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Clostridium difficile-associated Disease (CdAD), Infection Control and Fecal Management

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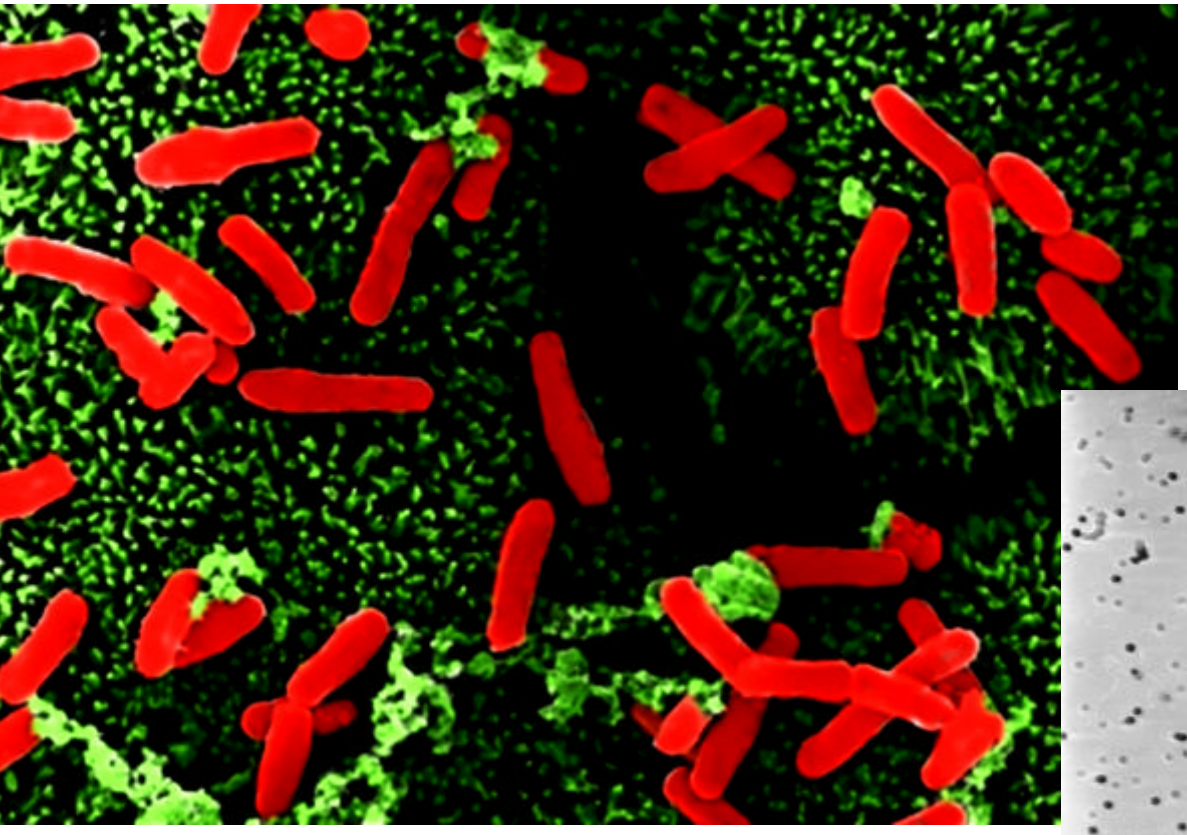
Clostridium difficile (*C. diff*)



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Fecal Incontinence (FI) and the Flexi-Seal® Fecal Management System (FMS)

- FI is associated with skin breakdown, excoriation, cross infection and loss of comfort for the patient
- Current methods of managing FI include disposable absorbent pads, diapers, rectal tubes and faecal collection pouches
  - Can lead to extended hospital stay due to skin breakdown, perineal wounds, damage to rectal mucosa and infection
- Flexi-Seal® FMS is designed for the diversion & containment of faecal effluent in immobilised patients with episodic FI
  - Consists of a soft silicone catheter, an inflatable retention balloon and a collection bag

Flexi-Seal® FMS

1. Catheter Irrigation Port
2. Balloon Inflation Port
3. Low-Pressure Retention Balloon
4. Position Indicator Line
5. Silicone Catheter
6. Hanging Strap
7. Connector
8. 60ml Luer-Lock Syringe
9. Collection Bag with Integrated Cap

In Vitro Study to Investigate the *C. diff* Containment Properties of Flexi-Seal® FMS

- Flexi-Seal® FMS compared against a standard disposable absorbent under pad
- A clinical wound isolate of *C. diff* used in the study
- A semi-solid agar medium (reinforced clostridial medium) was used to simulate faecal effluent in CdAD patients
- The Flexi-Seal® FMS study was conducted over 31 days (maximum intended use is 29 consecutive days)
- Swabbing of the device, environmental settle plates and air count techniques were used to assess transmission of *C.diff* through the Flexi-Seal® FMS and into the surrounding environment
- Swab samples were taken daily

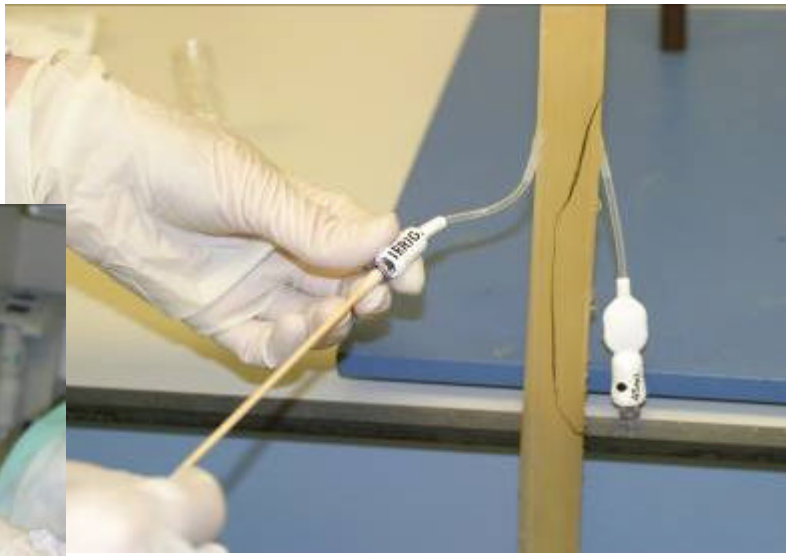
In Vitro Study to Investigate the *C. diff* Containment Properties of Flexi-Seal® FMS

- Four tests were conducted with the Flexi-Seal® FMS device, and a positive control was also included (i.e. a Flexi-Seal® FMS device which was purposely pierced with a sterile needle at various positions along the device)
- The disposable absorbent under-pad was tested using a standard ConvaTec method for testing the bacterial barrier properties of wound dressings (5-day test)

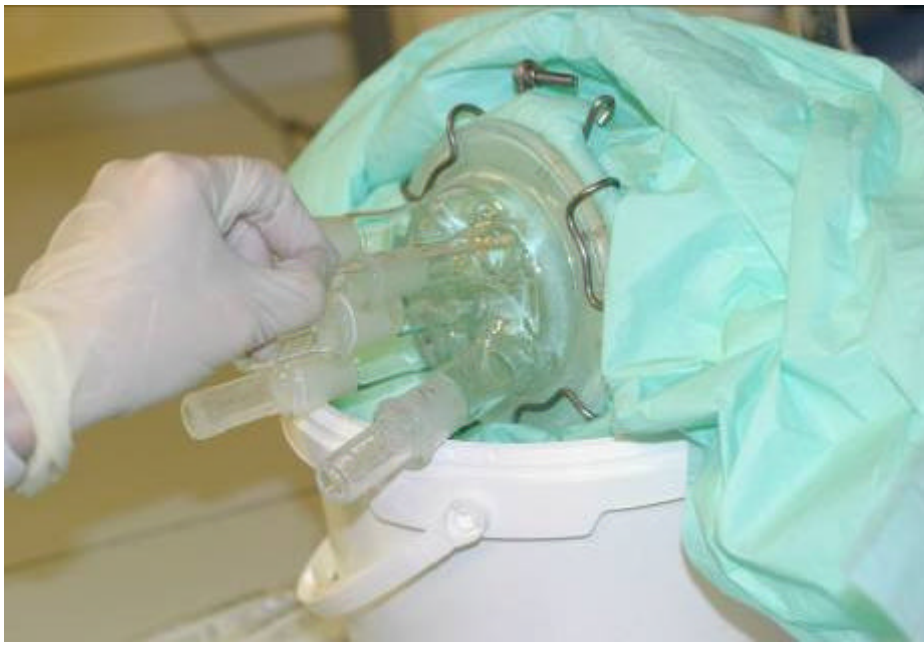
Ameen H et al. *J. Wound Care*. 2000; 9.

Flexi-Seal® FMS *In Vitro* Methodology: Set-up

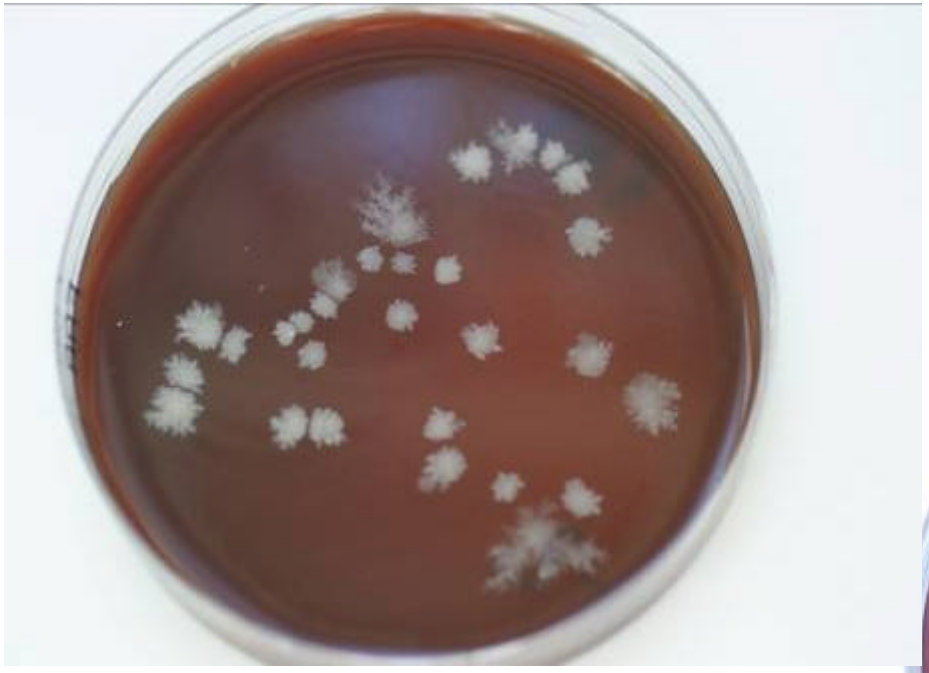
Flexi-Seal® FMS *In Vitro* Methodology: Sampling



Testing of Disposable Absorbent Under-pads



Culture & Identification of *C. diff*



Results

- No detection of *C. diff* spores on the outer side of the Flexi-Seal® FMS (n = 4)
  - No evidence of *C. diff* in the surrounding environment (environmental settle plates and air counts)
- *C. diff* spores were consistently detected from the positive Flexi-Seal® FMS control device
  - Evidence of *C. diff* on environmental settle plates in the vicinity of the positive control
- There was no evidence of transmission of *C. diff* through the absorbent under-pad; however the *C. diff* fluid suspension wicked across the absorbent surface of the under-pad

Summary & Conclusion

- A stringent *in vitro* model designed to simulate and monitor containment of faecal effluent and *C. diff* in a CdAD patient demonstrated that:
  - The Flexi-Seal® FMS effectively contained *C. diff*
  - The Flexi-Seal® FMS was not associated with environmental contamination with *C. diff* in the vicinity of the collection system
  - Based on *in vitro* data, the Flexi-Seal® FMS device effectively contains *C. diff* and should consequently be considered as part of an infection control strategy in the management of CdAD patients

The Team

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