SAFE PRACTICES in Patient Care

Helping to promote a culture of safety

In April 2006, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a *Sentinel Event Alert* that urged healthcare organizations to pay special attention to how tubes and catheters are connected to patients. Reports to JCAHO, ECRI, FDA, and the United States Pharmacopeia (USP) show that tubing and catheter misconnection errors occur frequently and lead to deadly consequences in many instances. The reality prompted JCAHO to issue the *Sentinel Event Alert* to more than 12,000 healthcare organizations nationwide, including hospitals, ambulatory care centers, home care agencies, and nursing homes, to create a new awareness of the problem and to offer practical solutions to avoiding occurrences. Beverly Gallauresi, Melissa Eakle, and Audrey Morrison, nurse-consultants with the FDA, have been monitoring misconnections events over the past few years. In their article they point out that Luer connector misconnections continue to occur because Luer connectors are widely available, easy to use, and inexpensive. Following JCAHO recommendations on proper practice is part of the solution, as is the creation of new standards by patient safety organizations.

Safe Practices interviewed healthcare professionals in acute care and homecare facilities to find out what these organizations are doing to prevent misconnections and how they will comply with the alert.

Misconnections between medical devices with Luer connectors: *under-recognized but potentially fatal events in clinical practice*

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by Beverly Gallauresi, RN, MPH; Melissa Eakle, MSN, MBA; Audrey Morrison, RN, BSN

Luer-connector misconnections are under-recognized but common and potentially fatal events. Luer connectors easily link many medical components, accessories, and delivery systems. Unfortunately, because Luer connectors are so easy to use, clinicians mistakenly connect the wrong devices and deliver substances through the wrong route. Such errors have caused serious injury and death. Prevention of these errors is dependent upon the clinician's knowledge of the Luer connectors used and careful attention to all connections and tubing involved. The Food and Drug Administration (FDA) continues to monitor misconnection events and to encourage clinician education and awareness of the danger of misconnections and actions necessary to reduce occurrence of these events.

Luer connectors

Prior to the 1800s, medication was administered by mouth or inhalation, onto the skin, or into an accessible body cavity such as the rectum (e.g., enema, suppository). During the 1800s, physicians experimenting with ways to deliver medications more quickly through subcutaneous or intravenous (IV) routes began using syringes, trocars, lancets, and cannulas. In 1855, Dr. Alexander Wood was the first to use a hollow needle attached to a syringe to inject morphine subcutaneously for pain relief.[1]

The Luer connector was developed in 1896 by a Parisian surgical instrument manufacturer, the H. Wulfing Luer Company.[2] It was designed to securely attach a hypodermic needle to a glass syringe using a push fitting that also allowed for easy separation when administration was complete.[3] Today, Luer connectors are used worldwide to connect a variety of vascular, enteral, respiratory, epidural, and intrathecal medical devices, components, and accessories.

The International Organization for Standardization (ISO) describes the Luer connector as a "conical fitting with a 6% taper for syringes, needles, and certain other medical equipment."[4,5] The Luer connector has a male and a female component that are joined to form a secure yet detachable leak-proof connection. The connection is achieved by use of a push fitting (a Luer slip) or a screw-in threaded fitting (a Luer lock) that joins the male and the female tapered fittings.[2]

Multiple connections between medical devices and tubing are common in patient care. The Luer connector design allows direct or functional connection between unrelated delivery systems (e.g., vascular, enteral, respiratory, epidural, and intrathecal medical devices, components, and accessories).[6] In 2000, the European Committee for Standardization stratified the levels of risk associated with Luer-connector misconnections between

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Preventing tubing misconnections: *a practical view*

On April 3, 2006, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a Sentinel Event Alert: Tubing misconnections—a persistent and potentially deadly occurrence. Safe Practices *asked clinicians and administrators in several organizations to discuss the origins and impact of this alert.*

United States Pharmacopeia (USP)

Rodney Hicks, PhD, ARNP
Manager, Patient Safety Research, Department of Patient Safety

Laura N. Provan
Director, Corporate Communications

How did the USP become involved in this issue?

Hicks: The USP is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States. We also administer two national medication-error reporting programs—MERP (Medication Errors Reporting Program) and MEDMARX—and now have the largest-known repository of reports of medication errors arising from tubing misconnections.

Around five years ago, there was a spike in the number of reports of wrong administration technique and wrong-route errors. Many of these errors were attributable to tubing interconnectivity: Luer connectors allow many kinds of tubing to be connected rapidly and easily, even though they were not intended to connect. A classic example of this is mistakenly connecting IV tubing with a pneumatic blood-pressure cuff.

Our Center for the Advancement of Patient Safety (CAPS) did an extensive analysis of the thousands of incidents registered. We then approached the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) to discuss how to deal with the situation. NCC MERP referred the issue to a USP body, the Safe Medication Use Expert Committee (SMUEC)—a logical choice, since SMUEC helps to develop standards. At the same time, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), which accredits hospitals (and keeps in contact with NCC MERP and SMUEC), received a report about a tubing misconnection: an infant in a neonatal-care unit had breast milk mistakenly given intravenously rather than administered through the feeding tube, causing permanent impairment. This triggered the sentinel event alert.

> Tubing misconnections are at once a practice issue, a manufacturing issue, and a regulatory issue.
>
> — Laura N. Provan —

What were the most common types of misconnections reported?

Hicks: We identified six main types of misconnections: parenteral-enteral, parenteral-parenteral, other tube-enteral, other tube-parenteral, medical device-enteral, and medical device-parenteral.

Are there any particular reasons for these misconnections?

Hicks: Patients nowadays are sicker and have more lines, tubes, and drains in them than ever before. A single patient can have a feeding tube, an epidural line, one or more IV lines, a surgical-site drain, a bladder catheter, and a pneumatic blood-pressure cuff. To make things worse, nearly all the tubing is clear plastic and looks alike. Having one connector type—the Luer—for tubes of various uses also encourages misconnections.

Clinicians counteract this with vigilance and strategies such as labeling tubes at point of origin and insertion. This is good practice, but good practice is not enough. As long as there is no single standard for labeling tubes, for producing specific tubes for specific purposes, and for making incompatible connectors that do not allow tubing for one purpose—parenteral feeding, for example—to be joined to tubing for another purpose—such as intravenous infusion—mistakes will be made.

What can the USP do about this situation?

Provan: Tubing misconnections are at once a practice issue, a manufacturing issue, and a regulatory issue. Let me give you an analogy: If you lift up the hood of your car, you'll find that the tubing there is better labeled than it is on any patient in hospital. It's also designed specifically for each purpose. That tubing and its connectors can be swapped among various makes of car; it's standard. Unlike automobile manufacturers around the world, the medical industry has not been able to agree on standardizing tubing and connectors and making each type sufficiently different to prevent misconnections. It's not as though it's not doable, but the economic incentives are not there, and the regulatory climate is complicated.

The USP has neither the power nor the mandate to insist on changes to and standardization of medical equipment and practices. In the USA, the standard for tubing is stated by the Association for the Advancement of Medical Instrumentation (AAMI): *Tubing shall not connect.* This is not prescriptive enough to provide a solution. But where will that solution come from? The FDA has no authority to propose a standard; it has to come from a standard-setting body such as AAMI or ANSI (American National Standards Institute).

At present there is no commercially available fix for the issue in the USA, with one exception: there is a company that makes neonatal feeding tubes incompatible with all other devices. IV connection is impossible. The tube uses a Christmas-tree connector for oral syringes, so injection syringes cannot be attached. That special connector is a key safety element.

Hicks: The USP is encouraging manufacturers to develop similar systems for

adults, but until that happens the best defense is vigilance and labeling all tubes at points of origin and insertion. There have been other approaches discussed—for instance, having two people verify all connections before equipment is activated—but we don't see that as a workable solution because of staffing shortages. Color-coding is not allowable because the user might have visual deficits. It hinges on that adaptor for connecting device A and device B. Adaptors have to be changed.

To complicate the issue, not all equipment for one purpose is made by the same manufacturer; for instance, the producer of feeding bags is not the manufacturer of the feeding tubes, and there's a third company in the middle that does the stopcocks. Without regulated standards, the three manufacturers must agree on what is their standard, and then convince the generic manufacturers to follow suit.

Provan: R&D time for a manufacturer to come up with a unique solution, such as the one used for neonatal feeding tubes, is at least three years. In the absence of clear guidelines and standardization, a manufacturer takes a big financial risk by coming out with a product that is the first in its field. For example, the manufacturer may produce a 12-mm tube, but the next week the FDA might mandate that it should be 13 mm. The financial incentive for manufacturers to effect change is really not there. Government regulatory bodies seem to be hoping for an entrepreneurial, marketplace solution, but manufacturers innovate at the risk of being told after the fact that the standard will be something other than what they produce. Industry appears to be searching for a government solution, and government seems to be hoping for an industry solution.

Hicks: There have been some steps towards finding a solution. Armed with the analysis done by CAPS for the USP, our Safe Medication Use Expert Committee joined the American Hospital Association and the Institute for Safe Medication Practices in a think-tank, convened in October 2006, to discuss the issue. The think-tank is currently studying parenteral-enteral misconnections. It's also pursuing grants to begin studying parenteral-parenteral misconnections. The first draft of its report is due out in the first quarter of 2007.

The exciting thing about the think-tank is that there was a spirit of collaboration: Enough is enough; we've got the issue identified, so now let's go forward. It included manufacturers, clinicians, group purchasers, federal government (FDA), the USP, JHACO, American Hospital Association, risk managers. The major stakeholders were at the table and agreed to work together.

Did your analysis help you to identify any particular approaches to tubing connection that clinicians can use right now?

Hicks: The USP educational arm is currently continuing the spotlight on issue identification. However, through all this there's a basic idea that we must not lose sight of: Label your ports; label your lines. Each tube should be labeled at point of origin and at point of insertion into the body. Any other point of access to a tube—for example, a Y-port—should also be labeled. Whoever is inserting a substance into the tubing at any given point must check the integrity of the tubing and be sure that it is the correct tubing.

References

1. Joint Commission on Accreditation of Healthcare Organizations. Sentinel event alert: tubing misconnections—a persistent and potentially deadly occurrence. 2006 April 3;36. Available from: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_36.htm Accessed December 7, 2006.

St. Francis Hospital and Medical Center, Hartford, Connecticut

Bob Zbuska
Director of Clinical Engineering
Mary Inguanti
Vice-president of Operations and Quality
Paula Hankard
Accreditation Manager

How has the sentinel event alert affected your facility?

Zbuska: We were already well aware of the issue and how to defuse it, because of something that took place in the early 1980s: A manufacturer changed the design of the cord on pneumatic blood-pressure cuffs. Before the change, tubing for blood-pressure cuffs had Luer connectors, as did tubing to other equipment; nonetheless, it was easy to discriminate between the two because the tubing for the blood-pressure cuff was coiled. With the change, the cuff's tubing was straight, and it became harder to distinguish between the two, especially with the common Luer connectors.

Ever since then, all new biomedical equipment goes through the clinical engineering department before being released to staff. We either change the Luer connectors ourselves, making it hard for accidental connection to occur, or we ask the manufacturers to do so.

Did you institute any education programs in response to the alert?

Inguanti: When we received the sentinel alert, we already had several committees in place that could look into it. The Product Standards Committee reviewed the alert and formed a subcommittee to integrate this "new" issue into existing committees and systems. It was important that we build upon what we had, that we didn't reinvent the wheel. That meant continuing to do what has worked for us in the past: keeping staff aware of the issue so that they consistently trace lines and label them. The hospital's strategy is to educate anyone—physicians and engineers as well as nurses—who uses potentially confusing products.

Hankard: A good four months before the alert was issued, the hospital's forum for quality and safety met to discuss tubing misconnections. We had a show-and-tell session at which we passed around and discussed endotracheal tubes, feeding tubes, IV tubing. It was valuable, hands-on experience for us. This year, in response to the alert, we're adding a slide on tubing misconnections to the nursing staff annual competency training kit.

Inguanti: We encourage patients and their caregivers to pay attention to what's going on around them and to speak up when things don't seem right.

Wheaton Franciscan Home Health & Hospice, Milwaukee, WI

Lisa A. Gorski, *MS, APRN, BC, CRNI, FAAN*
Clinical Nurse Specialist

How has the sentinel alert affected your facility?

Gorski: I'm responsible for the education related to infusion therapy in home healthcare but also work in a large healthcare system. The Sentinel Alert resulted in education and a change in our systemwide infusion therapy policy that addresses infusion therapy across all sites from acute care to home care. A PowerPoint presentation about the risk of

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Misconnections between medical devices with Luer connectors — Continued

unrelated delivery systems. The intravascular delivery system was identified as demonstrating the highest risk, because misconnections with enteral products or respiratory gases were likely to result in death.[6]

Despite efforts to reduce misconnections through education, protocol, and monitoring, the use of Luer connectors in unrelated medical delivery systems remains problematic. The FDA, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), ECRI (formerly the Emergency Care Research Institute), the Institute for Safe Medication Practices (ISMP), and others have all received reports of Luer-connector misconnections.

The FDA receives adverse-event reports of Luer misconnections through the Manufacturer and User Facility Device Experience (MAUDE) database. Misconnections, which have been made between numerous types of medical devices in diverse clinical settings, include but are not limited to the following: enteral feeding tubes mistakenly connected to IV lines; IV tubing connected to the tracheal-cuff pilot balloon port; noninvasive blood pressure (BP) cuffs connected to IV lines; and drugs intended for IV administration given intrathecally. Many similar adverse events may not have been reported because the event was either attributed to user error or not considered reportable. The common factor with these events is that the Luer connectors and tubing were compatible, allowing easy connection.

Case reports

The following cases are from actual adverse-event reports received by the FDA.[7] These examples represent both common and rare Luer tubing misconnection adverse events. They also demonstrate that Luer connector misconnections may occur in any clinical environment.

Blood-pressure tubing to IV catheter

A patient went to the emergency department because of nausea, vomiting, and rectal bleeding. An IV catheter was placed in anticipation of a computed tomography (CT) scan, but no IV fluids or medications had been started. The patient also had a noninvasive automatic BP cuff placed for continuous monitoring. The cuff tubing was disconnected when the patient went to the bathroom, and it was reconnected upon return. The patient's spouse found the patient "blue from the neck up." Despite resuscitation efforts, the patient died. The BP tubing had been connected to the IV catheter and had delivered about 15 mL of air. An autopsy confirmed a fatal air embolism.

Blood-pressure tubing to heparin lock

A patient had a BP cuff on the right arm. The cuff was removed to gain access to the right antecubital area, a peripheral IV was inserted, and the IV catheter was converted to a heparin lock. After access to the IV had been obtained, the BP cuff was replaced on the right arm, and the BP tubing was removed to deflate the cuff for proper fit. When the BP tubing was to be reconnected with the cuff, it was inadvertently connected to the IV heparin lock instead. This was made possible by the BP-cuff tubing ports and the peripheral IV heparin lock being in close proximity. In addition, the connectors on the heparin lock and the BP tubing were compatible. This resulted in a fatal outcome.

Epidural tubing to IV tubing

A customer contact reported that an epidural set delivering an unspecified medication was inadvertently connected to IV tubing, and a patient subsequently died. No specific information—including cause of death, pump programming, or event details—was provided. The customer contact indicated that there was no fault on the part of the pump or the set, and that an anesthetist and a midwife apparently mistakenly connected the epidural set to IV tubing.

Lithotripter suction tubing to roller pump

During a procedure to break up and remove kidney stones, an ultrasonic lithotripter suction hose was incorrectly inserted into the roller pump. Instead of fractured-stone debris being suctioned from the kidney, air was pumped into it. The hose was reconnected properly following discovery of the mistake, but the patient went into cardiac arrest and expired shortly thereafter.

Foley catheter to nasogastric tube

A patient misconnected her Foley catheter to her nasogastric (NG) tube. She was found with the Foley catheter disconnected from the drainage bag but with one end still in her bladder; the other end was connected to her NG tube, and urine could be seen going into her stomach. The patient's NG tube was reconnected to suction, which drew the urine out of her stomach. When the Foley catheter was re-attached to the urine drainage bag, more than 300 mL of urine drained. The patient stated that she thought that she had reconnected the tubes correctly, because they matched. She was oriented but displaying inappropriate behavior. Her vital signs were stable, and her laboratory results were within normal limits. Although there was no apparent injury, the physician was notified and a safety sitter was ordered.

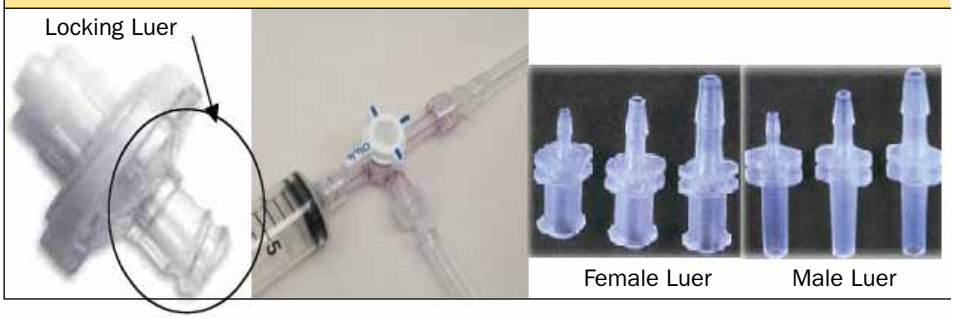
Feeding tube to suction catheter

A pediatric night nurse connected a tube-feeding line to a suction-catheter saline installation port instead of to the 10-Fr. feeding tube. She noted that both connectors looked the same and the room was dark. Some of the food was instilled into the sheath surrounding the catheter.

Nasal cannula to IV tubing

A nurse's aide inadvertently connected a nasal oxygen cannula to the patient's IV line. The misconnection was not detected until 4 hours had passed, when the patient began complaining of chest tightness and difficulty breathing. Liquid was detected coming from the patient's nose and mouth. The patient was treated for congestive heart failure and given furosemide IV. The facility acknowledged that this was a user error and that no medical devices should ever be connected without tracing the lines back to their points of origin.

Luer/Luer-lok Connnectors



Pulsatile anti-embolism stocking pump to IV heparin lock

A patient admitted to hospital for stroke had a pulsatile anti-embolism stocking (PAS) in place on the left lower extremity. Because of an IV heparin lock in the right ankle, there was no stocking applied to the right lower extremity. The patient was seen at 05:30 and was alert and oriented. At 05:45, the patient was found unresponsive and cyanotic and did not respond to aggressive resuscitation attempts. Staff found the tubing from the PAS pump hooked up to the IV heparin lock in the patients' right ankle. The connectors for IV and PAS tubing are compatible. The preliminary autopsy report indicates that death was due to a massive air embolus. It is believed that the patient connected the tubing from the PAS pump to the IV heparin lock.

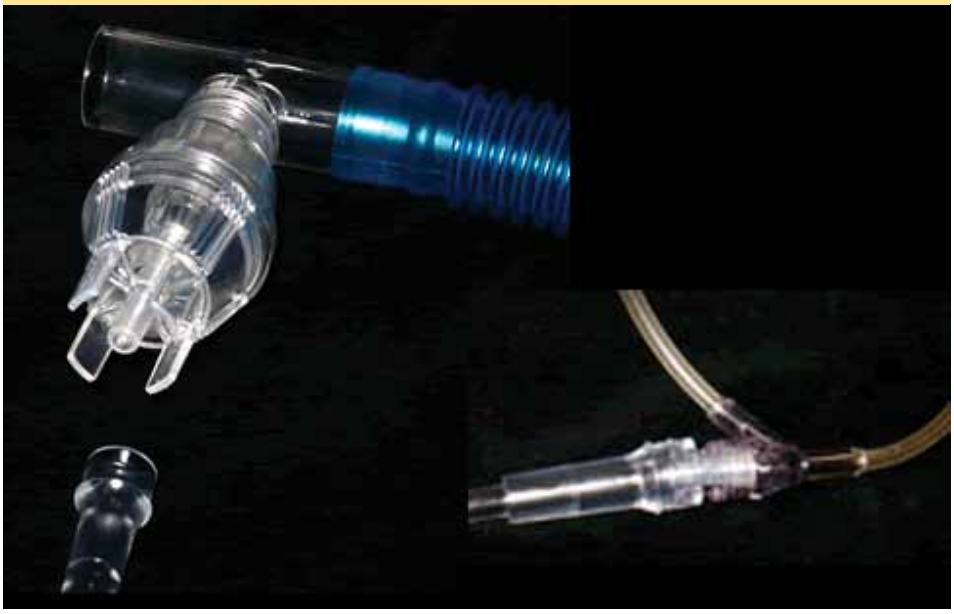
Cell-saver tubing and wall-mounted oxygen outlet

The patient had undergone total knee replacement. During surgery, a blood-recovery tube for a cell saver was placed at the surgical site. Following a stay in the recovery area, the patient was transferred to an orthopedic wing of the hospital. The suction tubing for the cell saver was connected to a wall-mounted oxygen outlet. The patient arrested shortly thereafter and could not be revived. The patient's death was listed as a cardiopulmonary arrest. After discussion with all parties involved—including the clinical staff caring for the patient, hospital administrative personnel, and biomedical staff—it was determined that the cell saver was not the cause of death. It is believed that user error, attributed to the easy misconnection of compatible connectors, caused or contributed to the patient outcome.

Transtracheal tubing to IV port

A patient was admitted to the cardiovascular-thoracic unit due to congestive heart failure. The patient had a transtracheal catheter connected to a wall-mounted oxygen outlet. Because of pneumonia, the patient developed a need for continuous positive airway pressure (CPAP). The tube from the transtracheal catheter was disconnected from the wall oxygen tree and the patient's nasal cannula was connected. The patient sat up at the bedside for lunch, and at that point the transtracheal catheter tube was still intact. After lunch the nurse discovered blood dripping from the tubing that should have been connected to the transtracheal catheter. The tubing was found to be attached to a port on the IV tubing. Due to gravity, blood was being pulled from the peripherally inserted central catheter line. No staff members had entered the room prior to the discovery, so it was concluded that the patient at some point had disconnected the clear oxygen tubing from the transtracheal catheter and inserted one end into the extension set of the IV tubing. The patient's blood loss was estimated at between 10 and 20 cc, and the patient was transferred to the critical-care unit for observation.

Tubing Misconnections



Tube delivering oxygen fell off nebulizer

The oxygen tubing was connected to a Needless Access System IV tubling Y-site

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Preventing misconnections

Recognizing the risks associated with Luer connector misconnections, interested parties—patient safety and standards organizations, medical-device manufacturers, healthcare facilities (user facilities), and the clinical community—have taken action in an attempt to reduce the likelihood of Luer connector and tubing misconnections. In April of 2006, the JCAHO issued a Sentinel Event Alert regarding Luer connector and tubing misconnections.[8] The alert contained the following recommendations to healthcare facilities:

1. Do not purchase non-intravenous equipment that is equipped with connectors that can physically mate with a female IV Luer connector.
2. Conduct acceptance testing (for performance, safety, and usability) and, as appropriate, risk assessment (e.g., failure mode and effect analysis) on new tubing and catheter purchases to identify the potential for misconnections, and take appropriate preventive measures.
3. Always trace a tube or catheter from the patient to the point of origin before connecting any new device or infusion.
4. As part of the hand-off process, recheck connections and trace all patient tubes and catheters to their sources upon the patient's arrival in a new setting or service.
5. Standardize this "line reconciliation" process.
6. Route tubes and catheters having different purposes in different, standardized directions (e.g., IV lines routed toward the head; enteric lines toward the feet). This is especially important in the care of neonates.
7. Inform non-clinical staff, patients, and their families that they must get help from clinical staff whenever there is a real or perceived need to connect or disconnect devices or infusions.
8. For certain high-risk catheters (e.g., epidural, intrathecal, arterial), label the catheter and do not use catheters that have injection ports.
9. Never use a standard Luer syringe for oral medications or enteric feedings.
10. Emphasize the risk of tubing misconnections in orientation and training curricula.

11. Identify and manage conditions and practices that may contribute to healthcare worker fatigue, and take appropriate action.

In addition, JCAHO urged product manufacturers to implement "designed incompatibility, as appropriate, to prevent dangerous misconnections of tubes and catheters."

ECRI has published information and recommendations about Luer connector misconnections. A recent publication[9] suggests that preventing Luer connector misconnections will not be accomplished through training and problem awareness, because these steps alone will not erase the possibility of human error. ECRI concluded that, in addition to developing institutional policies and practices that address this issue, there are two other key prevention components: identification of facility-specific misconnection hazards, and the purchase of medical devices and equipment designed to prevent the connection of unrelated delivery systems.

The FDA continues to monitor adverse events associated with Luer misconnections. In an effort to reduce their occurrence, the FDA participates as a member of the International Organization for Standardization. The FDA also encourages experts to disseminate event-prevention and -reduction information through publications such as the Device Safety column in Nursing, through the televised series FDA Patient Safety News, and postings on the FDA website.

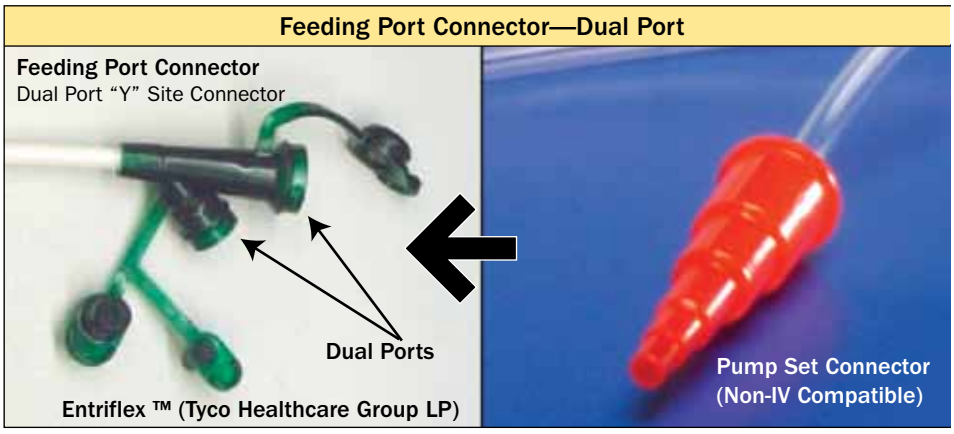
ISMP periodically publishes information about Luer connector and tubing misconnections. In response to continuing reports of such misconnections between non-invasive blood pressure (NIBP) monitors and IV lines, the ISMP reminded the clinical community in a June 2003 Medication Safety Alert[10] that BP monitor tubing can mistakenly be connected to IV ports. The alert described a misconnection in a radiology department after MRI: the radiology technician inadvertently connected tubing from the inflator to an IV line instead of to the cuff. ISMP recommended that BP cuffs and monitors have non-Luer connections to prevent this continuing misconnection problem. Until that can be accomplished, ISMP recommends the following: "develop a plan to replace all BP monitoring equipment to ensure incompatibility with Luer connections. Meanwhile, to protect patients, place BP cuffs on a different arm than the IV site, and remove IV catheters as soon as they are no longer needed."

The European Committee for Standardization (CEN) issued a report[11] in 2000 on the dangers arising from misconnections between Luer connectors and the tubing of medical-device delivery systems. Since Luer connector misconnections can result in fatal outcomes (as seen in the case studies above), a CEN forum task group (CEN FTG) published recommendations to reduce the occurrence of misconnections. In its recommendations, CEN proposed that use of Luer connectors be restricted to devices that connect to a vascular delivery system or a hypodermic syringe. CEN also recommended that enteral or respiratory delivery-system connectors should not be compatible with vascular delivery-system connectors and, in conjunction with the International Organization for Standardization, stated that different connectors should be developed for enteral and respiratory delivery systems.[11] In April 2006, an international ad-hoc group interested in medical device small-bore connectors met in Paris to discuss Luer connectors. The group decided that future work on Luer connectors would be managed by ISO TC 210 and the European Committee for Standardization (CEN BTTF 123), with ISO TC 210 taking the lead in this effort. One of the five resolutions proposed was to extend the scope of ISO TC 210 and to develop standards for small-bore connectors for liquids and gases in specific healthcare applications. In July 2006, the ad-hoc group drafted a National standard on small-bore connectors for liquids and gases that will be published in early 2007.[12]

Manufacturers have also acknowledged the potential danger of compatible Luer connectors in unrelated delivery systems. For instance, Datascope has stated, "In response to the JCAHO Sentinel Event Alert, Datascope Corporation, a medical device manufacturer, will begin to discontinue small child through adult thigh reusable and disposable NIBP cuffs with Luer connectors as well as hoses that have male connectors. Datascope Corp. has a limited supply of NIBP Luer cuffs and hoses and once this supply is depleted they will no longer sell NIBP products with Luer fittings."[13]

Conclusion

Although Luer connector misconnections are a well-known and well-documented issue, they continue to occur because Luer connectors are widely available, easy to use, and inexpensive. Each misconnection event carries the potential for a lethal outcome. Practice recommendations may reduce, but will not prevent, the occurrence of these misconnections. Prevention will happen when non-compatible connectors are available for unrelated delivery systems. Although consensus about misconnection prevention has not been reached by patient safety and standards organizations, your healthcare facility can reduce the number of Luer connector misconnections by following JCAHO recommendations.



References

1. Spielman FJ. The syringe: getting to the point. Bull Anesth Hist. 2002;20(3):12-3.
2. McElwee D, Snyder EJ. The use of tapered plastic luer connectors in neonatal extracorporeal membrane oxygenation. Heart Lung. 1996;25(4):324-9.
3. Ball C, Westhorpe R. Intravenous equipment—the ongoing development of the syringe. Anaesth Intensive Care. 2000;28(2):125.
4. Technical Committee ISO/TC 84. Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment—part 1: general requirements (ISO 594–1:1986). Switzerland: International Organization for Standardization; 1986.
5. Technical Committee ISO/TC 84. Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment—

part 2: lock fittings (ISO 594–2:1998). Switzerland: International Organization for Standardization; 1998.
6. Phillips P. Luer connectors and the prevention of misconnection. SMTL News. 2002;2(3). Available from: http://www.smtl.co.uk/Documents/Newsletters/Volume2-Issue3-Mar-2002/newsletter-v2i3.html Accessed: November 3, 2006.
7. Food and Drug Administration, Center for Devices and Radiologic Health. Retrieved from database MAUDE. 2006.
8. Joint Commission on Accreditation of Healthcare Organizations. Sentinel event alert: tubing misconnections—a persistent and potentially deadly occurrence. 2006;April 3;36. Available from: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert Accessed: November 3, 2006.
9. ECRI. Preventing misconnections of lines and cables. Health Devices. 2006;35(3):81-95. More information at: http://www.ecri.org/Newsroom/Document_Detail.aspx?docid=20060424_240 Accessed: November 3, 2006.
10. ISMP. Blood pressure monitor tubing may connect to IV ports. Medication Safety Alert. 2003;June 12. Available from: http://www.ismp.org/newsletters/acutecare/articles/20030612.asp Accessed: November 3, 2006.
11. Health and Environment Sector Committee. Luer connectors: a report to CEN CHeF from the CEN forum task group "Luer fittings" (PD CR 13825:2000). Brussels: European Committee for Standardization; 2000;June 15.
12. Technical Committee CEN/BT/TF 123 DRAFT "Small bore connectors for liquids and gases in healthcare applications;" (prEN 15546-1:2006).
13. Webster C. Datascope Customer Letter. 2006;July 13.

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Preventing tubing misconnections: — continued

tubing misconnections and preventive interventions was developed and emailed to all nursing staff across the healthcare system. Education was also addressed at staff meetings and in the homecare newsletter that I periodically produce for our nurses. Tracing the line from point of origin to point of entry within the patient's body was emphasized in education and in the policy. Line tracing needs to happen every time a new infusion container is hung and at the time of patient transfer, for example from hospital to the homecare setting. High-risk lines are also labeled, for example epidural and intrathecal.

You are primarily a homecare nurse. What are the most common types of misconnections in homecare?

Fortunately, I can't recall any occurrence of a tubing misconnection with our patients. The reality in home care is that it is unusual for patients to have more than one type of line at a time. For example, we care for a small number of patients with epidural catheters for pain management and I recall only one case where a patient had another line in place —a tube feeding. The more likely scenario in home care is a multi lumen intravenous catheter used for more than one type of infusion therapy. This requires teaching to ensure the infusions are run through the intended lumen to reduce the risk for inadvertent drug or fluid mixing and potential precipitate formation. Also, if the administration method is the same, that the fluid is hung with the correctly programmed pump to reduce any administration-rate errors. Even if our risks are low, due to our ability to treat more complex patients in the home setting, we are not immune from seeing patients with multiple lines.

It's our experience that patients and their caregivers at home who learn to do their own infusion therapy are very careful. As part of their general education for home care, we teach them the importance of double-checking the infusion container labels and comparing the program parameters from the infusion container to the read-out on the infusion pump. We teach the importance of line tracing when there is more than one type of line or multi-lumen infusions. We find that they tend to be quite conscientious about the process.

This continuing education activity was approved by the Vermont State Nurses Association, Inc., an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation (ANCC).

Provider approved by The California Board of Registered Nursing. Provider # CEP 1447

Upon completion of this offering the learner will be able to:

1. Describe a Luer connector,
2. Explain how Luer-connector misconnections occur and give an example,
3. Identify recommendations and practice behaviors used to reduce or prevent Luer-connector misconnections,
4. Utilize recommendations to reduce Luer-connector misconnections in the critical-care setting.

To earn continuing education credit, do the following:

1. Read both articles.
2. Complete the post test for the article. (You may make copies of the answer form.) Mark your answers clearly with an "X" in the box next to the correct answer.
3. Complete the participant evaluation.
4. Mail or fax the post test and evaluation forms to address below. **For immediate results, you may take this test online at www.saxetesting.com**
5. To earn 1.1 contact hours of continuing education, you must achieve a score of 70% or more. If you do not pass the test you may take it over one more time.
6. Your results will be sent within four weeks after forms are received.
7. The fee has been waived through an educational grant from Kendall, a business unit of Tyco Healthcare Group LP.
8. Answer forms must be postmarked by July 27, 2011.

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1. The Luer connector was originally developed to:

a. connect a hypodermic needle to a glass syringe
b. easily connect and disconnect tubing and delivery systems
c. provide an inexpensive medical device connector
d. connect intravenous tubing and catheters

2. The International Organization for Standardization (ISO 594/1 & 2) describes the Luer connector as a:

a. tapered connector made from plastic, glass, or metal used to connect various tubing and medical delivery systems
b. conical fitting with a 6% taper for syringes, needles, and certain other medical equipment
c. connector with a male fitting and a female fitting which is designed to produce a secure and leak-proof connection
d. tapered connector which allows the easy connection and disconnection of various medical devices

3. In 2000, the European Committee on Standardization performed a risk assessment of the various Luer misconnections, including which would result in death immediately and which would be fatal if left uncorrected. The _____ delivery system demonstrated the highest risk because "misconnections with _____ products or _____ were likely to result in death".

a. intravascular, enteral, respiratory gases
b. respiratory gases, enteral, intravascular
c. enteral, intravascular, respiratory
d. intravascular, epidural, intrathecal products

4. Numerous Luer-connector tubing misconnections have been reported to the FDA. Those described in this article include all of the following except:

a. NIBP to IV tubing
b. epidural tubing set delivering an unspecified medication connected to an intravenous (IV) cannula
c. Foley catheter to a nasogastric (NG) tube
d. nasogastric tubing to IV tubing

5. Numerous organizations continue to work towards the reduction of Luer-connector tubing misconnections and were discussed in this article. These organizations include:

a. European Committee on Standardization, International Organization of Standardization, Food and Drug Administration, Centers for Disease Control and Prevention
b. Centers for Disease Control and Prevention, Food and Drug Administration, ECRI, International Organization on Standardization
c. Joint Commission on Accreditation of Healthcare Organizations, European Committee on Standardization, International Organization of Standardization, Food and Drug Administration
d. ECRI, Institute for Safe Medication Practices, Hospital Safety Commission, Food and Drug Administration

6. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recommendations regarding tubing misconnections include the following:

a. Always trace a tube or catheter from the patient to the point of origin before connecting any new device or infusion.
b. Do not purchase non-intravenous equipment that is equipped with connectors that can physically mate with a female Luer IV-line connector.
c. Emphasize the risk of tubing misconnections in orientation and training curricula.
d. All of the above

7. The Institute for Safe Medication Practice believes the following could solve the Luer-connector misconnections issue:

a. NIBP cuffs should be placed on a different arm than IV sites.
b. Remove IV catheters as soon as they are no longer needed.
c. Develop a plan to replace all BP monitoring equipment to ensure incompatibility with Luer connectors.
d. Institute a requirement for non-Luer connectors on all BP tubing.

8. In 2006, ECRI published misconnection-prevention recommendations. These included:

a. Implement institutional policies and procedures to address the Luer-connector misconnection issue.
b. Purchase medical devices and equipment that are designed to prevent the connection of unrelated delivery systems.
c. Identify misconnection hazards.
d. All of the above

9. Homecare patients are not at risk for tubing misconnections:

a. True
b. False

10. Two practices to ensure correct tubing connections are

a. label lines
b. provide shift to shift report
c. Trace the lines from point of origin to point of entry
d. Both A &C

11. Luer connectors help to reduce the risk of tubing misconnections.

a. True
b. False

12. The organization with the authority to set standards for all prescription and over the counter medicines is

a. the Food and Drug Administration
b. the Joint Commission on Accreditation of Health Care Organizations
c. Untied States Pharmacopia
d. Institute for Safe Medication Practices

13. The following reasons for tubing misconnections have been identified

a. multiple lines
b. clear tubing
c. Luer lock connectors
d. all of the above

14. Standardization of tubing can help to eliminate potential misconnections.

a. True
b. False

What is the highest degree you have earned (circle one) ? 1. Diploma 2. Associate 3. Bachelor's 4. Master's 5. Doctorate

Indicate to what degree did this program meet the objectives: Using 1 = strongly disagree to 6 = strongly agree rating scale, please circle the number that best reflects the extent of your agreement to each statement.

At the end of the session the participant will be able to:

	Strongly Disagree					Strongly Agree
1. List the indications for home nutrition support therapy	1	2	3	4	5	6
2. Describe the potential complications of enteral tube feedings	1	2	3	4	5	6
3. Describe the strategies that HEN consumers can use to adapt and cope more successfully	1	2	3	4	5	6
4. Identify ways that clinicians can foster coping in HEN consumers	1	2	3	4	5	6

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Mark your answers with an X in the box identifying the correct answer(s).

	A	B	C	D		A	B	C	D
1	☐	☐	☐	☐	9	☐	☐	☐	☐
2	☐	☐	☐	☐	10	☐	☐	☐	☐
3	☐	☐	☐	☐	11	☐	☐	☐	☐
4	☐	☐	☐	☐	12	☐	☐	☐	☐
5	☐	☐	☐	☐	13	☐	☐	☐	☐
6	☐	☐	☐	☐	14	☐	☐	☐	☐
7	☐	☐	☐	☐	15	☐	☐	☐	☐
8	☐	☐	☐	☐	16	☐	☐	☐	☐

Safe Practices. V.3 No.3 **Score** ____ **14**