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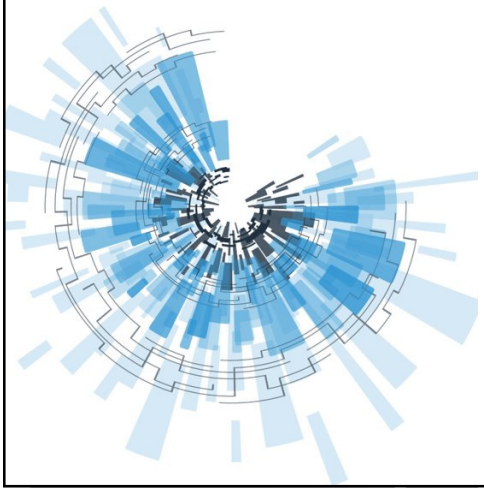
Council for Outbreak Response: Healthcare-Associated Infections Antimicrobial-Resistant Pathogens

How CORHA is Developing Standards on Notification and Disclosure of Clusters and Outbreaks



Marion A. Kainer, MD, MPH| Tennessee Department of Health; CORHA Governance Committee Member
Maureen R. Tierney, MD, MSc| Nebraska DHHS, Division of Public Health; CORHA Policy Workgroup Co-Chair
Joseph F. Perz, DrPH, MA| CDC, Division Healthcare Quality Promotion, CORHA Governance Committee Member

Spring SHEA Meeting
April 24, 2019

Why Discuss This Now?

- Increasing pushes for transparency and disclosure
  - *NYTimes* article April 8, 2019
  - *Reuters* article, December 22, 2016
- PH, ID and Epi Communities have been working on this complicated issue
- CORHA working on developing guidance for communicating on outbreaks with consistency based on principles transparency, right to know, avoidance of harm

Culture of Secrecy Shields Hospitals With Outbreaks of Drug-Resistant Infections

The lack of transparency puts patients at risk, some say. Institutions say disclosure could scare some people away from seeking needed medical care.

How hospitals, nursing homes keep lethal 'superbug' outbreaks secret

By Deborah J. Nelson, David Rohde, Benjamin Lesser and Ryan McNeill | Filed Dec. 22, 2016, 12:30 p.m. GMT

Across the U.S., vague rules give healthcare providers lots of leeway in deciding when, or even whether, to report unusual clusters of infections. And when they do alert officials, that information is usually kept from the public.

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Background

- Outbreaks of infections are a regular occurrence within healthcare facilities
- We lack standards for HAI outbreak patient notification and public disclosure
- Practices vary widely
- Public disclosure is uncommon and often incidental (e.g., stemming from large-scale patient notification or clinic closure)

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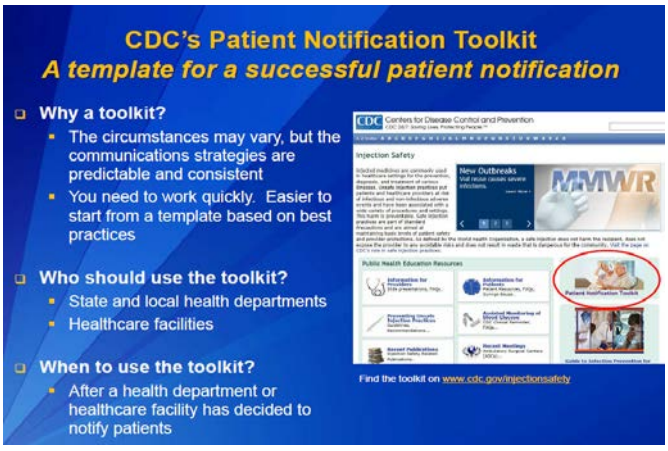
Existing Platform – Bloodborne Pathogen Risks

- Established expectations for triggering patient notification in the context of both
  - hepatitis outbreaks
  - 'category A' infections control breaches (e.g., syringe reuse)
- Recognizes patient's right to know about exposure which might have altered their health status
- Guidance on how to execute



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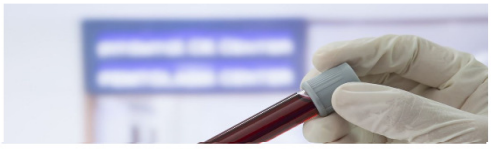
www.nphic.org/Content/Conferences/2013/NCHCMM/Presentations/Brinsley-RainischKristin.pdf

By SOUMYA KARLAMANGLA FEB 26, 2019 | 11:40 AM

Los Angeles Times



Hepatitis C cases prompt officials to urge tests for 500 patients of L.A. clinic

Los Angeles County health officials are investigating why six patients who had procedures at an L.A. clinic were diagnosed with hepatitis C, a liver infection that is spread through infected blood.

Health investigators sent letters to 500 patients of Westside Multispecialty Medical Group asking that they be tested for the disease. Most people who are infected with hepatitis C do not have any symptoms, so testing is the only way to understand the scope of the problem.

Left untreated, people with hepatitis C can go on to develop liver failure and liver cancer.

Health officials are recommending that anyone who received injections, infusions or

https://www.latimes.com/local/california/la-me-ln-hepatitis-la-clinic-20190226-story.html

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Example – Serious Infection Control Breach Reporting Requirement

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-36-ALL
REVISED 10.28.16

DATE: May 30, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Infection Control Breaches Which Warrant Referral to Public Health Authorities
****Additional Information has been added to Breaches to Be Referred. This policy memorandum supersedes policy memorandum S&C: 14-36-ALL*****

Memorandum Summary

- *Infection Control Breaches Warranting Referral to Public Health Authorities:* If State Survey Agencies (SAs) or Accrediting Organizations (AOs) identify any of the breaches of generally accepted infection control standards listed in this memorandum, they *must* refer them *as directed* to appropriate State authorities for public health assessment and management.

- Trigger for Reporting is clearly spelled out
- Includes reuse of injection equipment and breakdowns in reprocessing or sterilization
- Provides opportunity for health department to assess, assist and intervene
- Elevates these practices

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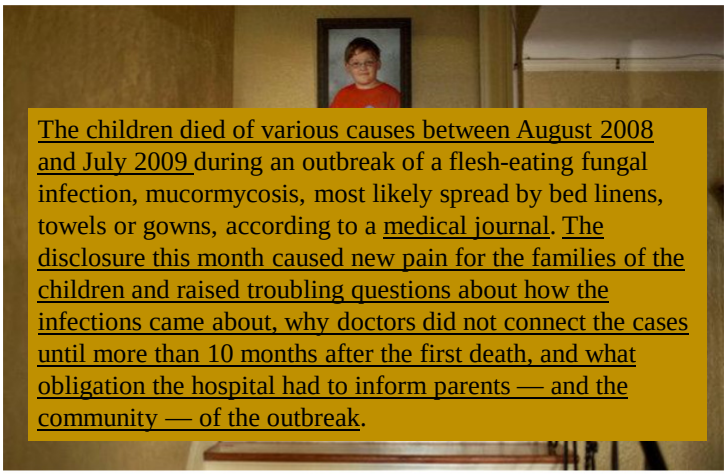
The New York Times

A Deadly Fungus and Questions at a Hospital

April 28, 2014



The children died of various causes between August 2008 and July 2009 during an outbreak of a flesh-eating fungal infection, mucormycosis, most likely spread by bed linens, towels or gowns, according to a medical journal. The disclosure this month caused new pain for the families of the children and raised troubling questions about how the infections came about, why doctors did not connect the cases until more than 10 months after the first death, and what obligation the hospital had to inform parents — and the community — of the outbreak.

A portrait of Zachary Malik Tyler hangs in the home of Stephen Tyler and Dolly Malik. Zachary underwent surgeries after contracting a fungal infection while at Children's Hospital in New Orleans.
Edmund D. Fountain for The New York Times

https://www.nytimes.com/2014/04/29/us/a-deadly-fungus-and-questions-at-a-hospital.html

USUAL SUSPECT: Clostridium difficile, a superbug linked to long-term antibiotic use, often tears through nursing homes in outbreaks like the one that afflicted Casa Maria in Roswell, New Mexico, in 2014. REUTERS/Courtesy of Centers for Disease Control and Prevention (CDC)

How hospitals, nursing homes keep lethal 'superbug' outbreaks secret

By Deborah J. Nelson, David Rohde, Benjamin Lesser and Ryan McNeill |
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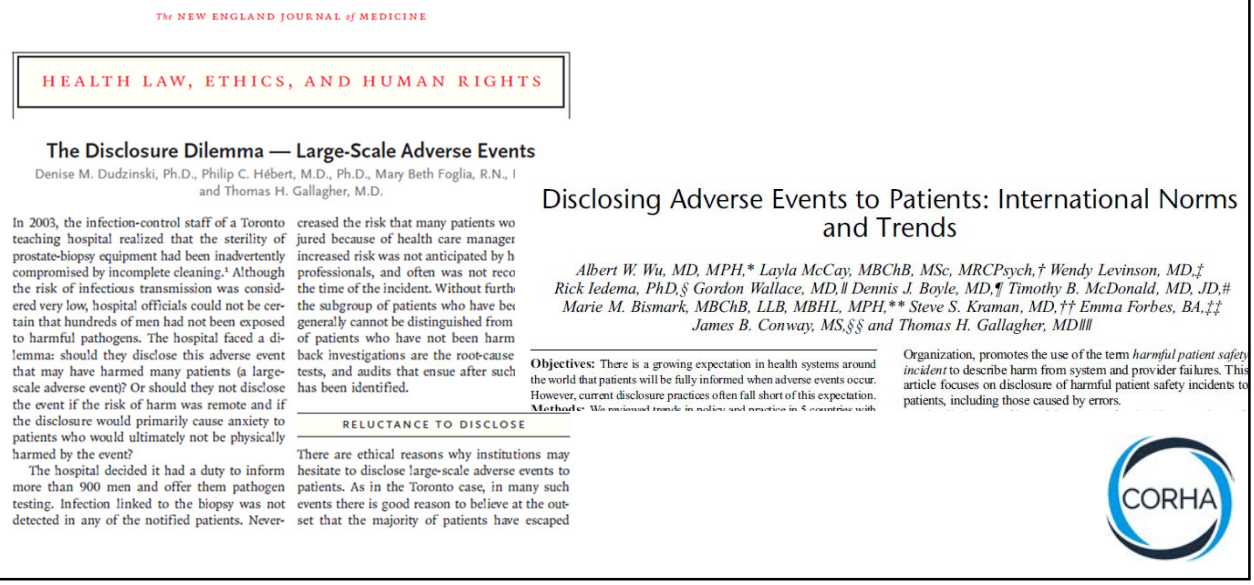
Across the U.S., vague rules give healthcare providers lots of leeway in deciding when, or even whether, to report unusual clusters of infections. And when they do alert officials, that information is usually kept from the public.

https://www.scientificamerican.com/article/how-hospitals-nursing-homes-keep-lethal-superbug-outbreaks-secret/

Increasing Demand for Transparency in Healthcare



The NEW ENGLAND JOURNAL of MEDICINE

HEALTH LAW, ETHICS, AND HUMAN RIGHTS

The Disclosure Dilemma — Large-Scale Adverse Events

Denise M. Dudzinski, Ph.D., Philip C. Hébert, M.D., Ph.D., Mary Beth Foglia, R.N., I and Thomas H. Gallagher, M.D.

In 2003, the infection-control staff of a Toronto teaching hospital realized that the sterility of prostate-biopsy equipment had been inadvertently compromised by incomplete cleaning.[1] Although the risk of infectious transmission was considered very low, hospital officials could not be certain that hundreds of men had not been exposed to harmful pathogens. The hospital faced a dilemma: should they disclose this adverse event that may have harmed many patients (a large-scale adverse event)? Or should they not disclose the event if the risk of harm was remote and if the disclosure would primarily cause anxiety to patients who would ultimately not be physically harmed by the event?

The hospital decided it had a duty to inform more than 900 men and offer them pathogen testing. Infection linked to the biopsy was not detected in any of the notified patients. Never-

creased the risk that many patients wo jured because of health care manager increased risk was not anticipated by h professionals, and often was not reco the time of the incident. Without furth the subgroup of patients who have be generally cannot be distinguished from of patients who have not been harm back investigations are the root-cause tests, and audits that ensue after such has been identified.

RELUCTANCE TO DISCLOSE

There are ethical reasons why institutions may hesitate to disclose large-scale adverse events to patients. As in the Toronto case, in many such events there is good reason to believe at the outset that the majority of patients have escaped

Disclosing Adverse Events to Patients: International Norms and Trends

Albert W. Wu, MD, MPH, Layla McCay, MBChB, MSc, MRCPsych,† Wendy Levinson, MD,‡ Rick Iedema, PhD,§ Gordon Wallace, MD,‖ Dennis J. Boyle, MD,¶ Timothy B. McDonald, MD, JD,# Marie M. Bismark, MBChB, LLB, MBHL, MPH,** Steve S. Kraman, MD,†† Emma Forbes, BA,‡‡ James B. Conway, MS,§§ and Thomas H. Gallagher, MD‖‖*

Objectives: There is a growing expectation in health systems around the world that patients will be fully informed when adverse events occur. However, current disclosure practices often fall short of this expectation.

Organization, promotes the use of the term *harmful patient safety incident* to describe harm from system and provider failures. This article focuses on disclosure of harmful patient safety incidents to patients, including those caused by errors.

Examples of Public Disclosure Policy- Adverse Events

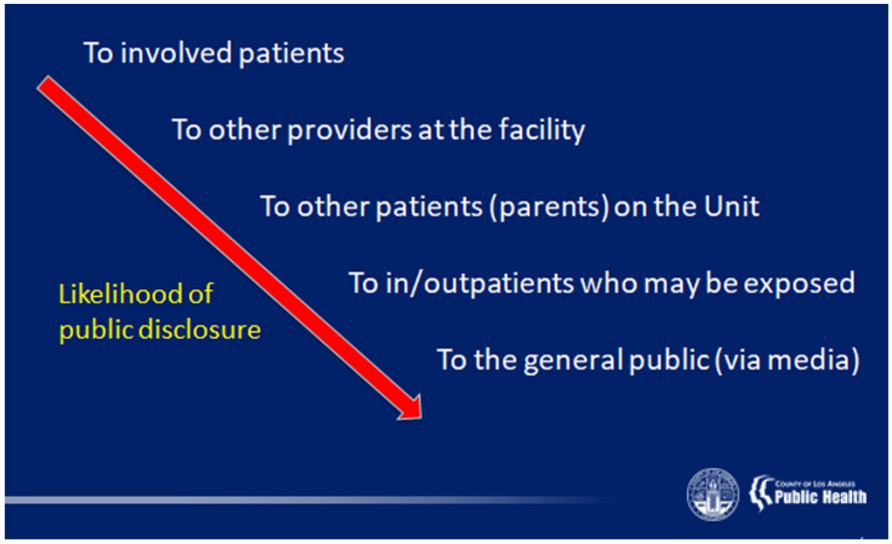
- Veterans Affairs guidelines "to ensure consistent practice in disclosing to patients…the occurrence of adverse events related to the patient's clinical care" (VHA Handbook 1004.08, Disclosure of Adverse Events to Patients, 2012)
- University of Michigan Model
  - Full disclosure of adverse events
  - Based on AHRQ CANDOR Toolkit
  - 5 years post implementation: fewer lawsuits and lower litigation/compensation costs

https://www.uofmhealth.org/michigan-model-medical-malpractice-and-patient-safety-umhs

International Examples -- Australia

- Australian Open Disclosure Framework
  - Developed by Australian Commission on Safety and Quality in Health Care (2013)
  - "Flexible framework designed to be used by health service organisations in all settings and sectors"
  - Open disclosure
    - "A patient and consumer right"
    - "An open discussion with a patient about **an incident(s) that resulted in harm to that patient while they were receiving health care**"

Levels of Notification and Disclosure



Notification and Disclosure are Influenced by Different Perspectives and Principles

- Patients- desire for knowledge if/how they have been harmed or if they are at risk
- Providers/institution- often not comfortable disclosing
- Public health- disease control and containment
- Media-public right to know, tell a story
- Ethical principles

Two Questions

- What is best? (**Utility** – maximize benefits versus risks; and efficiency)
- What is right? (other **Ethical Principles** such as beneficence, autonomy, justice)

Ethical Principles

- **Utility** – maximize benefits and efficiency; acts are right because they promote well-being of individuals and the community
- **Autonomy** – letting individuals make their own choices based on their values and preferences
- **Respect** – transparency and truth telling
- **Beneficence –**moral duty to act in patient's best interest
- **Non-maleficence-**No intentional harm
- **Justice** – equity; also procedural justice: a fair process for making important

Utility of Notifying/Disclosing

- Identify additional outbreak-associated infections
- Facilitate appropriate management & prevention by patients and providers
- Allows patients to make informed choices
- Encourages mutual trust (respect) between patients and the healthcare system
- New or serious threat that is causing widespread concern; counter misinformation
- Informs other facilities of a problem that also may affect them, facilitating preventive action

Disclosure as Warning to Other Facilities

A Pasadena hospital is investigating a suspected outbreak related to the same type of medical scope tied to superbug infections across the country.

Huntington Memorial Hospital said Wednesday it had alerted health authorities about a potential link between patients who have a pseudomonas bacteria and the Olympus Corp. duodenoscopes used to treat them.

> The UCLA outbreak was first reported by The Times in February. A month later, Cedars-Sinai Medical Center in Los Angeles said it had discovered four patients infected from tainted Olympus scopes.

"This may be a more common occurrence that's been going on for years with these scopes," said Dr. James McKinnell, an expert on hospital epidemiology at the L.A. Biomedical Research Institute at Harbor-UCLA Medical Center. "It's sort of opening up Pandora's box as we dig in."

Los Angeles Times

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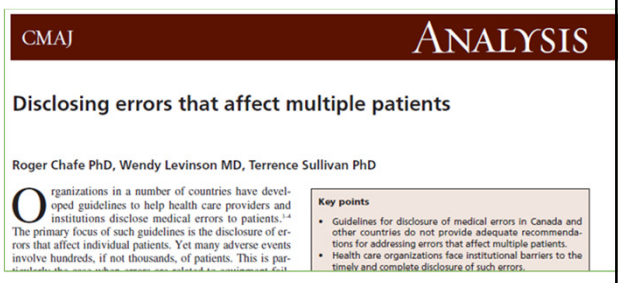
Utility of Not Disclosing (Publicly)

- Patient privacy considerations
- Encourages hospitals to report outbreaks [? vs. already a requirement]
- Avoids controversy when hospital and public health disagree about an outbreak occurring
- Maintains patient trust in the healthcare system [??]
- Avoids "unnecessary" patient concern
- Prevents patients from making "bad" decisions
- Avoids media pressure and inaccuracies



CMAJ ANALYSIS

Disclosing errors that affect multiple patients

Roger Chafe PhD, Wendy Levinson MD, Terrence Sullivan PhD

Organizations in a number of countries have developed guidelines to help health care providers and institutions disclose medical errors to patients.[1-4] The primary focus of such guidelines is the disclosure of errors that affect individual patients. Yet many adverse events involve hundreds, if not thousands, of patients. This is par-

Key points

- Guidelines for disclosure of medical errors in Canada and other countries do not provide adequate recommendations for addressing errors that affect multiple patients.
- Health care organizations face institutional barriers to the timely and complete disclosure of such errors.

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Autonomy and Respect

"Each patient should be given a fair chance to protect himself or herself from exposure to infection and to assume that a hospital is exercising its best efforts on his or her behalf in this area."

--Patient's perspective, letter to LA times 4/22/15

Autonomy: Bioethicists' Perspective

"There are relatively few bioethicists who argue that respect for autonomy is not the preeminent value governing the actions of healthcare providers"

-- Daniel Callahan, Co-founder of the Yale-Hastings Program in Ethics and Health Policy

"[In bioethics, autonomy occupies a place] at the top of the moral mountain."

--Daniel Callahan, Co-founder of the Yale-Hastings Program in Ethics and Health Policy

Beneficence

- All professionals have the foundational moral imperative of doing right. In the context of the professional-client relationship, the professional is obligated to, always and without exception, favor the well-being and interest of the client. (Kinsinger,J Ch Human,2009, 16.)
- What to do when there are competing acts of beneficence based on perspective-individual's best interest versus public best interest (PCP vs PH doc)
- Where does the facility best interest stand-ability to continue to provide care while avoiding spreading risk

Justice as an Ethical Principle Related to Disclosure

- **Justice**
  1) equity: treating like situations alike
  2) procedural justice: a fair process for making important decisions – may include transparency, community engagement, inclusiveness, accountability.
- **The Principle of Justice in Healthcare**

Justice in health care is usually defined as a form of fairness, or as Aristotle once said, "giving to each that which is his due."…… that some goods and services are in short supply, there is not enough to go around, thus some fair means of allocating scarce resources must be determined (TR McCormick Ethics In Medicine, U of Wash School of Medicine 2013.)

Council for Outbreak Response: Healthcare-Associated Infections and Antimicrobial Resistance (CORHA) Background and Overview

Despite significant progress, patients still experience preventable harms in the context of outbreaks and other adverse events that stem from emerging infectious diseases with potential for healthcare transmission, unsafe healthcare practices, contaminated drugs, and medical devices

CDC's Division of Healthcare Quality Promotion funded the Association of State and Territorial Health Officials (ASTHO) and the Council of State and Territorial Epidemiologists (CSTE) to co-lead the Council for Outbreak Response: HAI/AR (CORHA)

Mission

To **improve practices and policies** at the local, state and national levels for **detection, investigation, control and prevention of HAI/AR outbreaks across the healthcare continuum**, including emerging infections and other risks with potential for healthcare transmission.

Vision

Public health and healthcare collaborating effectively to **protect patients and prevent harms from HAI/AR outbreaks**.

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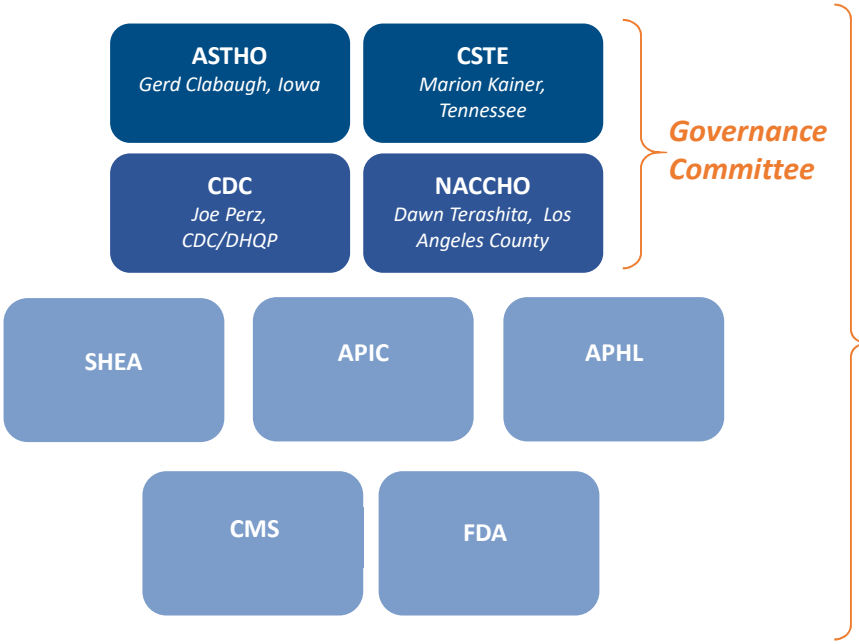
CORHA Structure



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CORHA Product Offerings

- **Suite of condition- or event-specific reference tools including…**
- **High-level guidance related to strategic objectives**
  - E.g., Best practices for improve detection of potential outbreaks using existing data sources
  - E.g., Laboratory best practices to support outbreak detection and investigations
  - E.g., Suggestions for improving data management for outbreak investigation and response activity tracking
  - E.g., Best practice guidance on patient notification and public disclosure regarding healthcare facility clusters and outbreaks

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CORHA Workgroup Framework

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CORHA Policy Workgroup

Charge: To address the legal, ethical and policy considerations related to HAI outbreaks, including those caused by AR pathogens, and make recommendations to policy makers at all levels to improve the detection, reporting, investigation, control and prevention of HAI/AR outbreaks. Policy Workgroup members will conduct activities to:

1. Improve policy and legal standards for reporting, investigation, notification and disclosure of HAI/AR outbreaks and exposure events.
2. Explore options to enhance legal authority and policy options to support best practices.

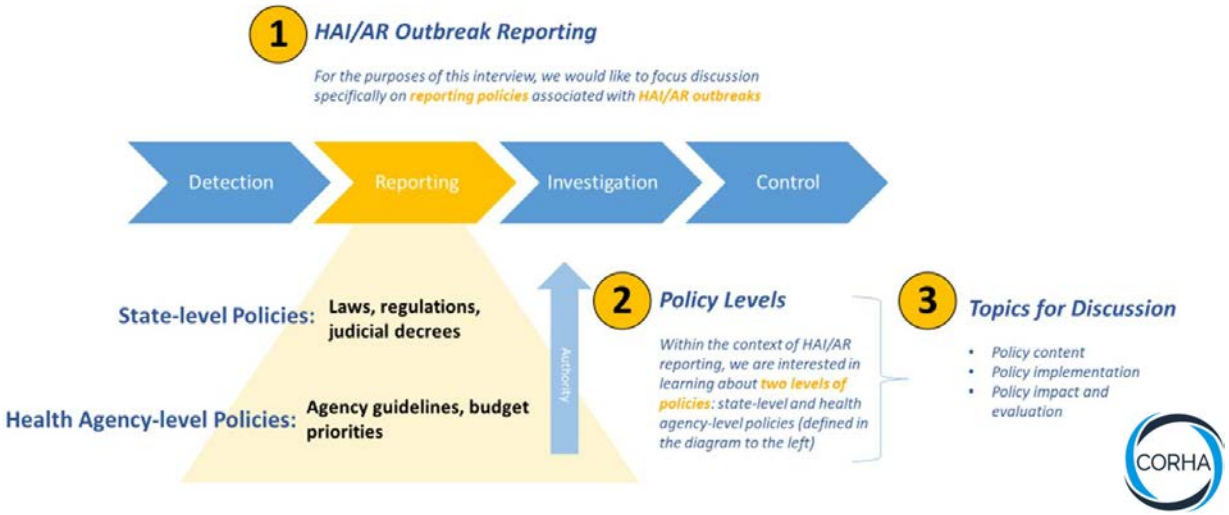
CORHA Policy Workgroup

- Launched Fall 2018
- Policy Workgroup membership include, or soon plans to include representation from the following perspectives:
- Legal counsel, Patient advocates, Healthcare epidemiologists, Public health professionals, Ethicists, Journalists/Reporters, Pathogen-specific experts
- Workgroup builds off earlier CORHA efforts to evaluate HAI reporting practices

The Process

- Review what has been done in policy as discussed above **plus**
  - Washington state
  - ASTHO
- Review legal process
- Seek guidance of experts
- Create a framework
  - For immediate notification in a small or at the beginning of an outbreak
  - For notification with an expanded outbreak
  - For public disclosure
- Involve ethicists
- Involve journalists

ASTHO-led Evaluation of State HAI/AR Outbreak Reporting Policies and Practices



Legal Scan of HAI Outbreak Reporting Laws

- HAI outbreak reporting requirements differ by state, and reporting HAI outbreaks to PH influenced by state statutes, administrative codes, and internal HD policies.
- From 2017 to 2018, a Policy Analyst from CDC's Division of Healthcare Quality Promotion conducted a legal scan on state laws requiring outbreak reporting from healthcare facilities to state and local health departments.
- Reporting requirements that used similar terms to outbreak such as "cluster," "epidemic," and "unusual occurrence" were also included.
- Most states have a requirement in their disease reporting regulations to report outbreaks
  - Most states have a very broad requirement, like Oklahoma:
    - Why its broad- you can see, "outbreak" isn't defined
  - Some states make it clear that HAI outbreaks are required to be reported
    - Tennessee, Nebraska
    - North Dakota: 42. Nosocomial outbreaks in institutions.
  - Some states define what an "outbreak" or "cluster" is- giving the facilities guidance on reporting

Guiding Principles for HAI Outbreak Notification and Disclosure-COHRA Policy Workgroup

1. Notification of harm
2. Duty to warn
3. Assessment of risk
4. Need to know
5. Good epidemiology
6. Timeliness
7. Risk benefit
8. Decisions based on science and when science is lacking, expert opinion and judgment
9. Notification and disclosure are not punitive

Other Considerations in Developing Guidance

- Notification versus disclosure:
  - Notification: informing patients and providers who are or may be affected
  - Disclosure: informing the public more broadly
- Engage hospitals in the process
- Importance of education with both notification and disclosure (patients, public, press)
- Be comfortable considering ethical issues

Guiding Principles: Immediate and Expanded Notification, and Public Disclosure of HAI Outbreaks

❑ Who to Notify	❑ Who has been infected
❑ When to Notify	❑ Who has been exposed
❑ How to Notify	❑ Who has been potentially exposed
❑ What to Notify	❑ Who is at risk for future exposure
❑ Why to Notify or Justification	

**HAI outbreak notification and disclosure is not punitive*

Where are we in the process

Framework for Immediate Notification close to complete

Framework for Expanded Notification in process

Framework for public disclosure-being developed

Involving ethicists and journalists-in the near future

Obtaining your input today and in the coming weeks

CORHA – Summary

- The Council is **evolving** and aims to provide a **practical forum** for the healthcare community, consumers, public health authorities, and professional associations to address the challenges of HAI/AR outbreak response
- Largely dependent on in-kind contributions (thanks)
- Engage with us:
  - Website: www.corha.org
  - SHEA and other CORHA Member Organizations can provide path to workgroup participation

Thank You

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Disclosure of Commercial Entities

"CDC has a long-standing practice of regularly disclosing names of commercial entities implicated in infectious disease outbreaks in order to protect public health. These disclosures have helped the public reduce their health risks and have helped commercial entities improve the safety of their practices and products. As each situation is unique, it is important that CDC programs evaluate whether to identify an implicated entity on a case-by-case basis working in partnership with affected states and other partners."

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

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CORHA Product Offerings

- **Suite of condition- or event-specific reference tools**
  - Threshold for reporting and investigation
  - Suggestions on how to improve reporting
  - Suggestions on how to improve the use of existing surveillance data for detection
  - Tools for investigation
  - Suggestions for standardized control measures
- **Completed prototype for Scabies**
- **Other examples in pipeline include *C. auris*, CRE, CDI, NTM**