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Assessing the Efficiency of CSTDs for Compounding

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Ensuring the safe handling of hazardous drugs (HDs) must be a primary concern for every health care worker who comes into contact with these medications. Given the potential dangers from improper management, organizations are wise to invest significant time in a comprehensive HD safety program.

Looking at available guidelines, including the 2004 NIOSH alert,[1] the ASHP guidelines on handling HDs,[2] and proposed USP Chapter <800>,[3] the number of steps required to safely compound HDs may appear daunting. However, safe handling of HDs is critical to effectively treating disease. In the health care environment, where facilities continually aim to improve efficiencies and reduce labor and supply costs using Lean methods, it is critical that the number of steps required to ensure the safety of critical tasks, including use of closed system drug-transfer devices (CSTDs), be carefully considered.[2,4] Safety steps must never be removed in the interests of efficiency.

Misperceptions Surrounding CSTDs

CSTD use is supported by numerous peer-reviewed studies and guidelines demonstrating the devices' effectiveness in enhancing HD safety programs and protecting health care workers and patients from HD exposure by reducing the level of HD residue in the environment.[5-11]

In 2000, the first CSTD was introduced in the US market to reduce the hazards of compounding and administering HDs.[12] While this new device clearly improved HD safety, it also impacted productivity compared with the standard needle/syringe Luer-lock practice. However, over the past 15 years, CSTD manufacturers have continually improved the design of these devices, bolstering their efficiency exponentially. Nevertheless, a common misperception that CSTD use increases the time required for drug compounding remains in the minds of many health care workers. This misperception, coupled with continual economic pressure to reduce costs, may cause organizations to falsely believe that they can do without CSTDs. But CSTD use should not be optional; purchasing these devices must be considered part of the cost of doing business in today's health care environment. And, thankfully, experience shows that with practice and increasing confidence, compounding with CSTDs can be as fast or faster than compounding with the traditional needle and syringe method.[13]

Comparative Assessment of CSTD Efficiency

A simple method for validating the efficiency of a process is to conduct a demonstrative, time-in-motion, comparative assessment. At Nebraska Methodist Hospital, we conducted a time-in-motion study comparing the time required to compound an IV piggyback dose from a liquid drug vial using three CSTDs: PhaSeal (BD), ChemoLock (ICU Medical), and Equashield.

The goal of this assessment was to determine whether the addition of an FDA ONB-approved CSTD used during the compounding process would have a negative effect on our staff's productivity. In a previous assessment, Nebraska Methodist Hospital demonstrated that CSTDs used in compounding and administration showed comparable times to needle and syringe methodology; the needle and syringe method was completed in 63 seconds, while compounding with the various CSTDs required between 53 and 98 seconds. For this new assessment, Nebraska Methodist Hospital undertook a bench-top

FIGURE 1
Visualizing CSTD Components

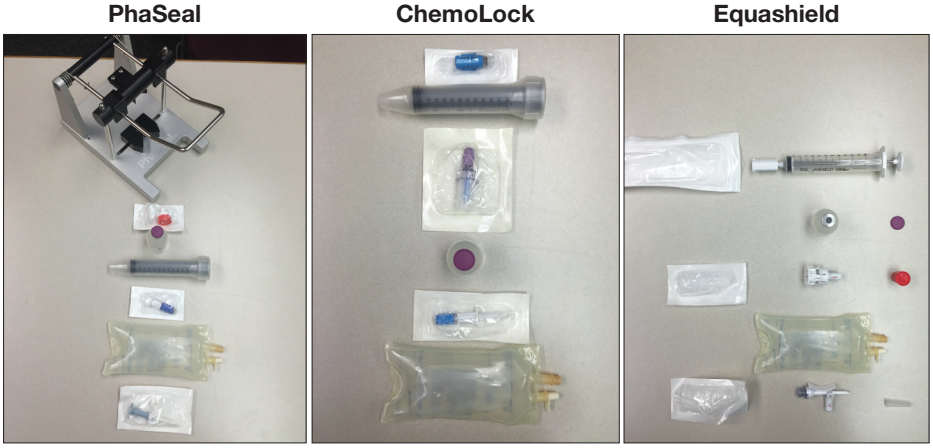


TABLE 1

CSTD Compounding Variances When Compounding an IV Piggyback from a Liquid Dose Vial

Use of a CSTD Syringe	PhaSeal	ChemoLock	Equashield
Number of Packages to Open	2	2	1
Setup Step 1	Draw ambient air into a syringe	None	None
Assembly	Luer-lock syringe to PhaSeal injector	Luer-lock syringe to ChemoLock	None
Connecting Method	Push-Turn-Push	Push to lock	Push
Setup Step 2	Inject air from syringe into the vial	None	None
Additional Steps for Transfer of Liquids	None	Push-Pull-Push technique required during the whole injection procedure of diluents	None
Flow Rate/Strains on User (relative)	Slow/high	Slow/high	Fast/low
Disconnecting Method	Pull-Turn-Pull	Pinch two levers/pull	Pull

evaluation that quantified the number of steps associated with compounding a simple liquid dose and timed the compounding process.

Sites considering a CSTD should conduct an analysis to assess the impact of CSTDs on their specific pharmacy workflow and to identify any safety and efficacy issues, a process which is paramount to any device acquisition decision.[14] In our assessment, five doses were prepared by one pharmacy technician for each CSTD and timed by an independent observer. The compounding was performed in a simulated bench-top setting (in a conference room) using sterile water for injection to simulate a liquid dose of an HD. Laying out the products helps to visualize the steps associated with compounding a simple dose (see **FIGURE 1**).

The results are presented in **FIGURE 2**, which summarizes the HD-handling continuum from the initial manufacturing through to the ultimate wasting, and includes a description of each step associated with compounding a dose using the three different CSTDs. The average time required to compound a dose with each CSTD as demonstrated during the product assessment process also is included.

The time-motion study revealed that although the number of seconds required to compound a dose varied among the different devices, none of the CSTDs required more than one-and-a-half minutes per dose, meaning none were time-prohibitive in a clinical environment.

Value of a Time-Motion Assessment

Understanding the impact of CSTDs on pharmacy compounding workflow and output is critical. In addition to safety, CSTDs should facilitate efficiency. Critically reviewing the steps for using each CSTD and summarizing the differences in mechanical manipulation can help assess the time required to compound CSPs using CSTDs (see **TABLE 1**).

Once the number of steps required and the time for the compounding process are determined, multiplying these metrics by the number of doses compounded daily, weekly, and annually will allow managers to quantify the time required for compounding over a given time period. In this way, managers can determine workload requirements and monitor the need for additional personnel or the reduction of hours based on changing compounding volume.

Limitations of Time-Motion Assessments

When conducting a time-motion assessment, note that times may vary based on the user's experience and expertise with each device and be impacted by their compounding knowledge in general. Therefore, it is important that sites conduct such assessments with staff that regularly use these devices.

CSTD Characteristics to Consider

When choosing a CSTD, it is wise to consider a variety of features, including effective containment and efficiency. Simple, intuitive connections ensure consistent use and ease the staff training process, while a secure locking mechanism is required for complete connections. The availability of pre-bonded components and efficient packaging (see **FIGURE 1**) also increase efficiency. Use of a vial-mounting device promotes stability during the compounding process. Other features to consider include pre-purging displacement air in the system, and the wetting potential of filters. Finally, limiting the number of steps in the overall process is a clear benefit. **TABLE 2** summarizes the features of CSTDs that should be considered for efficiency.

The risk of repetitive motion injuries is a long-standing issue in health systems, and avoiding repetitive strain is an important staffing concern, particularly in health systems that require high-volume compounding. Therefore, it is important to consider the number and ease of required connections when evaluating the impact a new device will have on users.

In addition, choosing a single device is ideal, as this approach saves time, helps control costs, and minimizes line items and training. However, employing more than one device may bring additional levels of efficiency to the compounding process and is acceptable as long as the chosen devices maintain the attributes of a CSTD as defined by NIOSH.[1]

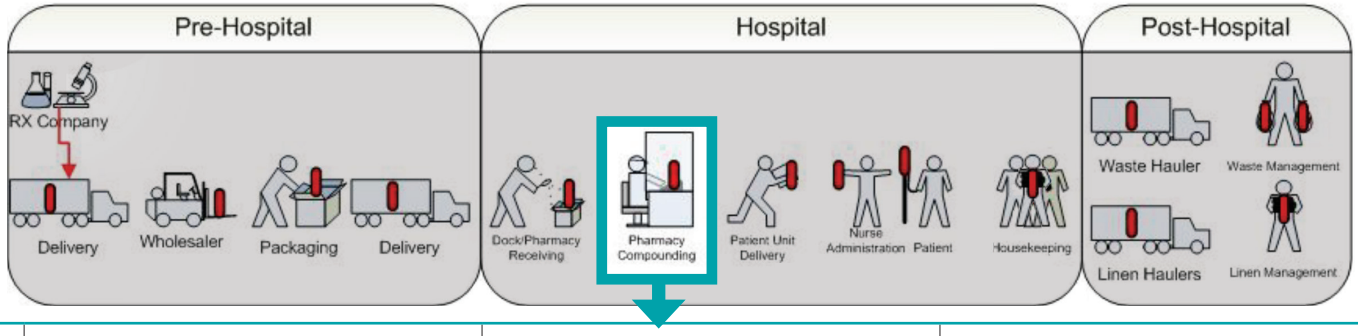
Conclusions

CSTDs are proven to reduce exposure to HDs during the drug compounding and administration processes. Contrary to common belief, when staff is properly trained and are experienced CSTD users, the time required to compound CSPs using CSTDs does not differ significantly from the time it takes to compound with a needle and syringe. Although this analysis shows variability in the time required for compounding using the three CSTDs evaluated, all the CSTDs increase safety without adding an untenable amount of time or work to the process.

FIGURE 2

Quantifying the HD Compounding Process Using ONB-Approved CSTDs*

Each CTSD was evaluated by timing only the CSTD-specific steps that occur during compounding. The assessment excluded compounding steps that are not influenced by the type of CSTD used, such as garbing with PPE, preparing the compounding space, pre-priming the IV tubing sets with naive fluid, labeling the product, and disposing of waste. The timed steps encompass those required for compounding a basic dose, including unpacking and setting up CSTD supplies, and transferring the drug from the vial to a syringe and then into an IV bag.



Steps	PhaSeal	ChemoLock	Equashield
1	Unpack PhaSeal protector	Unpack ChemoLock Genie vial spike	Unpack Equashield vial adaptor
2	Remove green protective cap	Remove the protective cap	Attach vial adaptor to a 50 mL vial
3	Place P50 on vial mounting device	Attach Genie to a 50 mL vial	Remove the protective cap
4	Attach protector to a 50 mL vial	Unpack a 60 mL syringe	Unpack Equashield 60 mL syringe unit
5	Unpack a 60 mL syringe	Unpack a ChemoLock with Luer lock	Connect the syringe unit to the vial
6	Draw 50 mL of ambient air	Remove the protective cap	Invert vial and draw 50 mL of liquid
7	Unpack Phaseal injector	Attach ChemoLock to syringe to form syringe unit	Disconnect syringe unit from vial
8	Attach injector to syringe to form the syringe unit	Connect syringe unit to vial	Unpack spike adaptor
9	Connect syringe unit to vial	Invert vial and draw 50 mL of liquid	Attach spike adaptor to an IV bag
10	Inject 50 mL of air into the vial	Disconnect syringe unit from vial	Connect syringe unit to empty IV bag
11	Invert vial and draw 50 mL of liquid	Unpack ChemoLock bag spike	Inject 50 mL of liquid into the bag
12	Disconnect syringe unit from vial	Attach ChemoLock spike to empty IV bag	Disconnect syringe unit from bag
13	Unpack infusion adapter	Connect syringe unit to the bag	
14	Attach infusion adapter to empty bag	Inject 50 mL of liquid into the bag	
15	Connect syringe unit to the bag	Disconnect syringe unit from bag	
16	Inject 50 mL of liquid into the bag		
17	Disconnect syringe unit from bag		
Total Steps	17	15	12
Time	87.7 seconds	62.8 seconds	36.4 seconds

*This assessment reviewed ONB-approved CSTDs only.

B.Braun's On-Guard was not yet ONB-approved at the time of this assessment.

CareFusion's Vialshield with Texium was not included in this assessment as it is not ONB-approved. However, in a separate assessment conducted at Nebraska Methodist, compounding with Vialshield was assessed as a 13-step process that required 41.1 seconds to complete.

Given the importance of HD containment, incorporating CSTDs into the compounding and administration processes is no longer optional. Organizations must identify which CSTD best suits their needs and adopt these safety devices into their workflow to ensure staff and patient safety. ■

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TABLE 2

Key CSTD Attributes for Efficiency

Device Attribute	PhaSeal	ChemoLock	Equashield
Containment System	Sealed diaphragm	Diaphragm; Compartmentalization within vial	Syringe device; Compartmentalization
Needle-free vs Needle-safe	Needle-safe (needle within system and vial spike)	Needle-free	Needle-safe (needles within system)
Volume of Air Displacement in Syringe Required	Yes	No	No
Syringe Safety Features	Yes (one-way engagement of syringe to device with reverse spinning function)	Yes (system rotates 360° in either direction at the female hub of the device)	Yes (pre-bonded syringe-to-syringe device)
Use of a Vial-Mounting Device	Yes, recommended	No	No
Device-to-Vial Interface	Needle spike	Plastic spike	Plastic spike
Device-to-Device Interface	Membrane-to-membrane with needle	Common fluid path (needle-free elastomeric double membrane system)	Membrane-to-membrane with needles
User-to-Device Interface	Push-turn-push	Click-to-lock	Color-to-color alignment, slide
Pre-Bonded Components	No	Yes (ChemoLock offers bonded IV sets)	Yes (closed-syringe bonded to syringe device)

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