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ISMP Seeks to Improve Safety of Investigational Drug Naming, Labeling, and Packaging

Horsham, Pa.— The Institute for Safe Medication Practices (ISMP) is publishing a two-part series in the ISMP Medication *Safety Alert*!® Acute Care newsletter that focuses on product-related safety concerns with investigational drugs. Many drugs being tested in clinical trials are considered high-alert medications that are more likely to cause harm when used in error, and yet little regulatory oversight exists to standardize their labeling, packaging, and nomenclature. This increases the risk for errors that may cause serious harm to patients and lead to inaccurate data about the drug's safety and efficacy.

Part I, which appears in the April 19, 2018 issue, explores current issues with investigational drug nomenclature, labeling, and packaging. Part II, which will be published in the May 3, 2018 issue, will detail ISMP strategies and recommendations for preventing potential errors.

Some of the safety issues that are identified in Part I include:

Drug Nomenclature

- **Look-alike "license plate-type" investigational drug identification**—similar series of numbers preceded by an abbreviation of sponsoring company's name can easily be confused.
- **Changing product names not reflected on labels and protocols**—when a drug moves into a new trial phase and is assigned a generic name, all labeling is not necessarily updated.

Drug Labeling

- **Unlabeled products**—in some cases, the investigational drug labeling appears only on the outside of the product shipping carton.
- **Missing, confusing, or unnoticeable drug names**—labels may contain the drug's identifier in nonstandard locations or not at all.
- **Missing or hard to find drug strength, formulation, and/or barcodes**—can force practitioners to have to verify the information in other ways.
- **International labels in multiple languages**—may be many pages long, making it difficult to find basic information quickly.
- **Small font size and no differentiation of text**--some labels require a magnifying glass to read. Most do not use bold type, color, tall man letters, or other strategies to differentiate products.

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Drug Packaging

- **Few unit dose packages are used**—many investigational drugs are shipped in bulk packages that require repackaging to avoid contamination of the bulk supply.
- **Packaging is often not appropriate for the route of administration**—for example, liquid medications intended for oral administration have been packaged in vials.
- **Tablets often appear too similar to other products**—the risk of errors increases when tablets are identical in color and size with no markings to help differentiate strengths.
- **Quantity in containers can vary**—some practitioners reporting that sealed bottles have contained different amounts than indicated on the label or packing slip.

The complete first newsletter article in ISMP's two-part series on investigational drug safety is available on ISMP's website.

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 more than 30 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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