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

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Why Discuss This Now?

• Increasing pushes for transparency and disclosure
  
  NYT 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
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)

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

www.nphic.org/Content/Conferences/2013/NCHCMM/Presentations/Brinsley-RainischKristin.pdf
Example – Serious Infection Control Breach Reporting Requirement

- 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
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.


How hospitals, nursing homes keep lethal ‘superbug’ outbreaks secret

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.

Increasing Demand for Transparency in Healthcare

The Disclosure Dilemma — Large-Scale Adverse Events

Disclosing Adverse Events to Patients: International Norms and Trends

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
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

To involved patients
To other providers at the facility
To other patients (parents) on the Unit
To in/outpatients who may be exposed
To the general public (via media)

Likelihood of public 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 decisions

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

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
**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

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**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
Benficence

• 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.

**CORHA Structure**

- **ASTHO**
  - Gerd Clabaugh, Iowa
- **CSTE**
  - Marion Kainer, Tennessee
- **CDC**
  - Joe Perz, CDC/DHQp
- **NACCHO**
  - Dawn Terasnita, Los Angeles County
- **SHEA**
- **APIC**
- **APHL**
- **CMS**
- **FDA**

**Governance Committee**

**Member Organizations**
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

CORHA Workgroup Framework

- Detection and Reporting Workgroup
  - Standardize Outbreak & Adverse Event Definitions & Thresholds for Reporting
  - Improve Reporting of Outbreaks and Exposure Events to Public Health
  - Improve the Use of Existing Surveillance Systems to Detect Outbreaks

- Investigation and Control Workgroup
  - Define Appropriate Levels of Response
  - Improve Response to Outbreaks
  - Improve Data Management for Outbreak Investigation and Tracking

- Original Workgroups

- Define Public Health, Clinical, and Commercial Laboratory Best Practices to Support Outbreak Detection and Response
- Explore Ethical and Regulatory Legal Authority to Support Best Practices

Develop Tools and Guidance
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

1 HAI/AR Outbreak Reporting
   For the purposes of this interview, we would like to focus discussion specifically on reporting policies associated with HAI/AR outbreaks

2 Policy Levels
   Within the context of HAI/AR reporting, we are interested in learning about two levels of policies: state-level and health agency-level policies (defined in the diagram to the left)

3 Topics for Discussion
   • Policy content
   • Policy implementation
   • Policy impact and evaluation
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
- When to Notify
- How to Notify
- What to Notify
- Why to Notify or Justification

- Who has been infected
- Who has been exposed
- Who has been potentially exposed
- Who is at risk for future exposure

*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

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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](http://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.”
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