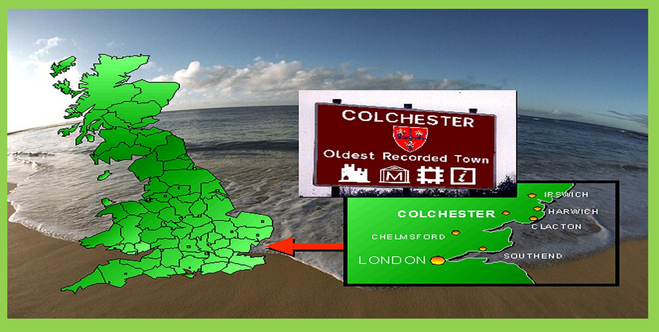

Improving safe preparation of injectable medicines: the effects of introducing a sporicidal agent

Oweikumo Eradiri and James Margetson
Colchester General Hospital, Essex, U.K.

Colchester Hospital University NHS
NHS Foundation Trust

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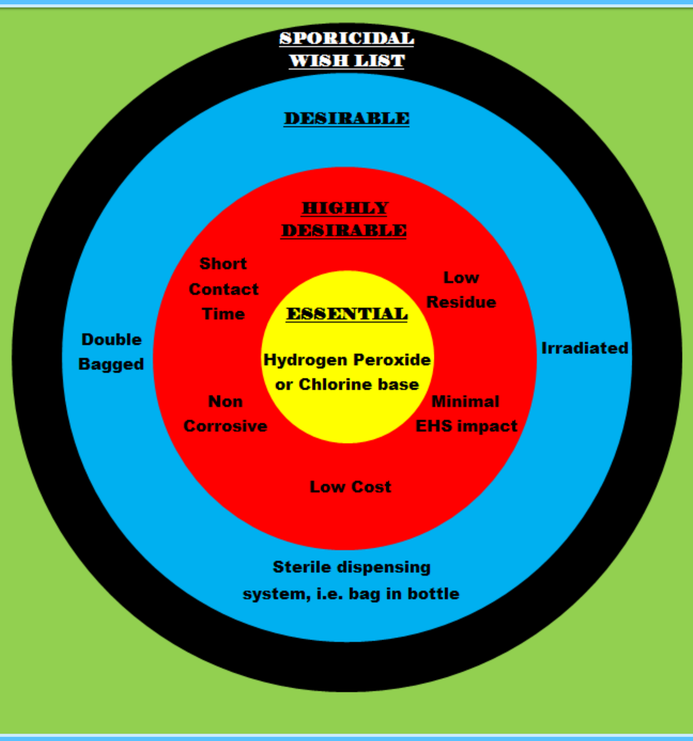
Introduction

- As a consequence of recent fatalities with the use of aseptically-prepared injectable medicines, the MHRA recommended the introduction of a sporicidal agent in the first stage of a two-step decontamination process[1].
- Our licensed Aseptics unit produces chemotherapy, named-patient radiopharmacy and other injectable (CIVAS) doses, using non-gassing isolator (Grade A) technology in a Grade C room environment.
- Traditional GMP environmental monitoring methods are employed, and historical monthly trending revealed a microbial recovery rate of 1.6% across Grade A.

Methods

Disinfectant Specification

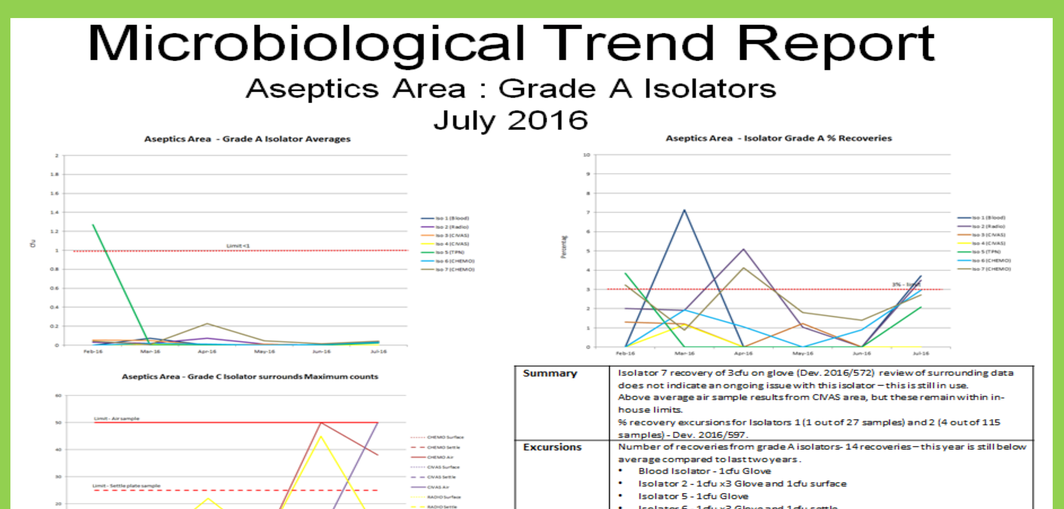


Defining Spray and Wipe Process

<u>Old Process</u>
1st Stage - Spray (alcohol)
2nd Stage - Spray then Wipe

<u>New Process</u>
1st Stage - Wipe then Spray (sporicide)
2nd Stage - Spray (alcohol) then Wipe

Impact Monitoring


Microbiological Trend Report
Aseptics Area : Grade A Isolators
July 2016

Aseptics Area - Grade A Isolator Averages

Aseptics Area - Isolator Grade A % Recoveries

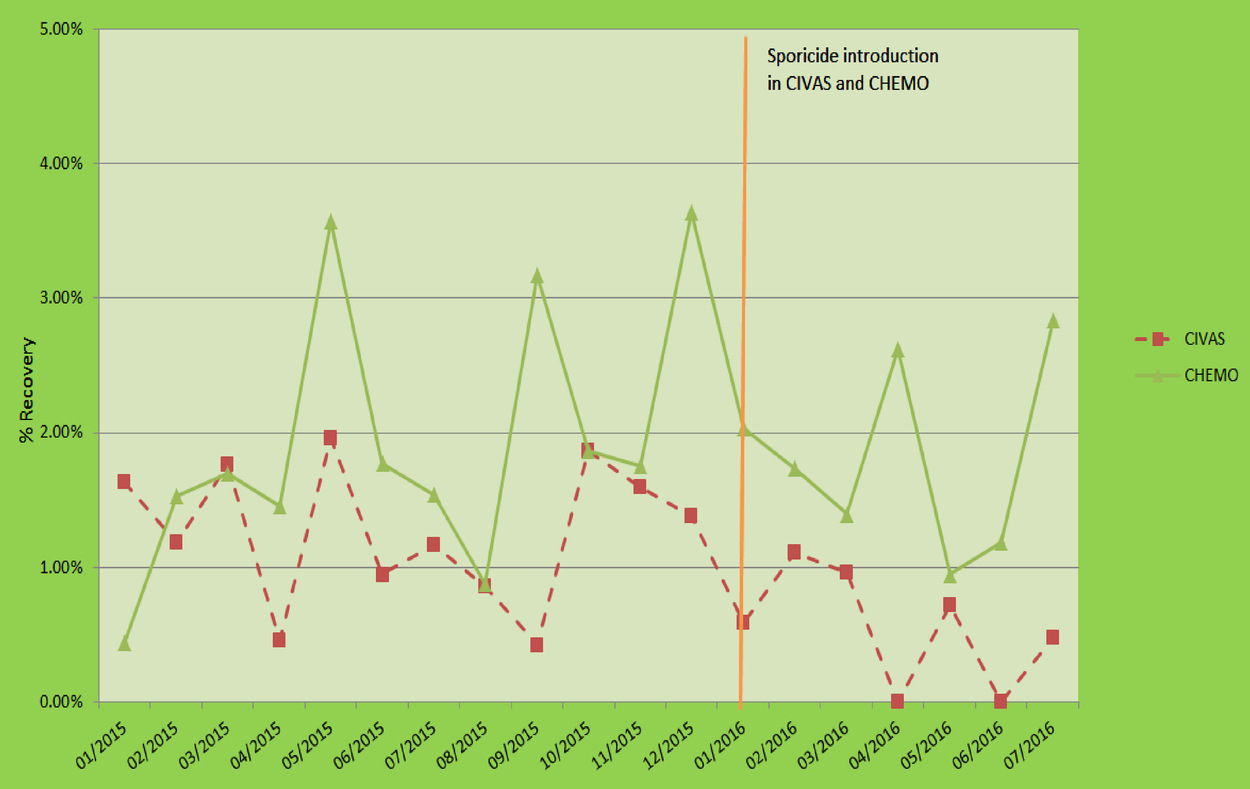
Aseptics Area - Grade C Isolator surrounds Maximum counts

Summary	Isolator 7 recovery of 3cfu on glove (Dev. 2016/572) review of surrounding data does not indicate an ongoing issue with this isolator – this is still in use. Above average air sample results from CIVAS area, but these remain within in-house limits. % recovery excursions for Isolators 1 (1 out of 27 samples) and 2 (4 out of 115 samples) - Dev. 2016/597.
Excursions	Number of recoveries from grade A isolators- 14 recoveries – this year is still below average compared to last two years. • Blood Isolator - 1cfu Glove • Isolator 2 - 1cfu x3 Glove and 1cfu surface • Isolator 5 - 1cfu Glove • Isolator 6 - 1cfu x3 Glove and 1cfu settle • Isolator 7 - 3cfu glove, 1cfu x2 glove and 1cfu settle • No Grade C isolator surround excursions
Upcoming	Validair qualification in September – aim is to maintain clean conditions during this period

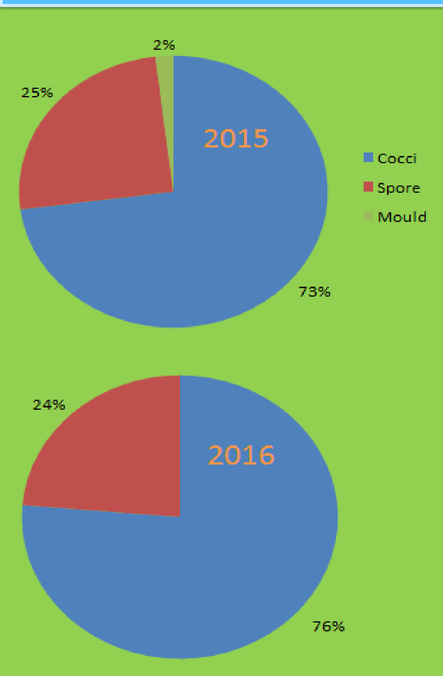
Report can be found in QA shared drive:\Environmental Monitoring\Aseptics\EM Reports\2016 by James Margetson - QA Microbiologist

Results

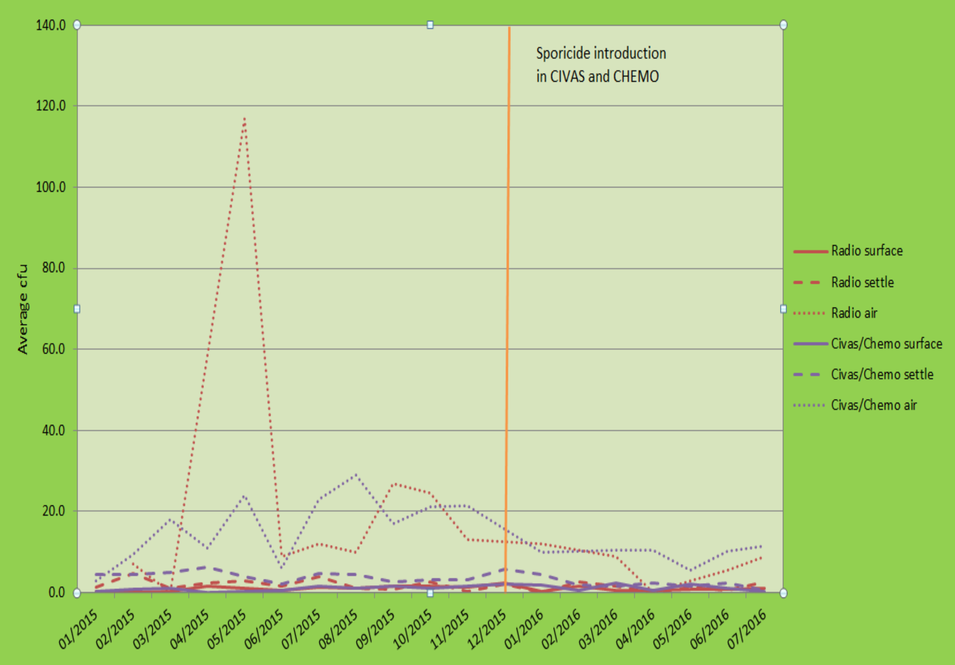
Grade A Impact



Grade A Organism Recovery Ratio



Preparation Room Impact



Outcomes

- 3% reduction in ratio of spore-formers to vegetative organisms
- 20% reduction in overall contamination
- 50% improvement in microbial air quality in Grade C isolator rooms
- 70% improvement in microbial air quality in Grade D preparation rooms
- 100% elimination of moulds in Grade A

Conclusion

A simple change of the sanitisation practice to a more robust wipe-spray-spray-wipe process, using a chlorine-based sporicidal agent for the first ‘spray’ step, significantly improves the background environmental conditions, reducing the risk of contamination, and thereby ensuring that injectable medicines are prepared safely for the benefit of patients.

Reference

1. Medicines and Healthcare products Regulatory Agency (MHRA) (2015) Guidance for Specials Manufacturers (accessed 07.02.17) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/400232/Guidance_for__specials__manufacturers.pdf

Contact

oweikumo.eradiri@colchesterhospital.nhs.uk
+44 1206 74 2744

22nd Congress of the European Association of Hospital Pharmacists, Cannes, France. 22 – 24 March 2017.