

USP Medication Safety Forum

Enteral Feeding Misconnections: A Consortium Position Statement

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A 24-year-old woman was 35 weeks pregnant when she was hospitalized for vomiting and dehydration. A bag of ready-to-hang enteral feeding was brought to the floor, and the nurse, assuming it was total parenteral nutrition, which the woman had received on previous admissions, pulled regular intravenous tubing from floor stock, spiked the bag, and started the infusion of tube feeding through the patient's peripherally inserted central catheter line. The fetus died—and then the mother, after several hours of excruciating pain.*

An invitation from the American Hospital Association (AHA) brought together a number of representatives from various organizations in Washington, D.C., on October 11, 2006, to (1) discuss the current state of practice pertaining to enteral feedings and (2) patient safety risks associated with medical misconnections involving enteral feeding systems. Although the initial focus was on Luer fittings, the scope of the discussion was expanded to the entire enteral feeding system to identify areas where misconnections could occur. This article presents the issues associated with enteral feeding misconnections and proposes a set of solutions.

Definition of the Problem

The definition of *medical misconnections* includes seemingly apparent incompatible systems that, when inadvertently connected, can result in life-threatening events in the clinical arena.¹ In 2007 The Joint Commission proposed—but did not adopt—a National Patient Safety Goal that would have stressed the importance of preventing catheter and tubing misconnections.²

This article focuses on only those misconnections related to enteral nutrition systems, specifically enteral misconnections.

* Submitted to Peggi Guenter; used with permission.

Enteral 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.³ An enteral misconnection is an inadvertent connection between an enteral feeding system and a nonenteral system such as an intravascular line, a peritoneal dialysis catheter, a tracheostomy tube cuff, and medical gas tubing. 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 (for example, into the intravascular system).

The reporting of inadvertent intravenous (IV) administration of breast milk in 1972 is one of the earliest publications of an enteral misconnection.⁴ One literature review found more than 60 references to enteral misconnections.⁵ As with other voluntary adverse event reporting systems, the reporting of enteral misconnections may greatly underrepresent the number of actual cases. Furthermore, a poor understanding of the causative factors also hinders a true record of incidents involving feeding connectors. Published reports consistently substantiate the severity of this type of error, which, too commonly, results in the death of the patient because of ensuing embolus or sepsis.

Enteral Feeding System

The enteral feeding system for adults and large children is the entire apparatus from the enteral nutrition 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.⁶ 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 one-piece device, with the container connected permanently to the tub-

ing. (Figure 1, right). In the case of pre-filled, ready-to-hang formula bags or containers, an enteral administration set must be spiked into the bag, making it a two-piece enteral set (Figure 2, page 287). The distal end of the enteral set connector attaches to the proximal end of the feeding tube. Some feeding tubes contain only one port, so that this single lumen tube does not have a side port for medication administration. Often, clinicians attach adaptive devices, such as Luer-lock stopcocks or extension tubing sets, between the feeding set and the feeding tube. These devices facilitate flushing and medication administration (Figures 1 and 2). 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 as described. In infants, low-volume feedings require slower rates. It is common to use syringes with syringe pumps rather than adult size feeding sets. Some settings use specially tipped oral syringes for enteral delivery of formula, breast milk, and oral medications.^{7,8} 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. The infusion devices (for example, syringe pumps), however, are only calibrated for use with parenteral syringes. In addition, the design of most infant feeding tubes allows the tubing to accept Luer-slip or Luer-lock connectors for compatibility with parenteral syringes.^{8,9} Despite calibration issues with syringe pumps and incompatibility with many feeding tubes, some facilities have converted to oral syringes for the delivery of low-volume enteral feedings and medications.⁸ This requires recalibrating and/or adjusting syringe pump flow rates. However, use of oral syringes and safety feeding tubes has not been widely adopted, and industry estimates that only a small percentage of patients receive oral liquid medication doses through a feeding tube with an oral syringe.

Enteral Feeding System Concerns

In 1996, the Association for the Advancement of Medical

One-Piece Enteral Administration Set in Enteral Feeding System

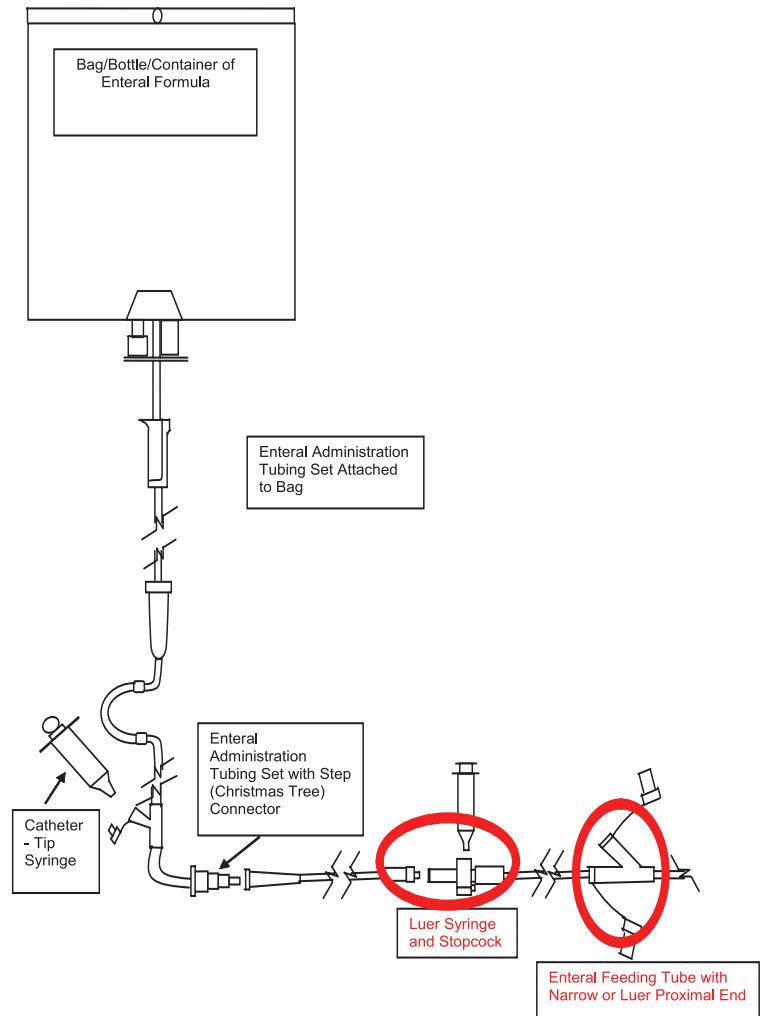


Figure 1. This feeding set may be a one-piece device with the container connected permanently to the tubing. Illustration provided courtesy of Sharp Healthcare, San Diego.

Instrumentation (AAMI) Infusion Device Committee convened an expert group to address the safety requirements for enteral feeding set connectors and adapters. The resulting voluntary standard, approved in 1996 and reaffirmed in 2005, recommended that adapters and connectors used in the enteral system be incompatible with female Luer-lock rigid connectors.¹⁰ However, no alternative design standards were ever developed or approved on the basis of that document.

A British Standards document describes the step connector (often referred to as a Christmas tree connector) as being an

alternative connector design.¹¹ Some manufacturers developed feeding sets with these step connectors in such a manner 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 remain a serious hazard to patients.

A number of public and private organizations (United States Pharmacopeia [USP], ECRI Institute [ECRI], Institution 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 (Figure 3, page 289). Despite warnings that date back to 1986, the number of case reports continues to accumulate.

In March 2007, a review of the USP MED-MARX[®] and the USP-ISMP Medication Errors Reporting (MER) Program, two voluntary medication error reporting systems, specifically identified cases involving enteral feeding systems. Between January 1, 2000, and December 31, 2006, the USP reviewers found 24 reported incidents involving an enteral feeding formula, 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 is 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, as shown in Table 1 (page 288), that can lead to wrong-route errors.

In early 2006, the FDA and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) developed a survey on the issues associated with enteral connectors and safety. 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 their members. Of the 182 responding clinicians, (includ-

Two-Piece Enteral Administration Set in Enteral Feeding System

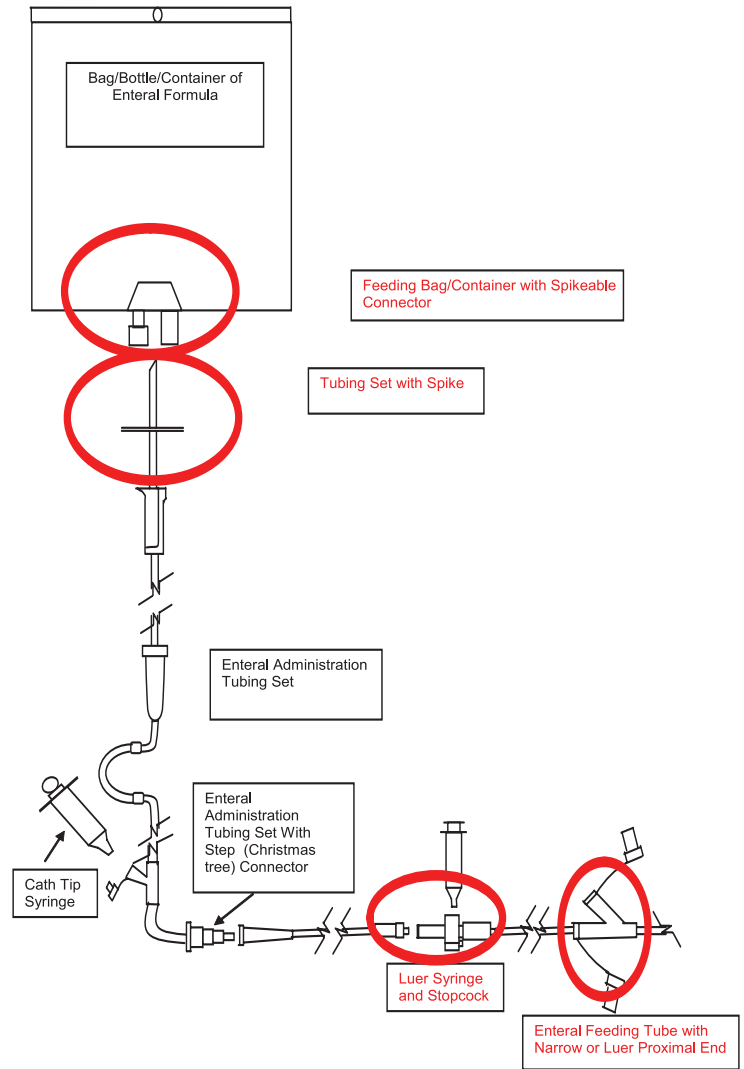


Figure 2. In the case of pre-filled, ready-to-hang formula bags or containers, an enteral administration set must be spiked into the bag, making it a two-piece enteral set. Illustration provided courtesy of Sharp Healthcare, San Diego.

ing nurses, dietitians, pharmacists, physicians, safety officers, and quality improvement coordinators), 29 (15.9%) stated that their institution had experienced an enteral misconnection incident; 105 (57.7%) reported negatively and 48 (26.4%) reported that they did not know. More than 30% of the respondents reported that they used Luer connectors in at least some of their enteral systems, and 20% used additional extension tubing with Luer connectors.

Table 1. Reported Enteral Misconnections and Related Factors (Jan. 2000–Dec. 2006)*

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%
Total	24	8	33%

* Data supplied by United States Pharmacopeia (USP) MEDMARX and USP-Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. IV, intravenous; med, medication.

A number of respondents expressed concerns regarding the use of the current enteral connectors. Responses indicated that over the course of time, the enteral connector (for example, Christmas tree connector) tends to stretch the opening of the feeding tube, and thus the connectors slip out of the tube, causing an interruption in the system’s integrity. Feeding pumps create pressure to deliver enteral formulas, which, combined with the small lumen of the feeding tube, caused the connector to disengage. In the pediatric population, the “slip-tip” mechanism of the enteral feeding connector allowed children to pull the system apart rather easily, compared with the twisting mechanism of Luer connectors.

Contributing Factors for Enteral Misconnections

HUMAN FACTORS

Errors involving feeding tube misconnections are a result of errors in performance—providers are unaware that the connection is occurring between two 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, who is 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 misconnection.¹² As suggested by the human factors literature, contributors include time pressure, rotating shift work, fatigue, attempts to use short-term recall for large amounts of information, inadequate training, and inadequate lighting (for example, night shift in a darkened patient room)—all endemic in the current patient care environment—as well as moving patients from one setting or service to another.¹

PHYSICAL AND DESIGN FACTORS

Luer connectors are implicated in or contribute to many enteral feeding connection errors because they permit functionally dissimilar tubes or catheters 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.¹ Also, the adoption of needle-free connectors as the standard replacement for latex rubber injection ports on IV administration tubing introduces many more opportunities when a Luer male connector can be attached to a female needle-free connector. Previously, the setup would have required attachment of a needle and was much less likely to be added to an enteral set or syringe. Caregiver safety should be considered along with patient safety, but with the widespread use of these IV set connectors (as many as three per IV line), the chances that a female-compatible male Luer connector will be inserted into a needle-free connector is increased by the high number of ports and the complexity of the IV tubing, especially if one is treating acutely ill patients.

Physical characteristics and connections along the enteral nutrition system also contribute to the risk of enteral misconnections. For example, in the connection of the enteral administration set to a pre-filled container (Figure 2), the two-piece system allows IV tubing to be substituted for an enteral administration set.^{13,14} 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. These use common

Use Only—NOT for IV Use”.¹⁸

- Ensure that all connections are made under proper lighting conditions.¹⁵

- Identify and minimize conditions and practices that may contribute to health care worker fatigue, and take appropriate risk mitigation action.¹

None of these strategies alone is a solution to the problem, but taken together they will help mitigate risk. A design solution that prevents cross-connections between IV and enteral products would prevent the problem.

PURCHASING STRATEGIES

The Joint Commission’s recommendations to reduce tubing misconnection errors include the recommendation, “Do not purchase non-intravenous equipment that is equipped with connectors that can physically mate with a female Luer IV line connector.”²¹ 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 they may not be available in the United States even though they are freely available elsewhere.¹⁹ Although a neonatal product system is 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 industrywide solutions. Health care delivery organizations can also support their purchasing committees and departments by recommending specific brands of safe products until preferred solutions become generally accessible. Specific purchasing strategies to decrease risk of enteral misconnections include:

- Avoid buying enteral equipment that can mate with female Luer connectors, more specifically, avoid purchase of gastrointestinal tubes that have female Luer connectors.¹

- Purchase adequate numbers of enteral pumps so that IV pumps are not used for enteral delivery for adult patients.

- Ensure that hospital purchasing policies mandate buying only enteral feeding sets that are compliant with American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) standard ID54, which effectively excludes any that could mate with female Luer connectors. These devices must also be clearly labeled (for example, “Not for IV Use”).¹⁰

- Avoid buying pre-filled enteral feeding containers, except

for those with design technology labeled non-IV compatible. This technology, just recently introduced in the United States, uses a screwtop design that reduces compatibility with IV equipment. This manufacturer’s goal is to have this equipment on the U.S. market by mid-2008. In all cases, ensure that the enteral administration set is packaged with the enteral feeding bag or container before it is sent to the floor. (The set should be secured to the bag, perhaps with a rubber band, or request that the manufacturer supply preattached sets). In either case, the objective is to prevent bags or containers from being spiked with IV administration sets.¹⁴

- Obtain enteral pumps that feature an automatic flush mode so that clinicians will not need to manually flush lines and therefore will be less likely to allow an adapter or Luer device between the enteral administration set and the feeding tube.^{15,20}

- Carefully evaluate the need for and 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 draw up and deliver medications into the enteral feeding system. Include pharmacy department recommendations to ensure the correct syringe type, along with dispensing and proper labeling protocols. Ensure that oral syringes are available on the nursing units where the enteral infusion and enteral/oral medications are being prepared.

- Before making a purchasing decision regarding enteral feeding systems, convene a multidisciplinary task force charged with performing a prepurchase evaluation.¹⁵

- Search all manufacturers’ products for the safest systems.

DESIGN CHANGES

The Joint Commission has urged product manufacturers to implement appropriate “designed incompatibility” to prevent dangerous misconnections of tubes and catheters.¹ 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.²¹ Forcing function designs have been used in medical gases and, most commonly, in the design of cars (for example, 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.^{10,19,22}

To make the environment safe from inadvertent misconnections between IV fluids and tube feeding for the gut, 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 enteral nutrition 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 United States, instituting forcing functions into the design of the equipment is a prudent safety feature.

During the past three 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 or forced into a tube that could be connected to a Luer or were incompatible with other commonly used products. Working in isolation, no individual manufacturer to date has developed a standard that has been as universally accepted in the marketplace as was the Luer connector decades ago. 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 connectors, however, 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. For example, companies that make feeding tubes are not necessarily the same companies that manufacture enteral formula bags or feeding pump sets.

Another design issue that must be addressed is the need to eliminate the spike-style connector into the pre-filled formula bag. The European standard for enteral feeding bags includes a smaller spike with a threaded collar that screws onto the bag or bottle. Many United States companies manufacture this type of bag for their European customers. This threaded collar and screw are not compatible with the currently marketed connector system on IV bags and tubing in the United States. This connector will shortly be made available for use in the United

States, and it should provide a near-term solution while global manufacturers work toward a more permanent solution.

In addition, the connector on the enteral feeding tube universally changes from a small proximal end capable of accepting a male Luer fitting to a fitting for the step connector. In addition, 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.

DIALOGUE PROMOTING CHANGE

Engaging manufacturers in equipment redesign is critical. Group purchasing organizations have used a variety of opportunities to share their concerns with suppliers and manufacturers of feeding tubes, feeding pumps, and syringe pumps.^{7,23–26} Such communications focused on the need to eliminate opportunities for tubing misconnections and other patient safety issues associated with enteral feeding. Discussions addressed system–product redesign and development of a non-Luer standard particularly for pediatric and neonatal products to highlight the need for development of non-Luer standards, changes in pumps, tubing sets (for example, elimination of the universal spike connection to the formula container), changes in feeding tubes, and modified labeling and containers.

In 2006 a manufacturer (Viasys, Inc., Conshohocken, Pennsylvania) released a line of feeding tubes and enteral feeding administration (extension) sets that accept only oral syringes. The system includes specifically labeled enteral oral dispensers (syringes), and all three components contain oral/enteral connectors, not Luer connectors, making a wrong connection to the infant's IV impossible.^{27–29} Calibration of the syringe pump for use with the enteral syringes remains an issue for this product.

Summary and Conclusion

Enteral misconnections remain a hazard to patient safety in health care settings. Standards that address misconnections of the entire enteral feeding system should be developed to prevent errors. In the interim, hospital and health care organization patient safety officers should work with their purchasing departments and users to perform a thorough assessment of current products and practices. Following the 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 dialogue with manufacturers, encouraging them to create alternative solutions that are compliant with the AAMI standard. Until the possibility for enteral misconnections is resolved, a risk to patient safety remains.

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