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ISMP Survey Links Parenteral Nutrition Component Shortages to Adverse Outcomes

Horsham, Pa---Medication errors, safety risks, and preventable adverse outcomes are occurring due to shortages in critical parenteral nutrition (PN) components, according to a recently released survey from the Institute for Safe Medication Practices (ISMP). Findings from the survey, which also explored use of imported PN replacement products, are published in the February 13 issue of the *ISMP Medication Safety Alert!* newsletter,

ISMP conducted the survey in November and December 2013 to assess how drug shortages involving essential components needed to prepare PN are affecting medication safety. More than 230 practitioners, mostly pharmacists, participated in the survey.

Depending on the PN component in short supply, anywhere from 3% to 28% of respondents reported medication errors associated with the inability to obtain those products, or with the use of an alternative product during the shortage. Medication errors were most often linked to shortages of trace elements, sodium phosphate, potassium phosphate, multivitamins, calcium gluconate, and IV fat emulsion. Overall, 1 in every 4 to 5 respondents reported preventable adverse outcomes due to shortages.

Survey participants indicated that omitted or delayed administration of electrolytes, minerals, trace elements, vitamins, and amino acids due to shortages have resulted in deficiencies in patients' serum levels of those key components. When PN components have been rationed, new variability in administration schedules has led to some patients not receiving the necessary elements. Some respondents reported that in the absence of calcium gluconate, they have administered calcium chloride peripherally, increasing the risk of precipitation with phosphate. A few also reported worsening anemia in patients who did not receive copper chloride, and bone fractures in infants who did not receive adequate phosphorous or other key minerals or vitamins.

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Common contributing factors with reported shortage-related errors included:

- Mix-ups between electrolyte salts
- Confusion between pediatric and adult alternative products
- Differences in concentration with alternative products
- Not making changes to protocols, templates, work labels, compounders, or order entry systems

During the past year, 68% of survey respondents reported using at least 1 of 6 products imported into the U.S. after the Food and Drug Administration (FDA) exercised regulatory discretion to ease the shortages of critical PN components. Adult multi-trace elements, organic phosphate injection, and IV fat emulsion were the most frequently used imported products. Overall, half of the survey respondents found importation of critical drug products during the shortage to be helpful (26%) or very helpful (24%) in meeting patient needs.

Survey participants who used an imported product during the past year were asked to report any associated problems. Expense was among the top three problems identified. The most frequently reported problem besides expense for calcium chloride injection, zinc gluconate injection, and IV fat emulsion was that the products required additional steps to prepare and dispense. The most frequent reasons provided by respondents who did not use at least 1 imported product during the past year included concerns about safe use. Compatibility, stability, and sterility concerns were also cited with imported products, particularly adult multi-trace elements, phosphate injection, and calcium chloride injection.

For a copy of the *ISMP Medication Safety Alert!* newsletter cover article on the survey, which contains additional data, go to: http://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=70

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. ISMP is a federally certified patient safety organization (PSO), providing healthcare practitioners and organizations with the highest level of legal protection and confidentiality for patient safety data and error reports they submit to the Institute. 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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