



Background on Heater-Coolers

- Hospital, operating room instruments
- Heat blood and cool patients
- Using during heart surgery
- Linked to O₂ CO₂ exchange
- October 2015: Post-operative *Mycobacterium chimaera* infections

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Mycobacterium chimaera

- Member of the M. avium complex (MAC)
- Natural inhabitant of natural and engineered water systems
- · Human opportunistic pathogen
- Disinfectant-, temperature-, and desiccationresistant
- Grows in water in biofilms
- Readily aerosolized from water



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The Sorin 3T Heater-Cooler

- · Major manufacturer of heater-coolers
- Manufactured in Munich, Germany
- Cardiac surgery infections all linked to Sorin 3T and M. chimaera
- Infections rare, but mortality 50 %
- M. chimaera isolated from Sorin 3T and from settle (aerosol) plates in OR

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Challenges

- *M. chimaera*, like other MAC, highly disinfectant- (e.g., chlorine) resistant
- Disinfectant-resistance increased by biofilm-formation
- Heater-cooler offers high surface to volume ratio = Biofilm-formation
- Recirculation of 37°C water = Growth

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Biofilm Formation

- Hydrophobic M. chimaera cells adhere to surfaces
- Growth on surfaces
- Production of extracellular matrix consisting of lipid, protein, and DNA
- Shields cells from disinfectant
- Adherence and biofilm-formation allows persistence in flowing systems

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M. chimaera in Heater-Cooler

- · Heater-cooler is an ideal habitat
- · High surface to volume ratio
- · Water warmed and circulated
- Adherence and biofilm formation
- Grows at low carbon (AOC) levels
- Grows at low oxygen levels (6 % O₂)
- Disinfectant-resistance

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Questions

- How to kill M. chimaera in biofilms?
- Why were Sorin 3T-linked infections all due to M. chimaera?
- Were the *M. chimaera* isolates from Sorin 3T heater-coolers identical?
- What was the source of *M. chimaera* in Sorin 3T heater-coolers?

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Disinfection

- Growth conditions for *M. chimaera*?
- Lab media versus water?
- · Cells in heater-coolers from water
- Water-acclimation after growth in media
- What disinfectant? Chlorine
- Water-acclimated cells significantly more chlorine-resistant

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Developing an *M. chimaera*Disinfection Protocol - 1

- Dosage = Concentration x Duration
- · Higher dosage to kill cells in biofilms
- Surviving cells in biofilms = reappearance of M. chimaera
- Disinfectant choice and dosage limited by machine susceptibility
- · Disinfectants (e.g., chlorine) corrosive

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Developing an *M. chimaera*Disinfection Protocol - 2

- Release M. chimaera cells from biofilm
- Detergent-exposure prior to chlorine exposure
- Prolystica® chosen
- 5 min Prolystica® followed by 5 min Chlorine = 3 logs killing

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Validation of *M. chimaera*Disinfection Protocol

- Challenge: 100 million M. chimaera/mL
- Sample: (1) pre-inoculation, (2) inoculum number, (3) post-inoculum number, (4) post-Prolystica® number, (5) post-chlorine number, (6) post-disinfection protocol numbers weekly to 12 weeks

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Lessons Learned - 1

- Disappearance of inoculum in 5 min
- Post-inoculum density only 0.1 % of expected, based on dilution of inoculum
- 99.9 % of *M. chimaera* inoculum lost due to surface adherence
- To attain 3-logs of killing, needed to inoculate with 10-billion cells





Lessons Learned - 2

- Prolystica® + Chlorine = > 3-log killing
- Met FDA requirement of > 3-log killing
- No absolute eradication of M. chimaera
- Reappearance of *M. chimaera* by 8-12 weeks
- Reappearance due to survival of biofilm-adherent *M. chimaera* cells

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Where Did *M. chimaera* Originate?

- Sorin 3Ts tested at factory before shipping
- Munich water carried M. chimaera
- M. chimaera "inoculated" at factory
- M. chimaera in biofilms before shipping

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Clonal *M. chimaera* in Sorin 3Ts

- Only M. chimaera isolated from Sorin 3T heater-coolers implicated infections
- Whole genome sequencing showed all M. chimaera from same clone.
- M. chimaera from Munich factory water identical to patient isolates

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M. chimaera Survival After Draining and Shipping?

- Rapid adherence and biofilm-formation after filling for testing
- Survival after draining due to high moisture content of biofilm (80 %)
- M. chimaera desiccation-tolerant:
- 50 % survival after 6 weeks

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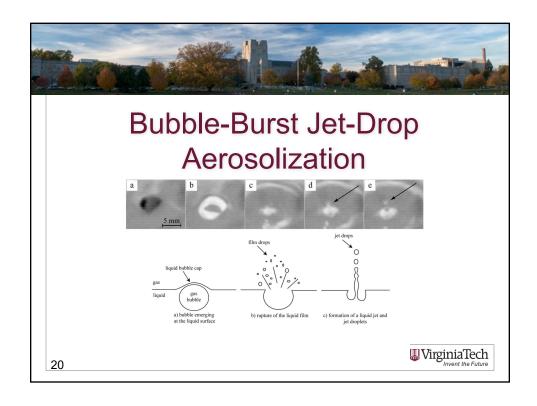


M. chimaera Aerosols - 1

- M. chimaera, MAC, and other Mycobacterium spp. hydrophobic cell surface
- MAC readily aerosolized from water
- Bubble burst jet drop mechanism
- Biofilm formation on underside of reservoir lid

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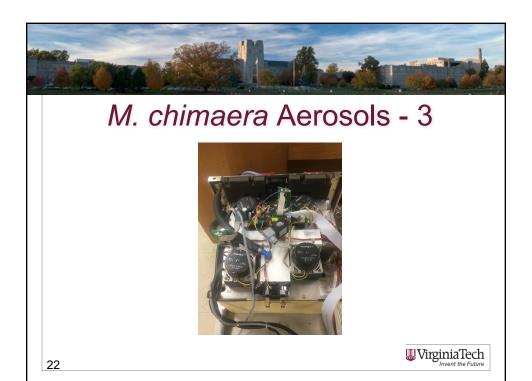


M. chimaera Aerosols - 2

- Moisture drawn to outside surface through screw holes
- Small fan above reservoir drew *M.* chimaera droplets to outside cabinet
- M. chimaera-laden aerosols circulate in operating room infecting patient

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Summary

- · Acclimate cells to water
- Release cells from biofilms with detergent
- · Chlorine effective disinfectant
- Mycobacteria will always return
- Regular detergent-chlorine disinfection

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March 25, 2021	SAFETY IN THE MEDICAL DEVICE REPROCESSING DEPARTMENT Speaker: Merlee Steele-Rodway, Reg. Nurse Educator/Consultant, Canada
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April 15, 2021	(<u>FREE Teleclass</u>) THE GLOBAL VIRUS NETWORK IN THE COVID-19 ERA Speaker: Prof. Christian Bréchot, Initiative on Microbiomes, University of South Florida
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