

Research paper

Immunisation errors reported to a vaccine advice service: intelligence to improve practice

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ABSTRACT

Background The success of immunisation programmes depends on the quality with which they are administered. The Vaccine Advice for Clinicians Service (VACCSline) is an advice service to support immunisers and promote excellence in immunisation practice, through specialist guidance and local education, covering a catchment population of two million people. All enquiries are recorded onto a database and categorised. Vaccine error is selected when a vaccine has not been prepared or administered according to national recommendations or relevant expert guidance.

Method All enquiries from 2009 to 2011, categorised on the VACCSline database as 'vaccine error' were analysed and subjected to a detailed free-text review.

Results Of 4301 enquiries, 158 (3.7%) concerned vaccine errors. The greatest frequency of errors, 145 (92.9%) concerned immunisations delivered in primary care services; 92% of all errors occurred

during either vaccine selection and preparation or history checking and scheduling. Administration of the wrong vaccine was the most frequent error recorded in 33.3% of reports. A shared first letter of the vaccine name was noted to occur in 13 error reports in which the incorrect vaccine was inadvertently administered. Consultations involving pairs of siblings were associated with various errors in seven enquiries. Failure to revaccinate after spillage (seven reports) showed a widespread knowledge gap in this area.

Conclusion Advice line enquiries provide intelligence to alert immunisers to the errors that are commonly reported and may serve to highlight processes that predispose to errors, thus informing immuniser training and updating.

Keywords: medication errors, quality assurance (healthcare), vaccination

How this fits in with quality in primary care

What do we know?

Immunisation programmes rely on a skilled workforce to deliver vaccines across different groups of the population. In the UK, immunisation programmes are largely delivered through primary care services. Errors can occur during the scheduling, preparation and administration of vaccinations, affecting the quality of the immunisation programme. Vaccine errors are not usually collated across clinicians to identify common features and approaches to reduce the risk of error.

What does this paper add?

Our data and analysis provide a contemporary overview of the nature of errors reported to a vaccine advice service from a large catchment population. Most errors would have been prevented if basic medicine management checks were undertaken. This paper highlights specific issues such as the association of error with multipatient consultations and with confusion between vaccine names sharing the same first letter. An aide-memoire based on intelligence gained from our data and other published literature is included to support immunisers in practice.

Introduction

Vaccination programmes seek high immunisation coverage across populations. The success of these programmes in protecting individuals and society depends on a number of factors, including the quality with which they are administered. From April 2013, an unprecedented number of new and catch-up immunisation programmes have been introduced in the United Kingdom (UK), largely delivered in general practice.

As with all medicines administration, vaccination errors are known to occur. The World Health Organization (WHO) recognises preventable immunisation errors as contributing to adverse events following immunisation (AEFI).¹ Given that vaccination is so extensive and actively promoted by health services to the population, there is a particular argument for excellence and avoidance of error in this healthcare activity. Population immunisation programmes rely on effective systems and a workforce of highly skilled immunisers able to meet the demands of complex immunisation schedules.

In 2007, 9% (71 612) of all reported incidents to the National Patient Safety Agency (NPSA) in England and Wales were medication errors, with 1% (949) of these being vaccination incidents involving children.² The Vaccine Information Service (VIS) run by Aventis Pasteur MSD UK Ltd (APMSD), supporting immunisers using APMSD vaccines, prospectively recorded enquiries regarding inadvertent administration of vaccines.³ Of the 124 010 enquiries VIS received, 302 (0.2%) were vaccine errors, with just over half (53.2%) involving children. The incidence of reported adverse reactions associated with inadvertent vaccine administration was low, with just six cases reported to VIS.

Other researchers have studied paediatric vaccine errors; either by analysing non-mandatory reporting databases^{4–6} or by identifying unreported errors from children's medical records.^{7–9} It is not possible to estimate the incidence of errors from reported error data because the denominator and completeness of reporting are not known. However, in the papers that systematically reviewed immunisation records, errors are reported to have occurred in 27–35% of all immunisations administered.^{7–9} Vaccine error data beyond the age of 18 years are not reported in the literature. The prevention of avoidable vaccination error remains essential for patient safety and to maintain confidence in vaccination programmes.

In this study, all errors reported over three years from a population-based immunisation advice service, Vaccine Advice for Clinicians Service (VACCsline), have been reviewed to describe the type of errors that are identified and reported and to identify recurrent themes or underlying factors amenable to intervention to reduce future errors. Understanding the type of vaccine errors occurring, when they occur and factors associated with errors, may help inform education, training and policy to reduce the risk of error.

Methods

Population and setting

VACCsline is an advice service provided jointly by Thames Valley Public Health England Centre and the Oxford Vaccine Group at the University of Oxford. A small team of specialist advisors, supported by local academic and clinical specialists, offer independent clinical advice to any healthcare professional who

administers immunisations or advises patients on immunisation in the Thames Valley area; covering a population of approximately two million residents. Education is integrated in the response to individual enquiries. This specialist team also delivers a range of training activities across the Thames Valley, in part guided by intelligence gained from analysis of enquiries. VACCsline is not part of line management or performance management arrangements for front-line immunisation staff in the region.

Source of data

All enquiries to VACCsline are entered onto a database. During data entry by the immunisation advisor, enquiries are classified using a predefined set of categories for the type of enquiry (including vaccine error), the vaccine or vaccines involved, the patient age group, a contemporaneous free text record of the enquiry itself and the advice given, and the professional discipline of the enquirer. The vaccine error category is used when a vaccine has not been prepared or administered according to national recommendations or relevant expert guidance. This excludes enquiries about maintaining the vaccine cold chain, which are recorded as a separate category.

All enquiries recorded on the VACCsline database from 2009 to 2011 ($n = 4301$) were extracted to Excel and sorted by enquiry type to identify those categorised as vaccine error. Enquiries relating to vaccine error were tabulated for the main fields to describe the overall pattern of errors. Individual enquiries were opened in the VACCsline database and reviewed by an immunisation advisor familiar with the database (SL). This review included reading the free text recorded the enquiry and response given. Codes to classify for both the nature of each error and the type of course of immunisation involved were created responsively during this review. This type of emergent coding aims that the data informs the codes rather than the data fit pre-defined codes.¹⁰ The codes created are presented on the axes of Table 1.

Results

Of the 4301 enquiries, 158 (3.7%) were recorded as vaccine errors. Three enquiries were about the same incident and were therefore combined, leaving 156 reported errors over the three years studied.

The greatest frequency of errors, 145 (92.9%), concerned immunisations delivered in primary care settings. Enquiries were received from 121 (83.4%) practice nurses, 13 (8.9%) general practitioners (GPs), eight (5.5%) other primary healthcare team staff and

three parents. The remainder of contacts concerned errors occurring in community health services (8; 5.0%) and one enquiry from secondary care.

Errors occurring during selection/preparation of vaccine ($n = 80$, 51%) and assessing the patients' history and/or schedule ($n = 64$, 41%), together comprised 92% of reported errors. Those relating to the actual physical administration of vaccines ($n = 8$, 5.0%) were reported less frequently and were dominated by vaccine spillage (see below for further details). Errors involving vaccine selection or preparation included selection of the wrong vaccine; the wrong dose; or vaccine that had expired, suggesting gaps in basic medicines management procedures. Errors relating to assessment of immunisation schedule and history resulted in extra doses, shortened intervals, missed doses and administration of vaccines that were contraindicated.

The frequencies of errors by type and immunisation course are presented in Table 1. In total, 65.3% of all errors were reported to have occurred in children under the age of five years. The main types of error, and identified contributing factors, are summarised below. No enquiry identified patient harm as a consequence of the errors reported.

Wrong vaccine ($n = 52$; 33.3%)

In 13 (25%) of these reports, the incorrectly administered vaccine contained a name beginning with the same letter as the intended vaccine. Five related to vaccines beginning with P – Pediacel® (TDaP/IPV/Hib), Prevenar® (PCV13) and Pneumovax® (PPV) – and four to confusing Repevax® (TDaP-IPV) and Revaxis (Td-IPV). Errors in vaccines beginning with the letter P were not restricted to the disease type of vaccine being given, such as between pneumococcal vaccines. In one case, the infant vaccine Pediacel® (TDaP/IPV/Hib) was administered to an over 65-year-old scheduled to receive Pneumovax® (PPV). Less commonly, various forms of hepatitis A- and B-containing vaccines were confused ($n = 3$) and measles, mumps and rubella (MMR) and meningitis C were confused in one reported case.

Thirteen reports (25%) related to mistakes involving the Hib/MenC vaccine, trade name Menitorix®. Hib/MenC vaccine was either given in error instead of the correct vaccine (11) or the reverse (2). In 10 of these 13 reports, the Hib/MenC vaccine was confused with a MenC vaccine, whose trade names all begin with M except one (Menjugate®, Meningitec® or NeisVac®).

The wrong tetanus-containing vaccine accounted for seven reported errors. The errors included all the tetanus-containing vaccines available at the time.

Table 1 Frequency of errors by type and immunisation course (*n* = 158)

Error type <i>n</i> (%)										
Course	Total	Wrong vaccine	Additional dose	Shortened intervals	Incorrect dose	Expired vaccine	Spillage	Contra-indication	Recording error	Other
Primary		52 (33.3)	30 (19.2)	28 (18)	17 (10.8)	9 (5.8)	7 (4.5)	4 (2.5)	3 (1.8)	6 (3.8)
	44 (28.2)	18	4	16		1	3		2	
	20 (12.8)	10	5			1	2		1	1
Pre-school booster	22 (14.1)	6	10	3		1	1			1
School leaver booster	2 (1.2)		1							1
HPV	7 (4.5)	3	1	3						
Child non-travel	21 (13.5)	3	5	1	7	1		2		2
Child travel	11 (7.1)		1	4	6					
Child not specified	6 (3.8)	2				2	1			1
Adult non-travel	17 (10.9)	7	3	1	2	2		2		
Adult travel	5 (3.1)	3			1	1				
Adult not specified	1 (0.6)				1					

In five of the enquiries regarding the wrong vaccine being given, enquirers had identified the presence of another sibling, also presenting for vaccination, as contributing to the error. On two of these occasions, both siblings received the wrong vaccine.

Additional dose or doses of vaccine ($n = 30$; 19.2%)

Nine related to preschool booster doses of MMR and Tdap-IPV ($n = 5$) or MMR alone ($n = 4$) and five to Hib/MenC vaccines.

Incorrect dose ($n = 17$; 10.8%)

A higher than indicated dose of vaccine accounted for 13 errors, with 11 reports of adult vaccine doses incorrectly administered to children. These involved hepatitis A, hepatitis B or pandemic influenza vaccines. In two of these, the presence of other siblings at the vaccination was judged by the enquirer to have contributed to the error. One error involved over 50 children being administered the adult dose of adjuvanted H1N1 pandemic influenza vaccine (H1N1 vaccine; Pandemrix).

Shortened interval ($n = 28$; 18%)

Errors due to shortened intervals related mostly to the primary course in infancy, where the standard interval between doses of vaccine in the UK primary schedule is 28 days. Ten errors concerned the interval between the first and second doses of Tdap/IPV/Hib (Pediace®), with reported intervals ranging from 14 to 26 days. Although recorded as an error on the VACCsline database, only five required re-vaccination as the vaccine had been given at an interval of less than 21 days.

In England, 21 days is considered to be the minimum acceptable interval between doses of Tdap/IPV/Hib (Pediace®).¹¹ A further six errors concerned the interval between the second and third doses of Tdap/IPV/Hib with intervals, ranging from one to three weeks.

Three errors were reported when the pre-school Tdap/IPV or Tdap/IPV was administered around two years of age.

Vaccine spillage ($n = 7$; 4.5%)

The corrective action of repeating the dose at the same visit was not taken for any of the seven cases of vaccine spillage. On one occasion, a patient had been advised to come back for another half dose of the vaccine. Reported factors contributing to the vaccine spillage were that the child being vaccinated moved ($n = 4$) and a needle and syringe came apart ($n = 1$).

Contraindication/precaution ($n = 4$; 2.5%)

MMR vaccine was administered to an immunosuppressed individual and to a pregnant woman, who received two doses. Two children were given an influenza vaccine that was not indicated for children (due to the increased risk of febrile convulsions).

Discussion

The data presented here are from VACCsline, a local specialist advice service by staff often known to service users through immunisation training. The immunisation advisors are independent of line management or institutional performance management responsibilities for the parallel process of incident investigation. This localised approach may encourage immunisers to use the advice service, reducing some barriers to error reporting that may exist.¹² Although advising that those reporting errors undertake incident reviews in line with their organisational policies, VACCsline are not usually part of this process and may be unaware of underlying factors identified in such reviews.

Avoiding errors

The NPSA made systematic recommendations that patients records should be checked more carefully prior to vaccination and record keeping improved.¹ A review of a large number of vaccine errors recorded in the US Vaccine Adverse Event Reporting System (VAERS) database concluded that most errors could be avoided by increasing attention to detail.¹³ The data reported here support these findings and suggest that by being careful and checking thoroughly, vaccine errors could be reduced substantially. Bundy *et al* suggest that because vaccine errors are largely predictable they can be prevented and has proposed the '5 rights' of medicine administration to analyse reported vaccine error (right vaccine, time, dose, route and patient).⁶ Whilst attractive as a method of reducing vaccine error, and providing more support than a generic 'check things carefully' exhortation, its approach to medicines administration may not capture some of the complexities that exist in an immunisation clinic or appointment, and does not identify which actions are needed to ensure that these rights are achieved. Table 2 presents a summary of information based on the five rights approach, but expanding it to incorporate the findings of this study on vaccine errors. This is designed to serve as a practical aide-memoire providing both a checklist and

Table 2 A practical checklist and rationale, to reduce vaccine errors

Information checklist <ol style="list-style-type: none">1. Check patient ID2. What vaccine/s are they attending for?3. Confirm by checking records4. Identify vaccines to give today5. Check any contraindications and precautions	Potential information errors <ol style="list-style-type: none">1. Sibling confusion2. Check both handheld and electronic records3. Avoid additional doses of vaccines being given4. Vaccines given at wrong time of schedule5. Is the vaccine safe for that individual?
Preparation checklist <ol style="list-style-type: none">1. Select correct vaccine/s from fridge2. Check expiry date3. Check condition of product4. Check dose5. Prepare according to SmPC	Potential preparation errors <ol style="list-style-type: none">1. Other vaccine names that sound/look alike2. Expired vaccines3. Vaccine should match description on SmPC4. Age-related vaccine doses5. Re-constitute all parts of vaccine
Administration checklist <ol style="list-style-type: none">1. Re-check is this the correct patient/vaccine?2. Re-check is this the right vaccine?3. Is this the correct site for this vaccine?4. Administer using correct route (IM/SC/oral)5. Immediate disposal of sharp/syringe into sharps bin6. Record vaccines in hand held notes/computer	Administration errors <ol style="list-style-type: none">1. Confusing patients2. Administering wrong vaccine/at the wrong time3. Injected and oral vaccines in use4. Child being well held/patient safely seated Ensure syringe and needle are firmly attached5. Avoid needlestick injury or re-using syringe6. Accurate record keeping, timely returns to CHIS

brief rationale for reducing this type of vaccine error in practice.

First letter confusion

Although many errors may be reduced by attention to detail and checking, other interventions may also reduce errors. Errors involving the administration of the wrong vaccine were reported at a similar frequency to those in an NPSA study,¹ but higher than in the APMSD study from the late 1990s.³

For many years, confusion has been reported between different tetanus containing vaccines^{3,4} and was identified again in this study. Similar sounding vaccine names have also been identified previously as contributing to vaccine errors,^{4,6} but there is no reference to vaccine name first letter errors in the literature, which was a striking pattern in this study. The data from these other papers are limited to classifying vaccines by disease of protection, e.g. pneumococcal vaccines and analysis of brand names was not undertaken. Our analysis identified vaccines for different diseases being confused, such as the pneumococcal vaccine, Pneumovax®, with the infant vaccine, Pediacel®, and MMR vaccine with Meningitis C vaccine. A larger dataset would allow quantitative testing of the hypothesis suggested by our data that shared first letter of vaccine names might contribute substantially to vaccine errors. As well as providing

further evidence to flag this risk to immunisers for their particular attention, a larger scale quantitative analysis may provide more convincing evidence to vaccine manufacturers who could review their naming strategies for future vaccines. Even on current evidence they might seek to avoid naming new vaccines with names that are similar to pre-existing ones, or using first letters for the vaccine name that are already in heavy use, such as P, R, H and M.

Stock storage systems

The frequency of vaccine name confusion, dose errors in which adult preparations are given to children, and our data confirming the well-recognised problem with out-of-date vaccines being given, highlight stock storage and handling as important in error reduction. In the USA, the CDC’s Vaccine Storage and Handling Toolkit endorses the pragmatic approach of separating adult and paediatric vaccines at the point of storage in order to minimise the risk of errors. In addition to this, those used in both age groups could be stored separately with a warning to check for age appropriate dose. Based on the observations of possible first letter effects, an alphabetically ordered fridge would be considered inadvisable.

Knowledge

Some of the errors reported to VACCsline, such as the administration of the adult dose of Pandemrix® to 50 children and a pregnant woman vaccinated with a two-dose schedule of MMR, suggest that errors of selection and administration may not be related to temporary inattention to detail alone but to a gap in practitioner knowledge. Such knowledge gaps may be a particular risk for new vaccine programmes or schedule changes. As well as the errors associated with the then-novel vaccine Pandemrix®, two other errors occurred when an influenza vaccine recently identified as increasing the risk of febrile convulsion in children was administered despite this precaution being highlighted in national alerts. The lack of appropriate immediate corrective action in any of the seven separate instances of vaccine spillage is also suggestive of a gap in knowledge and possibly clinical skills among some immunisers.

These results therefore highlight the intelligence that can be gained from reported errors to guide training and other forms of immuniser updates with a view to reducing future error. The errors identified here have been successfully included in training scenarios to facilitate conversations with learners about errors that can occur and how they should be addressed and avoided.

Multiple patient consultations

Bundy *et al* found that of all wrong patient errors, 44% (11) were associated with confusion between siblings, i.e. the vaccine intended for one child was given to its sibling.⁶ The presence of siblings during multiple patient consultations was reported as an underlying factor in seven of the errors in the VACCsline study. Although partially echoing the findings of Bundy *et al*, the type of error involved ranged beyond sibling confusion and included children receiving adult doses in this setting. This raises the challenges of safely managing multiple patient consultations for immunisation; it is not always practical in clinical situations to reduce those present in the room during consultations. When conducting multiple patient consultations, immunisers should be mindful of the particular risks associated with this and consider the aide-memoire in Table 2 to guide how they structure appointments per individual patient to minimise risk.

Patient safety

None of the errors reported in this study was identified as leading to resultant patient harm. One of the limitations of the system is that minor adverse events associated with errors may have been missed: for example, an increased rate of transient local or sys-

temic reactions among the 50 children who received an adult dose of the relatively reactogenic vaccine Pandemrix seems possible but would have been difficult to detect. Analysis of the APMsD database identified adverse events in six of the 302 errors reported and with symptoms in one of these persisting for more than 24 hours.³ This and other studies give reassurance that substantial harm does not appear to occur as a result of vaccine errors, in line with expectations, given the good safety profile of vaccines.

Limitations

In the current NHS structure, immunisers who wish to seek advice about a vaccine error may call a range of persons and institutions for advice. No dataset on vaccine errors will ever be complete and the types of errors reported to each may vary producing bias in any single source. An even greater gap in intelligence may be produced by errors that are not reported, and indeed not ever recognised as errors.

Conclusions

Given the underlying motivation to improve quality and patient safety in immunisation, there is also a need to ensure that interventions in response to reported errors are evidence based. Although there are many published recommendations for reducing medication errors, they are largely based on expert opinion rather than an empirical evidence base.¹⁴ In our recommendations above, we also extrapolate from the evidence of factors contributing to errors to interventions that we consider sensible, but without an empirical evidence base. The large-scale programmatic approach to immunisation in many countries could support trial-based evaluation of some interventions suggested from intelligence gained from error reports or other sources. This would allow more formal quantitative testing of hypotheses such as the role of shared first letters in names in contributing to vaccine error. A consistent approach to data collection and analysis for reported errors could contribute to the evaluation of interventions, and could provide a framework for evaluation of interventions randomised by area. The software and protocols used in the VACCsline service are available without cost to those wishing to use the approaches and tools developed for the service.

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ETHICAL APPROVAL

This study did not require ethics approval.

PEER REVIEW

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CONFLICTS OF INTEREST

AJP acts as chief and principal investigator for clinical studies conducted on behalf of the University of Oxford, some of which are funded by vaccine manufacturers. AJP does not receive any personal financial support from vaccine manufacturers. Unrestricted educational grants for organisation of conferences and seminars from vaccine manufacturers are paid to the University of Oxford. SL has received personal payments from vaccine manufacturers for provision of travel health training and attendance at advisory group meetings.

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