



SELECTING THE RIGHT PRIMARY CONTAINER FOR INJECTABLES IN ACUTE CARE

Alfred Harvey, Associate Director of Health Economics and Outcomes Research for BD Medical - Pharmaceutical Systems, explains why it's important to select the right primary container presentation – and what can happen if you get it wrong.

Understanding the unmet needs of hospitals and care centres is crucial for providing them with impactful solutions. In the healthcare setting, patient safety concerns exist across the entire drug delivery spectrum. Specifically, in an acute care setting, where decisions are often made quickly or under stress, error rates can be at their highest.¹ These errors result from normal human faults, cutting corners due to resource constraints and/or an inherent medical product failure. Collectively, drug delivery mistakes create challenges when it comes to maintaining optimal safety for patients and healthcare workers – and can increase clinical operating costs. Differences in primary container options for injectable drugs can add value by offering hospitals and care centres configurations that address universal pain points.

INJECTION-RELATED ADVERSE DRUG EVENTS ARE DANGEROUS AND COSTLY

Reducing medical errors, such as adverse drug events (ADEs), is a goal for the entire healthcare ecosystem. Currently, nearly 5% of hospitalised patients experience a drug-related ADE.² Of these, injection-related ADEs alone account for US\$2.7-5.1 billion (£2.1-3.9 billion) of preventable annual costs to US healthcare payers. On average, this leads to \$600,000 per year in extra costs for each hospital, with an additional \$72,000 in medical

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professional liability per hospital.³ The highest error rates (approximately 50%) have been reported in the administration of intravenous medications due to their greater complexity.¹

ADEs are dangerous and costly, but those related to administration errors could be limited in the case of injectable drugs by more widespread adoption of primary drug containers that improve workflow, decrease contamination risk and reduce sharps exposure.

VIAL RE-USE IS A RISKY BUT COMMON PRACTICE

Syringe, vial or ampoule re-use is an existing, risky injection practice that can lead to contamination. For example, a class action lawsuit was settled in 2012 against several endoscopy clinics in Nevada in the US because they were cross-contaminating patients with hepatitis C. The cause was found to be linked to the re-use of vials between patients. The two drug manufacturers supplying the drug involved had also been considered liable as it was argued that the large size of the vials induced a re-use, while the



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warnings on the vials and on packaging inserts were deemed inadequate.⁴ Data from the Netherlands suggests that 9-22% of its acute infusions contain some level of microbial contamination, 1-3% of these resulting in infections and increased hospital stays.⁵ The study showed that using prefilled syringes (PFS) instead of vials reduced the contamination risk to 4%.⁵ Despite the risks associated with re-use, a 2017 report revealed that more than half of surveyed nurses admitted re-using multidose vials between patients, and almost 25% admitted using the same needle to re-enter the bottle for the same patient. Also reported was that, in an oncology setting, about 20% of oncologists accepted the practice of re-using vials, bottles and bags between patients.⁶ Similarly, a study focused on vial re-use in an anaesthesia setting showed that about 80% of vials for an imaging agent were re-used between patients.⁷ In contrast, the same study showed that the re-use went down to less than 1% when the drug was supplied to the anaesthesiologist in a PFS format (Figure 1). These are clear examples where providing medicines in the most “ready to administer” form can help reduce vial/syringe use between patients, decrease cross-contamination and improve safety.

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PFS reduce drug reuse

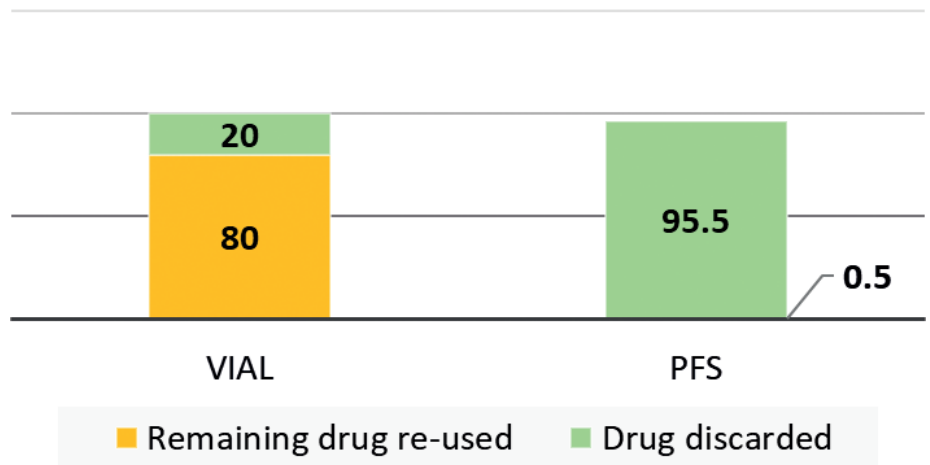


Figure 1: Imaging centre study⁷ shows 80% imaging agent re-use in vials compared with less than 1% in PFS.

SAFER FOR PATIENTS AND HEALTHCARE WORKERS

Drug dosage preparation mistakes with a syringe and vial/ampoule are all too common. These can occur from preparing the wrong medicine or the wrong dose.⁵ While some have minimal effects, critical dosing errors can cause severe problems and even death. A 2015 study looked at total dosing error rates in vials compared with PFS⁸ (Figure 2). They found that 22% of vial-prepared doses resulted in at least one dosing error, with two-thirds of the errors critical – severely over- or underdosing the patient. In contrast, only 4% of PFS-based syringes resulted in a dosing error event, and none of those were considered critical errors. Through the use of PFS instead of vials,

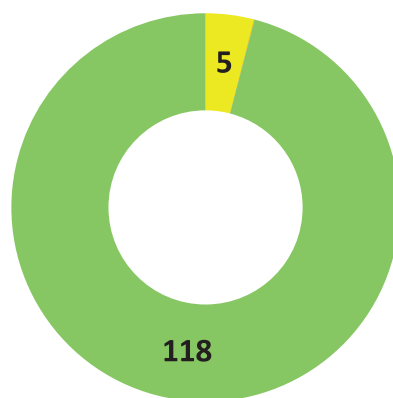
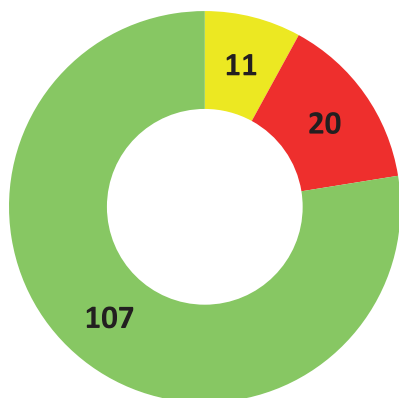
the hospital was able to show a complete elimination of critical errors and a significant reduction in non-critical errors. Also, a 2016 meta-analysis of 46 studies concluded that healthcare worker needle-stick injuries were significantly reduced when PFS were used instead of vials and ampoules.

SAVE LABOUR AND DRUG WASTE COSTS

Like all businesses, hospitals try to reduce costs as much as possible. Labour costs and product waste are two areas where the right drug delivery product can impact their bottom line. For example, patients in medical and surgical units receive an average of 10 injections daily.⁹ PFS products have been shown to reduce preparation and administration time significantly¹⁰ (Figure 3). In an average 150-bed hospital, if 10 injections daily are given to each patient using PFS instead of vials/ampoules, the hospital could save 14,600 hours annually – or \$420,000 in labour costs. Similarly, a 2016 study of drug use in an anaesthesia setting showed that drug waste from discarded vial-based drugs cost institutions around \$200,000 per year.¹¹ This cost was eliminated through the use of pre-packaged, PFS. Similarly, a study by a French university’s obstetrics unit compared drug waste between ampoules and PFS. It discovered that switching to PFS for one of its common drugs resulted in a 17% decrease in drug waste – or savings of €0.50 (43p) per patient.¹² Lastly, a budget impact analysis was conducted of French hospitals comparing PFS with standard delivery methods, considering medication

Syringe and vial

PFS



■ Dosing Errors ■ Critical Dosing Errors ■ Safe doses

Figure 2: Dosing errors decrease from 31 total errors with vials to five with PFS in pediatric study.⁸ Critical errors drop from 20 to zero.

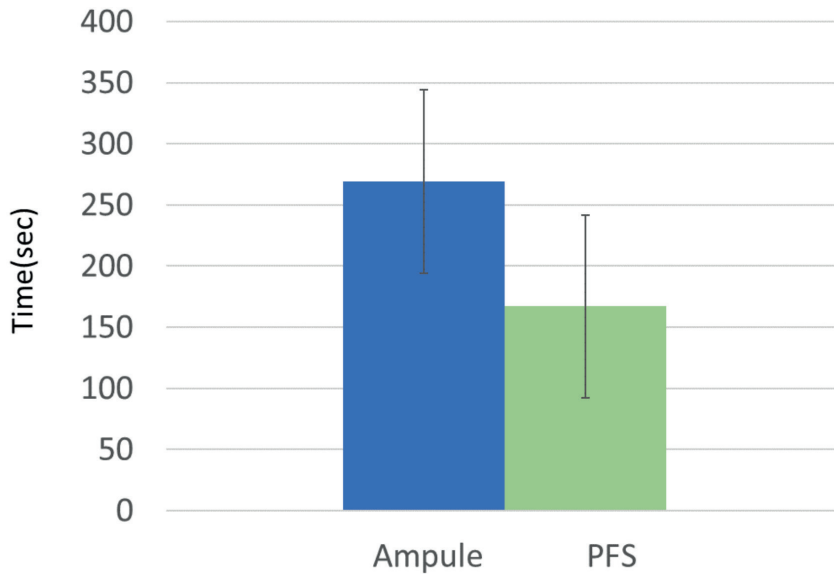


Figure 3: Ampoule preparation took approximately 100 seconds more than when PFS were used (260 seconds versus 157 seconds).¹⁰

“As hospitals start to calculate the potential savings PFS can bring, they are likely to look to drug companies that offer these convenient primary containers.”

error and drug waste. Looking only at one drug, atropine, PFS use was modelled to yield a net one-year budget saving of €5.3 million (£4.6 million). It concluded that even though PFS were more expensive upfront, their use would result in significant budget savings in both medical errors and drugs waste.¹³ As hospitals start to calculate the potential savings PFS can bring, they are likely to look to drug companies that offer these convenient primary containers when they are ready to make a purchase.

PFS OUTPERFORM VIALS FOR DURABILITY AND FILL VOLUME

Several product recalls have been linked to vials in the past, caused by flaws inherent in the vial manufacturing process.¹⁴ Vial glass can delaminate and cause glass particles to appear, reducing glass durability and contaminating the drug.¹⁵ These recalls are costly and inconvenient for both drug manufacturers and their customers. The PFS manufacturing process is different from the process for vials, and results in improved glass durability. In fact, PFS outperform glass vials in most test conditions and perform equivalently in others.¹⁵ For example, chemicals leaching into or out of a primary container can change the make-up of the drug inside. The

inner surfaces of PFS were found to have lower chemical leaching than glass vials.¹⁶ Another shared cost for customers and suppliers is the need to over-fill vials with drug. This is done because it is impossible to withdraw 100% of a dose from a vial. The cost of overfilling is either absorbed by the drug company or passed on to its

customers. Switching to a PFS as a primary container not only offers a more robust package but also eliminates the need to overfill the container.

SINGLE SOLUTION FOR SEVERAL CHALLENGES

Selecting the right primary container presentation for a drug is an important decision that can directly affect customers. As the healthcare industry focuses more on safety, it will be looking for ways to reduce ADEs and needle-stick injuries. When hospitals look to reduce spending, they will target workstream inefficiencies and product waste. In order to continue providing optimal care, they will seek out robust devices with a low likelihood of recall. PFS have shown the ability to address all these needs (Figure 4) and – now that they are available in a variety of formats up to 50 mL in highly resistant glass or advanced plastic – drug companies have many options to meet the needs of acute care hospitals and care centres.

ABOUT THE COMPANY

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company develops innovative technology, services and solutions that help advance both

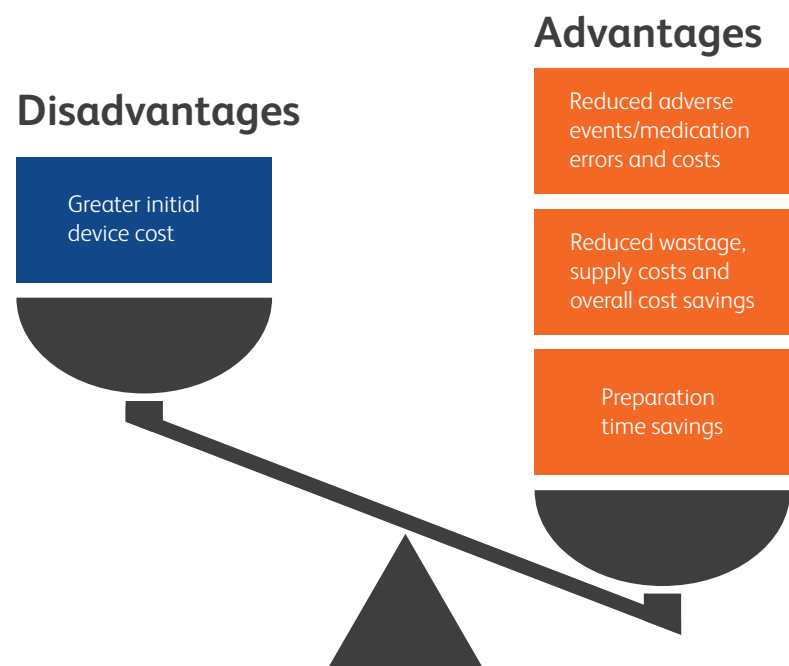


Figure 4: PFS advantages and disadvantages compared with vials. Whilst PFS may cost more upfront, vials are more costly overall.

clinical therapy for patients and clinical process for health care providers. BD has 65,000 employees and a presence in virtually every country around the world to address some of the most challenging global health issues. BD helps customers enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to healthcare.

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ABOUT THE AUTHOR

Alfred Harvey started his career with BD in 2001 as a Research Assistant working in early-stage R&D. With an initial focus on improving parenteral delivery systems, he took on greater roles, eventually managing device teams in a variety of areas such as oncology, diabetes, rheumatoid arthritis and intravenous therapies. In 2017, he took on his current role as Associate Director of Health Economics and Outcomes Research for BD's Medical – Pharmaceutical Systems division, where he is helping lead the strategic focus in prefilled, self-administration and safety systems. Mr Harvey received his MBA from Stetson University (FL, US) and his Masters in Pharmacy – Pharmaceutical Outcomes and Policy from the University of Florida (US).



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