Barrier-based CSTD versus filter-based systems: A review

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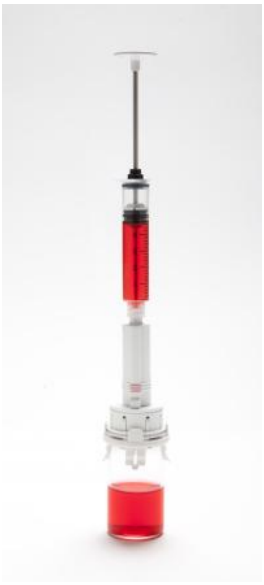
As hospitals and compounding centres look to upgrade their safe handling standards in compliance with regulation, there are many factors to consider.



Given the cytotoxic nature of hazardous drugs (HD), often used for life-saving cancer treatment, it is incumbent upon healthcare employers to thoroughly assess potential hazards their workers face, and then act to implement appropriate safety measures. As a Level 1 protection, the International Society of Oncology Pharmacy Practice (ISOPP) recommends elimination or substitution of hazardous drugs as a best defense against HD exposure. However, since in cancer care this is not feasible, several engineering controls have been determined as the best route of containment.

Closed system transfer devices (CSTDs), defined as "drug transfer device[s] that mechanically prohibit the transfer of environmental contaminants into the system and the escape of hazardous drug or vapour concentrations outside the system," are considered level 2 controls. They help to isolate people from hazards, while also protecting the sterility of costly hazardous drugs. In an optimal scenario, CSTDs should be used alongside Level 3 controls such as biological safety cabinets.

The global CSTD market is currently in a situation of flux, with the definition of what constitutes a true CSTD under scrutiny. While a simple "nothing in, nothing out" rule would appear ideal, other devices, incorporating filters, also claim to provide the necessary safety to healthcare workers.

At this stage, a scientific approach is essential in distinguishing between fully contained systems and filter-based alternatives. Hospitals and compounding centres are encouraged to do their own research on the efficacy of all systems on the market before making a decision.

A difference in design

It is common practice to utilise filtration systems to separate hazardous materials to enhance safety. One need only think of gas masks used to protect workers entering hazardous zones to understand this principle. In the case of CSTDs, some manufacturers have taken this approach, utilizing a 0.2-micron paper filter that can filter out any materials larger than this size. Some systems include a charcoal filter, which can filter out organic particles.

Fully contained systems take fewer risks, as they are designed to prevent external microbes from entering the system while preventing hazardous vapours and aerosols from escaping.

While protocols have been developed to test the efficacy of fully contained systems – such as the National Institute of Occupational Safety and Health's (NIOSH) proposed testing protocol and method with Isopropyl Alcohol in the US – filter-based systems have no such protocol defined. As such, there is currently no conclusive evidence that these systems a) are able to prevent escape of hazards, and b) will be able to maintain a safe environment with drugs that are developed in the future. Furthermore, there are commonly used drugs, such as cisplatin, that are smaller than 0.2-microns and, being inorganic, will not be neutralised by a charcoal filter nor by a paper

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In 2008, the University of Utah performed a comparative analysis using titanium tetrachloride to determine the abilities of four transfer devices to contain contamination. The two-part study simulates preparation and administration actions to determine the containment of hazardous liquids, aerosols and vapors. The results found visible leakage in the escape of smoke from both filter-based systems as well as some barrier-based systems. Only one closed system was able to fully contain the titanium tetrachloride at the time of the study. Following the initial research, a new product entered the market, Equashield. The company repeated the testing protocol. Equashield testing demonstrated that its CSTD could also visually contain vapour, making it the second device to do so.

Performing the NIOSH 2015 Proposed Vapour Containment Protocol

As awareness of the dangers of hazardous drugs has increased over the years, regulatory bodies have recognised that standards must also be set.

In 2015, NIOSH released a draft of its CSTD test protocol, to measure the level of contamination from each system on the market. Since alcohol detectors were already widely used for testing, and alcohol is a component of many HDs (reflecting the volatility of many HDs), NIOSH selected isopropyl as the testing surrogate. Various industry thought leaders, as well as academic institutions have now performed NIOSH's 2015 proposed protocol.

The University of North Carolina's (UNC) Eshelman School of Pharmacy conducted two tests comparing the efficacy of available CSTDs. The first study was based on NIOSH's 2015 proposed testing protocol – Application of Vapour Containment Protocol for Closed System Transfer Devices to Assess Efficacy During Pharmacy Compounding and Administration of Hazardous Drugs. Researchers compared six CSTDs' ability to contain vapor. Equashield and one other system displayed the ability to contain even the highly volatile vapor, maintaining a contamination level below the NIOSH-recommended 1ppm level. Filter-based systems were not able to prevent contamination. The data is consistent with the Titanium Tetrachloride study conducted in late 2000s.

Testing connector integrity

UNC performed a second test entitled, "Connector Integrity Testing to Assess the Efficacy of Multiple Closed System Transfer Devices," testing the same six CSTDs to compare how devices behave with common chemotherapy drug 5-Fluorouracil (5-FU). The drug was transferred using each CSTD. Researchers then performed a litmus paper tests, revealing a failure rate of over 80% for systems tested, while Equashield's CSTD maintained a 0% failure rate in accordance with the NIOSH definition of a leak-proof design.

Filter systems and barrier system go head-to-head

Cone Health performed testing to understand the different containment capabilities of barrier systems versus filter-based systems. Two barrier systems and two filter-based systems were tested, and researchers performed three manipulations on each. After each manipulation, ChemoGLO™ wipes were used to wipe the connector membranes of each system. Additionally, researchers wiped the laminar flow hoods between devices. Researchers found that barrier-based systems are associated with significantly less HD contamination than filter-based systems. They also believe that further testing is required to fully understand the effects of different HD types on CSTD performance.

Conclusions

As the CSTD industry works to finalise assessment methods, it is important for each healthcare institution to fully evaluate the available systems and select that system which will offer the best protection to its staff. Just as a hospital would not introduce a new drug into its practice without proper scientific evidence of efficacy, a device critical for the safety of employees must undergo rigorous testing to ensure the safety of patients, pharmacy worker, nurses and others.

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