An Evaluation of the Implementation of Routine Vaccination at GP Practice Level in England

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Declaration

I, Timothy Crocker-Buqué, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

[redacted]

Dr Tim Crocker-Buqué, 8th April 2019

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Abbreviations

ABC	Activity Based Costing
AD	Administrator
APM	Assistant Practice Manager
BCG	Bacillus Calmette–Guérin vaccine
BMA	British Medical Association
CCG	Clinical Commissioning Group
CCR	Capacity Cost Rate
CDVC	Care Delivery Value Chain
CHIS	Child Health Information System
CI	95% Confidence Interval
COVER	Cover of Vaccination Evaluated Rapidly
CQC	Care Quality Commission
CQRS	Calculating Quality Reporting Service
CRN	Clinical Research Network
CVD	Cardiovascular disease
DHA	District Health Authorities
DHSC	Department of Health and Social Care
DNA	Did Not Attend
DTP	Diphtheria, Tetanus and Pertussis combined vaccine
DTaP/IPV/Hib	Diphtheria, tetanus, pertussis, polio, *hamophilus influenza type b* vaccine
EoI	Expression of Interest
FCCR	Facility Capacity Cost Rate
GMS	General Medical Service contract
GPC	General Practitioners Committee
GP	General Practitioner
HCA	Healthcare Assistant
HPV	Human papillomavirus
HSCIC	Health and Social Care Information Centre
Hep B	Hepatitis B vaccine
Hib	*Hamophilus influenza type b* vaccine
HSCA	Health and Social Care Act
HV	Health visitor
JCVI	Joint Committee on Vaccines and Immunisations
Men ACWY	Meningococcal ACWY vaccine
Men B	Meningococcal Group B vaccine
Men C	Meningococcal Group C vaccine
MHRA	Medicines and Healthcare Products Regulatory Agency
MMR	Measles, mumps and rubella vaccine
MOV	Missed Opportunities for Vaccination
NHSD	National Health Service Digital
NHSE	National Health Service England
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NPT	Normalisation Process Theory
OECD	Organisation of Economic Cooperation and Development
OR	Odds Ratio
PARiHS	Promoting Action on Research Implementation in Health Services

PCV	Pneumococcal conjugate vaccine
PGD	Patient Group Direction
PHE	Public Health England
PM	Practice Manager
PMS	Personal Medical Services contract
PN	Practice Nurse
PPV	Pneumococcal polysaccharide vaccine
PSD	Patient Specific Direction
QOF	Quality and Outcomes Framework
QS	Quality Standard
R	Receptionist
RCN	Royal College of Nursing
RCT	Randomised Controlled Trial
SFA	Statement of Fees and Allowances
SFE	Statement of Financial Entitlements
SIL	Screening and Immunisation Lead
SIT	Screening and Immunisation Team
SCCR	Staff Capacity Cost Rate
SMS	Short Message Service (text message)
TDABC	Time-Driven Activity Based Costing
TPVT	Total Practice Vaccination Time
VPD	Vaccine preventable disease
WHO	World Health Organisation

1 Abstract

Background

There have been multi-year reductions in childhood vaccination coverage in England, with persistent low coverage in adults and urban areas alongside long-standing inequalities. The programme has become significantly more complicated and the overarching health system underwent a substantial reform in 2013. However, there has never been an evaluation of how GP practices implement delivering vaccinations nor an assessment of what factors may affect coverage, including the associated costs. Therefore, the aim of this study is to undertake an evaluation of the implementation of routine vaccination at GP practices in England.

Methods

Time-Driven Activity Based Costing was used to undertake a process evaluation and costing analysis, alongside semi-structured interviews to evaluate aspects of organisational sensemaking, in a geographically and demographically diverse set of GP practices.

Results

Nine practices completed data collection and 52 staff participated in 26 interviews. Information relating to 372 vaccination appointments was captured using activity logs. Childhood vaccination mean appointment length was 15.9 minutes (range 9.0-22.0 mins) and 10.9 minutes for adults (range 6.8-14.1 mins). There is a high administrative component, comprising 59.7% total activity (48.4-67.0%). The mean cost of a childhood appointment was £18.20 (range £9.71-£25.97) and an adult appointment cost £14.05 (range £7.59-£20.88). Appointment length and total time was not related to coverage; whereas increasing capacity may improve coverage. Most practices exhibited either fragmented or minimal sensemaking, characterised by low levels of leadership sensegiving, which may limit the ability of larger practices to modify programme delivery to improve coverage.

Conclusions

Reimbursement is likely to meet costs associated with the programme, however there is potential to improve the funding mechanism. Practices are isolated and lacking information on performance and support to make programme improvements. Greater strategic leadership at national and practice level and better coordination between professional groups could build on high levels of intrinsic motivation among staff to improve programme delivery.

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3 Introduction

This thesis presents a study evaluating how routine vaccinations are delivered through GP practices in England. The study was undertaken within the National Institute for Health Research (NIHR) funded Health Protection Research Unit in Immunisation, a joint research centre hosted at the London School of Hygiene and Tropical Medicine (LSHTM) in collaboration with Public Health England (PHE), the executive agency for public health of the UK government's Department of Health and Social Care (DHSC). The study is situated entirely within the English National Health Service (NHS) structures and includes consideration of all vaccines routinely delivered by GP practices, but excludes vaccinations given outside of a practice (e.g. at a school), non-routine vaccines (e.g. travel) and seasonal vaccines (influenza). In this introduction I will first provide a brief overview of the structure of this thesis and then move on to an introduction to the vaccine programme in England.

3.1 Thesis structure

This thesis is presented as a research paper style thesis with published papers integrated into the body of the text. In this introduction I provide a history of the provision of vaccinations to the population in England, then describe the current system following the implementation of the reforms as part of the 2012 Health and Social Care Act (HSCA), and finally examine some of the epidemiological data relating to coverage in England. Then I report the results of a scoping review, which is supplemented by two research papers: the first reporting the results of a document analysis to develop a logic model for the vaccine programme in England with a systematic review of interventions to increase coverage undertaken in an England context; and the second reporting the results of a systematic review of interventions to reduce inequalities in children and adolescents. The next chapter reports the methodology, study design and data collection methods. The results are reported in two research papers: one reporting a process evaluation of how the routine vaccination programme is implemented at GP practices in England; and the second analysing the costs associated with programme delivery. These are followed by the results of the qualitative analysis. The discussion then brings the elements of the results together for synthesis and development of policy recommendations.

3.2 History of vaccination in England

Edward Jenner published his findings relating to the protective effects of inoculation with cowpox against smallpox disease in 1798 and, despite some professional and public opposition, vaccination swiftly became widespread by the early 19th Century (Lakhani, 1992; Wolfe and Sharp, 2002). As a result of the growing recognition of the beneficial effects of vaccination at preventing infectious disease, the first Vaccination Act legislation was passed by the UK government in 1840 and made smallpox vaccinations free for new-born infants (Wolfe and Sharp, 2002). This Act was amended in 1853 to make vaccination compulsory – parents were given a blank certificate by the local registrar and they had to return with it completed by a medical practitioner or 'public vaccinator of the district'. If they failed to do this, parents faced a fine or imprisonment, which generated both immediate protests and longer-term public campaigns of resistance. The legislation was again updated in 1867 to integrate vaccination activities within the responsibility of the Boards of Guardians, local committees of landlords formed through the Poor Law Amendment Act of 1834, who administered local workhouses. The poor law guardians then became responsible for ensuring their local population had been vaccinated and provided a reimbursement for public vaccinators of between 1 and 3 shillings per child. The law continued to evolve over the course of the late 19th century as new vaccines became available, including those for typhoid (1896) and cholera (1900s) (PHE, 2015a). Due to increasing public anger and widespread anti-vaccination sentiment, compulsory vaccination resulting in penalties was abolished in 1898 (Wolfe and Sharp, 2002). With improvements in technology many new vaccines emerged in the first half of the 20th Century, including against diphtheria (1942), Bacillus Calmette–Guérin (BCG) vaccine against tuberculosis (1948), tetanus (1956), pertussis (1957), measles (1968) and rubella (1970) (Leese and Bosanquet, 1992).

3.2.1 Vaccination delivery in the National Health Service

From the late 19th Century onwards vaccinations were given in multiple locations, including child welfare clinics run by local government organisations, community health-visiting services, and in schools. These routes were particularly important for children whose families could not afford to visit a General Practitioner (GP) for vaccination, as this was very costly and insurance schemes were largely limited to employed adult males and their families (Leese and Bosanquet, 1992). Following the substantial restructure of the health system with the formation of the NHS in 1948, GPs started taking on a greater role in vaccinating the local population for which they were now responsible, and by 1964, around 50% of smallpox vaccinations and 75% diphtheria vaccinations were being given by GPs (Leese and Bosanquet, 1992). Prior to 1965 GPs were paid by Local Authorities for meeting pre-specified thresholds when they submitted records for childhood vaccinations. However, in 1965 a fee payment system was introduced to reimburse them for providing vaccinations as part of the 'Family Doctors' Charter'. The reimbursement amounts were detailed in the Statement of Fees and Allowances (SFA), otherwise known as 'The Red Book' regulations (BMA, 2014).

Following negotiations that began in 1986, a new contract for GP practices was agreed and implemented in 1990, for which the government's aim was to widen the range of services offered by GP practices and also to improve quality of care (Silcock and Ratcliffe, 1996). Improvements in quality of care were designed to be incentivised by a system of tying remuneration more directly to performance. The fees set out in the SFA 'Red Book' regulations for childhood vaccination were abolished and the amounts paid to practices were rolled into a 'Global Sum' capitation payment for 'health surveillance' of children under 5 years old. At the same time, a new system of payments was introduced if practices reached pre-specified targets – a lower payment at 70% coverage and a higher payment for 90% coverage – which placed the responsibility of achieving high levels of vaccination coverage in the hands of GPs. By 1990 the routine schedule consisted of eight vaccination events for immunisation against eight infectious diseases, all targeted at children or adolescents (Table 1 adapted from (Leese and Bosanquet, 1992)).

Age	**Disease(s)**	**Vaccine**
2 months	Diphtheria, pertussis, tetanus (DPT) & polio	DPT & oral polio
3 months	Diphtheria, pertussis, tetanus & polio	DPT & oral polio
4 months	Diphtheria, pertussis, tetanus & polio	DPT & oral polio
2 years	Measles, Mumps & Rubella (MMR)	MMR
School entry	Diphtheria, pertussis, tetanus & polio	DPT & oral polio
Girls aged 10-14	Rubella	Rubella
10-14 years	Tuberculosis	BCG
Leaving school	Tetanus, polio	Tetanus & oral polio

Table 1: the routine vaccination schedule in England in 1990.

The delivery of vaccines remained split between GPs and District Health Authority (DHA) clinics that were often delivered in in schools, leading to uneven levels of coverage depending on how well local services were coordinated. For example, Diphtheria, Tetanus and Pertussis combined vaccine (DTP) and oral polio were mainly given by GPs and health visitors; whereas rubella and BCG were given by the school health service via DHAs, and MMR was provided by both (Leese and Bosanquet, 1992). This led to a situation in the mid-1980s where more than 13 professional groups had some responsibility for vaccinating children with limited coordination and data sharing between organisations (Nicoll, Elliman and Begg, 1989). In order to improve coordination and clarify responsibility local immunisation coordinators were introduced. The financial incentives were successful in increasing the level of vaccination activity undertaken at GP practices and coverage increased relatively rapidly as practices employed increasing numbers of nurses to undertake health promotion activities (Rivett, 2018). The role of DHAs and their successor organisations in delivering vaccinations diminished through the 1990s as GP practices undertook more and more vaccination activity.

A new contract for GP practices, the General Medical Services (GMS) contract, was negotiated in 2003 and implemented in 2004 (NHS Employers, 2014). This contract remains in place and is modified annually through negotiations between the General Practitioners Committee of the British Medical Association (BMA) and the DHSC. The GMS contract moved from a system of funding GPs as individual practitioners to funding GP practices as organisational entities and increased the funding available for primary care services. It also introduced the Quality and Outcomes Framework (QOF), a pay-for-performance scheme that remunerated practices based on hitting targets for certain activities or outcomes (Gillam and Steel, 2013). The aims of this new contract were to develop and implement a new incentive system, that could be modified to improve GP practice performance in specified areas over time; increase autonomy of practices in designing and delivering services to their local population; and to allow a greater range of provider organisations to deliver NHS services, no longer bound to individual GPs (Peckham, 2007). It was hoped that any resulting increase in funding resulting from the contract would increase coverage of GP practice services and also be used to improve practice infrastructure, including the use of modernised IT systems to meet the data requirements of the QOF targets. The new contract had wide ranging effects on GP practice organisational structure, including in relation to the delivery of public health services. It changed the focus of some activity in GP practices from general clinical service delivery to maximising potential income by meeting targets, and one significant aspect of this was a greater role for practice nurses in delivering services that were newly incentivised by the QOF system (Peckham and Hann, 2008). Practices also increased the number of administrators they employed, particularly those responsible for managing the increased role of the new IT systems, and created divisions in responsibilities amongst practice staff between those who had responsibility for monitoring performance targets and those who primarily provided the clinical services (Checkland *et al.*, 2010). The increased role for practice nurses was generally viewed as positive, but this was also associated with a significant increase in workload and a perception of ‘box ticking’ activity, with less time spent with patients and the potential erosion of the relationship between nurses and their patients (McGregor *et al.*, 2008).

3.2.2 The Health and Social Care Act 2012

The most recent substantial change to NHS structure and function was the Health and Social Care Act (HSCA) 2012, which was implemented in April 2013, and aimed to put *“clinicians at the centre of commissioning, [and to] free up providers to innovate, empower patients and give a new focus to public health”* (DH, 2018). Aside from modifications to the way GP practices were remunerated, the vaccine programme delivery system had remained relatively stable since the late 1990s. However, the HSCA entirely changed the vaccine programme superstructure. The Health Protection Agency, a non-departmental public body responsible for health protection and communicable disease control, together with other national and regional public health organisations, including the public health laboratory services, were combined and moved into government to become Public Health England (PHE), an executive Agency of the Department of Health and Social Care. In the old system, Primary Care Trusts (PCT), housed in NHS organisations, were responsible for commissioning primary and secondary health services for local areas and provided some community health services directly. However, the HSCA dissolved PCTs and the majority of their commissioning functions were moved into new Clinical Commissioning Groups (CCGs). CCGs are led by local GPs and commission most primary and secondary care services for a local area, including elective and emergency hospital care, as well as mental and community health services. Local public health functions were moved from into new public health departments within local government organisations, including the provision of smoking cessation, drug and alcohol, and sexual health services. A new executive, non-departmental public body called NHS England (NHSE) was established which oversees the commissioning activity of CCGs, holds the GP contract and commissions specialised services on a national level.

Currently, the DHSC sets vaccine policy in collaboration with PHE. This policy is informed by additional evidence and recommendations from the Joint Committee on Vaccines and Immunisations (JCVI), an expert advisory group that has existed since 1977. NHSE then contracts GP practices to deliver the routine vaccination programme via the GMS contract (with a smaller number of practices contracted through an alternative Personal Medical Services contract). NHSE also provides regional screening and immunisation teams (SIT) to support programme implementation locally. On a national level there is a tripartite oversight group with representation from DHSC, PHE and NHSE to manage all elements of the programme. The roles and responsibilities of each organisation for selected aspects of the vaccine delivery system that are relevant to this project are displayed in Table 2 . Local Authority Public Health Departments and CCGs also have some local oversight for service quality, as does the Care Quality Commission (CQC), which is the national health services regulator. The complexity of this system and the required legal and contracting structure has been further explored in the paper presented in section 4.3, where a logic-model has been developed to describe this more clearly.

In this system the majority of vaccines are given at GP practices, including all primary vaccinations and boosters for infants and children, and all vaccines in adults, including the seasonal influenza campaign, which are funded through the GMS contract. A smaller number of influenza vaccines a provided through community pharmacies. Adolescent vaccines are mainly delivered through school nursing services, which are provided by Local Authorities. Health visitors are specialist community public health services who undertake community outreach activities. They do not give vaccinations but have a role in encourage vaccine uptake and since 2015 have been commissioned by Local Authorities.

Vaccination system component	GP Practice	Local Authority Public Health Departments	Screening and Immunisation Teams (local PHE/NHSE)	NHS England (NHSE) nationally	Public Health England (PHE)	Department of Health and Social Care (DHSC)
Vaccine Supply & Logistics	Takes stock of delivery and monitors cold storage before administration. Orders stock of seasonal influenza vaccine.	-	-	-	Supply planning and ordering of most vaccines from pharmaceutical companies. Responsible for ordering, storing and distribution to GP practices through logistics system. Manages national vaccine stock.	Provides PHE with the budget to procure vaccines.
Service delivery	Delivers most vaccines to a defined population, including all primary vaccinations to children and routine vaccinations to adults, including the seasonal influenza programme.	Provide school nursing programmes, which provide vaccinations to adolescents. Commission health visiting services with responsibility for encouraging uptake during home visits.	-	Contracts and funds GP practices to deliver the national vaccine programme.	-	Responsible for setting policy for national immunisation programme.
Surveillance	Enters data onto local electronic health record and submits data to data collection and aggregation systems. Responsible for reporting vaccine preventable diseases (VPD) to regional PHE teams.	Oversight of local vaccine programme delivery.	Monitoring of local and regional levels of coverage using routine data sources.	Commissions the Child Health Information Systems, to which GPs submit data for analysis. Monitors quality of primary care practices.	Regional Health Protection teams responsible for managing outbreaks of VPDs. Monitors VPD incidence, vaccine coverage and impact. Publishes national vaccine coverage reports. Supports outbreak response.	Commissions research into vaccine preventable diseases.

Advocacy and Communication	Responsible for reminder/recall system. Can display patient information and leaflets. Can develop local partnerships with Local Government and other agencies.	-	Providing advice and materials to GP practices.	Updates GPs on changes to vaccine schedule, together with PHE	Advises on the development of promotional materials for campaigns in some circumstances.	Advises government on vaccine policy.

Table 2: showing the roles and responsibilities of local and national organisations in the delivery of the routine vaccination programme in England for selected components of the vaccine delivery system.

A detailed qualitative study evaluating the impact of such a significant re-organisation was published in 2016, which involved interviews with 19 national-level decision-makers and 56 grassroots staff responsible for delivering the vaccine programme (Chantler *et al.*, 2016). Vaccination as a discreet programme area did not feature highly as a priority within the restructure, and, as a result, the system has become highly fragmented, with new ambiguity introduced due to the lack of clarity around roles of the new organisational entities. This was described by participants as being *"fractured"* and as a *"complex mesh"* that had required significant amounts of organisational and individual effort to manage, as vaccination was *"the bit that didn't fit"* into the reformed health structures.

3.3 Current vaccination schedule

Over the last 20 years there has been an explosion of new vaccine development. With the progressive addition of new agents, the schedule (during the data collection activities in 2017) involved 16 childhood, 2 adolescent and 3 adult vaccinations (PHE, 2017d, 2018b). This is shown along with the modifications made in 2018 in Table 3.

Age	**Disease(s)**	**Vaccine (Trade name)**	**Notes, including schedule changes implemented during the study period.**
8-weeks	Diphtheria, tetanus, pertussis, polio, *Hamophilus influenza type b* (Hib)	DTaP/IPV/Hib (Pediacel or Infanrix IPV Hib)	Changed to Infanrix Hexa, with Hepatitis B (Hep B) included in 2018.
	Pneumococcal (13 serotypes)	Pneumococcal Conjugate (PCV) (Prevenar 13)	
	Mengicoccal group B (MenB)	MenB (Bexsero)	
	Rotavirus	Rotavirus (Rotarix)	
12-weeks	Diphtheria, tetanus, pertussis, polio & Hib	DTaP/IPV/Hib (Pediacel or Infanrix IPV Hib)	Changed to Infanrix Hexa, with Hepatitis B (Hep B) included in 2018.
	Rotavirus	Rotavirus (Rotarix)	
16-weeks	Diphtheria, tetanus, pertussis, polio & Hib	DTaP/IPV/Hib (Pediacel or Infanrix IPV Hib)	Changed to Infanrix Hexa, with Hepatitis B (Hep B) included in 2018.
	MenB	MenB (Bexsero)	
	Pneumococcal (13 serotypes)	PCV (Prevenar 13)	
1 year	Hib & MenC	Hib/MenC booster (Menitorix)	
	Pneumococcal 13	PCV Booster (Prevenar 13)	
	Measles, mumps and rubella (MMR)	MMR (VaxPRO or Priorix)	
	MenB	MenB booster (Bexsero)	
2 – 6 years	*Influenza (seasonal)*	*Live attenuated influenza vaccine (LAIV) (Fluenz Tetra)*	*Seasonal vaccine - excluded from this study*

From 3 years 4 months	Diphtheria, tetanus, pertussis & polio	DTaP/IPV (Infanrix IPV or Repevax)	
	MMR	MMR (VaxPRO or Priorix)	
Females 12 – 13 years	*Human papillomavirus (HPV)*	*HPV (two doses 6 to 24 months separated) (Gardasil)*	*Usually given in school - excluded from this study unless given in the GP practice.*
14 years	*Tetanus, diphtheria & polio*	*Td/IPV (Revaxis)*	*Usually given in school - excluded from this study unless given in the GP practice.*
	Meningococcal groups A, C, W & Y	*MenACWY (Nimenix or Menveo)*	*Usually given in school - excluded from this study unless given in the GP practice.*
65 years	Pneumococcal (23 serotypes)	Pneumococcal polysaccharide (PPV) (Pneumovax II)	
> 65 years	*Influenza (seasonal)*	*Inactivated influenza vaccine (strain dependent)*	*Seasonal vaccine - excluded from this study*
70 years	Shingles	Shingles (Zostavax)	
Condition	**Disease(s)**	**Vaccine (Trade name)**	**Notes**
Pregnancy	*Influenza (seasonal)*	*Inactivated influenza vaccine (strain dependent)*	*Seasonal vaccine - excluded from this study*
	Pertussis	dTaP/IPV (Boostrix-IPV)	From 16 weeks gestation
Various underlying medical conditions	Meningococcal Pneumococcal Influenza Hepatitis A&B HiB	Various	Patients with a wide range of medical conditions (asplenia, diabetes, respiratory, neurological) are eligible for a range of vaccines

Table 3: the 2016-2017 Routine Vaccine Programme in 2016-2017 with schedule changes in 2018 (PHE, 2017, 2018)

The age-range of patients targeted by the routine programme has also increased, with the addition of new vaccines (e.g. HPV vaccine in adolescents), as well as targeting existing vaccines to new age groups (seasonal influenza in 2 to 6-year-old children), alongside the addition of new agents in existing age groups (MenB, shingles, rotavirus, MenACWY). This has added to the complexity of the programme and the amount of time required at GP practices to deliver the vaccinations, both in terms of the number of appointments required, but also the amount of time it takes to discuss and consent patients for each injection.

3.3.1 Included and excluded vaccines

This study is concerned with the routine vaccination programme, i.e. all those vaccinations recommended by Public Health England for the population groups specified in the Routine Immunisation Schedule and The Green Book, as detailed in Table 3 (PHE, 2017a, 2018b). This includes the primary course of vaccinations given at 8, 12 and 16 weeks, childhood boosters and MMR given at 1 year and pre-school, vaccinations given to eligible older people and those in specific clinical risk groups (e.g. pregnant women or people with underlying medical conditions), which can be given at any time during the year when a patient becomes eligible. This study is also specifically concerned with the role of GP practices in delivering vaccinations, therefore vaccinations given by services or in locations other than GP practices are excluded, including most adolescent vaccines, which are given in schools (unless they are given in a GP practice). Non-routine vaccinations, i.e. those given as a result of specific circumstances and not to the eligible population as a whole, are excluded. The two main groups of vaccines in this category are travel vaccines (those given to people who are travelling abroad) and those given as a result of a specific outbreak of infectious disease in a local population. These are provided for endemic diseases in countries other than the UK, or for localised epidemic disease within the UK, rather than focussed on reducing circulation of endemic microbials in the whole population in England, which is the purpose of the routine programme.

The only routine vaccination that is excluded from consideration by this study is seasonal influenza vaccine in children, older adults and pregnant women. Most seasonal influenza vaccine is given at GP practices, however activity is focussed during influenza season from September to March, with high concentrations of activity in September and October. It has been excluded for several reasons: firstly, the seasonal campaign has a different service delivery structure to the routine programme; secondly, due to the resource constraints of this project it is not possible to coordinate data collection activities at multiple GP practices within a short time period; thirdly, it is an extremely resource intensive activity for practices, making data collection significantly more challenging; fourthly, the funding arrangements for seasonal influenza are different and GP practices procure their own vaccine for this programme; and finally seasonal influenza programme delivery is relatively well studied already, however lessons from this evidence base have been compared to routine programme delivery throughout this thesis.

3.3.2 Funding

Payment to GP practices for undertaking vaccination activity remains organised through the GMS contract, with some of the payment amounts detailed in a separate document called the Statement of Financial Entitlements (SFE) (NHS England, 2013). The contract contains four sources of funding for practices for delivering the routine vaccination schedule (BMA, 2014)

1. The Global Sum: a continuation of the capitation-based payment derived from the SFA ‘Red Book’ regulations and rolled over from the 1990 contract. This covers a wide range of services offered by practices, including the basic costs of most routine childhood vaccinations. In practice, vaccination is not itemised separately within the sum received by a practice. However, if a practice decided to opt-out of offering vaccination services between 1% and 3% of the total global sum payment would be deducted from the total.
2. Threshold and timeliness payments (Table 4): these apply to a selection of primary childhood

vaccinations (mostly the older vaccines), with a lower payment made for coverage above 70% and a higher rate for coverage above 90%, alongside an additional payment if a child is vaccinated within 3 months of becoming eligible.

3. Fee-for-service payments (Table 4): these are available for newer childhood vaccines, the two routine adult vaccinations (pneumococcal polysaccharide and shingles) and pertussis in pregnant women. These are described as ‘Enhanced Services’ within the GP contracting system and this is also the mechanism through which the seasonal influenza campaign is remunerated.
4. Quality and Outcomes Framework: additional payments are available via the QOF pay-for-performance scheme, however during the study period the only vaccines included in QOF targets were influenza uptake in people with coronary heart disease, stroke, diabetes and chronic obstructive pulmonary disease, and thus excluded from this study (NHS Employers, 2016).

Vaccine(s)	**Doses and age(s) given**	**Item of service payment 2016-2017 (2018 change). Per dose, unless otherwise stated.**	**Other payments**
Diphtheria, Pertussis, Tetanus, Polio, *Haemophilus influenzae b, hepatitis B*	3 doses (2, 3 & 4 months)	-	Target payment thresholds: >70% standard payment, >90% extra payment. Additional payment if vaccinated within first 3 months of eligibility.
Measles, Mumps & Rubella	2 doses (1 year & 3 years 4 months)		
Diphtheria, Pertussis, Tetanus, Polio booster	1 dose (5 years)		
Hepatitis B (at risk children)	3 doses (new-born, 1 month, 12 months)	(£10.06)	-
Meningococcal B	3 doses (2, 4 and 12 months)	£9.80 (£10.06)	-
Rotavirus	2 doses (6 weeks and 6 months)	£9.80 for both doses (after second dose only)	-
Pneumococcal Conjugate	3 doses (2 months, 4 months and 1 year)	£15.02 for whole course (after third dose only)	-
Pertussis	Pregnant women (1 dose)	£9.80	-
Measles, Mumps and Rubella	Unvaccinated people over 16 years	£9.80 (£10.06)	-
Meningococcal ACWY	1 dose (18-25 years)	£9.80 (removed)	-
Pneumococcal Polysaccharide	1 dose (At-risk patients and aged 65 and over)	£9.80	-
Shingles	1 dose (Ages 70 and over)	£9.80 (£10.06)	-

Table 4: selected routine childhood and adult routine vaccinations and conditions for reimbursement to GP practices. (From the General Medical Services Statement of Financial Entitlements.

In 2016-2017 NHSE paid GP practices £227 million through this system for activity related to vaccination (excluding QOF payments and global sum reimbursement), comprising £94 million for the childhood vaccination programme, £106 million for influenza and pneumococcal, £11 million for rotavirus and shingles, and £16 million on meningitis vaccination programmes (NHS Digital, 2018d). Through the annual contract negotiation process the fee-for-service payment has been incrementally increasing over time, from £7.64 in 2013 to £10.06 in 2018, a 32% increase in 5 years.

3.4 Vaccination Coverage

The important question remains as to how well this system performs overall. Coverage is the proportion of eligible people known to have been vaccinated with a recommended agent and achieving high levels of coverage across the UK has long been a focus of the vaccination programme. Current levels of vaccination coverage across England are generally high, however there are some emerging trends that may indicate challenges in maintaining high coverage levels alongside persistent inequalities present between certain population groups and geographies, with longstanding challenges in achieving desired levels in some geographic regions, particularly inner city areas with high levels of deprivation (Leese and Bosanquet, 1992; White *et al.*, 1992).

3.4.1 Routine vaccine data collection and reporting

PHE is responsible for collecting and reporting statistics related to the routine vaccine programme and uses two main information systems (Table 5). Firstly, Cover of Vaccination Evaluated Rapidly (COVER) collects data for most vaccinations in children aged under 5 years old. GP practices, and other providers of vaccinations, collect and report these vaccine data to regional Child Health Information Systems (CHIS), which are local population level registers of children (Edelstein *et al.*, 2017). Data at this stage are aggregated and used by NHSE as the Unify2 data set for performance management purposes. The CHIS entries are submitted to PHE for cleaning and evaluation and the production of quarterly and annual coverage reports for most routine childhood immunisations. Due to the multi-layered nature of this system, data collection and processing errors are often reported that can undermine data quality on local level.

Secondly, for vaccines delivered to people over the age of 5, the seasonal influenza programme and some of the newer childhood vaccines (such as rotavirus), data is collected via the ImmForm platform. Data relating to vaccination events are extracted directly from GP practice records and aggregated nationally, which is a much more rapid system. However, it does rely on accurate coding in electronic health records and does not include all GP practices (about 5% do not participate), nor un-registered children. Further information on these data sources is presented in table 4 in the methods section.

	COVER	Unify2	ImmForm
Routine vaccinations included	DTaP/IPV/Hib MenC Rotavirus Hib/MenC PCV MMR	DTaP/IPV/Hib MenC Rotavirus Hib/MenC PCV MMR	Influenza PPV Shingles Prenatal pertussis HPV Rotavirus MenB MMR
Denominator population	Children in local authority areas (including unregistered) aged 12 & 24 months, and 5 years.	Children in local authority areas (including unregistered) aged 12 & 24 months, and 5 years.	Dependent on each vaccine, as many are age (e.g. >65) or health status (e.g. pregnant) specific.
Data collection process	Data reported to Child Health Information System (CHIS) is then reported to PHE for analysis.	Data aggregated from GP practices within CHIS accessed by NHS England for analysis.	Data extracted from GP IT systems and aggregated. Some data e.g. from schools' programmes added manually.
Reporting frequency	Quarterly & Annual	Not publicly available	Weekly (seasonal flu) Monthly (prenatal pertussis) Annually (HPV)
Geographic area of reporting	Reported for Local Authority area	Used by NHSE at CCG level and GP practice level for performance management.	National level Regional team level CCG level LA level SITs can access GP practice level data.
Data quality	May include children who have moved away, but not been removed from the system. This may lead to underestimations of coverage. Less accurate in older children.	Unverified data, known to be incomplete.	Variable completeness for different vaccines and timeframes. Known issues with identifying denominator populations using health status Read codes (e.g. pregnancy).

Table 5: showing characteristics of the three main sources of data relating to the routine vaccination programme in England

The most recent national report on vaccination statistics notes quality issues that have affected these data systems in recent years, as well as the challenges of comparing data sets following the 2013 NHS reorganisation (HSCIC, 2015). COVER data have been shown to be inaccurate in some cases, resulting in under-reporting vaccination coverage. A study in Coventry from 2006 showed how there were significant differences in the statistics reported through the COVER system to those collected by the local finance department (Lyon *et al.*, 2006). A previous evaluation of the impact that health service reorganisation had on the accuracy of data reported to the COVER system conducted in 2006 showed how changes in data management and reporting may cause under-estimations of vaccine coverage (Granerod *et al.*, 2006). However, a similar evaluation has not been conducted following the implementation of the HSCA in 2013.

3.4.2 *Childhood coverage*

Long-term trends of average coverage for childhood vaccines in England are shown in Figure 1 (NHS Digital, 2018b). The blue line shows the trend of completion of three doses of diphtheria containing vaccine by 1 year (completion of a course of ‘primary immunisations’) the 2017 formulation of which was DTaP/IPV/Hib (Pediacel or Infanrix IPV Hib), with Hep B added for 2018 (Infanrix Hexa). The orange line shows coverage of one dose of MMR vaccine by 2 years old.

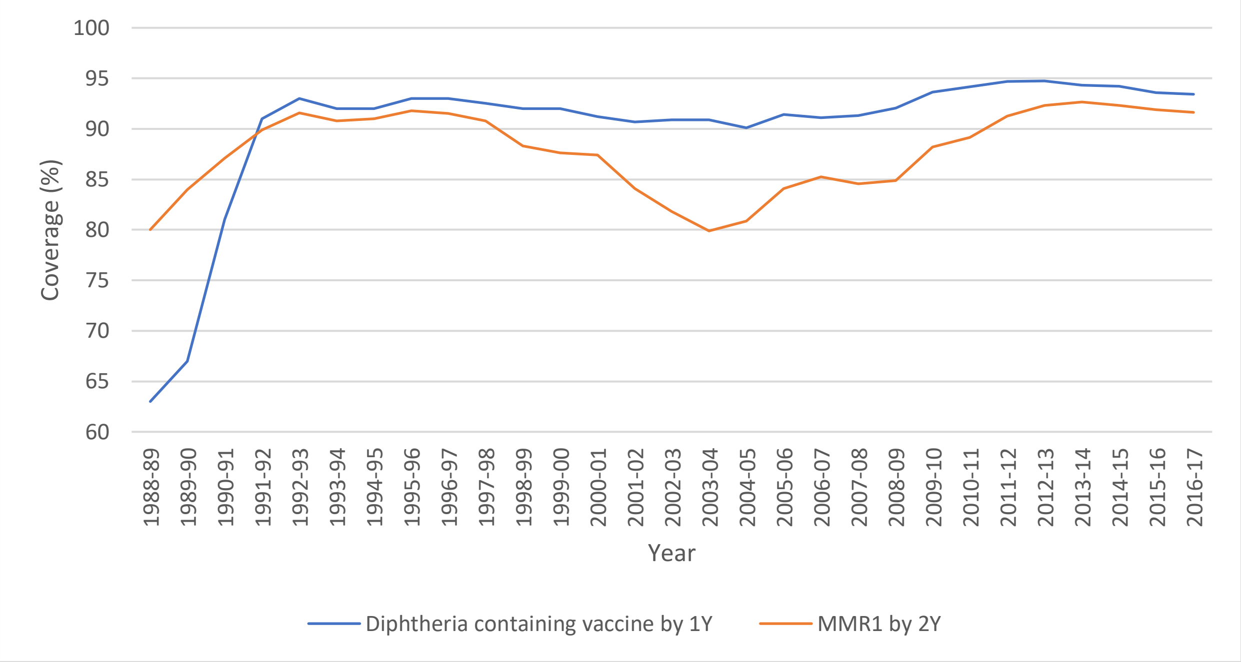

Figure 1: coverage of complete course of diphtheria containing vaccine (primary immunisations) by 1 year and one dose of MMR vaccine by 2 years in England between 1988 and 2017 (NHS Digital, 2018b).

Completion of the course of primary immunisations has been relatively high (>90%) since the early 1990s. There was a slight decrease in the early 2000s to a low of 90.1% in 2004-05, which recovered to a high of 94.7% in 2011-2013, however since then there has been four consecutive years of decline with coverage in 2016-17 standing at 93.4%. In the wake of the controversy resulting from the Lancet paper by Wakefield et al. that erroneously linked MMR vaccination to autism (Horton, 2004), MMR coverage of 1 dose by 1 year reduced from 91.8% in 1996-96 to a low of 79.9% in 2003-04. This then recovered to a high of 92.7% in 2012-13, before seeing three consecutive years of declines to 91.6% in 2016-17.

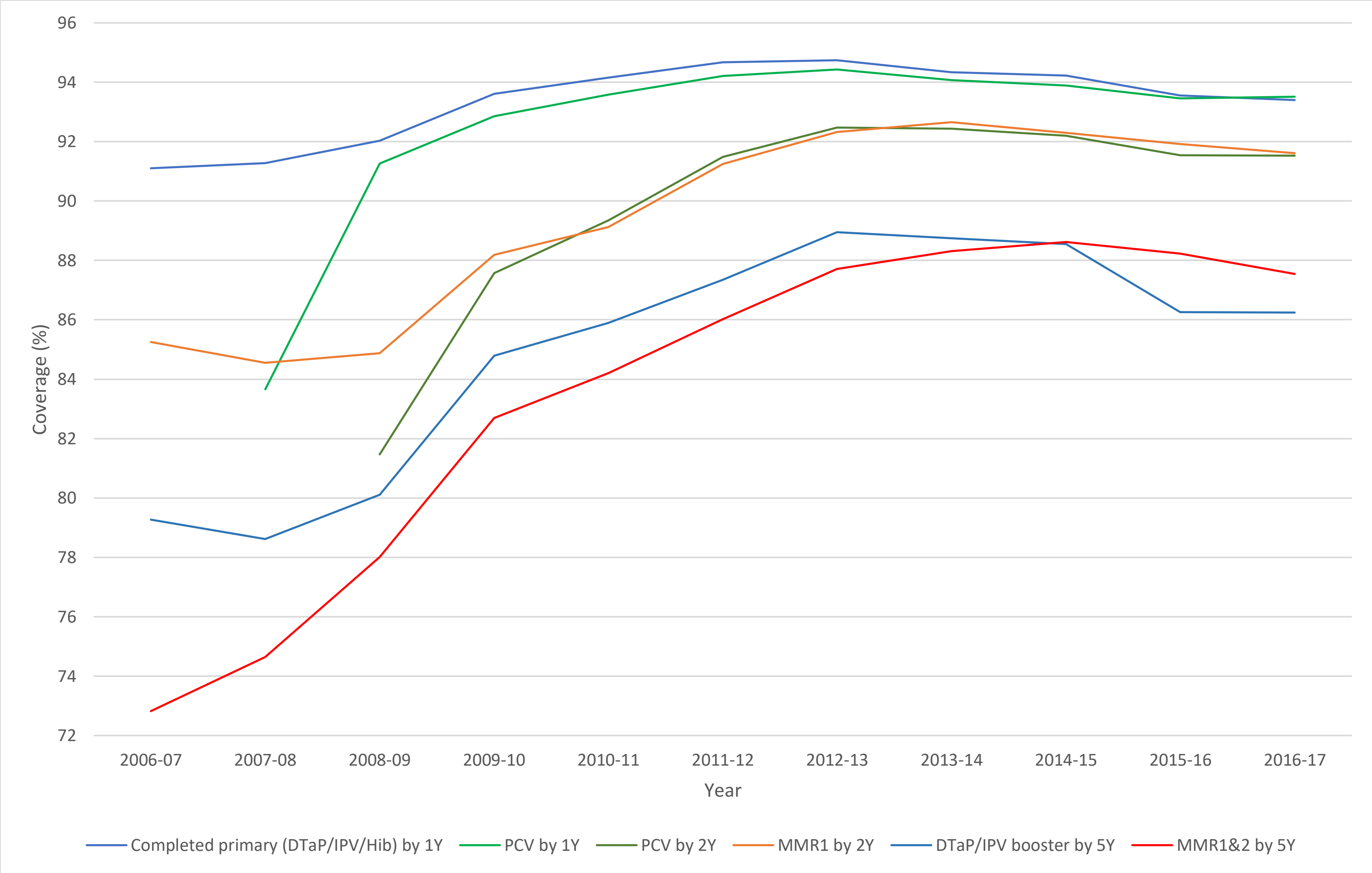

Figure 2: coverage of vaccines due between the ages of 1 and 5 years in England between 2006 and 2017.

There have been multi-year decreases in coverage across most childhood vaccinations between 2012-13 and 2016-17. Figure 2 shows that peaks of coverage were observed in 2012-13 for completed primary immunisations (DTaP/IPV/Hib) at 1 year (94.7%), PCV by 1 year (94.4%), PCV by 2 years (92.5%), and DTaP/IPV booster at 5 years (88.9%), all of which have declined for four consecutive years. Similarly, MMR1 by 2 years peaked at 92.7% in 2013-14 and has declined to 91.6% in 2016-17 and MMR1&2 have declined slightly in the last two years from 88.6% in 2014-15 to 87.6% in 2016-17.

Geographic variation exists in regions across England, with significantly lower coverage in London. Figure 3 shows the difference in coverage between the England and London averages for completion of primary immunisations, with London being 1.4% lower on average between 2010 and 2017.

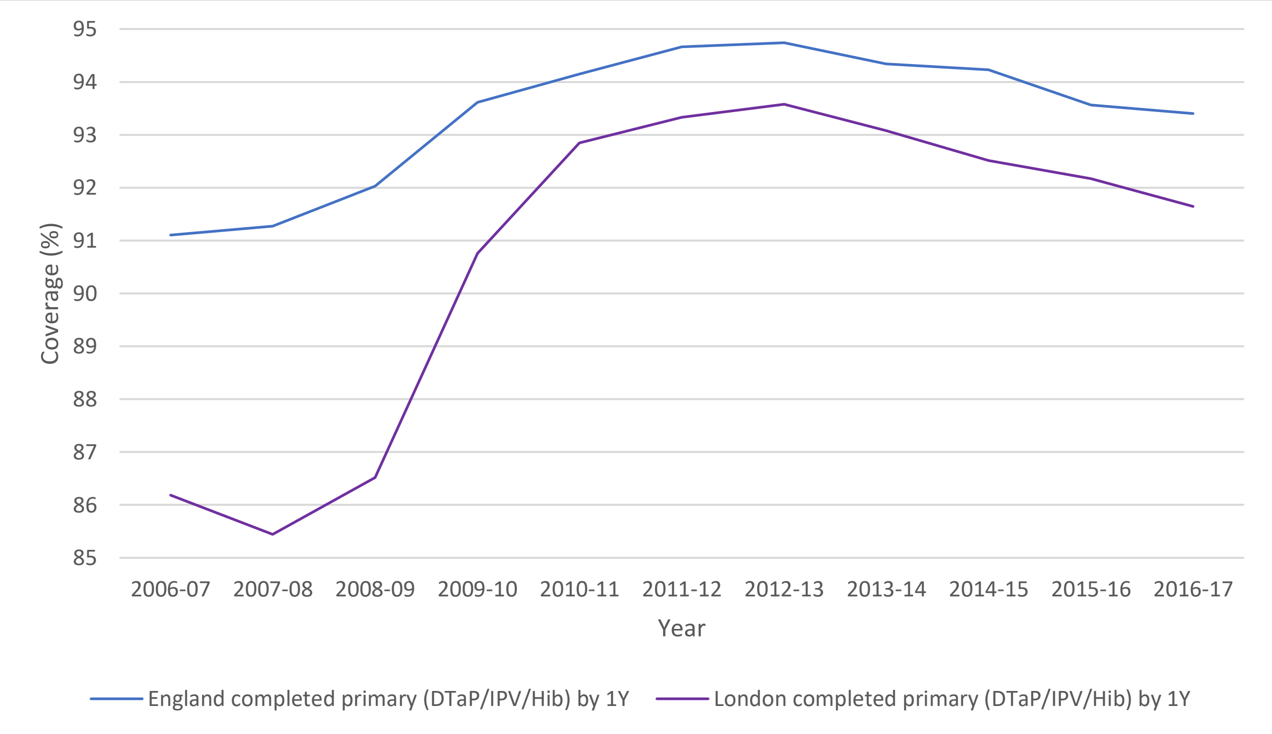

Figure 3: England and London average coverage of completed course of primary vaccines (DTaP/IPV/Hib) by 1 year (1Y) between 2006 and 2017.

This difference is more starkly delineated for MMR1 coverage by 2 years as shown in Figure 4, where the mean difference in coverage between London and the England average between 2006 and 2017 was -6.7%, and -9.6% when compared to the best performing region (North East).

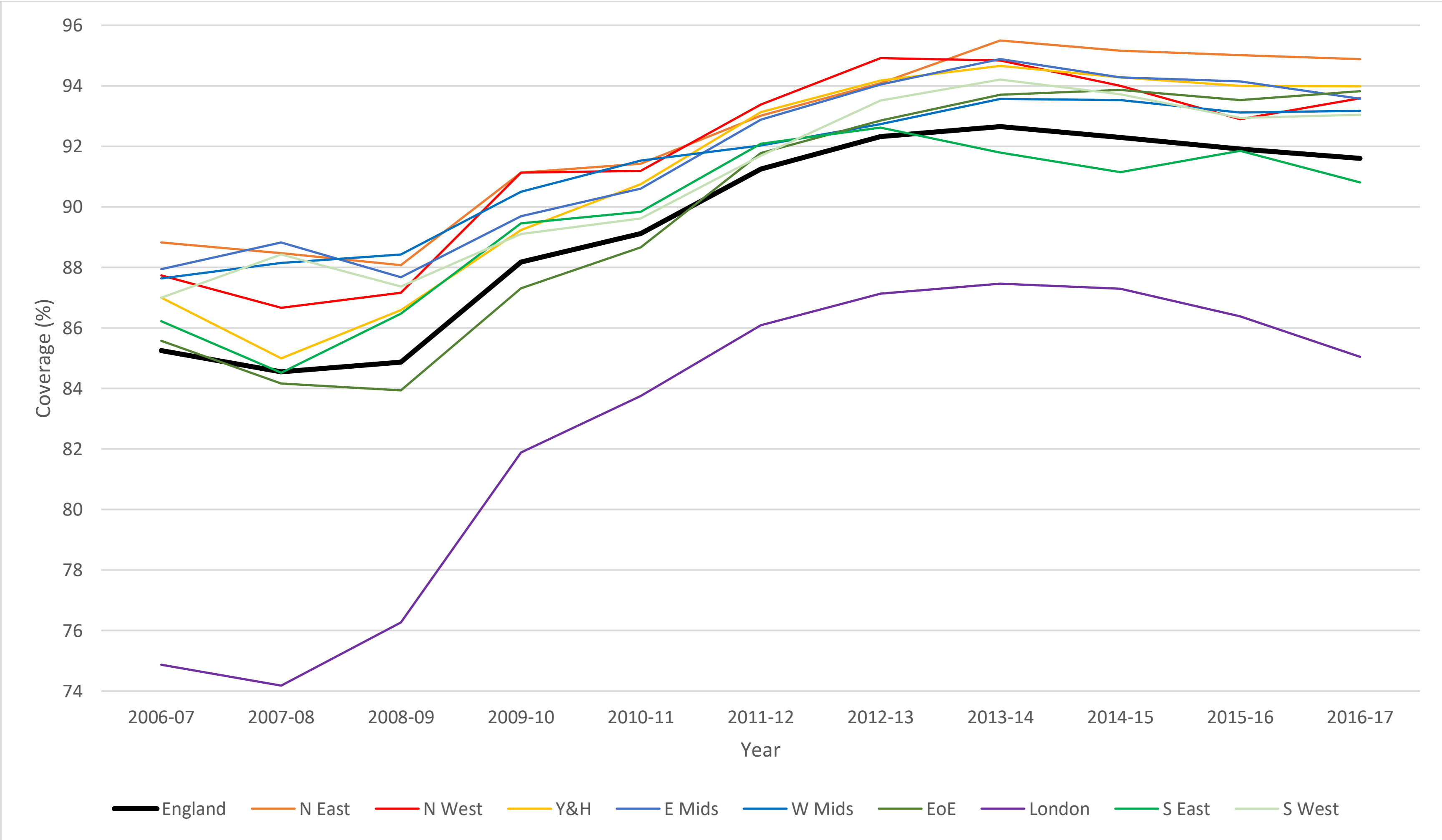

Figure 4: coverage of one dose of MMR vaccine by 2 years showing England average against average coverage across regions of England from 2006 to 2017. (N =North, Y&H = Yorkshire and Humber, E Mids = East Midlands, W Mids = West Midlands, EoE = East of England, S = South)

Figure 5 (below, from the Health and Social Care Information Centre 2015 report on vaccination coverage) shows the geographic variation in England in more detail, with the data displayed at Local Authority level (HSCIC, 2015). The concentration of lighter colour local government regions (equating to lower coverage) are clustered around London and the south East.

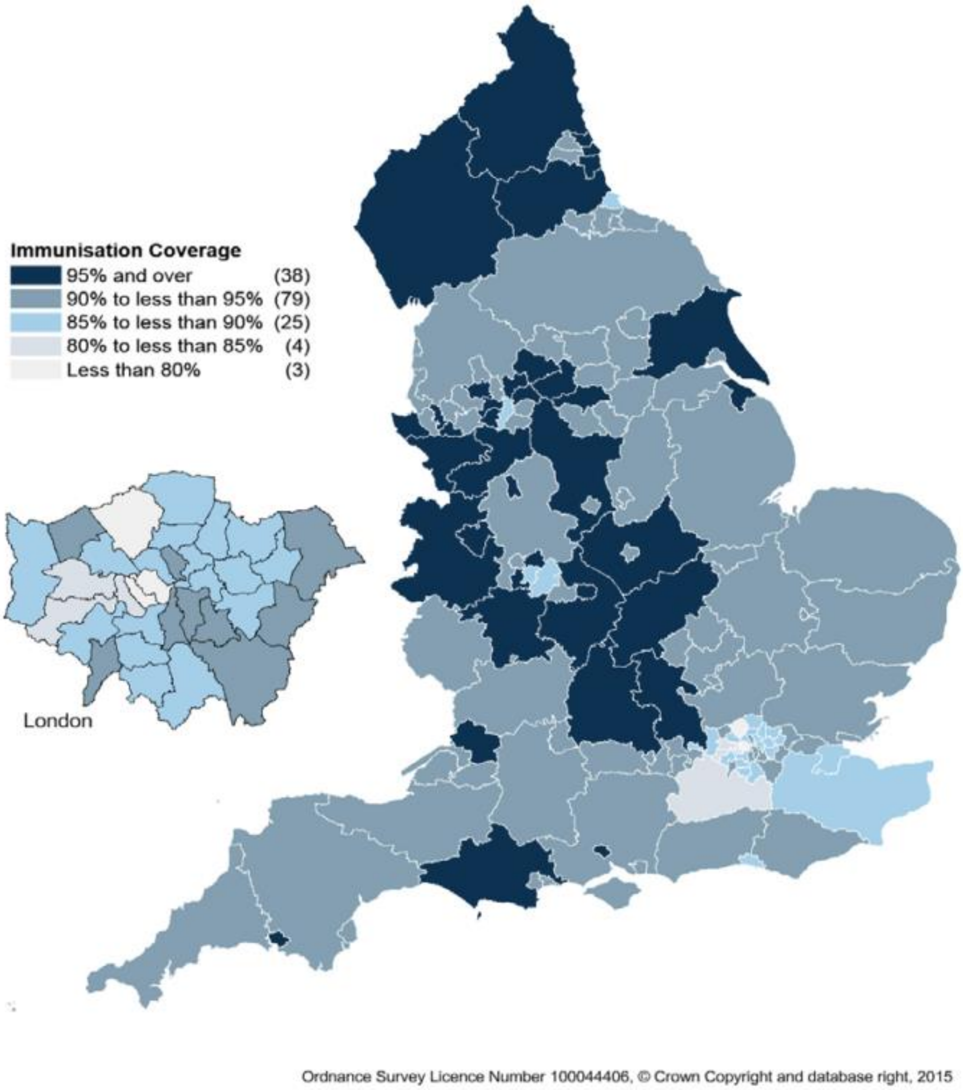

Figure 5: coverage of MMR at 2 years by upper tier local authority, from HSCIC 2015.

At this level, even starker differences in coverage become apparent. For example, DTaP/ITP/Hib coverage at 1-year ranges from 98.4% in South Tyneside (North East region) to 78.6% in the London Borough of Enfield. London generally has the worst performance overall – MMR coverage at 2 years was less than 90% in 17 boroughs, less than 85% in a further three and less than 80% in the worst three performers, as shown in Figure 5 (HSCIC, 2015).

Other socio-economic factors, such as ethnicity and deprivation, are not routinely reported from COVER or ImmForm data, in part due to quality issues, so any differences seen in groups are identified using special samples or through non-routine analysis of routine data. However, where the data quality is reliable enough, it appears that vaccination coverage is higher in the White British population than in minority ethnic groups. For example, data collected on the implementation of HPV vaccine showed lower coverage in minority ethnic groups (PHE, 2014). In 2009 the National Institute for Health and Care Excellence (NICE) published a review of the effectiveness of interventions to reduce differences in vaccine coverage in specific groups and highlighted that children living in areas with more overcrowding and greater deprivation had a higher risk of contracting meningococcal and pneumococcal meningitis; that ante-natal rubella vaccine had lower uptake in women from minority ethnic groups, in whom rubella incidence was higher; and that a range of socio-economic factors, including income and education, had evidence for affecting coverage (NICE, 2009). The association of deprivation with lower coverage has persisted since the 1980s, although was found to not be universally the case, with some districts with high deprivation also achieving high coverage (Begg and White, 1988). These issues are investigated further in the review of the literature in 4.2.4 and 4.2.6.

3.4.3 Adult coverage

Three non-influenza vaccines given to adults are included in this study: pneumococcal polysaccharide vaccine (PPV) given to people aged over 65 years, shingles vaccine given to people over 70 years, and pertussis vaccination given to pregnant women from 16 weeks gestation. Data on coverage are collected monthly through the ImmForm system.

PPV was introduced for people aged over 65 years in 2003. Mean coverage across England for eligible people aged over 65 years who have ever received PPV is 69.5% in 2018, ranging from 48.2% in the London Borough of Kensington and Chelsea to 78.1% in Knowsley (North West region) (PHE, 2018h). This has remained relatively stable since 2007, although slight declines in coverage have been seen in the last two years (now 0.6% lower than 2014-15). Shingles vaccination was started in September 2013, with an additional catch-up campaign in people over 78 years. Coverage is low, but relatively equal across areas of England. Total cumulative mean coverage 2013-2018 in the 70-year-old cohort is 41.0%, ranging from 37.1% coverage in Merseyside to 46.3% in West Yorkshire, and 42.0% in the 78-year-old catch-up cohort, ranging from 33.0% in Essex to 46.6% in East Anglia (PHE, 2018i).

Vaccination against pertussis for pregnant women in England was started in October 2013 in response to a national outbreak. Recording of pregnancy and gestation age in GP practice electronic health records is relatively poor, which makes identifying the eligible denominator for reporting of coverage challenging. The annual mean estimated coverage in 2017 was 71.9%, ranging from 56.2% in London to 79.7% in Yorkshire and Humber region (PHE, 2018f).

3.4.4 *Vaccine preventable disease*

Fortunately, outbreaks of Vaccine Preventable Diseases (VPD) remain rare in the UK, largely as a result of the high coverage achieved by the vaccine programme. The annual totals of some common childhood VPDs are presented in Figure 6, derived from notifiable disease data from PHE (PHE, 2018e). Of note is the relatively recent rise in the number of measles cases in both 2007-09 and again in 2012-13, as well as the large outbreak of mumps in 2004-05 and moderate rise in 2009, although both have since reduced. There has also been a recent increase in the number of pertussis cases starting with the outbreak in 2012. Diphtheria, tetanus and, more recently, rubella have become increasingly rare.

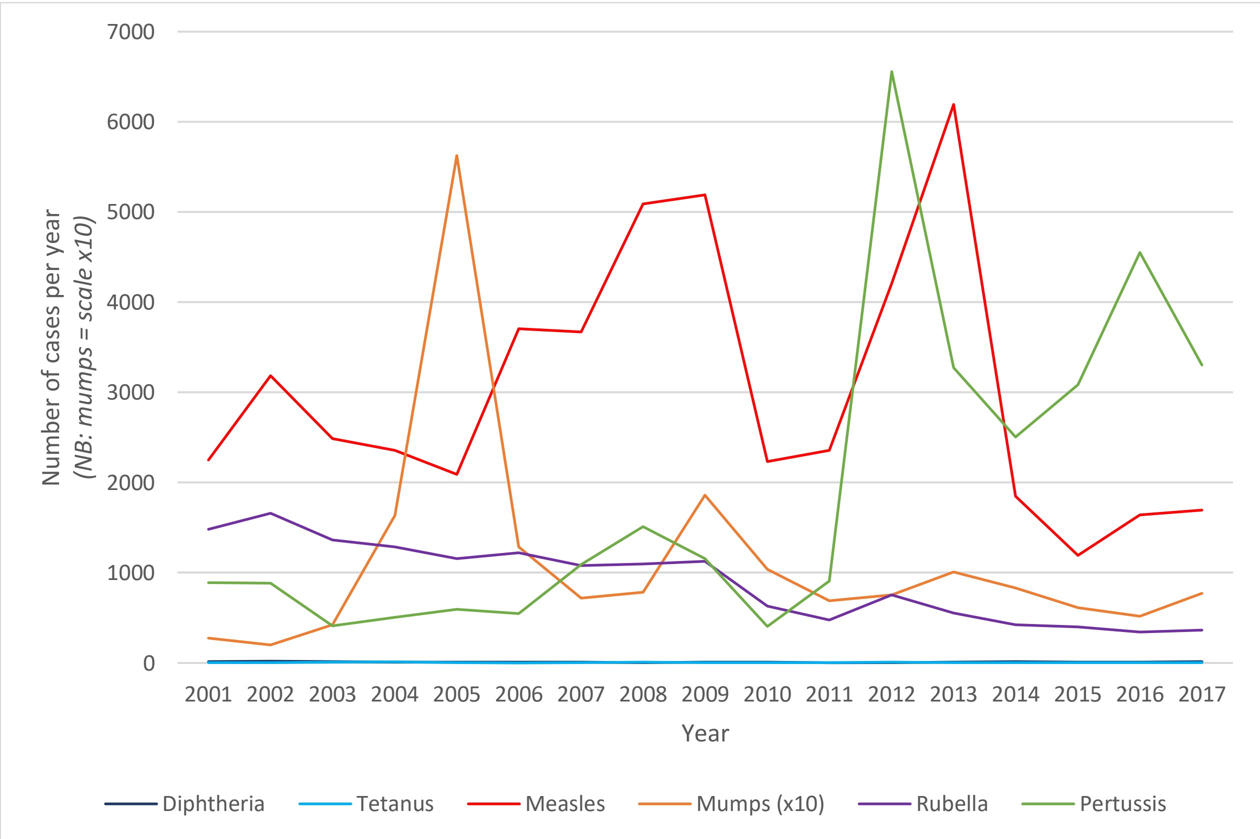

Figure 6: annual number of cases of vaccine preventable diseases in England 2001-2017, from (PHE, 2018e)

It is too soon to evaluate whether the ongoing reductions in annual coverage levels are contributing to increased circulation of VPDs, however continued reductions below population level immunity thresholds create the possibility for increased disease circulation. This is particularly important in the context of the large ongoing measles outbreak across European countries with nearly 15,000 cases reported in 2017, with large numbers of cases in Romania, Italy, Germany and France (ECDC, 2018), as well as the outbreaks in 5 areas of the UK in 2017-18, including Leeds, Liverpool and Birmingham (PHE, 2018c).

Laboratory isolates of *streptococcus pneumoniae* are referred to the PHE reference laboratory for analysis, creating a database of serotypes. There is some complexity in relation to evaluating the impact of the vaccination programme on pneumococcal disease, as children were initially vaccinated with PCV covering 7 serotypes (Prevenar 7) in 2006, which reduced disease incidence from PCV7 serotypes by 86% in all ages groups (Waight *et al.*, 2015). However, there was a subsequent rise in strains not covered by this vaccine and so it was switched to PCV covering 13 serotypes (Prevenar 13) in 2010 (PHE, 2018g). PPV covering 23 serotypes was added to the schedule for people over the age of 65 in 2003, however it has more limited effectiveness (Moberley *et al.*, 2013). When compared to the pre-PCV7 data (2000-06), incidence of invasive pneumococcal disease reduced 56% from 15.63 cases/100,000 population to 6.85/100,000 in 2013-14 (Waight *et al.*, 2015), with higher rates found in the over 65s (20.58/100,000) (Chalmers *et al.*, 2016). This translated into a reduction of admissions to hospital of children with pneumococcal disease as recorded in Hospital Episode Statistics, with relative reductions between 2004 and 2015 of 34% in children under 2 years, although there was no decrease in pneumococcal pneumonia admissions in older adults and an increase was observed overall in admissions of older people with unspecified pneumonia (equating to 250,000 cases) (Thorrington *et al.*, 2018). In 2015 there remained 1.7 million admissions for pneumonia, of which 30,500 had *streptococcus pneumoniae* confirmed as the cause, along with nearly 8,000 cases of pneumococcal sepsis.

The rate of hospital admissions associated with *herpes zoster* between 2004-2013 was found to be 8.8/100,000, equating to nearly 42,000 hospital days, and costing the NHS £13m annually (Hobbelen *et al.*, 2016). Before the introduction of shingles vaccine in 2010, incidence was estimated to be 7.1/1,000 person-years in the 75-89 age group. Following vaccine introduction there was a reduction of 35% in incidence (17,000 fewer cases), with an even greater reduction (50%) of the main complication of shingles infection – post herpetic neuralgia (3,300 fewer cases) (Amirthalingam *et al.*, 2018). Therefore, there is the potential for greater health benefits if coverage was higher in this population.

3.5 Rationale, aims and objectives

Over the course of last decade, the vaccination programme in England has become significantly more complicated, with a wider range of vaccines being delivered to a more diverse range of population groups. There has been a significant restructuring of the over-arching organisation and policy architecture, while GP practices remain relatively autonomous service providers. The funding arrangements have undergone evolutionary change and remain opaque, with a mixture of reimbursement mechanisms, while at the same time the overall negotiated payments have been increasing, due to claims of increasing costs at general practice level. This is partly due to inflationary pressures and in response to concerns raised by GP practices that reimbursement did not adequately fund the complexity of the programme, particularly as no specific reimbursement is provided for administrative activities. This is at the same time as an increasing overall workload, with demand for GP consultations up 15% between 2010 and 2015, alongside a contemporaneous reduction in real terms available funding of 0.4% over the same period (Baird *et al.*, 2016). From the nadir in the wake of the MMR crisis, coverage of childhood vaccines increased steadily from 2003 to 2012, but coverage of many vaccines has since reduced over the last three or four years. Coverage of vaccines in adult populations remains relatively low and stagnant. Geographic inequalities in coverage, particularly in London also remain.

In 1997 Watkins wrote in the BMJ of the UK's seasonal influenza vaccination campaign, which could reasonably apply to the administration and delivery of the vaccination programme as a whole: "*the present system… relies on the idiosyncratic behaviour of individuals with minimal central guidance, no mechanisms to ensure effective targeting of vulnerable groups and no link between remuneration and performance"* (Watkins, 1997). Things have improved somewhat since then, with better data collection and monitoring systems, clearer contracting and payment arrangements and better policy direction and oversight, however there remains an element of truth in the comment, with GP practices able to design their own systems and processes, and well recognised challenges in reducing inequalities in coverage. However, there has never been an evaluation of how the routine vaccination programme is implemented at GP practice level in England, nor an assessment of what factors may affect levels of coverage achieved by individual practices, including the costs associated with the programme to GP practices.

Therefore, the overall aim of this study is to evaluate how GP practices implement organisation and delivery of routine vaccination and develop hypotheses as to what factors may be associated with coverage.

The specific objectives of this this study are to:

1. Identify, describe and evaluate the evidence for interventions to improve coverage and reduce inequalities in vaccine coverage relevant to the context in England.
2. Describe and evaluate how GP practices organise the implementation of routine vaccination.
3. Identify and evaluate the factors that are associated with differences in coverage between GP practices in different contexts.
4. To make recommendations as to how implementation of the routine vaccine schedule at GP practices in England could be improved to maximise coverage.

4 Literature Reviews

To identify and describe the existing literature I initially undertook a broad scoping study. In the anticipation that there would be a great volume and diversity of studies (in terms of design, interest, temporality, geography, vaccine agents, subjects and contexts) the purpose of this was not to systematically aggregate, synthesise and evaluate the existing literature, but instead to uncover the overall scope and volume of available literature and identify areas for more systematic investigation.

4.1 Scoping review method

The method for the scoping review follows the recommendations by Colquhoun et al., (Colquhoun *et al.*, 2014). The following databases were searched: Medline, ASSIA, Campbell Collaboration, Cochrane Database of Systematic Reviews, Embase, Eppi Centre, Psych Info, Web of Science, SCOPUS, Social Policy and Practice, Health Systems Evidence, Health Management Information Consortium. Four main categories of search terms were used, and included all relevant MESH terms for the chosen database:

i) Vaccination OR immunisation (and related spellings)
ii) AND health services delivery, programme elements and coverage
iii) AND primary OR community care settings
iv) AND country limitations (OECD countries)

An example of the search strategy is presented in appendix 9.1.

For the purposes of the scoping review, the inclusion criteria were as follows:

- Studies conducted in high income (OECD) countries
- Published in English
- Evaluating the delivery of a routine vaccine programme, or an intervention to support the delivery of a routine vaccine programme, with coverage as the outcome
- Conducted at primary or community care level
- Using any interventional, quasi-experimental, observational or ecological study design
- These were not restricted by date of publication and included studies published up to November 2015.

However, to bring the evidence up-to-date for the purposes of this thesis, the systematic review evidence has since been updated to November 2018 using the same method above.

In reporting the results of the scoping review, I have primarily focussed on studies conducted in the UK, however, have supported this with evidence from systematic reviews that are relevant to the UK context and other studies from OECD countries that are of particular significance to this project. I have used a framework derived from process evaluation elements to organise the results into the following four categories:

1. Resources
2. Organisational factors
3. Activities and outputs
4. Population factors

4.2 Results

The flow chart showing the process of study selection is presented in Figure 7.

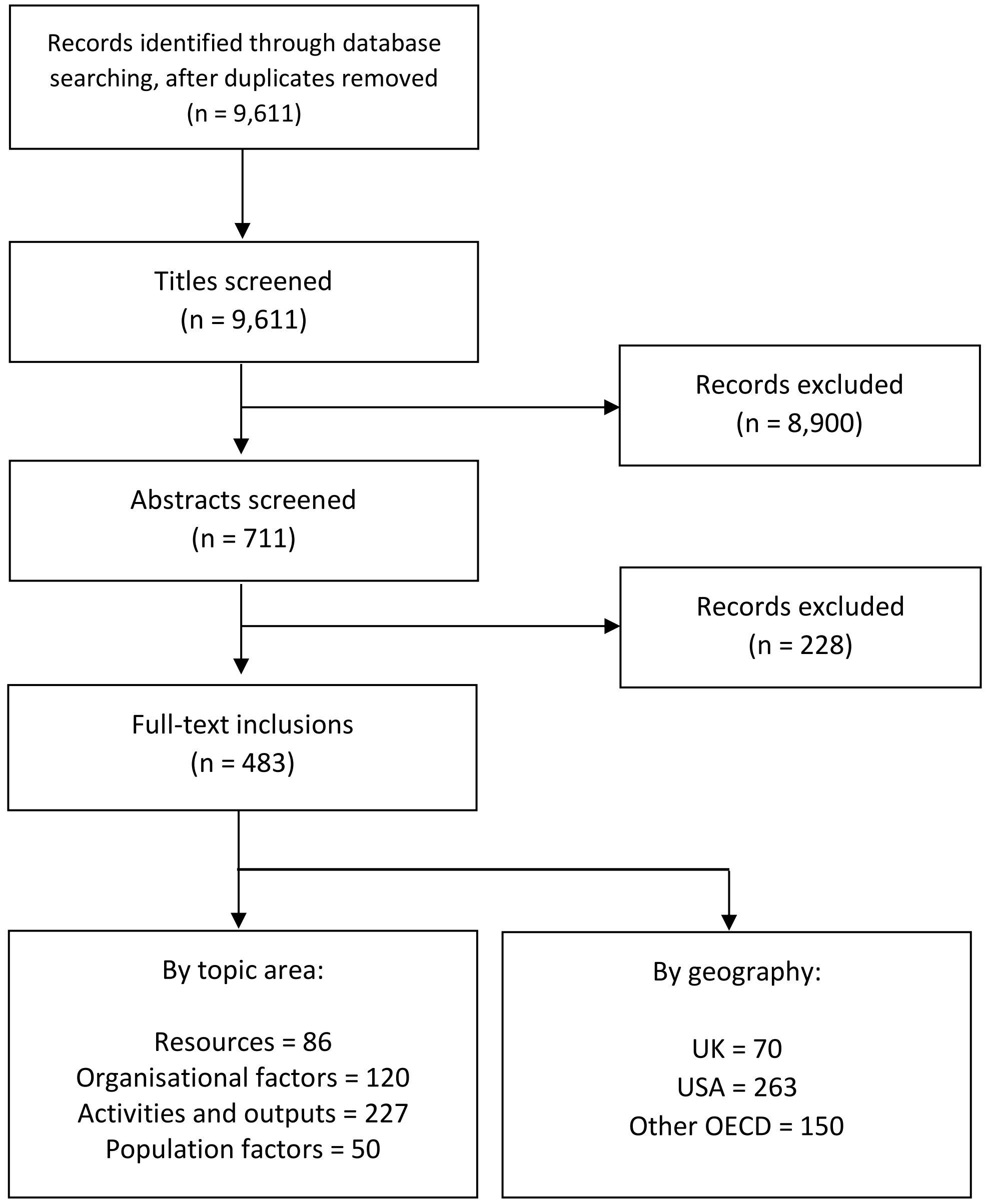

Figure 7: flowchart of literature selection for scoping review

4.2.1 Resources

This section of the review focusses on financial resources. There are also other inputs, including the vaccines, which are supplied directly by PHE and thus excluded. There are also guidelines and policy documents and human resources, which are considered in the section below on organisational factors and further analysis of the inputs into the system in England is detailed in section 4.3.

As described in the introduction, the funding system for the vaccination programme is extremely complex and opaque, involving capitation and fee-for-service payments, target and timeliness thresholds, and a pay-for-performance scheme. Complexity in funding healthcare services in the NHS is not unique to either the vaccination programme, or primary care more generally. The Health Foundation and NHS Providers (a membership organisation for primary and secondary healthcare providing organisations) recently published a review, based on extensive interviews with health professionals and managers, calling for reform to NHS funding systems based on eight proposed principles (Wright *et al.*, 2017). The rationale was partly due to the drive to integrate service providers operating at different levels (community, primary, secondary, mental health and through different geographies), but also the need to better align incentives within current operational priorities. The eight principles are as follows:

1. Clear primary purpose.
2. Realistic expectations about impact: considering the fact that overall payment systems may have a limited impact on quality and efficiency.
3. National consistency with local flexibility: with clear national level priorities, but acknowledgement that local providers may have specific, different needs.
4. Appropriate, aligned incentives: particularly across different providers, to share objectives and improve relationships.
5. High quality data: to ensure accuracy of the payment system.
6. Balance between complexity of design and ease of use: ensuring required complexity is proportionate to the purpose of the payment system.
7. Independent oversight and support: to ensure the system is delivering against its primary purpose and to help resolve issues.
8. Time to embed and evaluate systems: particularly at a time of implementing a change.

While relatively high-level principles, they form a robust over-arching framework within which to consider the vaccine programme funding system.

4.2.1.1 Funding methods

The vaccine programme system is a sub-component of the GP practice commissioning system, which itself is a sub-component of the wider NHS funding and payment system and so it is useful to think of these in terms of policy alignment. A review undertaken by The Nuffield Trust looked at the evidence of impact of the various payment systems that currently exist within the wider NHS (Marshall, Charlesworth and Hurst, 2014). It highlighted the conflicting incentives that exist within the system, with primary and community care being funded primarily through capitation payments that discourage activity, and secondary care organisations being funded through activity-based payments, which is at odds with the national policy objective of moving more care from hospitals into the community. However, they also highlight the importance of predictability and stability of funding streams to local providers, particularly when planning long-term services, which is particularly true of the vaccination programme. The review details the four most widely-used funding methods, which I have applied to the current vaccination programme funding system:

- Block payments (range of services for a period of time): these are not used for vaccination services and instead generally provide predictable income for budgeting purposes without incentivising any specific activity.
- Capitation (per patient, for a specific population): this is found in the vaccination programme in the ‘global sum’ payment, which provides a stable, predictable income to practices and encourages providers to register patients, but does not incentivise any specific activity. It has also been hypothesised that capitation payments could lower activity for things like preventative services to reduce costs while maintaining income. It has been suggested that capitation payments are the preferred core funding source for GP practices, as this enables the practice to manage a population-based budget and encourages practices to reduce costs, which can be used for reinvestment in services, or taken as profit (Addicott and Ham, 2014). Although there is a risk that practices could instead shift activity into secondary care to reduce these costs (Peckham and Gousia, 2014). Other evidence suggests that GPs recognise that although capitation payments should encourage prevention activities, in practice there is not time for these kinds of considerations to be implemented around the demands of clinical practice (Peckham *et al.*, 2015).
- Fee-for-service: this remunerates providers by activity and can be used to encourage desirable activity or implement new services. However, this creates complexity in data collection and submission and does not incentivise working with other providers. Fee-for-service payments that make up a significant proportion of the vaccine programme re-imbursement are known to increase volume of the service delivered, although if this results in highly variable payments to the provider, the incentive effect can be reduced (Peckham and Gousia, 2014). Two studies were meta-analysed in the Cochrane review evaluating interventions to increase influenza

vaccine coverage in people >60 years old and found that payments per vaccination increased coverage when compared to capitation payments alone (OR 2.22, 95% CI 1.77-2.77) (Thomas and Lorenzetti, 2018).

- Performance-related pay: this is where payments are linked to absolute or relative levels of achievement and the evidence for the effectiveness of incentives is considered in more detail in section 4.2.1.2. Within the vaccination programme, this includes the threshold payments for childhood vaccination coverage, as well as the QOF.

4.2.1.2 The evidence for incentives

Financial incentives are used to directly reward some element of provider performance or indicator of quality and act as a system of performance-related pay. There are many different systems for incentivising activity within healthcare organisations and so I have sought to summarise this evidence-base here and apply it to vaccination programme delivery. A Cochrane review of systematic reviews evaluating the effectiveness of financial incentives in changing healthcare professionals' behaviour and improving patient outcomes provides an overview of the types and possible effectiveness of incentive schemes (Flodgren *et al.*, 2011). The authors concluded that incentives that were paid for: a service or episode of care; provision of a service to a specific population; or achieving a pre-specified threshold or level of activity; improving processes of care; and increasing volumes of referrals were likely to be effective, whereas incentivising working for a defined period, or compliance with guidelines was likely to be ineffective. Thus, there are several mechanisms through which vaccination providers could be funded or incentivised to change behaviour of either the organisation or individual healthcare workers and, for the sake of this discussion, I have divided these into two categories: 1) incentives for specific activities or target thresholds that benefit at organisational level; 2) incentives with benefits for individual health workers.

4.2.1.2.1 Practice level incentives

A Cochrane review published in 2011 examined the effect of financial incentives on the quality of healthcare provided by primary healthcare providers (Scott *et al.*, 2011). Of the 7 final inclusions, 6 incentivised activity at organisational level, rather than to individual providers. A wide range of payment schemes were used that incentivised a range of behaviours, including: bonus payments for recording and providing smoking cessation advice; additional payment on achieving a threshold of referrals to stop-smoking services; or on enrolment to a health plan; withholding payments to an incentive fund for organisations if quality and satisfaction metrics were not achieved; additional payments based on achieving thresholds targets for quality improvement, and switching contracting arrangements. The quality of the included studies was too poor for the review to be able to draw conclusions, aside to say that 6 of the 7 included studies showed a positive effect on the incentivised indicators. However, there is some additional learning for both vaccination programmes and to the

UK health service. The only included study from the UK evaluated the impact of a change in the contracting system for GPs in England who switched from the GMS contracting arrangements (described in 3.2.1) to an alternative scheme called “Personal Medical Services” (PMS), as part of a pilot programme between 1998 and 1999, which went on to be rolled out more widely as part of the 2004 GP contract reforms (Gosden *et al.*, 2003). This study recruited practices involved in a pilot programme for PMS contracted GP services, where GPs at the sampled practices had switched to being paid by salary, as compared to the GMS contracting scheme, with its capitation and fee-for-service payments. These salaried GPs had slightly smaller list sizes, spent less time on administration and did more out of hours work, but importantly there was no effect on patient reported quality of care and, although PMS GPs had lower vaccination coverage, this was not statistically significant when compared to the GMS contracted GPs. Two other included studies also reported effects on vaccination coverage. Both evaluated a scheme implemented across care providers in California that incentivised organisations with small, quarterly payments per additional patient above a specific threshold target, and compared performance to non-participating providers in a different region (Rosenthal *et al.*, 2005; Mullen, Frank and Rosenthal, 2009). The vaccination target was set at the 75th centile of the year preceding study inception (2003), being 45%, however, while the overall effect was that participating providers had higher coverage, this was due to a commensurate reduction in the control providers. These studies did however identify and increase in coverage for cervical screening, another incentivised activity.

Interestingly no studies were included in the Scott et al., (2011) review that considered the implementation of QOF in the UK. This is primarily because it was implemented nationwide in 2004 and thus not subjected to formal research evaluation. Fortunately, the QOF has since been widely studied and as it does include some incentives for vaccination activity (currently influenza vaccine uptake in people in clinical risk groups), it is worth considering whether adding other vaccines or population groups to the incentive scheme could be effective, particularly as QOF point achievement has been shown to be a motivating factor when achieving high levels of influenza coverage (Dexter *et al.*, 2012), and that higher uptake is achieved when more money is available (Kontopantelis *et al.*, 2012).

Several reviews of the effectiveness of the QOF scheme have been conducted, which demonstrate some improvements in performance for several incentivised activities with some evidence in reduction in inequalities, but effects overall have been found to be modest given the funding associated with the scheme. A systematic review evaluating the impact on GP practice performance comparing incentivised and non-incentivised activities found mixed evidence for improvements in outcomes between the different target indicators, with improvements in clinical care for diabetes, but a more limited effect for heart disease, although no evidence was reported in relation to vaccination (Langdown and Peckham, 2014). Initial increases in performance towards QOF thresholds reduced over time, and the study did not find any associated negative effect on non-incentivised outcomes. Another similar systematic review of studies evaluating the evidence of impact of the scheme also found that difference in performance for QOF incentivised targets decreased between more and less deprived areas over time (Gillam, Siriwardena and Steel, 2012) and two other older review articles also found evidence that the QOF scheme may reduce healthcare associated inequalities, with practices in more deprived areas initially having lower QOF point scores, but that these increased over time towards the national mean, with more deprived areas seeing greater levels of improvement (Doran *et al.*, 2008; Dixon and Khachatryan, 2010). However, each of these studies also concluded that after initial improvements in performance, the rate of improvement has slowed to pre-implementation levels and that estimated mortality reductions have been modest. QOF has also had wider impacts on the organisation of health services at GP practice level. A qualitative ethnographic study found that practices had implemented local systems to maximise both achievement of the QOF points and the resources this provided (Grant *et al.*, 2009). This had involved creating management roles for clinical staff to monitor implementation of QOF incentivised practice, including both clinical and non-clinical aspects, alongside the development of an internal QOF team to provide oversight. However, a recent cost-effectiveness study of the QOF scheme as a whole using a simulation model has estimated that despite these improvements against QOF targets, the scheme as a whole was not likely to be cost effective at current levels of target payments to GP practices (Pandya *et al.*, 2018).

None of the studies cited in the previous paragraph consider the impact on vaccination specifically. However, there has been relatively little consideration of vaccination within the QOF incentive scheme, with only influenza coverage in risk groups receiving incentive payments. Childhood vaccination has never been included in the QOF scheme and pay-for-performance might not provide the same incentive for increasing coverage of childhood vaccines, particularly among specific population groups with lower coverage, as it may impact on the balance between intrinsic and extrinsic motivators experienced by healthcare staff and thus organisational behaviour. A study of a similar pay-for-performance scheme for primary care providers in a region of Canada, however, did include childhood vaccinations, but did not find a significant effect in increasing coverage and no effect in reducing inequalities by socio-economic status (Katz *et al.*, 2015).

There is currently ongoing debate about the future of the QOF scheme, especially as there is ongoing uncertainty about its cost effectiveness and impact on longer-term outcomes such as morbidity and mortality (Gillam and Steel, 2013). Overall, incentivising activity through QOF may be appropriate and effective for adult vaccines, as coverage for shingles and pneumococcal vaccines is generally low. Whereas, for childhood vaccines, on average, coverage is high, and the challenges are lower coverage in urban areas and in certain population groups, making a general incentive scheme based on thresholds less likely to be effective.

4.2.1.2.2 Individual level incentives

It is important to consider the motivation of staff when considering individual level financial incentives, as changing the basis of the motivation for behaviour, from an intrinsic, moral standpoint, to an extrinsic, financial standpoint may undermine the alignment of goals between the nurse and the organisation, both in terms of the priorities for the practice, as well as the overarching organisational structure. This may then create a dissonance between the intrinsic and extrinsic factors that may reduce motivation overall (Franco, Bennett and Kanfer, 2002). Placing a high level of priority on financial concerns can reduce the overall level of motivation towards achieving a social good or public benefit, which, in this context, could have the adverse effect of reducing coverage. Possibly as a result of this I did not find any studies that incentivise nurses to provide vaccinations and none were identified in the systematic reviews previously described. Nor have I found any studies incentivising individual management or administrative staff. However, it is more common that doctors receive individual incentive payments, through a range of payment and bonus schemes. As a result, there is some evidence about the effect of direct individual incentives on the activity of doctors. The only included study that incentivised individual doctors from the Cochrane Review by Scott et al., (2011) evaluated an intervention to train primary care providers in Germany and pay them a fixed amount for each additional patient who stopped smoking at 12 months after the intervention (130 euros) (Twardella and Brenner, 2007). The study did not find higher quit rates with training and an incentive alone, but only when this was combined with free prescriptions. An additional study that was excluded from the Scott et al., (2011) review as it incentivised paediatricians, has some relevance when considering vaccination specifically. The study was conducted in New York and incentivised paediatricians to document vaccination rates on children attending clinics in deprived areas, and found that both a bonus payment ($5,000-$7,500 for reaching 80% or 90% coverage rates) or additional fee-for-service payments ($5 per additional vaccine, $15 for each up-to-date child) significantly increased vaccination recording rates, by 5.9% and 7.4% respectively, as well as the number of vaccinations delivered (Fairbrother *et al.*, 2001).

4.2.2 Organisational factors

Aspects of how a GP practice is organised are likely to have an impact on the way the routine vaccination programme is implemented and the outcomes achieved by a practice. Organisational factors influence the experiences and perceptions of vaccination staff and impacts on their behaviour. Identifying and quantifying specific aspects of a health system (e.g. a computerised reminder/recall system) without understanding how it relates to the organisation that exists around its use limits the scope of understanding how a complex system works (Plsek and Greenhalgh, 2001).

Much of the literature has focussed on how GP practices are motivated to meet various kinds of quality or performance targets within a local health system. These indicators and targets include QOF, the CCG Outcomes Indicator Set, NHS Outcomes Framework and Public Health Outcomes Framework as well as standards set by the health services regulator, the Care Quality Commission (Care Quality Commission, 2018; DHSC, 2018; NHS Digital, 2018a, 2018c; NICE, 2018). A review of the current set of targets and indicators, undertaken by The King's Fund in 2015, highlighted the many performance indicators available to evaluate general practice and made recommendations as to how these could be streamlined into a more user-friendly set of indicators that would more accurately reflect GP practice performance (Veena *et al.*, 2015). Another report, also by The King's Fund, looked specifically at how the quality of general practice could be improved towards meeting this great array of performance indicators (Kennedy *et al.*, 2011). It details how general practice has increased in complexity, now dealing with a larger number of patients, many of who are older and suffer from multiple co-morbidities. The Health Foundation has also undertaken a review to try and rationalise indicators for quality of care at GP practice level, highlighting how the current plethora are not widely understood or used by practice staff (Dixon *et al.*, 2015). It also describes how the GP practice environment has changed, with large numbers of GPs working together in bigger practices, with a greater amount of the workload taken on by nurses and other allied health professionals. While overall quality of general practice is good in the UK, the report highlights several areas where it could be improved – notably in health improvement, including vaccination, and specifically reducing inequalities in the uptake of childhood vaccinations. Ultimately, the report concludes that there is not enough evidence on what factors cause the variations in performance seen between different practices in different contexts.

An extensive scoping study of the organisation and implementation of health improvement in general practice (which included vaccination) was undertaken by Peckham et al. (2015) and included 648 papers and 45 supplementary interviews with general practice staff. One of the primary conclusions was that very little research has been undertaken in the UK that considered either the way interventions are organised in general practices, or that investigated the organisational context in which they exist (Peckham *et al.*, 2015). Specifically, in relation to vaccines, it identified the strong evidence base for GP practice led interventions, but noted the increasing complexity of public health services commissioning following the implementation of the HSCA, including the contracting arrangements for the vaccine programme. The authors also noted that conflict between GP practice care being for individual patients, but health improvement interventions, such as vaccination, being a population level concern, and hypothesised that this conflict may affect the delivery of 'public health' interventions.

Practice staff must read, evaluate and decide how to implement the wide range of guidelines and policy documents they receive from DHSC and PHE in relation to both the achievement of targets, but also other policy aims, including evidence-based clinical practice guidance. Evaluating and understanding the influence of organisational factors has formed a significant part of the literature looking at how to implement evidence based recommendations and guidance at primary care providers (Mccormack *et al.*, 2002; Grol and Grimshaw, 2003; Dopson and Fitzgerald, 2005). An interesting example of this was an evaluation of the process of implementing NICE guidelines into clinical practice within local healthcare providers using a longitudinal sequence of semi-structured interviews with staff (Spyridonidis and Calnan, 2011). The study found that guidelines were implemented rationally at first following an element of planning, but over time the implementation became more unpredictable, as the outcomes of the implementation were experienced in real-time. The authors describe one of the key findings as *"while the national policy context was the same across the both case studies, the variations in the implementation could be best accounted for in terms of differences in the structure and nature of the local organisation context, particularly in the local implementation teams responsible for putting the NICE guidelines in practice."* It is likely that implementing the guidelines and policy for the vaccine programme undergoes a similar process, although this has not been studied.

There is some evidence that suggests that changes to certain organisational factors could improve performance at primary care level. A systematic review on managing people and performance within healthcare contexts highlighted how factors such as the experience of context, culture and inter-personal relations impact on aspects of people management, such as role descriptions, performance expectations, stress and leadership, to impact overall organisational effectiveness (Michie and West, 2004). A systematic review that included mainly American studies found dramatic results in improving uptake of screening and immunisation programmes as a result of implementing organisational changes (Stone *et al.*, 2002). For increasing vaccination coverage, this included having a teamwork and collaborative approach to quality improvement, using social influence, and having an active organisational learning strategy. Considerations of culture and culture-change in NHS organisations has increased in recent years. However, this success has not been readily replicated in other contexts and a systematic review from 2011 highlighted the lack of an evidence base for effective interventions to support culture-change to improve healthcare performance (Parmelli *et al.*, 2011).

Several studies conducted in the UK have highlighted potential organisational factors that may affect performance. The survey conducted by Dexter et al., in 2012 identified having a lead member for the flu campaign as a significant factor in achieving high coverage. A comparative qualitative study of 10 good and poor performing GP practices (in terms of meeting influenza vaccination targets) in Coventry and Warwickshire also found that characteristics of well performing practices were having a single identified leader for the programme, alongside having an aspirational approach to meeting targets, with an innovative use of IT systems to remind staff and a culture of opportunistically vaccinating patients in clinics (Newby *et al.*, 2016). A study looking at GPs in the north of England identified that having a strategic approach within an organisation was the single most important factor in determining MMR coverage (Lamden and Gemmell, 2008). A comprehensive report by The Kings Fund, which involved interviews with practice staff and surveys of workload in general, found that practices with a stable workforce, well organised management and administrative teams and strong working relationships increased perception amongst clinicians of having a manageable workload (Baird *et al.*, 2016).

However, what is missing is a comprehensive evaluation of the impact of organisational factors affecting implementation of the routine vaccination programme specifically. Four papers from the US provide examples of how to evaluate the organisational context of vaccine programme implementation in primary care. Ransom et al., (2012) used case studies of 117 high and low performing local health departments in the US to develop a theory of which aspects of organisational context affect vaccine coverage levels. These included leadership and organisational alignment, resources, politics, community engagement, credibility and community perspectives. A mixed methods analysis of a HPV vaccine programme examined policy and service delivery factors affecting coverage and identified shared goals and informed decision making to be the most important factors, alongside a wide variety of other barriers (low patient knowledge, time for discussion) and facilitators (clinician and patient receptivity) (Sussman *et al.*, 2015). Two related studies used semi-structured interviews to investigate factors associated with geographic regions that had the most improved vaccination coverage over 3 years, and those who exhibited sustained high coverage (Groom *et al.*, 2010; Kennedy *et al.*, 2010). For those most improved programmes, facilitators included visits by a vaccine programme specialist (from the AFIX programme, a widely used multi-component service delivery improvement intervention supported by the Centers for Disease Control and Prevention), good use of local data, outreach efforts, organisational collaboration, strong leadership and the development of vaccination coalitions. They noted increased parental concerns and difficulties with data as barriers. For those with sustained high levels of coverage, a very large number of systems and organisational factors were identified through the interviews, including the importance of provider education and communications, and barriers included changes to the programme, financial pressures, patient access and education.

4.2.3 Activities and outputs

Much of the focus in the literature has been on evaluating the effectiveness of interventions to improve coverage alongside the routine vaccination programme, particularly trying to establish what services or interventions offered at primary care level are associated with high vaccine coverage. A wide variety of study designs including interrupted-time-series analyses, cross-sectional surveys, organisational audits, qualitative analysis of semi-structured interviews and various kinds of mixed methods have attempted to evaluate the interaction of these components in the implementation of routine vaccine programmes.

- **Multi-component interventions**

Many interventions have been designed and evaluated that incorporate a number of individual elements, such as a reminder/recall system, patient and healthcare worker education, community involvement and information provision. These multi-component interventions have good evidence of effectiveness at improving vaccine coverage in children (Williams *et al.*, 2011), adolescents (Niccolai and Hansen, 2015), and older people (Thomas and Lorenzetti, 2014). Tackling inequalities in vaccine coverage is a significant challenge in the UK, with many organisational and resource challenges faced by GP practices in reaching those with worse health outcomes, leading to persistently worse outcomes for certain groups (Hutt and Gilmour, 2010). However, reducing inequalities in coverage is possible and supported by recommendations from an extensive literature review undertaken by NICE in 2009, which recommended the use of multi-component interventions as having good evidence for effectiveness (NICE, 2009). For example, a paper reporting on a complex quality improvement intervention in London, which included: the development of a GP network; vaccination care packages; financial incentive targets; and reminder/recall processes, was shown to increase coverage of MMR vaccine to 94% in the deprived London Borough of Tower Hamlets (Cockman *et al.*, 2011). A complex reminder/recall and data management system was implemented in another London borough and resulted in the maintenance of high levels of vaccine coverage, compared to non-intervention sites whose vaccination coverage reduced over the time of the intervention (Atchison, Zvoc and Balakrishnan, 2013). However, designing and delivering complex interventions can be time consuming and costly and GP practices may not have the capacity available to deliver them.

- **Single component interventions**

Reminder/recall systems have the best evidence for increasing vaccine coverage and should form the core component of any routine vaccine programme. This evidence is described in a Cochrane review from 2005, updated in 2018 (Jacobson Vann *et al.*, 2005, 2018), as well as in separate systematic reviews looking at interventions to increase vaccine coverage in children (Williams *et al.*, 2011), adolescents (Niccolai and Hansen, 2015), and older people (Thomas and Lorenzetti, 2014). In the Cochrane review any single or combination of reminder/recall interventions (phone calls, autodialer, letters, cards, text messages, with or without an outreach component) increased the proportion of people who were vaccinated with a relative risk of 1.28 (95% CI 1.23-1.35). The evidence was of high certainty for childhood and adolescent vaccines, but less certain for influenza in adults, with low certainty evidence for other adult vaccines, which remain under-studied. In the UK, a large cross-sectional survey of primary care professionals working in vaccination in 795 GP practices in England evaluated which strategies were effective to increase influenza vaccine uptake and found that practices providing a personal invite to patients was a key factor associated with high coverage (Dexter *et al.*, 2012).

The availability of appropriate staff with enough time and knowledge to provide advice on vaccines is important, as the lack of health worker recommendation has been shown to significantly reduce coverage (Hofstetter and Rosenthal, 2014; Yuen and Tarrant, 2014). A study conducted in Scotland in 1985 demonstrated how low GP knowledge and negative attitudes towards immunisation could contribute towards low levels of measles vaccine coverage (Carter and Jones, 1985). Education and training to increase confidence in vaccination are therefore important, particularly with the increase in the number of vaccinations in the programme, and associated increase in knowledge required for consent. A recent systematic review found some evidence that educating providers, including doctors and nurses, did improve coverage of childhood vaccinations (Williams *et al.*, 2011). However, a lack of training available was highlighted by a study conducted across 227 Primary Care Trusts in England in 2003 and demonstrated high levels of variability and often lack of suitable training for healthcare workers (Cummins *et al.*, 2004). Unfortunately, there is no more recent update of this evidence, but some healthcare workers have reported increasing difficulty in accessing training opportunities following the implementation of the HSCA in 2013 (Chantler *et al.*, 2016).

In addition, reminding healthcare workers to vaccinate patients opportunistically, when they may have come in for a different reason, has been shown to be effective in both a systematic review into interventions to increase influenza vaccine in older people (Thomas, Russell and Lorenzetti, 2010), and was found to be a key factor in the difference in performance between well and poorly performing GP practices in a qualitative study conducted in England also looking at influenza vaccine coverage (Newby *et al.*, 2016). A recent Cochrane review evaluated the strength and quality of the evidence for health worker reminders and found moderate-certainty evidence that computer-generated reminders increase coverage of preventative services, including vaccination (Arditi *et al.*, 2017). Although it is interesting to note that none of the included studies were conducted in the UK, with the vast majority conducted in the USA (29 of 35).

Several of the reminder/recall studies combined reminders with outreach visits for non-responding patients. Outreach programmes have been studied both in isolation and as part of multi-component interventions. A systematic review conducted by NICE to evaluate evidence of interventions to reduce inequalities in uptake of childhood vaccines found mixed evidence for the benefit of providing outreach services, such as home visiting (NICE, 2009). A more recent study from Dudley showed how intensive targeted outreach services significantly increased coverage of MMR vaccine in those who were not up to date (MacDonald, 2016). This was at a cost of £440 per MMR vaccination, however when other vaccinations were added to the analysis that had been given to patients opportunistically, this reduced to £200 per vaccination. A systematic review focussing on increasing coverage of flu vaccine in older people found moderate quality evidence for the use of outreach visits, which may be particularly useful in those who are housebound or in residential care (Thomas, Russell and Lorenzetti, 2010).

More broadly, a wide range of electronic health interventions with the aim of improving vaccination uptake or coverage have been developed and trialled. So much so that the World Health Organisation recently conducted a systematic review of systematic reviews of these eHealth interventions (Dumit *et al.*, 2018). This identified six systematic reviews, all of which reported positive results of eHealth interventions including interactive computer activities, message services, health service IT system improvements and immunisation information systems. However, none conducted a meta-analysis.

- **Missed opportunities for vaccination**

One topic that did not feature highly in the original scoping review, but has become a more significant area of research interest during the course of the study, is reducing missed opportunities for vaccination (MOV). In a recent systematic review evaluating the evidence for interventions to reduce missed opportunities, a MOV is defined as an occasion *"when a person who is eligible for vaccination, and has no contraindication to vaccination, visits a healthcare service and does not receive all the needed vaccine doses"* (Jaca *et al.*, 2018). This review only identified six studies that met the inclusion criteria, from which the authors concluded that patient education, community tracking of patients using community health workers, and tracking using provider prompts may reduce MOVs with moderate certainty evidence. Similarly to the previous reviews described, all the included studies here were conducted in the USA.

- **Capacity to deliver vaccination activities**

As the size of the routine vaccination programme has increased, so have many other demands on the resources in general practice, which have not been matched by the required additional funding (Baird *et al.*, 2016). This has created a situation of increasing workload and decreasing ability to meet the population needs. Capacity to deliver primary care services is key, but is often difficult to separate from other organisational factors from within the literature. What remains unclear to some extent is whether those practices that achieve high levels of coverage have higher or lower workload than those with low coverage, or whether organisational factors affect the perception of workload or vice versa. For patient facing interventions to be effective it is important to ensure that there is enough clinic time available for the demand generated, however little research has been conducted in this area. A study from 2001 showed that at the time much influenza vaccination was done during routine appointments, but 88% of 73 practices surveyed also put on extra clinics in order to increase coverage (Doran and McCann, 2001). The survey conducted by Dexter et al., (2012) found that offering flu vaccine clinics on evenings and weekends was not associated with an increase in coverage. Little evidence is available looking at additional clinics for children or adolescents in England.

Issues with capacity have been known for some time. A study from 2001 highlighted expense, administration and practical difficulties as two of the most important challenges when implementing the season influenza campaign in England (Doran and McCann, 2001). A recent report by Baird et al., (2016) for The Kings Fund undertook an extensive evaluation of activity levels in general practice, contrasting 2010/11 with 2014/15. They found a 15% increase in number of consultations overall, with a 13% increase in face-to-face and 63% increase by phone, and average practice list size has grown by 10%. They highlight the lack of systematic national data collection in relation to workload in primary care, particularly in terms of task allocation and the number and nature of consultations, as well as a lack of data reporting standards for this kind of activity. The nature of who is undertaking health promotion activity is key, as there is some evidence of task shifting, with increasing proportion being delivered by nurses (Peckham *et al.*, 2015; Baird *et al.*, 2016). The Kings Fund Report specifically highlights the addition of multiple immunisations to the programme as a factor in increasing workload, with the combined effects of more agents, more injections and more explanation and discussion with the patients. This year the GMS contract increased the remuneration to £9.60 for some vaccines delivered by a general practice (around 25% increase). However, it is not known how much it costs to deliver the routine programme in general practices, nor whether this adequately compensates for the workload, or would enable practices to increase capacity to meet demand.

A pair of studies from New Zealand in 1998 and 2009 quantify in great detail the resource use, staff time, financial cost and reimbursement of delivering the routine programme (McLeod, Bowie and Kljakovic, 1998; Turner *et al.*, 2009). In 1998 the cost, including one episode of reminder/recall, was NZ$15.15 (NZ$20 equivalent in 2009) and reimbursement was NZ$8.51, with a mean time of 12.44 minutes per immunisation encounter. In 2009 the mean time had risen to 23.8 minutes, taking up 15% of practice nurses' total work time. The cost per vaccination event was NZ$25.90, which is much higher than the reimbursement cost for the practice. Equivalent figures are not available for England.

4.2.4 Sociodemographic factors

Alongside the geographic variation highlighted in the routine coverage data, many studies have found differential vaccine coverage relating to other demographic factors. In children, the MMR vaccine is the most studied, due to the decrease in coverage observed following the controversy over the Lancet paper by Wakefield et al., that erroneously linked MMR vaccination to Autism (Horton, 2004). A large representative sample cohort study conducted in 2000-2002 found that children were more likely not to have been immunised with MMR if they lived with other children, with a lone parent or had a mother under 20 or over 34 (Pearce *et al.*, 2008). Those who were higher educated were also less likely to vaccinate their children, as were unemployed or self-employed parents. A large study of children in Scotland from 1987 to 2004 found that those in areas of deprivation had lower levels of MMR vaccination and were more likely to be vaccinated late, whereas those with affluent parents were either vaccinated early or not at all (Friederichs, Cameron and Robertson, 2006). Although the relationship between coverage and deprivation appears to be complex, as a study in Lancashire and

Cumbria found no link between MMR coverage and deprivation (Lamden and Gemmell, 2008). A smaller study has found that MMR coverage is lower in high density, inner-city urban areas, and amongst parents with higher levels of education (Wright and Polack, 2006). A number of studies in urban areas (Manchester, Birmingham and London) have found that children from minority ethnic groups have higher rates of MMR coverage than white children (Hawker *et al.*, 2007; Mixer, Jamrozik and Newsom, 2007; Baker, Garrow and Shiels, 2011).

More recently, seasonal influenza vaccine has also been extended to children, an evaluation of coverage levels at the end of the 2013/14 season showed lower coverage in more deprived areas, in areas with high proportions of minority ethnic groups and in areas where a high proportion of the population was Muslim (Green *et al.*, 2015). A study in London examining coverage of diphtheria containing vaccines found that larger ethnic groups had higher coverage compared to smaller ones, but did not find any separate association with deprivation (Wagner *et al.*, 2014). A recent study evaluated rotavirus vaccine coverage using ImmForm data linked with other routine data sources and Hospital Episode Statistics (Byrne *et al.*, 2018). Compared to London, after adjusting for deprivation and ethnicity, coverage was found to be 1.6-6.5% higher in all other regions, except the South West. Increasing deprivation was found to be associated with lower coverage, with 4.4% difference between highest and lowest quintiles, with coverage in non-white ethnic groups also universally lower (except in the Chinese population).

As shown in the routine data, coverge is particularly low in London. A recent study was published to evaluate the factors associated with lower coverage in London through the analysis of the vaccination histories of more than 300,000 children extracted from the CHIS data collection system between 2001 and 2010 (Tiley *et al.*, 2018). By 1 year old, 86.8% of this cohort were fully vaccined, with the majority (91.2%) having been vaccinated on time. Of the rest, 7.1% were unvaccinated and 2.1% had received only one dose and a further 4.0% two doses of DTaP/IPV/Hib. There was significant variation by ethnic group observed with 13.9% of Black or Black-British Nigerian and 11.8% in White Polish groups being unvaccinated as opposed to 2.6% in the White-British cohort. Black and Black-Somali children were also less likely to have received vaccinations on time. Timeliness also was lower in more deprived areas. Similar findings were reported for coverage of the pre-school booster between 3 years and 4 months and 5 years old, with coverage by 5 years very low at 59.5%. In this age group the white Polish population had the highest proportion of unvaccinated children (26.4%), followed by Black or Black British Nigerian (17.0%).

Although adolescent vaccines are mainly provided in schools, looking at differential uptake by socio-economic status may also add some context to the uptake of other vaccines delivered at GP practices. Coverage of HPV vaccine has also been relatively well studied due to its recent introduction into the programme. A global systematic review of studies evaluating HPV vaccine coverage found differences in ethnic groups, with black females less likely to initiate than white females, however it found no association with lower family income or parental education levels (Fisher *et al.*, 2013). The only included study from the UK, however, did identify lower coverage in more deprived areas, alongside lower levels in those from a minority ethnic background (Roberts *et al.*, 2011). This study also highlighted that those who did not receive the HPV vaccine were also less likely to have been vaccinated against other diseases, particularly MMR. Another study also came to similar conclusions and elaborated on how the interplay between ethnicity, deprivation and primary care quality may reduce HPV coverage (Kumar and Whynes, 2011). These socioeconomic factors are likely interdependent and synergistic and this has been highlighted in guidance from NICE, which recommends interventions to reduce inequalities in vaccine uptake in children under the age of 19 years (NICE, 2009).

The pertussis programme for pregnant women is relatively new (having started in 2012) and has thus been less well studied. A recent study used data from ImmForm and linked this to other routinely available health services data to determine factors associated with pertussis coverage in more than 190,000 pregnant women (Byrne *et al.*, 2018). Coverage in this population was found to be 57.4%, with the lowest coverage in London. More deprived areas were associated with lower coverage, being 14% lower in the lowest quintile compared to the highest, once adjusted for geography and ethnicity; and after adjusting for deprivation and geography coverage was higher in Indian, Bangladeshi and Chinese populations, but lower in all other non-white ethnic groups with the lowest in Black-other and Black-Caribbean (-16.3%/-15.4% respectively). A study that conducted interviews with 42 pregnant women in London to evaluate their experience of accessing pertussis vaccine found that most would accept the vaccine if offered, particularly by a trusted healthcare professional, but that pregnancy was a busy time with multiple time pressures and that offering the vaccine in other locations aside from a GP practice may help increase uptake (Winslade, Heffernan and Atchison, 2017).

In older adults, many individual studies have been conducted evaluating factors associated with vaccination coverage in older adults, particularly seasonal influenza. These studies included findings that influenza vaccination coverage in the over 74 years of age is worse in areas of deprivation (Mangtani *et al.*, 2005), and of those in risk groups aged over 65 coverage is lower in areas that are more deprived and have higher non-white populations (Coupland *et al.*, 2007). A large European study found that socioeconomic factors, including income and education, played a large role in determining influenza vaccination coverage rates in adults (Endrich, Blank and Szucs, 2009). Although most of the included studies focussed on seasonal influenza vaccine uptake, a more recent systematic review of social determinants of vaccine uptake in older population in Europe brought all these studies together into relevant meta-analysis and identified an older person living alone, as well as being of single status (as opposed to being married) as a significant factor in uptake of influenza and pneumococcal vaccines (Jain *et al.*, 2017). Not living alone was associated with a 39% higher coverage of influenza and 71% higher coverage of pneumococcal vaccination. Educational status and urban/rural residential location were not associated with uptake, but household income was, with people with higher incomes having 26% higher odds of influenza uptake. A sub-group analysis of five studies from the UK reported that coverage was 7-11% lower in areas with higher deprivation, which was independent of vaccine type (influenza or pneumococcal). Using country of birth as the indicator, immigrants to the country under study were also found to have a 33%/43% lower uptake of influenza/pneumococcal respectively.

A national-level population study was undertaken of shingles vaccine in 70-year-olds, evaluating the effect of sociodemographic characteristics on uptake in the 2014/15 cohort (Ward *et al.*, 2017). Coverage was lowest in London even after adjusting for ethnicity and deprivation. Coverage was lower in areas of higher deprivation with a difference of -8.2% in the most deprived quintile compared to the least. A range of lower coverage was also found in all non-white ethnic groups when adjusting for deprivation and geography. However, deprivation and ethnicity did not account for all the geographic variation suggesting some service provision factors also have an effect. These findings were then explored further in relation to shingles vaccine uptake using the Clinical Practice Research Datalink, a population level database of linked primary care and other electronic healthcare records. The study analysed more than 35,000 records and found that the following factors were associated with lower coverage: older people (aged >79 years, subject to a catch-up campaign, adjusted odds ratio (aOR) 0.89, 95% confidence interval (CI) 0.85-0.93), being resident in a care home (aOR 0.64, 95% CI 0.57-0.73), and confirmed the effect of living alone (aOR 0.85, 95% CI 0.81-0.90) (Jain *et al.*, 2018). Uptake was lower in groups living in areas of higher deprivation and for people of non-white ethnicity, although the finding of lower coverage by immigration status was not confirmed in this population once ethnicity had been adjusted for. Other factors, such as having a car or being able to walk to the GP practice have also been shown to be important in this population, and may synergise with other socioeconomic factors to act as barriers (Burns, Ring and Carroll, 2005). There is likely to be an interplay of socioeconomic and other demographic and circumstantial factors at play in the older age group. A study conducted in Northern Ireland and The Republic of Ireland found that a range of factors helped predict high levels of influenza vaccine coverage, including being older, being a widow and being in more regular contact with services such as meals-on-wheels, social work, chiropody and occupational therapy (Crawford, O'Hanlon and McGee, 2011). A more detailed study conducted in Birmingham identified having a car and being walking distance from the practice was associated with higher influenza vaccine coverage, compared to those older people who had to use public transport (Burns, Ring and Carroll, 2005). Other vaccines have received less attention, however Pebody et al., identified that PPV coverage was lower in areas with high ethnic diversity (non-white population >10%), but not necessarily those with high levels of deprivation (Pebody *et al.*, 2008). A study in a single GP practice in England looking at influenza vaccine in people aged over 85 years found that uptake was lower in men, patients who reported a history of allergies (not necessarily to vaccinations) and those resident in nursing homes (Fitchett and Arnott, 2014).

4.2.5 Hesitancy

Many people exhibit vaccine hesitancy, which is defined as indecision around vaccine choices that may lead to under vaccination (Jarrett *et al.*, 2015). This may be as a result of negative information gathered from the internet or the media on the safety or effectiveness of vaccinations. People have been hesitant, or opposed, to receiving vaccines since they were first introduced (Wolfe and Sharp, 2002). A study from Scotland published in 1985 highlighted how in some instances the underlying beliefs and attitudes of parents towards vaccination can over-ride recommendations by healthcare workers leading to lower vaccination coverage (Carter and Jones, 1985). More recently a systematic review to identify strategies to reduce vaccine hesitancy in patients found few examples of where interventions had been effective at increasing uptake (Jarrett *et al.*, 2015). However, a study conducted in the north of England found that a decision aid targeted at parents increased uptake of MMR vaccine and was associated with lower cost of delivering the programme, and so some strategies may be effective in certain circumstances (Tubeuf *et al.*, 2014). This remains an important area for further research.

4.2.6 Increasing coverage by patient group

The other way of considering the suitability and effectiveness of interventions to improve vaccine coverage is by population age or clinical risk group. It is plausible that the interventions required to improve coverage in parents bringing children in for their primary vaccinations in the first few months of life are likely to be different to those required to increase coverage in adolescents or older people. As a result, there are several systematic reviews that focus specifically on the evidence for interventions in different groups. Unsurprisingly coverage in children remains the most commonly studied group. A recent review article highlighted the array of interventions that have been trialled as well as the spectrum of study designs and outcomes (Frew and Lutz, 2017). This study highlighted the importance of reminder/recall systems for parents, as per the Cochrane review evidence described previously. It is also more robust in recommending outreach and home visit strategies in improving coverage. However, one of the over-arching conclusions is that often a programmatic approach using multiple components, including both patient and provider side interventions, is required to make the most significant difference. Another systematic review conducted by Public Health England staff looked at what interventions were effective to improve coverage of influenza vaccine in children with high-risk conditions, including cancers and respiratory diseases (Aigbogun, Hawker and Stewart, 2015). From studies almost exclusively conducted in the USA, they found similar results to the general systematic review, with reminder/recall using letters having good evidence for effectiveness, and weaker evidence for other methods. Of two complex interventions with multiple components, both achieved increases in uptake. Of note, there were no studies conducted in the UK. Another review evaluated the literature on vaccination coverage in looked-after children (children under the care of government social services) (Walton and Bedford, 2017). This has been a specific focus on the UK as looked-after children are known to have significantly lower coverage than the general population of children, and the study listed factors related to this, including frequent moves between residential locations, absence from school, and adolescents refusing to engage with health services. Although the literature was limited, for this population the study identifies evidence for improving data and information sharing between responsible organisations as an important factor in identifying under immunised children and supporting them to access vaccinations services.

Improving coverage in adolescents more generally was the focus of another recent systematic review, which is particularly important due the increase in number of vaccinations available for use in the adolescent population, with the multiple vaccinations required for HPV vaccination course of particular note (Das *et al.*, 2016). Again, only one study was included that was conducted in England, with the majority (15 of 23) being conducted in the USA. The review again identified the importance of reminders, but also highlighted the importance of requiring vaccination before entry to school, which was found to have a risk ratio of 1.94 (95% CI 1.39-2.71). However, this type of intervention would not be suitable for the context in England, where high coverage is achieved in most cases without mandatory vaccination directives.

There has also been an increasing focus on vaccinating pregnant women in recent years, particularly pertussis vaccination to prevent maternal-neonatal transfer, alongside the longer-standing programmes to maximise influenza vaccine coverage. A recent systematic review looking at studies designed to evaluate interventions to increase vaccination coverage in pregnant people found evidence for effectiveness of health provider recommendation, provider alerts and reminders, and educational interventions. However, most included studies were context specific multi-component interventions, focussed on influenza vaccine and were conducted in the USA, thus limiting the potential wider applicability to other contexts. Only four of the 22 included papers evaluated pertussis vaccine, all of which were from the USA (Bisset and Paterson, 2018).

Maximising coverage with seasonal influenza vaccine has long been the focus of research in older people. A recently updated Cochrane review including studies of people aged 60 years or older identified a total of 61 RCTs and make a wide variety of recommendations (Thomas and Lorenzetti, 2018). Many interventions were found to be effective, including a range of communications strategies, particularly the use of reminder letters, as well as strategies to improve access for patients, including the use of outreach visits. One other effective intervention was payments to physicians for providing vaccinations, which again highlights the dominance of studies conducted in the USA (36/61 in this case), as making bonus payments within the UK system is unlikely to be politically acceptable. With the addition of new, non-seasonal agents in this population, notably shingles vaccine, the broader applicability of these findings in this population will be increasingly important.

4.3 Defining programme delivery in England and synthesising the evidence base.

There is a large volume of evidence available for a range of aspects of the delivery of routine vaccinations in high-income countries, much of which has been synthesised within many systematic reviews evaluating the evidence for a wide range of interventions in a diversity of population groups. While having a robust reminder/recall system in place has good evidence for effectiveness in multiple contexts, evidence for other interventions has been more difficult to establish, particularly as modifications to existing vaccination delivery systems are not amenable to randomised controlled trials, which forms the bedrock of Cochrane review evidence. While complex multi-component interventions have often reported success in increasing coverage in a variety of contexts, they are often evaluated using quasi-experimental study designs, particularly before-and-after and interrupted time series designs, which are subject to higher risk of bias. The majority of the primary studies contained within the systematic review evidence have been conducted in the USA, where the heavily privatised health system, is very different in terms of policy formation, organisational management, provider delivery and funding, as compared to the publicly funded vaccination programmes in the UK and Europe.

As highlighted in the introduction, the system in England is not well described in any one location or document and is instead diffuse through multiple documents and policies published by a range of government departments and agencies. This lack of clarity presents a challenge in evaluating how the existing research evidence has been applied in the English system. It is also difficult to pick out all the studies conducted in England from within the USA dominated vaccination literature to identify what has been trialled and whether it was effective within the NHS system.

One of the most significant areas identified in the background to this study is the persistent and, in some cases, widening inequalities in coverage found in different populations within England. Of particular note is the lower coverage observed in urban areas, especially London, which is tied in with the lower coverage found in areas of higher deprivation and in certain ethnic groups. In 2009 NICE published a review of interventions to reduce inequalities in vaccine coverage in children and has since incorporated these into a selection of Quality Standards that should guide GP practices and other organisations when organising the delivery of the programme (NICE, 2009, 2017). Since then, there has been a significant expansion in the programme, particularly the number of vaccinations offered to adolescents, as well as substantial developments in electronic communications and health information and data systems.

Therefore, I have undertaken two more detailed systematic reviews of the existing literature, which are presented as two research papers. The first presents a logic model for the implementation of the vaccination programme based on a document analysis accompanied by a systematic review of interventions that have modified vaccination programme delivery in England to evaluate how this evidence relates to critical components of the logic model to identify potential targets for improvement to increase coverage. The second presents a systematic review to update the 2009 NICE systematic review focussing and refining the recommendations on effective interventions to decrease vaccine uptake inequalities in high-income countries.

4.3.1 *Research paper 1: Development of logic model and systematic review of interventions to improve vaccine coverage in England.*

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Please note that a cover sheet must be completed <u>for each</u> research paper included within a thesis.

<u>SECTION A – Student Details</u>

Student ID Number	LSH345619	**Title**	Dr
First Name(s)	Timothy		
Surname/Family Name	Crocker-Buque		
Thesis Title	An Evaluation of the Implementation of Routine Vaccination at GP Practice Level in England		
Primary Supervisor	Sandra Mounier-Jack		

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

<u>SECTION B – Paper already published</u>

Where was the work published?	BMC Public Health		
When was the work published?	6th December 2018		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	TCB conceived the study with advice from SMJ. TCB undertook the searches and screening by titles. TCB and SMJ reviewed the studies for inclusion and undertook quality scoring. TCB wrote the initial draft of the paper, with editorial advice from SMJ. Both authors read and approved the final manuscript.

SECTION E

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BMC Public Health

RESEARCH ARTICLE

Open Access

Vaccination in England: a review of why business as usual is not enough to maintain coverage

Tim Crocker-Buque* and Sandra Mounier-Jack

Abstract

Background: The vaccine system in England underwent radical changes in 2013 following the implementation of the Health and Social Care Act. There have since been multi-year decreases in coverage of many vaccines. Healthcare professionals have reported finding the new system fragmented and challenging. This study aims to produce a logic model of the new system and evaluate the available evidence for interventions to improve coverage.

Methods: We undertook qualitative document analysis to develop the logic model using process evaluation methods. We performed a systematic review by searching 12 databases with a broad search strategy to identify interventions studied in England conducted between 2006 and 2016 and evaluated their effectiveness. We then compared the evidence base to the logic model.

Results: We analysed 83 documents and developed a logic model describing the core inputs, processes, activities, outputs, outcomes and impacts of the new vaccination system alongside the programmatic assumptions for each stage. Of 9,615 unique articles, we screened 624 abstracts, 45 full-text articles, and included 16 studies: 8 randomised controlled trials and 8 quasi-experimental studies. Four studies suggest that modifications to the contracting and incentive systems can increase coverage, but changes to other programme inputs (e.g. human or capital resources) were not evaluated. Four multi-component intervention studies modified activities and outputs from within a GP practice to increase coverage, but were part of campaigns or projects. Thus, many potentially modifiable factors relating to routine programme implementation remain unexplored. Reminder/recall systems are under-studied in England; incentive payments to adolescents may be effective; and only two studies evaluated carer information.

Conclusions: The evidence base for interventions to increase immunisation coverage in the new system in England are limited by a small number of studies and by significant risk of bias. Several areas important to primary care remain unexplored as targets for interventions, especially modification to organisational management.

Keywords: Vaccination, Immunisation, Primary care, Organisational management, Systematic review

Background

The system for delivering vaccinations to the population in England underwent a radical change in 2013 following the implementation of the Health and Social Care Act 2012 [1]. Although General Practitioners (GPs) in primary care clinics (GP practices) retain responsibility for the delivery of vaccinations to their population, the organisations involved in agreeing the schedule of recommended vaccines, commissioning and funding of the service, and the collection and analysis of epidemiological data, changed radically with the formation of new organisations including NHS England (NHSE), Public Health England (PHE) and NHS Digital (NHSD). A tripartite group of organisations with responsibility for vaccination in England (the Department of Health (DH), PHE and NHSE) then went about developing and implementing a new operational model. This reorganisation was extremely disruptive to the delivery of the vaccination programme and the outcome has been described as *"fractured"* resulting in a *"complex mesh"*, causing difficulties for professionals delivering vaccinations on the ground [2]. At the same time the schedule of routine

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vaccines has continued to increase in size and complexity, now with 16 childhood vaccinations given to 6 age groups; 2 or 3 vaccines for adolescents; and 3 in older adults [3].

These factors may have influenced vaccine coverage. Although coverage for core childhood vaccinations remains high overall, downward trends have emerged since 2012 for several important vaccines, for example, measles, mumps and rubella vaccine (MMR) at 2 years decreased for the 3rd consecutive year and currently stands at 91.6%, below the 95% target set by the World Health Organisation [4]. This is particularly concerning given the 5 recent outbreaks in England and the measles epidemic currently affecting many other European countries [5, 6]. Similarly, coverage of pentavalent vaccine (containing diphtheria, tetanus, pertussis, polio and haemophilus inflenzae b) by 12 months has decreased each year since 2012 [4]. Coverage is also not evenly distributed, with specific geographic areas having significantly lower coverage than the England average. This is particularly important in London where the lowest coverage is found for all childhood vaccines [4]. Similar trends are found in vaccine coverage in adults. For example, shingles vaccine was introduced into the schedule in 2015 for people aged over 70 years, with a catch-up campaign for people over 78. However, this year coverage is only 34.6% and 34.8% in each of these age groups respectively, which is 5.5% and 5.3% lower than the preceding year and shows a downward trend [7]. While demographic and socio-economic factors are well known to impact vaccine coverage, resulting in significant inequities between population groups, [4, 8–19] the contribution of health service organisation is unknown. GP Practices are independent contractors to the NHS and so organisational management data relating to their operating structure and function are not readily available. Although GP Practices are critical for successful delivery of the programme, within the post-2013 system there is also much less advice and support available from both NHSE and PHE, compared to the previous model, leaving practices isolated [2].

Many systematic reviews have been conducted evaluating interventions to improve coverage in high income countries: in specific population groups, including children, [20], adolescents, [21] people over 60, [22], children with high-risk conditions, [23] and looked-after children; [24] in specific scenarios, including reducing hesitancy, [25] missed opportunities, [26] and inequalities; [27] and evaluating specific types of interventions, including reminder/recall systems, [28, 29] mobile phone messages, [30] education, [31] eHealth, [32] primary care service delivery, [33] health worker reminders, [34] and financial incentives for doctors, [35] and patients [36]. However, there has been no consideration of how this evidence has been applied in the England context, nor whether the outcomes of any trials match those in the broader evidence. Therefore, the aims of this study are to i) develop and describe a logic model for the implementation of the vaccination programme in England; ii) undertake a systematic review of interventions that have modified vaccination programme delivery in England; iii) compare the evidence in England to existing evidence from high-income countries; and iv) evaluate how this evidence relates to critical components of the logic model to identify potential targets for improvement to increase coverage

Methods

Document analysis and logic model

The purpose of developing the logic model is to accurately describe the components of the system for delivering the routine vaccination programme, including the underlying programmatic assumptions. To develop the model, we undertook a systematic analysis of documents published by organisations involved in designing and delivering the routine vaccination programme in England. We searched the websites of the following organisations for relevant documents: UK Government, including Department of Health and Public Health England (www.gov.uk), NHS England (www.england.nhs.uk), NHS Digital (www.digital.nhs.uk), British Medical Association (www.bma.org.uk), Royal College of Nursing (www.rcn.org.uk), and conducted a general search through Google (www.google.co.uk). Search terms consisted of "vaccination" and "immunisation" and spelling variants (Fig. 1). The focus was on documents relevant to the system since the implementation of the 2012 Health and Social Care Act, i.e. 2013-2017. We uploaded the included documents into NVIVO (v11) for qualitative analysis using document analysis methods [37].

The content of each included document was coded using deductive codes derived from the categories in logic model development (inputs, processes, activities, outputs, outcomes and impact). These were then synthesised and used to form a logic model with accompanying programmatic assumptions using the principles of process evaluation [38].

Systematic review

We designed the systematic review to identify interventions that have been conducted within vaccine delivery programme in England. This has been reported in line with the PRISMA Guidelines for Systematic Reviews [39].

Search strategy

We searched Medline, ASSIA, Campbell Collaboration, Cochrane Database of Systematic Reviews, Embase, EPPI Centre, Psych Info, Web of Science, SCOPUS, Social Policy and Practice, Health Systems Evidence and Health Management Information Consortium using the search strategy shown in Additional file 1.

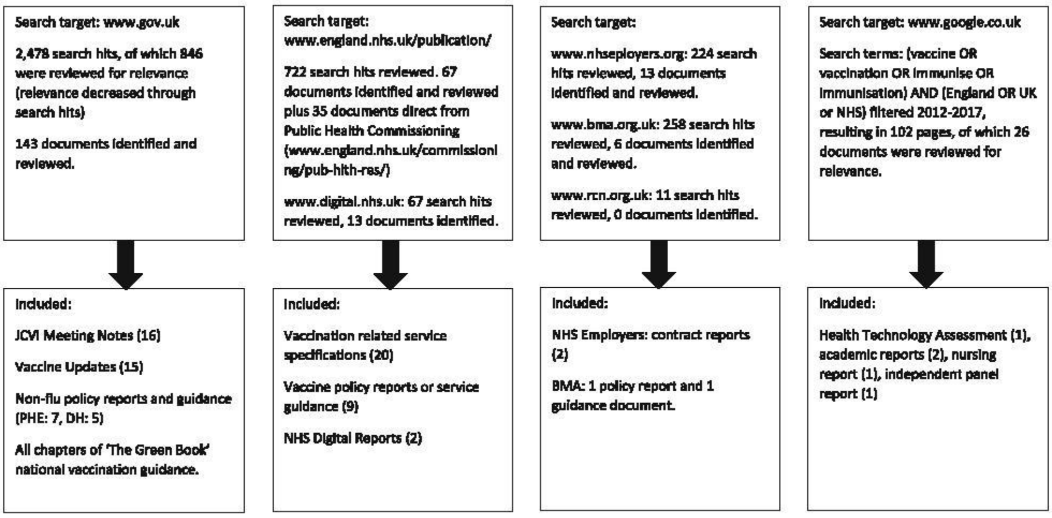

Fig. 1 grey literature search strategy for document analysis

Inclusion and exclusion criteria

Studies with the following characteristics were included:

- Population: any in England
- Dates: published between 1996 and 2016
- Study design: Randomised Controlled Trial (RCT), quasi-experimental (including time-series and before-and-after studies) and ecological studies.
- Interventions: any designed to increase vaccine uptake or coverage, including any associated economic analyses.

Due to the complex and diffuse nature of the immunisation delivery system in England, we allowed for a wide range of study designs to be included. Additionally, we reviewed the references for other systematic reviews on similar topics that could have contained studies that fitted our inclusion criteria.

Study selection process

One reviewer screened articles by title and manually de-duplicated records (TCB). Two reviewers screened potentially relevant abstracts independently (TCB, SMJ). Any disagreement was resolved by discussion, based on the inclusion criteria. Both reviewers agreed the final inclusions.

Data extraction and assessment of bias

We extracted the following data from each included study for comparison: design, dates, population, intervention, vaccine(s), comparison, sampling method, allocation method, randomisation method, blinding, outcome measure and effect measure.

For RCTs, risk of bias was evaluated using the Cochrane Collaboration tool, with aspects of each study relating to selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias extracted [40]. The Cochrane Collaboration tool is not specific to non-randomised study designs, and so, for quasi-experimental study designs, risk of bias was evaluated with the relevant Study Quality Assessment Tool published by the USA National Heart, Lung and Blood Institute, which are available for a variety of non-randomised study designs [41]. Both reviewers undertook assessment independently then compared outcomes and resolved differences by discussion.

Results

Logic model

For the grey literature search 2,230 search hits generated 303 documents that were reviewed for inclusion (Fig. 1). The components of the logic model were identified from 83 documents from the following sources:

- NHS England (NHSE): service specifications (n=20) and policy or guidance reports (n=9)
- Public Health England (PHE): Vaccine Updates published in 2017 (n=15), other policy or guidance reports (n=7), and The Green Book.
- Department of Health (DH): policy reports (n=5), Joint Committee on Vaccines and Immunisation (JCVI) meeting notes for 2013-2017 (n=16)
- NHS Employers: contract reports (n=2)

- NHS Digital (NHSD): reports (n=2)
- British Medical Association (BMA): reports or guidance (n=2)
- Other relevant academic or grey literature (n=5)

Purpose

The purpose of the routine vaccination programme is described in the NHS Public Health Functions Agreement 2017-18 Core Service Specification National Immunisation Programme document, published by PHE and NHSE, as *"to protect the population from vaccine preventable diseases and reduce the associated morbidity and mortality."* [42]. For the purposes of developing this logic model the intervention was defined as: the immunisation of individuals with pre-specified characteristics (e.g. age, co-morbidity, pregnancy) with immunological agents delivered by vaccination to prevent morbidity and mortality from vaccine preventable diseases (VPD) and reduce microbial spread within the population. The focus of this paper is the delivery of vaccinations through primary care facilities, so this is considered as the core activity.

Logic model and assumptions

The logic model derived from the document analysis is presented in Fig. 2. Alongside GP Practices, there are 7 core organisations identified within the system: Department of Health (DH), the government department responsible for health; Public Health England (PHE), an executive agency of the DH with responsibility for vaccination; the Joint Committee on Vaccines and Immunisations (JCVI), an advisory group of independent experts for which PHE acts as secretariat; NHS England (NHSE), an executive non-departmental part of the DH responsible for commissioning (buying) vaccination services; NHS Digital (NHSD), which provides data systems and published some coverage statistics; the British Medical Association (BMA), the trade union and professional association of doctors in the UK, and the General Practitioners' Committee (GPC), which is responsible for negotiating commissioning arrangements; the Medicines and Healthcare Products Regulatory Agency (MHRA), an executive agency of the DH with responsibility for safety of vaccines.

Inputs

We identified five key inputs for the vaccine programme: i) funding, ii) human resources, iii) primary care facilities, iv) data and v) vaccines. Funding is raised by general taxation and allocated by the Secretary of State from DH to NHSE via the Section 7A Agreement for use in commissioning public health services, including immunisation. The primary

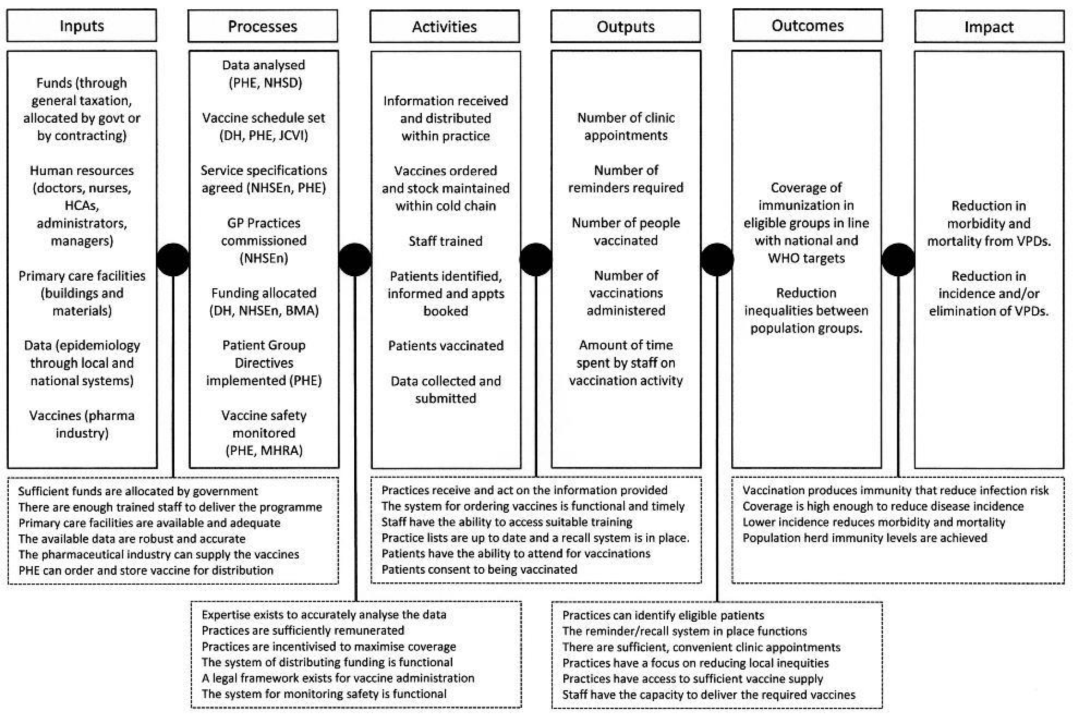

Fig. 2 Logic model of the process of delivering the routine vaccine schedule in England with underlying assumptions

assumption is that this funding is sufficient to provide the programme. Vaccines are not included in this funding and are instead bought directly by DH and stored at PHE. Human resources are considered primarily at the GP Practice level, with assumptions that there are sufficient staff locally who have access to all the required facilities and resources. The expectations of the core and specific requirements for immunisation service are set out in NHSE's Core Service Specification for the National Immunisation Programme, and each of the individual service specifications for each vaccine.

Processes

Seven core processes were described in the documents: i) data collection analysis, ii) setting the vaccine schedule, iii) producing the service specifications, iv) commissioning arrangements through contracting, v) allocation of funding, vi) production of patient group directives, and vii) monitoring vaccine safety.

Data are collected through two parallel systems: the Child Health Information System (CHIS); and ImmForm [43]. There are multiple, regional CHIS providers in England. It is a historical system that is commissioned independently by NHSE and collects data on core childhood immunisations [44]. ImmForm is a data collection, analysis and ordering platform commissioned by DH and PHE that mainly contains data on newer vaccines. Data analysis is primarily undertaken by PHE, with some stored and published by NHSD.

The recommended vaccine schedule is set by DH, following recommendations from the JCVI with specialist input from PHE. NHSE is tasked with commissioning vaccination services from GP Practices in England as per the Section 7A Agreement and does this through the immunisation service specifications and the more general contracting arrangements, such as the General Medical Services (GMS) and Personal Medical Services (PMS) contracts. The contents of these are negotiated annually with the GPC. PHE staff embedded within NHS England's regional area teams provide oversight of the implementation of the programme. Nurses and Healthcare Assistants (HCAs) are legally enabled to vaccinate specific population groups without an individual prescription using a Patient Group Directive (PGD). Safety is monitored both by PHE and the MHRA through individual reporting using the Yellow Card notification system, [45] and population level studies.

Activities at GP Practices

GP Practices are expected to provide a minimum set of activities with the aim of *"offering immunisation to 100% of eligible individuals in accordance with… guidance from DH, NHSE and PHE"* [42]. These are set out in the service specifications and The Green Book, [46] which is the handbook of guidance relating to immunisation, published and updated by DH and PHE, with advice from JCVI. Broadly, the activities include: contacting and vaccinating eligible patients; keeping accurate records; training staff annually; providing an accessible service; providing information to patients; collecting and submitting data; involving users in service design; considering vulnerable and under-immunised groups; managing vaccine stock; and maintaining the cold chain. The key assumptions are that practices are sufficiently resourced and incentivised to undertake these activities.

Outputs

The outputs expected from the GP Practice are not clearly defined. The focus in the specifications is on providing data on the number of vaccinations administered to the eligible population, although there is also some consideration of availability and uptake of appointments and the use of a reminder and recall system. There is no consideration of staff time, capacity or cost. The main assumptions are that: practices have accurate lists and make sufficient appointments available; the reminder/recall system is in place and functional; the system for ordering vaccine stock and maintaining the cold chain is in place; and that patients attend and consent to vaccination.

Outcomes

The outcomes are more clearly defined, with coverage of immunisation within eligible populations is a core focus of all the documents. National level coverage expectations are described in the Core Service Specification, through which DH holds NHSE to account, which are based on coverage achieved in previous years or global recommendations from the WHO. As a result, coverage levels are reported by PHE and considered by JCVI. There is also a statutory requirement to reduce inequalities between groups, specified as people with protected characteristics as defined in the Equality Act 2010 [47]. The assumptions here are that the systems and activities undertaken by the GP Practice's work sufficiently well to vaccinate high levels of the local population and that these local data aggregate to these thresholds nationally.

Impacts

The purpose of the programme as stated in the Core Service Specification *"is to enable [NHSE] to commission national immunisation services to a standard that will continue to minimise the infections and outbreaks caused by vaccine preventable diseases… and… to protect the population from vaccine preventable diseases and reduce the associated morbidity and mortality."* This aim is reflected as a disease specific aim in each of the individual service specifications. Much of the focus on vaccination policy at the JCVI is on reduction of circulating disease prevalence. Disease elimination is also a stated aim of the programme, for example, the Section 7A agreement contains the WHO European regional target to eliminate measles and rubella infections by 2020. The assumptions here are primarily that the vaccinations recommended in the schedule produce sufficient immunity to reduce disease incidence; and that coverage is high enough to reduce pathogen circulation to reduce outbreaks and move towards elimination.

Systematic review

The PRISMA Flow Chart of study selection and inclusion is presented in Fig. 3. Of 9,615 unique articles, 624 abstracts were screened, leading to 43 full text articles being reviewed. A further 2 studies were identified from the references of 8 other review articles [27, 33, 35, 36, 48–51].

In total 16 experimental studies were included: 8 RCTs (Table 1) and 8 quasi-experimental studies (Table 2). Four studies considered seasonal influenza, [52–55] with 2 more looking at influenza and pneumococcal vaccines together; [56, 57] 5 considered measles, mumps and rubella (MMR); [58–62] 3 the whole childhood schedule; [63–65] 1 each considered pneumococcal vaccines alone and human papillomavirus (HPV) vaccines; [66, 67] and 3 looked at the effect of the Quality Outcomes Framework (QOF), an incentive scheme, focusing on influenza coverage in specific risk groups [8, 68, 69].

Due to heterogeneity in study populations and intervention types meta-analysis was not possible, except in one case where it had already been performed elsewhere in the literature.

Randomised controlled trial interventions

Four studies examined reminder/recall interventions in increasing uptake of seasonal influenza vaccination in adults [52–55]. Two of these combined reminders to eligible patients with a home visit component, compared to reminders alone [52, 54]. One study had a high risk of performance and attrition bias and the other had a low risk of bias but was under-powered (90 subjects). In a previous systematic review and meta-analysis evaluating interventions to increase uptake of influenza vaccine in people over 60, the pooled effect of these studies involving 710 intervention patients (who received a reminder and a home visit) and 1402 controls with 'usual care' was an odds ratio (OR) of 1.30 (95% confidence interval (CI) 1.05-1.61, p=0.01). However, neither evaluated the additional cost of the home visit component. Of the studies considering reminders alone, one compared a phone call from a receptionist to sending a letter and found an OR of 1.29 (CI 1.03-1.62) and the other evaluated using text message reminders at practice level, finding a non-significant OR 1.12 (CI 1.00-1.25) increase in uptake. Both provided evidence with low risk of bias.

Two studies used educational interventions to increase uptake of MMR vaccine. One used a teddy-bear with signposting to government information and found no difference between intervention and control groups and was at high risk of bias [58]. The other evaluated a web-based decision aid as compared to a leaflet and compared to usual practice alone and found OR 0.14 (CI 0.02-1.14) lower coverage in the leaflet group compared to usual practice (OR 0.14 (CI 0.02-1.14)) and higher coverage in the decision aid group compared to the leaflet (OR 10.6 (CI 0.1-188.5)), but no difference between decision aid and usual practice groups [59]. However, sample size was small (220 in three groups) and confidence intervals were wide. An associated cost-effectiveness analysis found the decision aid was lower cost to deliver than usual practice (-£9.20) and leaflets (-£7.17), however no direct cost was assigned to the decision aid (e.g. development and maintenance costs).

One study focussed education on healthcare workers through use of an education visit to increase uptake of both influenza and pneumococcal vaccine in people aged over 65 years in specific risk groups at practice level [56]. It found mixed results with increases in coverage in some groups (e.g. OR 1.23, CI 1.13-1.34, pneumococcal uptake in patients with cardiovascular disease (CVD)) but not in others, making overall effect difficult to establish.

HPV vaccine is provided to adolescent females and a study at low risk of bias and a large sample (1,000 subjects), that compared the provision of a £45 voucher and text message reminders to an invitation letter alone found a significant increase in uptake of both first dose (OR 1.63, CI 1.08-2.47) and course completion (OR 2.15, CI 1.32-3.96) in the intervention group [67]. No evaluation of cost effectiveness was made.

Quasi-experimental interventions

Most of the quasi-experimental studies use routine or population level data to evaluate the effects of either specific interventions to changes to vaccination programme implementation (Table 2). All included studies focus on changes in proportion of the eligible population covered over time, or differences in coverage between groups. Two studies with low risk of bias evaluated complex, multi-component campaigns to improve MMR uptake in a local population, although no evaluation of cost [60, 61]. One other study evaluated offering MMR vaccine during home visits, but was at significant risk of bias [62].

Two studies evaluated complex interventions to improve influenza and/or pneumococcal coverage in adults in risk groups. One that used quality improvement methods found significant increases in coverage across a range of vaccines, [57] and the other found an increase in coverage from 6% to 33%, so from a low start to a relatively low overall coverage level [66]. Both of these had a significant risk of bias.

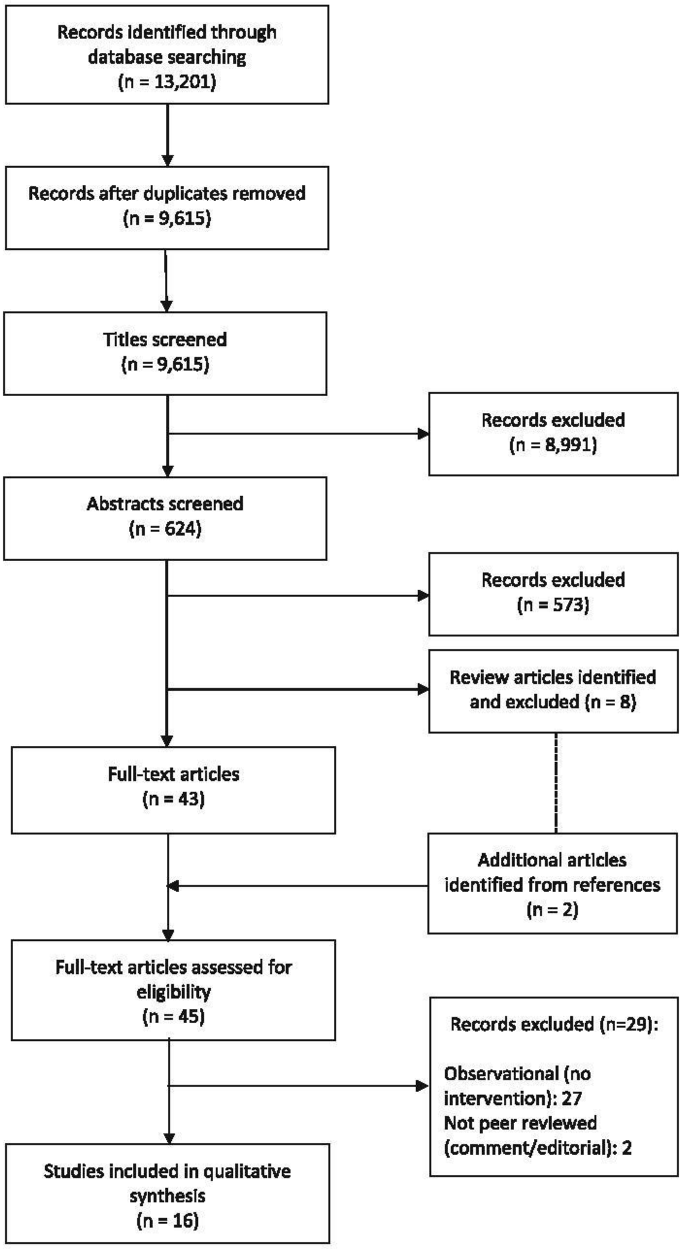

Fig. 3 PRISMA flowchart of literature selection

Table 1 Characteristics and outcome of included randomized controlled trials

First Author, year [reference]	Sample from population	Vaccine	Intervention category	Intervention vs. comparison	Total sample (intervention/ comparison)	Effect measure	Risk of bias
Arthur, 2002 [52]	Patients aged over 75 from a large rural general practice in Leicestershire.	Influenza	Reminder/recall & outreach	Personal letter of invitation to attend for vaccination vs. health check at home where vaccine was offered.	2052 (1372/680)	OR 1.28 (CI 1.03-1.58).	High risk of performance bias (no blinding) and attrition bias (high decline of health checks).
Hull, 2002 [53]	Patients aged 65-74 from at 3 general practices in London & Essex.	Influenza	Reminder/recall	Telephone call from receptionist to make appointment vs. letter & info leaflet alone.	1318 (660/658)	Adj OR 1.29 (CI 1.03-1.62) for phone call (p=0.026)	Low risk of bias.
Nuttall, 2003 [54]	Previous non-attenders aged 65-90 from a general practice in Lancashire.	Influenza	Reminder/recall & outreach	Letter vs. leaflet vs. letter & home visit to discuss vaccination.	90 (30/30/30)	OR 0.84 (0.26-2.74; p=0.77) [50]	Generally low, but risk of performance bias (no blinding)
Herrett, 2016 [55]	Patients aged 18-64 in risk groups from 153 general practices in London.	Influenza	Reminder/recall	Sending of pre-defined, recommended text message reminders vs. usual care.	102257 (77 practices/ 79 practices)	OR 1.12 (CI 1.00-1.25)	Low risk of bias.
Porter-Jones, 2009 [58]	All children eligible for 1st MMR from Flintshire, Wales.	MMR	Patient education	Teddy bear with t-shirt directing parents to information sources vs. no bear	974 (542/432)	OR 1.06 (CI 0.73-1.57)	High risk of selection bias (convenience sampling, no allocation concealment) and performance bias (lack of blinding).
[a]Shourie, 2013 & Tubeuf 2014 [59, 74]	First-time parents with a child aged 3-12 months eligible for MMR from 512 general practices in the North of England.	MMR	Patient education	Web-based decision aid vs. leaflet & usual practice vs. usual practice alone.	220 (48/85/70)	Non-significant difference due to small sample: leaflet vs. usual practice OR 0.14 (CI 0.02-1.14);); and decision aid vs. leaflet OR 10.6 (CI 0.1-188.5); decision aid vs usual practice 2.1 (CI 0.1-52.5)	Generally low, however small groups and lack of blinding.
Siriwadena, 2002 [56]	Patients aged >65 and those in eligible risk groups from 30 general practices in Trent region.	Influenza & pneumococcal	Healthworker education	Educational visit to GP practices based on principles of academic detailing lasting one hour vs. provision of information on performance alone.	30 practices (15/15)	Increases in uptake of pneumococcal in patients with CVD (1.23, CI 1.13-1.34; p=<0.001) and diabetes (1.18, CI 1.08-1.28; p<0.001). No difference in any group for influenza	Generally low, but unclear risk of selection bias (randomisation not described) and high risk of performance bias (analysts not blinded)
Mantzari, 2015 [67]	Females aged 16-18 eli gible for HPV vaccine in Birmingham and East North health region.	HPV vaccine	Incentive & reminder/recall	Vouchers worth £45 for completing vaccine course of 3 injections and text message reminders vs. invitation letter alone.	1000 (500/500)	First dose: OR 1.63 (CI 1.08-2.47) for first time and 1.63 (1.075-2.472) for previous non-attenders. Third dose: OR 2.15 (CI 1.32-3.96) for first time and 4.28 (CI 1.92-9.55) for previous non-attenders.	Unclear risk of detection bias (possible for analysis to identify groups) otherwise low.

MMR measles, mumps and rubella vaccine, *HPV* human papillomavirus, *CI* 95% confidence interval, *Adj* adjusted, *OR* odds ratio, *CVD* cardiovascular disease
[a]both studies report analysis and results from the same sample

Table 2 Characteristics and outcome of included quasi-experimental studies

First Author, year [reference]	Sample from population	Design	Vaccine	Intervention category	Intervention	Sample and comparison	Effect measure	Risk of bias
Le Menach, 2014 [60]	Children aged 6 months – 16 years from one general practice.	B&A	MMR	Multi-component	Campaign offering accelerated vaccination (6-11 months), early 2nd dose (6-11 months) and catch up vaccinations.	Coverage in 1538 children measured before and after campaign.	Increase in proportion of >14 months immunised by 3% (to 71%) and of >60 months by 5% (to 65%) following the campaign.	Low (assessors not blinded; unclear consideration of group effects)
Cockman, 2011 [61]	All children in the London Borough of Tower Hamlets.	Eco	MMR	Multi-component	Quality improvement project associated with campaign including: incentive payments; practice network; commissioning care package; new targets; IT for reminder/recall; active follow-up defaulters.	Coverage in all children in the area measured over time.	Coverage of MMR1 increased from 80% before the intervention to 94% after. Significant difference (p=0.001) in slope of coverage change pre (-0.07% per quarter) and post (1.86% per quarter).	Low (assessors not blinded; unclear consideration of group effects)
Siriwardena, 2003 [57]	Selected general practices from all practices in Lincolnshire.	B&A	Influenza & pneumococcal	Multi-component	Dissemination of clinical guidelines; advise on data and surveillance; organisational strategy; reminder/recall; comparative performance.	Coverage in 21 general practices before and after participating in project.	Significant increases in coverage before and after for both influenza and pneumococcal in a range of groups e.g. pneumococcal in CHD 27.5% increase (CI 12.6-42.3%; p=0.002)	Moderate (general objective; diffuse intervention; assessors not blinded; no consideration of group effects)
McDonald, 1997 [66]	Eligible patients in risk groups registered at general practices in Tameside.	B&A	Pneumococcal	Multi-component	Improved vaccine supply; clinical guidelines; patient materials; patient information leaflet translations; education.	Proportion of eligible patients immunised at participating practices before and after the intervention.	Increase in coverage from 6% before to 33% after the campaign.	Moderate (eligibility and selection unclear; diffuse intervention; assessors not blinded; no consideration of group effects)
MacDonald, 2016 [62]	Unimmunised children from Dudley local health area.	Eco ITS	MMR	Outreach	Immunisation offered during home visits	Comparison of coverage in local population using quarterly routine data.	Intervention contributed 2.6% of the MMR doses given during the study period.	High (enrolment and sample size unclear; assessors not blinded; limited statistical consideration)
Atchison, 2013 [63]	General practices in Wandsworth, London.	B&A	Childhood schedule	Reminder/recall	Standardised reminder/ recall system involving letters and referral to health visitors.	32 participating practices compared to 44 not participating before and after the intervention.	Significant increase in coverage in intervention group, but as a result of unexplained decreases in control group coverage.	Moderate (likely differences between intervention and control practices; assessors not blinded; no consideration of group effects).
Henderson, 2004 [64]	General practices in Highland NHS Health Board area.	Eco	Childhood schedule	Reminder/ recall	Participation in national reminder/recall system vs. use of general practices' own system.	Coverage between 8 practices using their own reminder/ recall system vs. 66 participating in a national system.	Higher coverage in national system practices of diphtheria by age 2 (6.4%, CI 1.7-11.1, p=0.001) and Men C by age 2 (7.6%, 2.7-13%, p=0.001) but no difference for diphtheria by 1 year or MMR by 2 years.	Moderate (natural experiment – intervention dose unclear; likely difference between intervention and control practices; assessors not blinded; group effects not considered)

Table 2 Characteristics and outcome of included quasi-experimental studies *(Continued)*

First Author, year [reference]	Sample from population	Design	Vaccine	Intervention category	Intervention	Sample and comparison	Effect measure	Risk of bias
Gosden, 2003 [65]	Selected general practices in England.	B&A	Childhood schedule	Incentive	General practice contracting arrangements: GMS vs. PMS contracts.	Coverage in 10 practices who had switched to PMS contract vs. matched 10 control practices on GMS contract.	No difference in immunisation coverage between practices (-1.08%, CI -17.95-15.8%)	Moderate (natural experiment – intervention dose unclear; likely difference between intervention and control practices; unclear if large enough sample; assessors not blinded; group effects not considered)
Norbury, 2011 [8]	315 general practices in Scotland	Eco B&A	Influenza in >65-year olds and risk groups	Incentive	QOF	Coverage in >65 yo and risk groups before (03-04) vs. after (06-07) introduction on QOF incentive in 2004.	Increase in coverage by 3.5% (CI 3.3 to 3.7%); higher in <65 yo 8.8% (CI 8.3 to 9.4%) than >65 yo 3.3% (CI 3.1 to 3.6%). Higher increases in those with disease risk, than age alone.	Low (no blinding of assessors)
Kontopantelis, 2012 [68]	All practices in England.	Eco CB&A	Influenza in people with CHD	Incentive	QOF	Coverage before vs. after the increase in upper payment threshold from 85% to 90% in 2006; and vs. other risk groups with no threshold change.	Immediate increase of 0.41% (CI 0.25 – 0.56%) population coverage, with larger increase seen in practices with <85% in 2006 of 0.85% (0.62 – 10.08%)	Low (no blinding of assessors)
Kontopantelis, 2014 [69]	Patients at 50 representative practices from 644 in CPRD	Eco ITS	Influenza in people with asthma	Incentive	QOF	Coverage before vs. after QOF target removed in 2006.	Small drop in coverage -0.70% (CI -1.1% to -0.39%	Low (no blinding of assessors)

B&A before and after study, *ITS* interrupted time series, *Eco* ecological, *MMR* measles, mumps and rubella vaccine, *PMS* personal medical services contract, *GMS* general medical services contract, *QOF* Quality Outcomes Framework, *CI* 95% confidence interval, *OR* odds ratio

A further two studies evaluated the effectiveness of reminder/recall interventions to increase coverage of all childhood vaccines in the schedule. One implemented a standardised, complex system of reminder letters and referral to health visitors in a London borough [63]. Although a significant increase in coverage was identified, this was due to an unexplained reduction in coverage in the control group, making the results difficult to interpret. The other compared practices in Scotland using a national reminder/recall system to those using their own local systems and found higher levels in coverage in the former group, but not across all vaccines [64].

Four studies evaluated the effects of various changes to the system of contracting and payments to GP Practices in England. The first evaluated differences between practices contracted using the Personal Medical Services (PMS) contract compared to the General Medical Services (GMS) contract. The ability to switch from the standard GMS to the new PMS contract occurred in 1999 and a relatively small number of practices did so. Under the GMS contract, GPs were incentivised to increase practice list size and meet targets for providing specific services (such as immunisation) to maximise income. The PMS contract was designed to be more locally responsive with lower levels of administration and with the GPs in receipt of a salary. Overall the study found no differences between GMS and PMS practices over time, although only 10 PMS practices were included [65]. Another change to the arrangements to pay GPs was the introduction of the Quality Outcomes Framework (QOF) in 2004, a pay for performance system that incentivised GPs to meet specific quality targets [70]. This included several targets for influenza coverage in specified risk groups, including patients with asthma, diabetes and heart disease, among others. One study evaluated the effect of the introduction of these targets in Scotland and found an overall increase in coverage in 3.5% (CI 3.3-3.7%), but that this was far greater in incentivised populations (aged under 65 in risk groups: 8.8%, CI 8.3-9.4%) that in the population eligible by age alone (>65 years: 3.3%, CI 3.1-3.6%). Another study evaluated the effect of raising the threshold for payment from 85% to 90% for influenza coverage in people with cardiovascular disease in 2006 across all practices in England and found a small increase overall (0.41%, CI 0.25 – 0.56%), but a larger increase seen in practices with <85% coverage in 2006 of 0.85% (0.62 – 10.08%) [68]. In 2006 the QOF target and payment for influenza coverage in people with asthma was removed and a study was conducted in 644 practices signed up to the Clinical Practice Research Datalink (CPRD) to evaluate the overall effect, which found a small drop in coverage of -0.70% (CI -1.1% to -0.39%) [69]. Together these studies provide evidence with low risk of bias that changes to the contracting and incentive payment system can affect coverage levels, but suggest that the overall effect is likely to be small.

Discussion

In this this paper we have presented a logic model of the theoretical structure of the vaccination programme in England following the implementation of the HSCA in 2013 and identified and described the underlying assumptions that allow it to function. This will enable further work evaluating the fidelity of the implementation of this system at GP Practice level, which has not yet been studied. Through the systematic review, we have identified which aspects of the system have been modified to improve coverage, and will now compare the evidence from England to the available evidence from other high-income countries. Overall, we identified a relatively small number of experimental studies (n=16). All studies used uptake or coverage to be the outcome of interest, rather than disease incidence or another impact indicator. Few of the interventions evaluated modification to routine activities and outputs within a GP Practice. Of those that did make changes at GP Practice level the modifications were associated with specific time-limited projects, [57, 63] or campaigns [60, 61]. Thus, potentially modifiable factors relating to programme implementation at GP Practice level remain unexplored. Using the logic model shown in Fig. 2 we have compared this evidence to areas of programme implementation to identify un-researched areas and potential targets for future studies, and to draw lessons for policy-makers.

Inputs and processes

Four studies that modified the contracting and payment systems for GP Practices in England increased coverage. This requires modification of both the inputs (financing) and processes (contracting). A Cochrane Review originally conducted in 2000 and updated in 2009 did not find enough evidence to support the use of target payments to increase vaccine coverage, [48] and another Cochrane Review published in 2011 considering incentives for primary care physicians more broadly concluded that there is growing evidence for their use in improving quality of care, but the evidence remains limited [35]. This is likely in part due to the restriction of the evidence to RCTs, as the evidence identified here was from quasi-experimental studies using ecological data. The four studies that evaluated the impact of the introduction and changes to the QOF incentive scheme for GP Practices found that the availability of incentives is likely to increase coverage, but only by a small amount. Currently, only influenza vaccine in people with risk factors are incentivised this way and there may be merit in considering adding other vaccines to the QOF system, if coverage is low. No other incentive or financing schemes were evaluated, and this remains a significant gap in the evidence base, and there is the potential for NHSE and PHE to develop and trial other forms of incentive schemes. Additionally, other process elements, such as modifying the legal framework for delivering vaccines (e.g. HCAs to deliver more vaccines); or non-financial programme inputs (e.g. provision of additional facilities) have not been considered.

Activities and outputs

Most of the studied focussed on specific activities that often were developed or existed outside of the GP practice structure, including reminder/recall systems (*n*=6), campaigns (*n*=2), or involving elements of outreach (*n*=3). Only four modified elements within the GP practice itself. One provided health worker education and 3 of the multi-component interventions modified a wide variety of elements of service delivery. These provide some evidence for effectiveness, although in some cases had significant risk of bias. There is wider international evidence that multi-component interventions can be effective at reducing inequalities in immunisation coverage in deprived, urban areas [27]. However, despite the chronic problems with low coverage in London, few well conducted intervention studies were identified [12]. Of those that were identified, the interventions were vaccine specific campaigns, [60, 66] which may not be easily reproducible, or highly diffuse interventions modifying many aspects of routine service delivery, [57, 61], which may not be relevant to other contexts. Overall, there was little consideration of the effects of interventions on core programme outputs, such as staffing levels, task shifting, information provision, service delivery models, or cost structures within GP practices. Organisational factors associated with immunisation coverage at GP Practice level have been widely studied using cross-sectional surveys. For example, a survey involving 759 practices in England evaluated factors associated with high levels of influenza coverage and found the following to have a significant independent association: identified lead staff member; written report of practice performance; personal invitation to patients; aiming for QOF targets; and using IT systems to identify patients [71]. A similar survey was conducted with 257 GP Practices in a region of England to identify factors associated with MMR coverage [72]. It found no association with practice size or number of staff (GPs or nurses); however having a strategic approach to MMR coverage and identifying clear objectives (e.g. target >90%) were associated with higher coverage. Modifications to the organisation of immunisation services at GP Practices should be a topic of further research and look promising as a target to increase coverage.

Robust and reliable reminder/recall systems are a core component of any vaccine programme and have very good, reproducible evidence for effectiveness [29]. Despite the risk of bias in several of the studies identified in this review, there is some evidence of effectiveness in the England context specifically, although more research would be required to identify the most cost-effective method.

Only one study considered the role of Health Visitors (HVs – community public health nurses) as part of an outreach campaign to increase MMR coverage in one area of the UK, [62] but this was compromised by very high risk of bias. One of the RCTs that had a high risk of bias found that home visits could increase coverage of influenza vaccine in older people, [73] and this may warrant repeating in areas of low coverage, with consideration of cost-effectiveness. Outreach work to improve child health, including immunisation, is usually conducted by HVs, who had formerly been based in GP Practices. In 2015, however, commissioning of HV services was moved to Local Authorities and most HVs left GP Practices to other locations. Currently the primary focus of a HV is to improve outcomes in 6 'high-impact areas', which do not include immunisation. A Health Technology Assessment review of the impact of HVs on child health outcomes, published in 2000, found good evidence for effectiveness [51]. This was not supported by the evidence identified in this study, possibly due to the nature of multiple restructures of HV services since 2000.

Surprisingly, only two RCTs studied the effect of information provided to patients or carers, and both were designed to improve uptake of MMR vaccine, due to the historical controversy in this area. The provision of signposting information on a teddy-bear was not found to be an effective method, although the study was at high risk of bias, [58] and a web-based decision aid produced mixed results with small intervention groups, making firm conclusions difficult to draw [59]. None of the other intervention studies considered reducing vaccine hesitancy as an explicit aim, which is in line with the wider available evidence from other high-income countries [25]. Improving the information provided to patients would be a key area for future evaluation in the England context.

One study found that provision of a financial incentives with reminder/recall messages to adolescent females could increase uptake of HPV vaccine [67]. An extensive Health Technology Assessment evaluating incentives for parents of children eligible for vaccination, published in 2015, found limited evidence of effectiveness overall, but concluded that incentives for parents might not be acceptable, but if introduced they should be universal and not targeted [36]. If coverage in adolescent vaccines is low, then incentives could be further explored in this population.

Outcomes and impact

Evidence of effectiveness of all included studies was measured as changes in vaccine coverage levels. None considered overall impacts such as reduction in cases of VPDs, or overall morbidity and mortality. However, this is likely to be considered on a national level by PHE independent of the research evidence. Although reduction in inequalities is a key outcome of the programme, only one study considered the reduction in inequalities specifically [61]. Focusing vaccine campaigns or outreach interventions in areas of higher disease incidence or outbreaks may enhance the effectiveness of such programmes and provide useful evidence if evaluated.

Lessons for policy

When compared to the logic model, we identified several areas where interventions are available to support modifications to the existing system to improve coverage. These include: multi-component interventions that improve service quality in geographic areas of low coverage; incentive payments to adolescents; effective reminder/recall systems; potential use of outreach programmes; and possible modifications to contracting and incentive payments. There are also several areas of programme implementation that have not been evaluated and could be potential future targets for policy changes or interventions, including: task shifting; additional non-financial resource inputs; information to patients; health worker training; and changes to organisational management within a GP practice.

Limitations

The limitations of this study include: the biased nature of the available evidence; diffuse nature of the interventions; the small number of studies overall; and the limited number of studies for different categories of interventions. Thus, the conclusions drawn here should be approached with caution.

Conclusions

The process of delivering the routine immunisation programme through GP Practices in England is well described, but contained across a wide range of documents. This has been synthesised into a clear logic model with underlying assumptions that will be valuable to policymakers and researchers to develop and test interventions in the context of declining national immunisation coverage. The evidence base for interventions to increase immunisation coverage in the England context are limited by a small number of studies for different categories of interventions; and by significant risks of bias in much of the evidence base. Several areas remain unexplored as targets for interventions, especially modifications to the organisational management of GP Practices.

Additional file

Additional file 1: Medline Search Strategy. (DOCX 15 kb)

Abbreviations

B&A: Before and after study design; BMA: British Medical Association; CB&A: Controlled before and after study design; CVD: Cardiovascular disease; CHIS: Child Health Information System; CI: 95% confidence interval; DH: Department of Health; GMS: General Medical Service contract; GP: General Practitioner; GPC: General Practitioners Committee; HCA: Healthcare Assistant; HPV: Human papillomavirus; HSCA: Health and Social Care Act; HV: Health visitor; ITS: Interrupted time series study design; JCVI: Joint Committee on Vaccines and Immunisations; MHRA: Medicines and Healthcare Products Regulatory Agency; MMR: Measles, mumps and rubella vaccine; NHSD: National Health Service Digital; NHSEm: National Health Service Employers; NHSE: National Health Service England; OR: Odds ratio; PHE: Public Health England; PMS: Personal Medical Services contract; QOF: Quality and Outcomes Framework; RCT: Randomised controlled trial; VPD: Vaccine preventable disease; WHO: World Health Organisation

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Availability of data and materials

The datasets used and analysed during the current study are available from the corresponding author on reasonable request

Authors' contributions

TCB conceived the study with advice from SMJ. TCB undertook the searches and screening by titles. TCB and SMJ reviewed the studies for inclusion and undertook quality scoring. TCB wrote the initial draft of the paper, with editorial advice from SMJ. Both authors read and approved the final manuscript.

Ethics approval and consent to participate

This study was approved by the LSHTM Ethics Committee. As it is a secondary analysis of publicly available data no consent was required.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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4.3.2 Research paper 2: A systematic review of interventions to reduce inequalities in vaccine coverage in children and adolescents aged <19 years.

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Student ID Number	LSH345619	**Title**	Dr
First Name(s)	Timothy		
Surname/Family Name	Crocker-Buque		
Thesis Title	An Evaluation of the Implementation of Routine Vaccination at GP Practice Level in England		
Primary Supervisor	Sandra Mounier-Jack		

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

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Interventions to reduce inequalities in vaccine uptake in children and adolescents aged <19 years: a systematic review

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ABSTRACT

Background In high-income countries, substantial differences exist in vaccine uptake relating to socioeconomic status, gender, ethnic group, geographic location and religious belief. This paper updates a 2009 systematic review on effective interventions to decrease vaccine uptake inequalities in light of new technologies applied to vaccination and new vaccine programmes (eg, human papillomavirus in adolescents).

Methods We searched MEDLINE, Embase, ASSIA, The Campbell Collaboration, CINAHL, The Cochrane Database of Systematic Reviews, Eppi Centre, Eric and PsychINFO for intervention, cohort or ecological studies conducted at primary/community care level in children and young people from birth to 19 years in OECD countries, with vaccine uptake or coverage as outcomes, published between 2008 and 2015.

Results The 41 included studies evaluated complex multicomponent interventions (n=16), reminder/recall systems (n=18), outreach programmes (n=3) or computer-based interventions (n=2). Complex, locally designed interventions demonstrated the best evidence for effectiveness in reducing inequalities in deprived, urban, ethnically diverse communities. There is some evidence that postal and telephone reminders are effective, however, evidence remains mixed for text-message reminders, although these may be more effective in adolescents. Interventions that escalated in intensity appeared particularly effective. Computer-based interventions were not effective. Few studies targeted an inequality specifically, although several reported differential effects by the ethnic group.

Conclusions Locally designed, multicomponent interventions should be used in urban, ethnically diverse, deprived populations. Some evidence is emerging for text-message reminders, particularly in adolescents. Further research should be conducted in the UK and Europe with a focus on reducing specific inequalities.

INTRODUCTION

In high-income countries, substantial differences exist in vaccine uptake relating to socioeconomic status, gender, ethnic group, geographic location and religious belief.[1–24] In 2009, the National Institute for Health and Care Excellence (NICE) conducted a systematic review of effectiveness and cost-effectiveness of interventions to 'reduce differences in the uptake of immunisations in children and young people under the age of 19 years'.[19] Since then new technologies have emerged, including data systems and online interventions, and have been applied to vaccination. In addition, new programmes have been implemented, such as human papillomavirus (HPV) vaccine in adolescents. An updated review of the evidence is therefore warranted. The aim of this study is to update the 2009 NICE systematic review, focusing and refining the recommendations on effective interventions to decrease vaccine uptake inequalities in high-income countries.

MATERIALS AND METHODS

We repeated the NICE guidance methodology,[19 25] conducting our review in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement.[26]

Search strategy

We searched MEDLINE, Embase, ASSIA, The Campbell Collaboration, CINAHL, The Cochrane Database of Systematic Reviews, Eppi Centre, Eric and PsychINFO using the strategy described in online supplementary appendix 1. Results were limited to publications in English from April 2008 until November 2015.

Inclusion and exclusion criteria

We included studies with the following characteristics:

- *Study design*: randomised controlled trials (RCTs), quasi-experimental (including interrupted time series and before-and-after studies), ecological and observational cohort studies.
- *Population*: children and young people (CYP) from birth to 19 years in OECD countries.[27]
- *Intervention*: delivered at primary/community care level, with the aim of increasing vaccine uptake in a specific population or in the overall population, with outcomes reported for specific subgroups.
- *Outcomes*: vaccine uptake, including initiation of vaccination course, schedule completion, being up-to-date (UTD) for age, or coverage, with either a focus on reducing inequalities or where outcomes in different population groups are reported.

In addition, we included references from review articles or protocols identified in the search that fitted inclusion criteria, but we did not consider inequalities.

Study selection process

One reviewer initially screened articles on title and manually de-duplicated records. Two reviewers screened potentially relevant abstracts independently. Any disagreement was resolved by discussion on the basis of the inclusion criteria. Both reviewers agreed the final inclusions.

RESULTS

The study selection process is presented in online supplementary figure S1. Of 12 386 unique articles, 315 abstracts were screened. Of these, 80 full text articles were reviewed, along with 23 studies identified from the references of 22 review articles or protocols.[28–49]

In total, 41 studies were included (17 RCTs, 20 quasi-experimental and 4 retrospective cohort studies), which were conducted in the USA (n=31), the UK (n=5), Canada (n=3) and Australia (n=2).

Studies reported on multicomponent complex interventions (n=16), patient-focused reminder/recall systems (n=18), outreach programmes (n=3), prompts for healthcare workers (HCWs) (n=2) and computer-based interventions (n=2).

We categorised results by using the intervention type and by vaccinations for the age group:

- Childhood vaccines from birth to age 11 (singly or in combination): tetanus, diphtheria and pertussis (TDaP); polio (IPV); haemophilus influenza b (Hib); pneumococcal (PCV); rotavirus; meningitis B (MenB); meningitis C (MenC); measles, mumps and rubella (MMR).
- Adolescent vaccines from age 11 to 19 (singly or in combination): HPV, MenC, quadrivalent meningitis (Men4) and relevant boosters.
- Seasonal influenza alone in CYP.

The terms 'uptake' and 'coverage' were used inconsistently in the literature. We have defined 'uptake' as the proportion of the eligible population who received a vaccine during a specific time period and 'coverage' as the proportion of an eligible population that is vaccinated, regardless of when they received the vaccine.

Complex interventions

Complex interventions comprise several interacting components that may impact on a range of outcomes or have variability in delivery.[50] Table 1 describes intervention components, sample size and study outcomes.

Childhood vaccinations

Six studies showed evidence of effectiveness for locally developed complex interventions to increase uptake in ethnically diverse, low-income populations. In the USA, a retrospective evaluation of 'Start Right', a community-developed intervention involving bilingual promotional materials, peer health educators, outreach, parental reminders and provider support, found that children aged 19–35 months enrolled in the programme had significantly higher uptake than control children.[51] Another intervention involving reminder/recall systems, increased clinic access, use of standing orders and provision of educational materials was evaluated in a before-and-after study, which found that children in the intervention year had a statistically significant increase in vaccine uptake.[52] An intervention identifying children not UTD attending a charitable community organisation for resource-poor families, providing information and vaccinations, followed by reminders, increased coverage rates after 9 months.[53] In Canada, an evaluation of the 'Families First' programme (involving identification of high-risk families, home visiting and signposting to health services) found small but significant increases in being UTD by first and second birthdays.[54] An RCT evaluating an intervention that escalated in intensity on the basis of vaccine status over time, which involved universal, language appropriate reminder postcards, targeted telephone calls and intensive outreach and home visitation, showed a significant increase in children being UTD at 12 months.[55] In the UK, a complex primary care focused intervention (developing a general practitioner (GP) network, financial incentives, better use of data and IT) significantly increased uptake of MMR coverage in a deprived, diverse community, although inequalities persisted in some smaller ethnic groups.[56]

The uncontrolled evaluation of an intervention to increase PCV coverage in Aboriginal infants in an Australian urban community (involving staff training, information materials, contact with parents, see online supplementary information, and stickers in health records) showed an increase.[57] However, no statistical analysis was performed and coverage remained under the national Aboriginal average.

Adolescent vaccinations

Two Scottish studies reported on the HPV vaccine programme national roll-out among females aged 12 and 13, alongside a time-limited catch-up programme for females aged up to 18 (in school and in the community) and an accompanying media campaign.[58 59] In the routine and catch-up programmes, uptake decreased by deprivation quintile for each subsequent dose, leading to a greater proportion of more deprived young people not completing the programme and thus increasing inequalities. Uptake was lowest in females who had left school and were vaccinated in the community (dose 1: 49%, dose 3: 30%), who were also more likely to be in a lower socioeconomic group. First-dose uptake was higher when regional health boards delivered the community catch-up clinic (52.3%), compared to GP practices (43.5%).

Two US studies used social marketing to increase HPV vaccine uptake in a large geographic area with an urban–rural divide, high ethnic diversity and a large low-income population: one in females aged 9–19 years and one in males aged 9–13 years.[60 61] In females, the approach overall had no differential effect. However, males who were unvaccinated in intervention counties were significantly more likely to be vaccinated after 6 months, with higher uptake among the non-Hispanic black population. However, males in intervention counties were also 24% less likely to receive a TDaP booster ($p\leq0.001$).

A large before-and-after American study involving 17 federally qualified health centres (that act as a safety-net healthcare provider for underserved communities) evaluated the impact of a webinar targeting clinic coordinators, aiming to increase implementation of AFIX, a CDC-recommended list of practice-based interventions to increase vaccine uptake (including data collection and analysis, feedback to providers, incentive and specific staff). It found a statistically significant 1.1% increase in adolescents becoming UTD.[62]

Another American study evaluated a practice-based intervention (involving educational meetings, reminder/recall system usage, targeted reminders and incentive payments) alongside a telephone reminder to parents delivered through schools, which sought to reduce an urban/rural inequality.[63] Results showed a significant increase in the uptake of first-dose HPV and Men4 vaccines (11–12 year olds) and HPV vaccine course completion (males aged 13–18 years). No significant differences found for other age bands or vaccine types.

Influenza vaccine in CYP

Two related American articles reported on the 'Four Pillars' intervention (increased service access, reminder/recall system, improved provider office systems and immunisation champions) to increase the uptake of seasonal influenza vaccine in CYP aged 6 months to 18 years.[64 65] Increases were seen in intervention

Table 1 Population, intervention components and outcomes of the included studies considering complex interventions

References	First author and year	Population	Vaccine (s)	Inequality	Sample (intervention)	Intervention name	Intervention components: Identification or targeting of CYP in risk groups	Promotional materials (eg, posters or media campaign)	Education children's parents or young people directly	Patient reminder/ recall and/ or tracking and surveillance	Outreach (eg, home visits)	HCW training (. allied professionals)	HCW prompts	Additional services (eg, clinics)	Standing Orders*	Community involvement	Outcome (effect measures and/or 95% CI)
[51]	Findley *et al*, 2008	Children 19–35 months	Schedule	Urban, ethnicity, low income	10 857 (895)	Start right	–	Y	Y	Y	Y	Y	–	–	–	Y	11.1% higher uptake and 53% more likely to be UTD (p<0.01, no CI)
[52]	Fu *et al*, 2012	Children aged <24 months	Schedule	Urban, ethnicity, low income	3945 (1999)	–	–	Y	Y	Y	–	Y	Y	Y	Y	–	16% increase in uptake to 87% (p<0.001, no CI)
[53]	Suryadevara *et al*, 2013	CYP<19 years	Schedule	Low income/ deprived	1531	–	Y	–	Y	Y	–	–	–	Y	–	Y	Increase in coverage In enrolled children from 28% to 40%
[54]	Isaac *et al*, 2015	High-risk infants identified at birth	Schedule	Urban, ethnicity, low income	9746 (4562)	Family First	Y	–	Y	–	Y	–	–	–	–	–	Intervention risk ratio 1.06 for being UTD (CI 1.03 to 1.08).
[55]	Hambidge *et al*, 2009	New-born infants until 15 months old	Schedule	Urban, ethnicity, low income	811	–	Y	Y	Y	Y	Y	–	–	–	–	–	Intervention OR of 1.6 for being UTD (CI 1.2 to 2.1)
[56]	Cockman *et al*, 2011	Children aged 2 years	MMR	Urban, ethnicity, low income	36 practices	–	Y	–	–	Y	–	Y	Y	Y	–	–	A significant quarterly coverage increase of 1.86%
[57]	Thomas *et al*, 2008	Aboriginal infants	7-valent PCV	Ethnicity	Ecological	–	Y	Y	Y	–	Y	Y	Y	–	–	–	10% increase in coverage to 50% (no statistical analysis)
[58, 59]	Potts *et al*., 2014; Sinka *et al*, 2013.	Girls aged 12–13, with catch-up for under 18s.	HPV	Deprivation	220 000	–	Y	Y	–	Y	–	Y	–	Y	–	–	Equal uptake by deprivation quintile for first dose, with uptake reducing for doses 2 and 3.
[60]	Cates *et al*, 2011	Girls aged 9–19	HPV	Urban, low income, ethnicity	100 counties (4 counties)	–	–	Y	–	–	–	–	Y	–	–	Y	Different responses across intervention sites, no significant difference overall.
[61]	Cates *et al*, 2014	Men aged 11–12	HPV	Urban, low income, ethnicity	28 counties (13 counties)	Protect Him	–	Y	–	–	–	Y	–	–	–	–	Intervention 34% more likely to be vaccinated (p<0.002), with higher uptake in non-Hispanic black population.
[62]	Moss *et al*, 2012	Adolescents aged 12–17	Schedule	Urban, low income, ethnicity	17 health centres	AFIX (by proxy)	–	–	–	–	–	Y (to increase use of complex intervention)	–	–	–	–	Intervention 1.1% increase in being UTD across the schedule 1 month later (to 32.2%, p=0.001)

Continued

Table 1 Continued

References	First author and year	Population	Vaccine (s)	Inequality	Sample (intervention)	Intervention name	Intervention components: Identification or targeting of CYP in risk groups	Promotional materials (eg, posters or media campaign)	Education children's parents or young people directly	Patient reminder/ recall and/ or tracking and surveillance	Outreach (eg, home visits)	HCW training (. allied professionals)	HCW prompts	Additional services (eg, clinics)	Standing Orders*	Community involvement	Outcome (effect measures and/or 95% CI)
[63]	Chung *et al*, 2015	Adolescents aged 11–18	Tdap, Men, HPV	Urban/rural	5 counties (1 county, 7 health centres)	–	–	Y	–	Y	–	Y	–	–	–	–	Increase in the first dose HPV in 11–12 year olds (OR 1.21, CI 1.01 to 1.50), quad men (OR 2.23, CI 1.7 to 2.9) and in 13 to 19 year olds HPV vaccine completion in men (OR 1.45, CI 1.02 to 2.05).
[64, 65]	Nowalk *et al*, 2014; Zimmerman *et al*, 2014	CYP aged 6 months to 18 years	Influenza	Ethnicity	24 practices	Four Pillars	–	Y	–	Y	Y	Y	Y	Y	Y	–	Greater increase in uptake in intervention group (9.9% vs 4.2% in controls, p<0.001) and higher in white children (16.7%, p<0.05)
[66]	Logue *et al* 2011	Children and adults aged >6 months	Influenza	Urban, low income, ethnicity	5061	–	–	Y	–	–	–	Y	Y	–	Y	–	Increase in uptake in 3–8 year olds (15%, p<0.05) and 9–17 year olds (19%, p<0.05), but not younger children.

*Standing orders allow non-prescribing health professionals to give medicines including vaccinations without a doctor's prescription in certain situations.
CYP, children and young people; HCW, healthcare workers, for example, doctors, nurses or allied health professionals; HPV, human papillomavirus vaccination; MMR, measles, mumps and rubella vaccination; PCV, pneumococcal vaccination; UTD, up-to-date with all recommended vaccines for age.

and control groups, with significantly greater increases in intervention areas and in white children, with a narrowing of the gap between ethnic groups.

One further uncontrolled before-and-after study in an urban, ethnically diverse family medicine centre examined a predominantly HCW-focused intervention (involving policy change, standing orders, health record modification and information to patients) and showed increases in coverage in children aged between 3 and 18 (but not younger), with greater increases in African-Americans.[66]

Outreach programmes

One study conducted in parents of children from birth to 35 months evaluated the 'BIRTH PIP' intervention (parental education at birth followed by home visits) among 400 African-American mothers.[67] When compared with the population, participants had significantly higher vaccination coverage (92% vs 49%), although there was significant loss to follow-up (50% loss by 19 months). Another RCT evaluating an enhanced prenatal and postnatal home visitation programme among 530 low-income women versus regular community care found no difference in vaccination uptake.[68] However, one other US study found that children living in deprived areas with an immunisation coordinator were less likely not to be UTD for age (adjusted OR 0.6) and that overall disparities had decreased between groups over the time of the programme.[69]

Reminder/recall systems

Table 2 describes the intervention type, sample size and study outcomes.

Childhood vaccinations

Two large American RCTs compared centralised systems versus Practice-based reminder/recall systems and concluded that centralised systems increased likelihood of children becoming UTD for age.[70 71]

A UK before-and-after study evaluating an escalating reminder/recall system, including letters and home visits, in an ethnically diverse, urban population, found that uptake was stable in intervention areas, but decreased in non-intervention areas.[72] In the USA, a large RCT targeting non-UTD children aged <20 months with a postal reminder or recall notices found no coverage difference in younger children (7 or 12 months), but a significant increase at 19 months.[73] The hypothesis offered was that younger children would be attending services more regularly and thus have higher uptake, whereas older children might not and thus be more responsive to reminders. Of two Canadian studies examining MMR coverage in deprived areas, one controlled before-and-after study found that telephone reminders increased MMR uptake in children not UTD at 24 months;[74] however, the other non-controlled time series found increases in intervention (targeted phone, mail and outreach) and non-intervention sites, with no decrease in socioeconomic disparities.[75]

The Text4Health study evaluated the effect of sending text messages to parents in an American, urban, low-income population, prompting them to have their children aged 7–22 months vaccinated with Hib.[76] It found a non-significant uptake difference after 2 weeks. An RCT undertaken in an urban, low-income minority ethnic population in the USA randomised participants to receive text-message reminders to schedule an appointment and/or reminders of the appointment details, or usual care to increase MMR vaccine uptake at 13 months.[77] There was no difference in uptake between the arms, except in children who did not have a vaccination appointment booked and who received scheduling and appointment reminders.

An uncontrolled before-and-after study evaluating an immunisation reminder calendar given to parents of Aboriginal children in Australia showed timeliness for being UTD for vaccines increased, once significant outliers were excluded.[78]

Adolescent vaccinations

Two studies examined the use of repeated SMS reminders. The Text4Health study found significant increases in MenC and TDaP vaccine uptake among 11–18 year olds in the intervention arm.[76] Another non-randomised trial looked at second and third doses of HPV vaccine in urban adolescent females and found that intervention individuals were significantly more likely to receive doses on time.[79]

Two studies examined different reminder/recall media. One RCT evaluated a tiered protocol with progressively more intensive reminder/recall and outreach dependent on continued lack of vaccine uptake.[80] It found that the intervention was associated with becoming UTD for each vaccine and was more successful among females and black and Hispanic adolescents. An uncontrolled study targeting ethnically and socioeconomically diverse parents of adolescents not UTD with a variety of reminders over 12 months showed that 25.5% participants received one missing vaccine.[81]

An RCT comparing uptake of Men4 and TDaP in adolescents not UTD using phone reminders only to parents, versus parents and adolescents, found significantly higher uptake in the parent and adolescent reminder group.[82] A non-RCT compared postal, email or SMS reminders for adolescent vaccination on the basis of parental preference and found that those who signed up were more likely to become UTD, irrespective of the method of reminder.[83]

A UK study evaluated giving a £40 incentive alongside a reminder/recall system and found significantly increased odds of completing the HPV vaccine course, irrespective of deprivation levels.[84]

Influenza vaccination in CYP

Three American RCTs examined the effect of SMS reminders targeted at low-income, minority ethnic parents on influenza vaccine uptake. Parents of CYP aged 6 months to 18 years receiving 5 weekly community-developed educational and clinic reminder text messages significantly increased uptake although overall levels remained low.[85] When comparing educational and conventional SMSs with postal reminders targeted to parents of children aged 6months to 8 years, those receiving the educational SMS had higher second-dose influenza vaccine uptake.[86] Another study compared interactive SMSs with educational ones, compared to usual care, in CYP aged 6 months to 17 years unvaccinated for influenza late in the season.[87] Children of parents who received an interactive SMS were slightly more likely to be vaccinated. However, only 1% parents used the interactive feature.

Reminder systems targeted at HCWs

A large retrospective before-and-after study in the USA examined the effect of a vaccine alert placed within electronic health records of females aged 9–26.[88] The intervention prompted cohort had higher initiation than the unprompted control cohort (35% vs 21.3%), with higher initiation rates seen in African-Americans. Another American RCT examined the effect of HCW prompts on adolescent vaccine uptake in a diverse population, but found no difference in uptake between intervention and control practices.[89]

Table 2 Population, intervention components and outcomes of the included studies considering reminder/recall interventions targeted at patients or clients.

References	First author and year	Population	Vaccine(s)	Inequality	Sample Size (intervention)	Intervention components: Identification of those not UTD*	Text message (s)	Letter (s) to home	Telephone call(s)	Outreach (eg, home visit)	Intervention description	Outcome (effect measures and/or 95% CI)
70	Kempe *et al*, 2013	Children aged 19–35 months	Schedule	Urban/rural, not UTD	55 173	Y	–	Y	–	–	Practices participating received financial assistance. Up to three notifications sent.	Increase in chances of becoming UTD if population based reminder system used (relative risk 1.23, CI 1.10 to 1.37)
71	Kempe *et al*, 2015	Children aged 19–35 months	Schedule	Urban/rural, not UTD	18 235	Y		Y	Y	–	Centralised reminder system involved either telephone and letters or letters alone. The practice-based system was variable at practice level, but involved calls or letters or both.	Increase in children being UTD by 2.5% (p<0.001) using the centralised system (adj OR 1.31, CI 1.16 to 1.48)
72	Atchison *et al*, 2013	Children under 5 years	Schedule	Urban, low income, ethnicity	32 practices	Y	–	Y	Y	Y	Escalating intervention comprising two letters, followed by a telephone call or home visit if no response.	Significant increase in proportion UTD in the intervention group, but as a result of unexplained decreases in the non-intervention group.
73	Dombkowski *et al*, 2014	Children under 20 months	Schedule	Urban, not UTD	10 175	Y	–	Y	–	–	Recall notices issued at 7 and 19 months, with a reminder notice at 12 months.	No difference in children at 7 or 12 months, but a significant difference of 7% (p<0.0001)| at 19 months.
74	Lemstra *et al*, 2011	Children not UTD with MMR at 24 months	MMR	Deprivation, low income	629	Y	–	–	Y	Y	Home visits targeted as a separate intervention in low-income areas.	Significant increase in intervention areas (rate ratio 1.10, CI 1.08 to 1.12). Increase in home visit areas, but not significant due to small numbers.
75	Cushon *et al*, 2012	Children aged 14–20 months	MMR	Deprivation, low-income	24 540	Y	–	Y	Y	Y	Identification of children not UTD, five telephone calls, letter home and then home visitation.	Increases observed in across all study sites, including low-income areas. No significant difference observed in intervention sites, disparities remained.
76	Stockwell *et al*, 2012 A	Children aged 7–22 months	Hib	Urban, low income	174	Y	Y	Y	–	–	Repeated reminders delivered five times until vaccination status registered as UTD.	Non-significant difference, possibly due to small sample size (n=174)
77	Hofstetter *et al*, 2015 A	Children aged 9.5–10.5 months.	MMR	Urban, low income, ethnicity	2054	–	Y	–	–	–	Participants either received reminders to schedule a vaccination appointment and then an appointment reminder; appointment reminder only; or usual care.	No difference between arms except in children with no vaccination appointment booked, who received scheduling and appointment reminders (relative risk ratio 1.11, CI 1.00 to 1.24)
78	Abbott *et al*, 2013	Aboriginal children from birth to 20 months	Schedule	Ethnicity	505	–	–	–	–	–	Reminder calendar given to parents	Significant increase in vaccinations being given on time, once outliers were excluded.

Continued

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Table 2 Continued

References	First author and year	Population	Vaccine(s)	Inequality	Sample Size (intervention)	Intervention components: Identification of those not UTD*	Text message (s)	Letter (s) to home	Telephone call(s)	Outreach (eg, home visit)	Intervention description	Outcome (effect measures and/or 95% CI)
76	Stockwell *et al*, 2012 A	Adolescents aged 11–18	Td, Men4	Urban, low income, ethnicity	361 (195)	Y	Y	–	–	–	Repeated reminders delivered five times until vaccination status registered as UTD.	Significantly more adolescents in the intervention arm received missing vaccines at 4, 12 and 24 weeks (eg, at 12 weeks 26.7% vs 13.9% in controls, 12.8% difference CI 4.7% to 20.9%, p=0.003).
79	Kharbanda *et al*, 2011	Adolescent girls aged 9–20	HPV (doses 2 and 3)	Urban	124	Y	Y	–	–	–	Up to three weekly reminders that child due for an HPV dose.	Intervention individuals were more likely than controls, contemporaneous (adjusted OR 2.03, CI 1.29 to 3.22 p=0.003) and historical (AOR 1.83, CI 1.23 to 2.71, p=0.002) to receive next HPV dose on time.
80	Szilagyi *et al*, 2011	Adolescents aged 11–15	Pertussis, Men, HPV	Ethnicity	7546	Y	–	Y	Y	Y	Reminder/recall and home visits undertaken by specialist vaccine system navigators.	Becoming UTD for each vaccine was 12% to 16% higher in the intervention group (p<0.001), with 71% of the intervention group having received a reminder and 12% a home visit.
81	Bar-Shain *et al*, 2015	Adolescents aged 11–18	HPV, MenC, Tdap	Deprivation, ethnicity	3393	Y	Y	Y	Y	–	Depending on availability of contact information either an email, text message or postcard was sent, repeated every 2 months for up to 12 months until UTD	25.5% of adolescents in the study received at least one missing vaccine and response to the messaging reduced with each round. There were no differential effects by age, gender, insurance status or ethnicity.
82	Brigham *et al*, 2012	Adolescents aged 13–17.	Tdap, Men4	Urban, not UTD	424	Y	–	–	Y	–	Compared calls to parents to calls to parents and adolescents.	Higher uptake in the parent and adolescent reminder group (adj OR 2.27,) however with a large CI (CI 1.00 to 5.18)
83	Morris *et al*, 2015	Adolescents aged 11–17.	HPV, Men4, Tdap, Var	Urban, deprivation	5050	Y	Y	Y	Y	–	Series of 3 batches of reminders over 6 months, based on parents' choice of message medium.	Those who signed up for any method of reminder were more likely to become UTD than those who only received an enrolment phone call (24.6% vs 12.4%, p<0.001).
84	Mantzari *et al*, 2015	Adolescent girls aged 17–18	HPV initiation and completion	Deprivation	1000	Y	Y	Y	–	–	Letter with incentive offer sent to house, followed by series of text messages between the second and third dose.	Increased uptake of the first dose in intervention individuals (OR 1.63). However, no differential impact by deprivation.

Continued

Table 2 Continued

References	First author and year	Population	Vaccine(s)	Inequality	Sample Size (intervention)	Intervention components: Identification of those not UTD*	Text message (s)	Letter (s) to home	Telephone call(s)	Outreach (eg, home visit)	Intervention description	Outcome (effect measures and/or 95% CI)
85	Stockwell *et al*, 2012 B	CYP aged 6 months to 18 years.	Influenza	Low income, ethnicity	9213	–	Y				Series of five text messages with educational information.	Higher proportion of CYP vaccinated in the intervention group (3.7% increase, CI 1.5% to 5.9%, p=0.001; relative risk ratio 1.09, CI 1.04 to 1.15), although overall rates remained low at around 40%
86	Stockwell *et al*, 2015	Children 6 months to 8 years	Influenza	Low income, ethnicity	660	–	Y	Y	–	–	Three arms: education vs conventional text plus letter, and usual care (letter only) control.	Children in the educational group were significantly more likely to receive the second influenza dose (72.7%, p=0.003) compared to conventional text (66.7%) and postal reminder only (57.1%).
87	Hofstetter *et al*, 2015 B	CYP 6 months to 17 years	Influenza	Low income, ethnicity	5462	Y	Y	Y	–	–	Three arms: interactive educational message vs educational text vs usual care control.	The interactive component of the messages had low uptake (1.0% using the service); however, slightly more in this arm were vaccinated than those who received the education only text (38.5% vs 35.3%, relative risk ratio 1.09 CI 1.00 to 1.19, p=0.04)

CYP, children and young people; HCW, healthcare workers, for example, doctors, nurses or allied health professionals; Hib, *Haemophilus influenzae* group b vaccination; HPV, human papillomavirus vaccination; Men4, quadrivalent meningococcal vaccination (A, C, W and Y); MenC, meningococcal group c vaccination; MMR, measles, mumps and rubella vaccination; Td, tetanus and diphtheria vaccination; Tdap, tetanus, diphtheria, pertussis vaccination; UTD, up-to-date with all recommended vaccines for age; Var, varicella vaccination.

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Computer-based interventions

Two studies examining computer-based interventions found no effect on vaccine uptake. An RCT evaluating an intervention targeting African-American females to increase HPV vaccine uptake ('Girls on Guard') found that only 12% of 216 participants initiated the vaccine course, with equal numbers in intervention and control groups.[90] Another randomised study examined a computer-based health message intervention delivered in school-based clinics in a population of ethnically diverse parents of non-HPV vaccinated children (n=445) and found that rhetorical questioning message prompts increased vaccination intention, but not uptake.[91]

DISCUSSION

The impact of socioeconomic context, including deprivation, ethnicity or geography, on health outcomes has been well documented[92] and is equally true of vaccine programmes.[93] Presented here is the evidence of effectiveness for interventions to reduce the resulting inequalities in vaccination coverage. Multicomponent locally designed interventions demonstrated the best evidence in children and adolescents in the short term. These interventions are designed for a specific context and population, so may not be transferable to other settings. The 2009 NICE guidance recommended home visiting as a possibly cost-effective intervention, which is partially supported by this evidence. All nine interventions that included a home visit component showed some evidence of effectiveness.[51 54 55 57 64 72 74 75 81] Although two of three studies considering outreach interventions alone were not effective, they were either small or had significant loss to follow-up.[67 68] The three studies using escalating intervention intensity seemed particularly effective, which is consistent with the previous review.[55 72 80] This may be a cost-effective way of incorporating home visiting into a programme. Social marketing interventions show mixed evidence, but could be a promising approach in adolescents.[60 61] No studies provided good long-term evidence of sustained uptake.

The evidence around reminder/recall systems continues to evolve. In the USA, centralised reminder/recall systems worked better than practice-based ones; however, this may be specific to the American health system. Evidence of effectiveness of text-message reminders in reducing inequalities remains limited. The type of messages received may impact vaccine uptake, particularly if educational or interactive messages are used. However, more research is required to confirm this effect. A recent systematic review of 'new media' to improve vaccine uptake found evidence of effectiveness for SMS reminders, but also considered a wide variety of other interventions such as mobile phone apps and the use of social media.[44] We did not identify any studies that used new media to reduce vaccine uptake inequalities, and this could form potentially useful future work. The two studies examining computer-based behaviour change interventions found no evidence of effectiveness.

There is some evidence for postal and telephone reminders in children and adolescents, although heterogeneity of interventions precludes from drawing firm conclusions. Choosing the reminder method and including adolescents alongside parents for reminders possibly improved effectiveness.[82 83] A recent systematic review found that targeting postal and telephone reminders to parents was most effective at increasing early childhood vaccination.[37]

We found mixed evidence for HCW-focused reminders, which adds to the previous review's two positive studies. The evidence for client-side financial incentives was mixed in the previous review, and we found one additional study that showed an increase in adolescent HPV uptake. However, a recent systematic review found no effect of incentives on vaccine uptake in children.[30]

Two studies noted intervention effectiveness in older children, but not younger children.[66 73] This may be because younger children are more likely to seek routine healthcare and should be a consideration when targeting interventions.

Tackling inequalities

Most interventions did not specifically target inequalities, but instead delivered interventions in low-uptake populations and focused on CYP not UTD for age.

Several interventions reported differential effects by ethnicity, including Aboriginal infants in Australia,[57 78] White children[64–66] and non-Hispanic black adolescents[65] as well as black and Hispanic adolescents in the USA.[61 80] These interventions are very context and population specific, and further work is required to develop the evidence base for interventions targeting specific ethnic groups or other characteristics associated with vaccine uptake inequality such as deprivation.

Limitations

Studies were mainly from the USA, with some from the UK, Canada and Australia. We found none from other European countries. This paucity mirrors the low number of European studies in the previous review. This may be related to the English language restriction or due to the unavailability of certain types of data (eg, it is illegal to collect data on ethnicity in France). We did not consider cost-effectiveness of interventions, although this was reported in some studies, due to challenges in comparing results between different health systems. Vaccine hesitancy was not considered for two reasons: first, a separate systematic review exists on interventions to reduce hesitancy and[40] second, very few inclusions in that review or this paper measured uptake or coverage as an outcome. There are likely to be opportunities to incorporate evidence-based interventions to reduce hesitancy more explicitly within interventions to reduce inequalities in uptake between different groups.

Recommendations

- Locally designed, multicomponent interventions have the strongest evidence for increasing vaccine uptake, particularly in urban, ethnically diverse, low-income or deprived population.
- Some evidence is emerging relating to the use of text messages and other types of reminder/recall systems, particularly in adolescents, and should be considered.
- Interventions that increase in intensity targeting persistent non-responders have some evidence of effectiveness and may be more cost-effective than other interventions, such as universal home visiting alone.
- Further research should be conducted: in the UK and Europe, focusing on reducing specific inequalities, such as by the ethnic or religious group and on smartphone technology to increase vaccine uptake.

What is already known on this subject

In high-income countries, substantial differences exist in vaccine uptake relating to socioeconomic status, gender, ethnic group, geographic location and religious belief. A previous systematic review from 2009 concluded that the evidence was promising for outreach programmes, mixed for reminder/recall systems and information provision and limited for text messages and service delivery interventions.

What this study adds

This study updates the systematic review to 2015 and concludes that locally designed, multicomponent interventions have evidence of effectiveness in urban, ethnically diverse, deprived populations. There is some evidence emerging for text-message reminders, particularly in adolescents, but that other types of technology have not yet been evaluated.

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5 Study design and methods

Using the background information on vaccine programme delivery and the results from the literature reviews I have developed a set of specific research questions to test hypothesis relevant to the overall aims and objectives, which are presented in section 5.1 below. In the subsequent sections I describe the methodology and rationale for each of the methods chosen to test the hypotheses. This is then followed by descriptions of the data sources and collection methods, ethical approval and sampling strategy.

5.1 Research questions and hypotheses

The introduction highlighted the current challenges facing the routine vaccination programme in England, including multi-year decreases in coverage in some core vaccines for children, low coverage for vaccinations in adults, persistent lower coverage in London, and inequalities in coverage in certain population groups. The evidence from the literature reviews suggest that there are many aspects of the organisation and delivery of vaccination activities that could be modified to improve coverage, ranging from improving the reminder/recall systems in place, to modifying the funding system to incentivise specific activities. However, the overall design of the vaccination programme is complex and opaque, being described across many documents, which have been synthesised into the logic model presented in section 4.3.1. Little is known about the role of the GP practice within this system and the experience of organising programme delivery at practice level. Therefore, the methods presented in this chapter have been designed to answer the following research questions and associated hypotheses:

Research question	Hypothesis
1. What are the similarities and differences between GP practices in different contexts in how the routine vaccination programme is organised and implemented?	That there will be variation in the way that GP practices in different contexts in terms of activities, staff allocation, resource use and outputs achieved.
2. What organisational factors related to programme delivery may be related to overall performance?	That differences in organisation will be related to programme outputs and outcomes, including coverage.
3. How are organisational factors related to the costs of delivering the programme?	That differences in organisation will have an impact on the costs of delivering the programme; and that overall costs of delivery may impact performance.
4. How and why GP practice staff undertake organising vaccine programme delivery?	That the experience of GP practice staff will affect the methods of organisation of

	programme delivery and the resulting activities, outputs and outcomes.
5. What is the role of GP practice within the overall vaccine programme delivery system?	That the interactions between the GP practice staff and aspects of the overlying healthcare system determine the role of the practice in delivering the programme.
6. What aspects of vaccine programme delivery could be modified to improve coverage and how could this be achieved?	That aspects of programme delivery and the role of the GP practice can be identified that can be modified to improve programme delivery performance in improve coverage.

In order to answer these questions a range of methods are required to collect and analyse data that can be both triangulated within each individual practice and compared between the practices. Therefore, this study uses multiple methods for data collection and analysis in the following three areas:

- Process evaluation: focussing on an evaluation of programme implementation to answer questions 1, 2, 3, 5 and 6.
- Costing analysis: to answer questions 2 and 3.
- Evaluation of organisational management: 2, 4, 5 and 6.

The methodologies underlying each of the methods used in this study are presented below.

5.2 Process and implementation evaluation methodology

Having defined the logic model through the document analysis in the paper presented in section 4.3, this can now be used as a basis to evaluate how these contracts and policies are translated into activities and output at GP practice level. GP practices are independent providers contracted to provide vaccine services by NHS England, which defines minimum service standards for vaccination in the Core Service Specification, alongside quality criteria defined by NICE (NHS England, 2017; NICE, 2017). However, it is currently not known how different practices go about organising the delivery of the programme, particularly as the specification leaves significant autonomy to practices, which makes it difficult to identify organisational variation and thus limits the ability to recommend interventions to improve coverage.

The UK Medical Research Council has developed guidelines for the evaluation of complex health interventions, which forms the core of the methodology for this element of the study (Moore, Audrey, Barker, Bonell, *et al.*, 2014).These are primarily designed to the evaluation of new interventions, rather than existing programmes and thus require some adaptation for the context of routine vaccination. However, it provides a robust foundation for creating a conceptual model of how a complex healthcare intervention can be evaluated. The starting point of the evaluation is the development of a logic model, which serves as the foundation of designing the evaluation structure, and this is presented in the paper in section 4.3. The question in relation to the vaccine programme in England is how the programme is implemented by GP practices. Implementation here is defined as *"a controlled activity aiming to introduce and encourage uptake of a policy or intervention that embodies pre-defined criteria"* (Spyridonidis and Calnan, 2011). In this context the controlled activity is providing the routine vaccination programme and the pre-defined criteria include national evidence-based policy and guidelines, including the quality standards for aspects of vaccination programme delivery for children and adolescents published by NICE (NICE, 2017). However, previous research on NICE guidelines specifically has shown that implementation is initially strategic, but as time passes it becomes increasingly sporadic and subject to local contextual factors (Spyridonidis and Calnan, 2011). Changes to policy and guidelines are outside the control of the practices and act as interventions with variable penetration. This raises the question of implementation fidelity, which is defined as *"the degree to which programs are implemented as intended by the program developers",* and acts to modify the relationship between the intervention (vaccination) and outcomes (coverage, VPD incidence) (Carroll *et al.*, 2007). A widely used framework for considering implementation fidelity proposed by Carroll et al. (2007), and more recently modified by Perez et al. (2016), has an explicit consideration as to how variations in fidelity can modify how an intervention is implemented overall. The modified framework considers the following factors that affect implementation fidelity: adherence (including content and amount (coverage, frequency and duration)), moderators (complexity, facilitation, quality and participant responsiveness), and adaptation (Carroll *et al.*, 2007; Pérez *et al.*, 2016). Adherence is consideration as to whether the programme is being delivered in the way it has been intended by his designers, and moderators are other factors that may affect implementation. A systematic consideration of these factors will enable a comparison between practices. Further information on the use of these frameworks is presented in the methods and results of the paper presented in section 6.2.1.

The other aspect of the evaluation is the method for generating the costing data and, as a result, the method for collecting and aggregating the process data must be able to be delivered alongside the method for generating the costing data, which is considered in the next section.

5.3 Costing methodology

Evaluating how much it costs GP practices to deliver vaccinations has never previously been attempted. Understanding how difference in practice structure and function impact on the financial base of a practice is likely to be key in evaluating differences in performance between different organisational models and will provide an explicit quantitative comparison considering aspects of vaccine programme delivery, but also wider contextual factors at play within the practice. Costing in primary health care services is notoriously challenging due to the complex and variable nature of the type of services delivered. The additional challenge in England is that each GP practice is an independent organisation and, in essence, a private business, although usually with the NHS providing the vast majority of funding. This means that data on costs and expenditure at practice level are very difficult to come by, as they are neither centrally collected nor publicly available. The specific challenge with vaccination is that, in most cases, activities are both distributed amongst multiple different staff groups, including doctors, nurses, managers and administrators; and have a wide temporal distribution with activity undertaken both unevenly throughout a working week as well as throughout the year. This makes both apportioning capital and operational costs and also staff time to vaccination particularly difficult without relatively extensive data collection in relation to vaccination activity within a practice.

5.3.1 Costing methods

To undertake costing at practice level costs must be identified for capital costs (buildings, land, equipment), overhead costs (utilities, maintenance, waste disposal consumables), and staff costs through salaries (Bowling, 2009b). The costing methods employed then need to generate sufficiently granular data to allocate these costs to vaccination activity.

A complex system of tariff payments is used to remunerate secondary care organisations in England based on activity. This is managed by NHSE and NHS Improvement and is based on costs reported via hospitals and other provider organisations, which are used to develop a national tariff, for which providers are remunerated based on their recorded activity (NHS England, 2016a; NHS Improvement, 2018b, 2018a). However, as GP practices exist as independent organisations contracted to provide services by NHSE, no such equivalent costing exists, and the original payment thresholds in the contracting arrangements have been set through mutual negotiation or rolled over at historical levels generated by past activity. Therefore, to identify costs associated with vaccination, all the information needs to be gathered in a suitable format from each included practice, as costing data are not otherwise available.

5.3.1.1 Measuring time and activity

To allocate costs, both overheads and staff salaries, time spent by staff on vaccination needs to be known. Since the Industrial Revolution, organisational management researchers have been interested in how workers spend their time. Perhaps surprisingly, the most widely used methods for evaluating time spent on specific activities have not changed significantly in the last one hundred years. There are broadly three methods that have been widely employed in business, industry and, more recently, in healthcare settings. The first is self-reported timekeeping and the second is observational work sampling. Self-report simply requires workers to write down the time spent on specific activities, either prompted or un prompted, whereas in work sampling the recording of time spent on specific activities is undertaken by a researcher through observation at specific intervals during a working period. One observer may then be responsible for measuring activity amongst multiple different staff members, if this activity is taking place in a well-defined work area. A study conducted amongst nurses in an Australian hospital compared these two methods and found differences in recorded outcomes and challenges with each method (Ampt *et al.*, 2007). Nurses found it difficult to fill in the self-reporting forms while busy with clinical tasks, which led to an under-reporting of activities. Staff found the observational method preferable and this also led to a higher volume of activity measurements, however this requires trained researchers available to observe clinical staff and there is a risk of creating a Hawthorne effect, where activity changes as a result of being observed.

The third is a time-and-motion study, which is a more detailed method of observational work sampling that usually involves an observer measuring all activity during an entire work period using a stopwatch. In this case the observer will usually follow a single staff member and accurately record all activity. This does produce a highly accurate picture of work activity, however it also has a higher risk of the Hawthorn effect where the researcher may change staff behaviour due to their close observation (Finkler *et al.*, 1993). It also necessitates observing a smaller sample of staff due to the high level of research resources required. Time-and-motion studies have been used extensively in health services research in recent years, particularly in hospital practice. However, a recent review of these studies highlighted significant methodological variability between studies, which made comparisons and aggregation of results difficult (Lopetegui *et al.*, 2014). This method has also been used in primary care. In one study, researches evaluated the effect of the implementation of an electronic care record on doctors' time in 5 clinics (Pizziferri *et al.*, 2005). This study required 7 research assistants to undertake the observations. In the context of evaluating the delivery of routine vaccinations in GP practices, a time-and-motion study would not be feasible, because, at most practices, vaccination appointments are randomly distributed throughout the week. Therefore, to capture time-and-motion data, a researcher would have to sit through many days of clinics to capture a relatively small number of vaccination appointments. Similarly, the administrative work is not distributed evenly, and would require administrators to plan their vaccination work in advance to enable the researcher to visit at the appropriate time, which may affect the outcome. In practices that do run specific vaccination clinics, most often there are multiple staff working simultaneously, including nurses and administrators, thus, either requiring multiple researchers, or multiple visits to a clinic to record activity from each different staff member. Overall, although time-and-motion studies may provide highly accurate data on activity on vaccination within GP practices, due to resource constraints it is not possible to use these methods for this study. In addition, while these methods identify time and activity, they do not provide a method for allocating costs to these activities.

5.3.1.2 *Time-Driven Activity Based Costing*

Activity Based Costing (ABC) is a method for allocating costs to complex processes within organisations to identify cost drivers and opportunities for lowering costs while improving quality. It was developed by Cooper and Kaplan for use within business and industrial contexts as a method that requires relatively low resources and is transparent while remaining accurate (Cooper and Kaplan, 1999). It focusses on identifying all costs for delivery of organisational outputs and allocating these to different processes and activities based on the time taken to complete them by actors within the system. Having been widely applied in the private sector, it was relatively swiftly adopted by public sector organisations in the USA, including health service providers (mainly hospitals). The cost of delivering vaccination at primary care level has previously been evaluated in New Zealand on two occasions using ABC methods and found to be feasible and capable of producing accurate and useful results (McLeod, Bowie and Kljakovic, 1998; Turner *et al.*, 2009). More recently ABC has been updated to reduce the administrative burden of data collection and is now termed Time-Driven Activity Based Costing (TDABC) (Kaplan and Anderson, 2007; Kaplan *et al.*, 2014). In part this development was to make TDABC more suitable to healthcare contexts, specifically to improve the ability for healthcare organisations to undertake costing as part of the new drive towards Value Based Healthcare, with a focus on achieving maximum health outcomes for given inputs (Porter, 2009). As a result, TDABC has since been extensively applied in a wide range of healthcare contexts, including both primary and secondary care, as highlighted in a recent review by Keel et al., (Keel *et al.*, 2017). The review identified that TDABC has been used to improve service delivery, allocate payments to providers, and that primary study authors had chosen this method due to its ability to accurately capture and allocate costs and describe the process of delivering care within complex healthcare organisations. TDABC has mainly been used in secondary care, however there are also a smaller number of studies in primary or community care settings. One successfully evaluated the implementation of a physical activity pathway in GP practices in England to identify the costs to practices associated with the programme (Boehler *et al.*, 2011).

TDABC follows a seven-step process (Kaplan and Porter, 2011):

- Step 1 is to define the condition under analysis, which should include clear definitions of the start and the end of the process under evaluation.
- Step 2 is to define the Care Delivery Value Chain (CDVC). This is a visual map that details the core activities of the process under evaluation across a single cycle of care.
- Step 3 is to develop a process map. This is more detailed than the CDVC and includes all the paths that a patient may follow through the process to any specific end point.

- Step 4 is to generate time estimates for each stage in the process. This can be done through any method (including those described in the paragraph above) and may be extracted from electronic patient records, self-report by staff, or through observation from researchers.
- Step 5 is to estimate the cost of providing a unit of care as per the CDVC and involves identifying the costs associated with the process and allocating these to the time estimates derived in step 4.
- Step 6 is to estimate the Capacity Cost Rate (CCR) for the resources described in step 5. The CCR is a cost per unit time of the available resources, whether it is being used or whether it remains available for use as part of the process.
- Step 7 then completes the process by calculating the total cost of one cycle of patient care.

Therefore, the outputs from the analysis are the CDVC, a process map, description of time per activity and both overall and individual unit costs for stages within the process. TDABC provides a comprehensive approach to identifying process, activities, time spent, and associated costs of interventions delivered in complex healthcare settings, including in primary care, with a relatively low burden on both practice staff and researcher resources, particularly as it allows flexibility of determining how time and activities are recorded. Therefore, I have selected to use this method to identify aspects of implementation and associated costs of routine vaccination at GP practices as part of this study. Applying this method across different practices will also enable a comparison of both differences in implementation and associated costs.

5.4 Evaluating organising

Alongside the descriptive component evaluating the process of implementing the vaccination at GP practices and identifying associated costs, there is also a need to understand how and why each practice has developed the system currently in place. While the process evaluation element will identify what activities are undertaken and by which staff, it does not explain how and why this system came to exist, nor how it is conceptualised by people working within each practice. This is particularly important as the vaccination programme is likely to have evolved over time and in different ways at each practice. Evaluating elements of the organisation of vaccination at GP practices will help identify factors that may affect performance, both in terms of costs and capacity, as well as quality, particularly patient experience, and outcomes, including coverage and disease outbreaks. However, defining what comprises an organisation, or the activity of organising, has been the subject of much debate within the organisational studies and health services literature in recent years.

5.4.1 Context, climate and culture

A useful starting point is a review published by Michie and West in 2004 that evaluated the impact of organisational characteristics on effectiveness and performance within the NHS, although also using research evidence from other similar countries (Michie and West, 2004). Through their review, a framework of five important points was developed: i) organisational context; ii) people management and human resources; iii) psychological consequences, including health, stress and motivation; iv) employee behaviour, including absenteeism and errors; and v) organisation performance in terms of patient care. The study defines organisational context in terms of local culture, organisational climate and inter-group relations, such as interactions with stakeholders, and identifies this as the starting point from which other elements of organisational performance are integrated (Michie and West, 2004). Within this is the associated concept of organisational climate, which is defined as *"the aggregate employee perceptions of their organisation"* and focusses on what systems, process and behaviours are valued and for which four dimensions that may affect organisational performance were described: i) role stress and lack of harmony; ii) job challenge and autonomy; iii) leadership facilitation and support; iv) work group co-operation and friendliness.

However, there is no agreed definition of 'context', and other researchers have taken a different view of its important components. The concept of 'context' is also highlighted in the MRC guidance for evaluating complex public health interventions, where it is defined as *"factors external to the intervention which may influence its implementation or whether its mechanism of impact act as intended"*, and it is also noted here that a simple intervention may be made significantly more complex by the way it interacts with an existing organisational context (Moore, Audrey, Barker, Bond, *et al.*, 2014). In a concept analysis paper studying the role of context in getting evidence implemented in practice, McCormack et al., focus on context as defined as the *"physical environment in which practice takes place [with its] boundaries and structure that together shape the environment"* (Mccormack *et al.*, 2002). Despite the relatively simple overarching definition, the review highlights the deep complexity of healthcare organisations in which healthcare workers exist and the very wide range of factors that may affect organisational performance. The paper further explores another aspect of organisational context, which is that of 'culture', defined as *"the way things are done around here"* and that culture at individual, team and organisational level is ultimately what creates the context. Clashes of cultural norms between individuals or groups within an organisation, or between an organisation and an external intervention is hypothesised to have a significant impact on aspects of implementation. However, there are different ways of understanding organisational culture in the context of health services research. For example, it can be considered from a positivist perspective, i.e. something that an organisation 'has' that can be identified and described, or from a post-positivist perspective, as something that an organisation 'is' and thus inseparable from the organisation itself (Davies, Nutley and Mannion, 2000). However, there is no consensus on these definitions and it remains a difficult concept to pin down and use for evaluating performance. Despite this, the idea of culture acting as a barrier to change has been the focus of a great volume of research studies in recent years. A review conducted in 2007 found 70 instruments used for evaluating organisational culture that were applied within the NHS (Mannion, 2007). The authors highlight that these tools were in a relatively preliminary stage of development and many did not provide very high levels of detail on organisational factors relating to culture. Their conclusion was that there is no such thing as an 'ideal' method for evaluating organisation culture and that different tools generate different insights, depending on what data they collect, and that a judgement should be applied by the researcher employing the tool to determine if it meets the needs of the research question.

An important outcome of the understanding of organisational context is how it manifests as an organisation's response to change. This is particularly relevant for the vaccination programme as it is in a constant state of being modified and amended through the distribution of policy and guidelines from national level organisations. Some of the differences in organising exhibited by practices are likely to be related to the interpretation and adoption of these changes over time. In part, this comes back to the very fundamental question of what an organisation is. One interesting definition from the organisational studies literature is that ultimately organising is a process of 'labelling', or 'noun making', whereby when confronted with a change to an understood system, actors within that system go through a process of discussion and debate to 'organise' understanding and activities (Bakken and Hernes, 2006). The result is an 'organisation', which is simply the result (including form, shape and location) of whatever the noun making process creates. This results in a process of organisational learning, which is defined as *"a process by which organizations develop rules, procedures and routines for solving recurring organizational problems"* (Osadchiy, Bogenrieder and Heugens, 2010). These solutions then get integrated into organisational memory and culture, which affects future response to change. If these solutions are effective when applied to changes to the organisation, then the problem can be understood as being 'absorbed'. However, if the rules are not appropriate for a new organisational problem, this can result in 'absorption failure', which can create an environment characterised by disagreement, dissonance and confusion between the actors in a system and prevent implementation of policies or activities.

Collecting data to evaluate elements of organisational context that may affect implementation, performance and quality can be particularly challenging. As such, many useful theories and frameworks exist to support researchers in systematically studying these aspects of organisations, which are worthy of consideration in the context of this study.

5.4.2 Theories and frameworks

There are many theories, models and frameworks that could be used to evaluate how information and evidence get translated into activities within organisations through a process of implementation, many of which could be applied to the routine vaccination programme. Many frameworks exist within both health service and organisational management literature that have been designed to evaluate both existing services and the implementation of new projects of programmes. These models often take a positivist approach, aiming to identify and describe empirical factors, conditions, barriers or facilitators to 'successful' delivery or outcomes of services (Bowling, 2009c). A recent study presented a narrative overview of the theories, models and frameworks used within implementation science and identified 5 overarching categories (Nilsen, 2015):

- **Process models**: these specify steps or stages through which something is implemented in practice, which can assist with planning an intervention.
- **Evaluation frameworks:** describe parts of implementation that could be subject to data collection and analysis to determine whether something has been implemented successfully
- **Determinant frameworks:** these specific factors, classes or domains of variables that can affect how something is implemented.
- **Implementation theories**: developed by implementation researchers from scratch or through adapting existing theories that allow for understanding or explanation of implementation.
- **Classic theories:** these originate from fields external to implementation science, including fields such as psychology, social science and organisational management.

Of these, the process model elements are covered within the TDABC methods and so I have not considered those in detail again here. Evaluation frameworks are not particularly appropriate as there are only two of these commonly used in public health, which focus on very high level aspects of implementation that could be studied to evaluate whether implementation has been successful and are largely too limited in scope for this aspect of the study, particularly as routine vaccination is already successfully implemented (Nilsen, 2015). However, I have considered some examples of Determinant Frameworks, Implementation Theories and Classic Theories in more detail below.

5.4.2.1 Determinant frameworks

One well-known determinant framework is the McKinsey 7-S model, which was developed by consultants working for the management consultancy McKinsey in the 1980s (Waterman, Peters and Phillips, 1980). Although it has been through some subtle revisions, the contemporary framework consists of consideration of the roles of the following seven S' on meeting organisational outcomes: strategy, structure, systems, staff, skills, style and shared values (Mindtools, 2018). These elements were categorised as 'hard' (strategy, structure and systems') and 'soft' (shared values, skills, style and staff). It has been widely used to evaluate performance in the context of the organisation and management of businesses and has also been applied in health services management contexts. However, this allows relatively little exploration of reflexivity, or consideration of how the experience of staff within their environment changes the meaning of the inputs or instructions they receive, and restricts the analysis to the pre-defined elements. It also takes an explicitly managerial, or external, view of an organisation, rather than seeking to understand it from within. Thus other models have since been developed that complement the 7S model, including the Balanced Score Card, which considers the function of an organisation from four specific perspectives: financial, customer, internal process and learning growth (Kaplan, 2005). This has been combined with the 7S model to take a more holistic and reflexive view of organisational structure and function to evaluate performance.

With the development of New Public Management (NPM) in the 1980s and 1990s, tools and models from business, such as those described above, have been increasingly applied to evaluate performance of healthcare organisations. The NPM agenda had the effect of disaggregating and deconstructing long-standing public sector management systems and increasing competition between service delivery organisations (McLaughlin, Osborne and Ferlie, 2002). This also allowed for a greater focus on improving the quality of services delivered to 'service users', particularly in evaluating the implementation of evidence-based guidelines and interventions. This shift and the increased focus on healthcare organisational management has resulted in the development of newer determinant frameworks for use specifically within the context of healthcare delivery. One widely used example, which draws on several of the theoretical paradigms already discussed, is the Promoting Action on Research Implementation in Health Services (PARiHS) Framework, which has been designed and developed to assist with the implementation of evidence in clinical practice, considering the three elements of the evidence itself, the context in which it is being implemented and the availability of facilitation for the change (Roycroft-Malone, 2004). The framework has been applied to evaluate implementation of evidence in a variety of health services contexts (Kitson *et al.*, 2008). However, it focusses heavily on the successful implementation of discreet pieces of evidence-based practice and thus it also has strongly positivist elements, such as its focus on the explicit outcome of 'successful implementation' (Helfrich *et al.*, 2010; Stetler *et al.*, 2011). More recent iterations of the framework have provided a 'guide' for researchers in how to apply the framework to evaluate 'targeted evidence-based practice' (Stetler *et al.*, 2011). This framework could be applied to the changes implemented as part of the vaccination programme, however vaccination has been implemented at GP practice level in England for many decades, and, although there is an element of implementing new evidence-based practice when changes are made to the programme, ultimately the change in activity is incremental and likely to be highly responsive to local culture and interpretation of organisational context by staff involved. An American review of the use of PARiHS conducted in 2014 found that although the framework had several strengths, including ease of application and good guidance for implementation projects, there was also confusion and uncertainty about the individual components, and, due in part to its positivist theoretical paradigm, there were not associated validated measurement tools (Ullrich, Sahay and Stetler, 2014).

Overall these methods aim to simplify a complex and evolving environment in which health interventions are implemented to identify potentially modifiable factors to investigators or managers and modify these to improve outcomes. However, there is relatively little consideration of the complexity of both organisational context and the working culture within organisations that may affect aspects of implementation and service delivery.

5.4.2.2 Implementation theories

One widely used implementation theory is Normalisation Process Theory (NPT), which has been developed as a structured framework to evaluate how complex interventions are integrated into regular working practice within healthcare organisations (Murray *et al.*, 2010). It focusses on 4 specific aspects of implementation of interventions within a specific organisational culture: coherence (meaning and sense making by actors), cognitive participation (commitment and engagement), collective action (work required), and reflexive monitoring; and has been designed to help explain why some interventions are easily adopted, while others do not integrate into daily practice. A survey tool has been developed to evaluate aspects of NPT, which has been used as a theoretical paradigm to evaluate interventions such as an intervention to encourage the adoption of the surgical safety checklist in secondary care (Gillespie *et al.*, 2018), as well as in primary care during the implementation of a new complex mental health project in GP practise (Reeve *et al.*, 2016). While NPT has a more explicit component focussing on organisational context, it has the explicit aim of identifying factors that act as barriers or facilitators to the incorporation of guidelines or practices into normal working life. Ultimately, vaccination is well incorporated into the working culture of GP practices and the local organisational context is likely to have developed over many years. Ultimately, the purpose of this study is to evaluate the experience of staff within GP practices in delivering a long-standing complex intervention that is already well integrated into working life, while also being subject to frequent change and so NPT is not suitable for use within this context without significant adaptation.

5.4.2.3 Classic theories

There is a very wide range of classic theories that have been applied to the organisational aspect of implementation, two of which I have considered in detail below. The first is complexity theory, which I considered as a potential option to use, and sensemaking, which I have chosen as the final theory for use in this study.

5.4.2.3.1 Complexity theory

Complexity theory presents an attractive option for evaluation of an organisation that moves away from the discreet factors or categories of the frameworks described in the previous section. Complexity theory was developed from beginnings in biomedical science where it was used to understand 'complex adaptive systems', where multitudinous interactions between building blocks of chemical or biological systems come together to generate a function that could be considered much greater than the sum of its parts (Reed *et al.*, 2018). Characteristics of these systems include interconnectedness of individual agents leading to uncertainty and emergence with the introduction of external stimuli, resulting in non-linearity in outcomes. The learning from evaluating complex biological systems has been applied to healthcare organisations in an attempt to learn how complexity effects adoption of evidence-based interventions or practices (Reed *et al.*, 2018), and a recent scoping review found that the theory has also been applied in long-term care facilities, primary care, hospitals and within the community, particularly in the UK and USA (Thompson *et al.*, 2016). However, this review also highlighted, that due to the lack of a robust definition or any defined framework, it had been applied in a wide variety of ways, primarily as a tool for study design development. This limits the theory's usefulness for application within a healthcare setting to produce meaningful analysis (Checkland, 2007; Thompson *et al.*, 2016). It is also firmly rooted within a positivist, empiricist paradigm with the underlaying assumption that a researcher can objectively measure elements of an organisation to evaluate factors associated with successful implementation of evidence or guidelines.

5.4.2.3.2 Sensemaking

"Reality is an ongoing accomplishment that emerges from efforts to create order and make retrospective sense of what occurs."

Karl E. Weick (1993)

Sensemaking is a concept of organisation derived from organisational theory that takes an explicit process orientation, where things are continuously being made within a flow of events, i.e. becoming rather than being. This is an active process and is thus inevitably bound up in a pragmatic philosophical paradigm (as opposed to an interpretivist view), where actions are considered as a precursor to meaning creation, and embedded in a social constructionist paradigm, with actors creating meaning through interpretation of the environment (Brown, Colville and Pye, 2015a).

Prior to the development of sensemaking as a concept in the early 1990s much of the organisational management literature had focussed on the decision-making processes (Reed, 1991). Although alternative paradigms such as Mintzberg's dichotomy between deliberate and emergent strategy proposed other ways of considering how managers and other actors undertake organising (Mintzberg and Waters, 1985). Emergent strategy is the development of patterns or consistencies that take place within an organisation without necessarily being subject to the intentions of a manager or organiser. Sensemaking is an emergent process concerned with how shared understanding between individual groups bring organisations into being, rather than simply the process and effect of individual decisions. It has been particularly developed and expounded by Karl Weick and widely applied to analyse organisational systems in a wide variety of fields. The concept of organisational sensemaking was developed by Weick from analysis of industrial disasters, for example the 1984 Bhopal Disaster, where thousands of people living around a pesticide plant in India were killed and hundreds of thousands were injured when an explosion at the plant released a cloud of highly toxic methyl isocyanate gas as a result of years of deterioration of safety protocols and failure to repair equipment (Weick, 2010b); and the 1949 Mann Gulch fire disaster, where 13 smokejumpers (fire fighters dropped from planes to extinguish wildfires) died as a result of a sequence of events that undermined the team's construct of the reality of the threat they were facing, leading some of them to disregard potentially life-saving advice (Weick, 1993). Both are very extreme examples of organisational sensemaking failure, but provide sharp relief of how these disasters can unfold in practice.

In their 2005 paper 'Organizing and the Process of Sensemaking' Weick, Sutcliffe and Obstfeld explain the process of sensemaking as *"turning circumstances into a situation that is comprehended explicitly in words and that serves as a springboard into action"* (Weick, Sutcliffe and Obstfeld, 2005). In the same paper Weick et al., argue that sensemaking and organisation are in essence the same thing, where the image and idea of the organisation is developed and realised through the process of sensemaking between those actors who exist within the organisation itself. The sensemaking process takes a disordered environment and, through the application of socially generated rules defined through verbal and written communication, creates organised activities: *"when we say that meanings materialize, we mean that sensemaking is, importantly, an issue of language, talk, and communication. Situations, organizations, and environments are talked into existence"* (Weick, Sutcliffe and Obstfeld, 2005). Much of sensemaking is about labelling emergent situations to generate a shared understanding between organisational participants, and thus *"a crucial stage in process thinking is attention drawing"* (Weick, 2010a). An important aspect of this is the idea of 'equivocality', whereby individuals use information and environmental cues to 'make sense' of changes to their context, through which an organisation can then develop (Brown, Colville and Pye, 2015b) by actors labelling new circumstances and creating rules to increase understanding and order in the new situation (Weick, Sutcliffe and Obstfeld, 2005).

It can also explain how a loss of organisational sensemaking can result in disastrous outcomes in different contexts. For example, Weick identified the 'minimal organisation' of the Mann Gulch team as a potential vulnerability leading to a sudden loss of sensemaking, where previously well-constructed group understanding of the situation alongside expected individual actions was lost as the team faced a sequence of unexpected events, and members were no longer certain of the appropriate course of action (Weick, 1993). Conversely, the opposite problem was present in Bhopal, where control room officers were faced with a bewildering array of inaccurate or entirely defunct equipment that provided limited information, leading to a scenario where potentially life threatening warnings were dismissed as further equipment malfunction, because *"operators found it difficult to generate plausible conjectures about the meaning of fragmentary evidence"* (Weick, 2010b). Thus, Weick makes the argument that 'organisational problems' do not intrinsically exist, but could be conceptualised as situations where sensemaking amongst actors has failed, creating a sense of uncertainty and discomfort due to a gap between the existent and desired organisational state.

This form of process theory moves on from the challenges of Alfred Whitehead's *"fallacy of misplaced concreteness",* where organisational components are labelled or experienced as fixed facts, instead of socially constructed abstractions around which rules can be developed and enacted (Stanford University, 1996). This misplaced concreteness is exemplified in Kurt Lewin's 1951 'unfreeze-change-refreeze' model of organisational change, which suggests that before and after a process of change an organisation exists in some discreet form, which can be identified, described and modified using a specified process (Burnes, 2004). However, this does not take into consideration elements of continuous ongoing equivocality and response to emergent conditions, which underlies Chia's alternative Rhizomic model of organisation change, based within the sensemaking paradigm, and described as *"firstly and fundamentally the task of becoming aware, attending to, sorting out, prioritizing an inherently messy, fluxing and chaotic world of competing demands that are placed on a manager's attention. It is creating order out of chaos. It is an art not a science"* (Chia, 1999). This is supported by Weick who developed this by asserting that the *"image of manager as author would be further refined by asserting that much of managerial work is akin to the work of a poet"*, due to their role in labelling and sensegiving in times of uncertainty and equivocality.

To create control out of potentially evolving, ambiguous or chaotic situations, mangers are often required to apply existing organisation rules to reclaim and become sensegivers. Thus, an organisational problem (or loss of sense), is given sense by the application of an existing rule. This phenomenon is known as 'problem absorption'. However, this also comes with its own set of challenges (Osadchiy, Bogenrieder and Heugens, 2010). These include situations where there is no suitable rule that can be applied (non-absorption), leading to a loss of sense, and the potential to generate new rules; or where there is a rule, but application to the problem would either enlarge the scope of the rule, or cause category shift (with difference in what was previously included). Repeated enlargement or category shift can eventually make a rule redundant and no longer useful, thus causing a failure of problem absorption and a loss of sensemaking, requiring new rules to be made, often with an additional round of labelling and noun creation by a manager or other sensegiver. Each of these scenarios can lead to organisational 'semantic learning', which is defined as *"changes to the intersubjective meanings underlying the labels and actions constituting the core of a collective's understanding of themselves"* (Corley and Gioia, 2003). This then forms an incremental process of organisational change in the face of repeated challenges of equivocality requiring problem absorption or sensemaking.

Ultimately, *"sensemaking is an ongoing activity underlying the process of organising"* (Hernes and Maitlis, 2010) and is bound in constructions of time, as organisation members construct the temporality of their organisation, where current understandings are informed both by the past and projected ideas towards a proposed or desired future state. In the development of sensemaking as an organisational concept, its temporality was firmly retrospective, as exemplified by the quote at the front of this section ('making retrospective sense'). However, more recently focus has moved towards 'future oriented sensemaking', which has been defined as *"the impact of the conscious and intentional consideration of the probable future impact of certain actions"* (Gephard, Topal and Zhang, 2010). This explicitly future-oriented sensemaking perspective then redefines the nature of the organisation in which the actors exist, resulting in *"a prospective, open-ended sensemaking resource used in talk to explain behaviours, prescribe and justify sanctions, and give organisationally relevant meanings to phenomena. Sensemaking is prospective and seeks to create reality"* (Gephard, Topal and Zhang, 2010). This is often achieved through institutional rhetoric, where plans and planning can orient actors within an organisation to a desired future state, which can either be functional (high likelihood, based on past experience) or fantastical (hopeful, imaginative fictions).

- **Forms of organisational sensemaking**

In her important study on 'The Social Processes of Organisational Sensemaking', Sally Maitlis sought to identify whether there were patterns of social interaction between actors and stakeholders in complex organisations during the process of sensemaking (Maitlis, 2005). Through in-depth analysis of multiple case studies of the organisational management of symphony orchestras, Maitlis described four forms of organisational sensemaking (Figure 8). The forms were categorised firstly by the level of sensegiving by an organisational leader and secondly by the engagement of stakeholders. Sensegiving is defined as *"the process of attempting to influence the sensemaking and meaning construction of others toward a preferred redefinition of organisational reality"* (Gioia and Chittipeddi, 1991). Leadership sensegiving could be high (engaging in behaviours to influence the sensemaking process amongst organisational members), or low (with few sensegiving behaviours). High levels of sensegiving activity from organisational leaders led to processes that were highly 'controlled', organized and systematic, as opposed to low sensegiving environments that were informal and ad-hoc. Similarly, high level of sensegiving from stakeholders led to 'animated' sensemaking process, characterised by high volumes of information between individuals and organisational groups. Where there was little stakeholder engagement in sensemaking, the process was characterised as being intermittent and suffering from broken rhythms.

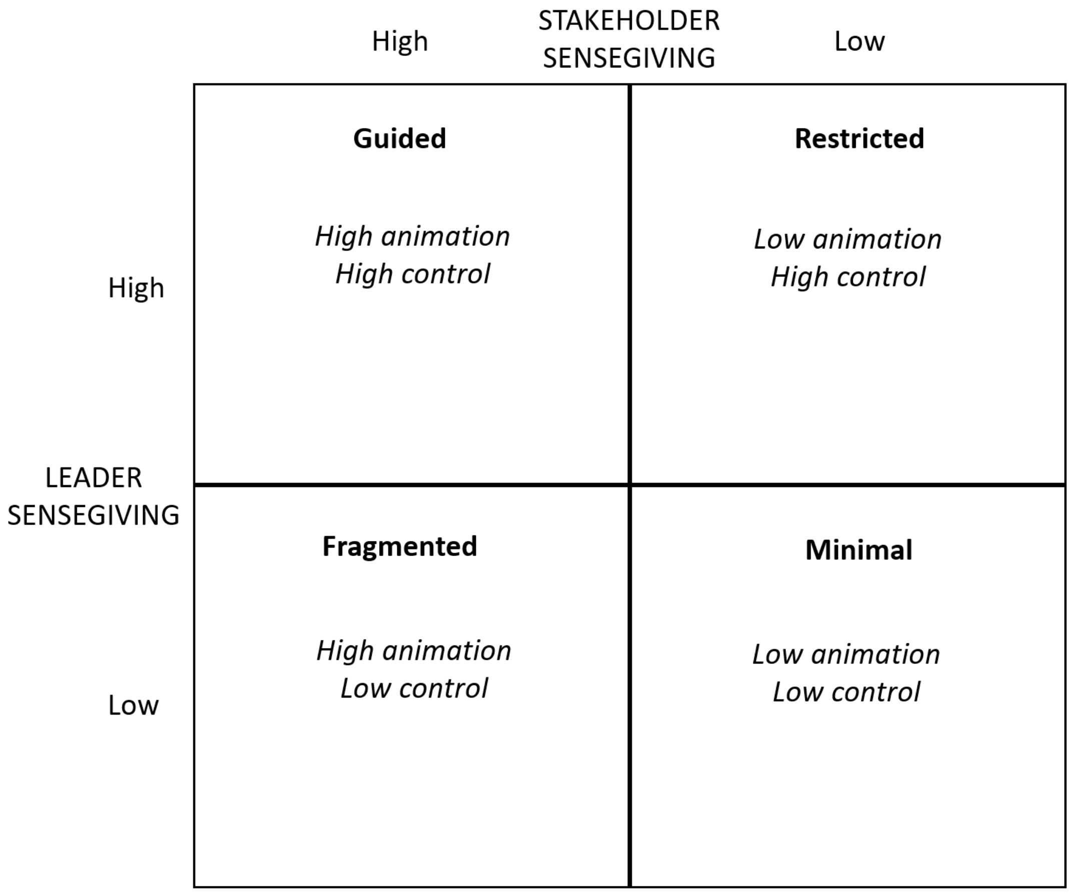

Figure 8: forms of organisational sensemaking derived from Maitlis 2005.

The four forms of sensemaking are thus categorised as follows:

1. **Guided:** high control and high animation, leading to a single, rich account, shared between stakeholders, leading to an emergent series of resulting actions that are internally consistent.
2. **Fragmented:** low control and high animation, leading to multiple, narrow sensemaking accounts from participating stakeholders, creating multiple narratives, resulting in emergent outcomes that are internally inconsistent.
3. **Restricted:** high control and low animation, lead to single, narrow accounts, that will result in a single isolated action, or a planned set of internally consistent actions.
4. **Minimal:** low control and low animation, produce 'nominal' accounts that are a poor basis for sensemaking and do not lead to action, as it is lacking both motivation (reasons for the action) and imagination (way forward). This may lead to a single, compromise action.

This provides a lens through which sensemaking within other organisations can be evaluated to help evaluate the organisational outcomes that result.

5.4.2.3.3 Sensemaking in healthcare, including general practice.

Since its origination in industrial disasters and development within the world of business, sensemaking has frequently been applied in the context of healthcare. In the 2005 paper by Weick, Sutcliffe and Obstfeld, the authors use an extended example of sensemaking within a paediatric nursing environment to describe the following distinctive features of sensemaking as a tool for understanding organisation, where sensemaking:

- **Organises flux:** starting with chaos, healthcare professionals apply sensemaking strategies to begin to organise stressful and complex situations.
- **Starts with noticing and bracketing:** when something 'abnormal' begins to happen, in the first instance it may not be clear what is causing the disintegration of understanding the environment aside from 'something is wrong', perhaps a set of symptoms, or a change in a patient's condition.
- **Is about labelling:** once the change in the environment has been noticed it can then be labelled, for example with a new diagnosis, or a situational label such as 'deteriorating patient'. Other actors can then be brought into the situation and a response can be generated.
- **Is retrospective:** which is true in this context, where something has happened in the past causing a change in the actors understanding of the situation, generating uncertainty or concern. However, as described in the section above, there can also be prospective aspects of sensemaking in other contexts.
- **Is about presumption:** this is particularly true in the healthcare setting, where an abstract feeling, based on past experience can lead to identifying a concern ('I am worried about this patient'), resulting in a label ('deteriorating patient') and leading to action, using the newly applied label to distribute the sense of the situation to others (e.g. the doctor in charge).
- **Is social and systemic**: particularly in healthcare where sensemaking unfolds because of the myriad of interactions between patients and multiple healthcare staff over a significant period and is heavily influenced by previous social interactions with colleagues.
- **Is about action**: where medical professionals interpret the situation using their knowledge and experience and applying rules-based frameworks to bring sense back to the situation.
- **Is about organising through communication**: through identification and labelling a change in situation can be communicated to others to share a new meaning and ultimately 'talk the situation into existence'.

These factors help explain both how individual actors apply sensemaking in their daily lives, how an organisation results from this process, and why it is especially relevant to healthcare organisations. Sensemaking as an analytical lens has been applied in secondary care to analyse communication between physicians and nurses to improve patient safety (Manojlovich, 2010); and how nurses decide who and how to ask for help (Hofmann, Lei and Grant, 2009). A proof of concept study has used a sensemaking lens to evaluate formation of life support teams in cardiac arrest situations (Hallas, Lauridsen and Brabrand, 2018), and a protocol has also been published looking at how sensemaking is applied in care transition process to reduce hospital readmissions (Penney *et al.*, 2018). Sensemaking has also been used as a lens to analyse: the development of organisational identities in primary care practice groups in Canada (Rodríguez and Bélanger, 2014); and the role of managers and other staff within primary care organisations in England (Checkland *et al.*, 2009, 2011).

Kath Checkland has developed a conceptual framework as to how sensemaking takes place within GP practices in England using case study research methods (Checkland, 2007). This describes a process of understanding and conceptualising a GP practice as an organisation and considers aspects including the beliefs staff hold about their role in the organisation; how they understand cues from the wider context; how these are interpreted within the organisation; and how this affects their response to change. It also considers aspects of on-going reflexivity, i.e. how staff interpret new information relating to performance based on their past experience, which is important with a well-established intervention like the routine vaccine programme, where staff will receive both feedback in terms of coverage data, as well as changes to policy and their practical experience of interacting with patients, which in turn will affect their behaviours and decision-making in reacting to change. Ultimately this model allows the development of a series of questions to describe 'how practices work' and enables conclusions to be drawn about how inputs are received and acted upon.

- **Sensemaking as applied to the vaccination programme**

To complement the process evaluation, I have used the concept of 'sensemaking' as the theoretical paradigm with which to analyse the organisation of implementing the vaccination programme at GP practice level, which will be explored during the data collection activities at the included practices. As sensemaking is a process through which actors in an organisational context seek to understand and generate rules around events or environments that are ambiguous, equivocal or otherwise confusing in order to maintain organisational stability (Brown, Colville and Pye, 2015a). The vaccine programme in England has been in place for many years and has undergone a long process of sequential changes handed down from national level organisations, with changes to these inputs being interpreted and acted upon at GP practice level. If sensemaking is an activity of equivocality reduction through communication, then the vaccination programme is a suitable target as it is possible that idiosyncratic aspects of organisation context and culture have a significant impact in how the programme is delivered locally. Figure 9 shows Checkland's conceptual model of sensemaking as applied to the implementation of the vaccine programme within a GP practice.

Stage 1 is the core process whereby a practice ‘makes sense’ of an input of new information into the vaccine programme. This contributes to the structure and processes implemented at the practice (stage 2). Stage 3 shows the experience of implementing the change amongst staff, which in turn becomes part of the on-going practice narrative in relation to vaccination (stage 4), i.e. *“how did we come to deliver the programme in this way?”* This then informs the assimilation of new information when a change is made to the programme (stage 5). Who undertakes the work related to the programme and how roles are distributed are affected by the practice narrative and previous experience of change (stage 6). Finally, stage 7 represents the importance of the distribution of power within the management structure of the practice and is important in determining how new information is made sense of. All together it is possible that this sensemaking process will determine how the vaccine programme inputs are interpreted at practice level and how this affects the activities offered to a local population and the outputs achieved. As the sensemaking process takes place, a range of activities will be determined at the GP practice level to meet the various targets set in guidelines, policy and incentives. These will include clinics, outreach visits, or the provision of reminder/recall systems. When implemented, these activities will result in outputs as the population access services to receive their vaccines, which include how many patients are seen in clinics, how many vaccines are given and how many people respond to reminders.

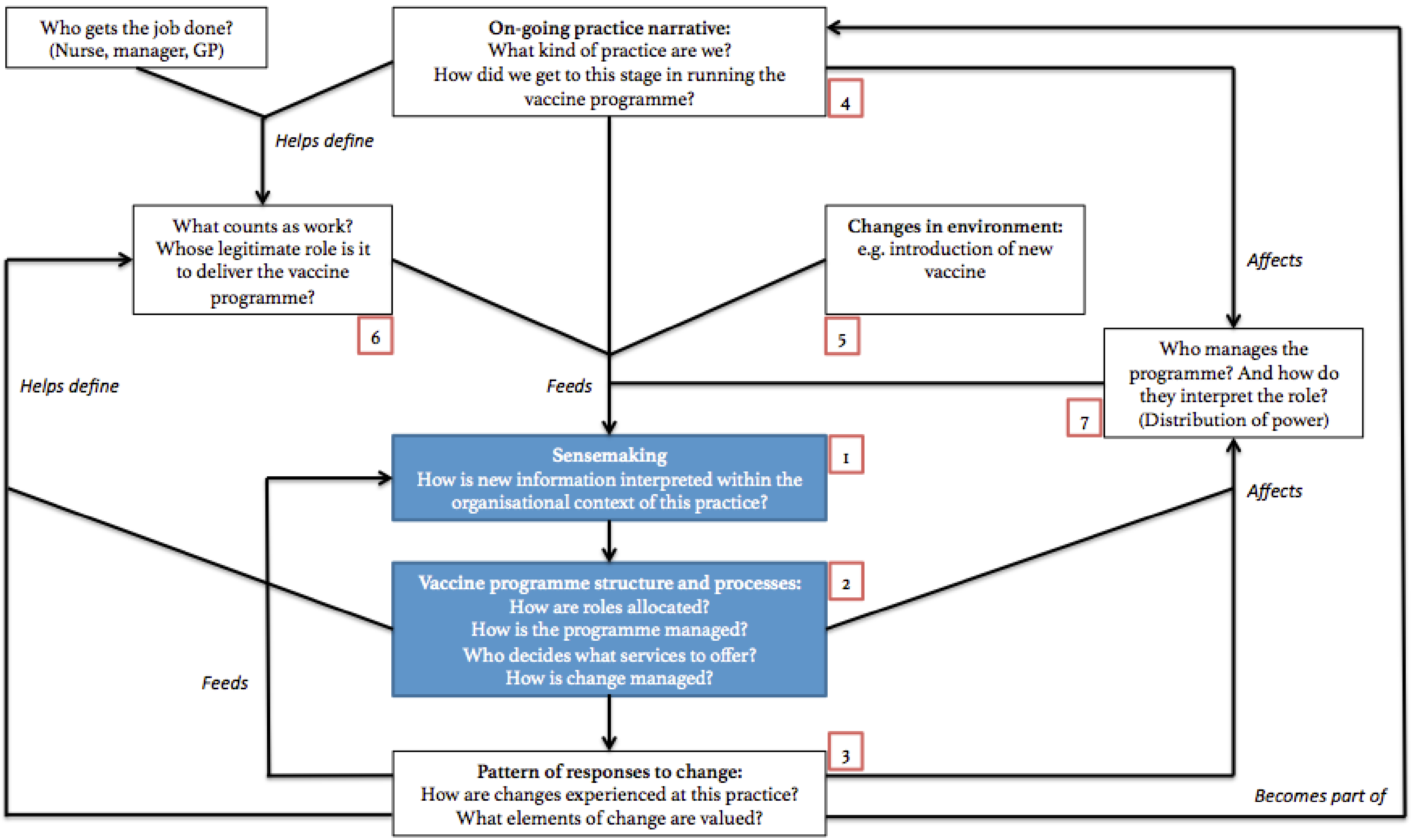

Figure 9: a conceptual model of sensemaking adapted from Checkland (2007) and applied to the implementation of the routine vaccine programme in England.

5.4.3 Qualitative methodology

There are several available methods that could be used to generate the data required to evaluate organisational sensemaking within the GP practices included in this study. Evaluating which is the most suitable must consider that it will be delivered alongside the TDABC methods and must not be too resource intensive for the participants within the GP practices. Ultimately, this study sits within a post-positivist view, that organisation is something that GP practices 'have' and can be described in some objective form, with actors within the organisation constructing meaning through interpretation and contributing to sensemaking and thus organisation formation.

The ideal method for collecting rich data on organisational sensemaking is direct observation of activities within the GP practice taking an ethnographic approach. This would involve direct observation of staff undertaking vaccination activities, including clinics and meetings, and may include written observations or recording of staff interactions and discussions. These methods have been used in a variety of studies within UK general practice, including looking at the impact of the implementation of QOF payments on both professional boundaries (Grant *et al.*, 2009) and organisational service delivery (Checkland *et al.*, 2010); on the role of middle managers in NHS organisations (Checkland *et al.*, 2011); and observing how GP practice receptionists interact with patients (Hewitt, McCloughan and McKinstry, 2009), and their role in managing the repeat prescription process (Swinglehurst *et al.*, 2011). However, this would be very difficult in practical terms within the scope of this study. Vaccination activity is highly diffuse for both clinical and administrative staff. In most cases, vaccinations are given in general clinics by nurses at different time throughout the week, therefore, to observe vaccination appointments would require a very high time commitment from the researcher to record information on a relatively small number of appointments. This study is designed to avoid observing or otherwise collecting data on patients, to avoid having to consent individual patients to participate from each of the different practices, which would also be significantly time-consuming. Although there are few data on how administrative activities are organised within practices, it is similarly likely that administrative tasks related to vaccination are undertaken in a diffuse manner, and, most likely, by individual staff, rather than as a team. However, this aspect of vaccine programme delivery is unknown. It is likely that there would be a benefit in undertaking further ethnographic work relating to vaccine programme delivery once the variation of implementation at practice level is better understood and observational activities can be more clearly focussed.

Other than direct observation, interviews are the most widely used method to collect qualitative data relating to organisations and can be conducted in various formats, including individual or group, and can be both unstructured and in-depth, semi-structured with some fixed questions but the ability to move off topic, or relatively structured that can act more like a cross-sectional survey (Bowling, 2009a). Interviews have been widely used to collect the required data as part of the process evaluation aspect of the TDABC. These need to be relatively structured in order to identify aspects of implementation of the vaccination programme and compare these between practices. Given the time and resource constraints present in conducting research within the working day of active GP practices, from a pragmatic point of view it makes most sense to aim to collect the data on organisational sensemaking activities with the same staff in the same interview. Therefore, although unstructured, in-depth interviews might have generated richer qualitative data, I decided to use semi-structured interviews with available staff at each practice, with flexibility of the interview participants, depending on practice staff availability, with some fixed questions in relation to process evaluation elements, with much of the rest of the interview free for exploration of issues arising at each practice in relation to organisation locally.

5.4.3.1 Analysis

The interviews will be recorded and professionally transcribed for analysis. These interviews will then have a dual purpose, firstly to derive the process evaluation elements as part of the TDABC; and secondly to evaluate sensemaking within GP practices. As such, two different methods of analysis are required. For the process evaluation, areas of interest from within the interviews are relatively fixed, and therefore a framework method of analysis is suitable for use when coding the data (Gale *et al.*, 2013). The data set is likely to be relatively large and comparisons will need to be made between results from participating practices in a structured way. Part of the overarching coding tree will be determined in advance and be based on process evaluation elements (inputs, processes, activities, outputs, outcomes and impact) as well as temporal associations within the implementation process (pre-appointment, appointment, post-appointment) and age-group codes (children and adults). While most of the coding will be deductive, emergent issues will be coded using inductive codes. The data will be analysed twice - during the first pass all data will be coded using the deductive codes and inductive codes will be generated. A second pass will be used to review accuracy and universally apply any inductive codes.

However, for the evaluation of organising, very little is known about the way practices organise delivery of the vaccination programme and so this study is in part an exercise in theory generation to establish what aspects of organising may have an impact on both activities and performance. Therefore, it is difficult to predict what elements may emerge from the interview data and this aspect of the qualitative work will be theory generating, thus the use of inductive coding alone should be appropriate. The most widely used coding theory underpinning coding methods in this circumstance is the use of grounded theory, which *"is one that is inductively derived from the study of the phenomenon it represents. That is, it is discovered and provisionally verified through systematic data collection and analysis of data pertaining to that phenomenon"* (Strauss and Corbin, 1990). This suits an investigation of sensemaking amongst general practice staff as it is concerned with analysing the meaning generated through social interactions (Starks and Trinidad, 2010). However, the investigation of this component is going to be undertaking using the sensemaking theory and conceptual model described in 5.4.2.3.3, so there is also a deductive element that is not purely emergent from the data. Therefore, a first pass of open coding will be used to categorise the data initially without the application of the sensemaking conceptual framework. However, during a second pass for axial coding the grouping of the individual codes will be undertaken keeping in mind the sensemaking paradigm to enable conclusions to be drawn in this respect. Finally, a third pass will be used for selective coding to fully understand the central phenomenon and enable comparisons between the participating practices.

5.5 Data collection methods

The final study design involves a Time Driven Activity Based Costing analysis, which includes a process evaluation, alongside an analysis of organisational sensemaking within each of the included practices. Three types of data require collection at each practice for the TDABC analysis:

i) Information on activities undertaken within each practice: collected through interviews with practice staff.
ii) Activity data from all practice staff involved in vaccinations, including activities undertaken and time spent: collected using activity logs.
iii) Cost data from practice management: collected using a costing survey.

For the sensemaking evaluation of organisational management, data will also need to be collected through interviews with practice staff. Therefore, to reduce the time and resource burden within each practice, the data collection for this evaluation was combined with that for the evaluation of activities (described in (i) above) into a single semi-structured interview format.

- **Interviews**

For the reasons described in 5.4.3 semi-structured interviews were used at each practice to generate data for use in the implementation evaluation and analysis of organisational sensemaking. A topic guide was developed, with topics and questions derived from important components of the process of implementing vaccinations, as well as factors identified in the literature related to organisational management and performance. The guide is presented in appendix 9.4. GP practices are very busy, high pressure environments, so great flexibility was allowed in terms of structure and staff participation in the interviews, depending on the availability of staff, in order to maximise participation. The main point of contact for the practice was the practice manager, who was requested to arrange the interviews. The request was to arrange for a cross-sectional profile of staff from within the practice who are involved in the organisation and delivery of the vaccination programme to participate. Interviews could be with individual staff, or groups of clinical or administrative staff, or mixed groups of staff, depending on what was convenient for the practice. The total data collection activity took place over a period of two to three weeks and so interviews could be conducted on one or more days at the practice. Due to the variation in organisation no prescription was given as to which staff should participate, only that they should cover experience of both clinical service delivery and administration and management and be able to provide a representative view of the practice.

At the start of each interview I briefed participants on the nature and the scope of the research and requested written consent, which was provided individually by all staff members. The interviews were recorded, and, in addition, I took contemporaneous notes in the interviews and in the following experiences of vising each practice to put the interview in context. Once completed the interviews were transcribed verbatim by a professional transcription service (www.transcriptdivas.co.uk). The coding method employed for the process evaluation is presented in 6.2.1 and for the organisational sensemaking analysis in 6.3.2.

- **Activity log and cost survey**

I requested the tools used in the previous ABC study conducted on the vaccination programme in New Zealand from the study team (Turner *et al.*, 2009). The activity log from this study was used by both clinical and administrative staff and comprised a daily log for the time spent on vaccination activities, within specified categories and a column for staff to enter their estimated time taken in minutes. To develop the activity log, I expanded the data points collected by the New Zealand team to allow much greater flexibility for staff to record their activity without being constrained by pre-defined categories. I also created separate forms for clinical and administrative staff. The forms were divided into three categories for the clinical staff:

i) Activity undertaken during clinics (i.e. giving vaccinations), where appointment start and end time, alongside vaccinations delivered and consumables used, were recorded.
ii) Activity undertaken outside of clinic time (administrative tasks, reading etc.)
iii) Activity undertaken regularly, but less than once per month, that was not captured in ii)

For the administrative staff, only activities ii) and iii) were included. The final activity log forms used during the study are presented in appendix 9.5. The logs were kept by all practice staff with a role in vaccination for a 2-week period. The list of staff working during the nominated 2-weeks was provided by the practice manager and logs provided to each staff member, and all logs had to be returned for the voucher to be provided, even if they were blank (i.e. the staff member did not undertake any vaccination activity). Staff were trained to use the logs on the same day that the interviews took place and so the activity logs were completed after the interviews in all cases. In the very small number of cases where a staff member could not be trained directly, a colleague was nominated to ensure they understood how to use the forms. Training was simple and took around 10 minutes.

I showed the costing survey to two practice managers of non-participating practices (one in Cumbria and one in London) to get feedback on its suitability and usability. The facility cost data requests were largely kept the same, with minor modifications to make the categories suitable to the England context, including separating out the staff salary costs more clearly. An additional section was added for costs specific to the vaccination programme, i.e. consumables, cold-chain and fridges. Practice managers were asked to fill it out as completely as possible using routine available accounting data for the last complete 12 months (usually the preceding financial year April to April) that they had available. Practice managers had concerns about the confidentiality of the data, so part of the agreement was to ensure that none of the costing data was reported separately, nor in a way that the practice could be identified. The costing survey is presented in appendix 9.6.

5.5.1 Piloting and modification

The sampling method is described in section 5.7, however the first practice recruited was used as a pilot practice to evaluate the data collection methods and modify these based on experience and feedback before being delivered in the other recruited practices.

At the pilot practice all the interviews were conducted on a single day, with a GP, the practice manager, the practice nurse and a receptionist. From the interviews, the most interesting information came from times within the interviews where the discussion was allowed to flow, and therefore in future interviews a loose structure of questioning was employed to encourage free flow of conversation and enable interesting ideas to emerge. No other modifications were made to the topic guide.

The practice nurse (PN), practice manager (PM) and reception staff were left with the activity logs to complete for 2 weeks, as the GP had no role in vaccination. There were only minor changes to the activity log, which were primarily to do with clarifying the instructions of what to include in which section and modifying headings for sections to more closely match language used within GP practices. Otherwise the data recorded were clear and matched the expectations of each section. One particular challenge however was recording activity from receptionists. Overall, vaccination activity formed a relatively small amount of time for each of the five reception staff, who all worked less than full time. Thus, they had only one or two vaccine encounters each, so recording was sparse and dropped off as the week went on. As a result, I decided to not collect individual data from all reception staff if their only role was to book appointments and check patients in. The mean time spent per patient on checking in and booking was 1.8 minutes and this will be correlated with data from the other practices where receptionists did fill out activity forms (if they had wider roles in reminder/recall for example), to determine an average time spent per patient on booking/checking in patients for appointments.

Minor modifications were made to the costing survey, particularly the naming of some of the facility level categories and adding in additional options around rent or facility payments, as there is wide variation in how this cost is described at practice level.

5.6 Ethical approval

Ethical approval for this study was received from the Ethics Committee of the London School of Hygiene and Tropical Medicine in October 2016, LSHTM ethics reference number 11793.

Ethical approval for the activities in GP practices was received from the NHS Health Research Authority in March 2017, Integrated Research Application System number 212278, protocol number HPRU-2012-10096.

Letters of approval are presented in appendix 9.2.

5.7 Sampling

The unit of analysis for this study is a GP practice, as it is the practice that is contracted to deliver vaccinations to a defined unit of population. Therefore, GP practices need to be recruited in their entirety, rather than, for example, individual staff members. As relatively little is known about how practices go about delivering vaccinations, the methods described below require a large volume of data collection from each practice and subsequent analysis, with each practice acting as an individual case study. Therefore, the aim of the sampling process was to identify and recruit 8 to 10 practices from a diverse range of geographic and socio-economic contexts with a range of performance, so factors could be compared as part of a hypothesis generation process, as there is currently not a theory of how organisational factors at GP practice level affect the implementation of the routine vaccine programme.

Eisenhardt and Graebner have argued that case study research is especially useful when faced with a situation where *"existing research either does not address the research question at all, or does so in a way that is inadequate or likely to be untrue"* (Eisenhardt, 1989; Eisenhardt and Graebner, 2007). In their 2007 paper they also make the case for 'polar-type research' where contrasting the experience of well and poorly performing organisations can result in more clearly defined patterns emerging in order to develop a testable theory. This is also known as a 'comparison by greatest difference' study. Ransom et al., (2012) used this method in their paper analysing the association between local health department organisational factors and childhood immunisation coverage rates in the US. They selected 117 outlier health departments with high or low levels of vaccine coverage to be case studies. In each, the researchers then undertook qualitative analysis of documents and semi-structured interviews with key informants to generate a theory of organisational context that affects vaccine coverage. Comparison of greatest difference case-studies has also been used in England to evaluate characteristics of well and poorly performing GP practices in delivering seasonal influenza vaccine (Newby *et al.*, 2016). Similar methods have also been used within case study research in New Zealand evaluating immunisation practices in organisations with greatest improvement or sustained high levels of coverage (Groom *et al.*, 2010; Kennedy *et al.*, 2010).

With this background in mind, as part of the upgrading process, I proposed a purposive method for identifying and recruiting a polar-type sample. However, this had to be abandoned part-way through the sampling process and a more convenience sampling method employed. Both methods are described below.

5.7.1 Initial sampling method

The purpose of the original sampling method was to identify outliers at the poles of GP practice performance, either those who have very good or poor performance. As described in section 3.4.1, there are three main data sources for routine vaccinations: COVER, Unify2 and ImmForm. The characteristics of each of the data sets are shown in Table 5. As the unit of analysis is the GP practice, practice level data were required for the sampling process. COVER data are not routinely reported at GP practice level and there are quality issues with the unpublished data. Similarly, Unify2 data are unverified and known to be incomplete, but are available and used by NHS England for performance management purposes. ImmForm data are available at practice level, however are only available for some vaccines and are held within the ImmForm system, rather than being publicly available.

As the Unify2 data sets were available with practice level data for all 7,800 practices in England in a useable format in Microsoft Excel, I initially focussed on these data to identify the sample, starting with the 2014-2015 data set. Two things were immediately striking. The first was that there were far more records than practices (13,900 entries total) and a large number of these had GP practice codes attached, but no data recorded. Most of these are historic records for practices that no longer exist. Therefore, all records with no data on number of registered children were excluded, which left 7,799 records. A further 526 records were excluded from the analysis for practices that had less than 20 recorded children, as these practices are unlikely to be able to generate the required data in the time available for this project.

The second striking feature was the very high level of geographic variation between practices in different regions, with high performance focused in rural areas and in the north of England, with much lover coverage in London and other urban centres. Therefore, the data were divided into individual NHS regions to allow well and poorly performing practices to be identified within their regional context. These 7,286 records were then ranked in order of coverage (within each region) for

DTaP/IPV/Hib at 12 months and 24 months and MMR2 at 5 years. The highest and lowest ranked 5% in each region were then selected for further analysis, which left a shortlist of 599 practices. A comparison was then made with the 2013-14 Unify2 data, and practices that had incomplete data or very high variation in number of children or coverage (>20% variance) were excluded, to ensure that included practices had consistent high or low performance. MMR2 at 5 years is the only vaccine in both data sets, so MMR2 coverage for the shortlist of practices was validated against the more reliable ImmForm data and practices with >20% variance similarly excluded, which left a final shortlist of 364 practices, which roughly resulted in 182 potential pairs of relatively high and low performing practices across different regions. To make sampling across geographies easier, I grouped the regions into the following 5 categories: inner London boroughs, outer London boroughs, urban excluding London, rural North, and rural South, which approximated geographical variations in coverage.

The learning derived from this process was integrated into a paper describing and evaluating the data collection and reporting system for vaccination in England, for which I am second author, and which has been included in appendix 9.3.

5.7.2 NIHR Clinical Research Network

Once the list of practices had been generated the next challenge was to recruit practices into the study. I initially approached practices directly, starting with the highest and lowest performing practices in each geographical category and then working through the list. I initially emailed with the study information and an offer of the provision of a £350 voucher for participation in recognition of the staff time required and then followed-up with a telephone call. However, in the majority of cases I received no reply from GPs or practice managers via email or telephone. In the small number of cases where I did receive a reply, practice staff informed me that they did not have the capacity to undertake this kind of work, unless an additional payment was involved.

We then discussed this with GPs within the personal network of our academic department who advised using existing research networks, which contain practices already set-up to deliver research projects and who receive additional funding to be able to do this. However, this then created a more significant problem with selection bias, as practices already participating in research projects are less likely to be typical of GP practices at large, and our assumption was they were more likely to be highly performing. However, as I had had no success at recruitment by contacting practices blind, I approached the NIHR Clinical Research Network (CRN), which comprises an extensive network of primary and secondary care organisations in all regions of England, including more than 2,000 GP practices, who apply to join a scheme of payment for participating in research projects funded by the Department of Health and Social Care and delivered via the NIHR (NIHR, 2018). Practices who have signed up to the scheme get an additional annual payment for completing a prespecified number of research projects per year, which mainly involve recruitment of primary care patients into clinical trials. The payment is highly variable depending on practice size and number of studies and so it is not possible to evaluate what the payment to individual practices recruited into this study would be, aside from saying in the region of several thousand pounds for participation. To gain access to the network and the associated funding, I applied, and the project was accepted as an NIHR Portfolio Project in March 2017.

5.7.3 Revised sampling method

The CRN is split into local networks corresponding to NHS Regions. As the project was based in North London, it was allocated the North London CRN office as main point of contact. This office then made recommendations on contacting other regional offices. I developed a study information and activity document that was sent to GP practices alongside an expression of interest (EoI) form by CRN staff, which practices then returned if they were interested in participating. Then I was able to contact the practice directly and make arrangements for data collection. As I already had a list of practices that I was interested in sampling, I submitted this to the North London CRN to evaluate how many were also research practices. A small number of the London practices were registered, but most had not been 'research active' (i.e. participated in a research project) for several years. The CRN then contacted relevant practices on my proposed sampling list to see if they were interested in participating. In order to evaluate if the practices outside London were registered, regional lists were drawn up and sent to each of the regional offices, who then tried to establish if any of these practices were registered and research active. This was a drawn-out process with different information held and submitted by the regional offices. Overall, only two practices on my list were both in the CRN and responded to the EoI (one in London, one in East of England), however both declined to participate as they were busy with other projects.

Therefore, at this stage, a new sampling strategy was required, and the original list of polar practices was abandoned. The feedback received from the two practices that were not able to participate and from staff within the CRN office was that most studies that go through the CRN require practices to recruit patients into clinical studies. This was the first study that people were aware of that focused on collecting data from the practice itself, therefore there was both some uncertainty and reluctance from practices to participate. I then reworked the study information sheet to make the study data collection process clearer, and this was sent out via the CRN offices across England in May 2017, with a view to recruiting a convenience sample of practices that returned an EoI and had the capacity to participate. Practices were recruited in order and data collection began as soon as was convenient. Between May and December 2017 14 practices returned EoIs to participate in the study. During the process two practices that returned EoIs were excluded as they were very similar in terms of geography and demography to already recruited practices. One practice stopped responding to follow-up emails to schedule data collection activities. As there were no expressions of interest from London practices by

August 2017, we increased the voucher payment to practices in London to £500 to compensate for staff time and requested that the CRN focus on recruiting London practices, which resulted in three practices returning expressions of interest between September and December 2017. However, one of these practices was not able to complete the data collection activities due to operational difficulties at the practice during the study period. This resulted in a final recruited sample of 10 practices, of which the first recruited practice was used to pilot the data collection activities and tools prior to use in the other practices. The final sample characteristics are presented in section 6.1 below.

6 Results

The results are reported in four sections. First is a description of the final sample of recruited practice. Secondly, due to the scale of conducting TDABC analysis at nine practices the results have been split across two separate papers: the first reporting the process and implementation evaluation and the second focussing on the findings from the costing analysis. The final section presents the results from the qualitative interviews on organisational sensemaking.

6.1 Sample characteristics

The characteristics of the included practices are presented in Table 6. They have been labelled in order of practice list size from A to J, ranging from 4,600 to 20,000 registered patients. Four are in rural areas, three in areas with a mix of urban towns and suburban areas surrounding, and two are in London. The range of deprivation is represented with practice C being in the most deprived decile and practice E in the least deprived. In the practices with larger catchment areas, particularly in London, the ranked decile is an average of the local population, which is likely to have a mix of very wealthy and very deprived populations. There is similarly a range of ethnic diversity within the catchment populations, with the practices in London (G and J) having a very high proportion of minority ethnic groups in their population, as contrasted with practices A, D, E and H, with very low ethnic diversity. Of note, these figures do not account for migration status or use of English as a secondary language, which are important factors in health services access. The proportion of children aged 0 to 4 years old was relatively close to the England average, ranging from 3.3% in practice A to 7.7% in practice J, with higher proportions of younger children in the urban practices. The proportions of older people however varied more widely, from 10.4% in practice B and 11-12% in the London practices (G and J) to above 30% in the affluent rural practices D and A. In all but two practices (C and J), achievement of QOF points was higher than the England average, in some cases by quite some margin, with five practices scoring above 98% (A, B, D, E, H). This suggests that these practices are relatively well performing in terms of meeting targets. While the ‘friends and family test’ has been criticised as lacking validity (Manacorda *et al.*, 2017), it is a routinely reported statistic pertaining to patients’ perception of health service quality that can provide an immediate and high-level comparison. Every practice scores higher than average on the proportion of patients recommending the practice to friends and family, except F, which scores very low (56.6%).

To compare coverage, I have extracted results from Unify2 for DTP-IPV-Hib three doses by 12 and 24 months, MMR1 by 24 months and MMR2 by 5 years. To compare to ImmForm data I have extracted the equivalent MMR2 by 5 years statistic, although this was not available for practice H. For adult vaccinations, only PPV coverage was available in an annual, comparable format from ImmForm and so this has been included as a proxy for adult vaccination coverage. Practices D and E have high coverage of both childhood and adult vaccines. Practice C has quite high childhood, although lower than average MMR2, and high adult coverage. Practice A has very high childhood, but average adult coverage, and B has average childhood and adult. Practice F has high 12 months coverage, but lower 5-year coverage and very low adult coverage (56.1%). Practice H, which is the large rural practice, has low childhood and low adult coverage. The two London practices (G and J) have very low childhood coverage (particularly G) and very low adult coverage (particularly J).

Overall the sample contains a selection of GP practices in a wide range of geographic and socio-economic contexts. However, there are some limitations to this sample. There are no very small practices included, nor any very large practices, and, overall, the practices appear to be relatively highly performing in terms of non-vaccination indicators. However, they do present a range of vaccine coverage profiles.

	England Average	A	B	C	D	E	F	G	H	J
Region	-	East Midlands	East of England	Yorks & Humber	South West	East Midlands	East of England	North East & Central London	South East	South London
Urban/Rural status (a)	-	Mainly rural	Urban, city & town	Urban, city & town	Mainly rural	Urban, city & town	Largely rural	Major conurbation	Largely rural	Major conurbation
List size (b)	7,000	4,600	6,600	7,000	8,100	12,600	13,800	14,000	16,000	20,000
Demography										
Deprivation decile (b)	-	8	2	1	8	10	7	4	6	4
Minority ethnic groups (%) (b)	-	1.6	6.2	12.0	1.3	1.8	3.4	30.3	2.1	41.4
Aged 0-4 years (%) (b)	5.7	3.3	7.3	5.7	4.4	4.6	5.0	5.0	5.4	7.7
Aged 65+ years (%) (b)	17.3	31.6	10.4	13.6	30.4	23.6	21.5	11.3	18.9	11.8
Quality Indicators										
QOF Achievement (%) (b)	95.6	99.6	98.2	94.5	98.9	99.3	96.2	95.7	99.6	93.7
Patients recommending practice (%) (b)	77.4	95.3	78.4	81.4	89.3	84.4	56.6	87.8	83.1	85.9
Childhood Vaccination Coverage										
DTP-IPV-Hib 3 doses by 12 months (%) (c)	93.4	98.9	96.0	97.3	96.0	98.9	98.7	78.7	90.6	91.2
DTP-IPV-Hib 3 at 24 months (%) (c)	95.1	100.0	95.8	100.0	97.5	100.0	98.1	91.4	90.8	94.6
MMR 1 by 24 months (%) (c)	91.6	100.0	97.9	98.6	93.7	97.2	97.5	78.1	85.5	86.9

MMR 2 by 5 years (%) (c)	87.6	94.4	94.2	95.5	98.3	94.4	93.1	69.6	85.1	88.4
MMR 2 by 5 years (%) (d)	83.4	100.0	92.7	93.0	98.8	96.8	93.8	79.7	-	74.5
Adult Vaccination Coverage										
PPV (%) 2017-2018, 70-74 (d)	70.2	79.0	71.3	81.9	83.3	88.7	56.1	64.4	65.6	42.9

Data sources: (a) 2011 Rural-Urban Classification of Local Authorities (https://www.gov.uk/government/statistics/2011-rural-urban-classification-of-local-authority-and-other-higher-level-geographies-for-statistical-purposes);(DEFRA, 2017) (b) National General Practice Profiles; for deprivation 1 is most deprived decile, and 10 is least deprived (https://fingertips.phe.org.uk/profile/general-practice);(PHE, 2017c) (c) derived from UNIFY 2 data 2016-2017, which are experimental management data and have lower reliability;(NHS Digital, 2017b) (d) derived from Immform data 2016-2017. QOF = Quality Outcome Framework; DTP-IPB-Hib 3 = Diphtheria, tetanus, pertussis, polio & haemophilus influenzae group b, 3rd dose; MMR = measles, mumps and rubella vaccine; PPV: pneumococcal polysaccharide vaccine.

Table 6: characteristics and performance of GP practices included in the study.

The information about each included practice in Table 6 has been summarised to create an adjective list to describe the overall characteristics of the practice and assist with the qualitative analysis, and is presented in Table 7. Aside from list size and urban/rural status, if a characteristic is not mentioned, it is close to the England average.

Practice	Characteristics
A	Small, rural, affluent, low diversity, few children, many older people, high childhood coverage.
B	Average, urban, deprived, many children and high childhood coverage.
C	Average, urban, deprived, high diversity, high childhood and adult coverage.
D	Average, rural, affluent, low diversity, many older people, high childhood and adult coverage.
E	Large, mixed urban/rural, affluent, low diversity, many older people, high childhood and adult coverage.
F	Large, rural, low patient recommendation, high childhood coverage, very low adult coverage.
G	Large, London, very high diversity, few older people, very low childhood and low adult coverage.
H	Large, rural, low childhood and low adult coverage.
J	Very large, London, very high diversity, many children, few older people, low childhood and very low adult coverage.

Table 7: descriptors of characteristics associated with each included practice.

The first recruited practice was used as a pilot of the methods as described in section 5.5.1. The pilot practice was the smallest of all the recruited practices, with a list size of 2,700. It was in a suburban area in the East of England region, with low deprivation, low ethnic diversity and high coverage of vaccinations. There was one GP employed and one practice nurse undertook all the vaccinations. This made it slightly different from the other practices, however it did enable me to undertake an in-depth review of the methods with the relevant staff and receive feedback on the tools.

6.2 Time Driven Activity Based Costing

The findings from the process evaluation analysing how routine vaccination is implemented at GP practices in England is presented in the following paper published in *Implementation Science*.

6.2.1 Research Paper 3: Implementation evaluation

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SECTION A – Student Details

Student ID Number	LSH345619	**Title**	Dr
First Name(s)	Timothy		
Surname/Family Name	Crocker-Buque		
Thesis Title	An Evaluation of the Implementation of Routine Vaccination at GP Practice Level in England		
Primary Supervisor	Sandra Mounier-Jack		

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?	Implementation Science		
When was the work published?	22nd October 2018		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**

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Where is the work intended to be published?	
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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	TCB conceived the study and chose the methods with support from SMJ and ME. TCB identified the practices, undertook the interviews, trained staff on use of the activity logs, collected and entered data, undertook the quantitative analysis, coded the transcripts (reviewed by SMJ) and wrote the final manuscript. SMJ and ME reviewed and edited the final manuscript. All authors read and approved the final manuscript.

SECTION E

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Implementation Science

RESEARCH Open Access

A process evaluation of how the routine vaccination programme is implemented at GP practices in England

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Abstract

Background: In recent years, the incidence of several pathogens of public health importance (measles, mumps, pertussis and rubella) has increased in Europe, leading to outbreaks. This has included England, where GP practices implement the vaccination programme based on government guidance. However, there has been no study of how implementation takes place, which makes it difficult to identify organisational variation and thus limits the ability to recommend interventions to improve coverage. The aim of this study is to undertake a comparative process evaluation of the implementation of the routine vaccination programme at GP practices in England.

Methods: We recruited a sample of geographically and demographically diverse GP practices through a national research network and collected quantitative and qualitative data as part of a Time-Driven Activity-Based Costing analysis between May 2017 and February 2018. We conducted semi-structured interviews with practice staff involved in vaccination, who then completed an activity log for 2 weeks. Interviews were transcribed and coded using a framework method.

Results: Nine practices completed data collection from diverse geographic and socio-economic contexts, and 52 clinical and non-clinical staff participated in 26 interviews. Information relating to 372 vaccination appointments (233 childhood and 139 adult appointments) was captured using activity logs. We have defined a 14-stage care delivery value chain and detailed process map for vaccination. Areas of greatest variation include the method of reminder and recall activities, structure of vaccination appointments and task allocation between staff groups. For childhood vaccination, mean appointment length was 15.9 min (range 9.0–22.0 min) and 10.9 min for adults (range 6.8–14.1 min). Non-clinical administrative activities comprised 59.7% total activity (range 48.4–67.0%). Appointment length and total time were not related to coverage, whereas capacity in terms of appointments per eligible patient may improve coverage. Administrative tasks had lower fidelity of implementation.

Conclusions: There is variation in how GP practices in England implement the delivery of the routine vaccination programme. Further work is required to evaluate capacity factors in a wider range of practices, alongside other contextual factors, including the working culture within practices.

Keywords: Vaccination, Immunisation, Implementation, Health service, Primary care

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Background

The introduction of vaccinations into public health programmes in European countries over the last century has resulted in a dramatic reduction in vaccine preventable diseases (VPDs), including the elimination of smallpox and polio from the region. However, in recent years, the incidence of several pathogens of public health importance such as measles, mumps, pertussis and rubella has increased in Europe [1]. Coverage of the combined measles, mumps and rubella vaccine (MMR) is below herd immunity thresholds in many European countries, and in 2018, several countries such as Italy, Greece, France, Romania and the UK were affected by outbreaks [2, 3]. The causes of disparities in coverage are complex, multifactorial and country-specific but include suboptimal delivery mechanisms, alongside inequities in access for some populations, particularly those living in low-income urban environments [1, 4, 5].

In England, primary care clinics (GP practices) are responsible for arranging most routine childhood and adult vaccinations for their local population. The regular addition of antigens into routine vaccine programmes has meant organising service delivery has become increasingly complex [6]. In 1990, the programme consisted of eight vaccinations for children and adolescents against diphtheria, pertussis, tetanus, polio, measles, mumps, rubella and tuberculosis [7]. The programme for 2016–2017 (study period) and changes for 2018 are presented in Table 1 and now contains 16 childhood, 2 adolescent and 3 adult vaccinations, as well as 2 in pregnancy and a wide range for people with medical co-morbidities [8].

Delivering these vaccinations has required an increase in the number of contacts needed with the healthcare system for a wider range of patients, alongside associated administrative activities, including reminding and recalling patients and collecting and submitting data. These activities add significantly to the cost base of a practice and have taken place contemporaneously with increasing demand for GP services from an ageing population with more complex health needs, without commensurate increases in funding or staffing [9]. In addition, the public health system in England underwent a dramatic reorganisation in 2013 following the implementation of the Health and Social Care Act 2012. This moved local public health functions from NHS providers into local government, created a new executive agency for public health within the Department of Health called Public Health England and moved commissioning of public health services to a new agency called NHS England, with the aim of putting 'clinicians at the centre of commissioning, free[ing] up providers to innovate, empower[ing] patients and giv[ing] a new focus to public health' [10]. However, this had unintended consequences for the vaccination programme, resulting in a 'complex mesh' of 'fractured' commissioning, policy and service provision organisations and reduced oversight and support [11].

Vaccination is a highly complex public health programme with multiple interdependent activities which currently exhibits divergent outcomes [12]. Routine coverage statistics derived from GP practice records show that while coverage for childhood vaccinations remains relatively high, there have been multi-year decreases in coverage across many vaccines (Fig. 1) [13]. While this could be a result of expected fluctuations, coverage had previously been on an upward trend for most vaccines over the preceding decade. Further year-on-year decreases may result in coverage for some vaccines reducing below international targets (> 95% coverage) and population immunity thresholds to prevent outbreaks (> 90% coverage). For example, MMR at 24 months increased every year between 2007-2008 and 2012-2013 and, however, has now reduced from a high of 92.7% (2013–2014) to 91.6%. The decreases shown for the DTaP/IPV booster and MMR at 5 years may mean the > 90% target will not now be reached. This is particularly concerning for the measles-containing vaccines in the context of current large outbreaks in several European countries and five UK locations [2, 3].

National averages also hide significant geographic inequities. For example, coverage is significantly lower in London than elsewhere in England (e.g. in 2016–2017 DTaP-IPV-Hib 12 months: England 93.4%, London 88.8%; MMR2 5 years: England 87.6%, London 79.5%). There is also lower coverage in some ethnic groups and in areas of higher deprivation [14, 15]. The causes for this are unclear at present, and this study aims to provide more information about what is happening at GP practice level.

Previous research has shown that lower adherence to programme components is associated with worse outcomes for prevention services [16]. GP practices are independent providers contracted to provide vaccine services by NHS England, which defines minimum service standards for vaccination in the core service specification [17]. The specification leaves significant autonomy to practices as to how they organise implementing the programme. The National Institute for Health and Care Excellence (NICE) has also published quality standards for aspects of vaccination programme delivery for children and adolescents [18]. However, it is currently not known how different practices implement the programme, i.e. how activities are managed, nor whether the quality standards are adhered to. This makes it difficult to identify organisational variation and thus limits the ability to recommend interventions to improve coverage. Therefore, the aim of this study is to undertake

Table 1 The 2016–2017 routine vaccine programme in England, adapted from Public Health England (2018) [8]

Age	Disease(s)	Vaccine (trade name)	Notes, including schedule changes implemented during the study period
8 weeks	Diphtheria, tetanus, pertussis, polio, Haemophilus influenza type b (Hib)	DTaP/IPV/Hib (Pediacel or Infanrix IPV Hib)	Changed to Infanrix Hexa, with hepatitis B (Hep B) included in 2018
	Pneumococcal (13 serotypes)	Pneumococcal Conjugate (PCV) (Prevenar 13)	
	Meningococcal group B (MenB)	MenB (Bexsero)	
	Rotavirus	Rotavirus (Rotarix)	
12 weeks	Diphtheria, tetanus, pertussis, polio and Hib	DTaP/IPV/Hib (Pediacel or Infanrix IPV Hib)	Changed to Infanrix Hexa, with hepatitis B (Hep B) included in 2018
	Rotavirus	Rotavirus (Rotarix)	
16 weeks	Diphtheria, tetanus, pertussis, polio and Hib	DTaP/IPV/Hib (Pediacel or Infanrix IPV Hib)	Changed to Infanrix Hexa, with hepatitis B (Hep B) included in 2018
	MenB	MenB (Bexsero)	
	Pneumococcal (13 serotypes)	PCV (Prevenar 13)	
1 year	Hib and MenC	Hib/MenC booster (Menitorix)	
	Pneumococcal 13	PCV Booster (Prevenar 13)	
	Measles, mumps and rubella (MMR)	MMR (VaxPRO or Priorix)	
	MenB	MenB booster (Bexsero)	
2–6 years	Influenza (seasonal)	Live attenuated influenza vaccine (LAIV) (Fluenz Tetra)	Seasonal vaccine—excluded from this study
From 3 years 4 months	Diphtheria, tetanus, pertussis and polio	DTaP/IPV (Infanrix IPV or Repevax)	
	MMR	MMR (VaxPRO or Priorix)	
Females 12–13 years	Human papillomavirus (HPV)	HPV (two doses 6 to 24 months separated) (Gardasil)	Usually given in school—excluded from this study unless given in the GP practice
14 years	Tetanus, diphtheria and polio	Td/IPV (Revaxis)	Usually given in school—excluded from this study unless given in the GP practice
	Meningococcal groups A, C, W and Y	Men ACWY (Nimenix or Menveo)	Usually given in school—excluded from this study unless given in the GP practice
65 years	Pneumococcal (23 serotypes)	Pneumococcal polysaccharide (PPV) (Pneumovax II)	
> 65 years	Influenza (seasonal)	Inactivated influenza vaccine (strain dependent)	Seasonal vaccine—excluded from this study
70 years	Shingles	Shingles (Zostavax)	
Condition	**Disease(s)**	**Vaccine (trade name)**	**Notes**
Pregnancy	Influenza (seasonal)	Inactivated influenza vaccine (strain dependent)	Seasonal vaccine—excluded from this study
	Pertussis	DTaP/IPV (Boostrix-IPV)	From 16 weeks gestation
Various underlying medical conditions	Meningococcal Pneumococcal Influenza Hepatitis A and B HiB	Various	Patients with a wide range of medical conditions (asplenia, diabetes, respiratory, neurological) are eligible for a range of vaccines

a comparative process evaluation of the implementation of the routine vaccination programme at GP practices in England.

Methods

We collected quantitative and qualitative process data in line with the Medical Research Council's process evaluation guidance as part of Time-Driven Activity-Based Costing (TDABC) analysis [12]. TDABC is a method for allocating costs to complex processes within organisations to identify cost drivers and opportunities for lowering costs while improving quality [19–21], which has been extensively applied to complex health service delivery in primary and secondary care [21]. Steps 1–4

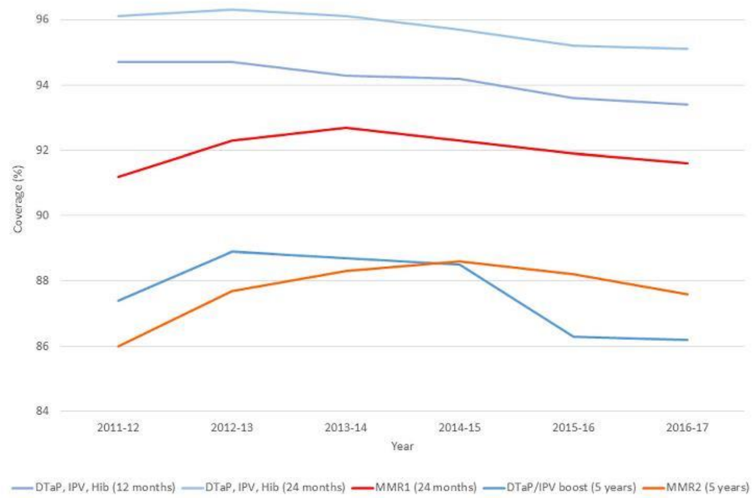

Fig. 1 Coverage (%) of selected vaccinations by age in England 2011–2017, from NHS Digital (2017) [11]

of the 7-step TDABC analysis generate process evaluation data [22]. Steps 5–7 involve calculation and allocation of costs and are excluded from this analysis. Qualitative components of this study have been reported in line with COREQ guidelines [23].

– Step 1: Define the condition and population

The condition under analysis is a patient registered at a GP practice who is eligible for a routine vaccination. The organisational boundary of this analysis is those activities that are undertaken within the GP practice by employees. Patients attending for all routine childhood and adult vaccinations were included (Table 1), except seasonal influenza, as this is funded through a different mechanism and activity is uneven throughout the year. Non-routine vaccines (e.g. travel vaccinations) and vaccines not given in GP practices (e.g. HPV vaccine given at school) were also excluded.

– Steps 2 and 3: Define the delivery value chain and develop a process map

The care delivery value chain (CDVC) is a visual representation of the main activities involved in providing routine vaccinations at GP practices [21, 22]. To define the CDVC, we conducted semi-structured interviews using primarily open questions with a selection of staff from each practice (individually or in groups depending on availability) using a pre-defined topic guide (Appendix). One author (TCB) conducted all the interviews during a single day at each practice, which were recorded, transcribed verbatim and uploaded into NVIVO v11 for analysis. Contemporaneous field notes were made during site visits. Coding was completed by one author (TCB) using a framework method. A deductive code tree was constructed from core process evaluation elements (inputs, processes, activities, outputs, outcomes and impact) as well as temporal associations within the implementation process (pre-appointment, appointment, post-appointment) and age-group codes (children and adults). Inductive codes were used to identify important issues arising from the data (e.g. funding, outbreaks, appointment length). During the first pass, we coded all data using deductive codes and generated the inductive codes. We then undertook a second pass to universally apply the inductive codes and check completeness and overall accuracy. The framework and a selection of transcripts were reviewed by a second author (SMJ) [24].

– Step 4: Allocate time estimates for each process step

We provided all staff involved in vaccination at each practice an activity log to contemporaneously record all clinical and non-clinical vaccination activity over a 2-week period. We modified logs used in a study conducted in New Zealand [25] and validated them with practice managers (PMs), practice nurses (PNs) and GPs at two non-participating practices. The first practice recruited was used as a pilot before data collection tools were finalised following minor changes to the interview guide and to the data collection tools, primary for clarity and usability. Following the interviews (step 2), a list of every member of staff involved in vaccination was developed for each practice who were then trained and provided with an activity log to keep for 2 weeks. Data were extracted and placed into a Microsoft Excel file for analysis.

Sampling

We recruited GP practices to participate through the National Institute for Health Research Clinical Research Network (CRN) [26]. This comprises an extensive network of primary and secondary care organisations in all regions of England, including more than 2000 GP practices, who apply to join a scheme of payment for participating in research projects funded by the Department of Health. We aimed to recruit a non-representative convenience sample of 10 practices (due to our available capacity) from a range of geographic and socio-economic contexts. Following circulation of the study details, 14 practices retuned expressions of interest to participate over a 9-month period before recruitment was ended. We excluded 4 practices as they were geographically similar to already included practices, and 1 did not complete data collection. A £350 shopping voucher (£500 in London) was provided to participating practices as compensation for staff time. Agreement to participate was made with the practice manager, who we then asked to identify relevant members of staff to participate in interviews to explore the organisation of vaccination within the practice. Due to the significant variation in size, staff profile and administrative organisation between practices, we specified only that the practice manager and a practice nurse must be included, and the manager was then free to recruit other relevant staff to participate based on the research aims.

Consent and ethical approval

We gained written, informed consent from each participating staff member prior to commencing data collection. No patients were involved. The study received ethical approval from the LSHTM Ethics Committee and the NHS Health Research Authority (project ID 212278).

Results

Nine practices completed data collection activities between May 2017 and February 2018. Their characteristics are presented in Table 2, which demonstrate wide geographic and demographic diversity. Two quality metrics are routinely collected and reported at GP practice level: Quality Outcomes Framework (QOF), a pay for performance scheme in which vaccination is not included (except influenza coverage in people with medical co-morbidities), and the proportion of patients recommending the practice to friends and family. All practices aside from C and J score higher QOF points than average, and every practice scores higher on the friends and family test, except F, which scores very low (56.6%). For childhood vaccination coverage, the smaller practices have higher than average coverage for most vaccinations (A, B, C, D, E and F) whereas the three largest practices (G, H and J), including the two in London, have lower coverage, with practice G having the lowest coverage overall. Adult vaccinations are similar with the smaller practices scoring above average and the four larger practices (F, G, H and J) below with particularly low coverage in practice J.

Care delivery value chain and process map

In total, 52 people participated in 26 interviews at the 9 practices. Interviews ranged from 10 to 75 min. The number and type of staff who participated at each practice is presented in Table 3. In one practice, a GP provided oversight to the programme out of personal interest (J), but otherwise, no doctors were involved in vaccination.

Interview data were supplemented with the activity log data to confirm details provided in the interviews, and information relating to 372 vaccination appointments was captured, comprising 233 childhood and 139 adult appointments. The resulting CDVC is presented in Fig. 2. Fourteen core activities were common to all practices and took place within the GP practice building, aside from the nurses' annual training, which was usually at another local organisation. Timings for three of the activities (dashed boxes) were aggregated with other activities by some practices. Although this is presented as a linear process, these activities often take place concurrently or non-sequentially creating a constant responsive workflow. A process map from the perspective of the practice is presented in Fig. 3.

Activities and task allocation

The task allocation of the activities shown in Figs. 2 and 3 is presented in Table 4. The role of the clinical staff was similar across practices, with practice nurses (PNs) having the primary role in delivering vaccinations, with some also delivered to adults by healthcare assistants (HCAs), who work under the guidance of the nurses. However, the roles for administrative staff varied widely, with some practice managers (PMs)

Table 2 Characteristics of GP practices included in the study

	England average	A	B	C	D	E	F	G	H	J
Region	–	East Midlands	East of England	Yorks and Humber	South West	East Midlands	East of England	North East and Central London	South East	South London
Urban/rural status[a]	–	Mainly rural	Urban, city and town	Urban, city and town	Mainly rural	Urban, city and town	Largely rural	Major conurbation	Largely rural	Major conurbation
List size[b]	7000	4600	6600	7000	8100	12,600	13,800	14,000	16,000	20,000
Demography										
Deprivation decile[b]	–	8	2	1	8	10	7	4	6	4
Minority ethnic groups (%)[b]	–	1.6	6.2	12.0	1.3	1.8	3.4	30.3	2.1	41.4
Aged 0–4 years (%)[b]	5.7	3.3	7.3	5.7	4.4	4.6	5.0	5.0	5.4	7.7
Aged 65+ years (%)[b]	17.3	31.6	10.4	13.6	30.4	23.6	21.5	11.3	18.9	11.8
Quality indicators										
QOF achievement (%)[b]	95.6	99.6	98.2	94.5	98.9	99.3	96.2	95.7	99.6	93.7
Patients recommending practice (%)[b]	77.4	95.3	78.4	81.4	89.3	84.4	56.6	87.8	83.1	85.9
Childhood vaccination coverage										
DTP-IPV-Hib 3 doses by 12 months (%)[c]	93.4	98.9	96.0	97.3	96.0	98.9	98.7	78.7	90.6	91.2
DTP-IPV-Hib 3 at 24 months (%)[c]	95.1	100.0	95.8	100.0	97.5	100.0	98.1	91.4	90.8	94.6
MMR 1 by 24 months (%)[c]	91.6	100.0	97.9	98.6	93.7	97.2	97.5	78.1	85.5	86.9
MMR 2 by 5 years (%)[c]	87.6	94.4	94.2	95.5	98.3	94.4	93.1	69.6	85.1	88.4
MMR 2 by 5 years (%)[d]	83.4	100.0	92.7	93.0	98.8	96.8	93.8	79.7	–	74.5
Adult vaccination coverage										
PPV (%) 2017–2018, 70–74[d]	70.2	79.0	71.3	81.9	83.3	88.7	56.1	64.4	65.6	42.9

QOF Quality Outcomes Framework, *DTP-IPB-Hib 3* Diphtheria, tetanus, pertussis, polio and haemophilus influenzae group b, 3rd dose, *MMR* measles, mumps and rubella vaccine, *PPV* pneumococcal polysaccharide vaccine

Data sources: [a]2011 Rural-Urban Classification of Local Authorities (https://www.gov.uk/government/statistics/2011-rural-urban-classification-of-local-authority-and-other-higher-level-geographies-for-statistical-purposes) [25]; [b]National General Practice Profiles; for deprivation, 10 is most deprived decile and 1 is least deprived (https://fingertips.phe.org.uk/profile/general-practice) [26]; [c]derived from UNIFY 2 data 2016–2017, which are experimental management data and have lower reliability [11]; [d]derived from Immform data 2016–2017

Table 3 Number and type of staff group participating in semi-structured interviews at each practice

	A	B	C	D	E	F	G	H	J	TOTAL
Practice nurse (PN)	2	2	2	2	6	1	3	2	3	23
Healthcare assistant (HCA)	0	0	0	0	4	0	1	2	0	7
Practice manager (PM)	1	1	1	1	1	1	1	0	1	8
Administrator (AD)	0	1	2	1	2	1	1	3	1	12
Receptionist (R)	0	0	1	0	0	0	1	0	0	2
Total	3	4	6	4	13	3	7	7	5	52

having an oversight role and some being directly involved in activities such as reminder/recall; some practices had general administrators with various roles in managing reminder/recall activities, following up patients, planning clinics and submitting data, while others employed specialist administrators with specific roles, such as data management, target focussed roles or managing aspects of finance. In other practices, an assistant practice manager (APM) filled this role. Most receptionists had a role booking in appointments and checking patients in on arrival, but in some practices, they had a large role in reminder/recall activities and counselling patients over the phone.

The two components that had the greatest variation between practices were (i) the mechanism and frequency of reminder/recall activities (Table 4, row 2) and (ii) the structure of the vaccination appointments, which varied in length and distribution throughout the week (Table 4, row 4). Several practices had specific clinics for vaccination: C (two clinics weekly, one for babies and one for older children), D and H (one weekly clinic for babies and children) and F (weekly baby clinic only). Elsewhere appointments were diffused throughout the week.

Outputs

The number of childhood vaccination appointments (Table 1) ranged from 9 to 71 during the 2-week data collection periods (Table 5). The mean appointment length across all practices was 15.9 min (range 9.0–22.0 min). Smaller practices (A and C) had the longest appointments, and the shortest were observed in F and H both medium-large practices in rural areas. We asked clinical staff to add information on any other issues occurring in the appointment that could have impacted on time, and no appointments were

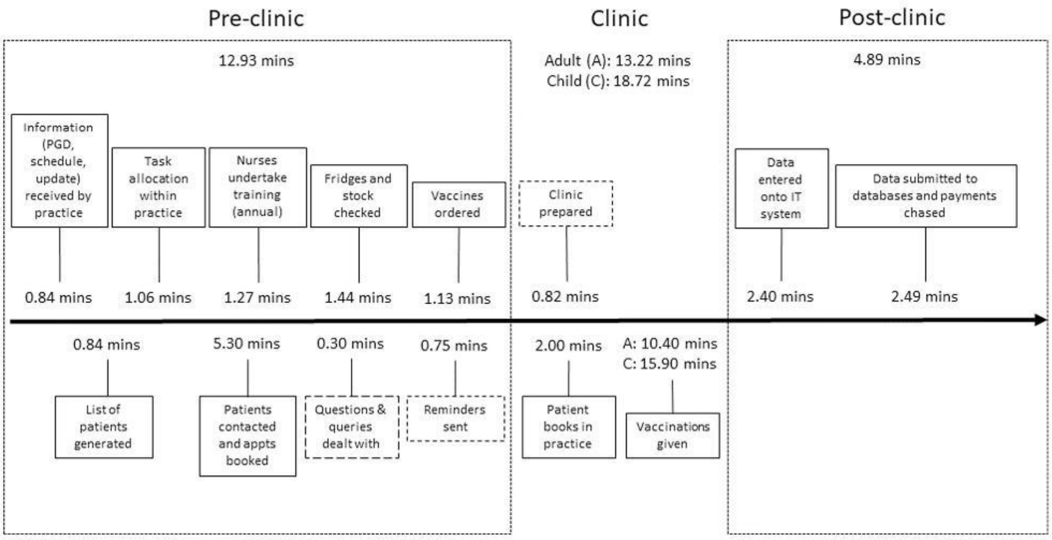

Fig. 2 The care delivery value chain for routine vaccinations from the perspective of a primary care practice. (The black arrow shows the process over time within the GP practice, with activities involving the practice above the line and patient-facing activities below the line. The blue arrow represents the patient's interaction with the practice during the process). Activity steps with dashed outline are those where times were sometimes recorded together with other activities by practices, so timings are less reliable. Timings are mean times calculated across the included practices for each step

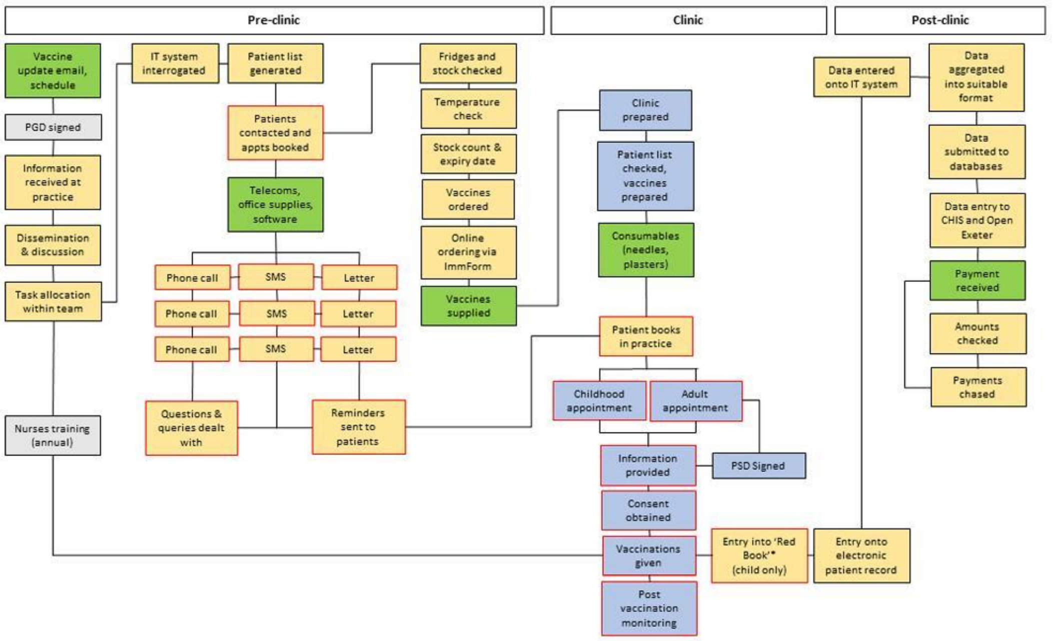

Fig. 3 A process map of the system of implementing routine vaccination at GP practices in England. Green box = resources; yellow box = non-clinical/administrative activities and processes; grey box = activity undertaken off GP practice site; blue box = clinical activity and processes; red outlines = activities and process with direct patient contact. *The Red Book is a paper health record held by a child's carers. PGD patient group directive, SMS text message (short message service), PSD patient-specific directive; CHIS Child Health Information System

identified that had a significant non-vaccination-related component.

To estimate the capacity available for vaccination, the number of children aged 0–4 was divided by an estimate of the annual number of child appointments (number during the study period multiplied by 25, equal to 50 working weeks). Practices A and D had the highest number (1.53 and 1.56 appts/child respectively) and are small-medium practices in rural areas of low deprivation with high coverage (Table 2). Practice B had relatively lower capacity (0.76 appts/child) and slightly lower coverage. Practice G (large practice in London) also had lower capacity (0.81 appts/child) and significantly lower coverage, whereas practice J (large practice with high number of registered children in London) had higher capacity (1.24 appts/child) and somewhat higher coverage overall.

The number of adult vaccination appointments ranged from 4 to 26 and are not related to practice size. The high number of adult vaccination appointments at practice A was due to a concurrent shingles campaign (23 of 26 appointments), and practice C was running a meningococcal ACWY campaign for adolescents (18 of 22 appointments). Appointment capacity was estimated by dividing the number of adults aged 65+ by an estimate of the annual number of adult appointments. This ranged from 0.04 (practice E) to 0.57 (practice C) and was not related to overall performance. This is likely due to the large number of PPV vaccinations delivered alongside the seasonal flu campaign, which has been excluded from this analysis. Observed appointment length ranged from 6.8 min (E) to 14.1 min (C), with the mean being 10.4 min. Overall mean time spent across the nine practices for each stage in the CDVC is presented in Fig. 2.

The mean proportion of total practice vaccination time (TPVT) spent on non-clinical activities was 59.7% (range 48.4–67.0%). At most practices (A, B, C, F, G, H), around two thirds TPVT was spent on non-clinical work, and in the remainder (D, E, J), it was split evenly. Practice J was the only location where clinical time (51.9%) outweighed non-clinical time due to the large number of childhood appointments.

Table 4 Organisation of responsibilities for processes involved in routine vaccination at the included practices

Activities	A	B	C	D	E	F	G	H	J
1. Pre-clinic administration (receiving info; generating patient list)	The PM runs searches and allocates tasks to the R staff.	An AD runs the searches and manages the list.	The PM runs searches and the PN has a role in allocating tasks.	The PM runs searches and allocates tasks to the R staff.	The APM is responsible for running searches and allocating tasks.	The PM runs the searches and then tasks allocated to the PN and AD.	An AD generates the list and allocates tasks, with some support from the PN.	An AD generates the lists of eligible patients, from info from CHIS and local records.	An AD is responsible for generating the list of patients.
2. Patient contact, appointment booking and reminder/ recall activities	The R staff are responsible for booking appointments and reminder recall activities, which involve letters and phone and text messages. Occasionally the PN will phone parents.	An AD is then responsible for all the reminder and recall activities, which primarily involves letters, but with some follow-up phone calls.	An AD has a large role in contacting patients, including calling patients and sending letters and SMS reminders, with some support from a R.	The R staff undertake all appointment booking and reminder recall activities and have a role in clinic preparation. Initial invite is by letter, followed by phone calls. Adult vacc is opportunistic.	This is split between the APM and the R staff and primarily involves sending letters, with some follow-up phone calls.	Some initial letters sent, then an AD books appts during the PN's clinic (below). The PN and PM both also have a role here in phoning patients who do not respond or DNA.	The R staff are responsible for sending out letters and SMS reminders and booking appts. An AD and PN also call parents who DNA or do not respond.	This is undertaken by an AD who sends letters to parents, or will phone or send a SMS in the case of no response. Adult vaccines are booked ad hoc, especially during flu season.	The AD also sends the l etters and manages the reminder recall activities, and the PN phones non-responders and DNAs.
3. Vaccine ordering, stocking and fridge maintenance	The PN primarily manages vaccine stock levels although with some support from the PM.	An HCA undertakes the vaccine ordering, which stock audit, and fridge maintenance is done by the PN.	Ordering is done by the PN and stocking and maintenance is split between the PN and an AD.	Ordering, stock management and maintenance is undertaken by a PN.	The PN does the fridge maintenance and an AD vaccine stocking and ordering.	Vaccine ordering and fridge maintenance are all undertaken by the PN.	Stocking and ordering is undertaken by an AD with some maintenance from the PN.	Stocking and ordering is done by an AD. Fridge maintenance is split between an AD, a PN and HCA.	Stocking, ordering and maintenance are all undertaken by a PN.
4. Vaccination appointments	Vacc takes place in general clinics with a PN. Childhood vaccines are allocated 20 min, with some adult vaccs having 10-min appts.	All vacc takes place in general clinics within 15-min appts with a PN.	Most primary imms are given in a specific baby clinic with a PN in a 15-min appt, al though some are also done in general clinics. All adult imms are done in general clinics and sometimes 10-min appts are used.	Almost all vacc takes place in a dedicated baby/child clinic with 10-min appts. Although rarely 20-min general appts are used.	A mixture of 15- and 20-min appts are used in general clinics with a PN. Rarely 10-min appts are used.	There is a dedicated clinic for the 8-week appts with 2 PNs working 5 min per patient. All the others in general clinics with 10-min appt with a PN.	All childhood and most adult vacc take place in 15-min appts with a PN. Some PCV and shingles vacc are done in 20-min appts with an HCA.	A specific vacc clinic is run that involves 2 PNs with 5-min appts and 2 HCAs undertaking data input. A few 15-min general appts with PN and 20-min appts with an HCA are used. Adult vaccs take place in general clinics and are often given by HCAs.	Almost all vacc are given in 15-min appts in a general clinic with a PN.
5. Post-clinic data collection and submission, including Open Exeter and CQRS.	This is entirely undertaken by the PM.	This is primarily done by the AD, with some support from the PM.	Some data collection is undertaken by the PN immediately after the appts, then an AD is responsible for upload and submission.	This task is split between the PM and the R staff, with a small amount of support from the PN.	This is undertaken by an AD staff member and however is primarily automated.	An AD is in the clinic with the PN to undertake data collection and submission simultaneously. The PM has a role in the financial submissions.	A member of the R team has a large role in this, supported by a specialist AD.	Aside from the data entry undertaken in the clinics, the remainder is done by the AD.	An AD has a large role in data submission, with some time spent by the PN, particularly on CQRS.
6. Professional tasks and activities (training, reading updates, PGD administration)	Reading the vaccine update and training are undertaken by the PN.	Reading the vaccine uptake is done by both the PM and PN, with the PN also doing training.	Reading the vaccine update and training are undertaken by the PN.	Reading the vaccine update and training are undertaken by the PN.	Reading the vaccine update and training are undertaken by the PN.	Reading the vaccine update and training are undertaken by the PN.	Reading the vaccine update and training are undertaken by the PN.	The PN undertakes annual training.	The PN undertakes annual training.

PM practice manager, *APM* assistant practice manager, *PN* practice nurse, *AD* administrator, *R* receptionist, *DNA* did not attend, *HCA* healthcare assistant, *PCV* pneumococcal vaccine, *SMS* text message

Table 5 Data derived from the number and length of vaccination appointments and time spent on vaccination during the 10-day study period at each practice

	A	B	C	D	E	F	G	H	J
Childhood appointments (*n*)	9	14	15	23	24	30	23	31	71
Mean length, min (95% CI)	20.2 (18.2–22.2)	15.4 (13.1–17.6)	22.0 (16.4–27.6)	13.9 (11.5–16.3)	18.1 (16.0–20.1)	9.8 (8.9–10.7)	18.3 (15.5–21.1)	9.0 (8.0–10.5)	16.7 (15.4–17.8)
Annual appts per child 0–4 (*n*)	1.53	0.76	1.01	1.56	1.28	1.01	0.81	1.20	1.24
Adult appointments (*n*)	26	10	22	17	4	23	7	14	16
Mean length, min (95% CI)	9.2 (8.6–9.8)	11.2 (8.7–13.7)	14.1 (12.6–15.6)	8.7 (6.9–10.5)	6.8 (2.9–10.6)	8.0 (6.8–9.2)	13.3 (11.4–15.1)	9.1 (7.6–10.6)	13.5 (11.9–15.1)
Annual appts per adult aged 65+ (*n*)	0.45	0.38	0.57	0.17	0.04	0.19	0.11	0.11	0.17
Total time spent on vaccination during study period (TPVT) (min)	1205	915	1821	1017	973	1224	1481	1231	2711
Proportion of time spent on non-clinical tasks, min (%)	784 (65.1)	588 (64.3)	1180 (64.8)	550 (54.1)	512 (52.6)	746 (60.9)	893 (60.3)	825 (67.0)	1312 (48.4)
Proportion of time spent on clinical tasks, min (%)	421 (34.9)	327 (35.7)	641 (35.2)	467 (45.9)	461 (47.4)	478 (39.1)	588 (39.7)	406 (33.0)	1399 (51.6)
Relative time per patient (mean time per patient on list = 1)	1.86	0.98	1.84	0.89	0.55	0.63	0.75	0.55	0.96

To account for practice size, TPVT was divided by list size to give time per patient. The relative time per patient was calculated where the mean time per patient equalled 1. Practices A and C (smaller practices with long childhood appointments and a high proportion of non-clinical time) spent the most time on vaccination activities, whereas practices E and H spent relatively little time overall. Figure 4 shows the proportion of TPVT spent by different staff groups with practice ranked in order of total proportion of time spent by the PN (from 70.8% at practice E to 32.6% at practice H). Practice E had a relatively streamlined and automated administration system, reducing the overall administration time. Practices E, F and B all had relatively large proportions of PN time spent on non-clinical activities, which was primarily due to a significant role in checking the fridges, stock and ordering vaccines. Practice G had a particularly large proportion of administrative time due to receptionist involvement on reminder/recall activities. Practice H's system of having two PNs and two HCAs in a vaccine clinic significantly reduced the overall amount of time spent by the PN. Overall, the PM had relatively small roles in vaccination, except in A where they were the only member of administrative staff and D where they had a large role in both running searches and submitting data.

Comparison to service requirements

Table 6 maps the provider requirements from the core service specification and quality standards (QS) recommended by NICE (except QS5 that relates to young offenders) [17, 18]. No practices had a focus on reducing disparities in coverage or interventions to focus on underserved population groups. Similarly, no local communication strategies had been implemented and only practices G and J had patient involvement. A range of contact, reminder and recall systems were used for childhood vaccines; however, for adults, most practices vaccinated only when the patient was attending for another purpose (e.g. health check or for seasonal flu).

Discussion

This is the first study to evaluate how GP practices organise the delivery of the routine vaccine programme in England. We have defined a 14-stage CDVC for vaccination at primary care level alongside a process map. Overall, two thirds (59.7%) of activity was spent on administrative tasks and there was significant variation in allocation of activities between clinical and non-clinical staff, with some models of delivery placing a higher time burden for administration onto nurses. Doctors were largely not involved in vaccination. The mean appointment length for childhood appointments was 2.4 times the length in the practice with the longest appointments (C) than the shortest (H). This was due to significant variation in how appointments were arranged within the practice's working week, as well as the fixed appointment length (10, 15 or 20 min) on the booking system. The range for adult appointments was narrower but still

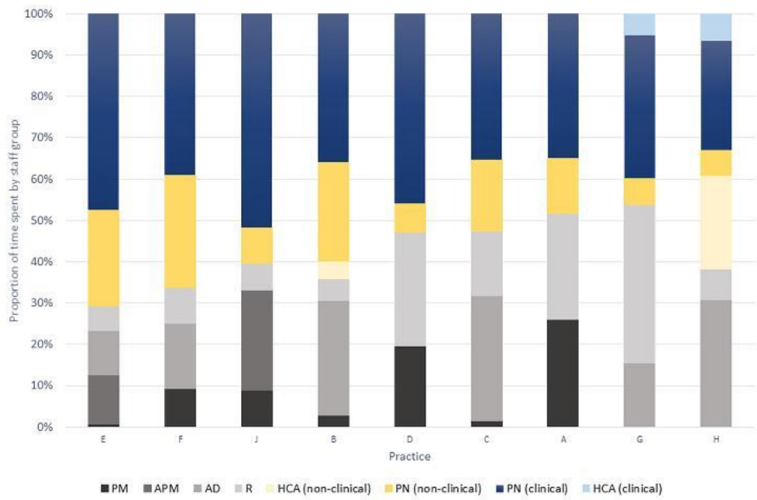

Fig. 4 Proportion (%) of total practice vaccination time spent by different staff groups on clinical and non-clinical tasks (PM = practice manager; APM = assistant practice manager; PN = practice nurse; AD = administrator; R = receptionist; HCA = healthcare assistant)

Table 6 A comparison between implementation of NHS England requirements and NICE quality standards by practices

Domain	Requirement/standard	Adherence by practice
Outcome	2.4: to offer immunisation to 100% of eligible individuals in accordance with guidance.	Childhood: coverage at the large practices G, H and J is much lower than average and well below the 95% target. Adulthood: similarly, coverage at the larger practice (F, G, H and J) is significantly lower than average.
Equity	2.11: to be able to demonstrate what systems are in place to address health inequalities and ensure equity of access to immunisation.	None of the included practices had any specific interventions or services in place to increase uptake in any population or demographic groups with low coverage.
	2.11: to have procedures in place to identify and support those persons who are considered vulnerable/hard-to-reach	None of the included practices had any specific system in place to identify vulnerable or hard-to-reach populations. All practices did follow-up with parents of all young children who did not attend for vaccination.
Service delivery	3.6: to provide core programme elements, as covered in The Green Book.	18 programme elements are described, of which were met by all practices, except reducing variation (none), patient involvement (G and J only) and local communications strategies (nothing, aside from information provision within practice).
	3.10: to address poor uptake for the services where local delivery is lower than the key deliverables to reduce the variation in local levels of performance.	None of the included practices had a system for accessing, evaluating and discussing data relating to their immunisation outcomes or focus on reducing local variation in their local population.
Missed opportunities	3.8: to take every appropriate opportunity to check vaccination status and offer immunisation to individuals who may have missed or not fully completed the national routine schedule. QS2: children and young people identified as having missed a childhood vaccination are offered the outstanding vaccination.	Practices A, E, G and J discussed having a commitment to opportunistic vaccination. However, this was primarily for providing adults with singles and PPV when attending for influenza or other chronic disease health checks. Children were followed up more intensively by all practices at earlier ages, leaving less room for opportunistic vaccination. None of the practices had a specific strategy or protocol for reducing missed opportunities.
Consent	3.9: to adhere to The Green Book guidance on consent.	This was undertaken by all practices.
Assessment	3.10: to have systems in place to assess eligible individuals for suitability by a competent individual prior to each immunisation. QS4: children and young people have their immunisation status checked at specific educational stages.	Aside from the use of searches on computer systems and the general commitment to opportunistic vaccination by some practices (A, E, G and J), no specific protocol or plan was used to check immunisation status. This was especially true for adolescents unless subject to a specific campaign (e.g. meningitis campaign).
Information systems	3.10: assessed the immunisation record of each individual to ensure that all vaccinations are up to date QS3: children and young people receiving a vaccination have it recorded in their GP record and the Child Health Information System (CHIS) and in their personal child health record.	Record keeping was a high priority for all practices, although it was found to be time consuming and complex.
	3.10: systems in place to identify those in clinical risk groups and to optimise access for those in underserved groups	In all practices, the electronic record system was used to identify patients in clinical risk groups, as per the schedule; however, no practices used it to identify people in specific underserved groups.
	3.10: arrangements in place to report and co-ordinate responses to outbreaks of diseases	This was undertaken by all practices.
Reminder, recall	3.10: systems in place to identify, follow up and offer immunisation to eligible individuals 3.10: arrangements in place that enable them to identify and recall under- or unimmunised individuals and to ensure that such individuals are offered immunisation in a timely manner. QS1: children and young people who do not attend their immunisation appointment are followed up with a written recall invitation and	There was large variation in method and frequency of patient contact, reminder and recall activities. For childhood appointments, all practices sent letters first and used phone calls to follow up non-responders. Practices A and C sometimes called patients first. Practices A, C, H and G also used text messages. All initial patient contacts were made by a receptionist or administrator and follow-up of non-responders to non-attenders was sometimes undertaken by the PN

Table 6 A comparison between implementation of NHS England requirements and NICE quality standards by practices *(Continued)*

Domain	Requirement/standard	Adherence by practice
	a phone call or text message	(A, F, G and J). For adults, most practices vaccinated opportunistically when an eligible patient was attending for a check (e.g. diabetes) or for flu vaccine (C, D, E, F, G and J). Practices B and H also sent invite letters. Practice A was alone in phoning older adults.
Vaccine administration	3.12: the provider has a duty to ensure it has, or will have, trained and competent staff to deliver (any) given immunisation programme they agree a contract for	This was undertaken by all practices.
	3.12: the professional lead in the provider organisation must ensure that all staff are legally able to supply and/or administer the vaccine	This was undertaken by all practices.
Storage and wastage	3.13: have effective cold chain and administrative protocols that reduce vaccine wastage to a minimum and reflect national protocols	Responsibilities for maintaining the cold chain was divided between practices who allowed administrative staff to do this (C, G and H) and practices that used the clinical staff (A, B, D, E, F and J).
Ordering	3.14: centrally procured vaccines must be ordered via the ImmForm online ordering system	The distribution of ordering was split similarly to the requirement above.

a more than twofold differential in length (2.1). Total time spent on vaccination relative to practice size varied greatly; however, this was not related to overall performance. Small- to average-sized practices, whether urban (B, C) or rural (A, D), had better performance overall. Greater capacity, as measured by appointments per patient, may be associated with higher coverage in children, but not for adults, and this requires further investigation.

Fidelity

To further compare and analyse the variation in implementation between the different practices, we have drawn on the concept of fidelity, which is defined as 'the degree to which programs are implemented as intended by the program developers', which acts to modify the relationship between the intervention (vaccination) and outcomes (coverage, VPD incidence) [27]. Vaccination is a long-standing complex public health intervention that has been modified over time to reflect an emerging evidence base. Implementation here is defined as 'a controlled activity aiming to introduce and encourage uptake of a new policy or intervention that embodies pre-defined criteria' [28]. In this context, the controlled activity is providing the routine vaccination programme and the pre-defined criteria include national evidence-based policy and guidelines. Changes to policy and guidelines are outside the control of the practices and act as interventions with variable penetration. This raises the question of implementation fidelity*:* To explore this further, we have drawn on the conceptual framework developed by Carroll et al. as modified by Pérez et al., which considers the following factors that affect implementation fidelity: adherence (including content and amount (coverage, frequency and duration)), moderators (complexity, facilitation, quality and participant responsiveness) and adaptation [27, 29].

Adherence

Adherence is defined as whether the programme is delivered as it has been designed. The use of evidence by practices when delivering the programme was variable depending on the content. For the vaccination programme, there are two relevant elements of content to consider: the clinical and administrative components. For the clinical component (i.e. the schedule), there was very high adherence from all practices for children. However, this was much lower for adult vaccines with six practices only vaccinating when an eligible patient attended for another service.

For the administrative components in both adults and children, there was very variable content adherence, particularly in terms of reminder/recall activities, communications and service design (Table 4). A range of systems was used for contacting patients, most often involving letters and phone calls (in which administrative and reception staff have a large role) with a smaller number of practices using text messages, which have good evidence of effectiveness at increasing coverage [30]. Only two practices used active recall for adult vaccines (G and J), despite evidence for interventions that reminder/recall activities can increase coverage [31]. This creates variability in the amount of intervention delivered to the population (sometimes described as the 'dose'—e.g. number of reminder letters, availability, frequency and duration of appointments, availability of education materials). This was particularly important for the larger practices with lower coverage, which all spent relatively little time delivering the vaccine programme (F, G, H). In a large, busy practice with no dedicated clinic (G, J), patients may have difficulty in accessing appointment time for vaccination and could have contributed to these practices' lower coverage. Despite low coverage for childhood (G, H and J) and adult (F, G, H and J) vaccinations, no practices had interventions or services in place to increase uptake in any population or demographic groups with low coverage and none had community information or education plans.

Reducing missed opportunities for vaccination (MOV) features in both the service specification and quality standards, the practices that did report a commitment to opportunistic vaccination (A, E, G and J) did not have a system of reducing MOV. This could potentially be a suitable programme intervention that may increase coverage without requiring significant increases in capacity (such as patient tracking or provider prompts), although evidence is limited for effective interventions [32].

Moderators

Organising vaccination is highly complex and thus is likely to have lower implementation fidelity as a result [27]. This in part is because the programme has evolved over time, rather than implemented from scratch, but also because some ability for local tailoring of the administrative content is planned into the guidance [17]. This means that the administrative recommendations are less specific than the clinical recommendations, which is known to reduce likelihood of implementation [33]. Research on NICE guidelines specifically has shown that initially implementation is strategic, but as time passes, it becomes increasingly sporadic and subject to local contextual factors [28].

Similarly, the facilitation strategies (training, support and guidance) are more robust for the clinical elements of the programme. Changes to the vaccine schedule and guidance in The Green Book are followed closely [34], particularly via the vaccine update email from Public Health England [35]. Nurses also undertake annual training, which is primarily clinical. However, there is no equivalent guidance for the non-clinical components to the programme and administrative staff do not receive any training, despite having a significant patient-facing role. Aside from outcome data, this study did not collect any quality metrics from practices, making quality, in terms of patient experience, difficult to assess. This may be a significant modifying factor affecting performance. Of note, the single practice with a low score for friends and family recommendation (F) also had very poor adult vaccination coverage (56.1%), suggesting a quality factor may be important. However, the family and friends test has been criticised as lacking robust rationale and evidence, so further work is required on relevant service quality factors for vaccination.

Participant responsiveness is related to a patient's view of whether an intervention is useful and relevant to them, thus affecting uptake. All practices reported some experience of having parents and patients decline vaccinations; however, overall, this was described as being a relatively minor problem. However, vaccine hesitancy is an increasing trend in high-income countries and interventions to reduce hesitancy require specific training to implement effectively [36, 37]. More common was persistent non-attenders, who either did not respond to letters or calls or booked appointments and did not attend (DNA). These patients were well known to the practices and often DNA for other appointment types as well. There is little research evidence on how to identify and provide services to improve coverage in persistent non-attending patients.

Adaptation

Adaptation is the process of an intervention being changed by an organisation after implementation and may be a critical component for intervention success [29]. The clinical component of the programme shows very little scope for adaptation and is delivered with high fidelity. However, both task allocation and administrative activities show relatively high adaptability, as evidenced by the different organisational structures in place at each of the practices included here. This is significant as people management factors within healthcare organisations, including role descriptions, performance management, stress and leadership, are known to impact organisation effectiveness [38]. It is likely that this adaptation is related to the specific organisational context of each practice, which will be explored in a subsequent analysis of the qualitative data.

Reducing inequities

There are long-standing inequities in vaccination coverage in many countries, including England and across Europe, as a result of vaccine programmes not providing adequate services to all communities [4, 13, 39–46]. Pockets of under-immunised children and adults are likely one of the factors to have contributed to the rise in VPD incidence and outbreaks seen across Europe in recent years [1, 45]. There is some expectations described in both the service specification and quality standards relating to practices implementing systems to identify and reduce disparities between local population groups. However, there is no clear mechanism for this to be delivered or monitored. Practice staff do not have access to data in sufficient detail to be able to assess local inequities and are unlikely to have the capacity to design and deliver a bespoke intervention without support and guidance. This is despite there being evidence of effectiveness for several categories of interventions to reduce inequities in low-income, ethnically diverse urban settings, such as community-designed multi-component interventions, focussed, escalating reminder-recall activities or alternative service provision models such as home visiting [4]. In practice, the responsibility of identifying and addressing inequities in immunisations is shared among organisations in the public health administration, where local, regional and national public health teams are best placed to identify inequities and suggest evidence-based approaches to addressing them, with general practice implementing these approaches in order to vaccinate those underserved communities. However, since the implementation of the reforms in 2013, data sharing is more complex and the role of regional vaccination managers has changed, reducing their ability to support and evaluate practices' performance [11]. None of the practices in this sample had experience of working with any external organisation in this way.

Capacity

A large review of the organisation and implementation of health improvement interventions in primary care identified the strong evidence base for GP practice-led interventions but also noted the increasing complexity of public health services commissioning following the organisation reforms implemented in 2013, including the contracting arrangements for the vaccine programme [47]. Relative time spent delivering the vaccination programme did not appear to have an effect on coverage. Of the two, large practices in London, practice G spent slightly less than average time on vaccination during the study period but had very low rates of coverage overall, and practice J spent roughly average amount of time but also had very low coverage. However, higher capacity for children, in terms of appointments per patient, may be associated with higher coverage. The strength of this association will need to be evaluated with a larger study. While one solution may be to expect these practices to increase the availability or frequency of vaccination appointments, this may not be possible due to the multiple competing demands on staff time at a busy, urban practice with a relatively deprived population with high need, without commensurate increases in funding [9, 48].

Implications for policy

Mandatory reforms of locally determined systems by national-level bodies are unlikely to be successful given the level of variation between practices. However, information relating to variation in staffing structure and task allocation should be distributed to practices to compare their model and determine if it could be made more efficient, particularly in terms of allocated appointment length. The role of administrators and receptionists was significant, and support in terms of education and training to this group of professionals could improve local service delivery. Task shifting, including support for a greater use of HCAs, could also increase practice capacity by reducing time spent by nurses. Either additional support needs to be given to practices to implement strategies to reduce inequities or this function should be allocated to another branch of the public health system. Rationalisation of the data collection and reporting systems required could also reduce the administrative time burden on practices.

Strengths and limitations

The strengths of this study include the collection of standardised information, using multiple methods simultaneously, to evaluate implementation of vaccination delivery at a broad range of GP practices in England. This has enabled detailed comparison of GP practice organisation for the first time. Limitations are that this is a small, convenience sample of practices and thus subject to selection bias, making them unlikely to be representative of the population of GP practices at large, especially as practices had higher QOF and recommendation scores than average. No very small or very large practices were included in the sample. The methods rely on self-reporting of activities, which may be subject to reporting bias. Activity logs were kept during different weeks at each practice and activity is not consistent throughout the year. The sample was too small for further statistical analysis to measure association effects.

Conclusions

There is variation in how GP practices in England implement the delivery of the routine vaccination programme. Areas of greatest variation include the method of reminder and recall activities, structure of vaccination appointments and task allocation between staff groups. Introduction of organised reminder and recall activities for adults could improve coverage. Most (60%) activity was spent on administrative tasks, which had lower fidelity of implementation to guidelines and standards. Implementation of clinical activities had very high fidelity. Appointment length and time spent on vaccination did not appear to be related to coverage; however, capacity in terms of availability of appointments per patient could be related and requires further investigation. Further work is also required to evaluate other contextual factors, including the working culture within practices.

Appendix

Topic guide

Table 7 A modified version of the below guide was used if the interview only had administrative staff

Topic	Prompt	Notes and possible questions
Welcome and introduction	Intro	- Background to the project - My role and LSHTM
	Scope of interview	- Overview of purpose - Confidentiality - Topics to be covered - Time for questions - Confirm consent
Organisation and role	Intro	This section is looking to understand how the routine vaccination programme is organised within your GP practice.
	Role and responsibility	- Please describe your role within the practice team in delivering the vaccination programme. - How long have you been in this position for? - How much of your working time do you spend on vaccination per week?
	Vaccination programme organisation	- How is the vaccination programme organised within your GP practice? - Which other staff members are involved?
Inputs	Intro	- This section is looking to understand how the practice uses information to make decisions about how to run the programme.
	Information sources and use	- What information sources do you use? - How are you informed of changes to the programme? - How often to you undertake training?
	Data knowledge and management	- Where do you get information from relating to your practice's performance? - How often do you receive updates about coverage levels?
	Resources (financial and human)	- Do you have responsibility for the financial management of the programme? - Do you know how the programme is funded? - Is the funding adequate to provide the programme? - What do you think about the current system of payments for the vaccination programme?
	Networks	- Are you a member of any local or national networks relating to vaccination? - What organisations do you interact with locally related to vaccination? - What information do you receive from these sources? - Do the networks provide any other benefits? - Which other external organisations (e.g. schools, local government) do you interact with regularly?
Sensemaking	Intro	This section is seeking to understand how vaccination is perceived and prioritised within your practice.
	Leadership	- Is there an identified person who leads the programme? - If the leadership role is split, please describe how this works? - Is leadership important for delivery of the programme in your practice?
	Decision-making	- Who is responsible for making decision relating to the programme? - Do you have a regular practice meeting to discuss vaccination? How often? Who attends? - Is there a local or regional committee or board that meets? How often? Who attends? - How often do you make changes in how you deliver the programme?
	Climate and culture	- How much of a priority is vaccination when compared to other areas? - Are staff members and the management supportive of vaccination? - Could the way your practice organises the programme be improved? If so, what are the barriers?
	Interpersonal relationships	- Do staff work together well to deliver the programme? - Do staff interact with external organisations well? - Are there any interpersonal barriers to running the programme?
	Responses to change	- How well does your practice respond to changes in the programme? - How long does it take changes to the programme to be implemented?

Table 7 A modified version of the below guide was used if the interview only had administrative staff *(Continued)*

Topic	Prompt	Notes and possible questions
Activities and outputs	Intro	This section is seeking to understand what vaccination activities you undertake and the uptake of these.
	Task allocation	- How are roles and responsibilities distributed? - Is it always clear who is supposed to be doing what?
	Time allocation	- How much time is dedicated to vaccination? - Is this enough? Or too much/little?
	Systems and processes	- Is the way the programme organised suitable? - Is the system of delivering vaccinations clear to all staff? - Could it be improved? - How are incidents reported?
	Data collection and submission	- How are data collected and submitted? - What is your role in this process? - Is it done well? Or could it be improved?
	Uptake and access	- Is there good uptake of vaccination in your practice? - Do you think patients have any problems accessing services?
	Interventions	- Are you involved with any interventions to improve access/uptake? If so, please describe. - If no, do you think there would be any role for an intervention at your practice? If so, for what purpose?
	Workload and capacity	- How do you find the workload of running the programme? - Do your colleagues feel the same way? - Do you have capacity to increase uptake of the programme?
Outcomes	Intro	This section is seeking to understand what the overall outcomes of the programme are in your practice.
	Patient factors and perception	- Do you think the type of population you service makes any difference to the coverage levels you achieve? - Do your patients hold any views that affect vaccination coverage?
	Community relationship	- Is the practice integrated into the local community? - How do you feel about the patients in your local area?
	Coverage levels and performance	- Do you know how well your practice performs? - What indicators do you use? - Do you feel this could be improved? If so, how?
Wrap up	Open space for discussion and questions	- Has everything been covered? - Space for any other questions/issues to be raised/discussed.

Abbreviations

AD: Administrator; APM: Assistant practice manager; CDVC: Care delivery value chain; CHIS: Child Health Information System; CI: Confidence interval; CRN: Clinical Research Network; DH: Department of Health; DTaP/IPV/Hib: Diphtheria, tetanus, pertussis, polio, *haemophilus influenza type b* vaccine; GP: General practitioner; HCA: Healthcare assistant; Hep B: Hepatitis B vaccine; Hib: *Haemophilus influenza type b* vaccine; HPV: Human papillomavirus; HSCA: Health and Social Care Act; Men ACWY: Meningococcal groups A, C, W and Y; Men B: Meningococcal group B; Men C: Meningococcal group C; MMR: Measles, mumps and rubella; MOV: Missed opportunities for vaccination; NHSD: National Health Service Digital; NHSE: National Health Service England; NICE: National Institute for Health and Care Excellence; PCV: Pneumococcal conjugate vaccine; PHE: Public Health England; PM: Practice manager; PN: Practice nurse; PPV: Pneumococcal polysaccharide vaccine; QOF: Quality Outcomes Framework; QS: Quality standard; R: Receptionist; SMS: Short message service (text message); TDABC: Time-Driven Activity-Based Costing; TPVT: Total practice vaccination time; VPD: Vaccine preventable disease

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Ethical approval and consent to participate

We gained written, informed consent from each staff member participating prior to commencing data collection. No patients were involved. The study received ethical approval from the LSHTM Ethics Committee and the NHS Health Research Authority (project ID 212278).

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Availability of data and materials

The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

TCB conceived the study and chose the methods with support from SMJ and ME. TCB identified the practices, undertook the interviews, trained staff on use of the activity logs, collected and entered data, undertook the quantitative analysis, coded the transcripts (reviewed by SMJ) and wrote the final manuscript. SMJ and ME reviewed and edited the final manuscript. All authors read and approved the final manuscript.

Consent for publication
No applicable

Competing interests
The authors declare that they have no competing interests.

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6.2.2 *Research Paper 4: Costing*

The second paper reports the findings from the costing analysis and has been submitted to the journal *Human Vaccine and Immunotheraputics* and is currently under review.

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Student ID Number	LSH345619	**Title**	Dr
First Name(s)	Timothy		
Surname/Family Name	Crocker-Buque		
Thesis Title	An Evaluation of the Implementation of Routine Vaccination at GP Practice Level in England		
Primary Supervisor	Sandra Mounier-Jack		

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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Where is the work intended to be published?	~~Vaccine~~ HUMAN VACCINES AND IMMUNOTHERAPUTICS
Please list the paper's authors in the intended authorship order:	Tim Crocker-Buque, Kitty Mohan, Mary Ramsay, Michael Edelstein, Sandra Mounier-Jack
Stage of publication	**Submitted**

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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	TCB conceived the study with SMJ, MR and ME. TCB designed the Time Driven Activity Base Costing methods and conducted the data collection activities and analysis, and produced the initial draft of the manuscript. KM developed the model to estimate payments to practices. All authors reviewed the manuscript and approve the final draft.

SECTION E

Student Signature	
Date	8/1/19

Supervisor Signature	
Date	8/1/19

What is the cost of delivering routine vaccinations at GP practices in England? A comparative Time-Driven Activity Based Costing analysis.

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ABSTRACT

Background

The expansion of available vaccines in recent years has increased the overall costs of the vaccine programme and put pressure on providers responsible for vaccination. In England in 2016-17, GP practices were responsible for vaccinating their local population and were reimbursed £227 million. However, how closely these reimbursements are to the costs of delivering vaccinations and the capacity of practices to successfully deliver this increasingly complex programme are unknown. Therefore, the aim of this study was to evaluate the costs of delivering the routine vaccination programme at GP practices in England and to compare these costs with amount reimbursed.

Methods

Time Driven Activity-Based Costing was undertaken at a convenience sample of 9 geographically and socio-economically diverse GP practices in 2017-2018.

Results

The mean cost of delivering a childhood vaccination appointment was £18.20 (range £9.71-£25.97) and an adult appointment cost £14.05 (range £7.59-£20.88), of which 75% was for staff, 24% for facility costs and 1% for consumables. Organisational factors contributing to lower costs include: shorter length of allocated appointment; greater use of administrative and reception staff; lower working time for practice manager and practice nurse; and use of health care assistants for adult vaccinations.

Conclusions

Reimbursement for vaccination activities was higher than costs at included practices. Several organisational factors could be modified to reduce costs, but it is not known if this improves coverage.

Keywords (6):

Vaccine; immunisation; primary care; costing; funding; organisational management.

ABBREVIATIONS

ABC: Activity Based Costing
AD: Administrator
CCR: Capacity Cost Rate
CDVC: Care Delivery Value Chain
DHSC: UK Government Department of Health and Social Care
FCCR: Facility Capacity Cost Rate
GP: General Practitioner
HCA: Healthcare Assistant
NHS: UK National Health Service
NHSE: National Health Service England
PM: Practice Manager
PN: Practice Nurse
R: Receptionist
QOF: Quality Outcomes Framework
SCCR: Staff Capacity Cost Rate
TDABC: Time Driven Activity Based Costing

INTRODUCTION

Vaccination against infectious diseases is an extremely cost-effective intervention,[1] however, with the rapid expansion of available vaccines in recent years,[2,3] the costs to governments and other payers for both vaccines and the associated delivery of vaccination have been increasing. After nearly a decade of steady increases in vaccination coverage in England, coverage has started to decline, with multi-year reductions observed in several important vaccines, including measles, mumps and rubella (MMR) and diphtheria, tetanus, pertussis and polio (DTaP/IPV) vaccines.[4] These reductions in coverage are particularly important in the context of the substantial measles outbreak currently affecting many European countries, including England.[5,6] In addition, the national averages do not reflect the significant and persistent regional variation, where coverage both in London and other large urban centres is significantly lower than other parts of the country (for example in 2017 DTaP-IPV-Hib 12 months: England 93.4%, London 88.8%; MMR2 5 years: England 87.6%, London 79.5%), which exists alongside lower coverage in certain ethnic groups and in areas of higher deprivation.[7,8]

Financing vaccination in England

In England, GP practices are contracted to provide vaccinations by NHS England (NHSE) based on the policy set by the Department of Health and Social Care (DHSC).[9,10] Practices are reimbursed through several different mechanisms. Firstly, they receive a 'global sum' capitation payment that is not related to activity, designed to fund 'structural costs' of the practice based on size.[11] If practices opt out of providing childhood vaccinations they receive a deduction of 1-2% of this payment. Secondly, delivery of some vaccines incur an item-of-service payment, while others are considered in groups and payment is received on completion of a course, or when specified levels of coverage are achieved as shown in Supplementary material 1 - Table 1.[12] There is also an additional payment for timely vaccination when children receive vaccines during the first 3 months of eligibility. Finally, a small number (primarily influenza vaccine in clinical risk groups) are incentivised through the Quality Outcomes Framework (QOF), a pay-for-performance scheme.[13]

Vaccine(s)	**Doses and age(s) given**	**Item of service payment 2016-2017 (2018 change). Per dose, unless otherwise stated.**	**Other payments**
Diphtheria, Pertussis, Tetanus, Polio, *Haemophilus influenzae b, hepatitis B*	3 doses (2, 3 & 4 months)	-	Target payment thresholds: >70% standard payment, >90% extra payment. Additional payment if vaccinated within first 3 months of eligibility.
Measles, Mumps & Rubella	2 doses (1 year & 3 years 4 months)		
Diphtheria, Pertussis, Tetanus, Polio booster	1 dose (5 years)		

Hepatitis B (at risk children)	3 doses (new-born, 1 month, 12 months)	(£10.06)	-
Meningococcal B	3 doses (2, 4 and 12 months)	£9.80 (£10.06)	-
Rotavirus	2 doses (6 weeks and 6 months)	£9.80 for both doses (after second dose only)	-
Pneumococcal Conjugate	3 doses (2 months, 4 months and 1 year)	£15.02 for whole course (after third dose only)	-
Pertussis	Pregnant women (1 dose)	£9.80	-
Measles, Mumps and Rubella	Unvaccinated people over 16 years	£9.80 (£10.06)	-
Meningococcal ACWY	1 dose (18-25 years)	£9.80 (removed)	-
Pneumococcal Polysaccharide	1 dose (At-risk patients and aged 65 and over)	£9.80	-
Shingles	1 dose (Ages 70 and over)	£9.80 (£10.06)	-

Table 1: selected routine childhood and adult routine vaccinations and conditions for reimbursement to GP practices. (From the General Medical Services Statement of Financial Entitlements [9])

Contracting arrangements are subject to annual negotiations between the DHSC, NHSE and the General Practitioners Committee of the British Medical Association.[14] In 2016-2017 NHSE paid GP practices £227 million for activity related to vaccination (excluding QOF payments and global sum reimbursement).[15] Through the annual negotiation process the fee-for-service payment has been incrementally increasing over time, from £7.64 in 2013 to £10.06 in 2018, a 32% increase in 5 years. However, due to the complexity of this system and lack of both transparent documentation of the system and absence of practice-level data, the payments to practices are opaque[9]. There are very few studies evaluating the costs associated with delivering vaccinations to determine the appropriateness of reimbursement levels. Together, these factors make it extremely challenging to recommend changes to the funding system that may improve coverage. Therefore, the aim of this study is to describe and evaluate the costs of delivering the routine vaccination programme at GP practices in England and to compare them with reimbursements.

MATERALS AND METHODS

The purpose of the study methods is to quantify all the costs incurred by the practice, including facility operating costs, staffing and consumables and allocate these to the activity associated with delivering vaccinations during the 2-week study period.

This has previously been undertaken in New Zealand using Activity Based Costing (ABC) methods,[16,17] which allocate costs to complex processes within organisations to identify underlying cost drivers.[18] More recently, ABC has been updated to reduce the administrative burden of data collection and is now termed Time-Driven Activity Based Costing (TDABC).[19–21] This method has been applied to evaluate the costs of complex health service delivery in both primary and secondary care.[21]

TDABC involves a 7-step process for identifying and allocating costs.[22] The results of steps 1-4 are presented in a precursor paper using the same sample.[23] In summary, the condition under analysis is defined as a patient registered at a GP practice who is eligible for routine vaccination. Seasonal vaccines (including influenza), other non-routine vaccines (e.g. for travel) and any vaccinations not given at GP practices are excluded. The Care Delivery Value Chain (CDVC; a visual representation of the main activities involved in providing vaccination) and a detailed process map have been developed in the linked paper.[23]

This study focusses on the results of steps 5-7. In step 5, data are generated on all vaccination related activity undertaken in the 2-week study period and all costs incurred by the practice in the preceding 12 months. Activity logs were provided to all staff involved in vaccination at each practice who then recorded all time spent on vaccination specific activities over a 2-week period, which were extracted and uploaded into Microsoft Excel for analysis. The included activities are presented in Supplementary material 9 - appendix 1.

To produce cost data, the practice manager completed a detailed survey, the components of which are presented in Supplementary material 9 - appendix 2. All costs incurred by the practice were included, but no data were collected on costs incurred outside the practice or by patients.[24] The costs captured were divided into facility costs (fixed: e.g. rent, utilities), staff costs, and vaccination specific costs (e.g. consumables). The costs of the vaccines are not included as these are paid for by Public Health England (PHE) and not borne by the practice or NHSE.

Steps 6 and 7 involve dividing and allocating the costs to the vaccination activity during the study period. Firstly, we calculated Capacity Cost Rates (CCR), defined as cost per minute of available time. The Facility Capacity Cost Rate (FCCR) was calculated by dividing the total annual facility cost by the total annual appointment time delivered by the practice (including vaccination and non-vaccination). This was then weighted by staff group (healthcare assistant (HCA), PN, GP) to account for differentials in resource use. A nursing appointment was allocated a weighting of 1, a GP appointment a weighting of 3 and an HCA appointment of 0.5, based on approximate salary differentials (HCA £16,000:PN £32,000:GP £92,500).[25,26] This weighted cost per minute of activity was then multiplied by appointment length (minutes) to give a cost per appointment. The Staff Capacity Cost Rate (SCCR) was calculated by dividing annual salary and all on-costs (i.e. employer national insurance and pension contributions), by the total number of available working minutes per year. Where salaries were provided without on-costs, these were estimated by the addition of 25% to the salary figures provided, based on advice from two PMs who participated in the study.

For clinical time the SCCR was calculated for each staff group based on 45 weeks worked each year, 2,250 minutes per week (37.5 hours, full-time) and then allocated to each appointment by length. For staff admin time not attached to a specific appointment (e.g. data uploading) the total amount of time was proportionally allocated to each appointment based on the number of appointments during the study period. To calculate the vaccination specific costs, information about the consumables used per appointment were recorded in the staff activity logs, and practice-level costs (e.g. fridges) were recorded in the practice manager's survey and allocated proportionally to each appointment. Therefore, the cost of a vaccination appointment of Z minutes is calculated as follows: (Z x FCCR) + (Z x SCCR) + (specific costs per appointment).

Reimbursement

To evaluate costs against reimbursement, the payments made to the included practices for vaccinations in 2016-17 were extracted from routine data published by NHS Digital[15]. The mean costs at each practice for childhood and adult vaccination appointment derived from this study were then multiplied by the total number of appointments required for these payments from 2016-17 routine vaccine coverage data [4]. Timeliness data are not publicly available and given that being vaccinated on time is high (>90%) even in lower coverage areas [27], for simplicity we assumed that all timeliness threshold payments were achieved.

Sampling

The sampling method and characteristics of included practices are described in detail in the associated paper.[23] We recruited a sample of 9 geographically and demographically diverse practices via the National Institute for Health Research Clinical Research Network of more than 2,000 GP practices signed up to a scheme of payment for participating in research projects. We aimed to recruit a non-representative convenience sample of 10 practices (due to our available capacity) from a range of geographic and socio-economic contexts. A £350 shopping voucher (£500 in London) was provided to participating practices.

Consent and Ethical Approval

We gained written, informed consent from each participant prior to commencing data collection. The study received ethical approval from the London School of Hygiene and Tropical Medicine Ethics Committee and the NHS Health Research Authority (project ID 212278).

RESULTS

Following circulation of the study details, 14 practices retuned expressions of interest. We excluded 4 practices as they were geographically similar to already included practices, and 1 did not complete data collection. Therefore, between May 2017 and February 2018, 9 practices completed the data collection activities. Their characteristics are presented in Supplementary Material 2 - Table 2. Detailed information on each practice is available in the precursor study.[23]

	England Average	A	B	C	D	E	F	G	H	J
Region	-	East Midlands	East of England	Yorks & Humber	South West	East Midlands	East of England	North East & Central London	South East	South London
Urban/Rural status (a)	-	Mainly rural	Urban, city & town	Urban, city & town	Mainly rural	Urban, city & town	Largely rural	Major conurbation	Largely rural	Major conurbation
List size (b)	7,000	4,600	6,600	7,000	8,100	12,600	13,800	14,000	16,000	20,000
Demography										
Deprivation decile (b)	-	8	2	1	8	10	7	4	6	4
Minority ethnic groups (%) (b)	-	1.6	6.2	12.0	1.3	1.8	3.4	30.3	2.1	41.4
Aged 0-4 years (%) (b)	5.7	3.3	7.3	5.7	4.4	4.6	5.0	5.0	5.4	7.7
Aged 65+ years (%) (b)	17.3	31.6	10.4	13.6	30.4	23.6	21.5	11.3	18.9	11.8
Quality Indicators										
QOF Achievement (%) (b)	95.6	99.6	98.2	94.5	98.9	99.3	96.2	95.7	99.6	93.7
Patients recommending practice (%) (b)	77.4	95.3	78.4	81.4	89.3	84.4	56.6	87.8	83.1	85.9
Childhood Vaccination Coverage										
DTP-IPV-Hib 3 doses by 12 months (%) (c)	93.4	98.9	96.0	97.3	96.0	98.9	98.7	78.7	90.6	91.2
MMR 1 by 24 months (%) (c)	91.6	100.0	97.9	98.6	93.7	97.2	97.5	78.1	85.5	86.9
MMR 2 by 5 years (%) (c)	87.6	94.4	94.2	95.5	98.3	94.4	93.1	69.6	85.1	88.4
Adult Vaccination Coverage										
PPV (%) 2017-2018, 70-74 (d)	70.2	79.0	71.3	81.9	83.3	88.7	56.1	64.4	65.6	42.9

Data sources: (a) 2011 Rural-Urban Classification of Local Authorities (https://www.gov.uk/government/statistics/2011-rural-urban-classification-of-local-authority-and-other-higher-level-geographies-for-statistical-purposes);[28] (b) National General Practice Profiles; for deprivation 10 is most deprived decile, and 1 is least deprived (https://fingertips.phe.org.uk/profile/general-practice);[29] (c) derived from UNIFY 2 data 2016-2017, which are experimental management data and have lower reliability;[4] (d) derived from Immform data 2016-2017. QOF = Quality Outcome Framework; DTP-IPB-Hib 3 = Diphtheria, tetanus, pertussis, polio & haemophilus influenzae group b, 3rd dose; MMR = measles, mumps and rubella vaccine; PPV: pneumococcal polysaccharide vaccine.

Table 2: characteristics of GP practices included in the study; adapted from [23]

Costing

The costs of delivering a single vaccination appointment during the 2-week study period at each practice are presented in Supplementary Material 3 - Table 3, alongside the number and mean length of appointments at the practices.

		A	B	C	D	E	F	G	H	J	Mean (95% CI)
Childhood											
	Total number	9	14	15	23	24	30	23	31	71	
	Mean length (mins)	20.2	15.4	22.0	13.9	18.1	9.8	18.3	9.0	16.7	15.9 (13.0-18.8)
Staff	A. Clinical staff (clinic time)	£9.27	£5.69	£10.86	£4.67	£6.73	£4.88	£10.14	£5.81	£8.51	£7.40 (£5.86-£8.93)
	B. Clinical staff (admin time)	£1.91	£3.69	£4.22	£0.59	£3.03	£3.02	£1.31	£0.86	£1.40	£2.22 (£1.37-£3.08)
	C. Admin staff	£6.91	£2.94	£4.41	£3.21	£2.55	£2.62	£5.19	£1.40	£5.84	£3.90 (£2.72-£5.07)
	Total admin time cost (B+C)	*£8.83*	*£6.63*	*£8.63*	*£3.79*	*£5.59*	*£5.64*	*£6.50*	*£2.26*	*£7.23*	*£6.12 (£4.73-£7.51)*
	1. Total staff cost (A+B+C)	£18.10	£12.31	£19.49	£8.46	£12.32	£10.52	£16.64	£8.07	£15.75	£13.52 (£10.80-£16.24)
Facility	2. Facility cost	£7.62	£2.57	£5.17	£1.00	£5.60	£4.98	£3.77	£1.80	£7.41	£4.44 (£2.91-£5.97)
Specific	3. Specific costs	£0.25	£0.25	£0.25	£0.25	£0.25	£0.25	£0.25	£0.25	£0.25	
	TOTAL COST (1+2+3)	**£25.97**	**£15.14**	**£24.91**	**£9.71**	**£18.17**	**£15.75**	**£20.66**	**£10.12**	**£23.41**	**£18.20 (£14.26-£22.15)**
Adult											
	Total number	26	10	22	17	4	23	7	14	16	
	Mean length (mins)	9.2	11.2	14.1	8.7	6.8	8.0	13.3	9.1	13.5	10.4 (8.7-12.2)
Staff	A. Clinical staff (clinic time)	£4.21	£4.15	£6.98	£2.93	£2.51	£3.99	£4.99	£2.92	£6.90	£4.40 (£3.33-£5.47)
	B. Clinical staff (admin time)	£2.10	£3.69	£4.22	£0.59	£3.03	£3.13	£1.38	£0.86	£1.40	£2.27 (£1.42-£3.12)
	C. Admin staff	£6.91	£2.96	£4.41	£3.21	£2.55	£2.75	£5.19	£2.17	£5.84	£4.00 (£2.91-£5.09)
	Total admin time cost (B+C)	*£9.01*	*£6.65*	*£8.63*	*£3.79*	*£5.59*	*£5.88*	*£6.57*	*£3.03*	*£7.23*	*£6.26 (£4.97-£7.56)*
	1. Total staff cost (A+B+C)	£13.22	£10.80	£15.61	£6.72	£8.10	£9.87	£11.55	£5.95	£14.13	£10.66 (£8.48-£12.84)
Facility	2. Facility cost	£3.81	£2.57	£5.17	£1.00	£3.11	£4.98	£2.51	£1.54	£4.94	£3.29 (£2.29-£4.30)
Specific	3. Specific costs	£0.10	£0.10	£0.10	£0.10	£0.10	£0.10	£0.10	£0.10	£0.10	
	TOTAL COST (1+2+3)	**£17.13**	**£13.47**	**£20.88**	**£7.82**	**£11.31**	**£14.94**	**£14.17**	**£7.59**	**£19.17**	**£14.05 (£11.03-£17.08)**

Table 3: the number and length of vaccination appointments and costs associated with vaccination activities for each practice.

The mean cost for a childhood appointment was £18.20 (95% CI £14.26-£22.15) and ranged from £9.71 at practice D to £25.97 at practice A. Of the cost, 74.3% (£13.52) of the mean total was staff costs and 24.4% (£4.44) facility and 1.4% (£0.25) vaccination specific. Of the staff costs, 54.7% (£7.40) was clinical and 45.3% (£6.12) administrative, of which 36.3% (£2.22) was attributed to clinical staff and 63.7% (£3.90) to administrative staff.

The mean cost for an adult appointment was £14.05 (95% CI £11.03-£17.08) and ranged from £7.59 (H) to £20.88 (C). The contributing costs were similar to those of childhood appointments with 75.9% (£10.66) from staff, 23.4% (£3.29) from facility, and 0.7% (£0.10) from specific. Of the staff costs, a lower proportion was from clinical staff (41.2%, £4.40) due to the shorter appointment times and thus a higher proportion was from administration costs (58.8%, £6.26). A similar proportion of the admin time was attributed to clinical staff (36.2%, £2.27) and admin staff (63.8%, £4.00) as for childhood appointments.

To preserve the anonymity of practices, the facility costs are not being published separately, however the overall annual facility costs per registered patient ranged from £9.88 to £50.02 with a mean across the practices of £28.67 (95% CI £20.86-£36.48). These costs are fixed and unchanged by the vaccination programme.

Vaccination specific costs

Most practice managers were not able to disaggregate the consumables used in vaccination from their general orders for the practice. However, two practices provided detailed information on the cost of consumables (e.g. needles, syringes) and detailed usage during appointments (D & J), which ranged from £0.19 - £0.24 per childhood appointment and <£0.10 for adult appointments with a single injection. Practice managers were not able to disaggregate the costs of providing and maintaining cold-chain (e.g. utilities and fridges) from the overall facility costs and so these have not been reported separately. Therefore, a nominal cost of £0.25 and £0.10 for consumables was added to each childhood and adult vaccination appointment respectively. Although it is possible there is some variation of consumables used by practice, it is not likely that this would be significant enough to greatly affect overall appointment costs.

Cost per childhood vaccine

Part of practices' remuneration for vaccinations is a fee-for-service payment per vaccine. Thus, another way of considering the costs is per vaccine delivered, rather than per appointment. Childhood appointments vary in length, cost and the number of vaccinations delivered (Supplementary Material 4 - Table 4). The appointments with the largest number of vaccinations (8-

week and 12-month) gave the lowest cost per vaccine (£5.19 and £4.72 respectively), despite having the longest appointment lengths.

	8-week	12-week	16-week	12-month	Pre-school
Sample (n)	57	45	36	55	47
Mean appt length (mins)	21	12	16	17	16
Mean appt cost	£20.74	£16.49	£18.23	£18.89	£19.09
Number of vaccines (n)	4	2	3	4	2
Cost per vaccine	£5.19	£8.25	£6.08	£4.72	£9.55

Table 4: showing the mean length, mean cost and cost per vaccine delivered for childhood vaccines.

Sensitivity analysis

The main are of the TDABC model with greatest uncertainty is the weighting of appointment resource use in calculating the FCCR. Sensitivity analysis around alternative weightings are presented in Supplementary Material 5 - Table 5. The FCCR was calculated by dividing facility costs between all the appointments delivered by the practice per year. However, these were weighted based on resource use, with a GP appointment being allocated 3 times the facility costs compared to a nursing appointment. Table 5 shows that if GPs were allocated 4 times the resources of nurses, vaccination appointment costs reduced by 4.5%. If GP appointments and nursing appointments are weighted equally, this increases vaccination appointment costs by almost 25%.

	Appointment weighting for FCCR		
	0.5:1:3*	0.25:1:4	0.5:1:1
Childhood appt cost	£18.20	£17.38	£22.66
		-4.48%	24.52%
Adult appt cost	£14.05	£13.42	£17.32
		-4.48%	23.28%
*Weighting of appointments within Facility Capacity Cost Rate (FCCR) calculation in the format - healthcare assistant : practice nurse : GP.			

Table 5: Sensitivity analyses around appointment resource allocation weighting.

Factors affecting costs

The underlying facility cost base of the practice made a moderate difference to the overall totals, with contributions ranging from 31.7% of the total childhood appointment cost at practice J to 10.3% at D. However, these costs are largely fixed.

The cost of staffing is the main variable cost, which is dependent on three factors: task allocation, time spent and salary costs. At the request of the practices we have not published reported salary costs, however the relative salary cost at each of the practices is presented in Supplementary Material 6 - Table 6. It was not possible to include the data for administrators and receptionists due to the wide range in job specifications and salary scales.

	A	B	C	D	E	F	G	H	J
Practice Manager	0.966	1.002	0.860	0.707	0.791	1.164	1.074	1.172	1.264
Practice Nurse	1.029	0.832	1.109	0.756	0.836	1.119	1.248	0.924	1.147
HCA	0.991	0.773	0.513	-	0.940	0.747	1.335	1.140	1.562

Table 6: relative cost to mean salary for staff groups at included GP Practices (mean = 1)

For childhood appointments, the lowest total clinical staff cost was at practice D (£4.67), which was primarily due to the low salary cost with an average appointment length (13.9 mins). Practice F had similarly low costs (£4.88), however this was due to very short appointments (9.8 mins), despite having higher than average clinical staff costs. This was achieved by their system of a dedicated baby clinic with 2 PNs and 2 HCAs with 5 min allocated appointments. The highest clinical cost (£10.86) was found in practice C that had the longest appointment length (22 mins) and slightly higher than average staff costs. Practice G had high costs (£10.14) primarily due to higher staff salaries in London, despite an average appointment length (18.3 mins). For adults, Practice E had the lowest clinical cost due to the very short appointment length (6.8 mins) and low salary costs. Despite having both average salary costs and average appointment length (9.1 mins), practice H had very low clinical costs (£2.92) due to the high use of HCAs.

The total administration costs generally fell within a relatively narrow range. The highest cost was found in practices A (£8.83-£9.01) and C (£8.63). Practice A had the smallest list size with a small management team, so the practice manager had a much larger role in data collection and submission than elsewhere. Practice C had a relatively high contribution from the practice nurse (£4.22, 48.9% admin cost), particularly relating to data collection, submission and vaccine ordering. Both the London practices (G and J) had relatively high costs from admin staff (£5.19, 79.8%; £5.84, 80.7% respectively) as they had specialist administrative staff to undertake the associated workload.

The lowest total admin cost was found in practices H and D. Practice H had the lowest staff admin costs overall (£2.26), despite relatively average staff salaries. This is due to the very low cost of clinical admin time (£0.86) as much of the data entry is undertaking during the baby clinic by one of the HCAs. The practice also employs a specialist administrator who undertakes most of the reminder, recall, ordering and data entry, with little involvement from the PM or PN.

Effect of delivery model on cost

To isolate the effect of different delivery models we standardised staff group salary costs, with the mean salary for each staff group (e.g. nurses, practice managers) put into the model in place of actual salaries. The mean cost for each component of the staff costs was then calculated and given a value of 1. Supplementary Material 7 - Table 7 shows the relative cost of each of the staffing components as compared to the mean cost using the standardised salaries. This demonstrates that the delivery systems in place at the smaller practices (A, B & C) are relatively costly. Smaller practices are less likely to have administrators or specialist receptionists to undertake the administrative workload, so instead this is completed by the PN and PM, who have higher salaries. Practice C is the most costly overall due to a combination of long appointment times and a large role for both the PN and PM in administration. In the case of practice B, the PN has the highest administration cost, being almost double the mean (1.97). These three smaller practices achieve high levels of vaccine coverage alongside their high costs.

The lowest cost system is in practice H, which is around 40% lower than the mean for both childhood and adult appointments. For childhood appointments, the clinical cost is close to the mean (0.8), despite the shortest appointment time (9.0 mins) as there are two staff contributing to the cost of each appointment, with the HCA undertaking preparation and data entry alongside the nurse. This reduces the amount of administration undertaken by PNs and the rest is undertaken by a specialist administrator with a relatively lower cost than the PM. Practice H also had the highest number of adult vaccinations given by an HCA (60% of the total), which meant that despite an average appointment length (9.1 mins), the relatively clinical cost was the lowest (0.72).

Practice F also had relatively lower costs for childhood appointments, partly due to the short appointment length (9.8 mins), reducing the clinical cost to 60% of the mean, and with a relatively low administrative cost (0.59) by using an administrator. This practice has relatively good coverage of childhood vaccinations, but low coverage of adult vaccinations. Practice D had the lowest administrative cost due to the large role for receptionists in both reminder/recall activities and data submission. Despite the relatively long appointment times for adults in practice G (13.3 mins), the cost was very close to the mean (0.99) as 55% of these vaccinations were given by an HCA during the study period.

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		A	B	C	D	E	F	G	H	J	Mean
Childhood											
	Total number	9	14	15	23	24	30	23	31	71	
	Mean length (mins)	20.2	15.4	22.0	13.9	18.1	9.8	18.3	9.0	16.7	
Staff costs	A. Clinical staff (clinic time)	1.23	0.94	1.34	0.85	1.10	0.60	1.11	0.80	1.02	1
	B. Clinical staff (admin time)	0.82	1.97	1.68	0.34	1.60	1.19	0.46	0.39	0.54	1
	C. Admin staff	1.80	0.92	1.46	1.11	0.61	0.59	1.17	0.36	0.99	1
	Total admin time cost (B+C)	*1.44*	*1.31*	*1.54*	*0.83*	*0.97*	*0.81*	*0.91*	*0.37*	*0.82*	1
	Total staff cost (A+B+C)	**1.33**	**1.11**	**1.43**	**0.84**	**1.04**	**0.70**	**1.02**	**0.61**	**0.93**	1
Adult											
	Total number	26	10	22	17	4	23	7	14	16	
	Mean length (mins)	9.2	11.2	14.1	8.7	6.8	8.0	13.3	9.1	13.5	
Staff costs	A. Clinical staff (clinic time)	1.04	1.26	1.59	0.98	0.76	0.90	0.99	0.72	1.52	1
	B. Clinical staff (admin time)	0.88	1.94	1.65	0.34	1.57	1.22	0.48	0.39	0.53	1
	C. Admin staff	1.75	0.91	1.43	1.08	0.59	0.60	1.14	0.54	0.96	1
	Total admin time cost (B+C)	*1.43*	*1.28*	*1.51*	*0.81*	*0.95*	*0.83*	*0.90*	*0.54*	*0.81*	1
	Total staff cost (A+B+C)	**1.28**	**1.28**	**1.54**	**0.88**	**0.88**	**0.86**	**0.93**	**0.58**	**1.17**	1

Table 7: the relative cost of the time and activity undertaken for routine vaccination within each of the systems at each GP Practice, where mean salary across all practices = 1.

Comparison with payments

Annual payments to the GP practices included in this study were extracted from data from 2016-17 and are presented in Supplementary Material 8 - Table 8 for each funding stream [15]. These payments integrate some activity that is not included in this study (e.g. seasonal influenza), which creates a challenge in making a direct comparison. However, estimated costs have been compared to reimbursements for total reimbursements for 1. childhood, 3. rotavirus and shingles, and 4. meningitis vaccination programmes, excluding 2. influenza and pneumococcal payments, which are reported together.

Due to limitations with the data comparisons the costs associated with programme delivery are lower than reimbursements in all cases, meaning that overall it is likely that reimbursement is likely to meet the costs associated with delivering the programme.

		A	B	C	D	E	F	G	H	J
A. Actual payments derived from NHS Digital data [15]	1. Childhood	£6,000	£16,000	£11,000	£12,000	£19,500	£24,500	£19,500	£39,000	£40,000
	2. Influenza and pneumococcal	£15,000	£9,000	£11,000	£22,000	£28,000	£30,500	£18,000	£29,500	£17,500
	3. Rotavirus and shingles	£1,000	£1,000	£1,000	£2,000	£2,000	£2,500	£2,500	£5,000	£3,000
	4. Meningitis	£1,500	£2,500	£2,500	£2,000	£3,500	£10,000	£2,500	£4,000	£6,500
	5. TOTAL	**£23,500**	**£28,500**	**£25,500**	**£38,000**	**£53,000**	**£67,500**	**£42,500**	**£77,500**	**£67,000**
	6. Total excluding influenza and pneumococcal	£8,500	£19,500	£14,500	£16,000	£25,000	£37,000	£24,500	£48,000	£49,500
B. Estimated cost to practice for delivering number of appointments required for the activity generating payments.		**(£5,600)**	**(£8,900)**	**(£11,200)**	**(£5,400)**	**(£11,800)**	**(£17,000)**	**(£16,400)**	**(£14,600)**	**(£31,700)**

Table 8: payments received by participating practices in 2016-17 as compared to costs estimated from study data.

DISCUSSION

The purpose of this study was to calculate the costs associated with delivering the routine vaccination programme at GP practices and compare this to the remuneration practices receive. Overall, the estimated operational costs and payments at practice level suggest that payments cover costs. Excluding cost variations outside an individual practice's purview (e.g. higher salary costs in London), organisational factors that may contribute to lower costs include: shorter allocated appointment length; greater use of administrative and reception staff; less time spent by higher salaried staff (such as the practice manager and practice nurse) for administration; and use of HCAs for adult vaccinations. However, each of these factors needs to be considered in the context of total GP practice service delivery, which is outside the scope of this study, especially as there is currently no evidence for any association between cost and coverage. Although, this should be subject to further investigation.

After standardising for salary differentials, the larger practices in this sample had lower costs, due to higher use of relatively less expensive administrators, receptionists and HCAs for administrative tasks. However, in this sample, the 3 largest (childhood vaccines) and 4 largest (adult vaccines) practices also had the lowest coverage, however this is likely to be affected by the two large practices in London, where coverage if childhood vaccinations is known to be lower than other areas of England [4,7,8]. Overall, the small sample size precludes regression analysis to evaluate the statistical significance of any association with cost and coverage and these factors should be evaluated on a larger sample

Cost comparison

To our knowledge no other studies have evaluated the costs of delivering non-influenza routine adult vaccination appointments, however, several studies have examined childhood vaccination costs. One recent study conducted in England used time-and-motion methods to record time per activity within an childhood vaccination appointment [28]. This reported a mean appointment time of 9.5 minutes (95% CI 7.7-11.3), with an additional 10.1 minutes of non-observed pre-appointment preparation. This was similar to the time we observed in practices F and H. The total cost described was £11.90, which did not include any facility costs. The equivalent mean cost of staff and specific costs in our study is £13.77. Much of the administrative activity involved in vaccination was not measured and instead times was allocated following an interview with a nurse, but did not involve any administrative or management staff. No information was provided on the task allocation or activities undertaken at each practice. A previous study conducted in New Zealand in 2009, which used ABC to analyse the vaccination delivery system at 24 practices, found a mean cost per appointment of NZ$25.89 (range NZ$14.38-32.50), which equates to £15.08 (range £8.38-£18.93) when adjusted for inflation (to 2018) and converted to British pounds.[16,29]

Task shifting

One of the ways of modifying the cost base of delivering the programme is to shift tasks between staff groups. The most widely studied form of task shifting in primary care is from doctors to nurses, where the evidence suggests that it can reduce costs and improve preventive outcomes, but may also result in increased number of return visits and longer consultations [30–32]. Within the context of this study two types of task-shifting may reduce costs when delivering the vaccination programme. The first is to shift some vaccination activity from nurses to healthcare support workers (including HCAs), who are able to give influenza, pneumococcal and shingles vaccines to adults within a GP practice setting. For each vaccination they have to receive a Patient Specific Directive signed by a prescriber before the vaccine can be given [33]. HCAs were only used at three practices included in this study (B, G and H). Given the low levels of coverage of adult vaccines at some of the practice included here, greater used of HCAs may be a mechanism to achieve higher coverage, although this remains an un-studied area. It could also reduce overall practice time spent on vaccination as HCA appointments were much shorter than most nursing appointments at the practices studied here. The second type is to shift administrative activity from nursing staff to administrative staff. Practices B, E and F all had high proportions of time spent on non-clinical tasks by the PN (~55%), with higher associated costs, which was mainly ordering and stocking vaccines. This had been shifted to HCAs or administrators in several other practices, including practice H which had one of the lowest cost systems alongside a low proportion of nursing time spent on admin. Practice G had shifted administrative activity from nurses to administrative staff and had the lowest overall cost for admin activities from the practice nurse, but relatively high costs for admin costs overall. Further work needs to be done in this area to evaluate the relative costs and benefits for making recommendations on how task shifting could improve programme delivery.

Funding system

The rationale for the amounts agreed during GP contract negotiations is not made public. Although from the results presented here, we have concluded that reimbursement is likely to meet costs, this may not be true for each component of the programme. This is particularly important as the cost of delivering each appointment varied across the practices 2.5-fold. It is also not clear in the contracting documentation how much of the underlying facility costs is expected to be covered by the 'global sum' capitation payment provided by NHSE to practices, which is important as facility costs comprise around a third of the overall childhood appointment cost for four of the practices included here (A, E, F & J).

Limitations

This is a small, convenience sample of practices, which are unlikely to be representative of all GP practices. No very small or very large practices were included. The methods rely on self-reporting of activities, which may be subject to reporting bias. Activity logs were kept during different weeks at each practice and activity is not even throughout the year. The small sample size precluded statistical analysis of practice characteristics with costs. This study only considers costs to the GP practice and not to patients or society.

CONCLUSIONS

It is likely that reimbursement covers costs associated with vaccine programme delivery at GP practices. However, this need confirming on a larger sample of practices. Organisational factors that could be modified to reduce costs, including reducing allocated appointment length; greater use of administrative and reception staff; reduction in working time for the practice manager and practice nurse for administration; and use of HCAs for adult vaccinations, however it is not known if this improves coverage.

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DECLARATION OF INTEREST

We declare that we have no conflicts of interest.

CONTRIBUTIONS

TCB conceived the study with SMJ, MR and ME. TCB designed the Time Driven Activity Base Costing methods and conducted the data collection activities and analysis, and produced the initial draft of the manuscript. KM developed the model to estimate comparisons of costs to reimbursement. All authors reviewed the manuscript and approve the final draft.

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6.3 Organisational sensemaking

Information on what activities practices undertake are covered in the TDABC analysis, so in this aspect of the analysis I have focussed on ‘how’ and ‘why’ questions relating to the organisational management of vaccination services at GP practices.

6.3.1 Qualitative methods

In total I conducted 26 interviews involving 52 staff (Table 8), of which 23 (44%) were PNs. The number of employees that participated at each practice ranged from 3 (A and F) to 13 (E).

	A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**J**	**TOTAL**
Practice nurse (PN)	2	2	2	2	6	1	3	2	3	**23**
Healthcare Assistant (HCA)	0	0	0	0	4	0	1	2	0	**7**
Practice manager (PM)	1	1	1	1	1	1	1	0	1	**8**
Administrator (AD)	0	1	2	1	2	1	1	3	1	**12**
Receptionist (R)	0	0	1	0	0	0	1	0	0	**2**
TOTAL	**3**	**4**	**6**	**4**	**13**	**3**	**7**	**7**	**5**	**52**

Table 8: showing the number and type of staff group participating in semi-structured interviews at each practice. PM = Practice Manager, AD = Administrator, R = Receptionist, PN = Practice Nurse, HCA= Healthcare Assistant.

Each interview was recorded. The total interview time was 742 minutes and the mean length of an individual interview was 28.5 minutes, which ranged from 8 to 65 minutes. The configuration of interview participants at each practice is presented in Table 9. At each practice at least two PNs and the PM participated (except at H where the assistant PM participated instead).

	A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**J**
Single admin	PM		PM		A		PM	A	PM
			A				A		A
			A						
			R						
Group admin		PM, A		PM, A	PM, A			A x 2	
Group clinical	PN x 2	PN x 2	PN x 2	PN x 2	HCA x3			PN x 2, HCA x 2	PN x 3
					PN x 3				
					PN x 3, HCA				
Group mixed						PM, PN, A	PN x 3, HCA, R		

Table 9: showing the configuration of interview participants at each practice. PM = Practice Manager, A = Administrator, R = Receptionist, PN = Practice Nurse, HCA= Healthcare Assistant.

The recordings were transcribed in intelligent verbatim by a professional transcription service (Transcript Divas, www.transcriptdivas.co.uk). Each transcript was reviewed for accuracy against the recording and errors or areas of unintelligibility corrected where possible.

6.3.2 Coding

The transcripts were uploaded into NVIVO (v11) for analysis and coded in three stages:

1. During the first pass I coded each transcript using an entirely inductive approach focussing on the verbs staff used during the interviews when describing and explaining aspects of delivering the vaccination programme as well as the emotional states generated by these experiences.
2. For the axial coding I then reviewed the codes and grouped them into categories based on gerunds into which the verb coding generated, while also considering elements of organisational sensemaking (described in section 5.4.2.3.2), to give an overarching view of the way vaccination was conceptualised. The categories are presented in the list below. I then recoded the transcripts based on this framework for completeness. No new codes were added at this stage. The final coding tree is presented in appendix 9.7. Five overarching categories emerged:

   i. **Situating:** relates to practice identity, both within the practice (between and within staff groups), and also in relation to patients. By focussing on narratives and explanations of the practice characteristics, this answers the questions of: who are we individually? How do we understand our professional role? Who are we as a practice? Who are our patients and how do we relate to them?
   ii. **Communicating:** relates to information sharing and decision-making within and between staff groups, as well as to patients and other external organisations. This answers the questions of: how do we know? How do we share this knowledge? How and why do we use this information?
   iii. **Organising:** relates to answering the question of why do we do these things in this way? How and why do we manage this system? What counts as legitimate work here?
   iv. **Experiencing:** relates to the emotional experience of delivering the vaccination programme. This answers the questions of: what has changed in the practice environment? How do we feel about these experiences? Why do we feel this way? How does this affect the way we do things?
   v. **Interpreting:** relates to overall performance and answers the questions of: how do we know how we're doing? How does this affect us? How does this affect the overall practice narrative and understanding of ourselves?

   The categories have significant overlap and some codes could fit in multiple categories. However, together these provide an overview of how sensemaking takes place at each of the different practices to allow a comparison to be made.

3. In the final stage, I summarised the coding and relevant quotes for each category and extracted these into separate documents to create practice-level descriptions and enable between practice

comparisons. I then recoded these summaries by hand to ensure a comprehensive description was available for each practice.

6.3.3 Results

The results of the qualitative analysis have been reported under the categories described in section 6.3.2, with sub-categories for specific issues that emerged from the data analysis. Within each category, a summary of the overall data is presented with relevance to delivering routine vaccination in a general sense, followed by a comparative exploration of the issue as experienced in different practices.

6.3.3.1 Situating

The two London practices (G and J) were both characterised by mixed populations about which staff found it difficult to draw conclusions, often citing challenges with both ends of population demographic characteristics:

"*We've got quite a deprived population, a lot of poverty, a lot of people on benefits, sick, etc, and then we've got the other extreme, where they come in for their holiday vaccines because they're doing round-the-world trips, etc."*

PN – practice G

However, both practices situated themselves within complex populations with characteristics that caused challenges when trying to meet targets, including vaccination coverage. Both practices described high population mobility, which was particularly highlighted as a challenge at practice G. Staff discussed frustrations about people moving out of area and not informing the practice, thus creating a pool of seemingly unvaccinated children who no longer lived in the area and felt as though this *"worked against us"*.

Both practices also situated themselves in contexts where they had to deal with the effects of poverty and deprivation, which had an impact on how the practice performed:

"[Our area] tends to be the bottom of the things you don't want to be bottom of and top of things you don't want to be top of".

PN – practice J

Despite this, practice J also highlighted that they were a popular practice as people were increasingly registering from out of area, probably as the practice was near their workplace, which the PNs felt was a good sign of the service they offered. Interestingly, neither focussed much on their size, despite being the largest of the sample. This may be because, although they are large compared to the England average, they may not see themselves as large practices in the context of London.

The other large practice was H, in a rural area in the South East of England. Staff noted that their population was not particularly ethnically diverse, however they did discuss having a large population of both transient and resident farm workers who often originated from Eastern Europe (Romania, Bulgaria and Poland). The population here was also described as mixed, but more in terms of age and class, with both a sizable proportion of children and older people, as well as a mix of patients from wealthy and deprived backgrounds. The practice staff felt as though they offered a flexible service to the local population who, as a result, were generally positive about vaccination.

Practice F in the East of England region, although smaller than H, situated themselves in a very similar context. Staff described the population as *"very white European"*, although also noted a large Polish and Romanian population. They also discussed having a large Traveller community in the area for whom they had put in a lot of work and developed a trusting relationship, particularly around vaccinations. Similarly, practice D, in a rural area of the South West, were aware that their population was stable in size with many retired elderly people who were relatively affluent. Although they also noted an increasing number of families with young children arriving to live in new housing being developed nearby. They described the practices as being accessible with a good relationship with the community, with one nurse adding the caveat of being *"perhaps too accessible sometimes".*

Practice A in the East Midlands was the smallest of the sample, and its small size was highlighted as an asset by all staff who participated in the interviews. It was described as a *"community practice"* at the *"centre of the community"*. Staff felt the population was relatively elderly with only a small number of births each year. Both the PNs and PM made comparisons with urban practices to show how this practice was different and the population made it easier for them to achieve good vaccination coverage:

"Here they know what they want, and they know what is available. My previous practice it was more town based, we had an ethnic population who, even though the literature had gone out, did they really understand it?"

PM – practice A

Practice E, also in the East Midlands, was in a somewhat different circumstance to the other practices, having recently been formed by a merger between two neighbouring practices. This meant that it was sometimes difficult to assess whether staff were referring to one or other of the individual practices or the two combined practices. For example, several staff referred to the practice as being quite small, but the combined population of the new combined practice was in fact relatively large. The population was also noted to be older and relatively affluent and good at sorting out attending for appointments.

Similarly to practice A, the advantages associated with the practice's population was described by comparison to various staff members' experience in local urban populations:

"This is a population of patients here that really are very proactive with their health. We don't have the same issues which they might do in poorer areas."

PN – practice E

Although practice staff note that their population is relatively affluent, they caveat this with the existence of local population of people living in deprived circumstances. However, overall, this does not match the socio-economic data which places the practice in the most affluent decile in England. The administrative staff are particularly conscious that a reduction in the availability of appointments has had a knock-on effect with the patient population, with increased waiting times, especially when combined with increasing demand from a population of older people with complex health needs.

Both B and C are average sized inner-city practices in deprived areas of the East of England and Yorkshire and the Humber respectively. Practice C reports having a relatively good relationship with the local population as well as not having difficulty getting people in for vaccination. Administrative staff described the population as *"mixed"* and *"of all different nationalities",* but were interestingly reluctant to elaborate. The PNs discussed the population as having both large Eastern European and Asian populations, alongside a mixture of affluent and very deprived communities.

Practice B described their population as *"highly deprived"*, which matches the practice's deprivation score as being in the lowest decile. The PM also noted many families with young children and described the patient population as being *"high maintenance"* and *"coming in for small things"*. The PM used relatively strong, militaristic language when describing the practice's relationship with the local population:

"Highly deprived practice, the most deprived in [the area]. I think we've battled over the years to get them to be immunised. We seem to constantly be chasing them, don't we? …We've got a high safeguarding list, so are constantly chasing people, and when they come in, they'll try and grab them there and then."

PM – practice B

Elsewhere, other staff talk about 'policing' the population's vaccine status. Staff also described a large local Traveller population that they felt they had put a lot of effort into getting into the practice for vaccinations. Both the nursing and administrative staff noted the large populations of often relatively newly arrived immigrant communities from a wide variety of places (Portugal, 'Eastern Europe', Bulgaria, Latvia, Poland, Lithuania, as well as from China and 'Asia'). However, the PNs felt as though being from a smaller practice was an advantage as they could get to know the local patients and provide coordinated information.

6.3.3.1.1 Language and vaccination abroad

Two specific factors had stressor effects on staff working within the vaccination system at practices with high levels of population ethnic diversity: i) language, and ii) vaccination abroad. Practices J, G, C and B, all urban practices in deprived areas, or with significant pockets of deprivation, discussed the challenges of meeting the needs of patients who do not speak English as a first language:

"So, we have to get interpreters quite often… Sometimes, people come and you ... you don't turn them away, but you can't necessarily do the injections on that day, you need to rebook them to come back. With an interpreter."

PN – practice J

For the large London practices (J and G), the use of interpreters was common and was not framed as constituting a significant burden. Staff also pointed out that they provided information in multiple different languages, which helped understanding of vaccinations. Whereas for the smaller urban practices (C and B) felt as though getting people to come in was difficult due to a lack of understanding in these communities.

Patients who had received some vaccinations abroad presented a specific administrative challenge to practices, often requiring significant amounts of time input in collaboration between PNs and Admins.

"They come in possibly from their own country, with having a few done, so that can be a bit difficult to police, because then obviously we're trying to catch them up on the UK schedule, aren't we? So, then we're chasing any immunisations they may have had in their home country, and then try and put them on our system, and then the nurses have to tell us what they're missing. So, that can be a little bit time consuming, can't it?"

AD – practice B

Trying to work out what vaccinations children had already received and thus what they needed to have at the practice, as well as how to code this information on the practice IT system was reported at many practices as an extremely time consuming and often stressful experience. These tasks were often undertaken outside of clinic time and often in staff rest periods (lunch break or after work).

These factors also presented a challenge at some practices with reportedly lower population diversity. For example, practice H reported having a significant population of farm workers from Romania, Bulgaria and Poland. Some of these families were temporary workers, but many will also stay and become long-term residents. This was a particular problem at this practice as their fast-paced baby clinic system of 5-minute appointments, with a PN and an admin in the clinic, did not leave room for interpreters to be present, and instead family members were used to translate where possible. Despite the self-identified issue with the practice system, much of the onus was placed onto the patients themselves for not understanding the importance of vaccination.

Interestingly, two practices (A and E), who identified their population as having low diversity and being predominantly white British, explained their perceived ease at achieving high vaccination coverage by contrasting their population with practices that had more diverse populations.

No staff reported being familiar with disparities in coverage between any specific population groups in their local area, and none had any specific services or programmes to provide different services to migrant populations or those requiring language support.

One conclusion from this is that while population demographic statistics are presented by ethnic group, a more sensitive indicator of the impact on vaccination services and coverage is likely to be migration status, as more recent migrants to England are more likely not to speak English, or speak English as a second language, as well as being more likely to return to their country of origin for vaccinations.

6.3.3.1.2 Parents and patients

Practices described a significant qualitative difference in the way they conceptualised vaccinations for children (via their parents) and adults, which was clearly articulated by a PN from practice B, and goes some way to explaining the differences in structure of childhood and adult systems for organising the delivery of the programme:

"With adults, there is that element of [being] responsible for your own healthcare to a certain extent, whereas with immunisations with children, it's not really their fault, if you want, if their parents are not bringing them. So, we should maybe be a bit more proactive, I suppose, because they are not in a position to make a decision."

PN – practice B

So, for children, the way that their parents were viewed by practice staff was very important in terms of the care they received and the services that the practice offers. Of note, practice J placed a significant emphasis on parental responsibility, where it was viewed as the parents' responsibility to book follow-up appointments for vaccination, and this was used as a justification for relatively light-touch reminder/recall activities.

The nurses at practice C noted the changing nature of parenthood can also impact on the way vaccination services are delivered, and highlighted the increased importance of being 'flexible', particularly with an increasing proportion of mothers working:

- *"PN1: I've heard of some practices only sticking to one clinic a week, but that doesn't work for us.*
- *PN2: I don't think it works for anyone. Mums work now, don't they? Mums, they're not home all the time – things have changed. Mums are out and about, so you have to offer that service, don't you?*
- *PN1: Fathers come in too, sometimes.*
- *PN2: Yes, sometimes dads bring them in now, don't they?*

PN 1 and 2 – practice C

6.3.3.1.2.1 Parental concerns

"I mean, patients are patients. Parents are parents. Of course, their attitudes vary, and some are more straightforward than others. I mean, you have to treat everyone as an individual."

PN – practice C

None of the practices identified a significant number of their local population who declined vaccinations outright, although all were aware of a small number of parents who declined everything. More commonly, a variety of reasons for under-vaccination were identified in the local population, including a mix of hesitancy factors, organisational factors, alongside outright vaccine refusers. An AD at practice G explained their role in terms of *"drilling down"* into the reasons for non-vaccination to find out whether children have been vaccinated elsewhere, weren't aware they were overdue, were decliners or if they were non-attenders for appointments.

Some specific concerns were identified that made parents less likely to attend for vaccination, despite not explicitly declining vaccines. The increasing number of injections, both overall and in one go at the 12-month appointment (4 separate injections), often came up as a parental concern:

The babies are having a lot more injections, which the mum's go 'Oh, not for more injections'; don't they? Oh, how many have I got to have… But it's just gone up and up, hasn't it, how many they have, and they don't like it much. You still get the mums that will say, 'oh, we'll just have one today and we'll bring him back' … you try not to do that…. you won't get them back in the door if you do that."

PN – practice F

The hangover from the MMR and autism controversy was still felt by every practice, although noted to be having a much lesser effect than it had previously:

"There's quite ... because there's quite a lot of, you know, educated people who have issues with things like MMR still, much, much less now than five or ten years ago. You know, I had very intelligent parents who didn't want their child to have MMR recently and so we did chat to them."

PN – practice J

However, overall most of the practices identified a group of persistently non-attending parents as the reason for lower vaccine coverage, rather than parents declining vaccination or having specific concerns.

6.3.3.1.2.2 Deprivation, DNA and safeguarding

Staff at almost all of the practices projected frustrations onto families from low-income or otherwise deprived backgrounds primarily for not attending (DNA = did not attend) booked appointments:

- *"PM: I think probably although it's a mixed area really and that you've got the very affluent and then you've got the very deprived, and it's probably like the deprivation really, those children we don't tend to get in."*
- *Interviewer: why do you think that is?*
- *PM: I just don't ... I think they're not bothered, or you've got really dysfunctional families. Like generally if you look at their history, they've made say seven appointments in two months and probably DNAd five of them. Yeah it's difficult."*

PM – practice J

Staff at practice J (PM), H (PN) and B (PN/PM/AD) all described patients as 'not being bothered' to come in for vaccinations or were 'chaotic'. Even practices in the most affluent areas noted this effect alongside the likelihood of these families living in challenging or chaotic circumstances:

"*Some are chaotic, just unfortunately, often, those who persistently DNA are ones who are on the child protection or child in need registers, so there's underlying issues there, poor parenting…"*

PM – practice D

This was particularly noticeable at practice B where the problem with DNAs was a significant burden on the practice. The solution to this was seen to be 're-education' of patients, however practice staff were frustrated at their lack of space to be able to run educational programmes:

"It's expectations, I think, patient expectation. I think people think it's a free service so it doesn't matter if you don't turn up… I think they think it's free; they don't think of the cost implications. It's trying to re-educate a lot of the patients that, fine if you can't make an appointment, but please let us know because there is a cost implication."

PM – practice B

One significant difference between practices was in their attitude to the use of safeguarding within the vaccination programme:

"We have a lot of safeguarding, and we've got lots of young families that're maybe on… drug, alcohol, domestic abuse problems, and they are on our radar, and it always seems to be the children on our child protection will be the ones that are not turning up for their imms."

PM – practice B

Safeguarding does not have a legal definition, however in practice it is the *"arrangement to take all reasonable measures to ensure that risks of harm to children's welfare are minimised"* (Royal College of General Practitioners, 2018). Usually this involves actions to identify children at risk of suffering abuse, including physical violence and neglect. However, vaccination is not compulsory, and, under English law, parents are free not to have their children vaccinated. Practice B had the strongest response towards failure to vaccinate as a safeguarding issue:

***"**One of our new GPs took over safeguarding, and we decided that if parents didn't bring children in for immunisations, they would then say to the parent, 'this is actually a safeguarding issue', and they would be referred for that reason."*

PM – practice B

However, the PM also noted that they would inform the patients of this action with a special letter to try and get them in before making the referral. Practices F and E also reported referring parents to safeguarding on occasion if they failed to vaccinate. However, during the interview at F there was a disagreement between the PM who reported referring cases to safeguarding *"if really bad"*, whereas the PN didn't see it as a safeguarding issue, but *"parental choice"*.

The idea that families and children on safeguarding or child protection registers needed additional vigilance and support was common in the urban practices. At J, where there are a large number of children on the safeguarding list, PNs and ADs would notice if a child on the list DNA for an appointment and would follow-up specifically with the parents. Similarly, at G, the PM would follow-up if parents repeatedly DNA for vaccination appointments and parents do not respond to communications. Staff at F would refer parents to a safeguarding team for repeated vaccination appointment DNAs. At H an AD had the responsibility for going through the safeguarding list and putting effort into getting unvaccinated children into the practice.

The combined effects of large families, deprivation and complex social circumstances was brought together in the practices that cared for large Traveller communities (B, F and H):

"They don't tend to be against having immunisations, it's just that their life is a bit chaotic, and because they do move around, it's just that it doesn't always enter their psyche to bother about and organise it."

PN – practice B

Despite not having any specific service for the traveller communities, staff often commented that they had built trust up with them over many years and being proactive and opportunistic were described as methods of increasing coverage in these communities.

6.3.3.1.3 Staff roles

There was a plurality of descriptions around staff roles and legitimate work for each professional group within each practice. Often it appeared that the interview was the first time practice staff had been asked to consider and define their role in relation to vaccination as separate from their general professional role, so sometimes this led to confusion around the premise of the question. Generating a definition of their role and work scope occasionally appeared difficult, particularly when applied to the non-clinical and management aspects of their role. In most practices (A, B, C, D, E, G, H, J) responsibility for vaccination was highly diffuse, with multiple staff members responsible for individual aspects of the programme. This was exemplified when asking about whether there was a 'lead' for vaccinations at the practice:

- *PN1: I was just thinking; do we have an immunisation lead? Because in my previous organisation we did and that was really helpful for looking at statistics, you know, who's been immunised, how we're coordinating it. Do we have -?*
- *PN2: I'm not sure we do. I mean I think possibly we... I think maybe you have to. I think if you have to, then we would have one.*
- *PN1: Is it the GP? Usually have a GP and a nurse.*
- *PN2: Well I mean with the travel... I think if there was one, then I would probably do it. But then I'm only here two days a week as well.*
- *PN1: But we do... we know who the safeguarding lead is; we know who the diabetes lead is for nurse and GP. With immunisation, maybe it isn't?*
- *PN3: I don't know.*
- *PN1: That would good. We could also look at our statistics as a practice every six months or something with the lead.*

PNs 1, 2 and 3 – practice J

In several cases multiple staff in different interviews described themselves as having a leadership role, or nominated various different other staff members, often considering professional hierarchy, making statements like 'well it should be a GP', or 'I think it is this PN as she's been here the longest', which were followed by statements like 'in reality people come to me'.

Occasionally, when different staff groups were present in the same interview, there would be a discussion between staff groups trying to identify who the lead was, often landing on a PN. From these conversations over multiple different practices it appears that there may be multiple leads for different elements of the programme, which are conceptualised differently:

- A clinical lead: a nurse, who is responsible for keeping up to date with changes to schedule and the PGDs.
- An administration lead: with responsibility for organising the reminder/recall and keeping up-to-date with the lists, which may be the PM (in smaller practices) or an administrator, or, in some cases, a receptionist.
- A finance lead: which may be a GP partner (in a smaller practice) or a specialist administrator or practice manager in a larger practice.
- A nominated lead for oversight, which was often a GP partner, although not all practices had someone in this role and it was not clear what the practical responsibilities of this position were.

However, in the contexts where responsibilities were diffuse, these different functions did not necessarily talk to one another, and none of the practices could firmly identify someone who had an overall leadership role for the whole programme at the practice. Only in practice F was there universal agreement on the lead, which was a PN who did all the vaccinating and had been at the practice for 25 years. Even in this scenario, this nurse did not have a role in overseeing the reminder/recall activities, which were the responsibility of an AD.

6.3.3.1.3.1 GPs

Vaccination was not seen to be legitimate work for GPs within most of the practices. The exception to this was at practice J where a long-serving GP partner did have an active role in overseeing the delivery of vaccinations, and would occasionally give vaccinations himself, however this was noted to be unusual by the PNs. Due to the increasing complexity of the programme, vaccination was seen as an area requiring the expertise of a PN, as exemplified by this conversation from practice F:

- *"PM: The changes over the years, when immunisation was a lot simpler it was much more general than in the practice, this is true, doctors… participated a bit.*
- *PN: I think they might have done years ago.*
- *PH: Now, because it's got so complicated it's shrunk down to experts like [the PN].*
- *PN: A doctor wouldn't give a vaccine, no. The only vaccination they would give would be a flu jab, now.*
- *PM: Yes, some of the registrars [GPs in training] try it and we stop them.*
- *PN: No, no.*
- *PM: Because you have to be experienced at doing it, you can't just do it occasionally.*
- *Interviewer: Yes.*
- *PM: And the immunisation programme, [the PN] does a presentation at the clinical meeting on when something changes or something, and they all… glaze over."*

PM and PN – practice F

At most practices the doctors were described as 'not being interested' in vaccination, and thus meaning they were not familiar with aspects of the PGD or the complexity of the schedule.

6.3.3.1.3.2 Nurses

"It's a very responsible job you're doing – you're immunising human beings, so you have to have the time to be able to deliver that."

PN – practice C

There was little variation in the clinical aspects of the role of the nurses and often the core aspect of their role (giving the vaccinations) went unexplained in any detail. When it was described, it was always framed in terms of the responsibility and professionalism required to vaccinate, particularly babies. Several times nurses explained the importance and necessity of vaccinating children when compared to the unpleasant or difficult nature of making children cry as a result:

"I think it's an incredibly important thing for us to do… I mean when I'm telling people what my job is, I say… I'm a practice nurse and one of the big parts is making babies cry. That's one of the major parts of my job… So when we get a new nurse in who isn't trained up, that's one of the first things you get trained up on… there are certain bits that are non-negotiable. So, making babies cry is one of the non-negotiable bits."

PN – practice J

For the nurses, the trade-off for the unpleasant experience of making babies cry was the underlying importance of immunising children, and if this aspect was removed there was an element of the nurses feeling as though they were being labelled as cruel, whereas this was a necessary part of an important professional task:

"It's not that we're cruel, but I think we see it as a necessary thing to do, and a very worthwhile thing to do."

PN – practice B

In the process evaluation and TDABC analysis, there was quite a large amount of variation in the amount and type of administrative activity undertaken by the nursing staff, with some PNs having a large role in things like reminder/recall and contacting patients, as well as for stocking and ordering. However, in the interviews, the PNs rarely spoke about this administrative component and most of the interviews with PNs focussed only on the clinical aspects of delivering the programme.

Both the practices in London (G and J) reported challenges around recruiting nurses when positions became vacant. This caused a particular difficulty for vaccination, because it is seen as a highly specialised skill that requires specific training, and newer practice nurses do not always come 'vaccine trained'. Having a nurse vacancy for a period of time can increase the workload for the other nurses and also have a knock-on effect on coverage. This was not raised as a problem at any of the non-London practices.

6.3.3.1.3.3 Healthcare Assistants

Healthcare Assistants (HCAs) were most commonly used to give influenza vaccine across the practices. During the study period, only HCAs at practices B, G and H recorded time for delivering vaccinations and all of this was related to shingles and pneumococcal vaccine in older adults. However, it was noted in several of the interviews that HCAs would usually give shingles and pneumococcal vaccine during the flu clinics and not at other times of year.

At practice H, HCAs reported frustrations with having to wait outside the doctor's office to get a Patient Specific Direction (PSD) signed, which wasted appointment time. Particularly in cases where they then found out that the patient who had attended for a shingles vaccine was also eligible for pneumococcal and would have to repeat the process over again. This was also discussed at practice E, despite no time being recorded here.

The interview at practice G was mixed, with PNs, an HCA and a receptionist who led on reminder/recall activities. When the HCA was describing his role in giving vaccinations in 5-minute appointments, the PN interrupted him to question this, as she thought they should be done in a regular 15-minute appointment and was surprised when he clarified he was giving shingles and pneumococcal vaccines regularly in 5-minute appointments. Later in the same interview, the HCA was describing his responsibility for ordering vaccines as *"not a real problem"* and that *"the system works well"*, however the PN again interrupted to add in further detail explaining how her role in calculating the required stock and flow was actually very difficult, particularly with the large and fluctuating number of births. In part, this appeared to be an assertion of professional authority at the complex and important nature of giving vaccinations. Given the importance that nurses place on doing vaccination as part of their role, it is possible that HCAs in some practices do not have such a large role outside of flu season because nurses are relatively protective in this area. Interestingly, the four HCAs at practice E spoke in detail about their experience of vaccination at the practice. Some of this was discussed in terms of influenza and shingles vaccine, but some was also discussed in terms of giving vitamin B12 injections, which were not seen as different to vaccinations. No time from HCAs was recorded in giving vaccinations at practice E and the HCAs felt as though they were being under-used to deliver vaccinations. However, part of the issue with this was laid at the feet of the administrative staff, who the HCAs felt needed updating to put vaccinations in their clinic. Nurses at practice D discussed the possibility of using HCAs to input data when giving vaccinations in the baby clinic with 10-minute appointments, however decided that it could be a source of error, rather than a support.

Overall, the value of HCAs giving vaccinations during flu season, where large numbers of vaccinations need to be given in a short amount of time, was clear. However, there were tensions between nurses and HCAs in relation to giving other vaccinations during the rest of the year. HCAs would not be used to give childhood vaccines, due to the complexity required for this, however it is possible that they are under-used to maximise coverage in older adults during the rest of the year.

6.3.3.1.3.4 Practice managers, administrators and receptionists

There was significant variation in the roles of the management and administrative staff across the practices. For the smaller practices, responsibility was either centralised in the PM or an APM, and most of the reminder/recall activity was allocated to the receptionists. However, the role of the PM in the larger practices (especially G and J) was seen as more about running the 'business' of the practice, or with a specific strategic role.

As a result, in many of the practices one specific AD role would exist that centralised much of the responsibility for reminder/recall, talking to patients, booking appointments, and following up the lists of attenders and non-attenders. Several practices reported situations where in the past reminder/recall activities had been distributed between different staff, or indeed held at a relatively senior administrative level within the practice, but this had since been delegated and concentrated into one member of staff who had overall responsibility for the administrative aspects of the programme:

- *"PM: I've been here since [mid 1990s] but took over as manager in [late 2000s], so up until about 2010, maybe, I used to do all the routine recalls for immunisations, and then [an AD] has taken over because I had too much other stuff to do.*
- *AD: I've been here about nine years now, and I deal with the admin, so I am the one who writes to the parents to ask them to come in for their child imms, keep an up to date list that Child Health give me, or [information organisation] give me, and then go through that periodically to make sure that we've sent enough recall letters and things to get them in for their vaccinations."*

PM and AD – practice B

"I think the system works all right because it's just streamed now to me. It used to be quite a few of us… but it didn't really work because no one knew who'd done what, and we [were] tripping over ourselves, and then it's not getting the time… So, it's worked better for me as well because if I'm doing it I like to just be able to do it and be tweak it to how it suits me, and how I think it betters the patients."

AD – practice J

There was a very broad range of views offered by different staff groups at each of the practices about what the optimal method was for roles in relation to the reminder/recall activities. Phoning was often seen as very time consuming, but effective at getting people to book appointments immediately. However, had the disadvantage of not being able to get through to all patients. Sending letters was seen as expensive and not always effective at getting people to spontaneously book appointments, so often required repeat letters or phone calls. These tasks were often delegated to a specific administrator or receptionist, and thus to some extent was based on that administrator's personal preference. Occasionally the PMs would have a defined opinion on which was most effective. For example, with a good telephone list and responsible patients (practice A) the PM preferred telephone calls, as the cost of letters was felt to be excessive. Whereas in the larger practices, letters were preferred due to the time-consuming nature of making multiple phone calls.

Despite the significant role administrators played in delivering the programme, none reported receiving any specific training. In some cases, recognising the usefulness of knowledge of the vaccines they were contacting patients about, administrators undertook their own research:

- *"Interviewer: So if you had to invite a different group of patients who hadn't been invited before, how would you find out about that?*
- *AD: I'd have to do a little bit of research on the vaccine, because obviously some patients do like to ask questions, so I just have a little bit of background knowledge on it, but it's always the same process, I just give them a call, explain what the vaccine is and book them in for an appointment."*

AD – practice C

6.3.3.1.4 Health Visitors

One area that highlights the differences between practices in responding to wider health system changes was the role of health visitors at each practice. Health Visitors (HV) are specialist community public health nurses who provide advice and support to pregnant people, parents, and children to meet a range of outcomes as part of the government's Healthy Child Programme, such as reducing smoking in pregnancy, encouraging breastfeeding and improving population vaccination coverage (NHS England, 2014). For many years HVs were based within GP practices, however after implementation of the HSCA, responsibility for commissioning HV services was given to local government in 2015 (PHE, 2018a). This has led to variation in the relationship between GP practices (commissioning and funded by NHS England) and HVs (commissioned and funded by local authorities and employed by a range of organisation). Historically, HVs were able to give vaccinations, however their current role is only to 'promote immunisations' during the new baby review and checking adherence at the 6-8 week review. In many cases the change in relationship with HVs was seen as a loss to the practice. Staff at practice H described trying to contact HVs as a 'nightmare' and the PNs at J were 'looked at like devils' if they suggested HVs give vaccinations. Similarly, staff at practice E described HVs as no longer 'being on the ball'. Staff at both C, D and G felt that HVs could be better used to improve vaccination coverage – C by having them in a clinic to encourage new mothers to come in; D if HVs could give vaccinations in the community as part of home visits; and G both of the former together. However, these ideas were couched in the seeming impossibility of developing a productive relationship with local HVs:

"Health visitors are not really interested, because they haven't got the capacity, whereas years ago, we could refer a health visitor to get engaged, and get them immunised, but they don't do that anymore."

PM – practice B

Despite this being a change of professional role for HVs and a high-level change to the commissioning and funding process, those practices who felt these changes to be a loss, often used negative language and descriptors towards the HVs themselves.

6.3.3.2 Communicating

Communication about vaccination in all practices was, for the most part, informal and iterative, relying on individual conversations between individual pairs or small groups of staff members. Often these professionals had known each other for a long time and the specific way the changes to the vaccination programme were implemented were difficult to pin down.

6.3.3.2.1 Internal

When questioned, most practices described how there was no formal system for sharing information or making decisions around vaccination. This often appeared to be most apparent in the administrative tasks, where there was often a long-standing member of practice staff who had developed a system of doing things, which other people were not familiar with and was not necessarily written down:

"In this practice, somebody like [the PM], because of the structure changes we've had… might be doing [the reminder/recall]. If I ever am not here, he wouldn't have a clue where to start, and I've picked it up just because I've been in practice management for 13 years, and that's not really right. Anybody should be able to walk in, and… follow a standard procedure."

AD – practice C

In most cases discussions around administrative organisation and clinical delivery happened entirely independently with relatively little communication reported between professional groups. The separation of administrative and clinical decision making was often described as being problematic when the system needed to be modified to undertake an activity in a different way, such as a catch-up campaign, as described by the PN at practice E:

"I think probably communication isn't… particularly for the meningitis B one, or I suppose for any of them… particularly [when starting] catch-up programmes, I think [is] where it gets tricky, when you don't involve the reception team, who've then got to fend off people, when they can come in or not, but for a catch-up vaccination, and they often struggle with that, to be fair. So, probably, overall, I would say communication could be a bit better."

PN – practice E

Similarly, practice G had relatively separate, informal systems for updating the nursing and administrative staff, where the PM was responsible for disseminating updates to ADs and Rs and the nurses had their own independent meeting:

"I think what would help, and I know it does happen at times, we could probably improve on it, is when people are being rung in that side of the building [the administrators], this side of the building [the nurses] knows so we can order more [and] prepare. We do have some hiccups with quantity of particular immunisations, which everybody rushes around to accommodate, and I've never sensed anything more than anxiety to get it done. I think a little bit more talking to each other could only help."

PN – practice G

Many of the practices reported having a regular meeting between the PNs, which were most often informal (B, C, E, F, J). Often, when the nurses were notified of a change, this prompted an informal meeting. The PM at practice B reports that having good engagement from the nurses when a change needs to be implemented is essential as it makes the frequent changes flow smoothly and allows them to *"get their heads together"* whenever the opportunity arises. During the interview at practice E, one long-standing PN was identified as key for disseminating information, but she clearly felt unsure about this role and felt as though communication should be improved: *"I don't know. Probably, I'm sure most communication for anything could be better, to be fair."* Both the HCAs and the PM and ADs reported relying on the nurses to keep them updated informally.

Practices H and D did have more formal systems of information sharing between staff groups. Practice H has a busy and fast-moving baby clinic with 5-minute appointments. In order to manage this environment, they have a 'baby clinic protocol', which is updated by the nurses and agreed by the HCAs and administrators involved in the process. Practice D did report having weekly meetings between the clinical and administrative staff. Although the PM still described this as 'informal'.

Overall, there wasn't a sense of a defined entity of 'vaccination' that was discussed explicitly within the overall practice culture of doing things. In most cases there were changes to individual professional tasks that were implemented separately without much communication between staff groups. In the small number of examples of more substantial changes, communication between staff groups was sometime reported to be a problem. The lack of regular meetings, either formal or informal, provided few opportunities for different professional groups to undertake a sensemaking process together to define how they delivered vaccination at their practice, although this may have taken place within individual groups, particularly amongst small groups of nurses.

6.3.3.2.2 To and from external organisations

Practices had very little contact with the overarching public health infrastructure. Practice J felt that there wasn't much communication at all. A, D, C, F and G said there was someone from 'public health' or sometimes the 'CCG' who they could contact if they needed to, but overall this was so infrequent they often didn't know who specifically it was:

"To be honest, with a thing like that, the way practices work is, if we're a bit unsure who the contact is, we just email round the other practices saying, 'Anyone know who the imms lead is at the moment?' and generally someone will email back, say, 'yes, it's this one', because someone will have called them at some stage. So, we have a bit of an informal network around the local practices where somebody always knows the answer."

PN – practice E

The Vaccine Update email produced by the DHSC and PHE was well received and used by all practices as their primary source of external information relating to changes to the programme. However, sometimes additional communications that practices identified were difficult to pin down:

"Yes, you know, you read these things, you know, quite sure where they've come from but there is some information that comes in and I think it's quarterly or it tells us what the uptake throughout practices been against other practices."

PN – practice H

Overall, practice staff had such little experience of interacting with external organisations in relation to vaccinations that very limited information was gleaned by following this route of enquiry within the interviews. External organisations were certainly viewed as sources of help and support, particularly if nurses had questions, but otherwise did not provide any contextual factors through which staff within the practices understood their own performance or methods for delivering the programme.

6.3.3.2.3 To patients

The specific rationale for each system of communicating with patients implemented at each practice is presented in the section below on organising (6.3.3.3). However, there is also a general comment to make about the nature of the communications between each practice and their patients. There was a stark divide between the communications responsibilities and strategy for childhood and adult appointments. For children, practices were broadly divided into those that had chosen to rely on postal letters to parents, and those who phoned people directly to book appointments. Often, the rationale was different in each practice and dependent on either how things had always been done, or a particular initiative of the PM.

For adults, appointments were either booked opportunistically, or there was high reliance on vaccinating people during the seasonal influenza campaign, as exemplified by this comment from a nurse at practice J:

"Traditionally it's more just opportunistic when people come in for whatever, you know, diabetes or COPD, or the people we've been trying to reach as well. Or we do it during the flu season, there's a big opportunity for us to give it."

PN – practice J

Practices J and D did not have any formal invite or reminder/recall system for adult patients (especially shingles). No clear reason was given for this in either of the interviews. Several of the other practices (including A & J) relied on notice boards or TV monitors in the waiting rooms to notify older patients of the availability of shingles vaccine.

Overall, communication to patients was largely conducted by ADs using a method that had been implemented over a long period of time. There was almost no active discussion of why this system was in place, nor its merits, aside from describing its function.

6.3.3.3 Organising

The reasons why practices organised delivery of the vaccination programme in the way that they did were sometimes difficult to elicit, often because things had simply always been done ‘this way’ and staff had not thought about how to do things differently. However, there were significant differences in practice organisation and, in some cases, this was related to how practice staff situated themselves in relation to their patient population. To assist with the comparisons between practices, I have placed the practices into four groups, as both size and geography had an effect on how practices went about organising vaccination and enable the identification of areas of similarity and difference: J & G (large, London); H, F & E (large, rural); A & D (smaller, rural, affluent); and B & C (smaller, urban, deprived).

- **Practices J and G**

Practices J and G were the two large practices in London and it was at practice J where the challenges of providing services to a very large population in a relatively deprived, diverse, complex and mobile community was most stark. J used general ‘treatment room’ clinic appointments for vaccination that were 15 minutes long, which was the same length for all nursing appointments in the practice. The PNs reported some difficulty in keeping to time with the first vaccinations (aged 8 weeks), due to questions and discussion with parents, and the 12-month vaccinations (four injections in one appointment). They used to use 10-minute appointments for vaccines, but this had caused the clinics to run over partly due to the increasing complexity of the schedule, so this had been changed recently. Unlike most of the other practices, responsibility was entirely put onto parents to arrange follow-up vaccination appointments and remember to bring their children back in:

“When the child comes for that, the nurse will give the injections and… [I] would always tell the parent when the next one is due. Then it's the parents' responsibility to book that. So, they would ideally go and book it at the same time, [but the appointment] is not always available… because maybe the next Monday is not on the computer, but it's the parent’s responsibility to book that.”

PN – practice J

In the quote above, the PN tacitly notes that sometimes there might not be the ability for a parent to book the appointment, however then follows this up with a further justification that it is the parents’ responsibility. This attitude is similarly reflected in their response when asked what happens to people who DNA appointments and they describe leaving it to the parents, with the ‘hope that a doctor would remind them’. The PM was quite passive about being able to make any effective changes to the system, as they felt as though everything had already been tried, and so this was the best that could be achieved within the patient population:

"I think there's always room for improvement isn't there. But I'm not sure what we would do because we've tried everything."

PM – practice J

Practice J reported vaccinating opportunistically, particularly for adult vaccines, however the nursing staff also discussed how sometimes this wasn't possible:

"*If it's a really busy walk and wait flu clinic and there's… 20 plus people to see in an hour, I hold my hands up, I don't start saying, let me give you a shingles and let me give you a pneumonia, because there's time constraints. Pop back ... [but] it's not as good as perhaps having a letter programme [saying] 'congratulations, 65, life isn't over, come on down'. At the beginning of my walk-in flu clinics I was bringing it up and I was going into long conversations about the pros and cons and then the queue was getting really huge outside, so I've stopped mentioning it, which is a lost opportunity I think.*"

PN – practice J

The same nurse then goes on to discuss a concern around recalling patients, questioning whether there would be enough appointments to go around if there was a mailout and expressing anxiety around having to turn people away. When it came to discussing prioritisation, one of the PNs felt very strongly that it was not much of a priority for the practice:

"Oh, a lower status, every time, from my perspective. Because we don't have any particular immunisation clinics, so it's bunched in with treatments… and there is I think a tendency… immunisations could wait a few extra days, or even a few extra months. I'm simply saying that kind of structurally or like as a business, or not business… as an organisation, I don't see it reflected that immunisation is up there… I have heard statements about… chronic disease is a priority, we can't reduce the number of slots there, that's what I'm getting at, not that I'm [an] anti-immunising horrible person."

PN – practice J

This was also supported by a slightly lukewarm statement about how much vaccination is prioritised by the PM:

"I think we try to prioritise everything equally in the sense that there are some things that would be at the bottom of that priority list. Obviously, it's the resource really. But imms is always up there, we always do try to get the children in ..."

PM – practice J

The ADs who undertook the reminder/recall at the two London practices reported similar difficult experiences with lack of response within the patient population, describing how they used to send a booklet out in relation to MMR, however, this was stopped as it didn't get a good response.

At practice G they rely on letters primarily, followed by follow-up calls and SMS messages if parents do not respond. The PM at practice G felt their in-house letters were not very persuasive, but if parents were persistent non-attenders, they would ask a GP to write a personal letter, which was found to be significantly more effective. However, overall, the AD described the system as very reactive, and relied heavily on opportunistic vaccination:

"So, we don't have a call and recall system for routine imms, it's very much seen who has come in, who has shown up when they should have, based on knowing information from their red book, maybe having an opportunistic reminder when they've brought their child in for a vaccination or maybe word of mouth from other mums. And then we're reacting to getting the Open Exeter [administrative activity] report, that shows that we are not at the achieving level, and then doing some reactive work from that."

AD – practice G

Staff at practice G wished that an external organisation would take on more of the responsibility for reminder/recall as it was considered a significant burden on the practice and the lead AD was particularly concerned with the level of responsibility for organising the reminder/recall and the relatively limited capacity they had to improve the system. The various experiences in clinic at G between the different nurses created some disagreement about whether their allocated 15-minute appointments were enough, and, ultimately it depended somewhat on the concerns that parents brought with them:

"I, personally, find it enough, there's always a situation where you've got a mum or a dad and, of course, depending on location, you can have more or less anxieties around the Daily Mail, etc, etc, and we've all really suffered from MMR mis-information. And we are still ... you must be doing this, picking up on the people who have refused and there has been another dip, because of Mr Trump's best friend and we were all suffering from that. But we work very hard and all of us follow up."

PN – practice G

Unlike J, practice G was concerned about their poor performance on the pre-school boosters, given at age 3.5-5 years and the PM discussed at length the initiatives they had tried to improve coverage in this age group. Of particular note, the PM discussed frustrations at the loss of supportive external systems, including the health visitors and children's centres.

For children, both J and G rationalised using general appointments in open clinics due to the large variation in the number of children at different times of year, as they used to have a specific baby clinic, but had abandoned this due to such variable attendance. Specific clinics would not work as sometimes they would be full and other times would be empty, so general appointments allow some flexibility:

"So, we've got an open access, babies could be booked into any appointment anywhere, all three nurses do it. We're always a little bit short of appointments but they can go into any appointment, any day, so there is quite a flexibility about when they get seen."

PN – practice G

Practice G also relied heavily on opportunistic vaccination, with very limited active reminder/recall, particularly for adults. However, the PM described a renewed effort to vaccinate opportunistically:

"We are getting better at shingles, pneumococcal, as well… because administratively, we've changed a lot of our processes and… we're trying to do opportunistic, and that's why the uptake is better. Because, say, if a patient is coming in for the flu vaccine, we make sure that our healthcare assistants are trained to give shingles [and] pneumo. Also… we've got a system in place where, a day before, the

admin team goes, "Who is coming in tomorrow to see a healthcare assistant or a nurse?" and if they are eligible for shingles or pneumo, we just add a note next to it, which means a nurse gives it while the patient is here for something else."

PM – practice G

One of the ADs also felt that it had been made a priority within the practice as the GP partners had made it a priority. This kind of senior leadership interest and commitment to vaccination may be the difference between practice G and J, where this was lacking.

- **Practices H, F and E**

Practices H and F were the two large rural practices, one in the South East (H) and the other in the East of England (F) regions. Practice E is also large and had a significant rural population in the East Midlands, although alongside some urban communities.

Practice H primarily used letters to invite patients to appointments. For the first appointments they had an in-house letter with a picture of a stork on it and for most other appointments the letters were developed in-house over many years. However, the AD noted an example of when a letter had been sent to them from PHE to encourage older teenagers to attend for MenACWY vaccination as part of a campaign:

"Some of it was a little bit sort of scary and frightening which actually I thought was quite good because it basically was saying to them, you know, you can die if you don't get immunised."

AD – practice H

However, H had also started to experiment with SMS messages as a way of increasing response rates, based on patient preferences:

"[SMS] is something that we will be looking to try and use a lot more because like [the AD] said most people only have a mobile now, they never answer the phone but if they saw a text coming in that said this is from your surgery, your child has missed, please ring, that might prompt them to do it as well but we are still quite old-fashioned [the AD] and I am."

AD – practice H

Practice F reported that their system for contacting patients was relatively simple and involved three recall letters, and then one from the CHIS. An AD will occasionally make a personal phone call to the patient if they persistently do not respond. They find this combination to be effective and it did not appear to place a significant burden on the practice. However, the PM was conscious of the increasing cost to the practice of sending out multiple letters and did note that they had the facility to send SMS messages, but only used this for flu currently:

"We find postage, you know, it's not cheap, I know it's only 50p but it's a lot of [the AD's] time, so there's a limit. Whereas if there was an easier way to remind patients. We do have the facility to text, and we do do it for flu, we send a lot of texts for flu."

PM – practice F

However, there was less of a clear commitment to vaccination as a priority, or making the most of opportunistic vaccination at practice F, particularly in relation to the doctors:

"Well, I'd say the doctors don't seem to be as vociferous or encouraging to the patients for the adult, they certainly will for the children. But if you see an alert on, say, adult shingles, a doctor would never think to remind the patient."

PM – practice F

There is an interesting comparison to make between the London practices and H and F, which had both chosen to run a dedicated baby clinic. Practice H used a baby clinic with two PNs and two HCAs, with 20-22 babies per clinic. Staff involved relied heavily on the baby clinic protocol to keep everything running smoothly, although noted that it often ran late and was often 'a push'. They did not note the problem with uneven attendance throughout the year, partly because they reported having fewer people DNA appointments. However, when they did, there was a commitment to getting them in:

"[The AD is] on the case. She'll send another letter. I think she will send at least three; she might even ring them and… try and give them an appointment that suits them better. She will bend over backwards to try get them in. She'll even overbook a booked clinic if they're that far behind in their schedule, which we've had that before hadn't we?"

PN – practice H

Although the admin team still felt as though they could do better, particularly phoning and persuading parents to come in by providing more information. However, they also reported that this is very time consuming, so instead just send a letter to "*tick a box to say at least I did try to get them in again".*

Practice F also used a baby clinic, but with five-minute appointments, which was described by the PNs as 'frantic' for the AD involved. However, alongside this they reported parents having the flexibility of booking appointments anywhere within the working week to support parents attending at a convenient time. However, they recently moved away from the baby clinic system for the 12-month appointments, which involve four injections in a relatively mobile child.

Practice E had recently changed from a system of sending an appointment to patients with their vaccination letters as people did not attend when sent a direct appointment, and so they now just send a letter advising them to call in and book. Practice E almost exclusively used letters to invite patients and had a specially written one for people who persistently DNAd. Prior to sending this letter, however, the PNs will try and directly contact the parents of the child to chase them up personally. However, failing that one of the ADs will regularly check to make sure everyone had attended:

"Yes. More often than not, most people will come to the appointment that's booked them, or they'll phone up, the parents will phone up, and if it's not convenient they'll rearrange it again. But,

obviously we do then run the search again to make sure that those children have come in, and that they don't get missed, because we do have some that DNA. That's why we run it so often, so that we keep a check on them."

AD – practice E

Practice E had a similar appointment system to F, where there is a dedicated baby clinic run by one of the PNs, but parents can also book into general appointments. There was a general debate between the PNs about whether the 10- or 15-minute appointment times were sufficient:

"I think, again, it depends... if mums have come with small babies, and they've come in with other problems and think, well, it's okay, I'll ask while I'm there, and sometimes want prescriptions for various bits of things, so I think it's on an individual basis, really, whether one will take a longer time than another, anyway, I suppose."

PN – practice E

However, overall, they did not experience any significant challenges of delivering vaccinations within their current set up. Similarly to many of the other practices, but surprisingly given so much effort put in to chasing up DNAs here, practice E also didn't have a plan for recalling older people for pneumococcal or shingles vaccines:

"*We haven't been doing those recently, so we've not really got a plan in place for that. We have got some shingles vaccines in, so I think the nurses are trying to grab people as they see them, as they see the opportunity, but we haven't actually got a plan in place for calling people in for that."*

AD – practice E

This was also reflected in the comments made about how much of a priority vaccination was here:

"I would say it's seen as a sort of priority, but in real terms, I think it sits just amongst everything else that needs to be done, to be fair."

PM – practice E

- **Practices A and D**

Practices A and D were in affluent, rural areas, with high proportions of older people. Practice D was of an average size in the South West of England, and A, in the East Midlands region, was the smallest of the sample with the lowest proportion of children.

Practice A primarily used phone calls to invite patients for vaccination appointments, as the PM found this to be more efficient:

"We don't do letters, we find that phoning is a lot better because it is while you are here can we get you an appointment, so we tend to do the phone. We also do text messaging by saying can you contact the surgery. … I switched from letters when I came here in '11, because it is costly, timely, and it wasn't that productive.

PM – practice A

Much of the conversation was framed around how few appointments for children they had, and how this had led to simply using ad-hoc appointments for vaccinations. This sentiment was echoed by the PM who also noted challenges with school-age children due to a relative lack of after-school appointments. The PM also described a situation where, if the practice has a full complement of nurses and seemingly available appointment capacity, they can increase reminder/recall activities to get patients to come in for vaccinations:

"[The time spent on vaccination] varies because last week I cracked the whip and said right no nurses are on holiday let's get some shingles and pneumo vac in. If I go out there and crack the whip now and say right we are doing shingles, doing this vac, that vac, then you will see all the team at it, they have all got parts of the list and they are all doing it. Then it could be a whole hour of three people on it. And we also have to check and say how many vaccines have we got in, so we check with [the PN] and she will say I've got 30. Right get 30 in."

PM – practice A

No other practice spoke about a focussed effort to bring in people for vaccinations when capacity was high and is likely to be related to the relatively smaller eligible population.

At practice D, also due to the relatively small number of childhood vaccinations delivered overall, the AD can keep track and follow-up with the people she was contacting to attend for vaccinations, using an initial letter then a follow-up phone call. However, in contrast to A, practice D runs a relatively open baby clinic, which still involves the health visitors, enabling the baby to be weighed, have a discussion of issues around immunisation and then get vaccinated. Prior to the clinic, all the vaccinations for the expected patients were pre-prepared for delivery in 10-minute appointments. This type of baby clinic was unique and was described at other practices as being historical. It may be that this practice managed to withstand the changes to the overarching public health structures and commissioning processes to maintain what they saw to be a valuable and safe service:

"What is excellent is having the baby clinic, so that it's not run - I really don't like the ad hoc ones that are thrown in during the week, that just – you're in a safe zone, aren't you, when you've got baby clinic? It just feels more secure, a safer environment."

PN – practice D

However, this organisation was not matched for older adults, where most of them were given opportunistically, either because specific clinics had been tried and failed (e.g. for MenACWY) or because they give shingles during the flu campaign, which was the most common mechanism and present to some degree in all practices.

- **Practices B and C**

Practices B and C, both in deprived urban areas, described a very different experience of managing the vaccination programme. At practice B an external organisation (just described as 'public health') sends the first letter to patients, via a third-party organisation commissioned for the purpose. However, the high level of DNAs causes a burden within the practice for both adults and children in managing the additional follow-up, reminder and recall this requires:

“Constant chasing. We send out three recall letters, as the routine, but then you carry on, and then they get stronger, and we ring them, and then obviously they’re flagged and the nurses and… they engage and try to get people in. Health visitors are not really interested, because they haven’t got the capacity, whereas years ago, we could refer a health visitor to get engaged, and get them immunised, but they don’t do that anymore.”

PM – practice B

At practice B all the vaccination appointments go in regular clinics, which was as a result of their high DNA rate:

“Yes, it’s just integrated. We used to have individual clinics for everything, and because we have a high DNA rate – we have about 120 a month [for all appointments] – it didn’t work because you’d have nurses who had got, like, six or eight… patients who didn’t come in, so they’re just put in anywhere, really, anywhere and everywhere.”

PM – practice B

The PM at practice B also pointed out that if parents do not attend for their vaccine appointments, particularly those parents who had been labelled by the practice as chaotic or disorganised, then they can receive up to nine very similar letters over a period of four months, which may not be an effective way of supporting parents to attend for vaccinations. However, the administrative team did agree that childhood vaccination was relatively high on the list of the practice’s priorities.

The staff at practice C primarily used phone calls, which was described as ‘old fashioned’ and an arduous task for the receptionists, however were seen to be much more effective by the PM:

“*I know in my short time here I’ve found that making contact over the phone is so much better because we seem to get it dealt with and we get the job done. Sometimes when a letter goes out, you’re waiting for them to come back. So, for me, I know… it can be a burden, ringing, but I think it gets the job done, and it gets the job done quicker, which I think is better”.*

PM – practice C

However, the receptionist sees the system slightly differently, describing a method whereby they send a letter first, then follow-up with an SMS reminder before phoning. Although this was reportedly limited by a lack of up-to-date phone numbers. One of the ADs had also noticed that some of the patients did not have good knowledge about the vaccination programme, so implemented their own intervention:

“A lot of it I’ve noticed is that they don't have much knowledge about the vaccine, so what I’ve started to do is, when I'm sending out letters, I send them a leaflet with it from the NHS, and I'm finding that that’s more productive actually.”

AD – practice C

The same AD has also started researching more about each vaccine so when she spoke to patients on the phone, she was able to explain the benefits and convince them to come in for an appointment more effectively.

Similarly to B, the view at C was that a dedicated clinic did not offer enough flexibility for the population, particularly working mothers:

"I don't think it works for anyone. Mums work now, don't they? Mums, they're not home all the time – things have changed. Mums are out and about, so you have to offer that service, don't you?"

PN – practice C

Due to the complexity in the first appointment, practice C allocated 20 minutes, with 15 minutes for all other appointments, although the nurses thought if they made the case for a long appointment this would be granted, even up to 30 minutes.

6.3.3.3.1 Finance and reimbursement

The finance system had relatively little impact on the delivery of the vaccination programme at any of the practices, as the rate and amounts of reimbursement were not easily matched to vaccination activity. Similarly, most practices had difficulty being able to say whether the reimbursement matched costs, as there was no clear way of identifying and calculating costs separately, nor matching them easily to the payments the practices received:

"*So basically the money will come in, and then if we can identify it… sometimes you get money in and you don't know what it is for and there may be a code number by it so you ring up and ask about the code number and they go 'well we don't know.'"*

PM – practice A

Because of this, practices A, F and H couldn't say whether reimbursement matched costs or not. Administrative staff at these practices made comments around never having had to consider the amount of funding they received.

Practices B, E and J did not think they were sufficiently reimbursed for the level of activity required and at each of these practices it was framed around the staff time, particularly for administrators:

"No, I don't think we're adequately reimbursed because when you take into account the overall running of the practice, the nurse's hourly rate, because it has to be a highly skilled nurse… the training that's involved. Also, the non-clinical staff, like booking appointments, marking them as waiting, making sure they get to the room, and then you've got somebody like we've got [an AD] who spends quite a lot of her time on the recalls and Open Exeter. So, no I don't think we get adequately reimbursed."

PM – practice J

Probably not. I mean, £9.80 per vaccine – when you think about how many letters we have to send out, and the majority of times, and the time that [the AD] spends putting stuff back, probably not."

PM – practice B

Practices G and D on the other hand did feel as though the reimbursement matched their costs, although G also focussed on the broad range of targets for the pre-school booster vaccines, which can often affect the overall amount of funding they received:

"I think it's enough for now, what I do want to see, if possible, I don't think I could say in the national way, but I do think the five-year-olds is very difficult and yes, there should be a 90% target, I'm not saying that there shouldn't be. But the difference between the 90% and the 70% is massive in what we get paid, so we do feel penalised and we've put in so much effort and achieved 88% and get paid for 70%."

PM – practice G

The PM at D on the other hand reported the practice always being over the required thresholds, so does not really pay attention to the finance.

Overall, the following quote summarises how many practices respond to the financial situation, highlighting how insensitive practice activity is to the overarching financial structure and incentives:

"We get this wodge of money each quarter on a statement for childhood imms, and we… know roughly what it's going to be, and… when we budget each year, we just say, 'oh, well, we'll get about that much from the childhood imms'. It doesn't incentivise us to improve, because to be quite honest… we do what we can to get everybody in, and the result is what it is – you can't really do any more. Obviously if we had a really rubbish year and we didn't get the money, that might focus our minds a little bit and think, hang on a minute, we've lost a few thousand pounds there, because we do rely on having the income, but it's one of those things that just gets paid quarterly, and we never think about it that much."

PM – practice E

The perceived usefulness and effect of targets on activity within the practice was often framed around the staff experience with the QOF system. Practices nurses at H and J felt as though QOF would be an effective way of increasing coverage in certain areas, saying "*anything that is for QOF will be done basically, regardless".* However, the general discussion at practice E was that vaccination was equally as important as achieving QOF points and therefore it would be unlikely that service delivery would be adjusted to make way for more QOF activity, even if that was vaccination related.

6.3.3.4 Experiencing

Two aspects of delivering the vaccination programme arose within the interviews as significant experiential events that varied between the practices. The first was dealing with and managing changes to the programme, which some practices almost didn't notice implementing, whereas others found the experience of this very difficult or stressful. The other was the management of both clinical and administrative capacity in terms of how much time practice staff felt they spent undertaking vaccinations activities, which varied in a similar way to how different practices dealt with changes to the programme.

6.3.3.4.1 Organisational change

There was great variation between the practices in the way they reported experiencing and responding to changes to the vaccination programme. Practices J, D, B and E reported difficult, challenging or stressful experiences of managing change within the vaccination programme. The staff at practice J had the most negative experiences of the recent changes to the programme. The PM reported the nurses 'pulling their hair out' due to the frequency of changes to the programme. A very long standing PN at practice J describes how this has affected their experience in clinic, particularly around having increased the appointment length due to the time-consuming nature of giving vaccinations, and how this was prompted by the arrival of a new member of staff:

"I think vaccines are a good thing, [but] it's more time consuming because you're giving more vaccines now… most of them… don't come readymade so you have to draw them all up. You have to talk obviously about what's going to happen next. As I say with Meningitis B you have to talk about the risk of temperature and give them paracetamol. So just in that sense it's more time consuming. We had a nurse a while ago who came from a different practice… she said ten minutes just isn't enough for you, you do need to have longer appointments. We thought, 'oh, this is actually quite nice, having longer appointments. This makes it much easier to see patients.' So, I think… we're giving more vaccines, we have to give more information. I think it's a good thing."

PN – practice J

The same nurse also suggested that both staff and patients can find the continually changing nature of the programme "*when you chop and change like that, for some people that's quite unnerving*", specifically in relation to the removal of MenC and changing the age at which MMR is given. A PN at practice D also reports a similar experience, finding the experience of change 'scary' and that it takes 'quite a lot of getting your head round' all the changes to the schedule. This was also supported by comments from the PM in a different interview, who reported the PNs funding the process of managing the changes within the clinic stressful:

"I think it puts stress onto the nurses, because they… obviously need to do it correctly, and it is quite a stressful situation for the nurses, I think, because in the olden days, I think you had… three [injections], [another] three and a three each month, whereas now you've got a mixture of them the first month, then a different mixture at the second month, and then a different mixture at the third month. So, I don't envy the nurses, and I don't think even that would be so bad, if then you didn't get patients who didn't want that one or didn't want that one. I mean, it's just… fraught with problems, I think."

PM – practice D

The experience of managing changes to the programme within practice B was also described as 'chaotic' and causing 'anxiety' amongst the nurses. The nurse at B also felt that the introduction of new agents into the schedule always felt rushed, leaving insufficient time for nurses to do the required training and become familiar with the requirements within the PGD, because the introduction of new agents always seemed to take place 'suddenly'.

Nurses at practice E also reported finding changes difficult, focussing on the fact that although the ages and appointments are the same, the cognitive aspect of getting used to the changes can sometime be a challenge, particularly in relation to 'getting your head round' what is being given and when. The difficulty at practice E may also be related to the complexity caused by the recent merger, or the general experience that some of the administrative staff were less confident in knowing how the vaccination programme was managed, which is supported by the discussion between the PM and one of the administrators:

- *"So, when we get changes to the programme, I think that usually comes in the form of immunisation newsletters. I think they come out...*
- *It doesn't, doesn't it?*
- *It does, yes. Yes, vaccination… [over talking].*
- *Do they come from the CCG, or from...? I think they do, don't they? They come from...*
- *They might not be CCG employees, but there's a local contact – I can't even remember her name, but there is a newsletter that comes out on a regular basis with updates to the vaccination programme, and we make sure that that's distributed to anybody who's involved in vaccinations."*

PM and AD – practice E

The PM and PNs both described delivering catch-up campaigns as extremely difficult, due to the increased workload required and the problems of finding spare capacity within an already busy workload.

Practices A, C, F, G and H gave the impression of managing change within the programme as being less of a challenge. At practice A the PM was very matter-of-fact and technical about how changes were implemented, which boiled down to simply keeping up to date and making the required changes with the PNs. Although he also reported the challenges of dealing with multiple changes at once:

"The only problem is it always seems to be that there is never just one change on its own, there always seems to be a few thrown in. It is we are introducing this, but we are stopping that, and we are doing that."

PM – practice A

One difficult experience reported by the PN was having to explain to parents when their child was outside of the age bracket for a new vaccine, as was the case when Meningitis B vaccine was introduced, which was also reported by several nurses at other practices.

Practice C dealt with change in a matter-of-fact way and some staff appeared to be unsure about the premise of the questions, which – reflecting on the interviews – is likely because dealing with the continual changes to the programme is simply part of the programme, which was very different to the experience of the nurses at practice B and D.

The primary challenge reported by a very experienced PN at F was the problem with managing the increasing number of injections given to children within the programme, particularly when parents protest or want to have vaccinations at different times.

At practices G and H the reported experience was of ‘getting on with it’ and ‘keeping up to date’ respectively. The PN at G framed this around the important of information sharing and everyone knowing what was going on and keeping updated with the changes, and this sentiment was echoed by the other staff involved in the mixed interview:

“I think for… any new vaccine we keep with mandatory training, we look at all the up-to-date information that’s coming through. So, we keep updated, we’re all very aware of what’s going on, what the new programme is, how we need to run it, but we don’t talk to patients about it until they actually come into the room. So, we only send out letters going, ‘this has all changed, blah, blah, blah’ whether the health visitor does or not, I don’t think so, but basically, it comes from us.”

PN – practice G

Due to the unique nature of the baby clinic with the specific protocol, keeping up to date with the required changes was an important task allocated to a small group of people within the practice, particularly one of the administrators:

“I’m part of a team that gets information from either Public Health or via … they call vaccine update and so normally it’s all down there about what’s going to happen. I will liaise with normally [one of the PNs]. [She’s] got a big protocol there; she keeps up to date with who’s going to have what when… We all work all together to find out when it [is] going to happen to make sure that the nurses who give it [know] but also, I [know] for getting in the new vaccines and things.”

AD – practice H

Although there was also a discussion around how the increasing complexity of the programme is making the pre-clinic preparation increasingly more difficult as well as concern about the increasing risk of a drug error within the fast-paced baby clinic.

There was rarely any disagreement between clinical and administrative staff, which suggests that whatever the experience of the practices of implementing changes within the programme, it was shared amongst all staff groups and is likely to be tied into the overall practice systems and working culture.

6.3.3.4.2 Capacity and time spent

During the interviews, participants were asked to estimate the proportion of their working time spent on vaccination, alongside a general discussion of the capacity of staff to undertake vaccination activities. To enable a comparison between reported time spent and recorded time spent, Table 10 of proportion of working time spent on vaccination activities during the study period has been included here:

	A	B	C	D	E	F	G	H	J
Childhood vaccinations (n)	*9*	*14*	*15*	*23*	*24*	*30*	*23*	*31*	*71*
Adult vaccinations (n)	*26*	*10*	*22*	*17*	*4*	*23*	*7*	*14*	*16*
Practice nurse	10.87	8.86	9.06	10.69	3.47	7.27	14.70	5.88	15.34
HCA	-	0.98	-	-	-	-	1.57	3.83	-
Practice manager	5.25	1.62	0.67	5.44	-	2.83	-	-	-
Assist. Practice Manager / specialist administrator	-	-	8.33	-	2.37	-	5.33	6.39	5.33
Administrator 1	-	6.83	17.44	6.32	7.58	1.16	-	7.53	-
Administrator 2	-	-	-	-	-	3.11	-	-	14.67
Receptionist	1.44	-	5.79	-	-	-	12.10	-	-

Table 10: number of vaccinations given and proportion (%) of working time spent by each staff group during the study period.

At practice A, despite only vaccinating a very small number of children (9 during the 2-week study period), this took up a relatively high proportion of the nurse's working time (11%), which is due to the PNs also doing a lot of shingles and pneumococcal vaccines (26) in the relatively elderly population, as there are no HCAs. Overall the PNs reported vaccination not taking much time at all.

At practice B the PNs found it difficult to put a precise figure on how much time they spent vaccinating. The largest time burden reported in the interviews was for the AD, who spent nearly 7% of her working time on vaccination, so this was a relatively accurate picture.

Similarly, staff at practice C made relatively accurate estimates of the time spent on vaccination and the PM reported that overall the practice has good appointment capacity to be able to cope with demand. The PNs estimated around 6 hours per week, which is slightly higher than the 9% recorded in the activity logs. The R reported doing about 2 hours of chasing patients per week, which is similar to the 5% recorded, and the AD estimated she spent around 10% of her time on vaccination tasks, which was somewhat of an underestimate of the 17.4% of her time recorded.

Practice D gave a relatively high number of childhood vaccinations during the study period (23) compared to adult vaccinations (17), when considering their population demography. The PNs significantly over-estimated the amount of time spent on vaccination (20%) compared to the time recorded (9%). The PM described building and running the reports to determine who needed vaccinations as 'taking far too much time', which was recorded as 5.4% during the study period. The AD reported a relatively steady stream of tasks through the week with a focus at the start of the month, which matched the modest 6.3% of her working time.

The interview discussion around capacity at practice E was all framed around their concern with the decreased appointment capacity compared to demand in their population and that this has significantly increased the waiting time for GP appointments, although the problem was less acute for nursing appointments:

"I think the biggest impact on how the population feel about us in the recent couple of years is, the deterioration of appointment capacity versus demand. That has had a big impact on how the population now view the practice, because it is a lot worse than it was a couple of years ago."

PM – practice E

Given the age profile of the population, practice E did relatively few adult appointments during the study period (4). PNs estimated around 1.5 hours of vaccination activity per week, which matches almost exactly the proportion recorded during the study period (3.5%), although highlighted that this can vary dramatically if one of the PNs is off on leave. Of note, the HCAs reported being under-used at this practice, which was evident during the data collection period, where no activity among HCAs was recorded.

The PNs at practice F had difficulty estimating the time spent, as activity was spread through the week, although they described this as *"not a massive amount".* The AD, who estimated spending about 3 hours per week, recorded about 3% of her working time on vaccination, and found sending letters out time-consuming.

The PM at practice G described a situation where they have relatively recently increased the number of admin staff, who were brought on to provide increasing flexibility within the practice to meet the population needs. Staff were also quite frustrated by their low coverage in pre-schoolers, and felt as though the time required to get these children in was not worth the additional money they would receive for meeting the 90% thresholds, as they are already 'doing everything they can'. The PNs estimated they spent around 10-15% of their working time on vaccinations, which matched the 14.7% recorded during the study period. The HCAs estimated about 15-20% of working time, but this was distorted by their inclusion of flu vaccine, as this was the primary vaccine they would give. The receptionist, who had a large role in reminder-recall, particularly in sending and chasing up letters, felt that some weeks vaccination activities could take up 70-80% of her working time, although 12% was recorded during the study period.

The biggest capacity challenge reported at practice H was related to the baby clinic, as often this was becoming over-booked. The nurses reported having to deal with vaccinations outside of the dedicated clinic as a 'bit of a nuisance'. Overall, the PNs estimated around 2 hours per week, which did not feel like a significant burden, and was reflected in the relatively low proportion of their working time spent on vaccinations (6.9%). The AD here, however, found managing the data collection and submission very burdensome and estimated that this took up around 25% of her time, although this was only recorded as 6.4% during the study period.

Practice J was in a different position to many of the other practices as it undertook an extremely high volume of childhood vaccines (70 during the study period). The PNs estimated they spent around 30-40% of their working time on vaccination, which, despite the large number of vaccines in the study period, was only 15.3% of their working time. It is possible that other vaccines may have been included in their estimates, particularly travel vaccines, of which they also did a large number. From the administrative side, the PM and AD reported not having capacity to be able to run an active reminder/recall system, and this instead remained an opportunistic only system. The PNs also reported having fewer admin staff, which meant they sometimes had to get involved with reminder/recall activities. The AD estimated she spent around 50% of her working time on vaccination, which was an over-estimation to the 14.7% recorded during the study period.

Overall, estimates of time spent on vaccinations activities were relatively accurate when compared to the actual time recorded during the study period. The exception of this was in circumstances where participants also reported capacity issues that were causing problems or stresses within the practice system, where time spent on vaccination was significantly over-estimated.

6.3.3.4.3 Outbreaks

The overall desired impact of the vaccination programme is to prevent outbreaks of infectious disease, and to this end it appeared largely successful, as few of the practices reported any significant experience with disease outbreaks. This was not discussed at all at practices A, C, G or H. Practices D and F explicitly reported having no experience of outbreaks in memory of the practice staff. Practice E reported having the occasional case of meningitis, and experience of getting a 'backlash' of people requesting appointments if someone in a school is diagnosed with something. Similarly, practice B reported occasional meningitis and a recent outbreak of whooping cough, although neither of these resulted in any specific action taken by the practice. Practice J reported a measles outbreak 'a few years ago' that resulted in them giving the second dose of MMR earlier than the national schedule. They also mentioned a recent Hepatitis A outbreak in a school that required a specific campaign led by Public Health England.

The overall experience of outbreaks amongst the included practices was relatively low, which is likely, at least in part, to the success of the vaccination programme.

6.3.3.5 Interpreting

There was significant divergence between practices in their reflexivity and how they identified and interpreted their performance and whether they took any action in relation to the coverage levels they achieved. Practices G, H, C, B did have some method of monitoring performance, which resulted in various combinations of staff at each practice knowing how well they were performing, and in some cases resulted in organisational change.

Practice G had low coverage of childhood and adult vaccinations, but was putting effort into improving this situation. The PNs were aware of some problems with their performance ("*we don't do* *as well as we think we do"*) and spoke about a new drive to monitor quarterly performance and hitting the 90% target. Interestingly, they had recently appointed a new administrator with specific responsibility for monitoring progress against targets, including vaccination coverage. This was appreciated by the PNs, who had previously been responsible for much of the monitoring and administrative work:

"And also, my point of view as well, I was, basically, doing it all on my own before, whereas now, we've got admin helping out as well on immunisations, which really helps a lot. So, I think that's why the targets have improved quite a lot."

PN – practice G

At practice H, which also had relatively poor performance on both childhood and adult vaccinations, there was a named PN who had responsibility for monitoring performance. However, this did not appear to result in any significant changes to the system, or communications between other staff members. After a conversation between several PNs and HCAs in one of the interviews expressing some confusion and uncertainty about both the practice's performance and the source of data, the PN stepped into clarify:

"Yes, we do [receive data on performance]. The stats do come through every now and again, but it's very high level and often it's just… the management [who] look at that. I am aware that there are stats available on how well we're doing; some things we're above average on, sometimes we're below average and if there is an issue or they want to know why [the AD] will often come and talk to me and just say, 'Why do you think, you know, we didn't get as many of these?' I don't get involved in that a huge amount, but I am aware that we do get figures reported to us."

PN – practice H

The other PNs appeared to measure perceived performance by the number of people they had through their clinics for vaccinations and reported that it was difficult to estimate this as vaccination appointments were diffuse throughout the week.

Practice C had higher than average coverage for both childhood and adult vaccinations, and PNs were aware that they performed relatively well, although were not able to give specific figures. There was an interesting comment made by one of the specialist ADs at this practice about how vaccination was conceptualised as a necessary part of the financial support for the practice. When asked whether vaccination takes up a lot of the practice's time:

"No. I've got the impression – I think we all have – that [external organisations] are ignoring the public health aspect… The way we get reimbursed in this area's changed in the last three years – it used to include a global sum, and we used to get a global figure for it. We then got switched over to a system where we're reimbursed on the activity. That made a big difference to us, and our income went up by about 50% because we're a high achieving practice in terms of childhood imms. So, now it's on an activity basis, so it's a fair system, which as a practice [is] important income to us, because we are quite tight on cash flow, so we do rely on it."

AD – practice C

Neither the nurses nor administrators at practice B knew specifically how well they performed. However, one of the ADs reported using the Open Exeter administration system as their primary method to see how well they were doing against the population who were eligible for vaccinations, leading to a proactive approach to get these patients in, presenting a fairly accurate picture of their performance overall:

"Again, we're very proactive about getting them in, and all our patients that should have them, but yes, we don't tend to reach the target that we're meant to. But, in babies, I think we do reach our target. I think if you look on the NHS England site, you can see, we're actually not too bad with them."

AD – practice B

Practices J, F, A and D didn't describe situations in which they were familiar with their performance, however for quite divergent reasons. Practice J had lower than overage coverage on childhood vaccinations and the lowest coverage of all practices in this sample for pneumococcal vaccine. The PNs at practice J felt their performance was *"quite reasonable"* and *"maybe not at the bottom"* stating that they *"think we've got better"*. However, when asked where they got information about coverage levels from, the response was that *"we don't look at it"*. The PNs also commented that they think it would be *"nice to get feedback"*. Surprisingly, the PM reflected a relatively similar view, stating that she thought the practice *"did quite well"*, but isn't involved that much and only focusses on the making the claims and managing the finances. There wasn't a clear person present in the interviews, not described by the interview participants, whose job it was to monitor performance against the targets.

At practice F the PNs were aware of information from the Vaccine Update emails that showed rotavirus incidence decreasing, which they found motivational. However, the PNs reported not knowing where to look to find their individual practice performance. The PM used the quarterly vaccination reimbursement payments to evaluate how well they were performing (*"well, I look at the money, again, and quarterly, if it's over 90% I'm happy"*), as well as information in their CQC report. Interestingly, staff here did not appear aware of their relatively low coverage of adult vaccinations.

Practices A and D were both in rural, affluent populations, with relatively small numbers of children, who had higher than average coverage for most vaccines. Staff at practice A were aware they performed well, but did not monitor their performance, describing being lucky that their patients were happy to come in and get vaccinated. Similarly, at practice D they were generally not aware of their performance. The PM reported that looking at coverage statistics 'has been done in the past', but not recently and doesn't know the 'actual statistics'. Similarly, the PN was not aware of their performance, but thought that they *"would be told if we were under target"*.

Practice E had a complex response across multiple interviews to the questions around monitoring performance, which didn't fit easily into either category. This is likely because they were in the process of merging two practices together, which had different cultures of using data, and some of these functions were in the process of being centralised. Overall it appeared that regular communication of overall practice data was one of the things that had currently fallen through the gaps while the health services were reorganised:

"We used to have certain meetings where we used to get all the data, how we were doing with everything, if you like, in relation to waiting times for appointments, and how we were doing on referrals and everything… and we used to have it up on a screen, and things like immunisations would have come alongside of all of that, and… we don't do that anymore, to be honest. So, I think I get the impression that we're… left out of the loop of immunisations, because in actual fact, I would've assumed, because there is no need to push it because we're doing okay anyway, but that might be totally wrong, the wrong perspective, I don't know."

PN – practice E

In another interview with PNs, they described doing 'generally well' and that someone would say something to them if they needed to improve. Although, they also described a former situation where data sharing was better. They also described a trusting situation with the admin team, who they described as 'really good'. Similarly, the administrators described the system as 'running really well'. This is reflected in their high coverage of both childhood and adult vaccines. Although it appears that there was a system of looking at performance data in the past, including some kind of data dashboard; this seems to have been lost at some point, possibly related to the transition to a larger practice.

6.3.3.6 Comparative sensemaking

To evaluate the impact of sensegiving on organisational sensemaking, I have categorised the practices using the definitions presented in 5.4.2.3.2 from Maitlis (2005) and presented in Table 11, alongside any evidence of impact on practice organising.

Overall, the most common form was fragmented organisational sensemaking in six practices (B, C, D, E, G, H). Two practices had minimal organisational sensemaking (A and J), and F exhibited restricted sensemaking. It is interesting to note that at all but one practice sensegiving was subject to low control, meaning that sensemaking was either minimal or fragmented, due to the lack of a defined leader (or leaders) providing sensegiving from either the administrative of clinical staff, and a lack of discussion of vaccination organising or interpreting of performance through formal meetings. The possible impact of this on practice performance is considered further in the Discussion section 7.1.3.

	Control (leader sensegiving)	Animation (stakeholder sensegiving)	Organisational sensemaking	Comments
A	Low	Low	Minimal	Although there was a named lead nurse, there was significant divergence in some of the views offered by the nursing team and the practice manager, suggesting that actually the lead PN did not having a significant sensegiving role. Information about changes was received and disseminated by the nurses, but the PM had a responsibility for determining how any required administrative changes were implemented. Little animation about vaccination was described, likely in part because of the relatively small number of vaccinations the practice undertakes.
B	Low	High	Fragmented	Leadership for vaccination was diffuse here, with the PM having some oversight, but most of the administration led by a single long-standing member of administrative staff, and multiple nurses involved in the clinical side. Information sharing was diffuse and undertaken through informal meetings. However, there were lots of opportunities for discussion and debate amongst the staff, particularly in respect to the challenges they faced encouraging the local community to attend for vaccinations and managing their high DNA rate, which created an environment of high animation. This had resulted in quite forceful and militaristic labelling of the problem between the practice and the population, which was unified amongst staff.
C	Low	High	Fragmented	Responsibilities were diffuse at this practice, with limited opportunities for sensegiving. The PM and one specified administrator had well defined roles in managing the administrative component of the programme, however both were relatively new in post and expressed some uncertainty about their roles. There was also a separate finance manager, which is a function usually associated with the PM. However, there was much informal discussion and debate between staff members, which created multiple narratives about the challenges of delivering vaccinations, depending on each professional group's perspective. There was divergence in the view of the challenges with the local population between the nursing staff, who felt as though there wasn't too much of a problem, and the administrative staff, who described things as being more challenging.
D	Low	High	Fragmented	There was no single staff member identified here as a lead for the programme. Practice D did describe slightly higher levels of animation with changes discussed at the weekly meeting of PNs as well as being diffused ('trickling down') to the administrative staff. Both the PM and PNs described managing the frequent changes to the programme as problematic and stressful, requiring discussions and meetings to make sense of the

				frequent schedule alterations. This retrospective view certainly affected their anxiety when new changes were introduced, which could be interpreted as a relatively narrow, but unified account of their experience. This had not resulted in significant amendments to the existing system.
E	Low	High	Fragmented	Practice E was in a slightly different position that resulted in fragmented sensemaking as two practices had recently merged to form one larger practice. There was no clear locus for sensegiving. Although several staff identified a long-serving PN as a lead for the programme, she herself demurred saying that organising and information sharing were diffuse. The management and administrative structure were undergoing a significant overhaul and so senior management was focussed on managing the change and implementing new systems, with little clear consideration of vaccination as a defined area. The fragmentation here did result in multiple narratives, particularly in terms of organising. Communicating was done informally with the PNs responsible for diffusing information to other staff groups. Although there was a practice meeting in place where it could be discussed, this had not been used in recent memory. Of note the HCAs, who could do vaccination, but felt under-used, reported that the administrative staff needed updating on their capabilities. Interestingly, the PN did describe the loss of a specific meeting where vaccine performance data were discussed. Much of the retrospectivity here was in terms of how there were previously meetings and systems in place to monitor performance, but this has since stopped being a priority for the population.
F	High	Low	Restricted	There was relatively little content on organising in the single, mixed interview at practice F, so this could potentially be classified as minimal as well. However, there was one long-standing PN who did have well defined responsibility for informing other staff about programme changes and therefore I have evaluated this as potentially having high control of sensegiving. This same nurse also had responsibility for undertaking most of the clinical vaccination activities leading to a likely situation of high control. There was also relatively little discussion demonstrating involvement from the management staff in delivering the administrative component, and so little evidence of animation.
G	Low	High	Fragmented	There was no formal mechanism through which sensegiving was enacted to staff involved in vaccination at this practice. Some of the administrative staff had well circumscribed roles in managing aspects of the programme, senior managers did not have detailed oversight. Responsibility was diffuse amongst ‘everybody’. As a result, there was relatively high animation at this practice. Vaccination had been discussed at the full practice meeting that happens every two months. As a result of the higher level of animation, the practice had tried to improve coverage with interventions to try and get pre-schoolers in. The system is described as

				'reactive system', which may be a result of the lower levels of control (particularly for future planning and vision setting), but high animation (with staff actively discussing emergent issues). Perhaps despite the fragmented sensemaking the practice narrative was fairly unified across staff groups.
H	Low	High	Fragmented	Practice H was in a similar position to G, although possibly with a slightly higher level of control over some aspects of the programme. There was no defined leader for vaccination, nor any regular meetings where vaccination was discussed. However, there was a lead administrator who had a very high level of responsibility for both the reminder/recall activities and also looking after and updating the 'baby clinic protocol', which determined how the intensive baby vaccination clinics were run. While this did provide some element of sensegiving, it was in a relatively restricted format and did not result in labelling of emergent issues in a way that allowed them to be discussed by all practice staff. There was however high animation, particularly informal discussions between staff groups when changes were introduced and the protocol had to be altered. Overall there was a general practice narrative of doing a good enough job, despite some challenges within the population. However, this was partly at odds with their overall performance, which could be improved. Certainly, the focus at the practice was on the procedural elements of running the baby clinics more than anything else.
J	Low	Low	Minimal	Although this was the only practice with a GP involved with an interest in and oversight of the programme, there was low control at practice J with no clearly defined lead for the programme and with limited involvement of senior administrative staff, including the practice manager. Although the nurses did have a morning meeting where vaccination could be discussed in an informal way, there was otherwise relatively low animation between staff members, with information being shared primarily via email. Much of the retrospective sensemaking was focussed on how things had been tried in the past and was both high effort and unsuccessful, leading to low motivation to change practice in the future.

Table 11: practices categorised by level of control, animation and type of organisational sensemaking exhibited.

6.3.3.7 Sensemaking conceptual framework

I have integrated these characteristics of sensemaking and sensegiving within the practices into the framework adapted from Checkland (2007) that is presented in 5.4.2.3.2 (Figure 9) to create a summary of the issues across practices.

1. Sensemaking

The analysis above demonstrates the challenges of sensemaking within the complex GP practice environment. In most practices limited sensegiving was observed, leading to either fragmented or minimal organisational sensemaking in relation to the vaccination programme. In most cases new information was received by multiple staff and then either informally distributed or passively diffused within the practice. Making sense of this information was achieved through corridor discussions, ad-hoc meetings, or in small professional groups. In the case of practice F, where one PN had a significant leadership role in managing the programme, this resulted in the decision-making largely resting with one person with limited involvement of other professional groups within the practice. This led to an appearance of a relative lack of agency by practice staff in organising and implementing changes to the activities or administration of the vaccination programme, possibly due to a lack of a coherent narrative about past performance and future ambitions, in part resulting from the limited interpreting of performance data undertakes by practices.

2. Vaccine structure and processes

One similarity across the medium and larger practices was that the clinical system and the administrative system were relatively separate, with little communication between clinical and administrative staff in the management of the programme. The distribution of administrative tasks to administrators, receptionists, HCAs or nurses rarely appeared to have been planned, but instead emerged as a result of organisational structure and, often, the availability of certain members of staff to undertake specific functions. This led to relatively high levels of variation in role, particularly for administrative staff. Aside from practice F, where authority for the programme was concentrated in one long-serving practice nurse, in all other practices management responsibilities were either non-specific or diffuse between multiple different staff. This resulted in the finding that practices primarily engaged in minimal or fragmented sensemaking. Decisions about the organisation of reminder/recall activities often lay with the PM, but not in all cases. For example, at practice H there was one administrator with a high level of management authority on the programme’s administration, with relatively little input from the PM. In several cases, organisation of reminder/recall activities were simply continued from historical processes, without any active management consideration.

3. Pattern of responses to change

At most practices the frequent minor changes to the program were simply diffused through the practice staff and the required changes integrated into existing practice. However, four of the practice found these frequent small changes difficult or stressful to manage (B, D, E, J). Due to the fragmented nature of sensemaking and a relative lack of sensegiving overall, it appears that this may in part reflect the high levels of animation required to discuss and diffuse the changes between practice staff. None of the practices reported a self-initiated intervention or programmatic/administrative improvement to try and improve coverage in the general population or a specific population group.

4. On-going practice narrative

Situating was actively undertaken by staff at all practices and was an important factor in how they viewed the relationship between the practice, the population and vaccination activities. The outcome of this largely fell into two categories – those who felt that they had a relatively responsive population who readily attended for vaccinations (A, D, E, F, H) and those with complex populations with higher perceived rates of DNA and lower vaccine coverage (B, C, G, J). Where the population was viewed as difficult or challenging patients were often labelled as not being bothered, or suffering from general life chaos that prevented them either from attending or from also using up the practice's resources. The outcomes for this could either be a very passive attitude in the face of a complex population (e.g. practice J), or a militaristic approach of 'battling' with the population (e.g. practice B).

For many of the nurses, vaccination was an unpleasant, but morally important activity to undertake and thus was framed in terms of acting in the best interests of protection children from future harm, despite causing immediate pain. This narrative was not extended to adult patients, who were viewed largely as consumers of offered services, so if they did not respond or attend, limited resource was applied to encouraging or reminding them to come in for vaccinations.

5. Changes in environment

Stages 3 (patterns of response) and stage 4 (ongoing narrative) did appear to determine the response to changes in environment, with those practices with challenging populations and experience of stress when managing the frequent small changes made to the programme (B and J) reporting the greatest difficulty in vaccinating their populations. The responses between these two practices, however, were different, with practice B taking a combative approach with their population, likely as a result of their situating as having a high level of responsibility to care for a relatively deprived population. Whereas, practice J, with minimal organisational sensemaking, very limited sense-giving within an extremely busy practice, with high levels of contact for childhood vaccinations particularly, largely took a passive approach to managing the changes, and simply integrated them as best they could.

6. What counts as legitimate work?

Interestingly, vaccination was almost universally viewed as not being legitimate work for GPs or GP registrars, and responsibility for the clinical aspects of vaccinating lay very strongly with the PNs. This had the effect of removing the discussion of vaccinations from senior management meetings (often called partner meetings, or clinical meetings) and PNs often described the GPs as not being interested in vaccinations. This also removed vaccination from a concentrated sensegiving environment, and this could have caused the diffuse communications, fragmented or minimal sensemaking exhibited at these practices. The clinical aspects of vaccination were firmly held as legitimate work for the nurses, requiring special expertise and a moral compass to be able to cause distress to children and parents for the longer-term benefit. This did however have the effect of reducing the legitimacy of HCAs in undertaking vaccination activities, and, aside from influenza vaccination, HCAs undertook relatively few vaccinations at any of the practices. The distribution of administrative tasks between PNs, HCAs, receptionists, administrators and managers partly appeared to be as a result of historical norms, with the allocation of certain tasks to long-standing staff-members who had always performed those roles, and partly through the views and initiatives for the PMs. There were a few examples where aspects of the vaccination programme had been allocated to specific administrative staff, e.g. a finance specialist, or a targets manager, and several of the practices had nominated lead administrative staff with responsibility for the reminder/recall and appointment booking activities. However, this was often felt to be a significant burden on practices, particularly the busier practices with high DNA rates, and several expressed a wish for this administration to be removed from within the practice. This experience had also affected several PMs' views on the most efficient way of managing the reminder/recall process, either with a preference for telephone calls, or letters.

7. What is the distribution of power?

Although several of the practices had individually powerful members of staff, particularly practice managers, this had relatively little impact on the vaccination programme. This was because of the relatively separate administrative and clinical functions, each with a locus of power around either a senior administrator or a PN respectively. Due to the relative lack of sensegiving opportunities and the informal communications mechanism, there was rarely an opportunity for power to be specifically directed towards modifications to the programme. One example where this was not true was practice A, where the PM reported being able to 'crack the whip' and increase activity levels to achieve higher levels of coverage, when staffing was high and areas of performance improvement had been identified. This type of intervention was not described at any of the other practices.

6.3.3.8 Reflection on methods

The interviews generated a very large volume of data and has enabled the portrayal of a rich picture of the challenges and experiences of delivering vaccinations at each of the different practices. Some interviews were more fulsome in the level of data generated than others, with single professional group interviews (e.g. with two or more PNs) generally generating the richest exploration of issues due to the sharing, agreement or contradiction of experiences. The interviews with individuals tended to be shorter and provided less opportunity for a detailed exploration. The group interviews were more difficult to manage and sometimes were dominated by a particular personality, often a PN who may have considered vaccination to be their area of particular expertise. The mixed group interviews did however also provide unique opportunity for sharing of professional experience between groups, which often did not appear to happen in the practices more generally. This created some of the most interesting data. However, the interview data were necessarily limited by the semi-structured interview format and it is likely that some of the reporting in relation to both staff experiences and the underlying sensemaking is incomplete or inaccurate compared to what actually happens in practice. This may particularly be the case where some staff were deferent to other, more senior staff in interviews at each of the practices. Occasionally staff qualified negative comments with apologies that they knew some of what they were reporting was not deemed appropriate, or attempted to rescind the comments quickly afterwards, which may suggest some underlying reporting bias.

All of the data were easily categorised into the five overarching gerund categories (situating, communicating, organising, experiencing and interpreting). However, this was largely because these categories were very broad and allowed significant overlap. Several areas of content could fit in several of the categories – for example the description of staff roles, which was partly an exercise in situating, but also of organising. Similarly, with the descriptions of situating parents and patients, which involved a significant amount of experiencing as well. Overall these categories did provide a useful framework to identify the main processes underlying the sensemaking at each of the practices, while also covering all of the main issues.

The impact of the analysis of sensegiving and resulting categories of organisational sensemaking on overall practice performance is not clear from this analysis. There was little sensegiving from leadership at any of these practices, but this did not have a clear association with overall practice performance. It is possible that although fragmented or minimal sensegiving is manageable within a smaller practice without a significant impact on performance, at larger practices this may result in a more limited ability to be able to improve the programme to increase coverage. However, based on the data presented here it is difficult to separate this effect from the other programmes and activities undertaken at each of the practices, particularly how vaccination is integrated into other nursing and administrative activities such as health checks for specific diseases.

Understanding the impact of the different types of organisational sensemaking could be undertaken with further ethnographic work, observing the way sensemaking takes place in practice. This would add much needed detail to these pictures.

7 Discussion

In this element of the thesis I will focus on integrating the results from the quantitative and qualitative work in relation to the research questions and relate this to the wider literature, as well as drawing overarching recommendations in relation to programme implementation. I have collated the quantitative outcomes presented in the results section into Table 12 for ease of reference throughout the discussion.

7.1 Major findings

There are several important epidemiological trends that motivated conducting this study, including: multi-year reductions in childhood vaccination coverage; persistent lower coverage in urban areas and particularly in London; long-standing inequalities within certain population groups, notably in areas of deprivation and in certain ethnic groups; and generally low coverage of vaccinations in adults, with some underlying inequalities in certain population groups. Alongside this is the increasing negotiated cost of delivering an increasingly complex programme, with more vaccinations being delivered to more population groups.

Overall GP practices design and delivery vaccination activities within a complex and opaque policy and funding system that provides relatively little oversight and support. This has created a system where there is high implementation fidelity of the clinical components of the programme, but low fidelity for organisational and administrative activities. As a result, although there were core areas of similarities of programme implementation identified, there were also significant areas of difference particularly in terms of appointments structure, reminder/recall systems and task allocation between staff groups. In part this was determined by practices' responses to local population factors, including the behaviours of populations groups in accessing vaccination services, such as providing services to patients who did not speak English as a first language, or who had received some vaccinations abroad, as well as the impact of patients who regularly did not attend booked appointments, or who had chaotic lives and did not attend for vaccinations. The resulting structural differences had effects on the capacity of practices to offer sufficient appointments to their eligible child and adult populations, which may explain some of the variation in coverage achieved. These factors also had effects on the costs of delivering the programme, which were extremely variable between practices. Overall it is likely that reimbursement levels at least meet the costs of delivering the programme, however activity, performance, costs and funding received are not clearly associated at practice level within the current system. Practices individual ability to be able to recognise these challenges and modify programme delivery to improve coverage was limited because vaccination was not conceptualised as a discreet programme entity at practice level, but instead delivered alongside the many other services offered at GP practices. This then limited opportunities for sensegiving to take place by both programme leaders and practice staff. There is thus also a disconnect between the national policy environment, in which the vaccination programme is a discreet programme entity, and the experience at GP practices, where it is blended with the overall activities of the service. However, although the clinical components of the programme were followed very closely by practice staff, there was limited evidence that national and regional policy direction and programmatic support was effective in supporting or modifying non-clinical aspects of service delivery. In the following sections I have synthesised the findings from the quantitative and qualitative components to answer each of the research questions.

	Mean	A	B	C	D	E	F	G	H	J
Urban/Rural status (a)	-	R	U	U	R	U	R	L	R	L
List size (b)	7,000	4,600	6,600	7,000	8,100	12,600	13,800	14,000	16,000	20,000
Demography										
Deprivation decile (b)	-	8	2	1	8	10	7	4	6	4
Minority ethnic groups (%) (b)	-	1.6	6.2	12.0	1.3	1.8	3.4	30.3	2.1	41.4
Aged 0-4 years (%) (b)	5.7	3.3	7.3	5.7	4.4	4.6	5.0	5.0	5.4	7.7
Aged 65+ years (%) (b)	17.3	31.6	10.4	13.6	30.4	23.6	21.5	11.3	18.9	11.8
Childhood										
DTP-IPV-Hib 3 doses by 12 months (%) (c)	93.4	98.9	96.0	97.3	96.0	98.9	98.7	78.7	90.6	91.2
MMR 2 by 5 years (%) (c)	87.6	94.4	94.2	95.5	98.3	94.4	93.1	69.6	85.1	88.4
Appt length (mins)	15.9	20.2	15.4	22.0	13.9	18.1	9.8	18.3	9.0	16.7
Appts/child	-	1.53	0.76	1.01	1.56	1.28	1.01	0.81	1.20	1.24
Cost/appt	£18.20	£25.97	£15.14	£24.91	£9.71	£18.17	£15.75	£20.66	£10.12	£23.41
Relative system cost	-	1.33	1.11	1.43	0.84	1.04	0.70	1.02	0.61	0.93
Adult										
PPV (%) 2017-2018, 70-74 (d)	70.2	79.0	71.3	81.9	83.3	88.7	56.1	64.4	65.6	42.9
Appt length (mins)	10.4	9.2	11.2	14.1	8.7	6.8	8.0	13.3	9.1	13.5

Appts/adult	-	0.45	0.38	0.57	0.17	0.04	0.19	0.11	0.11	0.17
Cost/appt	£14.05	£17.13	£13.47	£20.88	£7.82	£11.31	£14.94	£14.17	£7.59	£19.17
Activities										
TVPT ratio	-	1.86	0.98	1.84	0.89	0.55	0.63	0.75	0.55	0.96
Non-clinical admin	-	65.1	64.3	64.8	54.1	52.6	60.9	60.3	67.0	48.4
Clinical admin	-	34.9	35.7	35.2	45.9	47.4	39.1	39.7	33.0	51.6

Table 12: a summary of the demographic and performance characteristics of the included GP practices alongside an overview of the quantitative results derived from this study

7.1.1 *What are the similarities and differences between GP practices in different contexts in how the routine vaccination programme is organised and implemented? And what organisational factors related to programme delivery may be related to overall performance?*

Prior to this study, little was known about how GP practices organised the implementation of routine vaccination activities and how this may impact on overall performance and coverage achieved. Through this study I have identified areas of significant similarity between a diverse range of practices in how they implement the vaccination programme. However, there are also significant areas of difference, which highlight how practices respond to differences in organisation to meet the needs of a range of populations and may go some way to explain differences in coverage between practices.

The CDVC and detailed process map for routine vaccination demonstrate 14 key activities undertaken at all practices. These similarities suggest that important areas of vaccine programme delivery have high implementation fidelity based on national guidance and contracting arrangement, despite the opacity of the overall documentation related to programme requirements.

However, there were also significant areas of difference in core programme areas, with the greatest areas of variation in implementation between practices found to be the method of reminder/recall activities; structure and distribution of vaccination appointments; and task allocation between staff groups. These factors led to wide variation in the time spent between practices, ranging from 9.0-22.0 minutes for childhood appointments and 6.8-14.1 minutes for adult appointments. Of the total practice time spent on vaccination, a very high proportion (almost two-thirds on average) was spent on administrative activities, demonstrating the high level of administration required, particularly for appointment booking, reminder/recall and data collection and submission.

Although appointment length and total practice time did not appear to be related to coverage, capacity in terms of appointments delivered per eligible population may be, which presents an important area for further exploration. This indicator of capacity was linked to how practices had responded to demand side factors relating to their underlying population and the resulting structure for delivering appointments. The decision of practices to offer a baby clinic (primary vaccinations), a child clinic (any age vaccinations) or for children to be vaccinated at any time during the week depended on two factors: the preferences of local staff (particularly nurses), and the number of DNAs. Practices that experienced high level of non-attendance at appointments found specific clinics difficult to manage. This did have a knock-on effect on the mean length of appointments at each practice, with the shortest appointments at three of the practices with clinics (H: 9.0 mins, F: 9.8 mins, D: 13.9 mins) although practice C also had a clinic alongside long appointments (22 mins), which created a relatively high cost, high time system overall. The Royal College of Nursing has recently released guidance recommending that vaccination appointments should be 20 minutes long at a minimum (RCN, 2018a), with the rationale that this allows sufficient time to avoid vaccination errors (Lang *et al.*, 2014). This chimes with the description of the concern about drug errors in the faster clinic appointments used at practice H and D. On average, the first appointment and the 12-month appointment were longer than the others (21.1 mins, 17.2 mins respectively), with the others closer to the mean of 15.9 mins, and so it seems reasonable that given the amount of information required in the first appointment and the challenge of delivering four injections to a 12-month old, that these appointments may need to be longer. However, overall, it's likely that practices know their populations well and can structure a safe and effective appointing system to suit their organisation. There are areas of consideration however that could increase capacity and possibly coverage where coverage is low, including changing the length of some appointments to be able to increase overall capacity.

For the purposes of this study capacity is broadly considered to be the practice's ability to provide services to meet the needs of the local population. For children, I evaluated this by estimating the number of annually available appointments in relation to the population of children aged 0-4, who make up most vaccination recipients. This does mean that any variation in the number of appointments delivered in the study week will be magnified over the year, but it does provide a preliminary estimate. Practices A and D had the highest number (1.53 and 1.56 appts/child respectively) and are small-medium practices in rural areas of low deprivation with high coverage. Practice B had relatively lower capacity (0.76 appts/child) and slightly lower coverage. Practice G (large practice in London) also had lower capacity (0.81 appts/child) and significantly lower coverage; whereas practice J (large practice with high number of registered children in London) had higher capacity (1.24 appts/child) and somewhat higher coverage overall. There did not appear to be any relationship with the number of appointments available for older people at any of the practices, aside from to note that the overall number of appointments was very low in relation to the population, ranging from 0.04 (practice E) to 0.57 (practice C). This is likely to be distorted by the large number of appointments and concurrent vaccinations given in the seasonal influenza campaign.

There was variation between practices in terms of their reminder/recall activities to patients. There is good systematic review evidence that reminder/recall systems increase coverage in children and adolescents (Williams *et al.*, 2011; Niccolai and Hansen, 2015; Jacobson Vann *et al.*, 2018). All practices except for G and J had a reminder/recall system in place for children. Practice J did have a system of inviting for a first appointment, but then limited reminders to get patients back in or follow-up if they did not attend. Their ability to provide appointments appeared good (1.24/child), therefore some additional extra effort in reminding and recalling patients may increase their coverage. Practice G had the lowest coverage and a low number of appointments per child (0.81). Their system was described as reactive and opportunistic rather than being active. A more active reminder/recall system is likely to be key in improving their coverage, although one of the PNs noted that they always felt short of appointments. Of note both practices are in London, and the effect of reminder/recall systems in London practices is explored in more detail in section 7.1.6 below.

For adults, vaccination across all practices was largely opportunistic or associated with the seasonal influenza vaccination campaign. Using the data from the study period the overall number of appointments per person aged over 65 years was low at all practices (from 0.04 at E to 0.57 at C), suggesting that most of the vaccination for PPV was done at another time. Of note, the three smaller practices provided a larger number of appointments per patient (0.38 to 0.57) suggesting a higher proportion of their adult vaccination was undertaken outside of influenza season. In the smaller practices this appeared to be sufficient to vaccinate a high proportion of their population, however the four larger practices (F, G, H, J) had very low adult coverage using these opportunistic systems.

The organisation of vaccination activates was also related to the task allocation between different professional groups within the practice. There was a significant role for practice nurses and administrators, with a smaller role for the practice manager and HCAs. There was significant variation in the profile of administrative staff involved depending on the overall practice size and structure. At the practices included here doctors had little involvement in vaccine programme design and delivery. This type of variation in workforce distribution (and lack of role for GPs) in health protection services has previously been documented for screening in type-2 diabetes (Graffy *et al.*, 2010), and there is high variation in staffing profiles amongst different GP practices even of the same size (National Audit Office, 2015).

These differences in service delivery structure were related to several important population demographic factors. Providing vaccination services for patients who had vaccination abroad or whose first language was not English added significant amounts of time to the workload of practice nurses, in terms of arranging translation where required, but also following the protocol to work out what vaccinations a child is due. The added complexity of providing primary care to children of recent migrants has also been reported in other qualitative work, where it was highlighted that the funding system does not sufficiently take into account the additional workload required for these populations (Gill *et al.*, 2012). Similarly, in practices with higher levels of deprivation practices reported significant challenges with achieving high levels of coverage in patients who either did not respond to reminder/recall activities or who did not attend booked appointments. This created a significant time and cost burden to practices where these factors existed in the same population, causing particularly challenges with meeting coverage targets.

Data collection and submission is a significant administrative activity associated with the programme and impacts both on the costs to the practice, but also is the method through which practice receive reimbursement for their activities. Overall the data collection system for the vaccination programme is understood by actors involved in the system and functions well in terms of the analysis undertaken by

PHE, although there are elements of production that are challenging and could be modified to improve both reliability and data quality. The system is limited in terms of dissemination to GP practice level.

From the perspective of the practice, the process of collecting and submitting data to the CHIS system for the COVER programme is complicated and time-consuming, adding to an already high administrative burden. Non-clinical tasks consumed 60% of practice time spent on vaccination, ranging from 48% to 67%, with more than half in all but one practice (J). Although this included reminder/recall activities and ordering and stocking of vaccines, a large portion of this was for entering activity data to both Open Exeter and CQRS. Larger practices had a nominated member of staff, often a specific administrator, whose task it was to be responsible for the data submission. The newer ImmForm system, which also hosts the ordering facility, extracts data automatically from GP practice records and could be a tool for reducing overall burden for managing the administrative data for the programme and generating more timely and accurate coverage estimates (Edelstein *et al.*, 2017). However, this does not yet include all GP practices and excludes non-registered populations, whereas these are included in the COVER data system.

Data are not readily available at practice level through COVER or ImmForm (Edelstein *et al.*, 2017). The UNIFY2 management data are publicly available at GP practice level via an online dashboard, however there are significant issues with data quality and they are not considered official statistics (NHS Digital, 2017a). None of the practices used external data sources to monitor or evaluate their performance. Instead, for children, all practices relied on vaccinating those identified on the list from the CHIS, or by estimating the number of children who had come through the clinics. None of the practices monitored coverage of adult vaccinations. Staff at some of the practices reported wishing they received feedback on their performance, and others reported being motivated by seeing disease reduction in epidemiological data via the Vaccine Update email. None of the practices reported receiving information, advice or encouragement from SIT members in relation to their performance.

7.1.2 How are organisational factors related to the costs of delivering the programme?

The impact of the differences in service design and overall levels of activity was quantified through an analysis of the costs of delivering the vaccination programme at each of the included practices. The mean cost to each practice of delivering a childhood appointment was found to be £18.20 and ranged from £9.71 to £25.97 with an adult appointment costing £14.05, ranging from £7.59 to £20.88. The mean cost for delivering an individual childhood vaccination ranged from £4.72 (during a 12-month appointment) to £9.55 (for a pre-school booster).

The costs identified in this study (presented in 6.2.2) are of primary use to payers for the vaccine system (NHS England and the DHSC) to assist in calculating an evidence-based reimbursement rate for vaccination activity and a robust funding system, as described in 7.1.5.2. However, it may also be useful for practices to determine if there is a better way of using their available resources. Neither absolute (cost per appointment) or relative cost (system cost) had a clear association with overall coverage, although the sample size was too small to undertake statistical analysis. Smaller practices (A, B, C) had higher cost systems as they used more expensive staff, however they also had higher coverage. The low-cost system in practice H did not also achieve high coverage, but may have used up a lower amount of practice capacity. Practice G had high costs, low activity and low coverage. Organisational factors contributing to lower costs include: shorter allocated appointment length; greater use of administrative and reception staff; less time spent by higher salaried staff (such as the practice manager and practice nurse) for administration; and use of HCAs for adult vaccinations. Further work should be conducted in a larger sample to evaluate the impact of the cost base of GP practices with the vaccination coverage they achieve.

Despite the limitations of the available cost and reimbursement data for comparison, the results of the paper presented in 6.2.2 are that it is likely that payments to the GP practices in this study met the costs associated with delivering the programme, although this could not be confirmed for each individual element. However, it is not clear how the funding system affects organisation of service delivery nor activity levels, with variable performance found between high and low-cost practices. This was modified by the fact that staff at most of the practices included here were neither aware of their performance nor the implications of this in terms of the funding system. Overall, from the perspective of the practices involved in this study, payments in relation to vaccination were largely divorced from any association with the activity itself. Neither clinical nor administrative or management staff reported being particularly motivated by the fee-for-service payment, although the threshold payments for childhood vaccinations did occasionally come up in the interviews, especially when a practice was slightly under target. Practices with low adult coverage did not report being motivated by the fee-for-service payment to increase activity. The timeliness payments were never discussed. Thus, in most cases identified here, the vaccine reimbursement system acts largely as a fixed payment that is relatively insensitive to either coverage or activity, except at the very edges of the thresholds. This is despite the reported high level of administrative burden associated with making the vaccination returns to Open Exeter, the CHIS and Calculating Quality Reporting Service (CQRS), as well as following up payments with NHS England where necessary.

7.1.3 How and why GP practice staff undertake organising vaccine programme delivery?

To evaluate and compare differences in organising I undertook a sensemaking analysis to evaluate how and why GP practice staff organised vaccination programme activities. When organising programme delivery, most practices exhibited either fragmented or minimal sensemaking, characterised by low levels of leadership sensegiving with either high or low levels of stakeholder sensegiving respectively. This may limit the ability of practices, especially larger practices working in complex environments, to be able to modify programme delivery to improve coverage.

The most significant finding was that practices mainly exhibited fragmented sensemaking (B, C, D, E, G, H) with either minimal (A, J) or restricted (F) at the others. Organisations that exhibit fragmented sensemaking are prone to producing multiple, individual accounts of the organisational process, which are not often integrated. This matches the picture at many of the practices, with little inter-professional communication about objectives, performance or programme delivery. Minimal sensemaking can result in a lack of spontaneous development of narratives around organising, creating only a nominal account of issues that arise. Part of the reason for this was because within both fragmented and minimal contexts there was neither a process (e.g. a formal meeting) nor an actor (e.g. vaccination lead) to provide an opportunity for control of sensemaking by the provision of sensegiving. This may be an underlying cause for why many of the practices found the process of managing change stressful (J), chaotic (B), scary (D), difficult (E), or challenging (A).

In 2011 a review was published evaluating the role of middle managers and GP management practice within primary care organisations, which involved a review of the literature and qualitative case studies within primary care management organisations (Checkland *et al.*, 2011). This highlights the role of managers in translating from external sources and experiences into the context of the organisation and how involving a manager in strategic development can improve organisational outcomes. Some of this role is mediated through sensegiving, with active attempts by managers to implement strategic change, particularly in terms of presenting a desired future state of affairs (Gioia and Chittipeddi, 1991; Weick, Sutcliffe and Obstfeld, 2005). This is not to suggest that practices should employ a manager for the vaccine programme, but that there should be consideration of how sensegiving can be triggered or facilitated within GP practices, particularly in circumstances where coverage is lower than required. This may be particularly important where issues are ambiguous or unpredictable, such as frequent or substantial changes to the programme, or indeed after a significant health system reform (Maitlis and Lawrence, 2007). However, it was notable that in none of the practices was there a clear lead for the programme as a whole, with responsibility for monitoring and improving performance and responsibility for the clinic, administrative and financial tasks often sitting with different individuals. There was also no evidence of programme leadership from local SIT or SILs. Increasing sensegiving might move practices from fragmented to guided sensemaking, which could better unite staff around a shared goal.

However, from the perspective of practice staff, vaccination was not conceptualised as a discreet programme entity and instead integrated within overall practice activity. This resulted in a mixed perspective on how vaccination was prioritised within the overall workload of the practice, with some practices reporting achieving high vaccination coverage as an important organisational priority, with others reporting that it was simply considered equal to all the other service delivery requirements. It is likely that organising vaccination is more related to organising at the general practice level overall, rather than having a specific organisational structure separated from the overall practice organisational management system. This potentially limits the ability for changes in vaccine programme organisation and management to be implemented.

7.1.4 What is the role of GP practices within the overall vaccine programme delivery system?

GP practices are the core service delivery entity for routine vaccinations, however their role within the overlying public health system is relatively opaque and described in a wide range of documents that are updated by multiple national government agencies and other institutions. This has created a disconnect between the policy forming organisations, funding system and is likely to have a significant impact on practices' ability to change service delivery structures to improve coverage.

The logic and assumptions underlying the delivery of routine vaccinations have been defined for the first time in the logic model presented in section 4.3. The complete picture is described across many documents, not all of which are easily accessible, nor easy to understand, because they have been written by multiple government agencies over many years and, while some are updated annually, others are updated sporadically. This highlighted that many potentially modifiable programme delivery factors have not been investigated, particularly amendments to aspects of routine programme delivery such as the payment and contracting systems.

One important finding from this study is that there is no overall strategic framework to which service delivery organisations can refer to understand the direction and ambitions of the programme. Vaccination does feature in several high-level documents, including in PHE's 2016 *"Strategic plan for the next four years: better outcomes by 2020"*, which gives ambitions to expand the flu programme to children and review the ordering and distribution system (PHE, 2016b). Progress against these was reviewed and described in the 2016/17 PHE Annual Report, which contains further commitments to increase flu vaccine uptake in eligible groups, as well as describing progress on the roll out of flu to children and the review of the vaccines ordering system (PHE, 2016a). However, similarly to the Delivery Framework and Operating Model, these are technical documents describing the structure and function of the system. Vaccination does not feature in NHS England's *"General Practice Forward View"* document (NHS England, 2016b). NHS England does update and release the annual *"Public Health Section 7A Commissioning Intentions"* document, however this is largely technical in describing what services will be commissioned in the forthcoming year (NHS England, 2016c). As described in the logic model, the most detailed statement of the purpose of the vaccination programme is found in the *"NHS public health functions agreement 2016-17: core service specification, national immunisation programme"*, which again is updated annually and contains statements on the scope and objectives of the programme (NHS England, 2016c). This is then supported by the 17 individual service specifications for each disease/vaccination specific programme (NHS England, 2018). The complexity of the system means that, aside from vaccinating their population against the diseases described in the routine vaccination schedule, practice staff were generally unaware of both their current performance and the priorities and targets set by national government agencies, even when these were supposedly incentivised through the funding system.

As a result, practices were also relatively isolated from the overlying health systems architecture and acting independently when delivering the programme. From the core service specification document, much of the emphasis for local implementation is placed on the PHE Screening and Immunisation Teams (SIT), who are embedded within NHS England area teams. Their role is described as *"taking a lead in ensuring that inter-organisational systems are in place to maintain quality of the immunisation pathway"*(NHS England, 2017). However, none of the staff at GP practices in this study had meaningful relationships with local or regional arms of national governmental organisations responsible for public, and, in the interviews, staff struggled to identify the name of relevant local organisations or the designations of staff working at them. This would suggest that in practice this role for SITs may either be not well developed or not effective. The previous study of the immunisation system published in 2016 reported on the challenges faced by SITs during and following the transition process (Chantler *et al.*, 2016). These included having to move organisations, with the inherent disruption that entailed, as well as having to bring people together from across multiple new organisations to continue to manage the vaccination programme effectively. It also reported challenges with developing a team with sufficient skills to be able to deliver their role. SITs also reported a loss of both autonomy and responsibility within the new public health architecture, alongside the uncertainty of how the new system should work in practice. These challenges would certainly have been in place during the time-period of this study, which may have affected contact with practices. An alternative explanation is that the practices recruited here were all relatively highly performing practices and so may have not required significant input from the SITs, who would have better focussed their efforts elsewhere. Overall the ability of SITs to meet their responsibilities set out in the national service specification needs to be more fully evaluated as the evidence from the small number of practices collected here suggests that they have limited ability to affect or support change at practice level.

At a local level, GP Practices have a wide range of organisational priorities and deliver multiple services that are responsive to the needs of their local population, so a large element of their work is demand driven. Public health interventions and programmes require encouragement and support for otherwise well people to attend their GP practice to receive a service such as vaccination or screening. As a result, these programmes require separate systems for reminder/recall activities and data collection and submission, that are likely to be different from regular demand driven services. However, these services act in competition for GP practice time and resources, and thus in practices with significant demand for services from their local population (such as those in London) it's possible that this has reduced their ability to provide public health services, resulting in lower capacity for vaccination services. The focus of GP practices on providing services for individual patients rather than considering the population has a whole has been found in a previous large systematic review (Peckham *et al.*, 2015). These competing priorities and the dual role of GP practices in providing treatment and public health services simultaneously is not reflected in either the overarching policy context, nor in the contracting arrangements. Alongside this, GP practice staff have reduced access to other services and professional groups who previously provided links with the local community, especially health visitors. Similarly, the disruption caused by the implementation of the HSCA has created fragmentation of the local public health architecture, with regional variation in the role of the SITs and removal of public health professionals from NHS organisations (such as the PCTs) into Local Authorities, who have a more distant relationship with GP practices (Chantler *et al.*, 2016). However, in some areas groups of stakeholders have come together to improve vaccination coverage in recognition of local challenges. There are few examples of these in the published literature, but those that are available do provide models of how organisations within the post HSCA system can work together to improve coverage (Khatun *et al.*, unpublished; Cockman *et al.*, 2011). These models may be successful as a result of providing an overall public health view of the role of local GP practices, integrating the perspectives of the new organisational superstructure, including Local Authorities, CCGs, SITs and individual GP practices. It is important to note that many of these examples have received specific additional funding from various local or national sources as the level of coordination required is relatively high and so maintaining sustainability may prove challenging in the long run. Examples of these programmes are considered in more detail in section 7.1.6.2.

7.1.5 What aspects of vaccine programme delivery could be modified to improve coverage and how could this be achieved?

There are several elements identified from the results that may be contributing to programme performance that could be modified to improve coverage. To guide this section of the discussion I have used the categories from the World Health Organisation's Building Blocks Framework, as summarised in Figure 10 (WHO, 2007, 2010), to describe a theory of the causes and impacts of factors relating to the implementation of the routine vaccination programme and suggest potentially modifiable elements to improve coverage.

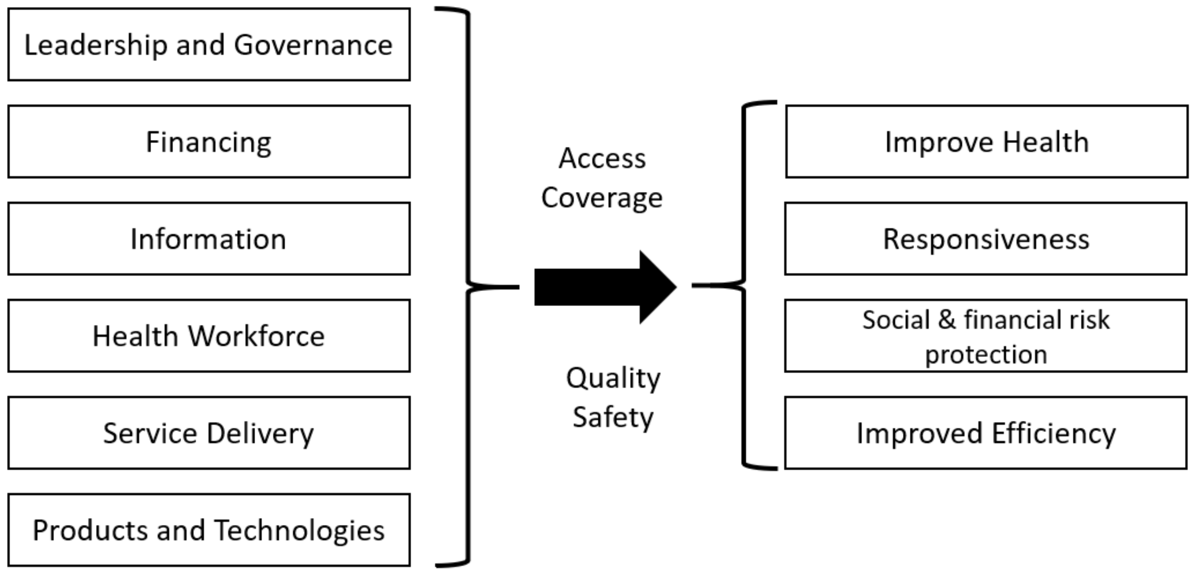

Figure 10: The World Health Organisation health systems building blocks. From WHO 2007.

Although there are a plethora of other available health systems frameworks (Hoffman *et al.*, 2012), the WHO framework has been very widely used and provides a useful frame for comparability between studies and countries. It has been criticised for lacking consideration of the demand side of the health system and for its static nature that neglects interactions between the different components (Mounier-Jack *et al.*, 2014). However, these elements are largely reported in the previous section, and instead it will provide an overarching set of widely understood categories through which to report and integrate the results. The framework involves six building blocks (leadership and governance, funding, information, health workforce, service delivery, and products and technologies), which are modified by four process elements (access, coverage, quality, and safety) and effect four outcomes (improved health, responsiveness, social and financial risk protection, and efficiency). I will consider the health systems elements of this thesis for each of the building blocks as modified by the process elements, with consideration of the effect on the outcomes.

7.1.5.1 Leadership and governance

The overlying public health system architecture is opaque and complex, with limited ability to support change within GP practices. Thus, this study has identified several areas where changes to leadership and governance components could be made at national, regional and individual practices level to improve coverage.

At national level, although the programme is described in detail across many different documents, none of these provide a clear overall direction to the programme, nor clearly communicate goals to stakeholders, including GP practices. This situation could be improved with the development of a vaccine programme strategic plan. Ten core activities have been proposed that form an essential part of strategic planning (Bryson, 2011):

1. Agree a strategic planning process
2. Agree organisational mandates
3. Clarify organisational mission and values
4. Asses internal and external environments
5. Identify strategic issues facing the organisation
6. Formulate strategies to manage these issues
7. Adopt strategic plan(s)
8. Establish and organisational vision
9. Develop and effective implementation process
10. Reassess strategies and process

In actioning these components, part of the challenge is that there is no one organisation with overall responsibility for programme delivery. However, considering the vaccination programme as a single entity with the tripartite group as having responsibility for strategic planning, within this system, organisational mandates (2) have been clarified and are understood by stakeholders, the programme has a clear mission and values (3), and, largely through the work of JCVI the external environment has been assessed (4). However, currently lacking is a strategic planning process (1) with facility for reassessment (10). There is some element of internal environmental assessment (4), but information on strategic issues facing the programme is presented in a highly diffuse manner, and there is no overall vision or agreed strategy to manage the issues (6, 7, 8). Component 9 is important to consider, as the information contained in the documents described above does not penetrate to general practice level, as only documents regularly used by the practices included in this study were the Vaccine Update email from PHE with associated updates to The Green Book, the Routine Immunisation Schedule, and the PGDs required for vaccine delivery (PHE, 2017a, 2017b, 2018j, 2018b). However, these primarily focus on the clinical aspects of service delivery rather than considerations of the health system, and the Schedule with accompanying guidance in The Green Book is the primary mechanism for modifying implementation at GP practice level. This was very effective at changing practice in terms of who gets vaccination with what when, with high levels of fidelity found for the clinical components, but the ‘how’ was largely left to individual practice prerogative. The 2017 NICE Quality Standards for vaccine uptake in under 19s were not used in any of the practices included in this study (NICE, 2017). This is likely because there is no clear mechanism for generating awareness of these standards, not an actor responsible for the planning aspect of their implementation, both of which are important for successful implementation into practice (Spyridonidis and Calnan, 2011). When the CQC visits health services to asses quality of provision, the focus is largely on two areas: whether vaccine coverage is in line with local and regional averages and whether vaccines are stored safely and cold-chain maintained, and so this does not appear to be an effective mechanism for supporting the implementation of NICE guidelines.

At regional level there is an opportunity to increase the role of SITs in providing support and programme guidance to GP practices to provide evidence-based advice on how to amend service delivery to improve coverage, especially in areas of low coverage or through coordinating activities between local stakeholders to reduce inequalities in coverage within a specific population group. As a result of the implementation of the HSCA, the fragmentation of the overarching public health structures has created variation in the role and responsibilities of SITs and further work is required within this professional group to identify successful models and share best practices within different regions.

At local level, better information and support to local GP practice leaders could be used to improve coverage, particularly in areas of lower coverage. Many studies have found the presence of a leader to provide strategic direction for the vaccination programme as a positive factor for programme performance. This includes for the influenza programme, where having a programme lead is associated with high influenza coverage in a wide cross-sectional survey of practices (Dexter *et al.*, 2012); and in a detailed qualitative study of ten practices where the presence of a lead for planning and coordinating influenza vaccine programme was found in practices with higher uptake (Newby *et al.*, 2016). However, this has also been noted for childhood vaccines, where a cross-sectional survey of 257 practices in the north of England found practices with a strategic approach and clear objectives had higher MMR coverage (Lamden and Gemmell, 2008). The vaccine delivery system in the USA is more complicated than that in the UK with a wide range of provider organisations and systems for funding vaccinations within a range of national and local legal contexts. Here too programme leadership has been associated with higher coverage of childhood and adolescent vaccines in a range of healthcare providers (Groom *et al.*, 2010; Ransom, Schaff and Kan, 2012; Sussman *et al.*, 2015). More broadly the presence of engaged leadership has been proposed as a core component to the successful implementation of evidence-based interventions, for example, as a core component of the Consolidated Framework for Implementation Research (Damschroder *et al.*, 2009), and the PARHIS framework (Helfrich *et al.*, 2010).

There should be support for developing and implementing leadership roles both within GP practices and within the regional public health teams in relation to supporting improvements in GP practice performance in vaccination, although the mechanism for achieving this requires further work and testing in practice. That being said, the practices with high coverage in this sample also exhibited fragmented or minimal sensemaking. This may be because a lack of sense giving is less impactful when there are fewer staff and less need for a team-based unitary account of what is going on. This is explored further in the section evaluating the impact of size on performance (7.1.5.5.1 below). More broadly, leadership within GP practices has been proposed by The Health Foundation as a key factor for success in improving the quality of care, including improving performance against targets (de Silva and Bamber, 2014; Dixon *et al.*, 2015). However, this has been proposed alongside a range of other aspects of modification of organisational aspects of practices. However, it is unlikely that wider culture change initiatives will be effective at improving vaccination programme performance specifically. This is in part because vaccine programme delivery is not separate from the rest of the GP practice's activities, but also because there is not clear evidence for effectiveness of any proposed 'culture change' interventions (Parmelli *et al.*, 2011).

7.1.5.2 Funding

Similarly to the diffuse nature of the overarching strategy for the vaccination programme, there is no published rationale for the overall funding system. This is partly because it has evolved over many decades and is subject to annual negotiations (as described in 3.3.2), however some principles can be inferred from the current structure of the payment system:

i. A proportion of the costs of delivering the programme should be met through a capitation payment, which is currently provided by the 'global sum'.
ii. Timely vaccination of children (within 3 months of eligibility) is incentivised.
iii. Coverage of >90% of DTaP/IPV/Hib/HepB (3 doses), MMR (2 doses) and DTaP/IPV booster (1 dose) is incentivised. (I have excluded the 70% threshold here as this is met in almost all cases).
iv. High levels of activity for all other childhood vaccines is encouraged through fee-for-service payments.
v. Completing the course (2 doses) of rotavirus vaccine is incentivised (payment after second dose).
vi. Completing the course (3 doses) of pneumococcal conjugate vaccine is incentivised (payment after third dose).
vii. High levels of activity for adult vaccines is encouraged through fee-for-service payments.

From the evidence generated as part of this study it is not clear that these activities are effectively incentivised at practice level, except for coverage thresholds (iii) when a practice is close to the threshold payment. However, this finding would need to be clarified in a wider sample of practices to be generalisable. While timeliness, high overall coverage, and completing courses of vaccines are important, there is not a good evidence base to establish whether these would not be achieved if the payment system was restructured, particularly in the practices who achieve good coverage without consideration of the finance system, as there was no evidence identified here to suggest that staff at practices had a good idea that these incentives and thresholds were in place. In a wider sense, the challenges facing the vaccination programme identified in the introduction include multi-year reductions coverage, low coverage in urban areas, generally low coverage of vaccinations in adults, and inequalities in certain population groups in both children and adults. These challenges are not reflected in the current payment system but could be options for reforming the funding system, to make it more effective at incentivising activities to improve coverage in these areas.

Fortunately, funding schemes for primary care workers have been well studied, with several large-scale reviews available considering the effects of different mechanisms. These are particularly important as the nature of any proposed change to the financing system can have both desired and undesired effects on health worker behaviour. The characteristics of the funding and payment system that are known to be important include: i) the overall features of the system, including how, when and to whom a payment is made; ii) the characteristics, cues and concerns that organisations and individuals use to interpret the purpose of the system, including the balance between intrinsic and extrinsic motivational factors; iii) mediating factors that affect response to the system, including things like opportunity costs and other organisational priorities (Giacomini *et al.*, 1996). It's particularly important to consider how any reforms to the funding system are likely to impact on factors known to affect health worker motivation, including individual goals and values, the quality of the working environment (context and culture), and aspects of self-concept and individual efficacy (Franco, Bennett and Kanfer, 2002). The choice of payment system will depend on what is hoped will be achieved by the programme. Currently, GP practices receive 52% of their funding from capitation payments, 14% from QOF, and 10% from 'enhanced services' (which includes, for example, much of the fee-for-service vaccination activity), with 10% from dispensing and 14% from other sources (Marshall, Charlesworth and Hurst, 2014). Unfortunately, the equivalent specific breakdown for vaccination payments is not readily available, as payments are pooled through the payment system, however a significant proportion will be from the fee-for-service payments, with some additional from meeting the childhood vaccination thresholds. Having target thresholds that incur additional payments could continue to encourage high performance amongst practices, particularly for childhood vaccinations, if practices know their performance and are aware of the thresholds. Fee-for-service payments have been hypothesised to increase activity, but coverage for adult vaccinations that are remunerated in this way remain low and practices included in this study did not report being incentivised to undertake additional activity. However, the most significant challenges faced by the vaccination programme at the moment include consecutive declines across the programme, persistent inequalities by population groups, and substantially lower coverage in London. A comprehensive review evaluating the evidence for payments systems in primary care providers published in 2014 concluded that *"there is no clear evidence from the studies we reviewed that there is any systematic relationship between remuneration method and prevention activities. Although there is some evidence that prevention is higher under capitation, the studies we reviewed do not model this relationship explicitly and is thus difficult to draw any conclusions on an underlying mechanism between payment and prevention"* (Peckham and Gousia, 2014). Therefore, further work is required to evaluate how the overarching funding and payment system may be improved to overcome these challenges, particularly if associated with an overall funding strategy.

Another option is to incentivise practice staff directly for vaccination activities, either with individual payments, or aggregate payments received by the practice, but for use by staff, rather than for practice administration. The nurses interviewed at this study reported very high intrinsic motivation for vaccinating children, often framed within a moral standpoint, as described in 6.3.3.1.3.2, with it being a necessary, but unpleasant task, which is important for protecting the children for life. The inference was that performance and, especially, financial concerns did not enter the frame when considering vaccination:

"We just think about vaccinating the kids, don't we?"

PN – practice E

Thus, there is some evidence that incentivising individual healthcare providers could improve vaccination coverage, however, this is likely to be controversial, especially with the additional risk of fuelling further anti-vaccination sentiment.

7.1.5.3 Information

The practices in this study were generally not aware of their current levels of performance, with many reporting higher coverage than they actually achieved, despite spending a large amount of time and effort on data collection and reporting activities. Two principles are important to improve the data collection and management system, which are supported by the research evidence that practices which know their performance and have relevant comparators achieve higher coverage in both the UK and USA (Kiefe *et al.*, 2001; Siriwardena *et al.*, 2002; Dexter *et al.*, 2012; Ivers *et al.*, 2012; Thomas and Lorenzetti, 2018). Firstly, the data collection processes should be designed to reduce the burden on practices and generate robust, reliable data at GP practice level. This could be achieved by moving all vaccination data collection to the ImmForm system, or through undertaking COVER data collection through electronic means, and ensuring all practices participate in the systems. Secondly, practice level data should be provided to practices alongside local and regional comparators by PHE with support from local SITs. Together these could have a significant impact on practice level programme performance.

7.1.5.4 Health workforce

Four workforce issues were identified that may have an impact on the delivery of routine vaccinations at GP practices and could be modified to improve coverage overall: training, task shifting, health visitors, and recruitment.

7.1.5.4.1 Training

Training features highly in the *"core service specification national immunisation programme"*, with requirements that *"regular training and development should be routinely available"* so that the vaccination programme is *"delivered and supported by suitably trained, competent and qualified clinical and non-clinical staff"* (NHS England, 2017). This then references PHE's *"national minimum standards and core curriculum for immunisation training for registered healthcare practitioners"* and equivalent guidance for healthcare support workers (including HCAs in this context) (PHE, 2015b, 2018d). While the nurses interviewed for this study generally reported a good experience with keeping up-to-date through training, this may not be the case in other parts of England, as responsibility for vaccination provider training was only loosely defined within the HSCA reforms and a variety of methods for organising training have been described (Chantler *et al.*, 2016).

Administrative and management staff had a significant patient-facing role in delivering the vaccination programme at most of the practices studied here, especially in terms of managing the reminder/recall system and contacting and counselling patients. However, none of these staff had received any formal training for this element of their role and this has not been studied in the wider literature. Provision of training to non-clinical staff at GP practices to improve vaccination coverage is a topic in need of further study.

7.1.5.4.2 Task shifting

Task shifting *"involves the rational redistribution of tasks among health workforce teams. Specific tasks are moved, where appropriate, from highly qualified health workers to health workers with shorter training and fewer qualifications in order to make more efficient use of the available human resources for health"* (WHO, 2008), and has been widely studied in low and middle-income countries where it has had significant impacts in improving efficiency and reducing costs in a variety of fields (Seidman and Atun, 2017). In high-income countries the most widely studied form of task shifting in primary care is from doctors to nurses, where the evidence suggests that it can reduce costs and improve preventive outcomes, but may also result in an increased number of return visits and longer consultations (Martínez-González, Rosemann, *et al.*, 2015; Martínez-González, Tandjung, *et al.*, 2015; Maier and Aiken, 2016). However, other kinds of task shifting have not been studied.

Within the context of this study two types of task-shifting may reduce costs and improve efficiency when delivering the vaccination programme. The first is to shift some vaccination activity from nurses to healthcare support workers (including HCAs), who can give influenza, pneumococcal and shingles vaccines to adults within a GP practice setting. For each vaccination they have to receive a PSD signed by a prescriber before the vaccine can be given (RCN, 2018b). HCAs were only used at three practices included in this study (B, G and H), although they were present in a fourth (E), where they did not give any non-influenza vaccinations and reported being under-used. In part this was because of the challenges of the system of having to get a PSD signed by a doctor, but there was also some suggestion that administrative staff did not understand the role of HCAs and so preferentially booked patients in with PNs. For example, a system of electronic PSD prescribing could reduce the paperwork required for this activity and be undertaken in an efficient way by prescribers outside of clinic time. Given the low levels of coverage of adult vaccines, especially shingles, greater use of HCAs may be a mechanism to achieve this, although this remains an un-studied area. It could also reduce overall practice time spent on vaccination as HCA appointments were much shorter than most nursing appointments at the practices studied here.

The second type is to shift administrative activity from nursing staff to administrative staff. The smaller practices are at a disadvantage as they have a smaller, more expensive staff base. However, larger practices have greater opportunity to reduce costs in this way. Practices B, E and F all had high proportions of time spent on non-clinical tasks by the PN, although this was mainly ordering and stocking vaccines. This had been shifted to HCAs or administrators in several other practices, including practice H which had one of the lowest cost systems alongside a low proportion of nursing time spent on admin. However, some nurses saw this as a core part of their role, so this may not be suitable for task shifting. Practice G had shifted administrative activity from nurses to administrative staff and had the lowest overall cost for admin activities from the practice nurse, but relatively high costs for admin costs overall. Further work needs to be done in this area to evaluate the relative costs and benefits for making recommendations on how task shifting could improve programme delivery.

7.1.5.4.3 Health visitors and outreach services

Practices had different experience working with their local HV team. However, those who no longer had a good working relationship with HVs lamented the loss of what was framed as a core part of the provision of childhood vaccinations, particularly in terms of community outreach. Overall the change in the role of HVs has removed a vital link between GP practices and their local community, particularly with the loss of a close working relationship to be able to provide outreach services. This is especially important for practices with significant populations who do not respond to reminder/recall activities or who do not attend for booked appointments.

HVs have a long history of providing a wide range of public health benefits in the community (Cowley *et al.*, 2015), and have previously played a significant role in providing vaccination information to parents, which may be particularly important in parents who express hesitancy or for families who do not regularly attend the GP practice (Redsell *et al.*, 2010). Certainly for the vaccine programme, they appear to be the only professional group with the ability to undertake outreach activities and have often been included in effective community-based multi-component interventions to improve childhood coverage (Elkan *et al.*, 2000; Atchison, Zvoc and Balakrishnan, 2013;

MacDonald, 2016). Reincorporating the skills of HVs to benefit the vaccination programme is likely to require significant inter-agency working and system level support should be made available to achieve this, particularly in areas where HVs are no longer collocated with GP practices. There could also be significant benefit for coverage in specific populations groups with low coverage if HVs could provide domiciliary vaccinations services when undertaking home visits, which is currently not part of their contract. This would have significant resource implications for the health visiting service and require increased local coordination between the Local Authority (who commission HV services), GP practices and SITs.

7.1.5.4.4 Recruitment

One of the challenges reported by the practices in London was difficulty in recruiting practice nurses, which fits in with the wider recruitment crisis for nurses in the city (RCN, 2014, 2015). This meant that when a nurse left a practice, it reduced overall availability for vaccination provision until either a trained nurse could be recruited, or an untrained nurse could be trained. This effect may be contributing to the challenges with improving vaccination coverage in London. The solution to this challenge lies outside the vaccination programme specifically, but increasing supply of vaccine trained nurses or supporting retention for nurses within GP practices would also support reliability in vaccine programme delivery.

7.1.5.5 Service Delivery

This study has identified several areas of variation in service delivery that could be modified to improve coverage across a range of GP practices. The most significant of these is the provision of a robust and reliable reminder/recall system. The evidence of effectiveness of reminder/recall systems for adults had primarily been conducted in relation to seasonal influenza vaccinations and is less robust than that for children, but the provision of a reminder/recall system does appear to have a positive effect on coverage (Jacobson Vann *et al.*, 2018; Thomas and Lorenzetti, 2018).

When communicating with patients most practices used letters that had been generated in-house, often many years ago, and no practices reported standardising the information provided by receptionists or administrators when contacting patients. For children, there is some evidence that the content of information provided to parents or patients can affect uptake (Jacobson Vann *et al.*, 2018). For example, a study in Canada found tailoring invitation letters can increase uptake of preventive services, although the evidence for vaccinations was relatively weak (Hogg *et al.*, 1998). Studies from the USA have found that using a script when phoning parents and adolescents to remind them about vaccination may also increase uptake in the short term, although this study found no effect after 12 months (Brigham *et al.*, 2012), and that sending personalised SMS messages to adolescents can also increase coverage (O’Leary *et al.*, 2015). The evidence for influenza in adults is slightly stronger in suggesting that tailoring the information in reminder letters increases coverage (Thomas and Lorenzetti, 2018), and a personal invitation to patients for influenza vaccination was found to be a predictor, or facilitator, of high coverage within GP practices in England (Arthur *et al.*, 2002; Dexter *et al.*, 2012). The development and provision of letters for GP practices to use in the reminder/recall activities, as well as suggested scripts for phone calls and content for SMS messages may be low-cost way to increase coverage and is worthy of further consideration in the England context. Further consideration of eHealth interventions is presented in section 7.1.5.6 below.

7.1.5.5.1 Cost and capacity

This study has been concerned with the implementation of the vaccination programme, however, this exists within an ever-expanding range of services provided by GP practices, with the associated effects of these on a provider's ability to be able to deliver vaccinations to their local population. A King's Fund report in 2016 highlighted the increasing demands placed on general practice, with the number of consultations increasing 15% between 2010-11 and 2014-15, with a very large increase in the number of phone consultations (Baird *et al.*, 2016). Over the same period the study found that activity performed by practice nurses increased 18.1%, of which an ever-increasing amount was on telephone consultations. Much of this was made-up from nurses' increasing role in managing long-term conditions, with more practices offering specialist nurse-led clinics. A study in the Lancet analysed GP and nurse consultation rates from 2007 to 2014 found a similar increase in workload for GPs, with an increase of 12.4% in the number of consultations and increase in mean length from 8.65 mins to 9.22 mins (Hobbs *et al.*, 2016). However, the picture for nurses was different, with the adjusted proportion of face-to-face and telephone consultations remaining stable and a slight decrease in home visits. The mean length for a face-to-face nursing appointment was 9.72 mins, which is significantly lower than the mean time for a vaccination appointment described here (15.9 mins for children).

Following the implementation of the 2004 GP contract and the QOF, with resulting increase in the number of practice nurses, the number of nursing consultations increased between 2003 and 2005, as did the complexity of the patients nurses were seeing (Gemmell *et al.*, 2009). However, relatively little is known about the roles practice nurses play at different GP practices, nor what an appropriate level of staffing should be (Ball, Maben and Griffiths, 2015). Increased capacity, in terms of number of nurses per registered population has been associated with improved outcomes in chronic disease management (Griffiths *et al.*, 2010), including when organisational variation was adjusted for (Griffiths, Maben and Murrells, 2011).

At several of practices included here staff reported having difficulty meeting capacity for vaccination appointments and over-estimated the amount of time spent on vaccination activities. Both practice D and E significantly over-estimated the time spent on vaccination and were concerned about available capacity. However, they both had high coverage and provided a high number of appointments per child (1.58/1.28 respectively). Practice H reported having capacity problems with their baby clinic, although this did not feel like a burden. This might explain their low coverage, although overall number of appointments per child was 1.2. Similarly, staff at J significantly over-estimated working time, but they also provided a large number of appointments, which appeared to meet the capacity of the population with 1.24/child. They reported experiencing a more significant capacity problem with administrative staff. Interestingly, staff at practice G, which had a low number of appointments per child (0.81) and very low coverage, accurately estimated the amount of time they spent on vaccination activities and felt as though they were doing 'everything they could' to maximise coverage, but did not report capacity to be a significant problem.

While it may be that smaller practices have capacity to offer the required number appointments, it was notable that the three largest practices in this sample (G, H, J) had significantly lower coverage for both childhood and adult vaccines than the smaller practices. Practices H and J did appear to provide a high number of appointments per child on their list (1.20 and 1.24 respectively), whereas G, with the lowest coverage, provided relatively few (0.81). The relative system costs were around the mean for G and J and were much lower at H, although the overall cost per appointment once the higher costs in London were factored in meant that G and J had relatively costly appointments, whereas H had a low-cost system. From these data it is not clear if there is a vaccination specific size effect, however it may be that there is a size effect on overall practice performance when other activities are also considered. Two studies have evaluated the effect of practice list size on MMR uptake and found no difference between smaller and larger practices, although both were conducted quite some time ago (Campbell *et al.*, 2001; Lamden and Gemmell, 2008).

Two large studies evaluating the effect of list size on achievement of targets from within the QOF, one for patients with diabetes and the other on overall points scored, both found no difference between smaller and larger practices (Ashworth and Armstrong, 2006; Vamos *et al.*, 2011), and another found very little difference on the quality of care of patients with cardiovascular disease (Saxena *et al.*, 2007). However, a review by the Institute of Fiscal Studies published in 2014 found that smaller practices, specifically single GP practices, had lower QOF scores, higher hospital admissions and higher referral rates (Kelly and Stoye, 2014). Specifically, the admissions for acute conditions included a category for vaccine-preventable diseases (influenza, pneumonia, tuberculosis and 'others'), which found that single handed and small-medium had significantly higher admission ratios than medium or large sized practices. This supports earlier findings of higher hospital admission rates for patients registered at smaller practices (Bankart *et al.*, 2011). In terms of access, a review by the National Audit Office did not find any evidence that practice size affect the ability of patients to get appointments, although they did report more difficulty in getting through on the phone at larger practices (National Audit Office, 2015). So, this evidence presents a mixed picture of the effect of practice size on GP practice quality overall, with some evidence that smaller practices may have worse outcomes in some domains. However, further work should be undertaken to evaluate any association between practice size and vaccination coverage, particularly as there is a trend for GP practices to increase in size (Kelly and Stoye, 2014; National Audit Office, 2015).

7.1.5.5.2 Non-attenders

One aspect of capacity that came up in the interviews was the problem some practices faced with patients booking and then not attending appointments (DNA – did not attend), which reduced the practice's overall capacity for appointments. This was particularly reported at B, D, H and J and all apart from J had a system of following up with people who DNA'd the appointment. This was a similar experience to that of the implementation of the intensive type-2 diabetes intervention, where following-up non-attenders was challenging and time consuming (Graffy *et al.*, 2010). This effect is not well quantified in the literature and public data on the number of missed appointments is not available. A study from 2005 found that of a small number of respondents who missed GP practice appointments, 40% said they forgot, 25% tried to cancel the appointment and 20% said they were ill (Neal *et al.*, 2005). This study also found higher odds of missed appointments for people who had already missed an appointment in the previous 12 months. A systematic review from 2003 found: higher DNA rates for practice nurse; higher rates for appointments booked further in advance; mixed evidence for the effect of previous DNA; and higher rates in younger patients, those from lower-socioeconomic groups, and who live in deprived areas (George and Rubin, 2003). A more recent review of non-attenders for NHS health checks found higher rates of DNA for men, those with low-income, from lower socio-economic groups and those with lower levels of education and who were unemployed (Dryden *et al.*, 2012). Practices in this study reported the problem with non-attendance being among 'chaotic' or 'dysfunctional' families who were 'not bothered' to attend, and further work would be required to identify the socio-demographic characteristics of this group. Further work is needed to evaluate the impact of non-attendance on practice capacity more generally, but also on vaccination coverage specifically. Several studies have used intensive follow-up methods to encourage attendance from parents with children who were due vaccinations but did not attend appointments (detailed in 4.2.3), these methods include outreach visits, but also text-message reminders, so it is a potentially modifiable factor for low coverage depending on the available resources (Thomas, Russell and Lorenzetti, 2010; Cockman *et al.*, 2011; MacDonald, 2016; Crocker-Buque, Edelstein and Mounier-Jack, 2017; Dumit *et al.*, 2018). More generally, a Cochrane review from 2013 found that SMS reminders significantly reduced non-attendance at healthcare appointments (Risk Ratio 1.14, 95% CI 1.03-1.26), which is considered in more detail in section 7.1.5.6 below (Gurol-Urganci *et al.*, 2013).

7.1.5.5.3 Language and vaccination abroad

Providing the additional services required to practices with significant populations of people who do not speak English as a first language has also been highlighted as one of the factors adding to the pressure experienced at GP practices (Baird *et al.*, 2016). Interestingly, HVs have previously reported undertaking a significant role in providing vaccination information to migrant families, however this might no longer be the case (Redsell *et al.*, 2010). The WHO's Tailoring Immunization Programmes framework recommends providing vaccination information in appropriate languages (WHO Europe, 2013), and providing services with information in a migrant's first language is a core principle of good practice for providing healthcare to immigrant communities (Devillé *et al.*, 2011), however this is not provided routinely at regional or national level and practices are required to source their own information, which is time consuming and unreliable. Consideration should be given to ways of providing appropriate vaccination services to migrant communities whose first language is not English, and there may be capacity benefits from moving this activity outside of GP practices.

In adults, however, the analysis of shingles vaccine uptake and immigration status was not associated with coverage, once ethnicity had been controlled for (Jain *et al.*, 2018). Why ethnicity should be such a potent determinant of coverage remains unexplained, but could be related to the more negative experiences that people from some ethnic groups have when accessing GP practice services in England (Lyratzopoulos *et al.*, 2012).

7.1.5.6 Products and technologies

There was limited use of new technologies within the practices included in this study, with some only recently having started using SMS messaging to contact patients and infrequent use of reminder prompts to doctors and nurses. Otherwise there was no use of new information and communication technologies for health (eHealth). There is much potential for the use of new eHealth within GP practices to improve vaccine coverage, however this must not come at the risk of increasing the already high administrative burden of the programme. An overview of systematic reviews of eHealth interventions in vaccinations programmes generally found a positive effect, although the scope of this review was somewhat limited, having not included any reviews from the Cochrane database (Dumit *et al.*, 2018). There are many examples of eHealth initiatives that could be applied to the vaccine programme in England. A systematic review published in 2015 evaluated the many uses of Immunization Information Systems (IIS), particularly the various types of electronic vaccine registers (as described in 7.1.6), and how these have been used to support the delivery of electronic communications interventions, including reminder/recall systems, assessment and feedback of performance to provider organisations, and reminder systems to staff in provider organisations (Groom *et al.*, 2015). One example was the use of SMS messages. These are not a new technology, but they were variably used by the practices included in this study, with iPLATO being a commonly used system both within these practices and more widely (iPLATO, 2018). There is high quality evidence of increased coverage with the use of SMS messages in the reminder/recall of patients for vaccinations, with a pooled risk ratio (RR) of 1.29, 95% CI 1.15-1.44 (Jacobson Vann *et al.*, 2018).

Another eHealth intervention that was not widely used at the practices included in this study was reminder notices to healthcare staff providing vaccines. These are most commonly prompts or notifications that are generated within a patient's electronic health record when they attend a GP practice. When used alongside patient reminders, provider reminders have moderate quality evidence for a large effect in increased coverage (RR 2.91, 95% CI 2.67-3.19) (Jacobson Vann *et al.*, 2018) These kind of clinical prompts have been proposed as a mechanism to improve the quality of care across a number of areas within general practice (Kennedy *et al.*, 2011). However, there were reminders programmed into the electronic health records at several of the practices, but these were reportedly under-used or not effective, particularly for adult patients, in part due to the large volume of reminders for various interventions and targets that can overwhelm providers.

There are also a range of innovative patient-facing communications tools to improve knowledge and understanding of vaccinations. It is not likely that GP practices would develop and implement these themselves, however these could be delivered in GP practice settings, particularly if there are parents with high levels of uncertainty or hesitance in relation to vaccinations. This could, for example, be used to provide information to new parents prior to the 8-week appointments, which were the longest of all the vaccination appointments, due to the volume of information and necessary reassurance required to be provided to new parents. These could also standardise the information delivered and indeed provide this information in suitable languages. One type is an online, web-based decision aid delivered to parents, which in the UK has been used to reduce 'decisional conflict' when parents were deciding about MMR vaccination, which had some small effect on uptake, but would need to be validated in a large sample (Shourie *et al.*, 2013). The wider evidence remains mixed, but could be a promising avenue to pursue with the development and trialling of high quality interventions in the UK population (Odone *et al.*, 2015). Interestingly, educational computer games are also emerging as a potential avenue for parent and patient education in relation to vaccination, with 16 identified in a recent systematic review, mainly aimed at improving influenza vaccine uptake or improving general knowledge of vaccinations (Ohannessian *et al.*, 2016). The quality of evaluation of these games was limited and none were developed or delivered in the UK, so further work is required to establish their effectiveness.

7.1.6 Improving coverage in London and reducing inequalities

Two specific challenges were identified in the background review of the data relating to performance of the vaccine programme that warrant specific consideration in light of the results of this study:

firstly, the persistent low coverage in London, and secondly, how to increase coverage to reduce inequalities in certain populations groups.

7.1.6.1 London

One of the most significant challenges facing the vaccination programme in England is the significantly lower coverage found in London, as described in section 3.4.2 and shown in Figure 3 and Figure 4. London presents a synergy of many of the issues that may contribute to lower coverage, as described by the staff from practices G and J. London has high levels of ethnic and cultural diversity with 43% of the resident population being of Black and Minority Ethnic background, 38% of residents having been born outside the UK, and more than half of children in London are born to mothers who were born in another country (GLA, 2012, 2018). There are also high levels of deprivation in many areas, with 27% of the general population and 37% of London's children living in poverty (Trust for London, 2018). Higher levels of deprivation have been associated with higher rates of consultations at GP practices - 15% higher in the most deprived compared to the least deprived quintile (Hobbs *et al.*, 2016), which also puts additional psychological stress on practice staff (Baird *et al.*, 2016). In terms of managing the vaccination programme, high population mobility makes tracking the registration of children through GP practices particularly difficult (Travers *et al.*, 2007; London Councils, 2018). Indeed, some of the low coverage recorded in London may in fact be erroneous and due to 'ghost children', who have moved out of London with their parents, but not been re-registered, so remain as unvaccinated counts on GP practice records (Tiley *et al.*, 2018). Given the high level of population mobility both within London and with other geographies, one solution would be to un-link vaccination status and GP practice registration by using a regional (London-wide) population level register to record vaccination status, such as those used in The Netherlands (van Lier *et al.*, 2012), Norway (Trogstad *et al.*, 2012) and Australia (Chin *et al.*, 2012). This would enable un-vaccinated and under-vaccinated children to be followed-up without increasing the burden on already very busy GP practices. The use of the Australian register in Perth to track unvaccinated children has been demonstrated and found that reasons for under-vaccination were that families had migrated from overseas and their vaccination status had not been recorded, with a smaller proportion of parents reporting objections to vaccination (Gibbs, Hoskins and Effler, 2015).

A report conducted by The Kings Fund examining the state of General Practice in London found that London practices employed fewer staff per-GP than practices outside of London (Raleigh *et al.*, 2012), and other research suggests that there are fewer available practice nurses per unit of population in London than in other parts of the country, with one nurse per 3058 patients in North Central and East London, compared with 1973 patients per nurse in South West England (Ball, Maben and Griffiths, 2015). The relatively small staff base of practices in London may also affect aspects of vaccination service delivery. A cross-sectional survey of the provision of a reminder/recall system undertaken among 684 GP practices in London (53% of the total), found that while only 2% of practice reported having no system in place and there was variation in how systems were used (Lonergan *et al.*, 2018). For primary vaccinations 12% did not actively invite parents, which rose to 15% for pre-school boosters, and 59% did not specifically invite children born to HepB positive parents for vaccination. Of those who did actively invite patients, 25% did not send a reminder if there was no response, and only 50% sent a pre-appointment reminder. The active use of a system was not related to list size, proportion of children aged 0-4 years, nor to deprivation, however did impact on coverage with practices actively recalling more likely to have >90% of MMR2. This study then conducted interviews with a sample of practice managers to explore reasons for the use of different systems. The PMs reported preference for personal contact, with information provision in letters being useful, and a general dislike for SMS service. Those with systems felt they were burdensome on the practice for little benefit, particularly chasing up patients who 'weren't bothered'. This was also the reason given by the practices with no system in place. However, the majority of PMs felt this task was core to GP practices and shouldn't be centralised. Given the time and cost implications of the reminder/recall system further consideration of support for practices in delivering reminder/recall services is warranted. However, implementing effective systems may increase demand for already stretched GP practice appointments, which was one of the concerns presented by staff at the London practices. The King's Fund report suggests changing the skill mix of practices as a potential solution, which is supported by the evidence from this study, as well as developing networks of practices and other health service organisations to better organise service delivery to a wider population (Raleigh *et al.*, 2012). Of note, the London Borough of Tower Hamlets, one of the most diverse with high levels of deprivation also has coverage of childhood vaccinations higher than the London average, which may be due to the concerted effort of a multi-agency team in delivering a project to improve coverage (Cockman *et al.*, 2011; NHS Digital, 2017b).

7.1.6.2 Reducing inequalities

Persistent inequalities exist in vaccine coverage in England in a range of areas highlighted in sections 3.4 and 4.2.4. The systematic review presented in 4.3.2 found that multi-component interventions had the best evidence for effectiveness in highly diverse, deprived urban settings, with some support for provision of specific reminder/recall services that escalate in intensity and outreach services in some circumstances (Crocker-Buque, Edelstein and Mounier-Jack, 2017). It is likely that increasing the provision of effective reminder/recall services with use of literature in appropriate languages may help increase coverage in certain populations, particularly in ethnically and culturally diverse areas. However, given the large range of services provided by GP practices, as well as increasing demands on staff time, it is unlikely that any practice is going to have the capacity or available resources to independently develop a meaningful intervention to reduce a disparity in coverage in the local population, especially if it involves outreach services, as there no longer appears to be a good mechanism through which GP practices can achieve this following the loss of health visitors. Often disparities in coverage are related to a synergy of factors including deprivation, socio-economic status and ethnicity. If the existing service is not meeting the needs of a specific local community, it's possible that an extension or a higher level of intensity of this service may not have a significant effect in increasing coverage. Similarly, unless GP practices are funded and contacted to provide additional services it is unlikely that they will do so (Peckham *et al.*, 2015). However, when additional funding is made available (for example through the QOF), this can have a positive effect on reducing inequalities in funded areas (Doran *et al.*, 2008). There is currently no facility for providing funds for practices to reduce inequalities, despite the fact that this forms part of the vaccination service specification and NICE guidance. From the evidence provided here it does not appear likely that GP practices in areas with significant under-vaccinated populations will have the capacity to be able to deliver additional services on top of their regular service provision, particularly in terms of off-site delivery, or multi-component interventions.

There are several published examples of effective multi-component interventions that have been used to reduce vaccination inequalities in England, which have been delivered at area level using collaborative partnerships (Cockman *et al.*, 2011; Atchison, Zvoc and Balakrishnan, 2013). There is also evidence of many other multi-agency collaborations being formed to reduce vaccination coverage disparities across other areas in England within the new public health and primary care landscape. In a (currently unpublished) survey of public health and primary care professionals in England, 12 such partnerships were identified involving some combination of the Local Authority, CCG, SIT, GP practice, health visitors and schools (Khatun *et al.*, unpublished). An associated selection of three in-depth case studies explored how: the development of a universal pathway for providers to track vaccination coverage overseen by a county level group; the recruitment and employment of child inequalities nurses; and the development of a local task-and-finish group to bring together a wide range of agencies, can be used to reduce local inequalities. Further work needs to be done to evaluate the effectiveness of these structures and highlight these to other areas to encourage best practice. It is likely that SITs are going to be key in the development and implementation of local strategies, but they are likely to need additional resources to meet this capacity, particularly in complex urban areas.

7.2 Strengths and limitations

- **Strengths**

This study is the first review of the implementation of the routine vaccination programme at GP practice level in England. GP practices in a wide range of geographic, socio-economic and demographic contexts were recruited and actively participated in the study, generating a wealth of comparative data in relation to programme delivery and organisation. The study methods collected standardised information from multiple practices, which would be easily reproducible to validate the results in other practices.

TDABC methods were found to be feasible, acceptable and proportionate to collect activity and costing data from a range of GP practices in different contexts. This has generated a CDVC, process map and a detailed picture of the full extent of the time spent on vaccination activities at a range of GP practices. This study has also presented the most detailed costing to date of activity in general practices for both vaccination and in any other field. This will enable increased accuracy during the annual negotiations between the government and providers to suitably fund the vaccination programme.

A large number of practice staff participated in the qualitative interviews, generating a wealth of information about organising vaccination activities. This has provided a deep insight into the experience of clinical and non-clinical staff in delivering the vaccination programme. Overall the results have generated a range of ideas and areas for programme improvements or interventions to improve vaccination coverage and reduce inequalities.

- **Limitations**

The sample is a small, convenience sample of practices, which are unlikely to be representative of the wider range of GP practices in England. No very small or very large practices were included, and practices had overall higher performance on the included domains of quality. There is no claim to wider generalisability of these findings, which will have to be repeated in a large sample of practices.

The TDABC methods relied heavily on self-reporting of activity, which is prone to reporting bias, and so may not represent an entirely accurate picture of activity. Some areas of the activity logs were completed with greater accuracy than others, but there was no attempt made to evaluate the accuracy of the reporting. The practices collected activity data at different times of year and vaccination activity is not evenly spread throughout the year, which may skew the results, particularly when the results were magnified to calculate annual figures. Practices did not respond to requests to follow-up information once the data collection period had finished, which prevented further clarification, validation and development of the results. The costing methods are novel and have not been used in GP practices before and replication in other practice contexts would assist in confirming the accuracy of the model employed. The costing only included costs borne by the practice and not any wider costs to the patients or society.

The interviews with staff were generally short and fairly structured as they were used to collect both process evaluation information and evaluate organisational sensemaking. GP practices are also extremely busy and under high pressure, so there was limited scope to increase the length or format of the interviews to collect more detailed data. It was not possible to undertake an ethnographic study, which would likely have collected a richer data set to evaluate organisational sensemaking, because: vaccination activity was undertaken diffusely throughout the working week and it would have been very time-consuming to undertake small amounts of infrequent observation; there was no facility to consent patients to observe their appointments; and there were few meetings that could be observed where vaccination was discussed and decisions made.

7.3 Implications for research

- This study demonstrates the feasibility and acceptability of TDABC methods within GP practices, which could be developed and used to evaluate the comparative cost base between other practices and other programmes.
- Organisational sensemaking is a useful and suitable theoretical paradigm with which to evaluate organising within GP practices and could be further developed for use in other contexts.
- These findings are from a small, convenience sample of GP practices that are not likely to be typical of GP practices more widely, therefore the methods should be developed and repeated in a wider sample of practices to validate the results and explore vaccination programme implementation and costing more widely.

There are also several areas identified where further evaluation is required to develop the results of this study:

- Further investigation of the role of a vaccination register, particularly in London, and the role it could have in reducing the workload on GP practice of improving coverage in high-pressure areas with low coverage.
- An evaluation of the structure and function of SITs and their capacity to be able to support GP practices in their local area with information provision and service improvement should be undertaken, as their role in implementing modifications to the delivery system is likely to be key.
- There should be development, piloting and evaluation of alternative funding streams for at least some components of the vaccination programme, in line with any new funding policy developed. This should take into consideration the effect on health worker motivation.
- A method for providing practices with feedback on their performance should be developed, implemented and evaluated in terms of the ability to improve coverage.
- A national study should be undertaken to evaluate the effect of practice size on coverage of both childhood and adult vaccinations.
- A larger evaluation should be undertaken of the impact of DNAs within GP practices. This is not likely to be specific to the vaccination programme and thus should be combined with the

impact of DNAs on GP practice capacity more generally. Interventions should be evaluated to reduce the rate of DNAs, particularly involving eHealth reminders and outreach to families with high DNA rates.

- Further evaluation of eHealth interventions, including SMS reminder/recall programmes and web-based communication tools should be undertaken in areas of low coverage.
- Testing should be undertaken of the most effective methods for communicating with patients by letter, SMS and telephone to maximise coverage through trials conducted via GP practices in England.

7.4 Policy recommendations

The policy recommendations arising from this study are presented in Table 13 alongside the organisations who would be responsible for their delivery.

Area	Recommendation	Responsible actor(s)
Leadership and governance	A multi-year childhood and adult vaccination programme strategy should be developed and agreed by the tripartite group, including targets for system performance for coverage and reduction in inequalities, considering both clinical and non-clinical aspects of the programme.	DHSC, PHE, NHSE
Funding	The funding and payment system should be simplified with financial incentives aligned to the desired outcomes in the strategy.	DHSC, PHE, NHSE
Information	The burden of administration placed on GP practice staff should be reduced through improvements to the COVER/CHIS data collection and reporting systems, particularly moving to electronic data capture.	PHE
	All GP practices should be supported in moving into the ImmForm system to enable the generation of practice-level data.	PHE, GP Practices, RCGP
	A system of providing GP practices with information on their performance, with comparisons to local and regional averages should be developed and implemented.	PHE, SITs
Health workforce	The role of Health Visitors in vaccination should be clarified, with consideration of increasing their role in outreach and providing specific services, with additional funding provided to achieve this if required.	NHS England, Royal College of Nursing, Local Authorities
	Guidance supporting an increasing role of HCAs in vaccination should be developed.	NHS England
	Training for non-clinical administrative and management staff in vaccination should be developed, delivered and evaluated.	GP Practices, RCGP, Practice Managers Association
Service Delivery	Leadership of the vaccination programme at GP practice and area level should be developed and supported, particularly in areas of low coverage.	PHE, NHS England, CCGs
	Information on child and adult vaccinations in a variety of common languages should be produced at a national level for use by vaccination providers	PHE
	Consideration should be given to moving the first vaccination contact from parents and children whose first language is not English and may be recent migrants out from GP practices, or providing a specific service for this population.	DHSC, PHE, NHS England

	A system of funding and support should be developed to SITs, or other immunisation professionals, to form local partnership groups to develop single or multi-component interventions to reduce inequalities in local areas.	DHSC, PHE, NHS England, GP Practice, Local Authorities, SITs, CCGs.
	The provision of a reminder/recall system to both children and adults should be added to the CQC evaluation of vaccination practices when an inspection is undertaken in order to encourage practices to implement robust systems.	DHSC, PHE, NHS England, CQC
	Standardised letters, text message content and telephone scripts employing best-practice for patient communication should be developed nationally and provided to GP practices to use to increase effective communication with patients and maximise coverage.	PHE, NHS England, RCGP, Royal College of Nursing, Association of Practice Managers
Products and Technologies	Practices should be supported to implement simple eHealth interventions to improve coverage, including SMS messages and effective reminder prompts.	PHE, NHS England, RCGP, Royal College of Nursing, Association of Practice Managers

Table 13: policy recommendations by category alongside actors responsible for implementation

7.5 Conclusions

There have been multi-year reductions in childhood vaccination coverage, alongside persistent lower coverage in urban areas and particularly in London; long-standing inequalities within certain population groups, notably in areas of deprivation and in certain ethnic groups; and generally low coverage of vaccinations in adults, with some underlying inequalities in certain population groups. Alongside this is the increasing negotiated cost of delivering an increasingly complex programme, with more vaccinations being delivered to more population groups.

The routine vaccination programme currently has many challenges, including a lack of an overarching strategy and a complex data collection and reporting system that does not provide individual level feedback to practices. The funding system is opaque and highly complex with limited ability to fund changes to the delivery system. However, overall practices are likely to be adequately reimbursed for programme delivery and are currently insensitive to changes to the funding system. The current system is also associated with a high administrative burden and associated cost, which could potentially be reduced. However, there are several modifications that could be implemented in order to improve programme performance. These include developing an overarching strategy that is clearly communicated to all practices, as well as modifying the funding system in line with these strategic goals to incentivise and adequately fund complex activity, such as reducing inequalities.

GP practices are relatively isolated from the overarching system and have limited ability to increase capacity to meet population demand or deliver additional activities, such as community outreach, particularly with the loss of health visitors. There is a lack of training and implementation of best practices for the administrative component of the programme, particularly involving administrative and management staff. There are, however, high levels of intrinsic motivation for delivering vaccinations within GP practice staff that should be preserved and built-upon to improve coverage and reduce inequalities. Stresses experienced by staff delivering vaccinations cause them to overestimate the time burden of delivering the programme. Practices would benefit from additional support and networking with regional and local organisations to support local delivery of the programme, particularly in areas with lower coverage.

TDABC is an effective and proportionate method to evaluate the implementation and costs associated with vaccination at GP practices. Sensemaking was a useful framework to explore and understand the factors relating to organisational management of vaccination at GP practices, although additional information would be generated from further ethnographic work to evaluate the effects in practice, rather than using reports through interviews alone.

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9 Appendices

9.1 Example Search Strategy

1 exp Vaccination/
2 exp immunization/
3 exp immunization programs/
4 (immuni$ation or immuni$e or vacci$).mp.
5 ((vacci$ or immuni$) adj3 (program or programme or schedule)).mp.
6 1 or 2 or 4 or 5
7 (uptake or cover$ or impact$ or receipt or accept$ or complete$ or prevalence or up to date).mp.
8 (delivery or clinic$ or appointment$ or staff$ or doctor$ or nurse$ or train$ or fund$ or incentive$ or payment or commission$ or organi$ or phone$ or text$ or message$ or online or remind$ or letter or post or mail or outreach or home visit$ or money or cash or invit$ or time or protocol or standing order$ or marketing or media or computer or database or track$).mp.
9 (deliver$ or system or policy or governance or management or manager$ or organi$ation or context or culture or factor$).mp.
10 exp health services/
11 exp health services accessibility/
12 exp delivery of healthcare/
13 exp "Delivery of Health Care, Integrated"/
14 7 or 8 or 9 or 10 or 11 or 12 or 13
15 exp Family Practice/
16 exp General Practice/
17 exp Primary Health Care/
18 (primary care or communit$ care or family medicine or general practice or family practice or local health$).mp.
19 ((primary or family or community) adj2 (health or care or practice)).mp.
20 15 or 16 or 17 or 18 or 19
21 6 and 14 and 20
22 (united kingdom or UK or great britain or britain or british isles or england or wales or scotland or northern ireland).mp
23 exp united kingdom/
24 exp "Organisation for Economic Co-Operation and Development"/
25 (australia or austria or belgium or canada or chile or czech republic or denmark or estonia or finland or France or germany or greece or hungary or iceland or ireland or israel or italy or japan or korea or luxembourg or mexico or netherlands or new zealand or norway or poland or portugal or slovak republic or slovenia or spain or sweden or switzerland or turkey or united states or USA or OECD).mp.
26 exp Australia/
27 exp Austria/
28 exp Belgium/
29 exp Canada/
30 exp Chile/
31 exp Czech Republic/
32 exp Denmark/
33 exp estonia/
34 exp finland/
35 exp france/ (
36 exp germany/
37 exp greece/
38 exp hungary/
39 exp Iceland/
40 exp ireland/
41 exp Israel/

42 exp italy/
43 exp Japan/
44 exp "Republic of Korea"/
45 exp luxembourg/
46 exp Mexico/
47 exp netherlands/
48 exp New Zealand/
49 exp Norway/
50 exp poland/
51 exp portugal/
52 exp Slovakia/
53 exp slovenia/
54 exp spain/
55 exp sweden/
56 exp Switzerland/
57 exp Turkey/
58 exp United States/
59 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58
60 21 and 59
61 limit 60 to english language

9.2 Ethical Approval

9.2.1 London School of Hygiene and Tropical Medicine Ethics Committee

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LONDON SCHOOL *of* HYGIENE &TROPICAL MEDICINE

Observational / Interventions Research Ethics Committee

Dr Tim Crocker-Buque
LSHTM

3 October 2016

Dear Tim

Study Title: Evaluating the implementation of the routine vaccination programme at GP practice level in England

LSHTM Ethics Ref: 11793

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	Tim Crocker-Buque upgrading report vaccine coverage	28/06/2016	1.0
Investigator CV	Tim Crocker-Buque CV Summer 2016	20/07/2016	1
Information Sheet	PhD Vacc implementation Information sheet	21/07/2016	1
Information Sheet	PhD Vacc implementation Consent form 19072016	21/07/2016	1
Advertisements	Activities at GP practices 15072016	21/07/2016	1
Covering Letter	Response to request for Clairfication	23/09/2016	1
Covering Letter	GP practice vaccination topic guide	23/09/2016	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]

Professor John DH Porter
Chair

Page 1 of 2

9.2.2 NHS Health Research Authority

NHS
Health Research Authority

Dr Timothy Crocker-Buque
Room 9, Third Floor LSHTM
15-17 Tavistock Place
London
WC1H 9SH

Email: hra.approval@nhs.net

09 March 2017

Dear Dr Crocker-Buque

Letter of HRA Approval

Study title:	**Evaluating the implementation of the routine vaccine programme at GP practice level in England to identify factors associated with levels of coverage**
IRAS project ID:	**212278**
Protocol number:	**HPRU-2012-10096**
REC reference:	**17/HRA/0985**
Sponsor	**London School of Hygiene and Tropical Medicine**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The attached document *"After HRA Approval – guidance for sponsors and investigators"* gives detailed guidance on reporting expectations for studies with HRA Approval, including:

- Working with organisations hosting the research
- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **212278**. Please quote this on all correspondence.

IRAS project ID	212278

Yours sincerely

Catherine Adams
Senior Assessor
Email: hra.approval@nhs.net

Copy to: *Ms Patricia Henley, Sponsor Contact*
Ms Selina Foroghi, Camden and Islington NHS Foundation Trust

NIHR CRN Portfolio Applications Team

IRAS project ID	212278

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement [Research Contract]	1.0	
Contract/Study Agreement [Statement of Activities]	1.0	27 February 2017
Contract/Study Agreement [Schedule of Events]	1.0	27 February 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [LSHTM Sponsor Letter (insurance)]	1.0	10 February 2017
GP/consultant information sheets or letters [Information Sheet]	2.0	08 March 2017
Interview schedules or topic guides for participants [Topic Guide]	1.0	27 July 2016
IRAS Application Form [IRAS_Form_15022017]		15 February 2017
Letter from funder [Award letter]	1.0	
Letter from sponsor [LSHTM Sponsor Letter]	1.0	10 February 2017
Participant consent form [Consent Form]	1.0	10 February 2017
Participant information sheet (PIS) [PIS]	1.0	10 February 2017
Research protocol or project proposal [Project Protocol (upgrading document)]	1.0	27 July 2016
Sample diary card/patient card [Participant log]	1.0	26 June 2016
Summary CV for Chief Investigator (CI) [TCB CV Autumn 2016]	1.0	01 November 2016
Summary CV for student [TCB CV Autumn 2016]	1.0	01 November 2016
Validated questionnaire [Time and cost questionnaire (FTPTQ)]	1.0	10 February 2017

IRAS project ID	212278

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name:Dr Timothy Crocker-Buque

Email: drtimcb@fastmail.com

Telephone: 07969959790

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	Minor changes have been made to the information sheet to comply with HRA standards
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A statement of activities will act as agreement of an NHS organisation to participate. The sponsor is not requesting and does not expect any other site agreement.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	Funding is available for this study. Details of funding is provided in the Statement of Activities.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Not Applicable	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
All organisations will be undertaking the same activity as detailed in the study protocol The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents

should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.
Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research**. • Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix. • The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Local PI and Collaborator are not required at site as the Chief Investigator will take responsibility for study activities at the participating sites. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
No access arrangements are required as this is a staff study undertaken on business premises.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

9.3 Data paper

LONDON SCHOOL of HYGIENE & TROPICAL MEDICINE

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Keppel Street, London WC1E 7HT

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed <u>for each</u> research paper included within a thesis.

SECTION A – Student Details

Student ID Number	LSH345619	**Title**	Dr
First Name(s)	Timothy		
Surname/Family Name	Crocker-Buque		
Thesis Title	An Evaluation of the Implementation of Routine Vaccination at GP Practice Level in England		
Primary Supervisor	Sandra Mounier-Jack		

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?	Vaccine		
When was the work published?	12th September 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)	ME, MR and JW contributed to the original manuscript outline and invited other authors to contribute specific sections of the manuscript. All authors designed their respective sections and contributed to the drafting and editing of the manuscript. All authors have approved the final version of the manuscript. TCB contributed sections relating to the comparison of COVER data and ImmForm coverage that are presented in sections 2.2, 2.2.2 and 3.1.

SECTION E

Student Signature	[redacted]
Date	8/1/19

Supervisor Signature	[redacted]
Date	8/1/19

Copyright information

I received written confirmation from the first author, Dr Michael Edelstein, for this to be included in this thesis, under the following copyright arrangement:

As the author of this Elsevier article, you retain the right to include it in a thesis or dissertation, provided it is not published commercially. Permission is not required, but please ensure that you reference the journal as the original source. For more information on this and on your other retained rights, please visit: https://www.elsevier.com/about/our-business/policies/copyright#Author-rights

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Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Extracting general practice data for timely vaccine coverage estimates: The England experience

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ABSTRACT

In England, primary care providers use standardised coding systems to record health events such as vaccination as well as patient characteristics. This information can be automatically extracted to estimate coverage for vaccine programmes delivered through primary care, in the general population as well as in specific geographical, ethnic, age or clinical groups. This system provides timely vaccine coverage estimates as well as the flexibility to extract tailored data in order to directly inform a continuously evolving national vaccine programme. It is however limited by the quality and completeness of clinical coding in primary care. A centralised, individual-level register would however improve data quality, completeness and reliability and remains the gold standard.

1. Introduction

Measuring vaccine coverage enables the national evaluation of vaccine programme delivery and the assessment of the overall level of population protection. Vaccine coverage data are also used to estimate vaccines' effectiveness and impact, and in making policy decisions [1]. At the local level, coverage data are also used for performance management; risk assessment; identifying underimmunised groups or areas; and responding to community outbreaks of vaccine-preventable diseases. Timely and high quality vaccine coverage data enables better delivery of vaccine programmes [2]. In England, most vaccine programmes are delivered in primary care through general practice (GP). Public Health England (PHE), the executive agency of England's Department of Health, is responsible for collecting and reporting coverage of vaccines included in the national vaccination schedule. Since the 1980s, PHE has used Child Health Information Systems (CHIS), local population registers of all children including those not registered with a GP, as a source of data to estimate coverage for routine and selective childhood immunisations as part of the Cover of vaccination evaluated rapidly (COVER) programme [3]. CHIS vaccination data mainly originates from GP data, as well as other settings where vaccination is delivered. COVER vaccine coverage measurements are published quarterly as official statistics and annually as national statistics [4]. The use of CHIS data to estimate vaccine coverage and the COVER programme have been described elsewhere [1]. To estimate coverage of some programmes delivered after the age of five, and for most new vaccine programmes since 2013, PHE has also used data automatically extracted from GP systems. This approach started in 2004 with the influenza and pneumococcal polysaccharide vaccine programmes in over 65 years-olds and has now been extended to an increasing number of vaccine uptake collections. Reporting was originally undertaken manually and moved to automatic extraction from around 50% of practices by 2008/09 [5]– this has now increased to over 95%. Extracting data automatically from almost all GP systems allows estimation of practice-level vaccine coverage in near real-time, enabling timely targeted action and analysis of dose-specific coverage by specific criteria, such as ethnicity, gender or co-morbidity. England is one of few countries to report vaccine coverage using this data source. The applications, challenges and limitations of this data may be of interest to other countries in Europe and beyond. We sought to describe how vaccine coverage is estimated

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http://dx.doi.org/10.1016/j.vaccine.2017.08.015
0264-410X/

using primary care data in England and to outline the advantages and limitations as well as future initiatives for measuring vaccine coverage using primary care data.

2. Vaccine coverage using general practice data

2.1. Clinical coding in general practice

In England, general practice is often the first point of contact when seeking healthcare and acts as a gatekeeper to specialist services. Individuals residing in England must register with a practice to see a general practitioner or to be referred for most secondary or other health services. As a result the vast majority of the population is registered with a GP [6]. The majority of clinical GP records have been fully computerised since the early 2000s [7]. When a patient registers with a practice several key demographic characteristics such as age, sex and ethnicity are recorded using Read codes [8], and this system is also used for recording clinical events such as vaccine administration and underlying clinical history. Read codes are currently used in England and are scheduled to be replaced by the Systematized Nomenclature of Medicine Clinical Teams (SNOMED-CT), an internationally used clinical terminology [9], in 2020. All clinical events should be recorded in the patients' records, including those occurring outside of a primary care setting, such as school and pharmacy delivered vaccinations (Fig. 1), although there are challenges to getting this information promptly back into the GP patient record. GPs receive financial incentives to accurately record some of these codes.

2.2. ImmForm

ImmForm (www.immform.dh.gov.uk) is the secure, web-based system used by the NHS and PHE to collect data on vaccine coverage for selected immunisation programmes and provide vaccine ordering facilities for the NHS. ImmForm allows GPs and local NHS England teams to analyse and review their vaccine coverage data [10]. ImmForm obtains data from each of the four main companies supplying information systems to GPs, covering approximately 7500 practices, 95% of GPs nationally. Aggregate data are directly and automatically extracted from these GP IT systems, following extraction specifications that, for each vaccine collection, specify which Read codes indicate eligibility (for inclusion in the denominator) and vaccination status (for inclusion in the numerator). Extraction details are available in the data specifications [11]. ImmForm also allows stratification of vaccine coverage by any variable recorded, such as age (by date of birth), ethnicity, gender, specific co-morbidities (e.g. chronic heart disease, diabetes) [12] and place of administration (practice, school, pharmacy etc). The specifications and outputs are internally and externally validated and quality assured to ensure the coverage reported is accurate. Data are collected and fed back directly at the GP level. Vaccine coverage estimates are published on PHE's website [3] down to clinical commissioning group (CCG) and local authority (LA) level. CCGs are independent statutory bodies governed by members of local GPs with support from health professionals and direct input from people representing patients and members of the public [13]. The ImmForm platform also allows access to relevant GP level data for local public services for operational purposes. It facilitates monitoring and evaluation of the implementation of the programme by PHE, NHS England and Department of Health (DH), allows early identification of areas where coverage of the vaccine is low for local public health teams, provides epidemiological data to allow assessment of the effectiveness and impact of the programme, data for vaccine safety assessment, and information for policy makers and the public. As of May 2017, ImmForm was used to collect vaccine coverage directly from GPs for the rotavirus, measles, mumps and rubella (MMR), Meningococcal group B (MenB) and groups ACWY (MenACWY), prenatal pertussis, adult

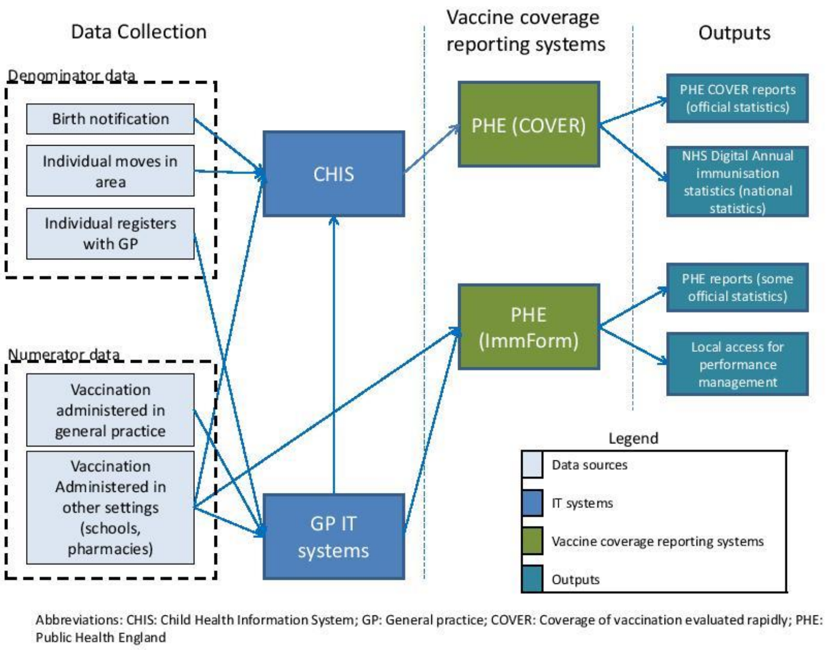

Fig. 1. Immunisation data flows, England, June 2017.

Table 1
Vaccine collection recorded in different systems, England, June 2017.

Age at which data is collected	Vaccine	Vaccine coverage collection system	
		ImmForm	COVER
6 months	MenB (1&2 doses)	x	
	Rotavirus (1&2 doses)		
12 Months	DTaP/IPV/Hib (3 doses)		x
	MenC		x
	PCV (2 doses)		x
	Rotavirus (2 doses)	x	x
	MenB (2 doses)	x	x
	HepB (3 doses)		x
	BCG		x
24 Months	DTaP/IPV/Hib (3 doses)		x
	MMR (1 dose)	x	x
	Hib/MenC booster		x
	PCV booster		x
	MenB booster	x	x
	HepB (4 doses)		x
All 2, 3, and 4 year olds	Influenza – (given in GP)	x	
5 years	DTaP/IPV/Hib (3 doses)		x
	DTaP/IPV Booster		x
	Hib/MenC booster		x
	MenB booster		x
	MMR (1 and 2 doses)		x
All children of school age Year 1 to Year 3	Influenza – (given at school)	x	
Adolescents	MenACWY – (given in GP)	x	
	MenACWY –(given at school)	x	
	Td/IPV – (given at school)	x	
	HPV girls – (given at school)	x	
Pregnant women	Pertussis	x	
	Influenza	x	
Patients aged 6 months to under 65 and in a clinical risk group	Influenza	x	
Healthcare workers	Influenza	x	
2–18 years	MMR (1&2 doses)	x	
65 and over	PPV	x	
	Influenza	x	
70 and over	Shingles	x	

MenB: Meningococcal disease type B; DTaP: diphtheria/tetanus/acelluar pertussis; IPV: inactivated polio virus; Hib: *Haemophilus influenzae* type b; MMR: Measles, Mumps and Rubella; MenC: Meningococcal disease type C; PCV: Pneumococcal Conjugate Vaccine; HepB: Hepatitis B; BCG: Bacille Calmette-Guerin; MenACWY: Meningococcal disease types A, C, W, Y; Td: tetanus/diphtheria; HPV: Human papillomavirus; PPV: pneumococcal polysaccharide vaccine.

Table 2
Comparison of the COVER and ImmForm vaccine coverage monitoring systems.

	Advantages	Limitations
ImmForm	• Can rapidly incorporate dose-specific coverage for new vaccines, or add coverage in sub groups of interest • Allows frequent collection of cumulative data during appropriate period (e.g. seasonal flu) • Can provide near real-time data • Can be accessed by local public health stakeholders for performance management	• Relies on accurate and complete clinical coding in primary care • Does not include all GPs • Vulnerable to technical issues in individual GP information systems • Excludes unregistered children • Variable quality of recording of vaccines delivered outside primary care (ie. schools, pharmacies)
COVER	• Mandated data returns ensures data completeness • Total population coverage (includes unregistered children) • Thorough quality assurance process mandated by official statistics status • Official source of vaccine coverage for England	• Complex, lengthy administrative process to add or amend data collection • Data extracted four times a year only, with a 3 month delay • Data not available at the most local level • Does not measure coverage in sub groups of interest

and paediatric influenza, polysaccharide pneumococcal and shingles vaccine programmes (Table 1). In addition, ImmForm is used to report manually collected annual data from LAs for the school-based influenza vaccine programme, influenza vaccine uptake in healthcare workers, human papillomavirus (HPV) programme delivered through school to girls aged 12–14 years of age, and the adolescent MenACWY and tetanus, diphtheria, and polio (with Inactivated Polio Vaccine) (Td/IPV) also known as the 'school leaver booster'. A comparison of the COVER and ImmForm vaccine monitoring systems can be found in Table 2.

2.2.1. Advantages of ImmForm

2.2.1.1. Flexibility. ImmForm allows the presentation of any clinical, technical or administrative information extracted from GP information systems. As such it allows routine estimation of coverage in sub-groups of the population, according to characteristics of interest. This possibility has been used to report vaccine coverage by age group (for MMR, up to the age of 30 years olds), dose (MMR, MenB and rotavirus) ethnicity (for influenza, prenatal pertussis, rotavirus and shingles), gender (all collections), refusal of vaccines (shingles, pre-natal pertussis, influenza), administration of vaccines by other health providers (influenza, pre-natal pertussis) and co-morbidities (for influenza and shingles). These characteristics can be amended or adjusted at any time in order to answer research or operational questions.

One difficulty with reporting coverage stratified by characteristics of interest is that these are dependent on the quality of data recorded on GP patient records as they can be coded using different Read codes (v2 or CTV3) and the frequency of use of the different codes can vary between the different GP information suppliers. For example, despite there being an information standard for the collection of ethnicity, we have shown though our PHE internal evaluations that only a minority of GP patients have an ethnicity code assigned to their record. Ethnicity coding also showed that the same ethnicity can be recorded using more than ten different codes and coding is more likely to be assigned in ethnically diverse areas and to patients in non-White ethnic groups. In order to maximise data completeness, the extraction specifications include the range of codes used to record a specific characteristic and are reviewed and evaluated on a yearly basis, or more frequently if needed, to reflect changes in coding patterns or the emergence of new codes.

2.2.1.2. Timeliness. Automated coverage estimates allow dose-specific frequent early assessment of newly introduced vaccination programmes ahead of the availability of routine coverage data collected alongside established programmes and weekly in-season estimation of cumulative influenza vaccine uptake in key target groups. Where data extraction is entirely automated, it does not represent any burden for GPs. Data consistency, quality checking, analysis and coverage reporting is done at the national level by a dedicated PHE surveillance team. It is therefore possible to extract and report preliminary coverage data at any frequency specific programmes require. In the case of the seasonal influenza vaccine programme, preliminary cumulative coverage data are extracted and reported weekly. For other programmes, the frequency of reporting can be monthly, quarterly, or annually.

2.2.1.3. Accessibility. Local public health teams responsible for performance management can access the platform and visualise coverage data at the practice level. This enables them to visualise performance in near real-time and identify under-performing practices.

2.2.2. Limitations of ImmForm

2.2.2.1. Quality. ImmForm data relies on GPs entering complete, timely and accurate data, including updating vaccine history when patients are vaccinated in other settings such as through pharmacies and schools. With some vaccines (e.g. influenza, MenACWY) offered through other settings (such schools or pharmacies), local teams are developing approaches to share such information in a more seamless way. The quality of vaccine coverage data are dependent on how well variables are recorded in GP information systems, and these are not always systematically recorded. For example it is estimated that date of delivery, used to identify monthly cohorts of women who were eligible for the pre-natal pertussis programme in pregnancy, is only recorded in the GP record for two thirds of deliveries in England [14]. Similarly, ethnicity is not recorded for all patients, limiting the precision of coverage estimates in specific ethnic groups [14]. In addition, when an individual changes practice for any reason, the migration of their health information to his/her new practice may not be either automated or systematic if the patient does not inform the new GP of their old practice. Although initiatives to directly transfer patient's record to a new GPexist, due to the different coding systems among GP system suppliers [15], some data may not always be accessible. This can lead to over-estimated denominators when patients move but remain in the GP register and under-estimated numerators if records do not migrate when patients re-register after moving. As a consequence, as time progresses and individual likelihood to change GP increases, the likelihood of vaccination data not migrating increases: data quality therefore degrades over time. This limitation affects the whole population but it disproportionally impacts areas with a high population turnover – specifically London, where annual population turnover reaches 35% is some boroughs [16]. It is thought this is one of the contributing factors to London's low vaccine coverage across all programmes compared with other English regions. A study validating vaccine coverage data found that among London children aged 10–16 with no record of MMR vaccination, 60% were in fact vaccinated, compared with 40% in the rest of the country [17]. Interoperability and automated data migration have however improved in recent years and will continue to improve with the move to SNOMED CT across all health services. Data migration issues are increasingly affecting historical rather than recently entered data. Inaccurate recording of vaccination status in patients moving from abroad remains problematic as these vaccine records are in paper format when they exist, may refer to products that are slightly different to or not currently offered in the UK schedule, and GPs are neither incentivised nor resourced to enter them onto their information systems.

2.2.2.2. Completeness and representativeness. ImmForm routinely extracts data from over 95% of England's GPs. However, the coverage estimates it produces do not include the unregistered population, which is small but likely to include mainly underserved groups or those who recently arrived in the country, who are more likely to be under-immunised. ImmForm therefore potentially over-estimates true population coverage. In addition, the four GP system suppliers are not homogenously represented throughout England. Two of the system suppliers represent 85% of English GPs – the failure of one of these to produce data at a specific time, for technical reasons, may preclude the reporting of national vaccination coverage. This is a real-risk particularly when reporting frequency is as often as weekly, as is the case for influenza. Some GP system suppliers supply a particular geographical area, making data for this region unreliable when data provided fail validation checks or if they do not provide data.

3. Futures initiatives for vaccine coverage in England

3.1. Childhood immunisation coverage reported through ImmForm

Most vaccination coverage rates up to the age of five for routine childhood immunisation are available through the COVER programme. However, this is only reported at the LA and not practice or CCG level. Since local authorities are not responsible for delivering the vaccination programme, the usefulness of COVER data for local performance management is limited. In response to this, from 2017/18, vaccination coverage for additional selected childhood programmes will be collated monthly through ImmForm for local monitoring. This dose-specific data will include early assessment of primary diphtheria/tetanus/acelluar pertussis/inactivated polio/*Haemophilus influenzae* type b/hepatitis B (DTaP/IPV/Hib/HepB) vaccine at 6 months of age (three doses), MMR at 16 months of age, and hepatitis B in high risk infants from 3 up to 18 months of age.

3.2. GPES

The GP extraction services (GPES) is an another system that collects information from GP clinical systems in England and forms part of NHS Digital GP Collections service [18]. GPES is currently mainly used for GP payment purposes and, in the short to medium term, vaccination coverage cannot be estimated from GPES data. However, NHS Digital is working with PHE to provide data that in the long term could be used to calculate coverage. Also in the longer term, GPES expects to produce a dynamic primary care dataset that will be a key contributing source of information for NHS England's Digital Child health strategy, which aims to ensure that systems collecting child health information will be able to contribute relevant information, including immunisation, to a core, individual level dataset [19]. The health information pertaining to a specific child could then be accessible in a timely manner to relevant healthcare professionals across the healthcare system, as well as to patient themselves. This approach would ensure the entire child health information system is interoperable and that data automatically migrate from one area to another when individuals move. The current objective is for this strategy to be implemented in 2021 [19].

4. Conclusion

Automated extraction of vaccination data from primary care enables estimation of vaccination coverage for the whole life-course in a timely manner and to a level of granularity that is unparalleled. It allows, at practice level and in real-time, coverage measurement for any chosen vaccine overall or in any sub-group based on dose, gender, age, ethnicity, co-morbidity, setting or any other characteristic of interest, provided it is recorded in the primary care system. However, this approach requires interoperability across the primary health care system and a vaccination programme mainly delivered through primary care. Although the system currently in place in England achieves this to some extent, a centralised, individual-level register would improve data quality, completeness and reliability and would be less vulnerable to individual GP system suppliers' technical issues. Such a centralised vaccination dataset should be considered the gold standard by countries considering implementing a vaccine register.

Conflict of interest

None.

Author contributions

ME, MR and JW contributed to the original manuscript outline and invited other authors to contribute specific sections of the manuscript. All authors designed their respective sections and contributed to the drafting and editing of the manuscript. All authors have approved the final version of the manuscript.

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9.4 Interview Topic Guide

For GP Practice Staff: immunization nurse, practice manager, GP.

	TOPIC	PROMPT	NOTES/QUESTIONS
1	**Welcome and introduction**	*Intro*	*- Background to the project* *- My role & LSHTM*
		Scope of interview	- Overview of purpose - Confidentiality - Topics to be covered - Time for questions - Confirm consent
2	**Organisation & role**	*Intro*	*This section is looking to understand how the routine vaccination programme is organized within your GP practice.*
		Role and responsibility	- Please describe your role within the practice team in delivering the vaccination programme. - How long have you been in this position for? - How much of your working time do you spend on vaccination per week?
		Vaccination programme organization	- How is the vaccination programme organized within your GP practice? - Which other staff members are involved?
3	**Inputs**	Intro	- This section is looking to understand how the practice uses information to make decisions about how to run the programme.
		Information sources & use	- What information sources do you use? - How are you informed of changes to the programme? - How often to you undertake training?
		Data knowledge and management	- Where do you get information from relating to your practice's performance? - How often do you receive updates about coverage levels?
		Resources (financial and human)	- Do you have responsibility for the financial management of the programme? - Do you know how the programme is funded? - Is the funding adequate to provide the programme? - What do you think about the current system of payments for the vaccination programme?

		Networks	- Are you a member of any local or national networks relating to vaccination? - What organisations do you interact with locally related to vaccination? - What information do you receive from these sources? - Do the networks provide any other benefits? - Which other external organizations (e.g. schools, local government) do you interact with regularly?
3	**Sensemaking**	*Intro*	*This section is seeking to understand how vaccination is perceived and prioritized within your practice.*
		Leadership	- Is there an identified person who leads the programme? - If the leadership role is split, please describe how this works? - Is leadership important for delivery of the programme in your practice?
		Decision-making	- Who is responsible for making decision relating to the programme? - Do you have a regular practice meeting to discuss vaccination? How often? Who attends? - Is there a local or regional committee or board that meets? How often? Who attends? - How often do you make changes in how you deliver the programme?
		Climate & culture	- How much of a priority is vaccination when compared to other areas? - Are staff members and the management supportive of vaccination? - Could the way your practice organizes the programme be improved? If so, what are the barriers?
		Interpersonal relationships	- Do staff work together well to deliver the programme? - Do staff interact with external organizations well? - Are there any interpersonal barriers to running the programme?
		Responses to change	- How well does your practice respond to changes in the programme? - How long does it take changes to the programme to be implemented?
4	**Activities and outputs**	Intro	*This section is seeking to understand what vaccination activities you undertake and the uptake of these.*
		Task allocation	- How are roles and responsibilities distributed? - Is it always clear who is supposed to be doing what?
		Time allocation	- How much time is dedicated to vaccination? - Is this enough? Or too much/little?
		Systems and processes	- Is the way the programme organized suitable?

			- Is the system of delivering vaccinations clear to all staff? - Could it be improved? - How are incidents reported?
		Data collection and submission	- How are data collected and submitted? - What is your role in this process? - Is it done well? Or could it be improved?
		Uptake and access	- Is there good uptake of vaccination in your practice? - Do you think patients have any problems accessing services?
		Interventions	- Are you involved with any interventions to improve access/uptake? If so, please describe. - If no, do you think there would be any role for an intervention at your practice? If so, for what purpose?
		Workload and capacity	- How do you find the workload of running the programme? - Do your colleagues feel the same way? - Do you have capacity to increase uptake of the programme?
5	**Outcomes**	Intro	*This section is seeking to understand what the overall outcomes of the programme are in your practice.*
		Patient factors & perception	- Do you think the type of population you service makes any difference to the coverage levels you achieve? - Do your patients hold any views that affect vaccination coverage?
		Community relationship	- Is the practice integrated into the local community? - How do you feel about the patients in your local area?
		Coverage levels & performance	- Do you know how well your practice performs? - What indicators do you use? - Do you feel this could be improved? If so, how?
			- Space for any other questions/issues to be raised/discussed.

9.5 Activity Logs

9.5.1 Clinical staff

Date: Site code: Log code:

Health Protection Research Unit in Immunisation

NHS
National Institute for Health Research

STUDY PERIOD:

<u>WEEKLY ACTIVITY LOG: Clinical Staff</u>

- This log consists of <u>4 sections</u> and should be completed <u>as you undertake activities</u> during the study period.
- Each section collects slightly different information about how much time you spend on immunisation activities.
- Sections 1 (details) and 4 (infrequent activity) need to be completed <u>once only</u>.
- Section 2 (non-clinic activity) and 3 (clinic activity) need to be populated <u>on a daily basis</u> during the study period.
- Please record **ALL activity** related to the delivery of the routine, CHILDHOOD and ADULT immunisations, including: DTaP/IPV/Hib, PCV, MenB, Rotavirus, Hib/MenC, MMR, LAIV, Td/IPV, PPV, shingles.
- Please also record any activity related to vaccinations given to pregnant women and people with specific medical conditions.
- Please only record MenACWY and HPV immunisation activity for young people if given at the practice.
- **<u>Do not include</u> any activities relating to <u>seasonal flu</u>, travel immunisations, or school vaccinations.**
- For any questions on how to fill out this form, please contact Tim Crocker-Buqué: timothy.crocker-buque@lshtm.ac.uk, or 07969 959 790.

SECTION 1: Your details

Staff group (e.g. nurse, GP, HCA):

Grade/status (e.g. band 6, salaried):

Week commencing date (Monday's date):

Scheduled working hours <u>this week</u> (e.g. Monday to Thursday, 8am to 1pm, 2pm to 6pm)

1

Date: Site code: Log code:

SECTION 2: Immunisation activities undertaken outside clinic times during study period.

- In this section please record any activity relating to immunisations during your regular working week, outside of scheduled clinic times.
- Please record activity that you undertake on a regular basis, most weeks. Do not record activity that you undertake less than monthly.
- If you are not sure, record the activity. Please record the times as accurately as possible.

Date	Activity	Time started	Time finished	Notes
e.g. 24th July	*Reading vaccine update from DH*	*8:00am*	*8:16am*	
e.g. 25th July	*Phoning parents who DNA for yesterday's clinic.*	*4:30pm*	*4:48pm*	*3 parents DNA. Spoke to one, the other two did not answer.*
e.g. 26th July	*Gave PCV vaccine during home visit*	*3:00pm*	*3:10am*	*Took 10 mins of a 20 min appointment.*

2

Date: Site code: Log code:

Date	Activity	Time started	Time finished	Notes

3

Date: Site code: Log code:

SECTION 3: Immunisation activities taking place <u>during clinics</u> during study period

- In this section please record <u>any activity</u> relating to immunisations that takes place during clinic hours.
- If this is an immunisation specific clinic, please record details every appointment, including DNAs.
- If this a general clinic, please record only the appointments that have relevant immunisation activity.
- In general appointments where immunisation activity takes place, please only record the amount of time spent on that immunisation activity.
- Please keep a record of any consumables used that are provided by the practice (i.e. not the vaccinations themselves), but other things like tape, plasters, cotton wool.
- If you are not sure, record the activity. Please record the times as accurately as possible.
- Please start a new form for each new clinic.
- A sample of the form is provided below

Record of immunisation activity:

Activity Description	Imms Given	Time started	Time finished	Consumables used	Notes
e.g. mother and infant 8 week appointment for immunisations	*DTaP/IPV/Hib, PCV, Rotavirus, MenB*	*9:27*	*9:48*	*1 x blunt needle 1 x cotton wool 1 x plaster 1 x alcohol wipe*	*Difficult to swallow oral rotavirus vaccine*
e.g. post clinic data collection and submission to CHIS	*n/a*	*12:30*	*12:45*	*n/a*	

Date: Site code: Log code:

1. Day and Date of clinic:

- Clinic start time (e.g. 8:30am):
- Clinic end time (e.g. 12:30pm):
- Scheduled breaks (e.g. 15 mins at 11am, none):
- Type of clinic (general, children's, immunisation):
- Scheduled appointment length (e.g. 10 mins, 15 mins):
- Record of immunisation activity:

Activity Description	Imms Given	Time started	Time finished	Consumables used	Notes

Date: Site code: Log code:

Activity Description	Imms Given	Time started	Time finished	Consumables used	Notes

6

Date: Site code: Log code:

2. Day and Date of clinic:

- Clinic start time (e.g. 8:30am):
- Clinic end time (e.g. 12:30pm):
- Scheduled breaks (e.g. 15 mins at 11am, none):
- Type of clinic (general, children's, immunisation):
- Scheduled appointment length (e.g. 10 mins, 15 mins):
- Record of immunisation activity:

Activity Description	Imms Given	Time started	Time finished	Consumables used	Notes

7

Activity Description	Imms Given	Time started	Time finished	Consumables used	Notes

Date: Site code: Log code:

3. Day and Date of clinic:

- Clinic start time (e.g. 8:30am):
- Clinic end time (e.g. 12:30pm):
- Scheduled breaks (e.g. 15 mins at 11am, none):
- Type of clinic (general, children's, immunisation):
- Scheduled appointment length (e.g. 10 mins, 15 mins):
- Record of immunisation activity:

Activity Description	Imms Given	Time started	Time finished	Consumables used	Notes

Date: Site code: Log code:

Activity Description	Imms Given	Time started	Time finished	Consumables used	Notes

10

Date: Site code: Log code:

4. Day and Date of clinic:

- Clinic start time (e.g. 8:30am):
- Clinic end time (e.g. 12:30pm):
- Scheduled breaks (e.g. 15 mins at 11am, none):
- Type of clinic (general, children's, immunisation):
- Scheduled appointment length (e.g. 10 mins, 15 mins):
- Record of immunisation activity:

Activity Description	Imms Given	Time started	Time finished	Consumables used	Notes

11

Date: Site code: Log code:

Activity Description	Imms Given	Time started	Time finished	Consumables used	Notes

Date: Site code: Log code:

5. Day and Date of clinic:

- Clinic start time (e.g. 8:30am):
- Clinic end time (e.g. 12:30pm):
- Scheduled breaks (e.g. 15 mins at 11am, none):
- Type of clinic (general, children's, immunisation):
- Scheduled appointment length (e.g. 10 mins, 15 mins):
- Record of immunisation activity:

Activity Description	Imms Given	Time started	Time finished	Consumables used	Notes

Activity Description	Imms Given	Time started	Time finished	Consumables used	Notes

SECTION 4: Infrequent immunisation activities

- In this section please record any activity relating to immunisations that you undertake infrequently, i.e. less than once per month.
- This may include annual training, quarterly vaccine update meetings, assisting with vaccine ordering, non-routine data submission.

Activity	Frequency	Time taken	Consumables used	Notes
e.g. Annual vaccine training day	*Once annually*	*1 day*	*None*	*Arranged by the local SIT. One day of study leave taken.*
e.g. Data cleaning for CHIS submission.	*Quarterly*	*4 hours*	*None*	*Ensuring that data submitted are accurate.*

9.5.2 Non-clinical staff

Date: Site code: Log code:

Health Protection Research Unit in Immunisation

NHS National Institute for Health Research

STUDY PERIOD:

WEEKLY ACTIVITY LOG: Administrative and Management Staff

- This log consists of 3 sections and should be completed as you undertake activities during the study period.
- Each section collects slightly different information about how much time you spend on immunisation activities.
- Sections 1 (details) and 4 (infrequent activity) need to be completed once only.
- Section 2 (weekly activity) need to be populated on a daily basis during the study period.
- Please record **ALL activity** related to the delivery of the routine, CHILDHOOD and ADULT immunisations, including: DTaP/IPV/Hib, PCV, MenB, Rotavirus, Hib/MenC, MMR, LAIV, Td/IPV, PPV, shingles.
- Please also record any activity related to vaccinations given to pregnant women and people with specific medical conditions.
- Please only record MenACWY and HPV immunisation activity for young people if given at the practice.
- **Do not include any activities relating to seasonal flu, travel immunisations, or school vaccinations.**
- For any questions on how to fill out this form, please contact Tim Crocker-Buqué: timothy.crocker-buque@lshtm.ac.uk, or 07969 959 790.

SECTION 1: Your details

Staff group (e.g. receptionist, practice manager):

Grade/status (e.g. band 6, salaried):

Date starting collection:

Scheduled working hours this week (e.g. Monday to Thursday, 8am to 1pm, 2pm to 6pm)

1

SECTION 2: Activities relating to immunisation that you undertake during your regular working week.

- In this section please record any activity relating to immunisations during your regular working week.
- Please record activity that you undertake on a regular basis, most weeks. Do not record activity that you undertake less than monthly.
- If you are not sure, record the activity. Please record the times as accurately as possible.

Activity	Time started	Time finished	Notes
Booked 8 week immunisation appointment	*9:17am*	*9:22am*	
Checked in mother and baby for nurse imms appointment	*3:30pm*	*3:32pm*	
Submitted data return to CHIS	*1:00pm*	*3:00pm*	*Took longer than normal due to computer problems*
Ordered vaccines from PHE centre	*3:00pm*	*3:30pm*	*Needed to update stock*

1. Day and Date:

- Working hours start time (e.g. 8:30am):
- Working hours end time (e.g. 4:30pm):
- Scheduled breaks (e.g. 15 mins at 11am, none):
- Record of immunisation activity:

Activity	Time started	Time finished	Notes

Activity	Time started	Time finished	Notes

2. Day and Date:

- Working hours start time (e.g. 8:30am):
- Working hours end time (e.g. 4:30pm):
- Scheduled breaks (e.g. 15 mins at 11am, none):
- Record of immunisation activity:

Activity	Time started	Time finished	Notes

Date: Site code: Log code:

Activity	Time started	Time finished	Notes

Date: Site code: Log code:

3. Day and Date:

- Working hours start time (e.g. 8:30am):
- Working hours end time (e.g. 4:30pm):
- Scheduled breaks (e.g. 15 mins at 11am, none):
- Record of immunisation activity:

Activity	Time started	Time finished	Notes

Activity	Time started	Time finished	Notes

4. Day and Date:

- Working hours start time (e.g. 8:30am):
- Working hours end time (e.g. 4:30pm):
- Scheduled breaks (e.g. 15 mins at 11am, none):
- Record of immunisation activity:

Activity	Time started	Time finished	Notes

Date: Site code: Log code:

Activity	Time started	Time finished	Notes

10

Date: Site code: Log code:

5. Day and Date:

- Working hours start time (e.g. 8:30am):
- Working hours end time (e.g. 4:30pm):
- Scheduled breaks (e.g. 15 mins at 11am, none):
- Record of immunisation activity:

Activity	Time started	Time finished	Notes

11

Date: Site code: Log code:

Activity	Time started	Time finished	Notes

Date: Site code: Log code:

SECTION 3: Infrequent immunisation activities

- In this section please record any activity relating to immunisations that you undertake infrequently, i.e. less than once per month.
- This may include annual training, reminder/recall, assisting with vaccine ordering, non-routine data submission.

Activity	Frequency	Time taken	Consumables used	Notes
e.g. Annual vaccine training day	*Once annually*	*1 day*	*None*	*Arranged by the local SIT. One day of study leave taken.*
e.g. Data cleaning for CHIS submission.	*Quarterly*	*4 hours*	*None*	*Ensuring that data submitted are accurate.*

9.6 Costing survey

INSTRUCTIONS

Purpose

The purpose of this data collection sheet is to gather information on the costs of running your practice.

This will be used for an Activity Based Costing analysis, to determine how much delivering the routine immunisation programme costs your practice, alongside the activity logs being completed by the practice staff.

Confidentiality

All the information provided here will be treated in **strictest research confidence**, anonymised and securely stored as per the protocol approved by the NHS Health Research Authority, NIHR Clincal Research Network and LSHTM Ethics Committee. This survey will not be shared with anyone other than the Prinicipal Investigator (Dr Tim Crocker-Buque).

No individual statistics from your practice will be reported. Nor will your practice be individually identifiable as part of the analysis. Please do not include any staff names or other identifable information in this form.

Outputs

This forms asks for detailed cost information, which is required for the analysis. The statistics derived from these data will include cost per vaccination event and total annual cost of delivering the immunisation programme, which will be added to similar data from other practices for comparison.

Other information such staffing costs or other expenses will not be reported.

Completing the form

The form comprises 3 sections, shown as tabs below: 1. Practice Info, 2. Facility Costs, 3. Batch and Unit Level Costs.

Please fill out the form using data for the previous 12 months from date of completion (i.e. if filling the form in June 2017, use data May 2016 - May 2017).

If there are any costs that are not relevant, please leave the spaces blank. Similarly, if there are any other related costs that are important to your practice, please add these in the spaces provided.

For the Batch & Unit Level costs, please only include costs related to the routine immunisation programme for children and adults, and do not include anything for seasonal influenza.

For any questions on how to fill out this form, please contact Tim Crocker-Buqué: timothy.crocker-buque@lshtm.ac.uk, or 07969 959 790

1				
2	PRACTICE CODE:			
3	DATE:			
4				
5	**PRACTICE INFORMATION:**			
6	Number of registered patients:			
7	Number of annual births:			
8	Number of service delivery sites:			
9	How many non-influenza immunisations did your practice deliver in the last 12 monts?			
10	What is the approximate size (sq M, or Sq ft of your practice?			
11				
12	**Opening Hours**			
13	Service type	Day(s) of the week	Hours	Comments
14	*Please amend*			
15	*GP Clincs*	*Mon, Tues, Weds, Fri*	*08-13, 14-18*	*4 GPs per clinic*
16	*GP Clincs*	*Thus*	*08 to 13*	*3 GPs on a Thurs*
17	*Nurse clinc*	*Mon, Thurs, Fri*	*08-12, 16-19*	*1 nurse per clinic*
18				
19				
20				
21				
22				
23				
24				
25				
26				
27	*PLEASE ADD*			
28				
29				
30	Please provide the total number of appointments at the practice in the last 12 months.			
31	If actual data are not available, please make an estimate of the total number.			
32	**APPOINTMENT INFORMATION:**			
33	**Staff members**	**Appointment length**	**Total number annually**	
34	General Practioner			
35	Practice Nurse			
36	HCA			
37	*Other*			
38				

1	FACILITY LEVEL						
2	**CATEGORY**	**ITEM**	**DESCRIPTION**	**UNIT (please select)**	**COST per Unit**	**TOTAL ANNUAL COST (12 months, year to date)**	**NOTES (please provide details)**
3	**Administration**						
4		Rent/mortgage	Costs of providing building	Monthly/annual			
5		Buildings tax	Council tax, business rates etc	Monthly/annual			
6		Insurance	Insurance relating to buildings or contents.	Monthly/annual			
7		Other facility insurances	Any other required insurance.	Monthly/annual			
8		Depreciation	Any accounting cost attached to depreciation of asse	Monthly/annual			
9		Accounting & legal costs	Cost for accouting and legal services.	Monthly/annual			
10		Subscriptions	Any regular require subscriptions.	Monthly/annual			
11		(Global sum)	If you pay a global sum, please state.	Monthly/annual			
12	**Finance**						
13		Interest charges	Any charges relating to interest payments	Monthly/annual			
14		Bank Charges	Any charges from banking.	Monthly/annual			
15	**Operating expenses**						
16		Office consumables	Paper, printing, stationary etc.	Monthly/annual			
17		Other consumables	Any other consumables (please describe)	Monthly/annual			
18		Cleaning	Building cleaning service	Monthly/annual			
19		Laundry	Laundry service (if relevant)	Monthly/annual			
20		Statutory training	Cost for providing statutory/mandatory training.	Monthly/annual			
21		IT services	Software, maintenance, helpdesk costs	Monthly/annual			
22		Telecommunications	Internet, phones.	Monthly/annual			
23		Waste removal	Waste, including sharps disposal.	Monthly/annual			
24		Repairs and maintenanc	To estates, buildings, or contents.	Monthly/annual			
25		Equipment costs	Capital costs for new equipment.	Monthly/annual			
26		Other service	Please describe				
27		Other service	Please describe				
28	**Staff costs** (please include individual costs for all admin and management staff members, and all clincal staff involved in immunisation employed at the						**Please include number of contracted hours and FTE status**
29	PLEASE NOTE BELOW	Practice Manager		Annual cost to practice			
30		Practice nurse		Annual cost to practice			
31		HCA		Annual cost to practice			
32		Receptionist		Annual cost to practice			
33							
34							
35	**Other costs**						
36		Please add	Please describe				
37							
38–41	Please note: having exact information in relation to staff costs makes the analysis significantly more accurate. However, if you are not able to provide staff costs, please provide an indicative profile of the staffing levels of the practice and I can insert estimated dummy costs for staff to estimate the human resource costs. If there are other costs you are not happy to provide, please contact the research team.						

1	**BATCH and UNIT LEVEL**					
2	**CATEGORY**	**ITEM**	**DESCRIPTION**	**UNIT**	**COST per Unit**	**TOTAL ANNUAL COST (12 months, year to date)**
3	**Office consumables**					
4	(specific to imms)	Printing, postage, stationary	For reminder/recall	Monthly/annual		
5		Telecommunications (e.g. text messages)	For reminder/recall	Monthly/annual		
6		IT/software	For appointing, or reminder/recall	Monthly/annual		
7	**Clinical consumables**					
8	(specific to imms)	Needles		Individual/box of n		
9		Syringes		Individual/box of n		
10		Plasters		Individual/box of n		
11		Alcohol wipes		Individual/box of n		
12		Distractors	Sweets, stickers	Individual/box of n		
13	**Other costs**					
14	(specific to imms)	Vaccine fridges	Capital and maintenance costs	Monthly/annual		
15		Cold chain accreditation	Any accreditation costs	Monthly/annual		
16						

9.7 Organisational sensemaking coding tree

1. SITUATING	
Comparison to other practices	
Describing practice character	
Describing practice history	
Ethnicity	
Explaining community	
Patients and Parents	
	Changing parental roles
	Educating patients
	Language
	Middle class parents
	Parental choice
	Parental concerns
	Parental responsibility
	Parents declining
	Patient participation
	Patients
	Patients knowing entitlements
	Patient's knowledge
	Patients not updating details
	Reasons for non-attending
	Vaccinating abroad
Physical space	
Population movement	
Staff roles	
	Admin
	Defined responsibility
	Defined staff roles
	Describing professional roles
	Describing team tasks
	Diffuse responsibility
	GP
	HCA
	Health Visitor
	Long-term staff
	New staff
	No training - admin
	Nurse
	Practice Manager
	Receptionist
	Undertaking training

2. **COMMUNICATING**
Admin sharing knowledge
Communicated to by external organisation
Communicating to patients
Communication between nurses and admin
Communication between staff groups
Interacting with SIL, SIT
Liaison with school nurses
3. ORGANISING
Admin capacity
Administration
Appointments
Admin sneaking appointments
Adolescent vaccines
Adult appointments
Appointment availability
Appointment length
Nurses appointing
Nurses appointing for adults
Pregnant women pertussis
Rationalising appointment time
Students
Clinic
Defined clinic time
Data submission
Concerns over data accuracy
Describing practice staffing
Finance
Finance unknown
Financial incentives
Formal vs Informal
Formal meeting
Informal organisation
Giving adult vaccines with flu
IT system
No campaigns
Opportunistic
Organisation history
Prioritisation
Reminder-recall
Pursuing children
Reminder message
Safeguarding

Stocking and ordering
4. EXPERIENCING
In clinic
12 month vaccines stressful
Child behaviour
Giving vaccinations - time
Number of vaccines
Pre-school booster appointment
Red book
Vaccine refusals
Of organisation
Capacity
Costs
Dealing with change
External organisations
Problem with DNA
Reminder-recall
Resources
Time spent
Outbreaks
Patient safety, errors
5. **INTERPRETING**
Information use
Overall practice system
Performance
Doesn't know performance