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Data Raises Questions about Who is Administering Sedation Drug

Over 100 reports cite drug in question and include four patient deaths. Other reported data show risks involving manufacturer's representatives, contaminated surgical instruments and look-alike packaging

HARRISBURG: Problems associated with the use of a sedation drug called propofol (PRO-pa-fall) have raised concerns about how the drug is administered and monitored, according to an article published in the March 2006 issue of the *Patient Safety Advisory*.

Use of propofol during endoscopic, radiologic and other procedures in hospitals, ambulatory surgical facilities and physician offices is growing around the country, including in Pennsylvania, because propofol works faster than other sedation drugs to sedate the patient and leaves the patient sedated for a shorter period of time. It also has fewer side effects like nausea and vomiting, and it allows the patient to wake up, recover and return to routine activities and diet sooner than other sedation drugs.

However, recent reports submitted to the Patient Safety Authority show that, in untrained hands, propofol can be deadly. The Pennsylvania Patient Safety Reporting System (PA-PSRS) has received over 100 reports in which the use of propofol has been cited. Sixteen percent of these reports have been classified as Serious Events, including four patient deaths in which propofol may have played a role. In many cases, the events show that the practitioners involved in administering the drug were not fully trained in the use of propofol and other heavy sedation drugs.

“The question ‘Who should administer propofol?’ is not easily answered,” said Alan B. K. Rabinowitz, administrator of the Patient Safety Authority, “since several respected professional medical associations disagree with other, equally respected professional associations on protocols governing the administration and monitoring of the drug.”

The article notes that the American College of Gastroenterology, American Society for Gastrointestinal Endoscopy and the Society of Gastroenterology Nurses and Associates, for example, endorse nurse-administrated propofol, consistent with state regulations, if the nurse is trained in the use of such drugs and is capable of resuscitating patients from general anesthesia or severe respiratory depression. On the other hand, the American Society of Anesthesiologists, American Association of Nurse Anesthetists and the American Association of Ambulatory Surgical Facilities do not agree and have stricter guidelines for use of propofol and similar sedation drugs.

“Since propofol has fewer side effects than other sedation drugs, some experts fear that practitioners are developing a false sense of security about the risks of the drug,” Rabinowitz said. “Practitioners who are not trained to administer drugs that cause deep sedation and general anesthesia are being given permission to administer propofol, which our analysis shows can put the patient in jeopardy and even cause death.”

The article, entitled “Who Administers Propofol in Your Organization?”, includes several safe strategy practices that facilities can follow to minimize the risk involving propofol and other sedation drugs.

Other articles in the March *Advisory* provide analysis of the following potentially harmful events:

- Risks associated with the presence of manufacturer’s representatives in the operating room: PA-PSRS reports document delayed procedures, photographs taken without the patient’s permission and increased risk of infection associated with inappropriate activity by so-called “Healthcare Industry Representatives” (HIRs) during medical procedures.
- Contaminated instruments: Pennsylvania hospitals have submitted several reports to PA-PSRS describing cases in which sterilized surgical instruments have been contaminated with organic material from a prior procedure—something healthcare workers call “bioburden.” While most of these cases are recognized before the devices reach the patient, in some instances these soiled instruments have contaminated the sterile field.
- Look-alike packaging: Two short articles describe confusion and the potential for patient harm when different items are packaged in similar containers. One report documents virtually identical packaging for a skin preparation solution and an adhesive remover, and a second report identifies similar packaging for two different doses of a widely administered analgesic. The articles are illustrated with color photographs.

To read the complete *Patient Safety Advisory* or an individual article, including “Who Administers Propofol in Your Organization?”, go to http://www.psa.state.pa.us/psa/lib/psa/advisories/mar_2006_advisory_v3_n1.pdf.

BACKGROUND

The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (“Mcare”) Act, as amended by Act 88 of 2005, to help reduce and eliminate medical errors by identifying problems and recommending solutions that promote patient safety. Under the Act, all Pennsylvania-licensed hospitals, birthing centers and ambulatory surgical facilities are required to report what the Act defines as “serious events” and “incidents” to the Authority. More than 445 healthcare facilities are subject to Act 13 reporting requirements.

Facilities submit reports of serious events and incidents through the Pennsylvania Patient Safety Reporting System (PA-PSRS), a confidential web-based system that was developed for the Authority under a contract with ECRI, a Pennsylvania-based independent, non-profit health services research agency, in partnership with EDS, a leading international, information technology firm, and the Institute for Safe Medication Practices (ISMP), also a Pennsylvania-based, non-profit health research organization.

More than 285,000 reports have been submitted through PA-PSRS since the program was initiated in June 2004. Ninety-six percent of these reports are Incidents or “near-misses.” Based on those reports, the Authority issues quarterly and supplementary Patient Safety Advisories to advise hospitals and other healthcare facilities about steps they can take to reduce and prevent patient harm.

For more information on the Patient Safety Authority, PA-PSRS, consumer safety tips, or previous *Patient Safety Advisories*, visit the Authority’s website at www.psa.state.pa.us.

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