Minimizing residual drug loss

Potential cost savings with BD PhaSeal™ Devices compared to common spikes and dispensing pins

Introduction

As a subset of hazardous drugs, chemotherapy represents the highest spend in the global pharmaceutical market[1] yet continues to be one of the fastest-growing expenses in the healthcare industry.[1,2] Increasing financial expenditure on these and other lifesaving injectable drugs creates concerns for patients, healthcare professionals, insurers, hospitals and governments.[3] More efficient use of these hazardous drugs could reduce waste, provide significant cost savings and help reduce consumption of medications that are often in short supply.[3-6]

Complete withdrawal of hazardous drugs from vials can help improve efficiency by minimizing discarded residual volume during cancer treatment.[7,8] A needle and syringe are customarily used to attempt complete removal of drugs from their vials; however, the approach requires additional steps and manipulation of drug vials and increases the risk of harm to healthcare workers through potential sharps injuries and exposure to harmful chemicals.[9,10] Drug-vial spike adapters or dispensing pins offer an alternative to the more traditional needle and syringe that allows for reconstitution and multiple withdrawals of a drug from a single entry through the vial septum.[11] These devices can, however, leave residual drug volume in vials and may not adequately address hazardous drug exposure risk.[11,12]

Closed system drug-transfer devices (CSTDs) provide an additional option to both the needle and syringe and the drug-vial spike adapters and dispensing pins on the market.[7,13] Designed to reduce the exposure of healthcare workers to hazardous drugs,[3] CSTDs have become recognized for allowing efficient withdrawal of drugs from vials, thereby minimizing drug waste and potentially lowering cost by reducing the volume of drug that remains in a vial after use.[3,7,8]

The BD PhaSeal™ System and the newer BD PhaSeal™ Optima System are CSTDs that securely attach to drug vials and create an airtight, leakproof connection for transfer of hazardous drugs (Fig. 1).

Figure 1. The BD PhaSeal™ Optima System Protector and Injector with vial and syringe attached.

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Their designs meet the National Institute for Occupational Safety and Health (NIOSH) definition of a CSTD because they prohibit the transfer of environmental contaminants into the system and the escape of drug or vapor outside the system,[14] thereby minimizing individual and environmental exposure to drug vapor aerosol and spills. In addition to meeting the NIOSH CSTD definition, the BD PhaSeal™ Optima System Protector was designed to maximize extraction of drug-vial contents and minimize residual drug loss, helping to reduce drug waste and costs with each drug vial.*†

A variety of drug-vial spike adapters, dispensing pins and CSTDs are currently available on the market (Table). They possess different designs and characteristics that may influence their effectiveness and cost. Two studies, supported by BD, were conducted to ascertain which devices are most efficient in terms of residual drug volume and potential cost savings.

Potential savings with real-world consumption data of high-priced drugs[7]

The pharmacy at the University Medical Center in Frieburg, Germany, evaluated the residual drug volumes of the BD PhaSeal™ System, the B. Braun Mini-Spike® Chemo Micro-Tip and the Baxter CHEMO-AIDE® Dispensing Pin with CLEARLINK. The analysis included several high-priced drugs commonly used in the pharmacy and showed that residual loss was significantly lower with the BD PhaSeal™ System vs. the other devices. The discarded drug volumes were calculated and used, along with the drugs' prices, the pharmacies' annual drug consumption data and device costs to determine potential cost savings.

The mean residual fluid volume was found to be significantly smaller ($P<.02$) with the BD PhaSeal™ System (0.25 mL), as compared with the Mini-Spike® Chemo Micro-Tip (0.64 mL), the Mini-Spike® Chemo (0.42 mL) and the CHEMO-AIDE® Dispensing Pin with CLEARLINK (0.29 mL).

For this particular pharmacy, use of the BD PhaSeal™ Devices had the potential to save 166,000 €, equivalent to $171,438‡, including material cost over the Mini-Spike® Chemo Micro-Tip, and incurred 15,000 € equivalent to $15,491‡ in additional expense over the CHEMO-AIDE® Dispensing Pin with CLEARLINK (Fig. 2).

While the BD PhaSeal™ Devices have a higher direct cost, the smaller residual volume is a means for cost savings, particularly with high-priced drugs,[7] and these devices help reduce workplace contamination and occupational and environmental exposure to hazardous drugs.[3]

Table. Devices evaluated as part of the two studies summarized in this report.

Device	Manufacturer	Product name
CSTD	BD	PhaSeal™[7,8]
Spike or pin	Baxter	CHEMO-AIDE® Dispensing Pin with CLEARLINK[7,8]
	B. Braun	Mini-Spike® Chemo Micro-Tip[7]
		Mini-Spike® Chemo (integrated 0.2-µm filter)[7]
		Chemo V Mini-Spike®[8]
	BD	CareFusion SmartSite™[8]
		CareFusion VM04[8]
	Fresenius-Kabi	Extra-Spike®[8]
	ICU Medical	ChemoClave® CH-70[8]
		ChemoClave® CH-74[8]

Note: This is not an exhaustive list of available devices.
Manufacturer locations: BD: Franklin Lakes, New Jersey; Baxter: Deerfield, Illinois; B. Braun: Bethlehem, Pennsylvania; Fresenius-Kabi: Lake Zurich, Illinois and ICU Medical, Inc.: San Clemente, California.
Updated product designations (per manufacturer catalog): **Baxter**: CHEMO-AIDE Dispensing Pin; **B. Braun**: Mini-Spike Chemo Micro-Tip, Mini-Spike V Dispensing Pin; **BD**: CareFusion Universal SmartSite Vented Vial Access Device, CareFusion 20-mm SmartSite Vented Vial Access Device; **Fresenius-Kabi**: Extra-Spike Plus Chemo red withdrawal cannula; **ICU Medical**: ChemoClave Locking Universal Vented Vial Access Device, ChemoClave CH-74 Protected Filter Vial Access Device.

*Compared to similar systems
†Bench test results may not necessarily be indicative of clinical performance
‡$1.032759 US for every 1 Euro as of November 29, 2022.

Figure 2. Potential cost savings calculated by comparing the BD PhaSeal™ System and the type of spike or dispensing pin predominantly used in the pharmacy. Reproduced from Groβ BN, et al. (2012).

Mini-Spike® Chemo Micro-Tip

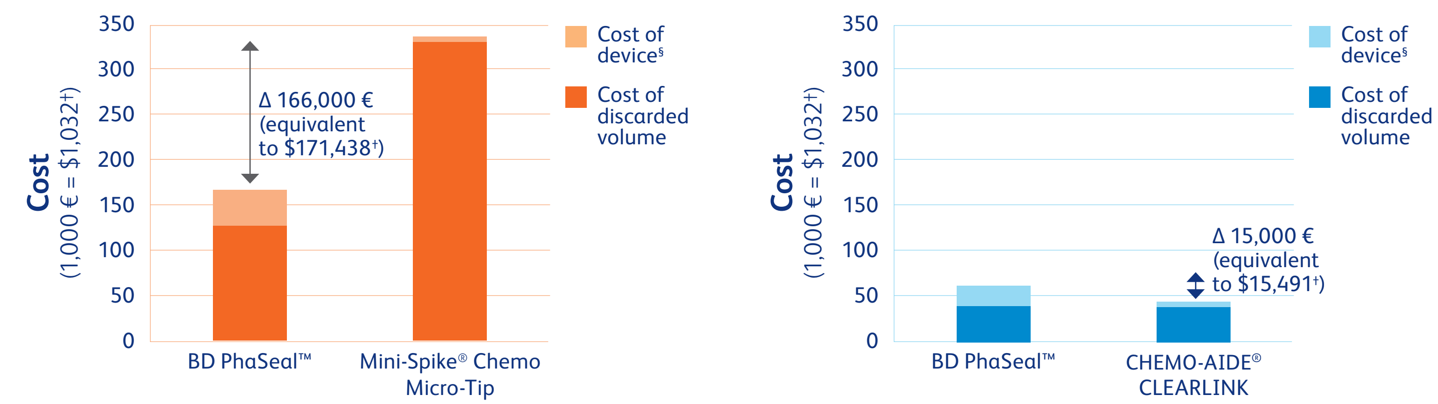
Drug	Cost per mL (€)
Bevacizumab 100 mg	94
Bevacizumab 400 mg	85
PEG-liposomal doxorubicin	61
Trastuzumab	98
Infliximab	60
Panitumumab	106

Total of 5880 vials used in 2013.

CHEMO-AIDE® CLEARLINK

Drug	Cost per mL (€)
Pemetrexed	103
Cetuximab 100 mg	12
Cetuximab 500 mg	12
Rituximab	34

Total of 3800 vials used in 2013.



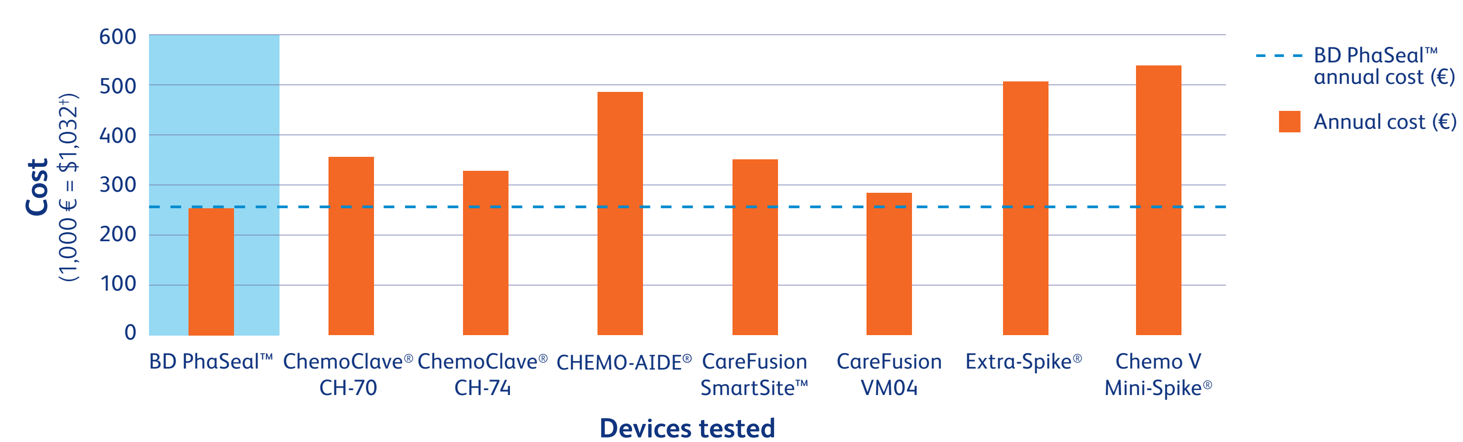
§Assumption of one transfer system per vial and additional cost of 5 € for the BD PhaSeal™ System per vial.

Cost-efficiency assessment[8]

The potential economic impact of incorporating the BD PhaSeal™ System, Baxter CHEMO-AIDE® Dispensing Pin with CLEARLINK, B. Braun Chemo V Mini-Spike®, BD CareFusion SmartSite™ and CareFusion VM04, Fresenius-Kabi Extra-Spike® and ICU Medical, Inc. ChemoClave® CH-70 or ChemoClave® CH-74 into a tertiary hospital in Spain was analyzed as part of a cost-efficiency study. Calculations of the annual estimated economic impact of each device included costs associated with residual drug loss, the cost of the syringes for cytostatic preparations and the costs of the devices (Fig. 3).

With an annual cost of 256,000 €, equivalent to $264,386‡, the BD PhaSeal™ Device was considered the most cost-efficient device analyzed in this study.

Figure 3. Annual economic impact accrued with the use of each device in the study. Adapted from Calzado-Gómez G, et al. (2017).



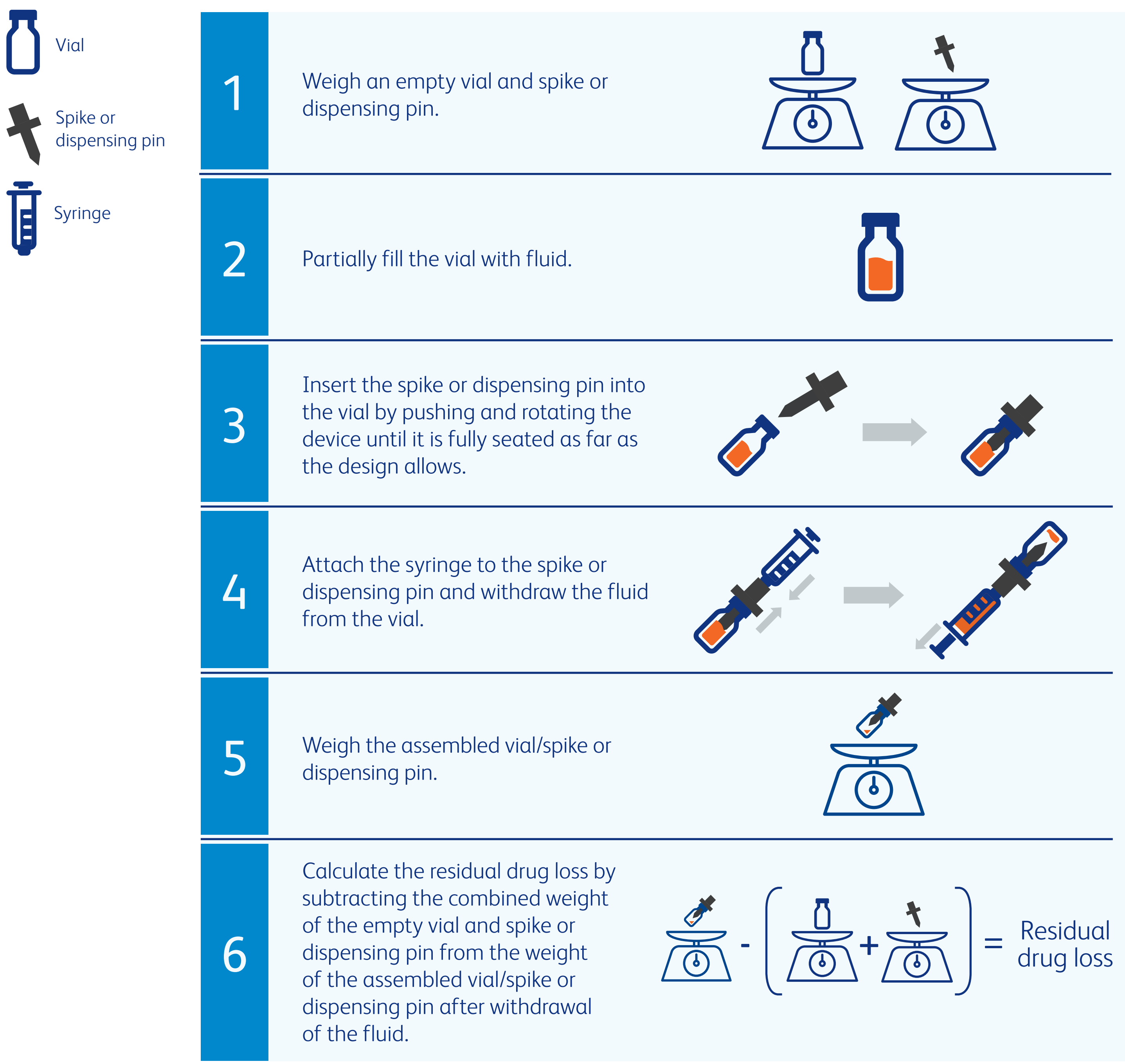
‡$1.032759 US for every 1 Euro as of November 29, 2022.

Estimating potential costs

The residual drug loss with each device can be determined by gravimetrically weighing empty vials, weighing the spike or dispensing pin, and then weighing the assembled vial and spike or dispensing pin after withdrawal of the liquid. A more detailed procedure that can be used to measure residual drug loss is outlined in Figure 4.

The residual drug loss can be used to determine the theoretically discarded drug volume on a per-vial basis and calculate potential cost savings by factoring in drug prices along with the typical doses used per patient. By using this procedure, BD can help healthcare institutions assess their current devices and the potential waste associated with them.

Figure 4. Outline of experimental design.



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