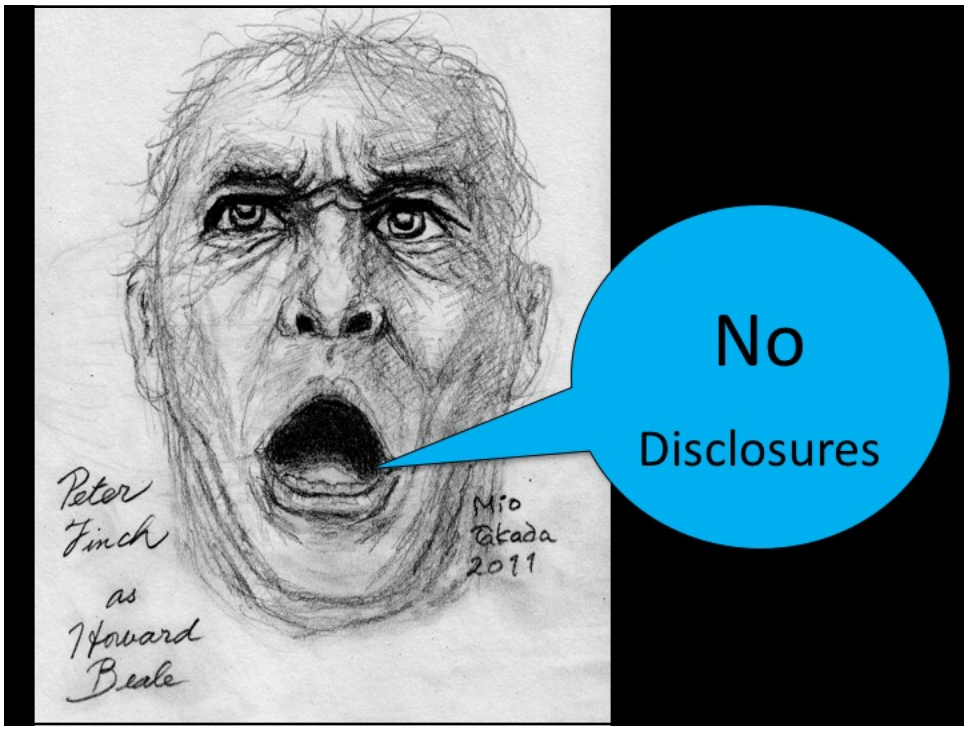
Trekking Safely Through the Storm – Managing Complex IPAC Issues

Prof. Mark Joffe, University of Alberta

Broadcast Live From the 2018 IPAC Canada Conference



Live broadcast sponsored by GOJO Canada (www.gojocanada.ca

A Webber Training Teleclass

www.webbertraining.com

Objectives

3 Stories:

- ARO Outbreak (MDR GNB)
- *M. chimaera* in CV Surgery
- Reprocessing Failure

Complex issues in IPC

Framework for response

We're used to crises…

Global Outbreaks

HOSPITALS CLAMP DOWN

30 new cases of SARS in Ontario

Five young children among latest stricken

CanWest News Service
TORONTO

With five young children now suspected of suffering from a virulent new respiratory disease, the Ontario government slapped strict restrictions Monday on every hospital in the province to try to slow the relentless spread of the illness.

At least three of the children believed to have the potentially deadly ailment are younger than two, provincial authorities say.

Hong Kong apartment quarantined / A5
Alberta patients are improving / A11

Ontario reported 30 more cases of SARS or severe acute respiratory syndrome Monday, bringing the total in Canada to 129.

British Columbia, Alberta and New Brunswick are also reporting probable or suspected cases.

See SARS / A11

THE ASSOCIATED PRESS

Reporters, wearing masks, gather outside of Hong Kong's Amoy Gardens, an apartment complex which was sealed off on Monday after being badly hit by Severe Acute Respiratory Syndrome.

Edmonton Journal April 1, 2003

CALGARY HERALD

PROUDLY CALGARY SINCE 1883 — A DIVISION OF CANWEST PUBLISHING INC.

EAKING NEWS AT CALGARYHERALD.COM — vancouver 2010 OFFICIAL SUPPLIER — REGIONAL NEWSPAPER PUBLISHER — •THURSDAY, APRIL 30, 2009

lberta
ostage
reed in
Nigeria

RICHARD WARNICA,
LAURA DRAKE
AND ELISE STOLTE
EDMONTON JOURNAL

fter nearly two weeks
captive in Nigeria, Julie
lligan called her family
ednesday afternoon to tell
n she was free.
he sounded great," said
di Dancey, who was with
husband John Mulligan
is Drayton Valley home
n the call came. "She was
ctly the same."
ulligan was abducted
April 16 while leading a

Imminent pandemic spurs global warning

Nations urged to 'ramp up' preparations

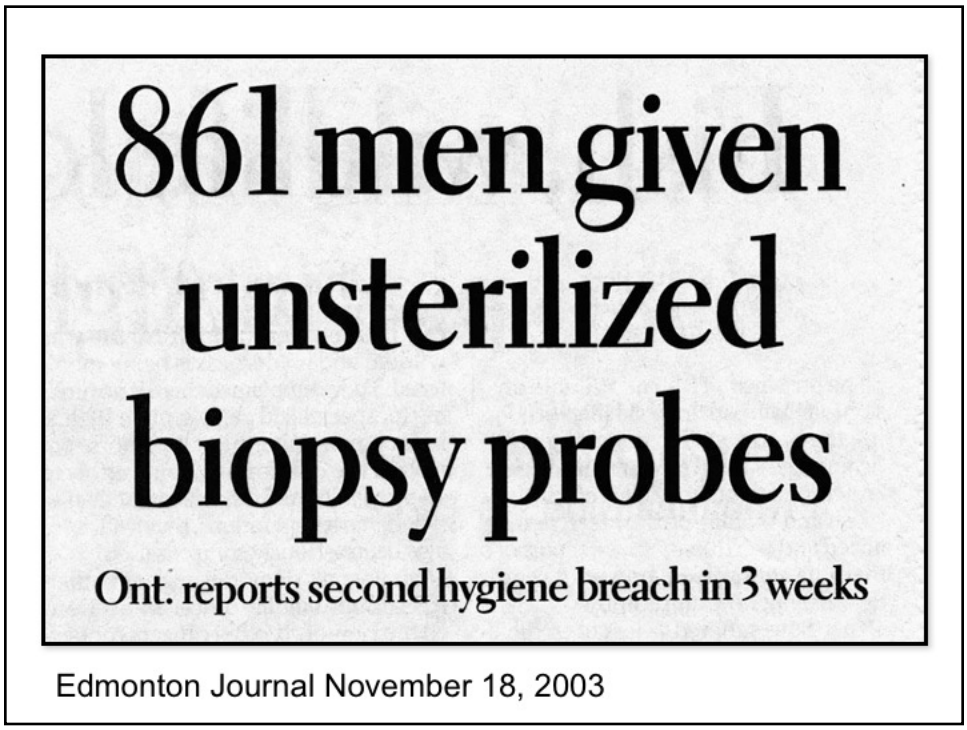
MEAGAN FITZPATRICK
CANWEST NEWS SERVICE

As Canada's swine flu infection total reached 19 Wednesday, the World Health Organization said the world is on the brink of a pandemic, raising its threat level as the swine virus spread.

Calgary Herald April 30, 2009

Local IPC

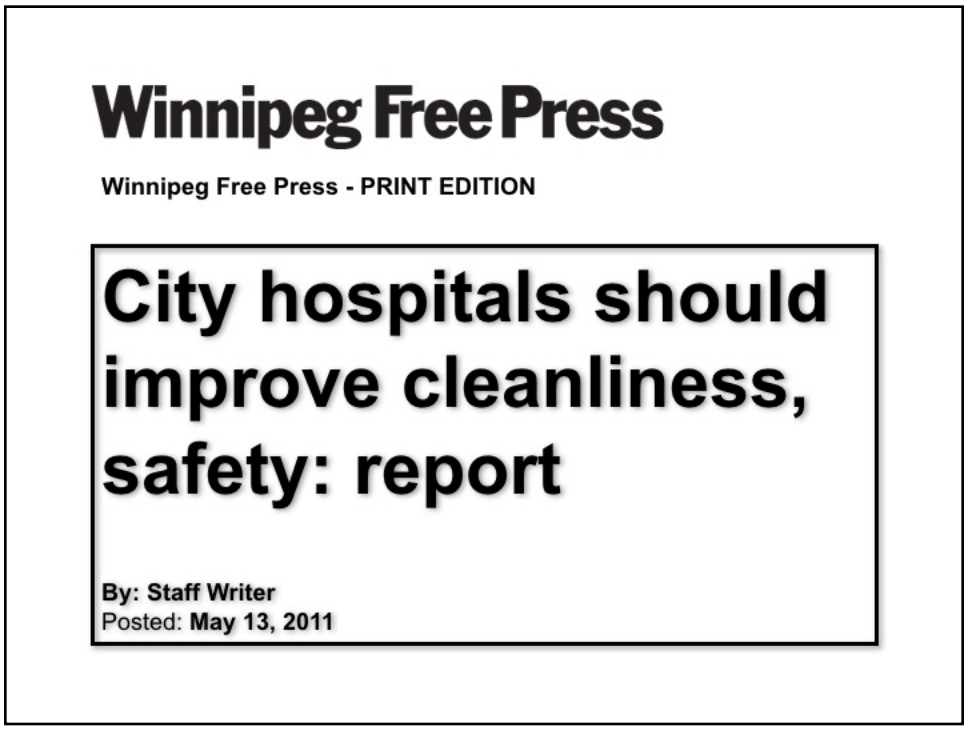
Disasters



861 men given unsterilized biopsy probes

Ont. reports second hygiene breach in 3 weeks

Edmonton Journal November 18, 2003

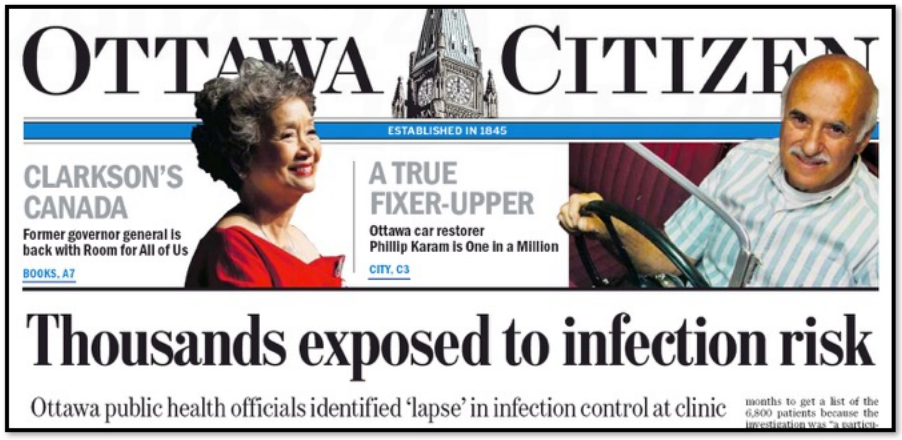


Winnipeg Free Press

Winnipeg Free Press - PRINT EDITION

City hospitals should improve cleanliness, safety: report

By: Staff Writer
Posted: May 13, 2011


OTTAWA CITIZEN

ESTABLISHED IN 1845

CLARKSON'S CANADA

Former governor general is back with Room for All of Us

BOOKS, A7

A TRUE FIXER-UPPER

Ottawa car restorer Phillip Karam is One in a Million

CITY, C3

Thousands exposed to infection risk

Ottawa public health officials identified 'lapse' in infection control at clinic

months to get a list of the 6,800 patients because the investigation was "a particu-

Ottawa Citizen October 16, 2011

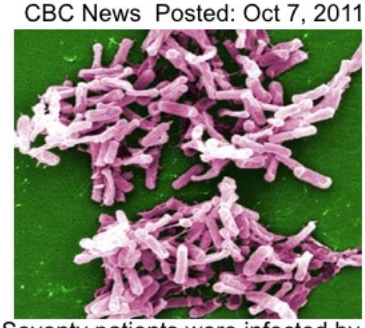
C. difficile victims settle suit with Quebec hospital

The families of patients who died after contracting C. difficile at a Quebec hospital in 2006 will each receive about $25,000 in compensation.
Jean-Pierre Menard, the lawyer representing the families announced details of a settlement with Honoré-Mercier hospital in St-Hyacinthe at a press conference Friday.

Seventy patients were infected and 16 died during the outbreak of C. difficile, or Clostridium difficile, infection.

The patients who survived the infection are also included in the settlement, but will receive a lesser amount.

CBC News Posted: Oct 7, 2011



Seventy patients were infected by a virulent strain of the C. difficile bacteria in 2006.

In 2007, the Quebec coroner faulted hospital administrators for failing to spend enough money on measures known to contain the spread of the superbug.

THE GLOBE AND MAIL

Thursday, Mar. 01, 2012

Negligence to blame for C. difficile outbreaks, B.C. doctors allege

B.C. Health Minister Mike de Jong cautioned against linking deaths to C. difficile, noting that it is medically difficult to pinpoint mortality rates from the bug.

Eighty-four patients died and hundreds more suffered serious complications following outbreaks of a highly infectious superbug at a Metro Vancouver hospital over the past two years. Now physician whistleblowers are saying the lack of infection control borders on medical negligence.

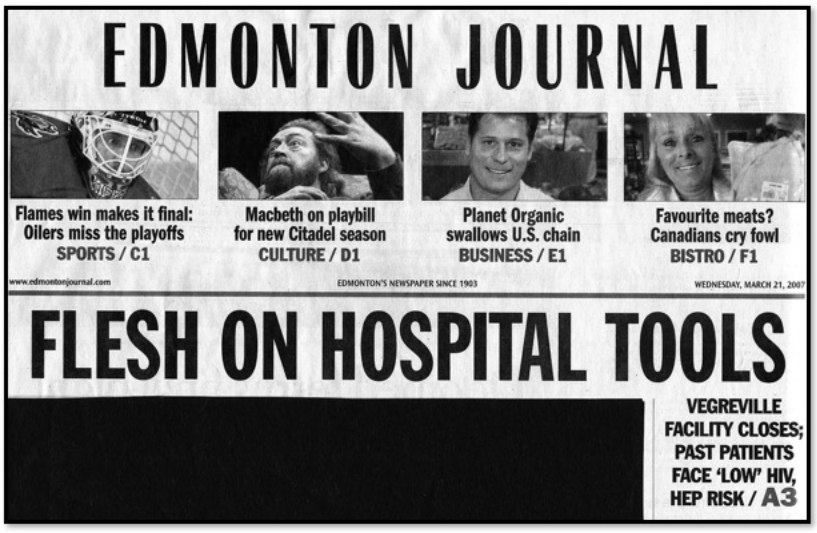
The infection rates of the bacteria *Clostridium difficile* at Burnaby Hospital have been two or three times the national average over the past two years and on par with the deadly outbreak in hospitals in the Niagara region that led to government reviews and reporting changes in Ontario.

The Province
Division of Canwest Publishing Inc.

vancouver 2010 OFFICIAL SUPPLIER
REGIONAL NEWSPAPER PUBLISHER

Surgeries cancelled after filth found on tools Hundreds must wait after audit finds glue, tissue on instruments

THE PROVINCE FEBRUARY 18, 2010



EDMONTON JOURNAL

Flames win makes it final: Oilers miss the playoffs SPORTS / C1

Macbeth on playbill for new Citadel season CULTURE / D1

Planet Organic swallows U.S. chain BUSINESS / E1

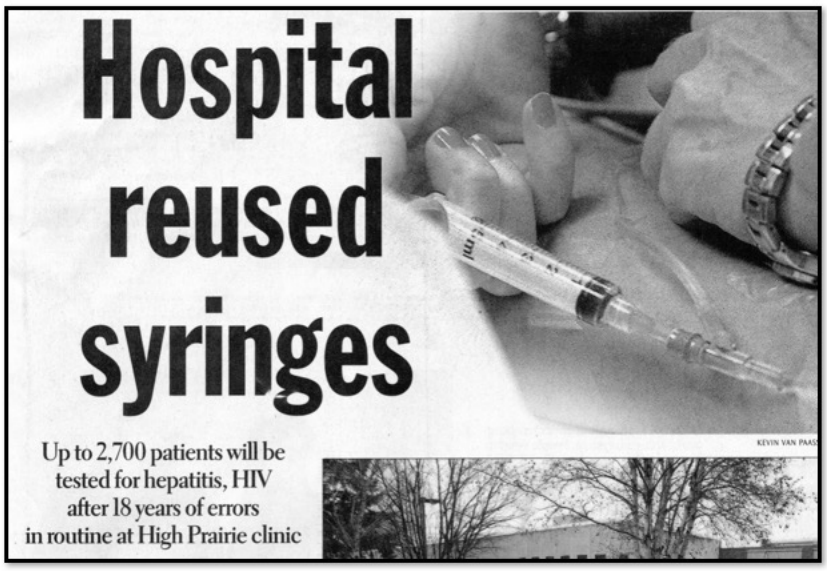
Favourite meats? Canadians cry fowl BISTRO / F1

www.edmontonjournal.com EDMONTON'S NEWSPAPER SINCE 1903 WEDNESDAY, MARCH 21, 2007

FLESH ON HOSPITAL TOOLS

VEGREVILLE FACILITY CLOSES; PAST PATIENTS FACE 'LOW' HIV, HEP RISK / A3

Edmonton Journal March 21, 2007



Hospital reused syringes

Up to 2,700 patients will be tested for hepatitis, HIV after 18 years of errors in routine at High Prairie clinic

KEVIN VAN PAASSEN

Edmonton Journal October 28, 2008

THE GLOBE AND MAIL

CANADA'S NATIONAL NEWSPAPER ◆ FOUNDED 1844

Hepatitis prompts warning at Scarborough Hospital

Colin Freeze May 20, 2006

Toronto Public Health authorities have warned **400** Scarborough Hospital **dialysis patients** that they may be at risk of hepatitis infection and urged them not to share their toothbrushes or razors with family members, and to use condoms during sex.

"There are eight patients we are investigating with new infections," said Dr. Michael Finkelstein, an associate medical officer with Toronto Public Health.

http://www.theglobeandmail.com/news/national/hepatitis-prompts-warning-at-scarborough-hospital/article966143/

Birth gear unsterilized at Halifax hospital

HALIFAX / A children's hospital in Halifax is warning women who gave birth this month that equipment used during their delivery had not been properly sterilized.

However, the IWK Health Centre says it's likely only seven mothers-to-be were treated with the equipment and the chances of anyone getting sick are "near zero."

The hospital issued a statement saying that "birth-related equipment (was) cleaned, decontaminated but not sterilized prior to being sent to the birth unit."

"As a result, 64 women who gave birth during a six-day period in March are being notified and provided with necessary information," the hospital said.

The seven sets of equipment were cleaned by hand and with a decontamination washer, but the sterilization machine wasn't used, the hospital said.

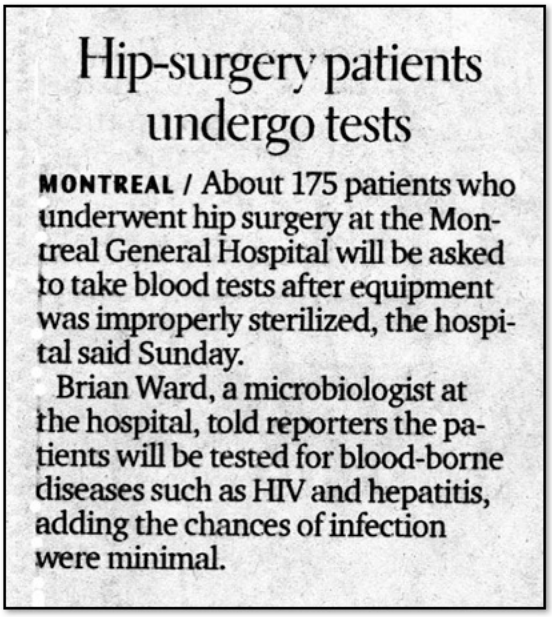
64 Women

Equipment Cleaned

But not Sterilized

Risk is "Near Zero"

Edmonton Journal
March 17, 2012



Hip-surgery patients undergo tests

MONTREAL / About 175 patients who underwent hip surgery at the Montreal General Hospital will be asked to take blood tests after equipment was improperly sterilized, the hospital said Sunday.

Brian Ward, a microbiologist at the hospital, told reporters the patients will be tested for blood-borne diseases such as HIV and hepatitis, adding the chances of infection were minimal.

175 Patients

Equipment

Improperly

Sterilized

Edmonton Journal
April 12, 2004

Sterilization error sparks testing for HIV and hepatitis in Peter Lougheed Centre endoscopy patients

Bryan Passifiume
TUESDAY, DECEMBER 23, 2014

Problems with sterilization equipment have resulted in **35 endoscopy patients** at Peter Lougheed hospital being screened for HIV & hepatitis.

With chances of infection for the 35 patients extremely remote, Finstad said AHS's policy in cases like these is that it's better to be safe than sorry.

Near Hanna, Alberta June 2017. Courtesy of Darren Sandbeck

The Basics

- Confirm the Diagnosis
- Mitigate
- Who Can help us? Who's the Boss?
  - Experts/IPC/Clinical Teams/Lab/Public Health/etc.
  - Legal/Comms/Risk Management
- Standing meetings – daily, twice daily, weekly, etc.
- Who Needs to Know? Communicate!
  - Senior Management; Public Health; Government
- What can we learn? Prevention!

Story #1

ARO Outbreak

New superbug renders antibiotics powerless

NDM-1 goes global, with confirmed cases in Alberta and B.C.

CARMEN CHAI
Postmedia News

An antibiotic-resistant superbug that emerged in India has been iden-

NDM/CPO/CRE/CRO

British researchers say the bac-

Edmonton Journal Aug. 12, 2010

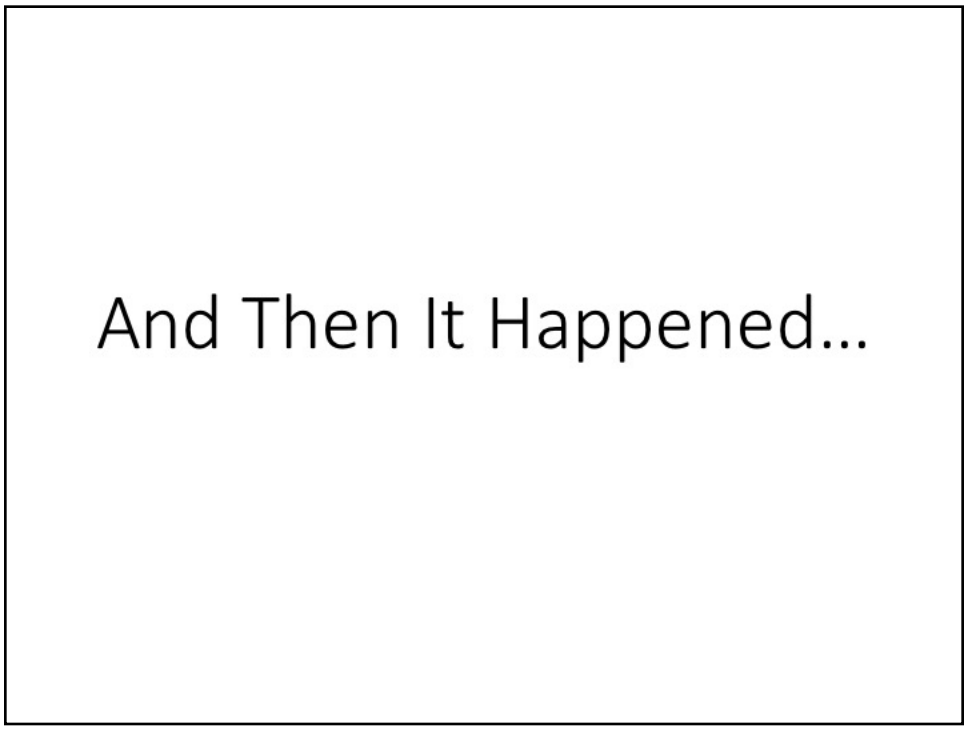
gladesh, says a report published Wednesday in the medical journal, *The Lancet*.

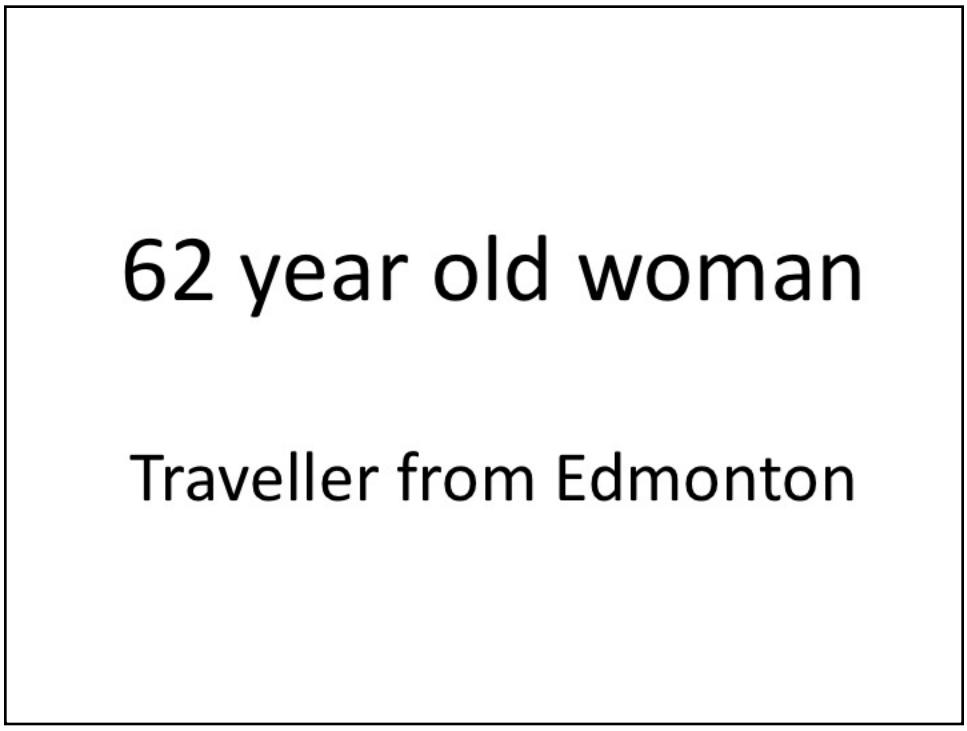
tional spread is cle
ing," their report st
Added Toleman
years, we've seen a
resistant genes, but

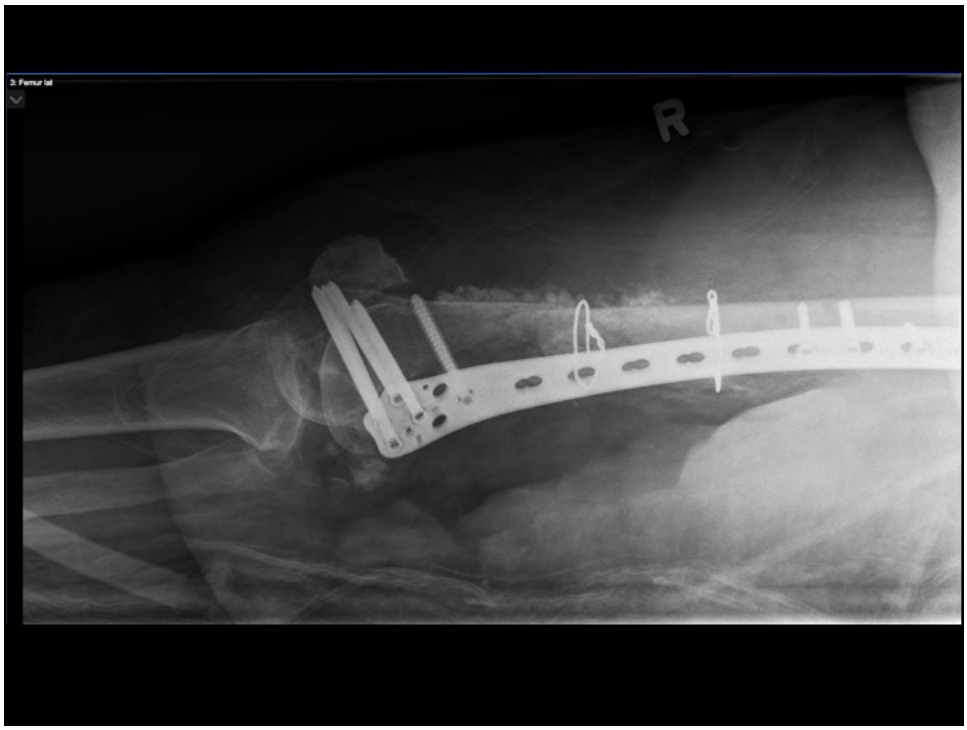
officer, Dr. Perry K

General Hospital th
Kendall said the p
isolated and appears

CODIE McLACHLAN, THE JOURNAL
Dr. Gerry Predy, Alberta Health Services senior medical officer of health, left, and Dr. Mark Joffe, senior medical director for infection, prevention and control, speak to the media at Royal Alexandra Hospital on Thursday.


And Then It Happened…

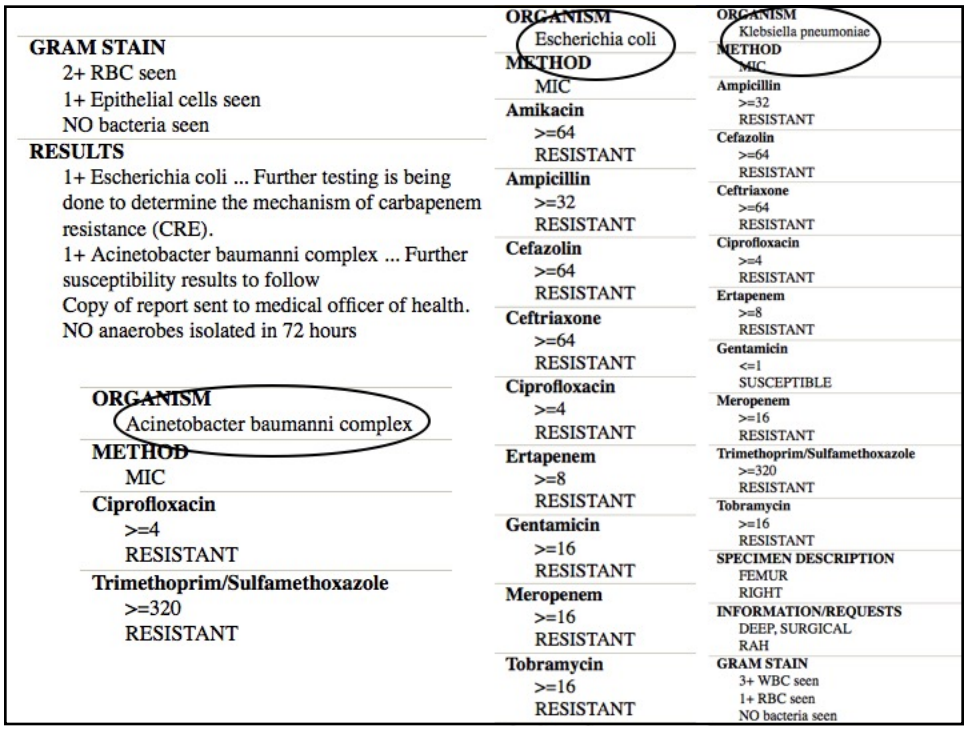

62 year old woman
Traveller from Edmonton



ED Note:

Huge wound dehiscence

Foul Smelling, +++ slimy exudate



GRAM STAIN
2+ RBC seen
1+ Epithelial cells seen
NO bacteria seen

RESULTS
1+ Escherichia coli ... Further testing is being done to determine the mechanism of carbapenem resistance (CRE).
1+ Acinetobacter baumanni complex ... Further susceptibility results to follow
Copy of report sent to medical officer of health.
NO anaerobes isolated in 72 hours

ORGANISM
Acinetobacter baumanni complex
METHOD
MIC
Ciprofloxacin
>=4
RESISTANT
Trimethoprim/Sulfamethoxazole
>=320
RESISTANT

ORGANISM
Escherichia coli
METHOD
MIC
Amikacin
>=64
RESISTANT
Ampicillin
>=32
RESISTANT
Cefazolin
>=64
RESISTANT
Ceftriaxone
>=64
RESISTANT
Ciprofloxacin
>=4
RESISTANT
Ertapenem
>=8
RESISTANT
Gentamicin
>=16
RESISTANT
Meropenem
>=16
RESISTANT
Tobramycin
>=16
RESISTANT

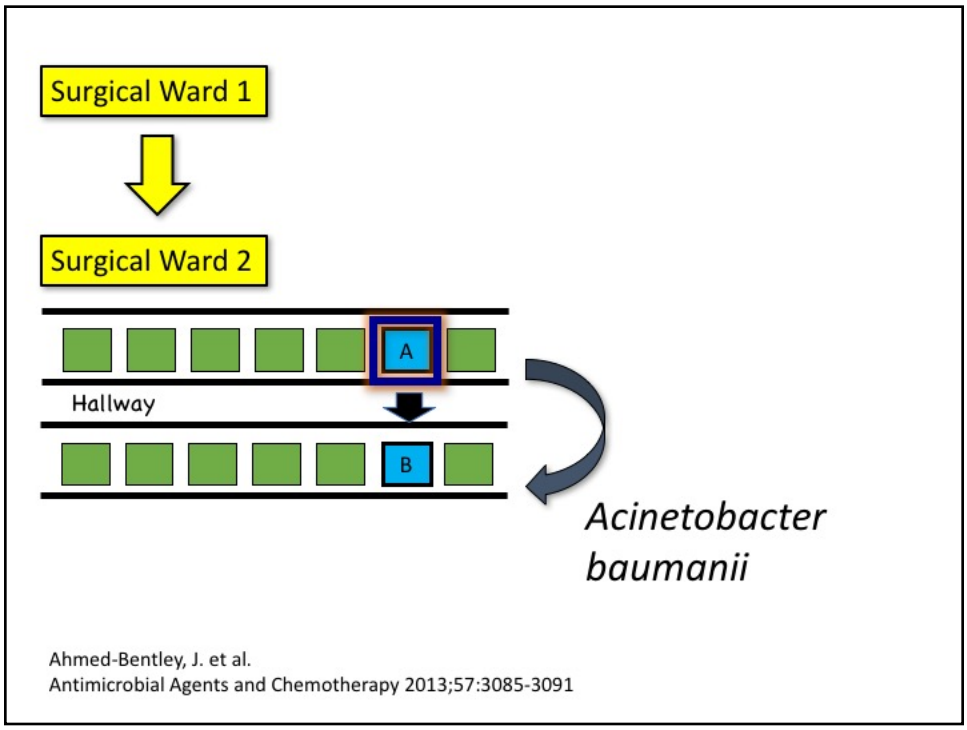
ORGANISM
Klebsiella pneumoniae
METHOD
MIC
Ampicillin
>=32
RESISTANT
Cefazolin
>=64
RESISTANT
Ceftriaxone
>=64
RESISTANT
Ciprofloxacin
>=4
RESISTANT
Ertapenem
>=8
RESISTANT
Gentamicin
<=1
SUSCEPTIBLE
Meropenem
>=16
RESISTANT
Trimethoprim/Sulfamethoxazole
>=320
RESISTANT
Tobramycin
>=16
RESISTANT
SPECIMEN DESCRIPTION
FEMUR
RIGHT
INFORMATION/REQUESTS
DEEP, SURGICAL
RAH
GRAM STAIN
3+ WBC seen
1+ RBC seen
NO bacteria seen

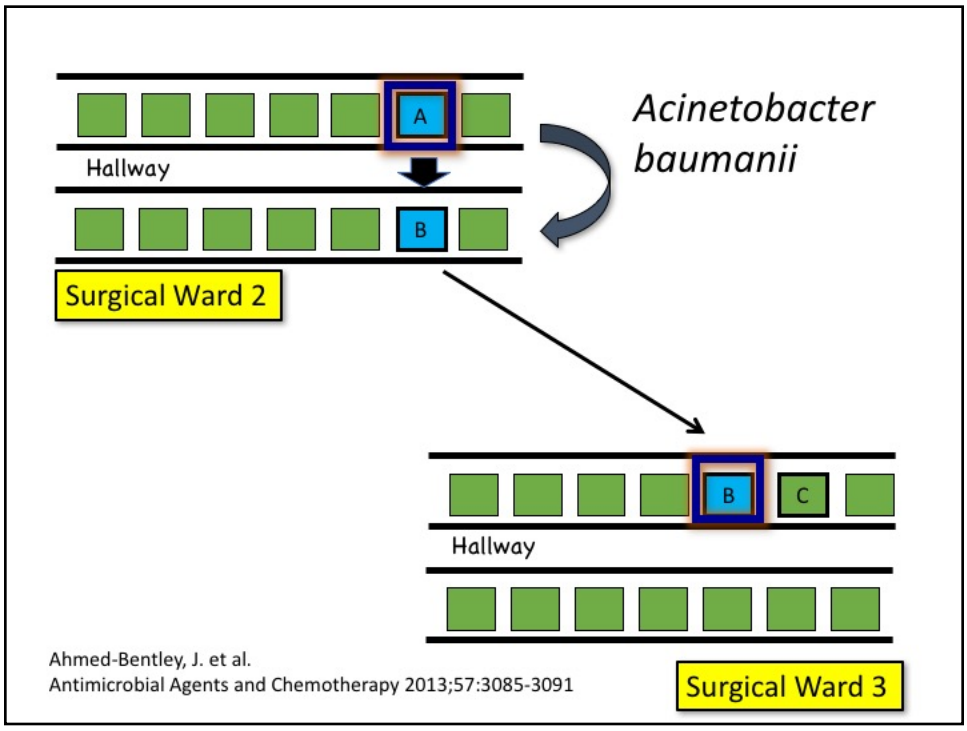
Multiple - Multiply Resistant Gram Negative Bacilli

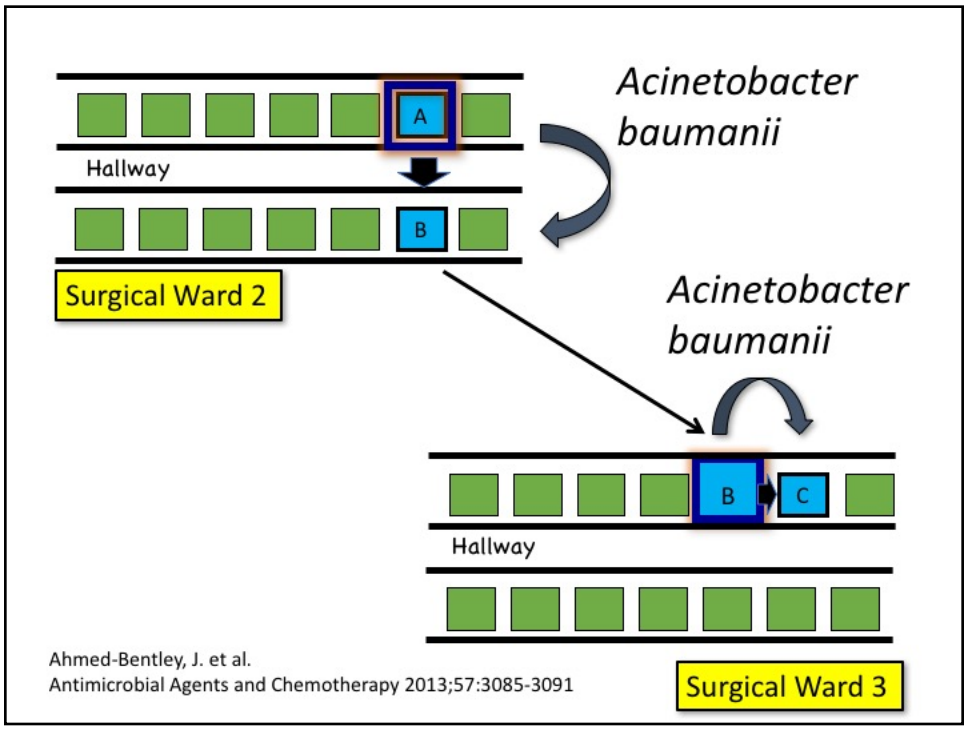
NDM-1 K. pneumoniae

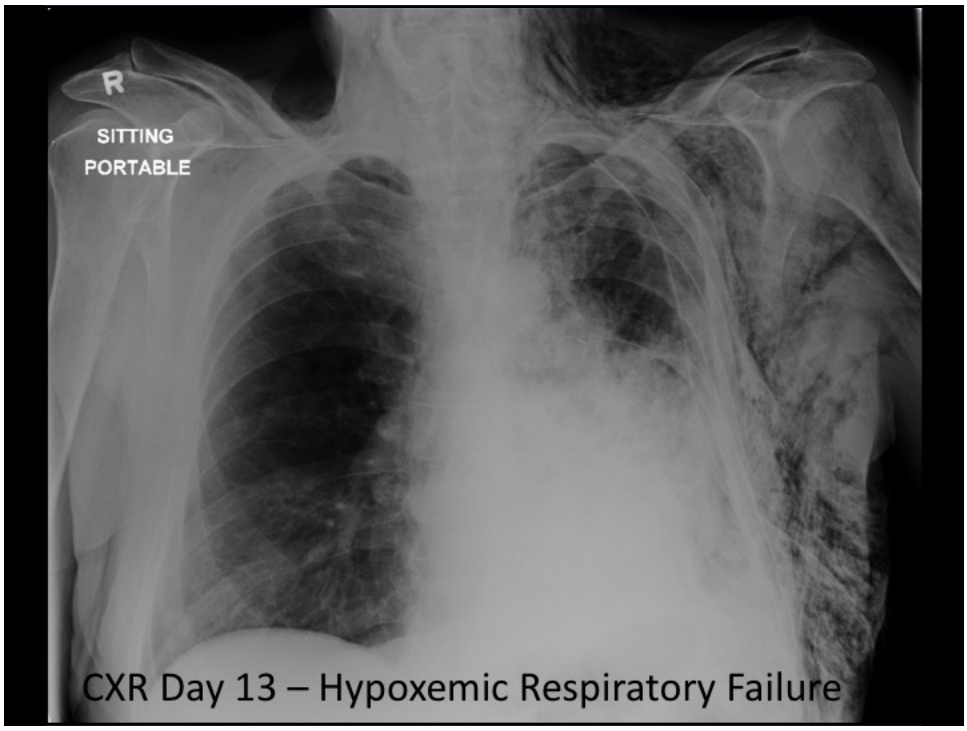
NDM-1 E. coli

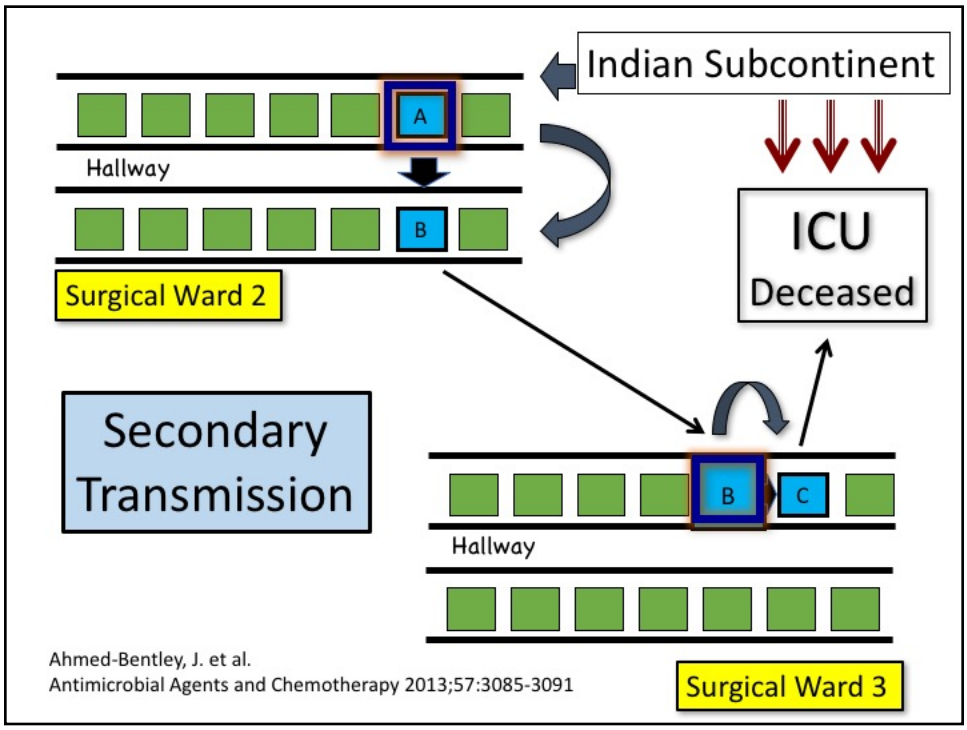
Acinetobacter baumanii


Surgical Ward 1
Surgical Ward 2
A
Hallway
B
Acinetobacter baumanii
Ahmed-Bentley, J. et al.
Antimicrobial Agents and Chemotherapy 2013;57:3085-3091


A
Hallway
B
Acinetobacter baumanii
Surgical Ward 2
B
C
Hallway
Ahmed-Bentley, J. et al.
Antimicrobial Agents and Chemotherapy 2013;57:3085-3091
Surgical Ward 3


A
Hallway
B
Surgical Ward 2
Acinetobacter baumanii
Acinetobacter baumanii
B
C
Hallway
Ahmed-Bentley, J. et al.
Antimicrobial Agents and Chemotherapy 2013;57:3085-3091
Surgical Ward 3

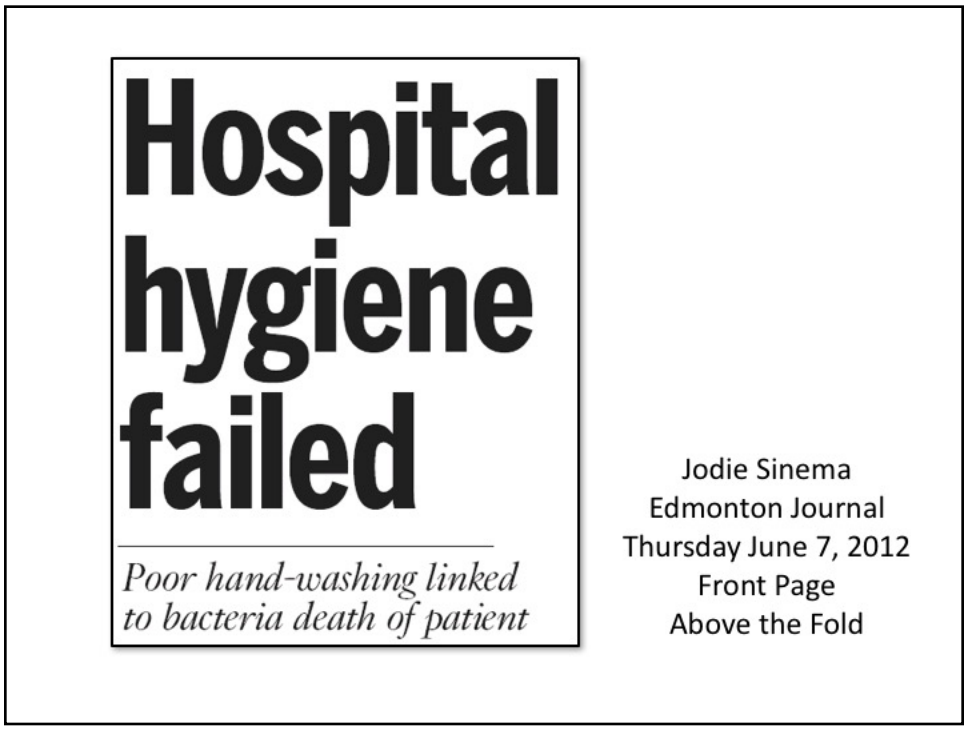

R
SITTING
PORTABLE
CXR Day 13 – Hypoxemic Respiratory Failure



Edmonton Sun
FRIDAY, MAY 18, 2012

Patient dead as AHS probes suspected outbreak


Fatality blamed on bacteria
Edmonton Journal May 19, 2012 - Front Page

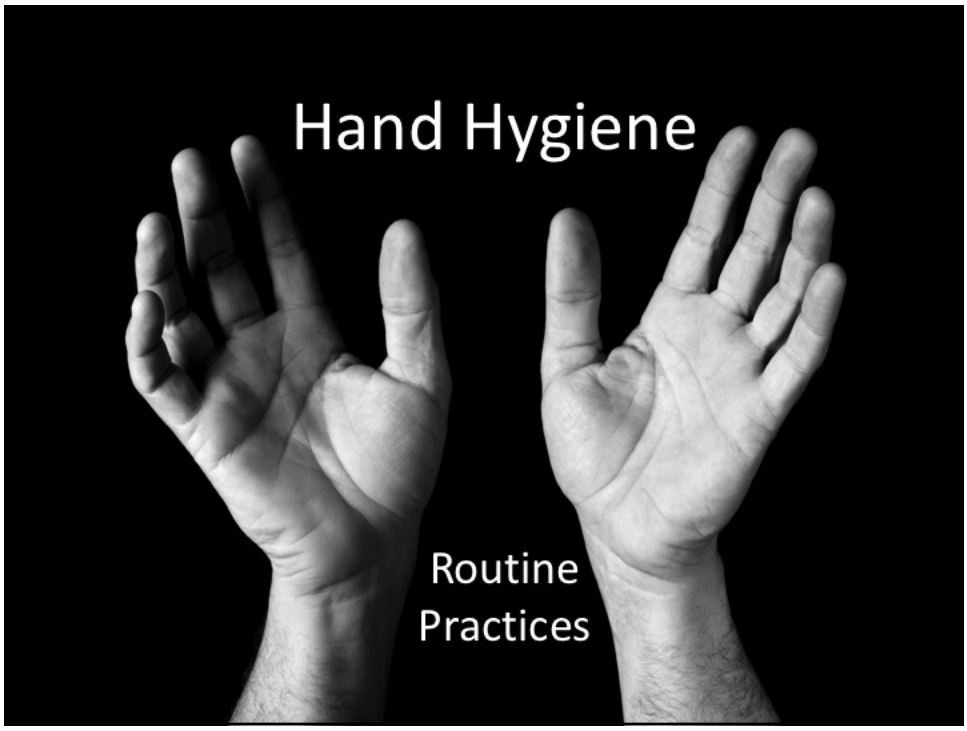

Hospital hygiene failed
Poor hand-washing linked to bacteria death of patient
Jodie Sinema
Edmonton Journal
Thursday June 7, 2012
Front Page
Above the Fold

Poor hand-washing likely led to spread of rare infection at Royal Alex

EDMONTON - Poor hand-washing rates in Edmonton and Alberta hospitals contributed to the spread of multi-drug-resistant bacteria that infected several people and likely played a part in the death of a Royal Alexandra Hospital patient.

June 6, 2012

Global EDMONTON



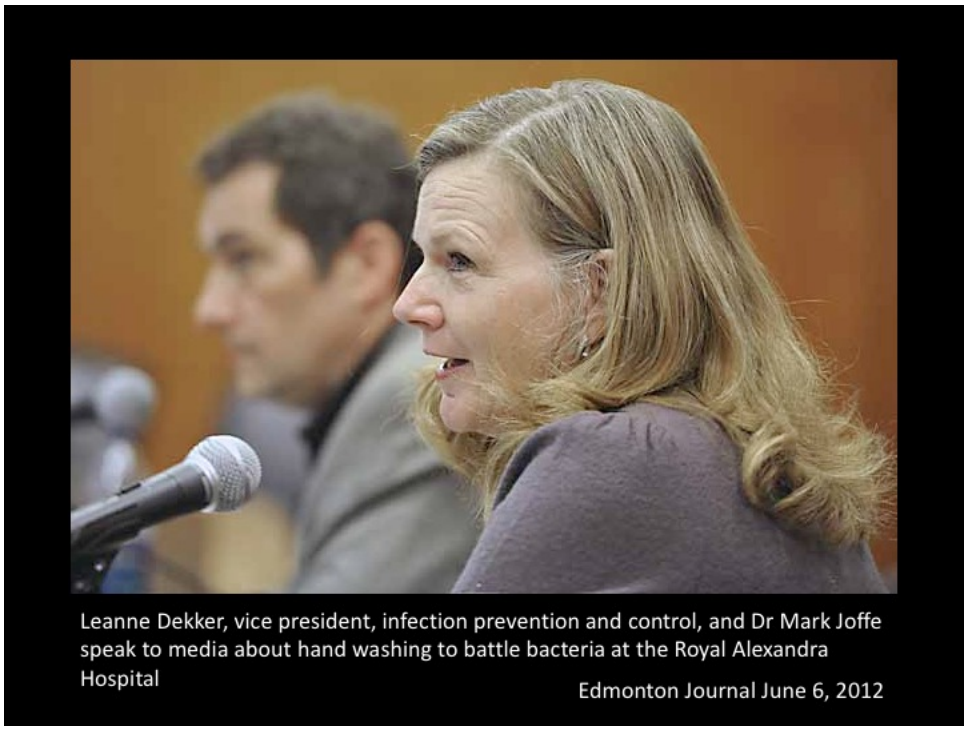
Impact

- 4 units + ICU involved
- total of 64 days of ward closure
- 410 patients
- 452 CRE screens
- 6 patients
- 1 death

- Reputational Impact

The Basics

- Confirm the Diagnosis
- Mitigate
- Who Can help us? Who's the Boss?
  - Experts/IPC/Clinical Teams/Lab/Public Health/etc.
  - Legal/Comms/Risk Management
- Standing meetings – twice daily…daily…weekly, etc.
- Who Needs to Know? Communicate!
  - Senior Management; Public Health; Government
- What can we learn? Prevention!



Leanne Dekker, vice president, infection prevention and control, and Dr Mark Joffe speak to media about hand washing to battle bacteria at the Royal Alexandra Hospital

Edmonton Journal June 6, 2012

Media Training

Controversy

Confusion

Calamity

Crisis

Chaos

Adapted from Ralph Klein

Media Training

Key Messages (+/- 3)

Concise

Conversational

Catchy

Control

Story #2

Global Outbreak of

M. chimaera

(IPC at its Best)

An Outbreak in Slow Motion*

* Dr. Dan Diekema
http://haicontroversies.blogspot.ca/2016/10/an-outbreak-in-slow-motion.html

Global Outbreak of *M. chimaera*

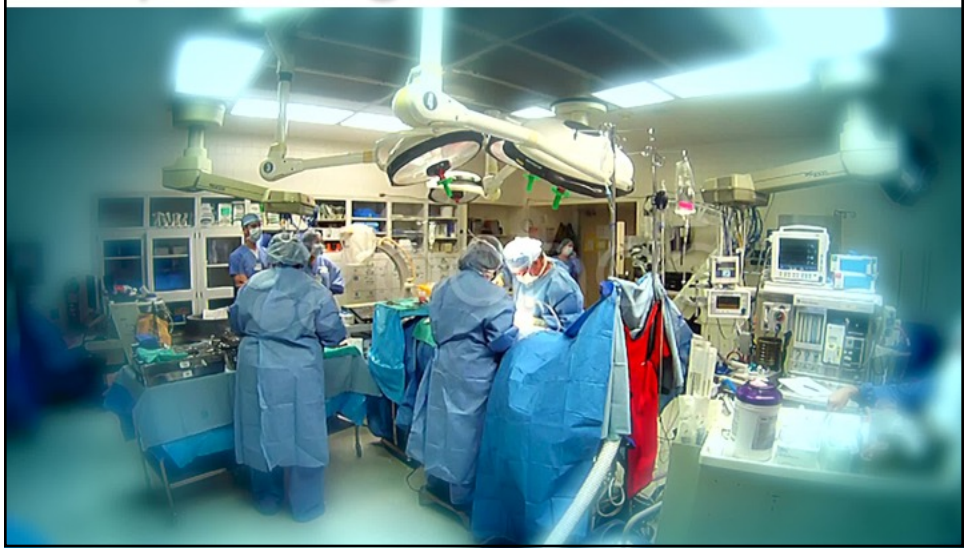
Some Basic Background

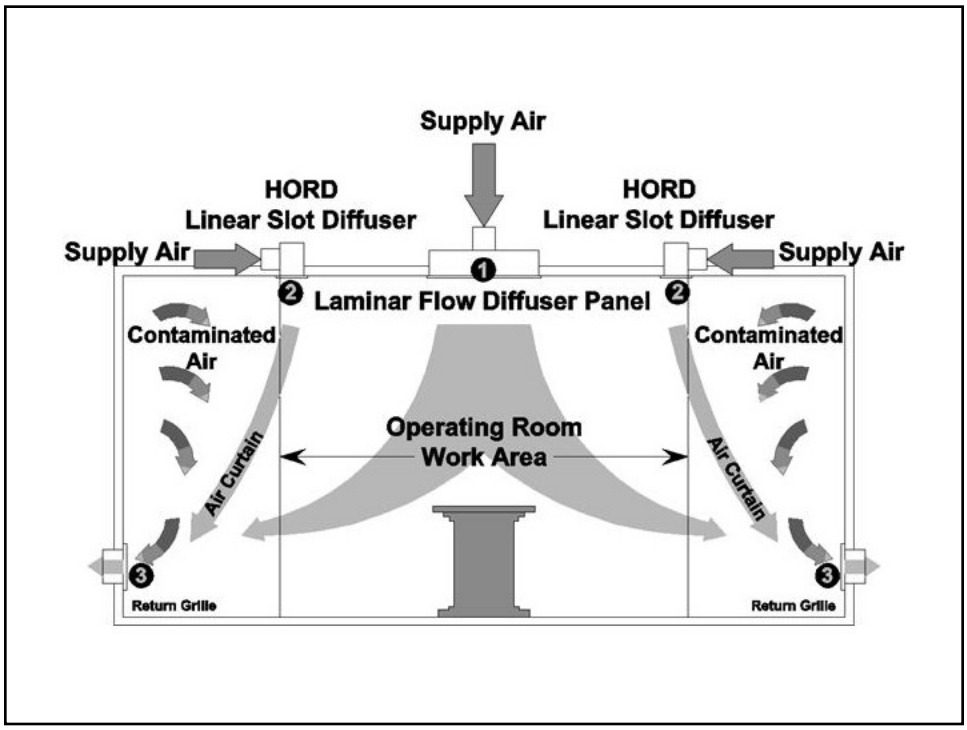
Operating Room Air Flow

Heater Coolers

Non-Tuberculous Mycobacteria

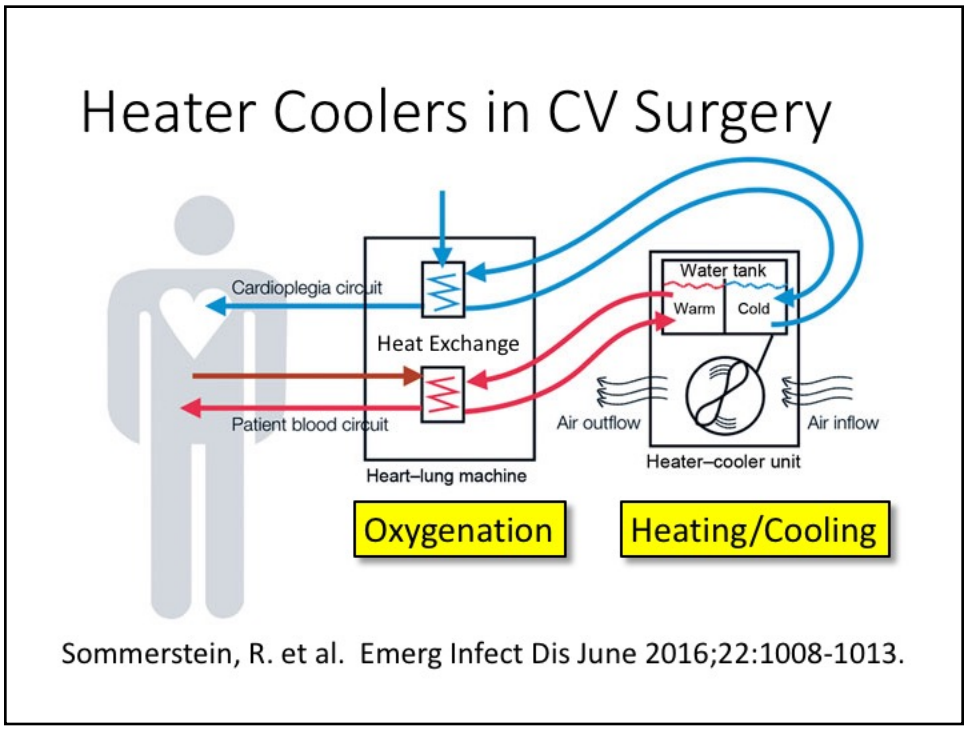
Operating Room Air Flow





Heater - Coolers


Sorin 3T
Heater
Cooler
3 sides
Air
Exhaust
Air
Intake


Heater Coolers in CV Surgery
Cardioplegia circuit
Heat Exchange
Patient blood circuit
Heart–lung machine
Water tank
Warm
Cold
Air outflow
Air inflow
Heater–cooler unit
Oxygenation
Heating/Cooling
Sommerstein, R. et al. Emerg Infect Dis June 2016;22:1008-1013.

Non-Tuberculous

Mycobacteria

TB or Non-TB

Mycobacteria

TB Complex
M. tuberculosis
M. bovis (BCG)
M. africanum
M. microti
etc.

Non-TB
~170
Low virulence
Environmental
(soil and water)
Opportunistic
Chronic Lung Disease

Mycobacterium avium Complex

= 10 - 11 species. (reported out as MAC)

- *M. avium*
- *M. intracellulare*
- *M. chimaera*

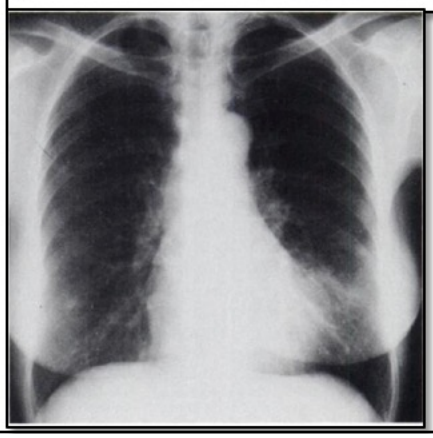
} 1 bp difference in 16s rRNA sequence

Mycobacterium avium Complex Pulmonary Disease Presenting as an Isolated Lingular or Middle Lobe Pattern*

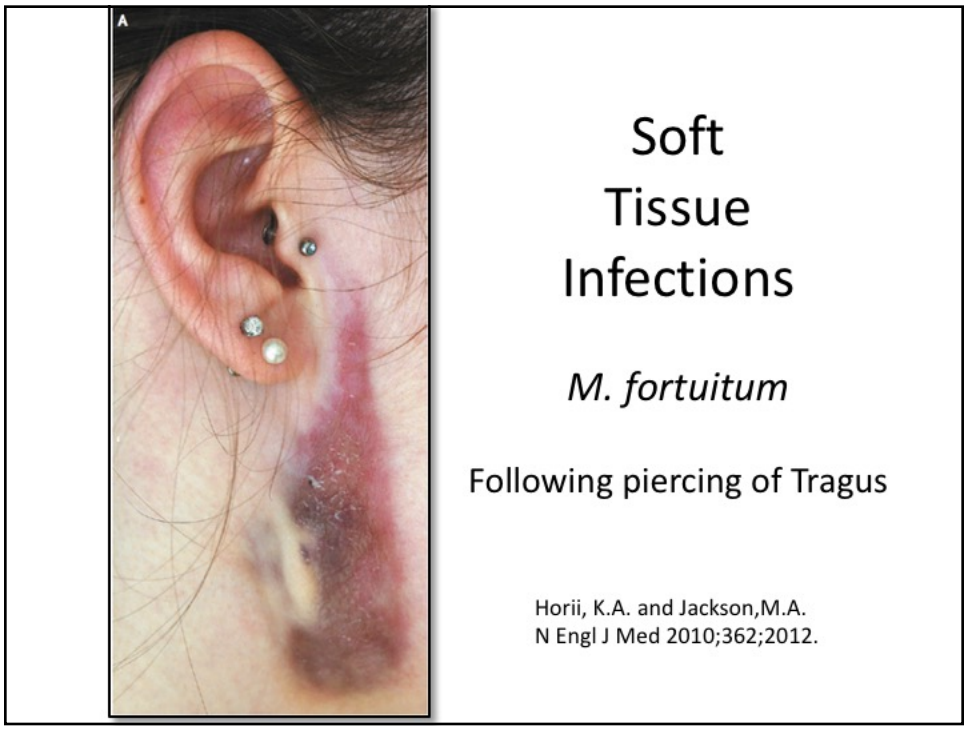
The Lady Windermere Syndrome

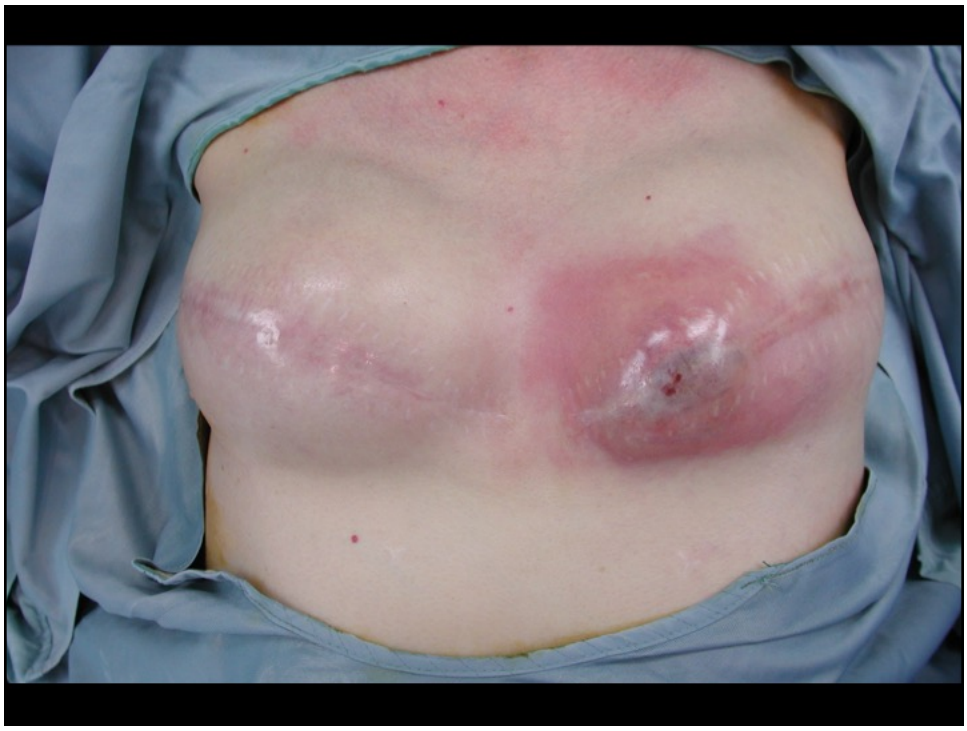
Jerome M. Reich, M.D.; Richard E. Johnson, Ph.D.†

Chest 1992; *101:1605-09.*



Middle age to elderly women, thin and often with scoliosis with progressive bronchiectasis, centrilobular nodules and eventual fibrosis and volume loss usually starting in the RML/Lingula

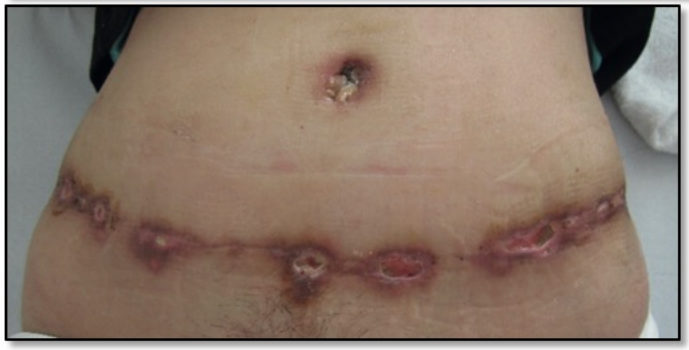

A
Soft
Tissue
Infections
M. fortuitum
Following piercing of Tragus
Horii, K.A. and Jackson,M.A.
N Engl J Med 2010;362;2012.



RAPID COMMUNICATIONS

Postsurgical wound infections due to rapidly growing mycobacteria in Swiss medical tourists following cosmetic surgery in Latin America between 2012 and 2014

F P Maurer (florian.maurer@imm.uzh.ch)[1,2], C Castelberg[1], A von Braun[3], A Wolfensberger[3], G V Bloemberg[1], E C Böttger[1,2], A Somoskovi[1,2]



7 Swiss Women with Mycobacterial infections in 2012-14 following cosmetic surgery in Mexico, Ecuador, or Dominican Republic

Maurer, F.P. et al. Euro Surveill. 2014;19(37):pii=20905.

Some Basic Background

Operating Room Air Flow

Heater Coolers

Non-Tuberculous Mycobacteria

The Outbreak Begins

M. chimaera and Heater Coolers

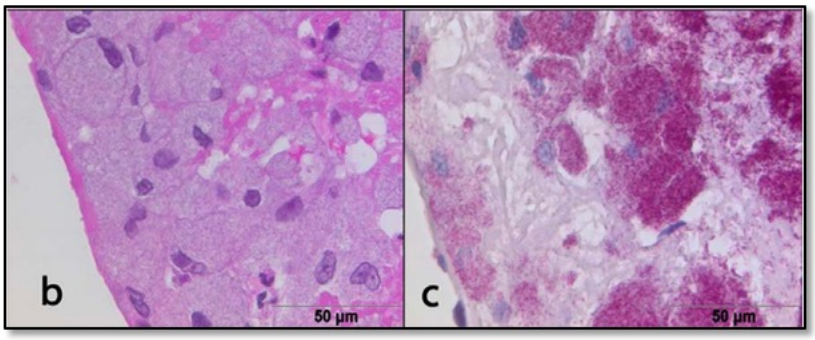
Prosthetic Valve Endocarditis and Bloodstream Infection Due to *Mycobacterium chimaera*

Yvonne Achermann,[a] Matthias Rössle,[b] Matthias Hoffmann,[c] Vanessa Deggim,[d] Stefan Kuster,[a] Dieter R. Zimmermann,[b] Guido Bloemberg,[d] Michael Hombach,[d] Barbara Hasse[a]

- **Patient 1** – 58 yo man
  - AVR & MVR – **2008**
  - Intermittent Fever, weight loss, SOB – Jun 2010
  - Dx. **Sarcoidosis** – BAL, liver/kidney biopsy
  - Repeat AVR/MVR **Jun 2011**
  - Frayed destroyed valves
  - **Cultures = *M. chimaera***

Achermann, Y. et al. J Clin Microbiol 2013;51:1769-1773. **Zurich, Switzerland**

Valve Histopathology – Patient 1



Swollen foamy macrophages

Acid Fast Bacilli on ZN Stain

Achermann, Y. et al. J Clin Microbiol 2013;51:1769-1773.

Prosthetic Valve Endocarditis and Bloodstream Infection Due to *Mycobacterium chimaera*

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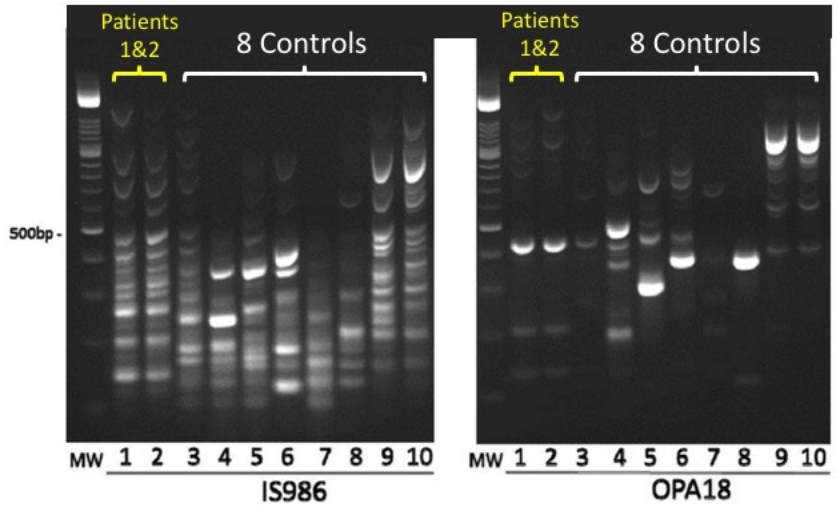
  - Dx. **Sarcoidosis** – BAL, liver/kidney biopsy
  - Repeat AVR/MVR **Jun 2011**
  - Frayed destroyed valves
  - **Cultures = *M. chimaera***

- **Patient 2** – 51 yo man
  - AVR and Aortic Root graft Jan. **2010**
  - Presents **July 2011** with 4 mos. of FUO, renal and liver dysfunction, chorio-retininitis, splenomegaly, pancytopenia
  - **Cultures = *M. chimaera*** in blood, marrow, urine

Achermann, Y. et al. J Clin Microbiol 2013;51:1769-1773. **Zurich, Switzerland**

M. chimaera from Patients 1 & 2 are Identical on RAPD - PCR



Achermann, Y. et al. J Clin Microbiol 2013;51:1769-1773.

We present one case of **PVE** and one **disseminated infection** caused by **identical *M. chimaera* strains** in patients having heart **surgery 2 years apart.**
No nosocomial link was identified.

Consider *M. chimaera* in the differential diagnosis of endocarditis or sepsis following valve surgery.

Achermann, Y. et al. J Clin Microbiol 2013;51:1769-1773.

Prolonged Outbreak of *Mycobacterium chimaera* Infection After Open-Chest Heart Surgery

Hugo Sax,[1,a] Guido Bloemberg,[2,a] Barbara Hasse,[1,a] Rami Sommerstein,[1] Philipp Kohler,[1] Yvonne Achermann,[1] Matthias Rössle,[3] Volkmar Falk,[4] Stefan P. Kuster,[1] Erik C. Böttger,[2,b] and Rainer Weber[1,b]

- 2 cases of invasive *M. chimaera* with identical RAPD-PCR patterns suggests **point-source** infection in the hospital
- **Outbreak Investigation launched:**
  - Identify additional patients
  - Focus on procedures involving water both inside and outside the OR's

Sax, H. et al. Clin Infect Dis. 2015;61:67-75.

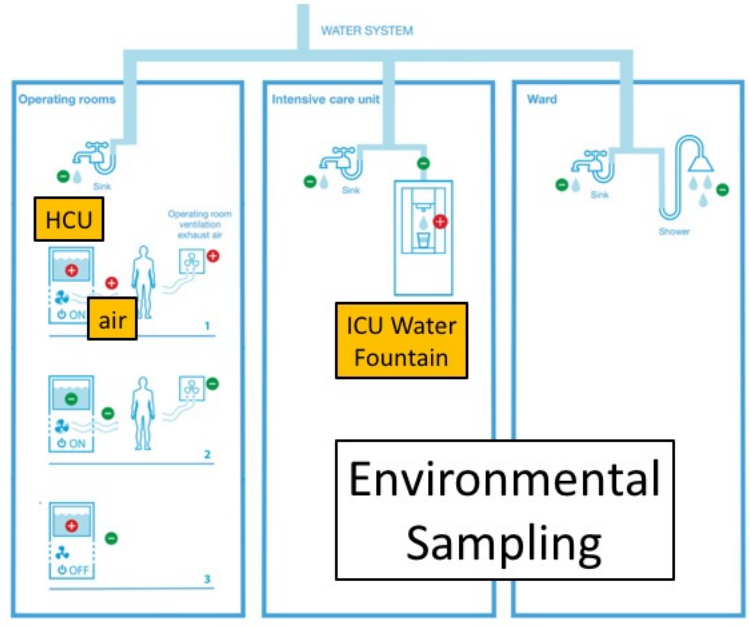
Retrospective Case Review

- All Mycobacterial cultures and culture-negative endocarditis reviewed
- Case = proven invasive *M. chimaera* infection following open-chest heart surgery since August 2006

Sax, H. et al. Clin Infect Dis. 2015;61:67-75.

Retrospective Case Review

- 2 known + 4 new cases of invasive *M. chimaera* infections – all had valve +/- aortic arch grafts
- Latency - **1.5 - 3.6y** from surgery
- Prosthetic Valve Endocarditis or Systemic Infections (fever, bacteremia, liver, renal, spleen and marrow)



Sax, H. et al. Clin Infect Dis. 2015;61:67-75.

It remains to be investigated how widespread this risk is for patient safety and what constitutes the most effective measures for its prevention.

Sax, H. et al. Clin Infect Dis. 2015;61:67-75.

SURVEILLANCE AND OUTBREAK REPORT

Contamination during production of heater-cooler units by *Mycobacterium chimaera* potential cause for invasive cardiovascular infections: results of an outbreak investigation in Germany, April 2015 to February 2016

- **5** invasive *M. chimaera* infections post-CV surgery (5 mos – 5 years) in **Germany**
- All exposed to Sorin 3T Heater-Coolers
- **Environmental sampling** revealed identical *M. chimaera* isolates from **patients**, **used HCU's** and **new HCU's** at the manufacturer site

Haller, S. et al. Euro Surveill. 2016;21(17):pii=30125.

M. chimaera infections in patients, from HCU's used in **3 different countries** and from **environmental cultures** in the the manufacturing site are consistent with a

Point Source Outbreak.

Manufacturing process added additional, terminal disinfection step in August 2014

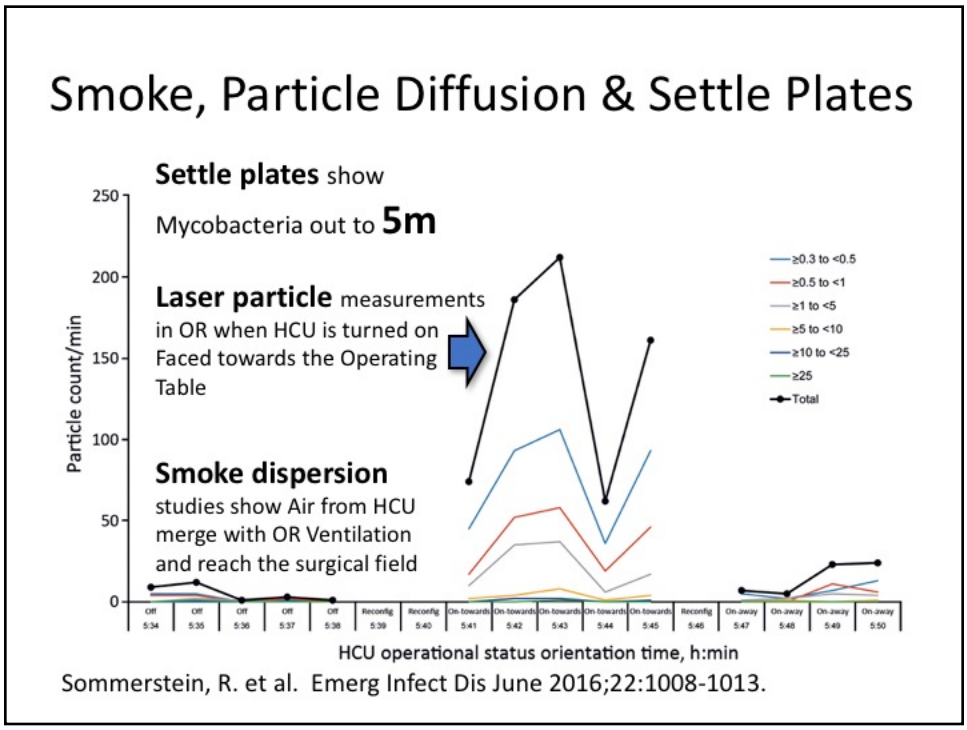
Haller, S. et al. Euro Surveill. 2016;21(17):pii=30125.

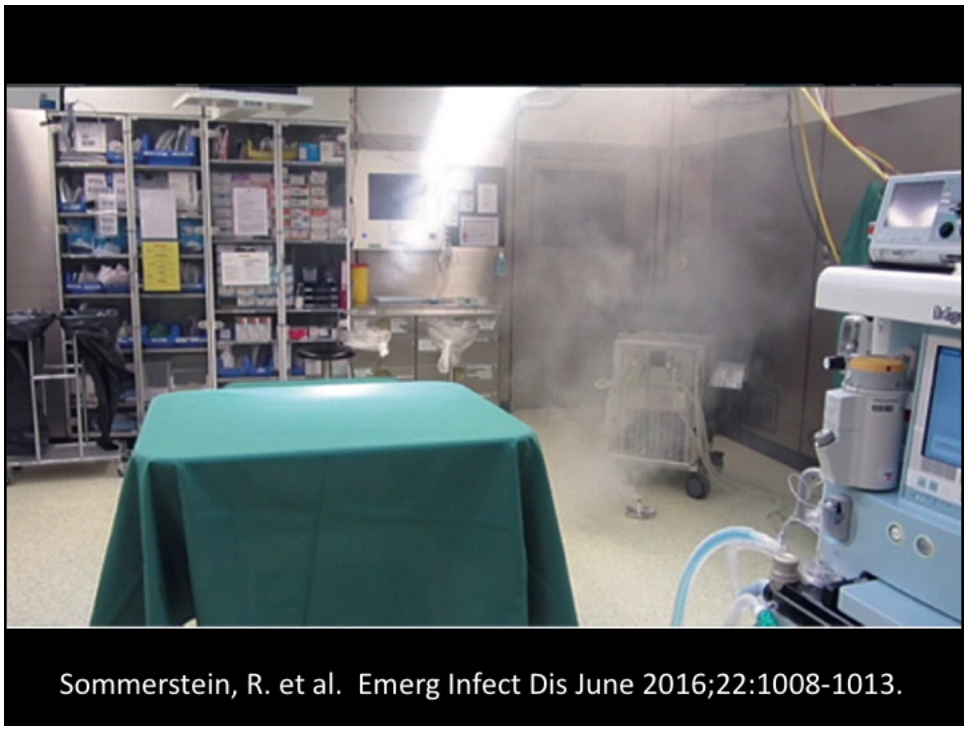
Transmission of *Mycobacterium chimaera* from Heater–Cooler Units during Cardiac Surgery despite an Ultraclean Air Ventilation System

Rami Sommerstein, Christian Rüegg, Philipp Kohler, Guido Bloemberg, Stefan P. Kuster, Hugo Sax

- Transmission of *M. chimaera* from Heater Cooler units to the surgical field in OR with ultraclean laminar airflow:
  - Laser Particle Measurements
  - Smoke Dispersion Studies
  - Mycobacterial Settle Plates

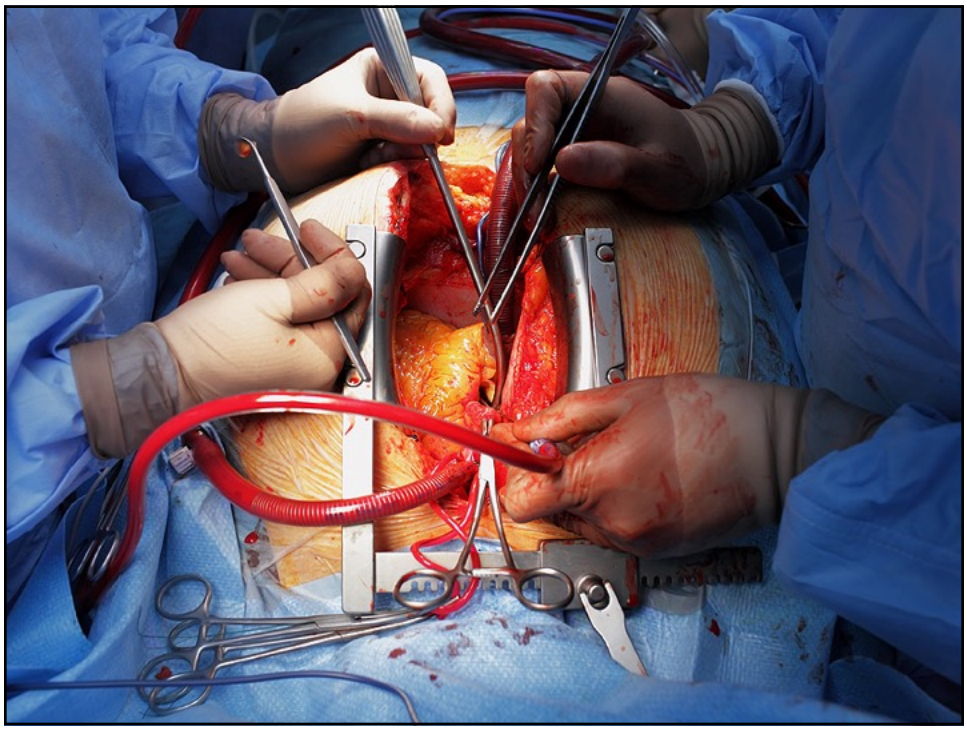
Sommerstein, R. et al. Emerg Infect Dis June 2016;22:1008-1013.

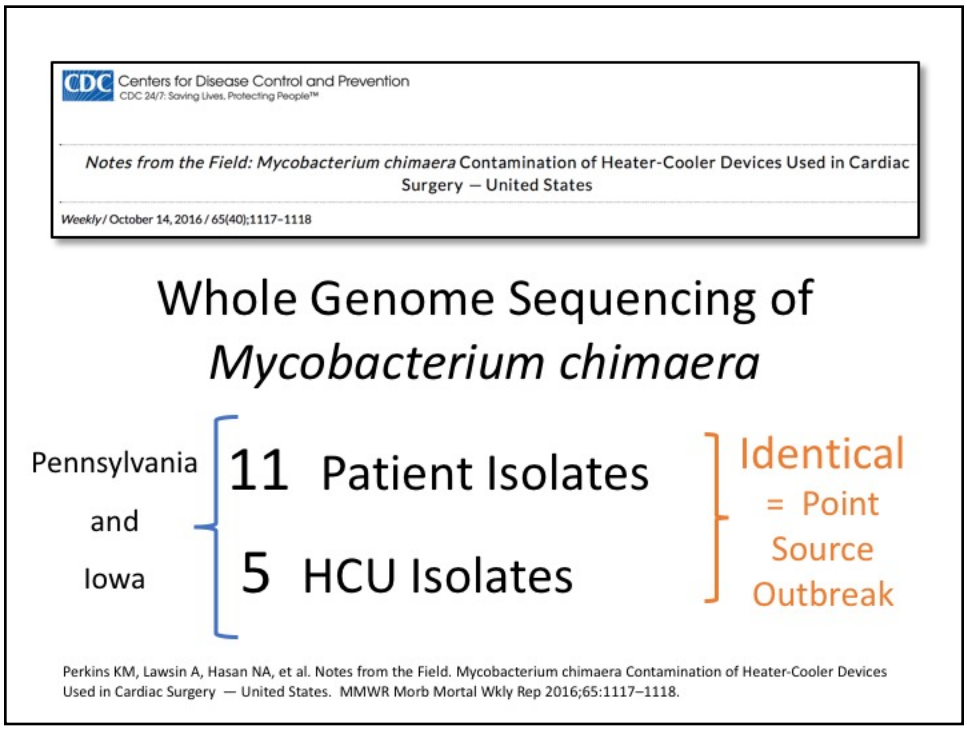

Smoke, Particle Diffusion & Settle Plates
Settle plates show
Mycobacteria out to 5m
Laser particle measurements in OR when HCU is turned on Faced towards the Operating Table
Smoke dispersion studies show Air from HCU merge with OR Ventilation and reach the surgical field
Particle count/min
250
200
150
100
50
0
≥0.3 to <0.5
≥0.5 to <1
≥1 to <5
≥5 to <10
≥10 to <25
≥25
Total
Off 5:34
Off 5:35
Off 5:36
Off 5:37
Off 5:38
Reconfig 5:39
Reconfig 5:40
On-towards 5:41
On-towards 5:42
On-towards 5:43
On-towards 5:44
On-towards 5:45
Reconfig 5:46
On-away 5:47
On-away 5:48
On-away 5:49
On-away 5:50
HCU operational status orientation time, h:min
Sommerstein, R. et al. Emerg Infect Dis June 2016;22:1008-1013.


Sommerstein, R. et al. Emerg Infect Dis June 2016;22:1008-1013.

Calgary Movie

Courtesy of Drs. John Conly,
Tom Louie and others




CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™
Notes from the Field: Mycobacterium chimaera Contamination of Heater-Cooler Devices Used in Cardiac Surgery — United States
Weekly / October 14, 2016 / 65(40);1117–1118
Whole Genome Sequencing of
Mycobacterium chimaera
Pennsylvania
and
Iowa
11 Patient Isolates
5 HCU Isolates
Identical
= Point
Source
Outbreak
Perkins KM, Lawsin A, Hasan NA, et al. Notes from the Field. Mycobacterium chimaera Contamination of Heater-Cooler Devices Used in Cardiac Surgery — United States. MMWR Morb Mortal Wkly Rep 2016;65:1117–1118.


The New York Times
Bacteria on Device Said to Infect at Least 12 Patients in Pennsylvania
By SABRINA TAVERNISE. OCT. 13, 2016
WASHINGTON — A device used during open-heart surgery that infected at least 12 patients at a Pennsylvania hospital last year was probably tainted at the plant in Germany where it was made, a federal investigation has found.

An Essential Heart-Surgery Device Poses a Rare but Deadly Risk

Hospitals and federal officials are scrambling to manage a newly discovered infection risk in open chest surgeries. What patients need to know to protect themselves.

By Jeneen Interlandi
Last updated: November 09, 2016

What do we know?

Fall 2016

- Sorin 3T HCU manufactured prior to Sept 2014 may have been contaminated with *Mycobacterium chimaera* at source
- Manufacturer introduced an extra disinfection step in August 2014

- **BUT:**
  - Are post-Sept 2014 HCU's from this manufacturer O.K.?
  - What about other manufacturers of HCU?

What do we know?

Fall 2016

- 250,000 open chest heart surgeries per year are done in the U.S. (3200/yr in Alberta)
- Sorin/LivaNova has 60-70% of market share
- In Alberta, we have 15 HCU's
  - 12 Sorin 3T (all pre-Sept 2014)
  - 3 Maquet (in Calgary)

We cannot continue Cardiac Surgery without Heater Cooler Units

Recommendations

… Coming From Multiple Sources

… some Conflicting

… and difficult or impossible to implement

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Health Advisory

October 13, 2016

- The CDC is advising hospitals to **notify patients** who underwent open-heart (open-chest) surgery involving a Stöckert 3T heater-cooler that the device was potentially contaminated, possibly putting patients at risk for a life threatening infection.
- Consider **Informed Consent** with NTM Risk
- Conduct **retrospective surveillance** and consider **prospective surveillance**

FDA U.S. FOOD & DRUG ADMINISTRATION

Oct. 14, 2016

- Strict adherence to manufacturer **disinfection** instructions; **direct exhaust** away from patient
- Consider **transitioning away from 3T** devices manufactured before Sept. 2014
- **Culture of HCU's "presents technical challenges related to sample collection, the long culture time, and the high rate of false negative tests and is not recommended at this time"**

Health Canada
www.hc-sc.gc.ca

Recalls and Alerts
Heater-Cooler Devices - Risk of Nontuberculous Mycobacteria Infections
October 21, 2016

- International reports of NTM infections associated with HCU's – few possible Canadian cases
- Consider **testing** for NTM in ill patients - even months to years after surgery
- Strictly follow **cleaning/disinfection** procedures
- Review **position and exhausting** of HCU's
- **Remove 3T units "suspected to be contaminated…from the OR or, if feasible, from service as soon as practical"**

Health Canada
www.hc-sc.gc.ca

F/P/T Teleconference
Dec. 20, 2016

- Follow manufacturer recommendations: **Culture**

  Sorin/LivaNova Heater-Coolers **monthly** for *Mycobacteria* (and others)

- Those **"suspected to be contaminated"** should be **removed from service** and returned to the manufacturer in Germany for a deep-cleaning process (loaners will be provided)

Canadian Public Health Laboratory Network - F/P/T Teleconference
December 20, 2016

In conjunction with the PHAC IPC Group:

(statement to be published in 1.17)

Do ***NOT*** Culture Heater-Cooler Units

- Methods are not standardized
- It is unclear what to do with the results
- Impact on labs will be huge

Alberta Health Services

What Did We Do?

Risk Mitigation

(Should we suspend Cardiac Surgery?)

Risk Mitigation Team

- Confirm the Diagnosis
- Who Can Help?
  - Cardiac Sciences Program - LEAD
  - Operations
  - IPC and Lab
  - Public Health
  - Contract and Procurement Team
  - Legal and Communications
- Who Needs to Know? (Senior Leadership/ Government)

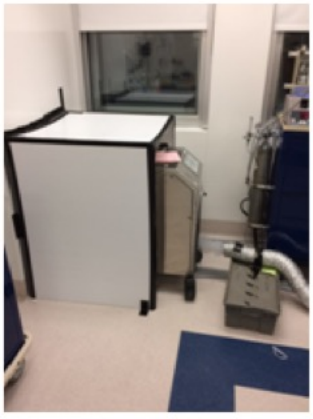
Immediate Response

- Working closely with the manufacturer and Health Canada to minimize risk
- Adhering strictly with cleaning/disinfection protocols
- Placement of HCU's as far away from patient as possible
- HCU Exhaust is directed towards OR Exhaust
- We await an **Engineering Solution**

Heater Cooler Unit

Outside of OR

Calgary Cabinet – "No Escape"



Next Steps - 1

- Every Alberta physician notified
- (ID Physicians have received additional info)
- Letters distributed to all 11,500 patients/guardians who have had open chest CV surgery in Alberta since Jan 2012 (Calgary) or Jan 2011 (Edmonton)
- Health Link and Patient Concerns prepped and triage system arranged

EDMONTON JOURNAL

Heart patients warned on risk of infection

KEITH GEREIN

Proactive Media

11,500 Patients notified

December 2, 2016

Alberta heart patients warned of exposure risk to bacteria during surgery

Risk of exposure to *Mycobacterium chimaera* 'extremely low,' AHS says

By Natasha Riebe CBC.ca on-line. December 1, 2016

Clinical Picture

- Incubation Period – 3 mos – 5y (av. 18 mos)
- Highest Risk: valves, tissue, VAD
- Presentation:
  - Systemic Features (fever, sweats, weight loss, SOB)
  - Culture Negative Endocarditis with embolic phenomena (esp. eye involvement – 50%)
  - Surgical Site Infection (sternum/mediastinum)
  - Extra-cardiac – bone, liver, kidney
  - Labs – cytopenias; abnormal liver/renal; CRP

Next Steps - 2

- Specific **Informed Consent** for those undergoing CV Surgery:
  - Risk approx. **1:100-1:1000** in centres that have had cases
  - Risk **less than 1:1000** with no cases
- **Retrospective Data Linkage**
- **Prospective Surveillance** for tracking (this will be an issue for at least the next 5 years)

Retrospective Data Link

- Linkage of databases for all patients who have had open chest surgery (FMC, MAHI, Stollery) with Prov Lab Mycobacterial Lab Database
- Focus on those isolating NTM ***after*** CV Surgery

20 Patients – Mostly Respiratory NTM

What's Next??

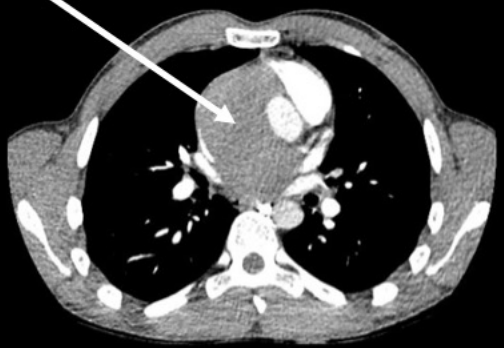
22 year old man

- Congenital Bicuspid Aortic Valve
- Mechanical AVR June 2015
- Presents 20 months later with Night Sweats
- 3 sets of blood cultures and one set for Mycobacterium - Negative
- One month later – Chest Pain

O'Neil, C.R. Open Forum in Infectious Diseases. 2018 Jan 24;5(2):ofy018. doi: 10.1093/ofid/ofy018.

Mar 13, 2017 (21 months post-op):

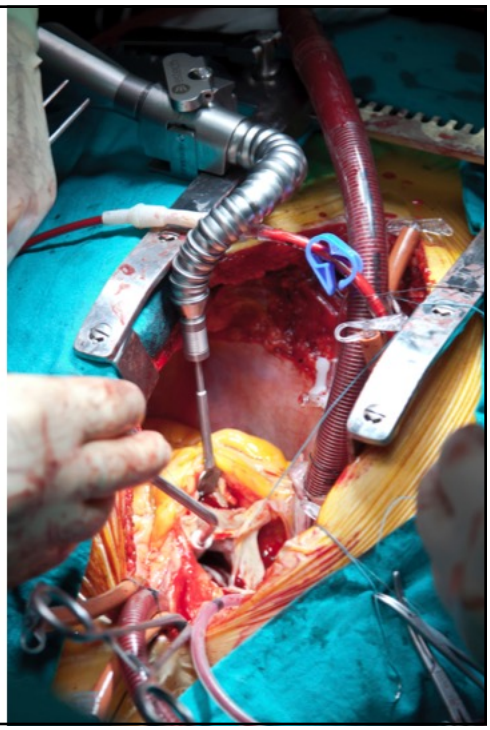
- one week history of chest pain
- CT chest: aortic dissection with large aortic pseudoaneurysm of ascending aorta



O'Neil, C.R. Open Forum in Infectious Diseases. 2018 Jan 24;5(2):ofy018. doi: 10.1093/ofid/ofy018.

Urgent OR (Mar. 14, '17)

- Intraop appearance - no obvious gross infection.
- Procedure: Repair of aortic rupture with aortic prosthesis.
- Pseudoaneurysm tissue and mediastinal fluid sent for culture



21 days later…

CONCENTRATED SMEAR FOR ACID-FAST BACILLI Verified:03/19/2017 08:32 MDT
No Acid-fast bacilli seen

FINAL REPORT Verified:05/01/2017 13:51 MDT
Mycobacterium chimaera ISOLATED using the automated system BACTEC MGIT
Growth detected after 21 days of incubation
.
Identification by 16S ribosomal RNA gene sequencing
.
Identified at the National Microbiology Laboratory, Winnipeg, MB, Canada

Risk Team Regroup

- Now, we've had a case
- Who needs to know?
  - Surgeons/Clinicians/Government/Health Canada/Public
- Change Informed Consent:
  - Risk increased from <1:1000 to 1:100-1:1000
- Is there anything further we can do to reduce risk?

Dr. Mark Joffe, AHS's senior medical director of infection prevention and control, said Mycobacterium chimaera is as a "very serious infection" that c... occasionally lead to death. An AHS patient contracted the infection during open-heart surgery two years ago. ...

Patient develops infection linked to heart surgery

Bacteria traced to faulty exhaust system on equipment used during procedure

Edmonton Journal
May 10, 2017

One Year Later…..

Remains on Medical Therapy

Complications

Plan Uncertain

3 More Cases

DISPATCHES

Global Health Estimate of Invasive *Mycobacterium chimaera* Infections Associated with Heater–Cooler Devices in Cardiac Surgery

~ 120 invasive *M. chimaera* cases reported

Estimate: 156 – 282 cases per year

Sommerstein, R. et al. Emerg Infect Dis 2018;24:576-78.

6 Infections in Canada

2 in Quebec

4 in Alberta

Health Canada

And We Wait…….

Will there be more cases over the 5 years following the definitive fix for the contaminated heater cooler problem?

drugwatch.

Sorin 3T Heater-Cooler Lawsuits Consolidated in Federal Court

Terry Turner. February 2, 2018.

The number of lawsuits claiming LivaNova's Sorin 3T heater-cooler systems caused injuries have more than doubled in the last year. Now, a federal panel has decided the cases should be transferred to a single federal court to move them more quickly through the legal process.

The Judicial Panel on Multidistrict Litigation on Feb. 1, 2018, consolidated **39** lawsuits over the heater cooler devices into a multidistrict litigation in Pennsylvania. At least another **33** state cases from around the U.S. may be included in the MDL.

www.drugwatch.com/news/2018/02/02/sorin-3t-heater-cooler-lawsuits-consolidated-federal-court/

In any outbreak situation, public health's two biggest enemies are ignorance of the facts and fear.

Dr. James Talbot

Chief Medical Officer of Health

Province of Alberta

Communicating Risk

Proclaim Uncertainty

Be clear about what we know.

Be confident in identifying areas of uncertainty.

Rosenbaum, R. N Engl J Med November 13, 2014

Story #3

Adventures in Reprocessing

Fertility Clinic IPC

Concern Dec. 2017

Vaginal Ultrasound Probes

Background

- 41 U/S probes on a Sunday - 25 was the max
- 141 Women with Ultrasounds over 7 days
  - Records inconsistent for 4 days
  - Records completely missing for 2 days
- 3 Service Workers – most of the challenges related to a single service worker

Reprocessing

"Uncertainty"

or Failure

What would you do?

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY FEBRUARY 2007, VOL. 28, NO. 2

ORIGINAL ARTICLE

How to Assess Risk of Disease Transmission to Patients When There Is a Failure to Follow Recommended Disinfection and Sterilization Guidelines

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

Rutala and Weber, Infect Control Hosp Epidemiol 2007;28:146-55.

(ICHE February 2007)

Risk of Infection (Bloodborne Virus)

- Prevalence of infection in population (A)
- Risk of transmission by route of exposure (B)
- Likelihood that contaminated device used (C)
- Efficacy of reprocessing steps (D)
- Effect of drying (E)

Risk – A x B x C x D x E

Risk of Bloodborne Virus & STI's

- 141 Women with Ultrasounds over 7 days
  - inconsistent or missing reprocessing records
- Fertility Clinic - Population has been screened (STI/BBV) in the last year
- One known chronic bloodborne virus infection – controlled on medication

Risk – A x B x C x D x E

Risk of Bloodborne Virus

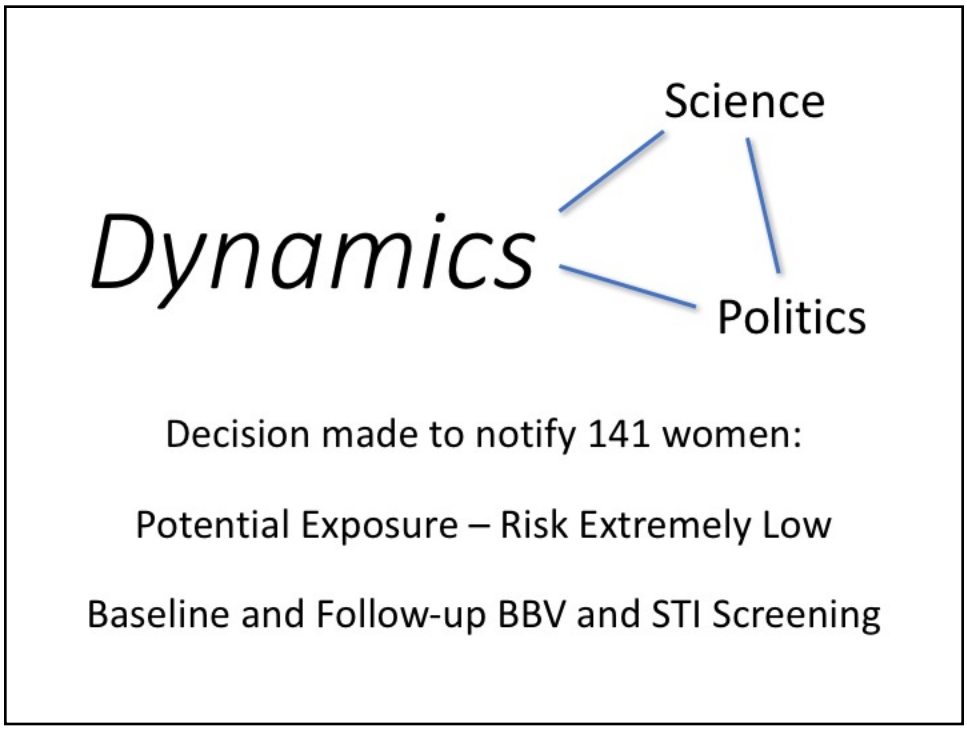
or STI

Near Zero

Would You Disclose?

Risk thresholds should be established in advance

(1:1,000,000 in Alberta)



Disclosure

- Script 141 patients called – 2 people make the calls
- Q&A's prepared
- Follow-up for anybody with "tough" questions or expressed anger (some are pregnant; ++ questions)
- Requisitions for lab tests completed for anyone wanting follow-up (baseline and follow-up)
- Call-in centre for questions

Proactive Media

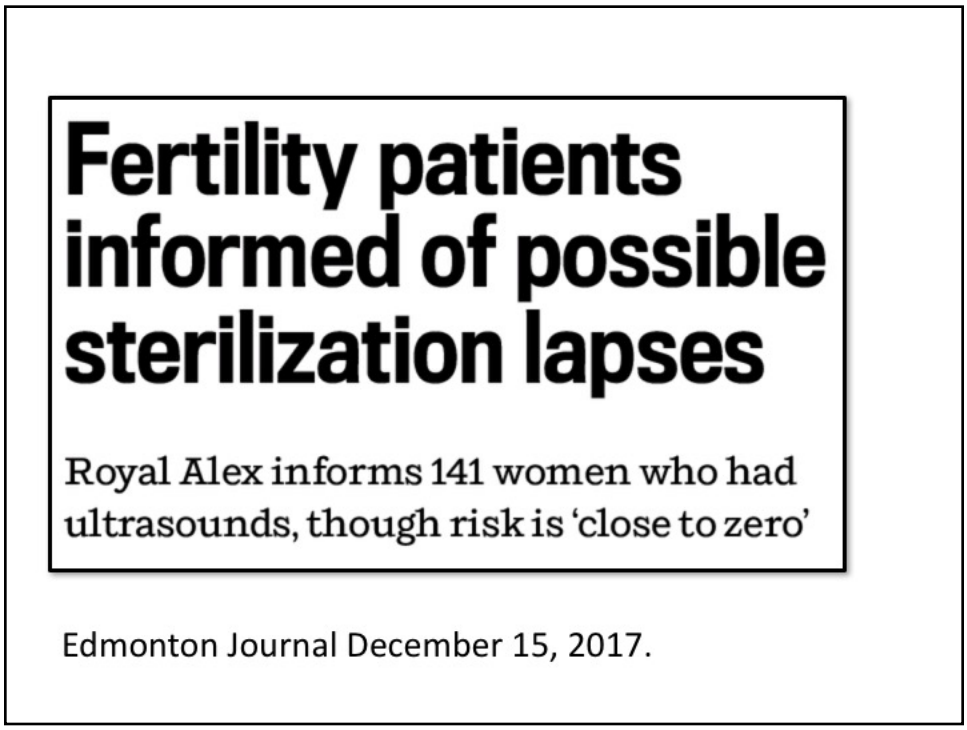
We can't be sure reprocessing met our usual standards of excellence

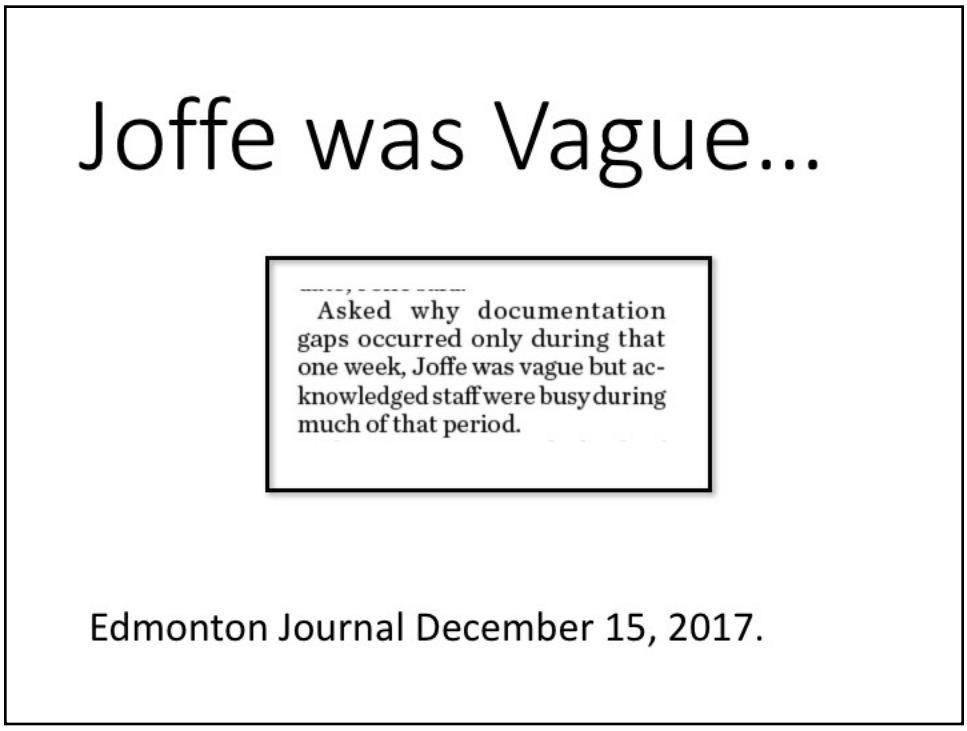
Risk Near Zero

Up to 141 fertility clinic patients exposed to sexually transmitted infections: Alberta Health Services

Women who received an endovaginal ultrasound at the Royal Alexandra Hospital's fertility clinic last month may be at risk of blood-borne and sexually transmitted infections due to a "possible lapse" ...

Edmonton Journal On-Line December 14, 2017


Fertility patients informed of possible sterilization lapses
Royal Alex informs 141 women who had ultrasounds, though risk is 'close to zero'
Edmonton Journal December 15, 2017.


Joffe was Vague…
Asked why documentation gaps occurred only during that one week, Joffe was vague but acknowledged staff were busy during much of that period.
Edmonton Journal December 15, 2017.

Objectives

3 Stories:

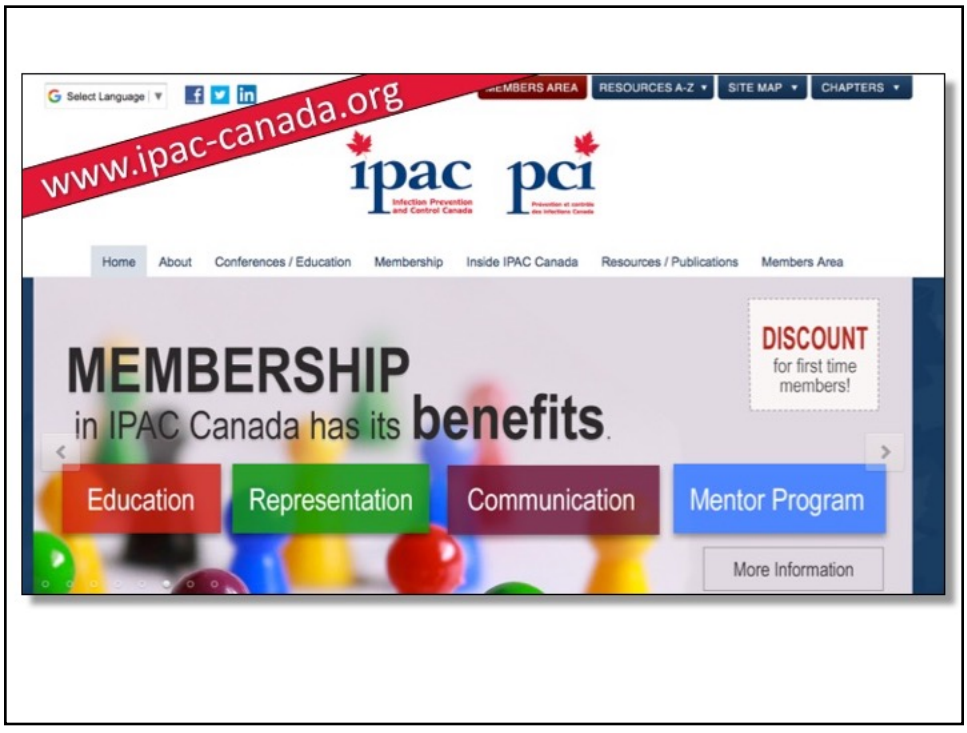
- ARO Outbreak (MDR GNB)
- *M. chimaera* in CV Surgery
- Reprocessing Failure

Complex issues in IPC

Framework for response

Thank-you


MAKE IPC
GREAT AGAIN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May 29, 2018	*(FREE Teleclass – Broadcast live from the IPAC Canada conference)* SIMULATION AS AN EDUCATION TOOL Speaker: **Dr. Ghazwan Altabbaa** and **Dione Kolodka**, Rockyview Hospital, Calgary, Alberta
June 13, 2018	*(South Pacific Teleclass)* INVOLVING PATIENTS IN UNDERSTANDING HOSPITAL INFECTION PREVENTION AND CONTROL USING VIDEO-REFLEXIVE METHODS Speaker: **Dr. Mary Wyer**, University of Sydney, Australia
June 21, 2018	*(FREE Teleclass)* THE FUTURE OF INFECTION CONTROL – BRIGHT OR BLEAK? Speaker: **Martin Kiernan**, University of West London
July 17, 2018	*(FREE European Teleclass)* HOSPITAL INFECTION CONTROL FROM A DEVELOPING COUNTRY'S PERSPECTIVE Speaker: **Dr. Aamer Ikram**, Director, National Institute of Health, Islamabad, Pakistan
July 19, 2018	FLOOD REMEDIATION IN HEALTHCARE FACILITIES – INFECTION CONTROL IMPLICATIONS Speaker: **Andrew Streifel**, University of Minnesota
	(FREE Teleclass)

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