

IMPROVING CYTOTOXIC SAFETY: COMPARATIVE EVALUATION OF CLOSED SYSTEM TRANSFER DEVICES

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Background and importance

- ❖ Handling cytotoxic drugs exposes healthcare staff to significant occupational risks. While biological safety cabinets are the standard, situations such as equipment failure or urgent bedside Methotrexate (MTX) preparation for ectopic pregnancy require safe alternatives.
- ❖ Closed system transfer devices (CSTDs) may provide additional protection, but their characteristics differ.

Aim and objectives

- ❖ To evaluate and compare four commercially available CSTDs.
- ❖ To develop two practical tools to support safe preparation outside CSCs : a dedicated MTX protocol for gynecology and a reference table covering 31 cytotoxic drugs each referring to a standardized preparation protocol.

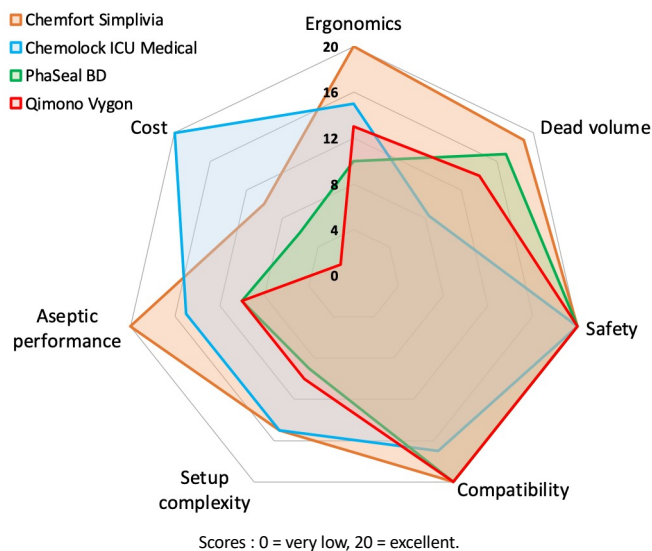
Materials and methods

- ❖ **Study type:** A comparative evaluation combining scientific literature, manufacturer data, and hands-on testing conducted jointly by the pharmacy team and the midwifery team.
- ❖ **CSTDs :** Chemfort® *Simplivia Healthcare*, Chemolock® *ICU Medical*, Qymono® *Vygon*, PhaSeal® *BD*.
- ❖ Each device was assessed across seven criteria: Ergonomics, Safety, Compatibility (NIOSH hazardous drug list), Setup complexity, Aseptic performance, Dead volume, and Cost.
- ➔ All seven criteria were equally weighted, and the global score was calculated as their average

Results

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Evaluation of CSTDs based on seven criteria







Overview of the pros and cons of each device

	👍	👎	Overall score
Chemfort®	<ul style="list-style-type: none"> Ease of use Low dead volume (0.061 mL) Compatibility with all cytotoxic drugs Single reference for 20 mm and 13 mm vial neck diameters 	<ul style="list-style-type: none"> High cost 	17
Chemolock®	<ul style="list-style-type: none"> Ease of use Low cost 	<ul style="list-style-type: none"> High dead volume (0.58 mL) Incompatible with certain solvents (N,N-dimethylacetamide) Multiple references depending on vial neck diameter 	15
PhaSeal®	<ul style="list-style-type: none"> Compatibility with all cytotoxic drugs Low dead volume (0,2 mL) 	<ul style="list-style-type: none"> Complex to use High cost Multiple references depending on vial neck diameter and expansion chamber size 	13
Qimono®	<ul style="list-style-type: none"> Ease of use Compatibility with all cytotoxic drugs 	<ul style="list-style-type: none"> High cost Need to include the QimoHarpoon for the reconstitution of cytotoxic powders Multiple references depending on vial neck diameter 	12,5

②

A standardized syringe preparation protocol was implemented for MTX in the Gynecology/Obstetrics department describing :

- Required materials for individual and environmental protection and for the preparation of methotrexate in a syringe.
- Detailed description of the different steps for syringe preparation.
- Management of waste disposal

		Méthotrexate 50 mg/2 mL	Cyomevan 500 mg	Bavencio (Avelumab) 200 mg/10mL	Etopophos 100 mg pdr
Reconstitution	Volume	Ready to use	10 mL	Ready to use	10 mL
	Solvent		Eau PPI		NaCl 0,9 %
Dilution	Solvent	Ready to use	NaCl 0,9 % or G5 %	NaCl 0,9 %	NaCl 0,9 % or G5 %
	Final concentration		10 mg/mL	< 20 mg/mL	0,1 - 20 mg/mL
Administration	Final container	Syringe	Infusion bag	Infusion bag	Infusion bag
	Route of administration	IM over 5 min	IV over 60 min	IV over 60 min	IV over 30 to 60min
Vial information	Neck diameter	20 mm	20 mm	20 mm	13 mm
Reconstitution and dilution	Chemfort 20mm vial adaptor with 13mm Converter Réf : 203113	 Dead volume = 0,035 mL	x1	x1	x1 with 13 mm converter
	Chemfort syringe adaptor Réf : 203118	 Dead volume = 0,020 mL	x1	x1	x1
Administration	Duoperf		x1	x1	x1
	Chemfort Luer-Lock adaptor Réf : 203115	 Dead volume = 0,006 mL	x1	x1	x1
	Filter			YES	

Extract from the final table presenting, as an example, 4 cytotoxic agents among the 31 analyzed

A cytotoxic drug reference table was developed within the Cytotoxic Reconstitution Unit (URC) :

- For each drug, provide the relevant Chemfort® CSTD references as well as the corresponding preparation protocols.
- This table has been established based on the characteristics of the cytotoxic agents present in the URC (e.g., vial neck diameter, type of final container, etc.).

Conclusion

This study confirms that Chemfort® is a suitable CSTD for safe cytotoxic drug preparation, with the best technical specifications aligned with the hospital's operational requirements.

Implementation will be accompanied by close monitoring of user satisfaction, preparation times, economic impact, and long-term sustainability.

The outcomes of this follow-up will support wider deployment and contribute to continuous improvement in the safety, efficiency, and quality of cytotoxic drug preparation



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