In 2006, when the birth of her second child was only weeks away, 24-year-old Robin Rodgers began losing weight and vomiting. Her doctor ordered her to be hospitalized and fed through a tube until she delivered. But the nutrition source container that was feeding her via a feeding tube in her stomach was mistakenly connected to an existing intravenous line. Tragically, both Rodgers and her unborn child died.

That same year, a Wisconsin nurse mistakenly injected a spinal anesthetic into an IV tube, killing 16-year-old Jasmine Gant, who was giving birth. In another incident, premature infant Chloe Back was mistakenly connected to a bag of breast milk through her IV tube. In this case, the baby did not die, but formed blood clots throughout her body, bled profusely, and suffered seizures for months afterward.

In response to these and the many other reports of tubing misconnections that have plagued healthcare workers and human factors engineers for decades, a Sentinel Alert was issued by the Joint Commission in 2006 to draw attention to the gravity of the matter. This year, articles in a number of publications, most prominently the New York Times and Las Vegas Review Journal, have again brought the issue to the forefront.

These articles led to a Congressional committee inquiry and a call for new regulations by the Nevada Medical Association. They also prompted the medical device industry and the U.S. Food and Drug Administration (FDA) to publicize the work that has been underway for some time in the development of a new international standard that many hope will virtually eliminate future tubing misconnections.

The first of a series of new standards is currently at final voting (FDIS) stage internationally, and will be issued after approval under the designation and title ISO 80369-1, Small-bore connectors for liquids and gases in healthcare applications. Other parts of the series will address connectors for specific applications. In the meantime, 80369-1 is expected to provide unprecedented methods to identify specific connector solutions for a variety of medical applications.

Brad Noé, technical resources manager at Becton Dickinson and Company, is co-chair of the AAMI small bore connectors working group, which serves as the U.S. technical advisory sub-group (sub-TAG) for the ISO/IEC connector standards, and is also project leader for two of the ISO/TC 210 project groups developing the series. Noé says that human error due to device issues, environment of care, and other factors certainly plays a part in such misconnections, although “how much a part,” he says, “is difficult to quantify. The misconnection of tubing sets due to working in dimly lit conditions, inability to trace the line from connection point to connection point, or incorrect or missing labels all contribute,” he explains.

AAMI is the secretariat for the international committees that are jointly developing 80369 (ISO/TC 210 and
IEC/SC 62D) and also administers the related U.S. TAGs. Concurrent with the ISO/IEC process, AAMI is considering the entire series of connector standards for national adoption as AAMI/American National Standards.

Many years ago, the AAMI Infusion Device Committee tried to address one type of misconnection with issuance of ANSI/AAMI ID54:1996/(R)2005, *Enteral feeding set adapters and connectors*, which recommends a redesign of connectors to remedy the misconnections problem between enteral and parenteral applications. However, it does not offer specific steps manufacturers can use in such a redesign and will ultimately be replaced when AAMI adopts the relevant ISO standards.

The new ISO standard aims to make small bore connectors standardized with their respective medical applications. It will offer guidelines for creating connectors that will not interface with traditional luer fittings or other fittings that have what are identified as high-risk medical applications. This will be accomplished, Noé says, “through the creation of defined sets of standardized connectors for specific families of clinical applications that are non-interconnectable with the traditional luer fittings and each other.”

Luer connectors—small fittings with both male and female components that join to form secure, yet detachable, leak-proof connections—are the most commonly used fittings for tubes. Since there can be as many as 40-plus such connectors on a single patient, each able to connect to a number of devices, it is little wonder mistaken connections occur. Although solutions such as color-coding or labeling tubes and their connectors and rechecking and tracing lines back to their source are often employed, most experts agree that the best fix is to eliminate connector cross compatibility—meaning, redesign the connectors so they fit only one type of tubing, and therefore cannot be accidentally joined to the wrong applications.

This forthcoming guidance, Noé says, should all but eradicate tubing misconnections by using engineering controls to reduce the dependence on human intervention, and thus avoid interoperability issues. According to Noé, such controls rely on the use of “forcing functions”—aspects of a design that prevent an action from being performed, or only allow it to be performed if another action is performed first. “The use of forcing functions in the unique design characteristics for the proposed connectors should have a significant, positive impact in reducing the likelihood of interoperability across various tubing sets,” Noé says.

Other, more product-specific standards are currently being created as well. These standards address explicit sections of the 80369-1 standard, and detail requirements for specific connectors for: breathing gas systems; enteral feeding, urethral and urinary applications; limb cuff inflation; neuraxial access; and vascular access and IV administration. These standards are in varying stages of development, and some are already in the review process.

The 80369-1 standard is currently being finalized, and those involved expect the document to be published in January 2011. In a July 2010 letter on this issue, FDA says it is considering recognizing this standard when it is published and, if so, will provide guidance to manufacturers about compliance timelines for currently marketed devices, and offer assistance regarding the effects of the standard on new devices.

“Standards are being finalized and we are well underway to completing this effort,” Noé says. “The ISO review process will be actively engaged in the review and evolution based on the inputs we receive to drive to completion. Once approved, we will then take the next hurdle of execution into the marketplace.”

### Short-term Strategies for Preventing Misconnections

Until the long-awaited standard ISO/IEC/FDIS 80369-1 *Small-bore connectors for liquids and gases in healthcare applications* is finalized, experts have advised healthcare providers to do all they can now to help with existing products by implementing risk-reduction strategies such as:

- Affixing labels or colored tabs on lines
- Adjusting lighting as needed
- Rechecking lines back to their source
- Performing risk assessments, which will help identify various catheters and fittings currently in use, call attention to the possibility for misconnections and their potential severity, and address any process changes that need to be made

Manufacturers should prepare by:

- Examining how the standard will impact their companies and devices
- Noting how and for what purposes customers are using their devices
- Educating customers about changes that will occur once the standard is in place