In a heart-wrenching article last year, The New York Times called public attention to a patient safety risk that has festered for years: tubing misconnections. The front-page story chronicled the death of a pregnant woman and her unborn daughter for a mistake that never should have happened.

Hospitalized for complications to her pregnancy, the woman’s feeding tube was mistakenly coupled with a tube that entered a vein. “Putting such food directly into the bloodstream is like pouring concrete down a drain,” according to the Times article. The 35-week-old fetus died first. The 24-year-old Kansas mother of a 3-year-old boy spent her last hours in excruciating pain before she died as well. The Times story blamed “U.S. inaction” for hundreds of deaths or serious injuries traced to tubing mix-ups.
An epidural set was mistakenly connected to 

A feeding tube was mistakenly connected to a 

A feeding tube was inadvertently placed in 

IV tubing was inadvertently connected to the 

An emergency room patient had been 


The impact of misconnections on patient risk has been very high, not so much in frequency, but certainly in severity of injury or death,” says Peggi Guenter, PhD, RN, director of Clinical Practice, Advocacy, and Research Affairs at the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.). “Many clinicians are not even aware of misconnections—and they don’t know what they don’t know.” Guenter is a member of an international standards committee focused on reducing patient risks from tubing misconnections through redesign of small-bore connector standards.

That international initiative is long overdue, experts say. But many healthcare professionals don’t even know about the potential dangers the standards aim to mitigate, which leaves them vulnerable now to catastrophic patient events. And, without careful preparation, healthcare institutions and professionals could be taken by surprise by the coming changes to tubing connectors.

‘A Persistent and Potentially Deadly Occurrence’

Tubing misconnections are “well-known and well-documented,” according to the U.S. Food and Drug Administration (FDA). The FDA, The Joint Commission, the Institute for Safe Medication Practices (ISMP), United States Pharmacopeia, the ECRI Institute, and others all have received reports of misconnection errors. Firm numbers are hard to come by, because these incidents are not consistently reported by hospitals and other healthcare facilities.

In a 2006 Sentinel Event Alert, The Joint Commission—the largest U.S. accrediting body for healthcare facilities—called tubing misconnections “a persistent and potentially deadly occurrence.” A few more cases in point, from the FDA’s Look. Check. Connect. Medical Device Safety Calendar 2009:

- A feeding tube was inadvertently placed in the trach tube of an infant in a pediatric intensive care unit. Milk was delivered into the infant’s lungs. The infant died.
- An epidural set was mistakenly connected to a patient’s IV tubing. Epidural medication was delivered to the IV. The patient died.
- IV tubing was inadvertently connected to the nasal oxygen cannula. Four hours later, the patient complained of tightness in the chest and difficulty breathing. The patient was treated for congestive heart failure and survived.
- A feeding tube was mistakenly connected to a patient’s ventilator in-line suction catheter, delivering the contents of the tube into the patient’s lungs. The patient died.
- An emergency room patient had been connected to an IV heparin lock, but no IV fluids had been started, and to a noninvasive automatic blood pressure (BP) cuff for continuous monitoring. The cuff tubing was disconnected when the patient went to the bathroom. When she returned, her spouse mistakenly connected the BP cuff tubing to the IV catheter and air was delivered to the IV catheter. The patient died from a fatal air embolus, despite resuscitation efforts.

The impact of tubing misconnections in terms of patient risk? “To date, it’s significant, not in the number of misconnections, but in the high percentage rate of fatalities and incidents requiring medical intervention,” says Brad Noé, manager of Technical Resources, Hypodermic Platform at Becton, Dickinson and Company, and co-chair of AAMI’s Small-Bore Connectors Committee. “The general consensus is those that are reported are the tip of the iceberg and many incidents go unreported.”

The Luer Connector

The focus of concern is the Luer connector, widely used to securely attach medical devices, tubes, catheters, syringes, and other accessories. Named for 19th century German medical instrument maker Hermann Wülfing Luer, the connector consists of male and female components that fit together snugly. A Luer slip or Luer lock mechanism prevents leaks.

Years ago, manufacturers produced proprietary Luer connectors. Standards issued in the 1980s and 1990s by the International Organization for Standardization (ISO) have led to a uniform design.

The beauty and the bane of the Luer connector, which has been used in healthcare for more than 100 years, is that it is a simple, “universal” fitting, says Alan Lipschultz, president of HealthCare Technology Consulting LLC and co-chair of AAMI’s Standards Board. Today’s relatively inexpensive and very reliable connectors are compatible with one another and with many different devices and accessories. This universal design makes it easy to use
the connectors in clinical settings tangled with “spaghetti”—clinicians’ lingo for the plethora of small-bore lines and cables used to pump all manner of fluids and gases into or out of patients. Multiple connections between medical devices and tubing are commonly used to deliver medications and other substances to patients through vascular, enteral, respiratory, epidural, and intrathecal delivery systems.

The disadvantage of Luer connectors, however, is that it is equally easy to mistakenly connect tubes that don’t belong together and inadvertently deliver substances through the wrong route. In a healthcare environment that’s typically subject to complaints about the increasing complexity of medical technology, experts say that it’s so easy to use Luer connectors that, to borrow from a popular advertising slogan, a caveman could do it. It’s also easy for clinicians who are momentarily inattentive, in a hurry, fatigued, surrounded by multiple lines, or working in rooms with dim lighting to make a mistake. Even well-meaning family members or other visitors can easily connect detached lines, which can lead to disastrous consequence—as the emergency room case cited earlier illustrates.

While the Luer connector is not the only source of misconceptions, it has been a lightning rod. In a 2010 letter to manufacturers of enteral feeding tubes, for example, the FDA warned: “FDA is aware that standard Luer lock connectors are found on a variety of tubing sets, solution bags, and other medical products. The ease of connection between these Luer lock connectors has led to misconceptions that have inadvertently linked unrelated systems, and at times, have resulted in serious adverse events. Luer lock misconceptions are often under-recognized; therefore, adverse events resulting from such misconceptions are likely to be under-reported.”

The ECRI Institute put Luer misconceptions on its Top 10 Health Technology Hazards for 2011. “Although misconceptions have been recognized as a serious problem for years, incidents are still common,” according to the Institute’s report.

Issue Slow to Gain Traction
“Problems with interconnections didn’t get a lot of traction for a long time,” Lipschultz says. “People think they know how to use these connectors.” No one ever thinks they will make a misconception. But the risk is real, particularly in intensive care, emergency room, pediatric, and other specialized hospital units.

“Tubing misconceptions are often the result of cognitive ‘slips’ in performance where the provider is not aware that he or she is connecting the wrong tubing,” according to a 2008 article by Debora Simmons that was published in The Joint Commission’s Journal on Quality and Patient Safety. “Cognitive psychologist James Reason describes this state as being in ‘automatic mode,’ the level of functioning where the error is not detectable by the participant at the time the event occurs.”

As far back as 1996, AAMI developed a standard stating that connectors used with enteral feeding tubes shouldn’t have the ability to connect with female Luer lock components. However, according to a 2011 article in Medical Product Manufacturing News, the standard was not widely used “and had little impact on tubing connector designs.”

In 2006, the same year that The Joint Commission issued its Sentinel Event Alert, the FDA and the American Hospital Association convened a meeting on Luer connectors and misconceptions. “I attended and ended up authoring a multiorganizational white paper,” says A.S.P.E.N.’s Guenter, who spent 20 years using enteral and IV small-bore connectors, first as a surgical intensive care nurse and then as a nutrition support clinical nurse specialist focused on enteral and parenteral nutrition.

Guenter and her co-authors cited human factors and physical and design factors as contributing to enteral misconceptions. They recommended several broad solutions, including attention to education, awareness, and human factors; improved purchasing strategies; and design changes to build in “design incompatibility” to prevent dangerous misconceptions.

Interim Measures
In the absence of clear guidance or standards, clinicians and manufacturers have come up with makeshift ways to prevent misconceptions over the years, such as color-coding and labeling lines. These efforts are helpful, but they tend to be used only for specific tubing, not as widespread applications, Lipschultz says.
Getting Started Now

Brad Noé

The ultimate goal ahead is broad acceptance and successful integration of new connectors into the market—without creating even greater risk during the transition period. Given that the driving need is to reduce patient harm and improve safe outcomes, it is imperative to reach this goal. The challenges lie in the details and subtleties of execution.

Avoiding misconnections across all six families of connectors, meeting perceived and real clinical needs, making connectors cost effective, and ensuring minimal disruption to clinical practice is an extremely tall order. It requires a deep understanding of customers’ needs, clinical input, and participation.

For manufacturers and clinicians, the preparation for the standards implementation has started—at least at the high level of industry organizations. Several organizations within the United States have risen to the challenge: The Institute for Safe Medication Practices (ISMP) has hosted one webinar on the topic, covers this subject in its newsletters, and offers subscribers a medication error reduction checklist and audit tool to minimize risk. The Joint Commission has incorporated certain requirements into its inspection plan and issued a Sentinel Event Alert about tubing misconnections. The U.S. Food and Drug Administration (FDA) has sought to increase awareness on the topic. Several of the major group purchasing organizations have had speakers attend their conferences and are actively participating through AAMI in the standards development process.

Today, clinicians and biomedical technology professionals can be working with their suppliers to ensure that their chosen supplier is actively engaged in the standards development process through AAMI. If they are not engaged, encourage them to become engaged. Clinicians and those making product choices or those who are part of the product selection process should be taking several actions:

• **Evaluate the number of “workarounds” occurring in the clinical workplace.** Workarounds mean the clinicians are doing something that is outside the realm of intended use because what they have to work with is not functioning appropriately or may not be optimal. Carefully addressing these reduces the likelihood of people becoming creative and circumventing the processes established to protect them and the patient from harm.

• **Eliminate adaptors in the workplace.** Adaptors are a form of workaround. The acceptance of adaptors in certain high-risk settings is a signal that workarounds or modifying clinical practice to accomplish a task is an acceptable practice. This should not be the case.

• **Conduct safety audits.** Make sure that policy is being practiced and, if not, enforce or rewrite policy to meet clinical needs and practice.

• **Create cross-functional clinical practice teams so that all stakeholders can have a role in the decision-making process to ensure continuity of action across the supply chain and pipeline.** For example, if pharmacy draws up a medication into a reservoir that is provided to the clinical area, but that is incompatible with the connectors used to administer that medication correctly, this would force a clinician to either create a workaround or modify the process to allow for administration, thus reducing the likelihood of effectiveness of the system.

• **View reporting of misconnections or near misses as instructive and informational—versus reacting in a punitive or threatening way.** Learning and documenting where misconnections occur provides insight into areas for clinical analysis and improvement. A root-cause analysis should then be performed to address this identified area.

It has become increasingly evident that every manufacturer of a device that uses a small-bore connector and every manufacturer of a connector that works in the space outlined within ISO 80369 will be impacted to some degree upon completion of the ISO standards. Manufacturers should be meeting routinely with their customers to better understand their clinical needs and challenges as the time draws closer to conversion. This will allow both parties to be better positioned to:

• Develop conversion-management tools for use when actually bringing the products with the new connectors into the market.

• Coordinate efforts between suppliers and customers.

• Set expectations, roles, responsibilities, and supply chain management—critical tasks for successful conversions.

It is my humble opinion that the overwhelming majority of participants in this effort see the need, wish to find workable solutions and do so because they embrace the need for reducing medication errors and improving patient outcomes. This common ground, with personal and professional adoption of the challenge, makes the effort worthwhile and allows us to retain our focus.

**About the Author**

Brad Noé is manager of Technical Resources, Hypodermic Platform with Becton, Dickinson and Company. He is also co-chair of AAMI’s Small-Bore Connectors Committee.
Cover Story

Noé agrees. “In several situations, some manufacturers have been offering interim solutions that meet certain needs but not all those proposed by the work underway with the ISO standards,” Noé says. “While they serve a good intermediate step, they are not the panacea some users may perceive them to be. There are many who would offer far simpler and easier solutions that miss the mark and do not consider all the implications and subtleties to this effort. Some would have you believe that color-coding is the answer. Based on extensive studies conducted by the military and the aerospace industry, this is a nice-to-have, but an engineering solution is superior and less given to variabilities, such as color blindness, lighting intensity, and material properties.”

Guenter says change is coming, but it has been too slow. “It has certainly taken far too long to make the necessary changes to connectors,” she says. “I think the industry is now responding better, but patients are still dying so we need to get this redesign completed.”

The Role of Standards

Action to improve patient safety as it relates to tubing connections has quickened over the last five years with the formation of an international joint working group between the ISO and the International Electrotechnical Commission (IEC), under ISO lead. The working group—the creation of which was first proposed by AAMI—has several project groups and more than 100 members from around the world.

The joint working group is developing an initial seven-standard series on small-bore connectors (ISO 80369) to address misconnections. In the United States, AAMI is responsible for developing positions on drafts of the documents and is also considering them for adopting as “ANSI/AAMI/ISO” standards.

ANSI/AAMI/ISO 80369-1, completed in April 2011, specifies general requirements for small-bore connectors for liquids and gases in healthcare applications. ANSI/AAMI/ISO 80369-1 offers manufacturers information on how to design a safe connector for just their medical devices within a specific clinical application.

“A committed group of experts are doing incredible work together this year on new design standards that address misconnections with small-bore connectors,” says AAMI President Mary Logan. “Two of the design standards cover Luer connectors for parenteral and intravascular applications (Part 7), and enteral connectors (Part 3), with at least the first ballot of the parenteral connector expected in 2012—and final approval likely in 2013. It’s highly unusual for AAMI to create a design standard, as opposed to our usual performance standards.”

Scott Colburn, deputy director of the standards program for FDA’s Center for Devices and Radiological Health (CDRH) and convenor of the ISO Technical Committee 210/Joint Working Group 4, which developed the 80369-1 standard, says it “provides the framework for risk mitigation, and how to validate the new design.” The FDA has recognized this standard, which gives it considerable weight in this country.
Six additional standards dealing with small-bore connectors are in development (Table 1). Other standards may be added later, if warranted by patient safety risk and clinical need.

**‘600-Pound Gorilla in the Room’**

“The general issue is called out in the preamble of ISO 80369-1,” Noé says. “That is to develop a series of engineering controls—forcing function designs—that would make the likelihood of misconnection across the defined families of high-risk clinical applications almost nonexistent. This takes into account that the Luer has been in existence for over 100 years and has become the widest and easiest connector to manufacture and use due to its known interconnectability standard—which is the heart of the issue. For these reasons, every step we take has to be carefully thought through, evaluated, and then assessed on a number of levels.”

<table>
<thead>
<tr>
<th>Standard</th>
<th>Application</th>
<th>Status</th>
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<tbody>
<tr>
<td>80369-1</td>
<td>General requirements</td>
<td>Completed in 2011</td>
</tr>
<tr>
<td>80369-2</td>
<td>Breathing systems and driving gases</td>
<td>Second committee draft due in 2012</td>
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<tr>
<td>80369-3</td>
<td>Enteral (feeding tube) applications</td>
<td>Committee draft due in 2012</td>
</tr>
<tr>
<td>80369-4</td>
<td>Urethra and urinary tubing</td>
<td>Work has not begun</td>
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<tr>
<td>80369-5</td>
<td>Limb cuff inflation or non-invasive blood pressure</td>
<td>Second committee draft due in 2012</td>
</tr>
<tr>
<td>80369-6</td>
<td>Neuraxial applications used to deliver medications to spinal fluid</td>
<td>Second committee draft due in 2012</td>
</tr>
<tr>
<td>80369-7</td>
<td>Luer fittings</td>
<td>Committee draft due in 2012</td>
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Table 1. Small-Bore Connector Standards

“To use a common phrase, today’s Luer fitting is the 600-pound gorilla in the room. It is the most commonly used and universal connector in medical practice today.”

—Brad Noé, co-chair of AAMI’s Small-Bore Connectors Committee
Noé characterizes the scope of the challenge as daunting: “To use a common phrase, today’s Luer fitting is the 600-pound gorilla in the room. It is the most commonly used and universal connector in medical practice today. Luer exists in various applications, is attached to more devices and is extremely low cost to manufacture. The Luer is simplistic in design and is well entrenched in medical practice because it has met its originally intended application of being a universally adoptable connector for administering medications and connecting various devices.

“The challenge facing the Luer team is to revise the Luer standard in such a way as to not completely disrupt these simple principles, disrupt medical practice, and layer in additional, significant costs to modify existing tooling that manufacturers already use and own. Luer, as we know it, has been morphed into a myriad of various connectors with a wide range of critical fluid path dimensions which pose some very real challenges to our teams of designers and experts when avoiding misconnection with other connectors.”

Once that is accomplished, Noé says that the focus could shift to “developing the connectors that will not interconnect with Luer, not interconnect with the other clinical family connectors, meet their own respective clinical needs and not disrupt clinical practice in a cost-effective fashion. Said quickly, this can be viewed as a simple task—but has proven to be extremely daunting. Keep in mind that a rough estimate of Luer fittings produced annually for consumption into global healthcare markets is in excess of several tens of billions.”

Implications for Biomeds, Clinicians, and Manufacturers

The ISO 80369 standards series is expected to bring dramatic changes in the coming years to the healthcare industry that will impact clinical engineers (CEs), biomedical equipment technicians (BMETs), clinicians, and manufacturers.

These standards are expected to be adopted in Europe as ‘harmonized standards,’ so we expect manufacturers will want to comply with them, and this will have an impact on all the markets, not just the E.U. For hospitals, the big questions is, ‘How do we get off the ground?’” Elliott says. AAMI plans to offer education forums to support their efforts, starting at the C-Suite level.

Some healthcare institutions are under a tight timeline and have begun their efforts already. California will be a place to watch. In addition to the ISO 80369 standards, California legislation bans acute-care facilities from using interconnectable IV and enteral feeding sets beginning Jan. 1, 2013, or 24 months after the approval of the ISO standard, whichever comes first. In addition, epidural connectors cannot mate with other sets beginning Jan. 1, 2014, or 36 months after standard approval.

“Huntington Memorial Hospital has taken a proactive approach in reviewing this in detail and ensuring that we continue to emphasize the awareness and be prepared for the new standards when they become available,” says Izabella Gieras, director of clinical technology at the Pasadena, CA, hospital. “More and more clinical engineers and BMETs are getting involved in this initiative. Some have started to work with clinical staff and manufacturers to identify and assess the risks misconnections pose on their environment. Many have also gone further and implemented mitigation plans such as policies and procedures, change in practices in how patient lines are labeled, educational initiatives and overall staff and patient/visitor awareness.”

Gieras is building on lessons learned in a notable hospital investigation of tubing misconnections. “While at William Beaumont Hospital in Michigan, I got involved in a multidisciplinary misconnections task force which was
TUBING MISCONNECTION CASE STUDIES

*Note: These photos depict misconnections and should not be followed. Information comes from the U.S. Food and Drug Administration’s Medical Device Safety Calendar 2009.

Enteral feeding tube connected to ventilator in-line suction catheter: This misconnection resulted in the tube feeding going directly into the patient’s lungs. The patient died.

Feeding tube connected to trach tube: The feeding tube for a hospitalized infant was mistakenly placed in the trach tube, delivering milk into the patient’s lungs. The infant died.

Epidural tubing connected to IV tubing: The medication was mistakenly delivered to the IV after a misconnection by the anesthetist and midwife. The patient died.

Syringe connected to trach cuff: The patient had a both central line with three ports and a trach tube. Medication intended for the central line was erroneously injected into the trach cuff, and the medication entered the patient’s lungs. The patient survived.

IV tubing connected to enteral feeding tube: The patient, a child, had both a gastric feeding tube and an IV for medication and hydration. After the child’s down was changed, a family member mistakenly attached the IT tubing to the feeding tube, sending medication into the patient’s stomach. The patient was not harmed as the mistake was quickly noted and fixed.

IV tubing erroneously connected to nasal cannula: A nurse’s aide inadvertently connected the IV tubing to the nasal oxygen cannula upon transfer to the step-down unit. The patient was treated for congestive heart failure, but survived.
charged to develop initiatives to prevent 
misconnections. The committee created a 
much-needed awareness campaign throughout 
the whole hospital through new policies, 
posters, and process changes.”

Lipschultz urges CEs to rise to the challenge 
of these changes. “Clinical engineers should be 
looking beyond the technology they’re comfort-
able with, participating in risk management 
audits, helping to articulate and translate 
issues, and adding value to their organizations,” 
Lipschultz says.

Noé put it another way. “Biomedical technol-
ogy professionals also can act as independent 
auditors for medication safety practices. They 
should be an active part of the process when 
evaluating new products for introduction into 
those high-risk applications. They should also 
be a part of the assessment process and 
potentially coordinate efforts across functions.”

Guenter says there will be a learning curve 
for healthcare professionals. “Clinicians will 
first need to be educated on misconnections so 
that they understand the ‘why’ surrounding 
this industry-wide change,” she says. “They 
then will need lots of education on how to use 
these new connectors in a well-planned, 
systematic fashion.”

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