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Comparison of devices supporting safe handling of cytotoxic drugs

This article cannot decide for you, but provides information to help you make up your own mind when buying cytotoxic handling devices. The questions to answer are: Is it simple? Does it make work safer? Is it affordable?

The risk of exposure to cytotoxic drugs may arise during the routine handling of drug vials, aseptic preparation or during administration. Numerous studies have shown that aseptic manipulation using a standard syringe and needle technique almost universally results in contamination. Droplets, leakage from vial stoppers after multiple punctures and aerosol generation resulting from increased pressure inside drug vials have also been observed.

There is no known threshold limit for exposure to cytotoxic drugs but even low-level exposure to cytotoxic drugs should be avoided as much as possible. It can be minimised or eliminated through proper handling and use of protective equipment. Nowadays pharmaceutical companies promote special devices for the reconstitution and administration of cytotoxic drugs. The main aim of these devices is to prevent or minimise any contamination. There is a variety of drug preparation and administration systems available today. However, before using any products, it is important to provide independent studies for each component of the system or device to validate its effectiveness.

The pharmacists from the Central Cytotoxic Department, Clinical Hospital of Poznań University of Medical Sciences, Poland, conducted simple in-house tests to evaluate the containment ability of drug transfer devices. We tested six different devices for the reconstitution and administration of cytotoxic



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drugs: **Cytoluer and Chemo-Aide Pin** by Baxter, **Chemo Mini-Spike** by B Braun, the **Tevadaptor** system by Teva Medical Ltd, **Clave** by ICU Medical Inc, **PhaSeal** by Carmel Pharma and **NeoSpike Onko** by Neo Care medical products.

Objective

The purpose of the study was to evaluate the effectiveness and efficiency of the six different devices for the reconstitution and administration of cytotoxic drugs. In addition, the drug

transfer devices were compared with the conventional needle/syringe.

Methods

In the first part of our study we evaluated all these devices during the routine reconstitution of cytotoxic drugs such as carmustin, cisplatin, cyclophosphamide, cytarabine, dacarbazine, doxorubicin, etoposide, rituximab. Every device was evaluated for its simplicity and ease of manipulation. We were focused on the subjective assessment of these devices.

In the second part of our study we used a simplified test to examine the spill/leakage containment of a vial transfer device involving the use of a fluorescein dye. This test is quick, repeatable and easy to perform. We used a 10% fluorescein sodium solution (commercial vial, volume: 5 mL). One drop of fluorescein was added to 10 mL of 15% potassium chlorate solution using the drug transfer device. All devices were used

Figure 1: Tevadaptor, Chemo-Aide Pin, Mini-Spike



Simulation test with fluorescein

Figure 2: Reconstitution with conventional syringe/needle



Simulation test with fluorescein

as specified by the manufacturer's instructions. Then, the simulated cytotoxic drug solution was prepared according to the pharmacy department's standard operating procedures. Every stage of this test was repeated 10 times. After reconstitution, components of the system or devices were disengaged, observed and photographed under ultraviolet light to visualise fluorescein leaks or spills, see Figure 1.

The fluorescent solution was also used to evaluate a reconstitution procedure using the conventional needle and syringe, see Figure 2.

Results

Each device tested was different in approach, but all of them were easy to use with straightforward connections. They are needle-free devices and protect against accidental needle stick.

The fluorescein test showed that during all phases of drug reconstitution no fluorescein leaks or spills were observed on the outside of any drug transfer devices. In comparison, during the reconstitution of a simulated cytotoxic drug solution using the conventional needle and syringe, two visible drops of fluorescein were observed on the gauze pad (average areas of contamination were 4–10 mm).

Conclusion

Drug transfer devices play an important role in preventing inadvertent exposure to cytotoxic drugs and should be considered part of a comprehensive safety programme.

In the study with the fluorescein solution we confirmed that all drug transfer devices can protect the operator during the reconstitution of cytotoxic drugs. This test also showed that compounding cytotoxic drugs using traditional needle/syringe

techniques is one of the riskiest points of occupational exposure due to vial over-pressurisation, which can lead to spraying and leakage.

At present, there is a need for ongoing reviews, independent studies and published clinical data to validate the effectiveness of every drug transfer device available on the market. However, before choosing the right drug transfer device pharmacists must also take into account other factors, e.g. worker acceptability and costs.

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