Enteral Feeding Misconnections: An Update
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Invited Review

Enteral Feeding Misconnections: An Update

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Enteral misconnections are defined as inadvertent connections between enteral feeding systems and nonenteral systems such as intravascular lines, peritoneal dialysis catheters, tracheostomy tube cuffs, medical gas tubing, and so on. Sentinel event data and causative factors are outlined along with potential solutions to prevent such medical errors. The solutions can be grouped into 3 areas: (1) education, awareness, and human factors; (2) purchasing strategies; and (3) design changes. Updates on safety innovations and programs are presented. (Nutr Clin Pract. 2009;24:325-334)

Keywords: enteral nutrition; safety

Evidence of Misconnections

A number of leading public and nonprofit organizations (ie, United States Pharmacopeia [USP]; Emergency Care Research Institute, now known as ECRI Institute [ECRI];
Institute for Safe Medication Practices [ISMP]; U.S. Food and Drug Administration [FDA]) have issued safety warnings that address the potential and actual risk from medical tubing misconnections (see Figure 1 for a timeline of reported misconnections and alerts). 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 miscon-nections in April 2006. The alert stated that multiple reports to patient safety organizations, including The Joint Commission, ECRI Institute, FDA, the ISMP, and USP, indicated that these misconnection errors continued to occur with significant frequency and, in a number of instances, resulted in deadly consequences.

In early 2006, the FDA and American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) developed a survey to help understand the issues associated with enteral connectors and safety. The FDA’s Center for Devices and Radiological Health sent this survey to hospitals in its MedSun network, and A.S.P.E.N. sent it to its members. There were 182 clinicians (including nurses, dietitians, pharmacists, physicians, safety officers, and quality improvement coordinators) who responded to the survey. When asked if their institution had experienced an enteral misconnection incident, 16.1% reported affirmatively, 57.8% reported negatively, and 26.1% reported that they did not know. Because of patient confidentiality issues, this survey did not ask about case details from those who reported in the affirmative. More than 30% of the respondents did report that they used Luer connectors (a prime connector for IV systems) in at least some of their enteral systems, and 20% used additional extension tubing with Luer connectors.

In early 2007, the British National Health Service issued a National Public Safety Alert regarding the risks of misconnections. 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 between 2001 and 2006.

In March 2007, a review of the USP MEDMARX and the USP-ISMP Medication Errors Reporting (MER) Program, 2 nationally recognized voluntary medication error reporting systems, specifically identified cases involving enteral feeding systems. Between January 1, 2000, and December 31, 2006, the reviewers found 24 reported incidents involving enteral feeding formulas, other solutions, or 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 factors that can lead to wrong route errors. This categorization of the failure factors illustrates the risks of present EN delivery systems (Table 1).

**History of Attempts to Eliminate Misconnections**

In 1996, the Association for the Advancement of Medical Instrumentation (AAMI) Infusion Device Committee convened an expert group to address the safety requirements for enteral feeding set connectors and adaptors. This expert group included members from the FDA,
A.S.P.E.N., various safety organizations such as the ECRI Institute, and manufacturers of feeding sets. The resulting voluntary standard, approved in 1996 and reaffirmed in 2005, recommended that adapters and connectors used in the enteral system should be incompatible with female Luer-Lok rigid connectors.

A British Standards document describes the step connector (often referred to as a “Christmas tree” connector) as being an alternative connector design. Many manufacturers developed feeding sets with these step connectors so that the feeding sets were incompatible with Luer connectors on IV lines. Following release of the AAMI standard, more manufacturers adopted this design. Unfortunately, these standards are voluntary, lack prescriptive direction, and are not universally followed by all device manufacturers, and thus connectors still remain a serious hazard to patients.

Currently, AAMI has convened a working group to first set standards for small-bore connectors. Once that is complete, a specific enteral connectors working group will convene. Each working group is made up of industry, association, and academic experts.

### Enteral Feeding System

The enteral feeding system for adults and older children is the entire apparatus from the EN formula container to the delivery tubing to the enteral tube itself. The system includes all connectors, pumps, or syringes that may come into connection with the system. The enteral feeding set is the feeding container or bag attached to the delivery tubing, which ends with a connector. This feeding set may be a 1-piece device with the container connected permanently to the tubing (Figure 2). 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 3). 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, this 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 (Figures 2 and 3). The general practice is to change the enteral feeding set daily, which results in an interruption of the feedings. There are also a number of other reasons to interrupt or discontinue feedings, including 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.

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. This has been accomplished by using 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. 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 (Baxa Corporation, Englewood, CO). The infusion devices (eg, syringe pumps), until recently, 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.
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 wrong tubes. These errors are often made by expert practitioners who are unaware they are connecting the enteral feeding or medication to the IV line but are fully knowledgeable that such a connection poses a danger to the patient. This error in performance is not under the conscious control of the practitioner. Cognitive psychologist James Reason describes this as “being in automatic mode” or operating at a level of functioning in which the error is

not detectable by the participant at the time of the mis-
connection. The human factors literature describes
environmental situations that predispose human beings
to such errors. Many of these contributors are endemic
to the current patient care environment, including time
pressure, rotating shift work, fatigue, attempts to use
short-term recall for large amounts of information, inade-
quate training, and inadequate lighting (e.g., during the
night shift in a darkened patient room). In the cases
reported to the Sentinel Event Database, contributing
factors also included moving patients from one setting or
service to another.¹
Physical and Design Factors

Luer connectors are implicated in or contribute to many of these errors because such connectors permit functionally dissimilar systems to be connected. The user receives no tactile feedback that he or she has made an error 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. Another opportunity for misconnection involves the use of needle-free connectors as the standard replacement for latex rubber injection ports on IV administration tubing. This system introduces many more opportunities when a Luer male syringe or tubing can be attached to a female needle-free connector. Previously, the setup would have required attachment of a needle that was much less likely to be added to an enteral set or syringe. The widespread use of these IV set connectors (as many as 3 per IV line) increases the chances that a female-compatible male Luer connector will be inserted into a needle-free connector. This is increased, then, by the high number of ports and the complexity of the IV tubing, especially in acutely ill patients.

Physical characteristics and connections along the EN system also contribute to the risk of enteral misconnections. These include connection of the enteral administration set to a prefilled container or bag (Figure 3) in which the 2-piece system allows IV tubing to be substituted for an enteral administration set. 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 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.

Solutions and Recent Innovations

Solutions to prevent misconnections are multifactorial and need to include a consortium of 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 by various agencies and clinical educators have been and must continue to be a priority. Educators should emphasize the risk of tubing misconnections in orientation and training. Nurses in healthcare settings where there are multiple common connectors must be continuously aware of the hazards of inadvertently connecting the wrong line and must develop strategies to decrease risks. Suggested strategies for educational initiatives can be found in Table 2.

Table 2. Educational Strategies to Minimize Misconnections Risk

<table>
<thead>
<tr>
<th>Educational Strategies to Minimize Misconnections Risk</th>
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<tbody>
<tr>
<td>• Review currently used systems to assess practices that include the potential for misconnection, including nonstandard, rigged work-arounds (Luer adapters, etc).</td>
</tr>
<tr>
<td>• 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.</td>
</tr>
<tr>
<td>• Do not modify or adapt intravenous (IV) or feeding devices because doing so may compromise the safety features incorporated into their design.</td>
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<tr>
<td>• Routinely trace lines back to their origins when making reconnections.</td>
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<tr>
<td>• Recheck connections and trace all tubes when the patient arrives at a new setting or as part of a hand-off process.</td>
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<tr>
<td>• Route tubes and catheters that have different purposes in unique and standardized directions (eg, IV lines should be routed toward the patient’s head, and enteric lines should be routed toward the feet).</td>
</tr>
<tr>
<td>• 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 connected improperly.</td>
</tr>
<tr>
<td>• 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.</td>
</tr>
<tr>
<td>• Identify and confirm the solution’s label because a 3-in-1 parenteral nutrition solution can appear similar to an enteral nutrition formulation bag.</td>
</tr>
<tr>
<td>• Label the bags with large, bold statements such as “WARNING! For Enteral Use Only—NOT for IV Use.”</td>
</tr>
<tr>
<td>• Ensure that all connections are made under proper lighting conditions.</td>
</tr>
<tr>
<td>• Identify and minimize conditions and practices that may contribute to healthcare worker fatigue, and take appropriate risk mitigation action.</td>
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(continued)
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 for this poster). The translation of recommendations from experts to the nurse actually delivering the EN is vital, and all nutrition support specialists can participate in such an awareness campaign. Baxa Corporation has a Web site (www.baxa.com/helpthemgrow) that focuses on neonates and enteral misconnection prevention. This educational Web site contains many resources and literature offerings.

**Purchasing Strategies**

The Joint Commission 2006 Sentinel Event Alert on tubing misconnection errors included the recommendation of not purchasing non-IV equipment that features connectors that can physically mate with a female Luer IV line connector. At present, alternative products that prevent the hazard of enteral misconnections are not always available for purchase, perhaps because enteral products that will not accept Luer connectors have yet to be manufactured or may not be available in the United States. Although non-Luer-compatible neonatal product systems are available, many adult products can still be interchanged and connected to IV equipment. Many health systems are beginning to demand—and are willing to purchase—this specialty IV-incompatible equipment, but the lack of knowledge about marketed products remains an issue.

Group purchasing organizations can work with their contracted suppliers to identify potential industry-wide solutions. Healthcare delivery organizations can also support their purchasing committees and departments by recommending specific brands of safer products until design change solutions become generally available. Specific purchasing strategies to decrease risk of enteral misconnections can be found in Table 3.

Premier, Inc is an example of such a purchasing organization. It is a healthcare alliance owned by more than 200 of the nation’s leading not-for-profit hospitals and healthcare systems. Premier organizes member committees to evaluate products and services and select those to be placed on contract. They do this by collecting and analyzing clinical and financial data from its member hospitals, where these committees make decisions and set direction for the alliance; sponsoring seminars and conferences; and sharing best practices. This group has been

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**Figure 4.** Be A.L.E.R.T. campaign poster to promote safe enteral feeding.
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working for years on the medical misconnections issue and is leading the way in purchasing strategies.

**Design Changes**

The Joint Commission has urged product manufacturers to implement appropriate “designed incompatibility” to prevent dangerous misconnections of tubes and catheters. Because vigilance and knowledge are not sufficient barriers to prevent critical and often fatal errors, connectors must be redesigned. Without change to a “forcing function” design, errors are not easily avoidable. Forcing function designs have been used in medical gases and, most familiar, in the design of cars (eg, cars cannot be started in drive mode). Forcing function design changes would make incorrect connections impossible because they would physically prevent the user from taking a harmful action. 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.

To make the environment safe from inadvertent enteral misconnections, the connections must be physically incompatible. 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 EN equipment must not fit into IV equipment to prevent work-around solutions or adaptation, as well as inadvertent misconnection. Because of the lethal consequences of infusing enteral feeding into an IV line and the documented evidence that this has occurred in numerous hospitals across the country, instituting forcing functions into the design of the equipment is a prudent safety feature. 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 specifically enteral connections, many of these products were not 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. The current challenge for enteral products is a lack of standards for the desired components. With the exception of the step connector at the distal end of many adult feeding sets, no ideal enteral connector standard is available for manufacturers. Graduated or step connectors are by the very fact 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 all of the points of connection for enteral feeding, 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**

During late 2008, members of the enteral industry were invited to share their program and product initiatives in regard to enteral misconnections with one of the authors (PG).
Their product highlights 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 3, 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. The 2006 FDA/A.S.P.E.N. survey previously referred to found that only 37% of respondents reported using a labeling or color-coding system. 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 United States, there is no current authorized standard color for enteral devices. At this time, Nestlé HealthCare Nutrition is using purple, and Abbott Nutrition will transition its components to lilac or purple coloring. CORPAK Medsystems (formerly VIASYS Medsystems), Baxa Corporation, Neomed, Children’s Medical Ventures, and Utah Medical are using orange for their systems.

**Containers/Bags**

Abbott Nutrition and Nestlé HealthCare Nutrition are using “Not for IV” symbols in red on their bags/containers. Nestlé’s bags also have highlighted “For Tube Feeding Only” in red 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 prefilled 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 U.S. market in 2008. Prior to launching this innovation, Nestlé made the nonproprietary design available to other manufacturers without licensing fees. CORPAK Medsystems has also switched to this design. Abbott Nutrition uses a screw-cap feeding set that screws onto its prefilled 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 but not always tapered to accept the “Christmas Tree” step connector. Abbott Nutrition has a “Not for IV” caution tag on the distal tubing of its administration set to alert the clinician. It is also planning to adapt the step connector and remove the smallest step to mitigate the risk of connection 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. Neomed has a comprehensive Enteral Safety System, including oral dispensers, extension sets, and feeding tubes designed to be incompatible with IV or Luer locking devices.

**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 oral syringes (also called dispensers) have a 2-dimensional bar code that is used in conjunction with its Neomed SafeBaby breast milk tracking system. Baxa Corporation has 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 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.

**Reporting Enteral Misconnections**

In the event that an enteral misconnection does occur, it is vital that it be reported. Often these reports prompt changes in the institutional systems, purchasing practices, and manufacturing design changes. Those to be alerted include the institutional quality assurance or safety officer, the state department of health as mandated, and the ISMP Medication Errors Reporting System. These reports can be analyzed and shared on a national level to raise awareness and make changes in the system. This reporting process can be found at http://www.ismp.org/reporterrors.asp.
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 that are compliant with the AAMI standard and address issues raised here. Until forcing function design change standards occur, there remains a risk to patient safety.

Acknowledgment

The authors gratefully acknowledge the product manufacturers that contributed information about their products and programs.

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