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Common Vaccine Error Leaves Patients Unprotected Against Serious Communicable Diseases

Horsham, Pa---The Institute for Safe Medication Practices (ISMP) has received frequent reports of errors involving vaccine administration to a patient where only one of two necessary vaccine components supplied is administered. These errors leave patients unprotected against serious and sometimes fatal communicable diseases.

When lyophilized (powdered) vaccines are co-packaged with manufacturer-supplied diluents, a danger exists that only the diluent will be dispensed and administered by practitioners who mistakenly believe it is the actual medication. Another serious risk exists with vaccines that are provided with two-component containers that must be mixed together prior to administering the dose.

These errors account for 6% of all error types reported to the ISMP National Vaccine Errors Reporting Program (ISMP VERP), which began in late 2012. There are currently 12 vaccines that come with specific diluents and 2 vaccines provided with two-component containers. Reported errors with these vaccines typically involved multiple patients; if not prepared and administered properly, patients could remain vulnerable when exposed to meningitis, pertussis, and other serious illnesses. Those individuals may not even know that they are still susceptible to a disease if the error goes unrecognized or unreported.

ISMP believes vaccine manufacturers must do more to improve the labeling on the vial to reduce the risk of errors. The labeling on vaccines and diluents or two-component vaccines must clearly distinguish each vial, yet connect the two products so their contents are administered together. Barring stability or similar issues, vaccine manufacturers also should determine whether they can package two-component vaccines and diluents in new and novel ways to promote safety.

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Healthcare practitioners can also reduce the risk of errors with vaccine dispensing and administration by implementing the following ISMP recommendations:

---Establish ongoing education of staff who may dispense and administer vaccines, and include discussion of safety issues with two-component vaccines and vaccines packaged with specific diluents.

---Distinguish the most critical information on vaccine containers by circling or highlighting the information, or using auxiliary flag-type labels without obscuring existing label information.

---If using a vaccine that requires a specific diluent or two components that must be combined before administration, if stability allows, keep the two vials together using a rubber band or place them together in a sealable plastic bag. Affix an auxiliary label to the vaccine to remind staff to use both vials.

---Label the areas where vaccines are stored to facilitate correct selection and remind staff to combine the contents of vials. Examples of vaccine labels for storage areas are provided by the Centers for Disease Control and Prevention (www.ismp.org/sc?id=367).

---To confirm administration of both vaccine components, document the NDC number for each vial in the vaccine log *before* administration. Documenting actual administration should always occur *after* it is given, which can also provide an opportunity for a double check. Patients and their caregivers should be involved in the documentation/double check process as well.

For a copy of an ISMP newsletter article that provides detailed examples of errors with specific vaccines as well as additional vaccine packaging and labeling recommendations, go to: http://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=80

About ISMP: The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents nearly 40 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit www.ismp.org

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