USP Medication Safety Forum

Error-Avoidance Recommendations for Tubing Misconnections When Using Luer-Tip Connectors: A Statement by the USP Safe Medication Use Expert Committee

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Since 1972, failures to connect the correct tubing to intravenous (IV), epidural, intracranial, intrathecal, and other high-risk systems[1–3] have been reported. One literature review made more than 115 separate references to errors of this type as found in the published literature.[4] It is recognized that voluntary reporting may greatly underestimate the number of cases that actually occur in health care errors.[5] Numerous adverse events have been reviewed, and the tubing industry has been alerted of these events by the U.S. Food and Drug Administration (FDA), the United States Pharmacopeia (USP), The Joint Commission, and the Institute for Safe Medication Practices (ISMP).

Tubing misconnections are often the result of cognitive "slips" in performance where the provider is not aware that he or she is connecting the wrong tubing. Cognitive psychologist James Reason describes this state as being in "automatic mode," the level of functioning where the error is not detectable by the participant at the time the event occurs.[6] Tubing misconnections may often occur at the subconscious level and, as a result, are not under the conscious control of the health care provider. Therefore, these are not errors that are readily avoidable without a "constraint" design change that puts a physical barrier in place when the misconnections are attempted.[7,8] Constraints prevent an error from occurring, and a constraint design would make misconnections physically impossible. They are similar to "forcing functions," which "would make incorrect connections impossible because they would physically prevent the user from taking a harmful action."[9(p. 290)]

The use of universal connectors, such as Luer tips or Luer locks (also called small-bore connectors; Figure 1 and Figure 2, right) in health care represents a fundamental failure to design safe systems. In simple terms, any system that carries a high risk of injury if connected unintentionally to another system should have design features that prevent the possibility of inadvertent connection. Unfortunately, in many cases, the only available tubing manufactured and available in the United States for critical monitoring and drug or solution delivery functions has universally fitting small-bore connectors commonly termed Luer locks or Luer tips.[10,11] This problem is not limited to the United States and is being addressed by the National Patient Safety Agency (NPSA) in the United Kingdom. The NPSA has set deadlines for National Health Service entities in England and Wales to adopt enteral feeding catheters that are not compatible with parenteral syringes (that is, adopting enteral catheters that do not contain female Luer ports). In 2006, The Joint Commission issued a Sentinel Event Alert addressing tubing misconnections,[11] and a National Patient Safety Goal regarding the prevention of catheter and tubing misconnections will continue to be considered.[12] Finally, Avoiding Catheter and Tubing Misconnections is one of the Nine Solutions promulgated by the WHO Collaborating Centre for Patient Safety.[13]

Common Luer-Lock Connector

Figure 1. *Two commonly used Luer-lock connectors are shown.*

Misconnection of Oxygen to Intravenous Solution Tubing

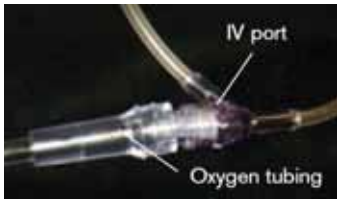

Figure 2. *Misconnection of oxygen to intravenous solution tubing is shown.*

The recommendations for avoiding medication errors resulting from tubing misconnections as presented herein are based on reports received through the USP MEDMARX® and USP-

Table 1. Public Policy Recommendations for Tubing Misconnections When Using Luer-Tip Connectors

1. Recommendations for Regulators and Standards Setters

A. The Food and Drug Administration and other standards setting organizations are requested to adopt a standard that encourages conversion of small-bore universal connectors (also called Luer locks and Luer tips) to sets that are physically incompatible with intravenous and other medical/circuit systems that are not intended to connect.

B. The Joint Commission is requested to reconsider tubing misconnections as a National Patient Safety Goal.

C. State health departments, hospital associations, and health professionals' organizations are requested to immediately offer alerts regarding the hazards of universal connectors to members.

2. Recommendations for Manufacturers and Group Purchasers of Common Small-Bore Connectors

A. Immediately begin to redesign and develop feeding tubes, feeding sets and adaptors, and connectors for non-intravenous equipment such as nebulizers, noninvasive blood pressure devices, compression devices, intracranial monitoring and other monitoring tubing, bladder irrigation sets, and epidural sets that cannot physically connect with intravenous tubing and any other connectors or with any other medical circuit/system to which it is not intended to connect.[1,2]

B. Upon redesign of connectors, manufacturers are recommended to assess the potential for unseen consequences of design changes and to conduct usability tests and risk analysis on all new products that have the possibility of connecting to other tubing, especially if such an inadvertent connection might be fatal or lead to serious patient injury.

C. Do not depend on the use of color-coding of tubing and labels, since this is not an adequate defense against misconnection errors.

D. Assist health care organizations and group purchasing organizations in selecting safer tubing options. Group purchasing organizations should use purchasing power to encourage manufacturers to speed changes in the design process and in introducing safer tubing connectors.

3. Recommendations for Health Care Organizations and Health Care Practitioners

A. Purchase and use, for non-intravenous functions only, small-bore connectors that are incompatible with intravenous tubing whenever possible.[1,3–15]

B. Never use syringes with Luer tips (intended for intravenous use) for administering oral medications by the enteral route. Oral (or catheter-tip) syringes should be used for administering oral medications and should be available in each patient care area where nasogastric/enteral tube administration may occur. Bedside providers should be trained on a preparation and administration technique that does not involve injection syringes.[16]

C. Conduct failure mode and effects analyses (FMEAs) on existing tubing, identify potential risks, educate staff regarding the hazards, and take steps to eliminate the possibility of misconnections.[17–19]

D. Report all incidents of adverse events regarding misconnections to the FDA through the MEDWATCH or MEDSUN programs (may be required by law).

http://www.fda.gov/cdrh/yr2000/cdrh/folder/y2kmedwatch.htm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/printer.cfm?id=404

https://www.medsun.net/about.html

E. Report all errors with misconnections to the USP-ISMP Medication Errors Reporting Program, a nationally recognized voluntary medication error reporting program that provides alerts, reviews, Web news items, etc., to practitioners, consumers, industry, and the government to help avoid future errors from occurring (http://www.usp.org/hqi//PatientSafety/mer/).

4. Special Instructions to Patients, Parents, and Caregivers

In all health care and home care settings, patients, parents, and caregivers should be provided verbal and written information regarding any universally fitting connectors in use, including warnings about the incompatibility of tubing and the consequences of a misconnection.

When in the health care setting, visitors, volunteers, patients, parents, and caregivers should also be advised that, should a tubing disconnection occur, NEVER reconnect or insert the tubing into what you think is the appropriate connection. Call the clinical staff immediately to reconnect the lines.[8]

(continued on page 295)

Table 1. Public Policy Recommendations for Tubing Misconnections When Using Luer-Tip Connectors (continued)

5. Interim Safety Actions

Until the manufacturers develop and supply appropriately designed tubing, health care providers, patients, parents, and caregivers are advised, that while labeling and color-coding are not an adequate solution against tubing misconnection errors, the following interventions may be helpful:

A. Oral syringes should be clearly labeled for the oral route ONLY.[20,21]

B. ALL tubing and catheters should be tagged clearly at the proximal and distal ends as well as at each possible connection point.[2,16]

C. All policies and procedures should include the function of tracing lines from the proximal to distal ends whenever any connection or reconnection is made. Independent verifications with another licensed health care provider are recommended, especially with each tubing reconnection for patients with multiple tubes.

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ISMP Medication Errors Reporting Programs, reports submitted to the Healthcare Safety Alliance Partnership (HSAP), FDA Alerts, and standards set by the Association for the Advancement of Medical Instrumentation (AAMI) and ECRI. In addition, research and retrospective analysis was performed by the Institute for Healthcare Excellence at the University of Texas M.D. Anderson Cancer Center. These recommendations may be applied and adopted in various health care settings.

Public Policy Recommendations

It is also recognized in the literature and in reported cases that tubing misconnection errors carry the most serious consequences including sepsis, embolus, and death. Because the redesign of these systems will require extensive resources and time to implement, and until safe designs are available, public policy recommendations are proposed to prevent the present risk of misconnection errors (Table 1, pages 294–295).

Conclusion

In spite of multiple alerts, meetings, and consensus statements, tubing misconnections continue to pose a serious danger to patients. Providers play a significant role in improving patient safety by sharing their experiences and suggesting ways to avoid these types of errors in the future. Tubing misconnections will only be addressed successfully with a systems approach that fully engages the frontline practitioner, the health care institution, regulatory and accreditation agencies, and manufacturers. J

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