Comparing The Efficiency of Closed System Transfer Devices for Compounding

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Adopted from "Assessing the Efficiency of CSTDs for Compounding" by Fouzia Berdi, et.al. July 2015. Pharmacy Practice & Products

Introduction

Hazards associated with handling of chemotherapy drugs are well documented[1-11]. Ensuring healthcare worker safety should be a priority and organizations are wise to invest significant time in development of a comprehensive HD safety programs.

Guidelines provided by NIOSH Alert[1], ASHP recommendations[2] and Proposed USP<800>[3] offer a large number of steps needed to safely compound hazardous drugs. As healthcare shifts to a model where improved efficiencies and reduced labor and supply costs are critical, it is important that number of steps and time to compound a dose be considered when a closed system drug transfer device is being chosen.

Objectives

The key objective of this study is to clarify the misperceptions surrounding CSTDs. Over the last 15 years, CSTDs have evolved in technology and offer various mechanism for containing vapor and protecting healthcare workers. This study aims at assessing various technologies for Hazardous Drug Compounding by performing a Time-Motion assessment. The study looks at both total steps and total time to compound a simulated dose of chemotherapy using the following ONB approved CSTDs:

- BD PhaSeal
- ICU ChemoLock
- Equashield

The study will also qualitatively assess key attributes that lead to increase in efficiency.

Methods

Each of the 3 tested CSTDs were assessed across the same set of compounding protocol to prepare an IV Piggyback dose from a liquid dose vial. Table 1 below outline the high level method and Figure 2 shows the CSTD Setup Structure.

Table 1: CSTD Dose Compounding Method

Use of CSTD Syringe	PhaSeal	ChemoLock	Equashield
Number of Packages to Open	2	2	2
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

Figure 1:
CSTD Setup

Results

Figure 2 below summarizes outlines the process steps and time needed to compound a dose of chemotherapy using various CSTDs.

Figure 2: Quantifying the HD Compounding Process Using ONB-Approved CSTDs

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 Equahsield 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 bag	
14	Attach infusion adapter to empty bag	Inject 50 mL of liquid into the bag	
15	Connect syringe unit to IV 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

It must be noted that process steps and compounding mechanisms were different across CSTDs tested. The time required to compound a dose correlated with the number of steps needed to complete a preparation. Table 2 below outlines the key CSTD attributes that contribute the increase in efficiency of one system relative to another.

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 (needle 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)

The process step that contributed to most time required to compound a dose with PhaSeal was the air displacement step. Due to product design, it was required to introduce premeasured air into the syringe prior to syringe adaptor connection. Similarly, for ICU the largest time consuming step was the Push-Pull-Push technique for injection procedure of diluents. It must also be noted that both PhaSeal and ChemoLock required use of standard syringe, while Equashield offered closed-syringe bonded to syringe devices. Equashield also required the least number of steps and overall time to compound a dose given design attributes that lead to optimal efficiency of the product for use when compounding hazardous drugs within a pharmacy.

Conclusion

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 to work to the process.

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.

Once the number of steps required and the time for the compounding process are determined, multiplying these metrics by 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.

Key take away from the study can be summarized below:

- PhaSeal required the most steps to compound a dose (17 steps) while Equashield required the least (12 steps).
- Similarly PhaSeal required over twice the time to compound a dose compared to Equashield
- ChemoLock performed in the middle with 15 steps and 62.8 seconds to compound a dose

As hospital budgets are trimmed and focus on cost cutting increases, it is important to select a closed system that is both safe and efficient for compounding Hazardous Drugs.

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