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Acute Care
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Educating the Healthcare Community About Safe Medication Practices

Should FDA reconsider allowing the pooling of COVID-19 vaccine doses to obtain additional doses?

ISMP thanks Kevin N. Hansen, PharmD, MS, BCPS, BCSCP, from the Moses H. Cone Memorial Hospital in Greensboro, North Carolina, for contributing this article.

Vaccinators have observed remaining residual volume in the current coronavirus disease 2019 (COVID-19) vaccine vials (**Figure 1**) after obtaining the full labeled quantity of doses available from each vial (**Table 1**) and have expressed a desire to pool the leftover vaccine to obtain an additional full dose for administration. This practice would have the potential to increase the number of Americans who could be vaccinated with the existing supply and prevent unnecessary vaccine wastage. The US Food and Drug Administration (FDA) has advised that "…any further product remaining that does not constitute a full dose should not be pooled from multiple vials to create one."[1] This has created frustration as vaccinators continue to witness potential additional vaccine doses go to waste coupled with the existing challenges of limited vaccine supplies. This presents an opportunity to review the practice of drug pooling, drug preservatives, contamination risks, aseptic technique, and future directions to maximize the doses withdrawn from vaccine vials.

Figure 1. Pfizer-BioNTech COVID-19 vaccine vial after 6 doses removed, showing remaining volume in vial.

Drug Pooling Defined

Drug pooling is the act of combining the volume from multiple drug vials into a container or syringe to obtain a specified dose for administration. This is a routine practice for many drugs, both with and without preservatives, prepared in ISO (International Organization for Standardization) classified pharmacy cleanrooms within a primary engineering control, such as a laminar airflow workbench, that provides ISO class 5 unidirectional airflow in a controlled environment. These engineering controls are critical to prevent the contamination of the sterile drug when proper aseptic technique is used and to reduce the risk of potential harm to the patient.

ISMP joins the author and others who encourage FDA to reconsider the safe and responsible pooling of COVID-19 vaccines...

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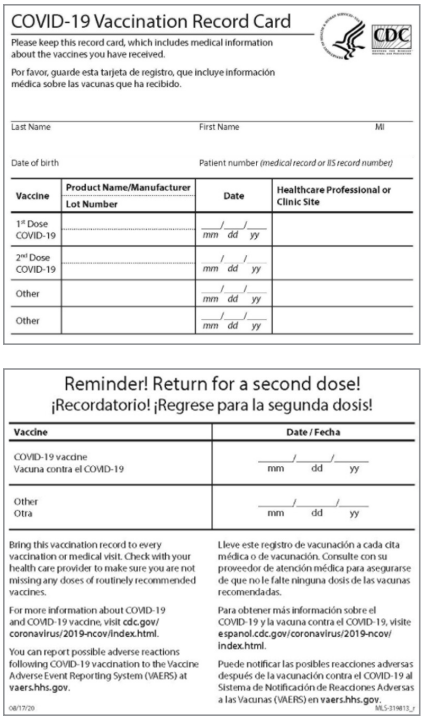
Table 1. Current FDA Emergency Use Authorization (EUA) COVID-19 Vaccines

COVID-19 Vaccine	Labeled Doses per Vial	Dilution Required?	# of Times Vial Accessed for Labeled # of Doses
Pfizer-BioNTech[2] multiple-dose vial, preservative-free	6*	Yes	7
Moderna[3] multiple-dose vial, preservative-free	10*	No	10
Janssen[4] multiple-dose vial, preservative-free	5*	No	5

* Reports have demonstrated that additional full doses may be present if using certain low dead-volume (LDV) syringes and needles; withdrawing these additional doses would require additional vial access.

SAFETY briefs

Vaccine card incorrect for single-dose COVID-19 vaccine. When a hospital received its first shipment of the single-dose Johnson & Johnson's Janssen coronavirus disease 2019 (COVID-19) vaccine, the accompanying supplies included COVID-19 Vaccination Record Cards that reference a two-dose vaccine series (**Figure 1**). The cards have the US Department of Health



COVID-19 Vaccination Record Card

Please keep this record card, which includes medical information about the vaccines you have received.

Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

Last Name | First Name | MI

Date of birth | Patient number (*medical record or IIS record number*)

Vaccine	Product Name/Manufacturer / Lot Number	Date	Healthcare Professional or Clinic Site
1st Dose COVID-19		mm dd yy	
2nd Dose COVID-19		mm dd yy	
Other		mm dd yy	
Other		mm dd yy	

Reminder! Return for a second dose!
¡Recordatorio! ¡Regrese para la segunda dosis!

Vaccine	Date / Fecha
COVID-19 vaccine Vacuna contra el COVID-19	mm dd yy
Other Otra	mm dd yy

Bring this vaccination record to every vaccination or medical visit. Check with your health care provider to make sure you are not missing any doses of routinely recommended vaccines.

For more information about COVID-19 and COVID-19 vaccine, visit cdc.gov/coronavirus/2019-ncov/index.html.

You can report possible adverse reactions following COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) at vaers.hhs.gov.

Lleve este registro de vacunación a cada cita médica o de vacunación. Consulte con su proveedor de atención médica para asegurarse de que no le falte ninguna dosis de las vacunas recomendadas.

Para obtener más información sobre el COVID-19 y la vacuna contra el COVID-19, visite espanol.cdc.gov/coronavirus/2019-ncov/index.html.

Puede notificar las posibles reacciones adversas después de la vacunación contra el COVID-19 al Sistema de Notificación de Reacciones Adversas a las Vacunas (VAERS) en vaers.hhs.gov.

Figure 1. COVID-19 Vaccination Record Cards accompanying the Janssen single-dose vaccine incorrectly call for two doses (front of card, top) and advises patients to return for a second dose (back of card, bottom).

and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) logos in the upper right corner. All vaccination sites receive these cards with the Moderna and Pfizer-BioNTech vaccines, which require two doses. The front of the card provides space to document the product name, manufacturer, and lot number of both the first and second vaccine doses.

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Multiple-Dose Vials and Preservatives

The current FDA Emergency Use Authorization (EUA) COVID-19 vaccines (i.e., Pfizer-BioNTech, Moderna, Johnson & Johnson's Janssen) are each labeled as multiple-dose vials. Drugs labeled as multiple-dose vials usually contain a preservative at high enough concentrations to kill or slow the growth of microbial contamination during the drug extraction process,[5] allowing extended use time after the vial stopper has been penetrated and numerous withdraws of vial contents using a needle and syringe. However, while the COVID-19 vaccines are labeled as multiple-dose vials, **they do NOT contain any preservatives**. For this reason, the current EUA for each vaccine explicitly states, "Do not pool excess vaccine from multiple vials"[2-4] due to the contamination risks from accessing a vial multiple times.

Table 2. Recommended Excess Volumes (Overfill) for Injectable Medications

Labeled Size in mL	Mobile Liquids in mL (Percent of Labeled Size)	Viscous Liquids in mL (Percent of Labeled Size)
0.5	0.1 (20%)	0.12 (24%)
1	0.1 (10%)	0.15 (15%)
2	0.15 (7.5%)	0.25 (12.5%)
5	0.3 (6%)	0.5 (10%)
10	0.5 (5%)	0.7 (7%)
20	0.6 (3%)	0.9 (4.5%)
30	0.8 (2.7%)	1.2 (4%)
Greater than or equal to 50	2%	3%

Source: USP General Chapter <1151> *Pharmaceutical Dosage Forms*[6]

Excess Volume and Drug in COVID-19 Vials

For injectable medications in solution, manufacturers provide minimal amounts of excess volume and drug in each vial (**Table 2**). These excess volumes are usually sufficient to permit withdrawal and administration of the labeled amounts and volumes.[6] With the overfill, the COVID-19 vaccines may have excess vaccine and volume remaining in the vial after the labeled number of doses have been removed.

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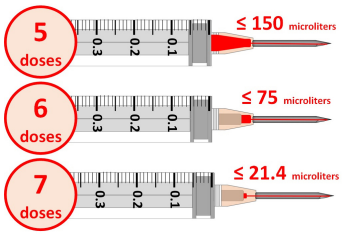
Table 3. Impact of Using Low Dead-Volume (LDV) Syringes for the Pfizer-BioNTech COVID-19 Vaccine[2]

Volume and Dose Calculations		Maximum Allowable Dead Volume to Achieve Target Doses Per Vial	
Pfizer-BioNTech Vaccine (undiluted)	**0.45 mL**		
Diluent	**1.8 mL**		
Total Volume	**2.25 mL**		
Theoretical Maximum Number of Doses *(assuming no dead-space volume losses)*	**7 x 0.3 mL** doses with **0.15 mL** remaining		
Doses per Vial	**Total Volume of Prepared Doses**	**Volume Remaining**	**Maximum Dead Space to Obtain Full Doses**
5	**1.5 mL** (5 x 0.3 mL)	**0.75 mL** (2.25 mL minus 1.5 mL)	**150 microliters* or less** [(0.75 mL/5) x 1,000]
6	**1.8 mL** (6 x 0.3 mL)	**0.45 mL** (2.25 mL minus 1.8 mL)	**75 microliters* or less** [(0.45 mL/6) x 1,000]
7	**2.1 mL** (7 x 0.3 mL)	**0.15 mL** (2.25 mL minus 2.1 mL)	**21.4 microliters* or less** [(0.15 mL/7) x 1,000]

*1 microliter equals 0.001 mL

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The back of the card includes a reminder to return for a second dose, which appears in both English and Spanish. Since the Janssen vaccine is only a single-dose vaccine, this may cause confusion and lead patients to seek an unnecessary second dose.

The hospital submitted an inquiry to the CDC and so did ISMP. The CDC noted that it is not presently considering an update to the card for the Janssen vaccine. The hospital is now affixing labels on the cards for use with the Janssen vaccine to note that a second dose is not required (**Figure 2**). They also cover the statement on the back of the card about returning for a second dose.

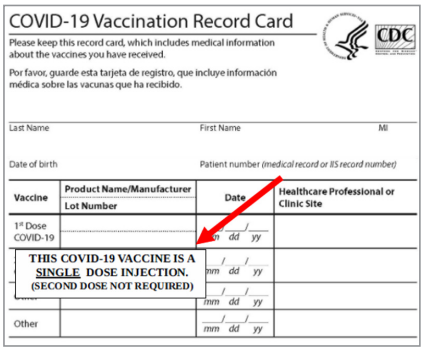

Figure 2. One hospital affixes a label to each card handed to patients who receive the Janssen single-dose COVID-19 vaccine, indicating that only a single dose is needed.

Practitioners should educate patients receiving the Janssen vaccine, emphasizing that a second dose is not needed. This is reinforced in the *Fact Sheet for Recipients and Caregivers*, which should be given to the vaccine recipient. This is similar to guidance that is recommended when a subsequent vaccine dose is not needed. For example, state vaccination record cards often include spaces for the dates of 4 doses of the Hib (*Haemophilus influenzae* type b) vaccine, but the child may only need 3 doses based on the age the doses were given or the product administered.

Beware of COVID-19 vaccines sold online. We recently became aware that empty coronavirus disease 2019 (COVID-19) vaccine vials and cartons may be available for purchase online through retailers like eBay (**Figure 1**, page 3). Although the event reported to ISMP was with the Moderna COVID-19 vaccine, empty containers of COVID-19 vaccines from other manufacturers may be for sale online as well. With the

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Low Dead-Volume Syringes and Needles

When preparing and administering the COVID-19 vaccines, there are a myriad of syringe and needle combinations that can be used, each with varying levels of dead space. The use of low dead-volume (LDV) syringes for vaccine preparation during a pandemic is not novel; however, the impact of their use should not be underestimated, as visually displayed in **Table 3** (page 2) using the Pfizer-BioNTech COVID-19 vaccine as an example. Furthermore, since the COVID-19 vaccinations require intramuscular (IM) injections, the needle length and gauge may vary based on the patient's age, gender, and weight, as recommended by the Centers for Disease Control and Prevention (CDC). This can affect the amount of liquid remaining in the needle after vaccine administration.[7]

In 2006, Strauss et al. described "the critical role of the syringe" during a pandemic, such as an influenza pandemic, and found that an LDV syringe could provide up to 19% additional vaccine (influenza) doses per vial when 10-dose vials were used.[8] This could equate to thousands or even millions of additional people becoming vaccinated during mass campaigns and ultimately reduce morbidity and mortality during a pandemic. The authors state explicitly, "It is therefore of paramount importance to stock a syringe which will reduce vaccine wastage to a minimum and thereby allow the greatest number of persons to be vaccinated."[8]

Potential Risks with Pooling COVID-19 Vaccines

There are several potential risks with pooling the current COVID-19 vaccines that must be considered, including the first two previously discussed:

1. **Lack of Controlled Environment:** A cleanroom or hood with an ISO class 5 environment is currently not required for dilution or preparation of COVID-19 vaccine doses.[9] Non-controlled environments are expected to be contaminated with bacteria and fungus in the air and on surfaces. Aseptic technique can minimize contamination but cannot eliminate the risk of contamination.
2. **Lack of Preservatives:** The vaccines are labeled as multiple-dose vials but do NOT contain any preservatives. Each access into the vial is an opportunity to contaminate the vaccine. Contaminated drug products have a higher propensity to cause patient harm.[10]
3. **Vial Coring:** With each vaccine, the vial's rubber stopper is accessed multiple times with a needle. The integrity of the vial stopper diminishes after each needle puncture, increasing the risk of introducing pieces of the rubber stopper or other particulates into the vaccine.
4. **Suspension:** Each of the current COVID-19 vaccines are suspensions requiring careful vial inversion prior to withdrawing a dose to uniformly distribute the active ingredient. There is a theoretical risk of combining vaccines from multiple vials that could have slightly varying levels of uniformity. Combining the vials may amplify this effect, creating a possible subpotent or superpotent dose.
5. **Mixing Lots:** Pooling vaccine doses across multiple vials may result in inadvertently mixing vaccines with different lot numbers. This has implications for proper documentation of vaccine administration to the patient, poses challenges with recalls or adverse event reporting, and may impact how vaccine supply is communicated to individual states, impacting potential future vaccine supply allocation.
6. **Beyond-Use Date:** The allowable beyond-use date (BUD) for diluted/punctured COVID-19 vaccine vials or pre-drawn syringes is 6 hours at room temperature (Pfizer-BioNTech, Moderna) and 6 hours refrigerated (Janssen). These BUDs are generous when compared to the 1 hour BUD currently allowed using the "immediate-use" provision when prepared outside of controlled environments in the USP General Chapter <797> *Pharmaceutical Compounding-Sterile Preparations.*[11] Furthermore, even when compounded sterile preparations (CSPs) are prepared

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authentic, empty vials and cartons available online, the concern is that these products may land in the wrong hands and can be easily filled with unknown substances and resold as the real vaccine. Since early in the pandemic, the World Health Organization (WHO) and the US Food and Drug Administration (FDA) have warned about counterfeit vaccines and treatment products sold online around the entire world (www.ismp.org/ext/664; www.ismp.org/ext/413).

Figure 1. Empty Moderna COVID-19 vaccine vials (top) and cartons (bottom) for sale online.

A recent newscast in Pennsylvania featured a community pharmacist expressing his concern about the proper disposal of empty COVID-19 vaccine vials (www.ismp.org/ext/665). The pharmacist reported that the Healthcare Distribution Alliance (HDA) recommends that empty COVID-19 vaccine vials be destroyed (smashed) to prevent unauthorized manipulations. It is important to remember that COVID-19 vaccines are currently being distributed by the federal government at no cost to the consumer, so any COVID-19 vaccines or treatments for sale online cannot be trusted as an authentic product. As healthcare facilities around the world continue to provide millions of COVID-19 vaccines per day, please be cautious of how you dispose of empty vaccine vials.

Reconstitution with alcohol instead of water. We received a report this month about a bottle of valGANciclovir powder for oral solution that was accidentally prepared using isopropyl alcohol 70% instead of water. The reconstituted product was dispensed, and one dose was administered to a child. The child's parents were contacted the following morning. Fortunately, home observation was recommended and the child

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within a controlled environment, the risk is elevated from 'low-risk' to 'medium-risk' when using more than two entries into any one sterile container. The COVID-19 vaccines are accessed a minimum of five times and as many as 10 times per single vial.

Should the FDA Allow Pooling?

Because the stated concerns associated with contamination and lack of preservatives can be mitigated by preparing the vaccine doses in an ISO class 5 environment and/or reducing and limiting the BUD, we believe FDA should further evaluate and reconsider whether the pooling of the current COVID-19 vaccines can be accomplished in a safe and responsible manner through risk-mitigation strategies of the process, such as those suggested in **Table 4**.

Table 4. Examples of Risk-Mitigation Strategies for FDA Consideration to Allow Safe Pooling of COVID-19 Vaccines

Environment	Beyond-Use Date (BUD)	Other Risk-Mitigation Requirements
Prepared in an ISO class 5 environment by trained and appropriately attired practitioners	Maintain the BUD in product labeling	■ No more than 3 vials to be pooled together at any time to create a single vaccine dose ■ Only pool together vaccine vials with the same lot number ■ Rotate the insertion point of the needle across various locations of the vial stopper for each withdrawal to reduce leakage of vaccine ■ To minimize the potential for coring, 25-gauge needles should be used and inserted at a slight angle with the opening of the needle tip facing up (i.e., away from the stopper); use careful technique to avoid bending/breaking the needle ■ Inspect each vial and prepared vaccine syringe for the presence of stopper material or cores; do NOT use if any observed
Prepared outside of an ISO class 5 environment by trained practitioners following aseptic technique	Reduce the BUD to 1 hour from the time of withdrawal of the pooled dose	

ISMP joins the author and many other practitioners who encourage FDA to evaluate and reconsider the safe and responsible pooling of COVID-19 vaccines, as suggested above. If pooling is approved, FDA, with USP, should provide specific details and guidance on a safe approach to pooling each of the current COVID-19 vaccines. For example, presented below are two different approaches to pooling the Pfizer-BioNTech vaccine, with the limitations noted for each approach.

Serial Approach: After dilution, the vaccinator withdraws 6 full doses from each vial. But upon withdrawal of dose 7, only 0.1 mL can be drawn into the syringe (need 0.3 mL for each full dose). The vaccinator then uses another full vial from the same lot and completes the dose, taking 0.2 mL out of the vial. The vaccinator continues to prepare syringes using that vial; however, they can now get only 5 full doses from the vial, with 0.2 mL remaining. The vaccinator withdraws the 0.2 mL into a syringe, and completes the dose using another full vial from the same lot, and so on.

- Limitations: This approach may be risky; if the vaccine in the vial is contaminated during the process, essentially every dose withdrawn from the vial and future vials would be contaminated.

Residual Volume Approach: After dilution, the vaccinator withdraws 6 full doses from each of 3 vials (18 full doses). Each used vial contains about 0.1 mL of residual, withdrawable volume. The vaccinator then withdraws the residual volume from the 3 vials until a full dose is achieved.

- Limitations: This method would not lead to a serial contamination issue; however, using a single needle to access 3 vials can cause blunting of the needle (which can result in pain when using the same needle for administration), as well as increase the risk of coring the rubber stopper. Also, the residual volume

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showed no adverse effects. Investigation of the event uncovered that there were two different labels on the bottle of isopropyl alcohol used—one read "isopropyl alcohol 70%" and the other "distilled water." The bottle containing isopropyl alcohol had been prepared and labeled in the pharmacy, using a labeled container that previously contained distilled water.

ISMP has received similar reports in which a solution was stored in reused bottles that previously contained a different substance, but the prior label had not been removed. Other events involved selecting a similar-looking bottle that contained an unintended substance. In one case, a pharmacist reconstituted **AMOXIL** (amoxicillin) suspension with a 50% alcohol and water solution instead of water. Both containers were on a counter beside each other. The pharmacist accidentally grabbed the alcohol solution, which was used for dermatological preparations, to prepare the suspension.

We have also received reports with more serious outcomes. For example, antibiotics were inadvertently reconstituted with 10% formalin solution (3% formaldehyde and 15% methanol) in two pharmacies that stocked gallon jugs of both distilled water as well as 10% formalin (for nearby laboratories or surgical centers). Empty jugs labeled "distilled water" were accidentally grouped with empty jugs labeled "formalin" that were awaiting refill. After incorrectly filling all the jugs with formalin, the containers labeled "distilled water" were returned to stock with other jugs of distilled water. Later they were used to reconstitute antibiotic suspensions. More than 35 children took the tainted antibiotics. Several required hospitalization for vomiting but none suffered permanent injuries.

Figure 1. A bottle of NxN 70% isopropyl alcohol looks similar to a bottle of drinking water.

Incidentally, another report we received last week involved 70% isopropyl alcohol from NxN Sanitize (**Figure 1**) in packaging that looks just like a similar-sized bottle of drinking water.

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present in the vial is highly variable and dependent on the specific syringes and needles used during the preparation.

An additional limitation for pooling using either approach—coupled with the option to prepare doses outside of an ISO class 5 environment—is that it will be challenging to ensure the pooled doses receive the appropriate BUD. A well-designed process for differentiating and separating the syringes that have different BUDs will be important for vaccinators to consider.

Considerations for Syringe and Needle Manufacturers

Syringe and needle manufacturers should consider mass producing LDV syringes (dead space less than or equal to 21.4 microliters) with affixed needles. They should ensure that they are easy to use, contain a needle safety mechanism, have affixed 25-gauge needles, offer varying needle lengths based on the CDC's recommendations for IM injections, and are produced in sufficient quantities to expedite the end of this pandemic.

Next Steps and Recommendations

ISMP, the author, and many other practitioners suggest reconsideration of pooling vaccine doses with good intent—to vaccinate more of the public to end this pandemic. However, we should not sacrifice quality and/or the safety of our patients in this process. In the interim, practitioners should maximize the number of doses withdrawn from each vaccine vial with the use of LDV syringes and needles, prepare vaccines using proper aseptic technique, and continue to get vaccinations into patients' arms.

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Could something similar happen at your practice site? Examine your supply of chemicals and discard any that are not regularly used. For chemicals that must remain, never store them near drugs. Determine if any could be confused with another product due to the container's color, size, or shape, the product's name, or the solution's color/clarity. Place prominent warning labels on non-drug products. Pharmacies should not store or supply chemicals (e.g., glacial acetic acid, formalin, phenol) for laboratories, surgical centers, or physician practices, and should not reuse or relabel empty containers, especially if they held another substance.

Special Announcements

Attend ISMP's April MSI

Transform the way you manage risk by participating in ISMP's virtual **Medication Safety Intensive (MSI)** workshop on **April 22-23, 2021**! The April MSI will help you get ahead of safety challenges and maximize your error-prevention efforts. For information and to register, visit: www.ismp.org/node/127.

Investigational drug labeling meeting

The **US Food and Drug Administration** (FDA) will be holding a Public Meeting on **May 18-19, 2021**, on medication error risks with investigational drug container labels. FDA is soliciting input from stakeholders (e.g., sponsors, investigators, clinical sites, entities that supply or label investigational drugs, study participants) about the risk of errors related to investigational drug container labels and practices that might minimize the risk of errors. For a tentative meeting agenda, visit: www.ismp.org/ext/666. Also see a two-part article on challenges posed by investigational drug container labels in our 2018 newsletters (www.ismp.org/node/1048; www.ismp.org/node/1068).

Free GEDSA summit

The Global Enteral Device Suppliers Association (GEDSA) is holding a **FREE** virtual international summit, ***Reducing the Risk of Device Misconnections***, on **March 30, 2021**. Learn how GEDSA can help you get started with transitioning to the new international standards for healthcare tubing connectors. For details, visit: www.ismp.org/ext/667.