

Sentinel Alert Event

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Published for Joint Commission accredited organizations and interested health care professionals, *Sentinel Event Alert* identifies specific types of sentinel and adverse events and high risk conditions, describes their common underlying causes, and recommends steps to reduce risk and prevent future occurrences.

Accredited organizations should consider information in a *Sentinel Event Alert* when designing or redesigning processes and consider implementing relevant suggestions contained in the alert or reasonable alternatives.

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Managing risk during transition to new ISO tubing connector standards

Tubing misconnections continue to cause severe patient injury and death, since tubes with different functions can easily be connected using luer connectors, or connections can be “rigged” (constructed) using adapters, tubing or catheters. This is why new ISO (International Organization for Standardization) tubing connector standards are being developed for manufacturers. Through an international consensus process, the standards are being developed, tested and approved to assure reliable designs and processes. The phased implementation of redesigned tubing connectors that are the result of these new ISO connector standards begins now. The Joint Commission urges health care organizations to be vigilant and begin planning for the upcoming period of transition, which will introduce changes and new risks into the health care environment. Under the new ISO connector standards, small-bore (less than 8.5 mm inner diameter) connectors will be engineered to make it nearly impossible to connect one delivery system to another delivery system that serves a completely different function^{1,2,3,4,5} – for example, accidentally connecting a feeding administration set to a tracheostomy tube, or an intravenous (IV) tube to an epidural site.

The first new ISO connector standard (ANSI/AAMI/ISO 80369-1) has been adopted and others are expected to be introduced and adopted through 2014 and 2015. Health care organizations should begin preparing for changes in connectors and do everything possible during the transitional period to avoid tubing misconnections. The benefit of the transition is that, ultimately, the engineered solutions will make systems safer for all patients.

The new ISO connector standards are being developed through a collaboration of the International Organization for Standardization (ISO), the Association for the Advancement of Medical Instrumentation (AAMI), clinicians, manufacturers and regulators, including the U.S. Food and Drug Administration (FDA). The Joint Commission does not anticipate introducing new accreditation or certification standards related to tubing connectors at this time.

Examples of adverse events

The New York Times reported on the death of a fetus and expectant mother after a feeding tube was accidentally connected into the mother’s bloodstream.⁶ In 34 various publications, 116 other case studies were found involving misconnections directing enteral feeding solutions into IV lines.⁷ These adverse events resulted in 21 deaths. It is believed that tubing misconnections are underreported; adverse events related to tubing misconnections are sometimes not reported, especially when the mistake does not result in harm to the patient,¹ and they are sometimes reported under another category, such as a medication error. The risk for tubing misconnection is high, considering that almost all patients admitted to the hospital are likely to receive an IV.⁸ This risk is also seen in other settings.



There are various types of misconnections posing dangers, including the following:^{3,9}

Types of misconnections		
Enteral feeding tube	connected to	IV (such as <i>The New York Times</i> example) ^{6,10,11}
Limb cuff inflation device	connected to	IV (For example, a 71-year-old woman died post-operatively after a blood pressure cuff was accidentally connected to her IV line, causing an air embolism.) ⁷
Epidural solution (intended for epidural administration)	connected to	Peripheral or central IV catheter ¹⁰
Epidural line	connected to	IV infusion ^{10,11}
Bladder irrigation solution using primary IV tubing (connected as secondary infusion)	connected to	Peripheral or central IV catheter ^{10,11}
IV infusion (intended for IV administration)	connected to	Indwelling bladder (foley) catheter ^{10,11}
IV infusion (intended for IV administration)	connected to	Nasogastric (NG) tube ^{10,11}
Primary IV tube	connected to	Blood product (intended for transfusion) ^{10,11}
Enteral feeding (gastric or nasal)	connected to	Tracheostomy tube ³
IV solution	administered via	Blood administration set ^{10,11}
Primary IV solution	administered via	Various functionally dissimilar catheters (such as external dialysis catheter, ventriculostomy port, amnio-infusion catheter, distal port of pulmonary artery catheter) ^{10,11}

Causes of connection-related injuries

According to medical literature, major factors contributing to connection-related injuries are:

- The luer connector, a type of connector that makes connecting unrelated tubing too easy.^{1,2,3,12} For pictures illustrating various types of tubing and luer misconnections, visit the [FDA website](#).
- Workarounds (rigging) – using adapters, tubes or catheters in a manner for which they were not intended.^{3,8}
- Providers making connection errors after going into “automatic” mode due to stress, fatigue or distractions.^{1,4,13}
- Poor lighting and other environmental factors.^{3,12}
- Positioning functionally dissimilar tubing in close proximity to one another – often called the “spaghetti syndrome.”^{3,12}
- Not rechecking or tracing tubing connections after a patient is moved as part of the handoff process, or during other key transitions.^{3,4,9}
- Less-than-optimal reporting of adverse events and near misses as part of efforts to educate and raise awareness⁸ – there is still a fear of repercussions and legal action.

The first of the new ISO connector standards has been adopted

AAMI has already adopted the first of the new ISO connector standards (ANSI/AAMI/ISO 80369-1), which provides guidance to manufacturers on how to create connectors for their own devices. AAMI plans to adopt several more standards during 2014 and 2015 (see current estimated [timeline](#)).¹⁴ It is anticipated that the new connectors will begin to reach the market as early as fourth quarter 2014. There will be a slow, deliberate and careful transition to each new connector. Enteral connectors will be introduced first. For patients who have old catheters in place, there will temporarily be an adapter that will allow continued use, even if the tubing is used with one of the new connectors. The ISO connector standards will cover connections for:

- Intravascular or hypodermic applications (for which the existing luer connectors will be maintained)
- Limb cuff inflation applications
- Enteral applications (involving or passing through the intestine, either via the mouth and esophagus, or through an artificial opening)

- Neuraxial applications (local anesthetics placed around the nerves of the central nervous system, such as spinal anesthesia and intrathecal or epidural anesthesia or analgesia)
- Breathing systems and pressurized (medical) gases applications (Note: manufacturers call these “driving” medical gases)

As of the publication date of this alert, the new ISO connector standards are not expected to be required or enforced in any state other than California ([see California law](#)),¹⁵ but in time, health care organizations will likely find the new connectors to be the only ones on the market.

Actions suggested by The Joint Commission

The Joint Commission offers the following strategies in preparation for the launch of the new ISO connector standards. These suggested actions update the recommendations in the [2006 Sentinel Event Alert #36 on tubing misconnections](#). The first four actions relate specifically to the new ISO connector standards and integrate the “aware, prepare and adopt” themes of the 2014 Get Connected campaign from the Global Enteral Device Supplier Association (GEDSA). The remaining strategies relate to effective processes and procedures, appropriate education and training, effective communication, as well as safety culture-related actions that can help prevent tubing misconnections.

In preparation for the new ISO connector standards

1. Assess and manage: Current risks of injury.
 - ECRI Institute recommends that an interdisciplinary task force (with personnel from nursing, pharmacy, risk management, health care technology management, biomedical engineering, and purchasing) be created to identify potential misconnection hazards and to develop mitigating strategies for combating them.² Focus on areas of highest risk with the most immediate need to convert to the new connectors.
 - Conduct acceptance testing (for performance, safety and usability) and, as appropriate, risk assessment (e.g., failure mode and effects analysis) on new tubing and catheter purchases to identify the potential for misconnections and take appropriate preventive measures.^{2,9,12}
2. Aware: Learn about the upcoming ISO connector standards and prepare for them by generating awareness of impending changes across the organization to all clinicians, administrators, supply chain, health care technology management and support staff. For an overview, see the [FAQs](#) on the Stay Connected 2014 website.¹⁶
3. Prepare: Assess and adapt existing systems, processes and protocols to carefully transition to the new ISO connectors. Begin a dialogue with supplier representatives to learn about their plans regarding the new ISO connector standards and what each supplier will do to help during the transition to these standards. Ensure that the supplier your facility uses is aware of the new ISO connector standards and intends to transition to the new connector designs. Train clinicians and supply chain management on transition plans, *including the use of temporary adapters*.¹⁶
4. Adopt: For each application, there will be a transition period during which current and new connectors are available. As the new connectors become available, purchase only equipment that will conform to the new ISO connector standards; and make an organizational commitment to avoid buying equipment with luer lock connectors for limb cuff inflation, neuraxial, enteral, breathing systems and pressurized gases applications. Luer connectors will continue to be used for intravascular or hypodermic applications.

Effective processes and procedures

5. Trace tubing or catheter from the patient to point of origin:
 - before connecting or reconnecting any device or infusion,^{2,3,9}
 - at any transition, such as to a new setting or service,
 - as part of the hand-off process.Standardize this “line reconciliation” process using high reliability practices. Some examples of high reliability practices include peer checking or peer coaching, and the [STAR \(Stop, Think, Act, Review\) error prevention technique](#) (the acronym is used to help remember to slow down and concentrate on an important action or task).
6. Route tubes and catheters having different purposes in different, standardized directions^{3,9,12} (e.g., IV lines routed toward the head; enteric lines toward the feet). This is especially important in the care of neonates.

7. When there are different access sites or several bags are hanging, tubing should be labeled to mitigate against the chance of misconnection, especially in circumstances where multiple IV lines are in use. Label tubing at both distal (near the patient connection) and proximal (near the source container).
8. Ensure the implementation of safe practices for the administration of high-alert medications. For high-risk medications delivered via an epidural, intrathecal or arterial route, label the catheter and do not use tubing or catheters that have injection ports. Implement an independent double-check procedure to be used during the delivery of high-risk medications, such as intrathecal drugs, as well as during other procedures that have an increased frequency of adverse events.²
9. Use tubing and related equipment only as they are intended to be used.
 - Never use standard luer syringes for oral medications or enteral feedings; use oral syringes for oral liquid medications or enteral feedings until enteral syringes with the new connector are available.
 - Do not use IV tubing or IV pumps for enteral feedings.¹⁷
 - Use distinctly different pumps for IV applications (rather than using similar pumps for intrathecal and/or epidural applications) to reduce the possibility that an intrathecal medication will accidentally be delivered intravenously and vice versa.² As soon as new connectors are available, for the administration of intrathecal chemotherapy, use only syringes, needles and other devices with non-luer connectors that cannot connect to intravenous devices.^{18,19}
 - Eliminate the use of temporary adapters as soon as possible.
 - Don't force connections, and avoid workarounds.^{2,3,9} Forced connections or workarounds could indicate that the connection should not be made.
 - Check vital signs immediately after making any connection.²
10. Take inventory and store carefully
 - Conduct an inventory of all supplies to identify products that need to be discontinued and products that need to be purchased when the new ISO connector standards go into effect.⁹
 - Store medications for different delivery routes in different locations (e.g., keep intrathecal medications in a separate location from IV medications).^{2,3}
 - Package together all parts needed for initiating enteral feeding, including tubing and catheters, to minimize the chance of using dissimilar tubes or catheters that could be connected improperly.

Appropriate education and training

11. Educate staff

- Make sure staff receives proper training, preferably from the manufacturer, before using any connecting equipment.^{2,3}
- Ensure that all personnel performing equipment repairs are aware of misconnection issues and that they avoid modifying devices in ways that might facilitate misconnections.
- After training, provide clear, easy-to-understand reference materials for staff.

Effective communication

12. Communicate to nonclinical staff, patients and visitors that **they must get help from clinical staff** whenever there is a real or perceived need to connect or disconnect devices or infusions.⁹ Inform nonclinical staff, patients and visitors that they should not attempt to connect or disconnect devices themselves. *Note: In some situations in the home care setting, family members and nonclinician caregivers could connect and disconnect devices if they have received training and demonstrated competency.*

Leadership

13. Make the safe adoption of the new ISO connector standards a high priority on the organizational patient safety plan.

Safety culture

14. Identify and improve unsafe working conditions that can lead to harm. Identify, manage and create awareness of conditions and practices that may contribute to health care worker fatigue, inadequate staffing and interruptions, and take appropriate actions to mitigate those working conditions.²⁰
15. Emphasize the responsibility of reporting adverse and serious safety events. Create a culture where the reporting of misconnections or close calls is viewed as a responsibility and an opportunity for learning rather than as something that may be punished.^{3,13} All incidents of adverse events regarding misconnections are reportable to:
 - The Joint Commission, as part of its [Sentinel Event policy](#)

- FDA, through the [MEDWATCH program](#) (may be required by law)
- Institute for Safe Medication Practices (ISMP) [Medication Errors Reporting Program](#)
- Appropriate state agencies

Related Joint Commission requirements

Requirements	Hospital	Ambulatory	Home care	Nursing care
Environment of Care (EC)				
EC.02.01.01 EP 2			✓	
EC.02.01.01 EP 3			✓	
EC.02.04.01	✓	✓		✓
EC.02.04.03 EP 1	✓	✓		✓
EC.02.04.03 EP 2	✓	✓		✓
EC.02.04.03 EP 3	✓	✓		✓
EC.04.01.01 EP 10	✓			✓
EC.04.01.01 EP 12	✓		✓	✓
EC.04.01.01 EP 13	✓			✓
EC.04.01.01 EP 14	✓	✓		✓
EC.04.01.01 EP 15	✓	✓		
EC.04.01.01 EP 17			✓	
EC.04.01.01 EP 18			✓	
EC.04.01.03	✓	✓	✓	✓
EC.04.01.05	✓	✓	✓	✓
Human Resources (HR)				
HR.01.05.03	✓	✓	✓	✓
Leadership (LD)				
LD.04.04.05	✓	✓	✓	✓
Provision of Care, Treatment, and Services (PC)				
PC.02.01.01	✓	✓	✓	✓
PC.02.01.09		✓		
PC.02.01.19	✓			+
PC.02.03.01			✓	

+ For organizations that elect Joint Commission Post-Acute Care Certification option

See the content of these [standards](#) on The Joint Commission website, posted with this *Sentinel Event Alert*.

Resources

- [Timeline](#) for implementation of new ISO connector standards
- [Stay Connected 2014 website](#) of GEDSA (The Joint Commission is a supporting organization of Stay Connected)
- [FDA website](#): Examples of tubing and luer misconnections
- Connections Portfolio: [Tubing misconnections self-assessment for healthcare facilities](#), ISMP and Baxter. Includes data collection instructions and tool, action plans, and action plan templates.
- [AAMI Resources on Small-Bore Connectors](#)
- [Executive Insights on Healthcare Technology Safety](#): See section on “Luer Connectors” and in the online [Report Resources](#). AAMI and ECRI Institute, June 2014
- Kimchi-Woods J, Shultz JP: Using HFMEA to assess potential for patient harm from tubing misconnections, *The Joint Commission Journal on Quality and Patient Safety*, July 2006, 32(7):373-381. Includes an assessment tool.

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Patient Safety Advisory Group

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