FDA Issues Guidance on Safer Hospital Bed Design

The Food and Drug Administration (FDA) has published its final guidance on reducing the occurrence of hospital bed entrapments through improved design of hospital beds. The guidance, prepared with input from both Government and private sector groups, notes that strangulation and death can result from patients’ becoming caught between parts of the bed. Elderly patients in hospitals and nursing homes, especially those who are frail, confused, restless, or subject to uncontrollable body movement, are most vulnerable to entrapment, with the head, neck, and chest the body parts most at risk.

Additional Information:

Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment
http://www.fda.gov/cdrh/beds/7

Information Technology: A Double-Edged Sword in Health Care

Clinical information technology (IT) is rapidly being added to virtually all health care facilities, yet such “progress” often generates new forms of failure and error. Robust health care computer systems need to be user-centered rather than technology-centered and to support successful human-computer interaction. In a well-documented case study analysis appearing in the AHRQ WebM&M, Dr. Richard I. Cook of the University of Chicago (who spoke at our MedSun annual conference in October in CA) illustrates how reliance on IT can confound patient care and delay appropriate treatment.

A 70-year-old woman admitted to a community hospital was shown by a CT scan of her brain to have an acute subdural hematoma. Transferred to a large referral center for urgent neurosurgical evaluation, the woman was subsequently misdiagnosed as having had a stroke, based on a CD containing relevant but outdated images that had been sent with her to the larger facility. A consulting neurologist later found more recent images that demonstrated the acute subdural hematoma, which was then urgently evacuated. The patient improved after a prolonged period of rehabilitation.

Dr. Cook uses this case study to explore the challenges inherent in introducing clinical IT to health care settings. Adding IT does not eliminate failure, he states, but
instead changes the type, frequency, and severity of failures, often in unpredictable and surprising ways. Such failures are often regarded as human (operator) error but actually arise from poor human-computer interaction.

Additional Information:

The complete text of Dr. Cook's analysis is available at http://webmm.ahrq.gov/case.aspx?caseID=899

C-Reactive Protein: Differences Among Various Assays

The Food and Drug Administration (FDA) has acknowledged possible confusion in the laboratory community and among clinicians and manufacturers as to the indications for use of different C-reactive protein (CRP) assays. As the agency responsible for approving device labeling (including package insert specifications), FDA requires appropriate evidence to support each clinical purpose assigned to assays. Differences between conventional CRP, high-sensitivity CRP (hsCRP), and cardiac CRP (cCRP) assays must be understood in order to meet the regulatory need to designate a CRP assay specifically for cardiovascular risk indications for use.

Additional Information:

FDA Guidance
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077167.htm11

JCAHO Launches Redesigned Web Site

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has introduced its revamped Web site, which features one-click navigation, increased accessibility, and new sections that focus on specific audiences. Consumers and health care organizations will now be able to tap into the latest information on health care quality and safety. Approximately 150,000 visitors each month use the site to research more than 15,000 accredited hospitals, home health agencies, health care clinics, and other health care organizations through JCAHO’s Quality Check mechanism. Extensive feedback from users of the site helped the agency in enhancing and improving its Web presence as a user-friendly destination.
The Benefit of Detailed Discharge Instructions at Ambulatory Surgical Facilities

According to reports submitted to the Pennsylvania Patient Safety Authority, there is a need for greater communication and detailed instruction for patients discharged from ambulatory surgical facilities (ASF). Although adequate instruction exists at most ASF’s, a summary of reports to the Pennsylvania Patient Safety Reporting System (PA-PSRS), highlighted in the December 2005 issue of the Patient Safety Advisory, suggests that more detailed discharge instructions may have curtailed the hospital-level care required for some patients discharged from ASF’s.

Additional Information:

December 2005 Patient Safety Advisory Report 14

First, Do No Harm ® Films Form Basis for Workshop Print Item
E–mail Item

The Partnership for Patient Safety is offering a workshop based on its film series used in 39 countries around the world to promote quality and safety in health care settings. First, Do No Harm: A Workshop to Heighten Patient Safety Awareness includes viewing the three films and then progressing to discussions and activities that can be custom-designed to each particular audience. Each film presents a fictionalized case study based on actual events from malpractice claims files that is intended to stimulate reactions and suggestions for best practices in moving health care organizations toward systems-oriented patient safety and effective management. The workshop, whose scope can range from a 2-hour high-level overview to a 2-day in-depth process, is appropriate for medical staffs, clinical and support departments, integrated delivery teams, administrative teams, and boards of directors.

Premier Safety Institute Information About JCAHO’s Current Position On Alcohol Hand Sanitizers Used In Corridors Print Item
E–mail Item
JCAHO clarifies position on alcohol hand sanitizers – foam and gel now permitted in corridors

Corridor location of alcohol-based hand rub (ABHR) dispensers has been viewed as a key strategy to improved access and adherence to hand hygiene.

Following concerns expressed by multiple stakeholders, JCAHO clarified its December 2005 interpretation that restricted foam dispensers to patient rooms; the new guidance treats gels and foams the same and now permits foam dispensers in corridors. This clarification was published in the March 2006 issue of Joint Commission Perspectives. This new interpretation removes what is hoped to be one of the last barriers to hallway placement of dispensers with alcohol-based hand sanitizers because of fire safety concerns.

Recent changes in national and international fire codes lifted previous restrictions for corridor placement of alcohol-based hand rub (AHBRs) dispensers, in part, because fire modeling studies on gel formulations showed a low risk for fire hazards if proper guidelines are followed (e.g., permissible placement and volumes). (See related stories in Safety Share)

Key points of the JCAHO clarification include:
- Foam dispensers are allowed in corridors if they meet the same conditions required for gel dispensers (Note: JCAHO states that this position may be modified if safety concerns arise in the future.)
- There must be at least six inches from the center of a dispenser to an ignition source (e.g., electrical outlets).
- An equivalent level of safety may be achieved (if all specific requirements cannot be met) by performing a product-specific risk assessment and determining alternative methods for managing the risks.
Abstract:
Utilizing MedSun sub-contract funds, UCLA Medical Center developed an improved “tag and sequester” program to help identify and isolate defective medical devices. The STAR Response Program (Stop, Tag, And Report) was created after eliciting staff feedback at inservices and an exposition. A system-wide roll-out of this program at UCLA Medical Center, Santa Monica-UCLA Medical Center and the UCLA Neuropsychiatric Institute and Hospital is currently being evaluated.

Identifying the Problem:
Despite multiple policy guidelines stipulating to "not use" and "not discard" defective devices, these devices continued to be used and discarded at UCLA Medical Center. Both clinical and financial incentives existed to improve the existing “tag and sequester” system being employed to identify and isolate malfunctioning devices. In addition to the potential harm that can occur to patients and healthcare workers when defective devices are not properly identified and repaired, defensible cases can also be lost as the result of “missing” devices. In May 2005, UCLA received MedSun funding via a sub-contract to raise staff consciousness about medical device safety, develop tag and sequester related labels, and implement a consolidated procedure. In August 2005, Nursing leadership hired an experienced consultant to design and help implement the “tag and sequester” program.

Obtaining Staff Input:
Beginning in August 2005, in order to better define the problem with the existing tag and sequester policy and procedure, elicit staff input on how to fix the problem, and generally raise staff understanding about the need to identify and isolate defective devices, a staff awareness campaign was initiated. The MedSun PowerPoint presentation, Improving Patient Safety by Reporting Problems with Medical Devices** was shown at regular staff meetings. In 30 days, presentations were delivered at 45 staff meetings.

In September 2005, the staff awareness campaign culminated in a two-day UCLA-MedSun Expo, in the cafeteria areas of UCLA Medical Center and Santa Monica-UCLA Medical Center.

• Three MedSun posters** were displayed in addition to other posters that were developed.
• Video presentations (Recognize, Remove and Report** from MedSun and the Safe Medical Devices Act by Medfilms, Inc.) and a 100-slide PowerPoint show "looped" continuously.
• Winners of the "Design a Tag" competition were announced and received $100 gift certificates.
• Participants who completed a "Which are Not Medical Devices?" quiz received $3 coffee gift cards.
• A local radio station promoted the event

Tag and Sequester Policy Development: STAR Response Program:
A consolidated policy and procedure called the STAR Response Program (Stop, Tag, And Report) was designed and developed in response to feedback received during the staff awareness campaign. The STAR program involves:

• Definitive identification and orientation of first responders. All device users were designated and oriented as first responders in device related events.
• Affixing clear and sequential first response instructions in the form of a Device Malfunction First Response tag (see below) to each device. This tag was created to eliminate confusion and uncertainty about what to do when the device failed and to redirect the initial instinctual response of device users to attempt impromptu “workarounds” and self-repair efforts that can undermine safe device management.
• Orienting and educating all device users. The purpose, location and responsibilities associated with medical device identification tags were clarified to ensure organization-wide knowledge, understanding and competency with device-related risk reduction strategies.

Lessons Learned/Conclusions:
The Risk Management Department is currently working with Clinical Engineering, Safety, Nursing, and hospital leadership to create and roll out a system-wide tag and sequester policy and procedure encompassing medical equipment, medical devices, and surgically implanted devices. The STAR Response Program will be modified as needed to meet the demands of the greater hospital community. A brief overview of the project will be presented at the University of California’s 2006 Risk Summit so that other University of California medical centers may learn from this experience.

*The Process Flow and Tag and Sequester labels that were developed as a result of this project have been made available to all MedSun facilities by UCLA Medical Center and Garry M. Walsh, Healthcare Consultant

**To order the above mentioned slide show, video or posters contact SSS at: medsun@s-3.com. See Educational Materials tab on this website for mentioned slide show.