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Nutr Clin Pract 2011 26: 286

DOI: 10.1177/0884533611406134

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Tubing Misconnections: Normalization of Deviance

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Financial disclosure: none declared.

Background: Accidental connection of an enteral system to an intravenous (IV) system frequently results in the death of the patient. Misconnections are commonly attributed to the presence of universal connectors found in the majority of patient care tubing systems. Universal connectors allow for tubing misconnections between physiologically incompatible systems. **Methods:** The purpose of this review of case studies of tubing misconnections and of current expert recommendations for safe tubing connections was to answer the following questions: In tubing connections that have the potential for misconnections between enteral and IV tubing, what are the threats to safety? What are patient outcomes following misconnections between enteral and IV tubing? What are the current recommendations for preventing misconnections between enteral and IV tubing? Following an extensive literature search and guided by 2 models of threats and errors, the authors analyzed case studies and expert opinions to identify technical, organizational, and human

errors; patient-related threats; patient outcomes; and recommendations. **Results:** A total of 116 case studies were found in 34 publications. Each involved misconnections of tubes carrying feedings, intended for enteral routes, to IV lines. Overwhelmingly, the recommendations were for redesign to eliminate universal connectors and prevent misconnections. Other recommendations were made, but the analysis indicates they would not prevent all misconnections. **Conclusions:** This review of the published case studies and current expert recommendations supports a redesign of connectors to ensure incompatibility between enteral and IV systems. Despite the cumulative evidence, little progress has been made to safeguard patients from tubing misconnections. (*Nutr Clin Pract.* 2011;26:286-293)

Keywords: enteral nutrition; nutrition therapy; feeding methods; equipment safety; nutritional support

Since 1972, several reports on unintentional failures to connect the correct tubing between intravenous (IV), epidural, intracranial, intrathecal, gas, and other tubing systems used for patient therapy have been published.¹⁻⁸ Inadvertently connecting an enteral system (meant to deliver nutrition to the gastrointestinal (GI) system) to an IV system (meant to deliver fluids and medications intravenously) has often resulted in patient

death by embolus or sepsis. The common element in misconnection of these tubing systems is the presence of a universally compatible luer connector. Luer connectors are used widely throughout healthcare in systems that deliver fluids and gases and in drains and inflation cuffs. The presence of luer connectors throughout these patient care systems creates a persistent opportunity for any tubing system with luer connectors to be accidentally misconnected to virtually any other tubing system with a luer connector. Because the luer connector is used across the continuum of healthcare settings, the potential for a misconnection is ever-present.

The luer tubing connector is commonly called the luer lock, luer slip, luer tip, or small-bore connector. For the purpose of this article, the connector will be called the luer connector. This article explores the published evidence of misconnections between enteral and IV systems. Posited causative factors, patient outcomes, and recommendations for prevention gleaned from a review of published case studies and current expert recommendations are reviewed.

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Healthcare Industry Actions

The healthcare device manufacturing industry classifies luer connectors as small-bore connectors, which are defined by industry standards for production of medical devices, as published by the Association for the Advancement of Medical Instrumentation (AAMI).⁹ In 1996, the Infusion Device Committee of AAMI passed American National Standard ANSI/AAMI ID54:1996, prohibiting the use of luer connectors on feeding sets (which by definition included feeding tubes). This specially convened expert group at AAMI had concluded that the universal connecting properties of luer connectors found on feeding sets and adaptors carried a high risk of patient harm. In 2004, the standard was revisited by the AAMI in response to a query by the United States Pharmacopoeia, and the standard was officially recognized as being “in force.”¹⁰ AAMI continues to participate in the International Standards Organization efforts to coordinate a change to safer connectors across healthcare tubing systems, including epidural, respiratory, and enteral tubing, but this laborious process will yield a voluntary standard in 2013 at the earliest. To date, there is no enforcement of the AAMI standard for luer connectors in feeding sets with manufacturers in the United States, and tubes are connected and reconnected an untold number of times during the day.¹⁰

Common luer connectors were considered a hazard to safety by expert organizations as early as 1986 when the ECRI Institute published the Medical Device Safety Reports describing the connection of enteral feeding tubing to a tracheostomy cuff.¹¹ ECRI followed in 2006 with another alert regarding safe use recommendations for feeding tubes.¹² Consistently, ECRI publications have acknowledged that the existing universal intercompatibility of the connectors in tubing systems in healthcare presents a safety hazard. The Institute for Safe Medication Practices (ISMP) has published multiple warnings and alerts, including a case report of a neonate accidentally infused with breast milk.^{6,13-15}

The Joint Commission (JC, formerly the Joint Commission on Accreditation of Healthcare Organizations) has also recognized the danger of tubing misconnections and, in April 2006, issued Sentinel Event Alert #36. The Sentinel Event Alert cited 9 cases reported to the Sentinel Event Database and noted that this type of error is often underreported.¹⁶ Internationally, tubing misconnections have been recognized as a patient safety hazard by the World Health Organization (WHO). Preventing tubing misconnections is a part of the WHO’s “9 solutions” for patient safety published in 2007.¹⁷ Although the JC jointly published the WHO patient safety solutions, the JC has failed to make the resolution of tubing misconnections a national patient safety goal in the United States.

The U.S. Food and Drug Administration (FDA) has alerted the public to the hazards of luer connectors in several publications and webcasts.^{18,19} In January 2007, the FDA met with concerned stakeholders and developed a consensus paper asking for a redesign of connectors.²⁰ The United States Pharmacopoeia, the standard-setting organization for pharmaceutical products, has issued error avoidance recommendations that ask for a redesign of connectors as well.²¹ Although the AAMI standard was passed in 1996 and 2004, the FDA continues to publish alerts and cautions regarding luer connectors.

Frequency of Tubing Misconnections

Understanding and preventing tubing misconnections has been affected by the same barriers as other patient safety issues. Classic research and epidemiological methods used to research healthcare issues have not been successfully applied to healthcare safety.^{22,23} Healthcare safety experts maintain that underreporting and nondetection of errors in healthcare, on both a national and an institutional level, are barriers to recognizing threats to patient safety, learning how to avoid errors, and quantifying errors.^{22,23} Medical error rates have been established on a population level by only 2 studies, the Harvard Practice Study and the Australian study.²⁴⁻²⁷ Acquiring safety data is problematic on many levels, requiring substantial efforts in retrospective data collection, aggressive case finding, complicated data mining from technology sources, or costly observational studies to uncover representational data.²³ Medical malpractice claims data are not fully representative of error rates.²⁷ Epidemiological data are not available across care settings, and the findings of the published studies that focus on 1 specialty or procedure are not generalizable.²⁴

The healthcare industry continues to rely on reporting systems to acquire safety data but barriers to reporting, such as cultural norms, preclude real progress. Cultural disincentives to reporting errors are often attributed to long-standing punitive healthcare traditions and include threats of legal and regulatory action coupled with disciplinary action at the institutional level.^{22,28,29} Poor character judgments rendered among professional peer groups and colleagues can also negatively influence reporting behaviors.^{22,25} In addition, errors may simply not be detected. James Reason,^{29,30} the author of *Human Error*, describes the poor detection of errors as a barrier to learning from errors and therefore a significant barrier to preventing recurrence.

Analysis of patient safety data is crucial to inform the industry regarding hazards to safe care and to creating proactive approaches to patient safety. The landmark

Table 1. Data on Enteral Tube Misconnections From Case Studies

Case Reports	Patient Outcome From 116 Cases	Threats Identified From 32 Reports	Recommendations From 32 Reports
(N = 116 in 34 reports) Patients	Death (N = 21) Survival		
<ul style="list-style-type: none"> • Adult (N = 60) • Child/infant (N = 30) • Not specified (N = 26) 	<ul style="list-style-type: none"> • Hypersensitivity and hypercoagulopathy reaction (N = 1) • Septicemia/sepsis (N = 16) <ul style="list-style-type: none"> ◦ 2 with neurologic damage ◦ 2 with respiratory arrest ◦ 33 with hypoxia ◦ 1 with seizure and hypoglycemia ◦ 5 with intracranial hemorrhage • Renal impairment (N = 8) • Respiratory arrest/distress (not listed above) (N = 2) • Neurologic damage (not listed above) (N = 2), 1 with blindness and deafness • No harm or outcome not given (N = 12) 	<ul style="list-style-type: none"> • Similar appearance of enteral feeds and IV infusion (N = 6) • Compatible (luer) tubing connectors (N = 15) • Enteral pumps and IV pumps <ul style="list-style-type: none"> ◦ On same IV pole ◦ Identical in appearance or used interchangeably ◦ Tubes running from pumps which look the same (N = 5) • Inadequate lighting (N = 2) • Lines <ul style="list-style-type: none"> ◦ Confused ◦ Use of tubes or catheters for unintended purposes ◦ Placing functionally dissimilar tubes in close proximity to one another (N = 5) • Using luer lock syringes instead of oral syringes and unlabeled syringes (N = 1) • Human factors <ul style="list-style-type: none"> ◦ Knowledge deficit ◦ Confusion ◦ Fatigue ◦ Mistake (N = 11) • Modified tubing connector (N = 1) 	<ul style="list-style-type: none"> • Write the order in full (N = 1) • Redesign connectors to prevent misconnection (eliminate cross-system-compatible connectors) (N = 22) • Visual cues <ul style="list-style-type: none"> ◦ Label or color to indicate system and contents ◦ Place catheters and tubing for differing systems on different sides of patient's body (N = 7) • Use oral syringes for feedings (N = 2) • Modify human factors through <ul style="list-style-type: none"> ◦ Training ◦ Changes in policies and protocols ◦ Routinely trace lines back to source increased vigilance ◦ Increased supervision ◦ Double checks (N = 6) • Other equipment modifications <ul style="list-style-type: none"> ◦ Use an IV-incompatible NG tube and administration set ◦ Use different pumps for different purposes, when possible (N = 1)

IV, intravenous.

publication by the Institute of Medicine (IOM), *To Err Is Human*,²² cited poor familiarity with safe practices in the industry and called for an increase in safe practices. Lack of evidence has remained a key barrier to progress. Further reports from the IOM have repeated the call for increasing the knowledge base for safety through “systems” analysis of error events. The IOM repeatedly has asked healthcare institutions to become learning organizations with increased organizational agility to respond to safety threats. Before healthcare providers can agilely respond to safety threats, they must understand how to analyze and learn from adverse events and to disseminate the resulting knowledge about safe practices.

Case Study Approach

In consideration of these barriers to learning about tubing misconnections and other errors, a case study

approach was used for this literature search. A case study approach is pertinent for 3 reasons. The first is that case study reports may be the only information published and available about specific healthcare errors. Second, case study reports offer narrative description of events that may not be found in traditional databases. These narrative reports can offer essential information regarding safety threats, patient outcomes, and interventions that are crucial to the success of any safety program aimed at error reduction.^{31,32} The third consideration for a case study approach is the absence of traditional research in the area of human performance and healthcare safety. Because safety research in human performance and error often relies heavily on retrospective analyses, case studies may prove the sole informative source.²⁴ This analysis of case study reports provided sole source information to answer the following questions: When completing tubing connections with the potential for enteral to IV tubing misconnections, what are the threats to safety? What are

patient outcomes following misconnections between enteral and IV tubing? What are the current recommendations for preventing misconnections between enteral and IV tubing?

Understanding any healthcare error is difficult without understanding the systems approach. The model of threats and errors authored by Helmreich³³ is an example of a theoretical model adapted to healthcare to explain threats to safety. In this model, threats are factors that increase the likelihood of an error occurring.³⁴ Consistent with Helmreich, van der Schaaf³⁵ presented an expanded model, explaining that threats and dangers to safety are a composite consisting of technical, organizational, human, and patient-related factors. Using these models, the case studies were gleaned for threats to safety.

Search Strategy and Limits

The terms used for the search was “misconnections of tubes carrying feedings, intended for enteral routes, to intravenous lines.” The search was limited to publications in the English language. Methods of inquiry included internet searches using major search engines, such as Alta Vista, MSN, Google, Google Scholar, Yahoo, and AOL, as well as searches conducted within major research publication databases such as PubMed and CINAHL. A web-published bibliography was included for review.³⁶ Keywords were used alone and in combination for this targeted search, and included *luer*, *luer slip tip*, *luer lock*, *small bore connector*, *enteral feeding*, *syringe set*, *intravenous connector*, *tubing error*, *feeding tube error*, *inadvertent connection and misconnection or misconnections*, and *misconnection of incompatible tubing or systems*. This case study search included results from 1972 through 2010. The cases are listed in Table 1.

Results

Notably, the oldest case identified in this search was a case report of an inadvertent connection of an enteral infusion into the IV system reported in 1972 in *The Lancet*. Wallace et al⁸ reported that a “milk drip” of pasteurized cow’s milk intended as therapy for a patient with exacerbation of a duodenal ulcer was accidentally connected to an IV line. The authors suggested that the error occurred because the written order by the physician did not specify an intragastric route and did not fully name the intragastric infusion. Although luer connectors are not specifically named in this early account, it is suggested that the enteral tubing was compatible with IV connections. The patient in this case survived a hypersensitivity reaction and developed a hypercoagulopathy after the event.

In 1979, in a letter to the editor of the *Journal of Parenteral and Enteral Nutrition*, O’Donovan³⁷ reported that an advertisement in the described a proximal connector of the enteric feeding tube as being able to connect to the standard IV sets. O’Donovan reported that he was aware of cases occurring in Australia where the accidental connection of enteral feeding to IV tubing lines resulted in patient deaths. The reasons for these inadvertent connections were identified as being the similar appearance of parenteral nutrition (with lipids) and enteral nutrition (EN).

A total of 116 case studies involving feeding intended for enteral routes misconnected to IV lines were reviewed (see details in Table 1). Full descriptions of the events the patients, and their outcomes were not available in each case. Of the representative cases, adults were reported in 60 cases and children or infants in 30 cases. Twenty-six cases did not specify an age for the patient. One case reported the death of a pregnant mother and her unborn child.²⁰ Patient death was reported in 21 cases. Frequent causes of death were sepsis and embolus related to the feeding. Hypersensitivity reactions, hypercoagulopathy, renal failure, multiorgan failure, severe and permanent neurological damage, and respiratory arrest were also reported.

Threats to Safety From Case Studies

The majority of case studies were focused on the description of the patient’s treatment, condition, and outcome, with very brief descriptions of the actual event. Despite the brevity of descriptions, threats to safety are identified within these case studies. The cases reviewed were written by clinicians who were most likely not familiar with safety science, and certainly those describing cases prior to the IOM reports had little or no awareness of systems analysis. It is important to note that current thought recognizes that attribution of an error solely to the individual’s actions is neither an informed opinion nor helpful in creating safer healthcare practices.*

Organizational factors that can increase threats to safety include the practice of purchasing ubiquitous connectors and deploying them in patient care areas and the use of confusing policies and procedures.⁴⁰ Insufficient supervision of nursing staff is cited within one case.⁴¹ Poor lighting design was also suggested as a contributor to confusing similar tubing.^{42,43} The locations presented in the case studies suggest that there are multiple care settings in which tubing misconnections occur, the majority of which occur in acute care. Cases are described occurring in intensive care, medical surgical units, rehabilitation facilities, emergency rooms, nursing homes, nurseries, and neonatal units.

Human factors (attributes of human performance) are also described within cases as being threats to safety. Several cases suggest that a lack of vigilance on the nurse’s part was a casual factor.^{41,42,44} However, expert

*References 2-4, 7, 22, 23, 25, 28, 34, 38, 39

opinion in most industries accepts that relying upon vigilance is a flawed defense against danger and errors.^{30,45-47} Confusion of lines attributable to the similar appearance of IV lipids and enteral feeding is named in 8 case reports.^{7,8,37,42,44,48-50} Knowledge deficits and a lack of experience are also described in several cases.^{51,52}

In the majority of the cases, the misconnection is described as being accidental in nature.^{43,47-62,76,77} In one case the written order for the feeding is described as "hard to understand" and therefore a contributing factor.⁸ Staff fatigue is cited in one case described in the JC Sentinel Event Alert.¹⁶ One case describes an adult patient who accidentally misconnected his own tubing for enteral feeding to an IV line during the night, when he woke and found it had come apart.⁵³

Technical factors presented in these cases point to one common factor. The luer connectors found on enteral lines are universal in their capacity to fit to IV catheters. In 25 of the published case reports reviewed, authors noted that the connector is interchangeable and therefore problematic, and they recommended a redesign of the connectors.^{**} The use of luer syringes for medication preparation and delivery, instead of oral syringes, led to multiple medications, intended for the enteral feeding tube, being injected into the IV system.²⁰

Reducing the Risk of Tubing Misconnections

Reducing the risk of a misconnection requires compound interventions.^{29,65} Typically, these interventions are aimed at the technical and human level in order to decrease risk.⁶⁵ Numerous connections can be attached to one patient, and there is an increased opportunity for errors with multiple connections and reconnections, which occur frequently in routine care.^{50,57} Reducing the risk of tubing misconnections requires a constant assessment of the risks in the environment and a reassessment each time compatible tubing is introduced. The following interventions are suggested within the case studies and within expert papers.

Visual cues such as labeling and color-coding were suggested in several articles, however, color-coding has been considered a disadvantage as a sole defense against an error.^{***} Color should serve only as an indication to the nurse that this connection should be carefully made and should never be used as sole cue when making a connection. Significant threats can be introduced when practitioners begin to rely on color-coding rather than on ensuring line type.⁶⁵ Color blindness and lighting problems that result in altered hue identification are well-known hazards to relying on color.^{21,50} Labeling is also recommended at the proximal

and distal tubing ends.^{16,20,21,50,67,68,69} Other visualization measures suggested include tracing lines to identify the correct tubing, routing tubing in different directions, and having independent practitioners who double-check and recheck lines at any transition point (ie, hand-offs and shift changes).^{4,12,16,21,65}

Expert groups have recommended changes in organizations' supply practices that will decrease risk by taking the possibility of a misconnection of enteral and IV lines away from the patient. The recommended changes include purchasing only tubing that is incompatible with IV tubing.^{4,9,10,16,50,65,68,69} In contrast, substituting a functionally similar medical device for a device with safety features increases risk of error. An example is using luer tip syringes when administering enteral feeding or medication instead of purchasing and using orange oral syringes.^{21,60,65,69,71} Therefore, purchasing and using tubing with incompatibility to other lines is suggested as a way to remove the risk to the patient. This can be very confusing and can introduce other hazards inadvertently into the clinical environment, because multiple products are available on the market that have "incompatible" connectors. Unless the full risk is understood and a comprehensive coordinated strategy in place, purchasing and using tubing with multiple incompatible connectors is a complex, time-intensive chore not accommodated by most organizations purchasing plans.

Increasing awareness of risk by conducting risk assessments, acceptance testing, training, and orientation is suggested as an interim intervention for reducing the risk of a tubing misconnection.^{12,16} Increasing awareness among providers has been attempted.^{16,21,67,70} The American Society for Parenteral and Enteral Nutrition.—Nestlé Be ALERT Campaign in 2009 was an initiative to raise awareness among staff nurses about safe practices for EN, including prevention of misconnections.⁶⁷ Increased vigilance is named in one report as a way to reduce risk, although present knowledge in safety recognizes that 100% human vigilance is an unobtainable state.^{22,44} Finally, it has been suggested that clinicians teach patients and caregivers not to reconnect a line that has become disconnected.^{16,20,21,67,71}

Simply stated, there is no substitute for a change in the design of connectors to force incompatibility of enteral to IV systems. Clearly, there is a pervasive understanding among safety experts that a redesign to incompatibility is the only fail-safe measure to reduce the possibility of an accidental tubing misconnection. Redesigning the connector to force incompatibility has been suggested as the most tangible intervention. A redesign to incompatibility is called for by consensus statements and expert groups and is recommended in the majority of case reports.^{****}

**References 6, 7, 15, 16, 20, 37, 41, 42, 48-51, 53-65

***References 12, 16, 39, 42, 57, 58, 66-68

****References 4, 6, 7, 9, 10, 12, 15, 16, 20, 37, 41-43, 48-51, 53-65, 68-72.

Conclusions

The use of universal connectors such as luer connectors in healthcare is a fundamental failure to protect patients. A system that carries a high risk of injury if connected unintentionally to another system should, by intent and pragmatic logic, have design features that prevent the possibility of inadvertent connection. It is clear that connectors in healthcare create a hazard to patient safety as evidenced by multiple alerts, patient deaths, and publications by safety experts and regulatory bodies.

In *The Challenger Launch Decision: Risky Technology, Culture, and Deviance at NASA*, sociologist Diane Vaughan⁷⁴ describes NASA as having an organizational culture that evolved to accept danger signals as normal and did not react to clear signs that the Challenger was doomed to fail. The term Vaughn uses to describe this phenomenon is “normalization of deviance,” which not only describes NASA’s culture but has been applied to healthcare as well.⁷⁵ Vaughn poses the idea that the decision to launch the Challenger in 1986, although not intended to kill the entire crew, was a decision made in the face of clear signals of danger. Vaughn states, “This was a story about routine decisions in a workplace” that have disastrous, though unintentional, consequences.^{74(p403)} The normalization of signals of danger created the tragedy of the Challenger.

The signals of disaster regarding tubing misconnections begin from a distance in time and diversity of locations that can encourage a sense of detachment on a personal level. The decisions made at the provider level, the institution level, and within the regulatory bodies have been routine decisions never intended to kill patients. The decisions are made in a healthcare workplace focused on production, where danger becomes normal and signals of impending tragedy are ignored. However, without a doubt, each patient’s death is a red flag to those using universal connectors—eventually, through daily repetition and relentless presence, a tubing misconnection death is possible. The healthcare industry, despite its acknowledgement of dangerous elements of the connectors and attempts to change the voluntary standard for these connectors, continues to produce, distribute, and use universal connectors.

In 2009, a story was published reporting a neonate who had been emergently delivered from a mother dying of the H1N1 viral infection and was killed in an inadvertent connection of enteral feeding to an IV line.⁵² The nurse in the case was reported to have pending charges of manslaughter. In May 2010, the accidental injection of barium sulfate through a central venous catheter in a 17-month-old was reported in the *American Journal of Health Systems Pharmacists*.⁶⁴ On July 15, 2010, the ISMP reported that a 19-month-old died after receiving

an oral medication through a central line.⁷⁸ On a broader perspective, these are clear signals of danger for all of us who use universal connectors; on a human level, these events simply should not have happened.

Acknowledgements

This article is dedicated to Flower, Glenda, Jerick, Robin, Addison, Chloe, and Johannah.

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