



# IMPROVING SAFETY AND QUALITY FOR ASEPTIC TRANSFER PROCEDURES IN HOSPITAL PHARMACIES

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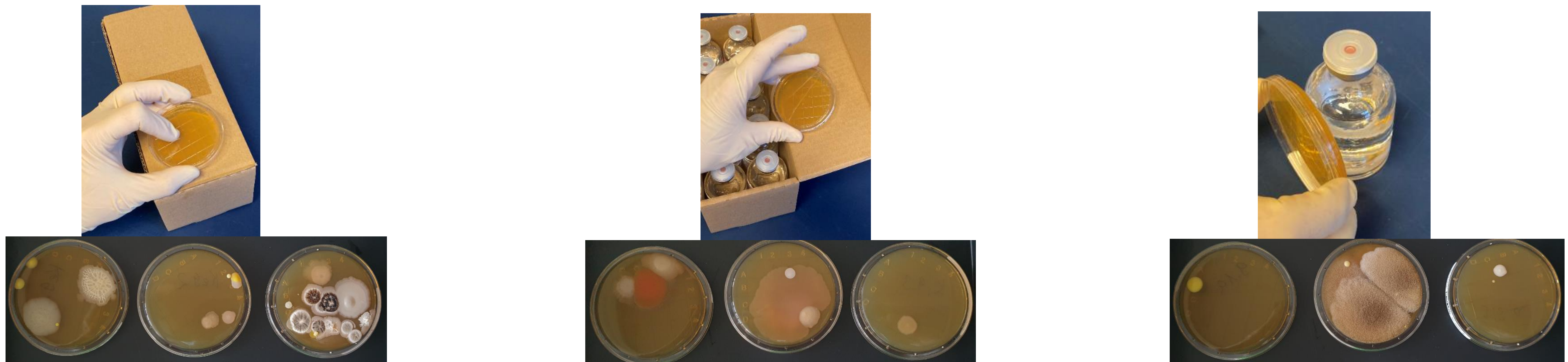
**Background and Importance:** Materials used in aseptic manufacturing like medical devices (MD), infusion bags (IB), bottles (B), infusion vials (V) and ampoules (A) most widely undergo disinfection with alcohol 70%. Alcohol disinfection, however, is known not to eradicate all microbes, e.g. bacterial spores.

**Aim and Objectives** To explore effectiveness of sporicidal aseptic transfer approach using High-Speed H<sub>2</sub>O<sub>2</sub><sup>TM</sup>.

**Materials and Methods** For 12 materials and their cardboard packaging (MD, IB, B, V, A), three samplings each at the outer and inner side of the packaging and at the unpacked material surface were tested with contact plates (108 plates) applied for 5 sec. After incubation for ≥72 hours at 20 - 25 ° C and 30 - 35 ° C, respectively, contact plates were observed for colony forming units (CFU). Unpacked materials were additionally tested, three samplings each (36 contact plates), after sporicidal disinfection using High-Speed H<sub>2</sub>O<sub>2</sub><sup>TM</sup> (wipes and foam).

**Results** Without disinfection, CFU appeared on 81% and 33% of contact plates referring to the outer and inner sides of the cardboard boxes. Surface of the materials showed contamination in 25% of plates. The microbes found on the plates included bacteria, aerobic endospore-formers (Bacillaceae) and Aspergillus. After sporicidal disinfection, on none of the plates microbial growth was seen.

Picture 1a – 1c: Example Infusion Vials



1.a: Contaminated samples cardboard boxes outer side

1.b: Contaminated samples cardboard boxes inner side

1.c: Contaminated Samples material surface

Picture 2 a-c: Example Infusion Bottles



2.a: Contaminated Samples cardboard boxes outer side

2.b: Contaminated samples cardboard boxes inner side

2.c: Contaminated samples material surface

**Conclusion and Relevance** As a risk-based approach to contamination control is fundamental to aseptic transfer procedures, our results reflect the strategy for minimizing contamination to aseptic manufacturing. Endospore-forming bacteria were found as part of the contamination flora on the surface of several material samples. Therefore a sporicidal agent, e.g. High-Speed H<sub>2</sub>O<sub>2</sub><sup>TM</sup>, is required to minimize contamination risk not only when materials are transferred to clean room classes B and A, but preferably when entering the production area (zone D) already.