

# SAFE PRACTICES *in Patient Care*

Helping to promote a culture of safety

**T**ubing misconnections can lead to medication errors and result in serious injury or death to the patient. Nine cases of tubing misconnections involving 7 adults and 2 infants have been reported to the Joint Commission's Sentinel Event database, resulting in 8 deaths and 1 permanent loss of function. Similar incidents have been reported to other agencies, including the ECRI Institute, the United States Food and Drug Administration, the Institute for Safe Medication Practices (ISMP), and the United States Pharmacopeia (USP). Data from these groups reveal that misconnection errors occur with significant frequency and, in a number of instances, lead to deadly consequences.

In her article, Ms. Guenter focuses on those misconnections related to enteral nutrition systems, specifically enteral misconnections. In each case, serious patient harm, including death, can occur if fluids, medications, or nutritional formulas intended for administration into the gastrointestinal tract are administered via the wrong route. Our panel is comprised of 3 national experts who have followed the issue of tubing connections for several years. Their discussion focuses on what is being done to correct the problem and what still needs to be done.

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## Enteral Feeding Misconnections

Peggi Guenter, PhD, RN, CNSN

**E**nteral nutrition (EN) is nutrition provided through the gastrointestinal tract via a tube, catheter, or stoma in order to deliver nutrients distal to the oral cavity.<sup>1</sup> This paper focuses on those misconnections related to enteral nutrition systems, specifically enteral misconnections. An enteral misconnection is defined as an inadvertent connection between an enteral feeding system and a non-enteral system such as an intravascular line, peritoneal dialysis catheter, tracheostomy tube cuff, medical gas tubing, and so forth. In each case, serious patient harm, including death, can occur if fluids, medications, or nutritional formulas intended for administration into the gastrointestinal tract are administered via the wrong route (e.g., into the intravascular system).<sup>2</sup> (Figure 1)

### Incidence of Enteral Misconnections

The report of an inadvertent IV administration of milk in 1972 is one of the earliest publications of an enteral misconnection.<sup>3</sup> In 1971, a young man with a duodenal ulcer exacerbation was receiving intragastric feedings of pasteurized milk which became connected to his IV. The authors concluded that the intragastric "milk" drip must be named (ordered) in full and that this was especially important now with parenteral fat emulsion in use, which resembles milk in appearance.

One published literature review found more than 60 citations on enteral misconnections.<sup>4</sup> Published reports consistently substantiate the severity of this type of error, which too frequently results in the death of the patient because of ensuing embolus or sepsis. As with other voluntary adverse event reporting systems, enteral misconnections may be greatly underreported as compared to the number of actual cases.

In early 2007, the British National Health Service issued a National Public Safety Alert regarding the risks of misconnections.<sup>5</sup> The alert was in response to 33 documented safety incidents involving oral liquids given intravenously in an 18-month period in 2005-2006. They also reported 3 patient deaths from this type of error from 2001-2006.

In March, 2007, a review of 2 nationally-recognized voluntary medication error report-



Figure 1. Feeding tube erroneously connected to trach tube. (Courtesy of FDA Medical Device Safety Calendar, 2009.)

ing systems identified cases involving enteral feeding systems.<sup>6</sup> Between January 1, 2000, and December 31, 2006, the reviewers found 24 reported incidents involving an enteral feeding formula or other solutions and medications intended for the feeding tube, but administered via the wrong route. Of those 24 incidents, 8 (33%) resulted in sentinel events (permanent injury, life-threatening situation, and/or death). Although the absolute number of reported cases is not large, the level of severity associated with the error was critical. Many of the cases resulted from the use of an IV syringe to dispense, prepare, or administer an enteral medication and then inadvertently attaching the syringe to the IV system, resulting in a wrong route error.

These 24 cases represent several failure factors that can lead to wrong route errors. See Table 1 on page 4 for more details on these failure factors and the risk of present enteral nutrition delivery systems.

### Enteral Feeding System

The enteral feeding system for adults and older children consists of the enteral nutrition formula container, the delivery tubing, and the enteral tube itself. The system includes all connectors, pumps, or syringes that in the system.<sup>6</sup> The enteral feeding set is the feeding container or bag attached to the delivery tubing, which ends with a connector. This feeding set may

*Continued on page 4*

## Panel Discussion Tubing Misconnections: Where are we today?

**Moderator:** Rodney Hicks, PhD, RN, FNP-BC, FAANP  
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Endowed Chair for Patient Safety  
Anita Thigpen Perry School of  
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**Panelists:** Nancy Pratt, RN, MS  
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Safe Medication Use Expert  
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Medical tubings that connect intravenous lines, hemodynamic lines, epidural connections, feeding tubes, etc. are essential to modern practice. Without such tubing, many patients would not receive fluid and electrolytes, nutrition, or medications. Thousands of times a day across the healthcare system, competent and caring practitioners assemble tubes by connecting the proximal and distal ends together to deliver the contents to patients. As the healthcare system has grown in complexity, so has the number and types of medical tubing. Along with this complexity, the opportunity for connection errors has increased. That is, tubing on one device, such as an intravenous line, may be inadvertently connected to another source, such as a feeding tube. While rare, the potential and actual consequences of such connection errors can be serious. In fact, at least one lethal case is reported every year. National and international calls for redesigning tubing systems to prevent such errors have yet to result in a 100% fail-safe system.

This panel is comprised of three national experts who have followed the issue of tubing connections for several years. Together, they represent unwaivering support for the need to redesign the system so as to permanently eliminate the opportunity for a tubing connection error.

*Can you briefly tell the history that lead to the Joint Commission issuing the Sentinel Event Alert for tubing misconnection?*

**Nancy Pratt:** On April 3, 2006 the Joint Commission released a sentinel event alert on this subject entitled “Tubing misconnections—a persistent and potentially deadly occurrence.”<sup>1</sup> As of 2006, there were 9 cases of tubing misconnections reported which resulted in 8 deaths and 1 permanent loss of function in 7 adults and 2 infants. The results, although rare, are catastrophic and should not be ignored.

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human error, so education  
alone is insufficient to  
eradicate them.

- Pratt -

The fundamental problem is that all the line and tube fittings use Luer connectors, a design standard in health care disposable supplies. This created a hazard because it allows lines to be misconnected, which could result in fatal outcomes. The most common response to this situation has been to re-educate nurses, as if a knowledge deficit was the problem. These mistakes are due to human error, so education alone is insufficient to eradicate them.

The Joint Commission made several recommendations, including that tubing connectors be designed in such a way so that they cannot be mistakenly connected. An optimal design would introduce a forcing function, thus signaling the caregiver that they are making a connection mistake. However, this not universally available on today’s market. There are niche products, such as for the NICU, and a single enteral feeding tube that is not IV compatible is available for adults.<sup>2</sup> Among other strategies, the Joint Commission currently recommends tracing the tubing back to its origin before connecting to reduce the chance for error.<sup>1</sup>

*What is the current state of affairs since the Sentinel Event Alert release?*

**Nancy Pratt:** After the alert was released, it became clear there were no products on the market that would prevent misconnections, so a group of stakeholders were invited to a meeting in Washington, DC, hosted by the AHA. The meeting included representatives from the Joint Commission, the FDA, ISMP, ECRI, ASPEN, health care providers and industry participants. We asked the regulatory agencies (JC and FDA) to mandate a different design standard as the Europeans had done this work 3 years prior. Although the regulatory agencies were sympathetic to our concerns, there was no agreement on what the new standard should be. An international group seeking a new standard had not agreed to adopt the European standard, so while they continued their work, we felt we should seek an answer to the problem in the US.

We wrote a white paper, published in May 2008 in the Joint Commission Journal on Quality and Patient Safety.<sup>3</sup> As a follow up, ECRI did a webcast and Nestle has agreed to develop the European standard, a screw-type connector, for US distribution.

The screw connector for the tubing and container are currently on the market and the tubes themselves are available from one manufacturer. The whole connection issue was brought to the California Hospital Association Quality Committee, which sent letters to manufacturers asking for their support in solving the problem. In addition to working with legislators on other safety legislation, the committee, headed by Debby Rogers, recommended language in state legislation stating connections that were not interchangeable be required. This law passed in the state of California in 2008.

Therefore, beginning January 1, 2011, general acute care hospitals, acute psychiatric hospitals, skilled nursing facilities and special hospitals in California will be prohibited from using an intravenous connection, epidural connection, or enteral feeding connection that would fit into a connection port other than the type for which it was intended, unless an emergency situation exists and the prohibition impairs the ability to provide adequate health care. Essentially, we wanted to create a market for new products so the manufacturers would make them. With California being the 10th largest economy in the world, it was felt that there would be sufficient market demand for these new products.

*Debora, how are other states addressing the issue? Can you describe the role of state nursing boards in handling complaints involving tubing connections?*

**Debora Simmons:** We are fortunate that the Texas State Board of Nursing has been very proactive in safety and is also involved in creating a national database to track and analyze errors. This is painstaking work and will not yield significant results for the near future. But without this information, we have no idea how many of these reports are going to state boards, so we really need better reporting systems from regulatory licensing boards, private and public sectors, and at the national level we need aggregate databases to combine and analyze these reports. At this time, I don’t think many people understand this error, including regulatory boards, so for the most part people are blaming and punishing individuals. We know from experience that this does little to improve safety. In fact, it usually drives information underground as people try to avoid punishment. Boards struggle with this balance – when someone makes an error, we want to punish the person responsible and the public even demands it, but we need to understand how these errors occur and fix them. True accountability means we take the time and effort to design a new system to prevent these errors – this is truly honoring an injured patient. Hopefully, state boards will take into consideration these very serious system level flaws when the individual nurses are reported and begin to make changes to the way

they discipline nurses based on systems analysis and safety knowledge - we have a long way to go.

*Nancy, what is role of group purchasing organizations in advancing the cause?*

**Nancy Pratt:** If group purchasing organizations could drive demand across the country, it would help provide a market. Indeed, the Premier Safety Institute was hot on the trail to push a design solution with manufacturers. They assembled a group of stakeholders in Chicago at the same time the group of regulatory agencies was meeting in Washington D.C. They have posted safety alerts on their website and have lobbied manufacturers to assist in creating a solution. If all group purchasing organizations joined in this effort, it would certainly help advance the cause.

**Rodney Hicks:** want to say a few words about education and training. These alone will not eliminate the issue of tubing misconnections. That is not to say that they are not important; on the contrary, education and training do have a valuable role in raising awareness of the issues and the subsequent threat to patient safety. As I travel the nation and meet with nurse educators and nursing students, it is readily apparent that the educational system is not equipped to solve the problem.

Why such a bleak outlook? First, I believe that there is a disconnect between educational initiatives in our colleges and schools of nursing and the practice setting. Competent faculty are producing competent students but the education is too narrow. Take, for example, the task of teaching beginning students to insert a nasogastric tube. The simulated skills lab makes it difficult to not pass the exercise. Sometimes, the mannequin does not have other tubes or openings. Therefore, the student achieves only the task at hand without recognizing the risk of crossing tubes or other openings. What is needed is a simulated complex setting within which the student is taught and graded in the broader scope of task completion, including the awareness of threats to patient safety. I am pleased that some simulation labs are doing this.

I am also concerned about the pace of information coming from national organizations and a lack of penetration into curricula. For example, changes in national patient safety goals and other Joint Commission initiatives are well understood at the organizational level, but not in the educational setting. Another area that is lagging is the increasing demand for pay-for-performance, especially in areas such as “never ever events.” There needs to be a better way of aligning national initiatives with educational programs.

When I get the chance to interview faculty and students about organization policies and procedures, the results are all over the map. Some students are unaware of how to access the facility’s policies.

Part of bringing students to the clinical site requires an investment on both the school and the organization. The organization can not just say

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- Hicks -

“here is the policy manual.” As with the strategic plan, the P&P manual needs to be a living document. I encourage using the P&P manual as the basis for compiling care needs before implementing care. Also, current text books are highly out of date. Few, if any, relate the hazards of the tubing issue. There is a lot to be done for educating our future care providers.

*Debora, is there a single organization that will oversee the redesign of the present system? How are other clinicians handling this critical issue?*

**Debora Simmons:** Here is the sad history. Regulatory and safety organizations have considered the threat of common connectors as early as 1986 when ECRI published the Medical Device Safety Reports, which called for a new design for connecting enteral feeding tubing to a tracheostomy cuff. In 1996, the Infusion Device Committee of the Association for the Advancement of Medical Instrumentation (AAMI) passed American National Standard ANSI/AAMI ID54:1996 after considering the universally connected properties of feeding sets, adaptors and the possibility of harm when these connectors were inadvertently connected to other devices. This standard was reconsidered by the expert committee and pronounced “in force” in 2005 but has not been enforced by the FDA (Association for the Advancement of Medical Instrumentation (AAMI) .The current AAMI committee focused on tubing will take up to 5 years to issue another standard.

The Sentinel Event Alert mentioned by Nancy (#36 April, 2006) noted that cases of misconnection are under-reported. The authors stated “the basic lesson from these cases is that if it can happen, it will happen. Luer connectors are implicated in or contribute to these errors because they enable functionally dissimilar tubes or catheters to be connected.” They encouraged manufacturers to implement “incompatibility by design” to prevent dangerous misconnections. Preventing tubing misconnections are a

part of the World Health Organization’s “Nine Solutions” for patient safety, as recognition of tubing misconnections occurring in other countries.

The Food and Drug Administration has also recognized the threat of universal connectors. In 2005, an alert was published citing cases of blood pressure monitors inadvertently connected to intravenous devices, resulting in air embolism and death. The advisory agreed with the Joint Commission that the use of universal connectors in healthcare is a fundamental failure to design safe systems. In 2006, the FDA met with concerned stakeholders at the American Hospital Association. The consensus paper from the meeting clearly called for a redesign of tubing connectors to prevent accidental misconnections. The FDA has not enforced the standards despite their own warnings and alerts to healthcare. Most recently the FDA published a 12-month calendar warning of the multiple ways tubing can be misconnected.

Today, manufacturers continue to make universally connecting Luer tips for critical and incompatible tubing systems. There will be no action from the FDA until the AAMI group revises the standard and until manufacturers respond, which could take 7-to-10 years. We are caught in a cul de sac of failures here – the FDA cannot tell you to buy incompatible systems because the manufacturers are not making them, and the manufacturers are waiting for a mandate from a regulatory body. There are some early adopters, manufacturers who recognize the risk of universal connectors, who are making alternatives, but they are doing so willingly and it is not standard in the industry.

Clinicians may not be aware of the risk. It is well known that healthcare has operated as if humans can operate perfectly and we design our environment based upon this bad assumption. Often the first response to an error is to blame the individual for not being vigilant or to say the individual needs more education and training. Neither of these responses are correct with regard to this type of error. The error is a result of imperfect human performance and only a design change to will decrease its occurrence. These errors are not based on lack of vigilance or education.

So, unfortunately, there is no one coordinating body to take charge and we have misconceptions in the clinical area regarding the cause. Therefore, we really need a response from the industry. Advocating people to be more careful is not going to fix this, nor will color coding or improved labelling – we need a redesign and we need it quickly.

#### References

- 1 The Joint Commission. Sentinel Event Alert, Issue 36, April 3, 2006. Tubing misconnections—a persistent and potentially deadly occurrence. Available at: [http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea\\_36.htm](http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_36.htm). Accessed May 4, 2009.
- 2 For examples: [www.safeenteralconnections.com](http://www.safeenteralconnections.com)
- 3 Guenter P, Hicks, RW, Simmons D, Crowley J, Joseph S, Croteau R, Gosnell C, Pratt NG, Vanderveen TW. Enteral feeding misconnections: A consortium position statement. The Joint Commission Journal on Quality and Patient Safety. 2008; 34(5):285-292.

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- Simmons -

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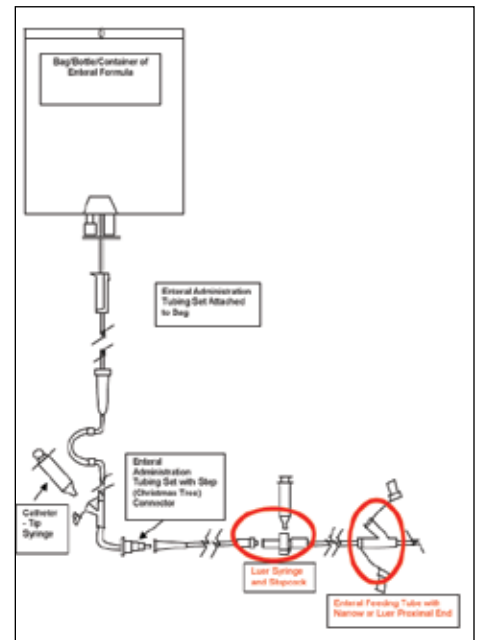
**Nancy Pratt, RN, MSN** is Senior Vice President, Clinical Effectiveness, at Sharp HealthCare, San Diego, Calif. Ms. Pratt has championed for change not only from the purchasing aspect, but also from a regulatory approach within her home state of California. She possesses a broad knowledge base of clinical requirements for information technology within the healthcare industry. She has published several papers on tubing misconnections and other topics and is the recipient of several academic and industry awards. She is a noted national and international presenter on topics related to nursing.

**Enteral Feeding Misconnections**  
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be a 1-piece device with the container connected permanently to the tubing. In the case of prefilled, closed system formula bags or containers, an enteral administration set must be spiked into the bag, making it a 2-piece enteral set (Figure 2). The distal end of the enteral set connector attaches to the proximal end of the feeding tube. Some feeding tubes contain only 1 port, that is, the single lumen tube does not have a side port for medication administration. Often, clinicians attach adaptive devices, such as Luer-Lok™ stopcocks or extension tubing sets, between the feeding set and the feeding tube. These devices facilitate flushing and medication administration. There are a number of reasons to interrupt or discontinue feedings, including daily set change, patient testing, intermittent feedings, patient intolerance, and for flushing and medication administration when the tube does not have side ports and the main port is in use for feeding.<sup>6</sup>

The system used to provide enteral feedings in some pediatric and nearly all neonatal patients differs from the system described above. In infants, small-volume feedings require low infusion rates. In many settings, this has been accomplished by utilizing syringes with IV syringe pumps rather than adult size feeding sets and pumps. Some care settings use specially tipped oral syringes for enteral delivery of formula, breast milk, and oral medications.<sup>7,8</sup> Oral syringes or dispensers are syringe-like devices with a unique tip configuration that cannot accommodate a hypodermic needle or actuate a needleless IV access port are available from several manufacturers. Until recently, the infusion devices (e.g. syringe pumps) were only calibrated for use with parenteral syringes. In addition, the design of most infant feeding tubes allowed the tubing to accept Luer-Slip™ or Luer-Lok connectors for compatibility with parenteral syringes.<sup>8,9</sup>

**Concerns Specific to Enteral Feeding**  
A number of leading public and non-profit



**Figure 2. One-Piece Enteral Administration Set in Enteral Feeding System.** Reprinted with permission from Guenter P, Hicks, RW, Simmons D, et al. Enteral feeding misconnections: A consortium position statement. *The Joint Commission Journal on Quality and Patient Safety*. 2008; 34(5):285-292.

organizations (i.e., United States Pharmacopeia [USP], Emergency Care Research Institute, now known as ECRI Institute [ECRI], Institution for Safe Medication Practices [ISMP], US Food and Drug Administration [FDA]) have issued safety warnings that address the potential and actual risk from medical tubing misconnections (Figure 3). Despite warnings that date back to 1986, the number of case reports continues to accumulate. The Joint Commission issued a Sentinel Event Alert regarding tubing misconnections in April 2006.<sup>10</sup> This alert stated that multiple reports to patient safety organizations, including The Joint Commission, ECRI Institute, FDA, the ISMP, and USP, demonstrate that these misconnection errors continue to occur with significant frequency

Related Factors	Number of Cases	Number of Sentinel Events	Percent of Cases with Sentinel Events (Life-Threatening or Fatal)
Use of Syringe Pump and IV Tubing	1	0	0
Use of Ready-to-Hang Enteral Containers/Bags and IV Tubing	3	2	66%
Enteral Meds Administered IV (Used IV Syringe)	13	3	23%
Other Solution Intended for Enteral Route given IV	4	2	50%
Enteral Tube Not in Place, Med Given IV	3	1	33%
<b>Total</b>	<b>24</b>	<b>8</b>	<b>33%</b>

**Table 1. Reported Enteral Misconnections and Related Factors (Jan. 2000–Dec. 2006).** Data supplied by USP MEDMARX and USP-ISMP Medication Errors Reporting Program. Reprinted with permission from Guenter P, Hicks, RW, Simmons D, et al. Enteral feeding misconnections: A consortium position statement. *The Joint Commission Journal on Quality and Patient Safety*. 2008; 34(5):285-292.

and, in a number of instances, resulted in deadly consequences.

## Factors That Contribute to Enteral Misconnections

### Human Factors.

Errors involving feeding tube misconnections are often a result of errors in performance—providers are unaware that the connection is occurring between 2 misplaced tubes. These errors are often made by expert practitioners who are unaware they are connecting the enteral feeding or medication to the intravenous line but know that such a connection poses a danger to the patient. This error in performance is not under the conscious control of the practitioner.<sup>6</sup> The literature describes environmental factors that predispose human beings to such errors.<sup>11</sup> Many factors are endemic to the current patient-care environment, including time pressure, rotating shift work, fatigue, attempts to use short-term memory to store large amounts of information, inadequate training, and inadequate lighting (e.g., during the night shift in a darkened patient room).<sup>6</sup> In the cases reported to the Sentinel Event Database, contributing factors also included moving patients from one setting or service to another.<sup>10</sup>

### Physical and Design Factors.

Luer connectors contribute to many of these errors because they permit functionally dissimilar systems to be connected. The user receives no tactile feedback indicating an error has occurred because the connectors fit together easily. Other identified causes include the routine use of tubes or catheters for unintended purposes such as using IV extension tubing to extend enteral feeding tubes.<sup>10</sup>

Physical characteristics and connections along the enteral nutrition system also contribute to the risk of enteral misconnections. These include connection of the enteral administration set to a pre-filled container or bag in which the 2-piece system allows IV tubing to be substituted for an enteral administration set.<sup>12,13</sup> (Figure 2) Both types of tubing have a universal

spike at the proximal end, but the IV set has a male Luer distal end that can be attached to a female Luer of another system, thus permitting a misconnection. The next point in the system is the use of Luer stopcocks, adapters, or extension sets between the enteral feeding administration set and the feeding tube in order to accommodate medication or flush syringes. Other factors that may contribute to misconnections are disconnections (either accidental or intentional) at any of the connection points. The more often lines or systems must be disconnected and reconnected, the greater the chance for a misconnection because some practitioners who reconnect a line may not remember to trace the line to its origin.<sup>14</sup>

### Solutions and Recent Innovations

Solutions to prevent misconnections are multifactorial and need to include all stakeholders, including healthcare clinicians, patient care institutions, regulatory agencies, quality improvement organizations, purchasing groups, and manufacturers. The solutions can be grouped into 3 broad and not mutually exclusive areas: education, awareness, and human factors; purchasing strategies; and design changes.

### Education, Awareness, and Human Factors

Educational efforts and alerts must continue to be a priority. Educators should emphasize the risk of tubing misconnections in orientation and training. Nurses who work with multiple common connectors must be constantly aware of the risk of inadvertently connecting the wrong line and must develop strategies to decrease this risk.<sup>15,16</sup> Suggested strategies for educational initiatives are listed in Table 2.

A.S.P.E.N., in cooperation with Nestlé HealthCare Nutrition has launched an awareness campaign for nurses at the bedside using the “Be A.L.E.R.T.” acronym. See (Figure 4) The translation of recommendations from experts to the nurse actually delivering the enteral nutrition is vital and all nutrition support specialists can participate in such an awareness campaign.<sup>17</sup> Covidien has a website —

Table 2. Educational Strategies to Minimize Misconnections Risk<sup>6</sup>

- Review currently used systems to assess practices that include the potential for misconnection, including nonstandard, rigged work-arounds (Luer adapters, etc.).
- Train nonclinical staff and visitors not to reconnect lines but to seek clinical assistance instead. Only clinicians or users knowledgeable about the use of the device should make a reconnection.<sup>14</sup>
- Do not modify or adapt IV or feeding devices because doing so may compromise the safety features incorporated into their design.<sup>14</sup>
- Routinely trace lines back to their origins when making reconnections.<sup>14</sup>
- Recheck connections and trace all tubes when patient arrives at a new setting or as part of a hand-off process.<sup>10</sup>
- Route tubes and catheters that have different purposes in unique and standardized directions (e.g., IV lines should be routed toward the patient's head, and enteric lines should be routed toward the feet.<sup>10</sup>
- Package together all parts needed for enteral feeding, and reduce the availability of additional adapters and connectors—this will minimize the availability of dissimilar tubes or catheters that could be improperly connected.
- Label or color-code feeding tubes and connectors, and educate staff about the labeling or color-coding process in the institution's enteral feeding system.<sup>10</sup>
- Identify and confirm the solution's label, because a 3-in-1 parenteral nutrition solution can appear similar to an enteral nutrition formulation bag.<sup>10</sup>
- Label the bags with large, bold statements such as “WARNING! For Enteral Use Only—NOT for IV Use”.<sup>10</sup>
- Ensure that all connections are made under proper lighting conditions.<sup>14</sup>
- Identify and minimize conditions and practices that may contribute to health-care worker fatigue, and take appropriate risk mitigation action.<sup>10</sup>

www.safeenteralconnections.com which offers information and educational resources for the entire patient population — neonates, pediatrics and adults.<sup>17</sup>

### Purchasing Strategies

The Joint Commission 2006 Sentinel Event Alert on tubing misconnection errors included a recommendation not to purchase non-intravenous equipment that is equipped with connectors that can physically mate with a female Luer IV line connector.<sup>10</sup> At present, more and more alternative products that prevent the hazard of enteral misconnections are available for purchase.

Group purchasing organizations can work with their contracted suppliers to identify potential industry wide solutions. Health-care delivery organizations can support their

**BE A.L.E.R.T. Practice Safe Enteral Feeding**

<p><b>Aseptic Technique</b></p> <ul style="list-style-type: none"> <li>• For preparation and delivery of enteral formula</li> <li>• Practice good hand washing technique</li> <li>• Wear gloves when handling feeding tube*</li> <li>• Avoid touching can tops, container openings, spike and spike port</li> </ul>	<p><b>Label Enteral Equipment</b></p> <ul style="list-style-type: none"> <li>• Patient name and room number</li> <li>• Formula name and rate</li> <li>• Date and time of initiation</li> <li>• Nurse initials</li> </ul>	<p><b>Elevate HOB</b></p> <p><math>\geq 30^\circ</math></p> <ul style="list-style-type: none"> <li>• When clinically possible</li> <li>• May mitigate risk of reflux and aspiration of gastric content</li> </ul>	<p><b>Right Patient</b></p> <p><b>Right Formula</b></p> <p><b>Right Tube</b></p> <ul style="list-style-type: none"> <li>• Match formula and rate to patient's feeding order</li> <li>• Verify ENTERAL tubing set connects formula container to feeding tube</li> </ul>	<p><b>Trace All Lines and Tubing Back to Patient</b></p> <p>EN ↔ EN</p> <ul style="list-style-type: none"> <li>• Avoid misconnections – trace all lines from origin to patient</li> <li>• Only enteral-to-enteral connections</li> </ul>
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\* Per facility policy and procedure.

Nestlé Nutrition | ASPEN American Society for Parenteral and Enteral Nutrition

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www.nestlenutrition.com/us 1-800-422-ASK2 (2752) | www.nutritioncare.org

An A.S.P.E.N. safety campaign, supported by Nestlé HealthCare Nutrition.

Figure 4. Courtesy of Nestlé and ASPEN

purchasing departments by recommending safer products until better products are available. Some purchasing strategies to decrease risk of enteral misconnections are listed in Table 3. Purchasers should consider buying whole enteral systems rather than replacement parts. This will allow the implementation of an entire system that addresses the needs of patients and healthcare professionals while minimizing risk.

### Design Changes

The Joint Commission has urged product manufacturers to implement appropriate “incompatibility by design” to prevent dangerous misconnections of tubes and catheters.<sup>10</sup> Because vigilance and knowledge alone are insufficient for preventing critical and often fatal errors<sup>19</sup>, connectors must be redesigned. Forcing function design changes would make incorrect connections impossible because they would physically prevent the user from taking a harmful action. A forcing function is an aspect of a design that prevents the user from taking an action without *consciously* considering information relevant to that action. It *forces* conscious attention upon something and thus deliberately disrupts the efficient or automatized performance of a task.<sup>20</sup> For the safety of the patient and the efficiency of the provider, the most effective preventive tool requires a physical barrier that is automatically enforced when inappropriate connections are attempted.<sup>21,22,23</sup>

The entire line of connections, including the bag or container of feeding, the tubing that connects to the enteral infusion pump, and the final connection to the enteral feeding tube must be unique to prevent mistakes in connection. The enteral nutrition equipment must not fit into IV equipment in order to prevent work-around solutions or adaptation, as well as inadvertent misconnection.<sup>6</sup> During the past 3 decades, a number of manufacturers

have attempted to address the issue of wrong-route administration by means of novel adapters, nonstandard connectors, and other unique product designs. Without a dedicated standard for non-Luer and enteral connections, many of these products have not been successful in the marketplace — they could be adapted to a Luer connection, forced into a tube that could be connected to a Luer, or were incompatible with other commonly used products. There is currently a lack of standards for components of enteral products. With the exception of the step connector at the distal end of many adult feeding sets, there is no standard for enteral connectors. Graduated or step connectors are adapters and do not create the forcing function required for a dedicated connection that could accept only an enteral device.

Without a defined standard for connectors, manufacturers will be severely challenged to create products that interface with parts that they do not manufacture. To further complicate the situation, companies that make feeding tubes are not necessarily the same companies that manufacture enteral formula bags or feeding pump sets.

### Innovations in Specific Parts of the Enteral System

The product highlights here should not be regarded as product endorsements by A.S.P.E.N. or these authors, they simply serve as an update for the readers. Each section of the enteral system as seen in Figure 2 will be addressed with some innovations in products to help reduce risk of medical error.

#### General Enteral Systems

Most enteral systems now have some color on the connectors, bags, proximal tube ends, and syringes. This visual clue simply alerts or triggers the clinician to remember that this is

not an IV connector, but the color itself does not prevent the misconnection. In the US, there is no current authorized standard color for enteral devices. At this time, Covidien, Nestlé HealthCare Nutrition, and Vygon are using purple and Abbott Nutrition will transition their components to lilac or purple coloring. Corpak Medsystems (formerly Viasys Medsystems), Baxa Corporation, Neomed Inc., Children’s Medical Ventures, and Utah Medical are using orange for their systems. It is not clear that standardization of enteral equipment to one color would prevent enteral misconnections. It might be more important to educate nurses to link color of any kind to the trigger that this “color” should not be connected to unlike systems.

#### Containers/Bags

Abbott Nutrition and Nestlé HealthCare Nutrition are using “Not for IV” symbols on their bags/containers. Covidien and Nestlé’s bags also have highlighted “For Tube Feeding Only” on the front and back of their bags. Abbott Nutrition has a “Not for IV” sticker on the Ready-to-Hang cap.

#### Container/Bag to Administration Set Connection

Another design issue that is being addressed is the universal spike-style connector into the pre-filled formula bag or container. The European standard for enteral feeding bags includes a smaller spike with a threaded collar that screws onto the bag or bottle. This threaded collar and screw are not compatible with the currently marketed connector system on IV bags and tubing. This SpikeRight™ (Nestlé HealthCare Nutrition) enteral specific spike port was introduced to the US market in 2008. Prior to launching this innovation, Nestlé made the non-proprietary design available to other manufacturers without licensing fees. Covidien and Corpak Medsystems are also using this design. Abbott Nutrition uses a screw cap feeding set that screws onto their pre-filled formula containers.

#### Administration Set to Feeding Tube Connection

The proximal ends of feeding tubes vary greatly as to the number of ports and the general configuration of the end. The main feeding port and/or side ports for medication and flushing are often capable of accepting a male Luer fitting. They are generally tapered to accept the “Christmas Tree” step connector. Abbott Nutrition has a “Not for IV” caution tag on the distal tubing of their administration set to alert the clinician. Covidien has already adapted the step connector to a larger diameter to mitigate the risk of connections to a Luer system. In July 2006, Corpak Medsystems launched the neonatal and pediatric CORFLO™ Anti-IV Feeding system which features all non-Luer connections and is designed to accept only a dedicated enteral syringe.<sup>24</sup> Neomed, Inc. has a comprehensive Enteral Safety System including oral dispensers, extension sets and feeding tubes designed to be incompatible with IV or Luer locking devices. In June 2008 Covidien introduced a complete line of safe enteral feeding connectors incompatible with luer lock or IV connections.

Table 3. Purchasing Strategies to Minimize Risk of Enteral Misconnections<sup>6</sup>

- Avoid buying enteral equipment that can mate with female Luer connectors. More specifically, avoid purchase of gastrointestinal tubes that have female Luer connectors.<sup>10</sup>
- Purchase adequate numbers of enteral pumps so that IV pumps are not used for enteral delivery in adult patients.
- Ensure that hospital policies restrict the purchase of enteral feeding sets to only those that are compliant with the American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) standard ID54. This effectively excludes feeding sets that can mate with female Luer connectors. These devices must also be clearly labeled (e.g., “Not for IV Use”).<sup>11</sup>
- Avoid buying prefilled enteral feeding containers, except for those with design technology labeled “non-IV compatible.” Package the enteral administration set with the enteral feeding bag or container before it is sent to the patient care unit. (The set should be secured to the bag, perhaps with a rubber band, or request that the manufacturer supply preattached sets).<sup>13</sup>
- Obtain enteral pumps that feature an automatic flush mode so that clinicians will not need to manually flush lines and therefore be less likely to install an adapter or Luer device between the enteral administration set and the feeding tube.<sup>14</sup>
- Reduce the purchases of adapters and connectors that can be used to make enteral feeding sets compatible with female Luer connectors.
- Purchase oral syringes instead of Luer syringes to deliver medications into the enteral feeding system. Develop pharmacy department recommendations to select the correct syringe type, along with dispensing and proper labeling protocols. Have oral syringes available in all areas where enteral formula and enteral/oral medications are being prepared for administration.
- Convene a multidisciplinary task force charged with performing a prepurchase evaluation before making a purchasing decision with regard to enteral feeding systems.<sup>14</sup>
- Seek manufacturers who produce the safest systems.

## Syringes (Dispensers) and Pumps

The growing use of oral syringes necessitates the addition of an oral syringe port on the enteral administration set or the enteral tube. Oral medications typically are administered via the feeding tube in patients receiving enteral feeding. If the volume is sufficiently large, a catheter tip syringe can be used. If the volume is small, the oral syringe is preferable. Both the catheter tip and oral syringe ports must be available. What should *not* be present is a Luer connector, even though these are still found on some enteral feeding tubes. Neomed, Inc. oral syringes (also called dispensers) have a 2-dimensional bar code that is used in conjunction with their Neomed SafeBaby™ breast milk tracking system. Several manufacturers have enteral only syringes (also called dispensers) that will not mate with Luer connectors. Baxa is currently the only manufacturer on the market with a small volume, low rate enteral pump with volume titration to 0.1 mL. This pump system called Neothrive™ allows for enteral only oral syringes and tubing to be used to deliver enteral formula or breast milk to neonates without the risk of connection to the infant's IV line.

## Adoption of New Technology

New innovations in enteral system technology such as some of those listed above require some thought when using. Key issues in new technology adoption as outlined by Allan Frankel, MD include education of individuals on the technology in a simulation lab and then at the bedside; and, use of intelligent deployment of new technology. This means that new systems need to be rolled out in a smart way, not too many new things at once in order to improve safety processes.<sup>25</sup> Carol Haraden, PhD, of Institute of Healthcare Improvement reminds administrators that fit testing of new technology needs to be done not just by seasoned professionals in a lab, but by new nurses and residents in a stressful bedside environment to be sure that any possible problems with a new system can be identified.

## Summary

Enteral misconnections remain a hazard to patient safety in healthcare settings. Standards that address misconnections of the entire enteral feeding system should be developed to prevent errors. In the interim, hospital and healthcare organization patient safety officers should work with their purchasing departments and users to perform a thorough assessment of their current products and practices. Following this risk assessment, the organization can implement appropriate steps to reduce risks, including education and training addressing good work practices to reduce harm.

Hospital leaders can work with their respective group purchasing organizations to continue the dialog with manufacturers, encouraging them to create alternative solutions. Until forcing function design change standards occur, there remains a risk to patient safety.

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**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.\***

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

- Describe the contributing factors for enteral misconnections.
- List the best practices in regard to safe enteral delivery.
- Identify at least one approach that nursing education can use to potentially eliminate the opportunity for errors; and
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- Answer forms must be postmarked by June 5, 2013 (Nurses) and June 6, 2012 (Dietitians).
- Faculty disclosure: No conflicts were disclosed.
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1. An enteral misconnection is defined as:
  - a. infusing enteral formula into an IV or dialysis catheter
  - b. infusing the wrong enteral formula
  - c. infusing IV solution into the wrong IV port
  - d. infusing gastric medication into the jejunum
2. The following agency issued a sentinel event alert about enteral misconnections in the U.S.:
  - a. Centers for Disease Control
  - b. U.S. Food and Drug Administration
  - c. National Institutes of Health
  - d. The Joint Commission
3. All but which of the following contributing factors increase risk of an enteral misconnection:
  - a. transferring patient from one area to another
  - b. similar appearing solutions
  - c. dark patient care areas
  - d. nurses on 8 hour shifts
4. Nurses should trace lines back to their origin in all but which of the following circumstances:
  - a. adjusting drip rate
  - b. patient arriving from another area
  - c. administering new medication
  - d. shift change
5. What type of syringe should not be used when administering enteral medications?
  - a. oral syringe
  - b. catheter syringe
  - c. Luer IV syringe
  - d. none of the above
6. Which of the following strategies should be used to reduce risk of enteral misconnection?
  - a. put all IVs at the head of the bed
  - b. label all infusions with green tape
  - c. put TPN and EN at top of the bed
  - d. use Luer stopcocks for all connectors
7. Which of the following hospital personnel should reconnect a disconnected enteral line?
  - a. housekeeping
  - b. dietary
  - c. nursing
  - d. TV installer
8. Hospital equipment purchasers should not buy enteral equipment with:
  - a. Luer connectors
  - b. flush pump capability
  - c. ports for medications
  - d. color coding
9. A common connector device that has been implemented in connection errors is:
  - a. The slip tip stop cock
  - b. an epidural tubing
  - c. a Luer-lock
  - d. a foley catheter
10. Most current nursing text books adequately describe the problem of tubing misconnections?
  - a. True
  - b. False
11. Design and manufacturer standards of connector devices can be guided by which one of the following agencies?
  - a. The Joint Commission
  - b. The United States Pharmacopeia
  - c. Association for the Advancement of Medical Instrumentation
  - d. California Health Foundation
12. Color-coding is one of the most useful tools today to prevent tubing connection errors?
  - a. True
  - b. False

	Mark your answers with an X in the box identifying the correct answer(s).																																																				
<p><b>What is the highest degree you have earned (circle one) ?</b></p> <p>1. Diploma    2. Associate    3. Bachelor's 4. Master's    5. Doctorate</p> <p><b>Indicate to what degree did this program meet the objectives:</b> 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.</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 80%;"></th> <th style="width: 10%; text-align: center;">Strongly Disagree</th> <th style="width: 10%; text-align: center;">Strongly Agree</th> </tr> </thead> <tbody> <tr> <td>At the end of the session the participant will be able to:</td> <td></td> <td></td> </tr> <tr> <td>1. Describe the contributing factors for enteral misconnections.</td> <td style="text-align: center;">1   2   3   4   5   6</td> <td></td> </tr> <tr> <td>2. 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1. Describe the contributing factors for enteral misconnections.	1   2   3   4   5   6																																																				
2. List the best practices in regard to safe enteral delivery.	1   2   3   4   5   6																																																				
3. Identify at least one approach that nursing education can use to potentially eliminate the opportunity for errors and	1   2   3   4   5   6																																																				
4. Describe the role of purchasing departments in the attempt to rectify risk.	1   2   3   4   5   6																																																				
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or Mail to: Saxe Communications, PO Box 1282, Burlington, VT 05402 Fax: 802.872.7558	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%;"><b>Safe Practices. V.4 No.2</b></td> <td style="width: 10%;"><b>Score</b></td> <td style="width: 20%; text-align: center;"><b>12</b></td> </tr> </table>	<b>Safe Practices. V.4 No.2</b>	<b>Score</b>	<b>12</b>																																																	
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