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, Medication Error Reporting Program) have found product labeling and human error as contributors to VAEs; however, existing surveillance systems are not specifically designed 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.
- VAE types are self-reported online at http://verp.cdph.ca.gov.
- Providers participating in CDPH programs were notified of VERP via 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., dosing.
  - **Labeling/ Packaging Problems:** Similar or confusing product names, labeling or packaging.

Vaccines Most Frequently Associated with VAEs

- The Kinrix® brand of DTaP-IPV vaccine was reported most frequently in 90% of reports, followed by Engerix-B® hepatitis B vaccine and Adacel® Tdap vaccine packaging.
- Labeling/ Packaging Problems contributed to the majority of VAEs, most frequently, comprising 44% of all error types.

Contributing Factors for “Wrong Age” and “Wrong Vaccine” Errors

- **Wrong Age** Error Example
  - **Vaccine** Errors: Patient was given correct vaccine antigen(s), but was the incorrect age for the vaccine ordered, prepared or given.
  - **Contributing Factors:**
    - Knowledge Deficiency: The most common contributing factor reported for “Wrong Age” errors with 55 reports, comprising 71% of all “Wrong Age” errors.
    - Product/ Packaging Problems: 28 reports (44%) followed by Storage/Inventory Factors with 21 reports (33%).

- **Wrong Vaccine** Error Example
  - **Vaccine** Errors: Patient was given correct vaccine antigen(s), but was given incorrect vaccine.
  - **Contributing Factors:**
    - Knowledge Deficiency was the most common contributing factor reported for “Wrong Vaccine” errors with 67 reports, comprising 90% of all “Wrong Vaccine” errors.
    - Product/ Packaging Problems were the most common contributing factors noted for “Wrong Vaccine” error types.

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. IMEPR’s Medication Error Reporting Program (IMEPR): http://www.imepr.org
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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 Kinrix® brand of DTaP-IPV vaccine was reported most frequently in 90% of reports, followed by Engerix-B® hepatitis B vaccine and Adacel® Tdap vaccine packaging. Labeling/ Packaging Problems contributed to the majority of VAEs, most frequently, comprising 44% of all error types.

**Proportion of “Wrong Vaccine”/ “Wrong Age” Knowledge Errors by Vaccinator Type**

- **Medical Assistants (MAs):** More frequently reported for vaccine knowledge deficiency than RNs, 15% reported for vaccine knowledge deficiency compared to 9% for RNs.
- **Registered Nurses (RNs):** More frequently reported for failure to follow protocol, 29% reported for failure to follow protocol compared to 15% for MAs.
- **Other:** More frequently reported for labeling/packaging errors, 30% reported for labeling/packaging errors compared to 20% for MAs.

**Discussion**

- Similar to other research on VAEs, the most frequent errors reported to VERP were “Wrong Age” and “Wrong Vaccine.”
- **Vaccine Knowledge Deficiency:** Contributed to the majority of “Wrong Age” vaccines.
- **Labeling and Packaging Problems:** Contributed to the majority of “Wrong Vaccine” error types.
- Peri-natal confusion 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 are more likely to give vaccines.