Vaccine Error Reporting Program: A System to Collect Data on Vaccine Administration Errors

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Background

Vaccine Administration Errors (VAEs) are preventable events that could lead to reduced vaccine effectiveness or adverse patient outcomes. Examples of VAEs include:

- Incorrect vaccine or vaccine dose
- One or more components of vaccine omitted
- Patient is the incorrect age to receive vaccine
- Expired, contaminated, or deteriorated vaccine

Previous studies using vaccine adverse event or medication error reporting systems (e.g., Vaccine Adverse Reporting System[1], Medication Error Reporting Program[2]) have found product labeling and human error as contributors to VAEs[3,4]; however, existing surveillance systems are not designed specifically to collect data on VAEs.

Identifying trends in VAEs could result in targeted education efforts, and changes to product labeling, name, or design that prevent errors.

Objectives

1. To develop a surveillance system for VAEs
2. To describe reported VAEs

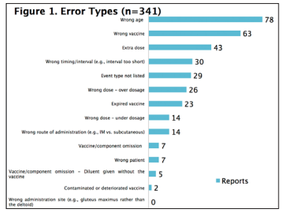
Methods

- The California Department of Public Health (CDPH) partnered with the Institute of Safe Medication Practices (ISMP) to develop a web-based VAE surveillance tool, the Vaccine Error Reporting Program (VERP).
- VERP collects data on VAEs, including type and description of error, implicated vaccine, and provider information.
- VAEs are self-reported online at: http://verp.ismp.org.
- Providers participating in CDPH programs were notified of VERP by email in October of 2012 and the Immunization Action Coalition notified subscribers via its newsletter in December 2012.
- Data entered into VERP from Sept 12, 2012–Sept 16, 2013 were analyzed.
- Factors that contributed to the most frequently reported VAE types were categorized as follows:
  - **Vaccinator Knowledge Deficiency:** Vaccinator unaware of product, product components, or age requirements.
  - **Failure to Follow Protocol:** Vaccinator failed to follow vaccine administration protocols, e.g., distraction.
  - **Labeling/Packaging Problems:** Similar or confusing product names, labeling or packaging.
  - **Storage/Inventory Problems:** Crowded storage areas, vaccines stored in mislabeled or incorrect location, or age-appropriate vaccine unavailable.
  - **Communication Problems:** Wrong vaccine ordered or miscommunication between practitioners.
  - **Other Factors:** Factors that did not fit in another category.

RESULTS

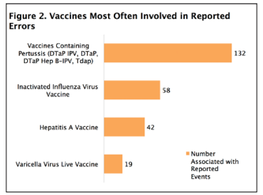
- VERP went live on September 12, 2012.
- 341 unique errors were reported from September 12, 2012–September 16, 2013.
- 90% of reports were errors that reached the patient, 7% were errors that did not reach the patient, and 3% were categorized as hazardous conditions where no error occurred, but was a situation that warranted concern.

Event Types



- Error types "Wrong Age" and "Wrong Vaccine" were reported most frequently, comprising 23% and 18% of all errors, respectively.

Vaccines Most Frequently Associated with VAEs

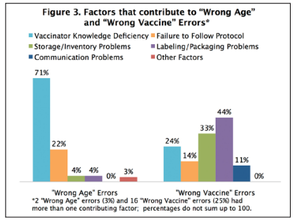


- The Kinrix® brand of DTaP-IPV vaccine was reported most frequently in errors with 50 total reports, followed by the influenza vaccine Fluzone® with 37 total reports and the Havrix® brand of hepatitis A vaccine with 29 total reports.

Contributing Factors for "Wrong Age" and "Wrong Vaccine" Errors

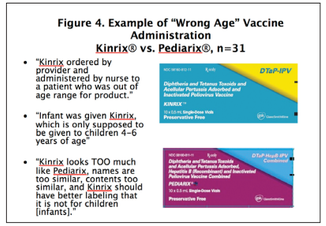
Wrong Age: Patient was given correct vaccine antigen(s), but was the incorrect age for the vaccine ordered, prepared or given.

Wrong Vaccine: Patient was given wrong vaccine antigen(s).



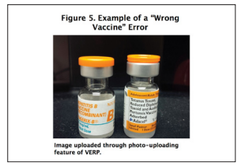
- Knowledge Deficiency was the most common contributing factor reported for "Wrong Age" errors with 55 reports, comprising 71% of all "Wrong Age" errors.
- The most common contributing factor for "Wrong Vaccine" errors was Labeling/Packaging Problems with 28 reports (44%) followed by Storage/Inventory Factors with 21 reports (33%).

"Wrong Age" Error Example



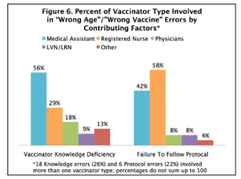
- Mix-ups between different types of pertussis containing vaccines, e.g., Tdap vs. DTaP, were common errors in the "Wrong Age" and "Wrong Vaccine" errors. A total of 67 such errors were reported within these two error types.
- A total of 31 mix-ups between Kinrix® (intended for children 4-6 years of age) and "Pediarix®" (intended for children 6 weeks- 6 years of age) was reported in the "Wrong Age" and "Wrong Vaccine" error types, with 26 reported as "Wrong Age" error types.

"Wrong Vaccine" Error Example (Labeling/Packaging Problem)



- The photo above was submitted to show the similarities between Engerix-B® hepatitis B vaccine and Adacel® Tdap vaccine packaging.
- Labeling/ Packaging Problems were the most common contributing factors noted for "Wrong Vaccine" error types.

Proportion of "Wrong Vaccine"/"Wrong Age" Knowledge Errors by Vaccinator Type



- Medical Assistants (MAs) were more frequently reported for Vaccinator Knowledge Deficiency Problems (38 reported, 56%) than Registered Nurses (RNs) (20 reported, 29%).
- Conversely, RNs were more frequently reported for Failure to Follow Protocol Problems (12 reported, 58%) than MAs (10 reported, 42%).

Discussion

- Similar to other research on VAEs[3,4], the most frequent errors reported to VERP were "Wrong Age" and "Wrong Vaccine."
- Vaccinator Knowledge Deficiency contributed to the majority of "Wrong Age" vaccines.
- Labeling and Packaging Problems contributed to the majority of "Wrong Vaccine" error types.
- Pertussis containing vaccines and influenza vaccines were associated with the greatest number of VAEs.
- MAs and RNs were more frequently involved in reported VAEs than other vaccinators; however, these reports may reflect that MAs and RNs or more likely to give vaccines.

Limitations

- VAEs are often multi-factorial and classification of errors by contributing factors may not have been accurate.
- "Wrong Age" and "Wrong Vaccine" errors had overlapping qualities which may have resulted in misclassification by users or during analysis.
- Limited numbers of providers are likely to be familiar with VERP, reducing the number of reports.

Conclusions

- VERP is a useful tool for tracking VAEs to identify common problems and potential solutions, but providers need to be aware of the system and willing to self-report.
- As noted in other studies and reports, similarities in vaccine names, labeling and packaging can lead to VAEs.
- Vaccine manufacturers should be educated about the relationship between labeling and packaging and VAEs.
- Evaluation of current methods of vaccine administration training is warranted; vaccinators may need more training.
- Clearly defined variables, instructions for filing reports and website directional tools such as a data dictionary and reminder pop-ups would improve the quality of data.
- Public and private partnerships are an effective way to address knowledge gaps and implement timely solutions.

References

1. CDC's Vaccine Adverse Events Reporting Program (VAERS): http://vaers.hhs.gov
2. ISMP's Medication Error Reporting Program (MERP): www.ismp.org
3. Bundy DG, Shore AD, Morlock LL, Miller MR. Pediatric vaccination errors: Application of the "5 Rights" framework to a national error reporting database. 2009.Vaccine. 27(29):3890-6.
4. Chang, S, Pool V, O'Connell K, Polder JA, Iskander J, Sweeney C, Ball R, Braun MM. Preventable Mix-ups of Tuberculin and Vaccines: Reports to the US Vaccine Drug Safety Reporting Systems. 2008. Drug Safety 31(11):1027-1033.

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