# Indiana State Department of Health

# LONG TERM CARE NEWSLETTER

ISDH Long Term Care
Newsletter Issue # 09-27
September 4, 2009

In Today's Issue:
- Pressure Ulcer Initiative
- Recalls

## Pressure Ulcer Initiative Update

At the August 26 Outcomes Congress of the Indiana Pressure Ulcer Initiative, the Indiana State Department of Health (ISDH) announced preliminary data suggesting that pressure ulcers may have been reduced at participating facilities by up to 30%. While the data is preliminary and some participants have yet to report data, the indications support a significant reduction in pressure ulcers through the implementation of system-based improvements. The Initiative was launched in June 2008. The reduction was for the period from late 2008 to June 2009 and occurred at 95 nursing homes, 40 hospitals, and 28 home health agencies participating in the Indiana Pressure Ulcer Initiative. The ISDH hopes to have complete data in the coming months to better analyze results.

"The initiative demonstrates how health care quality can be improved through a collaborative effort," said State health commissioner, Judy Monroe, M.D. The initiative emphasized components such as risk assessments, regular skin inspections, and care coordination between providers. The University of Indianapolis Center for Aging & Community served as project director for the initiative.

Pressure ulcers have been a problem in Indiana health care facilities. For three straight years, the Indiana Medical Error Report cited the development of a stage 3 or stage 4 pressure ulcer while admitted to a hospital as the top reported event. In 2008 surveyors cited nursing homes 186 times for failure to adequately prevent pressure ulcers.

Several tools and resources were created as part of the initiative. Six online education modules were created to provide information about pressure ulcers. They are directed at nurse aides and health care staff to assist in entry-level pressure ulcer education. The modules also serve as a resource for patients and families in learning about pressure ulcers. The modules are found on the ISDH pressure ulcer web page at www.in.gov/isdh/24558.htm.

The origins of the initiative date to an October 2007 conference on pressure ulcer prevention presented by the ISDH. Based on GPRA Goal data from the Centers for Medicare and Medicaid Services that began in 2003, Indiana nursing homes had the highest rate of pressure ulcers in the six state region. The data from 2007 indicated Indiana had an 8.7% rate of pressure ulcers in nursing home residents. In December 2008 the rate was at 8.3%. Over the first quarter of 2009, the rate fell to 8.0% dropping Indiana to third in the region. That data showed a decrease of 171 pressure ulcers in nursing homes in the first quarter of 2009. While the CMS data covers all nursing homes, whether participating in the initiative or not, it likely is significant that the significant drop in one quarter occurred along with Initiative data showing a decrease among participants.

Based on the actual reduction of pressure ulcers in the first quarter, the ISDH calculated an estimated savings in health care costs. "The cost of treating pressure ulcers ranges from $10,000 to over $40,000 per pressure ulcer," said Dr. Monroe. "At a cost of $20,000 per pressure ulcer, the reduction of 171 pressure

ulcers would result in a savings of $3.42 million dollars. More importantly, preventing pressure ulcers significantly improves the quality of life for Hoosiers."

The initiative focused on the six essentials of pressure ulcer prevention:

- Assessment upon admission
- Reassess risk daily
- Inspect skin daily
- Manage moisture
- Optimize nutrition and hydration
- Minimize pressure

The ISDH thanks participants for their efforts and encourages continued efforts to significantly reduce pressure ulcers.

## Recalls

Alaris System (Cardinal Health)
Audience: Hospital risk managers

[Posted 08/05/2009] FDA notified healthcare professionals of the Class 1 recall of various modules of Cardinal Health's Alaris System, electronic infusion pumps that deliver controlled amounts of medications or other fluids to patients through an intravenous, intra-arterial, epidural, and other routes of administration. The firm initiated the recall after identifying five problems that affected the Alaris System, including failure of the occlusion warning message, syringe volume warning message, electrostatic discharge protection circuitry and fluid ingress tubing. It was determined that the five failures may result in patients experiencing under- or over-infusion which may result in serious injury or death.The device is intended for use with adult and pediatric patients in hospitals including critical care units, emergency rooms, outpatient surgical centers, hospices, and nursing homes.

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm174797.htm

Ibuprofen (Unapproved) topical drug products
Audience: Consumers, pharmacists

[Posted 08/21/2009] FDA informed consumers and healthcare professionals of its intent to take action against eight companies that market unlawful over-the-counter (OTC) topical drug products containing the pain reliever ibuprofen. The products, which contain ibuprofen in combination with a variety of other active ingredients and are marketed for pain relief, are unapproved new drugs that require an approved new drug application in order to be legally marketed. Orally administered ibuprofen has been approved as a safe and effective treatment for pain and inflammation. There are no approved applications for topical ibuprofen products. Topical ibuprofen is often promoted as a "safer" alternative that can be used in place of oral ibuprofen because of certain side effects, such as stomach ulcers and cardiovascular effects that are associated with prolonged use of oral ibuprofen. However, these safety claims for topical ibuprofen have not been reviewed by the FDA, nor has the agency evaluated what side effects might be associated with such products.

The names of the products and manufacturers that received warning letters are:
Emuprofen (Progressive Emu, Inc.)
BioEntopic 15% Ibuprofen Crème (BioCentric Laboratories, Inc.)
Ibunex Topical Ibuprofen (Core Products International, Inc.)
LoPain AF 15% Ibuprofen Crème (Geromatrix Health Products)
IB-RELIEF (MEKT LLC)
Profen HP (Ridge Medical Products)
IbuPRO-10 Plus (Meditrend, Inc. dba Progena Professional Formulations)
IBU-RELIEF 12 (Wonder Laboratories)

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm179925.htm

GDH-PQQ (glucose dehydrogenase pyrroloquinoline quinone) Glucose Monitoring Technology
Audience: Diabetes healthcare professionals, hospital risk managers, patients

[Posted 08/13/2009] FDA notified healthcare professionals of the possibility of falsely elevated blood glucose results when using GDH-PQQ glucose test strips on patients who are receiving therapeutic products containing certain non-glucose sugars. These sugars can falsely elevate glucose results, which may mask significant hypoglycemia or prompt excessive insulin administration, leading to serious injury or death.

GDH-PQQ glucose monitoring measures a patient's blood glucose value using methodology that cannot distinguish between glucose and other sugars. Certain non-glucose sugars, including maltose, xylose, and galactose, are found in certain drug and biologic formulations, or can result from the metabolism of a drug or therapeutic product. The FDA Public Health Notification provides a list of GDH-PQQ Glucose Test Strips and recommends that healthcare practitioners avoid using GDH-PQQ glucose test strips in healthcare facilities or take steps to never use them on patients receiving interfering substances.

FDA encourages the voluntary reporting of any medical device adverse events related to glucose meters or glucose test strips that do not meet the requirements for mandatory reporting. Adverse events should be reported to the FDA's MedWatch Adverse Event Reporting program online, by phone [1-800-332-1088], or by returning the postage-paid FDA Form 3500 by mail [to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787] or fax [1-800-FDA-0178].

[08/13/2009 - Public Health Notification - FDA]
[08/13/2009 - Advice for Patients - FDA]

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm177295.htm

The H1N1 virus continues to affect Indiana communities. The ISDH encourages health care facilities to work with their local health departments to plan for H1N1 vaccinations.

We look forward to seeing you at the Long Term Care Leadership Conference on September 17 on staffing strategies. Best wishes for the coming week. Have a enjoyable and safe holiday weekend. .

Terry Whitson
Assistant Commissioner
Indiana State Department of Health

Indiana State Department of Health

Visit the ISDH home page at http://www.in.gov/isdh/ for the latest public health information.

Visit the ISDH Division of Long Term Care home page at http://www.in.gov/isdh/23260.htm for information on long term care.