facility Name: ________________________________

Interview Date (DD/MM/YYYY): | | | | | | | | |

Interview Start Time (24 hour clock): | | | | |

Interview End Time (24 hour clock): | | | | |

Respondent's ID number:

Designation:

Gender:

Qualifications/profession (e.g. medical doctor; other health professional (specify); other professional (specify):

Length of service in your current position (yrs/months):

Length of service at current facility (yrs/months):

Years of service since qualifying/completing your basic training:

Section A: IPC guidelines & protocols

1. Does your facility have any systems in place for monitoring and maintaining hygiene and preventing cross-infection? If yes, what is the name used for such mechanisms?
2. What do you understand by the term Infection Prevention and Control or IPC? *(Prompt: Why is IPC important?)*
3. Can you mention some of the standard Infection Prevention and Control (IPC) practices (also known as standard precautions) at your facility? (*Let him/her mention without prompting*)
4. Can you tell me what your role is when it comes to maintaining IPC in this facility?
5. Are there guidelines/protocols/standard operating procedures on IPC at your facility as a whole and in the labour ward in particular? If YES, what are they?
6. If yes to no.5 above, are there any mechanisms in place for making sure that such guidelines/protocols/standard operating procedures are being adhered by facility staff at all times? Can you tell me more about such mechanisms? (*Prompts*: *mechanisms for ensuring constant availability of supplies; trained staff, infrastructure, accountability mechanisms, , etc*.). If NO, why not?
7. What other mechanisms are in place for monitoring and maintaining IPC in your facility? *(Prompts: does* your facility have a functional IPC/Quality Improvement Committee?, if present, does the committee perform its functions as expected? What does the committee do to ensure IPC at this facility?).

8. In your opinion are the mechanisms in place for maintaining IPC at your facility satisfactory? If NOT, why? *(Prompts: staffing, supplies, infrastructure)*.

<u>Section B: Barriers and Challenges for Maintaining IPC</u>

9. What challenges do you face in maintaining a clean environment and good IPC in the maternity ward and operating theatre (if present)? Can you provide some examples? (*Prompts: resources, infrastructure, water supply, staffing, - training, motivation, attitudes*, client visitors).
10. Of the challenges you just described, which three do you consider to be the biggest (of highest priority) and hence need urgent action?
11. What do you consider to be the main actions needed to address the biggest three challenges you just mentioned? (Prompts: Who is responsible for these actions? What is needed to ensure they happen? Why haven't they happened before?)
12. What do you think in relation to women's personal hygiene and maintaining IPC in the labour ward? (*Prompts*: *do you think this is an important area when it comes to preventing cross-infection in the labour ward? are there any challenges related to maintaining women's personal hygiene in the labour ward? If yes, what are they?)*
13. Are there any challenges/barriers to using toilets/latrines by staff and patients in the maternity ward? If yes, what are they? *(Prompts: accessibility the whole day, privacy, safety, cleanliness, smell, open defecation in facilities grounds)*
14. Considering the barriers you have just described, what do you consider to be the main actions needed to address the biggest challenges that staff and patients face in using the toilets/latrines? (Prompts: Who is responsible for these actions? What is needed to ensure they happen? Why haven't they happened before?)
15. What are the challenges to solid waste management for staff and patients in the maternity ward?
16. Considering the challenges you have just described, what do you consider to be the main actions needed to address the biggest three challenges that staff and patients face in relation to solid waste management? (Prompts: Who is responsible for these actions? What is needed to ensure they happen? Why haven't they happened before?)
17. Considering all the challenges that your facility is currently facing, what are your top 5 priorities to address and why? Could you rank them on a scale of 1 to 5 (where 1 is top priority and 5 is least important)?
18. If IPC is not one of the top 5 priorities, how important is it in your facility and why?
19. When it comes to decision making, do you feel you have enough power to make decisions related to improving/maintaining IPC at your facility? If yes, can you provide me with some examples of decisions you made that led to improving/maintaing IPC at your facility? If not, can you explain why not?

20. Do you feel your work as the facility in-charge is valued by other health workers here in this facility? Explain why?
21. Do you feel your work as the facility in-charge is valued by women coming for delivery? Explain why?

Section C. In-Service Training:

22. Have care providers and/or cleaners at this facility ever received training on IPC (if the answer is no, skip to question no. 27).
23. What type of IPC training is provided to a) healthcare providers and b) cleaners at your facility?
24. Do you think this training is adequate? If not, why?
25. How often is training provided?
26. When was the last training conducted?
27. Is there anything else you would like to say about hygiene/cleanliness/IPC on the maternity ward and/or operating theatre at your facility?

Additional question: Does the facility have a designated person for water and sanitation activities? If not, ask the facility in-charge module 7 questions on water and sanitation.

Thank the respondent for their time.
Enter the time interview ended in the relevant boxes at the beginning of the questionnaire.

ASANTE

MODULE 4 – HEALTH PROVIDERS INTERVIEW

WASH & CLEAN Module 4: Interview Photo Prompts & Questions
with **Healthcare Providers**

Facility name: ____

Interview Date (DD/MM/YYYY)								

Interview Start Time (24 hour clock):				
Interview End Time (24 hour clock):				

Respondent's ID number:

Designation:

Gender:

Qualifications/profession profession (e.g. medical doctor; other health professional (specify); other professional (specify):

Length of service at current facility (yrs/months):

Years of service since qualifying/ completing your basic training:

Section A: IPC guidelines & protocols

1. Looking at these photographs, what do you think they highlight? Can you tell me any differences you are seeing between the two photos? What comes in your head when you look at each photograph? If you had to wash your hands, which of the two sinks would you wish to use and why? If you had to use the toilet, which of the two toilets would you wish to use and why?
2. How important do you think it is to maintain good hygiene/cleanliness and IPC in toilets/latrines for patients and staff? (*Prompt; why it is important*?).
3. Does your facility have any mechanisms in place for monitoring and maintaining hygiene and preventing cross infection? If yes, what is the name used for such mechanisms?
4. What do you understand by the term Infection Prevention and Control? (*Prompt: Why is IPC important?)*
5. Can you mention some of the standard IPC practices (also known as standard precautions) at your facility? *(Let him/her mention without prompting).*
6. How important do you think it is to maintain good hygiene/cleanliness and IPC in the maternity ward and operating theatre (if present)? (*Prompt: why it is important*?).
7. Can you tell me what your role is when it comes to maintaining IPC in this facility?
8. Can you tell me about the health facility's guidelines/protocols/standard operating procedures on IPC in the maternity ward and operating theatre (if present)? In your opinion are these guidelines followed (Prompts: maternity ward, operating theatre?)

9. Can you briefly describe the processes related to IPC in the maternity ward and operating theatre (if present)? (*Prompts: hand hygiene, sterilization of equipment, fumigation, waste disposal,).* How do you think these could be improved (if necessary)?
10. Can you describe the supervision and monitoring processes related to IPC in the maternity ward and operating theatre (if present)? *(Prompts: staffing, supplies, infrastructure).* What is your role, if any, in monitoring IPC in these areas?
11. Do you feel your work as a healthcare provider is valued by other health workers here in this facility? Explain why? Are you included/made to feel part of the health care team in this facility?
12. Do you feel your work as a healthcare provider is valued by women coming for delivery? Explain why?
13. Do you think cleaners should be regarded as part of the healthcare workforce? Are there any challenges you face in working with cleaners at this facility?

Section B: Barriers and Challenges to Maintaining IPC

14. What are the main barriers faced to addressing IPC in the maternity ward and operating theatre (if present)? (*Prompts: supplies, infrastructure, number of hand washing stations, water supply; quantity and quality, soap, waste disposal training/bins/equipment, workload, gender, , staffing levels, , knowledge, , supervision, motivation etc.)*
15. Considering the barriers you have just described, which three do you consider to be the biggest (of highest priority) and hence needing urgent action?
16. What do you consider to be the main actions needed to address the biggest three barriers you just mentioned? (Prompts: Who is responsible for these actions? What is needed to ensure they happen? Why haven't they happened before?).
17. What do you think in relation to women's personal hygiene and maintaining IPC in the labour ward? (*Prompts*: *do you think this is an important area when it comes to preventing cross infection in the labour ward? are there any challenges related to maintaining women's personal hygiene in the labour ward? If yes, what are they?).*
18. Are there any challenges/barriers you face in relation to using toilets/latrines in the maternity ward? *(Prompts: accessibility the whole day, privacy, safety, cleanliness, smell, open defecation in facilities grounds).*
19. Considering the challenges/barriers you have just described, what do you consider to be the main actions needed to address the biggest challenges you face in using toilets/latrines in the maternity ward? (Prompts: Who is responsible for these actions? What is needed to ensure they happen? Why haven't they happened before?).
20. What are the barriers to accessing clean and safe water for staff and patients in the maternity ward?

21. Considering the barriers you have described, what do you consider to be the main actions needed to address the biggest challenges you face in obtaining access to clean and safe water in the maternity ward? (Prompts: Who is responsible for these actions? What is needed to ensure they happen? Why haven't they happened before?).
22. What are the barriers to hand-washing with soap for staff and patients in the maternity ward? *(prompts: access to clean water, soap, hand towels)*
23. Considering the barriers you have described, what do you consider to be the main actions needed to address the biggest challenges you face in ensuring hand washing with soap *(prompts: provision of soap, behaviour change)* (Prompts: Who is responsible for these actions? What is needed to ensure they happen? Why haven't they happened before?).
24. Considering all the challenges that your facility is currently facing, what are your top 5 priorities to address and why? Could you rank them on a scale of 1 to 5 (where 1 is top priority and 5 is least important)?
25. If IPC is not one of the top 5 priorities, how important is it in the labour ward and Why?

<u>Section C. In-Service Training:</u>

26. Have you ever received training on IPC? (if the answer is no, skip to question no. 31)
27. What type of IPC and WASH training have you received?
28. Do you think the training you received is adequate? If not, why?
29. How often is the training conducted?
30. When was the last time you received training in IPC?
31. Is there anything else you would like to say about cleanliness/IPC/WASH on the maternity ward and/or operating theatre?

Thank the respondent for their time.

Enter the time interview ended in the relevant boxes at the beginning of the questionnaire.

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WASH & CLEAN Module 5: Interview Photo Prompts & Questions
with Cleaners

Facility name: ____

Interview Date (DD/MM/YYYY)								

Interview Start Time (24 hour clock):				
Interview End Time (24 hour clock):				

Respondent's ID number:

Designation:

Gender:

Highest level of education (& qualifications if applicable):

Length of service at current facility (yrs/months):

Total years of service:

Section A: IPC guidelines & protocols

1. Looking at these two photographs, what do you think they highlight? Can you tell me any differences you are seeing between the two photos? What comes in your head when you look at each photograph? If you had to wash your hands, which of the two sinks would you wish to use and why? If you had to use the toilet, which of the two toilets would you wish to use and why?
2. How important do you think it is to maintain good hygiene/cleanliness and IPC in toilets/latrines for patients and staff? (*Prompt; why it is important?).*
3. Does your facility have any systems in place for monitoring and maintaining hygiene and preventing cross infection? If yes, what is the name used for such mechanisms?
4. What do you understand by the term Infection Prevention and Control? (Prompt: Why is IPC important?)
5. Can you mention some of the standard IPC practices (also known as standard precautions) at your facility? *(Let him/her mention without prompting).*
6. How important do you think it is to maintain good hygiene/cleanliness and IPC in the maternity ward and operating theatre (if present)? *(Prompt: why it is important?).*
7. Can you tell me what your role is when it comes to maintaining IPC in this facility?
8. Can you briefly describe the processes related to IPC and cleaning in the maternity ward and operating theatre (if present)? (*Prompts: hand hygiene, sterilization of equipment, fumigation, waste disposal,)* How do you think these could be improved (if necessary)?
9. Can you describe the supervision and monitoring processes related to IPC and cleaning in a) the maternity ward and b) the operating theatre? What is your role, if any, in monitoring IPC in these areas? *(Prompts: staffing, supplies, infrastructure)*

Section B: Barriers and Challenges to Maintaining IPC

10. What are the main barriers you face in maintaining a clean environment and good IPC in the maternity ward and operating theatre (if present)? (*Prompts: supplies, infrastructure, number of hand washing stations, water supply; quantity and quality, soap, waste disposal training/bins/equipment, workload, gender, staffing levels, , knowledge, type of employment, conflict resolution, , supervision, , , motivation etc.)*
11. Considering the barriers you have just described, which three do you consider to be the biggest (of high priority) and hence needing urgent action?
12. What do you consider to be the main actions needed to address the three biggest barriers you just mentioned? (Prompts: Who is responsible for these actions? What is needed to ensure they happen? Why haven't they happened before?)
13. What are the barriers/challenges to cleaning the latrines for staff and patients? *(prompts: lack of time, staffing, disinfectants, equipment, cleaning tools, recognition, supervision, bad/unpleasant smell,)*
14. Considering the barriers/challenges you have described, what do you consider to be the main actions needed to address the biggest challenges you face in cleaning latrines/toilets? (Prompts: Who is responsible for these actions? What is needed to ensure they happen? Why haven't they happened before?)
15. What are the barriers/challenges to cleaning the hand washing stations for the maternity ward and toilets/latrines? *(prompts: lack of time, staffing, disinfectants, equipment, cleaning tools, supervision)*
16. Considering the barriers/challenges you have just described, what do you consider to be the main actions needed to address the biggest challenges you face in cleaning hand washing stations? (Prompts: Who is responsible for these actions? What is needed to ensure they happen? Why haven't they happened before?)
17. Do you feel part of the healthcare workforce? Do you think others working on the maternity unit also regard you as part of the healthcare workforce? What challenges do you face in working with health care professionals and others?
18. Do you feel your work as a cleaner is valued by women coming for delivery? Explain why?

Section C. In-Service Training:

19. Have you ever received training on IPC (if the answer is no, skip to question no. 24)?
20. What type of IPC and WASH training have you received? Was this related to cleaning activities?
21. Do you think the training you received is adequate? If not, why?
22. How often is the training conducted?
23. When was the last time you received training in IPC?
24. What other activities do you carry out in the maternity ward apart from cleaning; routinely and/or when necessary? (*Prompts: injections, dressing, drug dispensing, delivery, immediate*

newborn care). Have you received any IPC training (formal and informal) related to these extra activities?

25. Is there anything else you would like to say about hygiene/cleanliness/IPC on the maternity ward and/or operating theatre?

Thank the respondent for their time.
Enter the time interview ended in the relevant boxes at the beginning of the questionnaire.

ASANTE

WASH & CLEAN MODULE 6: Women's Individual Semi-structured Interview Questionnaire

Location: ______________________________

Date of interview (DDMMYY): | | | | | | |

DATA COLLECTOR NAME: ____________________________________

Time interview started: …………………………………………… | | | | |

Time interview ended: …………………………………………………… | | | | |

RESPONDENTS ARE WOMEN WHO HAVE DELIVERED IN THE LAST 6 WEEKS AT ONE OF THE FOCUS FACILITIES

RESPONDENT INFORMED CONSENT:
SEEK EACH RESPONDENT'S AGREEMENT TO PARTICIPATE BY READING THE STATEMENT BELOW.
My name is ___________. I am from_____________. I would like to talk to you about your experience at_____________ [Health Facility]. Your answers are very important to us and will help to find better ways to deliver safe maternity services in ____________ [Country]. The information you give us will be treated in the strictest confidence. You are free not to take part in this study or to stop the interview at any time. If you do not wish to participate in the interview you will not be penalized. The interview will last approximately X minutes. Are you willing to take part in this study?

If the woman is not willing to participate in the study, thank her and end the interview.

If the woman is willing to participate in the study ask her if she gave birth in the last six weeks at ____________ [list focus facilities] and if she had a normal delivery (i.e. not by C-section).

End the interview and thank the woman for her willingness to participate if;
- She is below 18 years of age,
- She did not give birth in the last six weeks,
- Was delivered by C-section,
- Had experienced a stillbirth or their baby died, and/or
- She is severely ill (either physically or mentally) at the time of interview.

1. RESPONDENT DETAILS

1.2 Respondent ID:……………………………………………………………………………………… | | | | |

1.3 Facility/place where respondent delivered:
____

1.4. Date when respondent delivered?.. | | | | | | |

2. RESPONDENT CHARACTERISTICS

First of all I would like to ask you a few questions about yourself and where you live

2.1 What is your age?................... .... [ ][ ]
88 = don't know

2.2 What is your date of birth?......(DDMMYY)................................. [ ][ ][ ][ ][ ][ ]
888888=don't know Check numbers if in line with age at 2.1 (Probe if needed)

2.3 What is your current marital status?... [ ]
1=single; 2=living together; 3=married; 4=divorced/separated; 5=widowed

2.4 What is the name of the district where you usually live? ________________________________

2.5 What type of area do you live in?.. [ ]
1=large city; 2=medium city; 3=small city; 4=town; 5= village, 8=don't know.

2.6 What is the highest level of education you completed?... [ ]
0=no formal education; 1=did not complete primary education; 2=primary education;
4=secondary education; 5=post-secondary training; 6=University/College 7=don't know; 8=other*.

*Please specify: ______________________________________

2.7 What is your religion?.. [ ]
1=Islam; 2=Catholic; 3=Protestant; 4=Hindu; 5=Buddha; 6=Other*

*Please specify: ______________________________________

2.8 What is your occupation (e.g. housewife, cleaner)? ____

2.9 Including your most recent birth, how many times have you given birth? Live births................. Still births..................... [ ][ ]

3. RESPONDENT'S HOUSEHOLD CHARACTERISTICS

3.1 Does the place where you live have a separate toilet?... [ ]
1=yes; 2=no; 9=other*

*Please specify____

3.2 What is your main source of water?.. [ ]
1=Piped in to dwelling/yard; 2=Public tap/standpipe; 3=Borehole; 4=Surface water; 9=Other*

*Please specify____

3.6 Does the place where you live have electricity?... [ ]
1=yes; 2=no; 8=don't know

3.7 How many people (adults and children) usually live in your household including yourself?... [ ][ ]

4. MOST RECENT BIRTH – QUALITATIVE COMPONENT

I would now like to ask you some questions about your most recent childbirth and your opinions on the delivery environment (some will have delivered at home). For some of the questions I am going to show you some photographs and ask you to think about what they show.

4.1 First of all I'd like to know whether you had a normal delivery or a delivery with forceps/vacuum? **Mark X in the appropriate box**

Type	Delivery
Normal	
Forceps/vacuum	

4.2 Please have a look at these photographs and identify/describe the following;

i. Can you tell me any differences you are seeing between the two photos?
ii. Any positive or negative elements of the environment in these photographs?
iii. In which environment among these two photos would you want to deliver your baby and why?
iv. What does a good and poor delivery environment mean to you?
v. Why is cleanliness important, or not, in the delivery environment? Please explain your answer.

4.3 Secondly, I would like to you to tell me what you think CLEAN means.

In your opinion, which places should always be kept clean and why? (*Prompts; at home, in hospitals, elsewhere*).

Please use additional pages to record the answer if necessary

Please use additional pages to record the answer if necessary

4.4 Thinking about the answers you have provided to the previous question;

- **i.** Do you think the place/facility in which you recently delivered was clean?
- ***ii.*** Did you have any concerns about the environment in which you delivered? Please explain. *(Prompt; any other concerns?)*
- **iii.** What aspects of the delivery environment are most important to you? Please explain.

Please use additional pages to record the answer if necessary.

4.5 Would you be happy to deliver there again or recommend to a relative/friend to deliver there? If not, Why?

- What alternatives would be available to you and why would they be preferable?

5. MOST RECENT BIRTH – CLINICAL PRACTICE

I'm now going to ask you a few more specific questions about your delivery if you can recall the answers:

5.1 During your delivery who examined you inside and helped you to deliver your baby? (Please probe if needed) **Mark X in the appropriate box (es)**

Personnel	**Present**
a) Obstetrician/gynaecologist	
b) Doctor/Physician	
c) Midwife	
d) Nurse	
e) Traditional Birth Attendant	
f) Aya/Cleaner	
g) Other (please specify)	

5.2 Can you recall whether the person/people who examined you washed their hands before examining you? **Mark X in the appropriate box(es)**

Personnel	**Yes**	**No**	**Don't know/can't remember**	**NA**
a) Obstetrician/gynaecologist				
b) Doctor/Physician				
c) Midwife				
d) Nurse				
e) Traditional Birth Attendant				
f) Aya/Cleaner				
g) Other (please specify)				

5.3 Can you recall whether the person/people who examined you wore gloves? **Mark X in the appropriate box(es)**

Personnel	**Yes**	**No**	**Don't know/can't remember**	**NA**
a) Obstetrician/gynaecologist				

b) Doctor/Physician				
c) Midwife				
d) Nurse				
e) Traditional Birth Attendant				
f) Aya/Cleaner				
g) Other (please specify)				

5.4 Were you given antibiotics and/or other medicine for you and/or your baby after delivery? **Mark X in the appropriate box**

Antibiotics/medicine	**Yes (if appropriate, ask what medicine & enter in appropriate box below)**	**No**	**Don't know/ Can't remember**
For the mother			
For the Baby			

5.5 Before you left the hospital/place where you delivered your baby, were you given information or advice on how to look after yourself and your baby? **Mark X in the appropriate box**

Advice given	**Yes**	**No**	**Can't remember/ Don't know**	**Not Applicable/ Yet to be discharged**
For the mother				
For the Baby				

5.5b. If yes, what advice were you given on how to look after yourself and your baby? (*Prompt: were you given advice on hygiene, cord care, hand washing etc.?).*

5.6 Before you left the hospital/place where you delivered your baby, were you given information on what danger signs to look for that would require seeking medical advice? **Mark X in the appropriate box**

Information	**Yes**	**No**	**Don't know/ Can't**	**Not Applicable/ Yet to be**

			remember	discharged
Maternal danger sign				
Newborn danger sign				

5.6b: If yes, which danger signs were you told to look for in yourself and your newborn that would require seeking medical advice?

5.7a Have you ever received information from anywhere else about maternal and newborn danger signs? **Mark X in the appropriate box.** If yes, go to question 5.7b

Information	Yes	No
Maternal danger sign		
Newborn danger sign		

5.7b: If yes, what information did you receive?

5.7c: Where/from whom did you receive this information? **Mark X in the appropriate box**

Source of Information	Information Provided
Antenatal Class	
Traditional Birth Attendant	
Family Member	
Other (please specify)	

5.8 Lastly, I would like to learn about how you took care of your new-born's cord soon after delivery and thereafter; can you tell me something about that?

Thank the respondent for their time.
Enter the time interview ended in the relevant boxes at the beginning of the questionnaire.

ANSWER SHEET – ADDITIONAL SPACE

INCLUDE THE QUESTION NUMBER TO WHICH THE ANSWER REFERS.

DRAW A LINE AFTER EACH ANSWER TO SEPARATE DIFFERENT QUESTIONS/ANSWERS

WASH & CLEAN Module 7: Interview Questions with technician responsbile for water, sanitation, grey water and solid waste management for the facility

Facility name: ____

Interview Date (DD/MM/YYYY) | | | | | | | | |

Interview Start Time (24 hour clock): | | | | |

Interview End Time (24 hour clock): | | | | |

Respondent's ID number:

Designation:

Gender:

Length of service at current facility (yrs/months):

Qualifications/profession (specify):

Years of service since qualifying/finished basic training:

Years of service in current role:

Staff with responsibility for water, sanitation, grey water and solid waste management

1. Can you tell me about water supply at this facility (i.e. from water source/collection, to storage, to treatment, to distribution and consumption)?
2. How many litres of water does the facility use each day?
    - If collected from a tap/well – how many buckets are collected daily?
    - What size are the buckets?
3. What are the main barriers to staff and patients using water in this facility? *(prompts: quality, quantity)*
4. What are the main challenges/barriers to ensuring supply of sufficient and quality water at this facility? *(prompts: length of time to collect, breakages, no equipment, no training, treatment of water, testing of the water)*
5. Considering the challenges/barriers you have just described, what do you consider to be the main actions needed to address the biggest challenges you face in maintaining the water supply in this facility? (Prompts: Who is responsible for these actions? Why haven't they happened yet?)
6. What facilitates ensuring supply of sufficient and quality water at this facility?

7. How much water do you store on site? (Give or estimate water volume)? *Prompts: Is there enough water storage? Is the stored water covered? How often are water storage containers cleaned – who cleans them and how?*

8. Does water ever run out? If water runs out what do you do?
9. If the water broke down now, what would be the process to get it working again? What would be the challenges involved in following this process? *(Prompts: person in charge, timing, etc.)*

10. What are the barriers to maintaining drainage systems in the facility? *(prompts: someone is in charge of drainage network, staffing levels, flooding occurs, drainage system not working)*

11. Considering the barriers you have just described, what do you consider to be the main actions needed to address the biggest challenges you face in maintaining drainage systems? Who is responsible for these actions? Why haven't they happened yet?

12. What are the challenges/barriers to maintaining toilets/latrines in this facility? *(prompts: staffing, responsibility, knowledge, skills, equipment, priority)*

13. Considering the challenges/barriers you have just described, what do you consider to be the main actions needed to address the biggest challenges you face in maintaining toilets/latrines? Who is for responsible for these actions? Why haven't they happened yet?
14. Do you feel that the issues you face in maintaining water and latrine/toilet maintenance in the maternity ward are similar to the ones in other departments?

15. What facilitates maintaining toilets/latrines in the facility? (*prompts: staffing, responsibility, knowledge, skills, equipment, priority)*

16. What are the barriers to maintaining solid waste management in the facility? (*prompts: staffing, responsibility, knowledge, skills, priority, available space)*
17. Considering the barriers you have described, what do you consider to be the main actions needed to address the biggest challenges you face in solid waste management? Who is for responsible for these actions? Why haven't they happened yet?
18. Do you feel your work and as a technician is valued by other health workers here in this facility? Explain why?
19. Do you feel your work as a technician is valued by women coming for delivery? Explain why?
20. Do you feel you receive enough internal and/or external support to complete your job? (*prompts: training, supportive supervisor*)
21. Is there anything else you would like to add about water and sanitation at the facility?

Thank the respondent for their time.

Enter the time interview ended in the relevant boxes at the beginning of the questionnaire.

9.5. Appendix II (D) – STROBE checklist for Manuscript 2

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	In preamble onlys: Page 86
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 92
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 93-94
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 93-94
Methods			
Study design	4	Present key elements of study design early in the paper	Page 95
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 95-96
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	Page 95-96
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 89-92
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 94 last paragraph (continues on page 95); pages 96-98
Bias	9	Describe any efforts to address potential sources of bias	Page 107-108
Study size	10	Explain how the study size was arrived at	All facilities providing delivery services: Page 95, II paragraph
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 96-99
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Page 98-99
		(*b*) Describe any methods used to examine subgroups and interactions	Not applicable
		(*c*) Explain how missing data were addressed	Missing data was minimal. Data presented on page 101
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(*e*) Describe any sensitivity analyses	Not applicable
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing	Not applicable as all eligible facilities were surveyed

		follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	Not applicable
		(c) Consider use of a flow diagram	Not applicable
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 95-96
		(b) Indicate number of participants with missing data for each variable of interest	Page 101
Outcome data	15*	Report numbers of outcome events or summary measures	Page 100-104
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Not applicable
		(*b*) Report category boundaries when continuous variables were categorized	Not applicable
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 104,106,107
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 105-107
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 105-108
Generalisability	21	Discuss the generalisability (external validity) of the study results	Limited discussion. Page 107
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 110

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

9.6. Appendix III – Ethics approvals for study described in Manuscript 2

SERIKALI YA MAPINDUZI - ZANZIBAR
ZANZIBAR REVOLUTIONARY GOVERNMENT
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MINISTRY OF HEALTH

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MOH RESEARCH COUNCIL
P.O. Box 236
ZANZIBAR

ETHICAL CLEARANCE LETTER

PROTOCOL NUMBER: ZAMREC /0001/FEBRUARY/014 **DATE: 11 April,2014.**

IBRAHIM KABOLE M.D
COUNTRY RESPRESENTATIVE, WaterAid

PROTOCOL TITLE "Improving maternal health in Zanzibar through improved WASH services".

RE: ETHICAL CLEARANCE FOR CONDUCTING MEDICAL RESEARCH IN ZANZIBAR.

This is to certify that the research protocol entitled **"Improving maternal health in Zanzibar through improved WASH services."** was received and reviewed by the Zanzibar Medical Research and Ethics Committee on April, 2014.

We would like to inform you that the decision of the committee to this protocol was "**Approved**".

The permission to undertake data collection is for one year beginning from the date of this letter.

The principal investigator must ensure that the progress report is made available to the Ministry of Health and the Zanzibar Medical Research and Ethics committee.

Any change made to the protocol need to be submitted to the committee for approval prior to its implementation

Thanks in advance,

[redacted]

DR. JAMALA A. TAIB
CHAIRPERSON
ZAMREC
ZANZIBAR.

[redacted]

DR. MSAFIRI MARIJANI
SECRETARY
ZAMREC
ZANZIBAR.

ZANZIBAR MEDICAL ETHICAL COM.
DATE...

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Observational / Interventions Research Ethics Committee

Ms. Giorgia Gon
IDE / EPH
LSHTM

2 June 2014

Dear Ms. Gon,

Submission Title: Needs Assessment of WASH services in maternity units in Zanzibar

LSHTM Ethics Ref: 7797

Thank you for your letter of 27 May 2014, 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
Information Sheet	Consent Form.pdf	03/04/2014	Latest
Advertisements	Recruitment strategy.pdf	03/04/2014	Latest
Protocol / Proposal	Zanzibar Research Protocol - FINAL_v3.pdf	23/05/2014	v3

After ethical review

Any subsequent changes to the application must be submitted to the Committee via an Amendment form on the ethics online applications website. The Principal Investigator is reminded that all studies are also required to notify the ethics committee of any serious adverse events which occur during the project via an Adverse Event form on the ethics online applications website. At the end of the study, please notify the committee via an End of Study form on the ethics online applications website. Ethics online applications website link: http://leo.lshtm.ac.uk

Yours sincerely,

[redacted]

Professor John DH Porter
Chair

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

Improving health worldwide

9.7. Appendix IV – STROBE checklist for Manuscript 3 and 4

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	117-118
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	118
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	119-120
Objectives	3	State specific objectives, including any prespecified hypotheses	120, II paragraph
Methods			
Study design	4	Present key elements of study design early in the paper	120-126
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	120-121; 124 (second paragraph)
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	125
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	129
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Tool formats and elements on pages 121-123
Bias	9	Describe any efforts to address potential sources of bias	130-131
Study size	10	Explain how the study size was arrived at	123, last paragraph (cont. on page 124)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	157-161 within methods section
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	160-161 (data cleaning and analyses)
		(*b*) Describe any methods used to examine subgroups and interactions	Not applicable
		(*c*) Explain how missing data were addressed	Not applicable
		(*d*) If applicable, describe analytical methods taking account of sampling	Not

		strategy	applicable
		(*e*) Describe any sensitivity analyses	Not applicable
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	156
		(b) Give reasons for non-participation at each stage	Not applicable
		(c) Consider use of a flow diagram	166, Figure 5.2
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	125
		(b) Indicate number of participants with missing data for each variable of interest	Not applicable; 168 has a discussion on incomplete information
Outcome data	15*	Report numbers of outcome events or summary measures	162-166
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Not applicable
		(*b*) Report category boundaries when continuous variables were categorized	Not applicable
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	156
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	168
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	166-168
Generalisability	21	Discuss the generalisability (external validity) of the study results	167-168; 226
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	133

*Give information separately for exposed and unexposed groups.

9.8. Appendix V (A) – PDF version of Manuscript 4

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Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

AJIC American Journal of Infection Control

Major Article

Hands washing glove use, and avoiding recontamination before aseptic procedures at birth: A multicenter time-and-motion study conducted in Zanzibar

Giorgia Gon MSc [a,*], Marijn de Bruin PhD [b], Mícheál de Barra PhD [c], Said M. Ali MSc [d], Oona M. Campbell PhD [a], Wendy J. Graham DPhil (Oxon) [a], Mohammed Juma PGD [d], Stephen Nash MSc [a], Claire Kilpatrick MSc [e], Loveday Penn-Kekana MA [a], Sandra Virgo PhD [a], Susannah Woodd MSc [a]

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Key Words:
Maternal health
Newborn health
Behavioral medicine
Labor ward
Tanzania
Hand hygiene

Background: Our primary objective was to assess hand hygiene (HH) compliance before aseptic procedures among birth attendants in the 10 highest-volume facilities in Zanzibar. We also examined the extent to which recontamination contributes to poor HH. Recording exact recontamination occurrences is not possible using the existing World Health Organization HH audit tool.

Methods: In this time-and-motion study, 3 trained coders used WOMBATv2 software to record the hand actions of all birth attendants present in the study sites. The percentage compliance and 95% confidence intervals (CIs) for individual behaviors (hand washing/rubbing, avoiding recontamination and glove use) and for behavioral sequences during labor and delivery were calculated.

Results: We observed 104 birth attendants and 781 HH opportunities before aseptic procedures. Compliance with hand rubbing/washing was 24.6% (95% CI, 21.6-27.8). Only 9.6% (95% CI, 7.6-11.9) of birth attendants also donned gloves and avoided recontamination. Half of the time when rubbing/washing or glove donning was performed, hands were recontaminated prior to the aseptic procedure.

Conclusions: In this study, HH compliance by birth attendants before aseptic procedures was poor. To our knowledge, this is the first study in a low- to middle-income country to show the large contribution to poor HH compliance from hand and glove recontamination before the procedure. Recontamination is an important driver of infection risk from poor HH. It should be understood for the purposes of improvement and therefore included in HH monitoring and interventions.

Health care–associated infections (HAIs) in low- and middle-income countries (LMICs) affect an estimated 15% of patients, 3 times more than in Europe.[1] For mothers and newborns in LMICs, where infection is already a leading cause of death,[2,3] the risk of HAIs could escalate with increasing health care facility newborn deliveries as well as substandard infection prevention standards.[4]

Hand hygiene (HH) is deemed the single most important behavior for preventing HAIs.[5] Historical evidence suggests the importance of HH in reducing maternal infections in European hospitals, and recent studies support its value for newborns in LMICs.[6] The World Health Organization (WHO) recommends Five Moments for Hand Hygiene (5MHH) during patient care.[7] Among these, Moment 2—HH before

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Funding/support: Funded by the Medical Research Council–PHIND scheme, award number MR/N015975/1. The Soapbox Collaborative also contributed by funding staff involved in this project. The writing of this paper provided part of the background needed for the CLEAN Study, funded by the United Kingdom Joint Global Health Trials (Wellcome, MRC, DFID, and DOH), award number MR/R019274/1. SN is supported by an award jointly funded by the UK Medical Research Council (MRC) and the UK Department for International Development (DFID) under the MRC/DFID Concordat agreement which is also part of the EDCTP2 programme supported by the European Union. Grant Reference MR/K012126/1.

Conflicts of interest: None to report.

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clean/aseptic tasks when there is potential contact with patient's mucous membranes or nonintact skin—is considered the most significant for preventing bacterial transmission to patients, including the bloodstream, that could result in infection. During birth, this primarily occurs before and during a vaginal examination or delivery and related procedures.

Before these aseptic procedures, WHO guidelines require attendants to hand rub or wash, avoid recontaminating their hands, don gloves, and avoid recontaminating those gloves before starting the procedure.[7] The current WHO HH Observation Form does not distinguish whether the failure to comply with the 5MHH stems from not hand rubbing/washing or from, for example, subsequently touching potentially unclean surfaces,[7] thus negating the initial hand washing/rubbing action. Although successful multimodal interventions exist to improve HH, they require in-depth understanding of the context and achieve only variable long-term success.[5,7-9] Determining whether birth attendants comply with any of the steps in the prescribed behavioral sequence and, more specifically, within the workflow in our context—Zanzibar, a region of Tanzania—is important to inform successful improvement interventions.

Therefore, our study aimed to examine the complex workflow in relation to hand hygiene and glove use undertaken by birth attendants in multiple high-volume labor wards in Zanzibar. Our specific research questions were:

1. What is the compliance with hand rubbing/washing (and then avoiding hand recontamination) and donning gloves (and then avoiding glove recontamination)?
2. Is variability of these behaviors primarily greater *between* birth attendants or *within* birth attendants across different HH opportunities?
3. To what extent does failure to avoid recontamination (as opposed to not hand rubbing/washing before a procedure) contribute to poor HH?
4. What behavior sequences do birth attendants undertake most often before aseptic procedures compared with the behavior sequence prescribed by WHO guidelines?

METHODS

Context

This study is part of the larger Hand-hygiene of Attendants for Newborn Deliveries and Survival (HANDS) project: a mixed-methods study investigating drivers of birth attendant HH. HANDS ran between November 2015 and April 2017 in the 10 highest-volume labor wards in Zanzibar, with average monthly delivery volumes ranging from 75 to 930 (Appendix A, available from https://doi.org/10.17037/DATA.00000778). The project was a partnership of the London School of Hygiene and Tropical Medicine, the University of Aberdeen, and the Public Health Laboratory of Pemba. Previous work in 8 of these maternity wards found that most had policies and basic infrastructure to perform HH, but only 50% received HH training in the previous year.[10]

Study design and data collection

Within HANDS, we conducted a time-and-motion study wherein 3 observers recorded the hand actions (eg, procedures and hand touches on surfaces) of birth attendants 24 hours per day (1 data collector per 8-hour shift−morning, evening, and night), for a mode of 6 days (range, 5-14 days) per labor ward. Results are reported using the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.[11] All observers were trained midwives. Birth attendants were all staff involved in assisting deliveries, irrespective of cadre, including midwives and orderlies. Details of the tool, training, and data collection protocols can be requested from the authors.

To estimate an HH compliance of 10% with an absolute precision of ±3%, 768 HH opportunities were required. For the sample size calculation, we used the formula for estimating a proportion from a cross-sectional survey, with $\alpha = 0.05$ and a design effect of 2, based on a survey in Benin of facility quality indicators.[12] Using the reported number of deliveries in the 10 study facilities overall, we calculated the length of observation required to achieve this sample size.

Data were collected via tablets, precoded using WOMBATv2 software (© Centre for Health Systems and Safety Research, Macquarie University, Sydney, New South Wales).[13,14] An observation session began when an attendant started assisting a woman in labor. All observed hand actions were recorded as they occurred, and the time of each was automatically logged. A set of mutually exclusive actions was precoded and used specifically in this study. One attendant was observed per observation session, but multiple patients or procedures could be included. Multiple observation sessions were usually captured in 1 shift. To minimize the Hawthorne effect, attendants in all facilities but the one where the pilot occurred were told that the observation was about overall quality of care, not specifically HH.[15]

We trained on and piloted the observation tool over 2 weeks, following WHO guidelines.[7,16] During the first month of data collection, we also assessed interobserver agreement between pairs of data collectors (on 49 or 50 behaviors for each pair) and calculated kappa statistics. We provided tailored feedback to the data collectors based on these results.

Ethics

This project was approved by the Zanzibar Medical Research and Ethics Committee and the London School of Hygiene and Tropical Medicine Research Ethics Committee. Consent was obtained from women (patients) either in writing in the antenatal ward prior to observation or verbally in the labor ward, with written consent obtained before discharge. Women were informed that the person being observed was the birth attendant and that no information would be collected on them. Consent to observe the birth attendants was granted by the Ministry of Health Zanzibar and obtained verbally from the birth attendants when the data collectors first visited the facility. All observed health care worker information was anonymized.

DEFINITIONS

HH opportunity

HH compliance was calculated as the number of times HH was performed divided by the number of opportunities when HH ought to occur. The opportunities in this study were procedures at birth that ought to be aseptic (Table 1). We termed a "delivery flow" as any sequence of these procedures occurring one after the other without a break and considered as *1* opportunity for HH. We defined these opportunities using available guidelines,[16-18] unstructured observations in 4 of the study wards, and expert consultation. This aimed to capture realistic workflows within our setting and accurately observe HH according to WHO recommendations.

During a delivery flow, a birth attendant was permitted to undertake hand actions within the *patient zone*, defined for this study as the woman's perineal area and thighs, any clean or sterile equipment being used, and the newborn as it was caught and wiped (Table 2). The patient zone included the patient and some surfaces and items that were temporarily and exclusively dedicated to her, limiting the risk of transmitting pathogenic organisms.[17] We excluded the

Table 1
List of aseptic procedures during a delivery flow

Wiping the vagina
Vaginal examination
Artificial rupture of membranes
Episiotomy
Catching the baby (delivering the baby)
Cord cutting and clamping
Cord traction
Manual removal of placenta*
Postdelivery vaginal examination
Suturing of the perineum*
Wiping baby clean
Urinary catheter insertion or removal

*We allowed manual removal of the placenta or suturing to be considered within the delivery flow when these occurred before or after a vaginal examination, during post-delivery examination, or during vaginal wiping, or when manual removal of the placenta occurred after cord traction.

Table 2
Types of hand actions that did *not* indicate a new opportunity for HH

Touching the patient's thighs or perineal area and the newborn after birth
Touching her own (the attendant's) body*
Touching a clean† delivery surface—cloth or macintosh
Touching equipment contaminated only with the woman's own body fluids during the procedure
Touching other sterile or clean material (eg, cotton swabs or drying material already available in the area for patient care)‡
Performing an injection (oxytocin) or supporting breastfeeding
Carrying the placenta to be disposed (ie, "dragging" the patient zone)
Removing or adding gloves or rinsing hands with water,§ per WHO recommendations

HH, hand hygiene; *WHO*, World Health Organization.
*Unconscious touches (eg, touching briefly her own face) are allowed by WHO guidelines (7). During the training, we did not differentiate between this type of unconscious gesture and a longer behavior (eg, standing with hands on hips for minutes). This recommendation assumed overall cleanliness and health of the birth attendant. These "permitted touches" did not include the birth attendant's clothes or gown.
†Usually, a delivery surface was a large rectangular sheet of cloth or plastic (also called a macintosh) brought by the woman from her own household. The surface was presumed to be clean, provided it was not contaminated (eg, with a woman's feces or after falling on the floor). When the observer could not see what happened to the sheet, it was presumed to be clean.
‡If these items were collected outside the patient zone, they were also allowed as long as the birth attendant did not touch any other surface while collecting these items. Any other hand touch was recorded as a separate action and would indicate a new opportunity.
§We allowed for the donning or removal of gloves and rinsing hands with water only during the delivery flow (after the first procedure) without indicating a new HH opportunity. This is because the WHO Guidelines for Pregnancy and Childbirth suggest that birth attendants should change their gloves before cord cutting and clamping, without needing HH, or that they should wash their gloved hands,[18] although this is not a recommendation of the WHO HH guidelines.

delivery bed and trolley from the patient zone because previous work in Zanzibar found that these surfaces were often contaminated with bacteria.[10] A break in the delivery flow, indicating a new HH opportunity, arose if an activity occurred that was not exclusive to the patient zone (eg, inserting an intravenous line, touching the patient beyond the zone, or leaving the room).

Hand rubbing/washing, glove use, and recontamination

Before a delivery flow, a birth attendant should perform 4 behaviors sequentially, defined in our study as follows[7]:

1. Rub hands with alcohol-based hand rub or wash hands with soap and water (soap use was presumed if the observer could not see the action).
2. Avoid hand recontamination after rubbing/washing until gloves are donned (or until the procedure if gloves are not worn).
3. Don at least 1 glove.
4. Avoid glove recontamination before starting the delivery flow.

We defined recontamination of hands or gloves as any touch on potentially contaminated surfaces within the workflow; this included touching an unclean delivery surface (eg, a sheet that was in contact with the floor or with the woman's feces), unclean hand-drying material (eg, reusable material), the woman and newborn outside the defined patient zone, the woman's bed, trolley, unclean objects used during HH (eg, the sink tap or the bin), and *other* unclean surfaces, unless classified as outside the workflow (a full list of activities outside the workflow is shown in Appendix B, available from https://doi.org/10.17037/DATA.00000778). These touches were distinguished from a deliberate new activity outside the workflow that would lead to a new HH opportunity as per the 5MHH (eg, leaving the room or measuring blood pressure after completion of the aseptic procedure; see Appendix B, available from https://doi.org/10.17037/DATA.00000778).

When none of the 4 behaviors was implemented, we described the suboptimal glove-related behaviors practiced instead.

Data cleaning and analyses

One author cleaned and checked the data for consistency. When multiple actions were recorded simultaneously, we used the actions related to the hygiene behaviors and procedures of interest above other actions (eg, leaving the room), leading to some loss of information. When contradictory information was reported about the same action (eg, if observers recorded both that soap was used and that they did not see soap being used), we coded the data as *inconsistent information*. For software interruptions during data collection, we followed the WOMBAT guidelines to clean time data.[14] We censored opportunities with insufficient information on hand rubbing/washing glove use, and recontamination because they occurred too close to the start of a time-and-motion observation session.

We estimated percentage compliance (behavior performed over number of opportunities) and 95% confidence intervals (CIs) for the entire recommended behavior sequence (Behaviors 1-4), for partial completion of the sequence, and for each of the 4 hygiene behaviors individually. Behaviors 2 and 4 (avoid hand and glove recontamination) were, respectively, contingent on hand rubbing/washing (Behavior 1) and donning gloves (Behavior 3) (see Appendix C for numerators and denominators for each combination, available from https://doi.org/10.17037/DATA.00000778).

We calculated frequency of adequate rubbing/washing technique (right palm over left dorsum with interlaced fingers and vice versa (16) and duration ($\geq$10 seconds, following the Zanzibar infection prevention guidelines). We also described surfaces touched during hand/glove recontamination. Finally, we described within- and between-individual variation for the 4 behaviors using bar charts and intracluster correlation coefficients (ICCs), restricted to attendants with $\geq$5 opportunities. The ICC is a measure of the relatedness of data. It accounts for this relatedness by comparing the variance within clusters with the variance between clusters.[19] The ICC was calculated on the log odds scale from univariate logistic regression models accounting for individual-level clustering at the birth attendant level. G.G. coded all outcomes, and S. W. checked the coding. Analyses were performed using STATA v14 software (StataCorp LLC, College Station, TX).

DATA SHARING

Anonymized data at the opportunity level are available in Appendix F, from https://doi.org/10.17037/DATA.00000778.

RESULTS

Dataset

We observed a total of 7,893 hand actions (including procedures, touches, and HH). After cleaning, the final results present the actions of 104 birth attendants across 10 facilities, with 4-18 attendants per facility. These data were collected during 336 observation sessions ranging from 13 minutes to 6 hours, 45 minutes, with a median time of 1 hour, 41 minutes. Each attendant was observed 1-9 times (observation sessions). The kappa statistic calculated for pairs of data collectors was good for 2 of 3 pairs at 0.93 and 0.90, but it was below the optimal level of 0.85 for 1 of the pairs, at 0.73.[14] Tailored feedback was provided to data collectors based on these results.

HH opportunities

There were 914 HH opportunities, of which 127 (13.9%) were censored because they occurred too close to the start of the observation period. Six HH opportunities were dropped because they had inconsistent information on HH. Our final dataset contained 781 HH opportunities.

Compliance levels

Birth attendants hand rubbed/washed in 24.6% (95% CI, 21.6-27.8; 192/781) of opportunities, and 6.3% (12/192) of these instances were hand rubbing. Compliance with hand rubbing/washing did not vary much by observer or by shift—the CIs overlapped (Appendix D, available from https://doi.org/10.17037/DATA.00000778). Hand rubbing/washing was performed with adequate technique 30.7% (59/192) of the time, and 14.6% (160/192) of the time lasted ≥ 10 seconds (Appendix E, available from https://doi.org/10.17037/DATA.00000778). Birth attendants avoided hand recontamination after rubbing/washing in 68.8% (95% CI, 61.7-75.2; 28/192) of opportunities.

In 63.0% (95% CI, 59.5-66.4; 492/781) of opportunities, attendants added at least 1 glove before the procedure (with or without prior hand washing/rubbing). Of these, 61.8% (95% CI, 57.3-66.1; 304/492) avoided glove recontamination. Overall, birth attendants risked recontaminating their hands or gloves in 45.3% (95% CI, 40.9-49.8; 227/501) of the opportunities when rubbing/washing or glove donning occurred.

Consider now the actions that led to failures in avoiding glove or hand recontamination (Table 3). On average, 1.3 unclean touches occurred after hand washing/rubbing (standard deviation [SD] = 0.7; range, 1-4), and the most commonly touched surfaces were the glove packs and unclean hand-drying material. On average, 1.5 unclean touches occurred after adding gloves (SD = 0.5; range, 1-7), and the most commonly touched surfaces were the patient outside the defined patient zone and unclean delivery surfaces.

Between-person and within-person variability

The 65 individuals with ≥ 5 HH opportunities contributed to the individual-level analyses of hand rubbing/washing (Behavior 1) and glove donning (Behavior 3) (Fig 1). However, recontamination could only be examined among 11 individuals who rubbed/washed and 44 individuals who donned gloves ≥ 5 times.

Fifteen attendants never rubbed/washed, 1 had 100% compliance, and the rest ranged between 5% and 85.7% compliance. The ICC indicates that most of the variation was within individuals (72%; 95% CI, 0.57-0.84) rather than between individuals (28%; 95% CI, 0.16-0.43). One attendant always avoided hand recontamination. The rest ranged between 28.6% and 83.3%. Most of the variation was within individuals rather than between individuals (10%; 95% CI, 0.01%-0.59%).

Two individuals never added new gloves before an aseptic procedure, and 5 individuals always did. The rest ranged between 10.5% and 88.2%. Almost all of the variation was within individuals (96%; 95% CI, 0.86-0.99) rather than between individuals (4%; 95% CI, 0.01-0.14). After glove donning, 2 individuals always avoided recontamination. The rest ranged between 14.3% and 88.2%. Only 8% (95% CI, 0.03-0.22) of the variation was between individuals, and most of the variation was within individuals (92%; 95% CI, 0.78-0.97). All ICC analyses were also carried out with all 104 individuals and yielded remarkably similar results.

Behavior sequences

Figure 2 presents the specific behavior sequences of birth attendants. Sequence 1, the WHO recommendation, was followed in only 9.6% (95% CI, 7.6-11.9) of opportunities. The most common practice, Sequence 9, was to perform none of the 4 behaviors (35.8%; 95% CI, 32.5-39.3), followed by donning gloves without hand rubbing/washing and avoiding glove recontamination (24.8%; 95% CI, 21.9-28.0) or not avoiding recontamination (14.7%; 95% CI, 12.3-17.4) (Appendix F, available from https://doi.org/10.17037/DATA.00000778).

In most opportunities in Sequence 9 (55.0%; 95% CI, 49.0-61.0; 154/280), attendants wore gloves used in a previous delivery flow. Other patterns are described in Appendix G, available from https://doi.org/10.17037/DATA.00000778.

DISCUSSION

In this time-and-motion study of 104 birth attendants across the 10 highest-volume labor wards in Zanzibar, we observed 781 HH

Table 3
Surfaces touched risking recontamination after hand rubbing/washing or glove use

Type of surface touched	After hand rubbing/washing, % (n) (N* = 78)	After adding gloves, % (n) (N* = 275)
Gloves pack	47.4 (37)	0
Unclean material when drying hands	20.5 (16)	0
Other unclean touches	16.7 (13)	16.4 (45)
Patient touched in areas that are *not* within the defined zone (ie, the pelvis and thighs or the newborn)	9.0 (7)	56.0 (154)
Personal bag	5.1 (4)	2.2 (6)
Unclean delivery surface (cloth or macintosh)	1.3 (1)	20.0 (55)
Patient bed	0	5.1 (14)
Waste bin	0	0.4 (1)

*Overall number of touches performed when birth attendants did not avoid hand or glove recontamination. These touches are spread across 60 opportunities when birth attendants did not avoid hand recontamination, whereas these touches are spread across 187 opportunities when birth attendants did not avoid glove recontamination.

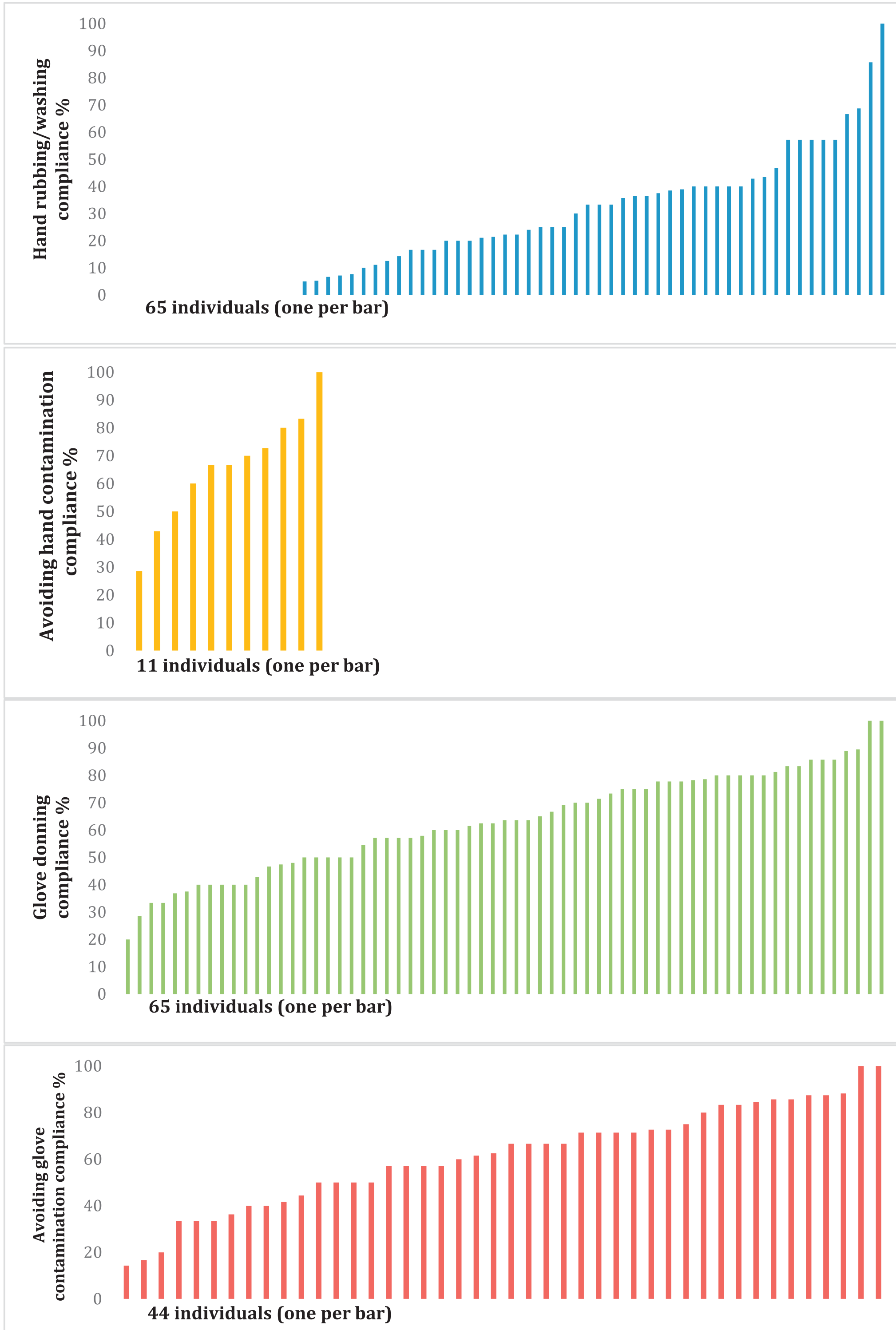

Fig. 1. Distribution of individuals' compliance with hand rubbing/washing, glove use, and recontamination.
NOTE. Only individuals with >5 opportunities were included in each of these graphs.

opportunities before aseptic procedures. Compliance with hand rubbing/washing occurred in a quarter of opportunities, but in only 9.6% of opportunities attendants also donned gloves and avoided hand and glove recontamination before the procedure, in accordance with WHO guidelines.[16] Half the time, attendants either rubbed/washed hands or donned gloves that they subsequently touched unclean surfaces with, thus potentially recontaminating their hands and contributing substantially to poor HH compliance. The variation in behavior was much larger within individuals than between individuals, suggesting that these behaviors are not habitual.

Our findings of poor compliance are similar to those of other studies from LMICs. Low HH compliance (21%) before aseptic procedures

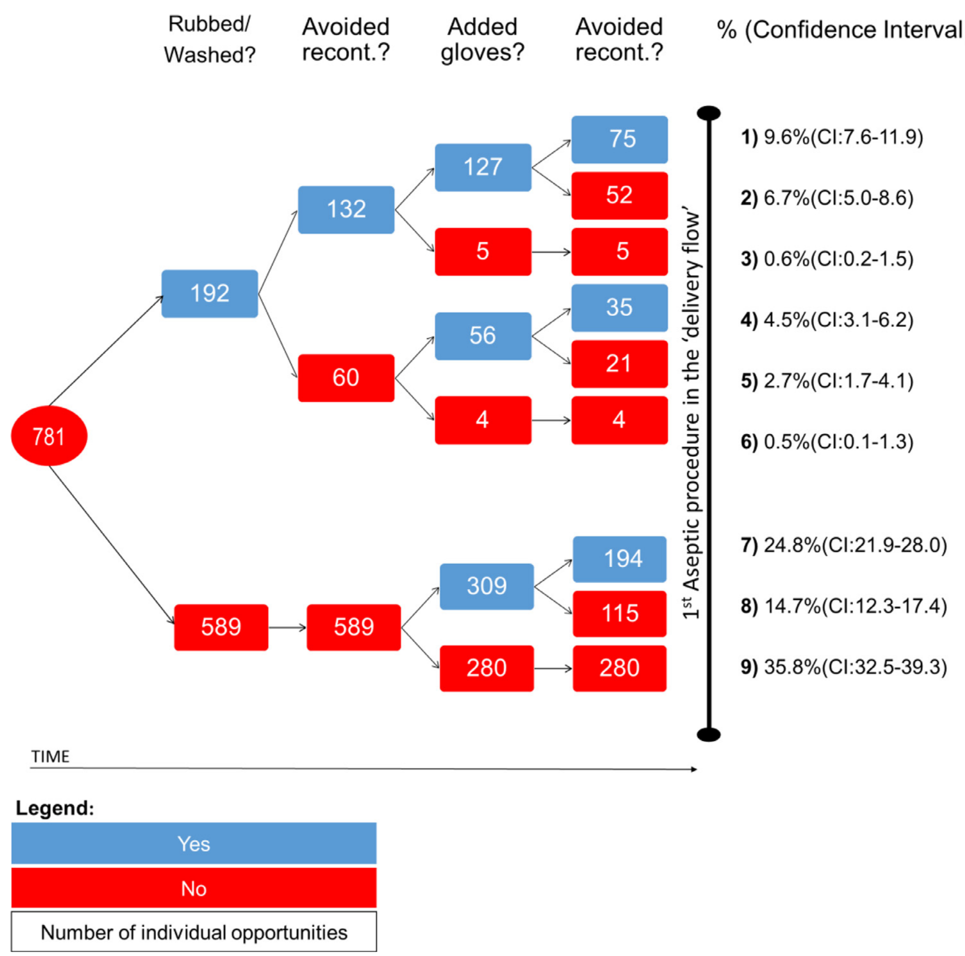

Fig. 2. Behavior sequences for 781 hand hygiene opportunities. NOTE. This figure describes the 781 opportunities available in the dataset. For each opportunity, it outlines whether each of the 4 behaviors was performed. Percentages refer to the number of opportunities in the last column (eg, in the first sequence, 9.6% refers to 75/781). *Recont.*, recontamination.

was recently reported in a Nigerian hospital.[20] In Indian labor wards, compliance before delivery was only 10.6%.[21] A study from Iran reported similar levels during the second stage of labor.[22] A study of a labor ward in Ghana reported that compliance ranged between 21% and 27% before aseptic procedures.[23] In Zimbabwe, a study found that 62% of midwives never washed their hands before procedures.[24] HH definitions vary in these studies, making direct comparison with our results challenging. However, all studies highlight extremely poor HH behavior.

Although for most opportunities birth attendants did not rub/wash hands, in two-thirds of opportunities they did wear at least 1 new glove for the procedure. In the remaining third, birth attendants adopted suboptimal glove-use behaviors that are not recommended[7] but may imply an attempt at placing a barrier between the birth attendant's hands and the patient. The most common was to attend different patients and procedures using the same gloves, consistent with other studies on the misuse of gloves.[15,25]

Although delineation between patient zones to address recontamination was studied in Vietnam,[26] to our knowledge, ours is the first study that sought to quantify the contribution of avoiding recontamination to HH compliance. Our findings are supported by studies in the United Kingdom and Australia where health care workers were observed to touch privacy curtains between HH or glove donning and patient care.[15,27] In a study based in Ghana, Cronin et al. describe qualitatively how birth attendants' gloved hands were observed touching the patient bed before the delivery.[28] Loftus et al[29] demonstrated microbiological recontamination of hands at the point of care despite high levels of self-reported HH compliance, indicating the relevance of recontamination in infection transmission. Recontamination may be an indication that there is a lack of understanding of the definition of the WHO 5MHH in its attempt to direct an approach to HH action at times when recontamination risk within or between patients has been established. Future versions of the WHO HH Observation Form could add a recontamination option for the "missed" HH opportunities (when compliance was not met), which would allow for recontamination to be monitored for both implementation and research purposes.

The contribution of avoiding recontamination to overall HH compliance in our study calls for further research, to investigate its importance in other contexts, its drivers, and its direct contribution to HAIs.[7] Acknowledging the avoidance of recontamination as a distinct behavior and incorporating its measurement into existing tools for observing compliance, such as the WHO HH audit tool, would help quantify this problem and inform interventions to tackle it.

Our analyses revealed that variation in behavior was much larger within individuals than between individuals, suggesting that varying factors, such as availability of materials and workload, may be more important drivers than individual psychological determinants and that behavior-change strategies need to be tailored to actual practices and contexts.[30,31] It is important to note that these findings were generated in settings with limited resources; hence, in settings with more stable resources, practices may be more habitual. Future studies could further investigate this.

We monitored health care workers' behavior using state-of-the-art time-and-motion methods that have rarely been employed in low-resource settings.[32] This allowed us to investigate compliance with the complete sequence prescribed by the WHO guidelines on HH as well as each individual behavior and behavior sequence. It also reduced the risk of observer bias, because HH opportunities were identified retrospectively in a standardized way rather than relying on observer judgment.

Our study had some potential limitations. A residual Hawthorne effect may have caused overestimation of compliance, despite blinding attendants to the study purpose in all but 1 facility. The 13% of opportunities with incomplete hand hygiene or glove information might not be random, as they may have occurred when procedures were rushed and HH more difficult, leading us to overestimate compliance.[33] In 5 of 336 observation sessions, we did not have data on attendance of new patients and assumed that the same woman was attended throughout, potentially underestimating opportunities for HH and overestimating compliance.

In conclusion, in this time-and-motion study of hand hygiene and glove practices in the 10 highest-volume labor wards in Zanzibar, we found, as did previous studies, low compliance with WHO HH guidelines. The major addition of this study is that it revealed the potential effect of recontamination, after initial washing/rubbing and donning gloves, on infection risk and the importance of including this as a separate item in HH measures. Additionally, variability in this behavior seems to reside primarily within individuals across opportunities. Reducing the threat of HAIs in mothers and newborns calls for further research into drivers of recontamination and effective behavior-change strategies to tackle it.

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APPENDICES

All appendices are available from https://doi.org/10.17037/DATA.00000778.

Appendix A

Facilities description.

Appendix B

Actions that indicated a new hand hygiene opportunity and were outside of the workflow.

Appendix C

Numerator and denominator definitions for each outcome combination reported in the Methods section.

Appendix D

Hand hygiene compliance by observer and shift.

Appendix E

Duration and technique of hand rubbing/washing.

Appendix F

Sequence of actions preceding the first aseptic procedure in the delivery flow.

Appendix G

Patterns of glove behavior under Sequence 9 (from Fig 2).

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9.9. Appendix V (B-D) – Ethics approvals for study described in Manuscript 4,5,6

SERIKALI YA MAPINDUZI ZANZIBAR
ZANZIBAR REVOLUTIONARY GOVERNMENT
WIZARA YA AFYA
MINISTRY OF HEALTH

ETHICAL CLEARANCE LETTER

PROTOCOL NUMBER ZAMREC/0001/December/2015 DATE: 10 FEBRUARY,2016.

Prof. Wendy Graham
Principal Investigators

PROTOCOL TITLE: **"Development of a hand hygiene intervention to reduce bacterial infection among newborns and mothers delivered in maternity units in Zanzibar, Tanzania (The HANDS study), "**

RE: ETHICAL CLEARANCE FOR CONDUCTING MEDICAL RESEARCH IN ZANZIBAR.

This is to certify that the research protocol entitled "**Development of a hand hygiene intervention to reduce bacterial infection among newborns and mothers delivered in maternity units in Zanzibar, Tanzania (The HANDS study),** "was received and reviewed by the Zanzibar Medical Research and Ethics Committee on February, 2016.

We would like to inform you that the decision of the committee to this protocol was "**Approved**".

The permission to undertake data collection is for one year beginning from the date of this letter.

The principal investigators have to provide progress report after six months and final report to the Ministry of Health and the Zanzibar Medical Research and Ethics committee ZAMREC.

Seek permission to publish from ZAMREC.

Any change made to the protocol need to be submitted to the committee for approval prior to its implementation

Thanks in advance,

[redacted]

DR. MOHAMMED DAHOMA
/CHAIRPERSON
ZAMREC
ZANZIBAR

[redacted]

DR. MSAFIRI MARIJANI
SECRETARY
ZAMREC
ZANZIBAR.

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

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Observational / Interventions Research Ethics Committee

Dr Susannah Woodd
Research Fellow, Epidemiology
Department of Infectious Disease Epidemiology (IDE)
Epidemiology and Population Health (EPH)
LSHTM

24 May 2016

Dear Susannah

Study Title: HANDS

LSHTM Ethics Ref: 10583

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
Protocol / Proposal	290115 HANDS study PHIND application WJ Graham Univ of Aberdeen_Steering Committee	29/01/2015	1
Investigator CV	SUMMARY CURRICULUM VITAE	01/02/2016	1
Information Sheet	Consent for interviews_020216	02/02/2016	2
Information Sheet	Consent for observations - patients020216	02/02/2016	2
Local Approval	ethical Approval	17/02/2016	1
Local Approval	aberdeen ethics	17/05/2016	2
Covering Letter	covering letter	17/05/2016	1

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,

[redacted]

[redacted]

Professor John DH Porter
Chair

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

Improving health worldwide

https://clsmiis.abdn.ac.uk/CERB/Admin/ApplicationAdmin.aspx?AppID=1268&LockID=A4xrL5OyQ1s3mHHCrLx85RtGStTRhYKBWhZKIUSXJ10%3d

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Application Overview

CERB/2016/1/1268 Hide

Development of a hand hygiene intervention to reduce bacterial infections among newborns and mothers delivered in maternity units in Zanzibar, Tanzania (The HANDS study)

Version - 1 Created On :

Submitted By:	Katherine Ritchie	Email :	katherine.ritchie@abdn.ac.uk
Principal Investigator :	Professor Wendy Graham	Email :	w.graham@abdn.ac.uk
PI Submitted on:	26/01/2016	Current Status :	Application Approved. (Locked)
Proposed Start Date :	01/01/2016	Proposed End Date :	28/02/2017
Peer Reviewed:	True	Peer Review Type:	Internal

Interventions : ☐ Measurements : ☐ Questionnaires : ☑ InterViews : ☑ Samples : ☐

Background

Hide

BACKGROUND: Neonatal and maternal mortality remains unacceptably high in many low-income countries. Bacterial infections acquired at birth and in the postnatal period are estimated to account for over 700,000 such deaths each year, as well as significant short and long-term morbidity. The hygiene practices of care providers and mothers have a major impact on these infections, and have been highlighted for attention in recent international initiatives, such as the Every Newborn Action Plan. AIMS & OBJECTIVES:(1) Investigating whether hand hygiene compliance differs in different cadres of birth attendants and by facility case-load, and between health workers and mothers at home (2) Investigating what individual (e.g., attitudes, skills) and environmental (e.g. norms, organisation, physical) factors explain variation in compliance (3) Assessing what intervention strategies to promote hand hygiene are likely to be effective, feasible and acceptable STUDY POPULATION: The research will be conducted in 10 facilities in Zanzibar, Tanzania, in maternity care contexts which are broadly generalizable to other maternity units in sub-Saharan African countries METHODS & ANALYSIS: The research will rely on a mixed-methods approach, with novel elements such as scenario techniques and intervention co-creation with key stakeholders introduced through questionnaires and observational methods. The Behaviour Centred Design (BCD) approach emphasizes the importance of emotional drivers (e.g. nurture, disgust) to shape hygiene behaviour. This model is grounded in both evolutionary anthropology and ecological psychology and relies on in-depth, qualitative methods. The second model categorises behavioural determinants into knowledge, attitudes, norms, ability and self-regulation factors (RANAS), and is based on the health belief model and the theory of planned behaviour, among others. It relies on survey methods that are quantitative in nature. The third base draws on theories of organisational learning and knowledge management. The importance of such a mixed-methods approach for developing sound complex interventions is widely-acknowledged.

Main Aim

Hide

to develop a sound explanatory model of the key determinants of hand hygiene among actors.

Sub Aim

Hide

to select appropriate behavioural and organisational change techniques for influencing these determinants, to develop pragmatic strategies and materials for the intervention, and to evaluate their feasibility and acceptability.

Project Key Words

Show

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Participants

1. What are the Inclusion Criteria? (50 words MAX)

For the mothers: Women 18+ that have recently delivered at a study facility; that are caring your their newborn baby; that provide fully informed written or thumbprint consent. For the healthcare workers: staff

2. What are the Exclusion Criteria? (50 words MAX)

Women have experienced a stillbirth or neonatal death. Women have been physically or mentally unwell since childbirth.

3. Are any under 16s involved?

No

3.11 All researchers coming into contact with children have the relevant certification from **Disclosure Scotland/PVG Scheme.**

3.2 Why are they being included?

4. Are Adults with mental incapacity or Prisoners involved?

No

4.1 Why are they being included?

5. How will participants be recruited?

Posters,Word of Mouth,Other:Offered non-

6. How many participants will be recruited?

300

7. How was the number of participants selected?

Based on approximate delivery figures for the 10 health facilities identified for the study, this figure provides a representative sample of mothers and healthcare workers. The figure is achievable within the timeframes laid

8. How will participants be given information about the study?

Information Sheet,Verbal,

9. How long to decide whether to take part

2-6 hours time at clinic.

10. How will participants give consent?

Letter

10.1 Please give details

11. Will the participants receive any payment or other incentive for taking part?

Yes

11.1 Please give details

For mothers a small financial contribution towards any travel costs incurred will be offered.

12. Please outline your recruitments strategy. (please submit a letter of invitation in the attachments section).

Within the 10 facilities, woman meeting the inclusion criteria will be approached/informed of the study. The first 150 women to consent to be interviewed will be interviewed. Healthcare staff working at the time of observation will be invited to participate.

Previous Next

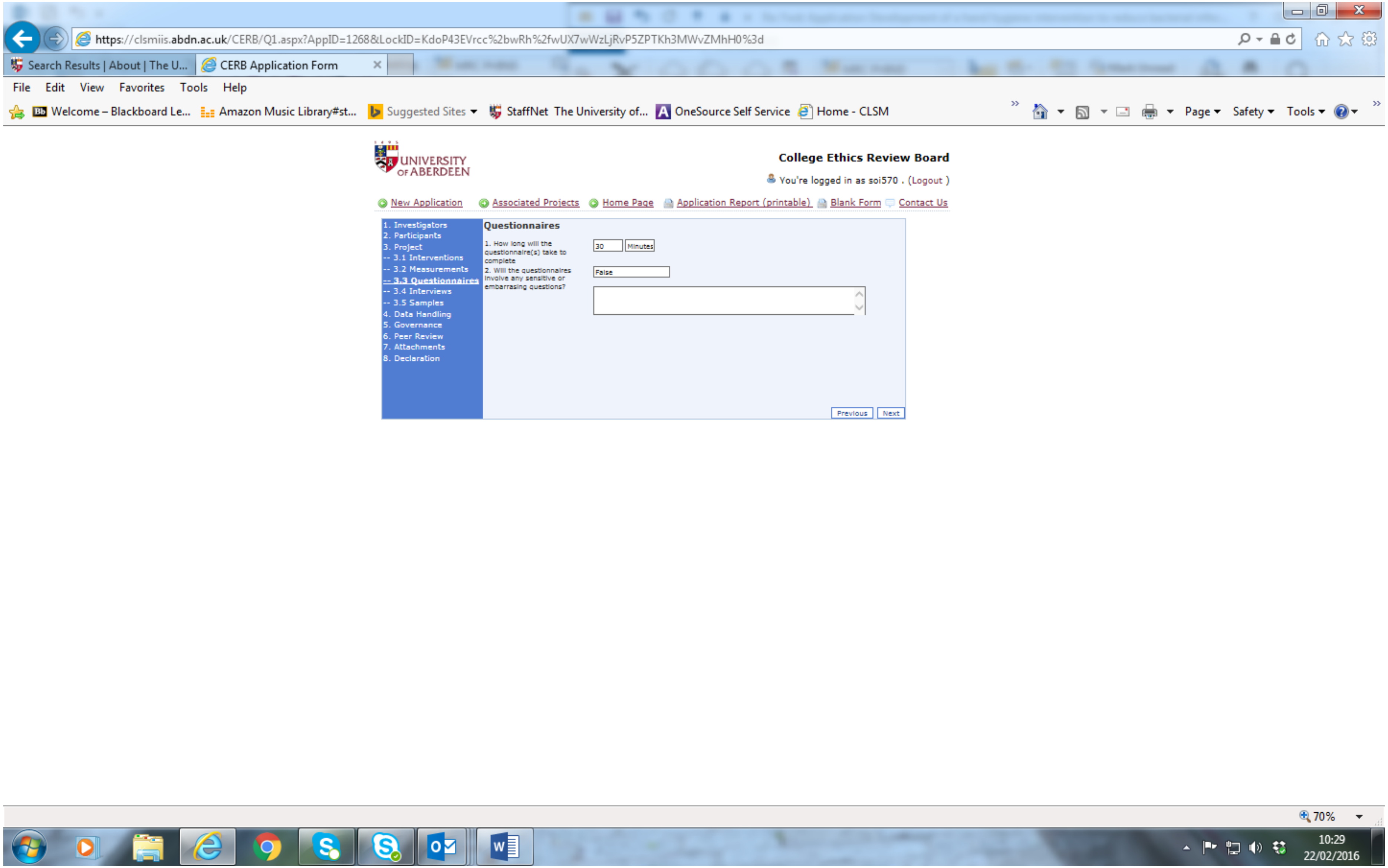
Project

1. Short Project Title	Development of a hand hygiene intervention to reduce bacterial infections among newborns and mothers delivered in maternity units in Zanzibar, Tanzania (The HANDS study)
2. Start Date	01/01/2016
3. End Date	28/02/2017
4. Main Aim (50 words MAX)	to develop a sound explanatory model of the key determinants of hand hygiene among actors.
5. Subsidiary Aim (100 words MAX)	to select appropriate behavioural and organisational change techniques for influencing these determinants, to develop pragmatic strategies and materials for the intervention, and to evaluate their feasibility and acceptability.
6. Background to Research (500 words MAX)	BACKGROUND: Neonatal and maternal mortality remains unacceptably high in many low-income countries. Bacterial infections acquired at birth and in the postnatal period are estimated to account for over 700,000 such deaths each year, as well as significant short and long-term morbidity. The hygiene practices of care providers and mothers have a major impact on these infections, and have been highlighted for attention
7. Outline Research Protocol (250 words MAX)	The formative research will be conducted in three consecutive work packages (WPs) with WP 1 and 2 further divided into a) an assessment of hospital personnel and b) an assessment of new mothers. The study will be informed by the experience and findings from the earlier (2014) partial needs assessment conducted by the applicants in maternity units across
8. Will any interventions be carried out?	No
9. Will any physical measurements be carried out?	No
10. Will any questionnaires be carried out?	Yes
11. Will any interviews be carried out?	Yes
12. Will any sample of tissue or body fluid be collected?	No
13. Please outline any Health and Safety aspects associated with this project. (250 words MAX)	This is a formative study involving interviews and observation and therefore the direct risks to individual participants; physical, psychological, social and economic, are very low. In addition, the interviews will be on the subject of hand washing and hygiene behavior and are not expected to raise distressing issues for the participants.

14. Key Words

Please check the 'Key Words' that relate to you application.

☐ Ageing	☑ Behavioural medicine	☐ Carers	☐ Communication	☐ Complementary medicine
☑ Community	☐ Childhood	☐ Dentistry	☐ Diet	☐ Drugs
☐ Disability	☐ Economics	☐ Education	☐ Elderly	☐ Employment
☐ Environment	☐ E-science	☐ Ethics	☐ Exercise	☐ Genetics
☑ Infection	☑ International	☐ Occupation	☐ Obesity	☐ Mental health
☐ Mobility	☐ Neuroimaging	☐ Nutrition	☐ Pain	☐ Pharmacology
☐ Phlebotomy	☑ Pregnancy	☑ Prevention	☐ Pollution	☑ Poverty
☑ Psychology	☐ Questionnaire	☐ Radiation	☐ Schools	☐ Smoking
☐ Statistics	☐ Student volunteer	☐ Tele-medicine	☐ Students	☐ Critically Ill
☑ Primary care	☐ Cancer	☐ Musculoskeletal	☐ Oral Diseases	☐ Epidemiology
☐ Survey	☐ Case-control study	☑ Evidence based practice	☐ Methodology	☐ Outcomes
☑ Intervention	☐ Alcohol	☐ RCT	☐ Trauma	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-- 3.3 Questionnaires
-- 3.4 Interviews
-- 3.5 Samples
4. Data Handling
5. Governance
6. Peer Review
7. Attachments
8. Declaration
Questionnaires
1. How long will the questionnaire(s) take to complete
30
Minutes
2. Will the questionnaires involve any sensitive or embarrasing questions?
False
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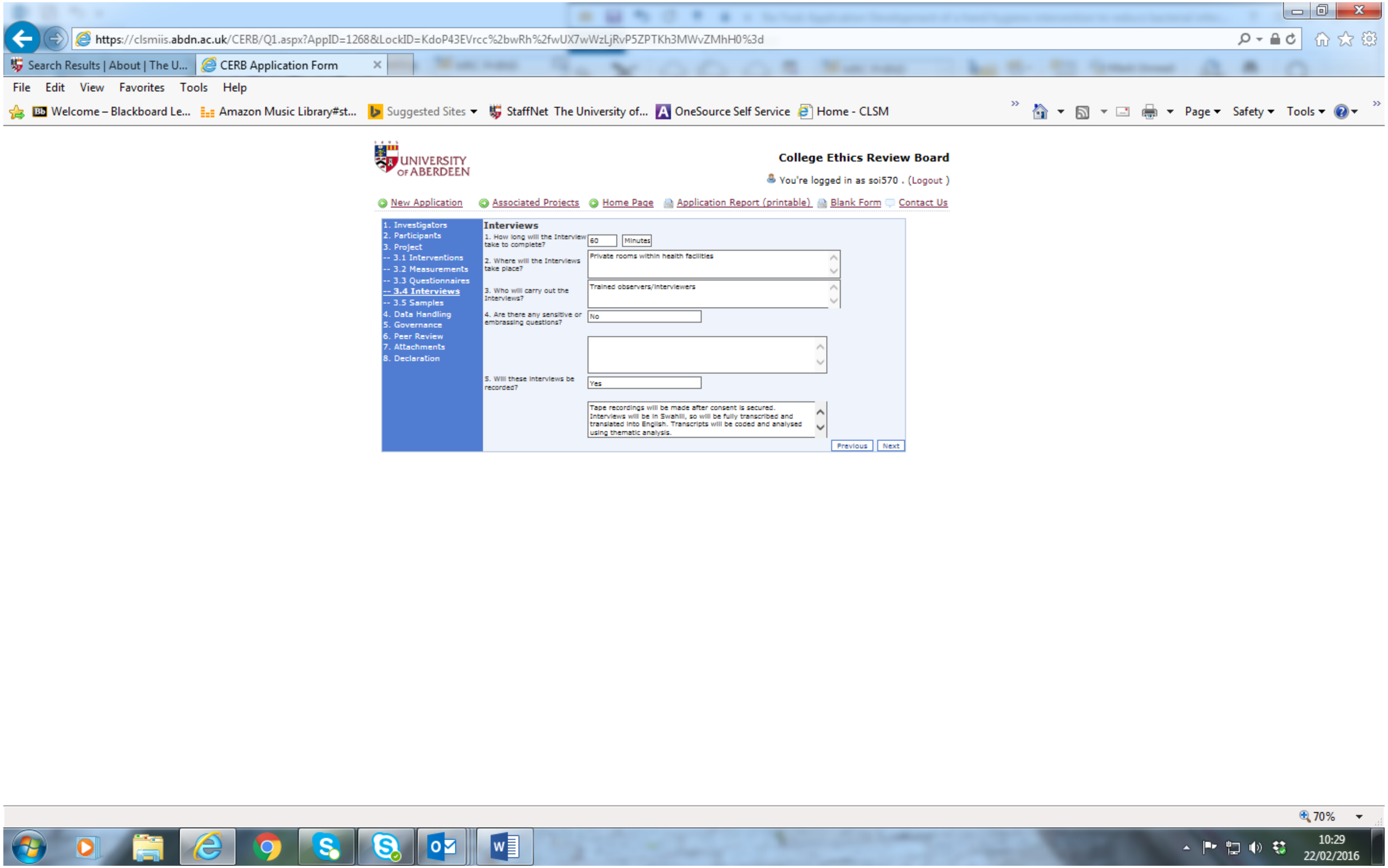

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7. Attachments
8. Declaration
Interviews
1. How long will the Interview take to complete?
60
Minutes
2. Where will the Interviews take place?
Private rooms within health facilities
3. Who will carry out the Interviews?
Trained observers/interviewers
4. Are there any sensitive or embrassing questions?
No
5. Will these interviews be recorded?
Yes
Tape recordings will be made after consent is secured. Interviews will be in Swahili, so will be fully transcribed and translated into English. Transcripts will be coded and analysed using thematic analysis.
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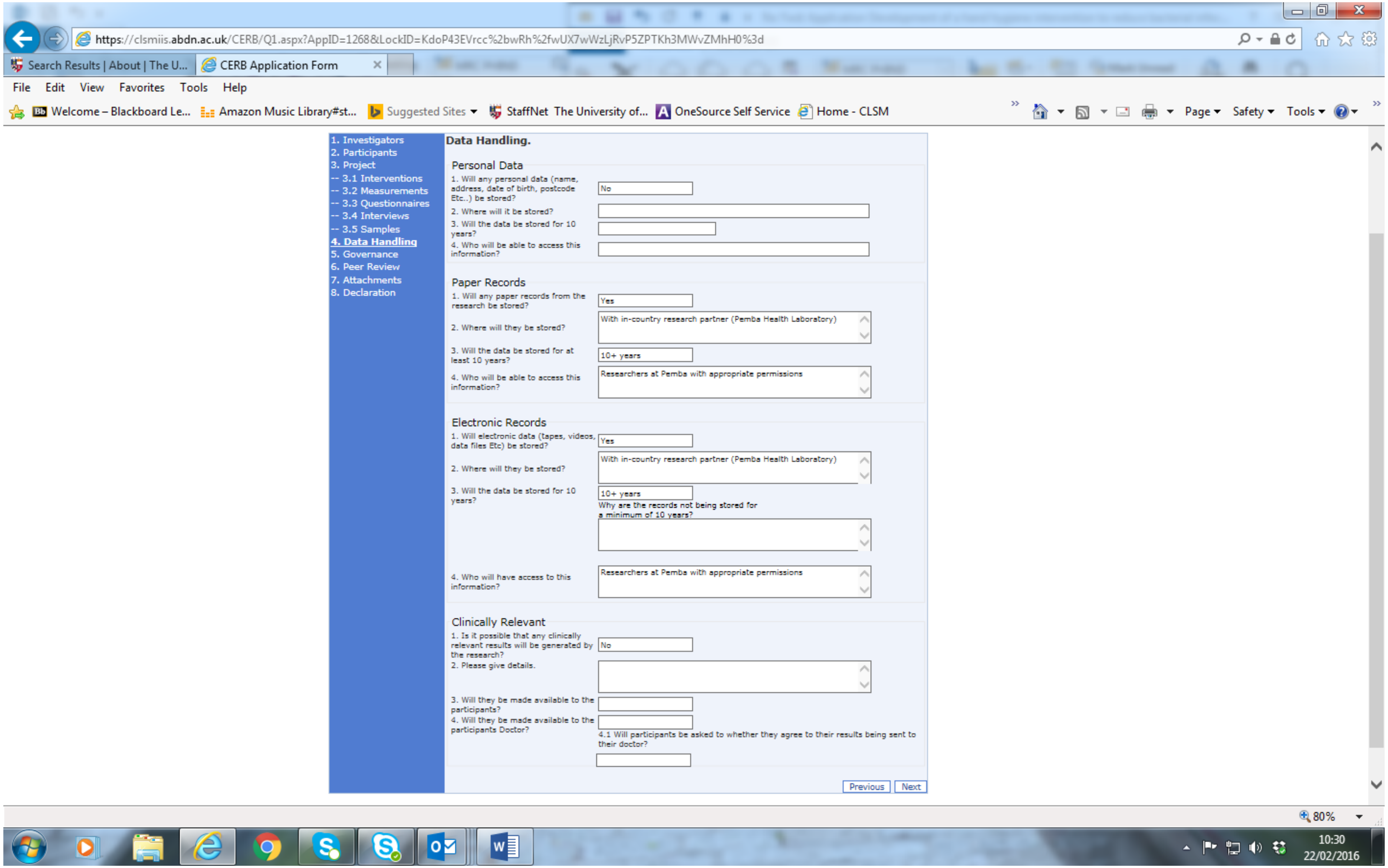

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8. Declaration

Data Handling.

Personal Data

1. Will any personal data (name, address, date of birth, postcode Etc..) be stored? No
2. Where will it be stored?
3. Will the data be stored for 10 years?
4. Who will be able to access this information?

Paper Records

1. Will any paper records from the research be stored? Yes
2. Where will they be stored? With in-country research partner (Pemba Health Laboratory)
3. Will the data be stored for at least 10 years? 10+ years
4. Who will be able to access this information? Researchers at Pemba with appropriate permissions

Electronic Records

1. Will electronic data (tapes, videos, data files Etc) be stored? Yes
2. Where will they be stored? With in-country research partner (Pemba Health Laboratory)
3. Will the data be stored for 10 years? 10+ years

   Why are the records not being stored for a minimum of 10 years?
4. Who will have access to this information? Researchers at Pemba with appropriate permissions

Clinically Relevant

1. Is it possible that any clinically relevant results will be generated by the research? No
2. Please give details.
3. Will they be made available to the participants?
4. Will they be made available to the participants Doctor?

   4.1 Will participants be asked to whether they agree to their results being sent to their doctor?

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Research Governance

1. Has this project been costed by Research Financial Services	Yes
2. Will this project be carried out within the time limit that has previously been agreed upon(research allocation), without requiring significant additional resources (including additional power requirements, accomodation, equipment or insurance)? (50 words MAX)	Yes
2.1 Please provide information.	Budget and timeline approved as realistic and achievable for this formative work.
3. Has the proposal been discussed with theme leader and head of school/division	Yes
3.1 Please provide information.	Proposal went through internal review process. Cover sheet fully signed off.
1. What is the source of funding for the proposed research?	MRC-PHIND
2. Which organisation will act as sponsor?	AS ABOVE
3. What arrangements are in place for claims for **negligent** harm to participants?	N/A
4. What arrangements are in place for claims for **non-negligent** harm to participants?	N/A

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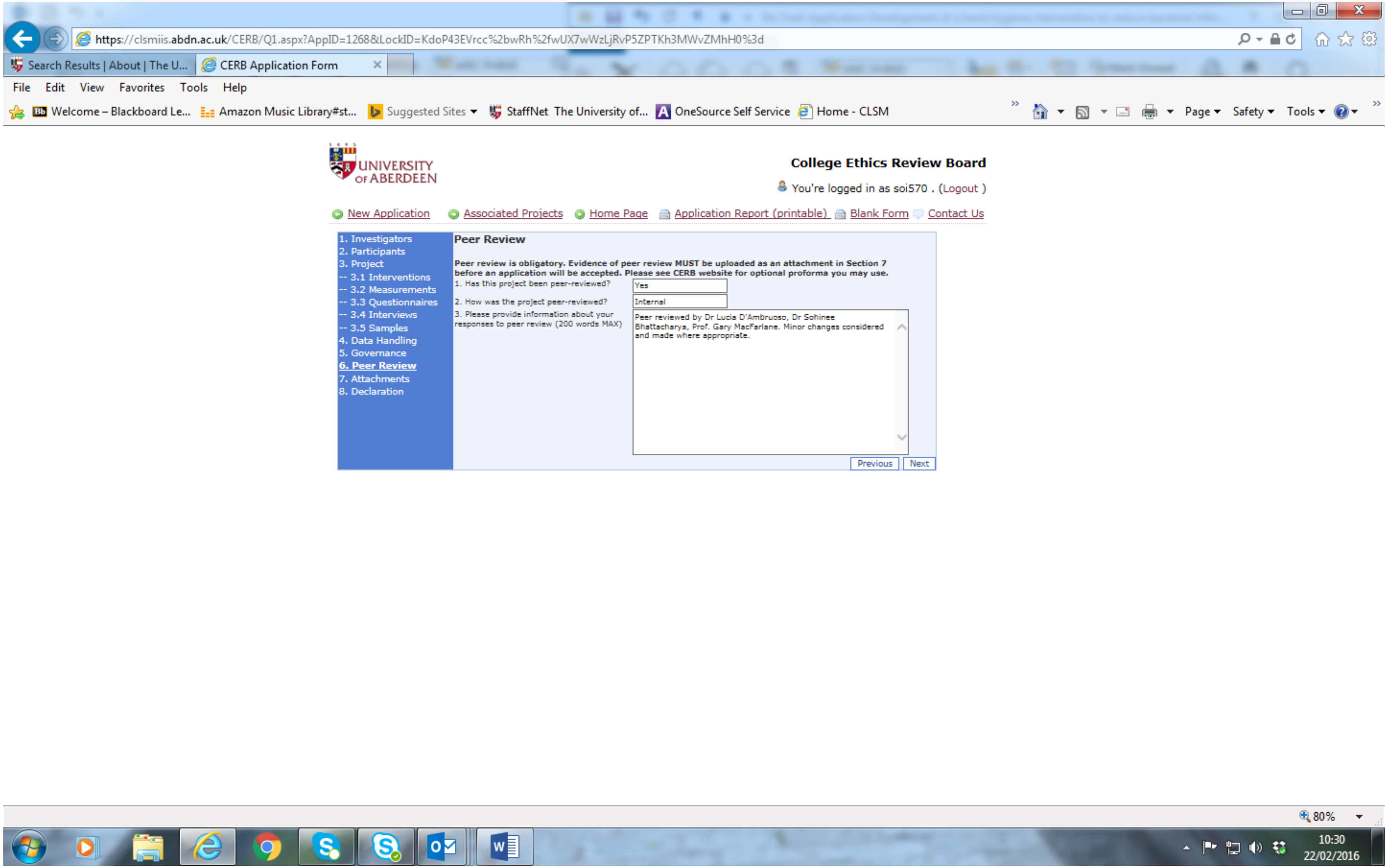

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8. Declaration

Peer Review

Peer review is obligatory. Evidence of peer review MUST be uploaded as an attachment in Section 7 before an application will be accepted. Please see CERB website for optional proforma you may use.

1. Has this project been peer-reviewed? Yes

2. How was the project peer-reviewed? Internal

3. Please provide information about your responses to peer review (200 words MAX) Peer reviewed by Dr Lucia D'Ambruoso, Dr Sohinee Bhattacharya, Prof. Gary MacFarlane. Minor changes considered and made where appropriate.

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Attachments

Please upload any attachments/evidence that MIGHT be required for the application review process. (e.g.)

1. Invitation Letter.
2. Information Sheet:
3. Consent Form
4. **Experimental Protocol*** (please rename file to PROTOCOL_[filename])
5. Questionnaires
6. **Evidence of Peer Review*** (please rename file to: PEER_[filename])
7. NHS ethics committe outwith remit letter

Other...

*** REQUIRED**

Please Note: If you do not upload any evidence required for peer review or Experimental Protocol then your application review WILL BE REJECTED.

Description of File

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Please ensure that documents are in the form of .doc, .docx, .pdf or .xls.

Upload File

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Consent for interviews.docx
Consent for observations - patients.docx
Consent for observations - postpartum women.docx
FGD for HWs.docx
FGD for women including translation.docx
Interview for managers.docx
Observed Cord care practice.docx
protocol assement form.doc
Site observations HWs.docx
Site observations women.docx
Structured observation.docx
Structured questionnaire with translation.doc
PEER_Hands.pdf

Attachment Checklist

Please indicate that you have uploaded all the required attachments

Experimental Protocol Uploaded	Yes
Information Sheet Uploaded	Yes
Consent Form Uploaded	Yes
Peer Review Evidence Uploaded	No

Previous Next

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9.10. Appendix VI – Qualitative manuscript under preparation mentioned in Manuscript 5 and the Discussion chapter

Understanding Infection Prevention Behaviour in Maternity Wards: A Mixed-Methods Analysis of Hand Hygiene in Zanzibar.

Mícheál de Barra[1,2], Giorgia Gon[3], Susannah Woodd[3], Wendy Graham[3], Marijn de Bruin[1], Catherine Kahabuka[4], Jess Williams[1], Khadidja Konate, Oona Cambell, Said Ali, (PHL authors), Loveday Penn-kekana[3].

[1] University of Aberdeen; [2] Brunel University London; [3] London School of Hygiene and Tropical Medicine; [4] CSK Research Solutions.

Author Note

Funded by the Medical Research Council. Award number MR/N015975/1 (PHIND scheme). The Soapbox Collaborative also contributed by funding staff involved in this project.

Target Journals: Social Science and Medicine

Abstract

Background. Although women are increasingly encouraged to give birth at facilities rather than in the home, hospital-associated infection of both the mother and newborn remain common. Am important cause of infection is poor hand hygiene. There is a pressing need to understand the environmental, behavioural, and organizational causes of poor and good hand hygiene practice.

Aims: To understand between facility variation in hygiene behaviour and to explore intervention targets.

Sample: Two large and two small delivery facilities in Zanzibar. Thirty-three interviews with birth attendants / nurses, senior management, orderlies and mothers (totalling 23 hours) and four focus-group discussions.

Procedure: Approximately 15 days of participant observation, semi-structured observation of deliveries and of day-to-day workings of the facilities. Semi-structured interviews with birth attendants, orderlies, managerial staff and mothers. Focus-group discussions with birth attendants.

Results: Hand hygiene was better supported in the two high-volume faculties with soap, water, gloves typically available. However, all of the facilities, hand hygiene appeared impeded by poor ergonomics (e.g., physical separation between taps, gloves etc). Interviews suggested that birth attendants found this to be an important barrier. Observation and interviews also suggested that birth attendants found it difficult to keep gloves clean before procedures. Interviews and focus groups suggest that birth attendants typically understood when and why hand hygiene should be implemented. Birth attendants are aware of low handwashing rates among co-workers. The use of a multi-purpose fabric brought to the facility by the patient as both bedsheet and a perineum/vagina cleaning material was identified as an important possible infection risk.

Conclusion: Hand hygiene appears to be impeded by the layout of the delivery room and the absence of low-cost consumables. While knowledge of when/how to perform hand hygiene was good, birth attendants are aware that few colleagues perform hand hygiene at high rates and that hygiene behaviour is not incentivised. Improvements in the ergonomic design of delivery rooms including convenient availability of soap, hand gel, hand towels and gloves may be a low-cost way to reduce the burden of hand hygiene.

Keywords: Risk of hospital-acquired infection; Hospital hygiene; Outbreak control and prevention; Health care professionals; Qualitative approach

Introduction

Bacterial infections acquired at birth and in the postnatal period are estimated to account for more than 700,000 such deaths each year, as well as significant short and long-term morbidity CITE. With the increasing global trend towards institutional delivery, now estimated at 87 million births annually, feasible and effective interventions which can be implemented to improve hand hygiene may reduce the burden of preventable bacterial infections in both new-borns and mothers.

A systematic review by Erasmus et al. (2010) found that while hand hygiene compliance rates have rarely been measured in robust and replicable ways, median compliance rates are approximately 40%, with higher rates after contact with body fluids and among nurses compared to doctors. Systematic reviews of hand hygiene practices in maternity wards in low and middle-income contexts are lacking but individual studies suggest significant problems exist. Kruk et al 2016 used Demographic and Health Survey data to examine the health facilities in maternity wards in five African countries including Tanzania and found many primary secondary care facilities lacked safe water and infection control resources.

While existing research indicates many facilities in Zanzibar – site of the current study – have the infrastructure needed to implement hand hygiene (Gon et al., 2017), a recent quantitative time-and-motion study conducted found that birth attendants performed inadequate hand hygiene before 90% of 781 observed procedures (i.e. no rubbing or washing or failure to keep gloved hands clean) (Gon et al., 2018). Data collected as part of the current project also indicates substantial differences between facilities in the rates of hand hygiene (Gon et al, CITE). These and previous finding suggest a need understand the reasons hand hygiene rates vary across facilities low and to develop and implement interventions to improve hand hygiene in low and middle-income countries like Tanzania. This need is particularly pressing since given ongoing encouragement of mothers to deliver in facilities rather than in the home.

Effective hand hygiene intervention development necessitates knowing how behaviour unfolds in context as well as understanding the environmental and psychological factors which enable or obstruct it (Eldredge, Markham, Ruiter, Kok, & Parcel, 2016; Grol, Wensing, Eccles, & Davis, 2013). Qualitative and observational research can offer unique insights into these questions by observing behaviour in context and by allowing staff members to reflect upon and share their own attitudes, beliefs and observations about hand hygiene. This paper summaries the qualitative data collected through interviews, focus groups and participant observation, which was carried out as part of a larger mixed methods study. The quantitative component of the research is described in detail elsewhere (Gon et al., *2018*).

The qualitative component of the research project had four objectives. Our first objective was to overview the infrastructure, organisation and workload of the four facilities studied. This overview provides context for the subsequent analyses. Our second objective was to describe how differences between facilities in layout and organisation appeared to enable or obstruct hygiene behaviour in the delivery rooms. Our third objective was to examine differences in similarities in how various consumables are used across individuals and facilities. In doing so, we draw attention to features of hand hygiene which have been underexplored in the literature but may have important implications for infection rate namely; the recontamination of gloves before procedures; and the use of potentially infective fabric for post-delivery cleaning of the mother. Our final objective is to explore the social context of hygiene examining for example, the normative status of handwashing and the influence of managers and other staff members.

Methods

Setting. The sample included two facilities on Unguja and two facilities on Pemba. These Zanzibarian islands are Muslim majority, semi-autonomous regions with 3% of the Tanzanian population.

Participants. Birth attendants – nurses and orderlies who deliver babies – were of primary interest, and three to four were interviewed per facility. The role of the birth attendants is to manage normal deliveries including antenatal and postnatal care, identifying complications to pregnancy, perform appropriate interventions and where necessary, refer the mother or baby to other health care workers with the relevant expertise. Given that more senior staff have the capacity to influence hand hygiene both through organizing a consistent supply of hygiene consumables and also by creating the workplace norms, rules, and expectations, we interviewed ward managers, hospital, and district level management. Finally, in the three facilities with a functional Infection Prevention Committee, we also conducted a focus-group discussion with the available members. The complete sample is described in Table 1.

Site and participant sampling. The four facilities were selected for diversity across the delivery-volume spectrum, as well as an urban and rural spread. Our visits were timed to coincide with shift ends, a convenient time for interviews, and birth attendant interviewees were selected based on their availability during these hospital visits. Since birth attendants cycle through shifts, this convenience sampling strategy approximates random sampling. Facilities typically had one maintenance person, ward manager etc, and thus no sampling took place at the within-facility level for these participants.

Table 1. Data sources by facility and source.

	Number	Total Duration (min)*
Interviews per facility		

	Facility 1	10	432
	Facility 2	10	340
	Facility 3	9	270
	Facility 4 **	10	270
	District / regional level	3	100
Interviews			
	Nurse birth attendants **	11	372
	Orderly birth attendants	2	83
	Infection control committees+	3	150
	Wash Maintenance Controllers	4	143
	Hospital managers	5	284
	District / Regional level supervisor	2	68
	Patron/matron	2	60
	Ward Manager	4	242
	Sepsis activity+	4	na
Observational data		Facility 1,2,3,4	
	Structured observations	3,3,2,2	~300
	Deliveries observed	5,0,3,1	na
	Vaginal exams observed	5,2,2,2	na
	Days team spent in facilities	5,4,3,3	na

*Note: * Excludes sepsis game which was not timed. ** Excludes one untimed birth attendant interview *** A series of group interactive activities focussed on infection.* + Focus group discussions rather than interviews.

Observational data collection: Our research team spent 3 to 5 days in each facility. During this time, we obsereved hygiene practices, other labour ward activity by birth attendants, consumable use, the organization and use of space within these rooms. Maps were created of each facility and the location of all hygiene-related infrastructure and consumables were noted. We also noted how staff members interacted with each other (e.g., who assists who? What supervision exists? Are there formal or change-of-shift meetings? What happens during discharge?) and with the mothers. We paid particular attention to the delivery procedures, newborn care immediately after birth, and the management of infection risks during this process. Other tasks during this time included waiting for and organising interviews, waiting for deliveries or other procedures for structured observations, and generally becoming acquainted with the facility and its staff members, asking questions about the layout and organisation, and observing daily life in the facility. This ethnographic approach was complemented by semi-structured observations.

Semi-structured observations were conducted in each facility in 30-minute sessions. During these sessions, a researcher sat in the delivery ward and took detailed time-stamped notes on all hygiene related behaviour (handwashing, glove use, recontamination) as well as on the broader behaviour patterns of which the hygiene was a part (delivery, cord cutting, vaginal exams, disposal of wastes, cleaning, delivery kit preparation, data entry, surface contact, colleague interaction etc.). During these structured observations, we followed one specific employee, though interaction with and support from other employees was also noted. The structured observation notes make use of the facility maps to show patterns of movement around the ward. Structured observation sessions were timed to coincide with deliveries or vaginal exams and the focal staff member was chosen on the basis that they were ones who were delivering the baby or conducting the vaginal exam. Recording sessions were limited to 30 minutes because they demanded significant focus and involved substantial note taking.

Interviews: The interview topic guides themes were derived from the constructs in integrated behavioural theory (Eldredge et al., 2016), social norm theory (Bicchieri, Lindemans, & Jiang, 2014) and WHO hygiene guidelines (World Health Organization, 2009, 2015). Additional topics were added based on other hand hygiene studies as well as our observations of hygiene in the maternity wards. Interviews were conducted in Kiswahili by an experienced

Tanzanian social scientist with medical-training (CK), with supplementary support from a second Tanzanian interviewer.

Focus group discussions and the sepsis activity: Focus group discussion with birth attendants aimed at understanding beliefs about the causes of sepsis in a more indirect manner, as advocated by Aunger and Curtis (2015). Groups of birth attendants from four facilities were asked to consider risk factors for hypothetical newborn cord infection and to rank these in order of importance. If hand washing/rubbing was not mentioned spontaneously it was asked about by the facilitator. The focus group discussions also sought to understand the role of hygiene in birth attendant's conception of a "good nurse", a potential point of leverage in hygiene interventions.

Analysis: The interviews were audio-recorded, transcribed, and translated into English. The development of the themes and codes was a two-step process. First, all transcripts and observation notes were read by a minimum two authors and the initial themes and codes were developed through discussion and reflection. Then, using theory frameworks and notes from these initial discussions, MdB and JW compiled these codes and jointly applied them to a subset of five interviews. During this initial application of the codes, the definition, scope and number of the codes evolved. Once the broader team reached agreement on these new definitions, these codes were then applied to the remainder of the transcripts by either MdB or JW, with some minor modifications occurring throughout the process.

Our selection of *themes* within the data was informed by existing theory (Bicchieri et al., 2014; Eldredge et al., 2016), by our observations within the delivery rooms and labour wards, by the overall goal of the project (to develop interventions for preventing infection), and by the content of the interviews themselves. Thus, both code and theme development were informed by both theory and data, as well as by *in situ* observations and behaviour-change relevance.

Results

1. Overview of the four facilities.

Table 2 summarises the differences between the facilities. Broadly speaking, two facilities (1 and 4) had a higher volume of deliveries and were better equipped while two facilities had a lower delivery volume and poorer infrastructure and consumable supply (2 and 3).

Table 2. Overview of facilities, their infrastructure, and consumable availability.

	Facility 1	Facility 2	Facility 3	Facility 4
Births per month	350	74	95	400
Piped water	**Yes**	Daily interruptions	None for 7 days	**Yes**
Functional sink in delivery room	**Yes**	No	No	**Yes**
Elbow tap at nearest sink	**Yes**	No	No	Poor design**
Disposable drying towels	No	No	No	At one sink
Liquid soap	**Yes**	**Yes**	**Yes**	**Yes**
Hand gel	**Yes**	In store	No	**Yes**
Delivery sets `prepared	No	No	Often incomplete	**Yes**
Clean gloves	No	**Yes**	No	**Yes**
Sterile gloves	**Yes**	**Yes**	Sold in ward	**Yes**
Plastic delivery sheet	From mother	From mother	Sold in ward	From mother
Apron	**Disposable**	**Reusable**	No	**Disposable**
IPC committee	**Yes**	**Yes**	No	**Yes**
Perineum cleaning material	Kanga*	**Gauze**	Kanga*	Kanga*
Orderlies deliver babies	Yes	Yes	Yes	**No**
Sink inside the delivery room	**Yes**	**Yes**	No	**Yes**
Footsteps from hand-wash sink to delivery beds	**2 to 4**	7 to 13	15 to 17 (inc a door)	**5 to 8**
Footsteps from bed to hand-wash to gloves to bed	**8 to 13**	33 to 34	32 to 34 (inc a door)	**14 to 17**
Delivery beds	3	2	2	3
Birth attendants per shift	2 to 4	2 to 4	0 to 2	3

Notes: These data describe the facilities on the week of the visits. Births per month, infrastructural problems, and the availability of consumables will vary over time. * Multipurpose rectangular pieces of cotton brought by the mothers; one used as sheeting for the bed during delivery and another used for wrapping the new-born. ** The elbow-opening faucet was small and difficult to use. Facility characteristics which may facilitate relatively better hygiene or lower infection risk are emphasised in bold typeface.

2. How ward layout and organisation facilitates/impedes hygiene.

Appropriate hand hygiene prior to a procedure like a delivery or vaginal exam involves several steps. First, any sterile and clean equipment, including gloves and hand drying material, must be prepared and laid out such that it can be accessed without recontamination of the hands after handwashing. Then, hands are washed or rubbed with gel, dried if necessary, gloves are applied, and the procedure can begin. There were substantial differences between facilities in the degree to which the layout of the delivery room and the consumables imposed temporal, energetic, and cognitive barriers on this process. The layout of Facility 3 necessitated a 33-step round-trip, including a door, to get from patient to tap to gloves to patient. Few gloves were kept in the delivery room, and birth attendants often needed to make an additional 40-step journey to retrieve more from the store cupboard once the patient has purchased them from the staff member. The consequences of this layout were recognised by staff members, particular in facility 3 where the sink was outside the delivery room:

> "Maybe it is a challenge in our labour ward as you have to move here and there, but it could be simple to wash hands if the sinks could be there, so if you put a water sink it will help." (birth attendant, facility 3)
>
> "It would have been better if the taps were available in every ward, it would have helped very much to make someone not forget to wash hands. ... You [receive the infant with the] kanga even without wearing gloves; when your assistant comes to scan the cupboard for gloves you have already touched the head of the baby." (birth attendant, facility 3)
>
> "If the sinks are available in every room, one cannot leave aside washing hands. However, when the sinks are far, one starts to think of going from here to there so one sees some sort of a burden." (birth attendant, facility 3)

The same set of tasks in Facility 1 involved fewer steps (8 to 13, depending on the bed) – see Figure 1 - but nonetheless, hand hygiene infrastructure/consumables were not located close to each other nor were they arranged in the order in which they are typically used. Moreover, key hand hygiene resources were sometimes kept in different rooms where they were not visible: in Facility 2 and 3 there was no functional sink in the delivery room and in Facility 2 the hand gel was kept in a separate store room. Only in Facility 4 were the sink, soap, drying material (gauze), and gloves kept within five steps of each other.

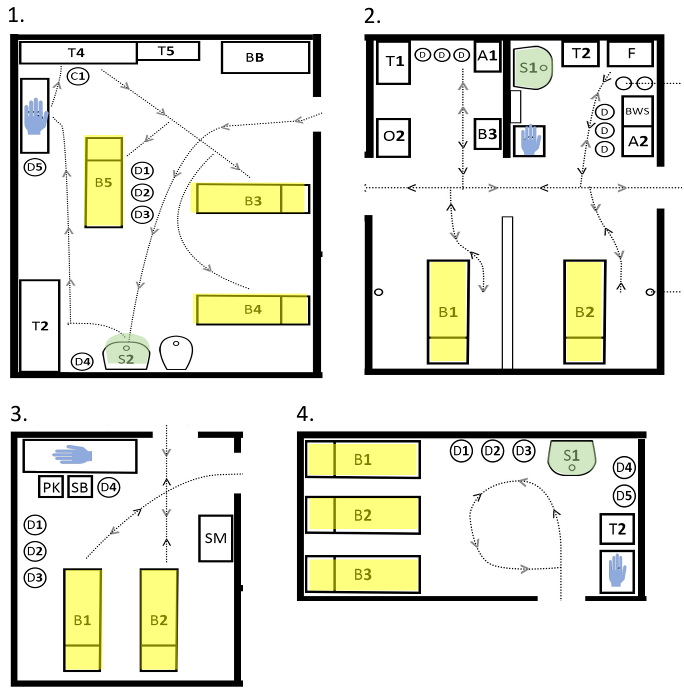

Figure 1. Layout of delivery rooms in facilities 1 to 4. *Yellow indicates delivery beds. Blue hands show where gloves are located; green indicates the nearest functional sink in use. Note facility 3 did not have access to water in the room (or building) at the time of visit. Lines indicate common paths around the delivery rooms. "D" indicates a decontamination buckets, "T" a table. Adjoining rooms typically have space for pre- and post-natal patients, toilets, autoclaves, and equipment storage.*

The ward manager in facility 1, a facility with better ergonomics, was sensitive to how the arrangement of sinks and other consumables can facilitate hygiene:

> "There should be enough hand washing stations, soap and paper towels should be available. There also should be a hand washing station at least after two to three patients' bed […] unnecessary movements will be reduced. […] [S]inks make it easy to remember to wash hands when observing patients." (facility 1 ward manager)

Note how the ward manager recognised the role of sinks act as physical reminders to engage in hand hygiene. Several birth attendants noted how the poor room organisation can be a particular impediment during periods of high cognitive load:

> "May be just the time, sometimes you are so busy it become difficult to go and find water and soap, you might find the mother is fully dilated and the baby is coming out, it becomes difficult to find the soap and wash hands in that situation" 001_MID_02

Facility 2 management's apparent lack of attention to ward organisation exemplified by a large machine (the size of a medium household fridge) of unknown function and origin which had resided in the labour room for "a long time".

Delivery kits include forceps and blades/scissors for cutting the umbilical cord, a ligature for tying the cord, gauze and cotton swabs. In facility 4 these were prepared in advance and wrapped with sterile cloth. This preparation might make the workload more manageable on midwives in the few minutes before a delivery, a critical time for hand hygiene. Facility 3 also prepared delivery kits in advance, but these were often incomplete forcing birth attendants to search for sterilised tools immediately before or during the delivery. Nurses described discovering mid-delivery that key components were missing. In facility 1 and 2, delivery kits were prepared once a woman was anticipated to deliver shortly. Pre-prepared delivery kits necessitate several full sets of equipment, and the ward manager of facility 2 listed equipment shortage as a reason delivery kits were not always available. Midwives in facility 4 noted the importance of a complete, convenient delivery kit for avoiding hand recontamination after hand hygiene:

> "Now if you do not have an assistant, you might take it if you draw that medicine and touch other things, sterility is broken, unless you prepare yourself with all the needed items on a tray close to the delivery bed". 004_mid_01

3. Consumables use, supply, and relevant attitudes and beliefs.

Soap and handwashing. Liquid soap bottles were present at least one sink in all of the labour wards during our observations. However, soap was not always available in the delivery room and birth attendants reported that liquid soap was absent for a few weeks at a time a few times a year, forcing the birth attendant to rely on cheaper powder soap which "dries your skin and cause irritation" (midwife, facility 1).

During observation periods, soap was typically used after "dirty" procedures where contamination with body fluids had occurred. In interviews, birth attendants often mentioned importance of hand washing after such procedures for protecting themselves and other mothers:

> "There are some women with infections and we as providers can't tell who it is. Therefore, in order not to infect yourself, when you remove gloves you have to wash your hands; and some gloves could be torn without you knowing so it is important to wash hands." [midwife, facility 4)
>
> "The importance of washing hands before is that it helps you to prevent the mother form infections so it is good to wash your hands, get rid of infection and then you go and do examination. When we talk of washing hand after a procedure it is important as it prevents you from acquiring infection form the mother and helps with personal hygiene." (midwife, facility 2]

Observation on the wards suggested that washing of hands *before* aseptic procedures was less common. During interviews, birth attendants described how such handwashing hand washing posed no major difficulty for them, with the exception of during emergency deliveries:

> "There are emergency situations in which one may forget to wash hands, like when a pregnant woman comes fully dilated in which you just wear gloves and assist her. But that doesn't happen all the time, most women come not fully dilated." [ADD SOURCE
> "Yes, it is important, one can wash your hands, dry them and then wear gloves especially when the situation allows, but when a woman arrives here fully dilated, one just wears gloves." [Orderly, facility 2]

However, when asked during the interview to estimate of the number of colleagues from 10 that washed hands before a delivery, responses ranged from 0 to 8, with many estimating that about half would wash hands before a delivery. Numeric estimates were similar for vaginal exams. Ward managers similarly understood hand hygiene was less than universal:

> "Up to five out of ten nurses can wash hands before a delivery… Eight to ten nurses could wash their hands after a delivery." [Hospital manager, facility 2].

Birth attendants explained this low compliance among peers as a consequence of laziness, lack of education, poor understanding of consequences, forgetfulness, negligence and, consistent with the quotes above, time constraints.

Gel hand sanitizer. Facility 4 was observed to make hand sanitizer and was the only facility where it was readily accessible and often used. While there were no religious concerns among the largely Muslim staff about alcohol gel use, there appeared to be some doubt about its relative effectiveness with birth attendants in other facilities describing it *as useful in an emergency* rather than as a viable replacement for water/soap before aseptic procedures.

Drying materials and hand drying. Wet hands are difficult to glove, and the sensation of wearing gloves over wet hands is unpleasant. During the observation periods, we noted that the absence of convenient, disposable hand drying materials created difficulty for the birth attendants. We observed air drying hands (which can take 15 seconds or more) and as well as the use of personal handkerchiefs, cotton gauze, or the front of the uniform to dry hands. Birth attendants mentioned that staff members do not wash hands before a vaginal exam “since they don’t have drying materials”.

Gloves and their use. During our observations, glove use during aseptic procedures was universal but contamination of gloved hands was common.

Birth attendants sometimes layed multiple pairs of gloves so that the inner layer remained relatively clean for a second procedure. This layering of glove use was observed in multiple facilities and described by multiple birth attendants. There were differences in when the top layer is removed. Contrast a birth attendant in facility 1:

> “Sometimes we put on 2 pairs of gloves at once, after receiving the mother, we take off the top pair and then receive the child”

who removed top layer before delivering the baby with another birth attendant who removed a layer before cutting the umbilical cord, a more common approach:

> “You are supposed to put on two pairs of gloves, use the first pair to deliver the baby and the second pair to cut the baby’s cord” (midwife, facility 3)

BAs also reported layering gloves so that they could efficiently attend to multiple patients.

Contamination of gloved hands through contact with potentially infective surfaces was common during observations. In interviews, birth attendants mentioned that potentially-contaminating with tables, drawer handles, the mother’s kanga, the injectable Pitocin, the drip, unsterilised Cheatle forceps, and syringe boxes, as well as the mother. Our observations notes illustrate the problems:

> While the woman is getting down the bed, the mackintosh falls down on the floor.
> Nurse A picks the mackintosh up with her sterile gloves on (while doing so, she is observed struggling not to touch the floor but she touches it a little bit)
> Nurse A asks woman A to get back on the delivery bed (DB). While woman A is getting back on the DB, nurse A holds the mackintosh (with her sterile gloves on) to prevent it from falling again on the floor. Nurse A also touches woman A's legs while assisting her to get back on the DB. Also unlike nurse A, nurse B does not seem to care much about not touching the woman or her surroundings, she touchers her clothes, the mackintosh without any precaution etc. she does not seem to try keep her hands away from things as nurse A does. Meanwhile, nurse A takes woman A's khanga and uses it to wipe her vagina several times.

Nonetheless, BA's sometimes go to some lengths to avoid contamination. In facility 4, for example, we observed the following:

> She puts on two pairs of sterile gloves and asks the mother to lay in a proper position. She uses the sterile gloves coverings to hold the mackintosh and put it properly (this was actually the first time seeing a birth attendant caring that much about not touching a mackintosh with sterile gloves).

A facility 4 birth attendants reported on how preparation can prevent glove recontamination:

> "[to avoid contamination] you have to prepare yourself well; when a mother is about to deliver before wearing gloves you put all equipment in place. We have folded the delivery sets on green towel so that each worker can use a set which is complete and not the set with missing equipment, this will avoid one from looking for thing unnecessarily."

Delivery surfaces: kanga and makintosh. Delivery bed were covered with a kanga – a multipurpose cotton rectangle – and a mackintosh – a plastic sheet during labour and delivery. These were both brought to the facility by the mother. Kangas were brought from home while mackintoshs were purchased them from nearby pharmacies. Selling mackintoshs to mothers on the ward was discouraged by managers who were concerned about the accusations that that the facility gained from such sales: “trouble comes in when she sells the things to a person who feels that the equipment is available but it is being sold to her”.

After the delivery the Kanga was used to clean the vagina/perineum in three of the four facilities (facility 2 used cotton gauzes). The use of an often-soiled kanga to clean the vagina after birth may pose a significant infection risk. After the placenta had been delivered, another kanga was sometimes used as a makeshift sanitary pad. A separate Kangas were also used to wipe clean and then wrap the baby after delivery.

4. Social and managerial influences on hygiene

Social norms and social sanctions. Birth attendants’ perceptions of hand hygiene rates before aseptic procedures were accorded with our own as well as with quantitative analysis presented elsewhere: they reported that hand hygiene compliance among colleagues was often low. Birth attendants also reported that negative consequences for those who do not handwashing were generally absent:

> Interviewer: “Have you heard of any complaints about health providers who do not wash hands before assisting women to deliver?”
> Facility 1 Orderly birth attendant: “I have never heard of such complaints, not only from here but from other hospitals as well, no woman has complained of being attended by a doctor who didn’t observe hand hygiene while assisting mothers during delivery”.

Sanctioning was seen by birth attendants as demeaning and childlike with one midwife in facility 3 reporting that “We do not give punishments because we are all adults, we just remind each other.” One midwife in facticity 3 hinted at how loyalty to one another precluded reporting poor hygiene:

> I: “Have you ever reported your colleague that he/she is not washing hands?”
> R:”There are no such customs and there is that habit of looking after one another.”

Indeed, in all facilities, we observed a notable degree mutual respect between staff members of different cadres. Senior staff members treated all staff, including orderlies, with politeness and kindness.

Most midwives denied that any kind of formal sanctioning for poor hand hygiene existed in their facility, but several mentioned “reminders”, which may act as a mild form of social sanctioning:

> I: “What do you think of them when you see [collegues who do not wash hand]?”
> Facility 3 midwife: “I usually tell them to wash hands according to the proper hand washing procedure to make sure that all the germs are killed…. We have to cooperate to push the wheel, those who were not following rules should follow those who adhere to the rules and learn. People do work but forget other things like hand washing so it is our responsibility to remind each other whenever we meet and whenever we work, if we get educated/training we will improve”.

However, other kinds of actions could result in sanctioning. This included destroying equipment, allowing relatives into the delivery room, or non-attendance and could be met with verbal or with a written warning or cancelled holiday/additional shifts. A minority of midwives as well as several managers advocated this kind of punishment for hand hygiene:

> “I would recommend that we decide to set some minor punishments for not washing hands accordingly. If the habit persists we can all decide to increase the punishment until a person really decides to change. If you have five days off, one of them is removed so that when you are at work during that day you will remember to wash hands.” (facility 4 midwife)

Facility organisation and management. Several managerial/organisational characteristics appeared to distinguish poorer performing facilities from better facilities. In facility 4, staff members were given specific tasks by their superiors (e.g., prepare six delivery kits) in the morning. In the other facilities the division of roles was less clear. The specificity of roles and the fact that named individuals took responsibility for their completion may have contributed to the better organisation observed in facility 4.

Another distinguishing feature of facility 4 was the “hands on” approach of the hospital manager. She was observed, for example, mopping the floor and engaging in other cleaning activities. In the interview, the manager described how she led by example. She also visited the maternity ward daily and relayed detailed observations on the quality of care to us. While it is difficult to gauge if the observed behaviour is representative, the midwives in that facility also noted that the facility management prioritised hygiene. This stands in contrast to other hospital managers who appeared to make more perfunctory visits to the maternity ward and who explicitly regarded hand hygiene as an issue for the staff members (asked if there are reminder for handwashing, a facility 3 ward manager responded: “*We do nothing; it is a person’s concern.”)* Facility 2 staff also noted that hand hygiene did not seem to be a major priority for the management mentioning that “I think [hand hygiene] is currently not of priority that is why they even don’t insist it during morning meetings”

Organisational features of facility 3 which may have impeded hygiene includes understaffing; there were no birth attendant in the maternity ward in the morning shift (a nurse come from the family planning unit if someone went into labour) and just one in the afternoon. Delivering a baby on one’s own is a significant logistical challenge, especially in a facility with poor layout. A birth attendant wishing to wash her hands before a delivery would need to leave the mother unattended for several moments. Moreover, the facility manager appeared to have little awareness of what was happening on the ground. For example, they appeared not to know that gloves were being sold on the premises. This was different from facility 4, where the hospital in-charge participated in cleaning tasks and had a thorough knowledge of issues on the ground.

Discussion

This study aimed to understanding the variation in hygiene and infection relevant behaviour in four facilities through a series of interviews and observations. We first review our main findings and explore their relevance for intervention and infection prevention and then examine the limitations and strengths of the study.

While the "essential" hygiene infrastructure was typically present, the physical organisation of different facilities appeared to impede or facilitate hygiene. Having soap, a functional tap, drying towels, gloves, and sterile equipment close to each other, close to the delivery bed, and laid out in the order in which they are used can facilitate hygiene in various ways. First, there is evidence that making frequent tasks *slightly* faster or easier can result in increased performance rate. Washing hands and donning gloves necessitated a 33-step round trip in facility 2; this degree of friction is likely to impede hygiene rated substantially. A second benefit of improved ward layout is that s*eeing* these objects in the right place at the right time can cue or remind one of the appropriate next step. This reduces the mental effort needed to execute the tasks since planning and searching in be "offloaded" onto the environment. Similarly, the provision of disposable handtowels may speed and ease hand hygiene. The importance minor improvements in the time or mental costs of hygiene should be seen in light of large number of hand hygiene opportunities each delivery presents. Findings from Salmon et al. (2015) resonate with this argument: an important barrier was poor access to functional sinks and relevant materials including hand towels. Results also are consistent with a systematic review (Erasmus et al., 2010) which found a positive association between hygiene and availability of materials in four of the seven samples studied.

The provision of hand gel may also constitute a relatively simple way to reduce the time costs of hand hygiene before aseptic procedures. However, while birth attendants understanding of the principles of infection prevention was typically good, some expressed scepticism about the effectiveness of gel. Attempts to increase the supply of gel may therefore be usefully accompanied with interventions targeting attitudes and beliefs about its value.

The two smaller facilities were less well-resourced for hygiene. This is consistent with a large survey of quality of maternal care across five countries, including Tanzania (Kruk et al., 2016). Quantitative analysis of hand hygiene before procedures in 10 facilities including these four also demonstrates that these smaller facilities had lower rates of hand hygiene before procedures (Gon et al., *2018*). One irony in our findings was that the better equipped and resourced facilities could afford to spend less. For instance, facilitates that ran out of cheaper "clean" gloves (.05 USD per set) were forced to rely on expensive sterile gloves (.8 USD per set) for tasks like emptying bins. Similarly, in facilities without economical paper towels, staff used more costly cotton gauzes to dry their hands. Better resourced facilities with functional and convenient taps and storage are likely to waste less staff time in long round trips. The high cost of being poorly resourced may help explain the marked variation in hygiene compliance across facilities.

One interesting challenge for behaviour change interventions in this context is that while management may find it difficult to assess hygiene compliance without spending long periods in the ward, birth attendants themselves are well aware of compliance rates. Social science literature suggests that such descriptive norms (i.e., one's beliefs about the others actions) has a strong influence on behaviour and this normative psychology will tend to make exacerbate problems in poorly performing facilities. Nonetheless, management led interventions involving audit and supervision seem effective (Rowe et al, 2005) and this study suggests that is some scope for improvement in facility organisation. Managerial interventions should be sensitive to the risk of demoralising or infantilising staff through inappropriate sanctioning however.

- There were several limitations to this study.
  - The coding and analysis of the transcripts was based on the English translation rather than the original Kiswahili, and some nuances were may have been lost during this translation.
  - Our presence in the facility is likely to have changed behaviour. Other evidence suggests researcher's presence alters hand hygiene in hospital contexts (Srigley et al 2014).
  - Social desirability biases are likely to have influenced responses in the interviews.
  - With just four facilities and a subset of people within each one, we cannot draw any firm conclusions about the causes of different hygiene rates. The problem is exacerbated by the fact that many of the "good" things were common in the better performing facilities (IPC committees, better management, better ergonomics).

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