

# Nurse AdviseERR®

Educating the Healthcare Community About Safe Medication Practices

## Ongoing risk: Misconnections of tracheostomy pilot balloon ports with IV infusions can result in fatal outcomes

Adventitious tubing misconnections pose a significant risk to patients. They often occur when luer-compatible tubing is mistakenly connected to another type of tubing into which it can fit, but for which it was not designed. To help prevent dangerous misconnections, the International Organization for Standardization (ISO) developed manufacturing standards (80369) for small bore connectors to make it nearly impossible to connect tubing delivery systems that serve different routes of administration and/or functions.<sup>1</sup> The standards are being introduced in phases, which began with enteral feeding connectors (ENFit) and are continuing presently with neuraxial connectors (NRFit). Unique challenges have led to slow implementation of the new enteral and neuraxial connectors, and until old supplies are depleted, temporary adaptors have been introduced for ENFit to connect the old tubing with the new tubing. Engineering changes for connectors associated with limb cuff inflation applications and breathing systems and driving gases applications have not yet begun. Thus, many catheters, medical tubes, and devices with different functions can still easily be connected or possibly rigged with temporary adaptors to make a leak-free connection, contributing to ongoing tubing misconnections.

### Recent tracheostomy pilot balloon port misconnection

We recently learned about a misconnection between intravenous (IV) tubing and a tracheostomy pilot balloon port (cuff inflation port) that led to a young patient's cardiac arrest. A nurse planned to administer an antibiotic to the patient via a triple lumen IV catheter. Before administering the antibiotic, the nurse removed a fully infused plain IV bag and tubing from the triple lumen IV catheter port. But instead of attaching the antibiotic to this port, the nurse accidentally selected the nearby tracheostomy pilot balloon port.

The pilot balloon port is part of the tracheostomy tubing that inflates the cuff at the base of the tracheostomy tube to hold it in place within the trachea. The balloon inflates along with the cuff and serves as an indication of how much air pressure is in the cuff. The pilot balloon port has a luer connector, forcing practitioners to use a parenteral syringe to inflate and deflate the cuff with air.



**Figure 1.** Example of a tracheostomy cuff filled with 85 mL of saline and ready to rupture.

The nurse noticed that the pilot balloon port looked different than expected for the IV connection but thought the triple lumen IV catheter connector had accidentally been removed from the central line when discontinuing the IV bag. Thus, a new multi-lumen extension tube was attached to what was thought to be the central IV line, and then the IV antibiotic was connected. However, the antibiotic was actually attached to the tracheostomy pilot balloon port. The infusion inflated the tracheostomy cuff (**Figure 1**), occluded the airway, and finally burst, allowing fluid to enter the patient's lungs. The patient arrested but fortunately was resuscitated.

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## check it out

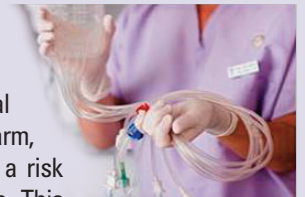
Consider the following recommendations to help prevent or decrease the risk of tubing misconnections within your organization.

### Purchasing decisions

- Conduct pre-purchase evaluations (e.g., failure mode and effects analysis [FMEA]) in which clinicians can manipulate new tubes, catheters, connectors, syringes, and tracheostomy/endotracheal tubes to uncover misconnection hazards before purchasing and using the new devices. Refusal to purchase unsafe equipment will also drive manufacturers to create better designed devices.
- When possible, only purchase luer-compatible connectors for IV routes. If you must purchase a device that allows for misconnections, determine risk mitigation continued on page 2—**check it out** >

### Tubing Misconnections Self-Assessment Tool

Catheter and tubing misconnections are a serious problem in healthcare and continue to occur. In 2012, ISMP collaborated with Baxter Healthcare's Clinical Center of Excellence to develop a self-assessment for healthcare facilities. This self-assessment was recently updated and can be accessed at [www.ismp.org/ext/82](http://www.ismp.org/ext/82). This tool guides users through a modified risk assessment that evaluates current delivery systems and mating devices, rates ease of connection and potential for patient harm, and assigns a risk priority score. This tool is an excellent resource to help hospitals mitigate the risk of tubing misconnections.



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It may be hard to understand how one could mistake a tracheostomy pilot balloon port for a triple lumen IV catheter port, but several underlying factors allowed this error to happen. First, the nurse had just traced and labeled the patient's lines and did not think to conduct this safety check again. Dim lighting and the position of the pump on the opposite side of the IV lines contributed to the nurse's inability to clearly visualize the IV lines. The risk of error was heightened because the patient's triple lumen IV catheter was not secured, hanging down at the same level as the tracheostomy pilot balloon port. Although the size of the tracheostomy pilot balloon tubing is narrower than regular IV tubing, triple lumen lines are also thin. Additionally, the pilot balloon port is usually not capped, inviting the insertion of a compatible connector.<sup>2</sup> The fact that the nurse thought the triple lumen IV connector had inadvertently been removed from the central line port when discontinuing the IV bag also played a role in this error.

In this hospital, antibiotics were typically being administered directly via the triple lumen IV catheter ports due to current fluid shortages; however, prior to the shortage, antibiotics were always infused via a secondary line. The error may not have occurred if the antibiotic had been administered as a secondary infusion and attached to an access port of the infusing primary IV solution. Finally, it is also important to mention that the multi-lumen IV extension tube easily connected to the tracheostomy pilot balloon port. Again, the pilot balloon port is compatible with luer syringes (and IV connectors and tubing) for easy inflation and deflation. Unfortunately, the infusion pump provided sufficient pressure to overinflate the cuff, but it did not alarm or stop.

Replication of this event confirmed that as long as the cuff can expand, the infusion pumps will not alarm before rupture. Because high-volume, low-pressure cuffs are used to lower the long-term risk of tracheal injury, they are compliant enough to accept a massive volume of air—or fluid as in this case. According to ECRI Institute, the pressure generated by a typical infusion (or enteral feeding) pump is sufficient to overinflate such cuffs and occlude a patient's airway.<sup>2</sup> Testing identified that infusion pumps will fill the cuff with approximately 70 mL of fluid<sup>3</sup> or more before rupture.

### Previously published tracheostomy pilot balloon port misconnections

While it is believed that medical tubing misconnections are vastly underreported,<sup>4</sup> especially when patient harm does not occur, misconnections between tracheostomy pilot balloon ports and IV or enteral feeding lines have been previously reported to external organizations such as ISMP, The Joint Commission (TJC), the US Food and Drug Administration (FDA), and ECRI Institute. Some of these misconnections have resulted in adult and pediatric fatalities.

As early as 1986, ECRI Institute reported an event in which an enteral pump set was inadvertently connected to a tracheostomy pilot balloon port on a cuffed endotracheal tube.<sup>2</sup> The port on the pilot balloon tubing was similar in shape and color to the feeding tube connector. The enteral formula overinflated the endotracheal tube cuff, completely occluding the tracheal tube. The ventilator alarmed, and the patient experienced respiratory arrest but fortunately survived.

In 2001, ISMP published a similar event that resulted in a fatality.<sup>5</sup> The patient had both a tracheostomy tube and a triple lumen IV catheter in place. A practitioner accidentally attached an IV fluid line to the tracheostomy pilot balloon port instead of the intended port on the triple lumen IV catheter. Once the IV infusion pump was turned on, the cuff continued to inflate with fluid causing the tracheostomy tube lumen to collapse and obstruct the airway. A roommate called a nurse when the patient developed respiratory distress. The patient arrested, and the obstruction was noticed when the code team was unable to inflate the lungs. The line was disconnected and the cuff was deflated, but the patient did not survive.

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> **check it out** continued from page 1

strategies to avoid or detect misconnections, and alert staff to possible misconnections through patient monitoring (e.g., pulse oximetry, capnography, cardiac monitoring, frequent observation).

### Staff education

- Alert clinicians, including respiratory therapists, to the risk of misconnecting IV/enteral tubing, parenteral syringes, or flushes to a tracheostomy pilot balloon port or any luer-compatible connector.
- Emphasize the risk of misconnections between IV/enteral tubing and tracheostomy pilot balloon ports in orientation and training curricula. Include discussions about possible sources of error identified during device pre-purchase evaluations and steps to avoid these errors. Use simulation of these misconnections to reinforce the education.

### Clinical practices

- Affix labels on lines near insertion sites when the patient has more than one connection into the body (e.g., IV, enteral, epidural, tracheostomy).
- When appropriate, position the respective delivery system (e.g., pump) on the same side of the patient from which the catheter exits. If possible, position catheters and tubes that have different purposes on different sides of the patient's body.
- Always trace lines from their respective sources (and infusion pump if used) to the patient's access site into the body before making connections or administering medications or solutions. Remind staff that, for patients with multiple tubes, situational awareness of each tube's location and insertion site can be lost, especially if tubing is obscured by bedclothes and sheets, or the tubes are located on the opposite side of the bed.
- Turn on the light in a darkened room or use an articulating lamp or flashlight before connecting or reconnecting tubes or other devices.

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> **Misconnections**—continued from page 2

In 2005, an IV-tracheostomy pilot balloon port misconnection reported to FDA's adverse event report database was published.<sup>6</sup> A patient injured in a car accident required a tracheostomy during hospitalization after attempts to wean her off of a ventilator were unsuccessful. Shortly after the patient was transferred from the intensive care unit (ICU) to a general medical unit, a visitor reported that the patient was having difficulty breathing. Attempts to suction the patient failed, and the suction catheter could not be advanced even after the tracheostomy tube's inner cannula was removed. Investigation revealed that, upon transfer, the patient's IV tubing had been inadvertently connected to the tracheostomy pilot balloon port, overinflating the cuff and partially collapsing the tracheostomy tube. The patient's outcome was not reported.

Another event reported to FDA and used as a case study for medical device misconnections involved a child in a pediatric ICU who had both an IV line and a tracheostomy tube.<sup>7</sup> The IV tubing was mistakenly connected to the tracheostomy



**Figure 2.** FDA case study of a misconnection is based on an actual event in which a child died after connecting an IV line to a tracheostomy pilot balloon port.<sup>7</sup>

pilot balloon port (**Figure 2**). The IV fluid expanded the cuff to the point of rupture, causing continuous IV fluids to enter the child's lungs. Tragically, the child died.

In 2006, TJC published one permanently disabling and eight fatal cases of misconnections, reported to its Sentinel Event database, affecting two infants and seven adults.<sup>8</sup> One of these cases involved the injection of IV fluid into a tracheostomy pilot balloon port.

In 2007, ISMP published yet another case.<sup>9</sup> While bathing a patient, a nurse accidentally connected IV tubing to the patient's tracheostomy pilot balloon port. Normally, patients wear gowns with sleeves that snap closed. But on this day, the patient wore a gown without snaps. To remove the gown, the nurse disconnected the patient's IV insulin infusion and threaded it through the sleeve. When reconnecting the tubing, she connected the IV line to the tracheostomy pilot balloon port. Fluid began to further inflate the cuff. The error was noticed when the patient became cyanotic. The IV line was disconnected from the pilot balloon port, and 30 mL of fluid was removed from the balloon. Fortunately, the patient was not permanently harmed.

Due to the continuing risks of tubing misconnections between IV/enteral tubing and tracheostomy pilot balloon ports, consider the recommendations listed in the **check it out!** column, starting on page 1 in the right column.

**References**

- 1) International Organization for Standardization (ISO). ISO 80369-1:2010. ISO 2010. [www.ismp.org/ext/99](http://www.ismp.org/ext/99)
- 2) ECRI Institute. Tracheal cuff inflation tube mistaken for enteral feeding tube. *Health Devices*. 1986;15(2-3):64-5.
- 3) Anesthesia Patient Safety Foundation (APSF). IV connection to tracheostomy cuff inflation port reflects larger problem. *APSF Newsletter*. 2002;17(3).
- 4) Infection Control Today. Joint Commission alerts organizations to tubing misconnection risks. August 20, 2014. [www.ismp.org/ext/97](http://www.ismp.org/ext/97)
- 5) ISMP. IV connection to tracheostomy cuff inflation port reflects a larger problem. *ISMP Medication Safety Alert!* 2001;6(24):1-2.
- 6) Eakle M, Gallares BA, Morrison A. Luer-lock misconnects can be deadly. *Nursing*. 2005;35(9):73.
- 7) FDA. Examples of medical device misconnections. December 13, 2017. [www.ismp.org/ext/92](http://www.ismp.org/ext/92)
- 8) The Joint Commission. Tubing misconnections—a persistent and potentially deadly occurrence. *Sentinel Event Alert*. 2006;(36):1-3.
- 9) ISMP. Worth repeating... IV tubing misconnected to tracheostomy collar. *ISMP Medication Safety Alert!* 2007;12(12):1,3.

> **check it out** continued from page 1

- Limit the frequency of disconnecting and reconnecting tubing (e.g., threading the tubing through clothing) to reduce the risk of misconnections and infections.
- Develop a standardized “line reconciliation” process to recheck all connections and trace all tubes and catheters to their source when patients arrive in a new setting or as part of a handoff process. Label all tubes and catheters at the point(s) of connection.
- At facility defined steps, independently double check all line attachments using available technology and/or a second practitioner for selected high-alert medications or solutions, or if administering products to high-risk patients, to verify correct line attachment before administration.

✓ **Assess and report misconnections**

- Annually assess the potential for tubing misconnections with medical devices, connectors, and tubing used in your facility. To accomplish this, one hospital told us that they collect all the different types of tubing supplies, connectors, and devices used in the facility and ask staff (e.g., nurses, respiratory therapists, radiology technicians, transporters) to try to misconnect the different components. Afterwards, they assign severity scores to the components that could be misconnected and develop a mitigation strategy to prevent potential patient harm. An updated **Tubing Misconnections Self-Assessment Tool for Healthcare Facilities**, which was created by the Baxter Clinical Center of Excellence in collaboration with ISMP, is also freely available to guide organizations through a comprehensive risk assessment ([www.ismp.org/ext/82](http://www.ismp.org/ext/82)). (See boxed feature about the tool on **page 1**.)
- Report all potential and actual misconnections—even those that are caught before harm occurs—to the patient/medication safety officer, risk management, the device manufacturer, ISMP ([www.ismp.org/merp](http://www.ismp.org/merp)), and ECRI Institute ([www.ismp.org/ext/91](http://www.ismp.org/ext/91)). ISMP shares all reports with FDA, anonymously if desired.



## what's in a Name?

### The “-gliflozin” drug name stem

Medications with the suffix “-gliflozin” are sodium-glucose co-transporter 2 (SGLT2) inhibitors,<sup>1</sup> which are approved for the treatment of type 2 diabetes. These medications reduce glucose reabsorption in the proximal tubules of the kidneys, allowing more glucose to be excreted in the urine.<sup>2</sup> There are currently four SGLT2 inhibitors available in the US, taken as oral tablets once daily, with or without food<sup>3-6</sup> (Table 1). These medications are also available in combination with other types of antihyperglycemics. In addition to the goal of reducing hemoglobin A1C levels, SGLT2 inhibitors can also lead to weight loss when taken with metFORMIN, and reduced hypoglycemic risk when taken with sulfonylureas (e.g., glipizide, glimepiride, glyBURIDE, and TOLBUTamide).<sup>2,3,7</sup>

**Table 1.** List of available SGLT2 inhibitors in the US (all are oral tablets), including combination products<sup>3</sup>

Single Medications		Combination Medications	
Generic Name	Brand Name	Generic Names	Brand Name
canagliflozin	INVOKANA	canagliflozin/metFORMIN	INVOKAMET, INVOKAMET XR
dapagliflozin	FARXIGA	dapagliflozin/metFORMIN	XIGDUO XR
		dapagliflozin/sAXagliptin	QTERN
empagliflozin	JARDIANCE	empagliflozin/linagliptin	GLYXAMBI
		empagliflozin/metFORMIN	SYNJARDY, SYNJARDY XR
ertugliflozin	STEGLATRO	ertugliflozin/metFORMIN	SEGLUROMET
		ertugliflozin/SITagliptin	STEGLUJAN

Because “-gliflozins” work independent of insulin secretion, they have a lower risk of hypoglycemia compared to other antihyperglycemics,<sup>2</sup> although both hypoglycemia and ketoacidosis should still be monitored while taking SGLT2 inhibitors.<sup>2-6</sup> These medications also can help lower systolic and diastolic blood pressure and reduce the risk of hospitalization due to cardiovascular events.<sup>8,9</sup>

All “-gliflozins” have been associated with an increased risk of genitourinary infections that should be managed without discontinuing therapy.<sup>2,6</sup> These drugs may also increase high-density lipoprotein (HDL), low-density lipoprotein (LDL), and serum creatinine (SCR) values.<sup>2</sup> Dapagliflozin is associated with an increased risk of respiratory infection.<sup>5</sup> Dosing adjustments for renal impairment should be monitored for efficacy and adverse effects that might signal a need for dose titrations. Therapy should be initiated after correcting existing volume depletion. Although a new study shows no increase in the risk of below-the-knee lower extremity amputation between SGLT2 inhibitors and other classes of antihyperglycemic medications, the prescribing information for ertugliflozin and canagliflozin urges evaluation of risk factors for amputation prior to starting therapy.<sup>3,4,9</sup> Canagliflozin includes a boxed warning regarding its association with lower limb amputations, most frequently of the toe and midfoot.<sup>4</sup>

#### References

- World Health Organization. Guidance on the use of International Nonproprietary Names (INNs) for pharmaceutical substances. Switzerland. 2017;22. [www.ismp.org/ext/26](http://www.ismp.org/ext/26)
- Barnes N, Lusk K. Role of sodium-glucose cotransporter 2 (SGLT2) inhibitors. *US Pharm*. 2016;41(11):26-9.
- IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>
- Invokana [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; 2016.
- Farxiga [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2016.
- Jardiance [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; 2016.
- Goring S, Hawkins N, Wygant G, et al. Dapagliflozin compared with other oral anti-diabetes treatments when added to metformin monotherapy: a systematic review and network meta-analysis. *Diabetes Obes Metab*. 2014;16(5):433-42.
- American Diabetes Association. Standards of medical care in diabetes-2016: summary of revisions. *Diabetes Care*. 2016;39(Supplement 1):S4,5,53.
- Ryan PB, Buse JB, Schuemie MJ, et al. Comparative effectiveness of canagliflozin, SGLT2 inhibitors and non-SGLT2 inhibitors on the risk of hospitalization for heart failure and amputation in patients with type 2 diabetes mellitus: a real-world meta-analysis of 4 observational databases (OBSERVE-4D). *Diabetes Obes Metab*. 2018;20(11):2585-97.

## SAFETY wire



**Contrived drug names wreak havoc.** An emergency department physician verbally requested “Neostick” from a bedside clinical pharmacist. However, the pharmacist misheard the request as “neostig” and retrieved neostigmine when the provider wanted phenylephrine (NEOSYNEPHRINE, a former US brand of phenylephrine). We were surprised by how many hits we received when we searched “Neostick” on Google. Apparently, it’s a very popular slang term. ISMP has occasionally received medication error reports in which other contrived drug names were an issue, such as “Ketofol” (ketamine and propofol combined in a syringe), “levo” (LEVOPHED [norepinephrine], levothyroxine, or levoFLOxacil [LEVAQUINI]), and “nitro” (nitroglycerin or nitroprusside). The hospital that reported use of the contrived name, Neostick, has discouraged further use of any made-up drug names and abbreviations in all forms of verbal and written communication.

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