

health. DEVICES

PREVENTING MISCONNECTIONS OF LINES AND CABLES

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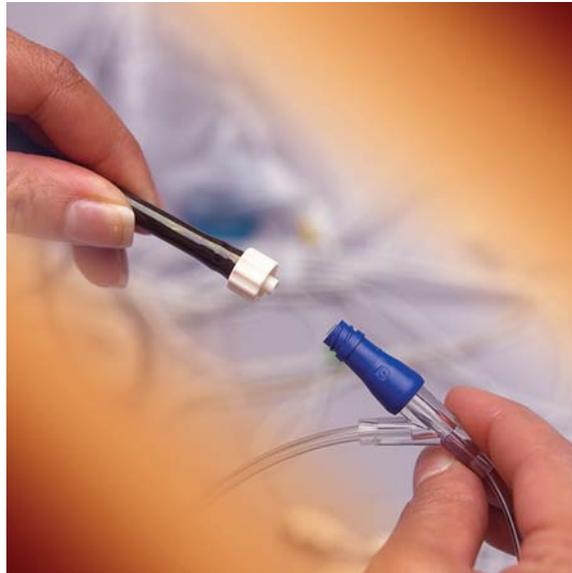
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Preventing Misconnections of Lines and Cables



Summary. The hospital environment is filled with lines and cables connecting medical devices with patients. With so many connections to be made, it's not surprising that, occasionally, one of them will be incorrect. Often, such mistakes are caught before harm is done. But when they aren't, patients can be harmed or even killed.

There are two basic ways in which hospitals can reduce the likelihood of misconnections, and they should be applied together. First, whenever possible, hospitals should purchase equipment whose design makes a misconnection unlikely or prompts users to make the correct connection. Second, hospitals should implement general policies and specific work practices that keep misconnections to a minimum. In concert with these efforts, hospitals should conduct a risk assessment to identify specific misconnection hazards within the facility.

This article describes the specific steps hospitals should take to tackle misconnections. It also pinpoints the more important misconnection scenarios to look for during a risk assessment. And it includes a checklist that will facilitate not only the risk assessment but also the overall misconnection-prevention endeavor.

Misconnection Risks in the Hospital

Overview of the Problem

Whenever lines or cables link patients to medical devices, or medical devices to each other, there is the potential for a misconnection. Even in routine care settings, lines and cables proliferate. For example, a single patient can be connected to several devices used for diagnostic, therapeutic, or monitoring purposes. This multiplicity of connectors can cause clinicians to become confused about each line's purpose and connection. Such visual clutter—added to the stress, fatigue, and distraction so typical of the clinical environment—can make misconnections more likely.

Clinical literature and event-reporting databases—such as the MAUDE database of the U.S. Food and Drug Administration (FDA) and ECRI's Problem Reporting System—cite numerous cases of misconnections that have resulted in patient injury or even death. Nitrous oxide (N₂O) has been mistakenly delivered in place of oxygen, for example, and enteral feeding solution has been delivered intravenously. And there are doubtless many more misconnections that aren't documented.

Human error is inevitable. Training and awareness can only accomplish so much. Therefore, a key aspect of prevention is to design devices in a way that makes misconnections unlikely or impossible. To that end, a number of standards have been developed that provide design guidelines for preventing certain types of misconnections. For example, to avoid misconnection to an intravenous (IV) line, enteral administration sets are now made with connectors that are physically incompatible with the standard Luer fittings found on IV lines. Design changes like this one have successfully reduced the frequency of these misconnections and, therefore, have reduced risk to patients.

Unfortunately, there are still many serious misconnection risks for which no design standards or guidelines exist. Healthcare facilities should develop institutional policies and staff work practices to address these sorts of risks. In addition, we recommend conducting a risk assessment to identify misconnection hazards that may be particular to your facility.

Types of Misconnections

Misconnections vary greatly in type and in the severity of their outcome. Below, we describe a number of potential

misconnection hazards, organized according to the types of lines or cables involved, and illustrated by case reports.*

CABLE MISCONNECTIONS

Cables are often attached to patients for monitoring purposes or are used to connect medical devices to power sources. Cable misconnections can have outcomes such as patient burns and equipment damage. Electrocuting is also possible, though much less likely.

The main scenarios for cable misconnections are:

- (1) A cable is plugged into the wrong jack.
- (2) A cable is plugged into the correct jack but in the wrong orientation—which can happen, for example, when a keyed connector becomes worn and no longer prevents misalignment.
- (3) A cable is plugged into the correct jack, but not fully inserted.

CASE REPORTS

Wrong jack, wrong fit. ECRI investigated an accident involving a cable for a heated OR mattress that was connected to the wrong jack of the temperature controller. The cable was plugged into a seven-pin jack instead of the intended, similar-size five-pin jack. This happened at two different hospitals and resulted in anesthetized patients being badly burned. The manufacturer had not labeled the visually similar jacks. Also, even though one of the jacks was used only rarely, no cover plate was originally available from the supplier (one was later provided to customers). For details, refer to the Hazard Report "Improperly Connected Cord Leads to Patient Burns on Advanced Surfaces Cool/Heat Mattresses" in the June 2005 *Health Devices*.

Right jack, incomplete fit. ECRI reported on a misconnection between a bipolar pacing catheter and a pacing cable. The design of the pacing catheter's connector led a user to unwittingly plug the catheter only partway into the pacing cable. As a result, the electrical connectivity between the components was unstable, and pacing suddenly stopped, causing the patient to go into asystole. For details, refer to the Hazard Report "Misconnection Between St. Jude Medical Pacel Bipolar Pacing Catheter and Pacing Cable Causes Improper Pacing" in the October 2005 *Health Devices*.

GAS-GAS MISCONNECTIONS

Gas lines are commonly used for respiratory support or to power pneumatic medical equipment. Because ventilation is critical, misconnecting the lines of a breathing circuit or delivering the wrong respiratory gas can seriously injure a patient. Gas misconnections that don't involve ventilation

* Note that, in addition to the misconnections listed here, cable-liquid and cable-gas misconnections are also theoretically possible. However, they are rare enough that we haven't addressed them in this article.

Factors That Contribute to Misconnections

This table lists some of the factors that can make misconnections more likely, along with some of the steps hospitals can take to reduce their likelihood.

Factors	Remedies
<p>Disconnections. The more often lines must be reconnected, the greater the chance for a misconnection (since not everyone who might reconnect a line will know to trace it back to its origin).</p>	<p>Train nonclinical staff—and instruct visitors—not to reconnect lines. Only clinicians or users knowledgeable in the use of the device should make a reconnection.</p> <p>When you make a connection, check that it is secure.</p> <p>Ensure that clinical staff know to trace lines back to their origin when making reconnections.</p> <p>When possible, use connector designs (e.g., locking connectors) that reduce disconnections.</p>
<p>Adapters. Using adapters can defeat design solutions by permitting connections that are meant to be impossible.</p>	<p>Use adapters only when necessary.</p> <p>Remove adapters from care areas where they aren't essential.</p>
<p>Luer fittings. Because they are so widely used, they allow a variety of lines to be connected, with no indication that the connection might be inappropriate.</p>	<p>Avoid buying nonintravenous/nonintravascular equipment that can mate with female Luer connectors.</p> <p>Consider replacing equipment having nonessential Luer fittings with equipment having less widely used connectors.</p>
<p>Look-alike connectors/unlabeled jacks. A jack that isn't labeled is more likely to have an incorrect line plugged into it.</p>	<p>During prepurchase acceptance inspection, look for unlabeled jacks, and have the manufacturer apply the appropriate labels.</p>

can cause serious harm, too. For example, patient injury has resulted when pressurized gas lines, intended to pneumatically power a device, are confused with suction lines.

CASE REPORTS

Respiratory gas misconnection. ECRI reported on a patient death from asphyxiation that occurred when N₂O was delivered instead of oxygen. Investigation revealed that the oxygen flowmeter had been forced onto an already damaged N₂O wall outlet, overriding the original safety mechanism. For details, refer to the following reports from *Health Devices Alerts*: “Oxygen Flowmeters: Report of Death Caused by Misconnected Flowmeter,” Accession No. A6033, January 7, 2005; and “Misconnected Flowmeter Leads to Two Deaths,” Accession No. S0003, January 25, 2002.

Breathing circuit misconnection facilitated by an adapter. ECRI recently investigated a case in which a newborn was seriously injured because a clinician mistakenly attached the inspiratory limb of a ventilator breathing circuit to the exhaust port of the ventilator. Normally, the inspiratory limb connector is not compatible with the ventilator's exhaust port. However, an adapter had been used, making the connection physically possible. For details, refer to the Hazard Report “VIP Infant Ventilator Seriously Injures Newborn” in the August 2005 *Health Devices*.

LIQUID-LIQUID MISCONNECTIONS

Liquid lines are primarily those that deliver nutrients or medications to patients, but this category also includes other solution lines, such as flush lines and those used for

circulating water baths. Because liquid delivery lines are often direct points of access into the body, misconnecting them can result in a substance entering the wrong body part, possibly with deadly consequences.

CASE REPORTS

Wrong delivery route. Mistaken delivery routes are found in dozens of case reports. Many reports describe IV medications being delivered into the intrathecal space or intrathecal medications being delivered intravenously. Other reports recount the confusing of epidural and IV delivery routes. In all these cases, the equipment was outfitted with Luer connectors that were physically compatible but should never have been connected. (See the discussion of Luer connectors on page 91 and in the supplementary article on page 84.) In many of these cases, the patient died.

Enteral or sterile water bags incorrectly connected to an IV line. ECRI recently received a report of a solution from an enteral feeding bag being delivered intravenously. A prefilled enteral feeding bag was incorrectly spiked using an IV administration set rather than an enteral one. The mistake was eventually noticed, but not before solution was infused. No permanent injury to the patient was noted in this case, but other reported cases have been fatal.

ECRI also received a recent report of a sterile water bag, intended for use with a humidification system, being misspiked with an IV administration set. (The facility had previously purchased sterile water in bottles rather than bags.) Fortunately, in this case, staff recognized their error before making

a connection to the patient, but ECRI is aware of similar instances in which patient injury did result.

GAS-LIQUID MISCONNECTIONS

These happen when gas and liquid lines are erroneously connected together. Gas-liquid misconconnections are typically severe and usually result in gas being introduced into the vasculature or liquid entering the respiratory tract.

CASE REPORTS

Unintended gas delivery in a liquid line. Numerous reports exist of respiratory gas or pressurized air lines being misconnected to patient IV lines. Fatal air embolisms have resulted. ECRI published a Hazard Report warning clinicians of the dangers of connecting the Luer fittings on IV administration sets to those on noninvasive blood pressure or pneumatic compression devices. Refer to “Fatal Air Embolism Caused by the Misconnection of Medical Device Hoses to Needleless Luer Ports on IV Administration Sets” in the June 2004 *Health Devices*.

Unintended liquid delivery in a gas line. Event-reporting databases list several instances of the Luer

fittings of IV administration sets being misconnected to the inflation (pilot) tubes of tracheostomy cuffs, such that IV solution was delivered to the inflation tube. The fluid buildup caused the inflation tube to rupture, obstructing the patient’s airway and resulting in severe injury or, in some cases, death.

Keeping Misconnections to a Minimum

General Preventive Approaches

There are two basic means by which misconconnections can be minimized: (1) equipment design solutions—that is, changes made by manufacturers to the design of their products—and (2) administrative controls implemented in the form of general hospital policies and specific work practices.

About Luer Fittings

Originally designed as connection systems for syringes and needles, Luer fittings have male and female components that are mated together to join two devices. Each component has a 6% conical taper, which keeps the components together once they are pressed into place. Two female components cannot be connected, nor can two male components.

The basic Luer fitting is referred to as a Luer slip. To enhance the security of the connection, a locking

mechanism can be added to the male component in the form of a threaded collar known as a skirt. With the skirt, the connector is called a Luer lock.

Luer fittings are easy to use and easy to manufacture. The simplicity of their design makes them very popular. A number of medical devices (including intravascular, enteral, and respiratory equipment) utilize these fittings. ♦



Female Luer connector



Male Luer connectors. A male Luer slip (left) and Luer lock (right). The threaded collar on the Luer lock secures the connection and reduces the likelihood of disconnection.



Visual cues aren't everything. These connectors are different colors and different shapes. But a user who overlooks these cues can still fit the components together—which is why introducing physical incompatibilities is important.

- **Equipment design** solutions either prevent the operator from making a misconnection or prompt the correct connection. Several types of design solutions exist, each with varying levels of effectiveness. The most reliable design approach is one that leaves the user with little or no choice but to make the correct connection—for example, by making a connector and jack compatible only with each other and not with any other type of fitting. Such a solution is called a *forcing function*. Solutions that attempt to prompt the user to make a correct connection, such as giving the connector and its jack the same color, are useful but less effective because they rely on the user to recognize the prompt and respond appropriately. And even the best of these solutions can be defeated by the use of adapters, excessive force, or wear and tear. Users must be taught how not to override these safety characteristics. (The supplementary article on page 86 describes the basic types of design solutions.)
- **Administrative controls** are work practices and policies that hospitals can implement to mitigate misconnection hazards. For example, the hospital might set a policy that all lines should be traced back to their origin before a connection is made. These solutions tend to be less effective than design solutions—particularly forcing functions—because they rely on clinicians to take the correct action instead of removing the hazard at the source. Still, these solutions can also help to increase safety.

It's important to recognize that neither of these approaches alone is universally effective. Even well-designed equipment can have its safeguards defeated by

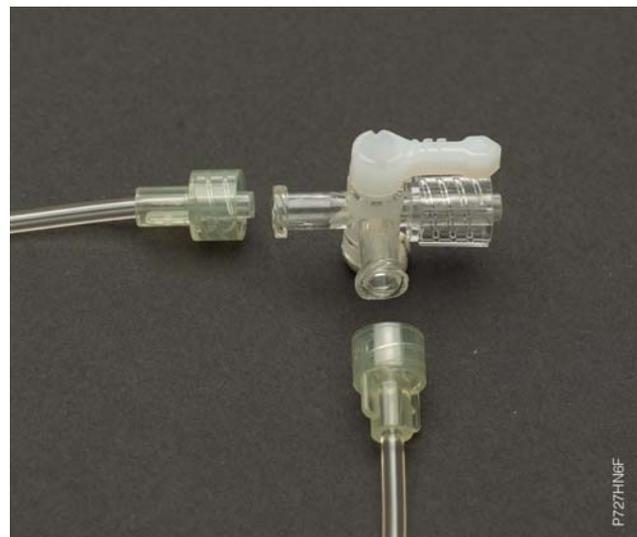
untrained individuals who are unfamiliar with the safety mechanisms of a device or unaware of the risks of inadvertently defeating those mechanisms. For example, an operator may use excessive force to make a connection that is meant to be impossible, or may obtain an adapter to attach two devices that normally wouldn't connect.

We recommend that hospitals do what is within their power to incorporate both preventive approaches—that is, buy well-designed equipment whenever possible and implement safe work practices and policies to complement that equipment. Of course, there may be some devices for which no effective design solutions exist. In these cases, hospitals should then rely on administrative controls to reduce the possibility of misconnection errors.

Specific Preventive Steps

In the sections that follow, we describe practices and policies you can put into place to reduce misconnection risks. We have divided our recommendations into essential actions that you should definitely pursue and additional strategies that you should consider if they seem workable in your environment.

The fact that most of these recommendations are directed toward healthcare facilities and users is not meant to minimize the responsibility that manufacturers bear for



The danger of adapters. The adapter shown here allows the connection of two male Luer locks, which ordinarily should not be connected. While there may sometimes be legitimate reasons for making such a connection, clinicians should be mindful that the very need for an adapter could be a sign that an incorrect connection is being attempted.

reducing misconnections through effective preventive designs. And hospitals should recognize that their purchasing power is an influencing factor driving the medical device market—if hospitals demand devices that can prevent misconnections, manufacturers will try to incorporate such features into their products.

ESSENTIAL ACTIONS

The following actions are ones we recommend for all hospitals. We have divided our recommendations into (1) work practice solutions directed toward clinical users and (2) policy-level solutions directed toward patient safety officers, clinical engineering, risk management, and purchasing (materials management) personnel. All these personnel, including nurses and clinicians, should be involved in developing and implementing solutions.

For Clinical Users

- Trace all lines back to their origin before making connections. Doing so verifies that the correct lines will be joined, thus avoiding obvious errors such as connecting a respiratory gas line to a patient's IV line. Although tracing each line may take extra time, it's a necessary measure to prevent mishaps.
- Don't force connections. If a connection is difficult to make—that is, if it requires a lot of effort—chances are you shouldn't make it. Also, if you notice that a connection is not secure, check to see that the right components have been connected.
- Don't use adapters unless they are clearly required for the application. Be aware that using an adapter might permit the connection of two inappropriate components (e.g., two female Luer connectors, two different-size breathing-circuit components). In fact, the very need for an adapter could be a signal that the connection you're trying to make shouldn't be made.
- Make sure you receive training from the manufacturer before using the equipment. Training makes staff less likely to use the equipment incorrectly and more likely to understand its safeguards.

Equipment Design Solutions

Equipment design solutions—which either prevent the operator from making a misconnection or prompt him or her to make the connection correctly—fall into three basic categories.

Physical Incompatibilities between Connectors

This solution serves as a forcing function because it forces the user to take the correct action. Physical incompatibilities have the effect of either (1) making certain types of connections physically impossible (under normal circumstances) or (2) allowing the connector to be linked only in the appropriate orientation. Keyed connectors, diameter indexing, and function-specific connectors are examples of physical incompatibilities.

Connectors with Locking Mechanisms

Often, misconnections are made after a device has become disconnected and is then mistakenly fastened to another component. Designs that reduce the likelihood of accidental disconnection—such as locking

mechanisms—also reduce the potential for a subsequent misconnection.

Connectors with a Distinct Physical Appearance

Misconnections have occurred when users have forced connections between connectors that are not designed to be physically compatible but that appear similar. Varying the size, shape, and color of connectors and matching these attributes with their intended jacks (e.g., a square blue connector plugs into a square blue jack) can help make it obvious to the user which items should be linked.

However, these solutions are not foolproof. Colors may fade over time, color-blind individuals may not see color-coding schemes, colors may not be visible in low light, and distracted individuals may ignore color, size, and shape cues. Such solutions are not effective by themselves because they rely on the user to both recognize them and use them correctly. They should be used in combination with other equipment design solutions and safe work practices. ♦

- Report all misconnections—even those that are caught before harm is done—to clinical engineering, the patient safety officer, risk management, the device manufacturer, and ECRI (through the Problem Reporting System at www.ecri.org/problemreport). Such reports will highlight the true frequency of misconnections and will drive industry change. It’s easier to justify applying financial and labor resources to find solutions when awareness of the problem is increased.

For Other Staff

- Provide periodic training about misconnection prevention to all personnel working in patient care. Clinicians need reminders of safe work practices, and all staff should know about the consequences of misconnections. For example, people not trained or authorized to use the equipment—including housekeeping and other personnel, and even the patient’s family and other visitors—should call for help rather than attempting to reattach lines that have become disconnected.
- Review the use of adapters throughout the hospital and discourage their routine use. Only adapters clearly required for specialized clinical applications should be stocked and used. Adapter review should be conducted by a multidisciplinary team that includes personnel from nursing, risk management, clinical engineering, and purchasing. (This team can be the same one that conducts the misconnection risk assessment described on page 89.)
- Review purchasing policies to ensure that, whenever possible, only equipment with effective design solutions is purchased. Conduct prepurchase evaluations, in which users (e.g., nurses, clinical engineers) have the opportunity to “play” with the device. This is a unique opportunity to uncover misconnection hazards and other issues before the device is acquired. A pre-purchase evaluation is important for two reasons: First, ensuring that “accident waiting to happen” products don’t enter the patient care environment reduces the potential for misconnections. Second, refusal to buy such equipment will drive manufacturers to create better-designed products. Some specific recommendations are provided in the supplementary article on page 88.
- Review inspection criteria and maintenance procedures to address misconnection concerns. During acceptance testing, clinical engineering personnel should look for unlabeled jacks on capital equipment and have the manufacturer apply labels. (If the hospital must apply them, first consult the manufacturer to determine what labels

are appropriate.) During inspection and preventive maintenance procedures, clinical engineering should assess all fittings and replace worn connectors to ensure that safety mechanisms, such as keyed connectors, are functional. Such maintenance could prevent errors in the clinical environment. In addition, plugs and jacks should be checked for interchangeability; if they can be interchanged, develop a mitigating strategy and notify the risk assessment task force (discussed later in this article). If possible, contact the manufacturer to have the connectors changed.

- Clinical engineering should ensure that all personnel performing equipment repairs are aware of misconnection issues and that they avoid modifying devices in ways that might facilitate misconnections.
- All misconnections should be reported and tracked by the hospital (this can be done by the misconnection task force) to identify new areas of concern. Compiling reports can also help to determine whether work practices or other mitigation efforts have been successful. In addition, report misconnections to both the manufacturer and to ECRI through the Problem Reporting System at www.ecri.org/problemreport.

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The value of keyed connectors. Although the three jacks look almost identical, the plug shown in the inset can only attach to the top right-hand jack because of the position of the pins and the slot in the plug. Thus, even if a clinician tries to insert the plug into the wrong jack, the connection won’t be possible.

Purchasing Strategies to Reduce Misconnections

One way to reduce misconnections is to purchase equipment whose design prevents inappropriate connections or facilitates correct ones. The following recommendations pinpoint specific measures that hospitals should adopt whenever possible.

- ▶ Avoid buying nonintravenous equipment—such as pneumatic compression devices, nebulizers, and noninvasive blood pressure devices—that can mate with female Luer connectors. (We specify nonintravenous equipment because Luer connectors are standard on certain intravenous equipment, and their use cannot be avoided.)
- ▶ Ensure that your hospital’s 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, or those that do not mate with female Luer connectors. These devices must also be clearly labeled (e.g., “Not for IV Use”).
- ▶ Avoid buying sterile water packaged in 1 L spikable bags that might be mistaken for IV fluids.
- ▶ Avoid buying prefilled enteral feeding bags, or ensure that the enteral administration set is packaged with the enteral feeding bag before it is sent to the floor. (You might secure it to the bag with a rubber band, or request that the manufacturer supply pre-attached sets.) Doing so will prevent the bags from being spiked with IV administration sets.
- ▶ Obtain enteral pumps that feature an automatic flush mode, so that clinicians won’t need to manually flush lines and are therefore less likely to want adapters to allow a link between the enteral administration set and a Luer connector.
- ▶ Only purchase electrosurgical equipment that complies with electrical safety standards such as ANSI/AAMI HF18 and the International Electrotechnical Commission’s IEC 60601-2-2.
- ▶ Verify that a device meets the U.S. Food and Drug Administration’s (FDA) performance standard for electrode lead wires and patient cables, and ensure that devices with conductive cables are protected so that they cannot be attached to a patient and plugged into an electrical outlet at the same time. The same applies to replacement lead sets. (The FDA performance standard is discussed in a Regulatory Update in the April 2000 *Health Devices*.)
- ▶ Only purchase medical gas equipment that comes with safety mechanisms such as pin or diameter indexing systems.
- ▶ Purchase equipment whose connectors have locking mechanisms. Often, mishaps occur when components become disconnected and are mistakenly reconnected, particularly when the person reconnecting the line—a visitor or family member, for example—doesn’t know to trace the line back to its origin to ensure the connection is correct. Preventing disconnections reduces the risk of misconnections.
- ▶ If you must purchase electronic devices that don’t prevent misconnections, choose those that alarm (visually and/or audibly) if a misconnection has occurred.
- ▶ In general, avoid buying equipment on which connectors for different functions are interchangeable or look alike.

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ADDITIONAL STRATEGIES

Consider the following strategies in addition to the ones just listed. Some of these may not be practical for your situation, but they're all worth thinking about.

- Ensure proper lighting when making connections. If necessary, use a flashlight to confirm that the correct lines are connected. The probability of joining similar-looking devices is reduced in well-lit environments. Well-lit areas also make color coding easier to see.
- Develop a policy of positioning different lines (e.g., catheters, feeding tubes) on different sides of the patient. Consistently putting lines in the same place might make it easier for clinicians to correctly identify them and connect them appropriately.
- For devices that are outfitted with Luer fittings but that are not intended to enter the vasculature—and for which Luer fittings therefore might not be essential—contact the manufacturer to determine whether the Luer fittings can be replaced with different types of connectors. (An alternative approach might be to get the manufacturer's written permission to modify the devices in-house.) Note, however, that if this new connector is used for multiple types of devices, as Luer fittings are, it could introduce similar misconnection risks. Also note the importance of ensuring that all lines and accessories purchased for use with the new connectors are compatible with them.



An additional level of protection. Not only is the plug physically compatible with just one of the jacks, but it is also color coded to further prompt users to make the correct connection. This is a good example of using multiple levels of equipment design solutions.

If alternate connectors cannot be used, consider altering the sequence of male-female Luer fittings—that is, arranging lines so that two components that should not be connected end in Luer connectors of the same sex. This simple solution could be defeated rather easily, however, by an adapter. (Luer fittings are discussed in more detail on page 91 and in the supplementary article on page 84.)

- 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. Independent double-check procedures can be very time consuming and labor intensive, however, and should not be applied to routine procedures. As part of the risk assessment described in the next section, facilities should identify situations in which a double-check policy would be beneficial and practical.
- Store medications for different delivery routes in different locations (e.g., keep intrathecal medications in a separate location from IV medications).
- Use distinctly different pumps for IV applications and intrathecal or epidural applications. Doing so will reduce the possibility that an intrathecal medication will accidentally be delivered intravenously and vice versa.
- Use color-coded, well-labeled administration sets to be used only with intrathecal or epidural delivery.

Conducting a Risk Assessment

The steps detailed above will go a long way toward minimizing your misconnection risks. But your hospital is likely to have specific circumstances that require special attention. For example, your work practices may increase the likelihood of certain types of misconnections. Or you may not be able to use devices that are protected against misconnections. To identify these sorts of situations, and to gauge your overall risk status, we recommend that you conduct a formal assessment of misconnection risks in your facility.

In 2002, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) mandated that accredited facilities perform at least one “proactive risk assessment” of a high-risk process each year. (Refer to “Failure Mode and Effects Analysis: A Hands-On Guide for Healthcare Facilities” in the July 2004 *Health Devices* for more information.) ECRI recommends making your misconnection evaluation one of these assessments.

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Misconnection Prevention Checklist

As described in the accompanying Guidance Article, ECRI recommends that a multidisciplinary task force (with personnel from nursing, risk management, clinical engineering, and purchasing) be created to identify potential misconnection hazards and to develop mitigating strategies for combating them. This checklist can then be used to determine whether misconnection concerns are being effectively addressed.

Prepurchase Equipment Evaluation/ Acceptance Testing

A prepurchase evaluation should be performed by a multidisciplinary task force before a purchasing decision. Whenever possible, avoid purchasing devices that are likely to facilitate misconnections.

These same items should also be checked during the acceptance tests conducted by clinical engineering. If misconnection risks are discovered at that stage, contact the patient safety officer and the misconnection task force to develop solutions.

- 1.1 Are all jacks labeled? If not, contact the manufacturer to have labels applied. (If you apply them yourself, first verify their correctness with the manufacturer.)
- 1.2 Does the device comply with relevant standards against misconnections? Or, if there are no relevant standards, does the device incorporate a forcing function such as connector incompatibility? In addition, do connectors and jacks discourage misconnection—for example, do different connectors look different? If not, consider other purchase options.
- 1.3 If a misconnection is made, will the device alert you to it? This is preferred.
- 1.4 Do the connectors have a locking mechanism? This is preferred.
- 1.5 Is the device designed so it cannot be inappropriately connected to an IV line? If not, consider other purchase options.

Scheduled Inspection

To be performed by clinical engineering.

- 2.1 Are all jacks on capital equipment still labeled?
- 2.2 Are connectors in good physical condition, without excessive wear or damage? Are keyed connectors and locking mechanisms fully functional? If not, have them replaced.
- 2.3 Are medical gas and vacuum systems inspected annually, or more frequently in areas of high gas use, such as the emergency department? (Refer to the *Health Devices Inspection and Preventive Maintenance System* inspection procedure for medical gas and vacuum systems, Procedure No. 440-20010301.*)
- 2.4 Are medical gas fittings, hoses, flowmeters, and regulators inspected at least every five years to ensure proper working order?

Clinical Use

To be performed by nursing staff/clinicians.

- 3.1 Have you been properly trained in the correct setup of this device? If not, ask for help from a trained individual.
- 3.2 Did you trace each line back to its origin before making the connection?
- 3.3 Did you have to use an adapter or excessive force? If so, this may be an incorrect connection.
- 3.4 Did you verify that the connection is secure? If there is a locking mechanism, did you activate it?
- 3.5 Is there adequate light to see the connection?
- 3.6 Did the patient's vital signs unexpectedly change after you made the connection? If so, it may have been the wrong one.
- 3.7 If there was a misconnection, did you report it? ♦

* The *Health Devices Inspection and Preventive Maintenance (IPM) System* includes more than 70 procedures covering more than 150 devices. For information about the *IPM System*, contact Tim Ritter at +1 (610) 825-6000, ext. 5168, or at ipm@ecri.org.

(continued from page 89)

To do this, you should assemble a multidisciplinary task force to identify potential misconnection hazards and develop the appropriate mitigating strategies. Clinical engineering personnel are likely to serve a primary or leadership role in this effort because they are normally involved in equipment purchasing, inspection, maintenance, and user training across multiple departments. Personnel from nursing, risk management, and purchasing/materials management also should participate.

Because connectors are everywhere in the hospital, the task force must prioritize its efforts. It should determine which locations or procedures pose the greatest risk and address those first. Below, we describe four scenarios that are likely to present high levels of risk for most hospitals. (Your facility's particular circumstances may vary.) We then note two other scenarios that pose lesser risks but that should still be examined. On page 90, we provide a checklist that can be used by the task force and by staff members carrying out the task force's recommendations.

HIGH-RISK SCENARIOS

Patients are at greatest risk when attached to devices without equipment design solutions or with only marginally effective ones. The scenarios described here involve such equipment.

Misconnection of Luer Fittings

Luer connectors, often called Luer fittings, are used in an array of medical devices, from syringes to IV catheters to blood pressure cuffs. (Further description can be found in "About Luer Fittings" on page 84.) The widespread use of Luer fittings means that there are a large number of devices used throughout a facility's clinical care areas that share compatible connectors even though they should never be connected. Examples of Luer misconnections include connecting intrathecal devices to IV lines and vice versa, connecting pressurized air lines to IV lines, and connecting IV lines to the pilot tubes of tracheal cuffs.

Addressing the misconnection risks associated with Luer-connected devices should probably be the highest priority for most healthcare facilities. For one thing, Luer misconnections can easily go unnoticed, since they involve the connection of physically compatible components. Additionally, the more Luer connectors used within a care area, the greater the odds of a misconnection. And some of the connections for which Luer fittings are commonly used—IV lines, for example—are ones for which a misconnection can be especially dangerous.

The most effective way to prevent Luer misconnections is to replace equipment that has Luer fittings with different connector types whenever feasible. Some Luer use is unavoidable—in particular, Luer connectors are standard on certain IV equipment, and replacing them isn't an option. But where Luer-connected equipment isn't required (e.g., on noninvasive blood pressure devices), its use should be kept to a minimum. And hospitals should keep this issue in mind when making equipment purchases.

Unfortunately, there are almost no standards for manufacturers to follow in making Luer connectors physically incompatible. (One exception, for enteral feeding sets, is discussed below under "Spiking Prefilled Enteral Feeding Bags with IV Administration Sets.") However, several standards committees are developing such guidelines. The Association for the Advancement of Medical Instrumentation (AAMI) recently formed a committee to create a standard entitled "Medical Device Tubings Connectors Standard to Prevent Mis-connections," and the European Committee for Standardization (CEN) has a working draft of a standard entitled "Small Bore Connectors for Liquids and Gases in Healthcare Applications."

These standards may restrict the types of devices that use Luer connectors and may provide instruction on the types of connectors that should be used instead. To be effective, however, such changes will require agreement between different standards committees and cooperation from the medical device industry. Consequently, it will likely be years before either of these standards is approved and widely implemented. In the meantime, hospitals should implement the misconnection-prevention work practices and policies described elsewhere in this article.

Misconnecting the Breathing Circuits of Ventilators and Anesthesia Units

Breathing circuit misconnections are becoming less common, but such mistakes are still made. They are often facilitated by the use of adapters. Also, many breathing circuit connectors do not have locking mechanisms, and misconnections often result after a line becomes disconnected and subsequently attached to the wrong component.

Several design standards specify connector dimensions for breathing circuits used in ventilators and anesthetic equipment. Specifying such dimensions ensures that connectors that are not meant to be connected will be of incompatible size. The adoption of these standards has greatly reduced the frequency of problems, though misconnections continue to occur.

Spiking Prefilled Enteral Feeding Bags with IV Administration Sets

Enteral feeding sets can be erroneously connected to devices that have female Luer connectors, such as parental administration sets, IV catheters or ports, epidural catheters, and balloon inflation ports. To address this problem, in 1996 the American National Standards Institute (ANSI) and AAMI published ANSI/AAMI ID54, “Enteral Feeding Set Adapters and Connectors,” which outlined requirements for such devices. Specifically, the standard required that enteral feeding set connectors and associated adapters not be compatible with female Luer connectors. Since the introduction of this standard, far fewer misconnections of this type have been reported.



Enteral feeding bags are marked (inset) to warn users against mistakenly using them for IV infusions, a potentially fatal error. But these markings are sometimes overlooked. A more effective safeguard is the “Christmas tree” connector (the red component in the main photo), which is incompatible with the Luer connectors used on IV lines. As an additional precaution, ECRI recommends buying enteral feeding bags with the administration sets preattached (as opposed to prefilled bags, which aren’t shipped with enteral sets attached), to keep them from being misspiked with IV administration sets.

However, the standard was issued before prefilled enteral feeding bags gained popularity, so it did not address the misconnection risks associated with them. Prefilled feeding bags are intended to be spiked with an enteral administration set. Unfortunately, it is easy to mistakenly spike them with an IV administration set instead, sending nutrients intended for the stomach into the patient’s bloodstream. The same is true of sterile water, which is sometimes packaged in bags and could be mistaken for an IV bag and consequently misspiked.

Misconnecting Gas or Vacuum Supplies

Instances of gas- and vacuum-supply misconnections still occur, although they have been reduced by the acceptance of standards for gas-supply connections. Such standards cover most commonly used gases, including oxygen, air, and N₂O, as well as vacuum; they also include both tank connections (e.g., 2,200 psi) and line connections (e.g., 50 psi) and apply to both source (e.g., wall outlet) connectors and equipment connectors. They are often required by local codes.

The standards apply systems such as pin and diameter indexing, both of which operate using physical incompatibilities to help avoid misconnections. For example, they prevent the connection of a flowmeter intended for oxygen delivery to the N₂O or vacuum connections that might be on the same wall panel as the oxygen outlet. Gas fittings and outlets are also color coded (e.g., green for oxygen, blue for N₂O) to help identify the type of gas they contain. The implementation of such designs has greatly reduced the frequency of medical gas misconnections.

However, misconnections still occur, since labels can be defaced or removed, colored plastic can change color, colors and labels can be ignored, or unique connectors can become damaged and allow the misconnections they’re intended to prevent. Misconnections can also result from the use of adapters or from intentional modifications or errors made during repairs (such that the wrong connector is placed on the equipment supply line). It is therefore important to train employees on the correct operation of such devices and to perform regular inspections and preventive maintenance on the connectors and fittings of gas systems.

LOWER-RISK SCENARIOS

The following misconnection risks are ones for which effective solutions are commonly available. The industry-wide adoption of design solutions has reduced misconnection risks in these two settings. However, healthcare facilities must remain aware of these situations so that

only well-designed devices are purchased and safety mechanisms are not overridden.

Electrosurgical Misconnections

As of 1993, the American National Standard for electrosurgical devices (ANSI/AAMI HF18) required that connectors on electrosurgical accessories not intended for connection to switched monopolar outputs be constructed to prevent connection to such outputs. Since the introduction of these standards, serious electrosurgical misconnections have decreased, but incidents are still reported—one as recently as March 2004. This is due in part to the fact that older equipment is still in use and to the fact that manufacturer compliance with these standards is voluntary.

Cable Misconnections Resulting in Electrocutation

In 1997, FDA published its final rule establishing a performance standard for electrode lead wires and patient cables. It required that any lead or cable used to make a patient connection from any diagnostic or therapeutic medical device had to be protected so that it was incapable of making conductive contact with an AC power source (e.g., power cord, wall outlet). Since this rule went into effect, the frequency of cable misconnections resulting in electric shock or electrocution has declined.

Because medical devices must now comply with this rule, misconnections involving patient-contacting cables and leads with line power sources are unlikely. Of course, facilities should be aware of this hazard and should only buy devices with protected leads, along with protected replacement leads and cables. (For details, refer to “FDA Establishes Performance Standard for Electrode Lead Wires and Patient Cables” in the January 1998 *Health Devices*.)

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More about Misconnections

In addition to the material cited in the bibliography, the following may be of interest:

JCAHO (the Joint Commission on Accreditation of Healthcare Organizations) is drafting a Sentinel Event Alert that will specifically address tubing misconnections. The alert is expected to include commentary from members of ECRI’s Health Devices Group.

Other related Sentinel Event Alerts include one on preventing the inadvertent intrathecal administration of vincristine and another on medical gas mix-ups. These can be found, respectively, in the July 14, 2005, and July 2001 issues of *Sentinel Event Alert*. (These alerts are available online at www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea.htm.)

FDA (the U.S. Food and Drug Administration) has included topics related to misconnections several times on its monthly Patient Safety News video shows—specifically in its June 2002, August and October 2003, September 2004, and March and December 2005 broadcasts. The December 2005 feature was called “Luer Lock Misconnections Can Be Deadly.” (The Patient Safety News shows can be accessed online at www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/index.cfm.) ♦

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