



Center for Clinical Standards and Quality /Survey & Certification Group

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DATE: March 8, 2013
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Luer Misconnection Adverse Events

Memorandum Summary

- **Luer Misconnections continue to result in adverse events and deaths** – Luer connectors easily link many medical components, accessories, and delivery systems. Clinicians, in any type of provider or supplier setting, can mistakenly connect the wrong devices and deliver substances through the wrong route. Despite numerous alerts and warnings, a patient’s blood pressure tubing was recently misconnected to an intravenous (IV) line in an ambulatory surgery center (ASC) resulting in a patient death.
- **Adverse Event Complaint Investigation:** During a complaint investigation for an adverse event involving delivery of an incorrect substance or utilization of an incorrect delivery route, surveyors must be alert to whether the event involved misconnection of a Luer device. If so, surveyors must determine whether the facility has taken actions to ensure systems are in place to prevent recurrence of this type of adverse event.
- **Facility Reporting to Food & Drug Administration (FDA):** Surveyors should encourage health care facilities to report problems with Luer misconnections to the FDA, even if no adverse event occurred.

Background

A Luer connector is a “conical fitting with a six percent taper for syringes, needles, and certain other medical equipment” used worldwide to connect a variety of vascular, enteral, respiratory, epidural and intrathecal medical devices, components, and accessories. Luer connectors have a male and a female component that are joined by use of a friction push and twist fitting (a Luer slip) or a screw-in threaded fitting (a Luer lock) to form a secure yet detachable leak-proof connection.

Since 1972, there have been more than 100 reports of Luer misconnections found in the literature and this may underestimate the actual number that result in adverse events. The Association for the Advancement of Medical Instrumentation, FDA, The Joint Commission, the Institute for Safe Medication Practices, United States Pharmacopeia, ECRI Institute, and others have received reports of misconnection errors.

Examples of adverse events that highlight the devastating impact of Luer misconnections (per FDA website listed below):

- A feeding tube was inadvertently placed in the tracheostomy tube of an infant in a pediatric intensive care unit. Milk was delivered into the infant's lung causing death.
- An epidural set was mistakenly connected to a patient's IV tubing. Epidural medication was delivered to the IV and the patient died.
- IV tubing was inadvertently connected to the nasal oxygen cannula. Four hours later, the patient complained of tightness in the chest and difficulty breathing. The patient was treated for congestive heart failure and survived.
- A feeding tube was mistakenly connected to a patient's ventilator in-line suction catheter, delivering the contents of the tube into the patient's lungs, causing death.
- An emergency room patient had an IV heparin lock (but no IV fluids had been started) and a non-invasive automatic blood pressure cuff for continuous monitoring. The cuff tubing was disconnected when the patient went into the bathroom. When she returned, her spouse mistakenly connected the blood pressure cuff tubing to the IV catheter and air was delivered to the IV catheter. Despite resuscitation efforts, the patient died from an air embolus.

Most reports in the literature involve patients with multiple lines and tubing in the hospital setting. However, a recent report involved a patient in an ASC undergoing a carpal tunnel repair. The patient's blood pressure tubing was mistakenly connected to the IV line resulting in a fatal air embolus. This case is illustrative of the risk to patient safety, in any provider or supplier type, from potential Luer misconnections.

Additional Information and Resources

The FDA, the international standards community, and the medical device industry are taking steps to reduce the likelihood of tubing misconnections. One step is the update of the FDA Tubing and Luer Misconnections website, which includes additional tips, an image of Luer connectors, and information for health care providers and manufacturers of medical devices that use small-bore connectors. The website provides case studies and additional resources about Luer misconnections and how to prevent them. The Web address is: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm>. This information may be shared with facilities to incorporate into their Quality Assessment and Performance Improvement (QAPI) program, educational programs, and action plans to prevent misconnections.

Organizations, such as the International Organization for Standardization (ISO), are working on the development of standardized connector designs for specific high risk medical applications to ensure that these connectors cannot be interconnected with a device of another medical application, including Luer. However, it may be some time before replacements have been fully implemented. Until then, the possibility of Luer misconnections and resulting adverse events will continue to present a serious threat to patient safety.

Examples of actions providers and suppliers can take in the interim to reduce the likelihood of Luer misconnections include, but are not limited to:

- changing to devices already on the market with alternative connector designs which reduce the likelihood of misconnections of incompatible lines;
- tracing lines back to their origins when reconnecting devices;
- positioning catheters and tubes that have different purposes on different sides of the patient's body or in unique and standardized directions; and
- implementing a multidisciplinary facility approach to address Luer misconnections.

Actions for Surveyors

During a complaint investigation for an adverse event involving delivery of an incorrect substance or utilization of an incorrect delivery route, surveyors must investigate whether the event involved misconnection of devices with Luer connectors or similarly designed connectors that allow for misconnection. If so, surveyors must determine whether the facility has taken actions to ensure systems are in place to prevent recurrence of this type of adverse event. When conducting standard surveys, surveyors should consider asking healthcare personnel, as well as managers they interview, what steps they take to prevent Luer misconnections.

Surveyors can also encourage facilities to report problems involving Luer misconnections to the FDA, even if an adverse event did not occur. General information on reporting a Luer misconnection problem, and what to include in a report, may be found at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/ucm313323.htm>. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements, found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm>, should follow the reporting procedures established by their facilities. Information on user facility reporting can be found at <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>. Healthcare professionals may also file a medical device report through MedWatch, the FDA Safety Information and Adverse Event Reporting program. Information about reporting may be found at the following website: <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm2007306.htm>.

Raising awareness in this manner may prompt actions that protect patients until new connectors are available.

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Questions about this memorandum may be addressed to Dr. Daniel Schwartz at daniel.schwartz2@cms.hhs.gov.

Effective Date: Immediately. This information should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management