How can secondary care-based clinicians access and use primary care-held vaccination data during a Paediatric Emergency Department attendance?

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Abstract

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Background

Before the SARS-CoV2/COVID pandemic, in the UK, coverage for some routine childhood vaccines e.g. MMR (measles, mumps, and rubella), were below global targets. A visit to hospital might provide an opportunity to offer a “catch-up” intervention to under-immunised children and young people, if clinicians could accurately identify them.

Aims

The overall aims were to look at sources of vaccination data available to clinicians working in the Paediatric Emergency Department (PED) and explore how an intervention might address under-vaccination.

Methods

A multiple methods pilot explored the feasibility and acceptability of delivering a brief public health intervention within a PED attendance. A scoping review summarised evidence for the delivery of interventions in hospitals to improve vaccination uptake in children and young people (CYP).

Unmet vaccination need in under-fives was estimated via a cross-sectional observational study with a single data collection point for participants attending a large PED in Greater Manchester, in October 2021.

Sources of vaccination data explored were: parent/carer recall, Child Health Information Services (CHIS), and Summary Care Records (SCRs). This was via a cross-sectional observational study (recall and SCRs) and a systems mapping approach (for CHIS).

Results

This work demonstrated that it was feasible and acceptable to deliver an intervention during a PED attendance and that vaccination interventions in hospital settings may be beneficial.

There was considerable unmet need amongst children under the age of five years old, attending the PED, with extremely low levels of MMR coverage amongst those old enough to be eligible for two doses.

Vaccination status was often over-estimated by parents/carers, CHIS were a definitive source of vaccination data but inaccessible to PED clinicians, and data within SCRs were presented in an inconsistent manner and often unstructured.

Conclusion

Whilst delivery of a vaccination-focused intervention during a PED attendance appears feasible, more work is needed to enable clinicians to identify those CYP with unmet vaccination need who might benefit from such an approach.

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Acknowledgements

This MD started out a project to try and solve a thorny issue in my clinical practice and has ended up being so much more. I started as a complete noob and will finish as Deputy Chief Clinical Informatics Officer at the UK's largest children's hospital. I did not see that one coming! And could not have done it on my own.

I would like to express my heartfelt thanks to my supervisors Professors Jo Knight and Nige Davies who somehow kept me on the straight and narrow for the last two years. Jo, your advice and guidance is second to none, and thinking "What would Jo do?" saved my a** on more than one occasion. Nige, supervising a medic must have been super hard for someone who loves all things medical as little as you do.

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p.s. thanks to everyone who ever laughed (politely or otherwise) when I made a joke about "back ends" being different in paediatrics and computing. I can only apologise. I am older and wiser now.

Declaration

I declare that this thesis is my own work and has not been submitted in substantially the same form for the award of a higher degree elsewhere.

Sections of this thesis which have been published in peer-reviewed journals or presented at conferences are clearly identified (and may appear in a journal-specific format).

As research is a collaborative undertaking, I have also indicated the nature of the contribution of others where relevant.

List of abbreviations

Please note: abbreviations are presented with capitalisation to identify the source letters of the acronym (for ease of understanding) but may not appear with same capitalisation in the main text or in everyday use.

CHIS = Child Health Information Service

COVER = Cover of Vaccination Evaluated Rapidly

COVID = COronaVIrus Disease

CP-IS = Child Protection Information Sharing

CYP = Children and Young people

ED = Emergency Department

EPR = Electronic Patient Record

GP = General Practitioner or General Practice (depending on context)

HCP = Health Care Practitioner

Hib = *Haemophilus influenzae b*

IT = Information Technology

MECC = Making Every Contact Count

MMR = Measles, Mumps, and Rubella

MMR1 = Measles, Mumps, and Rubella dose 1

MMR2 = Measles, Mumps, and Rubella dose 2

NHS = National Health Service

NICE = the National Institute for Health and Care Excellence

NIHR = National Institute for Health and Care Research

PED = Paediatric Emergency Department

Ro = R nought = basic reproduction number

RQ = Research Question

SARS-CoV-2 = Severe Acute Respiratory Syndrome CoronaVirus-2

SBIRT = Screening, Brief Intervention, and Referral to Treatment

SCR = Summary Care Record

UNICEF = United Nations Children's Fund

WHO = World Health Organization

Chapter 1

Background

Vaccines are one of the great global health successes. Since their discovery more than 300 years ago, they have saved countless millions of lives (1), reduced the incidence of dozens of diseases, and even lead to the eradication of smallpox (2). The World Health Organization (WHO) estimated that 10 million lives were saved from vaccine-preventable diseases, just between 2010 and 2015 (3). Vaccines have also had a profound impact on the course of the SARS-CoV-2/COVID19 pandemic in those countries with access to them (4).

As well as collecting data relating to vaccine coverage and vaccine-preventable diseases, the WHO also produces guidance on what should be included in national vaccination programmes (5). Whilst in 2019, 85% of children worldwide received a complete first set of three diphtheria/tetanus/pertussis-containing vaccines (6), the WHO identified “vaccine hesitancy” as one of its *Ten threats to global health in 2019* (7). Addressing vaccination hesitancy has enormous potential to improve health and the WHO estimates that if global vaccination levels increased, an additional 1.5 million lives could be saved each year (6,7). Whilst vaccination hesitancy (and the associated “anti-vaxx” phenomenon) is an important part of why vaccination levels are below target globally, other factors include ease of access (perceived or otherwise) to vaccination services, issues with data throughout vaccination systems, and, more recently, disruption to healthcare services and systems as a result of the SARS-CoV-2/COVID19 pandemic.

Despite the profound positive impact of vaccinations, in the UK, pre-pandemic uptake of routine childhood vaccination had fluctuated in recent years (8,9) and we already lagged behind some of our European peers for coverage for common vaccine-preventable diseases such as measles (10). This finding was on a background of global changes in the pattern of vaccination and an associated increase in outbreaks of vaccine-preventable diseases (11).

Routine childhood vaccination/coverage in the UK

In the UK, vaccination (or immunisation – used interchangeably here) has formed a cornerstone of the National Health Service (NHS) since its launch in 1948 (12). Children in England are routinely vaccinated (at no cost to them or their carers) against a wide range of potentially life-threatening or life-altering diseases (13). The schedule is complex and frequently reviewed and updated, but information is also provided about vaccinating those with “uncertain or incomplete immunisation” (14), for example those who are new to the UK and the NHS’ schedule.

In 2020-21 (the latest year for which complete data are currently available), routine childhood vaccination coverage (measured at 1, 2, and 5 years of age) remained within 0.5% of 2019-20 values for all vaccinations (14). However, peak coverage for many routine childhood vaccines in these age groups was a decade ago.

MMR (the vaccine that protects against measles, mumps, and rubella) data are often more labile than others for a combination of reasons. Recent years have seen decreases in coverage, partially reversing the slow recovery of vaccination uptake

seen after it plunged following the publication of the (now-retracted) *Lancet* paper spuriously linking the MMR vaccine with autism (15). Written by the (now struck-off) former doctor Andrew Wakefield, the article resulted in a drop in MMR coverage in the UK from around the 95% mark (needed for herd immunity for measles – see below), to 80% in the late 1990s (16). When looking at the most recent data for MMR, 2020-21 showed coverage in England for the first dose (MMR1, usually given around 12 months of age) at the age of 2 years at 90.3% and by the age of 5 at 94.3% (17). Coverage for the full course of MMR vaccination (two doses, with MMR2 given around the age of 3 years 4 months) by the age of 5 years was 86.6%.

In contrast, tetanus-containing vaccine uptake tends to show less variation. When looking at the data for these vaccines, coverage is reported for the primary course (vaccinations at 8, 12, and 16 weeks of age) and the so-called “pre-school booster” (scheduled with MMR2 at 3 years 4 months) (13). Coverage in 2020-21, in England, for a full course of age-appropriate tetanus-containing vaccination (i.e. primary and booster) by the age of 5 years was 85.3%, with 95.2% of children in this age group having received the primary course (9).

Some vaccines for other diseases that can spread person-to-person e.g. mumps (also covered by MMR), have now dropped below the level needed for so-called “herd immunity” – coverage of the general population that prevents outbreaks and protects those individuals who may not be able to receive the vaccine for medically-relevant reasons, e.g. immunosuppression (see section 1. of (17)).

These recent declines in vaccination uptake and coverage are likely to be underpinned by a number of things, including:

- issues with data throughout the vaccination cycle e.g. call/recall systems (18);
- inconvenience associated with accessing vaccination services e.g. convenience trade-offs in decision making (19);
- so-called “hard to access” (or underserved) populations (e.g. children in care (20), traveller communities (21));
- vaccination hesitancy (defined as “the reluctance or refusal to vaccinate despite the availability of vaccines” (7));
- opposition to vaccination on religious grounds (e.g. some Orthodox Jewish populations (22))
- non-religious “anti-vaccination” sentiment (known colloquially as “antivaxx” – used here to refer to those actively opposed to vaccination and often associated with other “anti-medicine” or “anti-science” opinions, involving the use and distribution of misinformation, and “conspiracy theories”, and distinct from hesitancy) (23).

Any attempts to increase vaccination uptake must therefore be sensitive to these complexities and avoid the temptation of focussing solely on, for example, “anti-vaxx”, when in fact more people show hesitancy or have issues around convenience of access (both of which might be more susceptible to modification via an interaction

with a healthcare practitioner). The SARS-CoV-2/COVID19 pandemic has had a multifaceted impact on vaccination intake and this is explored further below.

Two diseases have been chosen as examples for the work – measles (prevented via the MMR) and tetanus (prevented via various combination vaccines given throughout the life course). Vaccination against measles provides individual- and population-level protection but, for the reasons outlined above, uptake of MMR is relatively labile compared to other vaccines. The MMR vaccine is also often used as an exemplar in the literature and it was chosen for the sample size calculation. Tetanus vaccination is less controversial and vaccination coverage tends to be more stable. Vaccination offers individual-level protection but, as it is not communicable between individuals, does not offer any herd immunity.

Measles virus is extremely infectious, and the disease is serious and untreatable (only supportive care can be provided). Each index case of measles can infect around 12-18 susceptible individuals (this is known as the basic reproductive number, Ro) and the case-fatality rate (% of cases that die) depends on the characteristics of the individuals infected, but is in the range of 0.1-0.3% in high-income countries such as the UK. The burden of mortality falls on those under the age of 5 or with immune compromise (24). The virus spreads via airborne and droplet transmission and an un-vaccinated individual has a 90% chance of developing the disease if exposed. Receipt of two doses of MMR provides lifelong protection in the majority of cases. Herd immunity due to high levels of coverage with MMR can prevent outbreaks of the disease, but the vaccine can also be used

reactively within a measles outbreak, to stop the disease spreading further. High enough coverage could ultimately lead to eradication of measles, but the current global disruption (combined with suboptimal vaccination coverage) means that we remain at high risk of measles outbreaks in England (25).

The other two diseases – mumps and rubella – prevented by the MMR vaccine are less infectious than measles, but can also result in serious illness and associated morbidity. Mumps is caused by a paramyxovirus which is spread by droplets and has an Ro of approximately 4-7. Deaths from mumps are extremely rare, but it is a cause of preventable deafness(26). In contrast, rubella is a togavirus that usually results in a mild illness but presents a particular risk in pregnancy, with maternal rubella infection resulting in foetal loss or congenital rubella syndrome (28).

Tetanus is caused by a soil-dwelling bacterium (*Clostridium tetani*), is not spread person-person, and its spores are so widespread that it will never be eradicated (27). The case-fatality rate if untreated is up to 90%. In the UK, if a child or young person presents to the PED with a tetanus-prone wound, immediate management depends on recollection of vaccination status (28). Those of uncertain vaccination status are treated more aggressively than those that have definitely received an age-appropriate course of tetanus-containing vaccines, and treatment may include vaccination and administration of anti-toxin. Tetanus-containing vaccines are given frequently throughout the life-course and in multiple different combination vaccines, depending on the age of the recipient. Tetanus is amongst the first diseases vaccinated against at 8 weeks of age, where it is given as part of a hexavalent vaccine that also includes protection against diphtheria, pertussis (whooping cough),

polio, *Haemophilus influenzae* type b (Hib), and hepatitis B. It is also included in the final vaccination of childhood (given in Year 9 of school), where it is given in a trivalent vaccine along with diphtheria and polio (13).

The impact of the pandemic on vaccination coverage

There is evidence that during the first wave of the SARS-CoV-2/COVID-19 pandemic, uptake of routine childhood vaccination decreased as health services were disrupted (29). For example, 2500 fewer doses of the MMR vaccine were administered in England in the first 17 weeks of 2020, compared to the same period in 2019, although rates have fluctuated since then as services adapted but there were further periods of restriction and lockdown (30). This is likely to result in an overall drop in coverage of MMR1 and MMR2 for cohorts due for vaccination during the early part of the pandemic. This is of particular interest as the UK lost its measles-free status at the end of August 2019 (31). Obtained only three years earlier (32), loss of measles-free status means that a country has circulating measles virus and inadequate vaccination coverage levels (via MMR) to prevent spread within populations (16). The MMR vaccine protects against the viruses that cause measles, mumps, and rubella, and is a highly effective live vaccine given as a course of two doses, with good, protective “herd immunity” once coverage levels reach 95% (24). In 2020-21, 86.6% of 5-year-olds in England had received two doses of MMR, and no region in England had coverage levels at 95% or above. Coverage in the North West as a whole was 87.4% for MMR2 by the age of 5 in 2020-21 (down from 88.1% in 2019-20 (8)) and 79.2% for Manchester, down from 80.0% (9).

In April 2022, the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO) released a joint statement warning of a global "perfect storm of conditions for measles outbreaks" (33), citing pandemic-related disruptions increasing inequalities in access to vaccines and further compounded by conflicts and crises in countries including Afghanistan and Ukraine. Worldwide measles cases in early 2022 were nearly twice those seen in the same period 2021, but with reporting and surveillance also disrupted by the pandemic, numbers are likely to be underestimates. As measles is such a highly infectious disease, the increasing numbers may be an early indication of the impact of the gaps in vaccination more broadly. Combined with other pandemic-related phenomena, such as the theoretical "immune debt" (where reduced exposure to viruses and bacteria during periods of decreased mixing e.g. lockdowns, results in a lack of immune stimulation), decreased vaccination coverage makes other epidemics more likely (34), even in countries that do not usually experience them.

It is possible, therefore, that the UK's recovery from the current pandemic will be complicated by outbreaks of vaccine-preventable diseases such as measles, and within-pandemic outbreaks have been experienced elsewhere in the world as measles vaccination programmes have been suspended or disrupted (11).

If a system existed where hospital-based clinicians could easily and reliably access vaccination records, then UK PEDs could also offer the opportunity for delivery of reactive vaccination programmes in outbreaks e.g. of measles, in addition to the routine immunisation "catch-ups" suggested above.

Use of “IT” in NHS care

Despite commitment from successive governments, electronic patient records (EPR), “digital”, and information technology (IT) in the NHS have a long and complex history. Whilst successive NHS-wide IT programmes have failed to deliver (35), pockets of success do exist within the NHS ecosystem. For example, primary care has been using mainly digital systems for more than a decade now, following *Securing Excellence in GP IT Services*, first published in 2012 (36). However, even where there are areas where digital has been successfully harnessed, this tends to be restricted to a local area, with ongoing issues of interoperability between systems, data quality, and accessibility hampering a joined-up approach to the collection, storage, usage, and sharing of data within the NHS.

These issues exist at the interface between primary and secondary care but also within secondary care where, for an example, for a single patient, a clinician might have to log on to separate systems for outpatient clinic letters, blood results, radiology images and reports, etc., all within an individual NHS Trust. Even in organisations with EPRs, these are extremely variable, and range from fully integrated systems such as Epic (37), where notes, results, prescriptions, referrals etc. may all be in one place, to systems that are “paper-free” but fragmented and actually the EPR is made up of multiple interconnected (or not) parts. However, as patients often receive care over a number of organisations, even for those with a fully integrated EPR, sharing information with other parts of the NHS, across organisational boundaries is fraught with difficulties.

The current pandemic has seen a period of unprecedented change and digital has been part of that, leading to calls for a commitment to, amongst other things, integrated EPRs that are accessible to patients, carers, health, and care providers across multiple settings (38).

Recording of vaccination administration

In the UK, the majority of routine childhood immunisations are offered in community locations, commonly delivered via settings such as a GP surgery. Administration of one of more vaccines will be recorded in the GP electronic record, with returns sent from this system to the local Child Health Information Service (CHIS), and then on to the central surveillance system (39).

In addition, all children should have a handheld paper personal child record – the Red Book – that records important events in their health and development. However, if a parent/carer cannot provide the book during a consultation, this will not happen. Also other groups such as “looked after children” (those living in care) may not have a valid or up-to-date record, further disadvantaging them. An electronic version of the Red Book (eRedbook, (40)) is now available nationwide (41), and whilst it is commissioned locally, there was a national commitment to offer parents/carers the choice of a digital or paper-based version from 2023/24, as per the *NHS Long Term Plan Implementation Framework* (29, section 7.1). However, this digital version is designed for newborns, so anyone born before the local rollout of the digital Red

Book is very likely to have received a paper copy, so full coverage for those aged 0-16 years will not be achieved until 2039/40. It is also less likely that parents/carers of older children would use the Red Book routinely as its focus is mainly pre-school, so those who have missed out on one or more vaccinations in early childhood but who are now in school are going to be harder to identify via this approach. Additionally, any child or young person born outside the NHS may not have a Red Book (in any form) at their time of presentation to the PED. Those who present to the PED without someone who can access their Red Book will not have that information available to clinicians (and unlike the physical copy, the electronic copy cannot travel with the child). Finally, groups of CYP who currently experience profound health inequality e.g. those in the care system, are likely to continue to be disadvantaged by reliance on a Red Book of any kind.

Accessing primary care-held data in secondary care

As mentioned above, there are challenges for those attempting to access data across the primary/secondary care boundary. Increased integration of care and better sharing of data has the potential to improve the health of populations, increase patient and provider satisfaction, and reduce costs – the so-called “quadruple aim” of health system performance (43). However, issues of interoperability (getting systems to “talk” to each other) and issues of access (to primary care-based systems holding data), are particular problems for those working in hospitals, and this may be particularly acute in high-volume, time-pressured settings such as the Emergency Department.

Where they do exist, systems and pathways to integrate care are often developed with adult patients in mind, which means the challenges of data access may be further compounded for children and young people, leading in turn to additional avoidable harm (44). For example, the UK has death rates due to asthma in childhood far above those of its wealthy European peers (45). Part of the reason for this is that most care for CYP with asthma is delivered in the community, but specialist care is provided in hospitals, with extremely poor communication between the two around management plans (44,45). This lack of routine integration of pathways of care results in additional mortality, but also morbidity, further stretching hospital capacity.

Those working in settings such as the ED are likely to benefit from timely access to accurate data to augment the routine histories they may take from their patients (and accompanying parents/carers in the case of CYP). Given the volume of patients seen “at the front door” of the hospital and the increasing pressures of both time and space in the ED, accessing primary care-held data must involve the smallest number of steps and be as close to time-neutral as possible.

Perhaps the best (only) example of where this currently happens nationally for CYP is the Children Protection-Information Sharing (CP-IS) service. CP-IS alerts staff working in unscheduled care settings if a child is “looked after” (in care) or named on a child protection plan, provides the contact details for social care, and alerts the social care team of the child’s attendance automatically (46). Recent local attempts

to remove the primary/secondary care boundary include *Connecting Care for Children* in North West London (44) and *the Greater Manchester Care Record* (47).

Access to vaccination information in the hospital

If clinicians are to engage in a discussion around vaccination during a routine hospital consultation it is important to first find out if a child or young person is up-to-date with their routine vaccinations. In its 2009 guidance (updated 2017), the National Institute for Health and Care Excellence (NICE) recommended that the vaccination status of any patient in this age group be checked at every available opportunity (e.g. interaction with a clinician in the Emergency Department) (48). This is especially important for certain sub-populations of vulnerable children, for example those who are new to the UK (and the NHS vaccination schedule), or those who are at higher risk of poorer health as a result of their socioeconomic background.

As mentioned above, vaccination information is an example of primary care-held data that might be of use to those working in secondary care. In the PED, all practitioners should routinely enquire of the parent/carer accompanying a child or young person if that child has received all of their age-appropriate vaccinations, typically asking a relatively superficial question such as “Have they had all their vaccinations?” and then relying on the response given. However, past work has shown that often no question about vaccination status is asked or recorded in the patient’s notes (49). Other work has suggested that parents/carers tend to over-estimate vaccination status for those CYP in their care (see 40 for overview)

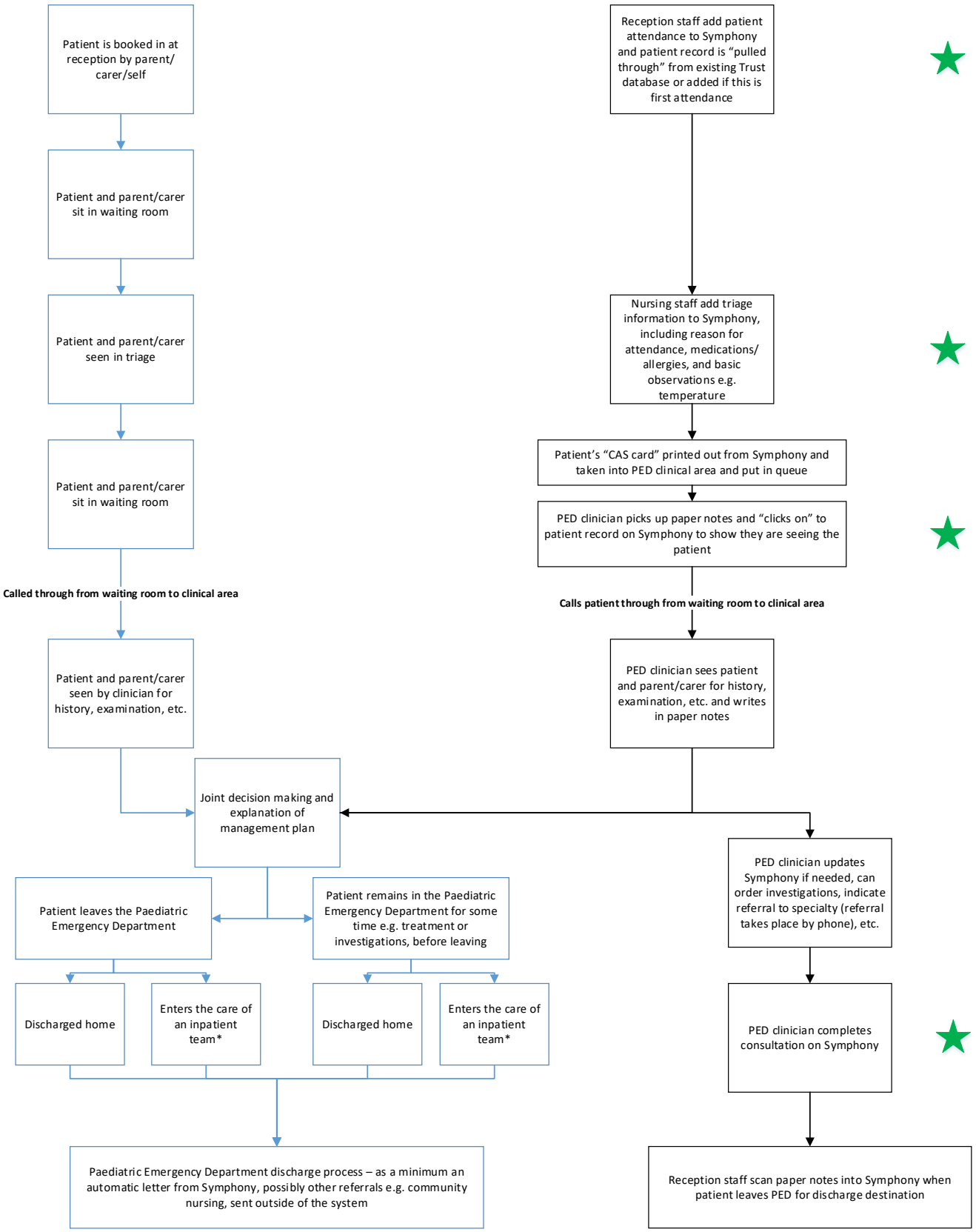
suggesting that clinicians might not be able to rely solely on this as a source of vaccine-related information.

In contrast, in primary care, if a child attends a General Practitioner (GP) appointment, the clinician is able to see, via the presence of a “pop-up window”, if the child is not up-to-date with their vaccinations (51). The difference here is that the vaccination data are held within the same data management system as the GP records, so the information is just pulled through, whereas the systems in primary care (that hold the vaccination data) are separate to, and different from, those used in the hospital, and they cannot communicate directly.

Whilst it may be that, with time, the NHS will be able to directly overcome the issues of interoperability between data systems, including those holding vaccination information, it is important that we are not over-reliant on waiting for a single part-solution to the issues outlined above. The time taken to access such a system, by the healthcare practitioner, must also be taken into account, particularly in a setting such as the ED where time, access to reliable IT, and departmental pressures may place restrictions upon what activity can be completed that is seen as “extra” to routine existing practice. For example, a system within the ED computer software that resulted in a “flag” (similar to that seen in the case of a GP consultation – described above) appearing automatically, might be accepted in the same way as flags for children protection are currently (as they require no extra effort on the part of the individual clinician). This might be preferable to a system where an individual clinician had to log on to a separate web-based system and find a personalised vaccination record for their patient. Those providing care in the PED throughout a

patient journey frequently interact with computer systems (see Figure 1 for a current example), so there are multiple opportunities for “flags” to be seen. If easily identifiable in the PED, under-vaccinated CYP could then be offered a suitable intervention, for example signposting to opportunities e.g. to “catch-up” with missing routine vaccinations.

Figure 1. An example of a patient journey in the Paediatric Emergency Department. “Symphony” refers to the electronic patient management and triage system used in the department at the time (now superseded by an integrated electronic patient record).



* those referred to an inpatient team will also have admission and discharge processes relating to that activity

= minimum interactions with Symphony system during a routine attendance

Delivering public health interventions in the (P)ED

Every year in England, millions of children and young people (CYP) attend hospital (secondary or tertiary medical care) (52) often with relatively minor illnesses and injuries, many of which could be more appropriately managed elsewhere, and which sometimes result in long waits to see a healthcare professional. However, despite numerous initiatives to redirect these CYP, hospital attendances (pre-pandemic) had increased year-on-year (53) – the pronounced decrease in Paediatric Emergency Department (PED) attendances seen early in the pandemic (54,55) was reversed in 2021, with attendances exceeding pre-pandemic levels, with an associated change in the patterns of illness (56).

In addition to their primary reason for presentation, CYP attending the hospital may have lower than average levels of health and wellbeing, additional unmet health need (e.g. sexual health), or not be engaged with preventive elements of routine healthcare (e.g. vaccination) for a myriad of reasons. A hospital attendance or admission might therefore offer an opportunity to improve health, beyond the initial reason for presentation (57). One way in which this might be done is by the delivery of public health-type interventions within routine hospital practice.

Whilst the vast majority of public health-commissioned interventions in England are delivered in the community e.g. some cancer screening programmes, a number are already delivered (at least in part) in secondary care settings e.g. harmful alcohol use screening. However, there are a very small number of interventions of this type

delivered in secondary care with a target population of children and young people e.g. newborn hearing screening. Despite this, many of the well-established public health programmes targeting younger age groups are well-suited to be adapted and adopted within secondary care. Most of the time there is very little specifically about these preventative approaches that means that they must be carried out in the community.

Ever-increasing demand for ED services means that CYP and their accompanying carers may spend several hours waiting in the PED for a consultation with a doctor or other healthcare professional that only lasts a relatively few minutes. Other CYP may need to be observed in the department for a period of time following treatment and before discharge. Whilst there are numerous initiatives to try and re-direct potential ED attenders to other, more appropriate parts of the system, e.g. re-routing a child with dental pain to a community dentist, there are very few that aim to use the waiting time in the department in a positive way to improve health. Ideally, this alternative approach – of using fallow time in the department to address wider health and wellbeing issues – has the potential to ultimately decrease attendances to the department, by avoiding future attendances with a preventable element, although over a much longer timescale than initiatives such as re-directing at the point of presentation.

Delivery of a vaccination intervention in the PED

Vaccination is an example of a public health-style intervention that could be relatively easily transferred to the hospital. Large volume settings within the hospital, such as

the PED, offer the opportunity to interact with high numbers of CYP every year, many of whom may be missing vaccinations from the routine NHS schedule, for a wide range of reasons. If any child or young person who had not received their age-appropriate routine vaccinations could be identified during a PED attendance, clinicians might (should it be clinically/situationally appropriate) be able to offer one or more tailored interventions to address this unmet vaccination need. The benefits of such an approach are potentially numerous and include:

- decreasing mortality and morbidity from vaccine-preventable diseases, by ensuring
  - individual and population coverage for diseases that cannot spread person-person e.g. tetanus (27),
  - higher levels of population coverage for non-epidemic diseases that can be spread person-person e.g. Hepatitis B (58),
  - and herd immunity for diseases that easily spread person-person and can cause outbreaks e.g. measles (24);
- a decrease in un-needed treatment in the case of individual exposure in the absence of an accurate vaccination history e.g. tetanus (28);
- a reactive response to outbreaks e.g. mumps (26), epidemics e.g. influenza (59), and pandemics e.g. SARS-CoV-2 (the virus that causes COVID19) (60);
- improving coverage of targeted vaccination programmes e.g. seasonal influenza (59).

Whilst it is likely that CYP attending the PED are actually under-vaccinated relative to their peers (as attendees are more likely to come from a sub-population shown to have lower levels of uptake), there are no UK data that look specifically at this (61–63). Previous work from outside the UK has looked at all due or overdue vaccinations amongst populations attending the hospital (not just the PED), suggesting that coverage is in the range of 44% (64,65) to 89% (66) for routine immunisations. As a special case (as it is given annually and often in school rather than healthcare settings), influenza baseline coverage is lower still in this population, with estimates in the 25-50% range (67,68).

Screening, Brief Intervention, and Referral to Treatment (SBIRT) is a public health approach to the delivery of early intervention and treatment services (69). Similar to the NHS' *Making Every Contact Count* (MECC (70)), SBIRT developed from the work of D'Onofrio and colleagues at Yale, who have shown it to be an effective approach to managing patients with drug and alcohol use disorders in the adult ED (71,72). Other recent studies have shown it can be used for interventions such as smoking cessation (see (73) for overview) and improved follow-up care for conditions such as asthma (74). Whilst almost all published work has focused on adults, a small number of studies have shown its potential use in younger age groups (75,76).

Applying the SBIRT approach to the model of vaccination in the PED, the process can be broken down as: *S*creening – identifying under-vaccinated CYP during a PED visit; *B*rief *I*ntervention – offering one or more interventions in the PED, for example a brief discussion between the clinician and parent/carer and signposting to services; and *R*eferral to *T*reatment – for example referring the child or young person back into

community-based programmes in order to complete catch-up vaccinations or administration of MMR in the context of an outbreak.

Given the issues around parent/carer recall, there is also an argument for not relying on the vaccination history from carers as a sole source of information. The research described here therefore seeks to compare vaccination coverage among PED attendees and their local and regional peers, but also to provide evidence that, in the PED setting, parent/recall (as part of a routinely-taken history) is insufficiently reliable to "screen" (as per SBIRT) and identify those who would benefit from a (brief) intervention, and "referral to treatment", and that an alternative source of information is required.

Aim

The overall aim of this MD was to explore how secondary care-based clinicians can access and use vaccination data during a Paediatric Emergency Department attendance, and what intervention/s might be offered by them to improve vaccination coverage.

Overarching research questions

More detailed research questions (RQ) appear in each of the relevant chapters, but the overarching RQs for the thesis are:

RQ1. Is it feasible and acceptable to deliver a brief public health intervention as part of an attendance at the Paediatric Emergency Department? (Chapter 2)

RQ2. What are the interventions delivered in secondary or tertiary medical care settings focused on improving routine vaccination uptake in children and young people? (Chapter 3)

RQ3. Do children (aged < 5 years) attending the Paediatric Emergency Department have lower levels of vaccination coverage than their peers in the general population? (Chapter 4)

RQ4. How accurate is parent/carer recall of the vaccination status of children and young people (aged < 16 years) attending the Paediatric Emergency Department, when compared to primary care records? (Chapter 5)

RQ5. What other sources of vaccination data are there and is it possible to access them from within secondary (hospital) care? (Chapter 5)

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Chapter 2

Delivery of a multi-focus public health intervention in the paediatric emergency department: a feasibility and acceptability pilot.

Research question (RQ1): Is it feasible and acceptable to deliver a brief public health intervention as part of an attendance at the Paediatric Emergency Department?

This paper was published online in December 2021 as:

> Isba, R. and Edge, R. Delivery of a multi-focus public health intervention in the paediatric emergency department: a feasibility and acceptability pilot study. *BMJ Open* 2021; 11: e047139. https://bmjopen.bmj.com/content/bmjopen/11/12/e047139.full.pdf

I conceived of the study, applied for the funding, was involved in the ethics application process, undertook the fieldwork, analysed the data, and was involved in all stages of the preparation of the manuscript.

Parts of the work were also presented at the 2020 Royal College of Paediatrics and Child Health Conference in the Association of Paediatric Emergency Medicine stream, in September 2020 (delayed from Spring that year due to COVID). The paper presented was “Feasibility and acceptability pilot of a public health intervention delivered in the paediatric emergency department” and won the Joan Robson Prize.

The abstract was then published in October 2020 as:

> Isba, R., Edge R. G212 Feasiblity and acceptability pilot of a public health intervention delivered in the paediatric emergency department. *Archives of Disease In Childhood* 2020; 105:A76-A77. https://adc.bmj.com/content/archdischild/105/Suppl_1/A76.2.full.pdf

Abstract

Objective

The objective was to see if it was feasible and acceptable to deliver a brief public health intervention as part of an attendance at the Paediatric Emergency Department (PED).

Design

A feasibility and acceptability pilot design was used as there is no previous work done in this clinical area, population, or using this approach in children and young people (CYP). Quantitative and qualitative data were collected. Follow-up was at one week and one, three, and six months.

Setting

This pilot took place in a single PED in Greater Manchester, England.

Participants

Participants were CYP (under 16 years old) and their parents/carers, attending the PED during a two-week recruitment period in September 2019.

Interventions

The intervention was a brief conversation with a Consultant in Paediatric Public Health Medicine, using Screening, Brief Intervention, and Referral to Treatment (SBIRT). The intervention focused on vaccination, dental health, household smoking, and frequent attendance.

Primary and secondary outcome measures

The primary outcome measure was information to support the effective development of a larger-scale study. Secondary outcomes were measures of health, again intended to provide additional information prior to a larger study.

Results

Thirty CYP were recruited from 29 households. Sixty percent of CYP triggered at least one screening question, most commonly household smoking and dental health. It was not possible to accurately assess frequent attendance and 97% of parents/carers stated that they thought their child or young person was fully vaccinated for their age, which is likely to be an over-estimate.

Conclusions

It is feasible to deliver a brief public health intervention in the PED and such an approach is acceptable to a variety of stakeholders including children and young people, parents/carers, and nursing staff. The pilot revealed issues around data quality and access. Future work will focus on vaccination and dental health.

Keywords

Public health, pilot study, children and young people, intervention, emergency department

Strengths and limitations of this study

This pilot study is the first of its kind in the UK, designed to assess the feasibility and acceptable of delivering a public health focused Screening, Brief Intervention, and Referral to Treatment (SBIRT) for children and young people attending a paediatric emergency department.

The study design enabled participation from children, young people, parents, and carers in the refinement of all aspects of the work.

Data access and quality issues were limitations of the study, particularly self-reported vaccination status (in the absence of a viable alternative source of data).

Introduction

In the UK, Emergency Department attendances have increased markedly over the last decade and in 2019/20 (April 1st 2019 to March 31st 2020), in England alone, there were more than 25 million attendances (1) for a population of 56 million (2). This pattern is mirrored globally, with increasing demand driven by a combination of factors, including an ageing population (3). However, children and young people (CYP) are also attending in greater numbers whilst, in the UK, their overall health and wellbeing continues to lag behind other high-income countries (4). Whilst the SARS-CoV-2/COVID-19 pandemic has had a profound impact on Paediatric Emergency Department (PED) attendances amongst CYP (5), it is likely that UK numbers will return to baseline during the post-pandemic recovery.

Those under 16 years old are more susceptible to the impacts of the full spectrum of health and social inequalities, such as poverty and lack of access to green spaces (6). The pandemic has resulted in widened inequalities as a result of disrupted services e.g. health and education (7,8). CYP who attend hospital are, by definition, less well than those who don't need to attend. However, as well as the reason for attendance, they may also be more likely to have other healthcare needs (9).

Whilst other work seeks to redirect CYP who attend the PED to other, more appropriate sources of care (often in the community), PED attendance may offer an opportunity to improve health and wellbeing. Patients often spend several hours in the PED, waiting to be seen, waiting for medication to work, etc. This "fallow" time could be used for one or more public health-style interventions designed to improve

health and wellbeing and, ultimately, prevent future avoidable attendance. For example, the National Institute of Health and Care Excellence (NICE) recommends that all interactions with healthcare providers should include checking that a child's routine vaccinations are up-to-date, with signposting to services offered if needed (10). Vaccination coverage in the UK lags behind other European countries for some vaccines (11) and in 2019 it lost "measles free status", meaning that there was free-circulating measles virus in populations and that coverage was below the 95% target uptake for MMR needed for measles-related herd immunity (12,13). Similarly, CYP in England experience growing dental health inequalities, with those from more socioeconomically deprived areas having higher levels of decayed, missing, or filled teeth. Children with tooth decay may have pain, poor growth, and miss school as a result (14). The pandemic has had a profound impact on delivery of routine community dental services, compounding these dental inequalities further (15). The health of the children of Greater Manchester is below the national average for many metrics (16) and whilst PED attendances increase year-on year, public health budgets across England continue to be cut, resulting in a reduction in community-based services (17,18). Whilst secondary care offers an opportunity to improve child health via preventative approaches, there are only a relatively small number of projects around the country that aim to do so, e.g. violence reduction programmes (19). In the face of increasing attendances to the PED and decreasing services elsewhere, emergency medicine is currently well-placed to support an innovative approach to deliver public health interventions that may ultimately reduce future hospital attendances with a preventable element.

Screening, Brief Intervention, and Referral to Treatment (SBIRT) is a public health approach to the delivery of early intervention and treatment services (20). Similar to the NHS' *Making Every Contact Count* (MECC), SBIRT developed from the work of D'Onofrio and colleagues at Yale, who have shown it to be an effective approach to managing patients with drug and alcohol use disorders in the adult ED (21,22). Other recent studies have shown it can be used for other conditions, such as smoking cessation (see (23) for overview) and improved follow-up care for asthma (24). Whilst almost all published work has focused on adults, a small number of studies have shown its potential use in younger age groups (25,26). A recent study in the US showed that the SBIRT approach could be used successfully in the PED for parental smoking cessation (27).

This pilot study aimed to adopt/adapt the SBIRT approach for use in the PED with CYP and their accompanying parents/carers. Any future intervention would be delivered in a setting already under considerable pressures of time, space, and staffing, therefore a feasibility and acceptability pilot model was used.

By focussing on four areas of health that are a particular issue for CYP living in areas of higher socio-economic deprivation – vaccination, dental health, household smoking, and frequent attendance – this pilot aimed to begin a process of improving child health that, if successful, could have a long term impact.

Methods

Ethics

Full prospective ethical approval was obtained from Lancaster University and the NHS (IRAS 214887, May 2018). Age-banded participant information sheets and consent forms were provided, with CYP encouraged to participate in the consent process in an age-appropriate way. Those competent to consent for themselves could solo sign for participation, those not yet competent could co-sign with their parent/carer (either by writing their name or making a mark of their choosing), and younger children were asked if they wanted to colour in a teddy bear picture whilst consent was given on their behalf.

Setting

This pilot was carried out in the PED of a large District General Hospital in Greater Manchester, in the North West of England. Children and young people in Manchester have lower than average levels of health and wellbeing, more than a quarter (27.1%) are in low income households, and 1 in 100 of them live in care (16). By 2 years of age only 88% of children in Manchester have received a first dose of the MMR vaccine and by the age of 5 years, 43% have at least one decayed, missing, or filled tooth (16).

Participants

Potential participants were CYP (less than 16 years old) and their parents/carers attending during a two-week period from the 5th of September 2019, on days where RI was onsite and able to deliver the intervention. Recruitment was carried out between the hours of 9am and 5pm on weekdays. Potential participants were identified by looking at the live patient list on the department's computer system and

then approached by RI as long as they didn't have one of the exclusion criteria (seriously ill or injured or not accompanied by someone legally able to give consent and not able to consent for self). Owing to resource constraints within the pilot, it was necessary to also exclude those requiring a translator for the primary PED consultation.

As this was a pilot, a sample size calculation was not carried out and a target for recruitment set at 30 "units" of recruitment, with each unit made up of at least one child or young person plus at least one parent or carer. This number was chosen as it was anticipated that, using the multiple methods approach outlined here, this would provide sufficient information for a meaningful reflection of the acceptability and feasibility of the intervention and provide sufficient information to inform the design of a larger scale trial.

Patient and Public Involvement

The feasibility and acceptability pilot enabled participation from children, young people, parents, and carers in the refinement of all aspects of the work, prior to any formal assessment of the effectiveness of the intervention via a full-scale study. Patients or the public were not involved in the reporting or dissemination plans of the research.

Interventions

The intervention was a brief conversation with a Consultant in Paediatric Public Health Medicine (RI). However, the intervention was designed to be flexible in terms of who could deliver it e.g. a suitably-trained allied health professional; adaptable in

terms of what other elements may be added in future depending on local need and services; and with the potential to be scaled-up e.g. extending to other settings.

In order to prevent disruption to the “normal business” of the department, participants were only recruited after they had been placed in a cubicle and were waiting e.g. to see a clinician. This also ensured that there was somewhere private to speak to participants.

The intervention was in several parts and followed the SBIRT approach. The first part was “Screening” and involved a public health “history” being taken from the CYP and parent/carer, including questions about the make-up of the household, the vaccination status of any CYP in the household (with a focus on the participating child), engagement with routine dental services, and household smoking (data relating to frequent attendance were extracted separately – see below). These four foci were chosen for reasons of importance to the local population, practicality (three of them have well-established, free, accessible, community-based programmes and systems to address them), and resource constraints within the pilot project. A wide range of other things could be considered for inclusion in future work, e.g. obesity, mental health, substance use disorders, food insecurity, etc. but were beyond the scope of this feasibility and acceptability pilot.

The “Brief Intervention” and “Referral to Treatment” then depended on the answers in the “Screening” part of the intervention:

- if any CYP had not completed their age-appropriate vaccine schedule, then a discussion was tailored to the reasons for this e.g. vaccination hesitancy, and signposting and information provided. If agreed with the parent/carer, this was

then followed up with a letter sent to the GP asking them to arrange “catch-up” vaccination;

- if there was not routine dental attendance, then information was given that included: a re-emphasis that all dental care for children is free, “first tooth first visit”, and support on how to find a dentist e.g. via 111;
- if the CYP stated that they smoked, then a brief negotiation approach was used to highlight services they could access when ready. If a household member reported smoking, then prior knowledge of sources of support for them was confirmed, along with the positive benefits for them and their household, should they feel ready to address their smoking;
- if the CYP was identified as a “frequent attender” (see below), then a discussion was had with their parent/carer around reasons for attendance.

If at “Screening” no triggers were identified, then positive reinforcement of existing activity was carried out and an opportunity offered to ask questions.

Follow-up was at one week, one month, three months, and six months, and completed the week before the global pandemic of SARS-CoV-2/COVID-19 was declared, so the study was not affected by the subsequent disruption of normal healthcare and dental services. An attempt was made to contact all participants at one week regardless of whether or not their screening questions had triggered the brief intervention. After that, if at follow-up there were no outstanding screening triggers, participants were thanked and discharged from the pilot (see Figure 1).

Outcomes

The primary outcome of the pilot was successful development of a "package" to inform a larger study that included:

- an intervention adapted based on the input of the pilot participants;
- an assessment of the feasibility of implementing such an intervention;
- an overview of acceptability from both the participant and departmental perspectives.

Secondary outcomes were measures of health outcomes in participants and households, intended to provide additional information for refinement prior to a larger study. These health outcomes were measured across the follow-up period and were: number of catch-up vaccinations given, number of dental appointments arranged and attended, number of new contacts with stop smoking services, and number of repeat PED attendances.

Other data collection

Data relating to frequent attendances were obtained from the "CAS card" for each CYP – a paper record that clinicians fill in during a consultation and which states at the top the total number of PED attendances to date, at the hospital, by that individual (it does not include any information about attendances elsewhere). A frequent attender was defined as a CYP with four or more attendances per year (28).

Qualitative data were collected via conversations with CYP and their parents/carers about how they felt about being asked about wider health issues during a PED attendance (during recruitment, the intervention, and follow-up calls), feedback on the content and form of the participant information sheets and consent forms, and

any other input they wanted to provide. Brief conversations with other key stakeholders e.g. nurses in the PED, were also undertaken ad hoc, in order to understand any potential barriers to future implementation from the department's perspective.

The main researcher (RI) also kept a field diary in the form of a notebook where reflections, informal conversations with stakeholders e.g. nurses, and any difficulties encountered/ideas about improving the approach were recorded. These data (from the conversations and the diary) were analysed to identify any broad overarching themes that could result in improvements to the intervention, approach, etc. for a future study, e.g. modifications to the written materials, in order to improve the feasibility and acceptability of the approach for key stakeholders. There was a particular focus on ways in which CYP could be more involved in future research in this area e.g. feedback on consent processes, language used in participant information sheets etc.

Results

Participants

Thirty participants (from 29 households) were recruited from the 40 who were approached (75% response rate). Recruitment took place over eight days during the two-week period. Reasons for non-participation appear in Figure 1. An additional child was not considered for recruitment as, on entering the cubicle, RI made an unexpected spot diagnosis requiring urgent action and therefore this was conveyed to the staff member caring for the child.

Half of all CYP participated in the consent process and five of them gave consent and chose to be followed up directly via their own mobile phones, having been judged to be competent to do so. Male participants were slightly over-represented in the sample (53.3%) and age at presentation (in completed years) ranged from 1-15. Seven children were pre-school, 11 were in primary school, and 12 young people were in high school. Forty percent of attendees had come with an illness and 60% with an injury.

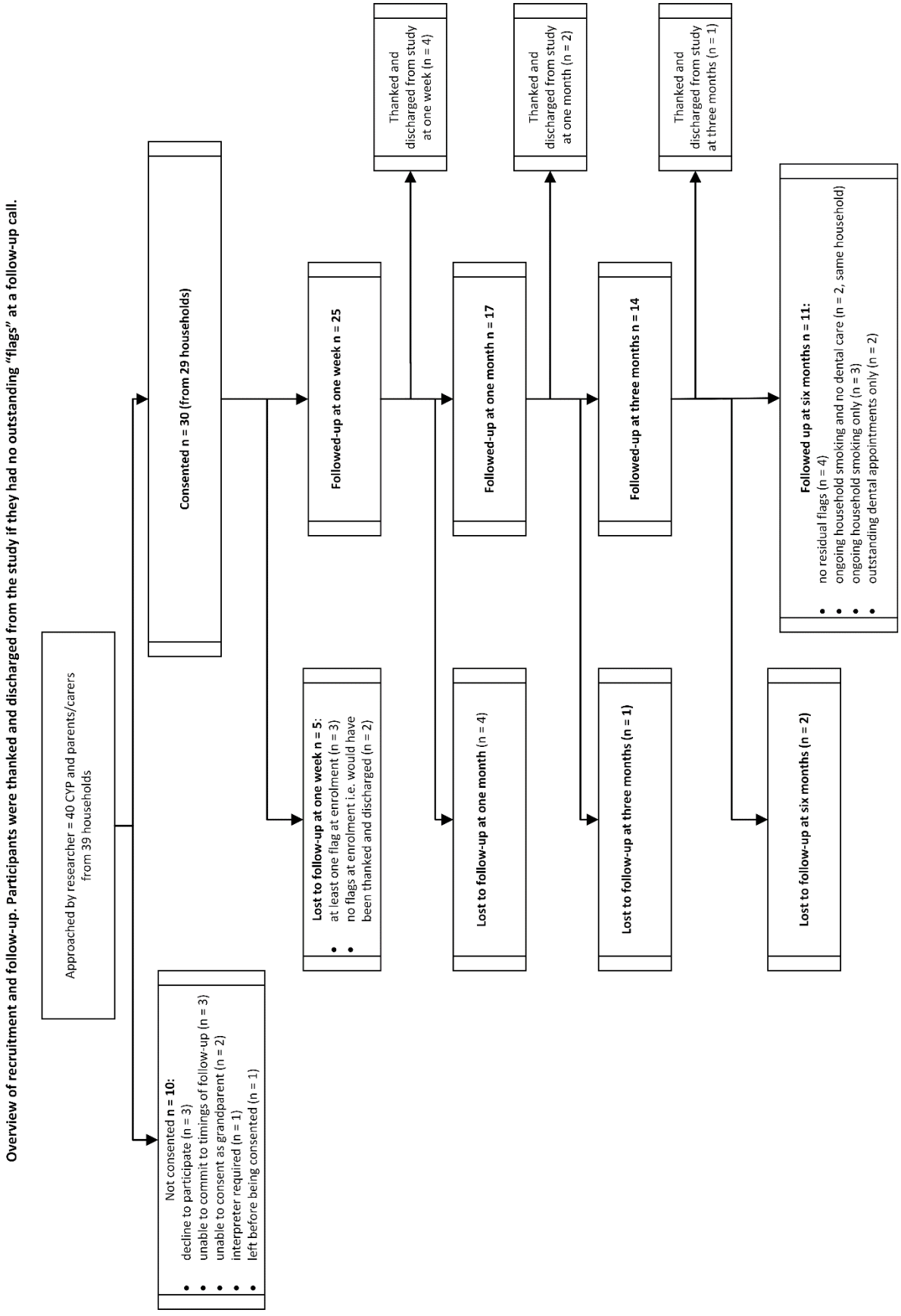

Figure 1. Overview of recruitment and follow-up for pilot study. Participants were thanked and discharged from the study if they had no outstanding "flags" at a follow-up call.

"Screening" triggers

At enrolment (n = 30)

Nearly two-thirds (60%) of participants triggered at least one of the screening questions – most often household smoking and inadequate engagement with dental services.

Vaccination

Twenty-nine parents/carers reported that the child/young person they were attending with was up-to-date with their vaccinations (96.7%). One parent had deliberately not had their child vaccinated with MMR as they were sure it had played a role in an older sibling's autism. After the intervention they agreed to have a letter sent to their GP to arrange an appointment for vaccination.

Dental health

The dental questions ("Is the child registered with a dentist?" and "Has the child seen a dentist in the previous six months?") followed by adaptive follow-up questions resulted in a wider than expected variety of responses which were then grouped into:

- Yes, registered (NHS or private dentist) and attending regularly as per guidance = 14
- Yes, registered (NHS dentist) but last attended more than 6 months ago and no appointment booked = 7
- Not sure if registered and last attended more than a year ago = 2
- No, not registered = 3
- Never been to a dentist = 4

As the intention of the dental part of the study was to improve routine engagement with a dentist (every 6 months), for the purposes of follow-up, the data were aggregated so that “Yes” was participants who were regularly engaging with NHS or private providers (n = 14, 46.7%) and “No” was all other responses (n = 16, 53.3%).

Household smoking

Eighteen (out of 29) households did not report any smokers (62.1%) and one of these was a parent who had recently quit (and remained an ex-smoker at the end of the study). Of the 11 households (12 participants) with at least one smoker living in them, one was a young person (who was also a secondary carer for one of the other participants).

Frequent attendance

The mean number of attendances per participant was 7.7 (range 1-36; median 5.5). Five CYP (13.3%) had attended more than ten times but unfortunately it was not possible to access all the records for each attendance during the intervention and this is a major weakness of the inclusion of frequent attendance in the pilot. However, four of these CYP were over the age of ten (so their attendances may well have been appropriate) and the fifth had an extensive history of asthma and anaphylaxis, so it was not possible to conclude that any of these were inappropriate attendances. Therefore, none of the participants were flagged as frequent attenders using the definition above of four attendances per year, as it was not possible to easily work out the timeframe for their total attendances.

Follow-up

Of the 30 CYP recruited at the start, 11 were followed up to six months (the end of the study) and of these four would have been discharged had the study continued, as they had no residual triggers (i.e. any earlier trigger had been address e.g. by attending the dentist). Three participants still had household smoke exposure, two CYP from the same family had household smoke exposure and no dental care, and two had outstanding dental appointments (one of whom had not been registered with a dentist at the start of the pilot).

During the study seven participants had been discharged (at the point at which they had no residual triggers) and 12 (40%) were lost to follow-up. Figure 1 provides an overview of the numbers followed-up, lost, or discharged at each stage of the pilot.

Vaccination

The only child with reported incomplete vaccination did not receive her MMR during the study owing to a number of factors reported by her parent (illness, holiday) that meant appointments needed to be moved. At the six-month follow-up her parent was still planning on attending a future appointment.

Dental health

Participants were followed up until they attended a dental appointment or reached the end of the study period. At one week there was an additional participant who had attended the dentist and one more was attending by one month. There was no

change at three months and at the final follow-up point at six months an additional three participants were engaging with dental services.

Household smoking

Participants were followed up until their household was smoke-free or if they reached the end of the study period. Of the 12 participants exposed to smoke (in 11 households) at enrolment, four were known to remain in smoking households at the end of the study (although one parent was considering stopping smoking but felt it wasn't the right time), seven had been lost (of which two had previously reported cutting down on smoking), and one household was newly smoke-free (for more than three months but remained in the study due to continuing dental need).

Frequent attendance

As outlined above, no participant was judged to trigger this at screening.

Qualitative data

Children and young people

Children and young people were interested in getting involved in the study and the consent process. They felt it was important to check things like going to the dentist and they provided some insightful feedback into the study design, for example suggesting that the information sheets and consent forms be printed on coloured paper to support people with dyslexia, and a suggestion that rather than use the hospital switchboard, the study team have a mobile phone so that people (young

people and parents/carers) could put the number into their own phone at recruitment and then they would know who was calling them.

Parents and carers

Parents and carers were broadly supportive of the approach used in the pilot and they were comfortable being asked about health-related topics that weren't directly related to the reason for presentation. The information sheets and consent form were felt by several parents/carers to be too formal and complicated, and on a number of occasions, when checking understanding prior to consent, they asked the meaning of one or more words that appeared. On these occasions the participant information sheet that had been prepared for young people was also provided, and the feedback about this was more positive, with several parents/carers suggesting that a future study could just have that for all non-primary readers.

Most of those who weren't able to participate in the study also gave feedback to say that they would have participated if the follow-up calls were outside of the working day (ethical approval stated the calls would only be between 9am and 5pm, Monday to Friday).

Staff

Staff were extremely enthusiastic about the study and reported that they did not find it got in the way of the day-to-day workings of the PED, even when it was busy. Nursing staff in particular were very invested in the idea behind the study and felt that Emergency Departments should do more to support the prevention approach to caring for CYP.

Field diary

During the recruitment phase of the study the field diary reflected the positivity with which the CYP and parents/carers responded to the intervention and also the enthusiasm of the nursing staff in the department. Issues around the inflexibility of the recruitment times were also noted and the need for a study mobile phone to facilitate follow-up with having to be within the hospital. Other observations included that it was easier to be in the department and deliver several interventions one after the other. With regard to the data collection, it became clear very quickly that the inclusion of the frequent attenders was not going to be meaningful within the current design. Also, the very wide range of responses to the dental “screening” and follow-up was unexpected and implications for a future large-scale study were noted. CYP were keen to be involved in the consent process and the colouring sheet for the very young children was popular.

Follow-up calls were well-received on the whole, some participants were very excited to share progress that they felt they had made e.g. giving up smoking, and often parents/carers would comment that the call itself had reminded them to take some action (most frequently related to making a dental appointment). This last observation has implications for future study design in that the follow-up may have formed part of the intervention. The lead researcher’s diary also included additional reflection on how the person delivering the intervention and making the multiple calls as part of the follow up might also have inadvertently formed a key part of the intervention (despite the intention being that any future intervention could be delivered by other staff groups e.g. nurses).

A final observation from the field diary was that it was difficult on occasion to just deliver the intervention without getting involved further e.g. giving preventative advice in the case of a dog bite.

Discussion

Principal findings

This pilot has demonstrated that it is feasible and acceptable to deliver a brief public health intervention to children and young people and their parents and carers, within a routine PED attendance. The pilot intervention could be refined to remove the frequent attendance (not possible to access the data in real-time as need to look at each attendance to judge whether or not it is “appropriate” for the PED and no programme exists to refer frequent attenders to, in contrast to the other elements). The follow-up calls at one week, and one, three, and six months should be considered part of the intervention and this should be taken into account when planning an intervention study. The dental outcome measures should be honed and elements of the intervention adapted to ensure greater clarity – this could be done via a co-design process with CYP as they provided valuable insights during the pilot. The issue of over-estimation of vaccination coverage by parent/carer recall should be considered a real possibility and future research should seek to address this data quality issue.

Strengths and weaknesses of the study

The method of translating an established model – SBIRT – into a different setting and population in the UK is a strength of this work, with only one study (from the USA) having used this approach previously (and published after this work was undertaken). The pilot approach is another strength and has resulted in valuable

information that can be used to improve all aspects of the work, prior to any full-scale study. Weaknesses include that the pilot used England's only PED-based Consultant in Paediatric Public Health Medicine to deliver the intervention and follow-up and this may have had an impact on aspects of the study. Access to data was a real weakness of the study – the frequent attenders' data quality issue meant that nobody was identified as triggering this screening question. It is almost certain that the self-reported data relating to vaccination were inaccurate and the inability to verify vaccination status during a consultation is a barrier. There were a number of logistical weaknesses that could be address in a full-scale study, for example ethical approval was for recruitment and follow-up only between 9am and 5pm Monday to Friday and a number of the parents/carers who didn't participate stated that their reason was that they wouldn't be able to receive the follow-up calls during the working day.

Meaning of the study and implications

This pilot study has demonstrated that whilst it is feasible and acceptable to deliver a public health intervention, that intervention should be adapted. The frequent attendance is complex and, unlike other aspects of the pilot, there is no way to "refer to treatment" (the "RT" of SBIRT). A decision has been made, therefore, that this will be removed for the next stage of this work. Likewise for household smoking, it was often the case that at least one household smoker wasn't in attendance, so the intervention could not be delivered directly to them. An unexpected result was participants' willingness to engage in a conversation around dental health and a lack of pre-existing knowledge, combined with considerable need amongst CYP, means that this is a key part of any future study. The apparent almost complete vaccination

coverage amongst participants is likely to be an artefact and warrants further exploration as it's unlikely that the CYP attending the PED have higher-than-average levels of vaccination. SBIRT is an existing model that could be further adapted and adopted within the ED to target a wider range of age groups and conditions. The feasibility and acceptability of the approach used in this pilot is positive and warrants further exploration. As many PED attendances may have a preventable element, this approach of embedding public health in routine healthcare interactions may be another way that the issue of ever-increasing numbers of hospital attendances could be ameliorated.

Future research

Rather than leading to the development of a single large-scale study using SBIRT, the challenges outlined above mean that the intervention will be divided up. The dental part of the study requires very little detailed recall for "screening" and is very amenable to the approach used in this pilot (of "brief intervention") and there is a well-developed system for CYP to be "referred for treatment" (completing SBIRT). The intention is, therefore, to develop a dental-focused intervention, in partnership with colleagues working in community and hospital dentistry, and co-developed and co-designed with CYP. However, at the time of writing this has been put on hold as routine dental services are severely disrupted by the pandemic – although when normal business resumes the unmet dental need of CYP is likely to be higher than ever.

The likely over-estimation of vaccination coverage amongst parents/carers in this pilot means that more work is needed to redesign the "screening" part of the

intervention for this element. A future study will therefore look at the accuracy of parent/carer recall of vaccination and compare vaccination coverage in the population of PED attenders to their peers. As it is not currently possible for hospital-based clinicians to routinely access other sources of vaccination data e.g. primary care records, other work will look at barriers/facilitators to provision of accurate vaccination data during a PED consultation. This would facilitate the development of a robust way of accurately identifying under-vaccinated CYP easily during a PED, before revisiting what intervention might be delivered in the case of identification of someone not up-to-date with their age appropriate vaccinations.

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Competing interests statement

None declared.

Author contributions

RI conceived of the study, applied for the funding, was involved in the ethics application process, undertook the fieldwork, and was involved in all stages of the preparation of this manuscript. RE led on the ethics application process, took part in discussions around coding of anonymised data, and was involved in all stages of the preparation of this manuscript.

Data sharing statement

Relevant data are available in the main text.

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Chapter 3

Interventions delivered in secondary or tertiary medical care settings to improve routine vaccination uptake in children and young people: a scoping review.

Research question (RQ2): What are the interventions delivered in secondary or tertiary medical care settings focused on improving routine vaccination uptake in children and young people?

The scoping review was submitted to *BMJ Open* in February 2022 and accepted for publication in July 2022. It was submitted as:

> Blagden, S., Newell, K., Ghazarians, N., Odunala, M., Sulaiman, S., Tunn, L., Isba, R, and Edge R. (with Isba and Edge as joint last authors). Interventions delivered in secondary or tertiary medical care settings to improve routine vaccination uptake in children and young people: a scoping review.

I contributed to the co-conception of the study, design of the study, title, abstract and full-text screening, and data extraction, along with supporting oversight of the project and revisions of the manuscript.

The protocol for this scoping review was previously published (July 2020) as

> Edge, R, and Isba, R. Interventions delivered in secondary or tertiary medical care settings to improve routine vaccination uptake in children and young people: a scoping review protocol, *JBI Evidence Synthesis*. July 2020 - Volume 18 - Issue 7 - p 1566-1572. https://journals.lww.com/jbisrir/Fulltext/2020/07000/Interventions_delivered_in_secondary_or_tertiary.11.aspx

Abstract

Objectives: To identify and analyse the interventions delivered in secondary or tertiary medical settings focused on improving routine vaccination uptake in children and young people.

Design: Scoping review.

Search strategy: We searched CINAHL, Web of Science, Medline, Embase, and Cochrane Database of Systematic Reviews for studies in English published between 1989 and 2021 detailing interventions delivered in secondary or tertiary care that aimed to improve childhood vaccination coverage. Title, abstract, and full-text screening were performed by two independent reviewers.

Results: After de-duplication, the search returned 3,436 titles. Following screening and discussion between reviewers, 53 studies were included in the review. Most papers were single-centre studies from high-income countries and varied considerably in terms of their study design, population, target vaccination, clinical setting, and intervention delivered. To present and analyse the study findings, and to depict the complexity of vaccination interventions in hospital settings, findings were presented and described as a sequential pathway to opportunistic vaccination in secondary and tertiary care comprising the following stages: 1) identify patients eligible for vaccination; 2) take consent and offer immunisations 3) order/prescribe

vaccine; 4) dispense vaccine; 5) administer vaccine; 6) communicate with primary care, and 7) ongoing benefits of vaccination.

Conclusions: Most published studies report improved vaccination coverage associated with opportunistic vaccination interventions in secondary and tertiary care. Children attending hospital appear to have lower baseline vaccination coverage and are likely to benefit from vaccination interventions in these settings. Checking immunisation status is challenging, however, and electronic immunisation registers are required to enable this to be done quickly and accurately in hospital settings. Further research is required in this area, particularly multi-centre studies and cost-effectiveness analysis of interventions.

Strengths and limitations of the study

- Our analysis and data synthesis have provided the first comprehensive overview of opportunistic interventions to improve uptake of routine vaccinations in secondary and tertiary medical settings.
- We searched a large range of databases over an extensive time period and included studies from all around the world.
- All data screening and extraction were performed by two independent reviewers.
- We did not search the grey literature and may have inadvertently excluded interventions that are used in practice, or that failed to show benefit.
- Only studies published in English were included.

Introduction

Vaccination has made an enormous contribution to global health. Every year immunisations save millions of lives and are one of the most successful and cost-effective public health interventions(1). Despite this, the United Kingdom (UK), United States (US), and other countries with successful immunisation programmes experience outbreaks of vaccine-preventable diseases because of sub-optimal vaccine coverage(2). Health inequalities exist in vaccination, with certain population groups more likely to experience poor vaccination coverage(3). The reasons for these inequalities are complex and influenced by a range of factors including(3):

- Vaccine hesitancy, due to -
    - concerns about vaccine safety and efficacy(4);
    - misunderstanding around disease severity due to low incidence(5);
    - parental/carer resentment of perceived pressure to risk their child's safety for population benefit(6);
    - mistrust of healthcare professionals, governments, and vaccine research(7, 8);
    - reliance on unofficial information sources(7, 8);
    - religious vaccination opposition (e.g. Orthodox Jewish populations)(9);
    - non-religious “anti-vaxx” sentiment(10, 11).
- Limited access to vaccines, due to -
    - location/timing of vaccinations(12);
    - poor access to HCPs such as health visitors and midwives due to reduced provision(13);

- under-served populations (e.g. looked-after children, travellers, refugees/asylum seekers) who experience difficulty accessing healthcare(14, 15).

Despite the success of vaccination programmes against COVID-19, evidence suggests that disruption caused by the pandemic has led to a global reduction in routine vaccination(16). For example, coverage of the first dose of human papillomavirus virus vaccine in UK females aged 12-13 years fell to 59.2% in 2019/2020, versus 88.0% in 2018/19 and 86.9% in 2017/18(17). UK childhood vaccinations are normally delivered in primary care settings, however COVID-19 vaccination has highlighted that different settings may allow for opportunistic vaccination. Children and young people (CYP) can spend significant time waiting to be seen in secondary or tertiary care settings, which could be utilised to provide public health interventions. Indeed, the National Institute for Health and Care Excellence (NICE) recommends that the immunisation status of children be checked at every opportunity, including visits to the Emergency Department (ED), outpatient clinics, and inpatient admissions, with vaccination either offered on the premises or referral to an appropriate vaccination service(18). NICE has also highlighted groups at risk of under-immunisation, including those with chronic illness or frequent hospitalisations, with secondary/tertiary care representing a key opportunity to vaccinate such children(18).

Maintaining vaccination uptake at levels required to prevent community disease spread may necessitate innovative approaches to vaccine delivery. This scoping

review seeks to explore interventions delivered in secondary or tertiary medical care settings to improve routine vaccination uptake in CYP.

Methods

As presented in the published protocol(19), this scoping review followed the Joanna Briggs Institute (JBI) methodology manual for scoping reviews(20).

Objectives

The scoping review question was:

> *What are the interventions delivered in secondary or tertiary medical care settings focused on improving routine vaccination uptake in children and young people?*

We aimed to identify and analyse interventions to obtain a broad understanding of how they are delivered in hospital settings and their impact on routine vaccination uptake.

Throughout the review, the terms ‘vaccination’ and ‘immunisation’ are used interchangeably. Secondary care generally refers to treatment provided in hospitals, whilst tertiary care is for patients needing complex treatment in hospital(21).

Eligibility criteria

The review considered studies that described interventions delivered in secondary or tertiary care to improve routine vaccination uptake amongst CYP published between 1 January 1989-11 October 2021. All countries were included.

Exclusion criteria

As detailed in the protocol, we excluded studies not published in English.

Search strategy and study selection

On 12 February 2020, we searched CINAHL, Web of Science, Medline, and Cochrane Database of Systematic Reviews for articles published between 1 January 1989-12 February 2020, using search terms outlined in the protocol(19). The search was repeated and extended to include EMBASE on 11 October 2021. Duplicates were removed electronically, after which titles and abstracts were screened by two researchers independently before full paper retrieval. At each stage, disagreements were discussed, and consensus reached. Full papers were assessed against the inclusion criteria prior to data extraction and further discussion determined the final study sample. Conference abstracts were excluded due to insufficient information on the included interventions.

Data extraction

A data extraction form was developed using JBI guidelines to collect the information necessary for data synthesis (Appendix 1). Two reviewers independently performed data extraction for all studies, with all authors involved at this stage.

Data synthesis

Following data extraction, studies were tabulated by setting and publication date with intervention information presented alongside outcome data. Summary data were also extracted and tabulated based on key characteristics of the studies and interventions. Due to the varied nature of studies and interventions, no meta-analysis was performed.

Deviations from the protocol

Although the protocol stated that we would include children aged under 16 years, we also included studies with an older upper age range (up to 21-years) due to inability to extract data for younger children from these studies.

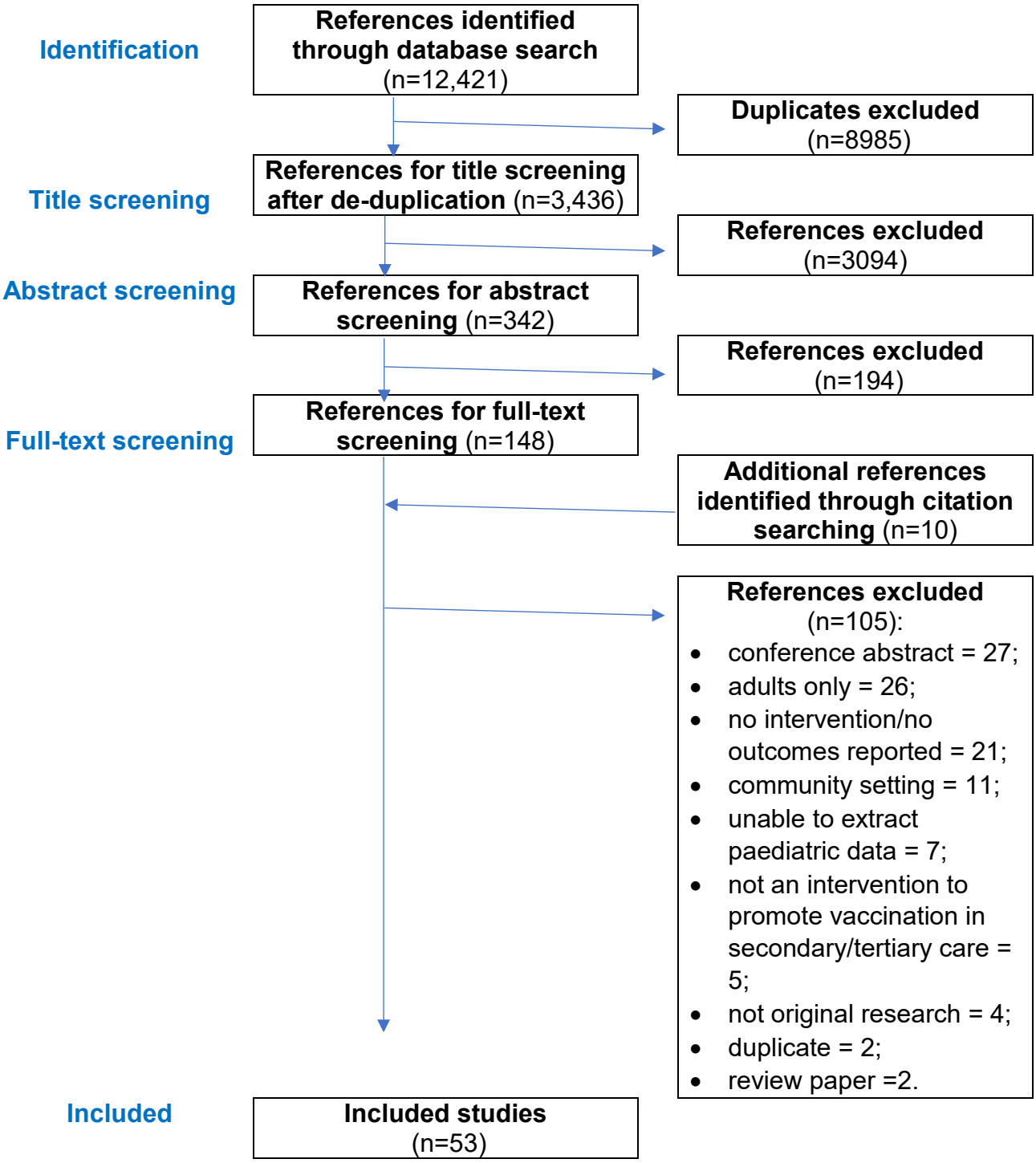
Patients and public involvement

No patients or public were involved.

Results

In total, 12,421 titles were returned from the search strategy, after which 8,985 duplicates were removed, leaving 3,436 for title screening. After this, 342 records remained for abstract screening. Next, 148 full papers were retrieved and underwent full text review. Finally, data was extracted from 53 texts (Figure 1). All stages were carried out by two independent researchers.

Figure 1: PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram



Study characteristics

The included studies were extremely variable in terms of their population, target vaccination, clinical setting, and intervention. Table 1 summarises the general characteristics of the included studies and associated interventions and Table 2 lists all included studies grouped by clinical setting and in chronological order.

Table 1: General characteristics of the included studies and their associated interventions

Characteristic	***Frequency - n (%)***
Clinical setting[1]:	
Paediatric inpatient wards(22-39).	16 (30.2)
Antenatal/neonatal setting(40-53).	14 (26.4)
Emergency department (ED)(54-62).	9 (17.0)
Paediatric inpatient wards AND outpatient clinics(63-68).	8 (15.1)
Paediatric outpatient clinics(69-74).	6 (11.3)
Type of hospital:	
Tertiary care paediatric hospital(24, 33-39, 54, 55, 58, 60-64, 66-68, 70-72).	23 (43.4)
Number of sites:	
Single centre(22-30, 32-37, 39-41, 44, 48-51, 53, 55, 56, 58-63, 65-70, 72-74).	41 (77.4)
Multi-centre(38, 43, 45-47, 52, 64, 71).	8 (15.1)
Two centres(31, 42, 54, 57).	4 (7.5)
Target immunisation(s):	
All due/overdue vaccinations(22-30, 32, 33, 35, 37, 39, 56-59, 65, 69).	20 (37.7)
Influenza(31, 34, 36, 38, 60-64, 66-68, 70-74).	17 (32.1)
All upcoming vaccinations (for neonates/infants)(41, 48, 49, 51, 53).	5 (9.4)
Hepatitis B(42, 43, 47, 50).	5 (9.4)
BCG(40, 44).	2 (3.8)
Measles, mumps and rubella (MMR)(54, 55).	2 (3.8)
"Voluntary" vaccination schedule[2](45, 46).	2 (3.8)
Country:	
USA(24, 30, 31, 34-36, 38, 43, 47, 50, 52, 54, 55, 57, 58, 60-63, 66-68, 70, 72-74).	26 (49.1)
Australia(28, 32, 33, 37, 39, 42, 51, 56, 59, 64).	10 (18.9)
United Kingdom(22, 25, 27, 40).	4 (7.5)
New Zealand(29, 65).	2 (3.8)
Japan(45, 46).	2 (3.8)
Canada(48, 71).	2 (3.8)
South Africa(49).	1 (1.9)
Ireland(44).	1 (1.9)
Bangladesh(23).	1 (1.9)
Nepal(41).	1 (1.9)
India(69).	1 (1.9)
Italy(53).	1 (1.9)
Switzerland(26).	1 (1.9)
Intervention population:	

Age-group[3]	
• Includes older children (up to 15-21 years old depending on study)(23, 26, 27, 30, 34, 37-39, 56, 60, 61, 63, 64, 66-68, 70-74).	22 (45.3)
• Pre-school and younger school-age children only(22, 24, 25, 28, 29, 31-34, 54, 55, 57-59, 62, 69).	16 (30.2)
• Neonates/under 1s only (+/- pregnant women)(35, 40-53).	15 (35.7)
• Family members of child also offered vaccination(23, 60, 64, 71).	4 (7.5)
Risk category for vaccine preventable disease(s) of interest	
• All children (low-risk and high-risk)(22-34, 36-48, 50, 51, 54-62, 65, 69, 70, 72, 73).	42 (79.2)
• High-risk due to underlying health problem(s)/maternal risk factors(35, 49, 52, 53, 63, 64, 66-68, 71, 74).	11 (20.8)
Study design:	
Quality improvement project(34-36, 38, 43, 50, 61, 63, 66, 67).	10 (18.9)
Clinical audit/service evaluation(28, 29, 32, 40, 42, 44, 49, 59, 65).	9 (17.0)
Cross-sectional study including description of intervention(22, 23, 33, 54-56, 62, 71).	8 (15.1)
Intervention study(24-26, 39, 58, 64, 69).	7 (13.2)
Randomised controlled trial(41, 45, 46, 48, 60, 73).	6 (11.3)
Cohort study(47, 52, 53, 57, 72).	5 (9.4)
Retrospective case note review(27, 31, 68, 70, 74).	5 (9.4)
Pilot study(30, 33, 51).	3 (5.7)
Aspects of intervention[4]:	
Offer of pre-discharge vaccination at the secondary/tertiary care setting(22-25, 27, 29-40, 42-44, 48-50, 52-73).	45 (85.9)
Patient/family education(23, 26, 34, 36-38, 41, 45, 46, 50, 51, 53, 58, 60, 63, 64, 66-68, 74).	20 (37.7)
Extra staff/funding involved in delivering the intervention(23, 24, 32-34, 37, 41, 44, 46, 54, 57, 58, 60, 64, 65, 67).	18 (34.0)
Training, education and/or promotional materials for staff(24, 32-36, 43, 50, 51, 55, 56, 59, 63, 64, 67, 69, 74).	17 (32.1)
Multi-disciplinary approach to leadership and delivery incorporating medical, nursing and pharmacy colleagues(24, 33, 34, 36, 38, 43, 50, 52, 61, 63, 68, 71).	12 (22.6)
Automatic vaccine ordering/in-built order sets(36, 38, 42, 47, 61, 63, 66, 72).	8 (15.1)
Ongoing feedback to staff regarding the success/uptake of the intervention(34, 36, 43, 55, 63, 67).	6 (11.3)
Collaboration with other external organisations(24, 55, 64, 71).	4 (7.5)
Method of screening vaccination eligibility[5]:	
Patient/parental recall(22, 23, 29-32, 40, 54-61, 69).	16 (30.2)
Handheld written record/immunisation card(23-26, 29, 30, 40, 54, 55, 57, 58, 69).	12 (22.6)
A local electronic clinical system that alerts staff of eligible patients(33, 34, 38, 52, 61-64, 66, 70, 74).	11 (20.8)
Checking against national/regional immunisation registry(22, 28, 32, 33, 36, 39, 59, 65).	9 (17.0)
Checking with primary care provider(24, 30).	2 (3.8)
Not required as universal vaccination offer(41-53).	13 (24.5)

[1]1 study included both ED and inpatient wards.
[2]In Japan the vaccination schedule is sub-divided into “routine” and “voluntary” vaccinations(75).
[3]Total does not equal 53 (100%) due to studies also including family members.
[4]Total does not equal 53 (100%) due to interventions containing multiple components.
[5]Total does not equal 53 (100%) as some studies used more than one method.

Table 2: Key characteristics and outcomes of included studies

Interventions delivered in the emergency department (ED)					
Author, year/country (reference number)	**Type of study - target vaccination (n)**	**Intervention summary (study population – age/characteristics)**	**Vaccine coverage amongst study population at baseline**	**Key results and outcomes reported**	
Lindegren et al., 1993/USA(54).	Cross sectional study, two centres – measles, mumps and rubella (MMR) (n=763).	Opportunistic MMR vaccination in two EDs during a measles outbreak including dedicated vaccination nurses (6-60 months).	**History of MMR vaccination:** • Hospital A = 72%. • Hospital B = 60%.	**Opportunistic MMR vaccination amongst those eligible:** 41%.	
Schlenker et al., 1995/USA(55).	Cross sectional study, single centre – MMR (n=541).	Opportunistic MMR vaccination in an ED during a measles outbreak (0-4 years).	**History of MMR vaccination:** • Vaccinated = 83%. • Uncertain = 10%. • Unvaccinated = 7%.	**Opportunistic MMR vaccination amongst unvaccinated children:** • Vaccinated in ED = 25%. • Refused vaccination = 37.5%. • Not offered vaccination = 37.5%. **Factors associated with vaccination:** Children presenting to ED with physical injury compared to children with respiratory illness.	
Burgess et al., 1996/Australia (56).	Cross sectional study, single centre* - all due/overdue vaccinations (n=5,162).	Screening vaccination status and offering opportunistic vaccination in an ED, GP practices and Early Childhood Centers (0-15 years).	**Fully immunised for age:** 71%.	**Catch-up vaccinations delivered:** 33% (of under-immunised children across ED, general practices and Early Childhood Centres). **Parental refusal of opportunistic vaccination:** 10%.	
Szilagyi et al., 1997/USA(57).	Prospective cohort study, two centres - all due/overdue (n=484).	Screening immunisation status and offering opportunistic vaccination in two EDs by project nurses (0-6 years).	**Fully immunised for age:** 64% (both hospitals).	**Timescale**	**Children fully immunised for age (%)**
					Manhattan ED / **Bronx ED**
				1 day	75% / 71%
				6 months	66% / 54%
Cunningham et al., 1999/USA(58).	Intervention study, single centre - all due/overdue (n=9,321).	Dedicated immunisation nurses in ED screening vaccination status and offering missing immunisations (0-72 months).	**Documented vaccination status:** 44%. **Fully immunised for age:** 44%.	**Uptake of catch-up vaccinations in ED:** • Amongst patients with documentation of under-immunisation = 71%. • Amongst patients with no documentation of vaccination status = 15% ($p<0.0001$, documentation of under-immunisation versus no documentation).	

Skull et al., 1999/Australia (59) (N.B. also includes inpatients).	Clinical audit, single centre – all due/overdue (n=866).	Education sessions, prompts within patient records and offer of vaccination pre-discharge for inpatients and ED patients (<7 years).	**Vaccination coverage at baseline:** • Pre-intervention = 74%. • Post-intervention = 60%.	**Opportunistic vaccination amongst eligible patients:** • Pre-intervention = 0. • Post-intervention = 24% (p=0.002 compared to pre-intervention).
Pappano et al., 2004/USA(60).	Randomised controlled trial (RCT), single centre – influenza (n=337).	Families randomised to opportunistic influenza vaccination in ED (whole family offered vaccination) or education only (0-19 years).	Information not provided.	**Families with 1 or more family members vaccinated:** • Vaccine offered (intervention) = 75%; Education only (control) = 55% (relative risk = 1.36, 95% confidence interval (CI) = 1.11-1.67). **Vaccine uptake for paediatric patients:** • Vaccine offered (intervention) = 57%. • Education only (control) = 36%. **Factors associated with vaccination:** • Age <6 months (odds ratio (OR) = 0.05, 95%CI = 0.01-0.27). • Influenza vaccination prior to enrolment (OR = 11.58, 95%CI = 5.54-24.20). • Intervention study arm (OR = 7.47, 95%CI = 4.57-12.22). • History of heart disease (OR = 5.74, 95% CI = 1.34-24.54). • Unspecified chronic illness (OR = 3.05, 95%CI = 1.27-3.51).
Buenger and Webber, 2020/USA(61).	Quality improvement (QI) project, single centre – influenza (n=32,231).	Series of electronic triggers, alerts and orders in patient records to increase opportunistic influenza vaccination in ED (≥6 months).	Information not provided.	**Vaccination uptake – proportion of eligible visits:** • Pre-intervention (2013/14) = 0.3%. • Post intervention (2014/15) = 8.8%.
Strelitz et al., 2021/USA(62).	Cross-sectional study, single centre – influenza (n=152).	Screening vaccination eligibility and offer of influenza vaccine in ED (≥6 months – 7 years).	Information not provided.	**Uptake of influenza vaccination in ED:** 37%. **Demographics associated with vaccine refusal:** • High school education or less (OR = 0.4, 95% CI = 0.2-0.9). • Ethnicity – Hispanic/Latino (OR = 0.2, 95% CI = 0.1-0.6).
Interventions delivered in paediatric inpatients				
Author, year/country (reference number)	**Type of study (target vaccination)**	**Intervention summary**	**Vaccine coverage amongst study population pre-admission**	**Key results and outcomes reported**
Riley et al., 1991/UK(22).	Cross-sectional study, single centre – all	Offer of overdue vaccinations for inpatients (5 months – 6 years).	**Vaccination coverage at baseline:** 81.1%.	**Vaccination uptake at discharge amongst all eligible cases:** 75%.

	due/overdue (n=296).			
Bell et al., 1997/USA(24).	Intervention study, single centre - all due/overdue vaccinations (n=2,006).	Programme to vaccinate under-immunised pre-school inpatients before discharge (0-2 years).	**Fully vaccinated:** 44%. **Due for next vaccination:** 33.4%. **Overdue:** 17.7%.	**Opportunistic catch-up vaccinations amongst those eligible:** • 66% received at least 1 immunisation. • 55.8% received multiple immunisations. • 50.6% were brought up to date. **Fully immunised for age at discharge:** (70% versus 44% at baseline, p<0.001).
Conway, 1999/UK(25) .	Intervention study, single centre – all due/overdue (n=1,000).	Discussion of the importance of vaccination with families of inpatients and offer of immunisation pre-discharge (3-66 months).	**Vaccination coverage at baseline:** 80%.	**23% of eligible children were offered immunisation as an inpatient:** • 65% accepted. • 35% of parents/carers refused.
Muehleisen et al., 2007/ Switzerland(26).	Intervention study, single centre – all due/overdue (n=430).	Under-immunised inpatients encouraged to arrange missing vaccines and primary care physicians informed (61 days – 17 years).	**Vaccination coverage at baseline:** • Intervention group = 54%. • Control group = 49%.	**Catch-up immunisations at 1 month:** • Intervention group = 27%. • Control group = 8% (p<0.001). **Immunisation coverage at 9 months:** • Intervention group = 45%. • Control group = 35%.
Walton et al., 2007/UK(27).	Retrospective case note review, single centre – all due/overdue (n=207).	Offer of inpatient vaccination pre-discharge (≥3 months).	**Vaccination coverage at admission:** 69%.	**Proportion of those eligible vaccinated pre-discharge:** 3%.
Ressler et al., 2008/Australia (28).	Clinical audit, single centre – all due/overdue (n=539).	Vaccination catch-up plans given by nursing staff (2-24 months).	**Fully immunised for age:** 86%.	**Vaccinated within 30 days of admission:** • Those with a catch-up plan = 57%. • Those without a catch-up plan = 15%.
Gilbert and Wrigley, 2009/New Zealand(29).	Clinical audit, single centre – all due/overdue (n=369).	Documentation of immunisation status for inpatients, catch-up immunisations as an inpatients or referral to GP (3-23 months).	**Fully immunised for age:** 60%.	**Of children behind with immunisation:** • 36% had a reason recorded. • 3.4% given catch-up immunisations on the ward. • 4.2% referred to primary care for vaccinations. • No action documented in remainder.
Pollack et al., 2014/USA(72).	Retrospective cohort study, single centre – influenza (n=42,716).	Screening for eligibility, automatic ordering and administration of inpatient influenza vaccination (≥6 months).	**Already vaccinated at time of screening:** 49.2%.	**Vaccination uptake (all subjects):** • Pre-intervention = 2.1%. • Post-intervention = 8% (p<0.001 compared with pre-intervention). **Factors associated with vaccination uptake:** • Automated screening (OR = 6.77, 95% CI = 6.14-7.47). • Female gender (OR = 0.88, 95% CI = 0.8-0.96).

				• Race – Native Hawaiian/Pacific Islander (OR = 1.85, 95% CI = 1.15-3.30). • Ethnicity – Non-Hispanic/Latino (OR = 0.77, 95% CI = 0.66-0.89). • Unit of admission (surgical unit = baseline) – Medical unit (OR 1.79, 95% CI = 1.6-1.99), Rehabilitation unit (OR 4.27, 95% CI = 3.19-5.72), Psychiatric unit (OR 1.63, 95% CI = 1.39-2.02). • High-risk status (OR 0.77, 95% CI = 0.67-0.87). • Age – 5-12years (OR 1.26, 95% CI = 1.1-1.44), >12 years (OR 1.44, 95% CI = 1.26-1.65).
Pahud et al., 2015/USA(30).	Pilot study, single centre – all due/overdue (n=356).	Screening immunisation status and offering required vaccinations pre-discharge (<18 years).	**Fully immunised for age:** 73%.	**Age appropriately immunised at 1 month:** 80% (compared to 73% at baseline, p<0.001). **Percentage of under-immunised children appropriately caught-up at 1 month:** 25%. **Factors associated with under-immunisation:** Children aged ≥11 years (p<0.001).
Cameron et al., 2016/USA(31).	Retrospective case note review, two centres – influenza (n=786).	Influenza assessment form followed by offer of vaccination for inpatients (6 months – 8 years).	**Influenza vaccination coverage at baseline:** 50.5%.	**Influenza vaccination uptake amongst those eligible:** 50.1%. **Factors associated with vaccine acceptance:** • Private health insurance (OR = 0.6, 95% CI = 0.37-0.97). • Child up-to-date with routine immunisations (OR = 2.39, 95% CI = 1.05-5.41).
Jose et al., 2016/Australia (32).	Clinical audit, single centre – all due/overdue (n=188).	Immunisation status screening using national registry and employment of dedicated nurse to immunise eligible inpatients (2 months – 6 years).	**Vaccine coverage of inpatients:** 81.4%.	**Vaccination outcomes amongst inpatients eligible for vaccinations:** 8% received immunisations in hospital.
Elia et al., 2017/Australia (33).	Pilot study, single centre – all due/overdue vaccinations (n=3,374).	In-house dedicated immunisation service including screening inpatients and offering vaccinations pre-discharge (6 weeks – 7 years).	**Vaccination coverage of inpatients:** 75%.	**Vaccination outcomes amongst the 25% of inpatients eligible for vaccinations:** 42% brought up-to-date.
Rao et al., 2018/USA(34).	QI project, single centre - influenza (n=2,552).	Multi-component QI project targeting influenza vaccination of inpatients (<32 months).	**Already vaccinated at admission:** 35%.	**Percentage of patients with an influenza order during hospitalisation:** • Intervention group 1 (provider reminders) = 52%. • Intervention group 2 (family education) = 30%. • Comparison group = 25% (p<0.0001, versus intervention group 1). **Percentage of patients immunised against influenza (includes those vaccinated pre-admission):** • Intervention group 1 = 61%. • Intervention group 2 = 52%. • Comparison group = 53% (p=0.0017, versus intervention group 1).
Rao et al., 2020/USA(36).	QI project, single centre – influenza (n=8,573).	Multi-component QI project targeting influenza vaccination of inpatients (≥6 months).	Information not provided.	**Percentage of patients with an influenza order during hospitalisation:** • Pre-intervention period = 28.8%. • Intervention period = 50.2% (p<0.001). **Percentage of patients vaccinated at discharge:**

				• Pre-intervention period = 61.8%. • Intervention period = 69.1% (p<0.001). **Predictors of vaccine ordering:** • Intervention (odds ratio (OR) = 2.27, 95% confidence interval (CI) = 2.01-2.56). • Government insurance. • Underlying medical condition. • Increased length of stay. • Admission from ED. • Being asked about vaccination status on admission. **Predictors of being vaccinated at discharge:** • Intervention (OR = 1.39, 95% CI = 1.27-1.53). • Younger age. • Underlying medical condition. • Increased length of stay. • Admission to a sub-specialty team. • Admission from ED. • Being asked about vaccination status on admission.
Orenstein et al., 2021/USA(38).	QI project, multi-centre – influenza (n=17,740).	Multi-component QI project to increase uptake of influenza vaccine amongst inpatients (≥6 months).	Information not provided.	**Proportion of eligible hospitalisations with at least 1 dose of vaccine pre-discharge:** • Intervention group = 31%. • Concurrent control group = 19% (p<0.001 compared with intervention). • Historical control group = 14% (p<0.001 compared with intervention). **Proportion of eligible hospitalisations with an influenza vaccine order placed pre-discharge:** • Intervention group = 77%. • Concurrent control group = 27% (p<0.001 compared with intervention). • Historical control group = 15% (p<0.001 compared with intervention).
Tarca et al., 2021/Australia (39).	Intervention study, single centre – all due/overdue (n=563).	Dedicated immunisation service for inpatients including screening for eligibility and vaccination pre-discharge (<18 years).	**Vaccination coverage at admission:** • Pre-intervention = 75%. • Post-intervention = 89%.	**Vaccination coverage at 3 months amongst those not fully immunised for age:** • Pre-intervention = 28%. • Post-intervention = 64%.
Interventions delivered in paediatric outpatients				

Author, year/country (reference number)	Type of study (target vaccination)	Intervention summary	Vaccine coverage amongst study population pre-admission	Key results and outcomes reported			
Deivanayagam et al., 1995/India(69).	Intervention study, single centre – all due/overdue (n=634).	Educational intervention for clinicians, immunisation screening documentation change and offer of opportunistic vaccination for outpatients (<2 years).	**Children eligible for immunisations:** • Medical outpatients = 26.5%. • Newborn outpatients = 31.8%. • Immunisation clinic = 8.7%.	**Setting**	**Baseline - %**	**Post-intervention 1 - %**	**Post-intervention 2 - %**
				Missed opportunities			
				Medical outpatients.	35.5	24.5	18.4 (p=0.001 compared with baseline)
				Newborn outpatients.	23.1	12.2	8.0
				Immunisation clinic.	9.7	0	0 (p=0.001 compared with baseline)
				Advised immunisation by clinician			
				Medical outpatients.	-	2.0	18.4
				Newborn outpatients.	-	24.5	30.4
				Immunisation clinic.	-	8.7	16.0
				Improvement in children immunised (compared to baseline)			
				Medical outpatients.	-	-	16.4
				Newborn outpatients.	-	-	5.9
				Immunisation clinic.	-	-	7.3
Patwardhan et al., 2011/USA(70).	Retrospective case note review, single centre – influenza (n=4,778).	Electronic health record reminder for influenza vaccination of outpatients (1-21 years).	Information not provided.	**Vaccination uptake:** • 2007/08 (pre-intervention) = 15.4%. • 2008/09 (pre-intervention) = 17.6%. • 2009/2010 (post-intervention) = 34.9%.			
Dubé et al., 2014/ Canada(71).	Cross-sectional study, multi-centre – influenza (n=2,478).	Offer of influenza vaccination for children with chronic illness (and their household contacts at one site) in outpatient clinics (2-17 years).	**Pre-intervention coverage (based on previous years):** 35%.	**Uptake of influenza vaccination in clinic:** 60%.			
Hutchison et al., 2018/USA(73).	RCT, single centre – influenza (n=235).	Randomised to treatment as usual or offer of influenza	**Vaccination coverage at baseline:**	**Intervention group outcomes:** • Vaccination uptake during clinic visit = 39%.			

		vaccine in outpatient clinic (≥6 months – 18 years).	• Intervention group = 27%. • Control group = 25%.	• Total vaccination coverage at end of clinic visit = 67% (p<0.001 compared with control group).
Lo and Sobota, 2019/USA(74).	Retrospective case note review, single centre – influenza (n=124).	Screening immunisation status, arranging influenza vaccination and educational materials for families and clinicians (6 months – 18 years with sickle cell disease).	Information not provided.	**Influenza vaccine uptake:** 90.32%. **Tested positive for influenza:** 4.84%. **Influenza-related hospitalisations:** 0.

Interventions delivered in paediatric inpatients and outpatients

Author, year/country (reference number)	**Type of study (target vaccination)**	**Intervention summary**	**Vaccine coverage amongst study population pre-admission**	**Key results and outcomes reported**
Islam et al., 1992/ Bangladesh(23).	Cross sectional study, single centre – all due/overdue (n=212,206).	Preventive health service comprising health education and immunisation (all inpatient and outpatient children and their mothers).	Information not provided.	**Catch-up immunisation amongst children with incomplete immunisation:** **Timescale** / **Immunised** / **Contraindicated** / **Refused** 1989 / 84.6% / 2.84% / 0.98% 1990 / 82.4% / 1.44% / 1.10% 1991 / 74.6% / 5.83% / 1.9%
Britto et al., 2007/USA(63).	QI project, single centre – influenza (n=18,866).	Multi-component QI project to vaccinate inpatients and outpatients (0-16 years with underlying medical conditions).	Information not provided.	**Total of patients vaccinated against influenza across all settings:** 49.7% (ranging from 38.9% in new hospital clinics – 82.1% in cystic fibrosis clinics). **Vaccine refusal:** 0-12%.
Wood and Cashman, 2011/ Australia(64).	Intervention study, multi-centre – influenza (n=3,458).	6-month period with nurse immunisers to vaccinate inpatients and outpatients. Parents and siblings of children with medical conditions also offered vaccinations (≥6 months).	Information not provided.	**Number of vaccines administered to children and their families:** 3,458 vaccines. **Percentage of vaccines administered to children with chronic medical conditions:** 36%.
Shingler et al., 2012/New Zealand(76).	Clinical audit, single centre – all due/overdue (n=5,583).	Opportunistic vaccination of inpatients and outpatients (≤32 months).	**Fully immunised for age:** 70.6%.	**Outcomes for under-immunised children:** • Opportunistically vaccinated = 53.6%. • Medical indication not to immunise = 20.5%. • Missed opportunities = 11%. • Preferred to defer immunisation to be given in primary care = 5.4%. • Chose not to immunise = 9.4%.

Freedman et al., 2015/USA(66).	QI project, single centre – influenza (n=1,128).	Multi-component QI project to increase uptake of influenza vaccine (oncology inpatients and outpatients ≥6 months).	**Vaccination uptake pre-intervention:** • Complete vaccination = 44.4%. • Partial vaccination = 10.4%. • Unvaccinated = 45.2%.	**Vaccination uptake post-intervention (p value – comparison to pre-intervention):** • Complete vaccination = 64.5% (p<0.001). • Partial vaccination = 13.0% (p=0.19). • Unvaccinated = 22.5% (p<0.001).		
Olshefski et al., 2018/USA(67).	QI project, single centre - influenza (n=872).	Multi-component QI project to vaccinate inpatients and outpatients (paediatric oncology patients undergoing active treatment).	Information not provided.	**Timescale:** 2012/13 2013/14 2014/15 2015/16 2016/17	**Percentage of eligible patients vaccinated against influenza:** 74.9% 88.5% 89.3% 88.5% 87.4%	**Percentage of eligible patients not offered influenza vaccination:** 19.8% 2.1% 0.5% 3.8% 2.5%
Gattis et al., 2019/USA(68).	Retrospective case note review, single centre – Influenza (n=800).	Screening for eligibility and opportunistic vaccination of inpatients and outpatients (solid organ transplant recipients <18 years).	Information not provided.	**Opportunistic inpatient flu vaccination:** • Pre-intervention (2011) = 19%. • Post-intervention (2016) = 72%, p<0.001. **Time from beginning of flu season to 50% influenza vaccination:** • Preintervention (2011) = 163 days. • Post-intervention (2016) = 94 days, p<0.001. **Influenza diagnosis rates:** Declined amongst vaccinated compared to unvaccinated in each season, significant difference in 2014. **Influenza hospitalisation:** No significant differences.		
Elia et al., 2021/Australia (37).	Cross-sectional study, single centre – all due/overdue (not provided).	In-house immunisation service including offer of immunisations to inpatients and drop-in clinic for outpatients and visitors (all children).	Information not provided.	**Increase in the proportion of inpatients opportunistically immunised since employment of the immunisation nurse practitioner:** 15%.		
Interventions delivered in neonatal/antenatal settings						
Author, year/country (reference number)	**Type of study (target vaccination)**	**Intervention summary (study population)**	**Key results and outcomes reported**			

<table>
<tr><td>Bakshi and Sharief, 1993/UK(40).</td><td>Clinical audit/service evaluation, single centre – BCG (n=201).</td><td>BCG vaccination of neonates at high-risk of TB on post-natal ward (neonates).</td><td>Uptake of BCG vaccination in the neonatal period: 85%.
Vaccinated in hospital before discharge = 84%.
Vaccinated in the community = 1.5%.
Unimmunised = 14.4%.
Never offered vaccination = 5.5%.
Parents refused vaccine = 1%.
Moved out of area and lost to follow-up = 8%.</td></tr>
<tr><td>Bolam et al., 1998/Nepal(41).</td><td>RCT, single centre – all infant vaccinations (n=540).</td><td>Mothers randomised to educational intervention at birth and 3 months, birth only or control (neonates).</td><td>Immunisation coverage at 6 months:
Group A (health education on post-natal wards and at 3 months post-natal) = 95%.
Group B (health education on post-natal wards only) = 96%.
Group C (health education at 3 months only) = 93%.
Group D (no intervention) = 94%.</td></tr>
<tr><td rowspan="2">Connors et al., 1998/ Australia(42).</td><td rowspan="2">Service evaluation, two centres – hepatitis B (n=4,165).</td><td rowspan="2">Birth dose of hepatitis B vaccination on post-natal ward (neonates).</td><td>Hepatitis B vaccine uptake pre-discharge<table><tr><th>Timescale</th><th>Hospital A</th><th>Hospital B</th></tr><tr><td>1993</td><td>96%</td><td>71%</td></tr><tr><td>1994</td><td>93%</td><td>77%</td></tr></table></td></tr>
<tr><td>Factors associated with vaccination:
Use of standing orders for hepatitis B vaccination.
Routinely recommending hepatitis B vaccination for both low and high-risk neonates.</td></tr>
<tr><td>Mercier et al., 2007/USA(43).</td><td>QI project, multi-centre – hepatitis B (n=719).</td><td>A multi-aspect QI intervention covering various aspects of post-natal health care including neonatal hepatitis B vaccination on post-natal wards (neonates).</td><td>Hepatitis B vaccination uptake:
Pre-intervention = 45%.
Post-intervention = 30%.</td></tr>
<tr><td>Braima et al., 2010/ Ireland(44).</td><td>Clinical audit/service evaluation, single centre – BCG (n=4,368).</td><td>Policy to universally offer BCG vaccination on post-natal ward (neonates).</td><td>Uptake of BCG vaccination in hospital: 80%.</td></tr>
<tr><td>Saitoh et al., 2013/Japan(45).</td><td>RCT, multi-centre – voluntary vaccinations (n=119).</td><td>Mothers randomised to educational intervention delivered antenatally, postnatally or control (neonates).</td><td>Uptake of voluntary vaccines at 3 months:
Intervention group 1 (pre-natal education) = 29.4%.
Intervention group 2 (education on post-natal wards) = 38.9%.
Control group (care as usual) = 8.3%.</td></tr>
<tr><td>Massey et al., 2015/USA(47).</td><td>Retrospective cohort study, multi-centre – hepatitis B (n=20,442).</td><td>Implementation of 2015 national policy to deliver dose of hepatitis B vaccination pre-discharge from maternity unit (neonates).</td><td>Hepatitis B vaccination uptake in post-natal unit: 80.2%
Factors associated with hepatitis B vaccination:
All births –
Hospital birth.
Medical attendant at birth.</td></tr>
</table>

<table>
<tr><td></td><td></td><td></td><td colspan="3">Hospital births only –
• Illicit drug use.
• Maternal age <35 years.
• Weekday birth.
• Use of admission orders.</td></tr>
<tr><td>Saitoh et al., 2017/Japan(46).</td><td>RCT, multi-centre - voluntary vaccinations (n=188).</td><td>Mothers randomised to educational intervention (delivered antenatally, on the post-natal ward and at 1 month) or control (mothers/neonates).</td><td colspan="3">Uptake of voluntary vaccinations at 2, 3 and 4 months as measured at 6 months:
• Intervention group (prenatal education and education on post-natal wards) = 43.0%.
• Control group = 45.5%.</td></tr>
<tr><td>Schniepp et al., 2019/USA(35).</td><td>QI project, single centre – all due/overdue (n=54).</td><td>Education for nurses and clinicians in cardiac critical care to increase uptake of due/overdue immunisations for neonates with congenital heart defects (≤1 year).</td><td colspan="3">Immunisations given/parent refusal documented pre-discharge:
• Baseline = 57.1%.
• Post-intervention = 87.5%.</td></tr>
<tr><td>Lemaitre et al., 2019/ Canada(48).</td><td>RCT, single centre – all upcoming vaccinations (n=2,572).</td><td>Randomised to treatment as usual or motivational interviewing on post-natal wards (parents/neonates).</td><td>Timeframe (months)
3
5
7
13
19
24</td><td>Vaccine coverage – experimental group
88.1%
91.3%
83.2%
75.9%
66.2%
56.7%
79.4%</td><td>Vaccine coverage – control group
78.3%
68.6%
59.5%
46.1%
74.3%</td></tr>
<tr><td></td><td></td><td></td><td colspan="3">Predictors of vaccination status at 24 months:
• Intervention group (OR = 1.05, 95% CI = 1.02-1.07).
• Complete vaccination status at 3 months (OR = 6.81, 95% CI = 5.58-8.30).</td></tr>
<tr><td>Tooke and Louw, 2019/South Africa(49).</td><td>Clinical audit, single centre – routine infant vaccinations (n=60).</td><td>Vaccination of neonatal unit inpatients at chronological age pre-discharge (pre-term neonates).</td><td colspan="3">Vaccination uptake amongst infants admitted at 6 weeks:
• 95% received their 6 weeks vaccines.
• 5% were not vaccinated due to being too unwell.</td></tr>
<tr><td>Bradshaw et al., 2020/USA(50).</td><td>QI project, single centre – hepatitis B (n=21,108).</td><td>Multi-component QI project to increase uptake of birth dose of hepatitis B vaccine (neonates).</td><td colspan="3">Newborn hepatitis B vaccination pre-discharge:
• Pre-intervention = 52.4%.
• Post-intervention = 72.5%.</td></tr>
<tr><td>Kaufman et al., 2020/ Australia(51).</td><td>Pilot study, single centre – all infant vaccinations (n=62).</td><td>Educational intervention for midwives and pregnant women targeting antenatal</td><td colspan="3">Uptake of birth hepatitis B vaccine: 91%.
Uptake of two-month childhood immunisations: 96%.</td></tr>
</table>

		and newborn immunisations (pregnant women/neonates).	
Kushner et al., 2021/USA(52).	Cohort study, multi-centre – hepatitis B (n=372).	Electronic alerts and a joint liver/obstetric clinic to increase uptake of hepatitis B vaccine and immunoglobulin (neonates of mothers with hepatitis B).	**Uptake of hepatitis B vaccine (uptake at correct time interval):** • Dose 1 = 100% (91%). • Dose 2 = 81% (78%). • Dose 3 = 74% (49%).
Di Mauro et al., 2021/Italy(53).	Prospective cohort study, single centre – all infant vaccinations (n=170).	Parental education, health promotion materials and vaccinations offered at chronological age for inpatients (pre-term neonates).	**Vaccination coverage at 24 months in pre-term study cohort (comparison with historical cohort of pre-term infants):** • DTaP-IPV-HBV-Hib dose 2 – 98.2% vs. 91.2% (p=0.009). • DTaP-IPV-HBV-Hib dose 3 – 96.4% vs. 87.3% (p=0.005). • MMR – 94.6% vs. 76.4% (p<0.001). • Varicella – 94.6% vs. 80.9% (p<0.001). • No significant difference for DTaP-IPV-HBV-Hib dose 1, PCV doses 1-3 and Men C. **Vaccination coverage at 24 months in pre-term study cohort (compared with regional paediatric population):** • No significant difference in coverage of any vaccination dose. **Age of vaccine administration in pre-term study cohort compared to recommended age:** Timeliness of vaccination significantly delayed for all vaccination doses.

*Single secondary/tertiary care setting included in study, along with primary care settings

General characteristics of studies

The studies were from 14 countries, predominantly the USA, Australia, and other high-income countries. The most common settings were inpatient wards, followed by antenatal/neonatal settings, emergency departments (EDs), and outpatient clinics. A range of age groups were examined in individual studies, with the most frequent being children of all ages, followed by younger age-groups and four studies also including family members. Several vaccinations were studied, most commonly all due/overdue immunisations and influenza. Various study designs were utilised, encompassing quality improvement (QI) projects, clinical audits/service evaluations, cross-sectional studies, intervention studies, randomised controlled trials, cohort studies, and pilot studies.

Characteristics of the interventions

Interventions varied substantially according to their content and delivery. Most involved pre-discharge vaccination and one in three involved extra staff and/or funding. Other common features were patient/family education, staff training/education, a multi-disciplinary approach, and the use of automatic vaccine ordering. The most common approach to checking immunisation status was parental/carer recall.

Note on settings

There were some considerations specific to setting, particularly neonatal settings. Here, several studies explored hepatitis B and BCG vaccination administered post-

birth. Although opportunistic in that it took place in hospital without appointment, this was often the recommended care setting for the vaccination. For example, national policy in the UK is for babies born to mothers with hepatitis B to receive vaccination within 24 hours of birth, usually in hospital(77). Therefore, as part of standard care, uptake may be greater.

The pathway to successful opportunistic vaccination in secondary and tertiary care

The heterogeneity of the included studies illustrates that opportunistic vaccination represents a complex pathway and involves several steps to be successful, all with potential for patient drop-out. We have attempted to summarise this pathway below and provide a narrative summary of the approaches and interventions utilised at each stage:

1. *Identify patients eligible for vaccination.*
2. *Take consent and offer vaccination.*
3. *Order/prescribe vaccine.*
4. *Dispense vaccine.*
5. *Administer vaccine.*
6. *Communicate with primary care.*
7. *Ongoing benefits of vaccination.*

It should be noted, however, that not all interventions will encompass all steps; for example, educational interventions delivered in hospital, but where vaccination occurs in the community.

1. ***Identify patients eligible for vaccination***

Baseline vaccination coverage

Several studies had assessed baseline vaccination coverage to determine the pool of eligible patients(22, 24-34, 39, 54-59, 65, 66, 69, 71, 72). For all due/overdue vaccinations, baseline coverage ranged from 44%(24, 58)–89%(39), with little difference by setting and lower coverage in older studies. For influenza, baseline coverage was lower, ranging from 25%(73)-50.5%(31).

Determining immunisation status

For vaccination to be successful, eligible patients must be accurately identified. This requires individual data, such as age, presence of underlying disease, immunisation status, and clinical condition.

Checking immunisation status (henceforth referred to as ‘screening’) was most straightforward in neonatal studies where all infants were generally eligible. However, the complexity increased with age and cumulative number of required vaccinations. The target vaccination and setting were also important. As a single yearly vaccination, screening influenza vaccination status was more straightforward as it required shorter recall. In outpatient

studies, patients had an ongoing relationship with the teams, reducing the complexity of screening, whilst inpatient stays afforded greater time to screen. Contrastingly, in ED there was limited time and rapid patient turnover.

In terms of personnel, screening was most successful in studies with extra staff and/or funding, including dedicated research staff(23, 24, 32-34, 37, 44, 57, 60, 64, 65, 67). Elsewhere, there was no clear consensus regarding who was best placed for this task, although two studies had successfully utilised pharmacy staff(36, 68).

A range of methods were used to screen immunisation status:

a. Patient/parental recall

Used in 30.2% of studies, this was the most common approach(22, 23, 29-32, 40, 54-61, 69). Although straightforward, it was inaccurate for studies of all due/overdue immunisations and was more appropriate for influenza. Szilagyi et al. found that 20% of children reported as under-immunised in ED were actually up-to-date, whilst a quarter of those reported as up-to-date were under-immunised(57). When compared to immunisation registers, Ressler et al. and Riley et al. found that immunisation status based on recall was incorrect for 14.5% and 32.1% of patients respectively(22, 28).

b. Electronic clinical alert system

These were utilised by 20.8% of all studies and involved influenza and hepatitis B vaccination(33, 34, 38, 52, 61-64, 66, 70, 74). Systems were designed to generate automatic vaccination alerts, based on age and clinical risk factors. Alerts were often delivered alongside other digital initiatives, such as automatic ordering, or within wider QI initiatives. However, Pollack et al. found automated screening to be a predictor of inpatient influenza vaccination uptake(72).

c. Handheld immunisation documentation

This was used in 22.6% of studies, usually alongside other methods(23, 24, 26, 29, 30, 40, 54, 55, 57, 58, 69). The approach was unreliable, with Cunningham et al. and Lindegren et al. finding that 56% and 24-26% of patients respectively had no documentation with them in ED(54, 58).

d. Phone calls to primary care

Two studies had screened immunisation status by telephoning primary care(24, 30). This was inefficient, with Bell et al. reporting an average of 1.5 calls to obtain a vaccination record and 4-5 hours spent daily calling primary care(24).

e. Checking against a national or regional immunisation registry

This was the gold standard and most accurate approach. Two UK studies had combined checking handheld documentation with telephoning the local health authority to check registry data(22, 25). Several Australian

studies had utilised the Australian Immunisation Register, a national register that records all vaccines administered and which staff can access remotely(28, 32, 33, 39, 59). A New Zealand study had used a similar approach(65).

Confirming clinical condition is compatible with vaccination

At this stage of the pathway, the patient's clinical condition and any clinical contraindications must also be considered. Studies reported varying proportions of children too ill to be vaccinated, ranging from 0-20.5% and with no obvious relationship to setting(22, 31, 34, 49, 54, 56, 60, 65, 67, 72). Leading reasons to defer vaccination were fever, diarrhoea, upcoming/recent surgery, vaccine allergies, or oncology patients undergoing treatments.

2. Take consent and offer immunisations

Although clinical contra-indications were important, vaccines not being offered and parent/carer refusal were greater contributors to non-uptake. Non-offer ranged from 11-77%, with the upper and lower range both in studies examining all due/overdue vaccines(25, 55, 65, 69). No studies had evaluated why vaccines weren't offered.

Many studies had explored parent/carer refusal of vaccination(23, 25, 31, 40, 42, 55, 56, 60, 62, 65, 72). This varied according to target vaccination and was low for neonatal vaccines, with Bakshi and Sharief reporting that 1% of parents refused neonatal BCG vaccination and Connors et al. reporting that

parental refusal was rarely or never a reason for not vaccinating against hepatitis B at birth(40, 42). In contrast, refusal was higher for other vaccines in high-income countries. Here, for measles, mumps and rubella (MMR) or all due/overdue vaccines, parental refusal ranged from 9.4-37.5% where vaccination status was known, with Cunningham et al. also reporting 87.5% refusal where status was unknown(25, 55, 56, 58, 65). For influenza, refusal ranged from 25.6-72% and was greater when offered in the ED(31, 60, 62, 72). Across all vaccinations, four studies had evaluated underlying reasons, with common responses encompassing preference for vaccination in primary care, belief that the child was too unwell, concerns about the safety and efficacy of vaccination and belief that it was not needed for healthy children(31, 58, 72, 73).

3. **Order/prescribe vaccine**

Several studies of influenza and neonatal hepatitis B vaccination utilised automatic ordering/built-in order sets(36, 38, 42, 47, 61, 63, 66, 72). Massey et al. found that admission orders were associated with increased neonatal hepatitis B vaccination and Connors et al. found that uptake of hepatitis B vaccination in a hospital where it was on a standing order was 93-96% versus 71-77% where it wasn't(47).

4. **Dispense vaccine**

Pharmacy involvement was frequently identified as essential to ensuring that vaccines were consistently available and dispensed quickly, with pharmacy

staff involved in the leadership and delivery of several interventions(36, 50, 59, 61, 63). Gattis et al. described a pharmacy-led intervention for influenza vaccination of solid organ transplant recipients whereby pharmacists were responsible for screening patients, assessing appropriateness, recommending vaccination to providers, educating patients/family, and verifying and dispensing vaccines(68). Vaccination uptake rates increased from 36% pre-intervention to 72% post-intervention ($p<0.001$), with influenza diagnoses also falling(68).

5. Administer vaccine

Next, vaccinations must be administered, with the potential for further drop-out. This was evidenced by Orenstein et al. and Rao et al. (2020) who had evaluated how vaccine orders translated into administration, with only 40.3% and 61.2% of those with orders receiving vaccination respectively(36, 38).

For each study, Table 2 summarises baseline coverage and subsequent outcomes, including administration and uptake of vaccination. Although uptake varied by study, virtually all demonstrated an improvement in coverage post-intervention. It is difficult to compare administration rates due to variable study conditions and outcome measures, however, Table 3 summarises ranges by setting and vaccination.

Table 3: Ranges of administration of vaccination amongst eligible patients across the included studies by setting and target vaccination.

Setting	Target vaccination		
	Measles, mumps and rubella (MMR)	**Influenza**	**All due/overdue**
Emergency department	35-41%(54, 55)	8.8-57%(60-62)	24.0-75.0%(56-59)
Inpatients	-	31.0-69.1%(31, 34, 36, 38)	3.4-80.0%(22, 24-30, 32, 33, 39)
Outpatients	-	8.0-90.3(70-74)	53.6-84.6%(23, 37, 65, 69)[1]
Inpatients and outpatients	-	49.7-87.4%(63, 64, 66-68)	
	BCG	**Hepatitis B**	**All neonatal/infant immunisations**
Neonatal/antenatal	80-85%(40, 44)	72.5[2]-100%(42, 43, 47, 50, 52)	91.3-96.0%(35, 41, 45, 46, 48, 49, 51, 53)

[1]Combined as there was only one study conducted exclusively in outpatients.
[2]Mercier et al. reported 30% uptake of neonatal hepatitis B vaccination but this coincided with the phasing out of this policy and the introduction of hexavalent vaccination containing hepatitis B at 2, 4 and 6 months and is not included in the range.

Looking firstly at influenza, higher uptake was generally seen in inpatients and outpatients than EDs, and in studies of children with underlying medical conditions(63, 64, 66-68). The highest uptake (90.32%) was reported by Lo and Sobota in an outpatient study of children with sickle cell disease(74). Similarly, Pappano et al. and Rao et al. (2020) found that underlying medical conditions were associated with increased vaccination(36, 60).

For all due/overdue vaccinations, there was higher uptake in studies with dedicated immunisation staff(23, 33, 37, 39, 54, 57, 58). Outside of these, intervention uptake was higher in older studies, with studies published pre-2000 reporting uptake of 65-82.4% and those post-2000 reporting uptake of 3.4-64%.

Uptake of neonatal vaccines was generally high. However, it was often unclear to what extent this was a consequence of the intervention, with little difference in outcomes pre/post-intervention or when compared to control. For example, Bolam et al. reported 94% uptake of infant immunisations in the control group versus 96% in the intervention group(41). In studies of pre-term and high-risk infants, however, interventions to increase uptake of routine vaccinations at chronological age through parental and staff education showed a marked improvement(35, 49, 53).

7. Communicate with primary care

After vaccine administration, primary or community care providers must be informed. This was a further benefit of a remotely-accessible vaccination registry, as used in Australia and New Zealand, with primary care updated of any vaccinations administered via this route(65).

Communication with primary or community care was also important to arrange vaccination of children not vaccinated in hospital. In some studies, patients were referred to primary care if they were not vaccinated in hospital. In others, such as Muehleisen et al., there was no in-hospital offer of vaccination, with the intervention consisting of education and a prompt to arrange vaccination and primary care informed as such(26). Here, 27% of patients in the intervention group had received vaccination one month post-discharge, compared to 8% of the control ($p<0.001$)(26).

8. Ongoing benefits of vaccination

Although not strictly part of the vaccination pathway, some studies had evaluated whether interventions had lasting impacts on coverage and vaccination behaviour.

Four studies had explored whether gains in coverage were sustained beyond the intervention's initial timeframe (Table 4). In the two examining all due/overdue vaccinations, initially increased uptake associated with the intervention was not sustained(26, 57). Similarly, Kushner et al. found that coverage of hepatitis B vaccination fell with time(52). However, in these studies it was unclear whether, in the absence of the intervention, coverage would have been even lower. In their study of all infant immunisations, Lemaitre et al. found that uptake was consistently higher in the intervention group at all timepoints(48).

Table 4: Summary of included studies detailing sustained coverage outcomes beyond the initial timeframe of the intervention

Study (target vaccination)	Baseline coverage	Post-intervention coverage	Sustained coverage – timepoint 1	Sustained coverage – timepoint 2
Muehleisen et al. (all due/overdue vaccinations)(26).	• Intervention group = 54%. • Control group = 49%.	**Patients with ≥1 catch-up immunisation within 1 month:** • Intervention group = 27%. • Control group = 8% (p<0.001).	**Patients with ≥1 catch-up immunisation within 9 months:** • Intervention group = 45%. • Control group = 35% (p>0.2)*.	-
Szilagyi et al. (all due/overdue vaccinations)(57).	64%.	**Fully immunised for age at 1 day:** • Manhattan ED = 75%. • Bronx ED = 71%.	**Fully immunised for age at 6 months:** • Manhattan ED = 66%. • Bronx ED = 54%.	-
Lemaitre et al. (all upcoming neonatal vaccinations)(48).	Not applicable (neonates).	**Complete vaccine status – at 3 months:** • Experimental group = 91.3%. • Control group = 88.1%.	**Complete vaccine status at 13 months:** • Experimental group = 66.2%. • Control group = 59.5%.	**Complete vaccine status at 24 months:** • Experimental group = 79.4%. • Control group = 74.3%.
Kushner et al. (neonatal hepatitis B vaccination)(52).	Not applicable (neonates).	Birth dose of hepatitis B vaccination = 100%.	Dose 2 (1-2 months) = 81%.	Dose 3 (6-18 months) = 74%.

*Exact p value not provided

Discussion

As far as we are aware, this is the first attempt to review the literature relating to opportunistic vaccination across secondary and tertiary care settings and we have provided a comprehensive overview of interventions used to improve vaccination in these settings. Despite established childhood immunisation programmes internationally, there were relatively few published papers available. Similarly, although NICE recommends opportunistic vaccination in the UK, there were only four

papers published between 1991 and 2007(15, 22, 25, 40). Our review has demonstrated that opportunistic vaccination in hospital settings is complex, requiring several steps to be successfully navigated for interventions to be effective.

Vaccination coverage amongst CYP attending secondary and tertiary care appears to be below that of the general paediatric population(78-81). This was evaluated by some of the included studies, with, for example, Shingler et al. reporting coverage of 70.6% in their study population versus a regional average of 85% and Tarca et al. reporting coverage of 75% in their first study cohort versus a state and national average above 91%(39, 65). This is important in the context of sub-optimal uptake of many UK vaccinations, with only 85.3% having received the pre-school booster and 86.6% the second MMR dose by age 5 in 2020/21(82). With ongoing outbreaks of vaccine-preventable diseases, such as measles pertussis, opportunistic vaccination in hospital-based settings may represent one route through which to vaccinate an under-immunised patient sub-group(83, 84).

An important finding was that, although the effect sizes were variable, virtually all interventions led to an improvement in coverage post-intervention. This suggests that interventions were able to reach and vaccinate patients not vaccinated via traditional methods. Previous literature has shown that a key barrier to childhood vaccination is access, including time constraints, distance, location, long waiting times, childcare challenges for siblings, and impermanent residence for groups such as homeless or looked-after children(85). Clearly, opportunistic vaccination overcomes these barriers and provides an opportunity to inform parent/carer

knowledge about vaccination. Both Gilbert and Wrigley, and Conway reported that a leading reason for under-immunisation in the community were minor illnesses at the intended time of vaccination, as identified previously in the vaccination literature(25, 29, 85). Thus, hospital settings may present a useful opportunity to discuss true medical contraindications to vaccination and to vaccinate children in a setting where they can be monitored and their safety assured.

This review found consistent evidence that the effectiveness of opportunistic vaccination depends on the ability to quickly and accurately assess vaccination status, particularly for all due/overdue vaccines. National UK policy is for patients to be offered vaccines if their current vaccination status is unknown(86). However, Cunningham et al found that parents were reluctant to do so, with uptake of catch-up vaccinations in ED only 15% amongst patients with uncertain status compared to 71% with documented under-immunisation ($p<0.0001$)(58). The review demonstrated that parental recall and handheld records were unfeasible screening options due to unreliability and unavailability, whilst confirming with primary care was time-consuming. Consequently, a remotely accessible electronic system is required to achieve this successfully, as demonstrated by studies utilising the Australian Immunisation Register(28, 32, 33, 39, 59). In the absence of this, inpatient admissions may be appropriate for catch-up of routine immunisations due to the prolonged time in hospital. Influenza vaccination may be possible in more time-pressured ED and outpatient settings due to the reduced screening required alongside the opportunity to utilise digital initiatives that reduce the burden on staff, such as electronic alerts and automatic vaccine ordering. This is especially relevant

given that influenza vaccine uptake in the UK is lower than other childhood vaccines, with 56.7% uptake amongst 2- and 3-year-olds in 2020/21(87). In the UK, the NHS is transitioning to a digital handheld child health record (the "eRedbook") from 2023, which may improve the long-term feasibility of opportunistic catch-up vaccination, although alternative short and medium-term interventions are likely to be required(88).

Several studies described interventions that utilised additional staff and/or funding, which were generally more successful than those that didn't. Even with digital interventions, delivering vaccination alongside routine care may be challenging without additional resources. In the study by Burgess et al, ED staff were reluctant to take on responsibility for vaccination and felt that they lacked sufficient time(56). Likewise, Cunningham et al. described how, in the absence of the dedicated immunisation nurse, combining tasks with the existing duties of ED staff made immunisation a low priority, whilst Buenger and Webber reported that ED staff prioritised other tasks over influenza vaccination(58, 61). In the inpatient setting, Walton et al. found that over half of staff expressed concerns or considered inpatient vaccination inappropriate(27). Therefore, it is important that new interventions are adequately resourced, with implementation facilitated by staff education and QI methodologies to ensure that they become embedded within care(24, 34, 36, 65). Additional factors limiting intervention success were high levels of parental refusal and non-offer of vaccination by staff. There has been extensive research into refusal of community-based vaccination, however future work should seek to understand the

specific barriers underlying parental refusal and non-offer of opportunistic vaccination in hospital settings.

Limitations

The included papers provided variable information about the interventions, often with limited detail rendering evaluation difficult. In addition, most interventions had utilised several components making it difficult to draw out the impact of individual aspects. Most were single centre studies that reported on local initiatives and it is challenging to determine their wider generalisability. Although studies demonstrated improved vaccination coverage, none had evaluated cost-effectiveness and few had evaluated the medium/long-term impact of interventions. Nevertheless, NICE suggests that any intervention that improves vaccination coverage is usually cost-effective, particularly if it benefits under-served groups(18). We did not search the grey literature and may have missed interventions used in practice via this route - this also increases the risk of publication bias. Additionally, we only included studies published in English, potentially biasing findings towards those from English-speaking countries. As with all scoping reviews, we did not formally evaluate evidence quality and, due to the studies' varied nature, only limited synthesis of results was possible.

Conclusions

This scoping review has explored and summarised the published literature relating to interventions delivered in secondary and tertiary settings focused on improving routine vaccination uptake in CYP, with most studies demonstrating improved vaccination coverage post-intervention. Furthermore, children attending hospital

appear to have lower baseline coverage than the general paediatric population and are likely to benefit from interventions in these settings. For interventions to be successful, however, there is a need for electronic immunisation registers to enable vaccination status to be quickly and accurately checked, with the UK's transition to the eRedbook a potential long-term route to facilitate this. Although existing research suggests that opportunistic vaccination interventions in hospital settings may be beneficial, further research is needed in this area, particularly multi-centre studies and cost-effectiveness analysis.

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Competing interests statement

The authors have no competing interests to declare.

Authors' contribution

SB was involved in the design of the study, title, abstract and full-text screening, and data extraction. In addition, SB performed the analysis and data synthesis, wrote the first draft of the manuscript, and undertook subsequent revisions to the manuscript.

RE contributed to the co-conception of the study, design of the study, the literature search, and project management. RE was also being involved in title, abstract and full-text screening, data extraction, and the write-up of the manuscript at all stages. RI contributed to the co-conception of the study, design of the study, title, abstract and full-text screening, and data extraction, along with supporting oversight of the project. RE and RI contributed equally to this paper and wish to be listed as joint last authors. KN, NG, LT, SS and MO contributed to data collection. All authors were involved in critically revising the manuscript and approved the final version for submission.

Data sharing agreement

Further information on the studies included in this review can be obtained by contacting the corresponding author via s.blagden@nhs.net.

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Appendix I – Data extraction instrument

Scoping review details	
Scoping review title:	A scoping review of interventions delivered in secondary or tertiary medical care settings to improve routine vaccination uptake in children and young people.
Review objective/s:	To identify and synthesize the available quantitative evidence to produce a map of public health interventions to improve vaccination uptake in children and young people that are delivered in secondary and tertiary healthcare settings.
Review question/s:	What are the interventions delivered in secondary or tertiary medical care settings focused on improving routine vaccination uptake in children and young people?
Inclusion/exclusion criteria	
Population	Children and young people (aged less than 16 years)
Context	Interventions to improve routine vaccination uptake delivered in secondary or tertiary medical care settings.
Types of study	Quantitative
Study details and characteristics	
Study citation details (e.g. author/s, date, title, journal, volume, issue, pages)	

Study design	
Country	
Setting (e.g. secondary care, ED, inpatient ward)	
Participants (details e.g. age/sex, number)	
Population sub-group	
Vaccination target (e.g. MMR, influenza, all)	
Details/results extracted from study (in relation to the concept of the scoping review)	
Intervention	
Outcome	
Cost effectiveness/effectiveness	
Acceptability to stakeholders	
Any differential effects	

Chapter 4

Unmet vaccination need amongst children under the age of five attending the Paediatric Emergency Department: a cross-sectional study in a large UK district general hospital.

Research question (RQ3): Do children (aged < 5 years) attending the Paediatric Emergency Department have lower levels of vaccination than their peers in the general population?

The first full draft of this paper is included here and will be submitted to *BMJ Open* as:

> Isba, R., Brennan, L., Egboko, F., Davies, N., and Knight, J. Unmet vaccination need amongst children under the age of five attending the Paediatric Emergency Department: a cross-sectional study in a large UK district general hospital.

I conceived of the study, led on the ethics application process, undertook the fieldwork, analysed the data, was involved in all stages of the preparation of the manuscript and am guarantor author.

Part of this work was presented as a poster entitled “Should we formally verify the tetanus and MMR vaccination status of all those < 2 years of age attending the Paediatric Emergency Department?” within the Association of Paediatric Emergency Medicine stream at the Royal College of Paediatrics and Child Health Conference, June 2022. The conference abstract will be published in a supplementary edition of *Archives of Disease in Childhood* later in 2022.

An abstract entitled “Should we address unmet vaccination need in under-fives during a Paediatric Emergency Department attendance?” has been accepted as a poster presentation at the American Public Health Association Conference, November 2022.

An abstract entitled “Unmet vaccination need amongst under-fives attending the Paediatric Emergency Department: a cross-sectional observational study in a large district general hospital.” has been submitted to the Lancet’s Public Health Science conference, November 2022 (decision due September).

Abstract

Objective

The objective was to estimate vaccination coverage amongst children under the age of five attending the Paediatric Emergency Department (PED) using tetanus and MMR vaccination as a proxy.

Design

A cross-sectional observational study with a single data collection point for each participant.

Setting

A single large PED in Greater Manchester, England.

Participants

Participants were children (under 5 years old) attending the PED during October 2021. Participation was “opt-out” and parents/carers were given until the end of the following month to request that their child’s data be excluded.

Primary and secondary outcome measures

The primary outcome of interest was the percentage of children who were up-to-date with their routine childhood vaccinations at their time of attendance to the PED. Secondary outcome measures were the percentage of children who had received

age-appropriate tetanus and MMR vaccination, and how these compared to local population data at the ages of 1, 2, and 5 years of age.

Results

One third of under-5s in this study had unmet vaccination need and were missing at least one dose of either MMR or tetanus-containing vaccine. In older age groups, many were missing their tetanus boosters and only 1 in 5 of those eligible had received two doses of MMR. Those in younger age groups had vaccination coverage levels comparable to the local data.

Conclusions

Those children eligible for pre-school boosters (tetanus and MMR2) appear to have considerable unmet vaccination need. Whilst the pandemic has had an impact, the observation that MMR2 uptake is considerably lower than tetanus booster (when they are scheduled together) warrants further investigation. Catch-up campaigns for MMR2 should focus on this cohort of children and the PED may offer an opportunity for an intervention.

Trial registration

The study was registered as an observational/non-interventional study on the clinicaltrials.gov website with the identifier NCT04485624.

Strengths and limitations of this study

- This study is timely given the pandemic's impact on routine childhood vaccination.
- A population has been identified with considerable unmet vaccination need who might benefit from an intervention not currently offered.
- A limitation is that the work was undertaken at a single centre and there were constraints with data collection and quality.
- A proxy for overall vaccination status was used, leading to a possible underestimation of unmet vaccination need.

Introduction

Vaccines are one of the great global health successes. Since their discovery more than 300 years ago, they have saved countless millions of lives (1), reduced the incidence of dozens of diseases, and even lead to the eradication of smallpox (2). In countries with access to them, vaccines have also played a key part in the control of the current SARS-CoV-2/COVID-19 pandemic (3).

However, pre-pandemic, in the UK, uptake of routine childhood vaccination had fluctuated in recent years (4) and coverage lagged behind some of our European peers for common vaccine-preventable diseases such as measles (5).

Every year in England, millions of children and young people (CYP) attend hospital (secondary or tertiary medical care) (6). Attendance is often with relatively minor illnesses and injuries, many of which could be better managed elsewhere. However, despite numerous initiatives to redirect these CYP, hospital attendances (pre-pandemic) had increased year on year (6). The pronounced decrease in Paediatric Emergency Department (PED) attendances seen early in the pandemic (7,8) was reversed in 2021, as lockdowns and other restrictions were eased, with attendance exceeding pre-pandemic levels and a change in the some of the seasonal patterns of illnesses presenting to the PED (9).

In addition to their primary reason for presentation, CYP attending the hospital may have lower than average levels of health and wellbeing, additional unmet health

need (e.g. dental health), or not be able to engage with preventive elements of routine healthcare (e.g. vaccination) for a myriad of reasons. A hospital attendance or admission might therefore offer an opportunity to intervene. A recent pilot study showed that time during a PED department attendance could be used to deliver a public health intervention and that this was both feasible (within the constraints of the department) and acceptable (to all stakeholders including CYP, parents and carers, and staff in the PED) (10).

If any child or young person who had not received their age-appropriate routine vaccinations could be identified during a PED attendance, clinicians might (should it be clinically/situationally appropriate) be able to offer one or more tailored interventions to address this unmet vaccination need. The benefits of such an approach are numerous and include:

- decreasing mortality and morbidity from vaccine-preventable diseases, by ensuring
    - individual and population coverage for diseases that cannot spread person-person e.g. tetanus
    - higher levels of population coverage for non-epidemic diseases that can be spread person-person e.g. Hepatitis B
    - and herd immunity for diseases that can easily spread person-person and can cause outbreaks e.g. measles;
- a decrease in un-needed treatment in the case of individual exposure in the absence of an accurate vaccination history at the point of treatment e.g. a tetanus-prone wound in the PED;

- a reactive response to outbreaks e.g. mumps, epidemics e.g. influenza, and pandemics e.g. SARS-CoV-2;
- improving coverage of targeted vaccination programmes e.g. seasonal influenza.

In its 2021 Health Equity Audit of the National Immunisation Programme (11), Public Health England (now the UK Health Security Agency) stated “Equality in immunisation is an important way to address health inequalities” and reported that whilst the Immunisation Programme had achieved high coverage in the population as a whole, within sub-populations there still existed “avoidable inequalities”. Whilst the reasons for these inequalities are complex, “institutional” and “policy” factors play a role (11). Addressing these factors by offering vaccination at the point of PED attendance may preferentially improve vaccination uptake amongst those experiencing avoidable inequalities.

Previous work to improve vaccination uptake via interventions delivered in secondary or tertiary care (see (12) for overview) has shown that vaccination coverage in CYP attending hospital settings is generally lower than in the general population. However, the vaccinations under investigation, location of presentation within the hospital, and way in which vaccination data were verified, varies considerably. Within the scoping review, for all due/overdue vaccinations (not a measure currently available in England), baseline coverage ranged from 44% (13,14) – 89% (15), with little difference by setting and a trend for lower coverage in older studies. For influenza, baseline coverage was lower, ranging from 25% (16) - 50.5% (17).

The overall aim of this work was to look at unmet vaccination need by answering the question: Do children (aged < 5 years) attending the PED have lower levels of vaccination coverage than their peers in the general population?

Methods

This was a cross-sectional observational study with a single data collection point for each child. The study was registered as an observational/non-interventional study on the clinicaltrials.gov website with the identifier NCT04485624.

Consent

Full prospective ethics approval was obtained from the North West – Greater Manchester East Ethics Committee (IRAS reference 278815, REC reference 20/NW/0423). Following an earlier part of the work, an ethics amendment was submitted and approved to move to “opt-out” consent for this part of the project (Amendment 1, substantial, non-CTIMP, approved 26 August 2021).

Prominently-displayed posters relating to the study were put up around the PED during the month of data collection, with flyers handed out in triage, and participant information sheets with opt-out consent forms available on request. Nursing staff in the PED were briefed so that they could support queries from parents/carers.

Parents/carers could choose for their child to opt-out by filling in the form or contacting a member of the research team within a month of attendance.

Setting

Data were collected from a single, dedicated co-located PED, in Greater Manchester, in the North West of England. The intention was to include a second, dedicated children-only ED in a specialist children's hospital, but the pandemic meant that this site was closed to new studies of this type at the time of data collection.

Participants

Participants were children (under 5 years old) attending the PED during October 2021. Children and young people in Manchester have lower than average levels of health and wellbeing, around a third live in low-income households, and 1 in 100 of them reside in care (18).

Patient and public involvement

Reading materials were designed to be read by the parent or caregiver. Following patient involvement in a previous study (10) all reading materials were designed for a reading age of 7-9 years old, in order to be as accessible as possible.

Vaccination schedule

The routine NHS vaccination schedule (19) recommends tetanus-containing vaccines (given as multi-component vaccines) are given at 8, 12, and 16 weeks ("primary course") and at around 3 years 4 months (as part of the so-called "pre-school booster"). MMR1 is due around one year of age and MMR2 is given at 3 years 4 months, alongside the pre-school booster.

Data collection

A list of dates of birth and hospital numbers was generated for all attendees during the month of October 2021. Duplicates (where the same child may have attended more than once in the month of interest) were removed. As no date of attendance was available, age at presentation was calculated based on a date of birth of October 1st 2021 and any vaccination before the end of October 2021 was included when checking status. This approach was taken to ensure that the data tended to over- rather than under-estimate coverage e.g. at the lower age limits.

Data were extracted from individual Summary Care Records (SCRs) by RI and anonymised before analysis. Extraction took between 2 and 5 minutes per record (depending on the quality of network access/connectivity). The quality and presentation of the data within the SCR was also very variable and this finding is presented elsewhere (20).

The variables of interest were numbers of children aged:

- > 2 months and < 5 years who were “up to date” with all their age-appropriate tetanus-containing and MMR vaccinations at the time of PED attendance;
- > 2 months and < 5 years who had received all their age-appropriate tetanus vaccinations at the time of PED attendance;
- > 12 months and < 5 years who had received at least one dose of MMR at the time of PED attendance;
- between 2 and < 5 years who had received MMR1 by their 2nd birthday;
- between 3 years 4 months and < 5 years who had received two doses of MMR at the time of PED attendance;
- between 3 years 4 months and < 5 years who had received MMR2 by their 5th birthday.

Sample size calculation

The MMR vaccine was chosen for the sample size calculation as this is the vaccine that has attracted the most controversy over the past decades (resulting in lower than target coverage). Two doses of MMR are given to complete a routine course and the second dose, designated “MMR2” is given around the age of 3 years and 4 months, but national data are normally presented for MMR2 at the age of 5 years.

At the time the sample size calculation was carried out, the most recent data for MMR2 coverage at 5 years were available for the year 2018/19 (21). In England, coverage for MMR2 was 86.4% and for Manchester, coverage for 5 year olds was

82.1%. The sample size calculation was carried out using STATA version 16 (22) and a comparison made between population prevalence (between the “PED” and “general Manchester” populations). The sample size calculation was based on the difference between the population prevalence in Manchester of 0.82 and in the study PED of 0.77, with the required power at 0.8, using a two-sided test, with probabilities set at $p < 0.05$. This suggested a sample size of 577 was needed.

Outcomes

Primary

The primary outcome of interest was the percentage of children under the age of 5 years who were “up-to-date” with their vaccinations at the time of their PED attendance, using tetanus-containing and MMR vaccination status combined as a proxy for overall vaccination. Children were coded as “up to date” with their vaccinations if they had received all tetanus and MMR vaccinations for which they were eligible (based on their age) by 1st October 2021.

Secondary

Secondary outcomes of interest were age-appropriate tetanus-containing vaccination coverage, and uptake of MMR1 and MMR2.

Statistical Analysis

Descriptive statistics were prepared for primary and secondary outcomes. We compared our data to data published for the year April 2020 - 2021 in the COVER

programme (4). The COVER programme publishes quarterly and annual vaccination coverage statistics for children aged 12 months, 24 months, and 5 years in the UK. Data from 2020-21 was chosen as it was the most recent published data and was independent of our data, so statistical analysis was possible.

We mirrored the methodology (23) used to obtain numerator and denominator values for the COVER data to obtain a comparable sample from our study in PED. We compared our data at 12 months, 24 months, and 5 years with the publicly available data for the Lancashire and Greater Manchester footprint. This geography includes the majority of the catchment area for the PED in our study. Due to the age-range in our sample (2 months – 5 years) it was not possible to mirror the 5-year-old denominator methodology used for national samples (total number of children responsible for reaching their 5th birthday within the evaluation dates), we therefore used children aged 4yrs 0 months – 4 years 12 months as a proxy for 5-year-old data.

We also compared the coverage figures for children in our study with local and national data obtained from the COVER programme. Chi-squared tests were used to examine differences in proportions and generate significance levels.

Results

A total of 1,450 children under the age of 5 years attended the PED in October 2021. Of these, 113 were under 2 months old (approximately 8 weeks, the age at which

first tetanus-containing vaccines are given) so were excluded. For the remaining 1,337 children, records were available for 1,223 (91%) of them and are included in subsequent analyses. Children in the under-5s age group made up around 60% of all attendees to the PED (aged < 16 years at the time of presentation) in October 2021.

Participants

As the main variable of interest was attendance at the PED, no data beyond age were collected. The age distribution of children appears in Table 1.

Tetanus-containing and MMR combined as a proxy for overall vaccination status

At the time of their presentation to the PED, two thirds of the 1,223 children had received all of their age-appropriate tetanus-containing and MMR vaccines (n = 807; 66.0%). This effectively equates to 416 missed opportunities to identify under-vaccinated children during their attendance within this sample.

Vaccination status varied by age band, with younger age groups tending to have higher levels of coverage (Table 1). There were notable “dips” within the age bands where vaccines were due, for example MMR1 falls within the band 12m to <15m and coverage in this band was 70.3%, compared to 96.1% in the preceding band and 80.3% in the subsequent band. As a group, four-year-olds had very low levels of tetanus and MMR coverage, with just 1 in 5 of them having received a full set of primary and booster doses of tetanus plus two MMRs. Twenty-nine children in the sample appeared to be wholly unvaccinated.

Age band [1]	Total number of children attending	Total number of children attending with vaccination data available	Children "up-to-date" with age-appropriate tetanus and/or MMR vaccination at attendance n (%)	Children "up-to-date" with age-appropriate tetanus at attendance n (%)	Children "up-to-date" with MMR 1 at attendance n (%)	Children "up-to-date" with MMR 2 at attendance n (%)
2m to < 6m	91	79	69 (87.3)	69 (87.3)		
6m to < 9m	74	66	58 (87.9)	58 (87.9)		
9m to <12m	113	102	98 (96.1)	98 (96.1)		
12m to < 15m	80	74	52 (70.3)	69 (93.2)	48 (64.9)	
15m to < 18m	86	76	61 (80.3)	70 (92.1)	61 (80.3)	
18m to < 1y9m	90	84	72 (85.7)	78 (92.9)	75 (89.3)	
1y9m to < 2y	77	72	61 (84.7)	66 (91.7)	62 (86.1)	
2y to < 2y3m	72	68	61 (89.7)	66 (97.1)	62 (91.2)	
2y 3m to < 2y6m	68	62	56 (90.3)	60 (96.8)	56 (90.3)	
2y 6m to < 2y9m	71	68	64 (94.1)	67 (98.5)	64 (94.1)	
2y9m to < 3y	62	55	48 (87.3)	50 (90.9)	48 (87.3)	
3y to < 3y3m	70	65	35 (53.8)	63 (96.9)	35 (53.8)	
3y3m to < 3y6m	53	49	7 (14.3)	33 (67.3)	20 (55.6)	2 (5.6)[2]
3y6m to < 3y9m	60	56	7 (12.5)	34 (60.7)	19 (33.9)	7 (12.5)
3y9m to < 4y	69	63	18 (28.6)	49 (77.8)	27 (42.9)	19 (30.2)
4y to < 4y3m	53	49	7 (14.3)	29 (59.2)	14 (28.6)	7 (14.3)
4y3m to < 4y6m	39	34	6 (17.6)	15 (44.1)	10 (29.4)	6 (17.6)
4y6m to < 4y9m	59	57	18 (31.6)	45 (78.9)	23 (40.4)	18 (31.6)
4y9m to <5y	50	44	9 (20.5)	31 (70.5)	16 (36.4)	9 (20.5)
TOTAL	1337	1223	807 (66.0)	1050 (85.9)	640 (65.6)	68 (20.1)

[1] Age of child on October 1st 2021. Displayed in quarter year intervals, except for the first age band, which includes children for a four-month period.

[2] Denominator for calculation is number of children aged 3y4m < 3yr 6m (n=36)

Table 1. Age distribution of children and details of tetanus-containing and MMR vaccination. Vaccination points: tetanus at 8, 12, and 16 weeks (approximately 2, 3, and 4 months); MMR1 at 12 months; and MMR2 and tetanus booster at 3 years 4 months.

Tetanus-containing vaccination

In the sample of children included in this study, 85.9% had received all of their age-appropriate tetanus-containing vaccinations at the time of presentation at the PED. Again, this varied by age group with higher levels of coverage present in children eligible only for their primary tetanus vaccines and coverage dropping in children from the age of 3 years 4 months when the “pre-school” booster vaccine is due.

MMR vaccination

MMR1

During October 2021, 976 children attending PED were eligible for their first dose of the MMR vaccination. Of these, 640 (65.6%) had received the immunisation, meaning one third of children had not received their MMR vaccine despite being eligible (Table 1).

MMR2

Of the 339 eligible children (older than 3 years and 4 months), only 68 had received their second MMR vaccination (20.1%). This was lowest in the youngest age band (3years 4 months – 3 years 6 months), with only 5.6% already having received the vaccination before their PED attendance. However, this rate remained low, even in the oldest children, e.g. only 14% of the children aged 4years – 4years and 3 months had received their MMR2 vaccine (Table 1).

Estimate of “missing” tetanus and MMR vaccinations in a year

To estimate the total number of “missing” vaccinations amongst children under the age of five attending the study PED in a year, we assumed that the attendance figures for October 2021 were representative of a typical month in 2021 (recognising that pandemic-related restrictions and impacts were ongoing throughout 2021 and PED attendance would usually fluctuate across the year). Scaling up, it is estimated that a total of 4,992 children would have attended the study PED in 2021 with at least one missing tetanus or MMR vaccination. Specifically, if PED teams were equipped to administer catch up vaccinations (and all children were eligible and all parents/carers consented), up to 4,032 MMR1s, 3,252 MMR2s, and 1,404 tetanus boosters could potentially have been administered during 2021. Vaccines could also have been given to start, continue, or complete 960 primary tetanus courses (which would have required varying numbers of additional doses depending on the age of the child).

Comparison with National COVER data

Comparisons between publicly available data for the catchment area (Greater Manchester and Lancashire) and the children in our sample found no statistically significant differences in coverage at 12 and 24 months (Table 2) or for the receipt of the full primary course of tetanus-containing vaccines by the age 5 years.

However, uptake of MMR1, MMR2, and the tetanus-containing booster (all by the age of 5 years) were all significantly lower in our sample of children than the general local population ($p<0.001$).

	12 months		24 months		5 years	
	L&GM	PED	L&GM	PED	L&GM	PED [3]
Tetanus-containing primary course vaccine [1]	91.2	92.4	93.7	96.0	95.5	96.1
MMR1			91.0	90.9	95.2	34.2*
MMR2					87.0	21.7*
Tetanus-containing booster [2]					85.8	64.7*

[1] COVER data reports DTaP/IPV/Hib/HepB3

[2] COVER data reports Diphtheria, Tetanus, Polio, Pertussis Hib booster

[3] Children aged 4yr0mo - 4yr12mo used as a proxy for 5-year-olds

*Statistically significant difference in proportions of children vaccinated between L&GM and PED p<0.01

Table 2. Proportion of children vaccinated and comparison of sample data (PED) with 2020-2021 COVER data for Lancashire and Greater Manchester (L&GM).

Finally, we compared the coverage in our sample to data for England from the national sample at age five years. The children in our study had a higher proportion of coverage for the primary tetanus containing vaccine than the English sample (0.9% higher), however this was not statistically significant. A significantly lower proportion of children in our study were vaccinated with MMR1, MMR2, and the tetanus-containing booster vaccine than in the 2020-21 English cohort (60.1%, 64.9%, and 20.6% less respectively; all p <0.01).

Discussion

The World Health Organization (WHO) recommends that at least 95% of children should be vaccinated against diseases preventable by immunisation to ensure elimination and control (24). Our data suggests that the children attending this PED

in Greater Manchester were below this recommendation for MMR1 and 2, and for the tetanus-containing booster.

Principal findings

In the month of October 2021, 416 children (34% of those attending) were not up-to-date with their routine vaccinations at the time of their PED attendance. This equates to almost 5,000 potential vaccination moments in a single large PED – a currently unutilised opportunity to address unmet vaccination need, particularly amongst those experiencing vaccination inequity. MMR vaccination uptake in this PED-attending population was particularly low in older age groups. Whilst some of this is likely due to pandemic-related disruption, the finding that tetanus booster uptake, whilst low, was not as low as MMR2 uptake (despite them being offered during the same appointment), suggests that there may be something else contributing to the very low MMR2 numbers.

Strengths and weaknesses of the study

Whilst not in the original study design, a particular strength of this work is that it captured data within the pandemic and has provided additional insights into sub-populations of children who are now very under-immunised. Due to the pandemic, the study was restricted to a single site as the second study site (a local children's hospital) was not able to open to recruitment.

As with all studies of this type, there were issues around data quality and access, with around 10% of potential participants excluded due to inaccessible data. There were some obvious errors and inaccuracies within the SCR data (e.g. too many vaccines recorded or “immunisations given” with no further detail), which may have contributed to over- or under-estimation of vaccination status.

A proxy was used for overall vaccination status (tetanus and MMR) which is not ideal, but will only have led to an underestimate of the unmet vaccination need of children presenting to the PED. During the course of the work it became apparent that trying to find meaningful comparators for the study data would be tricky as national data are presented by individual vaccine type with no data available as to children’s overall vaccination status i.e. whether or not they are up-to-date with all their age-appropriate vaccinations. For the comparison at five years of age, we used a slightly younger cohort than the COVER data. However, as vaccination coverage rates locally, regionally, and nationally usually only increase by around 5% between the ages of 2 and 5 years, this is not likely to have led to a change in the statistical significance of the results, as the coverage at age 5 for everything except primary tetanus was so low.

Meaning of the study and implications

Under-5s attending the PED have unmet vaccination need, particularly amongst those eligible for MMR2 and tetanus boosters, and uptake of these so-called “pre-school boosters” differed by vaccine type.

Although there was no difference in vaccination coverage between the younger PED attendees and their peers in the local general population, they still had uptake levels below the “ideal” of 100% and mostly below the 95% target suggested by the WHO.

If one or more interventions were available to deliver to these under-vaccinated children during a PED attendance, hundreds of thousands of additional potential vaccine opportunities would be available to practitioners every year. Any future local or national campaigns e.g. “catch-up” for MMR, could look to utilise the PED as a potential site for delivery of vaccinations.

Future research

Future research will look at those aged 5 and older, to see if the patterns of unmet vaccination need are sustained in these other age groups, or if they are a pandemic-related phenomenon (or a combination of both). The cohort identified in this study as being under-immunised for tetanus and MMR might benefit from a “catch-up” campaign, and the PED would seem to be a potential additional location for this to be delivered. Future work will also look to co-design one or more interventions to support MMR catch-up in this age group, as well as exploring the potential for the development of other vaccination-focused programmes that could be delivered in the case of an outbreak e.g. mumps. or for routine vaccination e.g. influenza.

Having identified this under-immunised population attending the PED, it may be that there are other under-immunised children and young people attending other settings

within the hospital who might benefit from the offer of a vaccination-focussed intervention. Identification of these populations e.g. those attending outpatient clinics, would facilitate more opportunities to offer vaccination interventions as part of routine hospital care.

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Competing interests statement

None declared.

Author contributions

RI conceived of the study, led on the ethics application process, undertook the fieldwork, analysed the data, was involved in all stages of the preparation of this manuscript and is guarantor author. LB analysed the data and was involved in all stages of the preparation of this manuscript. FE supported data extraction and was involved in later drafts of the manuscript. ND and JK were involved in oversight of the project and were involved in later drafts of the manuscript.

Data sharing agreement

Relevant data may be requested from the lead author and will be provided in anonymised format as soon as legally and ethically possible.

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Chapter 5 Part 1

How accurate is parent/carer recall of the vaccination status of children and young people (< 16 years old) attending the Paediatric Emergency Department?

Research question (RQ4): How accurate is parent/carer recall of the vaccination status of children and young people (< 16 years) attending the Paediatric Emergency Department when compared to primary care records?

This work was presented at the World Society for Pediatric Infectious Diseases' Virtual Congress in February 2022 as "Can we rely on parent/carer recall of vaccination status in the Paediatric Emergency Department, or is it time for an alternative source of data?".

The manuscript presented here was submitted to *BMJ Open Paediatrics* but rejected and we are currently looking for a secondary target journal.

I designed the study and was responsible for data collection, data analysis, and drafting of the article.

Abstract

Pre-pandemic, in the UK, coverage for some routine childhood vaccines e.g. MMR, were below World Health Organization targets. A visit to hospital might provide an opportunity to offer a “catch-up” intervention to under-immunised children and young people, if clinicians could accurately identify them. In the Paediatric Emergency Department, vaccination status is commonly checked by asking accompanying parents/carers. This cross-sectional study looked at the accuracy of parent/carer recall by comparing it to data in the summary care record, using age-appropriate MMR vaccination and tetanus vaccination combined as a proxy for overall vaccination status, and found that parents/carers often over-estimated vaccination.

Introduction

Vaccines save millions of lives annually. However, in the UK, uptake of routine childhood vaccination remains below World Health Organization (WHO) targets for a number of diseases, e.g. measles (included in the MMR vaccine) (1). Every year in England, millions of children and young people (CYP) attend hospital and many may have additional health needs. Hospital visits therefore offer an opportunity to improve health, beyond the initial reason for presentation.

Guidance recommends the vaccination status of CYP be checked at every opportunity (2). However, past work has shown incomplete or inaccurate vaccination histories are common (3,4) and that parents/carers often forget to bring a child’s handheld health record (e.g. Red Book) to hospital (5). In the Paediatric Emergency Department (PED), practitioners should routinely enquire about vaccination, most commonly asking the accompanying parent/carer. A recent pilot intervention study (n

= 30) found that parents/carers were likely to over-estimate the vaccination status of the child or young person in their care (6), suggesting clinicians shouldn't rely solely on this source information.

The objective of this work was to estimate the sensitivity and specificity of parent/carer recall of vaccination status in the PED as part of a project looking at the potential for a PED-delivered vaccination intervention.

Methods

Full prospective ethics approval was obtained from the North West – Greater Manchester East Ethics Committee (IRAS reference 278815, REC reference 20/NW/0423).

This was a cross-sectional observational study with a single data collection point for each participant. Materials were designed for a reading age of 7-9 years old in response to patient involvement in a previous study (6) and there was no direct patient involvement in this study. A secure electronic platform – QualtricsXM – was used to share information, take consent, and collect data. This facilitated inclusion via multiple language choices, adjustable text size, etc. Paper copies (English only) were available for those unable to access the platform.

Data were collected from a PED in Greater Manchester, England. Those < 16 years old, and accompanying parents and carers, were eligible to participate (unless seriously ill or injured) and were invited via staff and advertising materials around the department.

The two data sources used were parent/carer recall and individual primary care Summary Care Records (SCRs) accessible from the hospital (assumed to be accurate). Combined age-appropriate tetanus and MMR vaccination (MMR1 by two and MMR2 by five years-of-age) was used as a proxy for overall vaccination status. Sensitivity (the percentage of CYP whose parents/carers believed were fully vaccinated, out of the total number of CYP who were up-to-date according to the SCR) and specificity (percentage of CYP whose parents/carers believed were not fully vaccinated, out of the total who were not up-to-date according to the SCR) were calculated.

- Name (of child or young person who is the patient today): *free text*
- Date of birth (of child or young person who is the patient today): *free text or select from calendar*
- Is this person up-to-date with their vaccinations (also known as immunisations or needles)?
    - Yes
    - No
    - Not sure (*select one of the three*)
- It is okay to check the GP notes to see if this person has had all their vaccinations (also known as immunisations or needles)?
    - Yes
    - No (*select one of the two*)

Figure 1. Data collection tool available online and in paper form.

Results

Data collection was from January 31st to September 30th 2021 and severely impeded by the pandemic's impact on the PED. A total of 218 data collection tools resulted in 150 complete data sets, with abandonment of the electronic platform before the end of the information page being the most common reason for non-completion (n = 52).

The SCR showed that 84% of CYP were up-to-date (Table 1 for summary). Of the 137 parents/carers who reported their CYP as up-to-date, 21 of them were incorrect (14%). When "Not sure" recall data were combined with "No", sensitivity and specificity were 92.1% and 12.5% respectively. If "Not sure" was combined with "Yes", then sensitivity increased to 96.8% and specificity decreased to 8.3%.

		Vaccination status		
		Up-to-date	Not up-to-date	Total
Parent/carer recall	Yes	116 (77.3%)	21 (14%)	137
	No	4 (2.7%)	2 (1.3%)	6
	Not sure	6 (4%)	1 (0.7%)	7
	Total	126	24	150

Table 1. Comparison between parent/carer recall (in response to the question "Is this person up-to-date with their vaccinations (also known as immunisations or needles)?") and vaccination status according to the Summary Care Record (using tetanus plus MMR vaccination combined as a proxy for overall vaccination status). Percentages are given out of the total number of participants (n=150).

Discussion

This study shows that parent/carer recall of vaccination tends towards over-estimation and should therefore be used with caution, especially in clinically relevant

situations e.g. tetanus-prone wound. A weakness of this study is that combined MMR and tetanus vaccination was used a proxy measure for overall status – this was necessary owing to the structure of the vaccination data in the SCR. However, this approach is most likely to have resulted in an underestimate of missing vaccinations. Supplementary/alternative sources of accurate vaccination data in secondary care settings should be explored so that under-vaccinated CYP can be identified routinely and offered an intervention where appropriate.

Contributors

RI designed the study and was responsible for data collection, data analysis and drafting of the article. ND and JK were research supervisors and were involved in drafting and revising the article. RE was involved in the design of the work, data analysis, and drafting and revising the article. All authors approved the version to be published.

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Competing interests

None declared.

Patient and public involvement

There was no direct patient involvement in this study, but the methods used were based on the involvement of children and young people and their parents and carers in a previous, related, study.

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Chapter 5 Part 2

Are Child Health Information Services (CHISs) a viable source of accurate vaccination data for clinicians working in Paediatric Emergency Departments in England?

Research question (RQ5): What other sources of vaccination data are there and is it possible to access them from within secondary care?

This paper was published in December 2021 as:

> Isba, R., Davies, N., and Knight, J. Are child health information services a viable source of accurate vaccination data for clinicians working in paediatric emergency departments in England? *BMJ Health and Care Informatics*
>
> https://informatics.bmj.com/content/bmjhci/28/1/e100486.full.pdf

I conceived of the study, collected and mapped the data, and was involved in all stages of preparation of the manuscript.

Part of the work was also presented at the Faculty of Clinical Informatics' Conference, July 1st 2021. The paper presented was "You can't touch this: timely access to reliable vaccination data during a Paediatric Emergency Department attendance.".

Abstract

Background

Vaccination is a global success story, yet UK coverage remains under-target for a number of diseases. The Paediatric Emergency Department (PED) offers the potential for opportunistic vaccination interventions.

Objective

To map the Greater Manchester (GM) Child Health Information System network, to see if it was a viable source of vaccination data for clinicians working in the PED as a case study.

Method

Post-primary care vaccination management systems for GM were visualised using a systems mapping approach, with data obtained from the Office for National Statistics and commissioners in the GM Health and Social Care Partnership.

Results

Once vaccination data left primary care it passed through one of ten local CHIS, using an assortment of different IT systems, after which it shed individual identifiers and was aggregated within national systems. None of the existing GM CHIS was accessible to PED practitioners.

Conclusion

More work needs to be done to explore possible alternative sources of accurate vaccination data during a PED consultation.

Introduction

Vaccination remains one of the great global public health successes. Since their discovery more than 300 years ago, vaccines have saved countless millions of lives (1) reduced the incidence of dozens of diseases, and even lead to the eradication of smallpox (2). However, in the UK, uptake of routine childhood vaccinations (provided by the National Health Service at no cost to the parent/carer) has fluctuated over recent years and remains below World Health Organization (WHO) targets for a number of vaccinations e.g. MMR – which protects against measles, mumps, and rubella (3). This finding is on a background of global changes in the pattern of vaccination and an associated increase in outbreaks of vaccine-preventable diseases, further compounded by disruptions to delivery of routine vaccination programmes during the SARS-CoV-2/COVID-19 pandemic.

Every year in England, millions of children and young people (CYP) attend the Paediatric Emergency Department (PED) (4), and may sometimes have a long wait to see a healthcare professional. In addition to their primary reason for presentation, CYP attending the hospital may have unmet health need (e.g. sexual health), or not be able to access preventive elements of routine healthcare (e.g. vaccination) for myriad reasons. A hospital attendance might therefore be an opportunity to improve health, beyond the initial reason for presentation, and early work has shown that this would be an acceptable approach to parents/carers (5).

If any child or young person who had not received their age-appropriate vaccinations was identified during a PED attendance, clinicians might (should it be

clinically/situationally appropriate) be able to offer one or more tailored interventions to address this (6). The benefits of such an approach are numerous and include ensuring appropriate management e.g. in the case of a tetanus-prone wound (where management depends on vaccination status), and increasing community coverage in the case of an outbreak of a vaccine-preventable disease e.g. measles.

However, in order to be able to intervene with those at greatest risk of being under-vaccinated, it is first necessary to be able to identify them in a timely and accurate way, given the time-limited interaction in the department and departmental pressures. Guidance recommends professionals “Check the immunisation status of children and young people at every appropriate opportunity.” (7). In the PED, therefore, all practitioners should routinely enquire of parents/carers accompanying a child or young person if they have received all their age-appropriate vaccinations. However, past work has shown that often no question is asked or recorded in the notes (8) and if the enquiry is made, it is usually done in a superficial way via a question such as “Have they had all their vaccinations?”. When asked, parents/carers tended to overestimate vaccination coverage (5).

In contrast, in primary care, if a child attends a General Practitioner (GP) appointment, the clinician is alerted, via the presence of a “pop-up”, if the child is not up-to-date with their vaccinations. The difference here is that the vaccination data are held within the same system as the GP records, but the hospital systems are separate. In the UK, the majority of routine childhood immunisations are offered in community locations, commonly delivered via settings such as a GP surgery. Administration of one or more vaccines will be recorded in the GP electronic system,

with returns sent from these systems to the local Child Health Information Service (CHIS), and then on to the central surveillance system.

The objective of this work was to map the CHIS network in Greater Manchester (GM), to assess its potential as a source of accurate vaccination data for clinicians working in PEDs across the region, given the issues with obtaining information from parents/carer. This work was carried out as part of a bigger project looking at the potential for a PED-delivered vaccination intervention.

Methods

The work was carried out in Greater Manchester, England. The Office for National Statistics (ONS) mid-2019 estimates were used to describe the GM population of CYP <16 years old (9). Names of the Local Authorities (LA) and associated CHISs, the provider organisations for each CHIS, and the data management systems used were obtained via requests to GM Health and Social Care Partnership (GMHSCP) – the organisation responsible for commissioning vaccination services in GM. Lists of LAs, CHIS, and provider organisations (where relevant) were compiled and then combined with ONS data using systems mapping (10), an approach commonly used in public health. The map in Figure 1 (which represents the structure of the system in GM in mid-2020) was created using Microsoft Visio (2016) and fact-checked by GMHSCP, before the names of individual organisations and IT systems were removed (to protect commercially sensitive information).

Results

In GM, a population of around 582,000 CYP had their vaccination data held by ten different CHISs, provided by four different organisations, using three different national IT management systems commissioned in GM (although this has recently been reduced to two). Figure 1. shows the population served (by LA), the CHIS holding and managing data for each population, and the provider organisations commissioned to manage multiple CHISs (where relevant). Flow of vaccination data is represented by directional arrows (labelled with the IT system used).

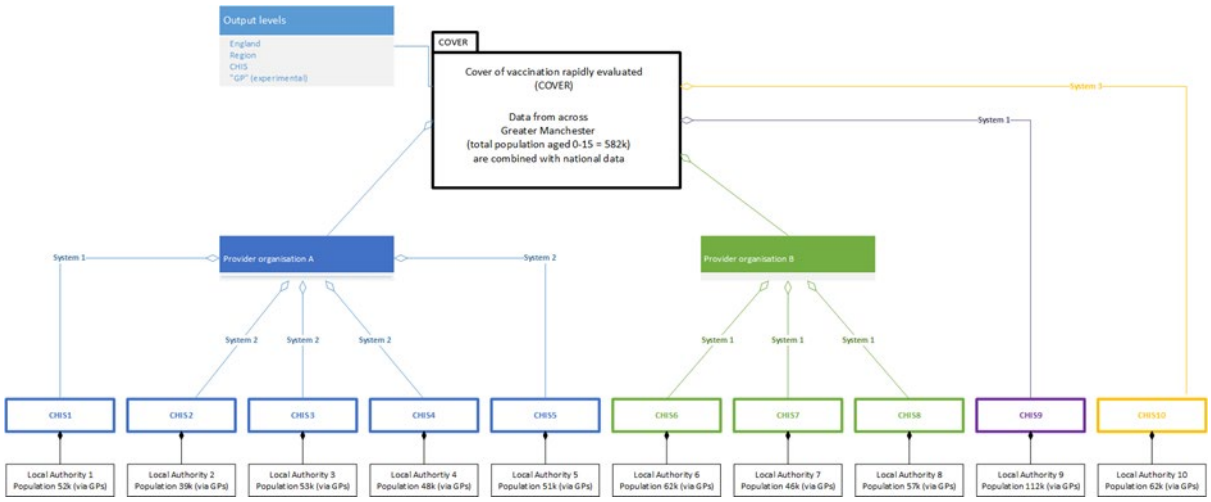

Figure 1.[1] Management of data relating to vaccination in children and young people (aged < 16 years old) in Greater Manchester. The names of the local providers and systems have been anonymised. CHIS = Child Health Information Service; GP = General Practitioner surgery; Population = ONS 2019 mid-year estimate for those aged 0-15 years inclusive, to the nearest 1000.

[1] Larger copy of this figure appears at the end of this part of the chapter.

No CHIS was accessible to practitioners working in secondary care (each system is password protected and only accessible to those working in community-based services), nor was there a focal point for GM that would have acted as a meaningful target for connecting the CHISs to secondary care data systems (aside from issues of interoperability) as none of the CHIS were connected to each other (even if managed by the same provider organisation). Once the vaccination data left GM CHISs, they shed individual identifiers and progressed up the national system in aggregated anonymised format.

Discussion

CYP attending settings such as the PED may benefit from interventions to improve vaccination coverage, however, it is not currently possible to reliably identify those who are not up-to-date. Although parent/carer recall remains the most common source of vaccination data during a PED consultation, clinicians often don't take a (meaningful) vaccination history and parent/carer recall tends towards over-estimation (5,8,11). An alternative approach is needed for checking vaccination status for all CYP as part of routine care, but would also add value in special circumstances, such as those where subsequent medical management might be altered by the child's vaccination status e.g. tetanus, or in controlling outbreaks of vaccine-preventable diseases e.g. measles.

Potential alternative sources of data include the Red Book (a handheld paper or electronic record of child health), the GP summary care record (where available and accessible), phoning GP surgeries (on an individual patient basis), and local CHIS.

This work has used a system mapping to approach to show that, whilst an individual CHIS may contain accurate vaccination data, it is inaccessible to hospital-based clinicians and also part of a prohibitively complex system with no single focal point, so does not represent a viable option in GM at the current time. The simplest solution might be a unified regional CHIS, but that is a commissioning decision beyond the influence of secondary care clinicians. A limitation of the study is that it only used a single mapping approach to visualise the data. Another potential limitation is that GM has a commissioning structure which may not be replicated elsewhere, so collating the CHIS data may be more complex in other settings.

Future work will look at the potential for accessing primary care-held vaccination data (e.g. via summary care records), as an alternative. However, preliminary work suggests that whilst these records are technically accessible, extracting relevant data takes a disproportionate amount of time as the vaccination data are unstructured and only interpretable by someone with an extensive working knowledge of the NHS childhood vaccination schedule.

Until a viable (in terms of time and effort for clinicians), accurate, and real-time alternative to parent/carer recall is available, it is not going to be possible to progress to delivering an intervention to those CYP who are under-vaccinated at the time of their attendance to the PED.

Conclusions

The PED offers an under-utilised opportunity to deliver interventions to improve the wider health and wellbeing of patients, with vaccination being an example of such an intervention. However, the lack of access to reliable vaccination data in a timely fashion, during a PED attendance, means that it is not currently possible to identify those CYP in need of an intervention. The complex structures of post-primary care data management mean that in Greater Manchester, the Child Health Information Services (CHISs), whilst considered the definitive source of vaccine data, are wholly inaccessible in their current form and are therefore not a viable source of vaccination information for clinicians working in the PED.

Acknowledgements

Thanks to colleagues on the Great Manchester Screening and Immunisation Team for their invaluable input into the system mapping work.

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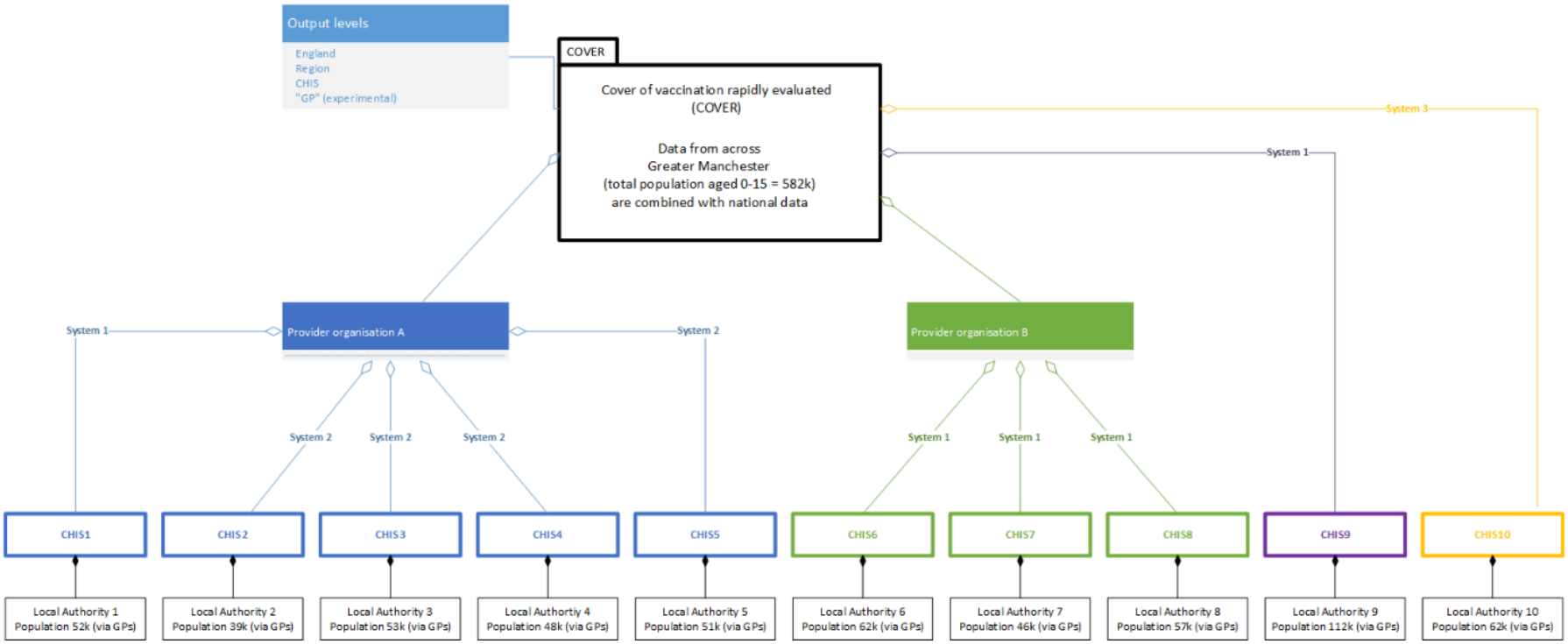
Output levels
England
Region
CHIS
"GP" (experimental)
COVER
Cover of vaccination rapidly evaluated
(COVER)
Data from across
Greater Manchester
(total population aged 0-15 = 582k)
are combined with national data
System 3
System 1
System 1
Provider organisation A
System 2
Provider organisation B
System 2
System 2
System 2
System 1
System 1
System 1
CHIS1
CHIS2
CHIS3
CHIS4
CHIS5
CHIS6
CHIS7
CHIS8
CHIS9
CHIS10
Local Authority 1
Population 52k (via GPs)
Local Authority 2
Population 39k (via GPs)
Local Authority 3
Population 53k (via GPs)
Local Authority 4
Population 48k (via GPs)
Local Authority 5
Population 51k (via GPs)
Local Authority 6
Population 62k (via GPs)
Local Authority 7
Population 46k (via GPs)
Local Authority 8
Population 57k (via GPs)
Local Authority 9
Population 112k (via GPs)
Local Authority 10
Population 62k (via GPs)

Chapter 5 Part 3

How practical is it for secondary care-based clinicians to access accurate vaccination data via primary care-derived Summary Care Records?

Research question (RQ5): What other sources of vaccination data are there and is it possible to access them from within secondary care?

This abstract was presented as a poster entitled “Should we use Summary Care Records to access vaccination data in the Paediatric Emergency Department?” at Child Health Technology 2022.

Background

Vaccines save millions of lives globally each year. However, UK uptake of vaccines such as MMR remains below target. Annually in England, millions of children and young people (CYP, aged < 16) go to hospital. This attendance offers a chance to improve health more broadly, especially for those who experience greater inequalities e.g. difficulty accessing routine childhood immunisation. To offer a vaccination intervention, however, we need to be able to identify those who are under-immunised.

Aims

This work is part of a larger project looking at sources of vaccination data during a Paediatric Emergency Department (PED) attendance, with a view to offering an intervention to under-immunised CYP. The aim of the component of work presented here was to explore the vaccination data available to PED-based clinicians via the community-based Summary Care Record (SCR).

Methods

Full ethical approval was obtained and data collected from the SCRs of individuals visiting a single PED in Greater Manchester. Alongside extraction of vaccination data, detailed notes were made on data issues for the first 200 participants.

Results

Approximately 1 in 10 SCRs either didn't load fully or contained limited/no information. Within SCRs, data were unstructured and there was variability in how

the data were coded e.g. children the same age might have 11 records (listed by vaccine) or 48 (listed by disease). There were also some obvious errors e.g. administration of too many doses of a vaccine. Whilst it was relatively simple to look for the presence (or absence) of a single vaccine (if the SCR loaded in full) it was virtually impossible to assess if a child was under-immunised overall.

Discussion

It is not currently possible to easily and routinely identify under-immunised CYP using SCRs alone, but they may be a useful source for checking protection against an individual disease e.g. tetanus.

Chapter 6

Discussion and conclusion

Overview of findings

This thesis explored how secondary care-based clinicians might access vaccination data to identify under-vaccinated CYP during a PED attendance and what approaches might be available to them to then offer an intervention. Initially a pilot study was carried out that looked at the feasibility and acceptability of delivering a public health intervention during a PED attendance. This was followed by a scoping review of existing literature around interventions delivered in hospitals to improve vaccination uptake. A two-part cross-sectional observational study was then used to quantify unmet vaccination need and look at parent/carer recall of vaccination status. Alongside the observational study, a mapping exercise captured the structure of vaccination data systems across Greater Manchester. The findings are presented briefly by research question below and then discussed in more detail as a whole.

Is it feasible and acceptable to deliver a brief public health intervention as part of an attendance at the PED?

In chapter 2, the pilot study demonstrated that it is both feasible and acceptable to deliver a brief public health intervention as part of a PED attendance. This study also highlighted two issues that were then explored further in later studies presented in this thesis – that parent/carer recall of vaccination status tended towards over-estimation and that there were no other widely-used sources of vaccination data for identifying under-vaccinated CYP.

What are the interventions delivered in secondary or tertiary medical care settings focused on improving routine vaccination uptake in children and young people?

In chapter 3, the scoping review demonstrated that it was possible to have a positive impact on vaccination uptake amongst hospital attendees under the age of 21. The review also suggested that CYP attending the hospital had lower levels of vaccination coverage than their peers in the general population. Challenges around checking immunisation status were also highlighted, with a suggestion made that access to electronic immunisation registers would facilitate timely access to accurate data. In the context of this work, Child Health Information Services (CHIS) would fulfil the role of electronic immunisation register and their utility was explored in chapter 5.

Do children (aged < 5 years) attending the Paediatric Emergency Department have lower levels of vaccination coverage than their peers in the general population?

The study presented in chapter 4 showed that the population of children attending the PED before their fifth birthday had lower levels of vaccination than their peers in the general population. Unmet need varied by age group, with four-year-olds most likely not to be up-to-date with their tetanus-containing and MMR vaccinations. There was also variation between the two vaccines included in the study, with a much higher proportion of “missing” doses of MMR compared to tetanus.

Sources of vaccination data

How accurate is parent/carer recall of the vaccination status of children and young people (aged < 16 years) attending the Paediatric Emergency Department, when compared to primary care records?

The sensitivity and specificity of parent/carer recall (as a source of data) were estimated, with the main finding being that parents and carers tended towards over-estimation of the vaccination coverage of the CYP in their care. Whilst sensitivity was above 90%, specificity was closer to 10% – suggesting that a history taken from a parent/carer should not be used as the only source of vaccination data during a PED attendance.

What other sources of vaccination data are there and is it possible to access them from within secondary (hospital) care?

Part 2 of chapter 5 looked at the potential of Child Health Information Services (CHISs) as a source of accurate vaccination data for use within a PED attendance. Whilst the network was considered to contain definitive vaccination information, a system map created for Greater Manchester showed the network to be complex and inaccessible to those working in secondary care.

The third part of chapter 5 examined data available via Summary Care Records (SCRs) and found it was relatively easy to use the records to check for the presence (or absence) of a single vaccine or protection against a specific disease. However, the inconsistent and unstructured nature of the data meant it was not a viable source for routinely assessing if a child or young person was under-immunised across all vaccinations. There were also issues around access to the system (e.g. the portal timing out) and obvious errors in some records (e.g. too many doses of the same vaccine given).

How can secondary care-based clinicians access and use primary care-held vaccination data during a Paediatric Emergency Department attendance?

This work has explored the extent of under-vaccination amongst PED attendees, how PED-based clinicians might identify those who are not up-to-date with routine immunisations, and what might be offered (and how) to the CYP and their parents/carers by way of an intervention during their time in the PED.

The idea of delivering a public health-style intervention has been explored and found to be both feasible and acceptable to a wide range of PED stakeholders. This finding has implications not only for future work focusing on vaccination, but also has the potential to lead to other targeted or broad-based public health interventions that can be developed for delivery in secondary and tertiary care settings. The published literature around vaccination interventions delivered in hospital settings suggests interventions focussed on immunisation have the potential to increase vaccination uptake in target populations. Despite this, there is little evidence from the PED, and interventions were not comparable across the literature. There is, therefore, no well-established and/or evidence-based approach to intervening in the PED to improve vaccination uptake.

Additionally, it remains difficult for clinicians in hospitals to identify those children and young people in their care who are under-immunised, meaning that even if an intervention were available, it would be difficult and time-consuming to work out who would benefit from it. It is, in fact, completely impossible at the current time to make a rapid evaluation in secondary care as to whether or not a child in Greater Manchester (attending the PED or another hospital setting) is fully up-to-date with all

their age-appropriate vaccinations. However, clinicians may be able to check vaccination status relating to a single disease, within summary versions of primary care-held records, accessible from secondary care.

Despite the current pandemic and the profound positive impact of new vaccines on its course, uptake levels for routine childhood immunisations remain below target levels for a number of diseases. Whilst the reasons for this are complex and numerous, it could be argued that ease and convenience of access to vaccination should not be barriers to vaccination for children and young people. Opportunistic offers of “catch-up” vaccination might be one way to address suboptimal uptake and might have a bigger impact on those who are already experiencing vaccination inequality in the community and might be relatively over represented within other populations, for example those accessing secondary medical care. CYP living in more socioeconomically deprived areas are more likely to experience ill health or have accidents than their peers in other areas, and as a result, there are proportionally more of them attending the Paediatric Emergency department (1).

This thesis demonstrates that there is considerable unmet need amongst PED attendees, that this need is sometimes greater than amongst their regional and national peers, that some age groups are worse affected, and that the MMR is particularly over-represented amongst “missing doses”. This all suggests that there is a population of children and young people, attending PEDs, who might benefit from a vaccination-focused intervention delivered during fallow time within their attendance. However, it is clear that much more needs to be done to improve access

to and interoperability between systems holding vaccination data, to facilitate the easy and accurate identification of those who might benefit most from this approach.

Implications of the work for current practice

This work began in September 2019, pre-pandemic, and at a time where the UK had just lost its measles-free status (2) and vaccination coverage levels amongst CYP living across all areas of England were frequently below national and international targets (3). These sub-optimal vaccination coverage levels were the result of an accumulation of different factors – some individual, some structural – and needed new ways of thinking to address them. This was on a background of widespread concern around falling vaccination uptake which had lead the WHO to list "vaccination hesitancy" as one of its top ten risks to global health in 2019 (4).

Increasing PED attendances and longer waits to see clinicians during an attendance are rightly a cause for concern to many with responsibility for delivering healthcare services within the NHS. However, those accessing hospital services such as the PED are more likely to experience other sorts of unmet need and may not be able to access routine healthcare in the same way as some of their peers, so their attendance may also offer an opportunity to have a broader positive impact on their health and wellbeing.

Service delivery in acute settings, such as the PED, is currently structured around clinicians focusing on addressing a single reason for hospital attendance, rather than the more holistic approach taken in primary care and other community settings. However, this means that the PED is currently an under-explored potential space for delivering preventative services, such as those relating to vaccination. These interventions may in turn prevent future attendances with a preventable element, for example an admission for a vaccine-preventable disease such as measles.

In its recent *Health Equity Audit of the National Immunisation Programme* (5), Public Health England (now the UK Health Security Agency) stated “Equality in immunisation is an important way to address health inequalities” and reported that whilst the Immunisation Programme had achieved high coverage in the population as a whole, within sub-populations there still existed “avoidable inequalities”. Whilst the reasons for these inequalities are complex, “institutional” and “policy” factors were identified as playing a role.

NICE guidance recommends that professionals “Check the immunisation status of children and young people at every appropriate opportunity.” (6). This might include during a PED attendance, where immunisation status should be included as part of a routine clinical history. By identifying under-immunised CYP during a PED attendance, and then offering an intervention (if appropriate), clinicians might be able to remove some of the “institutional” and “policy” factors currently contributing to “avoidable inequalities” in immunisation. The ease of perhaps being offered a vaccine (or a discussion about vaccination) during a PED attendance, and the

perceived (and actual) safety of receiving a vaccination within a hospital setting, may also address some aspects of vaccination hesitancy.

Six months into this MD the UK was in lockdown as the world grappled with the first wave of the biggest pandemic for a hundred years. Vaccines have played an undisputable role in altering the course of the pandemic for those lucky enough to be able to access them (7). However, the SARS-CoV-2/COVID19 pandemic has also caused massive global disruption, and healthcare services have been badly disrupted, including those delivering vaccination programmes.

Very early on in the pandemic, the WHO's Regional Office released *Guidance on routine immunization services during COVID-19 pandemic in the WHO European Region* that stated "… Any disruption of immunization services, even for short periods, will result in an accumulation of susceptible individuals and a higher likelihood of VPD [vaccine-preventable diseases] outbreaks." (8). This has certainly proven to be the case, with a recent report from UNICEF and the WHO warning of a "perfect storm of conditions for measles outbreaks" as 19 measles campaigns worldwide remain paused, putting 73 million children at risk due to missed vaccinations (9). In England, the urgent need to increase MMR vaccine uptake in order to prevent outbreaks was recently highlighted, including catch-up vaccination (as there is no upper age limit for receiving the MMR) (10). Worldwide events such as the war in Ukraine (which, immediately pre-pandemic, had the highest measles incidence in Europe, with 115,000 cases reported in 2017-2019) increase further the likelihood of outbreaks amongst vulnerable populations (9).

The SARS-CoV-2 vaccination programme has shown that mass immunisation can be delivered in a multitude of different settings, many of which were unimagined and unutilised pre-pandemic. The work presented here has shown that the PED is also an under-utilised opportunity to offer a vaccination intervention, whether it be direct delivery of a vaccine during the attendance or something else designed to increase uptake. PED attendees are a population that appears to have a greater level of unmet need than their peers (who in turn still have sub-optimal coverage). There are clear implications for practice which, in the face of the pandemic – which has seen unmet need increase further – will be even more important if we want to avoid recovery being further complicated by vaccine-preventable disease.

The PED offers an opportunity to address under-immunisation and parents, carers, PED staff, and other stakeholders are amenable to the approach. There are many ways in which access to accurate vaccination data in the PED and the development of one or more interventions could improve clinical practice. For example, if it were easy to accurately check a child's tetanus status during a PED visit, it is likely that there would be less over-treatment in the case of tetanus-prone wounds, as clinicians treating those with uncertain vaccination histories must currently err on the side of caution and therefore manage them as if they are under-vaccinated (11). Similarly, in the case of a local measles outbreak, the PED could offer on-site catch-up vaccination to any child or young person attending the department who had not yet received their age-appropriate MMR vaccinations. Any model for checking vaccination and offering opportunistic delivery in the PED in the case of a local

outbreak could then be scaled up in case of an epidemic or pandemic. In fact, in the current pandemic there is also potential for opportunistic SARS-CoV-2 vaccination of eligible populations in the PED, as uptake in CYP remains low relative to the rest of the population (12).

The PED is arguably an under-utilised opportunity to deliver a wider range of public health-type interventions than just those aimed at increasing vaccination. The pilot study suggested that dental health could also be improved via an intervention in the PED and there are likely to be other aspects of health and wellbeing that could be improved by embedding existing public health approaches in routine clinical interactions in secondary care. Basing these interventions on the approach of SBIRT (Screening, Brief Intervention, and Referral to Treatment) – which has been used very successfully in the management of alcohol and opiate use disorders in adults presenting to the ED – may improve their likelihood of success.

In terms of implementing this work and the findings presented in this thesis, this remains a challenge during this phase of the pandemic. PED workload rebounded from the massive drop in attendances seen in the first wave, and then went on to exceed the levels of attendance seen before early 2020. Winter 2022/23 was predicted to be an extremely challenging one for the NHS as the pandemic was potentially compounded by outbreaks of other respiratory diseases, whilst also attempting to catch up on work that was postponed during various phases of the pandemic to date. Other locations within the hospital might be better placed – in the short to medium term – to offer a setting for this work to be explored further.

Strengths and weaknesses of the work

The work presented here has taken a holistic approach to providing an evidence base to underpin a future programme of work. This has been achieved by showing that there is unmet vaccination need amongst PED attendees, that it is feasible and acceptable to deliver an intervention to this group in this setting, and that such an approach has the potential to improve vaccination uptake, whilst also highlighting that existing sources of vaccination data are inadequate. This holistic approach is a particular strength of the work presented here. Another strength of this work is that it took the existing approach of SBIRT and adapted it for a paediatric population – the pilot study was only the second time work using SBIRT in this population had been published.

The biggest weakness of this work is that it became obvious early on that it was not going to be possible to make a global assessment of a child's vaccination status and that it was therefore necessary to choose proxies for their overall status. The choices of tetanus and MMR (as the most widely discussed and probably the least and most controversial vaccinations of early childhood respectively) as proxies will, however, only have led to an overestimate of vaccination coverage. Additionally, towards the very end of the work (and in conversation with a colleague at the local CHIS), it became apparent that there is no system available (outside of an individual GP practice record) for seeing if a child or young person is up-to-date with all of their age appropriate vaccinations (with the exception of a small number of children in the care

system). This weakness is, therefore, inherent in the whole system, not just the work presented here.

As with any study that attempts to use NHS data, issues around data quality and access were also weaknesses. The data extracted had to be done by hand, via a portal, within another portal, on the hospital's intranet (via a virtual network if off site), and took approximately 85+ hours to extract. There were frequent system errors, faults, and portal timeouts, as well as the issues with the ways in which the data were (or weren't structured). As a result, the data were single extracted, which may have resulted in a small number of errors. However, by including those with missing data in the unmet vaccination need analysis, the quality of data was partially mitigated. As the data for individual patients were extracted by hand (which was an extremely time-consuming process), this meant that the second part of the observational study only included those up to the age of five years. Future studies could overcome this by co-designing data extraction with a local CHIS provider – an option that was not available for this study. However, local systems are now in place that might enable it in the future e.g. the trust-wide EPR at Manchester University NHS Foundation Trust (which is also the current provider of one of the CHIS in Greater Manchester). It is likely that CYP in older age groups also have lower than background levels of vaccination, so being able to access bigger data sets more easily in the future would facilitate work that included over-fives.

One unintended strength of this work is that it captured a moment in history as it ended up being carried out during the biggest global pandemic in a century. This

meant that valuable data about the impact of the pandemic on the vaccinations of a specific cohort of children were collected, which suggested that those attending the PED who were four years of age may have been particularly badly affected by disruptions to vaccination programmes and may need targeted “catch-up” in the future.

The pandemic did, however, also have a negative impact on this work – data collection was planned to take place at two hospitals, however the second site never opened as its parent NHS Trust closed to all new non-COVID studies shortly after ethics approval was granted. A weakness is therefore that it became a single-centre study (albeit a busy PED caring for a diverse population). The population of CYP served by North Manchester General Hospital experiences higher levels of socioeconomic disadvantage compared to other parts of Manchester (which in turn experiences higher levels of deprivation than the England average). It is possible, therefore, that this, combined with other sociodemographic characteristics of the population included in this thesis has led to an over- or (less likely) under-estimate of the magnitude of unmet vaccination need. However, if the aim of the work is to improve vaccination uptake and decrease inequality of access, then it could be argued that need is need, and that this work has highlighted the presence of unmet need in a population, so this in itself merits further work. Having the second site (a tertiary provider of children’s care but also a secondary provider of care to the population in the immediate local area) would have potentially made the results more applicable more widely and would definitely have provided additional interesting data. However, given the striking findings, particularly around MMR2, this work is not

diminished in importance as a result and is likely to be the only work of its kind given the pandemic and the cohort captured.

Additionally, it was extremely difficult to recruit into the cross-sectional study, so a decision was made to move from opt-in to opt-out, meaning that data relating to parent/carer recall was collected for a much smaller population than first intended.

Suggestions for future work

Having shown that the PED is a viable location for delivery of interventions to improve vaccination uptake, but having found no well-established or evidence-based intervention for delivery in this setting, any future work must include development of one or more interventions. These interventions should be co-developed with children, young people, parents, and carers, with input from other stakeholders such as nursing staff in the PED (who may deliver an intervention in the future) and local commissioners of vaccination services. As well as co-designing one or more interventions, it would be interesting and useful to undertake a qualitative exploration of how attitudes to routine childhood vaccination (and associated actions around getting CYP vaccinated) might have changed during the pandemic. For example, the observation in the cross-sectional study that four-year-olds had such low levels of uptake of MMR2, yet higher levels of tetanus-containing vaccines, even though they are offered at the same appointment, warrants further investigation. It is possible that the pandemic has resulted in a shift in attitudes to vaccination overall (which might explain the drop in tetanus-containing vaccine uptake amongst the four-year-olds)

but also a disproportionate shift for those vaccines, such as MMR, which are perhaps inherently considered more “controversial”.

Other multi-methods work that could be undertaken alongside this intervention development work might include an exploration (with staff) around the practicalities and assumptions associated with taking/checking a vaccination history and/or offering an intervention. For example, given the structural inequalities “baked in” to big organisations such as the NHS, it may be that staff are un/consciously biased in their approach to talking about vaccinations, and it would be important to explore this (not least as a future potential barrier to implementation). Equality of access to vaccinations cannot be improved if, in reality, it is actually further widened within a hospital setting by assumptions made by practitioners about a parent/carer’s willingness to engage based on a number of factors such as religion (declared or perceived) and socio-economic status.

Alongside development of any interventions, it would also be prudent to explore other locations within the hospital that might be suitable settings for their delivery, for example outpatient clinics. In the shorter term, it might be possible to build and test models for opportunistic vaccination delivery in secondary care settings using seasonal vaccinations e.g. influenza, which require less in the way of recall on the part of parents/carers or other data sources.

“Natural experiments” such as a local measles outbreak might also provide opportunities for learning and it would be useful to have a set of interventions ready and waiting, should such a thing occur, so that a wider range of options for MMR vaccine delivery – including “pop-ups”, possibly outside of care settings – could be used. The current pandemic has driven so much innovation in the field of vaccination that it seems a shame that important learning can’t be taken, adapted, and adopted, to address the ongoing issue of wider unmet vaccination need in CYP.

It also remains necessary to develop new ways of accessing accurate vaccination data in a timely manner from within the PED (or other hospital-based setting). Future work should also seek to design one or more tools to identify CYP (< 16 years old) at higher risk of being non- or partially immunised, that can be embedded in existing PED patient management systems or electronic patient records. Two possible approaches to this might be so-called logic (or look up) templates that could check for the presence (or absence) of the correct number of doses of an individual vaccine, or the use of machine learning to routinely identify those at higher risk of under-immunisation. Other approaches might address easy access to CHIS from secondary care or tackle the issues of interoperability within and between secondary and primary care data systems that occur throughout the NHS.

Once an accurate way of identifying under-vaccinated CYP is available and one or more interventions developed, the interventions must be piloted and evaluated, before their effectiveness is tested via a suitably rigorous study. This must be accompanied by further stakeholder engagement, particularly with those

commissioning and delivering services, so that the resulting programme can have maximum impact, whether it is for everyday use or only for deployment in case of an outbreak. The final step will be to codify the approach via local, regional, and/or national policy.

There are also broader implications for future research around embedding public health interventions in routine clinical care – for example around the potential to extend interventions into areas such as dental health, or develop a public health workforce to deliver a wider range of interventions in secondary care. Given the receptiveness of CYP and their parents and carers to the possibility of a public health intervention delivered during a PED attendance (and on a background political landscape that is increasing inequalities and hardship amongst the most vulnerable), future work might also look at the development of in-situ public health practitioners within a variety of settings in secondary care.

Conclusion

There is currently unmet vaccination need amongst the children and young people attending the Paediatric Emergency Department, but there is also unexplored potential to deliver one or more vaccination-focused interventions in this setting. However, delivery of any future intervention/s would be reliant on an improved system for identifying those who might benefit. Whilst there are currently several sources of individual patient data relating to vaccination, there remain issues around data quality and ease of accessibility for those working in secondary care.

Future work should take a dual approach of co-producing one or more interventions and improving systems for identifying under-immunised CYP in as close to real-time as possible. Multiple potential approaches could then be taken to offering interventions in the PED, for example focusing on deployment of opportunistic vaccination during a local measles outbreak, or ensuring that those with a tetanus-prone wound are not over- or under-treated due to the lack of a reliable vaccination history.

A system that “flagged-up”, in real-time, to those working in secondary care settings (in the same was as currently happens in general practice), whether or not a child or young person was up-to-date with all their age-appropriate vaccinations would potentially be a powerful tool for improving vaccination coverage amongst some of the most underserved populations. However, the way in which data are dispersed e.g. within and between CHISs, means that it is not currently possible to say which children have not received all their vaccinations, even if these systems were accessible from inside the hospital.

As we recover from a pandemic and emerge into a world that is very different, with a healthcare landscape with a massive backlog of work, it seems logical to harness all available opportunities to embed prevention in healthcare provision. As children and young people disproportionately experience the effects of health inequalities (and are going to have to live with the consequences of the pandemic for much longer than the rest of us) it seems sensible to start recovery with a focus on them.

Ensuring that they have adequate protection against vaccine-preventable diseases is one simple way that we can start to do this.

References

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12. Office for National Statistics. Coronavirus (COVID-19) latest insights. [cited 2022 Jun 12]. Available from: https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/articles/coronaviruscovid19latestinsights/vaccines#vaccinations-in-young-people

Appendices

Appendices

Appendix 1.

Copy of clinicaltrials.gov entry.

ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
Last Update: 01/30/2021 08:29

ClinicalTrials.gov ID: NCT04485624

Study Identification

Unique Protocol ID:	IRAS278815
Brief Title:	Vaccination Coverage Amongst Children/Young People Attending the PED
Official Title:	Do Children and Young People Attending the Paediatric Emergency Department Have Lower Levels of Vaccination Coverage Than Their Peers in the Local General Population?
Secondary IDs:	

Study Status

Record Verification:	January 2021
Overall Status:	Recruiting
Study Start:	January 24, 2021 [Actual]
Primary Completion:	October 31, 2021 [Anticipated]
Study Completion:	October 1, 2022 [Anticipated]

Sponsor/Collaborators

Sponsor:	Lancaster University
Responsible Party:	Principal Investigator Investigator: Rachel Isba [risba] Official Title: Professor of Medicine and Consultant in Paediatric Public Health Medicine Affiliation: Lancaster University
Collaborators:	Pennine Acute Hospitals NHS Trust Manchester University NHS Foundation Trust

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Not required
Data Monitoring:	

Study Description

Brief Summary: In the United Kingdom (UK), most childhood vaccinations are given in the community, although uptake has decreased in recent years. A Paediatric Emergency Department (PED) attendance offers an opportunity to check the vaccination status of children and young people (CYP) and all parents/carers should be asked about this routinely. Those not up-to-date with vaccinations could then be signposted to existing services or perhaps offered a vaccine in the PED.

CYP attending the PED may also have lower vaccination coverage than their peers, so may benefit even more from interventions to increase uptake. However, recall by parents/carers is not always sufficiently accurate to identify those who have not yet received all their age-appropriate vaccinations. The most complete record of an individual's vaccination history is held within their primary care records. However, these records are often in a separate computer system that is inaccessible from the hospital's main computer system, although some information (including vaccination) may be accessed from within the hospital via a third system.

This study aims to see if CYP attending the PED are under-vaccinated compared to their peers and assess the accuracy of parent/carer recall. The results of this study will then be used to inform recommendations for developing better ways to access accurate vaccination data during a PED consultation. If such a system existed, under-vaccinated children could be identified routinely during an attendance, and an intervention offered if appropriate. This would be particularly useful if there was an outbreak of a vaccine-preventable disease such measles.

All CYP (< 16 years old) attending two PEDs in Manchester will be invited to participate, one in a district general hospital and one in a specialist children's hospital. CYP/their parent/carer will be asked to provide consent for their vaccination records to be accessed as well as being asked if the child/young person is up-to-date with all their vaccinations. Approximately 600 participants will be enrolled at each PED.

Detailed Description: NOTE : Detailed Description has not been entered.

Conditions

Conditions: Vaccination/Immunisation Status

Keywords: Vaccination
Immunisation
Opportunistic
Child
Young person
Paediatric Emergency Department

Study Design

Study Type: Observational

Observational Study Model: Case-Only

Time Perspective: Cross-Sectional

Biospecimen Retention: None Retained

Biospecimen Description:

Enrollment:	1200 [Anticipated]
Number of Groups/Cohorts:	2

Groups and Interventions

Groups/Cohorts	Interventions
Attendees at Paediatric Emergency Department 1 (PED1) These participants will be recruited from the children and young people (under the age of 16) attending the PED of a large district general hospital.	No intervention Observational study
Attendees at Paediatric Emergency Department 2 (PED2) These participants will be recruited from the children and young people (under the age of 16) attending the PED of a large children's hospital.	No intervention Observational study

Outcome Measures

Primary Outcome Measure:

1. Percentage of children/young people attending the PED who have received all of their age-appropriate vaccinations.
   The % of children and young people attending the PED who have received all of their age-appropriate vaccinations will be compared to their peers in the local general population.

   [Time Frame: Through study completion (estimated one year)]

Secondary Outcome Measure:

2. Accuracy of parent/carer recall of the vaccination status of children/young people attending the PED.
   The accuracy of parent/carer recall of the vaccination status of children/young people attending the PED will be made by comparing their responses to electronic community records.

   [Time Frame: Through study completion (estimated one year)]

3. Percentage of children attending the PED who have received two doses of MMR by the age of 5 years.
   The % of children attending the PED who have received two doses of the Measles, Mumps, and Rubella vaccine (MMR) by the age of 5 years will be compared to their peers in the local general population.

   [Time Frame: Through study completion (estimated one year)]

4. Percentage of children attending the PED who have received at least one dose of MMR by the age of 2 years.
   The % of children attending the PED who have received at least one dose of MMR by the age of 2 years will be compared to their peers in the local general population.

   [Time Frame: Through study completion (estimated one year)]

Eligibility

Study Population:	Children and young people accessing PED1 or PED2
Sampling Method:	Non-Probability Sample
Minimum Age:	0 Years NOTE : Minimum Age '0 Years' is treated as no limit.
Maximum Age:	16 Years
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	Yes

Criteria: Inclusion Criteria:

- attending one of the two study site PEDs; under the age of 16 at the time of attendance; able to give consent or accompanied by someone able to give consent

Exclusion Criteria:

- life threatening illness or injury

Contacts/Locations

Central Contact Person:

Central Contact Backup:

Study Officials: NOTE : Study Official is required by the WHO and ICMJE.

Locations: **United Kingdom**

Paediatric Emergency Department, North Manchester General Hospital
[Recruiting]
Manchester, Greater Manchester, United Kingdom, M8 5RB
Contact: Rachel Isba, BM BCh, PhD 44(0)1616240420
rachel.isba@nhs.net

Paediatric Emergency Department, Royal Manchester Children's Hospital
[Not yet recruiting]
Manchester, Greater Manchester, United Kingdom, M13 9WL
Contact: Rachel Jenner, MB ChB 44 (0)1612761234
rachel.jenner@mft.nhs.uk

IPDSharing

Plan to Share IPD: Yes

Supporting Information:
Study Protocol
Clinical Study Report (CSR)

Time Frame:
Protocol intended to be published in an open access journal within the first year of receipt of ethical approval.

Results of study intended to be published in an open access journal within a year of completion of analysis of data.

Anonymised data will be shared under certain circumstances; no patient-identifiable data will be available to other researchers.

Access Criteria:
Anonymised data will be made available following reasonable request.

URL:

NOTE : IPD Sharing Plan Description has not been entered.

References

Citations:

Links:

Available IPD/Information:	

Appendix 2.

Copies of REC and HRA confirmation letters (REC 20/NW/0423 and IRAS 278815).

Copy of approved IRAS form and covering letter.

Copy of amendment approved September 2021.

Health Research Authority

North West - Greater Manchester East Research Ethics Committee
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

18 December 2020

Professor Rachel Isba
Professor of Medicine and Consultant in Paediatric Public Health Medicine
Lancaster University and the Pennine Acute Hospitals NHS Trust
Lancaster Medical School
Lancaster University
Lancaster
LA1 4YG

Dear Professor Isba

Study title:	**Do children and young people attending the Paediatric Emergency Department have lower levels of vaccination coverage than their peers in the local general population?**
REC reference:	**20/NW/0423**
Protocol number:	**N/A**
IRAS project ID:	**278815**

Thank you for your response of 13 December 2020, to the 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

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

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

Document	*Version*	*Date*
Covering letter on headed paper [Headed Letter Isba Vaccination Coverage in the PED October 9th 2020]	0.1	09 October 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Lancaster University Insurance]	0.1	26 June 2020
IRAS Application Form [IRAS_Form_12102020]		12 October 2020
Letters of invitation to participant [Updated poster for the department advertising Vaccination Coverage in PED study]	2.0	13 December 2020
Other [Data collection questions]	1.0	23 October 2020
Participant consent form [eConsent for Vaccination Coverage PED version 2.0 December 13th 2020 IRAS ref 278815]	2.0	13 December 2020
Participant information sheet (PIS) [ePIS for Vaccination Coverage PED version 2.0 December 13th 2020 IRAS ref 278815]	2.0	13 December 2020
Research protocol or project proposal [Protocol for Vaccination Coverage in PED version 1-0 September 2020 IRAS 278815]	1-0	29 September 2020

Summary CV for Chief Investigator (CI) [Summary CV September 2020 Professor Rachel Isba]	0.1	14 September 2020
Summary CV for student [Summary CV September 2020 Professor Rachel Isba]		14 September 2020
Summary CV for supervisor (student research) [Professor Knight 4 page CV (Supervisor)]	0.1	01 September 2020
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flowchart for Vaccination Coverage in the PED v 0-1 October 9th 2020 IRAS 278815]	0.1	09 October 2020

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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 use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

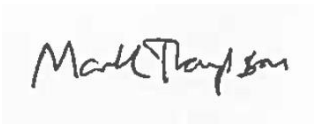
HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 278815 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely



On behalf of Mr Simon Jones
Chair

Email:gmeast.rec@hra.nhs.uk

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: Mrs Becky Gordon

Professor Rachel Isba
Professor of Medicine and Consultant in Paediatric Public Health Medicine
Lancaster University and the Pennine Acute Hospitals NHS Trust
Lancaster Medical School
Lancaster University
Lancaster
LA1 4YG

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

07 January 2021

Dear Professor Isba

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Do children and young people attending the Paediatric Emergency Department have lower levels of vaccination coverage than their peers in the local general population?**
IRAS project ID:	**278815**
Protocol number:	**N/A**
REC reference:	**20/NW/0423**
Sponsor	**Lancaster University**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- 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.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **278815**. Please quote this on all correspondence.

Yours sincerely,
Amber Ecclestone

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Mrs Becky Gordon*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Covering letter on headed paper [Headed Letter Isba Vaccination Coverage in the PED October 9th 2020]	0.1	09 October 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Lancaster University Insurance]	0.1	26 June 2020
IRAS Application Form [IRAS_Form_12102020]		12 October 2020
Letters of invitation to participant [Updated poster for the department advertising Vaccination Coverage in PED study]	2.0	13 December 2020
Organisation Information Document [Organisation_Information_Document_Non-Commercial_v0-1 for Vaccination Coverage PED September 29th 2020 IRAS ref 278815]	0.1	29 September 2020
Other [Data collection questions]	1.0	23 October 2020
Participant consent form [eConsent for Vaccination Coverage PED version 2.0 December 13th 2020 IRAS ref 278815]	2.0	13 December 2020
Participant information sheet (PIS)	2.1	18 December 2020
Research protocol or project proposal [Protocol for Vaccination Coverage in PED version 1-0 September 2020 IRAS 278815]	1-0	29 September 2020
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Summary CV for supervisor (student research) [Professor Knight 4 page CV (Supervisor)]	0.1	01 September 2020
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flowchart for Vaccination Coverage in the PED v 0-1 October 9th 2020 IRAS 278815]	0.1	09 October 2020

IRAS project ID	278815

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
All sites will perform the same research activities therefore there is only one sitetype.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	Organisation Information Document acts as the agreement	No study funding will be provided to sites as per the Organisation Information Document	A Principal Investigator should be appointed at study sites	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain a Letter of Access based on standard DBS checks and occupational health clearance.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Lancaster University
Medical School

Friday October 9th 2020

Dear colleagues,

Please find enclosed an application for approval of a study *Vaccination coverage amongst children/young people attending the Paediatric Emergency Department* (IRAS Project ID 278815).

I am carrying out this work as part of my MD studies at Lancaster University and will be collecting data via two Greater Manchester Paediatric Emergency Departments, one of which I work in as a Consultant in Paediatric Public Health Medicine.

The study is registered at clinicaltrials.gov using their epidemiology/observational/cross-sectional study template and is available here:
https://clinicaltrials.gov/ct2/show/NCT04485624?term=Isba&draw=2&rank=2

The work has Lancaster University as the sponsor.

Thanks and best wishes,

Professor Rachel Isba

rachel.isba@lancaster.ac.uk

Professor of Medicine, Lancaster Medical School | Lancaster University
Associate Dean (Engagement), Faculty of Health and Medicine | Lancaster University
Consultant in Paediatric Public Health Medicine | North Manchester General Hospital
Visiting Scholar, Department of Emergency Medicine | Yale School of Medicine
Honorary Teaching Fellow | Liverpool School of Tropical Medicine
Visiting Medical Faculty | University of California, Riverside

GMC: 6075446
ORCID: 0000-0002-2896-4309

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Vaccination coverage amongst children/young people attending the PED

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

(●) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Will you be processing identifiable data at any stage of the research (including in the identification of participants)? (●) Yes ( ) No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

[x] England
[ ] Scotland
[ ] Wales
[ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (●) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which applications do you require?

- [x] IRAS Form
- [ ] Confidentiality Advisory Group (CAG)
- [ ] Her Majesty's Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

( ) Yes (●) No

5. Will any research sites in this study be NHS organisations?

(●) Yes ( ) No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative in all study sites?

Please see information button for further details.

( ) Yes (●) No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

( ) Yes (●) No

The NIHR Clinical Research Network (CRN) provides researchers with the practical support they need to make clinical studies happen in the NHS in England e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, information from your IRAS submission will automatically be shared with the NIHR CRN. ***Submission of a Portfolio Application Form (PAF) is no longer required.***

6. Do you plan to include any participants who are children?

(●) Yes ( ) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent

for themselves?

◯ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

◯ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ◯ No

Please describe briefly the involvement of the student(s):
The applicant is an NHS Consultant in Paediatric Public Health Medicine and Professor of Medicine at Lancaster Medical School. She has also registered as an MD student in order to undertake the research that this forms part of.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ◯ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

◯ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

◯ Yes ◉ No

Integrated Research Application System
Application Form for Study limited to working with data (specific project only)

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Vaccination coverage amongst children/young people attending the PED

Please complete these details after you have booked the REC application for review.

REC Name:
North West - Greater Manchester East Research Ethics Committee

REC Reference Number:
20/NW/0423

Submission date:
12/10/2020

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Do children and young people attending the Paediatric Emergency Department have lower levels of vaccination coverage than their peers in the local general population?

A2-1. Educational projects

Name and contact details of student(s):

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Professor	Jo	Knight
Address	Lancaster Medical School		
	Lancaster University		
	Lancaster		
Post Code	LA1 4YG		
E-mail	jo.knight@lancaster.ac.uk		
Telephone			
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- (●) Student
- ( ) Academic supervisor
- ( ) Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Professor	Rachel	Isba
Post	Professor of Medicine and Consultant in Paediatric Public Health Medicine		
Qualifications	BA (Hons) BM BCh MA MPH PhD PGCert DLSHTM DRCOG MFMLM FFPH FAcadMEd		
ORCID ID	0000 0002 2986 4309		
Employer	Lancaster University and the Pennine Acute Hospitals NHS Trust		
Work Address	Lancaster Medical School		
	Lancaster University		
	Lancaster		
Post Code	LA1 4YG		
Work E-mail	rachel.isba@lancaster.ac.uk		
* Personal E-mail	rachel.isba@nhs.net		
Work Telephone	0152465201		
* Personal Telephone/Mobile	07902988999		
Fax	0152465201		

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Mrs	Becky	Gordon
Address	Head of Research Quality and Policy		
	Lancaster University		
	Lancaster		
Post Code	LA1 4YW		
E-mail	sponsorship@lancaster.ac.uk		
Telephone	+44 (0)1524 592981		
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	N/A
Sponsor's/protocol number:	N/A
Protocol Version:	1.0
Protocol Date:	29/09/2020
Funder's reference number (enter the reference number or state not applicable):	N/A
Project website:	N/A

Additional reference number(s):

Ref.Number Description	Reference Number
Clinicaltrials.gov (https://www.clinicaltrials.gov/ct2/show/?term=lsba&draw=2&ran)	NCT04485624

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

(●) Yes ( ) No

Please give brief details and reference numbers.
This study is a follow up to part of "Pilot of a public health intervention in the PED" (IRAS 214887) which included looking at the vaccination status of children and young people, but revealed that parental recall likely over-estimates coverage. This forms part of the rationale for this current study.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

In the UK, most childhood vaccinations are given in the community, although uptake has decreased in recent years. A Paediatric Emergency Department (PED) attendance offers an opportunity to check the vaccination status of children and young people (CYP) and all parents/carers should be asked about this routinely. Those not up-to-date with vaccinations could then be signposted to existing services or perhaps offered a vaccine in the PED.

CYP attending the PED may also have lower vaccination coverage than their peers, so may benefit even more from interventions to increase uptake. However, recall by parents/carers is not always sufficiently accurate to identify those who have not yet received all their age-appropriate vaccinations. The most complete record of an individual's vaccination history is held within their GP records. However, these records are often in a separate computer system that is inaccessible from the hospital's main computer system, although some information (including vaccination) can be accessed from within the hospital via a third system.

This study aims to see if CYP attending the PED are under-vaccinated compared to their peers and assess the accuracy of parent/carer recall. The results of this study will then be used to inform recommendations for developing better ways to access accurate vaccination data during a PED consultation. If such a system existed, under-vaccinated children could be identified routinely during an attendance, and an intervention offered if appropriate. This would be

particularly useful if there was an outbreak of a vaccine-preventable disease such measles.

All CYP (< 16 years old) attending two PEDs in Manchester will be invited to participate. They/their parent/carer will be asked to provide consent for their vaccination records to be accessed as well as being asked if the child/young person is up-to-date with all their vaccinations. Approximately 600 participants will be enrolled at each PED.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

The main ethical issue is that the participants in the study are parents/carers consenting on behalf of children/young people, and/or children/young people providing their own consent (where applicable), in the setting of a Paediatric Emergency Department. These populations may be more vulnerable than others. However, the study seeks to ask about routinely-collected data (a vaccination history from a parent/carer) and then check the accuracy of this against systems that collect vaccination data, rather than do anything that would not form a part of normal care in the department.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- [ ] Case series/ case note review
- [ ] Case control
- [ ] Cohort observation
- [ ] Controlled trial without randomisation
- [x] Cross-sectional study
- [ ] Database analysis
- [x] Epidemiology
- [ ] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [ ] Qualitative research
- [ ] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

Do children and young people attending the Paediatric Emergency Department have lower levels of vaccination coverage relative to their peers in the general population?

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

How accurate is parent/carer recall of the vaccination status of children/young people attending the Paediatric Emergency Department, when compared to primary care records?

Other research questions in this programme of work, but that don't require primary data collection are included for

completeness:

What barriers and facilitators are there to overcoming issues of inter-operability between primary (community) and secondary (hospital) care data systems holding vaccination information?

What opportunities might the Paediatric Emergency Department offer for vaccination during an outbreak e.g. of measles, if it were possible to identify under-vaccinated children and young people?

The overall aim of this whole project (of which this study is a part) is to provide an evidence base and make recommendations for the development of a system that automatically flags up to clinicians, in real-time, those children and young people who have not completed the full course of age-appropriate vaccinations, during a PED attendance, in the same way the majority of GP-based systems would during a primary care consultation. If such a system was to be put in place, clinicians could then deliver one or more interventions designed to facilitate "catch-up" with missing vaccinations, via novel or existing programmes.

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

The majority of routine childhood immunisations in the UK are offered in community locations, commonly delivered via a setting such as a General Practitioner (GP) surgery. Administration of one of more vaccines is recorded in the GP electronic record, with returns sent from this system to central surveillance systems.

In its 2009 guidance (updated 2017) on improving routine childhood vaccination in children and young people (CYP), the National Institute for Health and Care Excellence (NICE) recommended that the vaccination status of any patient in this group be checked at every available opportunity (e.g. interaction with a clinician in the Paediatric Emergency Department, PED). This is especially important for certain vulnerable sub-populations, for example those in care, or those who may be new to the UK (and the NHS vaccination schedule). Under-vaccinated CYP could then be offered opportunities to "catch-up" with missing vaccinations.

If clinicians are to engage in a discussion around vaccination during a routine hospital consultation, it is important to first find out if a child or young person is up-to-date with their routine childhood vaccinations. However, a small number of studies have suggested that clinicians take incomplete or inaccurate vaccination histories when clerking patients.

A recent pilot study by the Chief Investigator for this project showed that 97% of parents/carers attending the PED at one hospital reported that their child/young person was up to date with all of their vaccinations, despite local community data suggesting that this number was closer to 82%. This observation fits with the limited research in this area, that suggests parents/carers are likely to over-estimate vaccination uptake.

These observations are further complicated by the fact that frontline clinicians in the hospital are not currently able to routinely access reliable data relating to an individual patient’s vaccination status, despite this information being held within electronic primary care (GP) systems and also nationally as part of the Child Health Information System (CHIS).

Whilst it is very likely that CYP attending the PED are actually under-vaccinated relative to their peers (as attendees are more likely to come from a sub-population shown to have lower levels of coverage), there are no data that look specifically at this. Given the issues around parent/carer recall, there is also an argument for not relying on this as a sole source of information. This research therefore seeks to compare vaccination coverage among PED attendees and the general local population of their peers, but also to provide evidence that, in the PED setting, parent/carer recall (as part of a routinely-taken history) is insufficient to reliably identify those who would benefit from an intervention to increase their uptake of routine childhood vaccines.

Additionally, there is emerging evidence that during the SARS-CoV-2/COVID-19 pandemic, uptake of routine childhood vaccination has decreased. This is particularly important in the case of MMR. In autumn 2019, the UK lost its WHO measles-free status, indicating that the UK had circulating measles virus and inadequate vaccination coverage levels (via MMR) to prevent spread within populations. The MMR vaccine protects again measles, mumps, and rubella, and is highly effective live vaccine given as a course of two doses, with good, protective “herd immunity” once coverage levels reach 95% (i.e. if 95% of the population have received two MMRs, then the whole population is protected from outbreaks).

Measles virus is extremely infectious, the disease is serious and untreatable (only supportive care can be provided), and pre-pandemic MMR coverage for the second dose in the UK was 87.5%. In Manchester, where this work will be undertaken, pre-pandemic coverage was even lower, at 82.1%. It is therefore increasingly probable that there will be outbreaks of measles in populations such as the UK, and that they are likely to begin before the pandemic is declared over, further compounding global recovery.

If a system existed where hospital-based clinicians could easily and reliably access vaccination records, then PEDs could also offer an opportunity for delivery of reactive vaccination programmes in outbreaks (as well as routinely identifying under-vaccinated CYP attending the department who can then be referred on to primary care services).

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Study design
This is a cross-sectional epidemiological study and this design has been chosen as it is the most appropriate for making an estimate of the proportion of a population that has been vaccinated. It will provide a "snapshot" at a moment in time for children and young people (aged less than 16) attending the study sites. As it is an observational study design, there is no intervention or control group. The study builds on the findings of a small pilot and is intended to provide additional evidence which can be combined with other work to inform recommendations for future research, practice, and policy.

The null hypotheses for this study are:

1. There is no difference in coverage of routine childhood vaccination in children and young people (aged less than 16) attending the Paediatric Emergency Department when compared to the general local population of their peers.

2. There is no difference between parent/carer recall of a child or young person's vaccination status in the Paediatric Emergency Department and the formal records held in primary care.

Settings and participants
The research will be carried out in two PEDs in Greater Manchester - at the Royal Manchester Children's Hospital and North Manchester General Hospital. All children and young people (and their parents and carers), aged less than 16 years, attending the PED will be eligible to participate in the study, except in case of life-threatening illness or injury.

Participants will be recruited by word of mouth, as infection prevention control measures currently in place mean that physical recruitment materials will need to be minimised and will probably be restricted to laminated (easy-wipe) single sides of A4 with the link to the study site and the QR scan code on. All staff working in the PED will be encouraged to mention the study to attendees and provide the link/code to those who would like to know more. All subsequent information presented and collected will be done via a web-based platform. If there is a change during the study (e.g. the end of the pandemic), the possibility of lending an ipad to potential participants will be explored, if it is possible to do so in a safe way. If someone would like to participate but does not have a smartphone or cannot access the hospital Wifi, then a physical set of paperwork will be made available to them.

Consent to participate (and therefore have the hospital record, electronic primary care vaccination records, and child health information system of the patient accessed) will be obtained via the use of a QR code or shortlink to a Qualtrics-hosted (secure, GDPR-compliant) form. This will be carried out on participants' own smartphones and the existing free hospital WiFi, to fit with presumed ongoing social distancing. Whilst the information collected is likely to need to be entered by the parent/carer (CYP are unlikely to know about their own vaccination status), the intention is that the CYP can participate in giving consent for the study. As above, if this is not technically possible, then paper copies will be made available.

Participants will only be able to progress to the data collection pages once they have indicated that they have read the patient information screen and given consent. To enable broad participation, and in response to feedback from participants in the earlier associated pilot study, all materials will be produced in English with a target reading age of 7-9 years old. If possible, we will also offer information in our most common local other primary languages - Polish, Somali, Urdu, and Hebrew.

Data collection
Participants (likely to be parents/carers, but with CYP involved as above) will then be asked to give basic information about the child or young person and their vaccination status via a series of questions.

Name (of the child or young person who is the patient today)
FREE TEXT ANSWER

Date of birth (of the child or young person who is the patient today):

FREE TEXT ANSWER

Is this person up-to-date with their vaccinations (also called immunisations or needles)?
YES
NO
NOT SURE

I allow the researchers to check GP notes to see if they have had all their vaccinations (also called immunisations or needles):
YES
NO

The data collected will then be used to identify the hospital notes and then electronic primary care summary record for each participant. The NHS number for participants will be extracted from hospital notes and used to access the electronic summary care and the relevant child health information system (CHIS).

Sample size
A power calculation has been carried out to work out how many participants we need in the study to be confident that we can accept or reject the null hypotheses. We used the two-dose MMR coverage levels to work this out and assumed that CYP attending the PED have MMR coverage rates of 77%, i.e. 5% lower than Manchester (82%). Comparing the population prevalence (0.77 vs 0.82), with power set at the conventional 0.8, using a two-sided test with significance at the conventional threshold of <0.05, gave a sample size of 577 participants needed for each setting. Each of the PEDs sees more than 35,000 CYP a year, so it should be feasible to recruit sufficient numbers within the planned timeframe.

Timetable for the research
The preparation, data collection, and initial analysis is expected to take place over a 12 month period. The departments each see between 50 and 150 CYP a day, so it is likely that data collection will be possible over a period of a six months in each location, even if recruitment rates are relatively low.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [x] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine

- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [x] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 0	Years
Upper age limit: 16	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Child or young person attending the Paediatric Emergency Department before their 16th birthday.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Very serious or life-threatening illness or injury.
Unable to engage with the participant information etc. for any reason.
Child or young person unable to self-consent and attending with someone not legally able to give consent on their behalf.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

All children and young people and their parents and carers will be invited orally by members of staff in the two PEDs involved in the study. This is to minimise the amount of physical materials associated with the study, given the setting of a hospital in a pandemic.

If potential participants indicate that they would be interested in learning about the study, they will be given, or directed to, a laminated A4 sheet (that will be cleaned very regularly) that will have on it a scannable QR code and a short link that can be copied into a phone. The code/link will take potential participants to a patient information sheet and they will then be able to click through to the consent form if they are interested in joining the study. If they do not have access to a smartphone or the hospital Wifi, then paper copies will be used.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

◯ Yes ◉ No

Please give details below:
All attendees at the Paediatric Emergency Department will be potential participants.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

Potential participants will be directed to the data collection QR code/short weblink by a member of the clinical team (most likely a member of nursing staff).

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Consent will be taken via the use of the data collection platform to avoid the use of physical consent forms where possible. It will only be possible to proceed to the data collection screen when consent has been given.

A universal consent form has been produced (and associated participant information sheet) that will be used by parents/carers but also any CYP who would like to be involved in the research process. This approach has been used to take into account:
- the starting point for the paperwork was the University's standard information sheet and consent form (rather than a blank sheet) and this has been extensively adapted;
- feedback from previous work with this population of parents/carers who expressed a preference for the paperwork produced for CYP as it meant that they didn't need to ask the researcher to explain some of the more complex words (that appeared on the "adult" version) to them in easier to understand language;
- input from a content expert (Nurse Consultant) used to producing communication with our local populations and based on her extensive past experience;
- the pandemic means that we are attempting to carry out the research in a "paper light" way - just as the web platform allows us to offer translations into different languages, using a single format information and consent screen will make it easier for potential participants to use.

Although it is very unlikely that the CYP themselves will be able to answer the question about their vaccination status (and will likely therefore need to consult their accompanying parent/carer), an active decision has been made to involve CYP in the recruitment and consent processes, so that they do not feel like research is being done "to them". This fits with the PI's research with this population previously - for example in a recent study 50% of CYP were involved in the consent process (either giving consent themselves if legally able, or co-signing with a parent/carer).

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

Participants will be allowed the time that they are in the Paediatric Emergency Department (likely to vary between 1 and 12 hours in the majority of cases). This timescale is in line with the recruitment used in the successful recent pilot intervention study in the same department.

Although this study is not hyper-acute in the same way that the vast majority of studies that would be recruited in an Emergency Department setting e.g. treatment-based interventional RCTs, past experience supports the use of an "in-

department" decision around participation. This is for a number of additional practical reasons (aside from the setting) that include:

1. an ability to recruit 24/7 as the PI would not need to be present to take contact details from potential participants in order to follow up with them at a later time.
2. a reduction in the amount of data collected around participants and support the "paper light" approach, in light of the pandemic.
3. not impacting on the achievement of the recruitment targets - each setting sees 50-100 CYP a day, so it is likely that the decision time around participation will not have a marked impact as contacting people after they have left the department will likely not yield a high % of all those recruited.
4. the response rate to the related pilot was 75% of those approached and during the qualitative aspects of the work, CYP and their parents/carers provided extensive suggestions as to the way research could be modified in future e.g. the use of simplified information sheets, but nobody asked for longer to think about whether or not they wanted to join the study.
5. that parents/carers who took 48 or 72h to make a decision might also use that time to check their child's vaccination status, then enrol in the study, possibly skewing the results for the assessment of recall part of the study.

When making this decision, we also took into account a balance between the amount of information that would need to be collected and safely stored in order to contact parents/carers after they had left the PED but, for example, within 48 or 72h of their attendance (name of parent/carer, name of CYP, telephone number) versus the amount of data that would be collected if the participant joined the study (name of CYP, date of birth of CYP, vaccination status - all of which would be collected routinely during a consultation, plus consent to access primary care-held vaccination records).

It was thought, therefore, that the suggested approach of decision-making within the visit to the PED was, on balance, commensurate with the nature of the study, the setting for recruitment (in the context of a pandemic), and in light of the success of this same approach used recently for another study.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

All reading materials will be designed for a reading age of 7-9 years old and the intention is that it will be available in our most common other local 1st languages: Polish, Somali, Urdu, and Hebrew. This is facilitated by the use of an electronic platform for sharing patient information, gaining consent, and data collection. The use of an electronic format will mean that those with additional visual needs will be able to adjust the content accordingly.

The participant information sheet and consent forms have been adapted from Lancaster University templates to take into account feedback from participants in the associated pilot (parent/carers who often had to ask for words to be explained to them in terms they could understand, and when offered, said that they preferred the sheet prepared for young people), and with input from a Nurse Consultant who is used to working with our local CYP and their parents/carers on work like this.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

The study consists of a one-off consent to access vaccination records and associated data collection administered at the same time i.e. there is a single point of data collection.

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- [x] Access to medical records by those outside the direct healthcare team
- [ ] Access to social care records by those outside the direct social care team
- [ ] Electronic transfer by magnetic or optical media, email or computer networks
- [ ] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [ ] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [ ] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [ ] Use of audio/visual recording devices
- [ ] Storage of personal data on any of the following:
  - [ ] Manual files (includes paper or film)
  - [x] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [ ] University computers
  - [ ] Private company computers
  - [ ] Laptop computers

Further details:

A37. Please describe the physical security arrangements for storage of personal data during the study?

Name and date of birth will be collected via the secure Qualtrics platform used by Lancaster University for studies of this type. These are the only personal data that will be collected. Data will only be downloaded from this system onto a personal NHS computer for the Chief Investigator and housed at North Manchester General Hospital. Any paper records generated (likely to be small numbers) will be destroyed after inputting into the qualtrics system on behalf of participants, so that all data are only held electronically.

Participants will be assigned a sequential participant number based on order of recruitment.

When extracting the data from the GP notes (via the interface system in the hospital), the results will be recorded against the participant number in an excel spreadsheet. This will ensure that there is no complete data record for any participant that includes their name and date of birth.

Once the complete set of anonymised data has been extracted into the excel sheet, the qualtrics data (which will include the consent from participants) will be managed in-line with University procedures and deleted at the end of the programme of study (MD) which the Chief Investigator is enrolled on.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

All patient identifiable data will be removed for each participant as soon as a complete data set is achieved for them. Only the Chief Investigator will extract data from the GP system.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Only the applicant will have access to the participants' personal data and this will be anonymised as soon as a complete data set is acquired (i.e. after accessing the electronic vaccination record). Anonymous data only will be shared with those providing statistical support.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

The data generated by the study will be analysed by the applicant, with expert statistical support from the supervisor. However, this will be anonymised data only.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Professor	Rachel	Isba
Post	Professor of Medicine and Consultant in Paediatric Public Health Medicine		
Qualifications	BA (Hons) BM BCh MA MPH PhD PGCert (Leadership) DLSHTM DRCOG MFMLM FFPH FAcadMEd		
Work Address	Lancaster Medical School		
	Health Innovation One, Sir John Fisher Drive		
	Lancaster University, Lancaster		
Post Code	LA1 4AT		
Work Email	rachel.isba@lancaster.ac.uk		
Work Telephone			
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

- (●) Less than 3 months
- ( ) 3 – 6 months
- ( ) 6 – 12 months
- ( ) 12 months – 3 years
- ( ) Over 3 years

A44. For how long will you store research data generated by the study?

Years: 10
Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended.*Say where data will be stored, who will have access and the arrangements to ensure security.*

Data will be stored for a time period commensurate with that in Lancaster University policy. However, these will be anonymised data - no personal data will be stored past the end of the study.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

◉ Yes ○ No

Please give details, or justify if not registering the research.
Clinicaltrials.gov

https://www.clinicaltrials.gov/ct2/show/NCT 04485624?term=Isba&draw=2&rank=2

Whilst this study is not a clinical trial using a definition that involves an intervention, it has been successfully accepted onto the clinicaltrials.gov database and was submitted using a standard template approach (for observational, cross-sectional, epidemiological-type studies). The intention is that the protocol will be submitted to BMJ Open after completion of the ethics approvals process.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☐ Internal report
- ☑ Conference presentation
- ☐ Publication on website

☐ Other publication

☐ Submission to regulatory authorities

☑ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators

☐ No plans to report or disseminate the results

☐ Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

There will be no identifiable personal data beyond the stage of data collection i.e. well before publication of results.

A53. Will you inform participants of the results?

○ Yes ◉ No

Please give details of how you will inform participants or justify if not doing so.
No contact details for participants will be collected.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed?*Tick as appropriate:*

☐ Independent external review

☐ Review within a company

☐ Review within a multi−centre research group

☑ Review within the Chief Investigator's institution or host organisation

☐ Review within the research team

☑ Review by educational supervisor

☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The IRAS form and associated documentation has been reviewed by the sponsorship team within Lancaster University, a senior research development team member provided in-depth critique of the protocol, and two members of the MD supervision team were invited to comment on the protocol. The development of the research has been extensively discussed amongst the supervisory team and Greater Manchester immunisation colleagues have also been involved in verbal discussions.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed?*Tick as appropriate:*

☐ Review by independent statistician commissioned by funder or sponsor

☐ Other review by independent statistician

☐ Review by company statistician

☑ Review by a statistician within the Chief Investigator's institution

☐ Review by a statistician within the research team or multi−centre group

☐ Review by educational supervisor

☐ Other review by individual with relevant statistical expertise

☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Dr	Thomas	Keegan
Department	Lancaster Medical School		
Institution	Lancaster University		
Work Address	Health Innovation One Sir John Fisher		
Post Code			
Telephone			
Fax			
Mobile			
E-mail			

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

Percentage of children and young people attending the PED who have received all of their age-appropriate vaccinations. This will then be compared to their peers in the general population.

A58. What are the secondary outcome measures?*(if any)*

Percentage of children and young people attending the PED who have received two doses of MMR by the age of 5 years. This will then be compared to their peers in the general population.

Percentage of children and young people attending the PED who have received at least one dose of MMR by the age of 2 years. This will then be compared to their peers in the general population.

Accuracy of parent/carer recall of vaccination status compared to electronic records.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	1154
Total international sample size (including UK):	1154
Total in European Economic Area:	1154

Further details:
577 to be recruited at each of the two sites.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

A power calculation has been carried out to work out how many participants we need in the study to be confident that we can accept or reject the null hypotheses. We used the two-dose MMR coverage levels to work this out and assumed that CYP attending the PED have MMR coverage rates of 77%, i.e. 5% lower than Manchester as a whole (82%). Comparing the population prevalence (0.77 vs 0.82), with power set at the conventional 0.8, using a two-sided test with significance at the conventional threshold of <0.05, gave a sample size of 577 participants needed for each

setting. Each of the PEDs sees more than 35,000 CYP a year, so it should be feasible to recruit sufficient numbers within the planned timeframe.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

The primary care-held records will be assumed to be accurate for the purposes of statistical analysis. Vaccination status and recall will be expressed as % and an assessment made of the sensitivity and specificity of recall made (with the records as "truth"). When comparing the proportion of CYP in the study population for variables 2, 3, and 4, a series of two proportions z-tests will be used. Other statistical approaches may be used if appropriate.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

Title Forename/Initials Surname

Post
Qualifications
Employer
Work Address

Post Code
Telephone
Fax
Mobile
Work Email

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
○ NHS or HSC care organisation
◉ Academic
○ Pharmaceutical industry
○ Medical device industry
○ Local Authority
○ Other social care provider (including voluntary sector or private organisation)

Commercial status: Non-Commercial

◯ Other

If Other, please specify:

Contact person

Name of organisation	Lancaster University
Given name	Becky
Family name	Gordon
Address	Head of Research Quality and Policy, Lancaster University
Town/city	Lancaster
Post code	LA1 4YT
Country	United Kingdom
Telephone	+44 (0)1524 592981
Fax	
E-mail	sponsorship@lancaster.ac.uk

A65. Has external funding for the research been secured?

Please tick at least one check box.

☐ Funding secured from one or more funders

☐ External funding application to one or more funders in progress

☑ No application for external funding will be made

What type of research project is this?

◉ Standalone project

◯ Project that is part of a programme grant

◯ Project that is part of a Centre grant

◯ Project that is part of a fellowship/ personal award/ research training award

◯ Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

◯ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

◯ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Ms	Katie	Doyle
Organisation	Northern Care Alliance (currently has a SLA for R&D at North Manchester General)		
Address	Research and Innovation Department		
	Salford Royal NHS Foundation Trust		
	Summerfield House, 1st Floor, 544 Eccles New Road, Salford		
Post Code	M5 5AP		
Work Email	katie.doyle@srft.nhs.uk		
Telephone	01617897373		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/01/2021
Planned end date: 01/10/2022
Total duration:
Years: 1 Months: 9 Days: 1

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☐ Scotland
- ☐ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study

Does this trial involve countries outside the EU?
○ Yes ○ No

A72. Which organisations in the UK will host the research?*Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

- ☑ NHS organisations in England 2
- ☐ NHS organisations in Wales
- ☐ NHS organisations in Scotland
- ☐ HSC organisations in Northern Ireland

- ☐ GP practices in England
- ☐ GP practices in Wales
- ☐ GP practices in Scotland
- ☐ GP practices in Northern Ireland
- ☐ Joint health and social care agencies (eg community mental health teams)
- ☐ Local authorities
- ☐ Phase 1 trial units
- ☐ Prison establishments
- ☐ Probation areas
- ☐ Independent (private or voluntary sector) organisations
- ☐ Educational establishments
- ☐ Independent research units
- ☐ Other (give details)

Total UK sites in study: 2

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

As this research is being undertaken as an MD, the applicant will have regular supervisions.

Please note that one of the research sites - North Manchester General Hospital - is currently part of the legal entity "The Pennine Acute Hospitals NHS Trust" but is being run under a management arrangement by Manchester University NHS Foundation Trust. Pennine Acute is due to be dissolved at the end of the current financial year and at this stage North Manchester will formally join Manchester University NHS Foundation Trust (the second site, Royal Manchester Children's Hospital is already part of this Trust). However, at the time of application, research support to North Manchester General Hospital is provided via a Service Level Agreement with Salford Royal, part of the Northern Care Alliance (which North Manchester was previously managed by).

Contact has been maintained with representatives of all of the above parties as part of this ethics application but I felt it was worth making a note of why so many different organisations are involved.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- ☐ NHS indemnity scheme will apply (NHS sponsors only)
- ☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

○ Yes ◉ No ○ Not sure

PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

All children under 16 will be included. Research is being carried out in this age group as they are the bulk of attendees at Paediatric Emergency Departments (older young people may be seen under certain circumstances but are not included in this study). The vast majority of routine vaccinations are given to children under the age of 16, so they form the target population for this study.

2. Indicate whether any children under 16 will be recruited as controls and give further details.

Not applicable - this is a cross-sectional observational study.

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

Any child or young person who wants to be involved partially or wholly in giving consent will be able to do so. As the

consent will be taken electronically, this will also make it more accessible to those who may have additional needs. Please see elsewhere on this form for additional context to the approach used.

4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.

All information will be targeted at a reading age of 7-9 based on the feedback and qualitative work carried out previously by the applicant in this area and the reading age of adults in England. Additional context appears elsewhere on this form and expert input has been obtained during the development of the associated written materials.

It is not the intention to provide younger children with information about the research - this was done in a previous study via the use of a colouring sheet that children could complete whilst their parent/carer read the information sheet and gave consent. However, in the current pandemic this is not possible as shared crayons present an infection prevention and control risk.

As the intention is that all "paperwork" will be replaced with an electronic platform (except in the case of lack of access e.g. no smartphone, in which case paper will be provided), those that fall between "colouring" and "giving consent" will perhaps be able to press the buttons on the survey with their parent/carer. This would be the in-pandemic equivalent of the approach used previously where this intermediate age/understanding group were able to make a mark with a pen or crayon next to their parent/carer signature to feel part of the process (even though they didn't understand exactly what was happening, they wanted to join in).

Again, this approach builds heavily on past experience working with and feedback from the specific population that will be involved in this study, but has been adapted for pandemic conditions and a very changed PED.

Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site		Investigator Name	
IN2	(●) NHS/HSC Site ( ) Non-NHS/HSC Site		Forename Middle name Family name Email	Rachel Isba rachel.isba@nhs.net
	Organisation name	PENNINE ACUTE HOSPITALS NHS TRUST	Qualification (MD...)	BM BCh, PhD, MPH
	Address	TRUST HEADQUARTERS NORTH MANCHESTER GENERAL HOSPITAL DELAUNAYS ROAD, CRUMPSALL MANCHESTER	Country	United Kingdom
	Post Code	M8 5RB		
	Country	ENGLAND		
IN3	(●) NHS/HSC Site ( ) Non-NHS/HSC Site		Forename Middle name Family name Email	Rachel Jenner rachel.jenner@mft.nhs.uk
	Organisation name	MANCHESTER UNIVERSITY NHS FOUNDATION TRUST	Qualification (MD...)	MB ChB
	Address	COBBETT HOUSE OXFORD ROAD MANCHESTER	Country	United Kingdom
	Post Code	M13 9WL		
	Country	ENGLAND		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 2018.

10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 2018.

12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

HRA would like to include a contact point with the published summary of the study for those wishing to seek further

information. We would be grateful if you would indicate one of the contact points below.

- ◯ Chief Investigator
- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Dr Rachel Isba on 12/10/2020 09:56.

Job Title/Post:	Professor of Medicine and Consultant in Paediatric Public Health Medicine
Organisation:	Lancaster University and North Manchester General Hospital
Email:	rachel.isba@lancaster.ac.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by An authorised approver at sponsorship@lancaster.ac.uk on 12/10/2020 17:13.

Job Title/Post:	Head of Research Quality and Policy
Organisation:	Lancaster University
Email:	b.gordon@lancaster.ac.uk

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr Joanne Knight on 12/10/2020 09:58.

Job Title/Post:	Professor in Applied Data Science
Organisation:	Lancaster University
Email:	Jo.Knight@Lancaster.ac.uk

Appendix 3.

Selected study paperwork:

- protocol for *Vaccination coverage amongst children/young people attending the PED*
- flowchart of data collection
- sample advertising materials including QR and tinyurl for NMGH Qualtrics survey
- participant information sheet
- consent form
- copy of data collection and mock-up of sample Qualtrics data collection screen

Protocol for Vaccination coverage amongst children/young people attending the PED, IRAS Project ID: 278815 (clinicaltrials.gov identifier NCT04485624)

Professor Rachel Isba, Lancaster University
Version 1.0 September 2020

Do children and young people attending the Paediatric Emergency Department have lower levels of vaccination coverage than their peers in the local general population?

Introduction

Vaccines are one of the great global public health successes. Since their discovery more than 300 years ago, vaccines have saved countless millions of lives (1), reduced the incidence of dozens of diseases, and even lead to the eradication of smallpox. However, in the UK, uptake of routine childhood vaccination is declining and we now lag behind some of our European peers (2). This finding is on a background of global changes in the pattern of vaccination and an associated increase in outbreaks of vaccination-preventable diseases such as measles.

Every year in England, millions of children and young people (CYP) attend hospital (secondary or tertiary medical care) (3), often with relatively minor illnesses and injuries, many of which could be managed elsewhere, and which sometimes result in long waits to see a healthcare professional. However, despite numerous initiatives to redirect these CYP, hospital attendances continue to increase year-on-year (4). In addition to their primary reason for presentation, CYP attending the hospital may have lower than average levels of health and wellbeing, additional unmet health need (e.g. sexual health), or not be engaged with preventive elements of routine healthcare (e.g. immunisation). A hospital attendance or admission might therefore offer an opportunity to improve health, beyond the initial reason for presentation.

Background

Vaccines have been one of the most successful public health interventions of all time, with the World Health Organization (WHO) estimating that 10 million lives were saved from vaccine preventable diseases, just between 2010 and 2015 (5). As well as collecting data relating to vaccine coverage and vaccine-preventable diseases, the WHO also produces guidance on what should be included in national routine childhood vaccination programmes (6). Whilst more than 80% of children worldwide now receive at least one vaccination by their first birthday (7), the WHO identified "vaccine hesitancy" as one of its *Ten threats to global health in 2019* (8). Addressing vaccination hesitancy has enormous potential to improve health and the WHO estimates that if global vaccination levels increased, an additional 1.5 million lives could be saved annually.

Routine childhood vaccination uptake/coverage

In the UK, vaccination (or immunisation – used interchangeably here) has formed a cornerstone of the National Health Service (NHS) since its launch in 1948 (9). Children in England are routinely vaccinated (and at no cost to parents/carers) against a wide range of

potentially life-threatening or life-altering diseases and a summary of the most recent (June 2020) schedule appears on the UK government's website (10). The schedule is complex and frequently updated, but information is also provided about vaccinating those with "uncertain or incomplete immunisation" (11).

In 2018-19 (the latest year for which complete data are currently available), routine childhood vaccination coverage in England declined in all routine vaccinations (2), meaning that the country continues to lag behind European neighbours such as Sweden and Portugal (12-14). Amongst these vaccines, MMR (the vaccine that protects against three highly contagious viruses – measles, mumps, and rubella) saw a fifth consecutive annual decrease (any recovery in 2019-20 will be unlikely given the pandemic). These decreases are partly reversing the upward trend seen since MMR coverage plummeted following the publication of the (now retracted) *Lancet* paper spuriously linking the MMR vaccine with autism and written by the (now struck-off) former doctor Andrew Wakefield (15). Many vaccines against diseases that can spread person-to-person e.g. measles, have now dropped below the level needed for so-called "herd immunity" – coverage in the general population that prevents outbreaks and protects those individuals who may not be able to receive the vaccine for medically relevant reasons (e.g. immunosuppression) (see section 1. of 16 for overview).

This decline in vaccination uptake/coverage is likely to be underpinned by a number of things including:

- issues with data (e.g. knowing who needs vaccination);
- inconvenience associated with accessing vaccination;
- "hard to access" populations (e.g. looked after children);
- vaccination hesitancy (defined as "the reluctance or refusal to vaccinate despite the availability of vaccines");
- opposition to vaccination on religious grounds (e.g. Orthodox Jewish populations);
- non-religious "anti-vaccination" (or anti-vaxx) sentiment (active opposition to the use of vaccines).

Any attempts to increase vaccination uptake must therefore be sensitive to these complexities and avoid the temptation of focussing solely on, for example, "anti-vaxx", when in fact more people show hesitancy or have issues around convenience of access (both of which might be more susceptible to modification via an interaction with a healthcare practitioner).

Recording of vaccination administration

The majority of routine childhood immunisations are offered in community locations, commonly delivered via a setting such as a GP surgery. Administration of one of more vaccines will be recorded in the GP electronic record, with returns sent from this system to local Child Health Information Systems (CHISs) and then on to the central surveillance system (17). In addition, all children should have a handheld paper personal child health record – the Red Book – that records important events in their health and development, including immunisations. However, if a parent/carer cannot provide the book during the consultation, this will not happen. Also, other groups such as looked after children (those living in care) may not have a valid or up-to-date record. An electronic version of the Red Book (eredbook) is now available, although it must be commissioned locally (18). It is also less likely that parents/carers of older children would access this, compared to those with

younger children (the focus of the Red Book is mainly up to the age of 5), so those who have missed out on vaccinations in early childhood would not be easy to identify via this approach (of checking the paper or electronic Red Book).

Access to vaccination information during a consultation in secondary care (hospital)

If clinicians are to engage in a discussion around vaccination during a routine hospital consultation, it is important first to find out if a child or young person is up-to-date with their routine childhood vaccinations. In its 2009 guidance (updated 2017) on improving routine childhood vaccination in children and young people (CYP), the National Institute for Health and Care Excellence (NICE) recommended that the vaccination status of any patient in this group be checked at every available opportunity (e.g. interaction with a clinician in the Emergency Department) (19). This is especially important for certain sub-populations of children, for example those in care, or those who may be new to the UK (and the NHS vaccination schedule).

However, a number of studies have suggested that:

- incomplete or inaccurate vaccination histories are common at the point of hospital attendance/admission (20-22);
- around half of parents/carers will forget to bring a child's handheld health record (see Red Book) to the hospital (20);
- parent/carer recall of vaccinations leans towards over-estimation (23).

These observations are further compounded by the fact that frontline clinicians in the NHS are not currently able to routinely access reliable data relating to an individual patient's vaccination, despite this information being held within primary care (GP) systems.

Whilst it may be that, with time, systems will be in place within the NHS to enable those working in secondary care settings such as the Emergency Department to access timely and accurate vaccination records as part of a routine consultation, it is important that we are not over-reliant on a single part-solution to some of the issues outlined above. The time taken to access such as a system, by the healthcare practitioner, must also be taken into account, particularly in a setting such as the ED where time, access to reliable IT, and departmental pressures must also be taken into account. For example, a system that is co-ordinated with the IT system within the ED, so that a "flag" appears automatically that an under-vaccinated child is registered at the reception desk or triage, might be preferable to a system where an individual clinician had to log on to a web-based system and find an individual vaccination record for their patient. Under-vaccinated CYP could then be offered a suitable intervention, for example signposting to opportunities e.g. to "catch-up" with missing routine vaccinations, or administration of a vaccine e.g. in the case of an outbreak of measles.

Delivering public health interventions in the Paediatric Emergency Departments (PED)

CYP attending the PED may have lower than average levels of health and wellbeing, aside for their primary reason for attendance. Additionally, many attendances are for minor illnesses and injuries, and the reasons why people access care in this way (when they might be better served by a different part of the health system) is not well understood. Ever-

increasing demand for services means that these CYP and their accompanying carers may spend several hours waiting in the PED for a consultation with a doctor or other health professional that lasts only a few minutes. Whilst there are numerous initiatives to try to re-direct potential PED attenders to other, more appropriate parts of the system e.g. re-routing a child with dental pain to a community dentist, there are very few that aim to use the waiting time in the department in a positive way to improve health. Ideally, this alternative approach – of using fallow time in the department to address wider health and wellbeing issues – has the potential to ultimately decrease attendances to the department, although over a much longer timescale than initiatives such re-directing at the point of presentation.

This study is a follow up to part of "Pilot of a public health intervention in the PED" (IRAS 214887) which included looking at the vaccination status of children and young people, and forms part of the rationale for this current study. The pilot showed that 97% of parents/carers attending the PED at one hospital (PED1 – see settings below) reported that their child/young person was up to date with all of their vaccinations, despite local community data suggesting that this number was closer to 82% e.g. for the second dose of MMR (24). This observation fits with the limited literature in this area that suggests parents/carers are likely to over-estimate vaccination uptake (23) and further complicated by the fact that clinicians in the hospital are not currently able to routinely access reliable data, so have to take the parent/carer report at face value.

Whilst it is very likely that CYP attending the PED are actually under-vaccinated relative to their peers (as attendees are more likely to come from a sub-population shown to have lower levels of uptake), there are no data that look specifically at this (25-27REF). Given the issues around parent/carer recall, there is also an argument for not relying on this as a sole source of information. This research therefore seeks to compare vaccination coverage among PED attendees and the general local population of their peers, but also to provide evidence that, in the PED setting, parent/carer recall (as part of a routinely-taken history) is insufficient to reliably identify those who would benefit from an intervention to increase their uptake of routine childhood vaccines.

Additionally, there is emerging evidence that during the SARS-CoV-2/COVID-19 pandemic, uptake of routine childhood vaccination has decreased (28). This is particularly important in the case of MMR. In autumn 2019, the UK lost its WHO measles-free status, indicating that the UK had circulating measles virus and inadequate vaccination coverage levels (via MMR) to prevent spread within populations (29). The MMR vaccine protects again measles, mumps, and rubella, and is highly effective live vaccine given as a course of two doses, with good, protective “herd immunity” once coverage levels reach 95% (30).

Measles virus is extremely infectious, the disease is serious and untreatable (only supportive care can be provided), and pre-pandemic MMR coverage for the second dose in the UK was 87.5%. In Manchester, where this work will be undertaken, pre-pandemic coverage was even lower at 82.1%. It is therefore increasingly probable that there will be outbreaks of measles in populations such as the UK, and that they are likely to begin before the pandemic is declared over, further compounding global recovery.

If a system existed where hospital-based clinicians could easily and reliably access vaccination records, then PEDs could offer an opportunity for delivery of reactive vaccination programmes in outbreaks e.g. of measles, as well as routinely identifying under-

vaccinated CYP attending the department who can then be referred on to primary care services.

Objectives

The overall objective of this project is to answer the question "How can secondary care-based clinicians access and use accurate primary care-held vaccination data to identify under-vaccinated children and young people during a Paediatric Emergency Department attendance?". This research will provide original evidence to support the theory that PED attendees are a target population for opportunistic interventions to improve vaccination uptake and that being able to identify those who have not completed age-appropriate vaccinations during a consultation by means other than parent/carer recall is needed.

The research questions relating to this research study are:

1. Do children and young people attending the Paediatric Emergency Department have lower levels of vaccination coverage relative to their peers in the general population?

2. How accurate is parent/carer recall of the vaccination status of children/young people attending the Paediatric Emergency Department, when compared to primary care records?

Methods

Study design

This is a cross-sectional observational study with a single data collection point for each participant or their parent/carer.

All reading materials have been designed for a reading age of 7-9 years old (literacy Entry Level 2) as 1 in 7 adults in England have a literacy level at or below that of a 9-year-old (31). Materials have been produced with input from a Nurse Consultant (with a special interest in this area) and based on comments from participants in the pilot study. The intention is that it will be available in our most common other local 1st languages: Polish, Somali, Urdu, and Hebrew.

Consent will be taken via the use of the data collection platform (qualtrics) to avoid the use of physical consent forms. The study consists of a one-off consent to access vaccination records and a question around recall administered at the same time.

Settings

PED1 – Paediatric Emergency Department, North Manchester General Hospital (NMGH), a co-located (but spatially separate) PED in a district general hospital in Manchester, England. The department has approximately 30,000 attendances a year. NMGH is currently under a management arrangement with Manchester University NHS Foundation Trust with a transaction underway for it to become formally part of the Trust in April 2021. It is currently part of the Pennine Acute Hospitals NHS Trust and the Research and Innovation support is provided via a service level agreement with the Northern Care Alliance (of which the hospital was a part until early 2020), via Salford Royal.

PED2 – Paediatric Emergency Department, Royal Manchester Children's Hospital (RMCH), a dedicated children-only ED in a specialist children's hospital in Manchester, England, on a site with a number of other hospitals that form part of the Manchester University NHS Foundation Trust. The department has approximately 50,000 attendances a year.

Participants

All children and young people plus their parents and carers will be invited to participate by members of staff in the two PEDs involved in the study. This is to minimise the amount of physical materials associated with the study, given the setting of a hospital in a pandemic.

If potential participants indicate that they would be interested in learning about the study, they will be given, or directed to, a laminated A4 sheet (that will be cleaned very regularly, to minimise handling of paper in the department) that will have on it a scannable QR code and a short link that can be copied into a phone, then accessed using the department's free WiFi. The code/link will take potential participants to the patient information sheet (PIS) and they will then be able to click through to the consent form if they are interested in joining the study. They will only be able to proceed to the data collection part of the platform once they have given consent. Paper copies (in the relevant language) can be printed out on a case-by-case basis if needed (e.g. in the case of those with no smartphone).

Participation in the study will be recorded in the patient's notes via the use of a sticker to minimise the amount of contact (e.g. if writing in the notes) with multiple sets of notes by those involved in recruiting.

Data sources/measurement

The two data sources will be parent/carer recall and primary care-held records accessed via the hospitals' electronic summary care records.

The data to be collected from parents/carers will be via a single screen on the qualtrics platform:

Name (of child or young person who is the patient today): FREE TEXT

Date of birth (of child or young person who is the patient today): FREE TEXT

Is this person up-to-date with their vaccinations (also known as immunisations or needles)?

Yes TICK BOX
No TICK BOX
Not sure TICK BOX (CAN ONLY SELECT ONE OF THE THREE)

It is okay to check the GP notes to see if this person has had all their vaccinations (also known as immunisations or needles):

Yes TICK BOX
No TICK BOX (CAN ONLY SELECT ONE OF THE TWO)

The date that the participant joins in the study will be automatically recorded via the data collection platform.

The data collected from GP records will be:

1. Up-to-date for age?
    a. Yes
    b. No
    c. Not clear
2. Older than 2 years and had at least one dose of MMR?
    a. Yes
    b. No
    c. Not clear

3. Older than 5 years and had two doses of MMR?
    a. Yes
    b. No
    c. Not clear

Bias

Selection and responder bias are a possibility as an opportunistic sampling process will be used and there are a small number of exclusion criteria. Other forms of bias are unlikely due to the nature of the data being collected and analysed.

Study size

The MMR vaccine was chosen for the sample size calculation as this is the vaccine most commonly given in an outbreak scenario and has attracted the most controversy over the past decades (resulting in lower than target coverage). It is also frequently used in other studies of this nature as an example. Two doses of MMR are given to complete a routine course and the second dose, designated "MMR2" is given around the age of 3 years and 5 months, but to allow for late administration, data are normally presented for MMR2 at the age of 5 years.

The most recent data for MMR2 coverage at 5 years are available for the year 2018/19. In England, coverage for MMR2 was 86.4% (down from 87.2% in 2017/18) (2). For Manchester coverage of MMR2 for 5 year olds was only 82.1% in the same time period (24). The sample size calculation was carried out using STATA version 16 (32) and a comparison made between population prevalence (between the "PED" and "general Manchester" populations). We carried out a sample size calculation based on the difference between the population prevalence in Manchester of 0.82 and in our PEDs as 0.77, with the required power as 0.8, using a two sided test, with probabilities set at $p<0.05$. This suggested a sample size of 577 for each site.

Quantitative variables

The variables of interest will be:

1. Vaccination status of CYP (aged less than 16 years) attending the PED, as reported by parents/carers (up-to-date vs. not up-to-date vs. don't know).
2. Vaccination status of CYP (aged less than 16 years) attending the PED, according to primary care-held records (up-to-date vs. not up-to-date vs. data issue).
3. Number of CYP (aged 5 years and over) who have received two doses of MMR according to primary care-held records.
4. Number of CYP (aged 2 years and over) who have received at least one dose of MMR according to primary care-held records.

Statistical methods

The primary care-held records will be assumed to be accurate for the purposes of statistical analysis. Variables 1 and 2 will be compared via means of a simple % of parents/carers who responded accurately and an assessment of the sensitivity and specificity of recall made (with the records as "truth" and recall as "the test"). When comparing the proportion of CYP in the study populations to the general population for variables 2, 3, and 4, a series of two proportion z-tests will be used.

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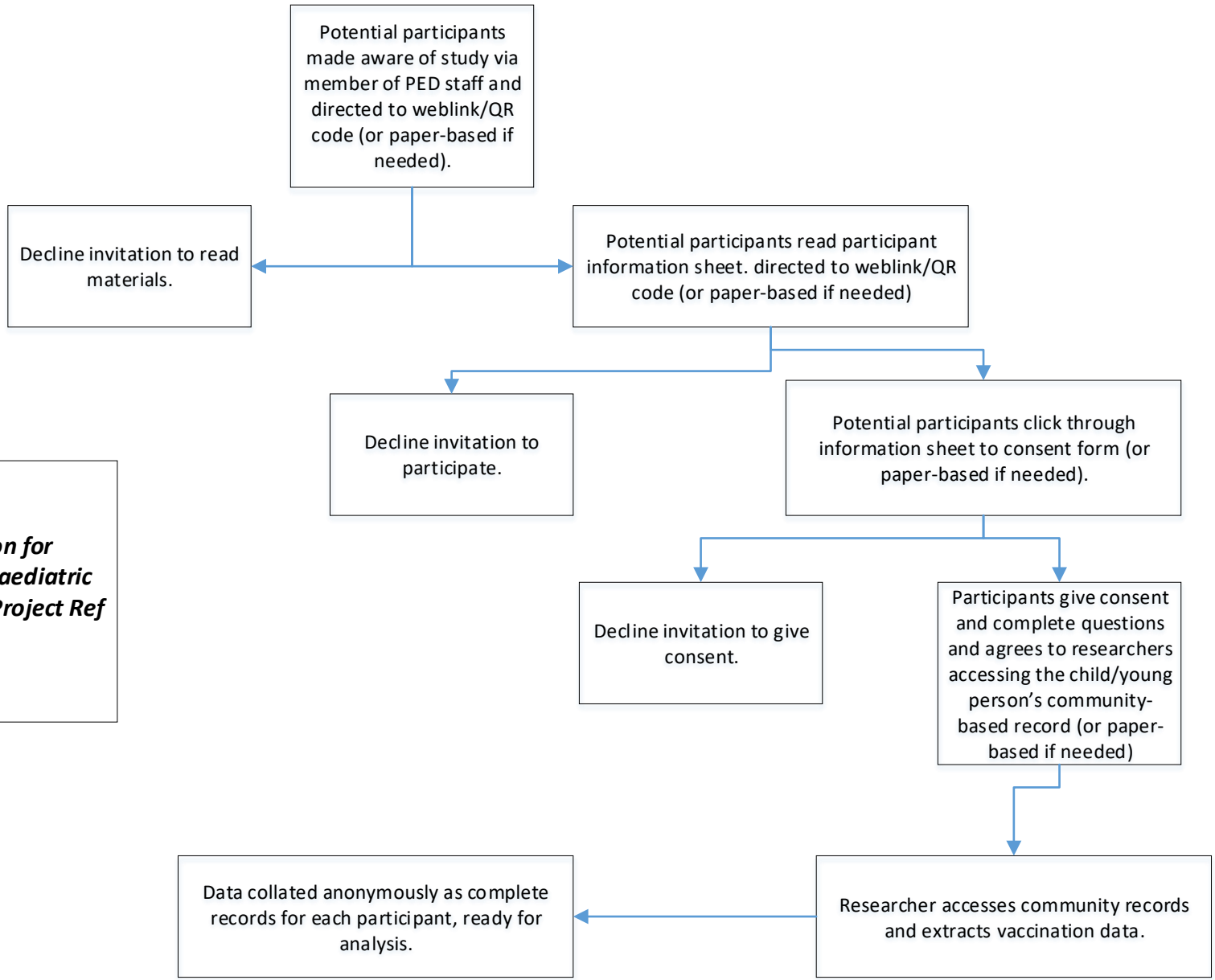
Flowchart of data collection for Vaccination Coverage in the Paediatric Emergency Department, IRAS Project Ref 278815



This department is helping with a research project being done by one of the doctors who works here.

The research involves answering a few questions that will take less than five minutes to fill in.

Please can you help?

To learn more, please scan the code below on your phone
(just open up the camera and point it here)

or type this short weblink into your phone's browser.
https://tinyurl.com/y2sfcfo4

Professor Rachel

Thank you!

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Medical School

Information page

Project title: Do children and young people attending the Paediatric Emergency Department have lower levels of vaccination coverage than the general population?

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage: www.lancaster.ac.uk/research/data-protection

In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data for future research.

We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this.

Hi, my name is Professor Rachel Isba, but you can call me Professor Rachel. I am doing this project at Lancaster University, Lancaster, United Kingdom, but I am also a doctor working in a hospital.

What is the project about?

The purpose of this project is to see if children and young people who come to hospital have had all their injections (also known as immunisations or needles). You will only be asked questions as part of this project, nothing else.

Why have I been approached?

You have been approached because the project needs information about people who are less than 16 years old and have come to the hospital.

Do I have to take part?

No. You can choose. Your medical care will not be affected, whatever you choose to do.

What will I be asked to do if I take part?

If you decide you would like to take part, you will be asked a few questions.

Will people be able to see my answers?

The information you provide is confidential. This means that we will keep it safe and only the people doing this project will be able to look at it. As soon as possible your name will be taken off it and then we will not know that the answers belong to you. The files on the computer will be encrypted (this is a way of making things secret) and the computer itself will have a password.

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What will happen to the results?

The results will be added together and your name will not be on anything as it will have been taken off before I do all the maths on the information. The results will then be shared with other scientists and doctors, by putting them on a website used for research – here is a link to this project if you would like to have a look:
https://clinicaltrials.gov/ct2/show/NCT04485624?term=Isba&draw=2&rank=2

Are there any risks?

There are no risks expected with taking part in this project. However, if you aren't happy about anything, you can email me or my boss (emails are at the bottom).

Are there any benefits to taking part?

Although you may find joining in interesting, there are no benefits in taking part. Hopefully this project will help children and young people in the future.

Who has reviewed the study?

This project has been reviewed (looked at) and approved (said it's okay) by the University (Faculty of Health and Medicine Research Ethics Committee) and the NHS' Greater Manchester East Ethics Committee meeting. This is to make sure I am following the rules for projects properly.

Where can I get further information about the study if I need it?

If you have any questions about the project, please contact me:
rachel.isba@lancaster.ac.uk.

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your name, date of birth, hospital number, and vaccination records. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

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What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to sponsorship@lancaster.ac.uk, or
- by ringing us on 01524 65201

Complaints
If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to me (Professor Rachel), you can contact:
Professor Jo Knight, Research Director for Lancaster Medical School
jo.knight@lancaster.ac.uk or via 01524 65201

If you wish to speak to someone outside of the Medical School, you may also contact:
Professor Roger Pickup, Associate Dean for Research
r.pickup@lancaster.ac.uk or via 01524 65201
Faculty of Health and Medicine
(Division of Biomedical and Life Sciences)
Lancaster University, Lancaster
LA1 4YG

or
Lancaster University Research and Development Office
sponsorship@lancaster.ac.uk or via 01524 65201

Thank you for taking the time to read this information.

If you think you would be able to help with this project, please click here.

Lancaster University Medical School

Consent (Agreement) Form

Project title: Do children and young people attending the Paediatric Emergency Department have lower levels of vaccination coverage than the general population?

Name of research: Professor Rachel Isba

We are asking if you would be able to say yes to helping with a project asking questions about vaccinations (also known as immunisations or needles). This is the project that you just read about on the information screen.

Before you agree to help with the project we ask that you read the information below and tick each box to say yes, that's okay.

If you have any questions before ticking the boxes, please ask to talk to Professor Rachel or one of the nurses.

Please tick each box

1. Yes, I have read the information and know what I need to do for this project. ☐
2. Yes, I have had the chance to ask questions. ☐
3. Yes, I know that I don't have to help if I don't want to and I can change my mind, without my care being affected. ☐
4. Yes, I understand that my name won't be on anything after today. ☐
5. Yes, I understand that parts of the medical notes and data collected during the study, may be looked at by people from Lancaster University, from regulatory authorities or from the hospital, where it is relevant to taking part in this research. I give permission for these individuals to have access to the records. ☐
6. Yes, I agree to join in the project. ☐

Your name:
Today's date:

When you have filled in all the boxes, please click here to go to the project questions.
Thank you!

Data collection questions for Vaccination Coverage PED version 1-0 October 23rd 2020 IRAS 278815

Data to be collected via Qualtrics

Name (of child or young person who is the patient today): FREE TEXT

Date of birth (of child or young person who is the patient today): FREE TEXT

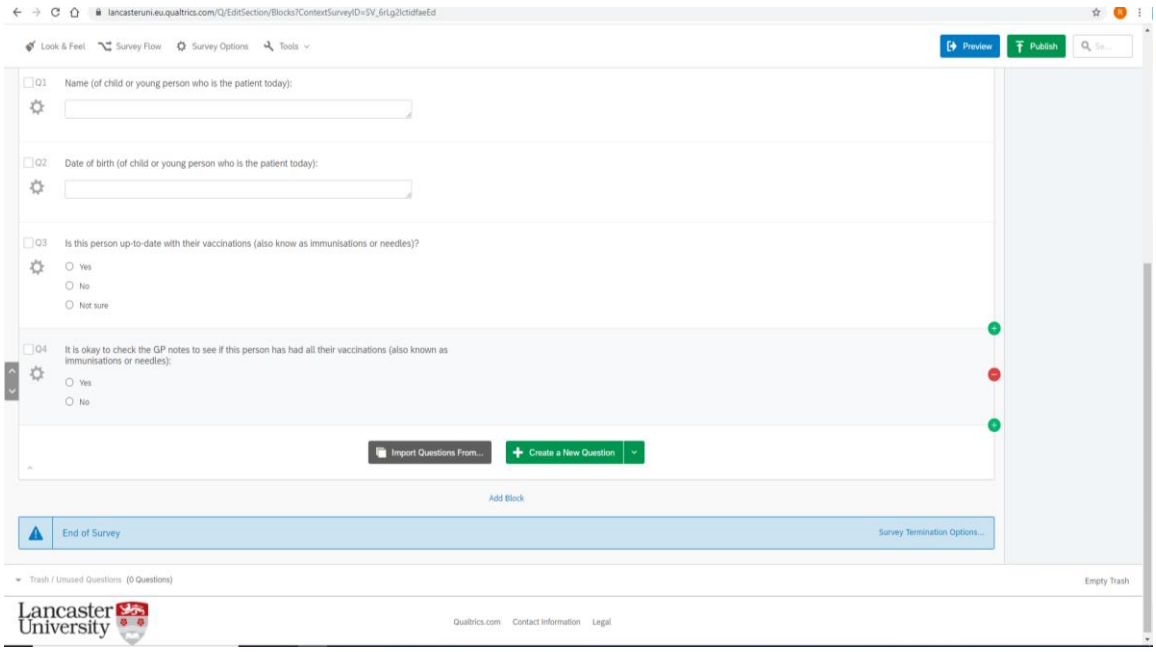
Is this person up-to-date with their vaccinations (also known as immunisations or needles)?

Yes TICK BOX
No TICK BOX
Not sure TICK BOX (CAN ONLY SELECT ONE OF THE THREE)

It is okay to check the GP notes to see if this person has had all their vaccinations (also known as immunisations or needles)?

Yes TICK BOX
No TICK BOX (CAN ONLY SELECT ONE OF THE TWO)

Mock-up of sample qualtrics data collection screen



Health Research Authority

North West - Greater Manchester East Research Ethics Committee

3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Tel: 02071048199

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

16 September 2021

Professor Rachel Isba
Lancaster Medical School
Lancaster University
Lancaster
LA1 4YG

Dear Prof Rachel Isba

Study title:	**Do children and young people attending the Paediatric Emergency Department have lower levels of vaccination coverage than their peers in the local general population?**
REC reference:	**20/NW/0423**
Protocol number:	**N/A**
Amendment number:	**Amendment 1**
Amendment date:	**26 August 2021**
IRAS project ID:	**278815**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Completed Amendment Tool [Amendment tool 278815 Amendment 1 26 08 2021]	1.0	26 August 2021
Copies of materials calling attention of potential participants to the research [Amendment Advertisement for Vaccination Coverage in	3.1	02 September 2021

PED]		
Participant consent form [Amendment Opt-out for Vaccination Coverage PED IRAS 278815]	1.0	23 August 2021
Participant information sheet (PIS) [Amendment PIS for Vaccination Coverage PED IRAS 278815]	3.1	02 September 2021
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Amendment Flowchart Vaccination Coverage PED 278815]	2.0	23 August 2021

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS Project ID - 278815:	**Please quote this number on all correspondence**

Yours sincerely

pp
Mr Simon Jones
Chair

E-mail: gmeast.rec@hra.nhs.uk

Copy to:

Health Research Authority

North West - Greater Manchester East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting held via correspondence.

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Michael Hollingsworth	Retired Senior Lecturer in Pharmacology	Yes	
Mr Simon Jones	Podiatrist	Yes	Chaired the meeting.

In attendance:

Name	*Profession*
Miss Mia Cooper	Approvals Administrator

From: gmeast.rec@hra.nhs.uk
To: Isba, Rachel; IRAS Sponsorship
Subject: [External] IRAS Project ID 278815. HRA and HCRW Approval for the Amendment
Date: 16 September 2021 16:14:41

This email originated outside the University. Check before clicking links or attachments.

Dear Professor Isba,

IRAS Project ID:	278815
Short Study Title:	Vaccination coverage amongst children/young people attending the PED
Amendment No./Sponsor Ref:	Amendment 1
Amendment Date:	26 August 2021
Amendment Type:	Substantial Non-CTIMP

I am pleased to confirm **HRA and HCRW Approval** for the above referenced amendment.

You should implement this amendment at NHS organisations in England and Wales, in line with the guidance in the amendment tool.

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 use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

Please contact amendments@hra.nhs.uk for any queries relating to the assessment of this amendment.

Kind regards

Nabeela Gaulton (nee Iqbal)
Approvals Specialist

Health Research Authority
Ground Floor | Skipton House | 80 London Road | London | SE1 6LH
E.amendments@hra.nhs.uk
W. www.hra.nhs.uk

Sign up to receive our newsletter HRA Latest.

Amendment Tool

v1.5 25 Mar 2021

For office use

QC: No

Section 1: Project information

Short project title*:	Vaccination coverage amongst children/young people attending the PED
IRAS project ID* (or REC reference if no IRAS project ID is available):	278815
Sponsor amendment reference number*:	Amendment 1
Sponsor amendment date* (enter as DD/MM/YY):	26 August 2021
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	This amendment relates to the estimation of vaccination coverage levels amongst children and young people (CYP) attending the PED (not the estimation of parent/carer recall). It proposes a move from opt-in consent and the collection of data from participants (children/young people and their parents/carers) to opt-out consent where the vaccination status of every CYP attending over a fixed period of time will be checked via the primary care record. This approach is being used in order to ensure the scientific value of the study under the current circumstances of an ongoing pandemic and increased burden on the PED, both of which have had a negative impact on recruitment and the timeline for the study to date. The parent/carer recall aspect is unaffected and the intention is that, should the amendment be approved, the original work planned to assess recall will be carried out with the original data set collected at that point. The power calculation related to the vaccination coverage amongst the PED-attending population (not parent/carer recall), and an opt-in approach would enable vaccination data for attendees to be collected over a one month period (during which time an estimated 1500+ CYP will attend the PED). This new approach would also likely provide a more representative estimate of vaccination coverage as the whole attending population would be included (unless they have requested to opt out) - this would decrease the possibility of responder bias and improve inclusion. Included with this submission is an opt-out PIS/consent form which will be available in the department and posters that will advertise the study and the opt-out process within the department (these are based on the existing posters that advertise participation in the study at the moment). An attendance list for the study month will be generated that only includes local hospital number and date of birth. Vaccination data will then be hand extracted from the primary care records in the same way as described in the original application.

Project type (select):	◉ Specific study ○ Research tissue bank ○ Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	◉ Yes		○ No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	◉ NHS/HSC REC ○ Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	○ Yes		◉ No	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	◉	○	○	○
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	○ Yes		◉ No	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	○ Yes		◉ No	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	◉ Yes		○ No	
Did the study involve prisoners OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve children OR does the amendment introduce this?:	◉ Yes		○ No	
Did the study involve NHS/HSC organisations prior to this amendment?:	◉ Yes		○ No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes		◉ No	

	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	◉	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☐	☐	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☐	☐	☐

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, tick the "Add another change" box.

Change 1				
Area of change (select)*:	Participant Procedures			
Specific change (select - only available when area of change is selected first)*:	Recruitment - Change in identification, approach, recruitment or consent of participants			
Further information (free text - note that this field will adapt to the amount of text entered):	The amendment is requested to change from opt-in consent (and completion of a data collection tool) to opt-out consent, where no primary data collection is required directly from participants, but instead collected from primary care records.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	◉ All		○ Some	

Add another change: ☐

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]:*	Claire O'Donnell
Email address:*	Sponsorship@lancaster.ac.uk

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

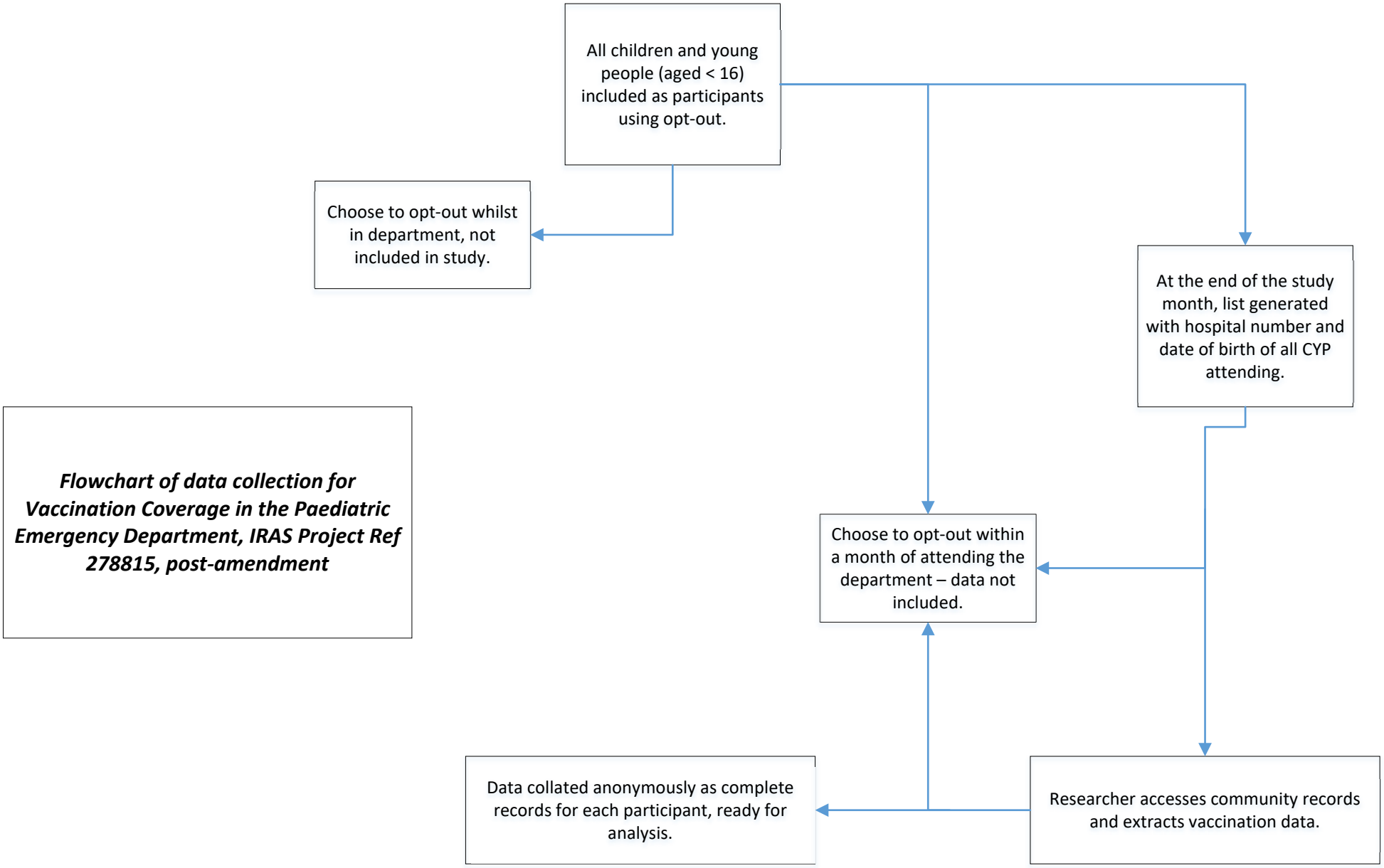
After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:	Y					Y		(Y)		Y									A

Overall reviews for the amendment:																		
Full review:	Y					Y		N		Y								
Notification only:	N					N		Y		N								
Overall amendment type:	Substantial																	
Overall Category:	A																	



Flowchart of data collection for Vaccination Coverage in the Paediatric Emergency Department, IRAS Project Ref 278815, post-amendment

Lancaster University
Medical School

Information page – you can opt-out of this study, please see details below

Project title: Do children and young people attending the Paediatric Emergency Department have lower levels of vaccination coverage than the general population?

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage: www.lancaster.ac.uk/research/data-protection

In this research study we will use information from your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data for future research.

We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this.

Hi, my name is Professor Rachel Isba, but you can call me Professor Rachel. I am doing this project at Lancaster University, Lancaster, United Kingdom, but I am also a doctor working in a hospital.

If you would prefer not to be included in this study, please ask for an opt-out form, or email rachel.isba@nhs.net (please include the name and date of birth of the child or young person who was the patient, as well as the date that you came to hospital, so we can find the right record) within one month of your attendance.

What is the project about?

The purpose of this project is to see if children and young people who come to hospital have had all their injections (also known as immunisations or needles). We are doing this by checking the vaccination records of everyone who comes this month.

Why have I been approached?

You have been approached because the project needs information about people who are less than 16 years old and have come to the hospital.

Do I have to take part?

No. You can choose. If you decided that you don't want to take part, please let us know by filling in the opt-out form or emailing rachel.isba@nhs.net. Your medical care will not be affected, whatever you choose to do.

Lancaster University
Medical School

What will I be asked to do if I take part?
If you decide you would like to take part, you don't need to do anything and you will be automatically included, and the research team will collect the information from your records.

Will people be able to see my answers?
The information from your vaccination records is confidential. This means that we will keep it safe and only the people doing this project will be able to look at it. As soon as possible your name will be taken off it and then we will not know that the answers belong to you. The files on the computer will be encrypted (this is a way of making things secret) and the computer itself will have a password.

What will happen to the results?
The results will be added together and your name will not be on anything as it will have been taken off before I do all the maths on the information. The results will then be shared with other scientists and doctors, by putting them on a website used for research – here is a link to this project if you would like to have a look:
https://clinicaltrials.gov/ct2/show/NCT04485624?term=Isba&draw=2&rank=2

Are there any risks?
There are no risks expected with taking part in this project. However, if you aren't happy about anything, you can email me or my boss (emails are at the bottom).

Are there any benefits to taking part?
There are no direct benefits to you in taking part. However, hopefully this project will help children and young people in the future.

Who has reviewed the study?
This project has been reviewed (looked at) and approved (said it's okay) by the University (Faculty of Health and Medicine Research Ethics Committee) and the NHS' Greater Manchester East Ethics Committee meeting. This is to make sure I am following the rules for projects properly.

Where can I get further information about the study if I need it?
If you have any questions about the project, please contact me: rachel.isba@lancaster.ac.uk

How will we use information about you?

We will need to use information from your medical records for this research project.

This information will include your date of birth, hospital number, and vaccination records. People will use this information to do the research or to check your records to make sure that the research is being done properly.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study within a month (using the opt-out form or emailing), without giving a reason, and we will remove the information about you.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to sponsorship@lancaster.ac.uk, or
- by ringing us on 01524 65201

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to me (Professor Rachel), you can contact:

Dr Jemma Kerns, Research Director for Lancaster Medical School
j.kerns@lancaster.ac.uk or via 01524 65201

If you wish to speak to someone else, you may also contact:
Professor Jen Logue, Associate Dean for Research
j.logue1@lancaster.ac.uk or via 01524 65201
Faculty of Health and Medicine
Lancaster University, Lancaster
LA1 4YG

Or

Lancaster University Research and Development Office
sponsorship@lancaster.ac.uk or via 01524 65201

Thank you for taking the time to read this information.

Lancaster University Medical School

Opt-out form

Project title: Do children and young people attending the Paediatric Emergency Department have lower levels of vaccination coverage than the general population?

Name of researcher: Professor Rachel Isba

Please only use this form if you have decided that you DO NOT want to be part of the study. If you are happy to be included, you do not need to do anything.

Thank you.

- I have read the information provided and have had the chance to ask questions
- I **DO NOT** want my child's information to be included in this study.

Your name:

Your signature:

Today's date:

Your child's name:

Your child's date of birth:

Date that your child came to the department:

Children and young people attending this department may be included in a research project being done by one of the doctors who works here.

No change is being made to your treatment or care.

Professor Rachel

The research is being done to see if children and young people (as a group, not individuals) who come to the hospital are up-to-date with their vaccinations (also known as immunisations or needles). We will do this by looking at the vaccination records of all the children and young people who come to this Emergency Department this month.

If you would prefer that we don't check the vaccination records, please ask for an opt-out form, or email rachel.isba@nhs.net (please include the name and date of birth of the child or young person who was the patient, as well as the date that you came to hospital, so we can find the right record) within one month of your attendance.

You don't need to do anything if you are okay with being included, and the child or young person's name will not be on anything once we've seen the records. If you would like more information, please ask for an information sheet.

Thank you!

Appendix 3

Scoping review protocol.

Archives of Disease in Childhood publication of abstract from Royal College of Paediatrics (RCPCH) Conference, September 2020.

Interventions delivered in secondary or tertiary medical care settings to improve routine vaccination uptake in children and young people: a scoping review protocol

Rhiannon Edge • Rachel Isba

Lancaster Medical School, Lancaster University, Lancaster, UK

ABSTRACT

Objective: The objective of this review is to identify and collate the available evidence, and to produce an overview of interventions delivered in secondary and tertiary healthcare settings with the aim of improving vaccination uptake in children and young people.

Introduction: Vaccine hesitancy appears in the World Health Organization's Ten Threats to Global Health in 2019.[1] Time spent in secondary or tertiary healthcare settings with a child or young person may present an opportunity to deliver vaccination-focused interventions. National Institute for Health and Care Excellence guidance highlights a gap in the evidence of the effectiveness of different interventions aimed at increasing immunization uptake among children and young people.[2]

Inclusion criteria: Quantitative studies that describe interventions delivered in secondary and tertiary care settings will be included. Participants will include children and young people aged less than 16 years and/or their parents/carers (potentially interventions could be delivered to the child-parent/carer dyad) present in a secondary or tertiary care setting as either a patient or relative.

Methods: This scoping review will be conducted using MEDLINE, CINAHL, Cochrane Library, Embase, Web of Science, as well as gray literature. The scoping review will exclude publications not available in English and any publication older than 30 years. Two reviewers will independently select articles using the inclusion criteria, based on their title and abstract. Data will be extracted from selected full text articles using a data extraction tool based on JBI recommendations. Study findings will be presented in tabular form detailing the interventions identified in the literature.

Keywords intervention; scoping review; secondary/tertiary care; vaccination

JBI Evid Synth 2020; 18(7):1566–1572.

Introduction

Vaccination has made an enormous contribution to global health. Today, however, the UK, US, and many other countries with successful immunization programs are experiencing concerning outbreaks of disease (particularly measles) as a result of declines in vaccine coverage.[3] For example, Public Health England describes the National Health Service (NHS) routine immunization schedule as world-leading; however, reduced engagement with the program means that children may be at an increased risk of vaccine-preventable diseases. In England in 2018–19, coverage declined in all of the routine childhood vaccinations compared with the previous year.[4] Additionally, since 2010, routine immunization coverage of the first dose of a measles-containing vaccine (MMR) has declined in 12 European Union member states.[5] In 2018, more than 80,000 people in European countries contracted measles, three times the total reported in 2017.[6] Globally, there has been a surge in measles due to gaps in vaccination coverage, with an estimated 110,000 deaths related to the disease in 2017, a 30% increase on 2016.[7] Recently, the World Health Organization (WHO) stated that, globally, all targets for disease elimination are behind schedule, and lists vaccine hesitancy as one of the top 10 threats to

Correspondence: Rhiannon Edge, r.edge@lancaster.ac.uk

The authors declare no conflict of interest.

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global health in 2019.[1] Likewise, the recent 2018 Global Monitoring report from the Wellcome Trust named vaccine hesitancy as one of 10 major threats to global health.[8] The 2018 assessment report of the Global Vaccine Action Plan (GVAP) stressed the need to "maintain its hard-won gains but also aim to do more and to do things better, which may involve doing things differently."[9(p.4)]

The decline in vaccination uptake is likely to be underpinned by a number of factors including:

- concerns about the vaccines[10]
- misunderstanding around the severity of the diseases[11]
- parents who are resentful of perceived pressure to risk their own child's safety for a public health benefit[12]
- inconvenient or limited access to vaccines[13]
- mistrust of health professionals, governments, and officially endorsed vaccine research[14]
- reliance on media and other unofficial information sources[15]
- increased anxieties about the vaccine's safety as the perceived threat of that disease decreases due to its absence[12]
- "hard to access" populations (e.g. looked-after children, traveler communities, etc)[16,17]
- vaccination hesitancy[18] (defined as "the reluctance or refusal to vaccinate despite the availability of vaccines"[1(p.1)])
- opposition to vaccination on religious grounds (e.g. Orthodox Jewish populations)[19]
- non-religious anti-vaccination (or "anti-vaxx") sentiment.[20,21]

Every year, millions of children and young people attend hospital (secondary or tertiary medical care) as outpatients or inpatients.[22] Those who attend the pediatric emergency department (PED) for example, often do so with minor illnesses and injuries, which could be better managed elsewhere. Despite numerous initiatives to re-direct these children and young people, PED attendances continue to increase year-on-year.[23] In addition to their primary reason for attendance, children in hospital may have lower than average levels of health generally.[24] The increased use of hospitals has led to increases in waiting times over the past few years (the median waiting time in the emergency department (ED) in 2017 was two hours and 28 minutes, up from two hours and nine minutes in 2013).[25] Whilst many children and young people may have to wait whilst in hospital to see a healthcare professional, little has been done to use this waiting time to improve their health. Hospital settings, where patients have available time, may offer opportunities to deliver novel interventions to improve routine childhood vaccination uptake – this might include: motivational interviewing, referral to vaccination services, or immediate catch-up vaccination, amongst others. The concept of delivering an intervention based, for example, in the ED is not novel. In recent years, several studies have explored the effectiveness of a range of ED-based interventions (alcohol cessation, smoking cessation, improved follow-up care for asthma, mental health). However, the literature is weighted heavily towards interventions for adults. For example, D'Onofrio and Degutis[26] performed a systematic review of the medical literature to evaluate screening and brief intervention programs for alcohol-related problems in the ED. The study populations included in the review were diverse, with participants from inpatient and outpatients, and ages ranging from 12 to 70 years. They recommended that these be incorporated into routine clinical practice.

The routine vaccination schedule in the UK is offered in primary/community care, and the majority of interventions to improve vaccination uptake have been implemented in this setting.[27] Changes in the way patients engage with healthcare services indicates that alternative settings, such as secondary/tertiary care may also offer appropriate settings for the delivery of interventions such as routine vaccination. However, before we can explore the potential for hospitals to be used as settings for interventions – such as screening, brief intervention and referral to treatment – to increase vaccination, the existing evidence base must first be understood. National Institute for Health and Care Excellence (NICE) guidance recommends that research should explore the most effective ways of modifying services to increase vaccination among children and young people.[28] The same NICE guidance highlights gaps in the evidence including "a lack of UK evidence on the effectiveness and cost-effectiveness of different interventions aimed at increasing immunization uptake among children and young people aged under 19 years, particularly among those who may not have been immunized or only partially immunized."[2(p.1)] A scoping review will provide evidence towards assessing this issue by identifying novel

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interventions to improve routine childhood vaccination uptake delivered in secondary and tertiary care settings.

A preliminary search for existing scoping reviews or systematic reviews has been conducted using the *JBI Database of Systematic Reviews and Implementation Reports*, PROSPERO, and Cochrane Database of Systematic Reviews. No relevant systematic or scoping reviews were found. The objective of this scoping review is to identify and collate the available quantitative literature to identify and describe the interventions that are delivered in secondary and tertiary healthcare settings to improve vaccination uptake in children and young people. This protocol follows the JBI approach to the conduct of scoping reviews[29,30] by using the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist and guidelines.[31]

Review question

What are the interventions delivered in secondary or tertiary medical care settings focused on improving routine vaccination uptake in children and young people?

Inclusion criteria

Participants

Participants will include children and young people (aged less than 16 years) and/or their parents/carers (potentially interventions could be delivered to the child-parent/carer dyad) present in a secondary or tertiary care setting as either an inpatient, outpatient, or visitor. In the UK, an individual is legally a child until their 18th birthday;[32] however, in clinical practice, most young people will transition from pediatric services to adult services around the time of their 16th birthday.

Concept

This review will consider studies that explore interventions to improve routine vaccination uptake delivered in secondary or tertiary care settings. These interventions may include: motivational interviewing, referral to vaccination services, educational intervention or an immediate catch-up vaccination.

Context

The scoping review will include studies based in secondary and tertiary healthcare settings within any country.

Types of sources

This scoping review will consider quantitative study designs for inclusion. In addition, quantitative systematic reviews and meta-analyses will be considered for inclusion in the proposed scoping review. Articles published in English will be included. Articles published from 1989 to the present will be included. This cut-off coincides with significant changes to the NHS routine vaccination schedule (the inclusion of the MMR vaccine).

Methods

The proposed scoping review will be conducted in accordance with the JBI methodology.[30]

Search strategy

The search strategy will aim to locate both published and unpublished primary studies, reviews, and opinion papers. An initial limited search of MEDLINE was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles were used to develop a full search strategy for MEDLINE (see Appendix I). The search strategy, including all identified keywords and index terms, will be adapted for each included information source. The reference lists of articles selected for full text review will be screened for additional papers.

Information sources

Articles published since 1989 in English and indexed in MEDLINE, CINAHL, Cochrane Library, Embase, and Web of Science will be searched. Gray literature will be included through searches of The Healthcare Management Information Consortium (HMIC) Database (containing the UK Department of Health Library and King's Fund Library), and OpenSIGLE.

Study selection

Articles identified by the search, and considered to meet the inclusion criteria, will be collated and uploaded into EndNote X9.0 (Clarivate Analytics, PA, USA). Duplicates will be removed. Two reviewers will independently select articles matching the inclusion criteria, firstly based on their title, and then abstract. Articles identified through reference list searches will also be considered for inclusion

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based on their title. Discrepancies in reviewer selections will be resolved through discussion between reviewers prior to full-text retrieval of selected articles. Reasons for excluding full text studies will be documented and reported in the review. The results of the search will be reported in full in the final scoping review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses for Scoping Reviews (PRISMA-ScR) flow diagram.[31]

Data extraction

Data will be extracted from papers included in the scoping review by two independent reviewers using a data extraction tool developed by the reviewers. Data will be extracted using a draft data extraction tool based on JBI recommendations (Appendix II). The draft data extraction tool will be modified and revised as necessary during the process of extracting data from each included paper. Modifications will be detailed in the full scoping review. Two reviewers will independently read all articles retrieved through the search strategy; any that do not fit with the aims of the scoping review will be discussed and, if necessary, removed. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer. Authors of papers will be contacted to request missing or additional data, where required.

Data presentation

Study findings will be presented in tabular form detailing the interventions identified in the literature and the corresponding outcomes. If appropriate, a diagrammatic chart will be used to describe themes derived from the literature. Data will be presented alongside a narrative summary of the findings. Expert methodological advice and input will be sought if necessary.

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Appendix I: Search strategy

MEDLINE. Search date: September 2019

Search	Title/abstract	MeSH terms	Records retrieved
#1	vaccin* OR immuni*ation* OR shot OR inoculation OR jab	Vaccin* OR immuni*ation*	356,299
#2	intervention OR programme OR program OR strateg* OR campaign*	immunization programs OR Preventive health services OR health promotion OR Early Intervention	2,183,283
#3	secondary care OR tertiary care OR hospital* OR emergency	Secondary Care Centers OR Tertiary Care Centers OR Emergency Service, Hospital	192,456
#4	#1 AND #2 AND #3		1001
Limited to 1989, in English			

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Appendix II: Data extraction instrument

Scoping review details	
Scoping review title:	A scoping review of interventions delivered in secondary or tertiary medical care settings to improve routine vaccination uptake in children and young people.
Review objective/s:	To identify and synthesize the available quantitative evidence to produce a map of public health interventions to improve vaccination uptake in children and young people that are delivered in secondary and tertiary healthcare settings.
Review question/s:	What are the interventions delivered in secondary or tertiary medical care settings focused on improving routine vaccination uptake in children and young people?
Inclusion/exclusion criteria	
Population	Children and young people (aged less than 16 years)
Context	Interventions to improve routine vaccination uptake delivered in secondary or tertiary medical care settings.
Types of study	Quantitative
Study details and characteristics	
Study citation details (e.g. author/s, date, title, journal, volume, issue, pages)	
Study design	
Country	
Setting (e.g. secondary care, emergency department, inpatient ward)	
Participants (details e.g. age/sex, number)	
Population sub-group	
Vaccination target (e.g. measles/mumps/rubella, influenza, all)	
Details/results extracted from study (in relation to the concept of the scoping review)	
Intervention	
Outcome	
Cost effectiveness/effectiveness	
Acceptability to stakeholders	
Any differential effects	

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Aims Explore whether clinicians working in EDs address paediatric obesity, identify obstacles, and seek opinions on whether this can be improved.
Methods A survey was distributed to clinical staff seeing children in EDs through the PERUKI network. Data were analysed to identify current attitudes towards addressing obesity, obstacles, and ideas for improvement.
Results 693 responses were received from 57 sites. Current rates of addressing obesity are low. 127 (18.3%) respondents address it with nearly every/every patient. Paediatric/Paediatric Emergency Medicine (PEM) doctors are more likely than Non-paediatric/PEM doctors or Advanced Care/Emergency Nurse Practitioners. (AC/ENP) (25.6% v 12.3%, $\chi^2=20.26$, $p<0.0001$). Barriers included: lack of referral options (78.6%), time (77.8%), concern regarding negative responses (77.3%), obesity being a familial issue (61%) and lack of training (53.1%). 'Concern regarding negative responses' was the most commonly cited barrier for those from Non-Paediatric/PEM doctors (83.2%) and AC/ENP's (84.1%). 'Lack of training' was higher amongst Non-Paediatric/PEM doctors (63.9%) and AC/ENP's (71%). 'Concern regarding negative responses' was also highest in those working 0–5 yrs in ED (81.6%), whereas 'Lack of time' was the biggest barrier in those working over 10 years in ED. To improve addressing obesity within EDs clinicians requested support with diagnosis, easier referral pathways, training, and changes in ethos both within departments and at local and national levels.
Conclusions Like other healthcare professionals, ED clinicians currently face many barriers in addressing obesity with their patients. However, by addressing these at a local and national level, the majority of ED clinicians feel they can have a role in helping to address the paediatric obesity crisis.

G211 DESIGNING A CRITICAL CARE OUTREACH SERVICE – AN AUDIT AND NATIONAL SURVEY

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Critical Care outreach services for adults have been shown to reduce mortality. It has also been demonstrated consistently that review of step-down patients on the ward reduces readmission to ICU and is therefore cost effective. There is, however, no published evidence on the benefit or lack thereof of critical care outreach services for children.

The Bedside PEWS score has been found to predict critical deterioration with a median score of 8 in deteriorating patients on paediatric wards.

A review of recent serious incident investigations within our NHS Trust identified a common theme of 'failure to escalate care in the deteriorating patient.'
Aims With a view to designing a critical care outreach programme, we completed a national survey of all British paediatric intensive care units to discover what percentage of units have a funded service, and whether this is staffed by nurses or doctors. We then carried out a review of the last 1 year of 'internal collapse' admissions from the paediatric wards to PICU within 1 NHS Trust to assess the time of day that critical care admissions most commonly occurred, and to confirm that a BPEWS of 8 would predict deterioration in our population.
Method A telephone survey of all PICUs listed in the PICANET database. A case note review of the previous 1 year of admissions to PICU from wards within the same hospital. Recorded was time of admission, BPEWS score at admission, and maximum BPEWS in the 12 hours prior to admission.
Results Of the 27 PICUs listed in the database, 9 have funding for a critical care outreach service. In all apart from 1 this was a nurse led service.

The mean and median PEWS scores for the internal collapse patients were 8 at the time of admission, and a mean maximum of 9 during the previous 12 hours.

39% of admissions to PICU from paediatric wards occurred between 0800–1700 hrs, 45% between 1400–2200 hrs and 26% between 2200–0800 hrs.
Conclusion A third of PICUs had a dedicated critical care outreach service. A day-time only service would miss 25% of admissions. A BPEWS of less than 8 should be used as a trigger for review.

G212 FEASIBLITY AND ACCEPTABILITY PILOT OF A PUBLIC HEALTH INTERVENTION DELIVERED IN THE PAEDIATRIC EMERGENCY DEPARTMENT

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Aim Paediatric Emergency Departments (PEDs) are well-placed to deliver public health interventions. Whilst numerous studies describe the effectiveness of a range of ED-based interventions for adults, less has been done to assess interventions for Children and Young People (CYP).

Every year in England, millions of CYP attend hospital, often with relatively minor illnesses/injuries, which sometimes result in long waits – time that could be used to improve wider health and wellbeing.

This pilot study assessed the feasibility and acceptability of delivering a public health intervention in the PED of a busy district general hospital.
Methods Full prospective ethical approval was obtained. Participants were CYP and their carers attending a PED in England. An opportunistic sampling strategy was used, with a focus on recruiting those who had a wait whilst in the department.

The intervention was a consultation delivered by a public health specialist, based around the 'Screening, Brief Intervention, and Referral for Treatment' (SBIRT) model and focussed on: household smoking, vaccination status, dental health, and frequent attendance.

Quantitative outcome data (e.g. registering with dentist) were collected by phone at one week and then one, three, and six months post-enrolment (where indicated). Qualitative data came from engaging with participants and completion of a field diary by the public health specialist (primary researcher).
Results Thirty participants were recruited over the two-week pilot, with 50% of CYP participating in the consent process. Twenty participants (67%) triggered at least one screening question, with dental health and (household) smoking being the most common triggers.

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Four participants were lost to phone follow-up at one week and a further five were 'thanked and discharged' as they had not triggered any of the categories during screening. Of the remaining participants, five had taken action as a result of the study and others had plans, all relating to dental appointments. Follow-up is ongoing and due for completion in March 2020.

Conclusion The PED offers an underutilised opportunity to deliver public health interventions. Findings from this study will be used to refine the intervention before an assessment of its effectiveness is made, using an appropriate study design.

Acknowledgements This study was funded by a grant from the Sir Halley Stewart Trust.

G213 A NEW TECHNIQUE FOR ULTRASOUND-GUIDED CENTRAL VENOUS CATHETERIZATION IN PEDIATRICS (SYRINGE FREE APPROACH)

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Background Central line insertion, a very common and invaluable procedure in PICU has undergone a major improvement with the advent of ultrasound assistance. In the process of further refinement, literature shows a comparison of various techniques. For the aim of increasing the safety profile and decrease the time required for CVL insertion, a new technique has been introduced by the author. We tested this technique against the other techniques that have been used in tertiary PICU unit in KSA.

Methods We prospectively monitored all vascular access procedures guided by ultrasound from March 2018 to March 2019. All patients who underwent central line insertion were observed by an independent nurse recorder that was not involved in the procedure. The observer recorded the patient age, gender, weight and BMI, diagnosis, indication for insertion, blood pressure state, insertion time, size of the line, number of pricks and arterial punctures if happened

Results Central line was inserted in 141 out of 800 total admissions during the study period. The author applied Syringe-free technique in 16 patients while in 125 patients central line was inserted via transverse axis out of plane technique. For the syringe-free group: Mean age was 49 months. Mean weight was 13.6 kg and mean BMI WAS 15.2. The femoral vein was the selected site of insertion in 13 patients 81%. The mean time of insertion was 86 seconds with a mean of attempts was 1.1. For the transverse technique: Mean age was 39 months. Mean weight was 13.9 kg and mean BMI WAS 15.3.

Femoral vein was the selected site of insertion in 74 patients (59%). The mean time of insertion was 304 seconds with a mean number of attempts of 1.38.

Conclusion Syringe free technique is a safe procedure that can decrease the time of insertion by 400% and allow a continuous real time-US monitoring of the CVL insertion procedure.

G214 IMPLEMENTATION OF A CAMHS STICKER FOR IMPROVED DOCUMENTATION OF MENTAL HEALTH PATIENTS PRESENTING TO THE CHILDREN'S EMERGENCY DEPARTMENT

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Aims To devise and implement a new documentation sticker to be used by the CAMHS team (child and adolescent mental health services) in the Paediatric Emergency Department medical notes. To clearly document safety plans, diagnosis and follow up to the hospital and community teams co-caring for mental health patients.

Method Twenty sets of notes were taken at random from the year 2017–2018. The documentation of information in the notes, written by the CAMHS team, and quality of the discharge letter, written by the Emergency Department medical team, were assessed. The CAMHS sticker was introduced for the CAMHS team to use to document their assessment. Twenty sets of notes were assessed after the implementation of the CAMHS sticker.

Results There was improved documentation after the implementation of the CAMHS sticker in the notes. Specifically, the CAMHS team documentation of their assessment (Pre 40%: Post 85%), management plan (Pre 70%: Post 100%) and risk assessment (Pre 30%: Post 90%). The quality of the emergency department discharge letter also improved for diagnosis (Pre 90%: Post 95%) and risk assessment (Pre 30%: Post 70%). However, there was a fall in documentation in the management plan in the discharge letter (Pre 90%: Post 55%) for reasons unknown.

Conclusion The introduction of the CAMHS sticker has improved documentation and communication between clinical teams and primary care. This can be seen in all areas in the notes and discharge letter. However, documentation of the management plan in the discharge letter needs to be refined. It was also noted that the name, contact number, date and time of assessment by the CAMHS team could be improved. A new sticker has been designed to include these demographics in order for clearer handover between the CAMHS team and the emergency department.

The introduction and the positive effects the CAMHS sticker has had on the working relationship between the CAMHS team and the emergency department has been noted by the inpatient teams. The CAMHS sticker has now been revised by the inpatient teams in order for them to use for the mental health patients on the wards. A re-audit of the use of the stickers should be done at a later date to ensure compliance is improving as well as documentation.

G215 ECMO AND AUDIOLOGICAL FOLLOW UP IN CHILDREN

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Introduction Children who have been supported with extracorporeal membrane oxygenation (ECMO) require follow-up including neurodevelopmental screening and audiological

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