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Vaccine administration error rates at a large academic medical center and its affiliated clinics – Familiarity matters

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ABSTRACT

Objective: The purpose of this study was to track and describe the absolute number of vaccine administration errors and corresponding error rates over time and by patient age and vaccine type.
Methods: Total vaccines administered to patients aged 0 through 19 years 364 days from 1/1/2006 through 12/31/2017 at a large academic health system in the Midwest United States with primary, specialty and school-based clinics, and a pediatric hospital were obtained from an electronic medical record. Vaccine administration errors over the same time period for the same patient criteria were analyzed from the health system's incident reporting system and further compared to the frequency of all incidents reported. Vaccine administration error rates were calculated. Data were analyzed by patient age, vaccine type and year administered.
Results: Of the 1,431,206 vaccine doses given, 552 vaccine administration errors were identified (0.04%). The highest error rates occurred in children aged 2, 3, and 19 years. Vaccine types with the highest error rate were Td, rabies and pneumococcal polysaccharide vaccines. Overall vaccine doses given and errors reported increased over the study period. However, the increase was disproportionate, resulting in an increase in the error rate initially followed by a stabilization at the end of the study period.
Conclusions: Vaccine administration errors are uncommon. The error rate appears to be stabilizing. Errors are more likely at ages when vaccines are not commonly given, with vaccines that have age-specific dosing and with vaccines that are given less often. This suggests more safety checks are needed for vaccines that are rarely used or given off-schedule, and manufacturers should avoid vaccines with age-specific dosing.

1. Background

Nearly a decade ago, pediatric vaccine administration errors were characterized as predictable based on vaccine and patient related human factors such as vaccines with age specific formulations, similar names or packaging and patients with incomplete immunization records [1]. Despite this awareness and more recent validation of these contributing factors, vaccine errors have not decreased [2,3]. Moreover, the recommended United States immunization schedule continues to grow larger and more complex with new vaccines and expanded recommendations [4,5]. The Centers for Disease Control and Prevention (CDC) now recommends that children and adolescents be immunized against 16 different vaccine preventable diseases – which means a fully immunized young adult will have received nearly 50 vaccine doses [5,6]. This complex and expanded immunization schedule increases the opportunity for vaccine administration errors in children and adolescents at a time when the World Health Organization has identified vaccine administration related safety incidents as a priority area for improvement [7].

While vaccines have been shown to be cost-effective when properly administered, vaccine administration errors can result in unexpected costs to the practice and the public health system, including need for additional doses, and inconvenience to the patient [8,9]. Prior studies have shown that the vast majority of

Abbreviations: DT, diphtheria and tetanus vaccine; DTaP, diphtheria, tetanus and acellular pertussis vaccine; DTP, diphtheria, tetanus and pertussis vaccine; Hib, haemophilus influenza b vaccine; HPV, human papillomavirus vaccine; H1N1, pandemic (H1N1) influenza vaccine; IPV, inactivated poliovirus vaccine; MMR, measles, mumps and rubella vaccine; MMR+V, measles, mumps, rubella and varicella vaccine; OPV, oral poliovirus vaccine; Td, tetanus and diphtheria vaccine; Tdap, tetanus, diphtheria and acellular pertussis vaccine.

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vaccine administration errors result in low harm or no harm to the patient [3,10,11]. However, these errors do have the potential to harm the system – and ultimately the public's health – by eroding the trust of patients and parents in the national immunization program.

Recent reviews of national vaccine reporting systems have described the number of common error types reported but are unable to assess error rates (number of errors/total opportunity for error). This makes it impossible to identify the effect of the overall number of vaccine doses administered on the number of errors. One study that did report a vaccine administration error rate (0.4%) was based on short-term data from two clinics [12]. Yet, it is critical to examine the rate of errors (number of errors/total opportunity for error) which accounts for growth in vaccine use, and not just simply the number or frequency of errors reported. As a result, we have conducted a long-term study from a large multicenter academic health system that describes the absolute number of vaccine administration errors and corresponding error rates over time and by patient age and vaccine type.

2. Methods

2.1. Data sources

We obtained data from the University of Michigan Health System (UMHS), a large academic health system in the Midwest United States that provides over 200,000 pediatric primary care and over 100,000 pediatric specialty care outpatient visits annually at 17 clinic locations and four school-based clinics within a 50-mile radius. Data also included vaccines administered at the UMHS's 348-bed pediatric hospital that includes newborn and emergency room services. Each of the aforementioned sites is owned and operated by the health system and uses the same health system vaccine schedule that is updated annually based on the CDC recommendations.

2.1.1. Baseline vaccine data

At this health system, all vaccines, either historic or administered to patients, are entered into the same electronic medical record (EMR) by staff. This vaccine information, including lot number when a vaccine is administered, is stored in a separate section of the EMR's data repository.

We extracted vaccine doses administered, including vaccine name and date administered, from this section of the data repository during a twelve-year period from 1/1/2006 through 12/31/2017. We excluded vaccines that were historical entries (not administered in our health system) by selecting only the vaccines with an associated lot number. We identified all vaccine doses administered to children and adolescents 0 through 19 years and 364 days of age by using a formula to calculate the patient's age at time of administration using the number of months between the administration date and birth date.

2.1.2. Vaccine administration error data

Vaccine administration errors are self-reported as vaccine incidents by staff into an online patient safety reporting system per an internal UMHS policy, that requires that all patient adverse events and incidents (including near misses) are reported into a Patient Safety Reporting System [13]. Prior to 2004, incidents were reported using a paper-reporting process. The online incident reporting system includes an incident identification number, the date the incident was recorded, the date the incident occurred, the patient's medical record number, the patient's birth date, the location of the incident (i.e., building and unit), the drug class/type involved (i.e. vaccine), the vaccine reported to be involved, and subjective incident data. Subjective incident data include a brief description of the incident, the outcome details of the incident and the outcome of the person affected by the incident. We reviewed all vaccine administration incident reports (labeled as "drug class/type – vaccine" in the reporting system) from this online reporting system over the same time period and patient age range as the baseline vaccine data.

The errors reported annually may be influenced by changes in the health system's reporting policy, reporting system or efforts to increase reporting. Given the possibility that these factors may have resulted in changes in the vaccine administration errors independent of the number of errors occurring, we obtained the number of all staff reported incidents annually, regardless of type or patient age, from the same Patient Safety Reporting System over the same time period. We then compared the frequency of vaccine administration error incident reports to all incidents reported by year. We also requested a description and dates of efforts by the health system to improve voluntary reporting of incidents.

2.1.3. Identification of vaccine administration errors

The main outcome for our study was vaccine administration errors, defined as the administration or near administration ('near miss') of the wrong vaccine or diluent, the wrong dose, a vaccine at the wrong timing (interval too short or minimum age not met) or a vaccine not indicated for the patient. For each vaccine administration incident identified as a vaccine administration error, we used the patient's date of birth and date of vaccine administration to calculate the age at which the error occurred.

Determining which vaccine to attribute to an error can be challenging when a vaccine given may be different from the one ordered and/or the one recommended. For the purposes of this study, a vaccine administration error was attributed to the vaccine that was indicated for the patient based on the national childhood immunization schedule. (Example: If MMR was indicated at 12 months according to the CDC schedule, but Menactra® was ordered and Tdap was given, the error was attributed to MMR). For this reason, the vaccine attributed by the study authors may not have been the same as the vaccine identified by staff in the incident report. If no vaccine was indicated, the error was attributed to the vaccine given. Vaccines were grouped by the type of diseases covered – except if vaccines within a group had different indications on the immunization schedule. For example, pneumococcal conjugate was grouped separately from pneumococcal polysaccharide.

2.2. Data analyses

We conducted a stratified descriptive analysis to summarize all of the vaccine doses administered throughout the study period by patient age at time of vaccine administration, by vaccine type and by year to identify trends. We then repeated this analysis for all of the reported vaccine administration errors. To observe for error reporting influences, we further compared the frequency of vaccine administration error incident reports to all incidents reported by year.

We calculated the vaccine administration error rate by dividing the total number of vaccine administration errors by the total number of vaccine doses administered during the study period. We then performed similar calculations by age of patient at time of vaccine administration, by vaccine type, and by year to further describe the pattern of vaccine administration error rates. To more clearly identify the trend in error rates over time, we used Microsoft Excel's automated calculation of a moving average trend line with a period value set at two. This smooths out the annual fluctuations in the data to show the trend on a longer-term basis. Further, for the patient ages with the highest error rates, we examined the vaccine types attributed to the errors in this age group.

This study was approved by the Institutional Review Board of the University of Michigan School of Medicine HUM00120869.

3. Results

3.1. Vaccine doses administered

A total of 1,431,206 vaccine doses were administered over the study period. Nearly half (49.50%) of all vaccines were given during the first two years of life (n = 708,500), followed by 8.75% at age 4 years (n = 125,221) and 6.03% at age 11 years (n = 86,246) (Table 1). A total of 31 different types of vaccines were administered (Table 2). The vaccine types administered most often were influenza (n = 334,183; 23.35%), pneumococcal conjugate (n = 147,976; 10.34%) and hepatitis A (n = 124,016; 8.67%). In general, the number of doses administered annually nearly doubled over time (Table 3).

3.2. Vaccine administration errors

A total of 552 unique vaccine administration errors were identified within 505 unique vaccine administration incident reports. Thirty-four reports (6.15%) involved an error with more than one vaccine. Twenty-nine incident reports (5.25%) included statements from parents or caregivers expressing concern about the vaccine error, and eight error reports (1.45%) included specific subjective incident data: one patient had urticaria requiring diphenhydramine and observation in clinic, three patients developed fever (one of whom was evaluated in an ED and treated with acetaminophen), and four patients had pain or bruising at the injection site. Seventy-one errors (12.86%) were the result of an extra vaccine dose being given to the patient in error. Twenty-three error reports (4.17%) documented a need for the patient to return to clinic for an extra visit to compensate for the error (such as giving the correct dose of vaccine), including one error in which a patient received an influenza vaccination instead of medroxyprogesterone acetate, necessitating a return visit for appropriate contraception. In two errors (0.36%), vaccines were given when medically contraindicated: Tdap given to a patient with known allergy and live vaccines given to a patient with DiGeorge Syndrome. Ten errors (1.81%) were 'near-misses,' in which the error was caught before the vaccine was given.

Two hundred and six errors (37.32%) were reported between birth to two years, followed by 43 errors (7.79%) at both four years and 11 years of age (Table 1). Independent of patient age, the vaccine types most often attributed to an error were influenza (n = 97; 17.57%), hepatitis A (n = 79; 14.31%) or a DT/DTaP/DTP vaccine (n = 52; 9.42%) (Table 2). Nine vaccine types had no reported errors.

Table 1
Vaccine doses, administration errors and error rates by patient age at a large U.S. academic health system from 2006–2017.

Age (years)	Vaccine doses	Administration errors	Error rate per 10,000 doses
<1	460,436	108	2.35
1	248,064	98	3.95
2	54,475	48	8.81
3	35,856	28	7.81
4	125,221	43	3.43
5	41,019	17	4.14
6	24,582	8	3.25
7	23,000	13	5.65
8	23,058	12	5.20
9	22,413	5	2.23
10	22,787	9	3.95
11	86,246	43	4.99
12	45,535	10	2.20
13	35,451	23	6.49
14	31,639	13	4.11
15	29,438	16	5.44
16	38,272	14	3.66
17	32,839	13	3.96
18	27,838	15	5.39
19	23,037	16	6.95
TOTAL	1,431,206	552	3.86

Table 2
Vaccine doses, administration errors and error rates by vaccine type at a large U.S. academic health system from 2006–2017.

Vaccine type	Vaccine doses	Administration errors	Error rate per 10,000 doses
Td	1,590	5	31.45
Rabies	1,642	4	24.36
Pneumococcal Polysaccharide	2,892	6	20.75
DTaP + HIB + IPV	5,427	10	18.43
Yellow Fever	699	1	14.31
Typhoid	1,922	2	10.41
DT, DTaP, DTP	55,896	52	9.30
Hepatitis B	56,403	50	8.86
Tdap	45,749	37	8.09
Pandemic Influenza (H1N1)	20,099	15	7.46
Hepatitis A	124,016	79	6.37
DTaP + IPV	17,479	11	6.29
Polio (IPV, OPV)	24,657	13	5.27
HPV	74,997	32	4.27
Meningococcal	59,270	20	3.37
MMR	70,058	22	3.14
Influenza	334,183	97	2.90
Varicella	86,443	25	2.89
HIB	110,079	30	2.73
Pneumococcal Conjugate	147,976	20	1.35
Rotavirus	87,373	10	1.14
DTaP + Hepatitis B + IPV	98,693	11	1.11
DTaP + HIB	451	0	0.00
Hepatitis A + Hepatitis B	152	0	0.00
HIB + Hepatitis B	28	0	0.00
Japanese Encephalitis	154	0	0.00
Measles	25	0	0.00
MMR + V	2,791	0	0.00
Mumps	31	0	0.00
Rubella	26	0	0.00
Zoster	5	0	0.00
TOTAL	1,431,206	552	3.86

Abbreviations: DT: Diphtheria and tetanus; DTaP: Diphtheria, tetanus and acellular pertussis; DTP: Diphtheria, tetanus and pertussis; Hib: Haemophilus influenza b; HPV: Human papillomavirus; H1N1: Pandemic (H1N1) influenza; IPV: Inactivated poliovirus; MMR: Measles, mumps and rubella; MMR + V: Measles, mumps, rubella and varicella; OPV: Oral poliovirus; Td: Tetanus and diphtheria; Tdap: Tetanus, diphtheria and acellular pertussis.

Table 3
Vaccine doses, administration errors, and error rates by year at a large U.S. academic health system from 2006 to 2017.

Year	Vaccine doses	Administration errors	Error rate per 10,000 doses
2006	78,727	5	0.64
2007	104,129	30	2.88
2008	107,898	51	4.73
2009	121,825	46	3.78
2010	123,637	69	5.58
2011	113,896	32	2.81
2012	112,142	53	4.73
2013	122,679	52	4.24
2014	127,707	47	3.68
2015	128,233	58	4.52
2016	148,016	48	3.24
2017	142,317	61	4.29
TOTAL	1,431,206	552	3.86

The average number of errors reported per year was 46 with a range from 5 to 69 with the peak number of errors occurring in 2010 (Table 3). Initially the number of errors reported rose sharply, followed by some fluctuation and then a more gradual increase over the latter half of the study period (Fig. 1). Overall, there was a 12-fold increase in errors over the study period.

The average number of all incidents reported per year regardless of type (vaccine related and non-vaccine related) was 21,690. In 2006, 14,235 total incidents were reported and by 2017, this number was 32,014 (Fig. 1). All incidents reported increased gradually initially and then more sharply starting in 2012. The health system reported several efforts to improve voluntary reporting of incidents. In 2012, the health system launched an internal communication campaign to raise awareness of the importance of incident reporting. Then, the health system created daily safety huddles – brief care team meetings for sharing information about potential or existing safety problems facing patients – on the inpatient pediatric wards in 2013, the inpatient adult wards in 2014 and the cancer center in 2015. Lastly, in 2015, health system leadership announced an increased focus on promoting a culture of patient safety across the health system.

3.3. Vaccine administration error rates

Overall, the rate of vaccine administration errors was 3.86 per 10,000 vaccines given during the study period (0.04%) (Table 3). Despite the absolute number of errors being most frequent at ages birth to two years, four years, and 11 years, the highest error rates per 10,000 vaccines given occurred at ages two (8.81), three (7.81) and 19 years (6.95) (Table 1). Further review of incident reports for the vaccine types associated with the ages with the highest error rates showed that for patients two and three years of age, 47.37% of the errors involved the influenza vaccine; and in 68.44% of errors involving influenza, the wrong dose was given. Only one vaccine (seasonal influenza) is recommended in the two and three-year age group, yet the group had the highest error rate. To determine if other factors were contributing to the higher than expected overall error rate in this age group, we removed the influenza vaccine doses and influenza vaccine administration errors for patients two and three years of age. The revised error rate per 10,000 doses administered for this age group increased for both the 2-year olds (8.81 vs 9.82) and the 3-year olds (7.81 vs 8.92). The incident reports for the 19-years olds showed the vaccine type with the most errors was hepatitis A vaccine (50.00%) with all hepatitis A vaccine errors attributed to wrong dose.

Independent of patient age, five out of the six vaccine types with the highest error rate were vaccines infrequently indicated in children and adolescents with the exception of DTaP + HIB + IPV vaccine (Table 2). In general, the error rate by vaccine type decreased as the number of vaccine doses given increased (Fig. 2). The error rate per 10,000 vaccines given ranged from 0.64 to 5.58 annually with a peak in 2010 followed by a range of 3.24 to 4.52 between 2013 and 2017 (Fig. 3).

4. Discussion

Overall, we found a low vaccine administration error rate in our study of less than 0.04% over a 12-year period across multiple care settings. Similar to prior studies, the absolute number of errors reported increased over time. However, our study, with both number of errors and error rates, demonstrates stabilization of the error rate over the last half of the study period as the rise in absolute errors flattened and the vaccine doses given continued to increase. So unlike prior studies, this study suggests that efforts to decrease vaccine administration errors over the past decade may be having a positive impact when the increasing number of administrations is taken into account.

While only two patients in our study required additional medical care related to an administration error, numerous non-trivial effects were experienced by patients, caregivers and the health system. Some patients suffered minor inconveniences such as need for additional vaccine administration, and the health system incurred additional costs related to extra doses given and staff time

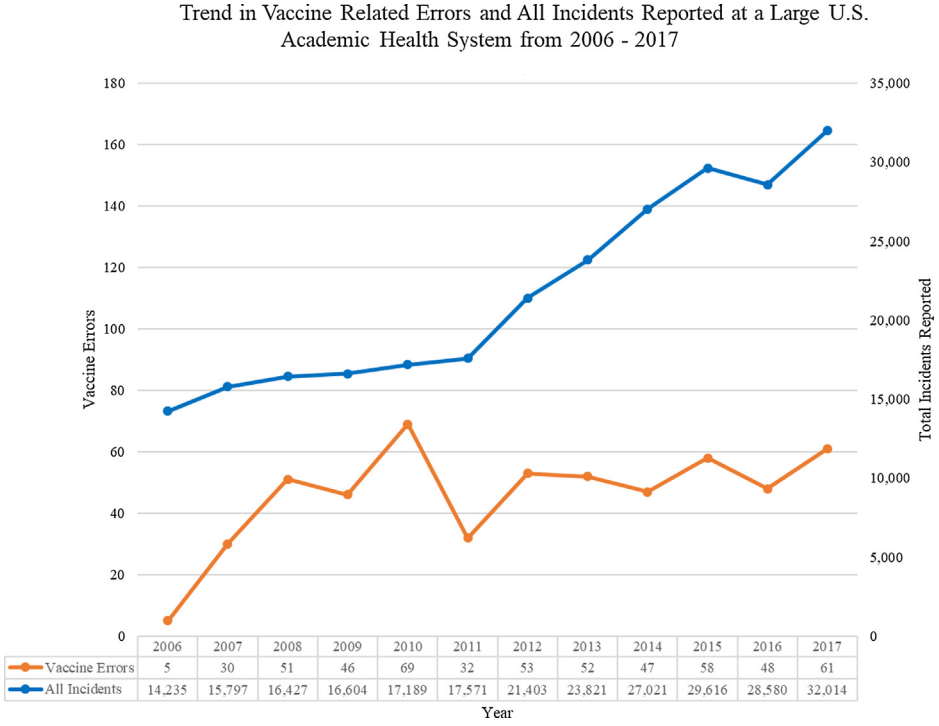

Fig. 1. Trend in Vaccine Related Errors and All Incidents Reported at a Large U.S. Academic Health System from 2006–2017.

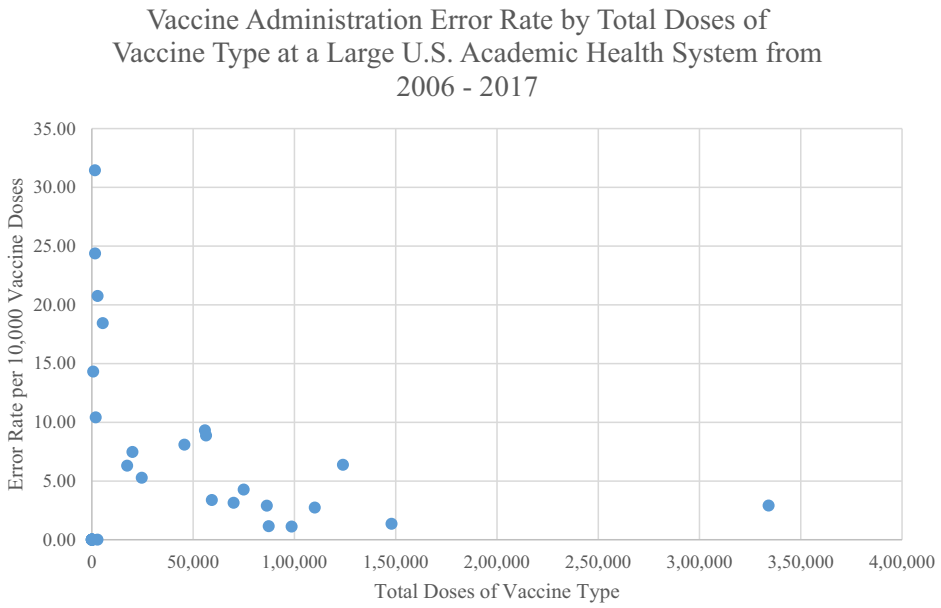

Fig. 2. Vaccine Administration Error Rate by Total Doses of Vaccine Type at a Large U.S. Academic Health System from 2006–2017.

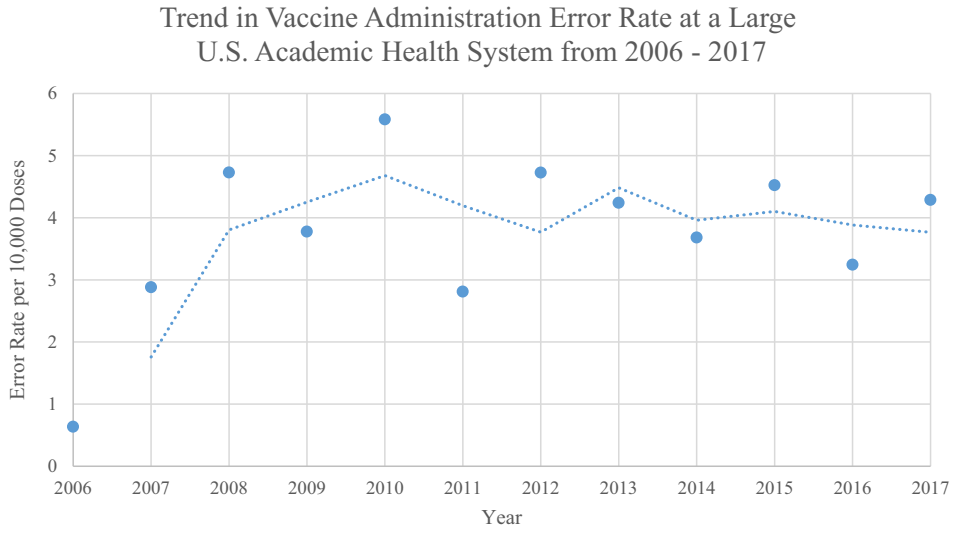

Fig. 3. Trend in Vaccine Administration Error Rate at a Large U.S. Academic Health System from 2006–2017.

to review and notify families of errors. From a public health perspective, some families expressed loss of trust over vaccination administration, which could lead to vaccine hesitation and refusal. These non-trivial adverse effects highlight the need to reduce vaccine administration errors to zero.

A closer look at the time periods with elevated error rates reveals potential leverage points for future interventions. The error rate was highest among children two and three years of age – a time period when relatively fewer doses are recommended and given. Children may be receiving vaccines in this age group for the following reasons: missed opportunity, delay of routine schedule or seasonal influenza vaccine. Nearly half of the errors for this age group in our study involved the influenza vaccine with over two thirds receiving the wrong influenza vaccine dose for age. This is consistent with prior studies showing that vaccines with age-based dosing are more likely to be associated with a wrong dose error [1,3]. The inactivated influenza vaccine used in the United States during the study period had a recommended dose increase for children beginning at 36 months of age [14]. Of note, even after removing influenza vaccine doses and influenza vaccine administration errors for the 2 and 3-year-olds, the error rate per 10,000 doses administered for this age group remained high suggesting that children receiving a vaccine in this age group because they are behind on vaccines are more likely to encounter an error. With some parents and even professionals advocating for a delayed or alternative schedule for the primary vaccine series, this finding raises concern [15].

A similar elevation in error rates was observed at 19 years of age. One-half of the errors in this age group were due to wrong dose given involving the hepatitis A vaccine, which also has a recommended dose increase at age 19 years. Increased education on the risk of errors associated with age-based dosing may help to decrease these type of errors along with efforts by manufacturers to avoid products with doses that vary by age.

Additional information that may guide future interventions to reduce vaccine administration errors can be found by examining the pattern of error rates by vaccine type. While one would expect that as the number of administrations increases for a given vaccine,

the opportunity for an error would increase, we found the opposite for vaccine types where an administration error occurred. For example, even though the influenza vaccine had the highest number of doses and absolute errors, its error rate was lower than nearly three quarters of the vaccines with a reported error. In contrast, the error rate was higher with Td, rabies, pneumococcal polysaccharide and the DTaP + HIB + IPV vaccine where the total doses given was relatively low. The only DTaP + HIB + IPV vaccine available in the US at this time was Pentacel® and this health system chose not to use the Pentacel vaccine in its formulary because of the concern with potential increased risk of errors with the requirement for reconstitution. However, a national Hib vaccine shortage occurred just around the time the Pentacel vaccine was FDA approved in mid-2008 and lasted until late 2009 [16,17]. During this time, Pentacel was the only available option to immunize infants against Hib. Fifty percent of the reported Pentacel incidents were due to improper reconstitution with the diluent; thus, the unfamiliar procedure variation associated with the Pentacel vaccine had a significant impact on the error rate. This supports the notion that the familiarity with the procedural steps of vaccine administration is important. Other examples in medicine have shown that the more often one performs a task, such as administration of intravenous fluids and medications, the less often errors are observed (familiarity matters) [18].

The number of vaccine doses given per year increased over time in this health system. This may reflect an increase in patient volume, an increase in the immunization coverage rates and/or additions to the recommended CDC immunization schedule occurring in 2007, 2008, 2009, 2010 and 2013 [19]. The increase in doses occurred despite national vaccine shortages occurring in this period. The number of vaccine errors reported per year in this health system also increased over time, consistent with a recent study of errors from the US voluntary vaccine adverse events reporting system (VAERS) from 2000 to 2013 [3]. Similar to this national data, the number of errors reported in our study more than doubled from 2006 to 2007 and nearly doubled from 2011 to 2012 with a peak in 2010. We believe the peak of errors seen in 2010 may be related in part to the H1N1 vaccine introduced in late 2009 for use during the 2009–2010 influenza season including the spring of 2010. The H1N1 virus was discovered after the seasonal influenza vaccine was already in production for 2009–2010 season resulting in a recommendation for children to receive both the H1N1 and the seasonal influenza vaccine adding to the potential for confusion with influenza vaccination in children [20].

It is not uncommon to find that surveillance systems "lead" to a reported increase in error rates by improving the attention and detection of previously uncounted errors. That phenomenon could be at work in our system. Efforts by the health system to increase voluntary reporting of patient safety incidents beginning in 2012 may have contributed to the increase in vaccine related errors reported from 2011 to 2012; however, efforts in subsequent years, which focused on inpatient units where relatively few vaccines are given, appear to have had minimal impact on reporting of vaccine related errors.

5. Limitations

The health system incident reporting system used in this study relies on voluntary reporting, which may lead to an underreporting of true errors [21,22]. While the error rate per year peaked at 0.06% during the study period, it did not approach the rate of 0.4% reported by Wise over a three-month period for two practices [12]. However, Wise performed chart review to identify errors instead of relying on reporting suggesting the actual error rate may be understated with reporting. In addition, voluntary error reporting may bias towards certain types of errors or vaccines. Because this study focused on assessing error reporting patterns by reviewing data available in the error reporting system, we were unable to capture additional factors that may contribute to errors, such as timing of vaccines or expertise of staff, that might be available through a chart review. Finally, this study looked at errors from a single large academic medical center and does not represent all entities providing vaccines to children. However, this is the largest long-term study of vaccine administration error rates in the United States.

6. Conclusions

Vaccine administration errors are uncommon and the rate of errors appears to be stabilizing. Vaccine administration errors are more likely to occur at ages when vaccines are not commonly given, and with vaccines that have age-specific dosing. Staff are less likely to commit an error with vaccines that are given frequently. Our findings suggest that additional safety checks should be instituted when a vaccine is given off-schedule, or has age-specific dosing, and with rarely used vaccines. With some families choosing to use alternative schedules, and rarely used vaccines, further study is needed to determine if alternate vaccine schedules are associated with more vaccine administration errors.

Contributors' statement

Lauren Reed designed the study, analyzed the data and drafted the initial manuscript and reviewed and revised the manuscript.

Beth Tarini made substantial contributions to the analysis and interpretation of data, and critically revised the manuscript for important intellectual content.

Margie Andreae conceptualized and contributed to the study design, reviewed and made substantial contributions to the analysis of the data, and provided critical revisions to the manuscript.

All authors approved the final manuscript as submitted, and agree to be accountable for all aspects of the work.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper

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