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HAI-lights from the Field

ELC Conference 2019

Presented by DSHS HAI Epidemiologists

Objectives

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Upon completion of this presentation, participants should be able to:

- Describe noteworthy healthcare-associated infection (HAI) investigations in Texas.
- Discuss outbreak control measures, evidence-based infection control practices, and the patient notification process.

Texas Demographics

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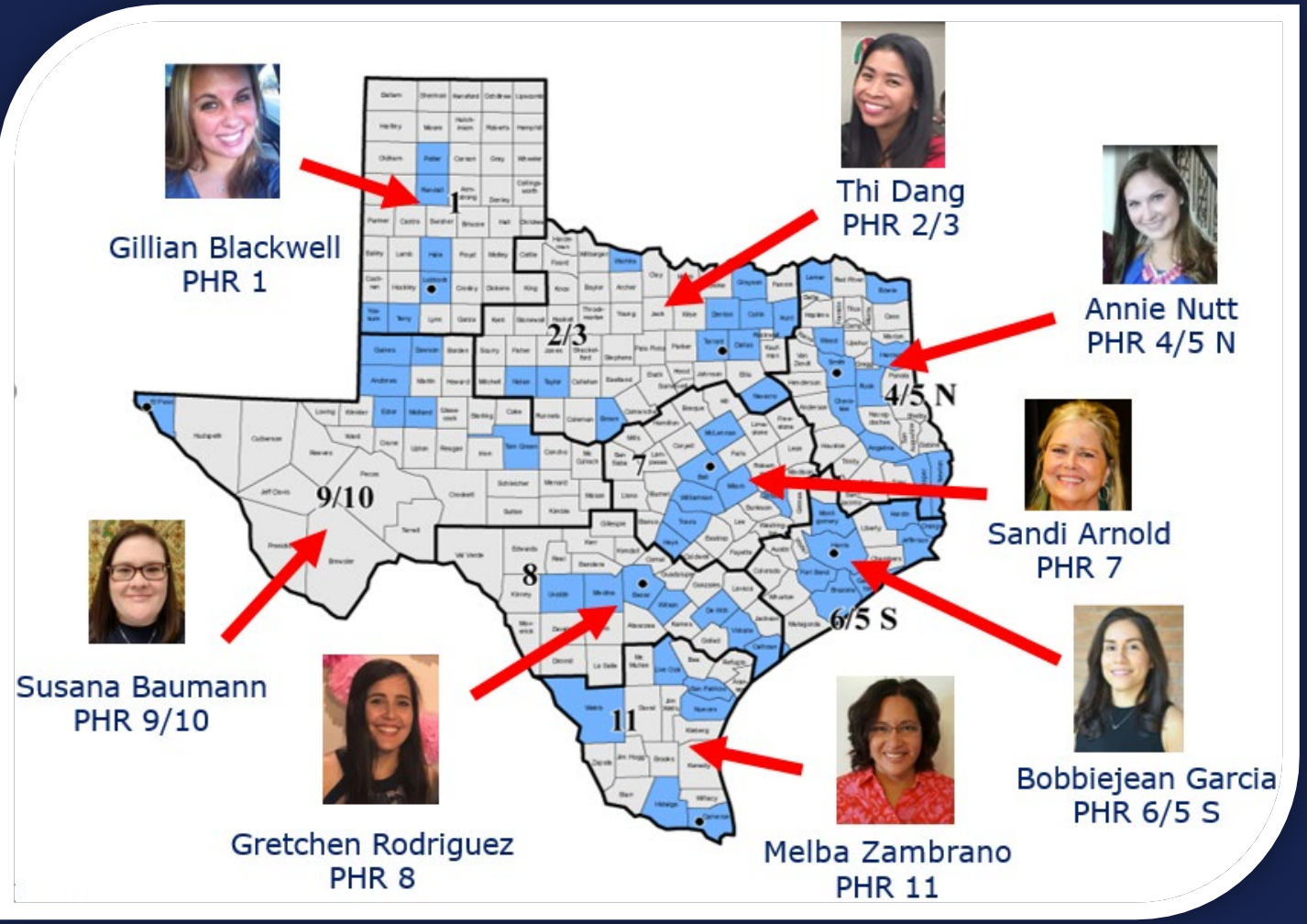
- Texas has 254 counties

As of March 2019 there were:

- 533 CIC certified individuals
- 640 acute care hospitals
- 523 ambulatory surgery centers
- 216 free standing emergency medical centers
- 1240 nursing homes
- 1982 assisted living facilities

Source

Regional HAI Epidemiologists



Regional HAI Job Duties

- HAI Outbreak Containment
- Infection Prevention Consultations
- Multidrug-Resistant Organism (MDRO) Reporting and Investigation
  - Carbapenem-resistant *E. coli* and *Klebsiella*
  - Multidrug-resistant *Acinetobacter baumannii*

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Regional HAI Job Duties con't

- Coordinating the Response for Antibiotic Resistance Lab Network (ARLN) Alerts
- Targeted Assessments for Prevention (TAP)
- Educational Presentations

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MDR-A Community Outbreak

Gretchen Rodriguez, MPH, CIC
HAI Epidemiologist PHR 8

How did it start?

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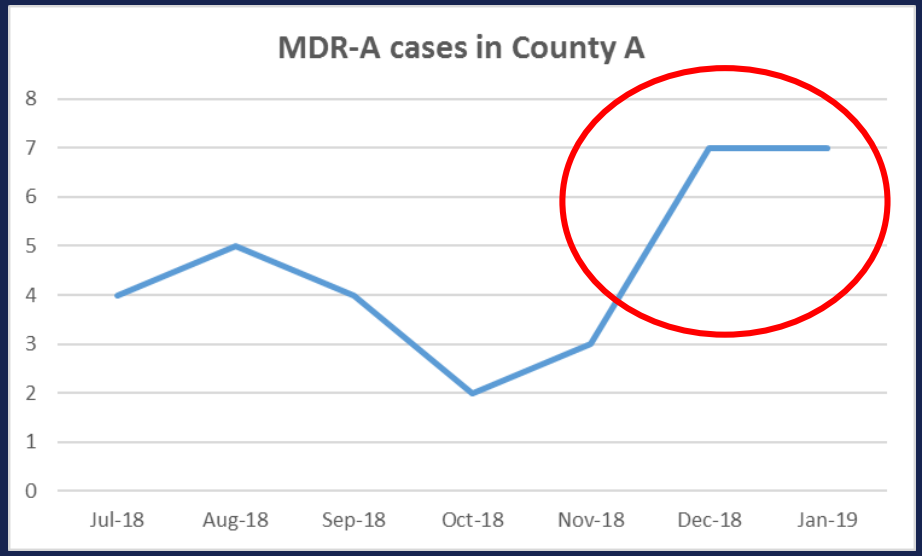
- Multi-drug resistant Acinetobacter (MDR-A) is a notifiable condition in Texas.
- Local Health Department identified an increase of cases reported in the county and notified HAI Epidemiologist.
- Investigation was initiated.

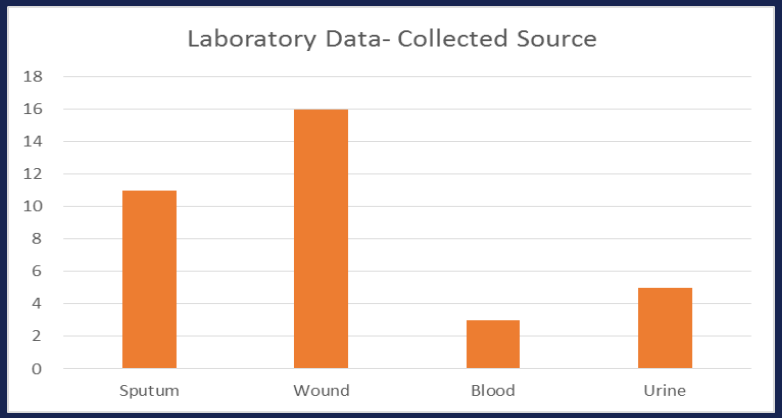


Investigation Steps

1. Create line-list to identify possible source

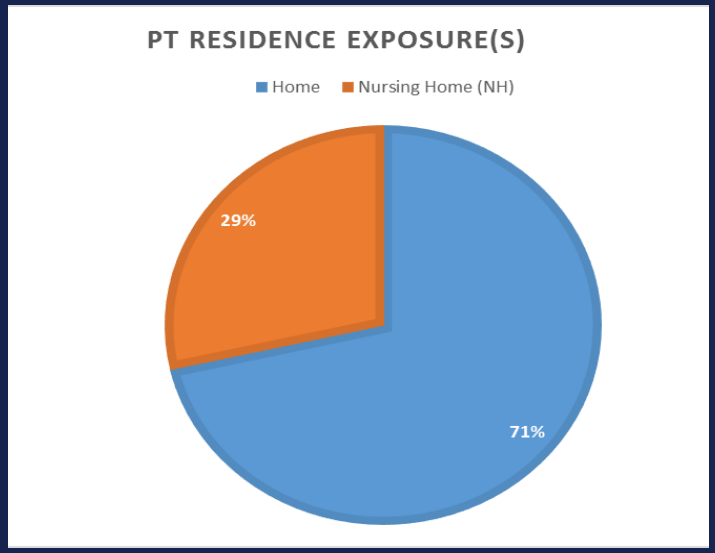
Line-list included:

- 35 patients with MDR-A since July 2018
- Specimen source, collection date, healthcare exposure, surgeries and indwelling devices.



Exploring Healthcare Exposures

- **80%** of cases had at least one overnight stay at a healthcare facility that was longer than 3 days.
- **74%** of cases had overnight stays in more than one healthcare facility.
- **12** healthcare facilities were identified as potential sources of transmission based on patients' exposures.

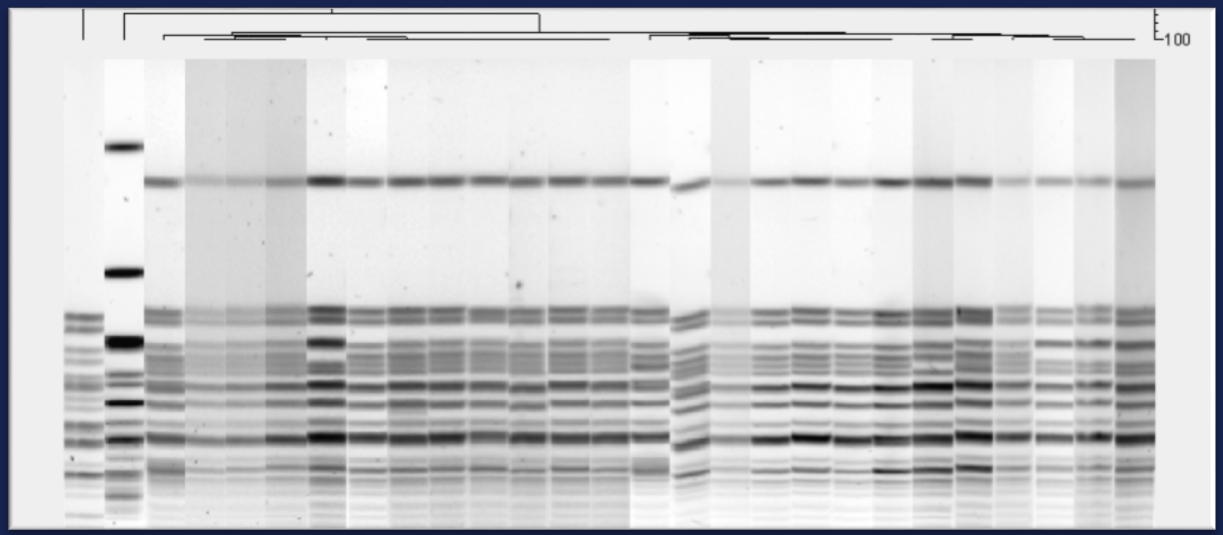


Multiple possible sources (patients move from facility to facility A LOT!)

Investigation Steps

2. Laboratory Testing to identify relatedness

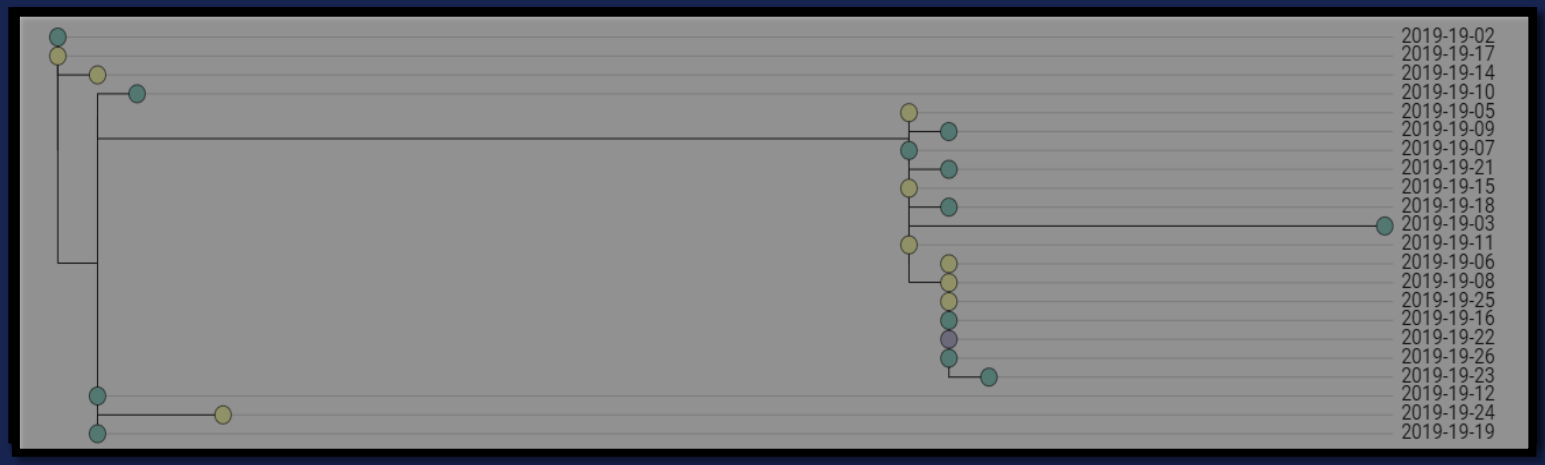
27 isolates tested by Pulse Field Gel Electrophoresis (PFGE)



Investigation Steps

2. Laboratory Testing to identify relatedness

25 isolates tested by Whole Genome Sequencing (WGS) by the CDC



85% **95%** **97%**

Investigation Steps

3. Provide Infection Control Consultation

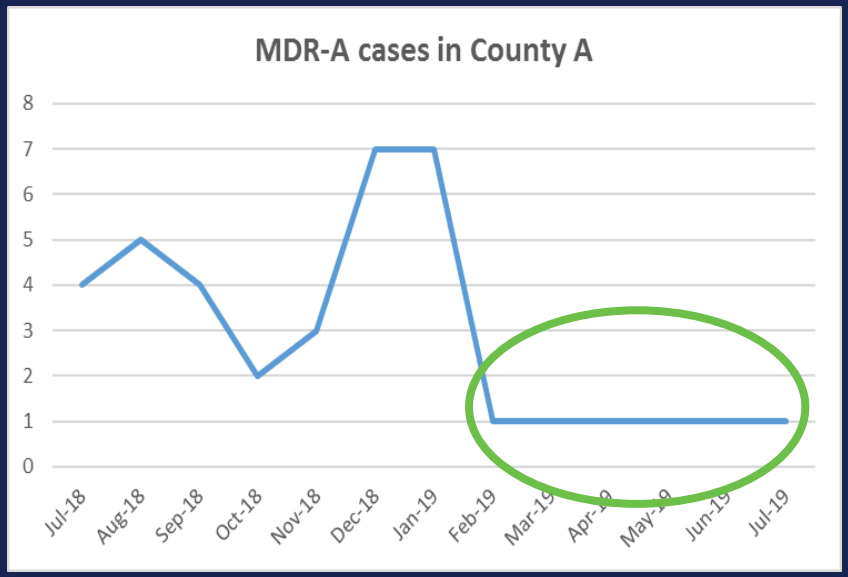
- Consultation was provided to the 12 healthcare facilities via onsite visits and/or phone meetings.
- Gaps in infection control practices were identified, recommendations were given and action plans were requested.

Identified gaps:

- Surveillance system to identify trends
- Inter-facility communication
- Environmental cleaning and disinfection
- Audits and feedback
- Competency-based training
- Compliance with contact precautions
- Policy familiarity

Then what?

- Hard to tell whether outbreak is over!
- MDRO transmission can be multi-dimensional
  - Person-to-person
  - Environmental contamination
  - Equipment contamination
  - Colonization transmission
- Further laboratory testing showed that all isolates were positive for OXA-23 (carbapenemase).



Conclusion: Infection Prevention is everyone's responsibility; community-wide efforts are needed to contain the spread of MDROs.

Acknowledgements

- **Victoria County Public Health**
  - Brittany Burgess
- **Centers for Disease Control and Prevention**
  - Lauren Epstein
  - Laboratory Services
- **Texas Department of State Health Services**
  - Miguel Cervantes
  - Cara Akrout
  - Deanne Gehlbach
  - Laboratory Services
- **12 Healthcare Facilities**

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VIM-CRPA in Lubbock, Texas: Conducting the First Antibiotic Resistance Laboratory Network Multi-Site Epi-Aid in the United States

Gillian Blackwell, BSN, RN, CIC
Texas Department of State Health Services

Terminology

- VIM
  - Verona Integron-Encoded Metallo-β-lactamase
  - Enzyme that degrades carbapenem antibiotics
  - VIM production makes the infection difficult to treat
- CRPA
  - Carbapenem-resistant *Pseudomonas aeruginosa*

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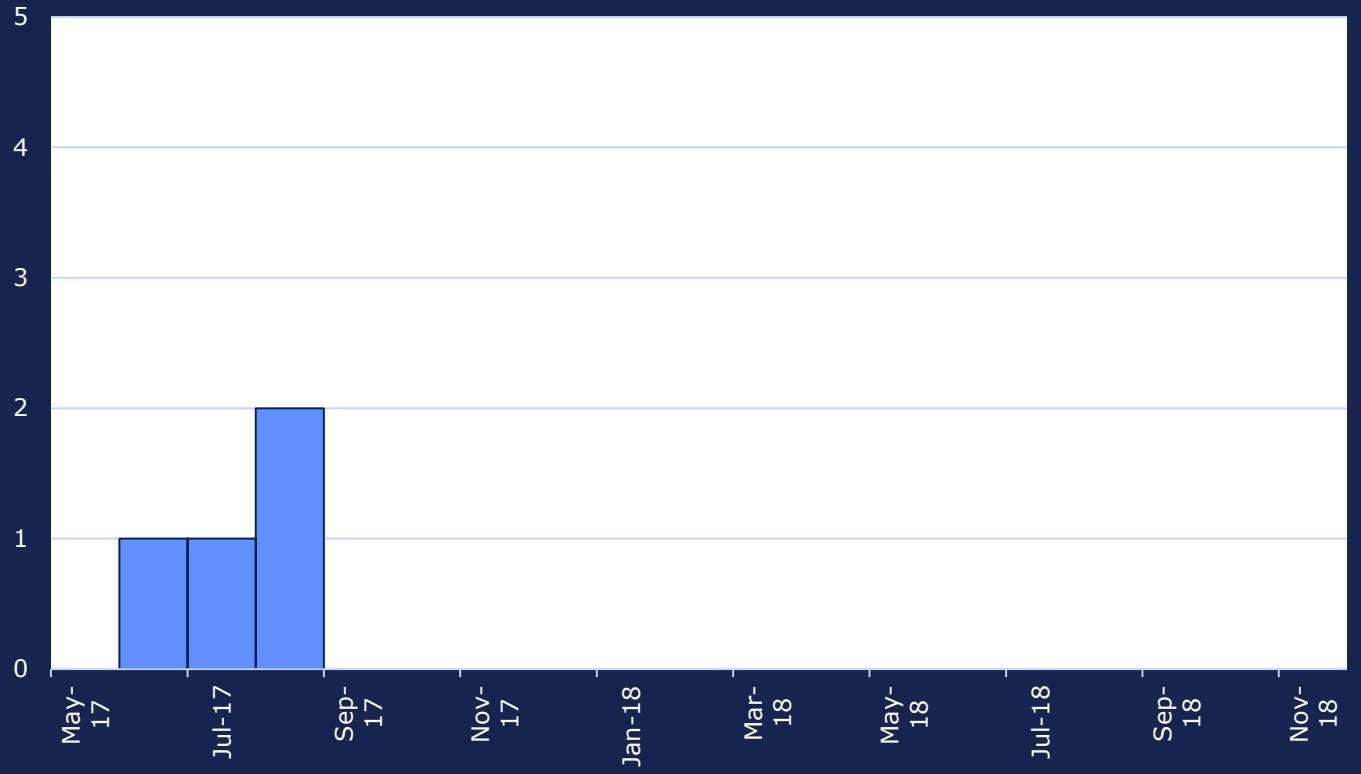
Initial 4 cases VIM-CRPA

Summer 2017



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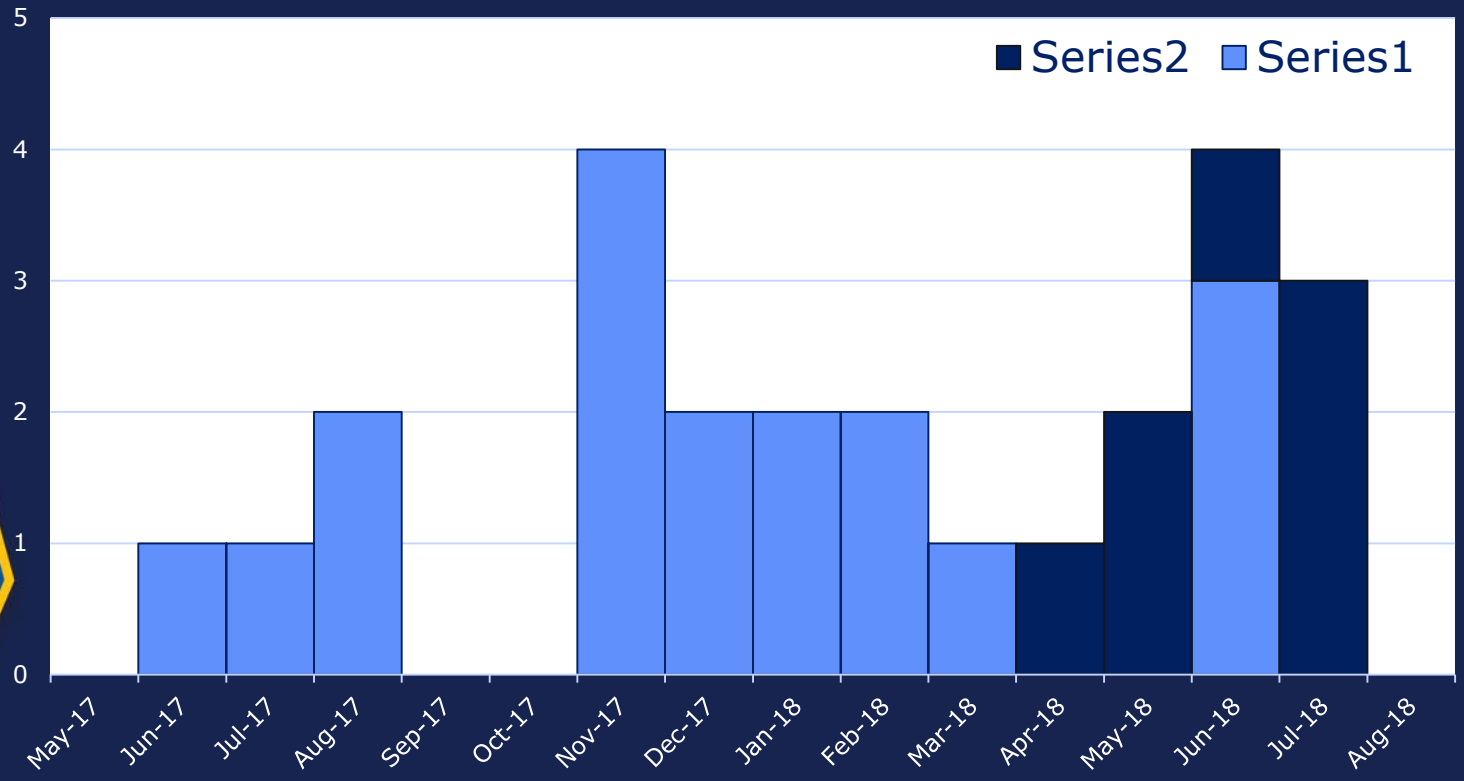
Epidemic Curve of VIM-CRPA
June 2018-Aug. 2018



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Characteristics

- 27 patients – 1 from NM
- 62% Male
- Median age - 63 years old
- 81% on antibiotics before culture
- 96% had an invasive procedure in the last year

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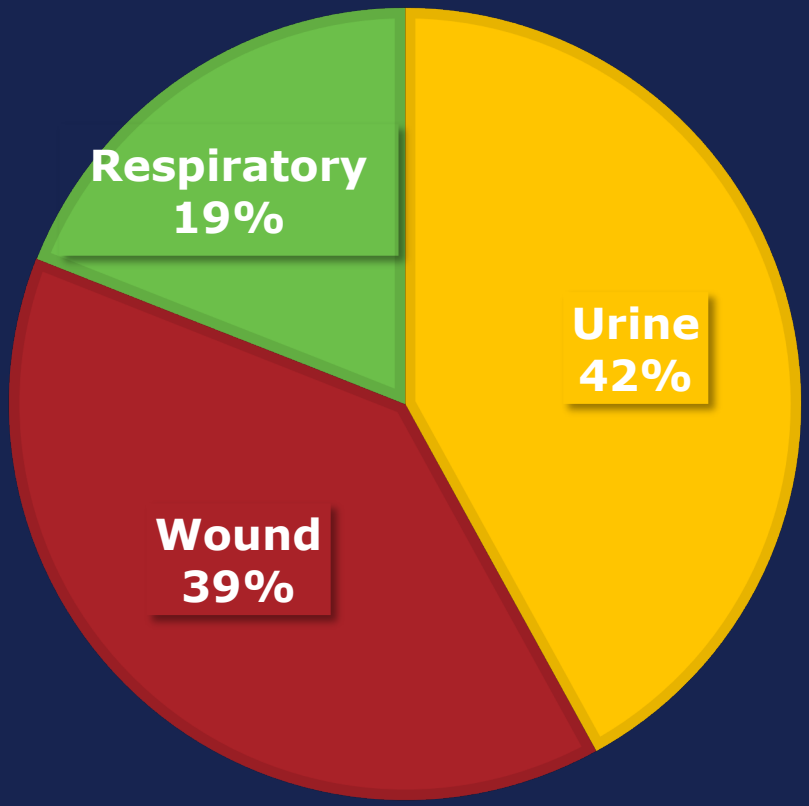
Specimen Sources



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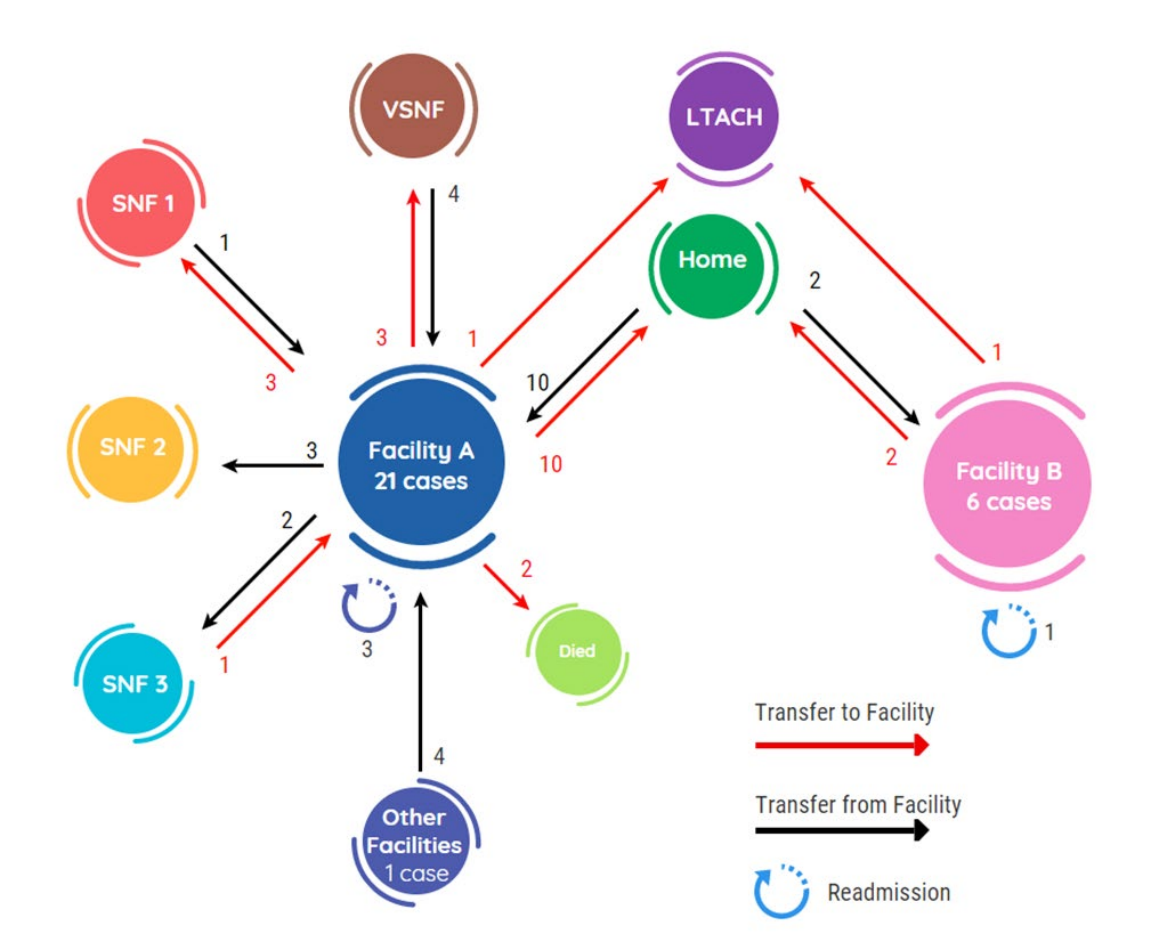
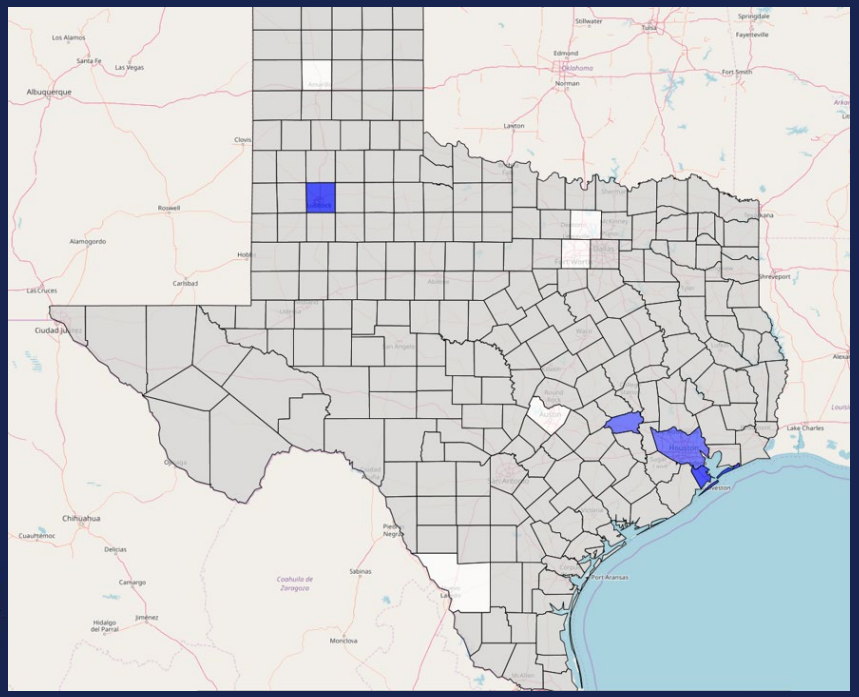
Connections



High Prevalence



- Total cases of VIM CRPA in Texas

  Region 1 with 27

  Region 6/5S with 5

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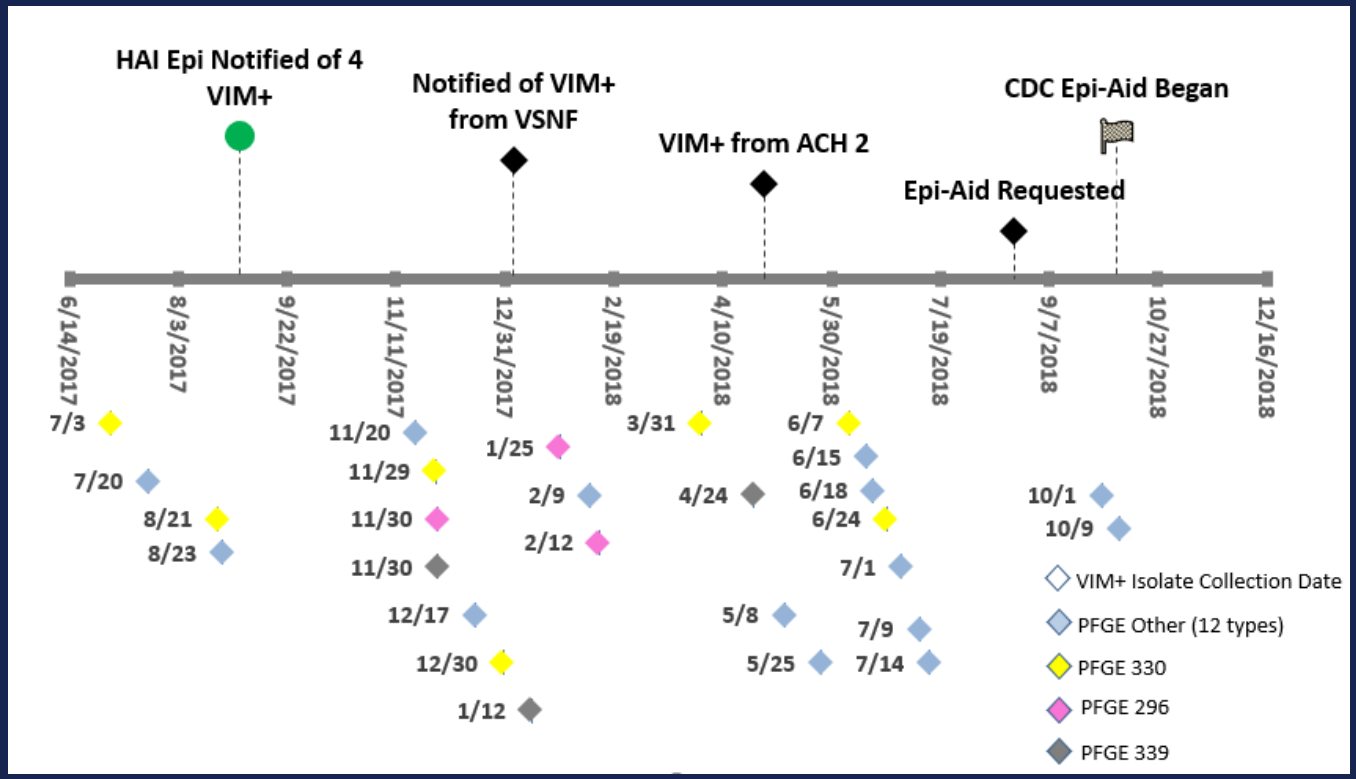
During the Epi-Aid

3-Week Visit from the CDC

West Texas VIM CRPA Timeline

July 2017 – October 2018



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Epidemic Stages

0 – No cases reported

1 – Sporadic occurrence
  – Single cases not epidemiologically related

2 - Single facility outbreaks
  - ≥2 epi-linked cases in one facility

3 – Regional spread
  - >1 facility cluster within one referral network

4 – Interregional spread
  – Multiple clusters occurring within different referral networks

5 – Endemic
  – Most facilities are repeatedly seeing cases admitted from unrelated sources

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Modified from: Grundmann H, Livermore DM, Giske CG, et al. Carbapenem non-susceptible Enterobacteriaceae in Europe: conclusions from a meeting of national experts. Euro Surveill 2010;15:19711.

The Goal of the Epi-Aid

To Develop & Implement Regional Containment Strategy

- Elements of a successful regional strategy:
  - Led by a central public health authority
  - Participation of most or all of facilities in the region
  - Surveillance cultures/screening
  - Inter-facility communication
- Goal: Decrease spread of MDROs in the regional network of facilities

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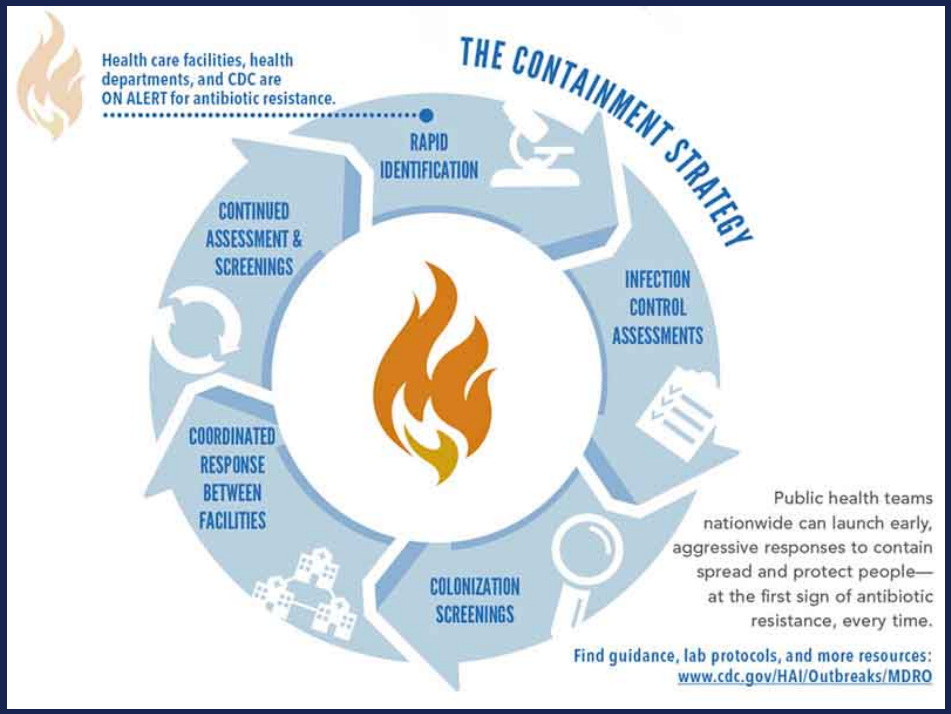
The Containment Strategy

Systematic public health response to slow the spread of emerging AR



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Preparing to Implement a Regional Prevention Strategy

1. Define the region through referral networks
2. Increase regional awareness of issue
3. Facilitate detection
4. Assess baseline regional prevalence
5. Assess baseline infection control at high risk facilities

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Onsite Assessments

- Conducted at 11 healthcare facilities in West Texas
  - 3 short stay acute care hospitals (ACH)
  - 1 long term acute care hospital (LTACH)
  - 1 inpatient rehabilitation facility (IHR)
  - 4 skilled nursing facilities (SNFs)
  - 1 ventilator skilled nursing facility (vSNF)
  - 1 outpatient wound care center

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Onsite Assessment Results

- 7/7 facilities with dedicated IP or IC personnel
  - Hours/week dedicated to IP/IC range from 5-240 hours (most at 20)
- 5/7 report standard communication procedure for MDRO status on transfer (often – always)
  - Most report only sometimes receiving MDRO status information when accepting a patient
- 4/7 have a method to identify MDRO status on readmission
- Hand hygiene audits range from 5–2500 audits/month
- 7/7 have policies specific for cleaning rooms with MDROs

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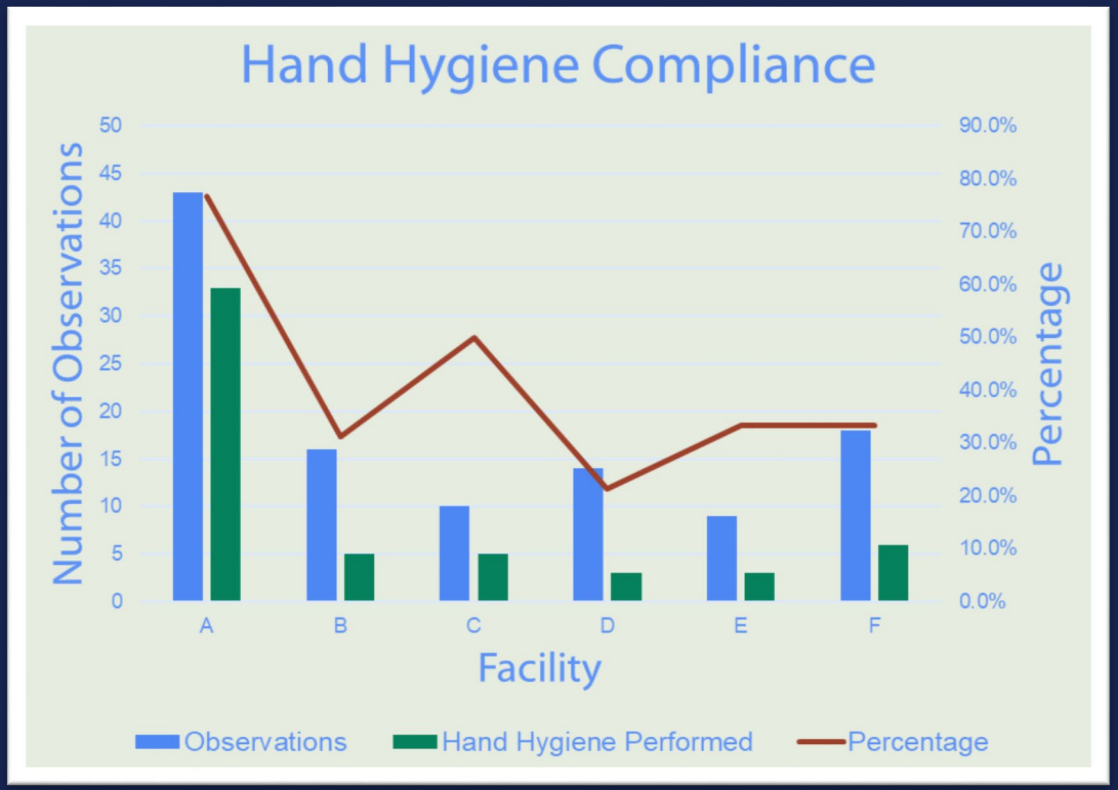
Hand Hygiene



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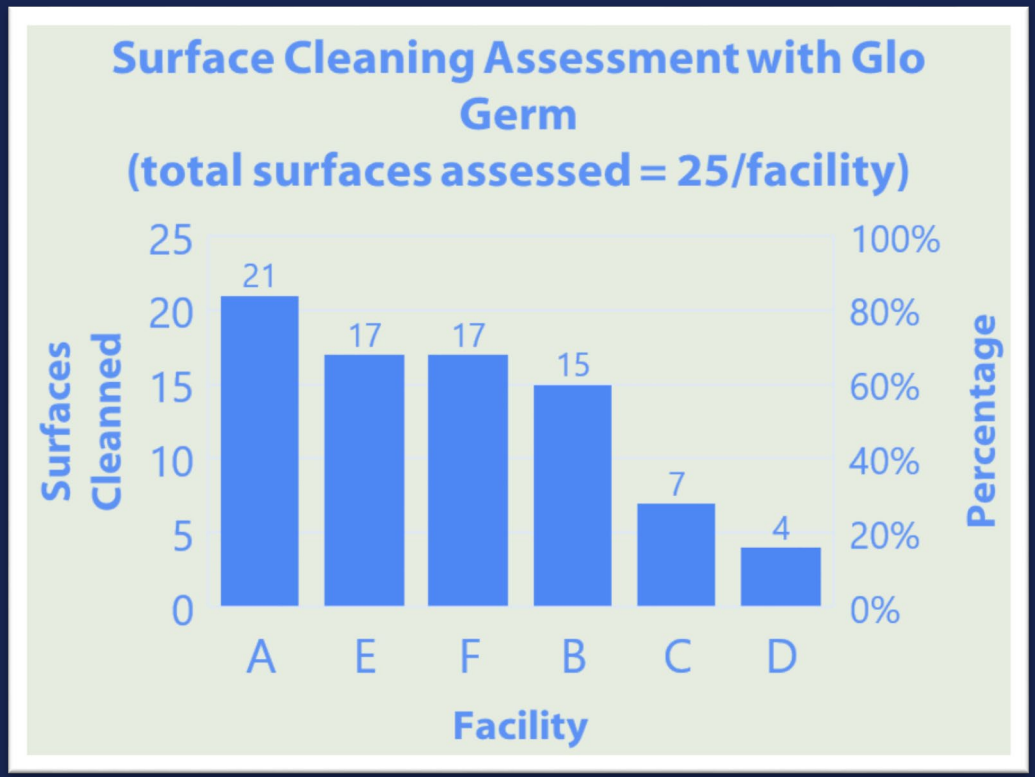
Environmental Cleaning



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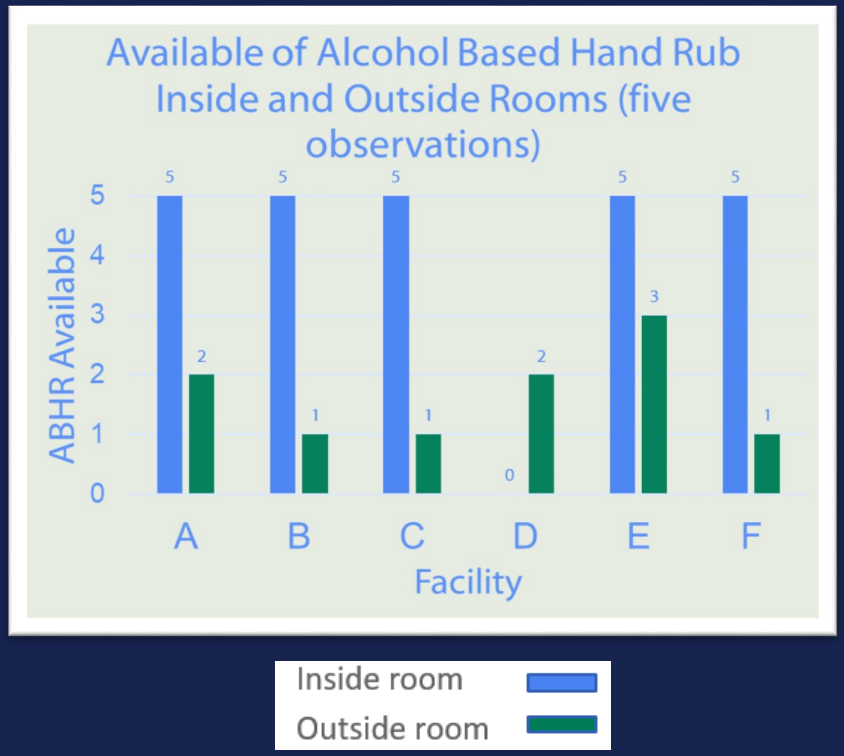
Alcohol Based Hand Rub

- Few easily accessible ABHR found
  - Many states used with fire marshal code
  - Many unclear what local regulation is



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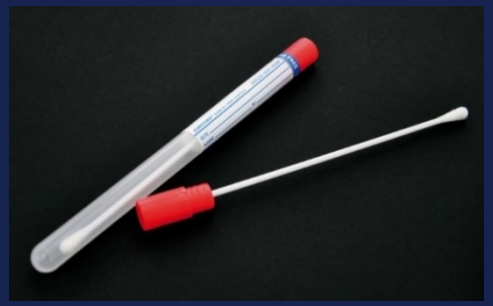
Point Prevalence Survey (PPS)

Evaluate the presence of CP-MDROs

- Conducted at 6 different facilities
- 261 colonization swabs collected
  - No additional VIM CRPA positives identified
  - 2 Previously unknown KPC+
- 1 facility screened directly after the epi-aid
  - 68 colonization swabs
  - No additional positives



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Environmental Sampling

Collected due to high *P. aeruginosa* rates at ACH1

- 45 samples collected
- Sites:
  - sinks
  - drains
  - toilets
  - showers
  - water samples
  - patient areas in the burn unit
  - medical ICU
  - emergency department

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Environmental Sampling Results

- 27% showed *P. aeruginosa* growth (VIM was detected but not isolated in 3)
- 4 KPC+ CRE
- 2 OXA+ CRAB
- 1 VIM+ Pseudomonas monteilli
- 2 First Catch water samples were over the EPC guideline – 1 grew *P. aeruginosa*

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Whole Genome Sequencing

Illumina MiSeq Platform

- 26 investigation related isolates tested
- All were sequence type ST308
- All carried *bla*VIM-2 gene
- Ranging between 0 – 88 SNPs but majority were very closely related
- The isolates were compared to 5 from Texas and 19 from other states
  - West Texas samples showed to be unique

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Educational Resources

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Carbapenem-resistant Acinetobacter baumannii (CRAB)

What is *Acinetobacter baumannii*?

- *A. baumannii* is a bacteria found in soil and is a common contaminant of medical equipment, surfaces and skin. It is a cause of healthcare-associated infections. These infections are common and can lead to severe infection or death.
- *A. baumannii* can become resistant to some of our strongest antibiotics called carbapenems. Examples include imipenem or meropenem. This is called Carbapenem-resistant *A. baumannii* or CRAB.
- This organism can carry any of the 5 plasmid-encoded enzymes of primary public health concern that degrade carbapenems: OXA (oxacillinase) (most common in CRAB), KPC, NDM, IMP, and VIM. Enzymes are also known as resistance mechanisms. CRAB with multiple resistance mechanisms can lead to epidemic spread.
- These organisms can be carried by individuals without causing illness (called asymptomatic carriage). These individuals can spread CRAB to others.
- High-risk patients include those who require medical devices like ventilators, urinary catheters, intravenous catheters, and/or those who are taking long-term courses of antibiotics.
- CRAB can be transmitted from person to person or through shared equipment or healthcare personnel.
- Testing individuals helps prevent spread in a facility and helps their doctor treat them should they become ill.

Prevention in Healthcare Settings

The Texas Department of State Health Services (DSHS) serves as the Antibiotic Resistance Laboratory Network (ARLN) regional lab for the Mountain Region.
In order to understand the occurrence of this organism in your community and prevent further spread of the bacteria, epidemiologists may perform infection control consultations or coordinate the collection of patient samples at healthcare facilities where care was received by patients with CRAB or other resistance mechanisms.

What can you do?

To prevent the spread, healthcare personnel should follow infection control precautions including:

- Adhering to hand hygiene recommendations
- Carefully cleaning and disinfecting rooms and medical equipment
- Wearing a gown and gloves when performing care of patients/residents that may lead to contamination of healthcare personal hands or clothes (bathing, assisting with toileting) in addition to using standard precautions
- Adhering to guidelines for use of personal protective equipment (PPE) in patients who require transmission-based precautions
- When possible, cohorting individuals and dedicating equipment and staff
- Only prescribing antibiotics when necessary
- Daily cleaning and disinfection of areas close to the individual (bed rails, tray table) and other frequently touched surfaces
- Participating in public health initiatives to prevent CRAB from spreading

For more information, please contact the Texas Department of State Health Services (1-888-963-7111) or visit the Centers of Disease Control and Prevention at https://www.cdc.gov/hai/pdfs/cre/CRE-guidance-508.pdf

Carbapenem-resistant Enterobacteriaceae (CRE)

What is Enterobacteriaceae?

- A large family of gram-negative rods including Enterobacter, Klebsiella, and E. coli found in normal gut flora; they are opportunistic pathogens.
- They are the most commonly encountered bacteria in clinical microbiology labs. Infections can lead to severe infection or death. They are difficult to treat because they have high levels of resistance to antibiotics.
- Enterobacteriaceae can become resistant to carbapenem antibiotics (such as imipenem or meropenem) – some of our strongest antibiotics. They can carry any of the 5 plasmid-encoded enzymes of primary public health concern that degrade carbapenems: KPC (most common in US), NDM, VIM, IMP, and OXA. Enzymes are also known as resistance mechanisms. CRE with multiple resistance mechanisms can lead to epidemic spread.
- High-risk patients include those who require medical devices like ventilators (breathing machines), urinary catheters, intravenous catheters, and/or are taking long courses of antibiotics.
- They can be carried on individuals without causing illness (caused asymptomatic carriage). These individuals can spread CRE to others or become ill from it.
- Can be transmitted person to person or through shared equipment or healthcare personnel.

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Carbapenem-resistant Pseudomonas aeruginosa (CRPA)

What is *Pseudomonas aeruginosa*?

- *P. aeruginosa* is bacteria that thrives in moist places like water and soil. It is a leading cause of healthcare-associated infections (CAUTI, CLABSI, VAE). These infections are common and can lead to severe infection or death.
- *P. aeruginosa* can become resistant to some of our strongest antibiotics called carbapenems. Examples include imipenem or meropenem. This is called carbapenem-resistant *P. aeruginosa* or CRPA.
- This organism can carry any of the 5 plasmid-encoded enzymes of primary public health concern that degrade carbapenems: VIM (Verona integron-encoded metallo-beta-lactamase) (most common in CRPA), KPC, NDM, IMP, and OXA. Enzymes are also known as resistance mechanisms. CRPA with multiple resistance mechanisms can lead to epidemic spread.
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Inter-Facility Infection Prevention Transfer Form

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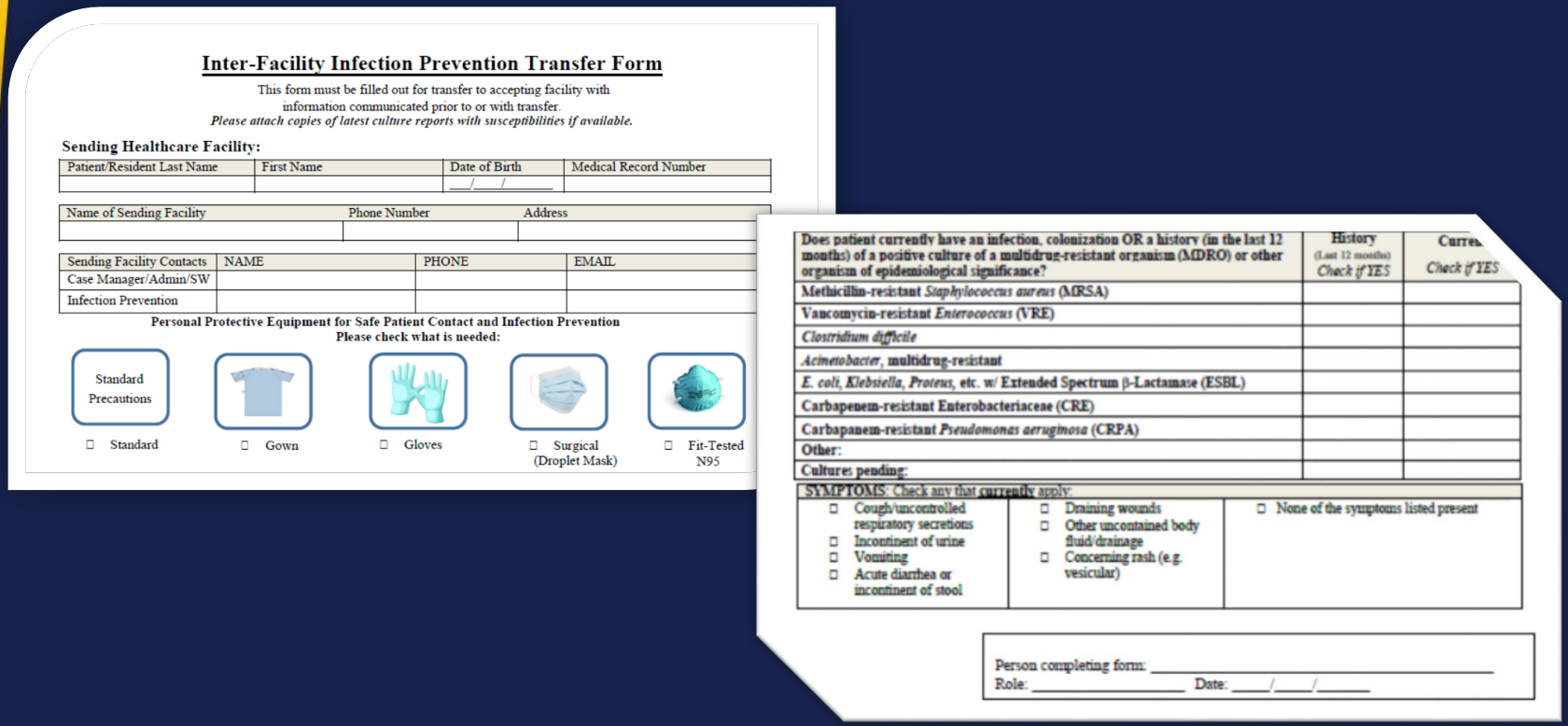

Inter-Facility Infection Prevention Transfer Form

This form must be filled out for transfer to accepting facility with information communicated prior to or with transfer.
Please attach copies of latest culture reports with susceptibilities if available.

Sending Healthcare Facility:

Patient/Resident Last Name	First Name	Date of Birth	Medical Record Number
		___/___/___	

Name of Sending Facility	Phone Number	Address

Sending Facility Contacts	NAME	PHONE	EMAIL
Case Manager/Admin/SW			
Infection Prevention			

Personal Protective Equipment for Safe Patient Contact and Infection Prevention
Please check what is needed:

Standard Precautions

☐ Standard ☐ Gown ☐ Gloves ☐ Surgical (Droplet Mask) ☐ Fit-Tested N95

Does patient currently have an infection, colonization OR a history (in the last 12 months) of a positive culture of a multidrug-resistant organism (MDRO) or other organism of epidemiological significance?	History (Last 12 months) *Check if YES*	Curre… *Check if YES*
Methicillin-resistant *Staphylococcus aureus* (MRSA)		
Vancomycin-resistant *Enterococcus* (VRE)		
Clostridium difficile		
Acinetobacter, multidrug-resistant		
E. coli, *Klebsiella*, *Proteus*, etc. w/ Extended Spectrum β-Lactamase (ESBL)		
Carbapenem-resistant Enterobacteriaceae (CRE)		
Carbapenem-resistant *Pseudomonas aeruginosa* (CRPA)		
Other:		
Cultures pending:		

SYMPTOMS: Check any that currently apply:

☐ Cough/uncontrolled respiratory secretions ☐ Incontinent of urine ☐ Vomiting ☐ Acute diarrhea or incontinent of stool	☐ Draining wounds ☐ Other uncontained body fluid/drainage ☐ Concerning rash (e.g. vesicular)	☐ None of the symptoms listed present

Person completing form: _____
Role: _____ Date: ____/____/_____

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Next Steps

Post 3-week Epi-Aid Visit

West Texas gives VIM the B.O.O.T.

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- Kickoff meeting for the implementation of the regional containment strategy
- **B**e prompt (investigate new cases and perform contact screening)
- **O**btain isolates (submit clinical isolates to AR Laboratory Network, conduct active surveillance)
- **O**ptimize Infection Prevention
- **T**ransfer using the regional interfacility notification form – every time!

Regional Prevention Strategy

1. Detection
   - Continue to recruit submission to ARLN
2. Infection control
   - Return site visits every 6 months
3. Inter-facility notification
   - Implement MDRO Transfer Form
4. Targeted screening in response to cases
5. Active surveillance at high-risk facilities
   - Every other month PPS at facilities involved
   - Admission screening at ACH1 and ACH2

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Thank you!

- Local Health Department
- CDC Epi-Aid Team
- Local LRN
- Support from State Health Departments
- Participating Healthcare Facilities

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Infections in U.S. Residents Associated with Invasive Medical Procedures in Mexico

Melba Zambrano, MSN-IC, CIC
HAI Epidemiologist PHR 11

Acronyms

- Verona integron-encoded metallo-β-lactamase (VIM)
- Carbapenem-Resistant *Pseudomonas aeruginosa* (CRPA)

Response

Multiple States Involved

- Investigation
  - Questionnaire
  - FAQs
- Containment
  - Travel history
  - Cultures of infected sites
  - Rectal screening
    - Hospital outside the US in previous 6mths.
  - Pre-emptive contact precautions
- Health Advisory
- MMWR- Notes from the Field
- Patient Notification

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Case Definition

- Confirmed
  - VIM-CRPA isolated from Texas resident who had an invasive medical procedure in Tijuana, Mexico within a month prior to collection of VIM+ culture.
- Suspected
  - CRPA isolated with no mechanism testing from Texas resident who had invasive procedure in Tijuana, Mexico within a month prior to collection of culture.

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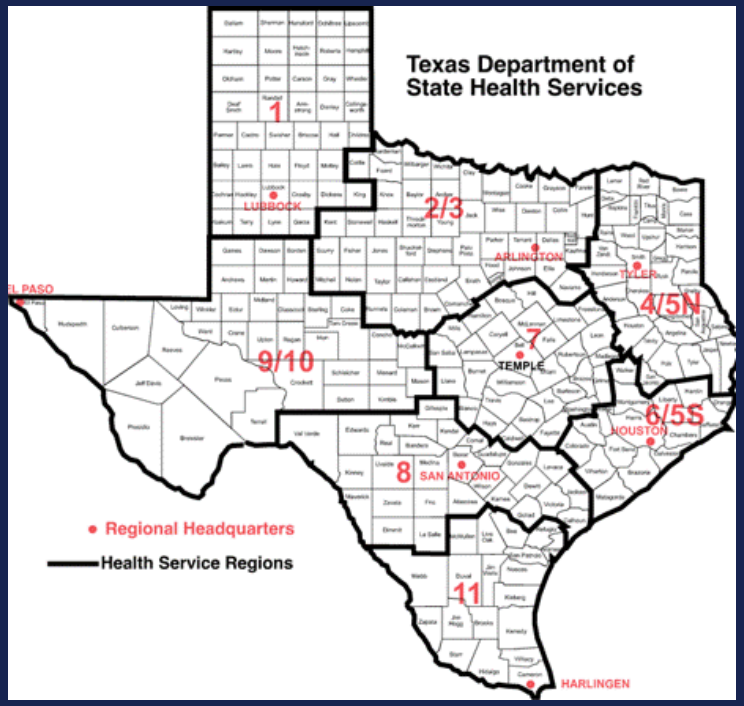
Texas Case Count



One confirmed VIM-CRPA case

- Texas Resident
- Required hospitalization
- Associated with Tijuana, MX

CRPA-VIM cases

Not meeting case definition

One lab confirmed VIM-CRPA

- Non-Texas resident
- Travelled through two Texas regions
- Required hospitalization
- Previous surgery in Mexico
- Not associated with Tijuana, MX cases

One CRPA, suspect VIM, no mechanism of resistance testing (notified 5-13-19)

- Texas resident
- Associated with Tijuana, MX
- Isolate not available for mechanism testing
- Did not requiring hospitalization
- Treated by PCP for symptoms.
- PCP notified Texas on 5/13/19

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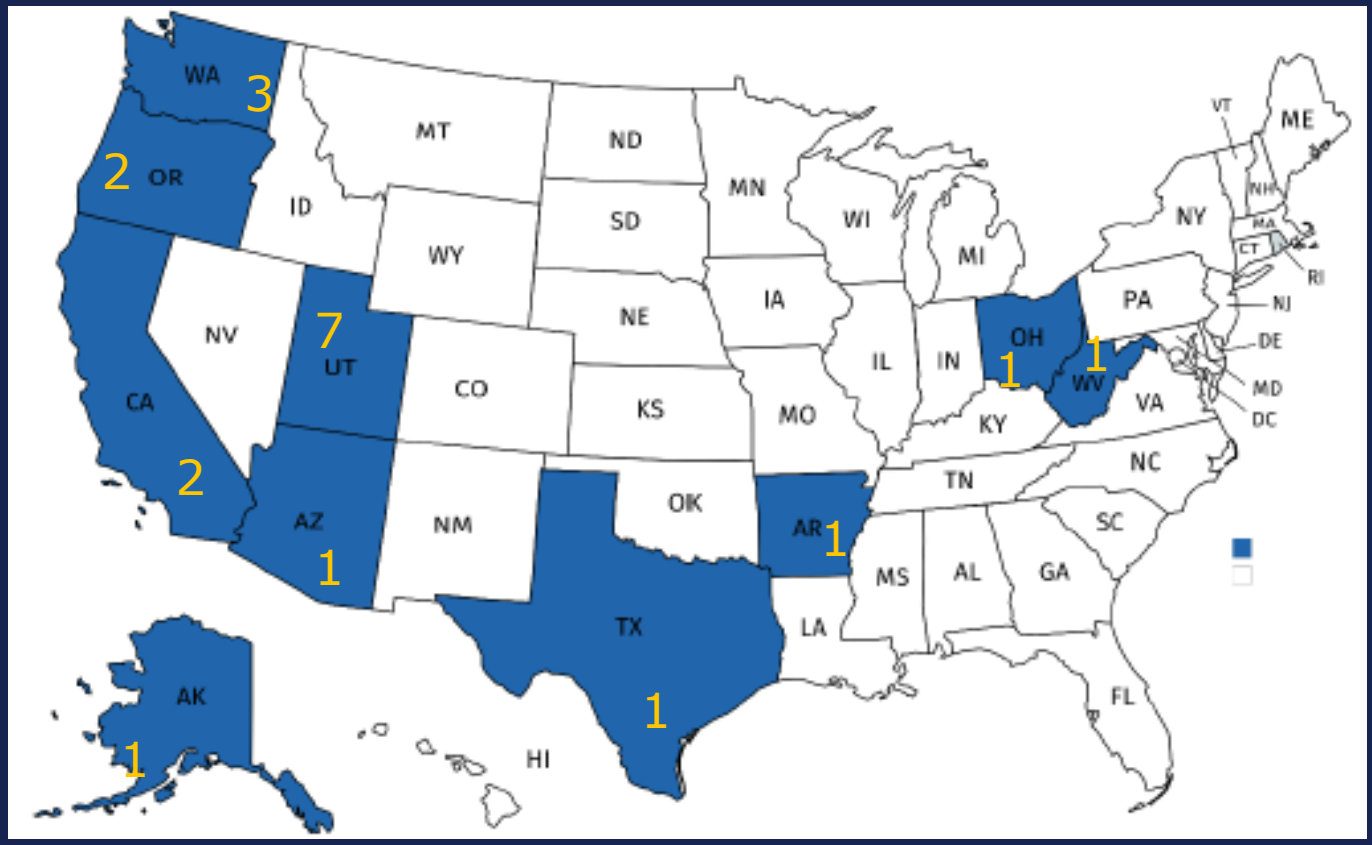
Originally Confirmed VIM-CRPA Cases per State, prior to patient notification



Total confirmed cases: 20

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National Case Count

As of August 26, 2019

- Seventeen U.S. states have identified VIM-CRPA associated with an invasive procedure in Tijuana, Mexico
- Thirty-seven confirmed cases spread across eighteen states
  - AK, AR, AZ, CA, OH, OR, TX, UT, WA, WV, CO, CT, KS, NJ, NY, PA, FL, MI
  - Dates of culture:
    - 9/5/18 - 2/26/19
    - One case in 2015

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Referred Patients

- Weight Loss Agents is a bariatric referring agency who refers patients to Grandview Hospital
  - Released list of referred clients to the CDC 3/6/19
- 741 U.S. Patients were referred to Grandview Hospital in Tijuana, MX for bariatric surgery
- Referees live in 45 States & Puerto Rico
  - 105 of these are Texas residents

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Notification

1. Bacterial & BBP infection
   - U.S. mail outreach
2. Multidrug-Resistant Organism Containment
   - Colonization studies
   - Letters to healthcare providers
   - Letters to admitting facilities

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Summary:

Risk of healthcare abroad

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- CDC identified an outbreak of infections in people who had surgery at Grand View Hospital in Tijuana, Mexico.
  - This outbreak appears to be over as of April 30, 2019.
- Mexican health officials identified poor infection control practices at the hospital
  - (Baja California, Mexico, Public Health Services Sanitary Control Section)
  - Failure to follow recommended practices related to the quality of sterilization of medical devices and instruments.
- Patients who had surgery at Grand View Hospital Between August 1, 2018 and January 30, 2019,
  - Talk to their healthcare provider
  - Tested for the bloodborne pathogens hepatitis B virus, hepatitis C virus, and human immunodeficiency virus (HIV),
  - Risk for developing one of these infections is low.

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Outpatient Cystoscopy: What's the Risk?

Annie Nutt, MPH, CIC
HAI Epidemiologist PHR 4/5N

Cluster of *Burkholderia cepacia* Urinary Tract Infections (UTIs)

- ER reported 3 *B. cepacia* UTIs
  - Recent outpatient cystoscopy at a nearby Urology clinic
- Site visit scheduled for that Friday
- Urine specimens not held at reference lab

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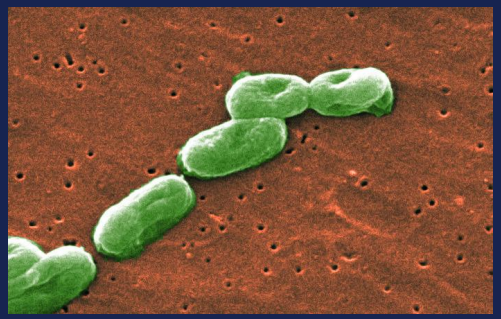
Burkholderia cepacia

- Can be found in soil and water
- Can cause infection in immunocompromised individuals
- Can be resistant to many common antibiotics
- *B.cepacia* poses a contamination risk in non-sterile, water-based drug products



CDC/ Janice Haney Carr

Documented contamination of *B.cepacia* in drug products

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CDC

Persons using assistive

Notice to Re

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major Article

Investigation of an outbreak of *Burkholderia cepacia* infection caused by drug contamination in a tertiary hospital in China

Qi Zou MD [a], Na Li BSN [a], Juyuan Liu MPH [a], Xiaolin Li MPA [a], Zhuofei Wang BSN [a], Xiaoman Ai PhD [b], Fengrong Tao PhD [b], Mei Qu PhD [c], Meng Cai MN [a,*], Yunjian Hu PhD [b,**]

[a] *Hospital Infection Prevention and Control Department, Beijing Hospital, National Center of Gerontology, Beijing, China*
[b] *Clinical Laboratory Department, Beijing Hospital, National Center of Gerontology, Beijing, China*
[c] *Chinese Center for Disease Control and Prevention, Beijing, China*

Onsite Assessment of Urologist's Clinic

- Additional case finding
  - No additional cases of patients with *B.cepacia* UTI following cystoscopy
- Review of Cystoscopy procedure
- Review of Cystoscope reprocessing

Review of Cystoscopy procedure

- Irrigation fluid
- Environmental cultures

Review of Cystoscope reprocessing

- Manual high level disinfection (HLD)
- 2 nurses who did the reprocessing
  - Were each trained once, years ago
- No manufacturer's instructions for use (IFU)
- No HLD log

Cystoscope reprocessing findings, continued

- QC for test strips
- Use of sterile water for final rinse
  - Change each time
- Purge the scope channels with air after the final rinse
  - Then purge with alcohol to enhance drying
- Scope storage

Demographic characteristics of the 3 patients with *B.cepacia* UTI

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Patient	Age (years)	Sex	Date of Cystoscopy	Date of positive sampling	Delay between cystoscopy and positive sampling (days)	Specimen
1	81	M	January 7, 2019	February 27, 2019	51	Urine
2	69	M	February 19, 2019	March 19, 2019	28	Urine
3	64	M	February 28, 2019	March 23, 2019	23	Urine

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Malaria Doesn't Just Come From Mosquitoes

Thi Dang, MPH, CHES, CIC, FAPIC
HAI Epidemiologist PHR 2/3

Case Patient

- 1 year old male seen at acute care ER 12/30/2016
- Admission Date: 12/31/2016
- Admitting Diagnosis: Respiratory failure due to metapneumovirus and rhinovirus/enterovirus infections
- Hospital Course: Respiratory failure requiring extracorporeal membrane oxygenation (ECMO)
- Fever Onset Date: 2/10/2017

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Lab Results & Diagnosis

- Test Date: 2/17/2017
- Test Result:
  - *Plasmodium vivax/ovale parasites* identified on thick and thin smears from blood;
  - Reference lab detected *P. ovale* by PCR & digital image slide review
- CDC Result:
  - *P. ovale* by PCR

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Risk Factor Review

Risk Factor	Yes	No
Mosquito Bites		X
International Travel		X
Newborn		X
Sharing of syringes or needles		X
Organ Transplant		X
Blood Transfusion	X	

Blood Transfusion History

- Received 48 units of packed red blood cells (RBCs) from 1/2/2017 through 2/1/2017

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Blood Donation Safety Measures

- Donor screening
- Blood testing
- Donor deferral lists
- Quarantine

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Traceback Investigations

Donor Traceback

- Child received blood components from 27 separate donors
- 22 donors were re-interviewed with the donor history questionnaire, which included a 3-year travel history
- 5 donors lost to follow up

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Donor Risk Assessment

- Two identified as Low Risk Donors
  - Previously resided in area with endemic malaria without having recent travel
- One identified as High Risk Donor
  - Previously resided in area with endemic malaria with recent travel

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Donor Risk Assessment

- Low and High Risk Donors
  - Asked to come in for testing
  - Their remaining donated products were recalled & tested, if available
  - Deferred from future donations until tests are negative

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Blood Components & Shelf Life

Blood Component	Shelf Life
Whole Blood	21 days
Red Cells	42 days
Platelets	5 days
Plasma	1 year
Cryo	1 year

Source: 21CFR610.53

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Test Results from Donors

- 1st Low Risk Donor
  - Negative test results
- 2nd Low Risk Donor
  - Lost to Follow up
- High Risk Donor
  - Negative PCR & serology
  - Donated product +IFA

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Donation History

- 3 Donations were made by the High Risk Donor from September 2016 through January 2017
- Donated Products
  - Red Blood Cells
  - Fresh Frozen Plasma
  - Random Platelets
  - Cryoprecipitate

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Blood Bank Notifications

- The blood donation center contacted the laboratories/blood banks that received the blood products from the high risk donor to inform them of the risk and product recall
- Products received at 4 Healthcare facilities
  - 3 in Region 2/3
  - 1 in Region 6/5S

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Recipient Traceback

- 4 Recipients
  - 2 had no known signs & symptoms
  - 1 was our case patient
  - 1 died of an unrelated cause

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Status of Case Patient

- Anti-malarial treatment started 2/17/2017 with Hydroxychloroquine followed by Primaquine phosphate
- Parasite load in blood was 0% after Day 3 of treatment.
- No further complications related to the malaria infection
- Discharged home in good condition on 3/31/17.

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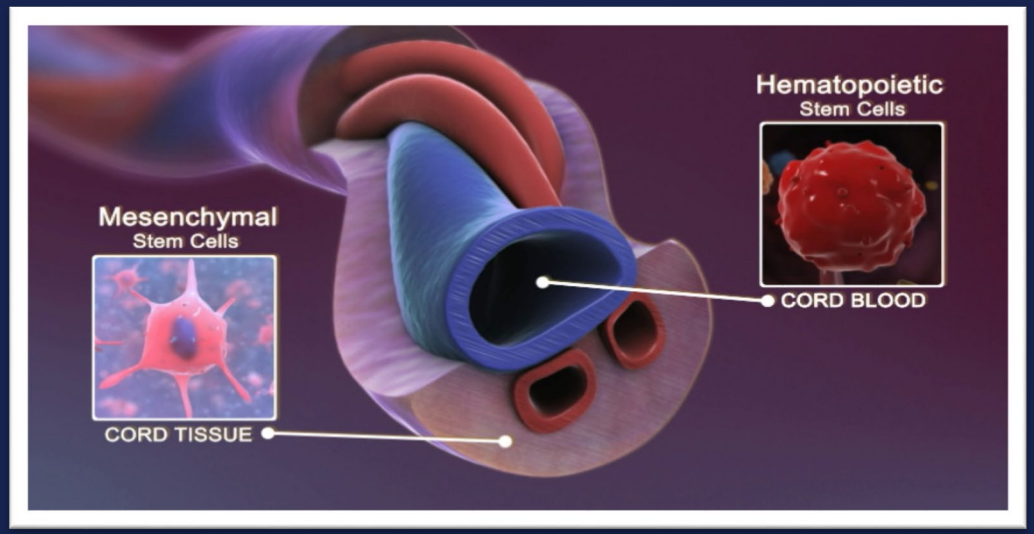
Multistate Outbreak of Post-Stem Cell Product Procedure Infections

Bobbiejean Garcia, MPH, CIC, FAPIC
HAI Epidemiologist PHR 6/5S

What happened?

Notification of 3 patients with bloodstream infections after non-FDA-approved umbilical cord blood-derived stem cell procedures at the same outpatient clinic.



Picture: https://advancedrejuvenation.us/wp-content/uploads/2017/10/ubmstemcell.jpg

Investigation: Act 1

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Infection control assessments

Findings:

- Not following manufacturer's instructions for pre-operative skin preparation.
- Gum chewing by technician.
- Patients' belongings placed on top of patient care supplies.
- Not wearing mask while conducting a lumbar procedure.

Investigation

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Infection control assessments → **Isolate and product testing**

Isolate and Product Testing Results

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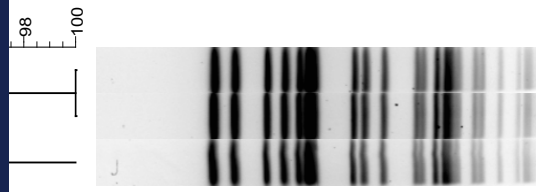
Isolate Testing



Key	Occurr	DSHS-XbaI-Pat	Genus	species
TXACB1802189	01	XB-ETCA-035	Enterobacter	cloacae
TXACB1802190		XB-ETCA-035	Enterobacter	cloacae
TXACB1802191		XB-ETCA-035	Enterobacter	cloacae

Product Testing

Bacterial contamination, including *Enterobacter cloacae,* was recovered from all stem cell product vials tested. *Citrobacter freundii* was recovered from all tested vials, except one.

Investigation

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Infection control assessments

Isolate and product testing

Active case finding

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Active Case Finding Results

67 clinics received product

5 additional cases

61 contacted (91%)

321 patients identified

54 reported back (89%)

Summary of Cases (8)

- 100% with bloodstream infections
  - 50% with others infections as well
- 100% hospitalized
- Organisms isolated: *E.coli, E.faecalis, C.koseri, C.freundii, E.cloacae*
- Reasons for administration: pain & arthritis
- Routes of administration: intra-articular injections and IV infusion

Texas Cases

Date product administered	Reason for administration	Specimen collection date	Organism isolated	Infection Site
6/13/18	Pain	6/14/18	*Escherichia coli*	Bloodstream
7/27/18	Pain	8/1/18	*Escherichia coli*	Bloodstream, epidural abscess, and osteomyelitis
8/18/18	Osteoarthritis	8/29/18	*Escherichia coli, Enterococcus faecalis*	Bloodstream, shoulder
8/28/18	Rotator cuff tear with cyst	9/9/18	*Escherichia coli*	Bloodstream
8/29/18	Lumbar back pain	9/1/18	*Citrobacter koseri*	Bloodstream
9/12/18	Pain	9/15/18	*Enterobacter cloacae, Citrobacter freundii*	Bloodstream, cellulitis at injection site
9/12/18	Pain, rheumatoid arthritis	9/16/18	*Enterobacter cloacae, Citrobacter freundii*	Bloodstream
9/12/18	Pain, rheumatoid arthritis, Osteoarthritis	9/16/18	*Enterobacter cloacae*	Bloodstream, lumbar epidural abscess

Conclusion

- Laboratory tests suggested the bacterial infections may have occurred due to stem cell product contamination prior to distribution.
- Unknown total case count in Texas due to self-reporting by facilities and patients.
- Having standard procedures in place for large-scale active case finding aided this investigation.

Investigation: Act 2

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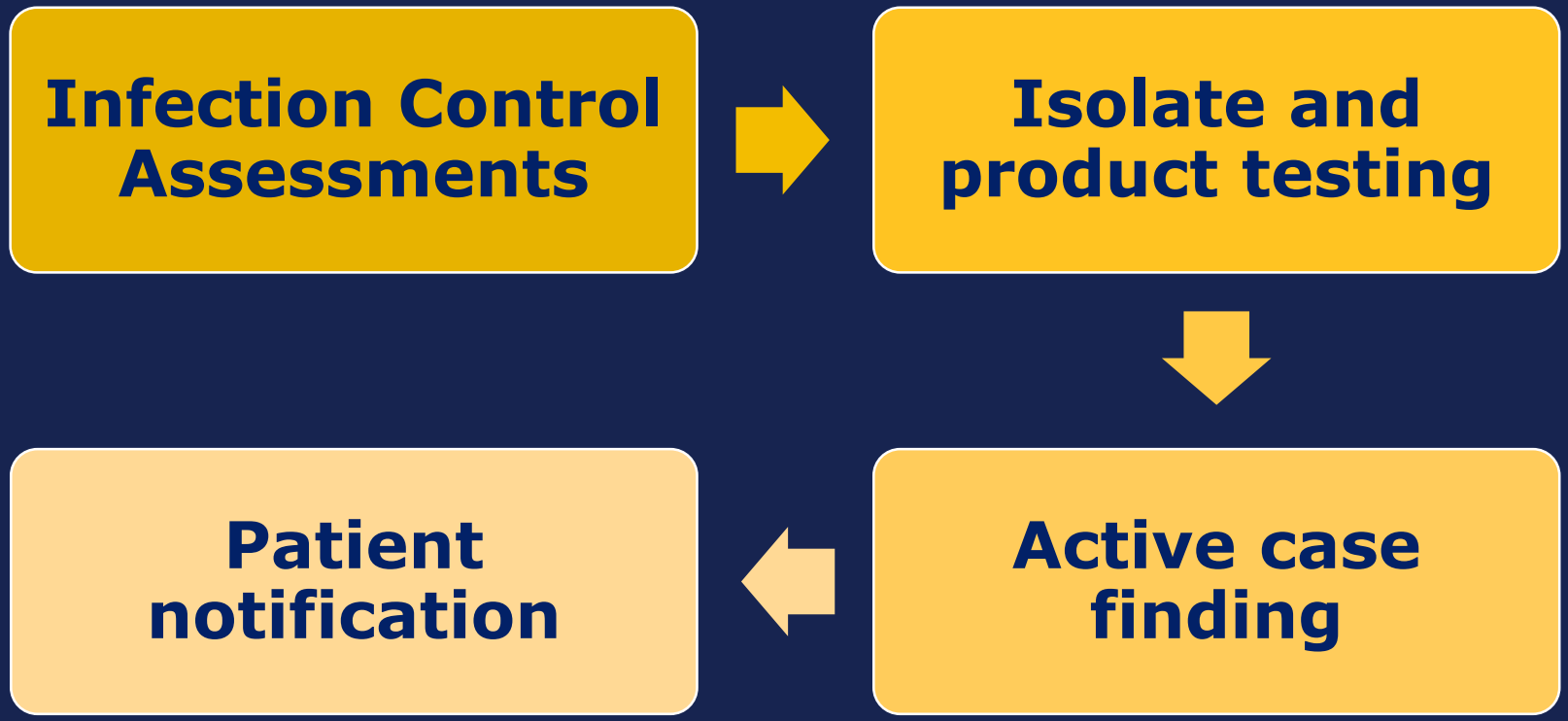

Patient Notification

- FDA inspection at the manufacturer found that testing and screening of the donors were not done appropriately.
- CDC recommended notifying patients of low risk of bloodborne pathogen infections and other communicable diseases.
- Texas health departments recommended patients consult with their doctors for BBP testing.

For more information:

- CDC's web page on contaminated stem cell products: https://www.cdc.gov/hai/outbreaks/stem-cell-products.html
- CDC MMWR Notes from the Field: https://www.cdc.gov/mmwr/volumes/67/wr/mm6750a5.htm?s_cid=mm6750a5_w
- FDA's news release that came out December 20th 2018, it includes the warning letter to Genetech Inc. and the notice to other companies: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628918.htm
- Text of the letter/notice to the other companies: https://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/UCM628912.pdf
- FDA's warns about stem cell therapies, contains link to FDA-approved stem cell products: https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm286155.htm
- FDA Recall of the All ReGen Series ® Stem Cell Product, effective 09/28/2018: https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Recalls/ucm622190.htm

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  - Kiran Perkins MD, MPH
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  - Linda Gaul, PhD, MPH
  - Jennifer Shuford, MD, MPH
  - Shawn Tupy, MT, MBA
  - Laboratory Services
  - HAI Epidemiologists
- **23 Texas Local Health Departments**

References

"Outpatient Cystoscopy: What's the Risk?"

1. US Food and Drug Administration. FDA advises drug manufacturers that Burkholderia cepacia complex poses a contamination risk in non-sterile, water-based drug products . Available at: https://www.fda.gov/Drugs/DrugSafety/ucm559508.htm.

2. Centers for Disease Control and Prevention. Notice to readers: manufacturer's recall of nasal spray contaminated with Burkholderia cepacia complex. MMWR Morb Mortal Wkly Rep 2004; 53:246.

3. Richard B Brooks, Patrick K Mitchell, Jeffrey R Miller, Amber M Vasquez, Jessica Havlicek, Hannah Lee, Monica Quinn, Eleanor Adams, Deborah Baker, Rebecca Greeley, Kathleen Ross, Irini Daskalaki, Judy Walrath, Heather Moulton-Meissner, Matthew B Crist, Burkholderia cepacia Workgroup, Multistate Outbreak of *Burkholderia cepacia* Complex Bloodstream Infections After Exposure to Contaminated Saline Flush Syringes: United States, 2016–2017, *Clinical Infectious Diseases*, , ciy910, https://doi.org/10.1093/cid/ciy910

4. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/voluntary-nationwide-recall-all-liquid-products-manufactured-pharmatech-llc-and-distributed-leader

5. Zou, Q., et. al. (2019). Investigation of an outbreak of Burkholderia cepacia infection caused by drug contamination in a tertiary hospital in China. *American Journal of Infection Control*.

6. Clemens, Quentin. *Reprocessing of Flexible Cystoscopes*. 2014, www.suna.org/resources/cystoscopyWhitePaper.pdf.

7. The Joint Commission. *High Level Disinfection and Sterilization BoosterPak*. www.jointcommission.org/assets/1/6/TJC_HLD_BoosterPak.pdf.

8. Sorbets, E., et. al. (2019). An outbreak of Pseudomonas aeruginosa urinary tract infections following outpatient flexible cystoscopy. *American Journal of Infection Control*.

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References

"Malaria Doesn't Just Come From Mosquitoes"

- Centers for Disease Control and Prevention (2018). About Malaria. https://www.cdc.gov/malaria/index.html.
- Code of Federal Regulations (2017). Title 21, Volume 7, 610.53.
- Food and Drug Administration (2017). Keeping blood transfusions safe: FDA's Multi-layered Protections for Donated Blood https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/BloodSafety/ucm095522.htm.

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Questions?

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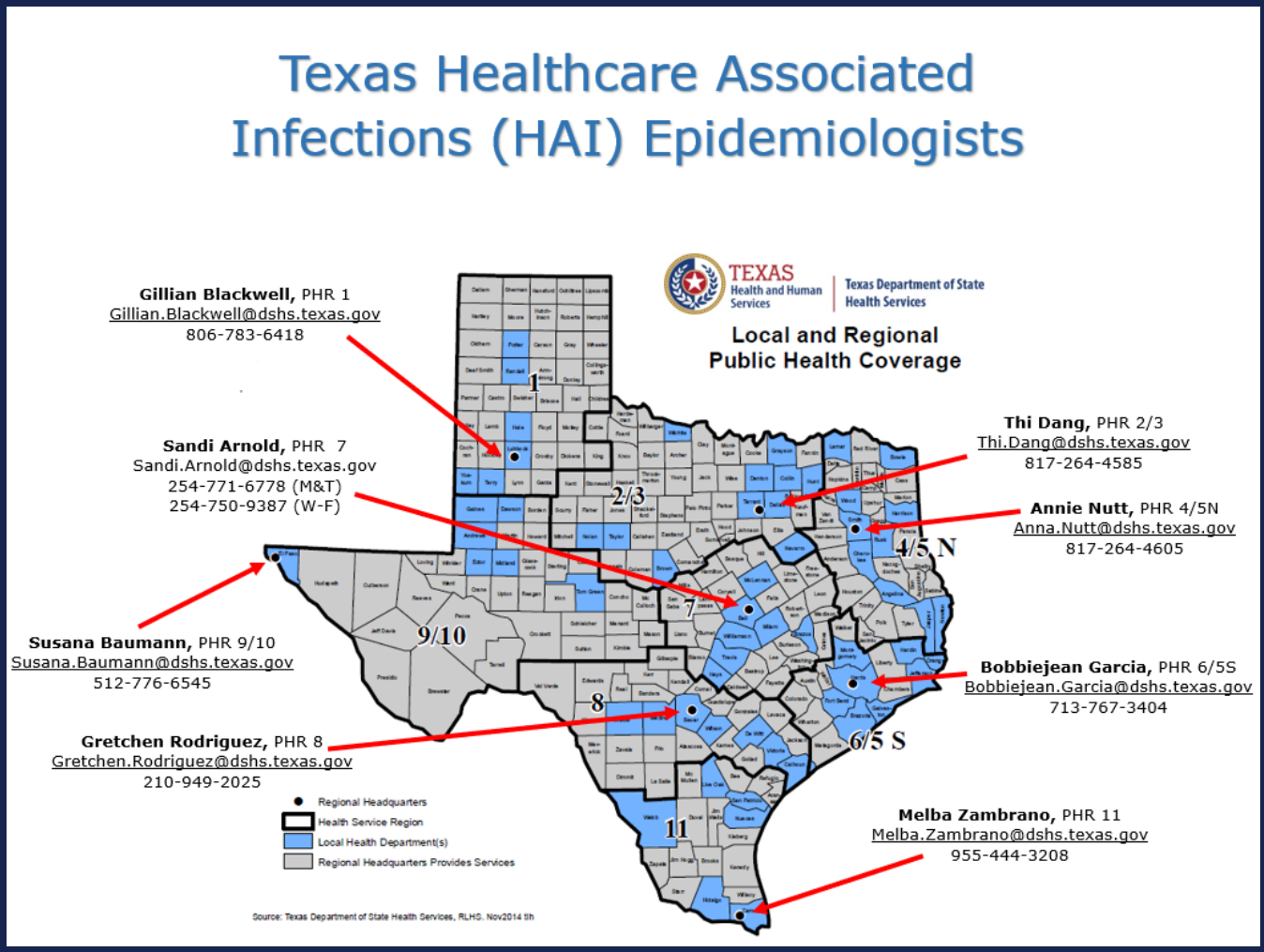
Texas Healthcare Associated Infections (HAI) Epidemiologists



Thank you!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