

# Tune in to Safe Healthcare: Unsafe Injection Stories from the Field

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## Featured Speakers

- **Pamela Dembski Hart, BS, MT(ASCP), CHSP, Principal and Founder, Healthcare Accreditation Resources, LLC**
  - Compliance with Safe Injection Practices:  
A view from the trenches
  
- **Zack Moore, MD, MPH, Medical Epidemiologist, Communicable Disease Branch, North Carolina Division of Public Health**
  - The Doctor and The Mask: Septic arthritis due to unsafe injections in an outpatient clinic



**CDC Disclaimer: The findings and conclusions in this presentation are those of the presenter(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.**

# Featured Speakers

- **Evelyn V. McKnight, AuD. President, HONOReform**
  - Hepatitis C: A Patient's Perspective, Its' Causes, and Possible Preventions



CDC Disclaimer: The findings and conclusions in this presentation are those of the presenter(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



- **Joseph Perz, DrPH, MA, CDC's Division of Healthcare Quality Promotion, Team Lead for Quality Standards and Safety in the Prevention and Response Branch**





# Compliance with Safe Injection Practices

A view from the trenches



# The Initial Greeting

What I hear...

...*"I think we are pretty good with the regs..."*

and.....What I Heard

...and *then* See



# Scenario I

## What I See and Hear

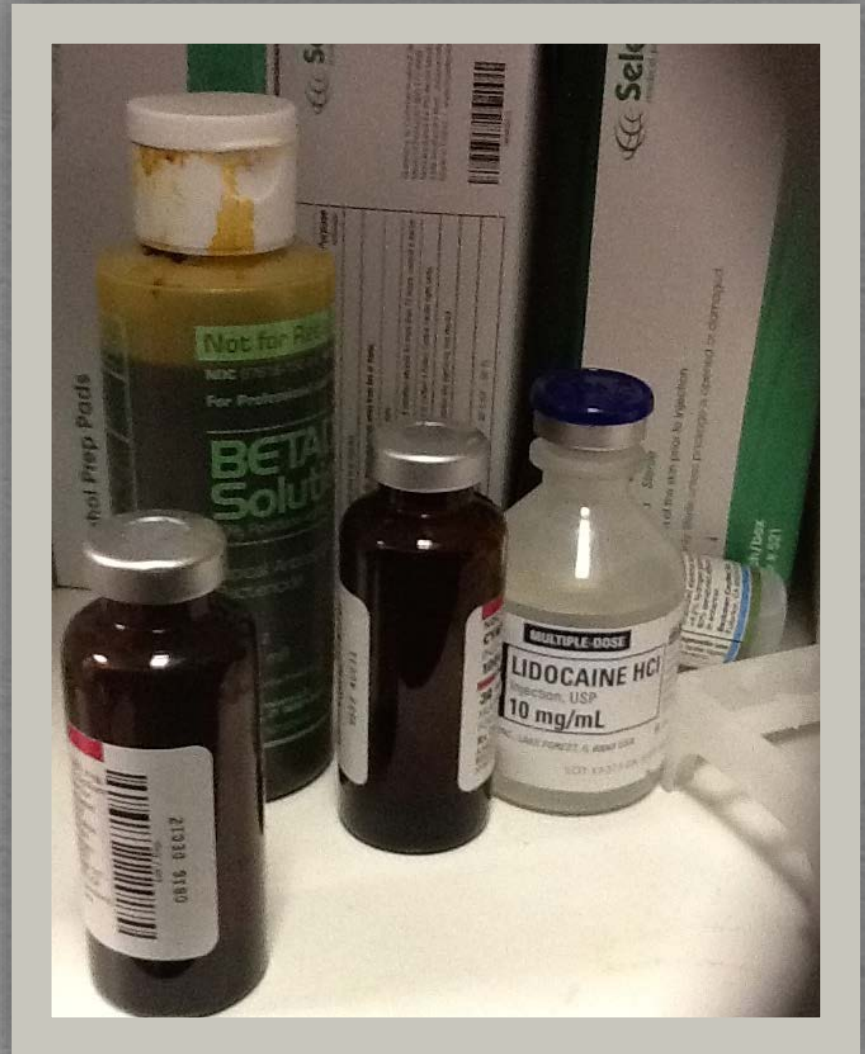
### ASC Procedure Room or OR Set Up

- Medications are prepared in the same area where they are administered
- The CMS Requirement and CDC recommendations
  - If MDV are used for >1 or multiple patients
  - Preparation is in a dedicated /separate area

***The response:*** “*We will put the partition up or use a different room when the surveyors (accrediting body) come to inspect*”



# What I See

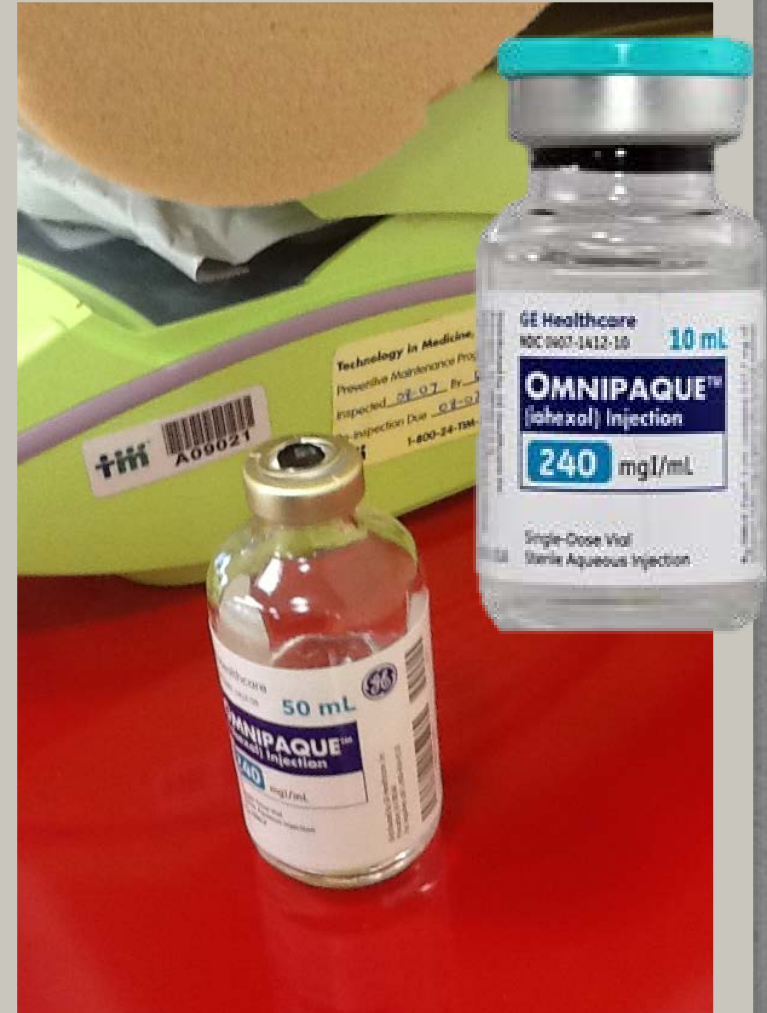
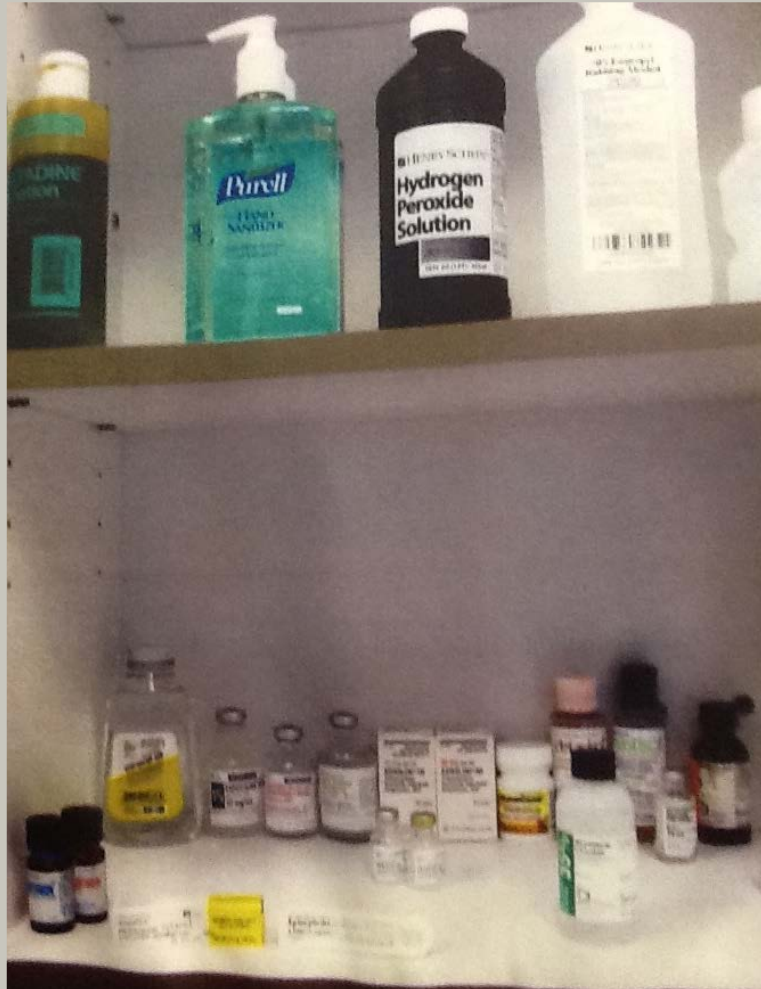


# And See





# Storage Matters





# Read the Labels



The pH is adjusted between 6.8 and 7.7 with hydrochloric acid or sodium hydroxide. No preservative added. Each bottle for one procedure only. Discard unused portion. Protect from light. For



# Scenario 2

## What I see

- Multi -dose vials are not labeled with beyond use dates(BUD) and/or are expired





# Scenario 2 *cont'd*

## What I also see

- Dates are incomplete or incorrectly recorded
- Single Dose Vials are not discarded after initial use





# Scenario 2

What I see..... *and hear and see*

## ***Observed:***

- QI Study abandoned
  - *Anesthesia Medication Cart Daily Checklist*
- *“no need since everything seemed to be ok”*



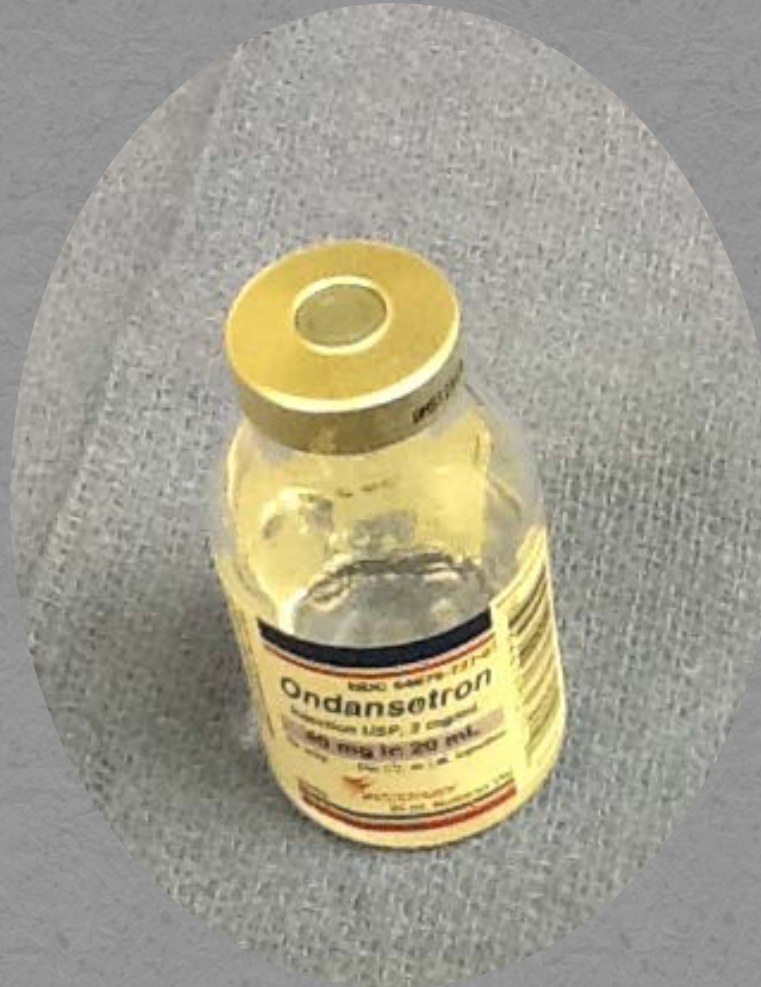


# Scenario 2

## What I see..... *and see*

### **Observed:**

- *Anesthesia Medication Cart Daily Checklist*
- *“no need since everything seemed to be ok”*



Zofran

After dilution:  
do not use  
beyond  
24 hours

Contains no  
preservatives



# Scenario 3

## What I See

Observed: Inconsistent volume of syringe (narcotic) contents

- IV conscious sedation : Several type narcotics/pre-drawn
- IV (saline) pre-spiked
- IV bags stored on the floor
- MDV pre- spiked

Response:

*The leftover contents of either the syringes or saline solutions are reused for next patient.*

Defense: “ IV line or syringe has a safety mechanism in

# Pre Spiked IV Bag





# Unlabeled Syringe



# Scenario 3 and 4

## What I hear

“I did not know BOTOX was single use only”

“I did not know SDV could not be used multiple times on the same patient or other patients”

“It is an FDA plot”

“I have used SDV on multiple patients and nothing has happened”



**FACT Single Use ,discard 24 hour after reconstitution**

# The Solution(s)

- Training : Initial and annually
- Random and unannounced Surveys
- Competency exams for license renewal for *all licensees* and in some cases for *non licensees*





# **Don't Turn Your Back on Safety**

- **Primum non nocere**



# The Doctor and The Mask: Part II

Zack Moore, MD, MPH  
North Carolina Division of Public Health



# Acknowledgement

- Slides adapted from Dr. Sarah Rhea, DVM, MPH, PhD, presented at 63rd Annual EIS Conference, April 30, 2014

# Part I

## The doctor and the mask: iatrogenic septic arthritis caused by *Streptococcus mitis*

A 72-year-old man developed septic arthritis in a prosthetic shoulder after intra-articular injection of radiographic contrast. This is the first published case in which molecular techniques matched oral commensal organisms cultured from joint aspirate with oral flora from the proceduralist, who was not wearing a mask.

### Clinical record

A 72-year-old man presented in 2011 with acute-on-chronic right shoulder pain. Bilateral shoulder replacements had been performed 8 years earlier for osteoarthritis, with no surgical complications.

In the 6 months before presentation, the patient experienced increasing pain and decreased range of movement of the right shoulder. Four days before presentation, a computed tomography (CT) arthrogram of the right shoulder was performed to look for glenoid osteolysis and assess the linear integrity of the shoulder prosthesis. Eight millilitres of radiographic contrast with bupivacaine were injected into the joint space. The proceduralist used an aseptic technique and skin preparation with 0.5% alcoholic chlorhexidine, but did not wear a mask. Within 24 hours, the shoulder pain dramatically worsened and the range of movement became severely

limited. The patient's organism and a strain of *S. mitis* recovered from the proceduralist's throat showed indistinguishable fragment patterns (Box). This strongly suggested droplet transmission of the proceduralist's oral flora onto the needle or skin, with subsequent inoculation into the shoulder joint.

Six months after the acute presentation, joint failure, confirmed on arthrogram and by arthroscopy, necessitated full revision of the right shoulder prosthesis. The procedure was uncomplicated, and the patient remains well with no signs of recurrent infection.

### Discussion

This is the first published instance of a molecular epidemiology technique showing probable transmission of oral flora from a proceduralist to the joint of a patient, resulting in

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# The Call

- October 18, 2013
- 2 patients hospitalized with *Staphylococcus aureus* (SA) septic arthritis
  - Intra-articular injections on same day, by same provider, at same outpatient facility (Facility A)
  - Injections contained
    - Autologous platelet-rich plasma (PRP)
    - Allogeneic human placental tissue product

# Autologous Platelet-Rich Plasma (PRP)

- Investigational / alternative therapy for osteoarthritis
- Patient's own blood centrifuged to separate blood components
- Plasma injected in joint space (+/- additives)



Centrifuge in use at Facility A

# Investigation Objectives

- Identify additional cases
- Assess for ongoing risk due to
  - Infection control (IC) breach, or
  - Intrinsic contamination of injected product



# Methods

- Conducted case finding
  - Contacting other injection recipients
  - National call for cases (Epi-X)
  - FDA MedWatch report
- Assessed IC procedures at Facility A
- Performed cultures of nasal and throat swabs from personnel involved with procedure

# Index Cases

- Patient 1
  - Woman >80 years of age
  - Right knee osteoarthritis
- Patient 2
  - Man 49 years of age
  - Cerebral palsy
  - Left knee osteoarthritis

# Clinical Presentations

- Intra-articular injection at Facility A on same day in October, 2013
- Joint pain and swelling 24–72 hours after injection
- Hospitalized for surgical debridement
- SA isolates from synovial fluid had same antibiotic-susceptibility profile

# Case Finding

- 7 other patients received similar intra-articular injections
  - Procedures ranged from August, 2013–October, 2013
  - No additional cases identified
- No reports identified through hospital records, Epi-X, MedWatch

# Visit to Facility A

- Single physician clinic
- Open since July 2013
- **Not in compliance with North Carolina requirements for IC**
  - No written IC policy
  - No designated staff member to direct IC activities



Procedure room: Site of injection preparation

# Review of Injection Procedures

- Procedures temporarily suspended
- Step-by-step walk through



Procedure room: Site of injections

# Procedure Description

- Venipuncture
- Blood centrifuged
- Combined autologous PRP
  - Human placental tissue product
  - Other sterile injectable materials (CaCl, thrombin)
- Injection site prepared
- Materials injected into intra-articular space over series of several steps



# Infection Control Observations

- Extensive manipulation of sterile medications in ambient air / non-sterile environment
- Intra-articular space accessed multiple times via previously placed needle
- Face masks used inconsistently



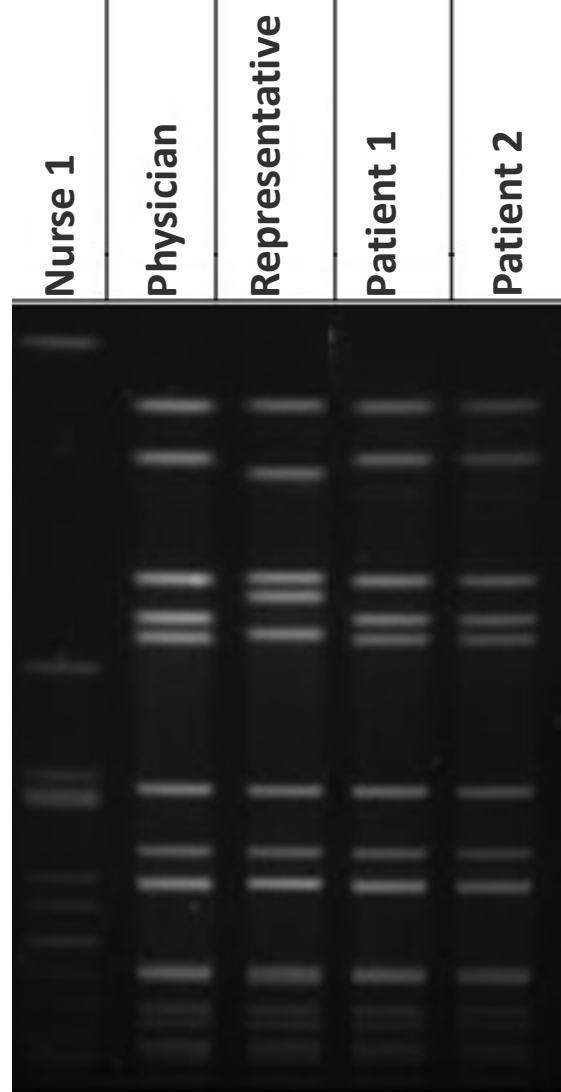
Injection preparation supplies

# Bacterial Culture Results

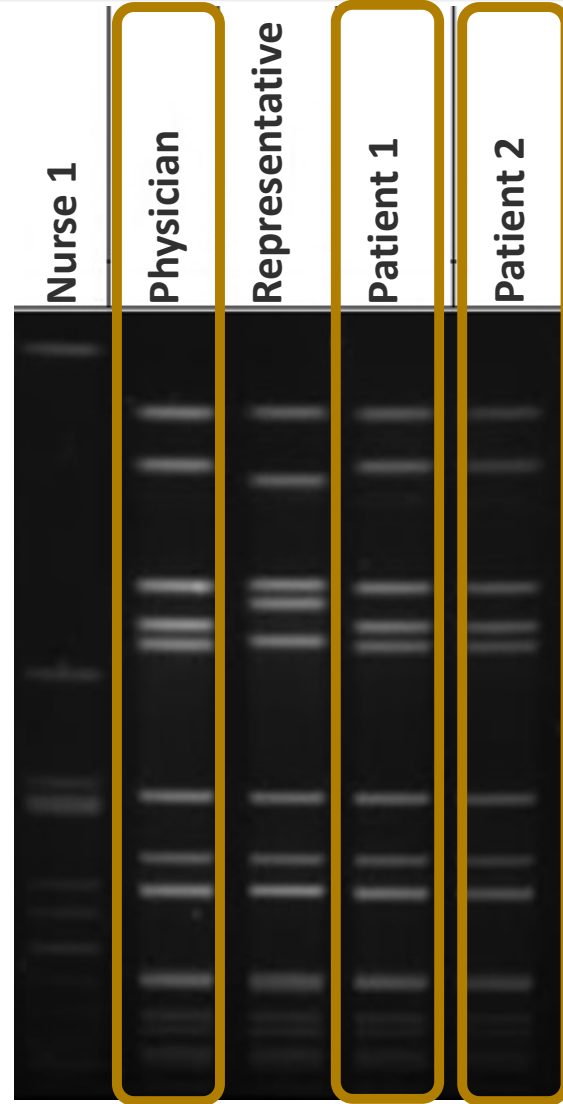
- 4 personnel present during procedures
  - Physician
  - 2 nurses
  - Company representative
- 3 out of 4 had SA throat carriage



# Pulsed-field Gel Electrophoresis (PFGE) Results



# Pulsed-field Gel Electrophoresis (PFGE) Results



# Conclusions

- Cluster of SA septic arthritis resulted from deficiencies in aseptic technique during joint injection procedures
- Allowed for transmission of oral flora from physician to patients



# Limitations

- Direct observation of injection procedure not possible
- Unable to determine whether transmission occurred during preparation or administration
- Unable to discern respiratory droplet versus contact transmission

# Aseptic Technique

- Method used to prevent contamination with microorganisms
- During medication preparation, includes
  - Using new sterile syringe and sterile needle to draw up medications
  - Preventing contact between injection materials and non-sterile environment
  - Performing proper hand hygiene
  - Using designated clean medication area

# Mask Use?

- Routine use of face masks recommended by HICPAC/CDC for
  - Administering epidural/intrathecal injections
  - Placing central venous catheters
- Routine use of face masks for administering injections in an intracapsular space (joints)
  - Not currently recommended by HICPAC/CDC
  - Recommended by APIC in 2016 position paper

# Mask Use?



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## APIC POSITION PAPER: SAFE INJECTION, INFUSION, AND MEDICATION VIAL PRACTICES IN HEALTH CARE (2016)

### ASEPTIC TECHNIQUE

- Aseptic technique refers to the use of various barriers and precautions to prevent the transfer of microorganisms from HCP and the environment to the patient during a procedure.<sup>32</sup> Sterile is the absence of all microbes.
- Perform hand hygiene (clean hands with alcohol based hand sanitizer or with soap and water) before accessing supplies, handling vials and IV solutions, preparing or administering medications, and conducting point-of-care testing (e.g., blood glucose, coagulation studies, etc.).
- Use aseptic technique in all aspects of parenteral medication preparation, administration, medication vial use, injection, and point-of-care testing.
- **Use a mask to contain respiratory droplets when preparing and injecting solution into an intracapsular space (joint), the spine and during lumbar puncture.**<sup>33</sup>

# Discussion

- Careful attention to aseptic technique is needed during
  - Injection procedures
  - Compounding / extensive manipulations of injectable products
- Preparation of injection materials offered opportunity for SA transmission
- Need for increased compliance with state regulations for IC in health care settings





# HONORreform

*An historic 'Never Event':*

*Don't let it happen in your facility!*

Evelyn V McKnight, AuD  
Thomas A McKnight, MD  
[www.HONORreform.org](http://www.HONORreform.org)

# Our story



# But why?



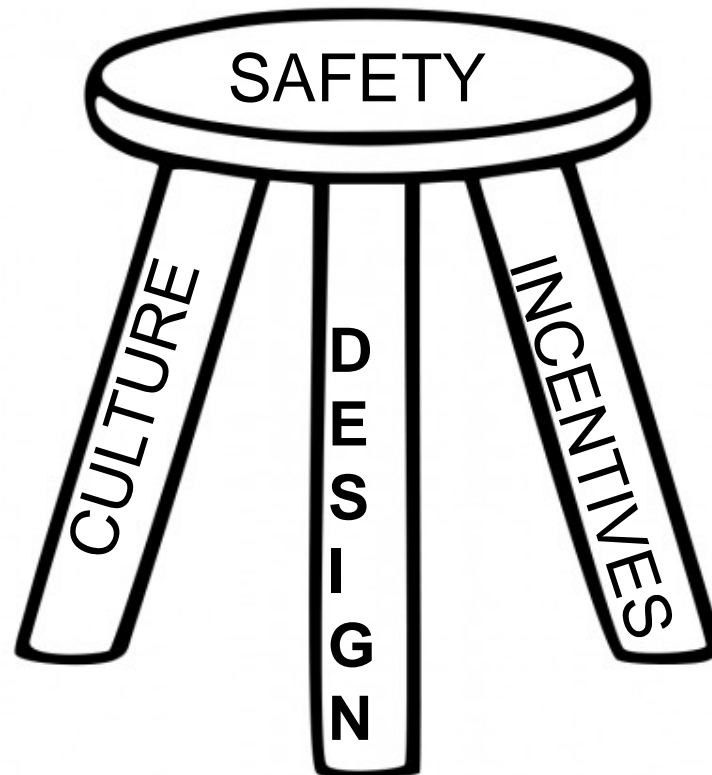
# Major categories of harm in the outbreak



- *Silo Culture*
- *Unsafe Technique*
- *Few Policy Incentives for Safety*



# 3 Legged stool of patient safety



# Silo culture → Safety culture



- *“team behaviors improves safety culture...provides ability to adapt and learn”\**
- *AHRQ’s TeamSTEPPS - Strategies & Tools to Enhance Performance and Patient Safety*  
*“I am **C**oncerned, I am **U**ncomfortable, This is a **S**afety Issue”*

\* Jones, et al., *BMJ Quality & Safety*, 2013;22:394-404.

Unsafe technique → Safety by design



- *mitigate unsafe technique*
- *in US are designed for provider, not patient safety*
- *in developing markets designed for patient safety*

# Few incentives → Safety incentives



- *Sticks - only regulatory oversight is provider licensure for private offices: ASC's have CMS certification*
- *Carrots - Pay for Performance programs such as Physician Quality Reporting System (PQRS)*



# Our thanks



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