

Background :

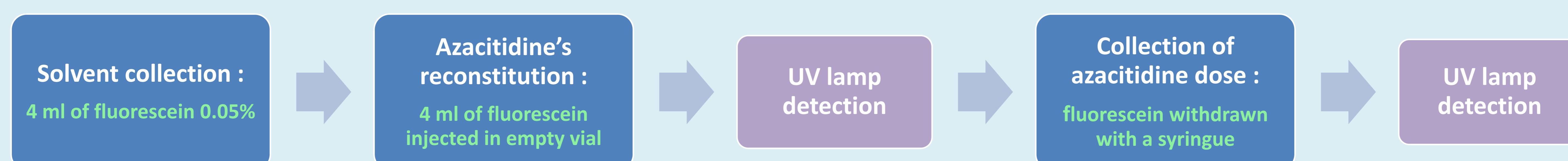
Closed-System Drug Transfer Devices (CSTD) are medical devices used for hazardous drugs preparations to protect workers from aerosolization, especially when the preparation can't be carried out in the regulatory conditions by the hospital pharmacy. In order to reference a CSTD in our hospital, a study about the effectiveness of the CSTD was performed to compare the various models available.

Material and methods:

An usability testing and a leak test confronted the different CSTD using pharmaceutical laboratories samples :

1. Usability test : three trained manipulators tested the CSTD and completed an analysis table with quality evaluation criterias.

2. Leak test : we conducted a simulation test of azacitidine's reconstitution because this drug has to be frequently prepared in care units because of its short stability. Fluorescein solution 0.05% was used as the solvent and azacitidine was replaced by an empty sterile vial. The empty vial was filled with fluorescein solution through the CSTD, the solution was withdrawn with a syringe. Then, ultra violet lamp revealed fluorescein spots respectively on the CSTD, on the gloves and the working area.



Phase I : test of 7 devices and selection of the 3 best

Phase II : 10 tests with the 3 devices selected in the phase I

Results :

Seven CSTD were tested : ChemoClave[®], ChemoLock[®], Equashield[®], Phaseal[®], Qimono[®], Tevadaptor[®] and Viashield[®].

1. Usability test : 21 usability test performed in total. Three devices were selected : Chemolock[®], Tevadaptor[®] and Equashield[®].

2. Leak test :

Phase I

Spots of fluorescein on the gloves : 0 device.

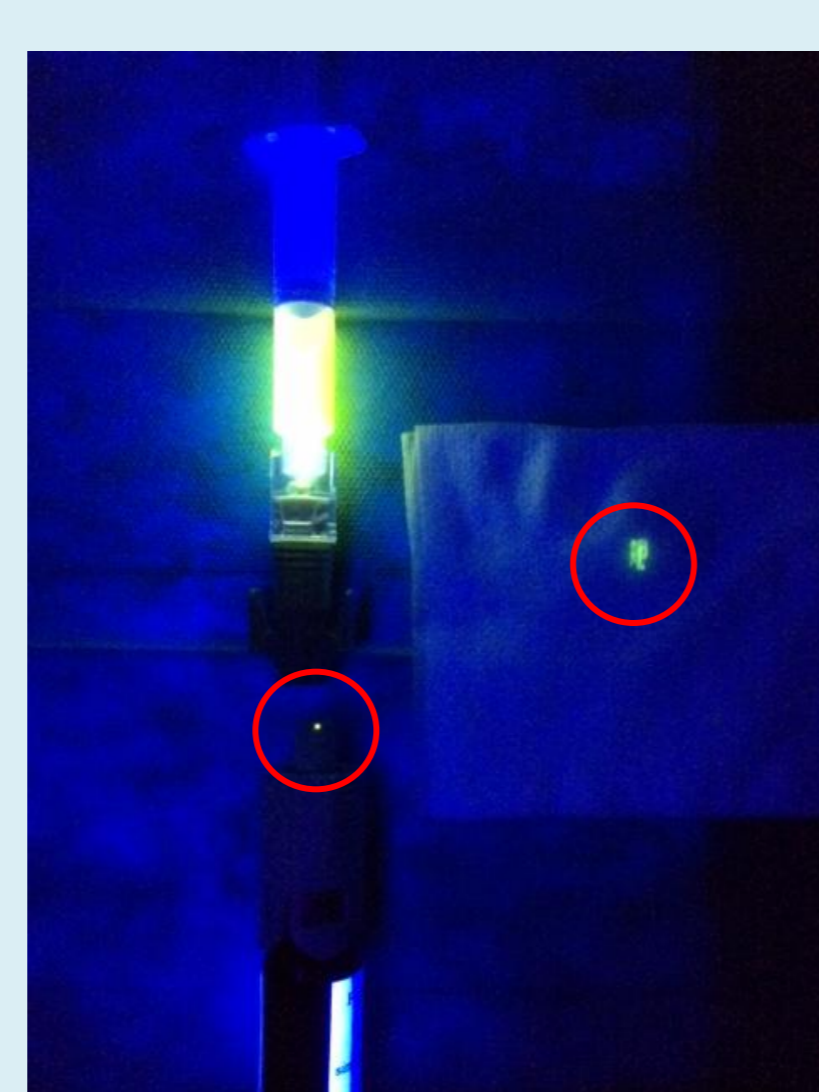
Spots on the working area : 0 device.

Spots on the CSTD : 4 devices.

	Chemoclave [®]	ChemoLock [®]	Equashield [®]	Phaseal [®]	Qimono [®]	Tevadaptor [®]	Viashield [®]
Spots on CSTD	+	-	-	+	+	-	+



Ex. 1 : no spot on device



Ex. 2 : spot on device

Phase II



Chemolock[®] Tevadaptor[®] Equashield[®]

Ten tests of each selected device.

Only one CSTD passed all the tests positively.

	Chemolock [®]		Tevadaptor [®]		Equashield [®]	
	Syringue adaptor	Vial adaptor	Syringue adaptor	Vial adaptor	Syringue adaptor	Vial adaptor
After injection	1+	2+	5+	1+	0	0
After withdrawal	0+	0+	6+	1+	0	0

Conclusion :

It is possible to secure hazardous drugs preparations with CSTD but all devices are not equivalent. These tests lead to choose one device rather than another to secure the preparation in the care units. This study should be repeated with more leak tests to be statistically significant and will be completed by another to dose cytotoxic drugs in surface samples.

Keywords : Closed-System Drug Transfer Devices (CSTD), hazardous drugs preparation, manipulator protection.