Enteral Feeding Misconnections in the NICU
A Continuing Patient Safety Threat
Suzanne Staebler, DNP, APRN, NNP-BC

ABSTRACT
Although the first case of tubing misconnection was reported in 1972, this patient safety issue received little national attention until The Joint Commission issued a Sentinel Event Alert in the spring of 2006. This was followed by a “Money and Policy” article in the *New York Times* in the summer of 2010 that initiated a public awareness outcry against the healthcare system’s delayed responsiveness in creating fail safe solutions. Since that time, many manufacturers have devised oral syringes, feeding tubes, and feeding “systems” for patients in the neonatal intensive care unit, but these devices’ ability to minimize risk is not well delineated. This article reviews the history of tubing misconnections and provides an in-depth look at current recommendations for manufacturing and device design, human factors contributing to misconnections, and specific strategies for minimizing patient safety risk.

Key Words: enteral nutrition, neonatal feeding, NICU, patient safety, tubing misconnections

Before The Joint Commission’s (TJC) Sentinel Event Alert in 2006, many hospitals and health systems used tubing, catheters, and syringes in multiple settings and for multiple purposes along the patient care continuum. This only made sense: a product with multiple functions was preferred to those with only 1 function, as the former could be bought in bulk numbers at lower cost. This “system design” was one factor in the rise of tubing misconnections over the past 3 decades. The currently accepted definition of a tubing misconnection is “apparent incompatible systems that, when inadvertently connected, can result in life-threatening events in the clinical area.” An enteral misconnection is an inadvertent connection between an enteral feeding system and a nonenteral system, such as an intravascular line, peritoneal dialysis catheter, medical gas tubing, and so forth.

HISTORICAL PERSPECTIVES
The earliest known report of an enteral misconnection was published in 1972 in *Lancet*. A young man who was receiving intragastric milk feedings received approximately 100 mL of milk intravenously before the error was discovered. This error was attributed to unclear ordering of therapy by the physician. The “look-alike” issue of the milk feeding with intravenous (IV) fat emulsion mixture, which was newly on the market and in use, also played a role in the error. Later, in 1983, a case report analysis recommended design of “incompatible connectors” as a means of preventing future errors. The first warning related to this issue came from the Emergency Care Research Institute in 1986. The Emergency Care Research Institute started in 1968 but broadened its scope beyond emergency care in the 1970s and now researches the best practices for improving safety, quality, and cost of patient care. It was then 10 years later (1996) when the Association for the Advancement of Medical Instrumentation (AAMI) published standards for feeding devices and recommended that adapters and connectors be incompatible with luer-lock rigid connectors.

It was another decade later when TJC issued their Sentinel Event Alert, “Tubing Misconnections: A Persistent and Potentially Deadly Occurrence.”
this point in time, TJC had reviewed more than 300 case reports from databases across the country. Misconnections were categorized into six categories:

1. Intravenous administrations connected to epidural and epidural solutions connected to peripheral or central IV catheters.
2. Bladder irrigation solutions hung with IV tubing being connected as secondary infusions into peripheral or central IV catheters.
3. Intravenous administration into indwelling bladder catheters.
4. Intravenous administration connected to nasogastric tubes or enteral feeding solutions connected to peripheral or central IV catheters.
5. Intravenous administration with blood administration sets and blood products transfused via primary IV tubing.
6. Primary IV solutions given through various other, functionally dissimilar catheters (dialysis catheters, ventriculostomy drains, amnio-infusion catheters, and pulmonary artery catheters).

The root cause analysis of these cases implicated the interchangeability of luer connectors as the major contributing factor. Other influences included the routine use of tubing for unintended purposes (IV extension tubing used for enteral feeding) and positioning of functionally dissimilar tubes in close proximity of each other. Human factors (HF s) identified in the root cause analysis included care transitions (patient moving from one service or location to another) and staff fatigue associated with working consecutive shifts.2

About the same time as TJC Sentinel Event Alert was published, the Food and Drug Administration (FDA) and the American Society for Parenteral and Enteral Nutrition (ASPEN) surveyed hospitals and members to better understand the factors associated with tubing misconnections. Of those who responded to the survey (n = 182), 16.1% affirmed an event in their institution and 26.1% reported an event in their institution and 26.1% reported an event in their institution and 26.1% reported an event in their institution and 26.1% reported an event in their institution and 26.1% reported an event in their institution and 26.1% reported an event in their institution and 26.1% reported an event in their institution and 26.1% reported an event in their institution and 26.1% reported an event in their institution.

More than 30% of respondents confirmed that they were currently using luer connectors in at least some of their enteral feeding systems and another 20% used extension tubing with luer connectors.3 It was a year later when the British National Health Service issued a National Public Safety Alert regarding misconnections, with 33 documented incidents related to oral liquids given intravenously from 2005 to 2006.8

In 2009, the ASPEN published an update on the enteral feeding misconnection issue and discussed progress toward quality, safety, and elimination of events through design standards and innovation in purchasing strategies.5 The ASPEN collaborated with Agency for Healthcare Research and Quality to develop national guidelines for enteral nutrition administration, which is now posted in the Agency for Healthcare Research and Quality National Guideline Clearinghouse.9 Recommendations were graded on the basis of the strength of evidence to support the recommendation (Grades A to C, with “A” being “good” evidence to support recommendation and “C” being recommendation based on expert opinion or editorial consensus). Recommendations from the National Guideline of Enteral Nutrition Administration are summarized in the Table.

Then, in early 2010, the Institution of Safe Medication Practices issued and alerted via NurseAdvise-ERR related to official color standards for enteral feeding equipment and PICCs (peripherally inserted central catheters). Purple is not an official color standard for either enteral products or PICCs in the United States, although it is the official color of enteral products in the United Kingdom.10 In January 2011, AAMI announced the adoption of international design standards seeking to reduce tubing misconnections among different types of devices.11 The first of a 7-standard series was designed for manufacturers to offer guidance to create proprietary small-bore connectors for their own devices to mitigate risk and offering strategies for validation of new designs. It is AAMI’s goal, in conjunction with the FDA and International Organization for Standardization, to fully implement these standards by 2014.12 The FDA later released draft recommendations for industry on safety considerations to mitigate risks of misconnections with small-bore connectors intended for enteral applications. These guidelines were published via the Federal Register on July 27, 2012, for public comment. Comments were closed after 90 days and release date of final guidelines is unknown. Once the standard is published, manufacturers will be given up to 18 months to revamp processes to meet the new standards.12,13

HUMAN FACTOR INFLUENCES

Based on the current discussion, the issue of misconnections appears to be one mostly related to design flaws in medical device equipment used in the healthcare setting. But that is not entirely true. Over the past several years, there have been several HF s tied to the patient safety risk of tubing misconnections. Human factor research studies the intersection of people, technology, policy, and work across multiple domains. Human factor research uses an interdisciplinary approach to evaluate the interaction of cognitive and organizational psychology, human performance, industrial engineering, and systems engineering.14 As applied to healthcare, HF research allows for improved processes, devices, and systems that support the work of caregivers and improve patient outcomes.
### TABLE. Neonatal Related Recommendations From National Guideline on Enteral Nutrition Administration

<table>
<thead>
<tr>
<th>Category</th>
<th>Recommendation</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practice</td>
<td>For premature infants weighing &lt; 1500 g and/or at risk for NEC, it is recommended that mothers be encouraged to supply breast milk for their infants</td>
<td>A</td>
</tr>
<tr>
<td>Practice</td>
<td>Extremely low-birth-weight (ELBW) and very low-birth-weight (VLBW) infants may benefit from minimal enteral (trophic) feeding starting very slowly at 0.5-1 mL/kg per day and advancing to 20 mL/kg per day</td>
<td>B</td>
</tr>
<tr>
<td>Practice</td>
<td>Advance nutritive feedings for VLBW and ELBW infants by 10-20 mL/kg per day</td>
<td>C</td>
</tr>
<tr>
<td>Enteral feeding pumps</td>
<td>Pumps should deliver prescribed accuracy within 5% accuracy for neonatal and pediatric populations</td>
<td>C</td>
</tr>
<tr>
<td>Enteral feeding pumps</td>
<td>Pumps should be calibrated periodically to assure accuracy</td>
<td>B</td>
</tr>
<tr>
<td>Enteral feeding pumps</td>
<td>HBM infused at low rates should be administered via syringe pump with the syringe tip elevated</td>
<td>C</td>
</tr>
<tr>
<td>Flushes</td>
<td>Flushing of feeding tubes in neonatal and pediatric patients should be done with the lowest volume to clear the tube</td>
<td>C</td>
</tr>
<tr>
<td>Flushes</td>
<td>Sterile water is recommended for use in adult and neonatal/pediatric patients before and after medications</td>
<td>C</td>
</tr>
<tr>
<td>Flushes</td>
<td>Use an administration pump when slow rates of enteral feeds are required and respond promptly to alarms</td>
<td>C</td>
</tr>
<tr>
<td>Misconnections</td>
<td>Do not modify or adapt IV or feeding device; doing so compromises the safety features incorporated in design</td>
<td>C</td>
</tr>
<tr>
<td>Misconnections</td>
<td>When making a connection or reconnection, trace lines back to their origins and ensure they are secure (even if it requires unswaddling the infant).</td>
<td>C</td>
</tr>
<tr>
<td>Misconnections</td>
<td>Route tubes and catheters that have different purposes in unique and standardized directions (e.g., intravascular catheters/tubing are directed toward the head; enteral catheters/tubes should be directed toward the feet)</td>
<td>C</td>
</tr>
<tr>
<td>Misconnections</td>
<td>As part of the hand-off process, staff should check connections and trace all tubes/catheters.</td>
<td>C</td>
</tr>
<tr>
<td>Misconnections</td>
<td>Standardize practice for labeling and color-coding feeding tubes and connectors; educate staff about institution’s enteral feeding system and processes</td>
<td>C</td>
</tr>
<tr>
<td>Misconnections</td>
<td>Avoid purchasing enteral equipment that can mate with female luer connectors</td>
<td>C</td>
</tr>
<tr>
<td>Misconnections</td>
<td>When using syringe pumps in NICU, pumps should be clearly distinct from syringe pumps used for IV medications. Ideally, they should be different in appearance, different model, color, etc</td>
<td>C</td>
</tr>
<tr>
<td>Misconnections</td>
<td>Ensure that hospital policies mandate purchasing only enteral feeding sets that are compliant with the ANSI/AAMI standards, which exclude any that are compatible with female luer connectors</td>
<td>C</td>
</tr>
<tr>
<td>Misconnections</td>
<td>Avoid purchasing prefilled enteral feeding syringes</td>
<td>C</td>
</tr>
<tr>
<td>Misconnections</td>
<td>Purchase and use oral syringes (nonluer) to draw up, dispense, and deliver medications into feeding systems</td>
<td>C</td>
</tr>
</tbody>
</table>

Abbreviations: AAMI, Association for the Advancement of Medical Instruments; ANSI, American National Standards Institute; ELBW, extremely low-birth-weight; HBM, human breast milk; IV, intravenous; NEC, necrotizing enterocolitis; NICU, neonatal intensive care unit; VLBW, very low-birth-weight.

*Grade A = good research-based evidence to support recommendation (prospective randomized controlled trial); grade B = fair research-based evidence to support recommendation (well-designed studies without randomization); grade C = recommendation is based on expert opinion and editorial consensus.

Concepts from this table are attributed to Bankhead et al.9
Patients in the neonatal intensive care unit (NICU) are not immune from the risk of tubing misconnections. Misconnection errors in the neonatal population often result in significant adverse outcomes (permanent loss of function or death).\textsuperscript{15,16} In 2010, Wallace and Steward\textsuperscript{17} conducted a descriptive study of enteral feeding practices in level 3 to 4 NICUs across Ohio. They had a 66\% return rate on the surveys (the total number of level 3 NICUs was 18). All (100\%) of the responding NICUs used medication syringe pumps for enteral feeding, only two thirds reported using safety tubing to prevent misconnections, and none reported the presence of a standardized protocol to address the safety concerns associated with syringe pumps designed for medication delivery use with enteral feeding.\textsuperscript{18}

Because error reporting (or near misses) is currently voluntary, enteral misconnections in the NICU may be greatly underreported as compared with actual or “near miss” cases. Each facility should have a protocol for reporting adverse events and near misses. Any misconnection issues should be reported to the FDA through its MedWatch reporting system.\textsuperscript{19}

The role of frontline providers of care in preventing these errors across the continuum cannot be ignored. Education deficits, awareness of clinicians, and other HF challenges were the impetus for the ASPEN campaign for nurses to “Be ALERT,” using the ALERT acronym to convey critical steps in the enteral feeding process (see Figure 1). In 2010, the campaign, in conjunction with Nestle Corporation, launched a second phase, this time aimed at safe practices of enteral medication delivery, encouraging nurses to “Be AWARE” (see Figure 2). In 2011, the third campaign phase focused on the pediatric populations with a “Be READY” acronym (see Figure 3). Many times, frontline staff are not involved in purchasing decisions. So equipment and devices are purchased without knowledge of “end-user” impact to workflow, possible failures, and potential safety risks. In an effort to decrease costs, some products are purchased for multiple functions, but this practice can have catastrophic impact on patient safety because of risk of misconnections.

At other times, misconnections are the result of performance errors. Expert clinicians who are “unaware” of the misconnection but have full knowledge of the danger related to such a connection often make these errors. There are many environmental contributors to performance errors in the healthcare arena. These factors include time pressures, rotating shift work, fatigue, inadequate training and inadequate lighting, and transfer of patients from one setting to another.\textsuperscript{5}
FIGURE 2. "Be AWARE" campaign: Safe practices of oral/enteral medication administration.

Source: http://www.nestle-nutrition.com/nirf/cm2/upload/59E493C3-1551-400D-8F09-DEB205531BA0/BeAWARE.pdf

FIGURE 3. "Be READY" campaign: Safe feeding practices in pediatrics.

Source: http://www.nestle-nutrition.com/nirf/cm2/upload/59E493C3-1551-400D-8F09-DEB205531BA0/BeREADY_PST_F0.pdf
underestimated. Providers can impact risk reduction in 3 arenas of prevention: purchasing strategies, human factors, and design changes.

**Purchasing Strategies**

- Develop a comprehensive coordinated purchasing strategy to minimize risk to patients and providers.
  - Substitute devices with safety features for those with functional similarities.²⁰
  - Conduct testing for performance, safety, usability, and risk assessment before new tubing and catheter purchases to identify potential for misconnections.²¹,²²
  - Involve frontline staff in new product evaluation and purchasing decisions.
- Stop purchasing non-IV equipment with connectors that can “mate” with a female luer IV catheter connector.² Specifically, avoid purchase of gastrointestinal tubes that have female luer connectors.²
- Purchase adequate numbers of pumps so that IV or medication syringe pumps are not used to deliver enteral feedings.
- Purchase/use oral syringes to draw up and administer medications into an enteral feeding system.

**Human Factors**

- Do not rely on color-coding to prevent misconnections. Remember that colors are not always consistent within or specific to device groups. Color coding also varies across institutions in the same community, thereby increasing risk with agency and travel staff.²
  - Hospitals and health systems are encouraged to standardize color-coding of enteral systems, both internally and within their local healthcare community.
  - Color-coding standardization is key within the entire hospital/health system so as to prevent errors caused by staff floating from unit to unit.
- Never modify feeding tube devices or exchange connectors.
- Do not use any type of IV or medication tubing for feeding.
- Follow standardized protocol for patient handoff and include line reconciliation process as part of the handover communication.²¹
- Trace lines and tubes back to site of insertion before accessing.
  - Ensure adequate lighting and visualization of line/tube prior to access.²³
  - Direct all vascular access lines toward the head of bed; direct all other tubes (enteral, renal, etc) toward the feet.
- Closely monitor staffing patterns and other practices that contribute to fatigue and take appropriate action to minimize.²,²⁴-²⁶
- Eliminate “bulk” dispensing of medications; use only oral syringes for administration of enteral medications.²⁷
- Clear and concise institutional policies/protocols related to enteral feeding and IV therapy practices. Incorporate these policies and processes into orientation and continuing professional development activities of care providers.²¹

**Device Design Changes**

- Redesign of connectors to a “forcing function design.”²¹,¹³ Forcing function design, used in medical gases, make misconnections impossible because they provide a physical barrier when incorrect connections are attempted.
- Enteral feeding equipment must not fit into IV equipment to prevent work-around solutions, which can lead to misconnections.
- Standardization for all of the points of connection for enteral feeding systems, including color, connectors, tubing, pumps, and ports.²,²⁰,²²
- Standardization of color-coding of tubing and connections.²¹

A comprehensive discussion of this topic would not be complete without addressing the potential barriers to implementation of risk-reduction strategies. The first, and possibly most significant barrier, would be that of cost. The cost of redesign of systems and connectors may be significant for manufacturers and medical device companies. There is also considerable cost associated with conversion to “forced function” systems and supply chain purchasing practices. This barrier is increased by insufficient research data and cost-benefit analysis data for implementation of these recommendations. Return on investment will vary from institution to institution.²¹ Human factors also present significant barriers to implementation. Staff acceptance of wrong route error prevention may be impacted through education and staff involvement in the error reporting and debriefing process. Staff involvement in purchasing processes and decision making will improve the diffusion and acceptance of policy and equipment changes. The potential for treatment delays after product conversion may occur, but prospective planning and accessible supply chain resources can minimize possible delays.

Long-term solutions to tubing misconnections appear to be several years away, as the medical device industry continues to offer resistance, the FDA approval process currently discourages safety-related changes and a final consensus from AAMI/International Organization for Standardization has not yet been published. Some organizations and

---

Copyright © 2013 National Association of Neonatal Nurses. Unauthorized reproduction of this article is prohibited.
advocates believe that feeding tubes that can be connected to IV catheters are fundamentally unsafe. The risks regarding tubing misconnections are ever-present in the NICU. Given the current state of evidence, and despite acknowledgment of the dangers associated with misconnections, the system continues to produce, distribute, purchase, and utilize feeding systems without “fail safe” connectors. As care providers of an extremely vulnerable patient population, it is our duty to take action on behalf of our patients to ensure that history does not continue to repeat itself.

References
17. Wallace T, Steward D. Survey of Gavage Feeding Practices Used in Very Low Birth Weight Infants in the United States. 6th Annual NANN Research Summit; April 3, 2011; Scottsdale, AZ.
18. Wallace T, Steward D. Poster Presentation: Use of Pumps for Providing Enteral Feedings to Very Low Birth Weight Infants. MNRS Conference, The Ohio State University School of Nursing; April B-10, 2010; Columbus, OH.