PSNet
PATIENT SAFETY NETWORK

The Empty Bag

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The Case

A 90-year-old woman with end-stage dementia was admitted to an acute care hospital for treatment of a hip fracture after a fall at a nursing home. During the hospitalization, her kidney function worsened, as did her mental status. Because of this, the patient's family chose not to put her through surgery, and she was placed on the hospice service for comfort care.

The care team identified that the patient had increasing restlessness and that the current order for intravenous (IV) push morphine PRN [when necessary] was not effective for pain control. The physician ordered a morphine drip for better pain control. The nurse set up the morphine drip along with a carrier solution of normal saline. He placed the normal saline on a pump but failed to place the morphine drip on a pump as well. He mistakenly set the rate intended for the morphine on the pump that the normal saline was on, and opened the clamps for both solutions. He turned the pump on and left the room to answer an alarm for another patient. The nurse had five other patients assigned to him that day.

The nurse checked on the patient approximately every 30 minutes, but only observed from the doorway and asked the family members present how things were going. Approximately 4 hours after the nurse started the morphine drip, he noticed that the patient was breathing very slowly and went to the bedside to examine her. He noted that the patient appeared near death and explained this to the family. Realizing that the morphine bag was empty, he immediately called the physician, obtained an order for naloxone, and administered it to the patient. However, the patient died shortly thereafter.

Later, the bedside nurse and the charge nurse went back into the room to examine the IV set-up and pump. They discovered that the morphine was connected into the tubing below the pump for the saline (instead of in its own pump), which meant it had flowed into the patient at an uncontrolled rate.

The Commentary

by Chris Vincent, PhD

Errors relating to intravenous (IV) medication are common. Between January 2005 and December 2009, 56,000 adverse events and 710 deaths relating to IV infusion devices were reported to the Food and Drug Administration (FDA).(1) A systematic review found that the probability of at least one error during the preparation and administration of an IV medication was 0.73.(2) A recent study found that 60% of infusions administered via smart IV pumps, with technology to support accurate calculation of dose and delivery rates, contained at least one error.(3) Such statistics motivated the FDA to hold a summit on infusion device safety in 2010, which generated a list of 13 priorities relating to, for example, the need to mitigate use errors with infusion devices (Table). Since 2010, significant work has occurred to address these issues. For example, research has shown how the design of infusion pump number entry systems can be used to reduce the potential for use-related error.(4)

Although good engineering practice can address concerns regarding the reliability and dependability of IV equipment, many of the issues that we see today relate to the potential for error during use. During the FDA summit, the relationship was highlighted between use error and suboptimal design (i.e., violations in human factors design principles). A traditional response to error queries whether the equipment has failed from a technical perspective or the user is to blame. The traditional approach might involve providing training to compensate for use-related error. In contrast, human factors engineering (HFE) seeks to reduce error through design (i.e., in the case above, remove the potential for misconnection). HFE professionals address use-related error by taking into account users, the tools they use, and the environments in which they live and work, and then designing accordingly.(5) In doing so, they provide opportunities to prevent errors by allowing for joint optimization between social and technical elements. This forms part of a sociotechnical approach—a holistic view of the work system as opposed to focusing on parts of the system in isolation.

For example, one might read this case and conclude that a double check, by a different nurse, should have been performed. Although such checks are usually beneficial (6), without a detailed understanding of the system and the context, it can be hard to make sure that a double check will work in practice. In fact, some double checks fail because the second observer defers to authority. Moreover, double checks can lead individuals to become less vigilant (assuming that the other party will catch an error), leading to an overall decrease in safety.(7) And, in an analog to the well-known problem of alert fatigue, individuals who constantly undertake verbal checks may treat the check as a rote exercise (a phenomena referred to as involuntary automaticity), sapping any potential benefit from the process.(8) All of these failures are more likely when staff are working under high levels of stress, workload, or time pressure. Human factors engineering approaches offer an opportunity to understand such phenomena and tailor the design of the system accordingly.

Sometimes it is necessary to look beyond the people and ask how the right equipment might reduce the potential for error. Purchasing practices offer an opportunity to shape the safety and usability of medical technology, particularly when they are informed by HFE professionals. For example, Namshirin and colleagues suggest that by involving various stakeholders and considering a range of frontline needs, hospitals can choose IV infusion equipment that enhances safety.(9) In another example, many palliative care providers in the United Kingdom now use the same type of syringe driver. Contained within a lockable box, the device was introduced after safety problems arose when users of a prior device had difficulty distinguishing 24-hour and 1-hour versions.(10)

HFE considers misalignments across the system as a whole, for example mismatches between the way that equipment is designed and the reality of clinical practice. In the case described, the morphine bag was attached to the tubing below the pump instead of in its own pump. This situation could have been prevented by the use of a so-called forcing function—in this case, the use of an IV accessory that did not allow this to occur (i.e., drugs contained in a lockable box and connected to the pump, within a cartridge, or that were impossible to connect to the tubing below the pump). Providing information on the morphine bag (e.g., "Not For Direct Administration") could also help reduce mismatches between the knowledge and expectations of those providing drugs and the behaviors of those administering them. For concurrent infusions through a single access point (multiple solutions being infused through a single catheter), the best way to ensure an accurate and controlled flow rate is for each solution to have its own infusion pump or pump channel. IV pumps offer many advantages over gravity infusions in terms of control, accuracy, logging, and the ability to detect and prevent dosing errors, free-flow, or air in line.(11)

This case highlights the issues that can be raised by multiple line, multiple solution infusions.(12) In the past, there was widespread confusion regarding the terms *secondary infusion* and *piggyback infusion* (Box).(11) Clearer nomenclature, standardization, and consistency in practice can help avoid such confusion. Particular attention should be paid to situations where equipment is transferring across care boundaries (such as a patient leaving the recovery room to return to the surgical ward) and to making sure that there are no gaps in understanding, differences in terminology, or issues that can occur as a result of a handover process.(13) For example, infusion devices may be required in an ambulatory context, in which case they should be small, discrete, and comfortable to carry. It is also important that the batteries do not run out and their constituent drugs are controlled.(14) Addressing safety concerns relating to IV therapy requires multiple groups and professions to collaborate, facilitated by a transparent, proactive, and nonpunitive culture.

Finally, HFE has informed training and instruction for management of multiple infusions and pumps. Good practice guidelines exist regarding the management of multiple line infusions (http://www.webcitation.org/6g1lmsoGj). The Institute for Safe Medication Practices recommends labeling IV tubing with the name of the solution above the injection port closest to the patient and near to the infusion pump. It also suggests making it easy for practitioners to map the IV container and associated tubing. This means organizing the top of the IV pole (where bags are hung) so that the physical layout of the hooks and way in which solutions are hung is aligned with the channels of the pump(s). It also means making it easy to trace lines (e.g., use of systems that illuminate the lines) when programming the pump, changing solution, and transferring patients.(15,16)

In summary, by considering the system that surrounds IV practice, HFE can help identify problems and implement practical interventions. In the health care context, intraprofessional collaboration is particularly important, as there are many different contexts in which IV pumps and syringe drivers may be used, and each has tradeoffs in terms of safety and usability. It is only when multiple disciplines work together—both frontline clinical staff and behind-the-scenes experts such as human factors engineers and purchasing professionals—that systems can be designed to protect against error without compromising the needs of patients and health care staff.

Take-Home Points

- Given a need for concurrent infusions through a single access point, the best way to ensure an accurate and controlled flow is for each solution to have its own infusion pump or pump channel.
- Practice guidelines exist regarding the management of multiple line infusions.
- Purchasing provides an opportunity to shape the safety and usability of medical technology.
- Good communication is one of the most important factors in reducing infusion risks.

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Table

Table. Infusing Patients Safely: Thirteen Priority Issues From the AAMI/FDA Infusion Device Summit Report (1)

Standardize systems and processes for reporting, aggregating, and analyzing infusion device incidents.

- 1. There is a poor (incomplete and inadequate) system for reporting aggregate state and national data about adverse events (e.g., MAUDE [Manufacturer and User Facility Device Experience] and Patient Safety Organizations). There is a lack of standardization to support data aggregation.
- 2. The reported incidents do not convey the bigger picture in terms of the volume of incidents involving infusion devices. User facilities are encouraged, but not required, to report close calls and near misses and to determine their root causes.
- 3. There is often an inability by manufacturers to determine root cause of infusion device incidents due to difficulty accessing and analyzing incident data from all sources. This also applies to continuous quality improvement reporting.
- 4. There is no process for collaborative failure analysis. There is no safe space for disclosing or accessing information about infusion device incidents or problems. Patient Safety Organizations should be considered.

Improve the integration of infusion devices with information systems and drug libraries.

- 5. There is incompatibility across devices and with systems (e.g., consistent bar coding, wireless, power supply, and health information technology systems). The unavailability of wireless in a natural disaster should be considered.
- 6. There is a lack of formulary and standards for drug libraries, including standardization of drug concentrations and transparency (e.g., for sharing of drug libraries between facilities).
- 7. Uploading, managing, and maintaining drug libraries can be difficult. There is a lack of coordination between pump requirements and hospital capabilities. There is a steep learning curve for configuring and managing drug libraries. There is difficulty in managing the same drug used in multiple units in multiple ways.

Mitigate use errors with infusion devices.

- 8. A high percentage of sentinel/adverse drug events are due to use errors. It is imperative to figure out how to develop design safety features that make it easy for the user to do the right thing. Applicable human factors, automatic identification (e.g., barcoding), and the value of all the steps involved in drug administration should be considered.
- 9. There is a lack of standardization of terminology used in infusion systems (upstream and downstream devices)—and a clear need for the same wording, same spelling, etc., across the process, devices, containers, etc.
- 10. There is a lack of knowledge/familiarity with infusion devices and a lack of effective training in their use—from both manufacturers and facilities.

Improve management of multiple infusions.

- 11. There is difficulty in infusion line management—including containers, manifolds, catheters, and transport—reflecting the complexity of multiple infusions, including secondaries, disposables, etc.

Reconcile challenges and differences in the use environments of infusion devices.

- 12. Alarm management is not effective. There are high numbers of false alarms, which also can lead to true alarms being ignored (e.g., air). Alarms are difficult to prioritize. It is unclear how to resolve alarm issues.
- 13. Injuries are caused by a lack of differentiation between the use of infusion devices in hospitals and in other environments (e.g., home use). Products designed for the hospital environment are being used in home environments (and vice versa). There are design and user issues and differences among home, hospital, and other environments.

Box

Box: Glossary of Terms Relating to IV Therapy.

Ambulatory infusion device: A portable or wearable infusion device. Continuous infusion: Delivery of a medicine and/or fluid (within a large volume of solution) at a constant rate over a prescribed period. DERS: (Dose Error Reduction Software/System): Technology designed to reduce the incidence of IV medication error. Also called Drug Error Reduction Software/System. Double pumping: Use of two pumps simultaneously. This occurs when there is a need to change infusions without interrupting the flow. Free-flow: Rapid and uncontrolled delivery of fluid into a patient's body. Gravity infusion: A pump is not used; gravity moves the fluid through the IV tubing into the patient's vein under control of a roller clamp. Infusion pump: A medical device used to deliver fluids into a patient's body in a controlled manner. Intermittent infusion: A small volume is infused over a short period of time. Multiple [line] infusion: Delivery of multiple solutions to a single patient through one or more catheters. Multiple channel infusion device: Solutions are delivered from multiple reservoirs at multiple rates. Piggyback infusion: [used interchangeably with secondary infusion]: The drug infusion is administered via the pathway of a primary solution. NB: It is typical for the primary infusion to be paused while the piggyback/secondary infusion occurs. Simultaneous infusion: The drug infusion is administered as a secondary infusion run concurrently with the primary infusion. Smart pump: An infusion device that is equipped with safety features, e.g., alerts when the pump's parameters fall outside of safety limits. Syringe driver: Type of infusion device—a moveable piston controls fluid delivery.

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