

Investigation of a Local Dialysis Center:

Collaboration at the local,
state, and federal levels

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Collaborating Agencies

Dialysis Center “X”

- Corporate and Affected Facility

Cuyahoga County Board of Health

- Admin, Epi, EH, and Nursing

Ohio Department of Health

- Bureau of Infectious Disease Control, Outbreak Response and Bioterrorism Investigation Team (ORBIT)
- Bureau of Community Health Care Facilities & Services, Division of Quality Assurance
- State Epidemiologist

Centers of Disease Control and Prevention

- Clinical and Environmental Microbiology Branch Division of Healthcare Quality Promotion, National Center for Preparedness, Detection and Control of Infectious Diseases, Coordinating Center for Infectious Diseases

Special Thanks

CCBH

- Andrea Arendt (*Epi*)
- Jackie Napolitano (*Epi*)
- Matt Johnson (*EH*)

ODH

- Sietske de Fijter (*O.R.B.I.T.*)
- Jane Carmean (*O.R.B.I.T.*)
- Marika Mohr (*O.R.B.I.T.*)
- Dr. Mary Diorio (*BID*)
- Dr. Forrest Smith

CDC

- Dr. Matt Arduino
- Dr. Rosemary Duffy

Dialysis Center "X"

- Corporate and Facility Staff

How Did We Get Here

Dialysis Center Medical Director called CDC



April 2:

- ODH Division of Quality sends staff to inspect Dialysis Center and contacts ODH ORBIT
- ODH ORBIT contacts CCBH Epi
- Conference call with Dialysis Center, ORBIT, and CCBH
- Dr. Duffy contacts Dr. Arduino
- CCBH Epi makes site visit in evening

April 21:

Dialysis Center re-opened for treatment

April 1:

- Dialysis Center "reaction" and closure late in the day

April 5-18:

-Worked with Dialysis Center, ODH, and CDC

April 4:

- CCBH onsite data collection at Dialysis Center
- Conference call with Dialysis Center, ORBIT, CCBH, and CDC

March 27-29

-Dialysis Center voluntarily closed for treatment
-Conducted complete disinfection of system

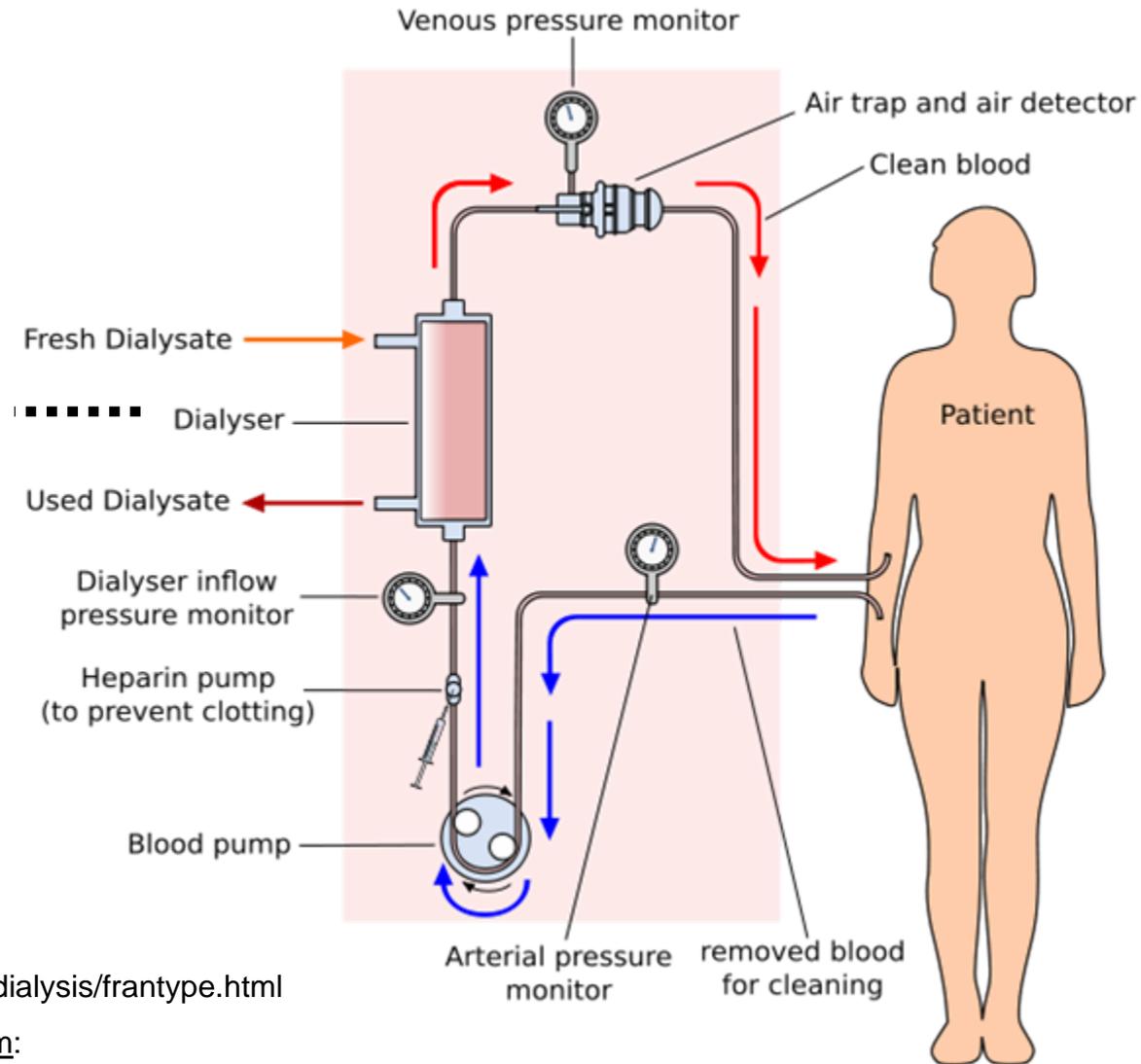
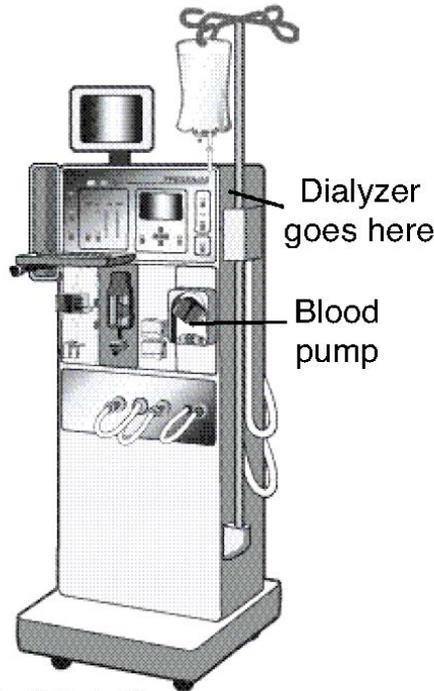
April 3:

-Conference call with ORBIT, CCBH, and CDC

Feb 28, Mar 6,

-Patients treated on above dates diagnosed with water-borne bacteria

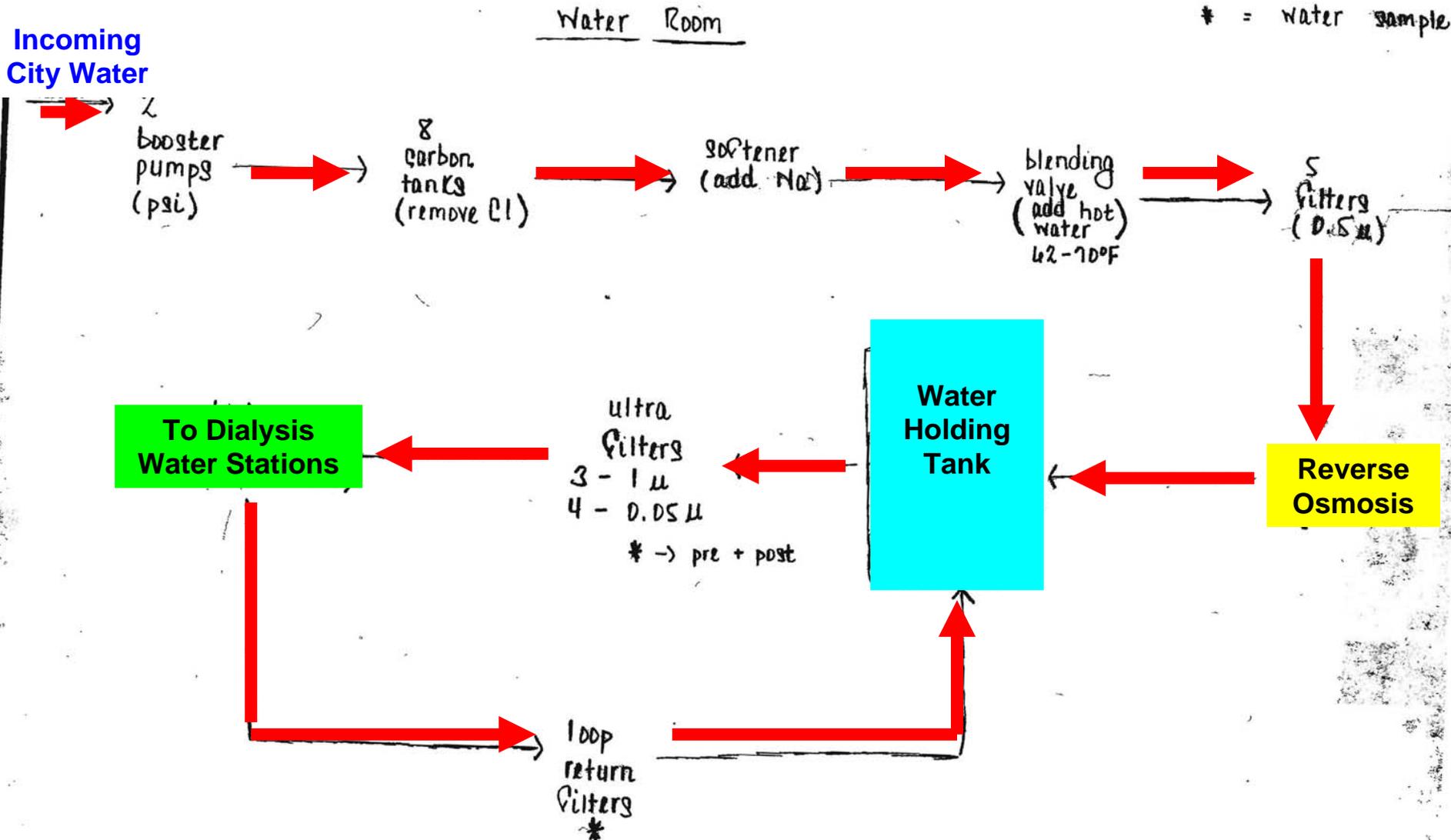
Overview of Hemodialysis



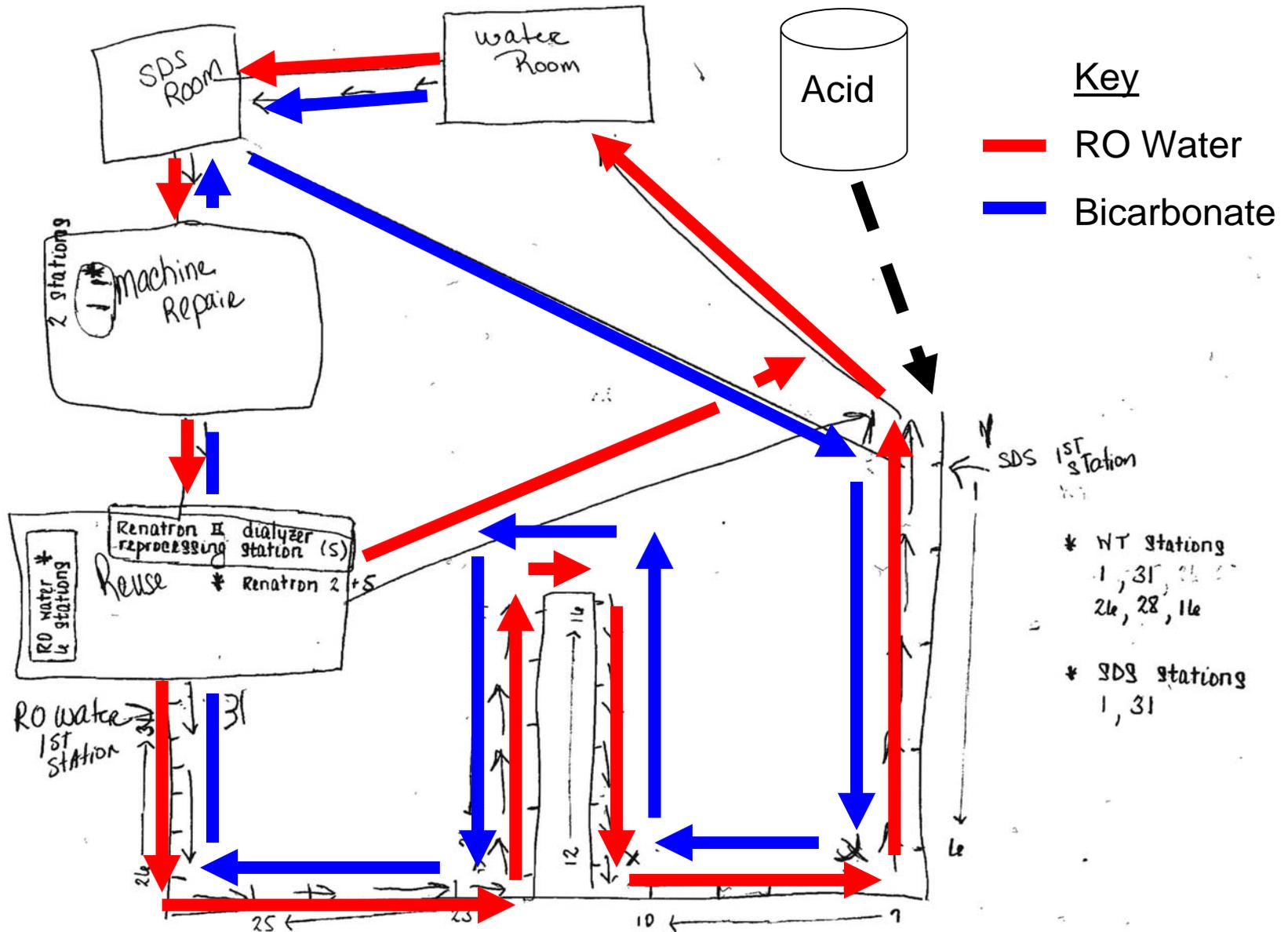
Filter image obtained from:
<http://classes.kumc.edu/cahe/respcared/cybercas/dialysis/frantype.html>

Dialysis and dialysis machine images obtained from:
<http://en.wikipedia.org/wiki/Image:Hemodialysis-en.svg#file>

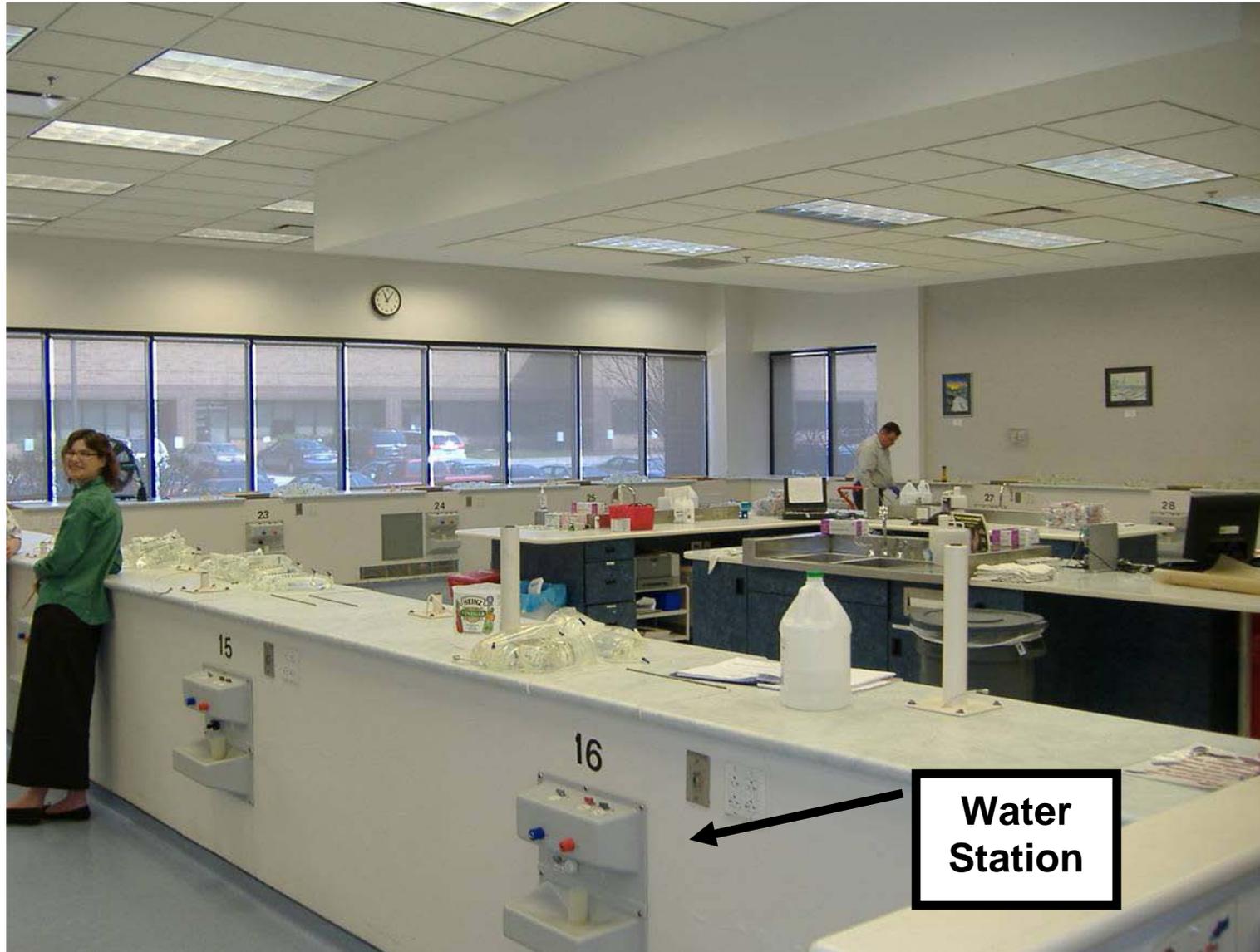
Schematic of Water Treatment Process



Making Dialysate (Dialysis Solution)



Patient Treatment Area



How are Water Quality Problems Detected?

Colony Forming Unit (CFU)

- Action Level ≥ 50
- AAMI Level ≥ 200

Endotoxin (LAL)

- Action Level ≥ 1
- AAMI Level ≥ 2

AAMI= Association for the Advancement of Medical Instrumentation

The Pyrogenic Reaction*:

- Fragments of bacteria enter the blood stream of patients
- These fragments interact with white blood cells that release chemicals called interleukins
- Interleukins cause fever ('pyr'...ogen) with or without chills, rigors, and low blood pressure
- The bacteria themselves may be present (sepsis, bacteremia), but are not necessary for the symptoms
- Pyrogens can be measured in water and dialysate but not in blood or bicarbonate concentrate

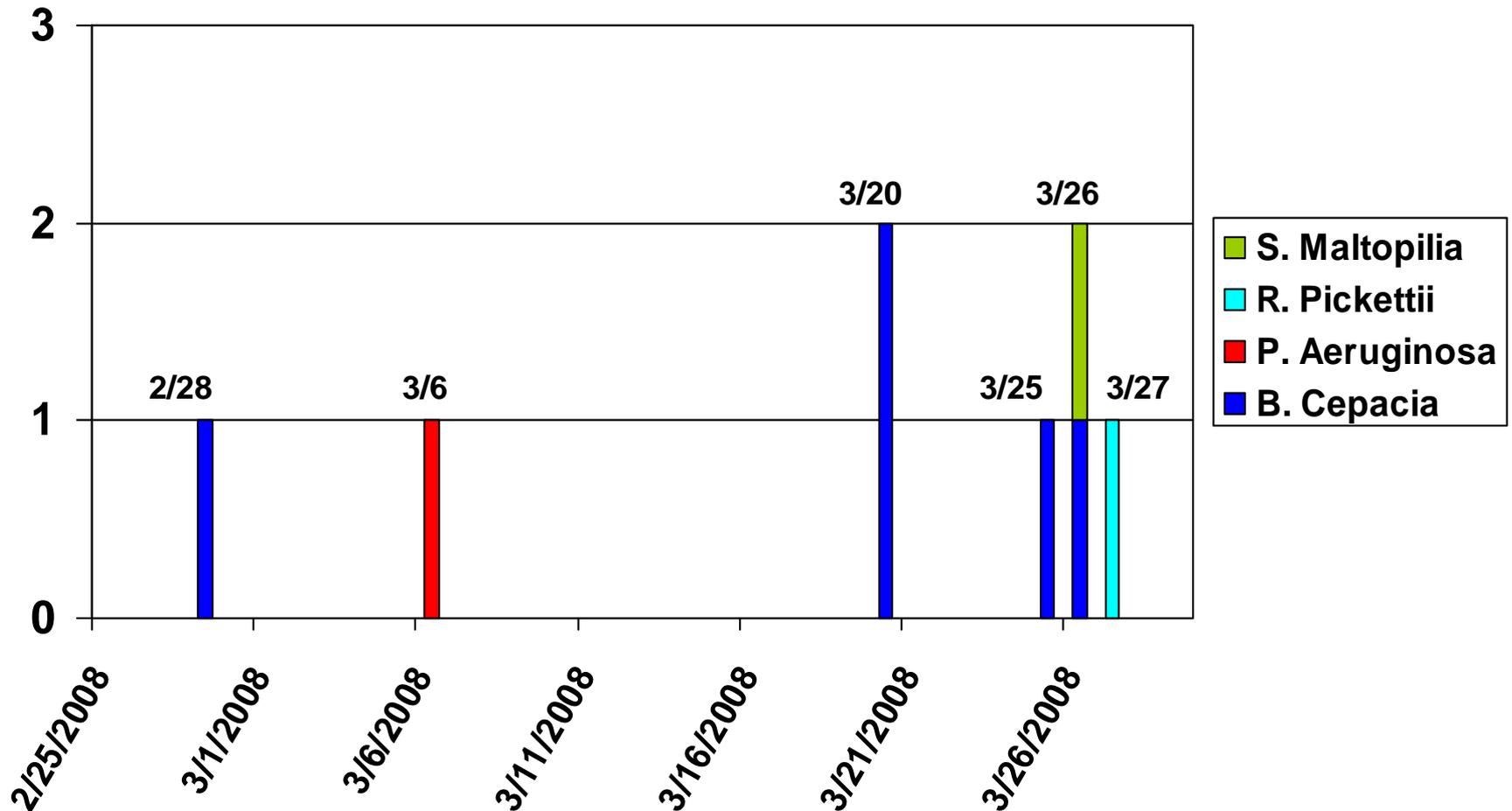
* Definition provided by Dialysis Center "X".

Defining a Pyrogenic Case*:

- Patient presents asymptomatic without fever
- Patient develops a fever ($+ 1\text{ C}^\circ$) for no other apparent reason during (toward end of) dialysis
OR
Patient develops rigors (chills) for no apparent reason during (toward end of) dialysis
- Hypotension is not required for the diagnosis
- Typically, these symptoms clear within hours of the cessation of dialysis

* Definition provided by Dialysis Center "X".

Epi Curve of Waterborne Bacterial Infections Diagnosed Among Patients Seen at Dialysis Center "X" by Specimen Collection Date



Burkholderia cepacia

- Gram-negative bacteria
- Found in soil and water
- Individuals w/ weakened immune systems are more susceptible to infection
- Environmental vehicles include:
 - distilled water
 - contaminated solutions and disinfectants
 - dialysis machines
 - nebulizers
 - water baths
 - intrinsically-contaminated mouthwash
 - ventilator temperature probes

Other Gram-negative Bacteria

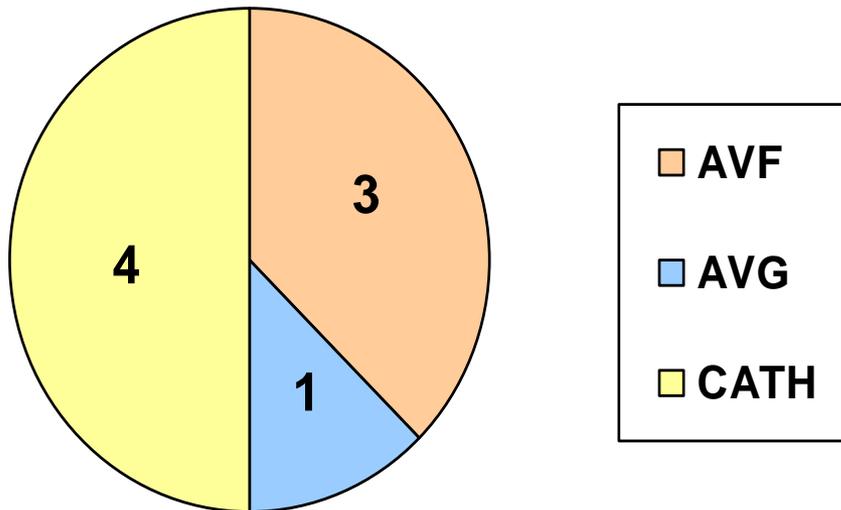
- Other opportunistic organisms in tap water include:
 - *Pseudomonas aeruginosa*
 - *Ralstonia pickettii*
 - *Stenotrophomonas maltophilia*

Select Treatment Characteristics

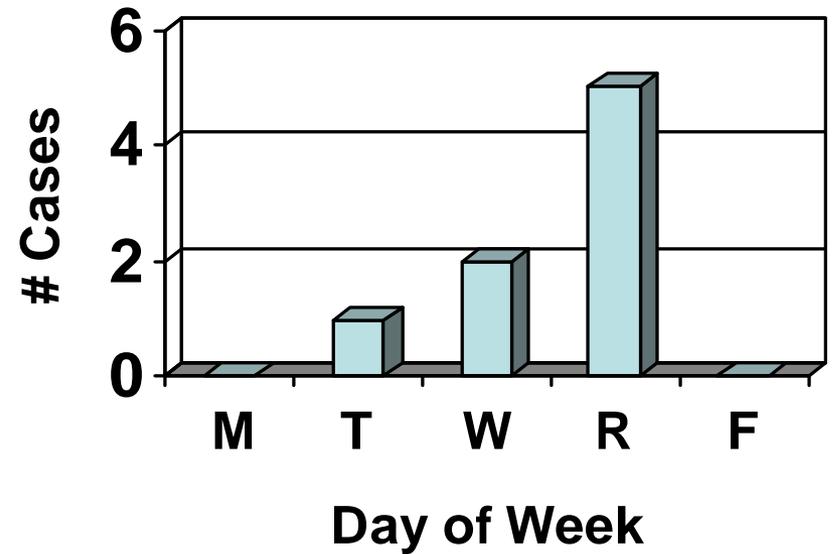
- 6 out of 8 cases received treatment on 3rd shift
- All cases received treatment at different Water Stations
- 7 out of 8 received treatment on different machines

Select Treatment Characteristics –cont'd

Type of Access



Treatment Day



Hypotheses

- Contaminated soap containers
- Contaminated multi use heparin vials
- Contaminated iodine bottle
- Contaminated SDS water
- Contaminated RO Water
- Cross-contamination with gloves/hands

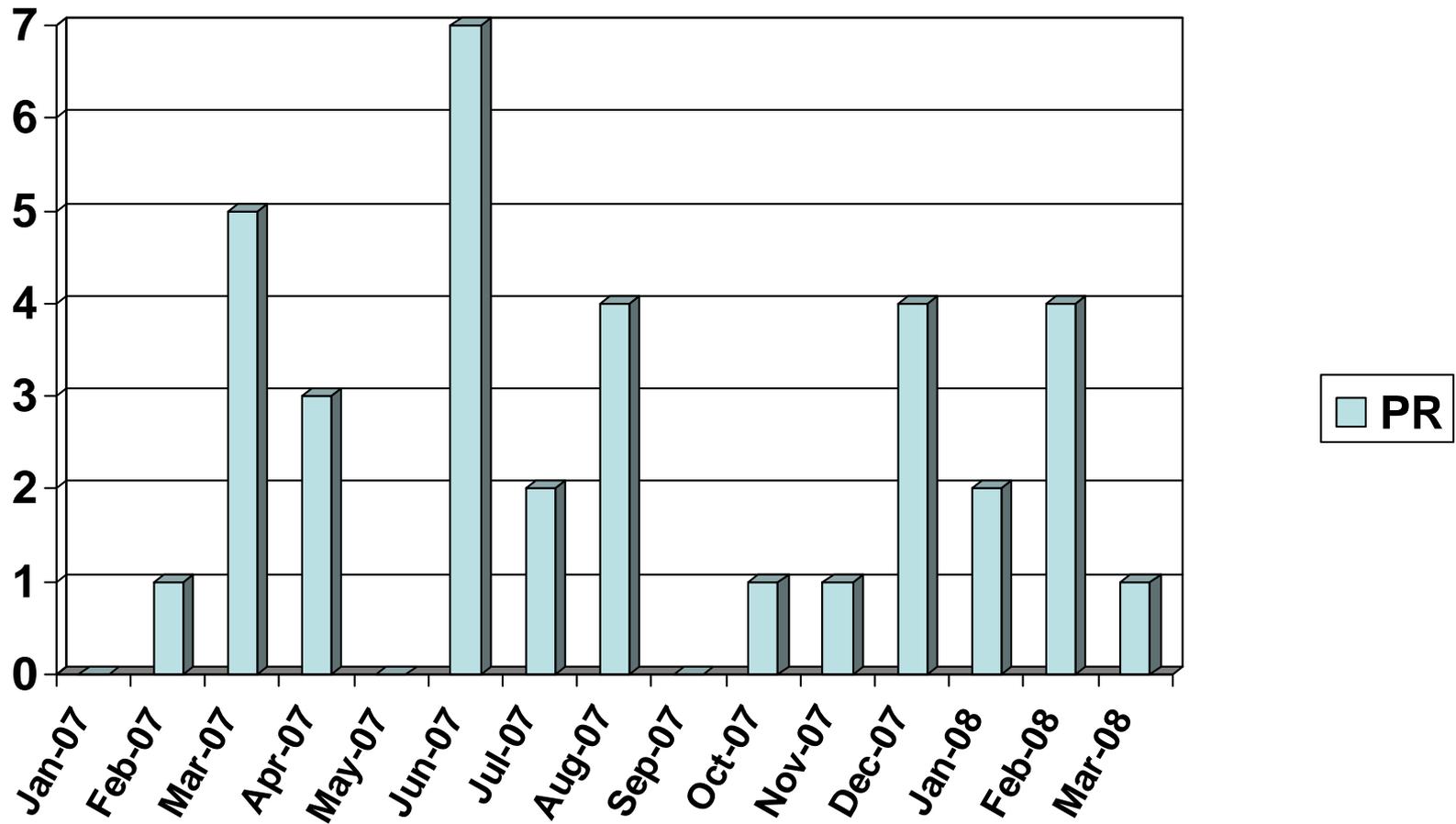
Temperature Data Summary

- 41,040 records representing 307 different patients between January 1, 2007 through March 31, 2008
- 40,235 unique treatments/assessments (i.e. different patient on different day)
- Mean number of assessments per patient was 85 (std dev. 54.5) ~ 1.3 visits per week

Temperature Data Summary – cont'd

- Mean Pre-treatment temperature 98.0 (sd 0.57)
- Mean Post-treatment temperature 98.0 (sd 2.6)
- 35 separate pyrogenic reactions (based on temperature change) occurred in 29 patients: equating to 0.9 per 1,000 treatments
- Shift: 7 on 1st, 8 on 2nd, 9 on 3rd, 5 on 4th, 6 had missing info

Pyrogenic Reactions (PR) by Month (as defined by temperature change only)



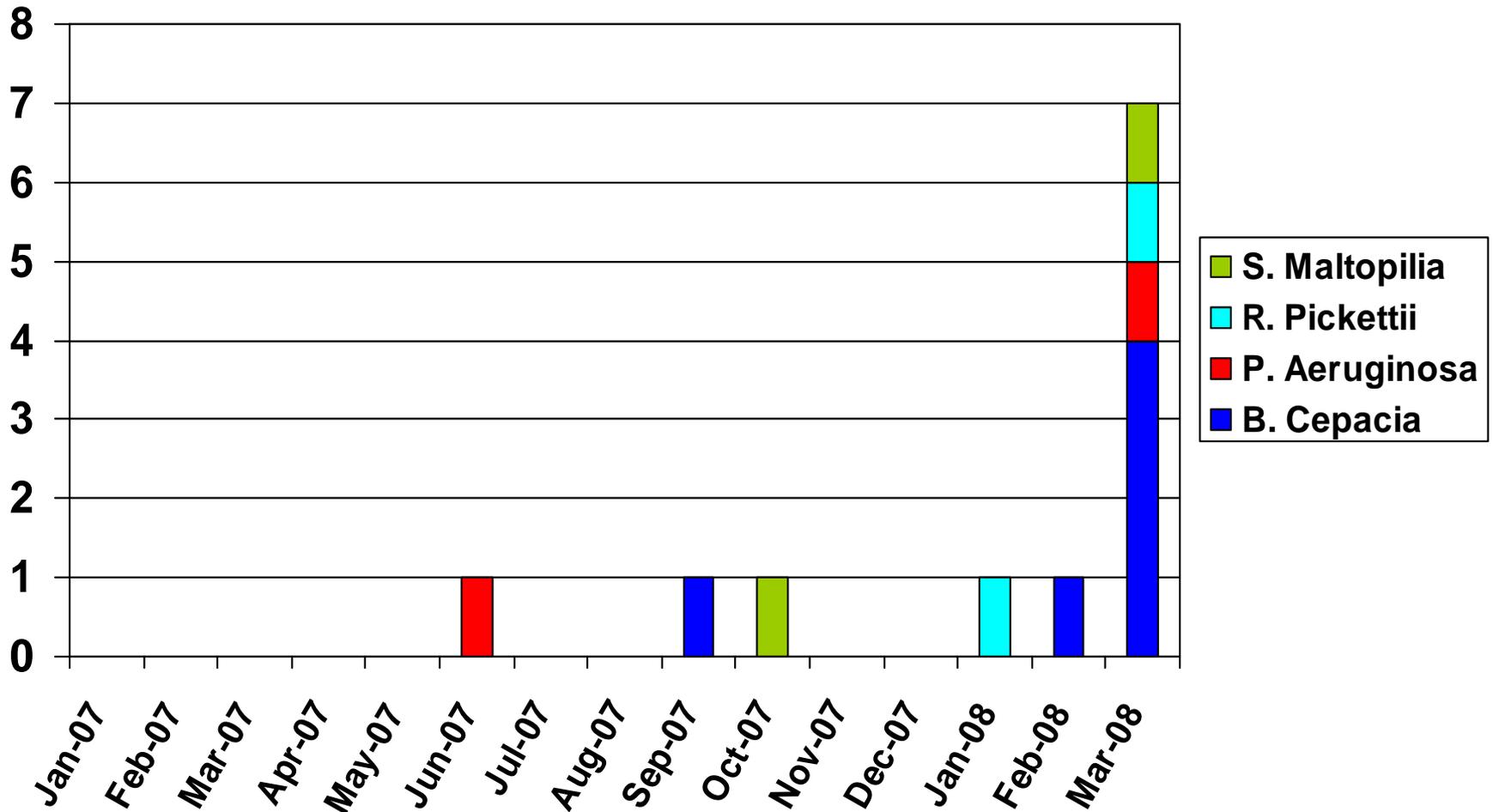
Pyrogenic Reactions (PR) by Time and Treatment

Time Period	Number of PR Reactions	Number of Treatments	PR Reactions per 1,000 Treatments
Jan-Jun 2007	16	16,415	1.00
Aug-Dec 2007	12	16,467	0.70
Jan-Mar 2008	7	7,353	1.00

Blood Culture Data Summary

- 58 different infections diagnosed among 33 different patients between January 1, 2007 through March 31, 2008
- 12 waterborne infections diagnosed among 11 different patients

Waterborne Bacterial Infections Diagnosed Among Patients Seen at Dialysis Center “X” by Specimen Collection Date



Infections by Time and Treatment

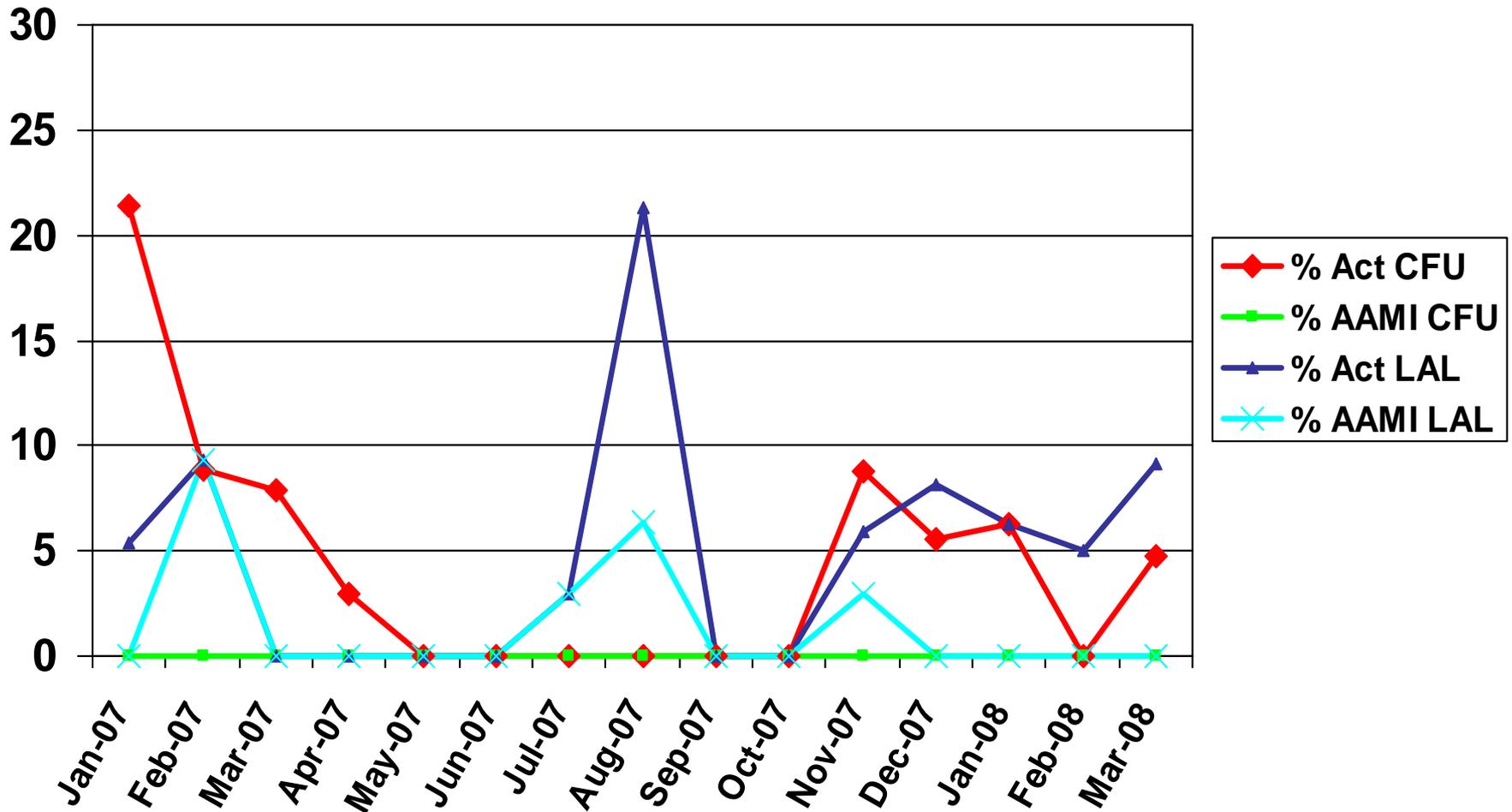
Time Period	Number of Waterborne Infections	Number of Treatments	Infections per 1,000 Treatments
Jan-Jun 2007	1	16,415	0.06
Aug-Dec 2007	2	16,467	0.12
Jan-Mar 2008	9	7,353	1.22

Dialysate Data Summary

- Samples taken from **38** different machines between January 1, 2007 through March 26, 2008
- Among 484 samples tested for CFU:
 - **24** at CFU Action level
 - **0** at CFU AAMI level
- Among 491 samples tested for LAL:
 - **26** at LAL Action level
 - **9** at LAL AAMI level

Percent of Elevated Dialysate Samples by Elevation Type and Month

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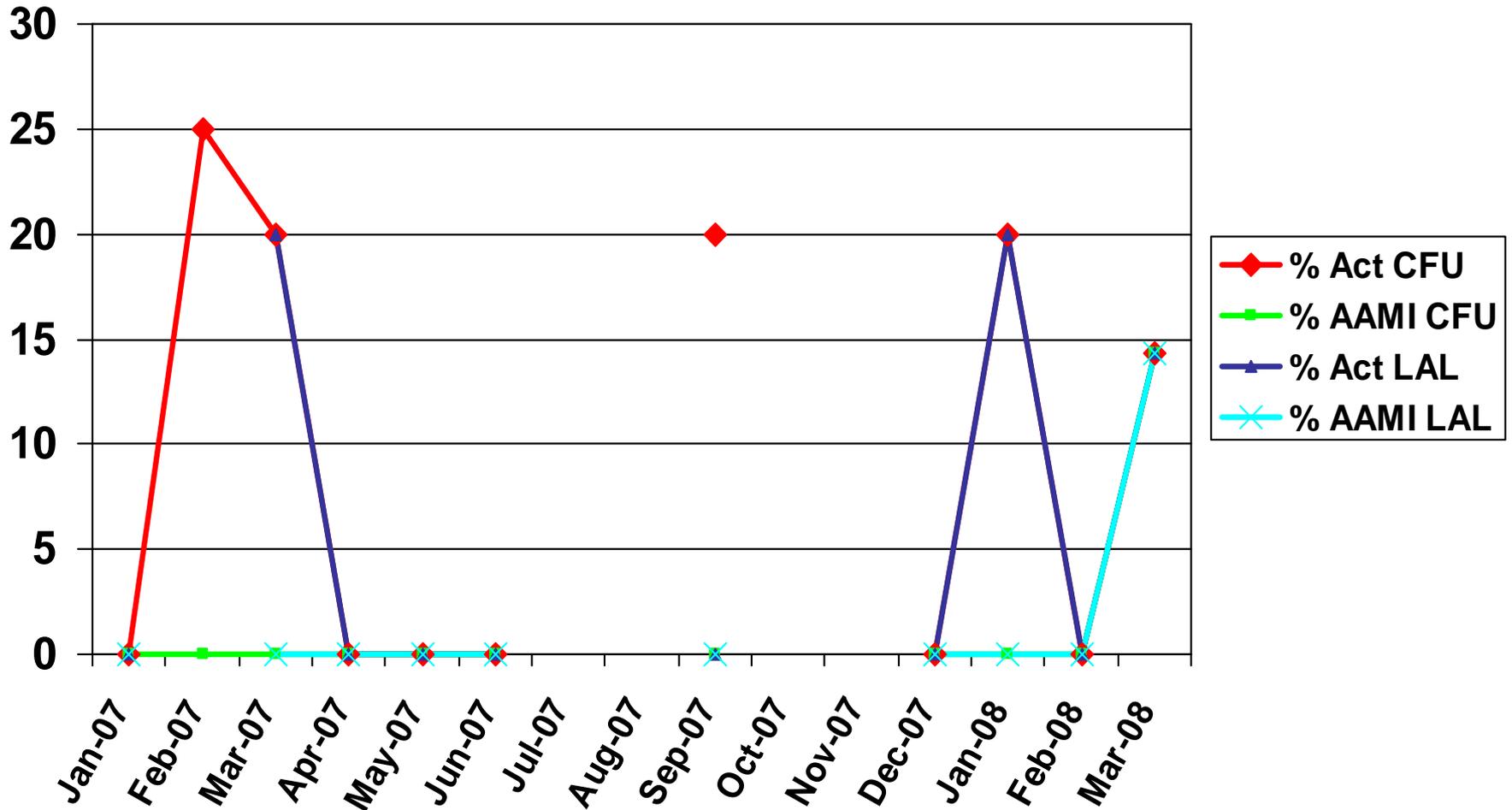


SDS (Bicarb) Water System Data Summary

- Samples taken from **5** different locations between January 1, 2007 through March 26, 2008
- Among **51** samples tested for CFU:
 - **5** at CFU Action level
 - **1** at CFU AAMI level
- Among **47** samples tested for LAL:
 - **3** at LAL Action level
 - **1** at LAL AAMI level

Percent of Elevated SDS Samples by Elevation Type and Month

AAMI= Association for the Advancement of Medical Instrumentation



Hypotheses Revisited

- Contaminated soap containers **No**
- Contaminated multi use heparin vials **No**
- Contaminated iodine bottle **No**
- Contaminated SDS water **Maybe**
- Contaminated RO Water **Maybe**
- Cross-contamination with gloves/hands
Maybe

Positive Samples

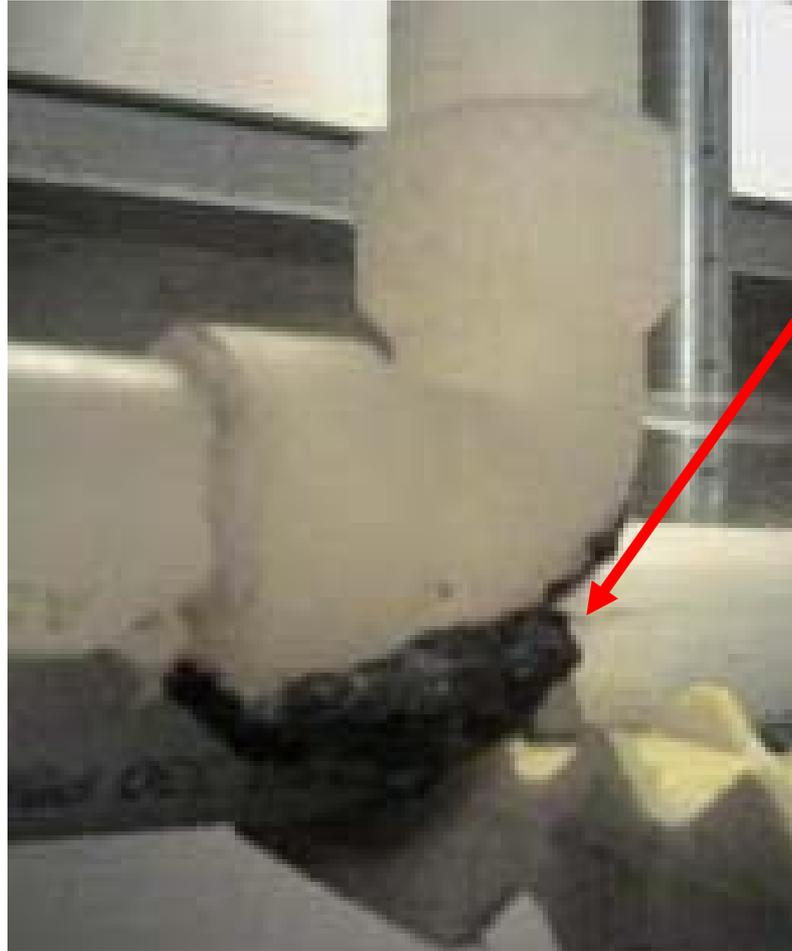
Sample	Microorganisms recovered
Dialyzer A, from patient	Stenotrophomonas maltophilia
Dialyzer B, from patient	Presumptive <i>Burkholderia cepacia</i> complex
SDS Distribution	<i>Pseudomonas aeruginosa</i>
SDS Loop Return	Mixed GNRs to be identified
Water Station	Presumptive <i>Burkholderia cepacia</i> complex

Latest Results

- Two blood isolates and the water isolate from one of the water stations used by a case were indistinguishable by pulsed-field gel electrophoresis.
- Suggesting that the water may have been the source.
- And.....

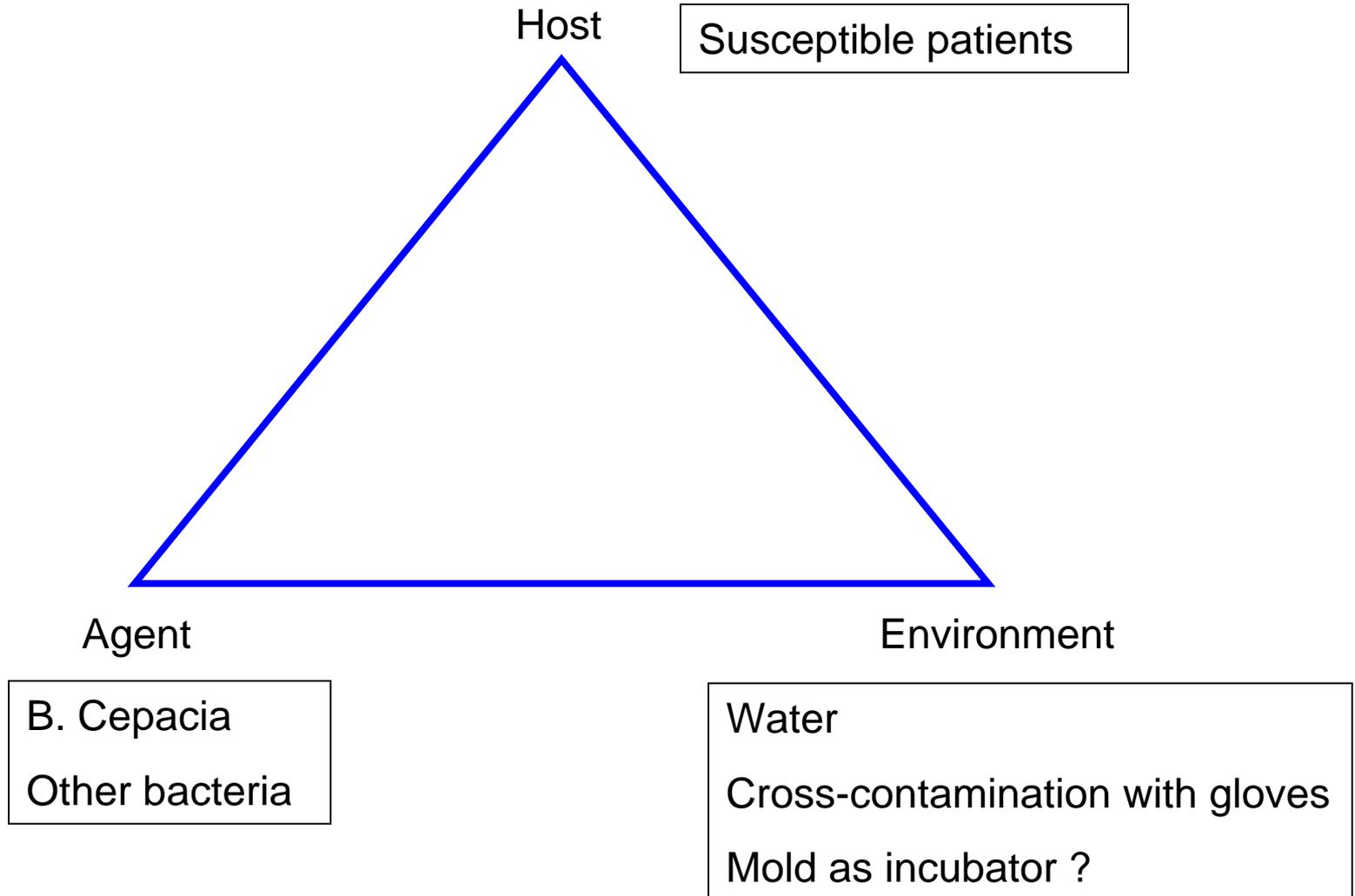
Potential Piece to Puzzle?

Tested and
was positive
for *B. cepacia*



4/7/2008
Black mold
found on pipe
that carries
treated water to
the dialysis
machines

Current Hypothesis



Steps to Successful Investigation

- Identify who is at the table and who is missing
- Establish presence and “Here to Help” scenario
- Assess gaps in knowledge and resources
- Identify data sources
- Schedule meetings/calls
- Track/update activities (e.g. what’s completed, what’s outstanding)
- Collaborative approach/consensus decisions

Questions???

