CONTAINMENT OF A NEW ADMINISTRATION SYSTEM FOR HAZARDOUS DRUGS

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Background/Significance

- clinicians regularly exposed to hazardous drugs (HDs)
- protective equipment more effective during preparation than administration
- USP 800 requires use of Closed System Transfer Devices (CSTDs) during HD administration.
- new closed administration system (Chemfort® CADM) recently marketed

Purpose

- evaluate efficacy of Chemfort® CADM (Figure 1) in preventing HD release during administration
- assessed upon first and final (10th) connection cycle at beginning and end of shelf life (3 years)

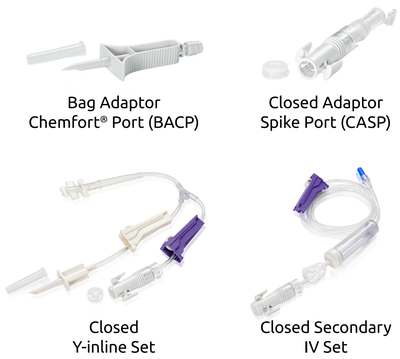

Figure 1 - CADM system and components

Methods

- based on principles of NIOSH 2015 containment performance draft protocol[1]
  - closed chamber
  - drug surrogate: 70% isopropanol (IPA)
  - acceptance criterion: <1.0 ppm increase in IPA vapor concentration
- Three test tasks[2] mimic administration and disconnection of different combinations of CADM components–assembly shown in Figure 2 placed inside closed chamber, connected to FTIR gas analyzer
- negative control: saline replaced 70% IPA
- IPA levels monitored during the task and for at least 30 minutes afterwards
- four repetitions per test group

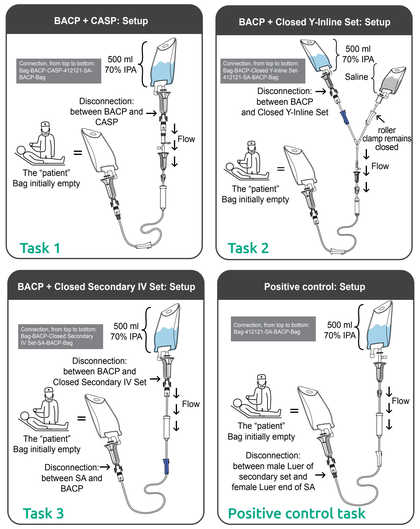

Figure 2 - Connections, flow, and disconnections for each test task

Results

- BG-0_{max} = highest increase in IPA vapor concentration over the course of a given task, relative to background levels
- well below the acceptance criterion for all tasks and test groups

Table 1. Results summary table. Test groups: (1) beginning of shelf life, 1st connection; (2) beginning of shelf life, 10th connection; (3) end of shelf life, 1st connection; (4) end of shelf life, 10th connection

Task	Test group or control	Number of BG-0_{max} Observations	Mean of BG-0_{max} Observations (ppm)	Lower 95% Confidence Limit (ppm)	Upper 95% Confidence Limit (ppm)	Standard Deviation (ppm)
1	1	4	0.00	0.00	0.00	0.00
	2	4	0.00	0.00	0.00	0.00
	3	4	0.00	0.00	0.00	0.00
	4	4	0.09	-0.08	0.26	0.18
2	1	4	0.00	0.00	0.00	0.00
	2	4	0.05	-0.04	0.13	0.09
	3	4	0.00	0.00	0.00	0.00
	4	4	0.00	0.00	0.00	0.00
3	1	4	0.06	-0.06	0.17	0.12
	2	4	0.00	0.00	0.00	0.00
	3	4	0.08	-0.07	0.22	0.15
	4	4	0.00	0.00	0.00	0.00
Positive control	N/A	4	43.43	34.05	52.80	9.56
Negative control	1	1	0.00	0.00	0.00	0.00
	2	1	0.00	0.00	0.00	0.00
	3	1	0.00	0.00	0.00	0.00
	4	1	0.00	0.00	0.00	0.00

Discussion

- CSTDs well-adopted in pharmacy, less so during administration
- Results of NIOSH-type evaluation show CADM prevents escape of hazardous liquid, aerosols, and vapors.
- New closed administration systems could potentially raise the standard of safety for clinicians to those already adopted in pharmacies.

References

[1] National Institute for Occupational Safety and Health. A vapor containment performance protocol for closed system transfer devices used during pharmacy compounding and administration of hazardous drugs. www.cdc.Gov/Niosh/Docket/Review/Docket288/Pdfs/a-Vapor-Containment-Performance-Protocol-for-Closed-System-Transfer-Devices.Pdf

[2] Simplivia data on file: Report TM0121R190

Acknowledgements and Conflict of Interest

EASS and AA are both employed by Simplivia Healthcare Ltd., the manufacturer of CADM.