Patient Notification of Infection Control Breaches and HAI Outbreaks

Kiran Perkins, MD, MPH
CDR United States Public Health Service
Lead, Response Team
Division of Healthcare Quality Promotion (DHQP)
Centers for Disease Control and Prevention

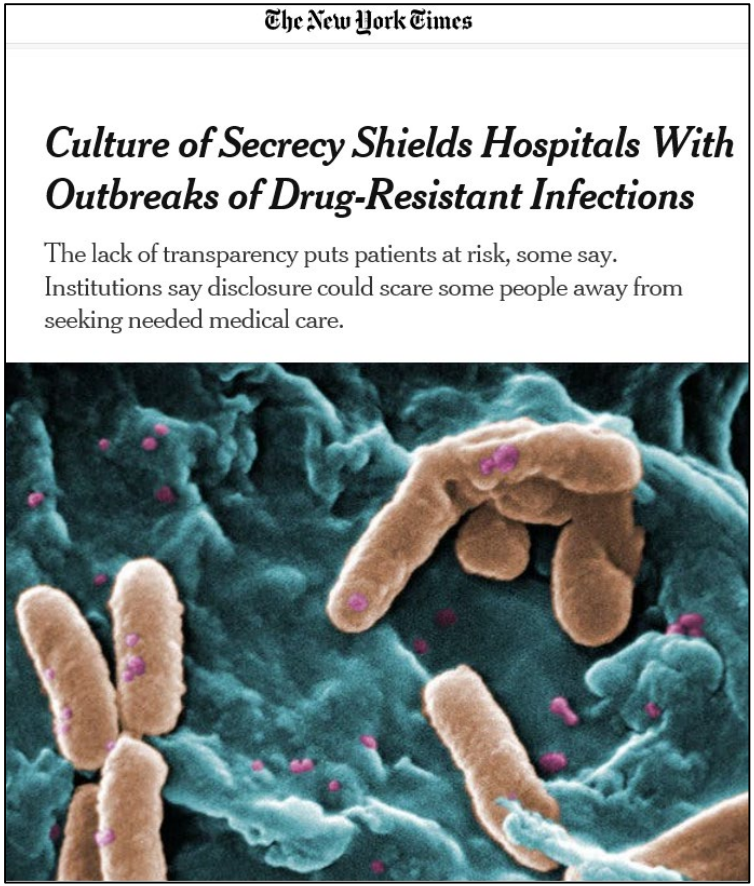
2019 Texas DSHS Healthcare Safety Conference
"Protection Through Prevention"

August 29, 2019

I have no financial disclosures.

Why Discuss this Now?

- Public health and healthcare facilities have been working on this complicated issue
- Increasing push for transparency and disclosure

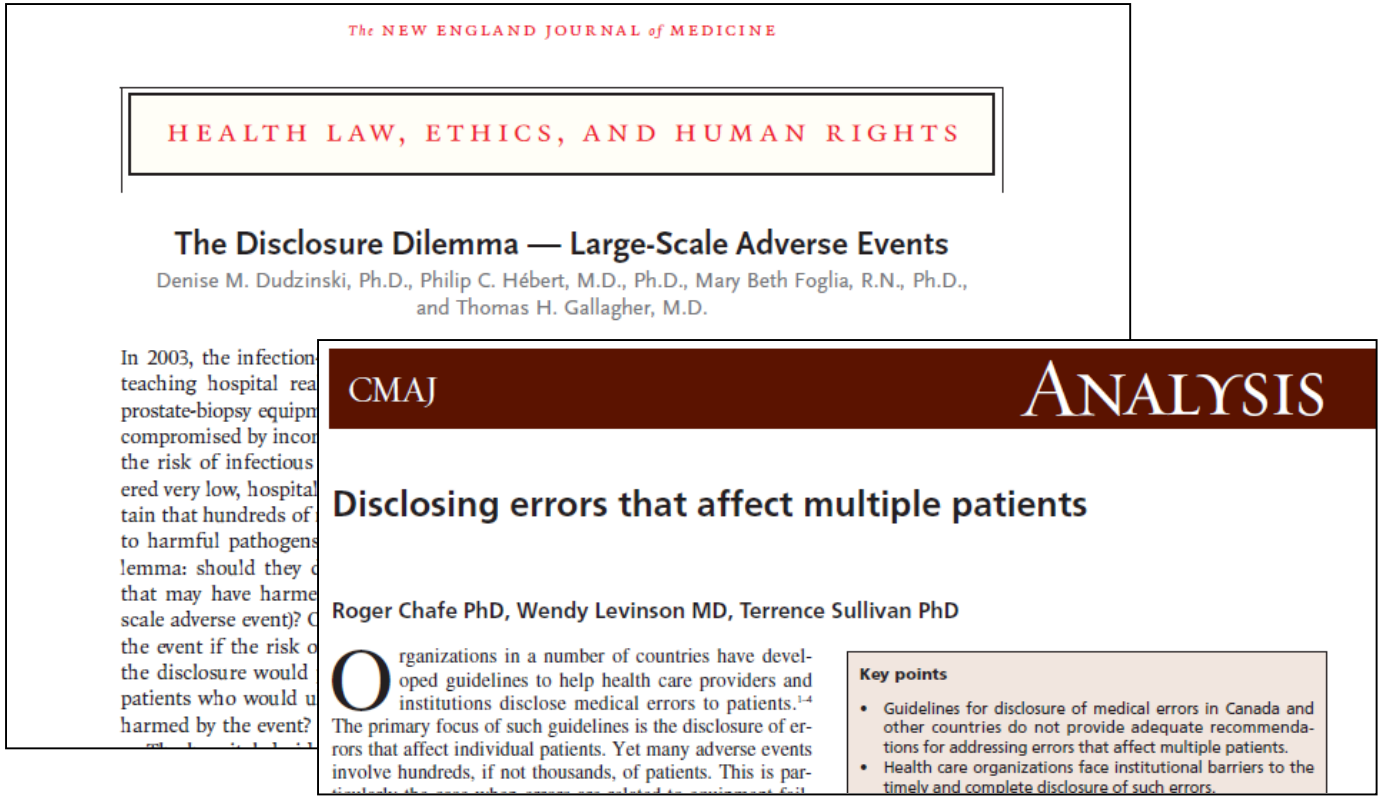


The New York Times

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.

Increasing Demand for Transparency



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., Ph.D., and Thomas H. Gallagher, M.D.

In 2003, the infection-
teaching hospital rea
prostate-biopsy equipn
compromised by incor
the risk of infectious
ered very low, hospital
tain that hundreds of
to harmful pathogens
lemma: should they c
that may have harme
scale adverse event)? C
the event if the risk o
the disclosure would
patients who would u
harmed by the event?

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.

Patient Notification vs. Disclosure

Patient notification

informing patients and providers who are or may be affected

Disclosure

informing the public more broadly

Patient Notification vs. Disclosure

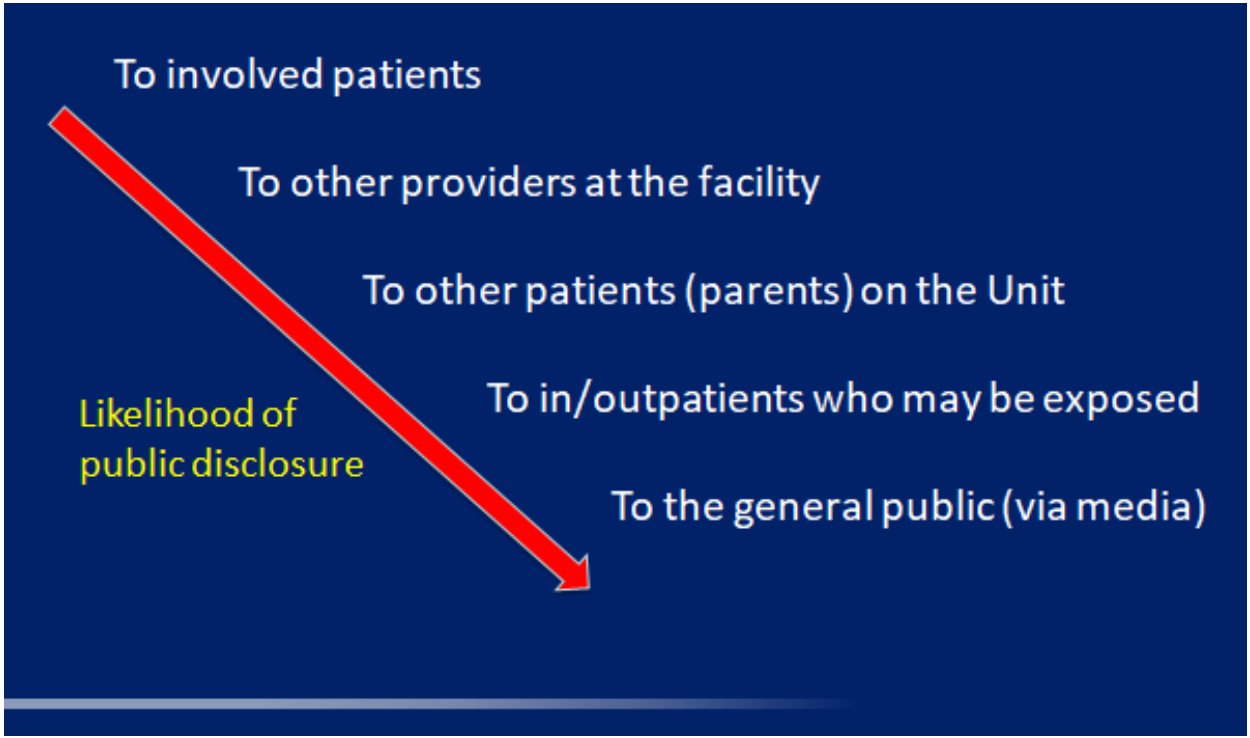
Patient notification

informing patients and providers who are or may be affected

Disclosure

informing the public more broadly

Levels of Patient Notification and Disclosure

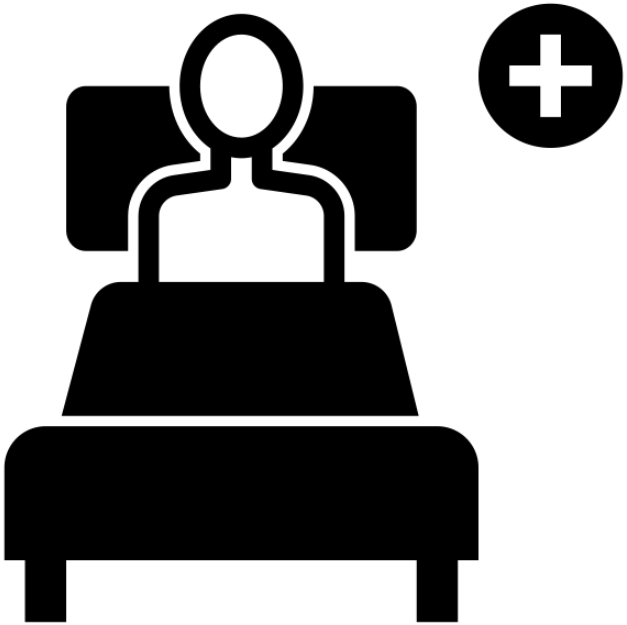


Courtesy of Los Angeles County Public Health

Patient Notification Challenges

- Limited available information
- No standards for patient notification
- Practices vary widely
- Available resources to conduct a patient notification may be limited
- Priorities and preferences of patients, healthcare providers, facilities, and public health may vary

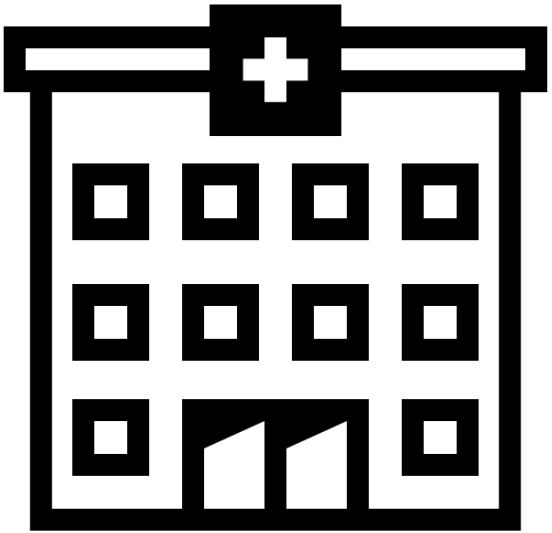
Decisions around Patient Notification Influenced by Different Perspectives



PATIENTS

Desire for knowledge if they have been harmed or if they are at risk

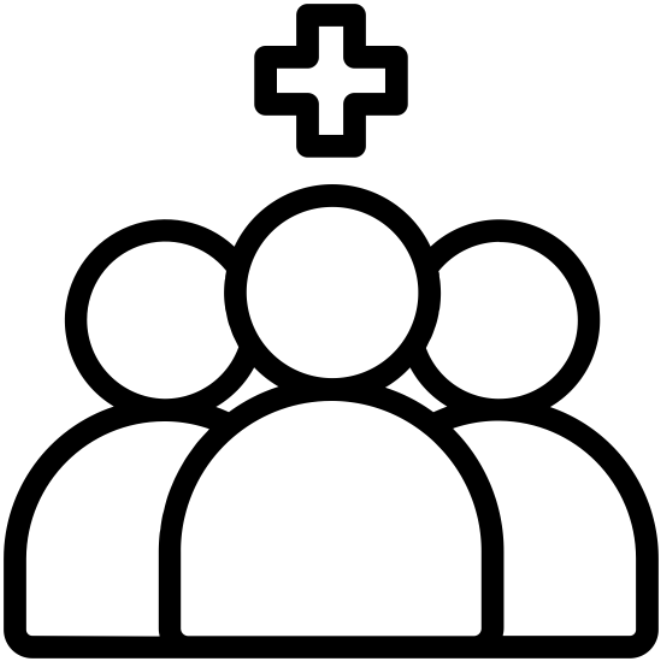
Decisions around Patient Notification Influenced by Different Perspectives



HEALTHCARE PROVIDER OR HEALTHCARE FACILITY

Not comfortable disclosing or fear reputational damage

Decisions around Patient Notification Influenced by Different Perspectives



PUBLIC HEALTH

Importance of disease control and containment

Decisions around Patient Notification Influenced by Different Perspectives

MEDIA

Public has a right to know and want to tell a story

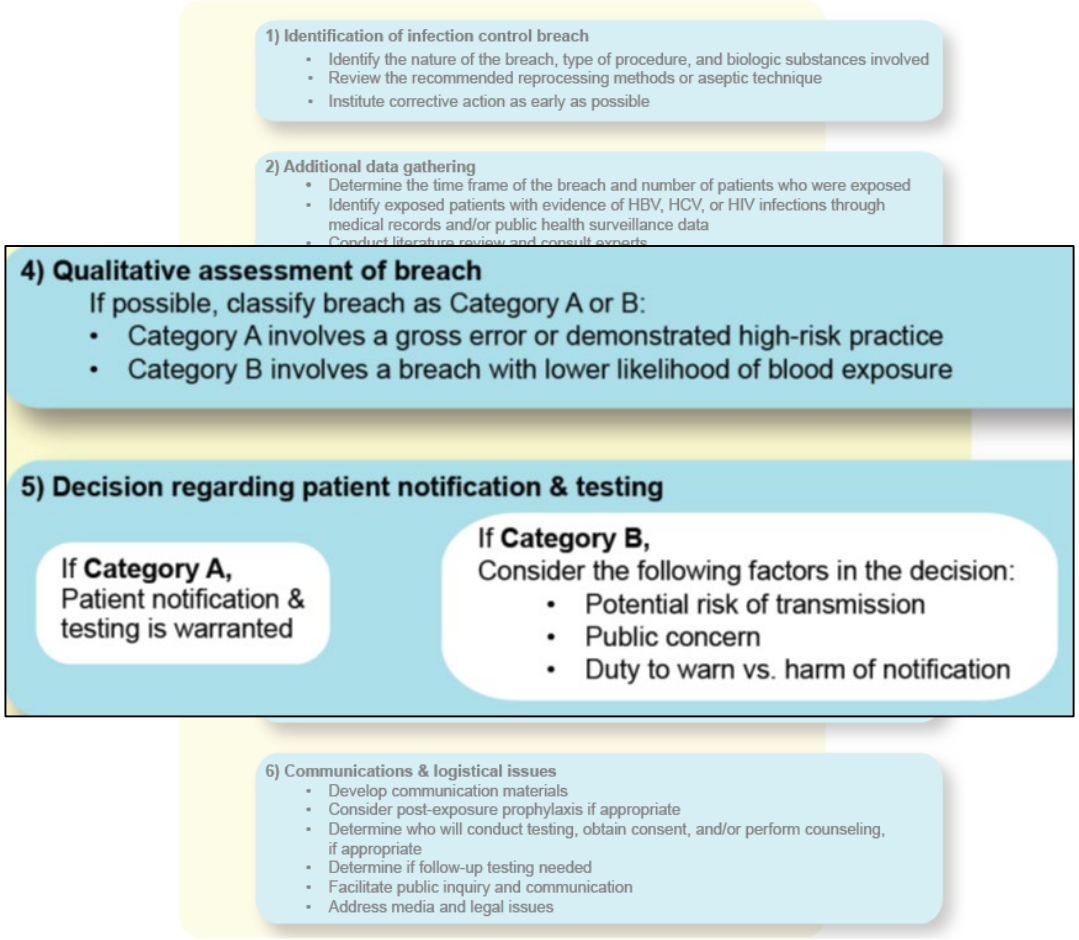
AJIC commentary

Developing a broader approach to management of infection control breaches in health care settings

Priti R. Patel, MD, MPH,[a] Arjun Srinivasan, MD,[a] and Joseph F. Perz, DrPH, MA[a,b]
Atlanta, Georgia

Our experiences with health departments and health care facilities suggest that questions surrounding instrument reprocessing errors and other infection control breaches are becoming increasingly common. We describe an approach to management of these incidents that focuses on risk of bloodborne pathogen transmission and the role of public health and other stakeholders to inform patient notification and testing decisions. (Am J Infect Control 2008;36:685-90.)

Figure 1. Approach to an infection control breach with potential risk of bloodborne pathogen transmission*

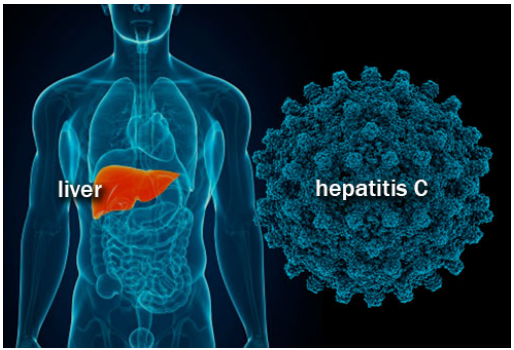


Category A Breaches

- Reuse of needles or syringes between patients
- Reuse of contaminated syringes to access multidose medication vials or intravenous fluid bags
- Reuse of fingerstick devices or glucometers between patients

Healthcare-Associated Hepatitis B and C Outbreaks Reported to CDC, 2008 - 2017

- 60 outbreaks
- 95% occurred in non-hospital settings
- Hepatitis B
  - 24 outbreaks
  - 179 patient infections
  - >10,935 persons notified for screening
  - 83% associated with assisted monitoring of blood glucose
- Hepatitis C
  - 37 outbreaks
  - >290 patient infections
  - >105,048 persons notified for screening



Category B Breaches

- Reprocessing of medical equipment, such as endoscopes, with incorrect disinfectant solutions or those performed with a shorter duration than recommended by the manufacturer

- Reprocessing and reuse of biopsy needles that were intended for single use

Limitations of Current Framework to Assessing Need for Patient Notification

- Limited to bloodborne pathogen transmission
- Relies on history of documented transmission
- Heterogeneity of errors in Category B
- No standard established for outbreak investigations

Three Guiding Ethical Principles to an Expanded Framework

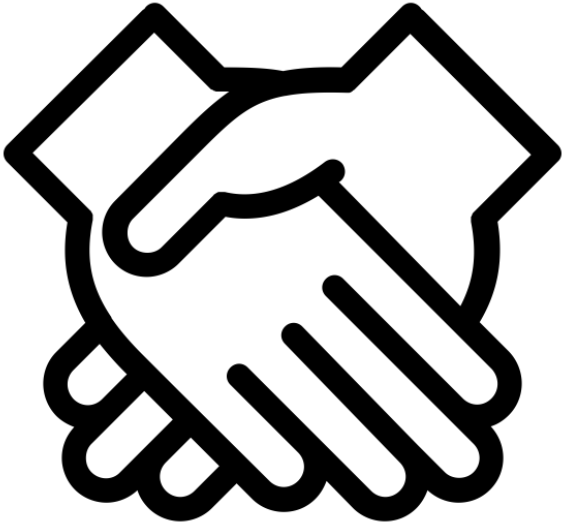
- Transparency
- Beneficence
- Autonomy

Three Guiding Ethical Principles

Transparency

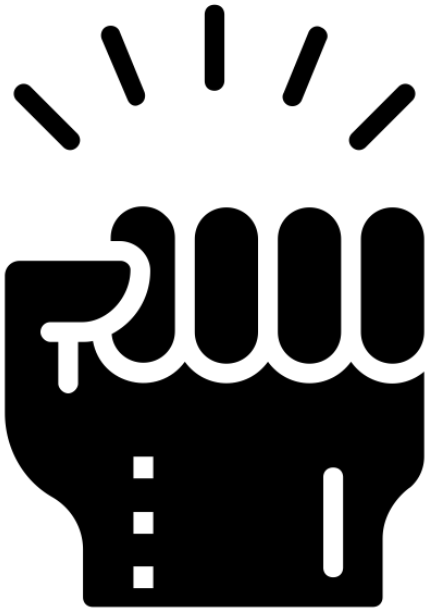
Three Guiding Ethical Principles

Beneficence



Three Guiding Ethical Principles

Autonomy



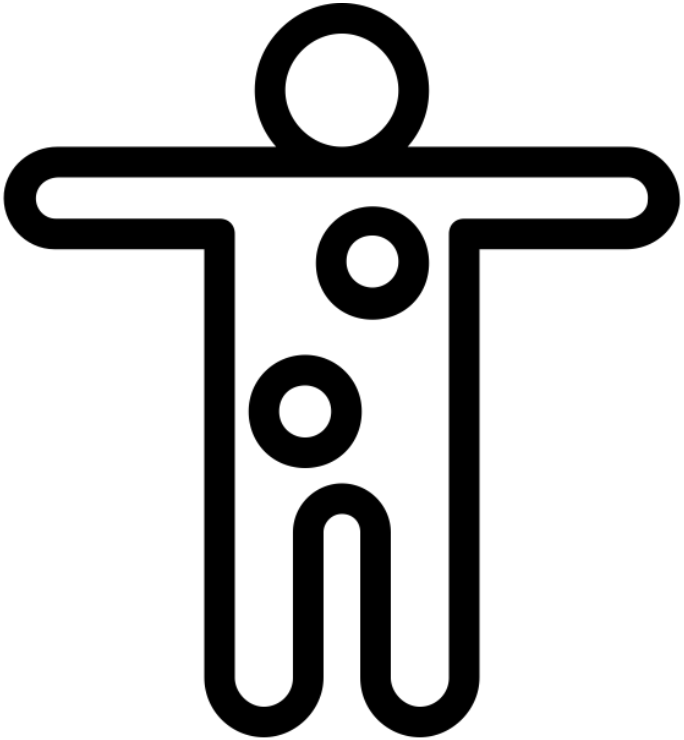
Triggers for Performing Patient Notification

1. Patients experienced harm
2. Patients require information to identify and/or mitigate a potential harm
3. Patients experience an alteration in care

1. Patients experienced harm

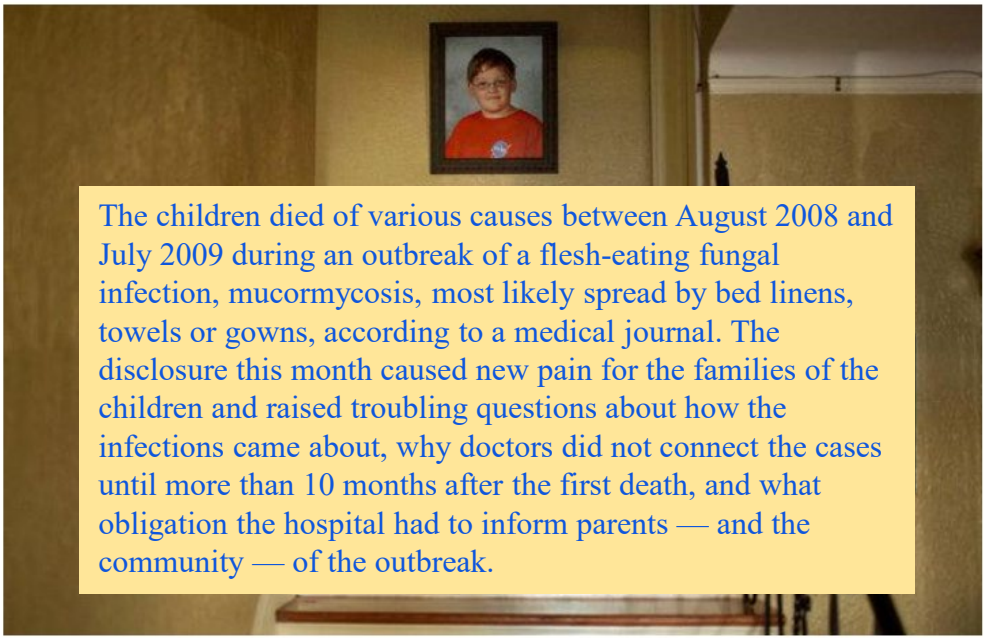
- Should be told how the harm or change to their healthcare status occurred

- "Harm"
  - Developing an infection
  - Becoming colonized with an emerging, highly AR pathogen



The New York Times

A Deadly Fungus and Questions at a Hospital



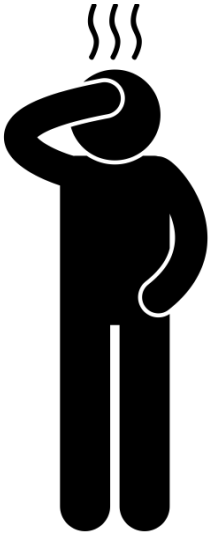
The children died of various causes between August 2008 and July 2009 during an outbreak of a flesh-eating fungal infection, mucormycosis, most likely spread by bed linens, towels or gowns, according to a medical journal. The disclosure this month caused new pain for the families of the children and 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

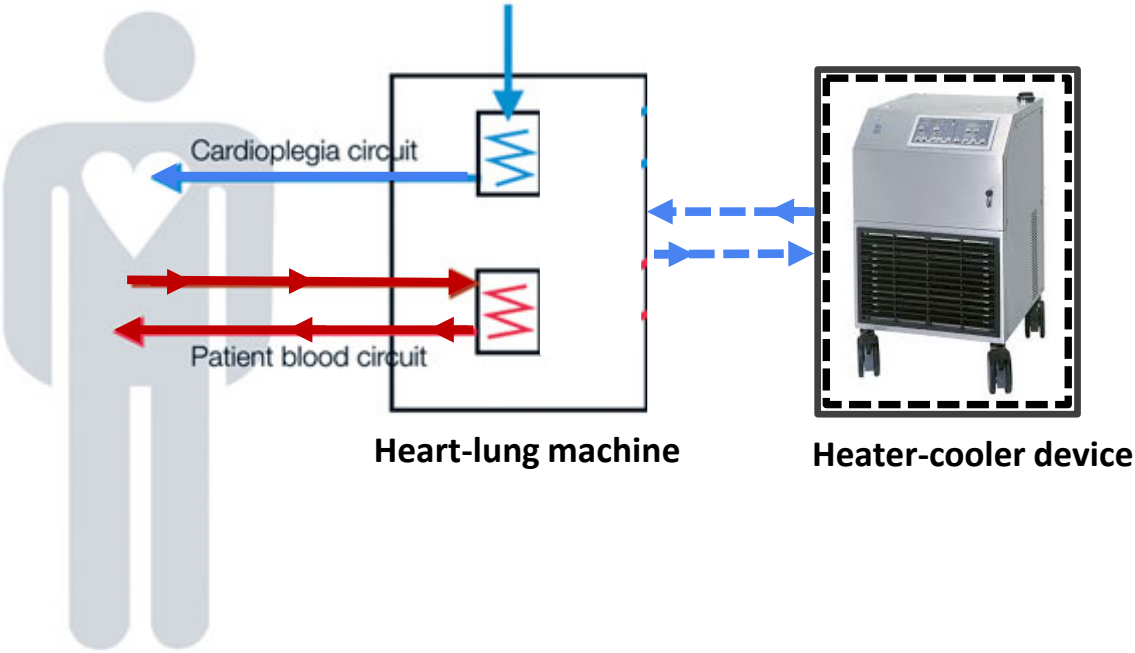
2. Patients require information to identify and/or mitigate a potential harm

- Patients potentially affected by an outbreak or IC beach should be informed
  - Need to be aware of signs/symptoms of infection



Heater-cooler Device

Cardiopulmonary Bypass



http://www.fda.gov/medicaldevices/productsandmedicalprocedures/cardiovasculardevices/heater-coolerdevices/default.htm

Courtesy of Meghan Lyman, MD

CDC Advises Patient Notification

HAN
HEALTH ALERT NETWORK
Distributed via the CDC Health Alert Network
October 13, 2016, 13:00 ET (1:00 PM ET)
CDCHAN-00397

This is an official CDC HEALTH ADVISORY

Summary

The Centers for Disease Control and Prevention (CDC) is advising hospitals to notify patients who underwent open-heart (open-chest) surgery involving a Stöckert 3T heater-cooler that the device was potentially contaminated, possibly putting patients at risk for a life threatening infection. New information indicates that these devices, manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH), were likely contaminated with the rare bacteria

Q.How far back in time should hospitals go to notify patients?

A. Hospitals should consider notifying patients **in writing** if they were exposed to the Stöckert 3T devices during open-chest cardiac surgery at their institution since **January 1, 2012**. Hospitals that did not use the Stöckert 3T device during this entire time period should adjust the patient notification timeframe accordingly.

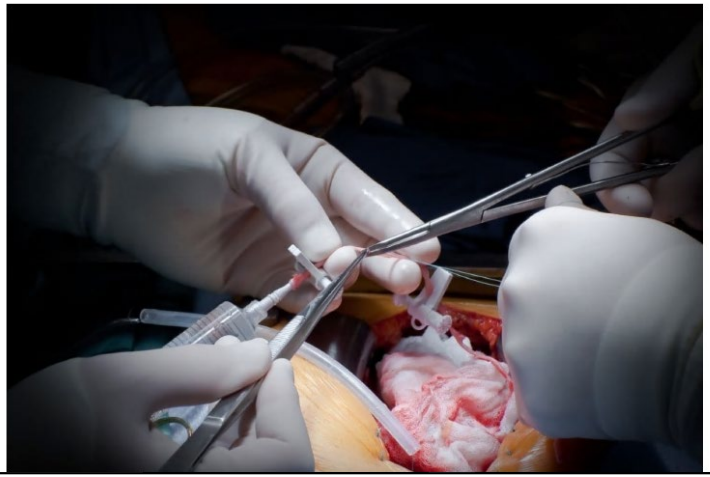
~ 600,000 patients

Cardiac Surgery and Fatal Bacterial Infections

To Your Health

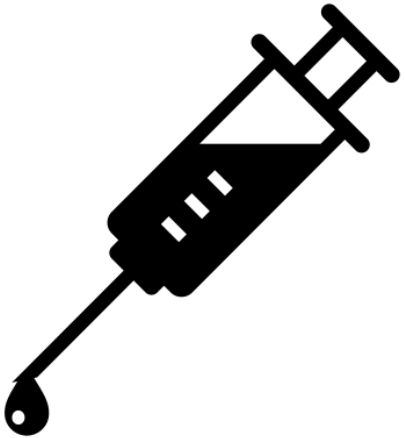
More than half a million heart surgery patients at risk of deadly infection

By Lena H. Sun October 13, 2016 Email the author



2. Patients require information to identify and/or mitigate a potential harm

- Patients potentially affected by an outbreak or IC beach should be informed
  - Need to have opportunity to be tested (e.g. bloodborne pathogens)



HEALTH

Over 3,000 Patients May Have Been Exposed To Hepatitis, HIV At A Surgery Center In New Jersey

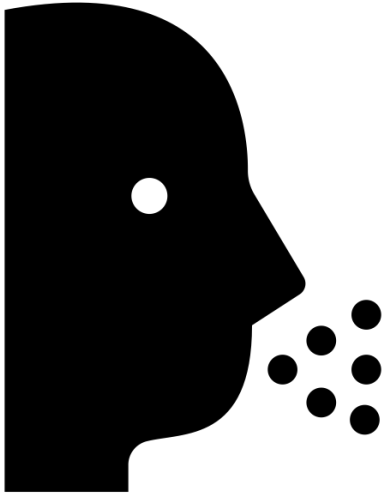
Thousands of patients are being urged to get tested after the surgery center was found to have unsanitary conditions.

Caroline Kee
BuzzFeed News Reporter

Posted on December 26, 2018, at 1:55 p.m. ET

2. Patients require information to identify and/or mitigate a potential harm

- Patients potentially affected by an outbreak or IC beach should be informed
  - Need to know of any actions needed to protect others



2. Patients require information to identify and/or mitigate a potential harm

- Important for case-finding

2. Patients require information to identify and/or mitigate a potential harm

- Patients potentially affected by an outbreak or IC beach should be informed
  - Need to be aware of signs/symptoms of infection
  - Need to have opportunity to be tested (e.g. bloodborne pathogens)
  - Need to know of any actions needed to protect others

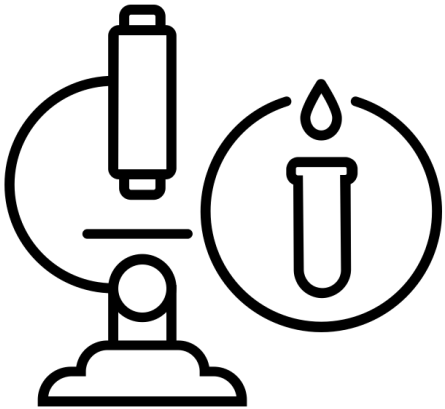
- Important for case-finding

3. Patients experience an alteration in care

- Inform patients of changes in their care:

3. Patients experience an alteration in care

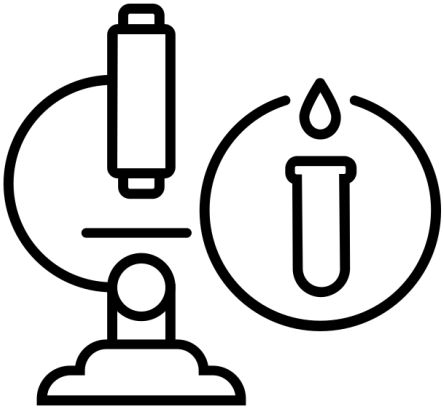
- Inform patients of changes in their care:



Additional diagnostic tests

3. Patients experience an alteration in care

- Inform patients of changes in their care:

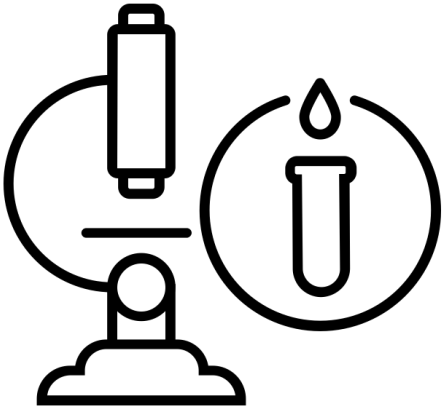


Additional diagnostic tests

Additional antibiotics

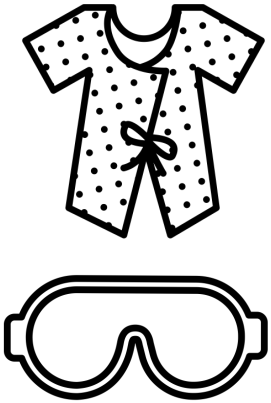
3. Patients experience an alteration in care

- Inform patients of changes in their care:



Additional diagnostic tests

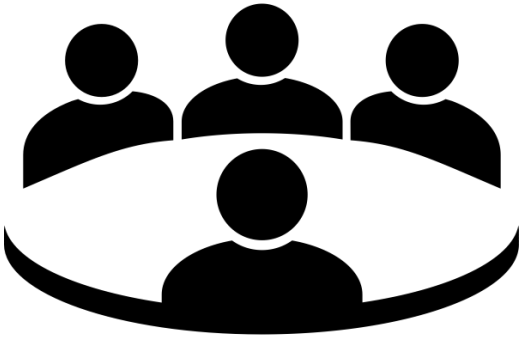
Additional antibiotics



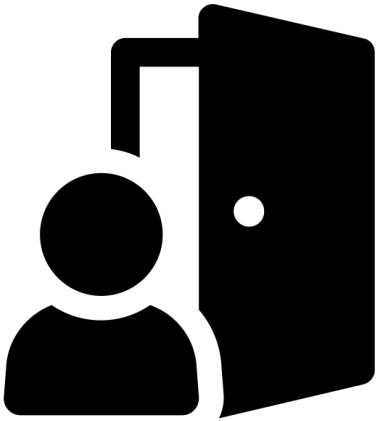
Additional infection control precautions

3. Patients experience an alteration in care

- May affect others



Restriction of group activities



Visitor restrictions

Triggers for Performing Patient Notification

1. Patients experienced harm
2. Patients require information to identify and/or mitigate a potential harm
3. Patients experience an alteration in care

Patient Notification Scenarios

Notes from the Field

Hepatitis C Transmission from Inappropriate Reuse of Saline Flush Syringes for Multiple Patients in an Acute Care General Hospital — Texas, 2015

Sandi Arnold[1]; Sharon K. Melville, MD[2]; Bonnie Morehead, MPH[2]; Gilberto Vaughan, PhD[3]; Anne Moorman, MPH[3]; Matthew B. Crist, MD[4]

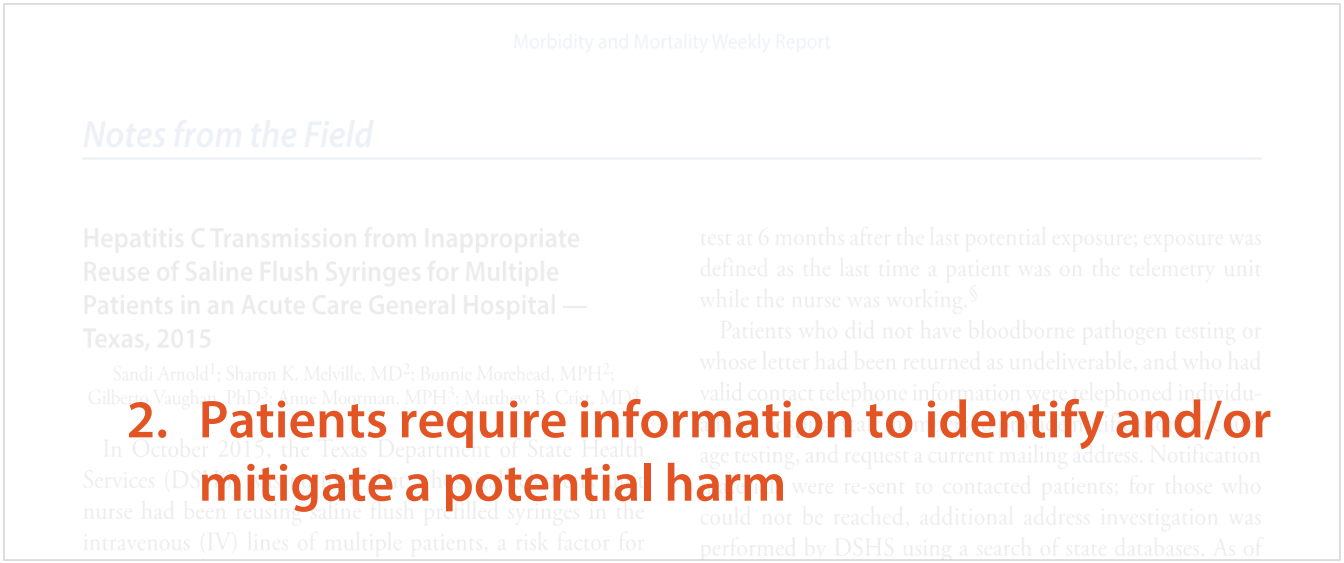
In October 2015, the Texas Department of State Health Services (DSHS) was notified that a hospital telemetry unit nurse had been reusing saline flush prefilled syringes in the intravenous (IV) lines of multiple patients, a risk factor for

test at 6 months after the last potential exposure; exposure was defined as the last time a patient was on the telemetry unit while the nurse was working.§

Patients who did not have bloodborne pathogen testing or whose letter had been returned as undeliverable, and who had valid contact telephone information were telephoned individually by hospital staff members to provide notification, encourage testing, and request a current mailing address. Notification materials were re-sent to contacted patients; for those who could not be reached, additional address investigation was performed by DSHS using a search of state databases. As of

- Nurse reusing syringes for >1 patient x 6 months
- No infections known when breach discovered
- Hospital notified all potentially exposed patients and provided free BBP testing
- HCV transmission documented

Arnold S, et al. Notes from the Field. Hepatitis C Transmission from Inappropriate Reuse of Saline Flush Syringes for Multiple Patients in an Acute Care General Hospital — Texas, 2015. MMWR Morb Mortal Wkly Rep 2017;66:258–260



2. Patients require information to identify and/or mitigate a potential harm

- Nurse reusing syringes for >1 patient x 6 months
- No infections known when breach discovered
- Hospital notified all potentially exposed patients and provided free BBP testing
- HCV transmission documented

Outbreak in a Nursing Home

4 residents with acute respiratory illness in the same unit

Outbreak in a Nursing Home

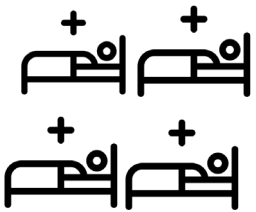
4 residents with acute respiratory illness in the same unit

Contact and droplet precautions for infected residents

Outbreak in a Nursing Home

4 residents with acute respiratory illness in the same unit

Contact and droplet precautions for infected residents

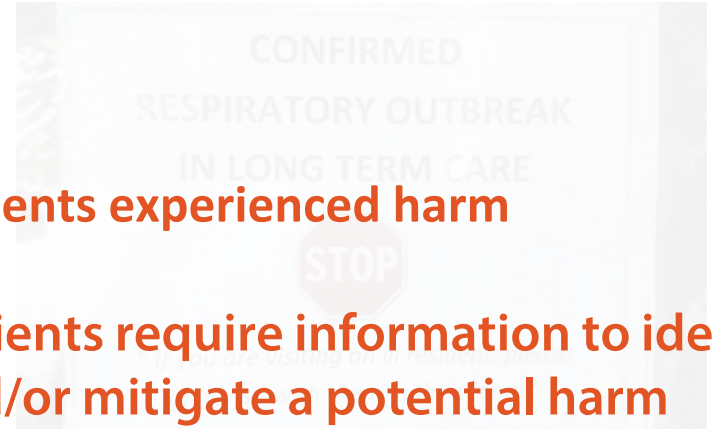


Infected residents cohorted

Outbreak in a Nursing Home

- All residents and healthcare personnel notified of:
  - Outbreak
  - Need to monitor for and report signs/symptoms of infection
- Unvaccinated residents/staff offered influenza vaccine
- Group activities suspended
- Letters sent to family members of outbreak and not to visit when ill

Outbreak in a Nursing Home



1. **Patients experienced harm**

2. **Patients require information to identify and/or mitigate a potential harm**

3. **Patients experience an alteration in care**

- All residents and healthcare personnel notified of:
  - Outbreak
  - Need to monitor for and report signs/symptoms of infection
- Unvaccinated residents/staff offered influenza vaccine
- Group activities suspended
- Letters sent to family members of outbreak and not to visit when ill

Reuse of Rectal Catheters in New Jersey

NJ Department of Health Issues Public Health Recommendations to Patients of Physician with Revoked License

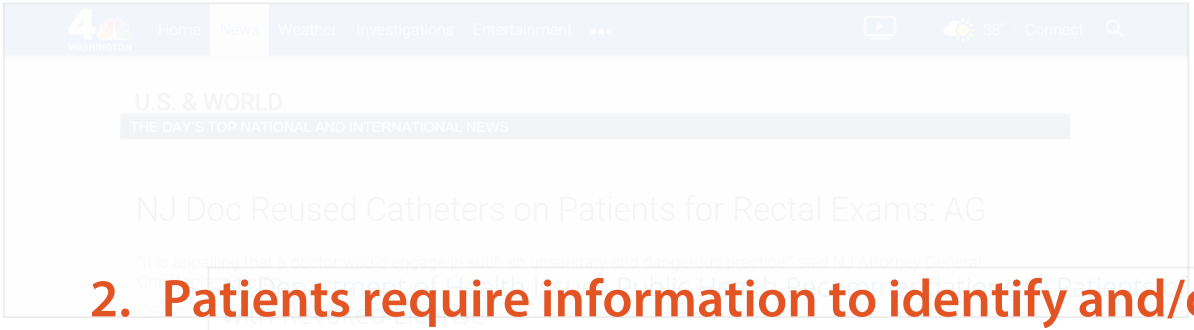
The New Jersey Department of Health (NJDOH) is encouraging patients of Central Jersey physician, Dr. Sanjiv Patankar, to consult with their primary health care provider if they have undergone procedures at his office because of potential infection control breaches. The State Board of Medical Examiners (BME) has revoked Dr. Patankar's medical license, after finding that he reused single-use rectal manometry catheters on multiple patients.

"While the Department believes that the risk of disease transmission from the rectal manometry procedure is low, we recommend patients who have had any procedures performed by Dr. Patankar discuss their risk and whether they should get tested for bloodborne pathogens with their health care provider," said Acting Health Commissioner Christopher R. Rinn.

At this time, NJDOH has not received any reports of disease associated with this doctor's practices. Based on information uncovered in the BME's investigation, the NJDOH cannot be certain that there were no additional infection control breaches at Dr. Patankar's practices.

Re-using single-use devices is an infection control breach and increases the risk of disease transmission. There is a concern about the possibility of disease transmission, specifically of bloodborne pathogens, such as human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). Blood may be microscopic and not visible to the eye. Bloodborne pathogens can cause disease with few or no symptoms, so blood tests are the only way to know if bloodborne pathogens are present.

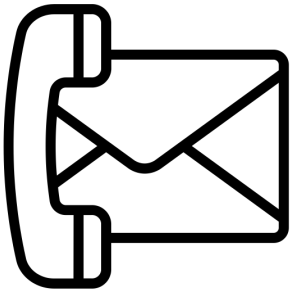
Reuse of Rectal Catheters in New Jersey



2. **Patients require information to identify and/or mitigate a potential harm**

Types of Patient Notifications

One-on-one discussions between providers and patients/family

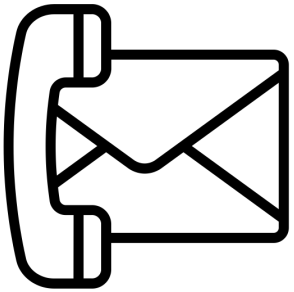


Individual patient letters/phone calls

Types of Patient Notifications

One-on-one discussions between providers and patients/family

Posted signs

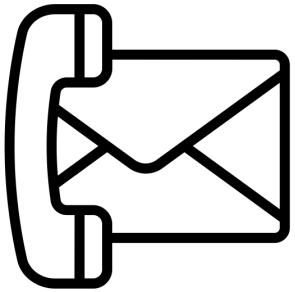


Individual patient letters/phone calls

Types of Patient Notifications

One-on-one discussions between providers and patients/family

Posted signs



Individual patient letters/phone calls

Press release (HD or healthcare facility)

Media

Concerns for Patient Notification

Patient anxiety

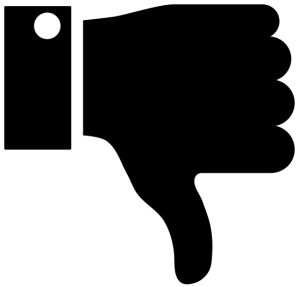
Concerns for Patient Notification

Patient anxiety

> 90% of patients would want facilities to tell them about any error in their care, even if the chance of harm was extremely low

Prouty CD et al. Patients' experiences with disclosure of a large-scale adv
event. Journal of Clinical Ethics. 2013;24(4):353-363.

Concerns for Patient Notification



Reputational damage
or loss of trust

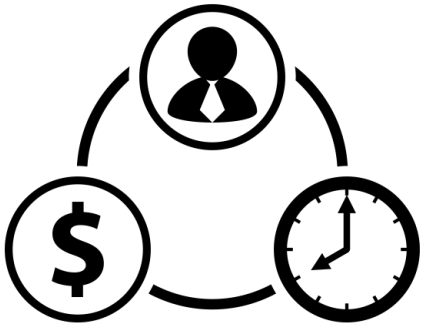
Concerns for Patient Notification

Reputational damage
or loss of trust

- Majority of patients have an improved perception of the facility's honesty and integrity
- No long term reductions in patients seeking care at such facilities

Laverty AA et al. High-profile investigations into hospital safety problems in England did not prompt patients to switch providers. Health Affairs. 2012;31(3):593-601.

Concerns for Patient Notification



Extensive resources needed

Concerns for Patient Notification

Extensive resources needed

Does not obviate the need to perform patient notification when one is warranted

Patient Notification Additional Considerations

- Consider the perspective of patients

- Engagement of additional stakeholders
  - Healthcare personnel
  - Facility leadership
  - Public health
  - Regulatory authorities and accrediting agencies

- Other groups to notify
  - Public (disclosure)
  - Healthcare providers
  - Other facilities (transfers)

Seattle Children's warns of potential infection risk

Originally published August 26, 2015 at 2:59 pm | *Updated August 27, 2015 at 6:15 pm*

Seattle Children's CEO Jeff Sperring, third from left, at a press c
in Seattle, addresses sterilization concerns for equipment used a
Bellevue campus that could affect. as many... (Bettina Hansen /
More

Hospital staff are sending out warnings to patients and their families and asking the patients to come in for blood tests for diseases, including hepatitis B and C and HIV.

KIRO 7
@KIRO7Seattle

Follow

Seattle Childrens Hospital asking 12,000 patients to get Hep B,C &HIV blood tests- more @ 4:58 kiro.tv/LiveNews

7:43 PM - 26 Aug 2015

On the Horizon…

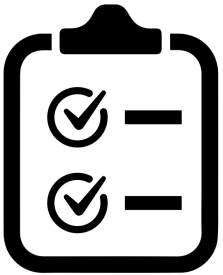
- Council for Outbreak Response: HAIs and AR Pathogens (CORHA) Policy Workgroup
  - Patient notification implementation guide
- Addressing public disclosure
- Assess CDC's patient notification toolkit

“Protection through Prevention”

Strong IPC program

Education of HCP

Verify adherence to recommended practices



Regular audits

Acknowledgements

- Melissa Schaefer, MD, DHQP/CDC
- Joseph Perz, DrPH, DHQP/CDC
- Council for Outbreak Response: HAIs and AR Pathogens (CORHA) Policy Workgroup
  - Maureen Tierney, MD, Nebraska DHHS
  - Moon Kim, MD, LA County
- Noun Project

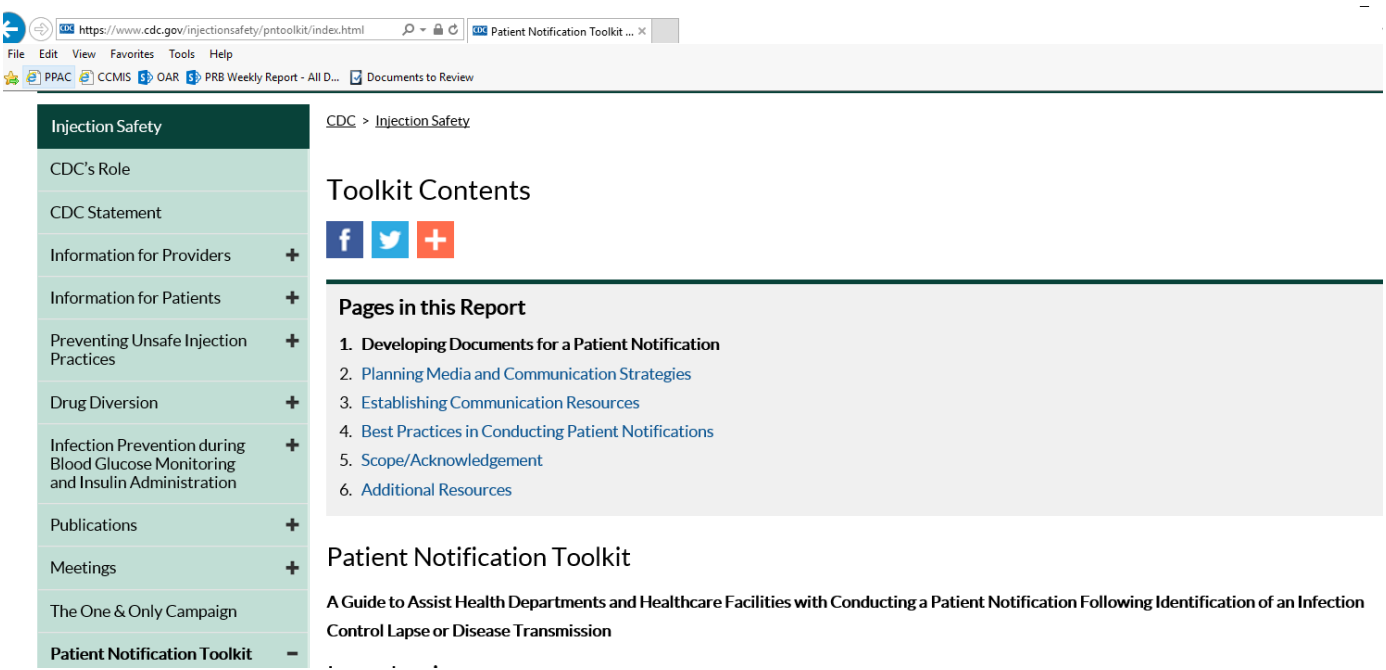
Thank you

KPerkins@cdc.gov

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

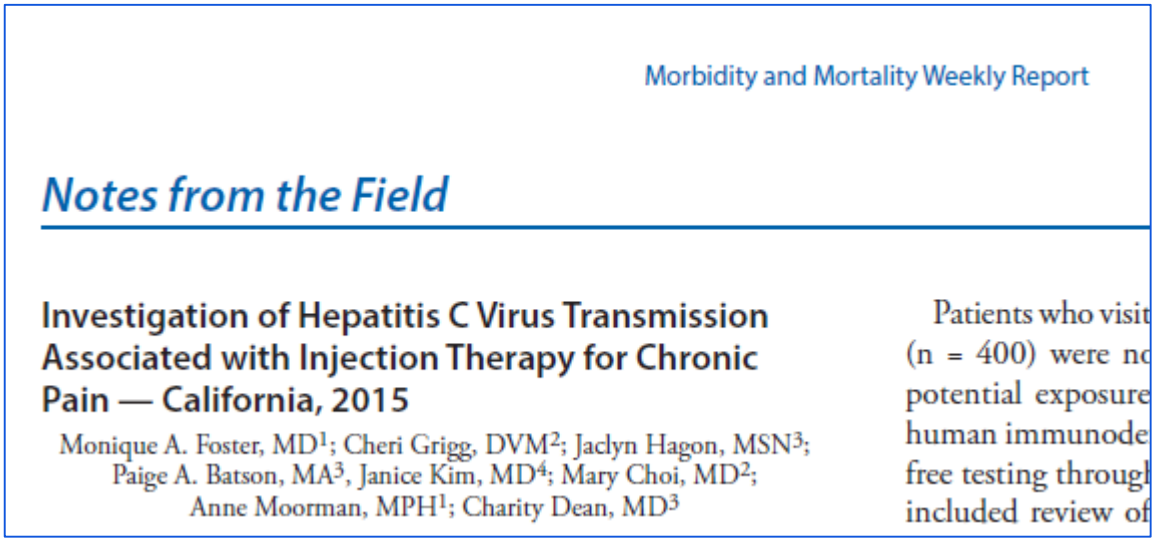
The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

CDC's Patient Notification Toolkit



https://www.cdc.gov/injectionsafety/pntoolkit/index.html

Hepatitis C Transmission in California



Morbidity and Mortality Weekly Report

Notes from the Field

Investigation of Hepatitis C Virus Transmission Associated with Injection Therapy for Chronic Pain — California, 2015

Monique A. Foster, MD[1]; Cheri Grigg, DVM[2]; Jaclyn Hagon, MSN[3]; Paige A. Batson, MA[3], Janice Kim, MD[4]; Mary Choi, MD[2]; Anne Moorman, MPH[1]; Charity Dean, MD[3]

Patients who visit
(n = 400) were nc
potential exposure
human immunode
free testing throug
included review of

- New, acute case of hepatitis C virus infection in a repeat blood donor
- Prolotherapy injection at a doctor's office
- Poor injection practices
- Notification of 400 patients
- 6 additional patients with HCV detected

Transvaginal Ultrasound Probes

- Several facilities found to not be properly reprocessing transvaginal ultrasound probes
- Consideration for bloodborne pathogen testing and testing for human papilloma virus (HPV)
- Patient notification was not pursued

Emerging Issue: Infections Risks Associated with Narcotics Tampering in Healthcare Settings

- **Healthcare settings rely on routine use of powerful narcotics and sedatives, many delivered via injection/infusion**
- **Healthcare personnel are susceptible to substance abuse like everyone else but have unique access to drugs**

Annals of Internal Medicine | ORIGINAL RESEARCH

Health Care–Associated Hepatitis C Virus Infections Attributed to Narcotic Diversion

Walter C. Hellinger, MD; Laura P. Bacalis, RN; Robyn S. Kay, MPH; Nicola D. Thompson, PhD, MS; Guo-Liang Xia, MD, MPH; Yulin Lin, MD; Yury E. Khudyakov, PhD; and Joseph F. Perz, DrPH

Background: Three cases of genetically related hepatitis C virus (HCV) infection that were unattributable to infection control breaches were identified at a health care facility.

Objective: To investigate HCV transmission from an HCV-infected health care worker to patients through drug diversion.

Design: Cluster and look-back investigations.

Setting: Acute care hospital and affiliated multispecialty clinic.

Patients: Inpatients and outpatients during the period of HCV

NS5B sequence homology with the HCV strains of the 3 case patients. Quasi-species analysis showed close genetic relatedness with variants from each of the case patients and more than 97.9% nucleotide identity. The employee acknowledged parenteral opiate diversion. An investigation identified 6132 patients at risk for exposure to HCV because of the drug diversion. Of the 3929 living patients, 3444 (87.7%) were screened for infection. Two additional cases of genetically related HCV infection attributable to the employee were identified.

Limitation: Of the living patients at risk for HCV exposure, 12.3%