

Research Article

Revaccination of large GP cohort due to inappropriate immunisation: Lessons learnt from an incident in Ireland

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ABSTRACT

Background: In Ireland, 335 children were identified as having been inappropriately vaccinated by their medical practitioner over a 16 year period.

Aims: This revaccination exercise attempted to identify the cohort of children who had been inappropriately vaccinated in order to revaccinate them according to recommended national schedule.

Methods: Children who received any or all of their primary childhood immunisations from the medical practitioner were identified from relevant databases. A customised age appropriate revaccination schedule was devised and offered to each child

Results: Between August 31st, 2012 and September 19th, 2013, 225 identified children attended designated revaccination clinics. An additional 39 children were referred to their current medical practitioner of whom 31 attended for revaccination. In total, in excess of 80% of the invited cohort was re-vaccinated either completely or partially in the health service clinics or by their medical practitioner. This attendance and completion rate

was higher than anticipated and also higher than previously reported in revaccination exercises elsewhere. No child in this cohort was notified as having any of the relevant 11 vaccine preventable diseases. There were 41 (14.8%) adverse reactions recorded in those who had commenced vaccination. All were local reactions 35 children had painful red arms and 6 had more severe local reactions. The direct cost of this revaccination exercise was estimated at €230,000.

Conclusion: There was a high attendance rate at the revaccination clinics. The most challenging activity was accurately identifying the cohort for revaccination. A multifaceted approach including mandatory professional education for medical and nursing personnel involved in the delivery of immunisation, regular audit of immunisation practice and considerations of sanctions for non compliance with contractual requirements must be considered to ensure delivery of a high quality immunisation service in primary care.

Keywords: Revaccination, cohort, adverse reactions, cost, governance

What do we know

Large revaccination exercises are infrequent occurrences in clinical practice. Reported attendance rates at these clinics have been low. Adverse vaccine incidents are unique events and their management is usually based on expert opinion than evidence base. Consequently, a conservative approach to their management is usually followed.

What this paper adds

Our description of the processes involved in organising a large revaccination exercise with resultant high attendance rates provides a useful guide to practitioners for management of future events. In our report the low recorded number and minor nature of adverse reactions and may also reassure professionals and parents of the safety of revaccination. There is a need to ensure ongoing training for vaccinators in primary care especially as the number and schedules of vaccines provided to young children will become increasingly more complex.

Introduction

Immunisation is the single best preventive medical intervention to reduce mortality and morbidity from vaccine preventable diseases.¹ In Ireland, the Primary Childhood Immunisation Programme (PCIP) is delivered in general practice, on behalf of the Health Service Executive (HSE). By adhering to the principles for delivery of a safe effective service as set out in the Guidelines for Vaccinations in General Practice the primary vaccine uptake in Ireland are at the highest levels ever recorded at 96%.^{2,3} However, with the large number of healthcare professionals involved in delivering the vaccination programme and increasingly complex vaccination schedules, it is inevitable that vaccination errors will occur.⁴ When such errors occur, revaccination is frequently the action recommended. The prevalence and epidemiology of such revaccination exercises are unknown and the potential risks of revaccination ill-described.⁵ This paper presents a case report on such a revaccination exercise in a general practice setting.

In 2011, an investigation into a query from a service user on the immunisation practice of a general practitioner (GP) confirmed that childhood vaccines had been administered inappropriately. The relevant primary childhood immunisation schedule required that, in order to be adequately protected against specific diseases, babies were given two or three separate vaccines at each of five GP visits between 2-13 months of age. The vaccinations provided protection against eleven diseases - diphtheria, pertussis, tetanus, polio, haemophilus influenza (Hib), hepatitis B, measles, mumps & rubella (MMR), meningococcal C (MenC) and pneumococcal infection (PCV). In this event the GP offered parents a choice for their child to be vaccinated with either multiple vaccines mixed and administered into one syringe or separate vaccines in appropriate number of syringes. There were no records available to confirm which children had received mixed or separate vaccines. In addition, many of these vaccines were given in the gluteal area a site that is not recommended by the National Immunisation Advisory Committee (NIAC).¹

A HSE investigation committee investigated this incident. The vaccine manufacturers stated they could not confirm the effectiveness of these vaccines when administered as described. The NIAC recommended that age appropriate revaccination should be offered to children who may have been incorrectly vaccinated by this GP. The relevant cohort was identified as all children who had received vaccinations while this GP participated in the PCIP. In June 2012, a multidisciplinary implementation committee was established to progress this recommendation.

Methods

This GP had been providing childhood vaccines as part of the PCIP between the years 1995-2011. As the seven primary childhood immunisation schedule in place since 1995 all recommended two or more vaccines per visit, and it was not

recorded which children had received vaccines that had been incorrectly mixed, all childhood vaccines given by the GP were considered invalid. Consequently, all children immunised with childhood vaccines by the GP over a 16 year period needed to be revaccinated. Annual influenza, pneumococcal polysaccharide vaccinations (PPV) and travel vaccinations were excluded from this revaccination exercise.

In Ireland there is no national immunisation information system and records are stored on multiple immunisation databases. Children who required revaccination were identified from the child health immunisation system (CHIS) which recorded names, addresses, dates of birth and primary vaccination history. The current addresses of children were confirmed with INFOSYS, a Department of Social Welfare database of client information. This list of children was also crosschecked with the school vaccination database to validate any additional vaccines received. Subsequently, this cohort of names was crosschecked with the General Registrar's Office death registration data to ensure that none of the identified children were deceased. All names were also checked with the computerised infectious disease notification system (CIDR) to determine if any child had been notified with a vaccine preventable disease (VPD) that could have been prevented by appropriate vaccination.

As this cohort of children ranged in age from 1-18 years a customised age appropriate revaccination schedule was devised for each child based on (a) whether they had received some or all of their vaccines from this GP, (b) their age and (c) participation in the school vaccination programme. Four core age appropriate schedules were devised for children based on key age groups: < 2 years, 2 <5 years, 5 <10 years and >=10years. These schedules were then colour coded for ease of use in the clinic setting. All schedules were developed independently by two consultants in public health medicine (CPHM) and crossed checked for concordance. When parents brought valid written documentation to the clinic (i.e. date, name of vaccine & batch number) and evidence that vaccines had been given by another named GP their revaccination schedule was appropriately amended. A formal training session was developed and delivered by a CPHM for administrative, medical and nursing staff involved in the revaccination clinics. These sessions explained revaccination schedules, likely queries from parents and the appropriate reconstitution and administration of vaccines.

In August 2012, letters were sent to parents explaining that an error had occurred that may have affected the vaccines that had been given to their children. An immunisation question and answer (Q&A) sheet was developed for parents outlining the reason for revaccination. A press statement was prepared and the Director of Public Health was nominated as lead spokesperson for subsequent media queries. A letter was also sent to all GPs in Ireland, informing them of the incident and of the revaccination exercise and referencing national documentation previously distributed to all GPs which detailed

the correct procedure for reconstituting and administering vaccines to patients.

To maximise convenience for parents a central clinic within the GP practice area was chosen as the most appropriate site for revaccination clinics. This facility was selected due to the availability of multiple consulting rooms, reception, recovery area and waiting areas. Parents were invited to make an appointment to revaccinate their child and requested to bring their child's vaccination records to the clinics. Each clinic was staffed by senior medical officers, public health nurses and administrative staff. Initially 15 minute appointments were given for the clinic but due to the complexity and individual nature of these consultations this appointment time was subsequently extended to 30 minute per patient. Clinics were held during holiday periods and at weekends so that parents were not unduly inconvenienced. A specific consent form was developed for this revaccination exercise. Those 16 years and older were able to provide their own consent. Defaulters from clinics were given an appointment for the next available clinic. A dedicated free phone helpline staffed by trained administrative staff was set up during working hours to answer parents' queries. A Q&A sheet was developed to allow administrative staff to answer expected queries. Specific queries that could not be answered by the helpline staff were forwarded to the medical members of the implementation team.

As local adverse events were considered possible after revaccination an information sheet on the management of adverse events was also developed for parents. A questionnaire administered by medical staff at the clinic was developed to document the number of local and systemic reactions to revaccination. From checking the GP cohort it became apparent that a small number of children had moved considerable

distances from the GP practice area so the option of attending their current GP for revaccination was facilitated. These GPs were provided with an explanatory letter and a revaccination schedule developed for their patient and advised to contact named medical staff if further discussion was required.

In August 2011, the immunisation contract between the GP and the HSE was discontinued. The estimated costs of this revaccination exercise were calculated based on the price of vaccines administered. In addition, direct staff costs were calculated based on hours accumulated by attendance at implementation meetings, training session and clinics by medical, nursing and administrative personnel. This information was obtained from the line manager of relevant personnel.

Results

In total, 335 children from 240 families were invited for revaccination. None of these children were notified as having a relevant vaccine preventable disease. Of those invited for revaccination 240 (71.6%) children attended thirteen clinics which were held during school holidays and at weekends between August 31st, 2012 and September 19th, 2013. An additional 39 (11.6%) children were referred to their current GP for revaccination. Of these 31(9.3%) attended for revaccination. Only 8 (2.4%) children refused vaccination and 48 (14.3%) children could not be contacted (Table 1). Over two-thirds of invitees completed their revaccination schedule and an additional 46 (13.7%) partially completed their schedule. Of the cohort invited 77 (30%) were less than five years, 173 (51.6%) were between 5<10 years and 85 (25.4%) were 10 years or older.

Of the 271 children who commenced revaccination there were 41(15.1%) reported adverse reactions. All were local

Table 1: Outcome of invitation for revaccination at HSE and GP clinics Dublin, 2013.

Attendance for revaccination	Total Number (%)	Number (%)
Invited for revaccination	335 (100)	
Completed revaccination	225 (67.2)	
by HSE clinic		210 (62.7)
by GP		15 (4.5)
Commenced revaccination	46 (13.7)	
by HSE staff		30 (8.9)
by GP		16 (4.8)
Planned vaccination by GP*	8 (2.4)	
Refused revaccination	8 (2.4)	
Unable to contact clients	48(14.3)	
returned letters		3 (0.9)
moved out of country		4 (1.2)
no response to two letters		41 (12.2)

reactions and 35 were primarily injection site swelling and redness. However, six children had more severe local reactions after the first dose of 6 in 1 vaccine which protects against diphtheria, hepatitis B, Hib, pertussis, polio and tetanus. Four children did not complete their recommended revaccination schedule due to these more severe local reactions. No child was hospitalised as a result of revaccination.

Forty phone calls from parents were referred by administrative staff for a medical response. These queries focused on (1) reason revaccination was required (2) availability and legitimacy of blood tests to check immunity and (3) requests for specific information on the vaccination error. Vaccines for revaccination cost €26,300. Direct staffing costs were estimated at €200,000.

Discussion

A GP cohort had to be informed that they may not be protected by the vaccines they received due to reported incorrect procedures used in the vaccine administration. A group of independent national experts determined that it was not possible to confirm that the vaccines given were effective and also as the vaccine manufacturers could not confirm the effectiveness of these vaccines, revaccination of the entire cohort was the recommended action. This revaccination recommendation was largely based on expert opinion rather than evidence based information. However, more recent experience of vaccine programme errors have suggested that such a conservative approach may not always be the only choice available and the option of providing additional boosters, rather than a complete vaccine course should be considered.⁴

In order to avoid having their children revaccinated many parents queried the use of blood tests to check vaccine efficacy. Expert national opinion suggested that this option was unlikely to be helpful as there was a dearth of data on the serological levels needed for long term protection against these vaccine preventable diseases.⁶⁻⁸ Also, if parents pursued this option privately their child would initially have to have phlebotomy, wait for numerous results, and then if non immune attend for vaccination with a resultant delay in the revaccination process. The attendance and completion rate at the revaccination clinics was considerably better than anticipated and also higher than previously reported in revaccination exercises elsewhere.⁴ This high attendance rate was likely facilitated by the clinic site which was geographically convenient and accessible at times that suited the majority of parents. In addition, the high completion rate for revaccination was likely enabled by efficient, professional and informed staff who were familiar with the complex immunisation schedules used at the clinics and open to answering parents queries. While we did not actively seek client feedback on the service provided we believe that the high attendance and completion rate for vaccination schedules indicated a high level of satisfaction with this revaccination exercise.

All the children in this cohort had received diphtheria,

tetanus and pertussis (DTP) vaccines as part of their primary vaccination schedule. As the incidence of adverse local reactions to DTP vaccines is known to increase with further doses our documented adverse reactions were not unexpected and have been reported previously.⁸⁻¹⁰ We believe that our reported incidence of adverse events is an accurate reflection of such reactions as parents were informed by medical staff of their likelihood and also were questioned on their occurrence at subsequent clinic visits. Given the good safety profile of vaccines this report and other studies provides assurance that an increased rate of adverse events did not occur as a result of revaccination.^{4,11}

A considerable amount of time, money and manpower was spent tracking down children who had received vaccine inappropriately. This additional workload put considerable demands on already stretched resources and resulted in significant opportunity costs as staff involved in revaccination clinics had to defer their regular immunisation activities. The availability of a national immunisation register as in other countries such as Australia and New Zealand would have considerably reduced the workload involved in identifying this cohort of patients.¹²⁻¹⁴ The development and availability of such a register in Ireland must be a priority for the health service in order to accurately access information on the immunisation status of children.

To date relatively few published studies have addressed the challenges of vaccine management and administration in primary care. This incident is the first such incident reported in Ireland. However, a recent German study among primary care physicians reported that only 19% of practices had good vaccination management.¹⁵ Correct vaccine preparation and administration are detailed in the Immunisation Guidelines for Ireland and the Product Information Leaflets packaged with all vaccines.² The decision to revaccinate this cohort of children was based on a risk assessment that had to balance the risk of being exposed to vaccine preventable diseases versus the risk of an adverse vaccine reaction. This revaccination process has not resulted in any discernible reputational damage to the national immunisation programme. Uptake levels nationally and in the area where this incident occurred are at the highest level ever recorded.³ That there has been no discernible impact on the PCIP is likely due to a combination of factors including, the professional multidisciplinary nature of the revaccination team, honest and transparent communication with parents and professionals, clinics open at times convenient for parents and staffed by skilled specifically trained medical professionals who were able to spend time with parents and answer their queries.

In view of increasingly complex immunisation schedules the governance of the primary care immunisation programme must be optimum to ensure that a quality safe service is delivered. The contract for providing PCIP stipulates an expectation, not an obligation, of participation in continuing medical education (CME) to maintain and update knowledge

on immunisation issues. Adverse events occur not infrequently in general practice and it is estimated that 70% of such errors could be attributed to failures in the processes of health care and 30% to failure of individual general practitioners knowledge and skills.¹⁶ The error described resulted from mistakes in vaccine preparation and administration that could have been avoided by adherence to National Guidelines.^{1,2} However, strategies that rely on guidelines alone have not been proven to be effective among GPs.¹⁶ Among the options that need to be considered to reduce the likelihood of a similar incident as described recurring are mandatory CME for medical and nursing personnel involved in the delivery of immunisation, regular audit of immunisation practice and considerations of sanctions for non-compliance with contractual requirements. However, relying exclusively on these top-down mechanisms may not suffice. Strict adherence to the widely used practical nursing mnemonic known as the “5 rights” which states that the right vaccine should be delivered to the right patient in the right dose by the right route at the right time should ensure the goal of safe vaccination.¹⁷ In order to assure a high quality service the physician should, ideally, be involved in vaccine selection and administration.⁽¹⁵⁾ However, additional interventions such as the involvement of the patient/parent in the vaccination verification process and establishment of individual practice protocols for frequently administered vaccines should also be considered.^{15,18}

Conclusion

Well organised convenient revaccination clinics staffed by informed multidisciplinary personnel resulted in high attendance rates for revaccination. Revaccination did not result in an excessive risk of local reactions and the major obstacle to this process was accurately identifying the cohort for revaccination. Our experience of organising this revaccination should be useful should similar events occur in the future even if a less conservative approach is taken than revaccination of the complete cohort. As primary vaccination involves the administration of complex expensive schedules to healthy children the governance of this process needs to be optimum at practice and policy level to ensure that a high quality safe service is delivered.

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CONFLICTING INTEREST

All named authors work for the HSE and have no conflicting interests.

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