

Global *Mycobacterium chimaera* outbreak in cardiac surgery

Hugo Sax, MD
Barbara Hasse, MD

Division of Infectious Diseases and Hospital Epidemiology
University Hospital of Zurich
University of Zurich
Zurich, Switzerland



Hosted by Julie Storr
World Health Organization, Geneva

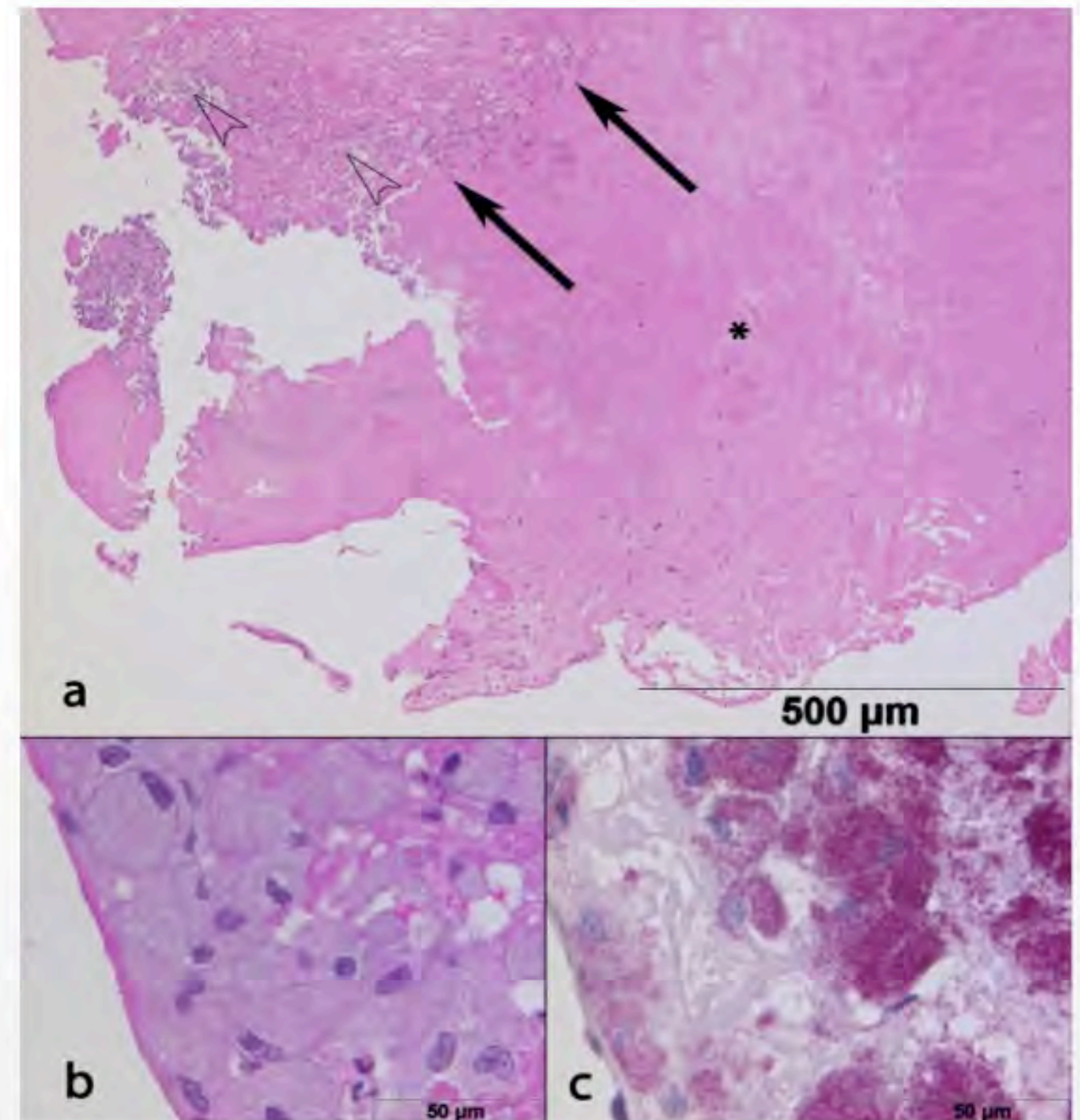
Prosthetic valve endocarditis mitral valve

Case #1 | 58-year-old male

2008 Mitral annuloplasty ring

2010 Dx of systemic sarcoidosis

2011 Respiratory distress, severe mitral and aortic valve insufficiency, at surgery fraying of ring and valve destruction...



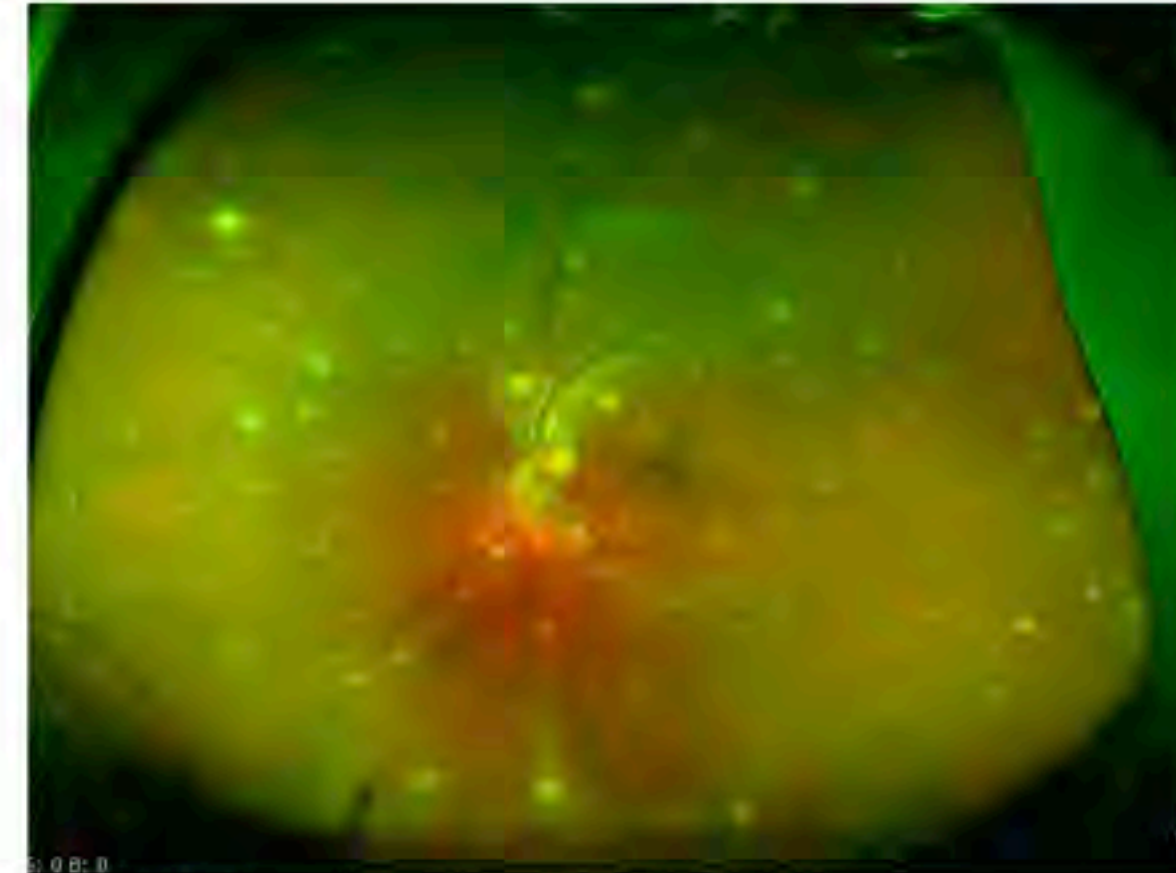
Fever of unknown origin and composite graft infection

Case #2 | 58-year-old male

2010 Composite (aortic valve & arch) graft for aortal dissection

2011 Fever of unknown origin, splenomegaly, renal insufficiency, liver enzyme, pancytopenia.

M. chimaera cultured from bone marrow, blood cultures, urine, tracheal swab.



2012 Exodus due to splenic rupture

Mycobacterium chimaera: what is known



Microbiology

Slow growing non-tuberculous mycobacterium

Acid-fast, non-motile and non-spore forming coccobacilli

Formerly classified as *Mycobacterium intracellulare*, described by Tortoli 2004

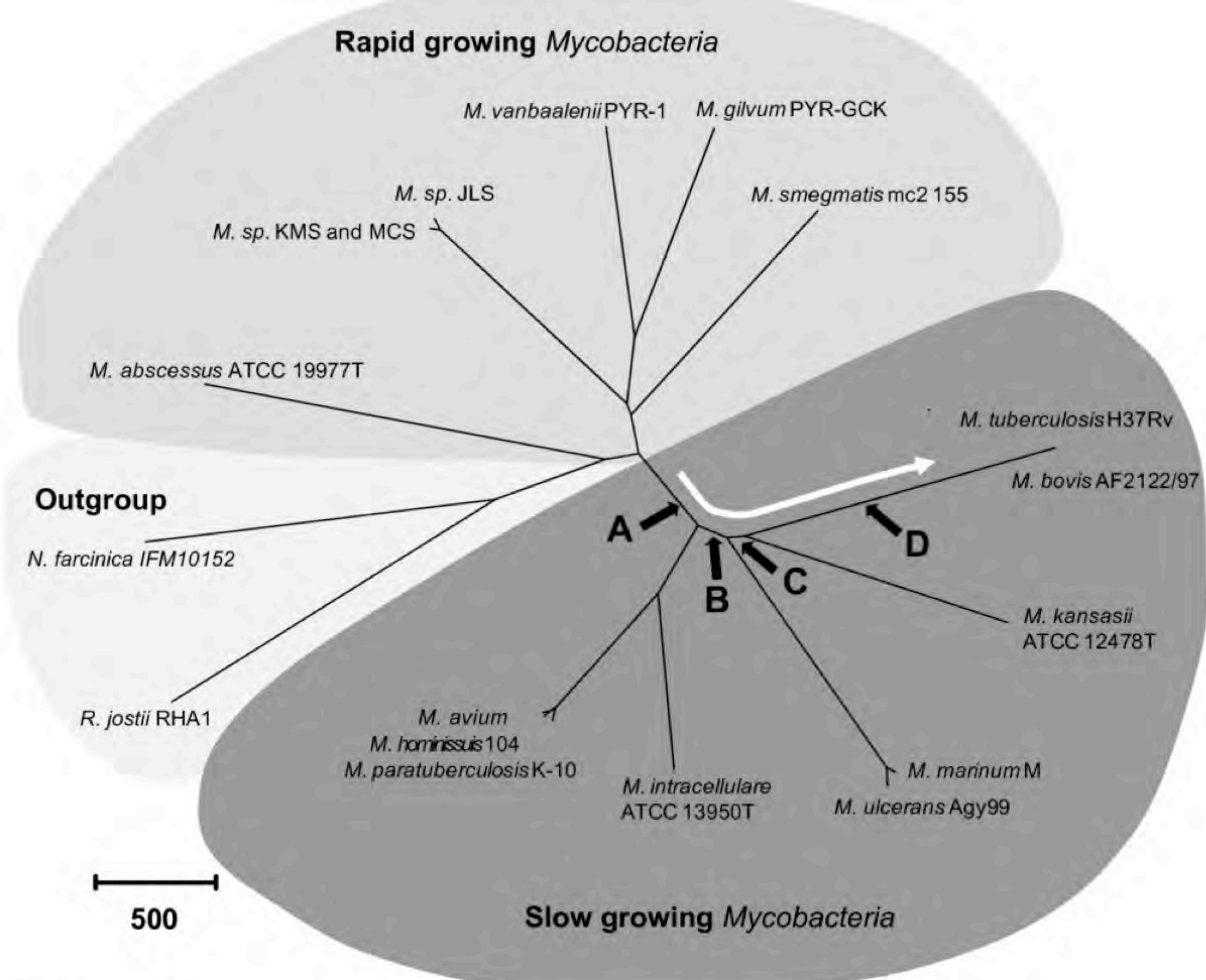
Clinics

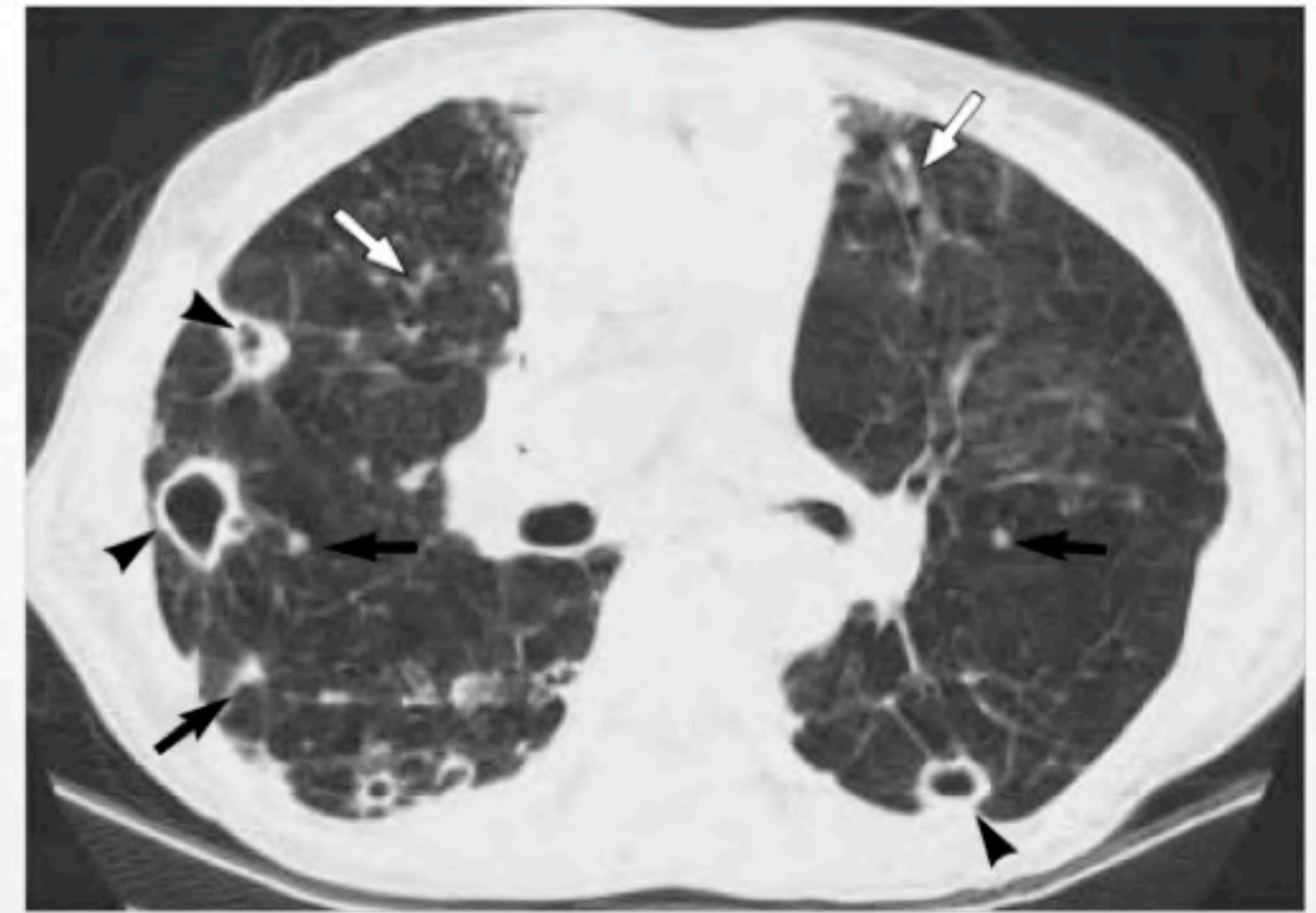
Lung disease among immunocompromised/elderly patients

Assumed as «less virulent.....»

Environment

Not found in water systems in Europe, but the US





Really «less virulent»....?



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

Division of Infectious Diseases and Hospital Epidemiology, University and University Hospital Zurich, Zurich, Switzerland^a; Institute of Clinical Pathology, University and University Hospital Zurich, Zurich, Switzerland^b; Division of Infectious Diseases and Hospital Epidemiology, Cantonal Hospital St. Gallen, St. Gallen, Switzerland^c; Institute of Medical Microbiology, University of Zurich, Zurich, Switzerland^d

Prosthetic valve endocarditis (PVE) due to fast-growing nontuberculous mycobacteria (NTM) has been reported anecdotally. Reports of PVE with slowly growing NTM, however, are lacking. We present here one case of PVE and one case of bloodstream infection caused by *Mycobacterium chimaera*. Randomly amplified polymorphic DNA (RAPD)-PCR indicated a relatedness of the two *M. chimaera* strains. Both patients had heart surgery 2 years apart from each other. A nosocomial link was not detected.

Operated two years apart at the same hospital with a rare pathogen

Cluster

Two or more cases of a relatively uncommon event or disease related in time and/or place **perceived** to be greater than expected by chance.

Outbreak

The occurrence in a community or region of cases of an illness with a frequency **clearly** in excess of normal expectancy.

The number of cases indicating presence of an outbreak will vary according to the infectious agent, size and type of population exposed, previous experience or lack of exposure to the disease and time and place of occurrence.

Randomly amplified
polymorphic DNA
(primers according
M. abscesses)

No other matching
strains found in
hospital

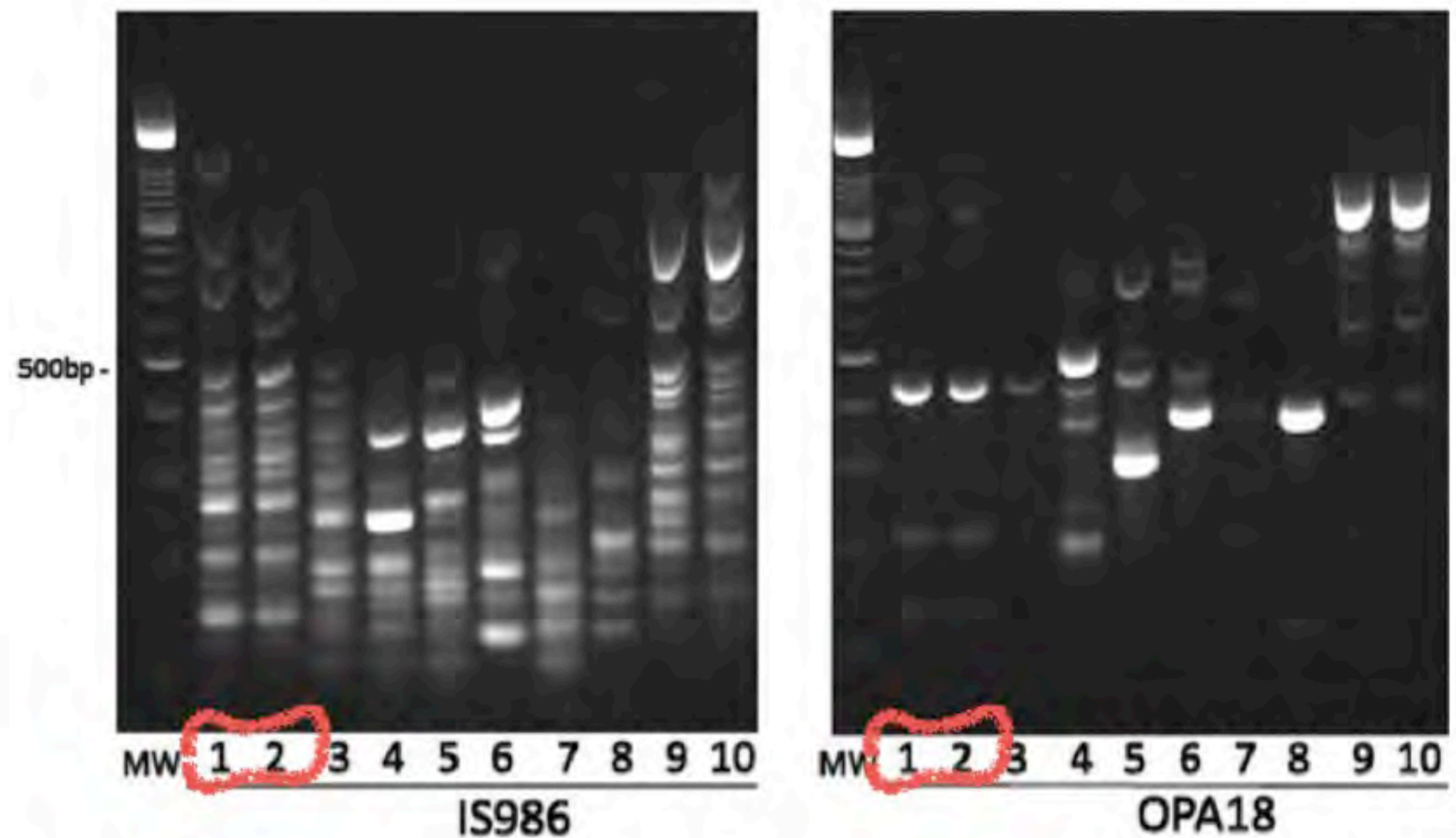


FIG 2 *Mycobacterium chimaera* strain typing using randomly amplified polymorphic DNA (RAPD)-PCR. Shown are RAPD-PCR patterns of *M. chimaera* clinical isolates from the two patients (lane 1, patient 1; lane 2, patient 2) and of eight respiratory culture isolates from eight different patients (lanes 3 to 10). RAPD-PCR patterns were generated with primers IS986-FP (A) and OPA18 (B). MW, molecular weight marker.

Outbreak investigation

Sax H, Bloemberg G, Hasse B, Sommerstein R, Kohler P, Achermann Y, Rössle M, Falk V, Kuster SP, Böttger EC, Weber R. **Prolonged outbreak of Mycobacterium chimaera infection after open chest heart surgery.** Clin Infect Dis 2015;61(1):67-75

Observations

Video analysis

Interviews

Workflow analysis

Mycobacteria cultures

Patient heating blanket water circuit

Heater-cooler unit water tanks/circuits

Showers

Drinking water fountains

Observations

Video analysis

Interviews

Workflow analysis

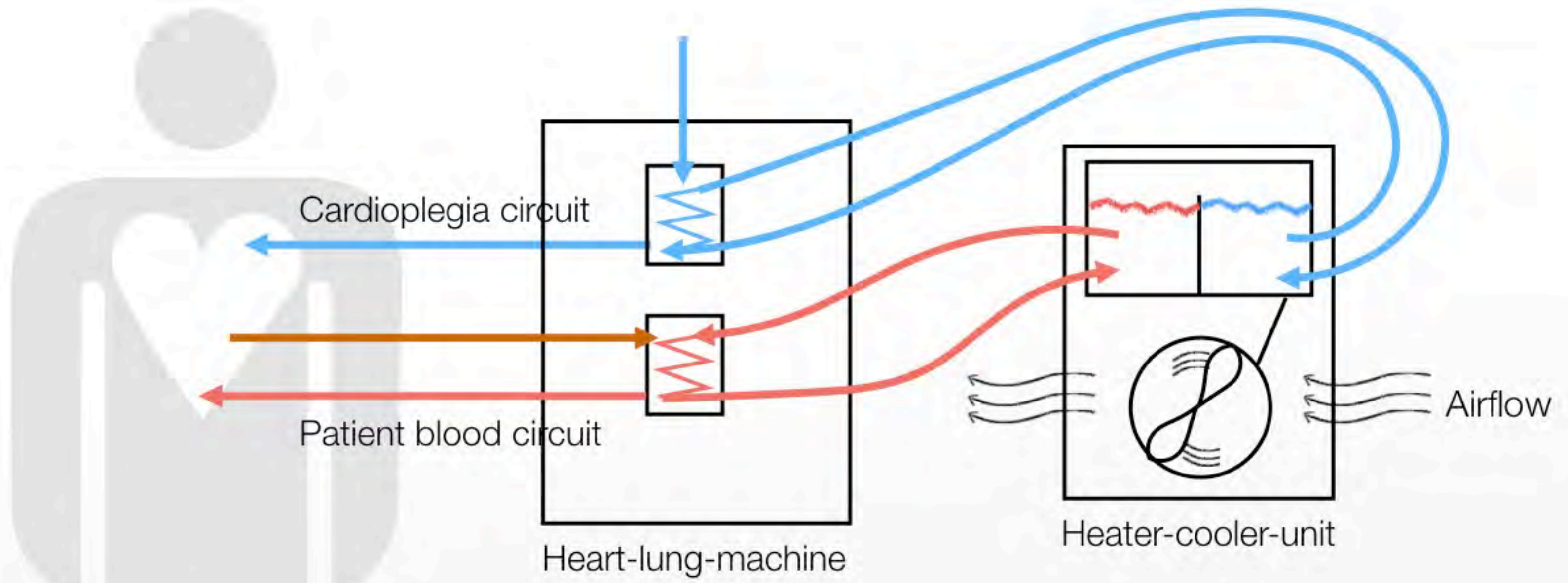
Mycobacteria cultures

Patient heating blanket water circuit

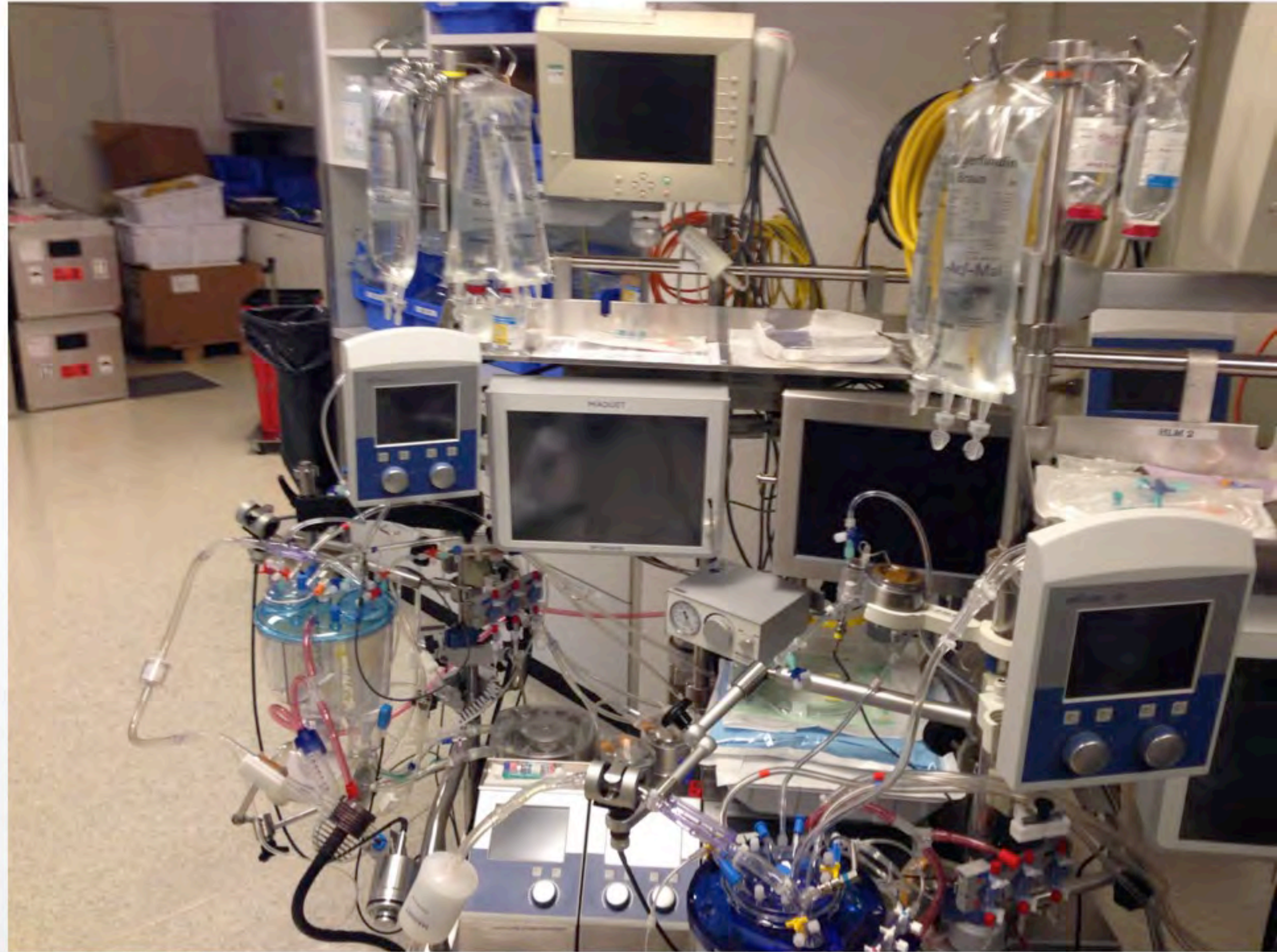
Heater-cooler unit water tanks/circuits

Showers

Drinking water fountains



Heart-Lung-machine



Heat-exchangers

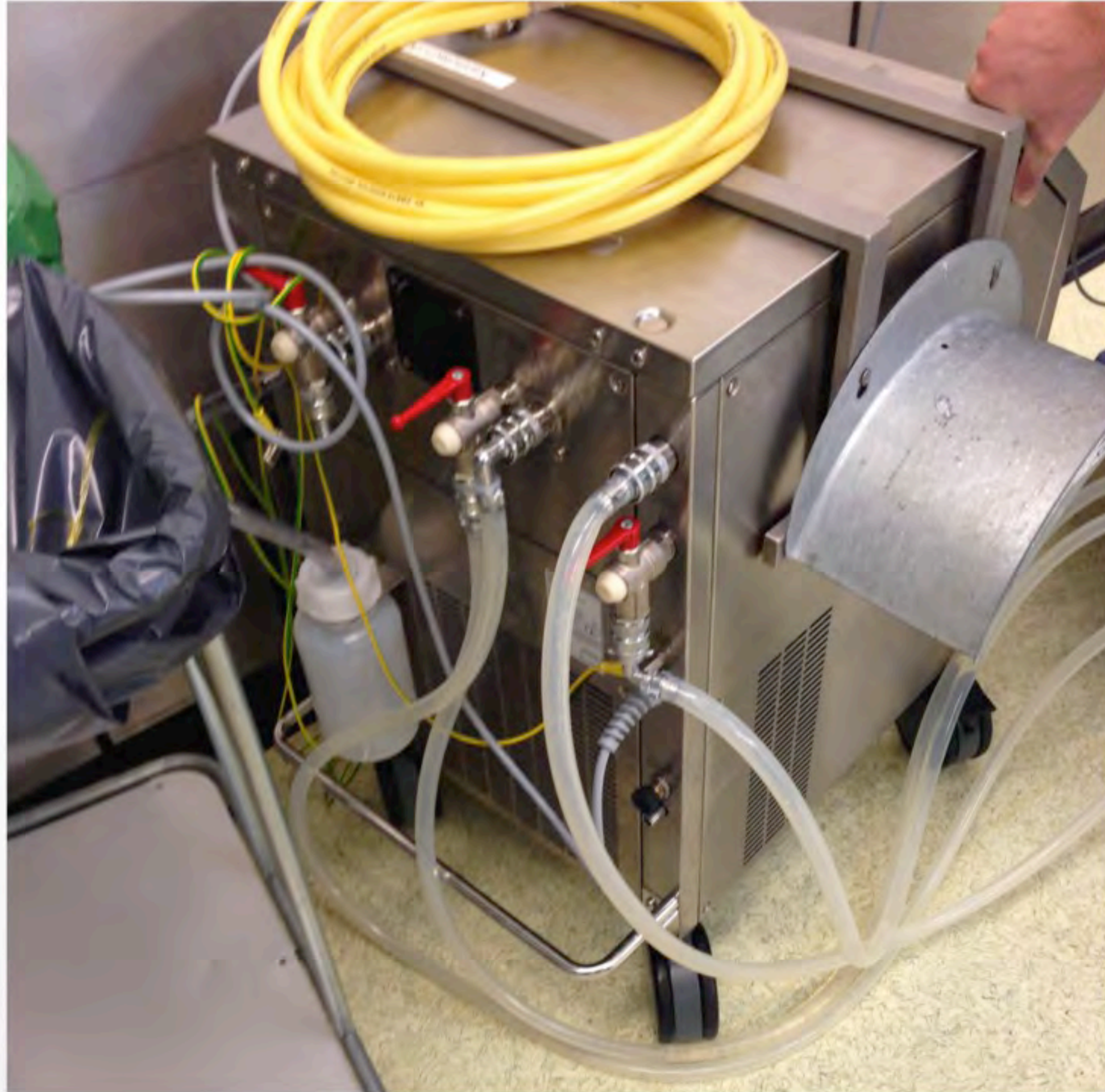
Cardioplegia solution

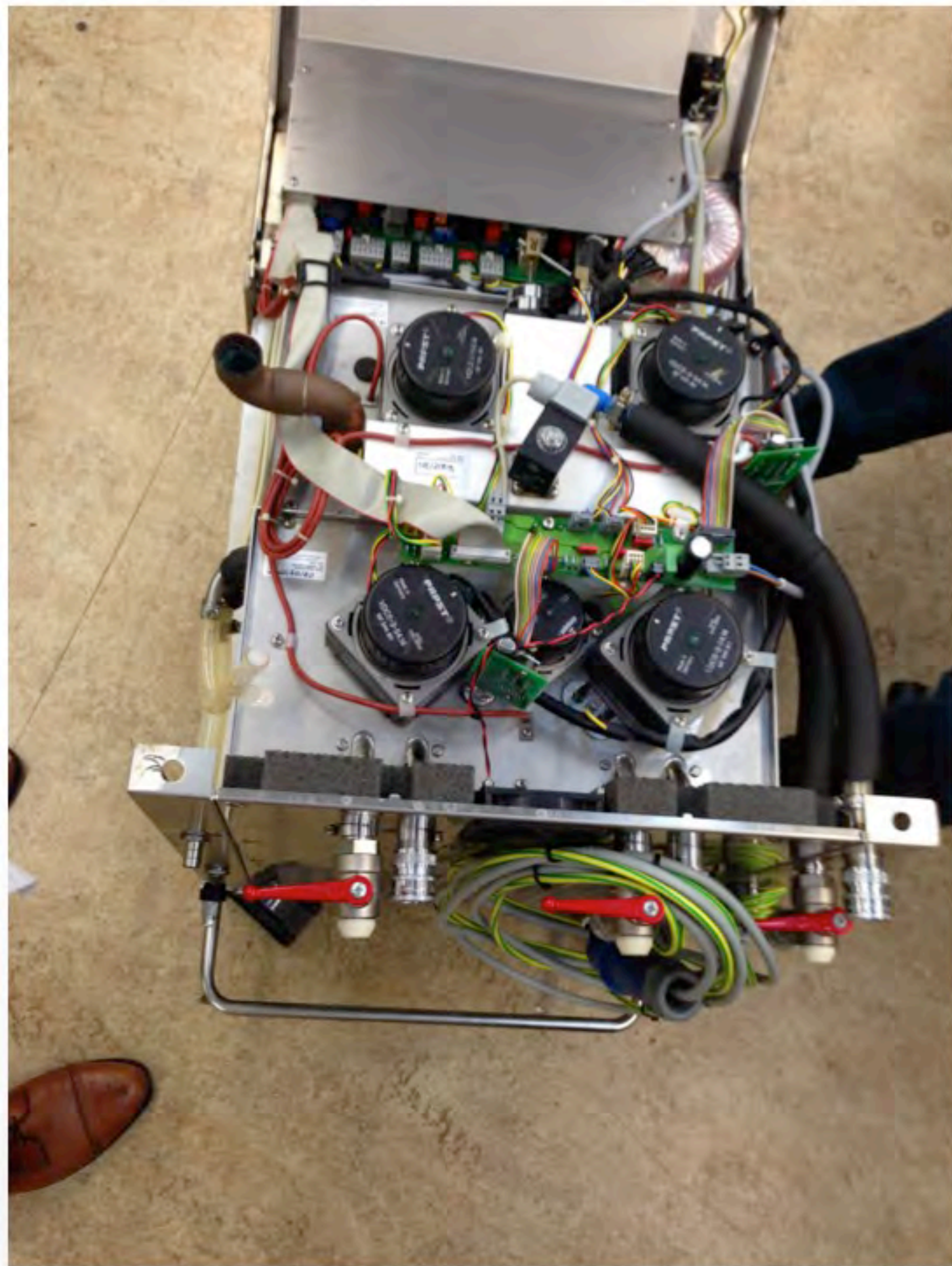


Patient blood circuit

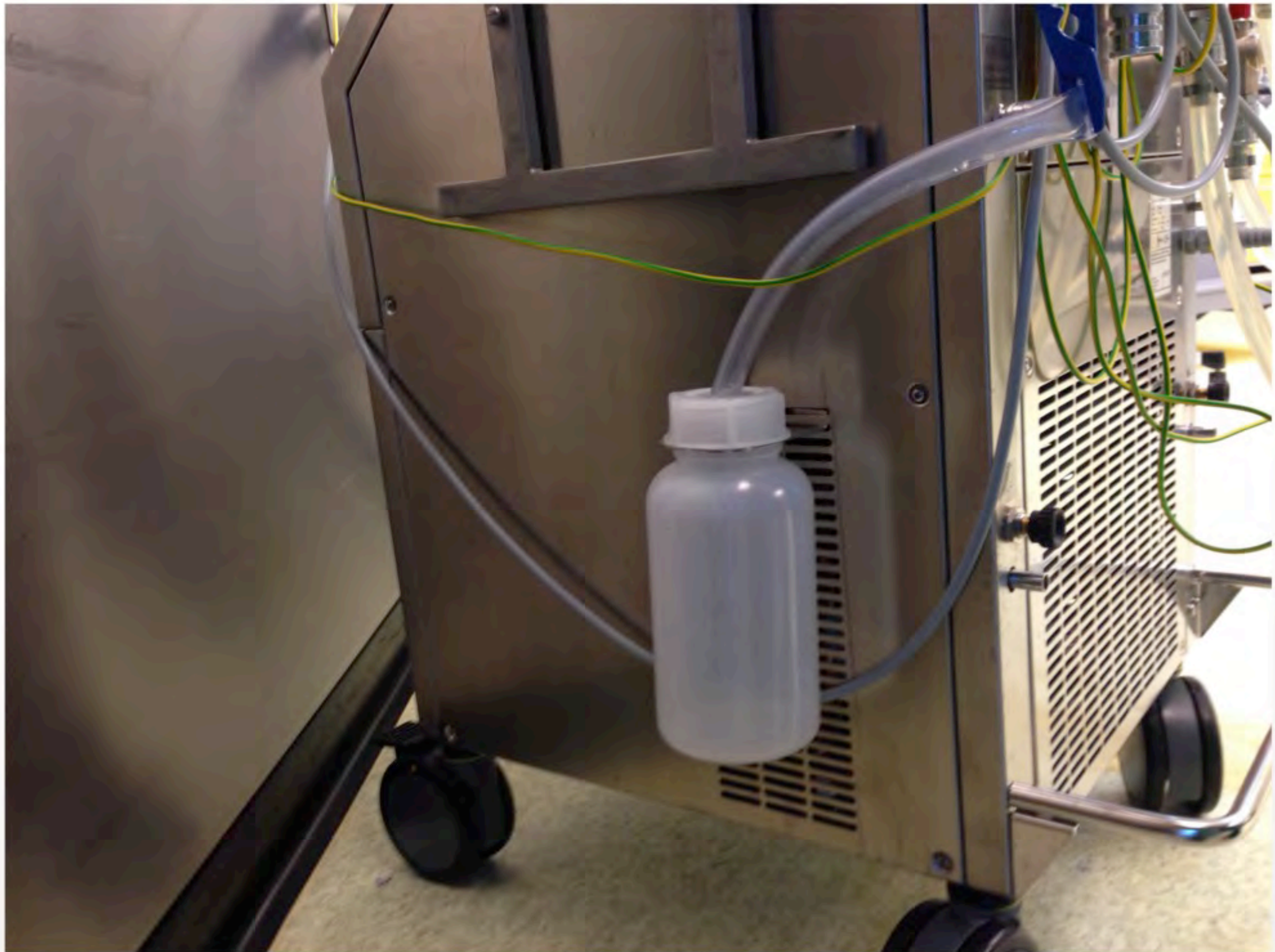


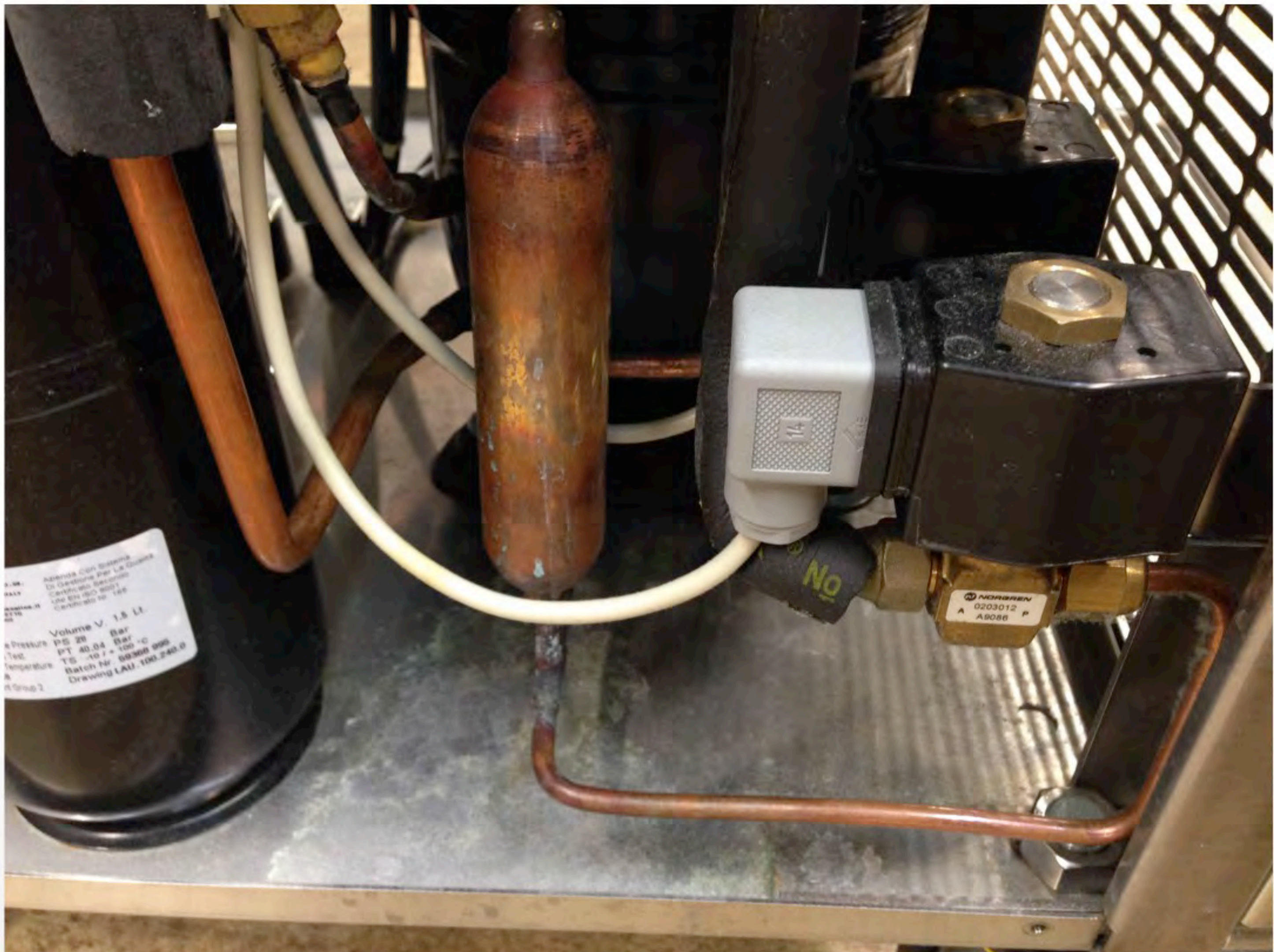
Sorin Stockert T3















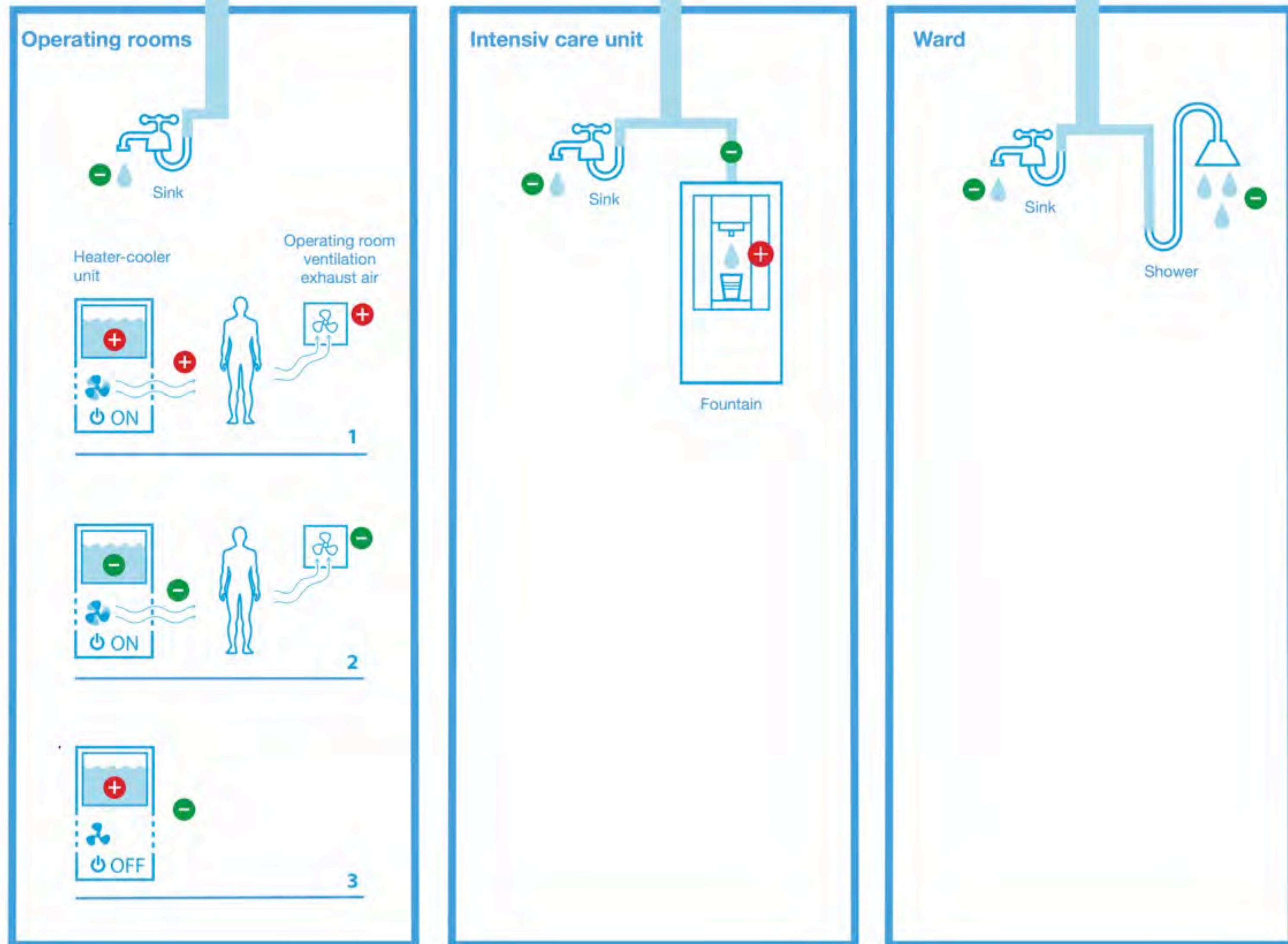
Air cultures with heater-cooler unit turned on
Air cultures with heater-cooler unit turned off



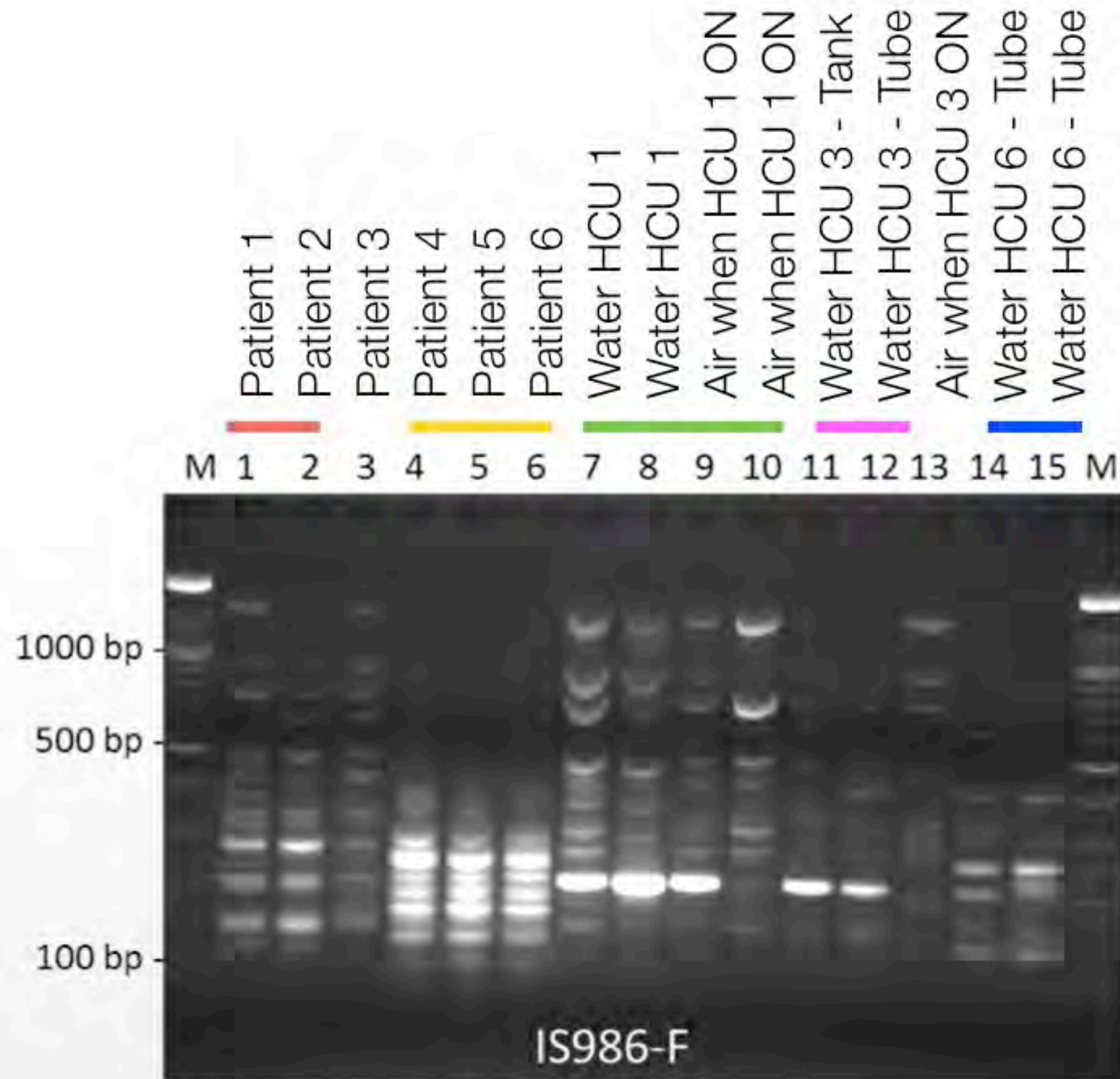
Air cultures with heater-cooler unit turned on

Air cultures with heater-cooler unit turned off

WATER SYSTEM



Randomly amplified polymorphic DNA PCR (RAPD-PCR)



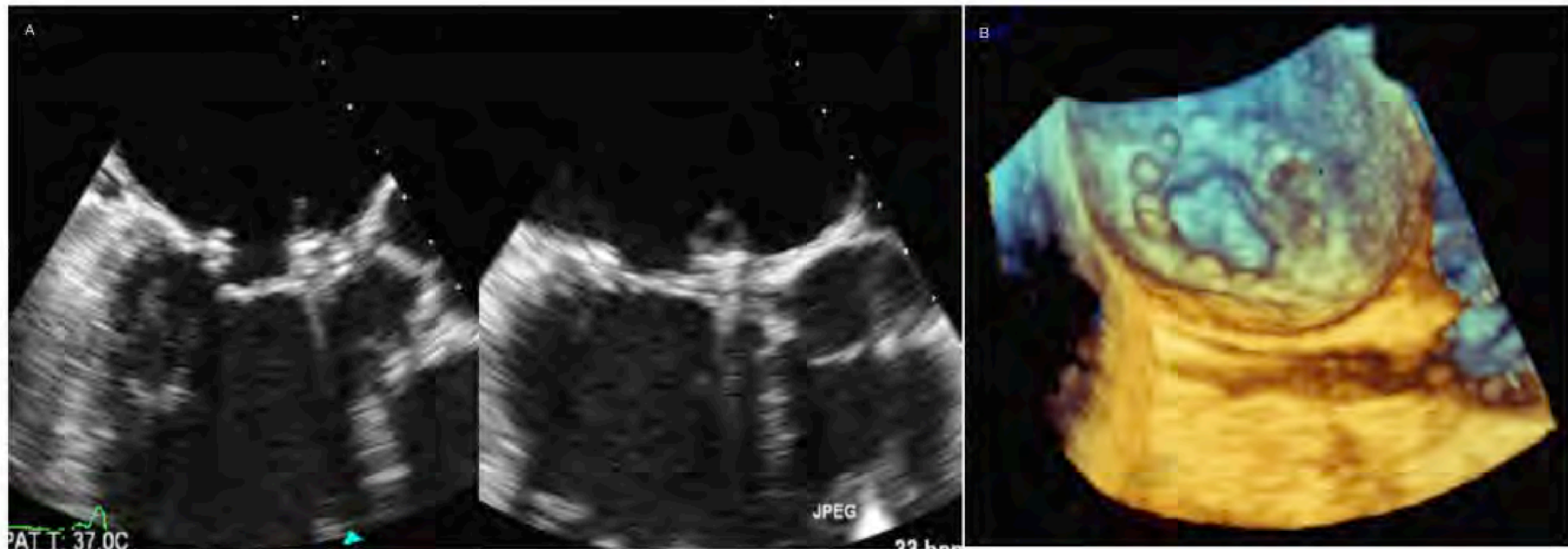
Many outbreaks of surgical site infections with NTM

Report	Outbreak period	No. of cases	Region	Surgical procedures (no. of cases)	Clinical manifestation (no. of cases)	Etiology	Typing method	Clustering	Source	Source or mode of transmission
Robicsek F, et al. [1]	1976	19	North Carolina, USA	Aorto-coronary bypass (14), valve prosthesis (3), porcine valves (2), ventricular septum repair (1)	Sternal wound infection; latency 6-40 days (median, 14); 5 fatal cases	<i>M. chelonae subspecies abscessus</i>	--	--	Not identified	Unresolved
Hoffman PC, et al. [3]*	1976	5	Colorado, USA	Coronary artery bypass (3), coronary grafts, and aortic valve (1), mitral commissurotomy (1)	Sternal wound infection; latency 5-44 days (median, 25 days); no fatal case	<i>M. fortuitum</i>	--	--	Not identified	Unresolved
Szabo I, et al. [2]	1977	6	Hungary	Open-heart surgery* not further detailed	Sternal wound infection; 3 fatal cases	<i>M. chelonae, M. abscessus</i>	--	--	Not identified	Unresolved
Kuritsky JN, et al. [4]	1981	6	Texas, USA		Sternal wound infection (4), endocarditis (1), saphenous graft-site infection (1); latency 21-92 days (median, 56); 2 fatal cases	<i>M. fortuitum biovar fortuitum</i> (4), <i>M. chelonae subspecies abscessus</i> (5)	--	--	Municipal water, tap water in operating room, water from ice machines; positive for <i>M. fortuitum</i> ; ice water for cooling of cardioplegia solution; many water sources positive for NTM, cardioplegia; swabs of scissors positive for <i>M. chelonae</i>	Hypothesis: hand transmission from cooling solution to surgical field
Yew WW, et al. [5]	1987-1989	21	Hong Kong, SAR	Aortic valve replacement (4), coronary artery bypass (9), mitral valve replacement (9), others	Sternal wound infections; fatality not reported	<i>M. fortuitum</i> <i>biovar fortuitum</i> , <i>biovar peregrinum</i> , <i>M. fortuitum</i> complex	Plasmid profiles, rRNA restriction analysis	2 clusters of 9 and 6 cases	Not identified	Unresolved
Vukovic et al. [7]	2009	3	Serbia	Septum defect patching	Endocarditis	<i>M. fortuitum</i>	Enterobacterial repetitive intergenic consensus PCR	1 cluster of 3 cases	Contaminated patch stored in 2% propylene oxide between interventions	Patch
Strabelli et al. [6]	1999-2008	13	Brazil	Mitral or aortic valve replacements	Endocarditis	<i>M. chelonae</i>			Contaminated prosthetic material by manufacturer	Valve
Nagpal et al. [8]	2008-2001	6	Minnesota, USA	Aortic valve replacement (4), aortic arch repair (1), tricuspid valve replacement (1), lung transplant (2)		<i>M. walinskyi</i>	PCR restriction fragment analysis	1 cluster of 3, another case 'closely related'	Cold air blaster, heater-cooler-unit incriminated but no growth of <i>M. walinskyi</i> from these sources	Unresolved
Current report	2008-2012	x	Switzerland		Endocarditis, sternal, vertebral, ulnar osteitis, disseminated disease	<i>M. chimaera</i>	RAPD-PCR	2 clusters of 2 and 3 patients	Heater-cooler-unit water tank of heart-lung-machine	Airborne

More cases



Mitral ring endocarditis



Case #3 | 61-year-old male

2009 Mitral valve reconstruction

2012 Arthritis due to *M. chimaera*

2013 Mitral ring endocarditis

2014 Redo surgery

Aortic prosthetic valve endocarditis

Case #4 | 49-year-old male with Crohn's disease

Treatment with azathioprin

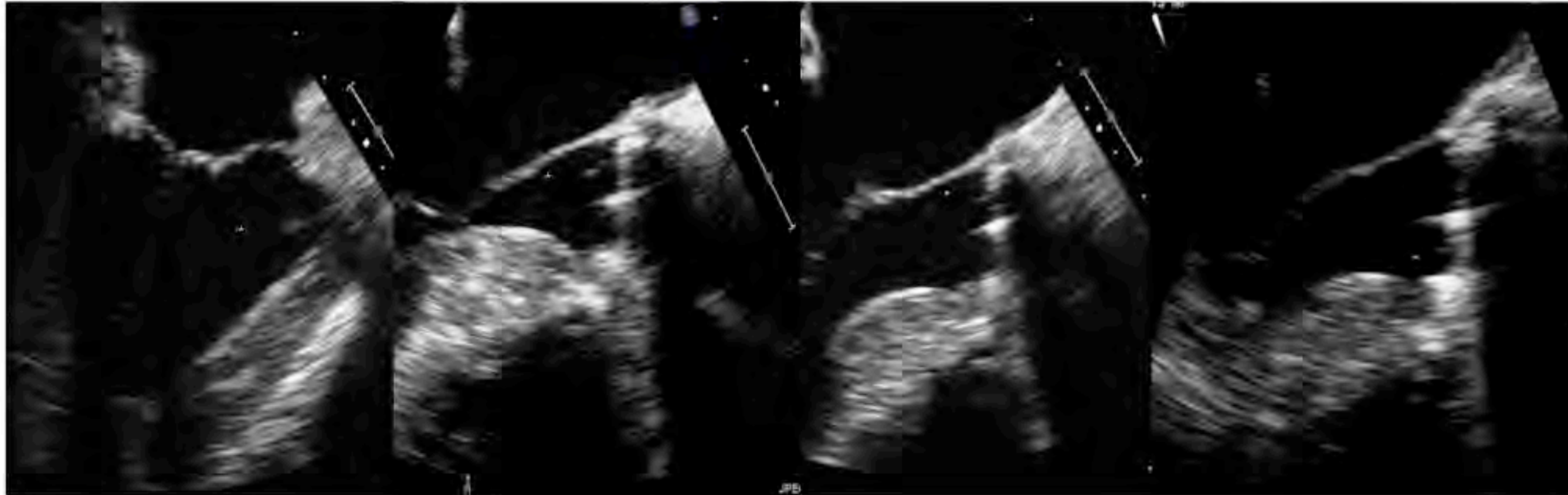
2009 Aortic valve replacement

2013 Progressive Dyspnea,
Ascites, icterus



Prosthetic valve endocarditis
Redo surgery

Composite graft infection



Case #5 | 59-year-old male

2010 Composite graft replacement

2013 Spondylodiscitis

2014 Composite graft infection due to *M. chimaera*

2014 Redo surgery

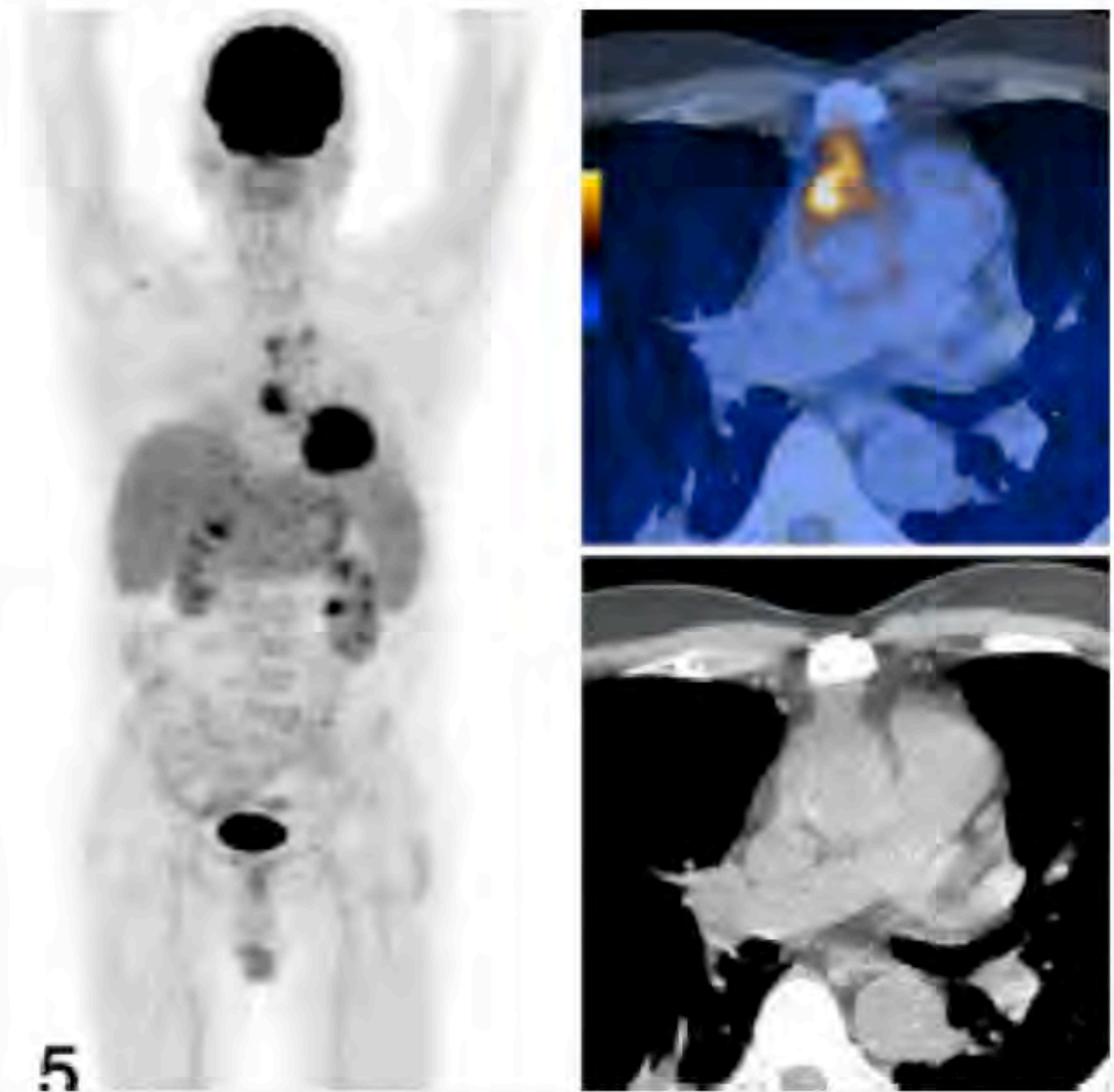
Aortic arch infection

Case #5 | 60-year-old male

2010 Aortic arch replacement

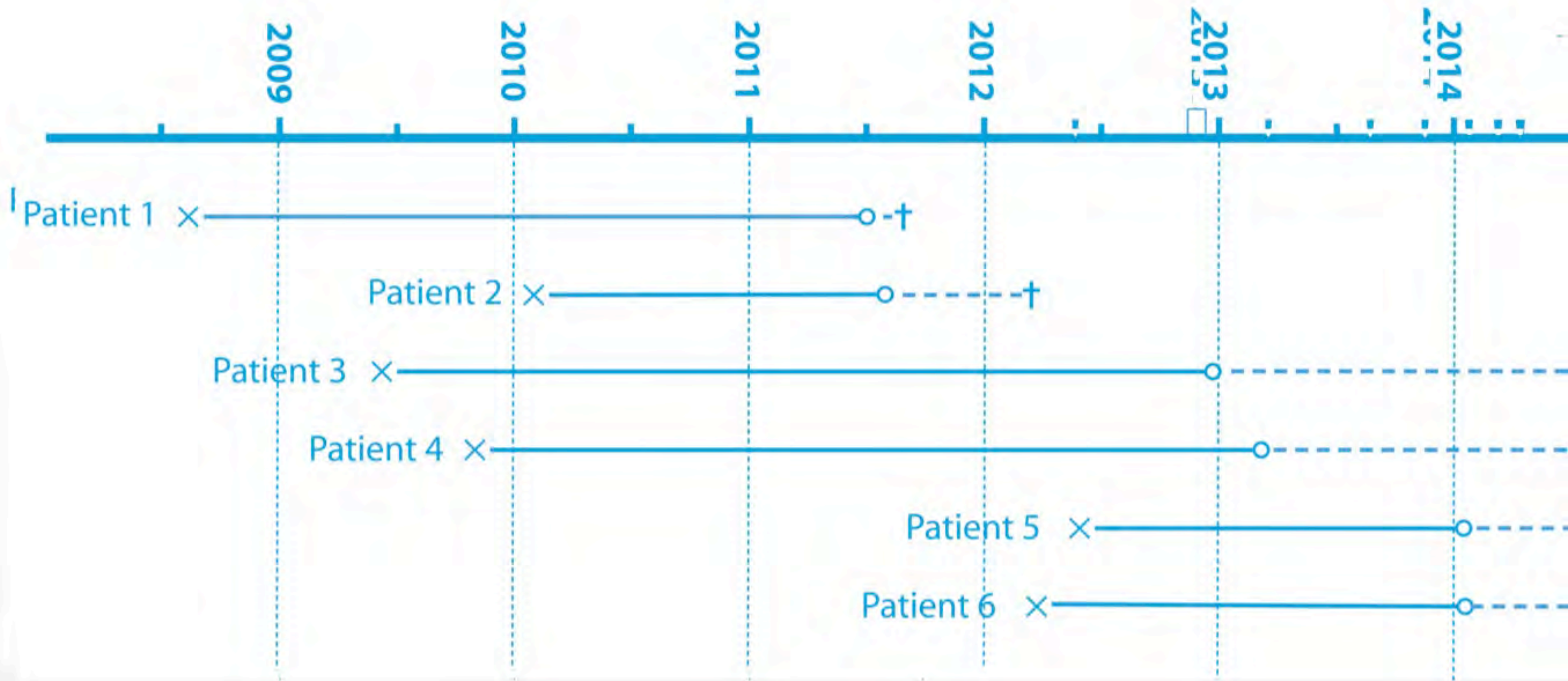
2014 Aortic graftinfection due to *M. chimaera*

2014 Debridement of periaortic tissue, retention of graft



Grade 5, focal and intense FDG-uptake plus fluid collections/abscess formation

Time line of infections



Prostheses differed in materials and manufacturers

	Age (years)	Date of index surgery	Latency (years)	Heart surgery	Implant	Material	Manifestations	Positive cultures for <i>Mycobacterium chimaera</i>	Histopathology
Patient 1* †	58	13.08.2008	2.9	Mitral valve reconstruction	28 mm C-E physio mitral annuloplasty ring (model 4450; serial no. 1716253, lot no. 08E134)	Layers of Elgiloy Sewing ring with layers of silicone covered by polyester knit fabric	Endocarditis, splenomegaly, pancytopenia, hepatitis, renal involvement	Blood, cardiac tissue prosthesis, sputum	Granulomatous hepatitis, nephritis
Patient 2* †	51	29.01.2010	1.5	Composite graft for aortic dissection	25 mm ATS composite graft (serial no. 408656, lot no. 502AG25) 8 mm GAHE Gelweave x prosthesis (serial no. 0001079837, lot no. 101385/1A 1577)	Heart valve: pyrolytic carbon; Graft: double woven velour; Hemiarch: woven polyester	Bloodstream infection, splenomegaly, pancytopenia, hepatitis, pulmonary, ocular emboli	Blood, sputum, bone marrow, urine	Granulomatous myocarditis, pneumonitis, nephritis involvement of spleen
Patient 3	64	12.06.2009	3.6	Mitral valve reconstruction	32 mm x 2 mm Carpentier ring (model 445, serial no. 1984171, lot no. 09B052)	Layers of Elgiloy Sewing ring with layers of silicone covered by polyester knit fabric	Endocarditis, wrist arthritis, pancytopenia, splenomegaly, hepatitis, renal impairment, ocular emboli	Cardiac tissue and prosthesis, bone (wrist)	Granulomatous endocarditis osteomyelitis
Patient 4	49	31.10.2009	3.4	Aortic valve replacement	24 mm ATS Open Pivot AP Series Heart Valve (model 505DA24, serial no. 408100)	Heart valve: pyrolytic carbon; graft: double woven velour	Endocarditis, pancytopenia, splenomegaly, hepatitis, ocular emboli, pacemaker pocket infection	Cardiac tissue and prosthesis, deep tissue samples of pacemaker pocket	Granulomatous hepatitis, myositis
Patient 5	61	30.05.2012	1.7	Aortic root and arch replacement	ATS AVG (model 502AG23, serial no. 523707) 26 mm graft as elephant trunk (model IGW0026-30 serial no. N 40552231, lot no. 11J15)	Valve: pyrolytic carbon; Hemashield Woven Double Velour Graft; Elephant trunc: collagen coated external velour polyester graft	Vascular graft infection, Bone (vertebral and sternal osteomyelitis) Splenomegaly Ocular emboli	Vertebral bone	Granulomatous osteomyelitis
Patient 6	63	26.03.2012	1.8	Aortic root and arch replacement	Medtronic Freestyle Aortic Valve (model 735026/8S, serial no. 222) 26x8mm, 50 cm Vascutek (serial no. 0001159261, lot no. 104998 1967) 10 mm Gelweave D: 10 mm, L: 15 cm (serial no. 0001383672, lot no. 119564/1 3441)	Biological Polyester	Vascular graft infection, splenomegaly, hepatitis, renal failure, multifocal chorioiditis	Cardiac tissue and prosthesis	Granulomatous interstitial nephritis

*Patients 1 and 2 have been reported previously (1, 11)
† Latency between open chest heart surgery and diagnosis of *M. chimaera* infection.

6 infected patients

3000 open-chest heart surgery interventions

Switzerland investigation in 2014

16 cardiac surgery centres

8 grew *M. chimaera* from heater-cooler units

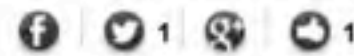
No further patient at that time

Going public

July 14, 2014

Tödliche Infektionen: Zürcher Unispital entdeckt Bakterium

Dienstag, 15. Juli 2014, 19:04 Uhr, aktualisiert um 19:58 Uhr



Das Zürcher Universitätsspital hat ein Bakterium entdeckt, welches bei Herzoperationen zu Komplikationen oder im schlimmsten Fall sogar zum Tod führen kann. Es befindet sich im Leitungswasser und ist im Normalfall ungefährlich.



Tagblatt Online, 14. Juli 2014, 17:36 Uhr

Tödliche Infektionen nach Herzoperationen



Zwei Patienten starben an den Folgen der Infektion. (Bild: Keystone/Symbol)

Bei Eingriffen am offenen Herzen in der Schweiz ist es zu vereinzelt Infektionen mit einem an sich harmlosen Bakterium gekommen. Vermutliche Quelle ist ein technisches Gerät, das bei den Operationen benutzt wird. In den Spitalern wurden Gegenmassnahmen getroffen.



European Heart Journal
doi:10.1093/eurheartj/ehv342

FASTTRACK CLINICAL RESEARCH
Cardiovascular surgery

Healthcare-associated prosthetic heart valve, aortic vascular graft, and disseminated *Mycobacterium chimaera* infections subsequent to open heart surgery

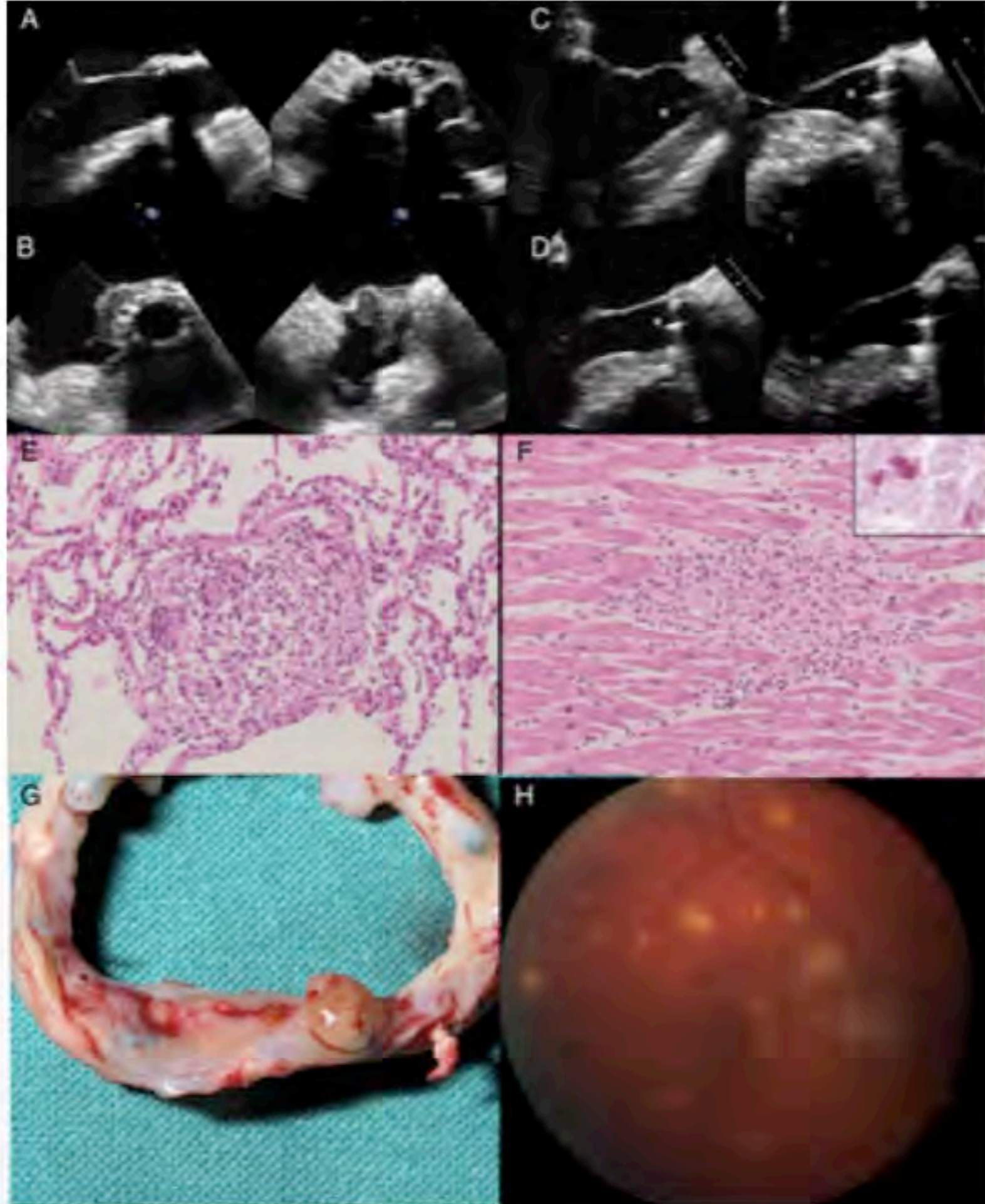
Philipp Kohler¹, Stefan P. Kuster¹, Guido Bloemberg², Bettina Schulthess^{2,3}, Michelle Frank⁴, Felix C. Tanner⁴, Matthias Rössle⁵, Christian Böni⁶, Volkmar Falk^{7,8}, Markus J. Wilhelm⁷, Rami Sommerstein¹, Yvonne Achermann¹, Jaap ten Oever⁹, Sylvia B. Debast¹⁰, Maurice J.H.M. Wolfhagen¹⁰, George. J. Brandon Bravo Bruinsma¹¹, Margreet C. Vos¹², Ad Bogers¹³, Annerose Serr¹⁴, Friedhelm Beyersdorf¹⁵, Hugo Sax¹, Erik C. Böttger^{2,3}, Rainer Weber¹, Jakko van Ingen^{16†}, Dirk Wagner^{17†}, and Barbara Hasse^{1†*}



UniversitätsSpital
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10 patients (CH, D, NL)

1-4 y latency since cardiac surgery

Peripheral or systemic manifestations

8/10 surgical re-intervention despite Rx

6/10 break-through infections, 4 fatal

3 patients are being monitored post-Rx



ECDC TECHNICAL DOCUMENT

EU protocol for case detection, laboratory diagnosis and environmental testing of *Mycobacterium chimaera* infections potentially associated with heater-cooler units: case definition and environmental testing methodology

August 2015

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Infektions- und Krankenhaushygiene

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Informationen zu einem internationalen Ausbruchsgeschehen mit nicht-tuberkulösen Mykobakterien im Zusammenhang mit Temperaturregulierungsgeräten bei Herzoperationen



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Department of Health and Human Services

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10903 New Hampshire Avenue
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DEC 29, 2015

WARNING LETTER

To our best knowledge

Switzerland	7 patients
Netherlands	4 patients
Germany	5 patients
UK	20 patients
Spain	1 patients
US	11 patients
France	2 patients
Irland	2 patients

And counting...

Now the work starts for clinicians...

Invasive *M. chimaera* infections

Table 3 Recommendations for future case detection

Exposure criteria

A patient having undergone surgery requiring cardiopulmonary bypass prior to symptoms of infection

Clinical criteria

Prosthetic valve endocarditis

Prosthetic vascular graft infection

Sternotomy wound infection

Mediastinitis

Fever of unknown origin

Disseminated infection including embolic and immunologic manifestations (e.g. splenomegaly, arthritis, osteomyelitis, bone marrow involvement with cytopenia, chorioretinitis, cerebral vasculitis, pneumonitis, myocarditis, hepatitis, nephritis)

Culture negative PVE/ aortic graft infections

High index of suspicion for *M. chimaera* infections needed

How to diagnose it:

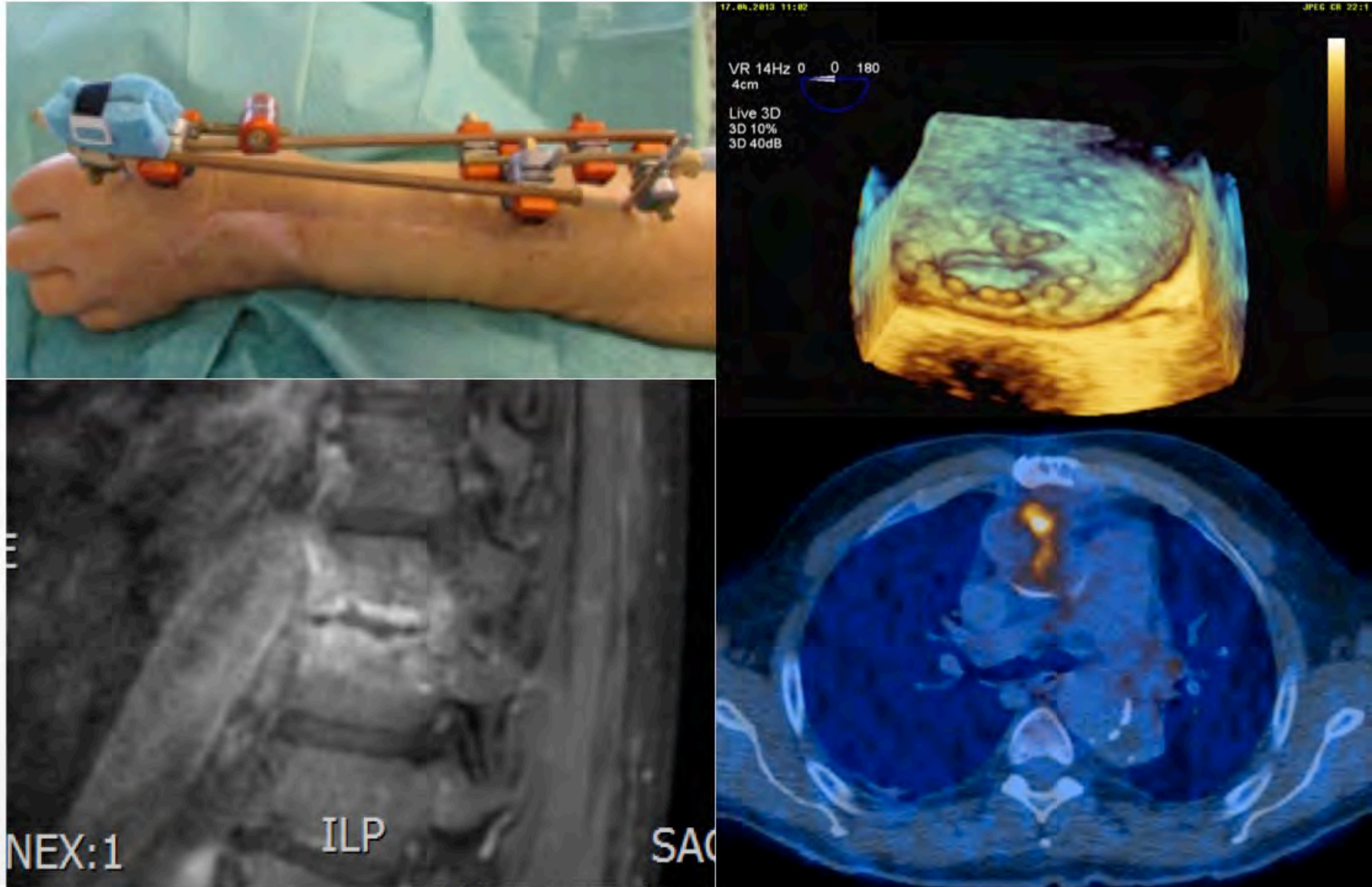
Microbiology Positive heparin blood cultures for <i>M. chimaera</i> Detection of <i>M. chimaera</i> by culture or PCR in cardiac tissue in the proximity of the prosthetic material
Histopathology Detection of non-caseating granuloma and foamy/swollen macrophages with/without acid fast bacilli in cardiac tissue in the proximity of the prosthetic material
Additional criteria Negative conventional blood cultures Serologic exclusion of Coxiella, Bartonella, Brucella, Tropheryma whippeli, Legionella, Mycoplasma, Chlamydia

New differential for «culture-negative»

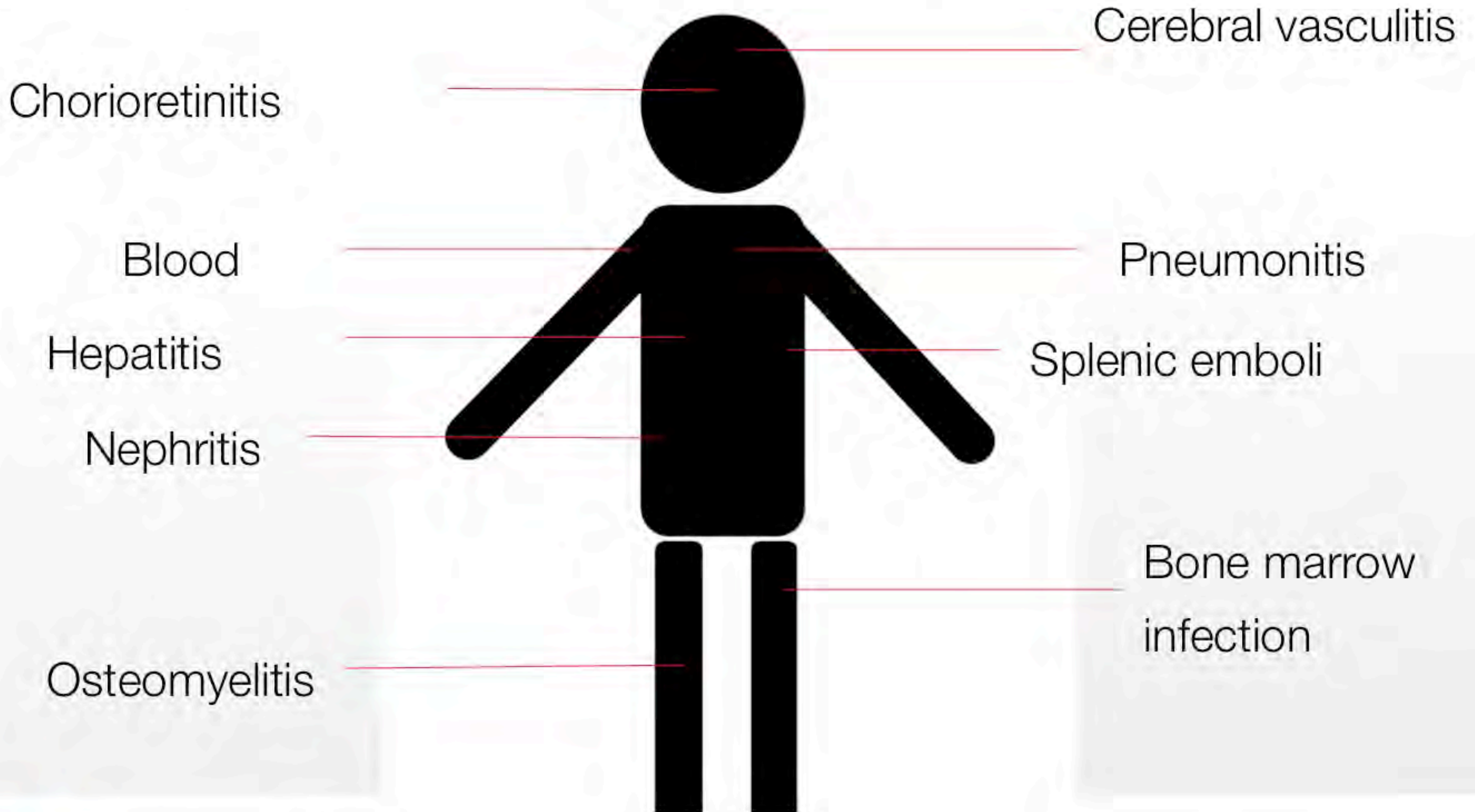
Brucella spp
Coxiella burnetii
Bartonella spp
Tropheryma whippeli
Mycoplasma spp
Legionella spp
Mycobacterium chimaera

Presentation often atypical and delayed

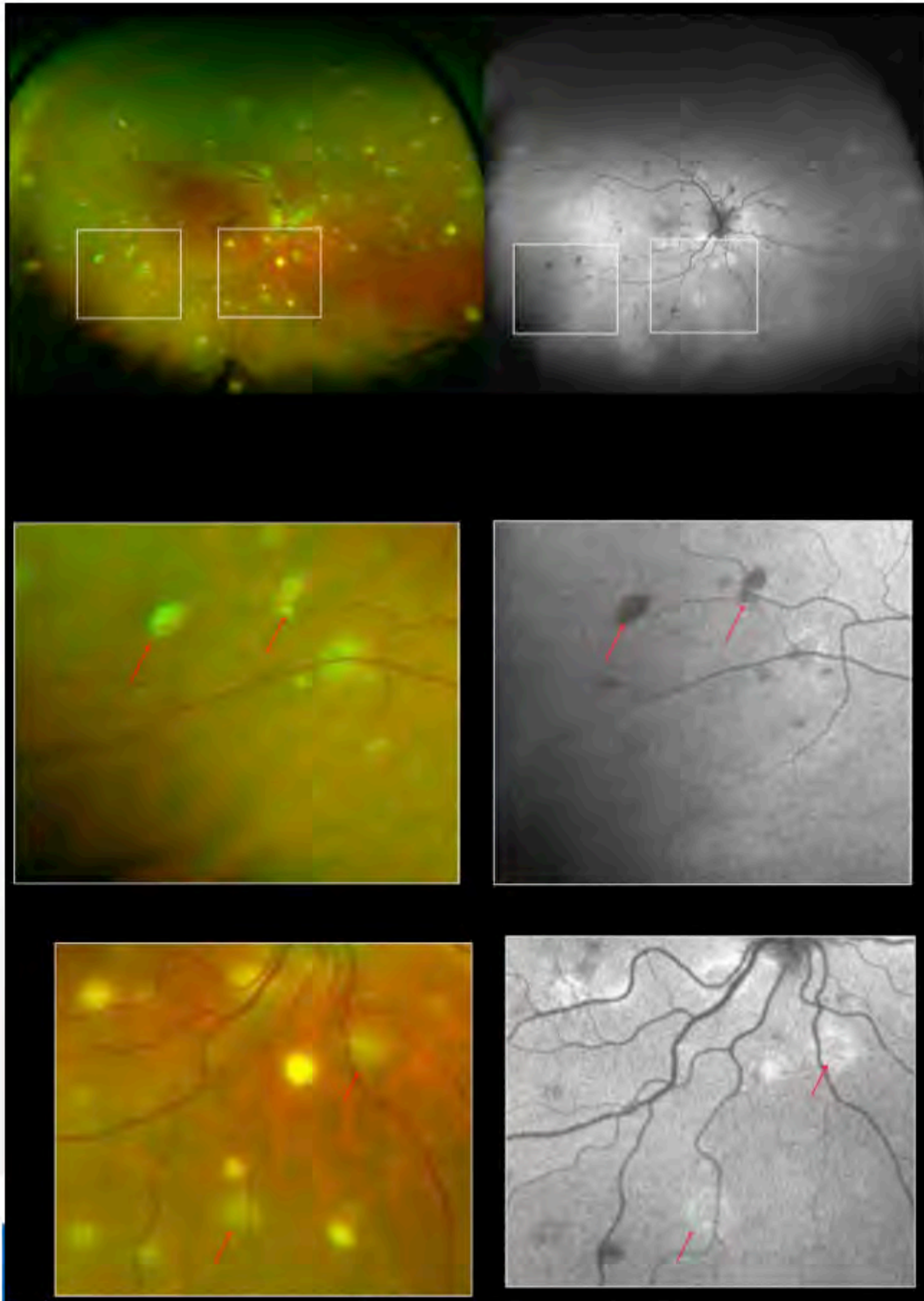
Extracardiac manifestations of preceed cardiac manifestations



Clinical presentation



Anterior and posterior uveitis/ chorioretinitis



51 year old male

Multifocal choroidal lesions

Multiple flat, cream colored lesions
with indistinct border

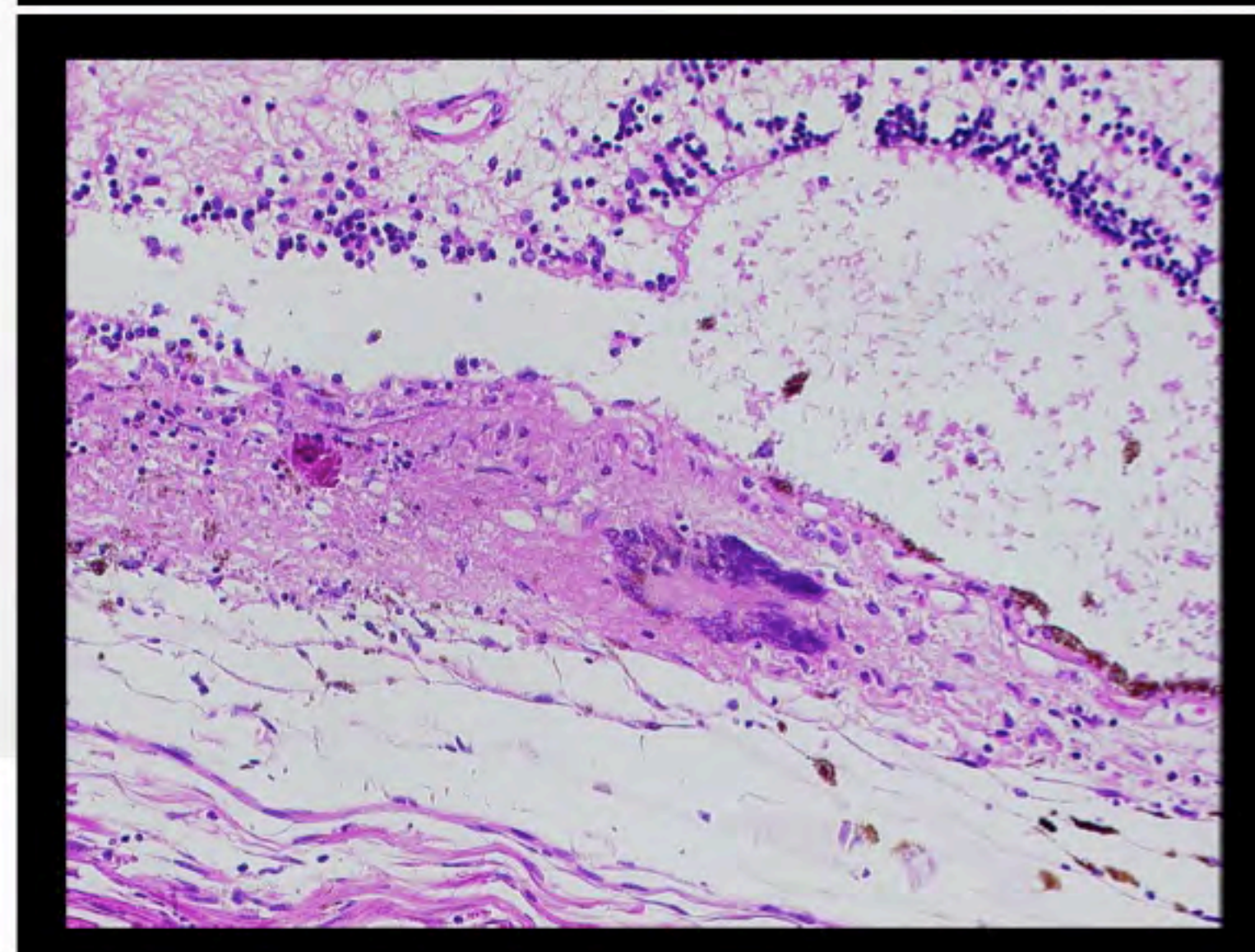
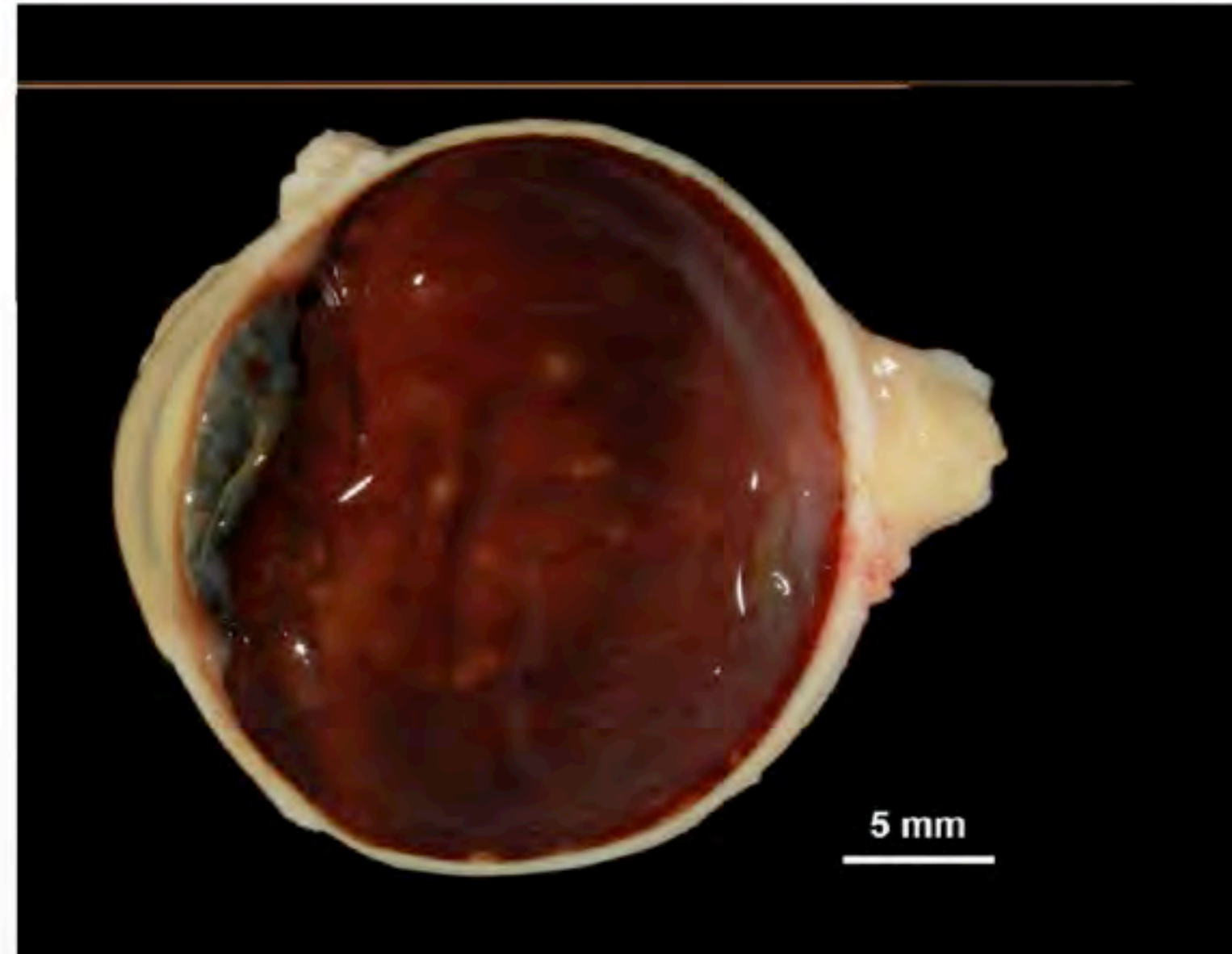
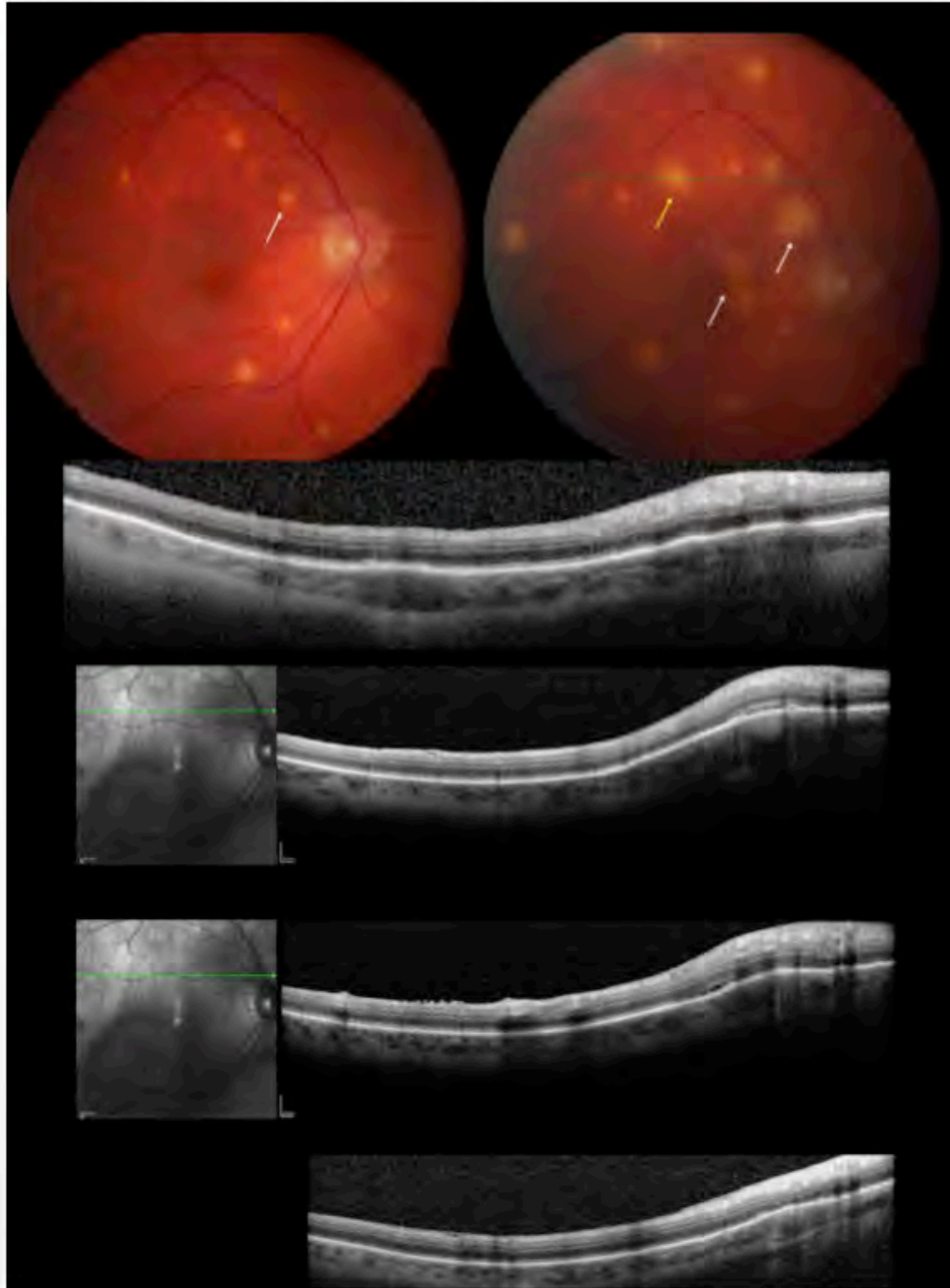
Depending on the activity status of the
lesion they appeared hyper- or
hypofluorescent

Treatment

Multidisciplinary approach!

- Infectious disease specialist
- Microbiologist
- Cardiovascular surgeon
- Cardiologist
- Cardiac anesthesia
- Nuclear imaging specialists
- Ophthalmologist

Ocular manifestations are good indicators of the systemic control of the disease process



Treatment

Lead-in phase:

Clarithromycin

Rifabutin

Ethambutol

+/-

Amikacin

Moxifloxacin

Goal:

Reduction of
bacterial load

Redo-Operation:



«Sine qua non»

Goal:

Removal of biofilm-
forming strains

Chronic phase:

Clarithromycin

Rifabutin

Ethambutol

+/-

Amikacin

Moxifloxacin

Goal:

Treatment, hindrance of
new dissemination

Break-through infections occur without removal of cardiac devices



Embolic events



Epicardial left wire
infection



Endocarditis

Drug susceptibility of *M. chimaera* isolates

Table 2 Phenotypic drug susceptibility testing of 15 *M. chimaera* isolates of the 10 study patients

Patients	1	2	3	4	5	6	7	8	9	10					
Sample date	30.06.11	27.07.11	10.05.12	20.03.13	07.02.14	06.03.13	13.06.13	06.01.14	10.09.14	14.01.14	26.11.14	12.06.13	23.04.13	16.01.13	30.01.13
Material	Mitral ring	Bone marrow	Urine	Bone Wrist	Mitral ring	Cardiac tissue	Pocket tissue	Vertebral bone	Urine	Cardiac tissue	Blood culture	Aortic valve	Mitral valve	Bone	Cardiac tissue
MIC (mg/L)															
Clarithromycin	≤4	≤4	≤4	≤4	≤4	≤4	≤4	≤4	≤4	≤4	≤4	2	1	2	0.5
Moxifloxacin	2.5	2.5	2.5	2.5	2.5	0.5	0.5	2.5	2.5	2.5	2.5	4	4	4	2
Linezolid	ND	ND	ND	4	16	ND	16	4	4	16	16	16	8	16	16
Amikacin	20	20	20	4	4	4	4	4	4	4	20	8	8	8	8
Rifampicin	>1<20	>1<20	>1<20	4	4	ND	4	4	4	4	4	2	2	2	1
Rifabutin	>0.1<2	>0.1<2	>0.1<2	0.4	0.4	2	0.4	0.4	0.4	2	2	0.5	0.5	≤0.25	0.5
Ethambutol	≤5	≤5	≤5	≤5	≤5	ND	12.5	≤5	≤5	12.5	12.5	8	8	4	8

Data are minimum inhibitory concentrations, in mg/L.

ND, not done, minimum inhibitory concentrations, MICs.

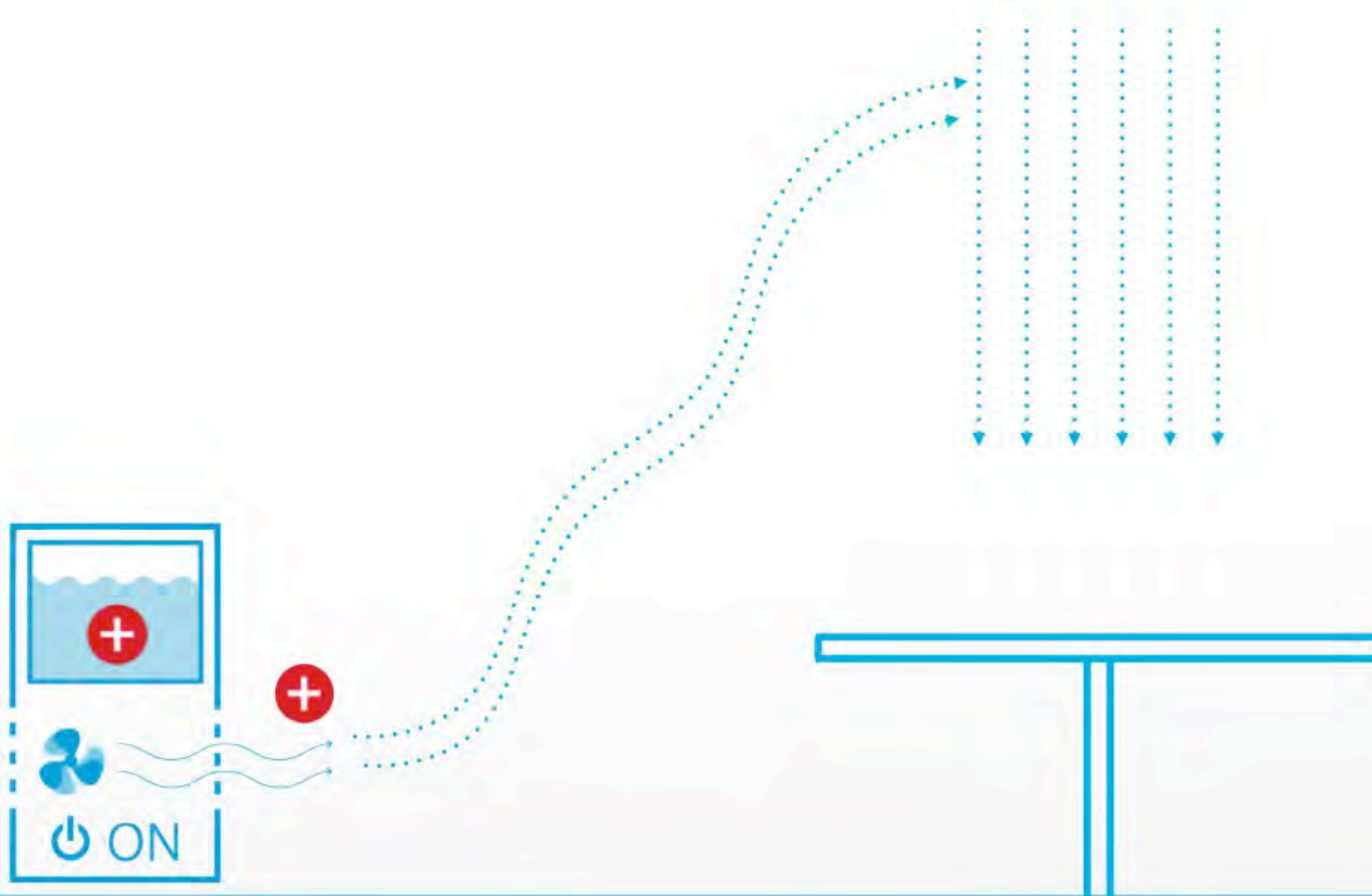
MGIT method applied in Patients 1–6, the broth dilution method has been applied in Patients 7–10.

Situation in vivo/ on prosthesis?

Prevention



Separating heater-cooler unit from operating room air

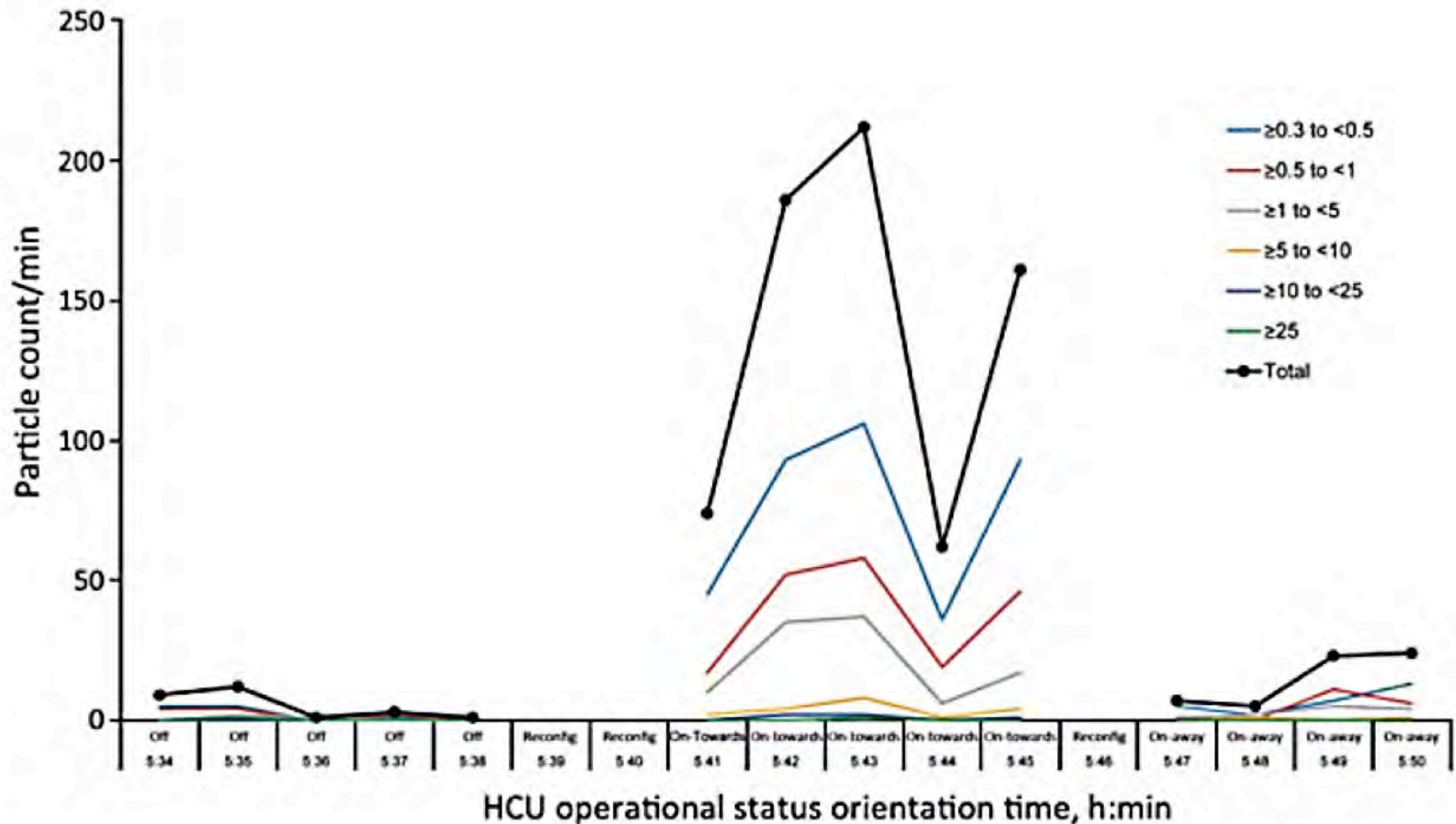


Sommerstein R, et al. Transmission of *Mycobacterium chimaera* from Heater–Cooler Units during Cardiac Surgery despite an Ultraclean Air Ventilation System. *Emerg Infect Dis* 2016

Video of smoke experiments showing contamination of ultra-clean ventilation in OR



<https://youtu.be/YZ41aLoHrhQ>



Early diagnosis Screening

Screening tools

Look for it !

Physical examination

Medical history

Heparin blood cultures, Perform mycobacterial cultures or

Mycobacterial specific PCR in case of biopsy

Histopathological work up (presence of granulomas)

Scrutinize Sarcoidosis, vasculitis or unknown systemic diseases

Look carefully at fever of unknown origin or vasculitis with former cardiopulmonary bypass surgery

63 year-old lady

2008 History of aortic valve replacement

Fatigue, fevers, and weight loss.

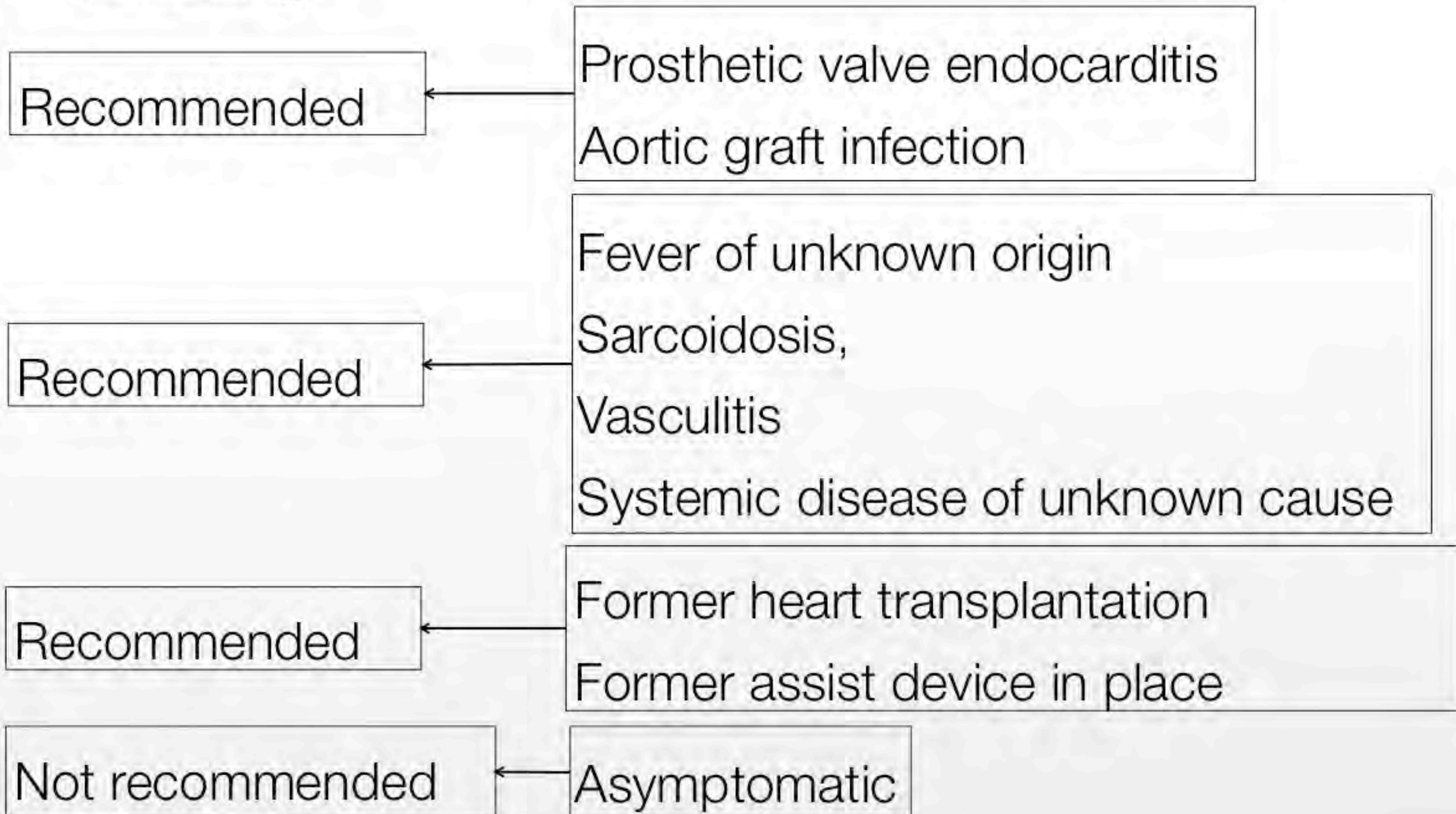
2011 Unknown vasculitis with 4/10 blood cultures positive for MAC

Retrospective review of echocardiography:

Endocarditis with strains

Screening approach among patients with former cardiopulmonary bypass surgery

Screening



Missed diagnosis....

Look back for MAC/ *M. avium* cases

Look back for culture-negative PVE, aortic graft infection

Look back yielded around 20 cases of presumptive cardiac infections with MAC with fatal outcome



Look back at University Hospital Zurich yielded no cases

Look back Switzerland: ongoing



The story is still ongoing...

Conclusions

When a system can fail, it will fail (Murphy)

A note on common sense

Medical devices are not grounded such as airplanes

Outbreak investigation on an international level is slow

We don't know yet how big this is

Take-home message:

Look for it!

Zürich Collaboration

Yvonne Achermann

Cornelia Bayard

Guido Bloemberg

Erik C Böttger

Leo Eberl

Carlotta Fabbri

Volkmar Falk

Barbara Hasse

Philipp Kohler

Francesco Maisano

Christian Rüegg

Peter Schreiber

Rami Sommerstein

Rainer Weber

Swiss Chimaera Collaborative

Daniele Genoni

Matthias Schlegel

Andreas Widmer

Many infection control supervisors

European Collaboration

Meera Chand, UK

Thomas Kohl, D

Katharina Krantzer, D

Stefan Niemann, D

Jakko van Ingen, NL

Dirk Wagener, D

Diamantis Plachouras, ECDC

The next WHO teleclass

April 20, 2016

THE CORE COMPONENTS FOR INFECTION PREVENTION AND CONTROL PROGRAMS AND ACTION PLAN



Jules Storr

Objectives:

- Outline the background and rationale
- Summarise the two-pronged approach
- Explore how the core components will contribute to the global knowledge
- Describe next steps and highlight how this work will strengthen approaches to IPC improvement and implementation across all countries

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