

# Dialyzer Reuse and Infections



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# Disclaimers & Objectives

## Disclaimers:

- ❑ The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of Centers for Disease Control and Prevention.
- ❑ I am not a microbiologist
- ❑ I am a healthcare epidemiologist

## Objectives:

- ❑ Review evidence linking dialyzer reuse and reprocessing to patient infections
- ❑ Discuss actions that can be taken to help protect patients

# Why are we talking about this?

My center  
doesn't reuse



# Why are we talking about this?

- ❑ **You are leaders in the dialysis community**
- ❑ **You are patient advocates**
- ❑ **It's a complex issue; your opinions are valuable**
  - How can we better protect patients, and also protect the environment

**Warning: There will be a quiz at the end**

# What is Reprocessing?

## AAMI Reprocessing of Hemodialyzers:

- ❑ Does not define
- ❑ “This recommended practice describes the essential elements of good practice for reprocessing hemodialyzers to help ensure device safety and effectiveness.”

## FDA :

- ❑ “When used on patients, reusable devices become soiled and contaminated with microorganisms. To avoid any risk of infection by a contaminated device, reusable devices undergo “reprocessing”, a detailed, multistep process to clean and then disinfect or sterilize them”

# What is Reprocessing?

- ❑ **It's about infection**
- ❑ **Must ensure safety**
- ❑ **It's not about dialyzer effectiveness**

# *Burkholderia cepacia* and *Stenotrophomonas maltophilia*

- **Gram-negative bacteria often found in water and soil**
- **Not a common cause of infections in humans**
  - **Except in people with cystic fibrosis or other conditions that result in a weakened immune system**
- **In healthcare settings, infections can be caused by contaminated medications or other types of water-source contamination**

# Previous gram-negative bloodstream infection outbreaks in dialysis: Organisms and associated breaches

- **General dialyzer reprocessing practices<sup>1</sup>**
  - *B. cepacia*, *S. maltophilia*, *R. pikettii*, and *P. aeruginosa*
- **Disinfection of dialyzer<sup>2,3</sup>**
  - *B. cepacia*, *S. maltophilia*, *C. freundii*, *A. caicoaceticus var. anitratus*, and *E. Cloacae*
- **Refrigeration of dialyzers prior to reprocessing<sup>4</sup>**
  - *S. maltophilia*, *B. cepacia*, and *R. pikettii*

1. Arnow PM, Garcia-Houchins S, Neagle MB, Bova JL, Dillon JJ, Chou T. An outbreak of bloodstream infections arising from hemodialysis equipment. J Infect Dis. 1998;178:783-91.
2. Flaherty JP, Garcia-Houchins S, Chudy R, Arnow PM. An outbreak of gram-negative bacteremia traced to contaminated O-rings in reprocessed dialyzers. Ann Intern Med. 1993;119:1072-8.
3. Oyong K, Marquez P, Terashita D, English L, Rivas H, Deak E, et al. Outbreak of bloodstream infections associated with multiuse dialyzers containing O-rings. Infect Control Hosp Epidemiol. 2014;35:89-91.
4. Rosenberg J. Primary bloodstream infections associated with dialyzer reuse in California dialysis centers. 43rd Annual Meeting of IDSA. 2005. Abstract



# Survey of California Dialysis Centers on Bloodstream Infections & Reuse Practices, 2003

- ❑ **In response to several outbreaks in 2003 of bloodstream infections caused by gram-negative water organisms or *Candida parapsilosis***
- ❑ **Surveyed all hemodialysis centers in California (n=353)**
  - Asked to report all bloodstream infections during 2003, including pathogen
  - Asked about reuse and reprocessing practices
  - Examined:
    - Rates of bloodstream infections caused by “key organisms” (*Stenotrophomonas maltophilia*, *Burkholderia cepacia*, *Ralstonia pickettii*, *Candida parapsilosis*)
    - Clusters of these organisms, defined as 3+ bloodstream infections caused by the same organism within 2 months

# Survey of California Dialysis Centers on Bloodstream Infections & Reuse Practices, 2003

## □ Results

- 316 centers responded to the survey
- Clusters of key organism infections were more common in centers that reprocessed dialyzers and refrigerated them before reprocessing

Rate of infection per 100,000 dialysis treatments by reuse practices

pathogen	Reprocessed and refrigerated	Reprocessed, not refrigerated	No reprocessing
B. cepacia	0.32	0.09	0.00
B. pickettii	0.07	0.00	0.00
S. maltophilia	1.57	0.78	0.00

# L.A. County cluster investigation, 2011

- ❑ **3 cases of bloodstream infection in 1 facility**
  - All 3 had *S. maltophilia* infections; 1 also had *Candida parapsilosis*
- ❑ **Laboratory testing, including pulse-field gel electrophoresis (PFGE)**
- ❑ **Tested 2 case-patient dialyzers post-reprocessing**
  
- ❑ **Results**
  - Both reprocessed dialyzers grew *S. maltophilia* and *C. parapsilosis* from under the O-ring
  - All 3 case-patient and 2 dialyzer *S. maltophilia* isolates indistinguishable by PFGE
- ❑ **Concluded**
  - Improper disinfection of dialyzer and O-ring

# **Investigation of Gram-negative Bacteremia Outbreak related to Dialyzer Reuse, 2013-2014**

Chris Edens, Jacklyn Wong, et al.  
Division of Healthcare Quality Promotion  
Centers for Disease Control and Prevention, and  
California Department of Public Health

# Background

- **Between May and August of 2014, clusters of bloodstream infections were detected among hemodialysis patients at Company A caused by**
  - *Burkholderia cepacia*
  - *Stenotrophomonas maltophilia*
- **On September 17, 2014 initiated an investigation**

# **Investigation Objectives**

- **Conduct case-finding activities to determine the extent of the outbreak**
- **Assess risk factors for infection among dialysis patients**
- **Evaluate infection control and dialyzer reprocessing practices and provide recommendations**

# **METHODS**

# Case Definition

- **Positive blood culture for *B. cepacia* or *S. maltophilia***
- **Culture date of 9/1/2013 or later**
- **The patient received hemodialysis at a clinic run by Company A within 1 week prior to the positive blood culture**



# Environmental Sampling

- **Sampling from various locations and reprocessing equipment**
  - Renaclear® and Renatron®
  - Post-reverse osmosis pre-distribution loop
  - Dialysis stations
  - Reprocessing room and reverse ultrafiltration rinsing system
- **Sampled blood compartment of used dialyzers after complete reprocessing**
  - Randomly selected dialyzers

# Environmental Sampling



# Facility Investigations

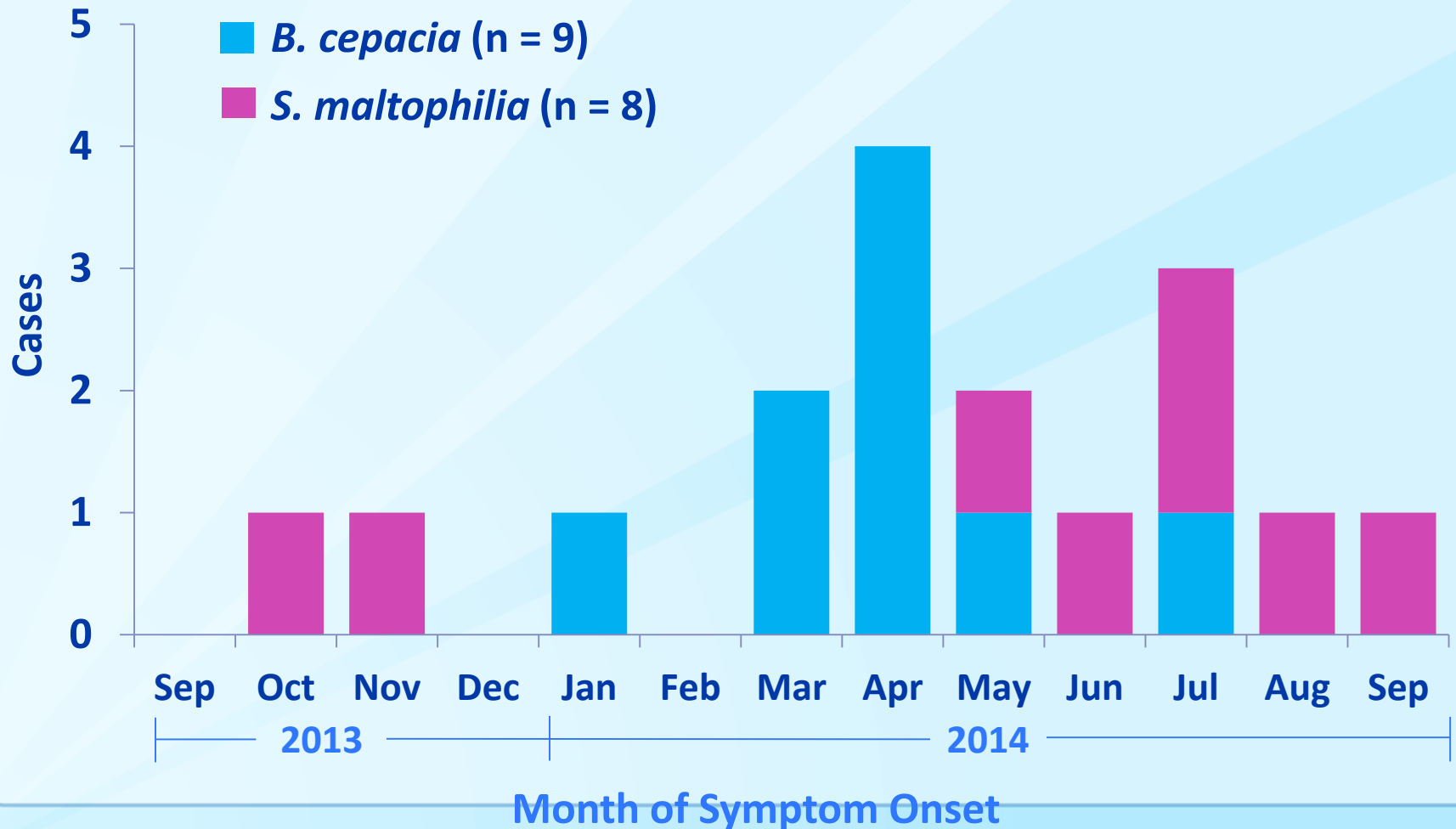
- **Observed injectable medication preparation and dialyzer reprocessing**
  - 6 clinics
- **Additional observations were performed at 2 clinics where most cases occurred**

# Case-Control Study

- **1:3 matched case-control study**
- **Controls matched on facility and presumed date of the exposure**
- **Data abstracted for cases and controls**

# RESULTS

# Outbreak Cases at Company A Clinics (n = 17)



# Case Characteristics

<b>Characteristics</b>	<b>Median (range) or n(%)</b>
<b>Age (years)</b>	59 (49–67)
<b>Female sex</b>	6 (35%)
<b>Treated with reusable dialyzer</b>	16 (94%)
<b>Dialyzer usage count*</b>	15 (7–21)
<b>Catheter use</b>	4 (24%)
<b>Model R dialyzer use</b>	10 (56%)
<b>Treatment schedule</b>	
<b>MWF</b>	10 (59%)
<b>Nocturnal shift</b>	4 (24%)
<b>Hospitalized for infection</b>	6 (35%)
<b>Died</b>	0 (0%)

\*Number of dialyzer uses prior to the session of interest

# Case-Control Analysis

	Median or % Cases	Median or % Controls	Matched OR (95% CI)	
Reusable dialyzer	94%	76%	4.42 197.19)	(0.60–
First use of dialyzer	6%	27%	0.16	(<0.01–1.28)
Dialyzer usage count (continuous)	15	4	1.07	(1.00–1.14)
Dialyzer usage count (> 6)	76%	41%	7.03	(1.38–69.76)
MWF shift	59%	65%	0.33*	(0.00–6.33)
Nocturnal shift	24%	6%	3.65	(0.48–42.85)
Model R dialyzer use	59%	16%	22.87* Infinity)	(4.49–

\* Median unbiased estimate



# Environmental Sampling Results

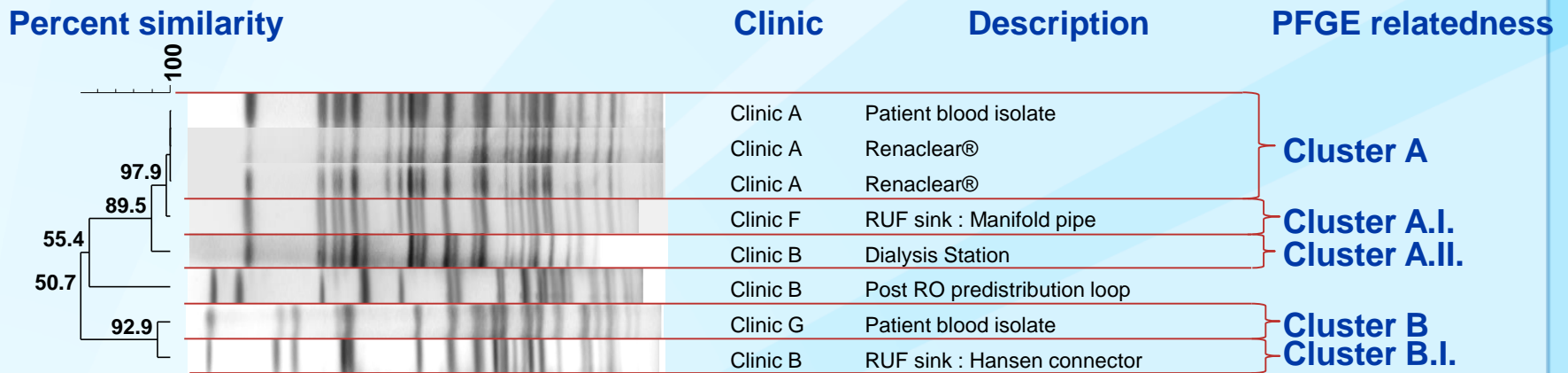
Clinic	Specimen Type	Specimen Description	Growth Results
Clinic A	Swab	Renaclear®	<i>Burkholderia cepacia</i>
Clinic A	Swab	Renaclear®	<i>Burkholderia cepacia</i>
Clinic B	Water	Reverse ultrafiltration sink: Manifold pipe	<i>Burkholderia cepacia</i> complex
Clinic B	Water	Dialysis station	<i>Burkholderia cepacia</i> complex, <i>Cupriavidus</i> <i>pauculus</i>
Clinic B	Water	Post Reverse osmosis predistribution loop	<i>Burkholderia cepacia</i> complex
Clinic B	Swab	Reverse ultrafiltration sink: Hansen Connector	<i>Burkholderia cepacia</i> complex
Clinic E	Swab	Reverse ultrafiltration sink: Hansen Connector	<i>Stenotrophomonas</i> <i>maltophilia</i>
Clinic B	Swab	Reverse ultrafiltration sink: Hansen Connector	<i>Burkholderia cepacia</i> complex*

\*Testing not performed at CDC

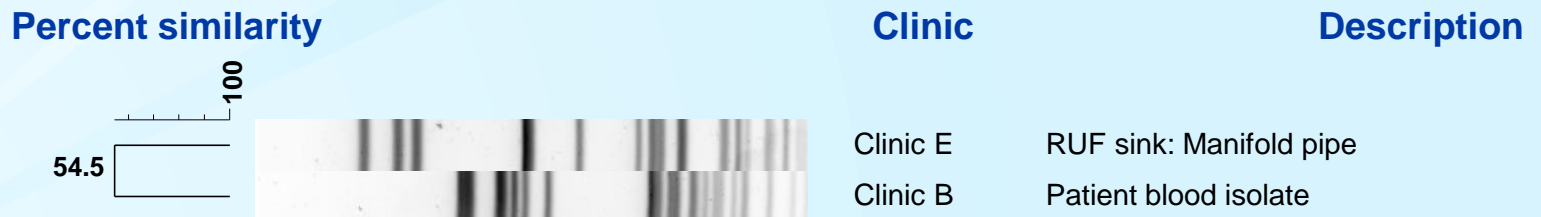
# PFGE Results

- *B. cepacia* environmental samples collected at Clinic A were indistinguishable from a Clinic A patient isolate (Cluster A)
- Samples collected from other clinics did not match remaining patient isolates

## *B. cepacia* Results



## *S. maltophilia* Results



# Dialyzer Testing Results

- **15 dialyzers submitted for testing were all Model R, reusable dialyzers with sealed headers**
  - All had undergone reprocessing and were filled with germicide
  - They were not from case-patients
- **All dialyzers had adequate concentration of disinfectant**
- **Blood compartment of dialyzers was rinsed with sterile saline; this eluent was cultured**
- **Two dialyzers were positive for gram-negative organisms**
  - Each had only been used twice previously

# **Observations**

## **Dialysis Procedures and Medication Preparation**

- **Injectable medications were not prepared in close proximity to a water source**
- **Prime buckets were sometimes incorrectly handled**
  - **Buckets at some clinics were rinsed with tap water after disinfection**
- **No other opportunities for water contamination were observed during initiation and termination of dialysis**

# **Observations**

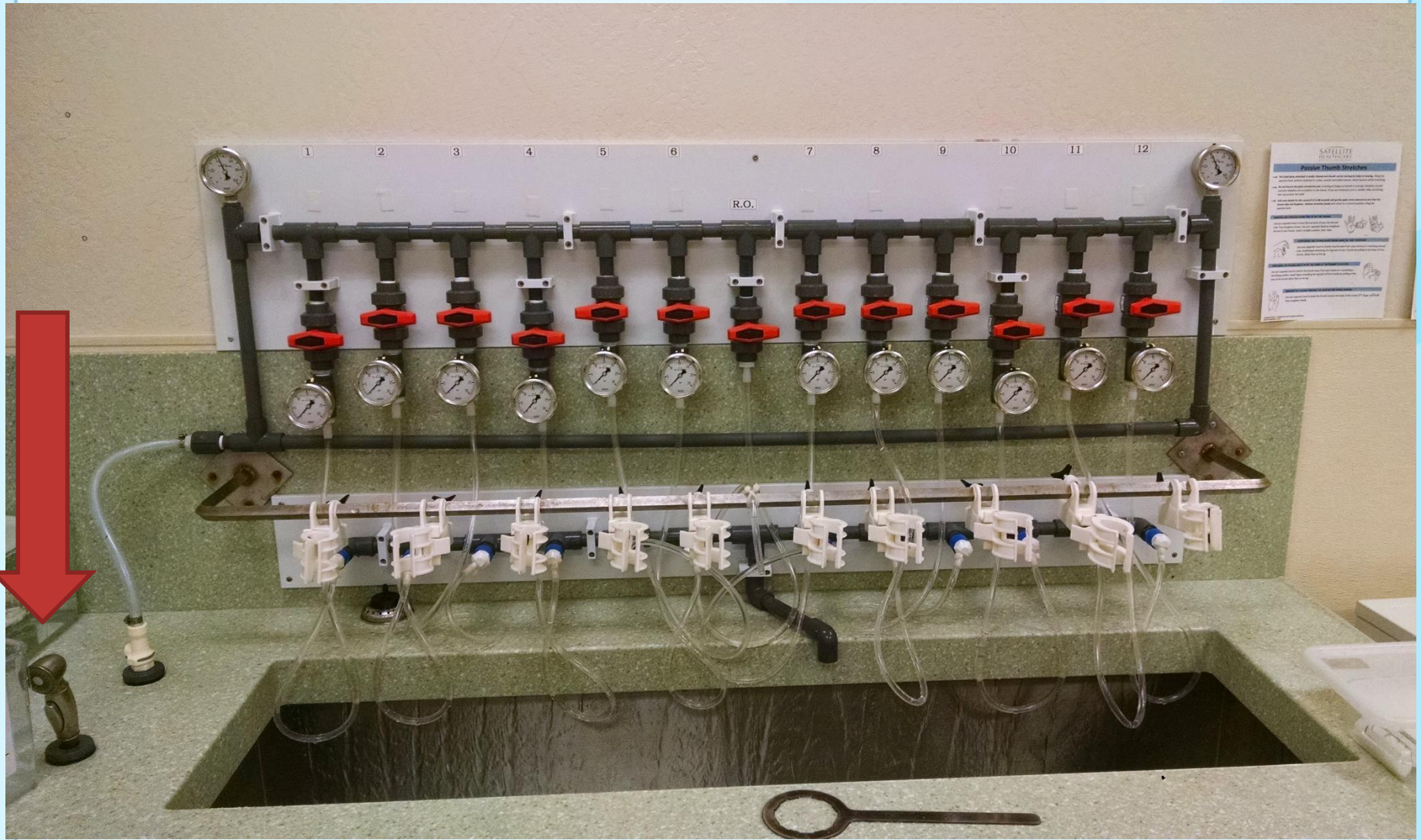
## **Dialyzer Storage & Refrigeration**

- **Although not observed, dialyzers were refrigerated**
  - **Company A protocols required refrigeration following nocturnal dialysis or if >2 hours elapsed between dialysis termination and reprocessing**
- **Dialyzer refrigeration records were not kept by Company A**
- **Information regarding storage duration was not readily available or reliable**

# **Observations**

## **Dialyzer Cleaning**

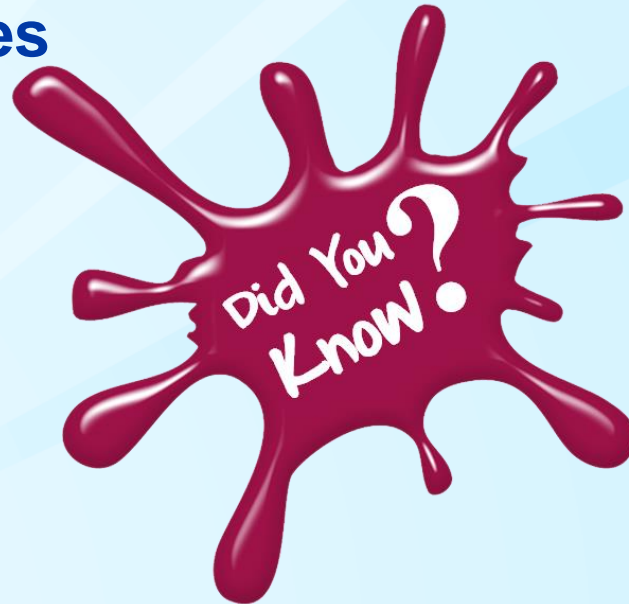
- **O-ring and dialyzer header cap cleaning protocols were inconsistent between clinics**
  - **Wipes were utilized at some facilities and not at others**
- **Model R dialyzers with sealed headers were difficult to clean**
- **High-pressure water spray nozzles were used to rinse uncapped dialyzers and header caps**



# Observations

## Dialyzer Reprocessing

- **Lapses in hand hygiene when moving between dirty and clean areas of reprocessing room**
- **Some facilities performed manual reprocessing**
  - **Additional challenge to assessing adequacy of processes**



**Brazil is  
outlawing  
manual  
reprocessing in  
2018**



# Observations Recap

- **Lack of standardization; lots of variability**
- **Some lapses identified, and some very concerning practices observed**
  - **These did not explain the infections**

# **SUMMARY**

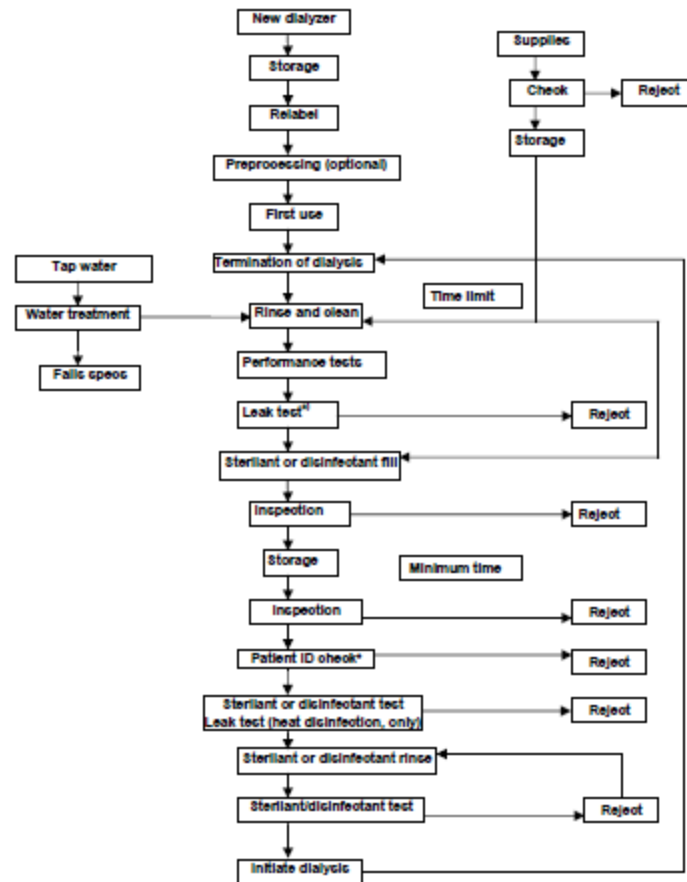
- **More frequent use of a dialyzer is associated with increased risk of a bloodstream infection**
  - Each subsequent dialyzer use was associated with a 7% increase in risk of acquiring a bloodstream infection
- **Renaclear® header cleaning machine tested positive for *B. cepacia* strain matching a patient isolate at Clinic A**
- **Model R dialyzer was associated with increased risk of a bloodstream infection**
  - Non-removable headers may hinder the ability to effectively rinse dialyzers and remove biological material
- **At Company A, opportunities to improve protocols and standardize reprocessing practices to reduce the risk of contamination were identified**

# Conclusions

- **Certain water-borne organisms can be introduced into dialyzers during reprocessing**
- **Identification of organisms in reprocessed dialyzers is extremely concerning**
- **Reprocessing is a complex, multistep procedure that is prone to variation and human error**
- **Some identified risks related to:**
  - **Sealed dialyzers (accumulation of biological material may inhibit adequate dialyzer disinfection)**
  - **Dialyzers with unsealed headers (requires proper disinfection of O-rings and caps)**
  - **Prolonged storage prior to reprocessing**
  - **Use of wipes or anything other than stream of RO water to rinse headers**

**Annex B**  
(normative)

**Systems diagram for reprocessing dialyzers**



a) This step may be done later but shall precede initiation of dialysis.

# So what can be done?

- **Dialysis providers should consider instituting less frequent reuse or non-reuse in the interest of patient safety**

## **For facilities that continue reuse:**

- **Increase standardization of practices**
- **Establish better quality assurance measures that more directly relate to infection risk**
- **Includes carefully tracking and assessing patient infection data**
- **Reprocessing procedures**
  - **Improved documentation of reprocessing procedures is needed**
  - **All factors that could impact reprocessing quality should be evaluated on a routine basis**
  - **Perform observations and audits of reprocessing**
- **Honestly communicate with patients about the risk of infection associated with reuse**

## **Test your knowledge!**

- 1. What is the main objective of reprocessing?**
  - A. Save costs**
  - B. Save the environment**
  - C. Disinfect the dialyzer, prevent infection**
  - D. Ensure effective dialyzer clearance**

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## **Test your knowledge!**

**2. Which of these measures directly addresses effectiveness of dialyzer disinfection?**

- A. Total cell volume**
- B. Visual inspection**
- C. Germicide presence test**
- D. None of these**

## Test your knowledge!

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## **Test your knowledge!**

- 3. What country is eliminating manual reprocessing?**
- A. Brazil**
  - B. United States**
  - C. France**
  - D. Who cares, it's not us**

## Test your knowledge!

3. What country is eliminating manual reprocessing?
- A. Brazil (what are we waiting for?)**
  - B. United States
  - C. France
  - D. Who cares, it's not us

## **Last question**

**4. If your mother was receiving dialysis in a facility that performs reuse, you would tell her...**

**A. Say no to reuse, request a single-use dialyzer**

**B. The facility is doing everything possible to ensure dialyzers are effectively cleaned and disinfected; you are not at going to get an infection from the reused dialyzer**

**(What would it take for a facility to meet the standard in option B?)**

# Thank you, NANT!



*Making dialysis  
safer for patients*

**<http://www.cdc.gov/dialysis/>**

Acknowledgements: Chris Edens, Duc Nguyen, Jon Rosenberg

**For more information please contact Centers for Disease Control and Prevention**

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National Center for Emerging and Zoonotic Infectious Diseases  
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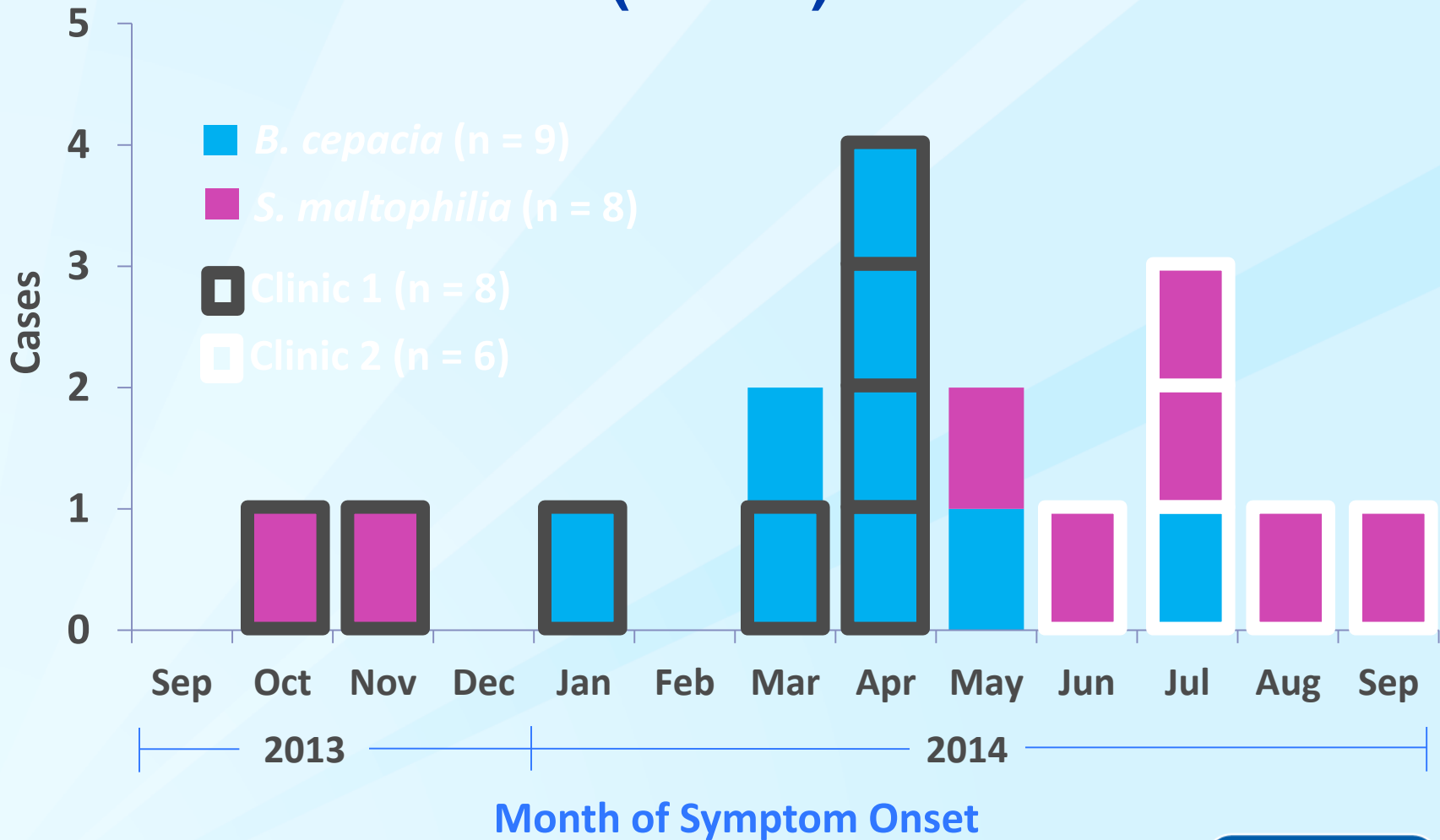
**EXTRA SLIDES**

# Investigations of Adverse Events Related to Reuse

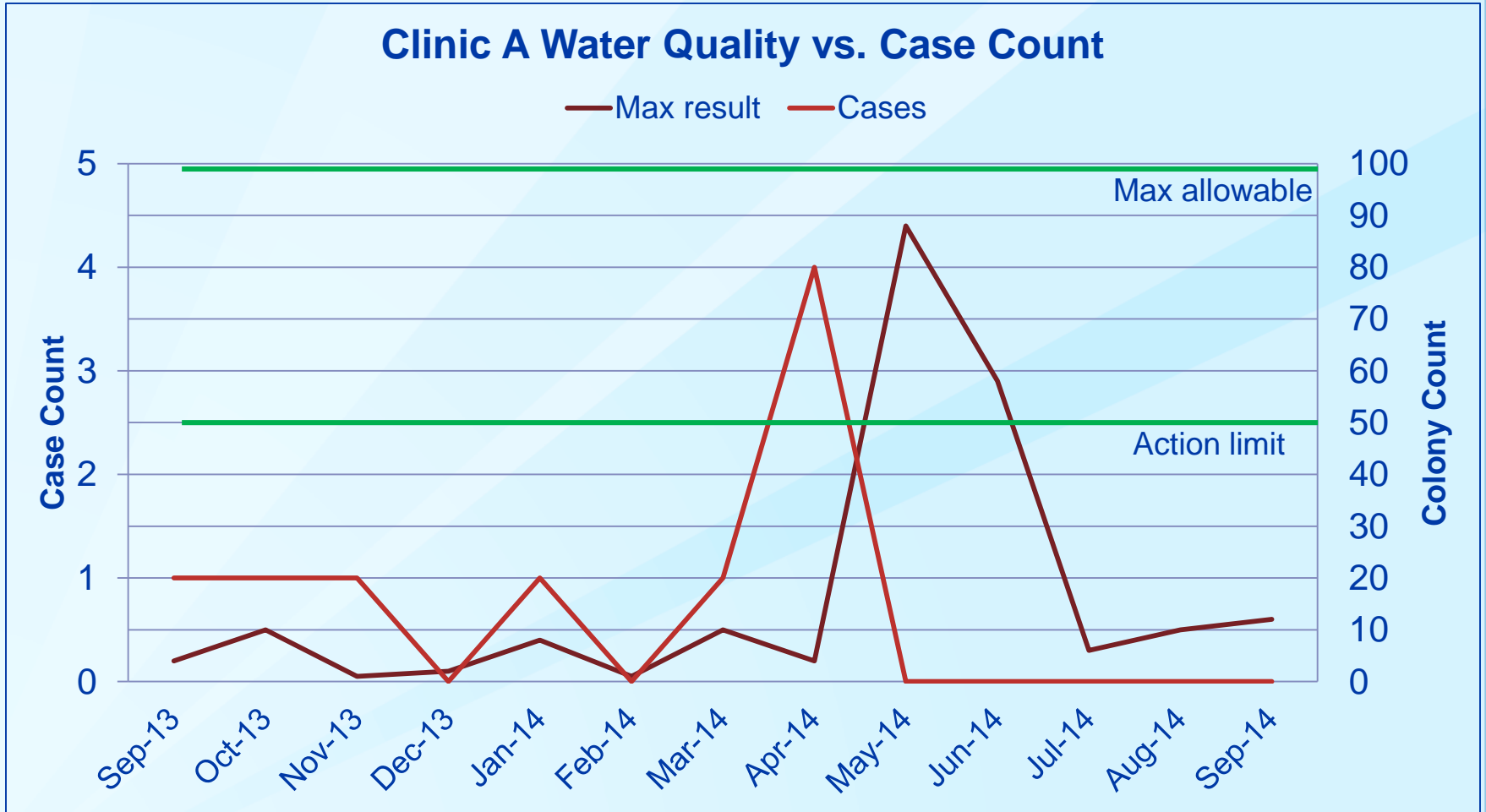
- Investigations are challenging
  - Outbreaks, clusters frequently not reported
  - Information not tracked, documented, or shared with investigators
- Problematic practices
  - Refrigeration
  - Methods used to remove dialyzer header clots
    - Pressurized water spray, insertion of mechanical instruments
  - Manual reprocessing



# Outbreak Cases at Company A Clinics (n = 17)

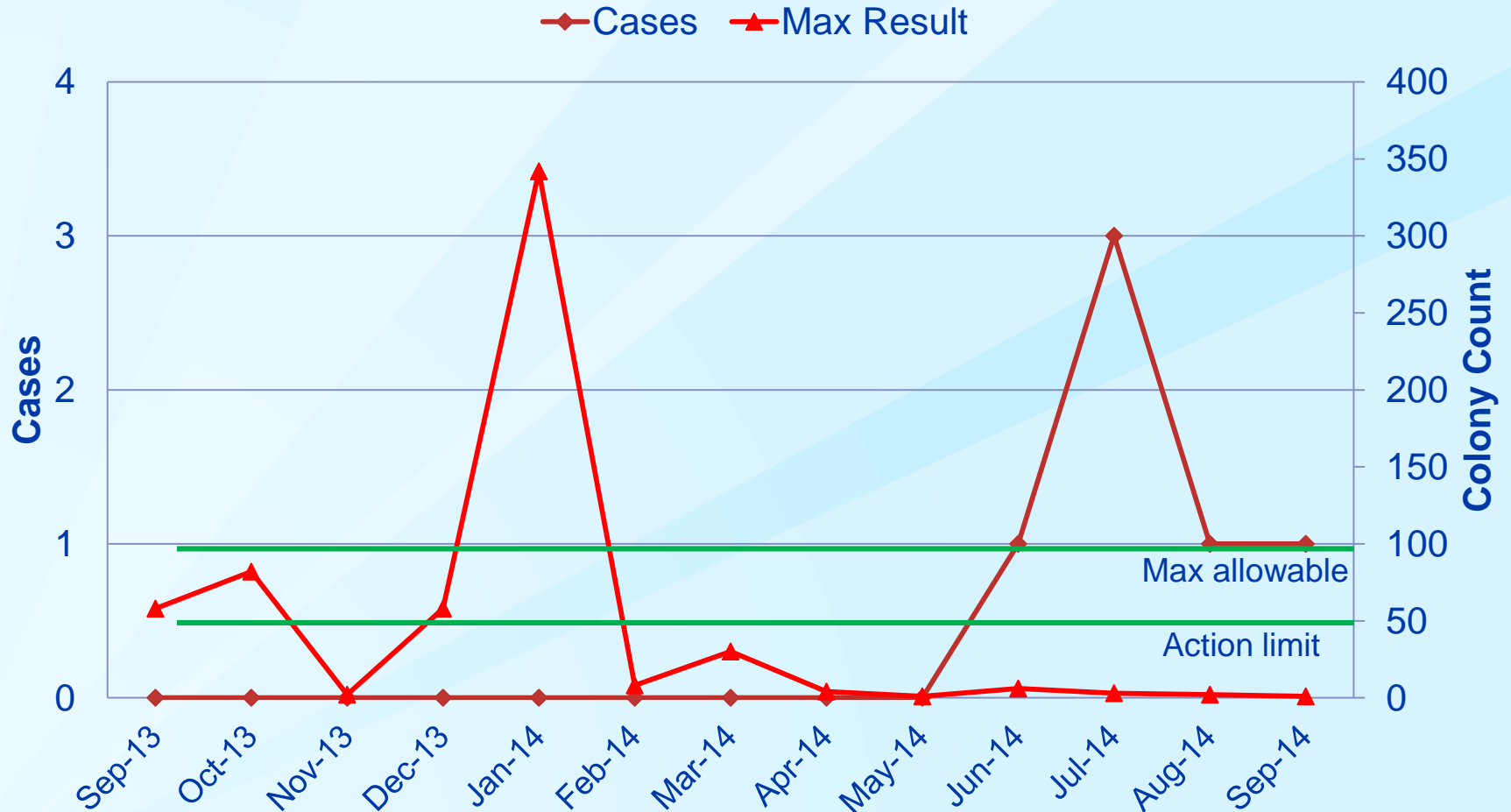


# Water Quality Results



# Water Quality Results

## Clinic B Water Quality vs. Case Count



- ❑ **Inadequate cleaning between patient uses can result in the retention of blood, tissue and other biological debris (soil) in certain types of reusable medical devices. This debris can allow microbes to survive the subsequent disinfection or sterilization process, which could then lead to Health care-Associated Infections (HAIs). Inadequate reprocessing can also result in other adverse patient outcomes such as tissue irritation from residual reprocessing materials, like chemical disinfectants.**