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Pediatric vaccination errors: Application of the "5 Rights" framework to a national error reporting database

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ABSTRACT

Little is known about vaccination errors. We analyzed 607 outpatient pediatric vaccination error reports from MEDMARX, a nationwide, voluntary medication error reporting system, occurring from 2003 to 2006. We used the "5 Rights" framework (right vaccine, time, dose, route, and patient) to determine whether vaccination error types were predictable. We found that "wrong vaccine" errors were more common among look-alike/sound-alike groups than among vaccines with no look-alike/sound-alike group. Scheduled vaccines were more often involved in "wrong time" errors than seasonal and intermittent vaccines. "Wrong dose" errors were more common for vaccines whose dose is weight-based and age-based than for vaccines whose dose is uniform. "Wrong route" and "wrong patient" errors were rare. In this largest-ever analysis of pediatric vaccination errors, error types were associated with predictable vaccine-related human factors challenges. Efforts to reduce pediatric vaccination errors should focus on these human factors.

1. Introduction

Vaccines are one of the great public health achievements of the 20th century [1] and the most valuable clinical preventive service provided to children [2]. Vaccines have substantially reduced the morbidity and mortality of target infections [3], and vaccination rates for young children in the United States are near record levels [4]. Though considerable recent attention has focused on the safety of childhood vaccines, almost no attention has been given to the safety of the vaccination process. Considering the substantial exposure of children to vaccinations throughout early childhood and the ever-increasing complexity of the recommended vaccination schedule, a clear, systems-based understanding of the causes and consequences of vaccination errors is warranted.

Adverse events following vaccination may be vaccine-induced (events due to the intrinsic properties of the vaccine that would not have happened without vaccination); vaccine-potentiated (events that would have occurred anyway but were precipitated by the vaccination); programmatic (technical errors in vaccine preparation, handling, or administration); or coincidental [5]. Vaccine manufacturers, medical researchers, and government regulators have extensively evaluated vaccine-induced, vaccine-potentiated, and coincidental adverse events following vaccination. The study of adverse events associated with programmatic errors (i.e., medication errors), however, has received far less attention. Despite this, the World Health Organization asserts that vaccine-related adverse drug reactions due to storage, handling and administration errors are more common worldwide than those due to the properties of the vaccines themselves [6,7].

The goal of safe vaccination administration is partly captured by the widely used nursing mnemonic known as the "5 Rights", which states that the right medication (i.e., vaccine) should be delivered to the right patient in the right dose by the right route at the right time [8]. While the 5 Rights are often discussed as a tool nurses can use to increase medication administration accuracy and safety, the 5 Rights are more appropriately viewed as the goal of, not the means for, safe medication administration [9]. Nonetheless, the 5 Rights also serve as a potentially useful framework for classifying vaccination errors and determining whether certain vaccinations or children are particularly susceptible to certain types of errors. The objective of this study was to use a nationwide medication error reporting database to evaluate the epidemiology of pediatric vaccination errors using the 5 Rights framework and to identify vaccine- and patient-related risk factors for various types of programmatic vaccination errors.

Abbreviations: CPOE, computerized provider order entry; IM, intramuscular; SC, subcutaneous; US, United States; VAERS, Vaccine Adverse Event Reporting System.

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2. Methods

2.1. Data source

Introduced in 1998, United States Pharmacopeia's MEDMARX [10,11] is an anonymous, de-identified, voluntary national Internet-accessible database that hospitals and health care systems use to collect, report, track, and share adverse drug reactions and medication errors in a standardized format. Errors are identified through spontaneous reporting, retrospective chart review, and computer triggers; data are entered by physicians, nurses, pharmacists, and ancillary providers. Hospitals and health care systems subscribe to MEDMARX on an annual basis; 762 hospitals were subscribers as of January 2005 and represented all 50 states. Subscribers can access de-identified records from a national database of nearly 1.4 million medication error reports for benchmarking purposes.

All MEDMARX error reports utilize a standard taxonomy and provide information regarding the error's timing, location, involved phase of care, harm caused, cause of the error, medication involved, type of error, and information on the facility in which the error occurred. Some data fields within the error reports are single-pick lists and some are multi-pick lists; the latter allow users to enter multiple answers while the former insist on a single selection. There are also free text fields allowing users to more fully describe errors.

2.2. Data query

We searched the MEDMARX database for reports involving outpatient vaccinations, including both active and passive (i.e., immune globulin) vaccines. Reports were included in the final sample if they (1) involved a vaccine; (2) occurred between January 1, 2003 and December 31, 2006 in an outpatient setting; and (3) involved children ages 17 years and younger (when age data available) or occurred in a pediatric clinic (when age data unavailable). For the 5 Rights analyses, a report was analyzed only if the vaccines cited in that report had at least 10 occurrences in the overall dataset.

2.3. Error category

Medication error reports each included a National Coordinating Council for Medication Error Reporting and Prevention Index for Categorizing Medication Errors category designation (A–I) depending on the severity of the error [12]. Since patient age is not included in category A and B errors, these records were included in the final sample only if they occurred in a pediatric clinic to insure that the error involved a child.

2.4. Error type

MEDMARX data include up to 15 error types per report. These error types correspond with the American Society of Health-System Pharmacists' Guidelines on Preventing Medication Errors in Hospitals [13]. We considered any listed value separately, such that the total counts of error types exceeds the report counts, with some reports citing more than one type.

2.5. Analysis

Errors were classified by category, node, type, and involved vaccines. For each of the 5 Rights, we hypothesized, based on the relevant human factors, which vaccines (or children) would be most susceptible to that type of error. For example, the inherent complexity of weight-based dosing led us to hypothesize that vaccines requiring such dosing would more often cite "wrong dose" as the error type than vaccines with standardized (i.e., non-weight-based) dosing. We used the Rao–Scott modified Chi-square test for the comparisons of the vaccine groupings [14]. This method takes clustering of error reports within institutions into account by treating the data as though they were obtained from a complex survey sample design, with facility as the primary sampling unit, and by dividing the Pearson chi-square statistic by a design correction to reduce the probability of Type I error [15]. Statistics were calculated with Stata (Version 8.2, College Station, TX) and SAS (Version 9.13, Cary, NC). This study of de-identified data received an exemption from the Johns Hopkins University Bloomberg School of Public Health Institutional Review Board.

3. Results

We identified 607 reports of outpatient vaccination errors in children from 149 facilities (Table 1). Most reports involved children less than 6 years of age; one quarter involved children less than 1

Table 1
Patient and error characteristics ($N = 607$ error reports).

	N (%)
Patient age (median = 2 years)	
<12 months	148 (24)
12–23 months	119 (20)
2–5 years	147 (24)
6–17 years	141 (23)
Not reported	52 (8.6)
Gender	
Male	137 (22)
Female	156 (26)
Not reported	314 (52)
Year error occurred	
2003	140 (23)
2004	160 (26)
2005	178 (29)
2006	129 (21)
Error category	
A—circumstances or events that have capacity to cause error	22 (3.6)
B—error occurred; did not reach the patient	22 (3.6)
C—error occurred and reached the patient; did not cause harm	517 (85)
D—error occurred, reached patient, and required monitoring to confirm no harm and/or intervention to preclude harm	36 (5.9)
E—error occurred that may have contributed to or resulted in temporary harm and required intervention	10 (1.6)
Node	
Administering	427 (70)
Prescribing	67 (11)
Transcribing/documenting	61 (10)
Dispensing	25 (4.1)
Not reported (category A)	22 (3.6)
Other	5 (0.82)
Error type[a]	
Wrong drug	152 (25)
Extra dose	149 (25)
Improper dose/quantity	82 (14)
Drug prepared incorrectly	51 (8.4)
Wrong time	48 (7.9)
Prescribing error	41 (6.8)
Omission error	27 (4.4)
Wrong patient	25 (4.1)
Mislabeling	16 (2.6)
Wrong administration technique	15 (2.5)
Expired product	13 (2.1)
Deteriorated product	9 (1.5)
Wrong dosage form	6 (1.0)
Wrong route	3 (0.49)
Not reported	2 (0.33)

[a] Percentages sum to greater than 100% since each report may list one or more error types.

Table 2
Vaccines involved (*N* = 607 reports involving 691 listed vaccines).

Generic name	Abbreviation	Trade name(s)	Periodicity	Dose	Route	*N* (%)
Standard childhood active vaccines						
Trivalent inactivated influenza	TIV	Fluvirin, Fluzone, Fluarix	Seasonal	Age dependent	IM	69 (10)
Haemophilus influenzae type B conjugate	Hib	PedvaxHIB, ActHIB, ProHIBit, HibTITER	Scheduled	Standardized	IM	61 (8.8)
Hepatitis A	HepA	Havrix, Vaqta	Elective/intermittent (2003-5) Scheduled (2006)	Standardized	IM	56 (8.1)
Diphtheria, tetanus and acellular pertussis/ hepatitis B/inactivated poliovirus	DTaP/HepB/IPV	Pediarix	Scheduled	Standardized	IM	55 (8.0)
Tetanus and diphtheria	Td	Decavac, [generic]	Elective/intermittent	Standardized	IM	52 (7.5)
Pneumococcal conjugate	PCV	Prevnar	Scheduled	Standardized	IM	51 (7.4)
Varicella	VAR	Varivax	Scheduled	Standardized	SC	47 (6.8)
Hepatitis B	HepB	Engerix-B, Recombivax HB	Scheduled	Standardized	IM	45 (6.5)
Inactivated poliovirus	IPV	Ipol	Scheduled	Standardized	SC or IM	44 (6.4)
Diphtheria, tetanus and acellular pertussis	DTaP	Daptacel, Infanrix, Acel-Immune, Tripedia	Scheduled	Standardized	IM	40 (5.8)
Measles, mumps and rubella	MMR	M-M-R II	Scheduled	Standardized	SC	40 (5.8)
Tetanus, diphtheria and acellular pertussis	Tdap	Adacel, Boostrix	Elective/intermittent	Standardized	IM	19 (2.8)
Haemophilus influenzae type B/hepatitis B	Hib/HepB	Comvax	Scheduled	Standardized	IM	12 (1.7)
Diphtheria and tetanus	DT	[generic]	Scheduled	Standardized	IM	10 (1.4)
Rubella		Meruvax II	Elective/intermittent	Standardized	SC	6 (0.87)
Meningococcal conjugate	MCV	Menactra	Elective/intermittent	Standardized	IM	4 (0.58)
Hepatitis A/hepatitis B	HepA/HepB	Twinrix	Elective/intermittent	Standardized	IM	2 (0.29)
Measles		Attenuvax	Elective/intermittent	Standardized	SC	2 (0.29)
Mumps		Mumpsvax	Elective/intermittent	Standardized	SC	1 (0.14)
Diphtheria, tetanus and acellular pertussis/ haemophilus influenzae type B	DTaP/Hib	TriHIBit, Tetramune	Scheduled	Standardized	IM	1 (0.14)
Diphtheria, tetanus and acellular pertussis/ inactivated poliovirus	DTaP/IPV	Kinrix, Quadracel	Scheduled	Standardized	IM	1 (0.14)
Live attenuated influenza	LAIV	Flumist	Seasonal	Standardized	Intranasal	1 (0.14)
Other active vaccines						
Pneumococcal polysaccharide	PPV	Pneumovax 23, Pnu-Imune 23	Elective/intermittent	Standardized	SC or IM	9 (1.3)
Meningococcal polysaccharide	MPSV	Menomune	Elective/intermittent	Standardized	SC	6 (0.87)
Rabies		Imovax Rabies, RabAvert	Elective/intermittent	Standardized	IM	6 (0.87)
Typhoid Vi polysaccharide		Typhim Vi	Elective/intermittent	Standardized	IM	4 (0.58)
Typhoid live oral		Vivotif Berna	Elective/intermittent	Standardized	Oral	3 (0.43)
Passive vaccines/immune globulins						
Palivizumab	RSV IG	Synagis	Seasonal	Weight dependent	IM	24 (3.5)
Rabies immune globulin		BayRab, Hyperab, Imogam	Elective/intermittent	Weight dependent	IM	8 (1.2)
Hepatitis B immune globulin	HBIG	BayHep B, HepaGam B, HyperHEP B S/D	Elective/intermittent	Age and weight dependent	IM	4 (0.58)
Tetanus immune globulin		BayTet	Elective/intermittent	Age and weight dependent	IM	4 (0.58)
Varicella zoster immune globulin	VZIG	VariZIG	Elective/intermittent	Weight dependent	IM	3 (0.43)
Cytomegalovirus immune globulin intravenous	CMV-IVIG	Cytogam	Elective/intermittent	Weight dependent	IV	1 (0.14)
Total						691 (100)

year of age. Errors were reported at similar frequency by gender and across the 4 study years. Most errors reached the patient (categories C–E = 93%), but only 10 errors caused harm (category E). Seventy percent of errors occurred during the administration phase. "Wrong drug", "extra dose", and "improper dose/quantity" were the 3 most commonly reported error types.

The 607 error reports listed 691 vaccines (Table 2). Intramuscular influenza was the most commonly reported vaccine. Hepatitis A

Table 3
Wrong vaccine (N = 465 reports).[a].

		Vaccine look-alike/sound-alike groups					
		"Hepatitis" HepA, HepB (N = 88)	"Influenza" Hib, TIV (N = 115)	"Pneumococcal" PCV, PPV[b] (N = 45)	"Tetanus" Td, Tdap, DTaP, DT (N = 95)	[No look-alike/ sound-alike group] VAR, IPV, MMR, RSV IG (N = 122)	Rao–Scott corrected chi-squared p-value
"Wrong vaccine" error type cited?	No (N (%))	73 (83)	88 (77)	32 (71)	61 (64)	106 (87)	0.008
	Yes (N (%))	15 (17)	27 (23)	13 (29)	34 (36)	16 (13)	

[a] Analysis limited to reports that could be categorized into a single look-alike/sound-alike group. Reports specifying vaccines from more than one group (e.g., HepB and PCV) were excluded. Similarly, reports involving Hib/HepB (Comvax) and DTaP/HepB/IPV (Pediarix) were excluded since each of these vaccines has look-alike/sound-alike problems with more than one group.
[b] PPV (N = 9) included because PCV, the corresponding look-alike/sound-alike pair vaccine, had greater than 10 occurrences in the raw data.

vaccine, which transitioned to a universal recommendation in the US during the study period, was the third most commonly involved vaccine. Overall, errors were distributed across a variety of vaccines with no vaccine being cited in more than 10% of reports.

3.1. Error type and the 5 Rights

3.1.1. Wrong vaccine

We analyzed wrong vaccine errors in groupings based on potential look-alike/sound-alike generic names (Table 3). In the "tetanus" group (Td, Tdap, DTaP, and DT), which had the highest prevalence of wrong vaccine errors, more than one-third of all errors cited this error type. Wrong vaccine confusion was also common in the "pneumococcal" group (29%), where the relatively new conjugate vaccine is often interchanged with the older, non-conjugate formulation. A parallel confusion was identified in the meningococcal conjugate/meningococcal polysaccharide group, in which 75% of errors were "wrong vaccine" errors, though the sample size was insufficient to include these data in Table 3. The vaccines for which we could not readily identify a look-alike/sound-alike group had the lowest frequency of wrong vaccine errors (13%, $p = 0.008$). In addition to the potential look-alike/sound-alike groups based on generic names, numerous additional look-alike/sound-alike groups are possible based on trade names. Vaccine manufacturers historically maintain similar naming structures across their vaccine products (e.g., GlaxoSmithKline: Infanrix, Kinrix, Pediarix, Havrix, Twinrix, etc.), yielding many potential look-alike/sound-alike problems. Brand name data in MEDMARX were not sufficiently complete, however, to permit analyses of look-alike/sound-alike brand name groups.

3.1.2. Wrong time

Wrong time errors comprised the error types "extra dose", "wrong time", and/or "omission" (Table 4). Overall, as we hypothesized, scheduled vaccines were more likely to be given at the wrong time, compared with seasonal and elective/intermittent vaccines (44% vs. 18% vs. 29%, respectively ($p = 0.006$)). This difference was driven primarily by the high frequency of "extra dose" errors in the scheduled vaccine group (32%, vs. seasonal (8.0%) and elective/intermittent (15%)). Of note, hepatitis A vaccine changed from an elective vaccine in most parts of the US to a scheduled one in 2006, accounting for its appearance in 2 different groupings.

3.1.3. Wrong dose

Palivizumab was the only vaccine with weight-based dosing; intramuscular (IM) influenza vaccine was the only vaccine with age-based dosing. More than half of palivizumab errors were assigned the wrong dose error type (Table 5), compared with 38% of influenza errors. These were significantly different from the 8.2% prevalence of the wrong dose error type among vaccines with standardized dosing ($p < 0.0001$).

3.1.4. Wrong route

Wrong route was a rarely cited error type (Table 6). When combined with wrong administration technique, wrong route error types were cited in 2.0% of IM vaccination errors and 5.7% of subcutaneous (SC) vaccination errors, a non-significant difference.

3.1.5. Wrong patient

The wrong patient error type was also rarely cited (25/607 of error reports). MEDMARX does not provide additional categorical data on the nature of wrong patient errors. However, in the free-text error description field, 11/25 (44%) wrong patient errors explicitly mentioned sibling confusion as the root of the error, most commonly where shots intended for one child were given to a sibling.

4. Discussion

Approximately 4 million children are born in the United States annually [16]. By the age of 6 years, US children will receive 30 or more vaccinations if fully immunized, amounting to more than 100 million opportunities annually for pediatric vaccine-related errors in the US alone. Despite this, little is known about ambulatory pediatric medication errors, and existing data often exclude vaccines

Table 4
Wrong time (N = 539 reports).[a].

		Vaccine schedule groups			
		Scheduled HepA (2006), HepB, Hib, DT, DTaP/HepB/IPV, PCV, VAR, IPV, MMR, DTaP, Hib/HepB (N = 365)	Seasonal RSV IG, TIV (N = 88)	Elective/intermittent HepA (2003-2005), Td, Tdap (N = 86)	Rao–Scott corrected chi-squared p-value
"Wrong time"[b] error type cited?	No (N (%))	206 (56)	72 (82)	61 (71)	0.006
	Yes (N (%))	159 (44)	16 (18)	25 (29)	

[a] Analysis limited to reports that could be categorized into a single schedule group. Reports specifying vaccines from more than one group (e.g., PCV and TIV) were excluded.
[b] The wrong time error type comprises the error types "wrong time", "extra dose", and "omission".

Table 5
Wrong dose ($N = 548$ reports).[a].

		Vaccine dose groups			
		Standardized	Age dependent	Weight dependent	Rao–Scott corrected chi-squared p-value
		DTaP, DT, Tdap, Td, Hib, HepA, HepB, PCV, DTaP/HepB/IPV, Hib/HepB, VAR, MMR, IPV ($N = 461$)	TIV ($N = 64$)	RSV IG ($N = 23$)	
"Wrong dose" error type cited?	No (N (%))	423 (92)	40 (62)	10 (43)	<0.0001
	Yes (N (%))	38 (8.2)	24 (38)	13 (57)	

[a] Analysis limited to reports that could be categorized into a single dose group.

[17]. We used the largest medication error reporting database in the US to examine ambulatory pediatric vaccination errors. Using the "5 Rights" framework, we found that error types were predictable, mainly due to vaccine- or patient-related human factors. While few vaccination errors were harmful, the damage done to the provider–patient relationship by vaccination errors may be substantial. This is of particular concern in an era of increasing parental scrutiny of the safety of vaccines.

4.1. Wrong vaccine

Administration of the wrong vaccine was a commonly reported error type in our analysis and the most commonly identified error type in 2 analyses of the Vaccine Adverse Event Reporting System (VAERS) database [18,19]. Inadvertent substitution of one vaccine for another has been reported repeatedly in the literature and usually involves vaccines whose generic or trade names look or sound alike. Look-alike/sound-alike errors have been reported for Tdap/DTaP (whose brand names, Adacel and Daptacel, also look and sound alike) [20] and Td/DT [21]. Non-tetanus vaccines are also implicated in this error type, including both generic (e.g., pneumococcal conjugate/pneumococcal polysaccharide) [22] and trade name (Recombivax HB/COMVAX) confusion [23]. Standardizing vaccine nomenclature has been proposed as one means of reducing the incidence of wrong vaccination errors [24,25]. Tall man lettering has also been shown to reduce confusion between medications with similar-appearing names [26] (e.g., TWINrix, INFANrix, and KINrix), though existing generic vaccine nomenclature confounds this strategy in some cases by the use of capital letters to signify the concentration of included components (e.g., Tdap vs. DTaP). Standardized nomenclature and tall man lettering have been endorsed by the Institute for Safe Medication Practices and the Pediatric Pharmacy Advocacy Group [27].

Similar appearing packaging is another root cause of wrong vaccine errors [28-30]. In addition to standardizing vaccine packaging and labeling, barcodes have been proposed as one potential solution to confusing packaging [25,31]. Such strategies, similar to those aimed at reducing look-alike/sound-alike confusion, would require the cooperation of major vaccine manufactures and regulatory agencies, such as the US Food and Drug Administration. Unfortunately, there is no current agency or organization empowered to oversee these needed patient safety fixes.

4.2. Wrong time

In our study, wrong time errors were a commonly reported error type. This finding is concordant with a British study in which 61% of all reported errors were "out of schedule", "outside the indicated age", or "inappropriate interval" [32]. Wrong time vaccination errors involve deviations from the recommended vaccination schedule [33] and include errors of omission and commission. Errors of commission, in turn, can involve giving a vaccine too early for patient age or by recommended interval or when it is no longer indicated, based on patient age or prior receipt of vaccinations. One study using this framework to evaluate invalid vaccination doses found that each of these 3 types of errors of commission were equally common [34]. These errors falsely inflate population vaccination rates, since the total number of vaccines received by a child may be adequate, though when minimum spacing and recommended vaccine timing is considered, true population 'appropriate' vaccination rates are substantially lower [35]. While under-vaccination is likely the greater public health problem, such errors are less likely to be reported than errors of commission, which result in extra-vaccination. In one study of nationally representative US data, extra-vaccination occurred in 21% of young children [36].

While the underlying causes of wrong time errors in our data could not be determined, one root cause of such errors is inadequate vaccination records [37]. With the complexity of the recommended vaccination schedule continually increasing, the importance of accurate vaccination record keeping is magnified. Many practices, cities, and states have adopted electronic vaccination records and registries. Sixty-five percent of US children under age 6 participate in large-scale, electronic immunization information systems; unfortunately, even for participating children, data are often incomplete and not reported in a timely fashion [38]. Future study should

Table 6
Wrong route ($N = 513$ reports).[a].

		Vaccine route groups[b]		
		Intramuscular DTaP, DT, Tdap, Td, Hib, HepA, HepB, TIV, PCV, DTaP/HepB/IPV, RSV IG, Hib/HepB ($N = 443$)	Subcutaneous MMR, VAR ($N = 70$)	Rao–Scott corrected chi-squared p-value
"Wrong route"[c] error type cited?	No (N (%))	434 (98)	66 (94)	0.11
	Yes (N (%))	9 (2.0)	4 (5.7)	

[a] Analysis limited to reports that could be categorized into a single route group.
[b] IPV excluded since it can be given IM or SC.
[c] Wrong route error type comprises the "wrong route" and "wrong administration technique" error types.

determine the impact of these electronic records on the vaccination status of children and wrong time vaccination errors.

4.3. Wrong dose

At least 3 mechanisms may contribute to wrong dose vaccination errors. The first involves the *improper volume* of vaccine being administered. A second mechanism involves incorrect reconstitution, resulting in the *improper concentration* of vaccine in solution. The latter errors may have a greater potential to result in larger overdoses, since administering a vaccine at 10 times the recommended concentration is more plausible than administering 10 times the recommended volume, which could be mechanically difficult. A third mechanism involves confusing multi-dose with single-dose vials.

Existing literature on wrong dose vaccination errors is limited. We identified 2 small studies of wrong dose errors involving yellow fever vaccine in which improper reconstitution of the vaccine caused substantial overdosing, though without apparent clinical consequences [39,40]. In a study of vaccination errors in Greece, wrong dose was the most commonly reported error type, though the overall prevalence of reports was low [41]. We could find no published studies evaluating dosing errors for palivizumab or influenza. Likewise, no published data exist regarding the potential harms of palivizumab in overdose, but its use in medically fragile children heightens the concern for potential adverse effects. Computerized provider order entry (CPOE) and prescription writing have been shown to reduce medication dosing errors in some settings, although uptake of this technology has been slow in ambulatory practices. In addition, vendor-supplied dosing logic is routinely inadequate for pediatric indications, so it remains uncertain whether CPOE could reduce pediatric vaccination errors without substantial out-of-pocket costs to providers or federal regulation of CPOE content.

4.4. Wrong route

Wrong route error reports were uncommon in the MEDMARX vaccine data. In 2 studies of vaccination errors reported to the VAERS database, wrong route was the third [18] and fourth [19] most commonly reported error type; neither study indicated which vaccines were involved in these wrong route errors. The majority of vaccinations in use in the US are administered by the IM route; the principal exceptions are MMR, VAR, and the meningococcal polysaccharide vaccine (MPSV). The use of the latter vaccine is being largely supplanted by the meningococcal conjugate vaccine (MCV), which is delivered IM. The CDC recently reported several clusters of patients erroneously receiving MCV by the SC route [42]. The CDC reported that numerous involved providers cited the decades-long history of administering MPSV by the SC route as contributing to their inadvertent administration of MCV subcutaneously. One possible solution to reduce wrong route errors would be to encourage physician offices to store IM and SC vaccines separately and with prominent labeling on each bin regarding the appropriate route.

4.5. Wrong patient

Wrong patient errors involve administration of vaccines to children for whom the vaccine is contraindicated (e.g., VAR vaccination of a child with immunodeficiency) [43] or administration of vaccines intended for one child to another. While only a single error in our data was assigned the cause "contraindicated in disease" (data not shown), we hypothesized that wrong patient errors involving the wrong child entirely would be more common. Our finding that more than 40% of wrong patient errors involved sibling confusion underscores the need for additional precautions when providing vaccines to more than one sibling, or with multiple siblings in the room. Moving siblings into separate rooms for vaccinations, while potentially disruptive to patient flow and family dynamics, would be one systems-based approach that could reduce this problem.

4.6. Study limitations

MEDMARX data do not include information regarding the total volume of vaccines administered. Therefore, calculation of error incidence rates is not possible. Additionally, MEDMARX data are entered by a variety of clinical staff and are not verified for accuracy. Inter-reporter reliability of the MEDMARX data has been confirmed for error category [44] but not for other data elements. As a voluntary reporting system, MEDMARX likely represents a substantial underreporting of true error incidence [45]. With no 'gold standard', there is no way to quantify this underreporting. Error reporting may be biased such that certain types of errors (e.g., more harmful ones) may be more likely to be reported than other errors. As a result, the relative frequencies of error characteristics reflect only those in reported errors, not in all errors that occurred. In addition, MEDMARX data provide limited information on the type of adverse events and harm that resulted from the reported errors and no information on the psychological impact of reported errors on patients and families. Finally, MEDMARX participants do not comprise a nationally representative sample of entities providing ambulatory medical care to children. In particular, hospital-based or affiliated ambulatory sites are over represented in MEDMARX, compared with free-standing, office-based practices. Despite these limitations, MEDMARX is the largest medication error reporting database in the United States [46] and sheds light on medication errors that would be difficult to analyze in smaller samples.

4.7. Conclusion

Vaccines are highly efficacious, widely utilized, and a cornerstone of pediatric preventive care. Nonetheless, like any medications, vaccines have the potential to cause harm when used improperly. Our study suggests that the types of vaccination errors observed in children are predictable, based on vaccine- and patient-related human factors. As target illnesses become rarer, adverse events associated with improper vaccination often exceed the incidence of the target illness. As a result, systems changes are needed, both at the practice- and policy-levels, in order to reduce the incidence of predictable and preventable vaccination errors in children.

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