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RESPONDING TO LARGE-SCALE ADVERSE EVENTS

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Learning Objectives

- By the end of this webinar, participants will be able to:
  - Describe the diversity of large-scale adverse events, and how responding to these events differs from managing adverse events that affect individual patients;
  - List the key elements of an effective response to a large-scale adverse events and the tools that are currently available to assist with this process;
  - Critique an actual large-scale adverse event patient notification letter and press release, and articulate opportunities for improvement in these documents.

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Duke Health System Quiet About Hydraulic Fluid Mistake

Posted June 13, 2005

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The hospitals used hydraulic fluid to clean surgical instruments.

Duke blames the mix-up on contractors working on hospital elevators.

Several patients are worried about possible health issues and want to know exactly what was in the fluid.

Hospital officials said they could not give the information to anyone while they investigate the mistake, but they did say that infection rates have not increased as a result.

The Benefits of the CRP Response

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	Traditional Response	CRP Response
Incident reporting by clinicians	Delayed, often absent	Immediate
Communication with patient, family	Deny/defend	Transparent, ongoing
Event analysis	Physician, nurse are root cause	Focus on Just Culture, system, human factors
Quality improvement	Provider training	Drive value through system solutions, disseminated learning
Financial resolution	Only if family prevails on a malpractice claim	Proactively address patient/family needs
Care for the caregivers	None	Offered immediately
Patient, family involvement	Little to none	Extensive and ongoing

Transparency practices after adverse events

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- Discussing event with patient/family
- Patient/family sharing concerns about care problems
- Talking with peers about adverse events
- Conversations across organizations following adverse events
- Large-scale adverse events

How Are LSAEs Different?

- Like individual adverse events
  - Type, cause, severity vary widely
  - Strong patient expectations for disclosure, learning
- Unlike individual adverse events
  - By definition, involve multiple patients (sometimes thousands)
    - Hard to keep quiet
    - High potential for negative impact on reputation of organization
    - Responding appropriately is highly resource intensive
  - Many represent near misses
    - Don’t know which patients are affected until investigation complete
    - Primary harm may be anxiety caused by disclosure itself
      - Related concern that loss of trust may lead patients to avoid needed follow-up care

Case 1: UW endoscope disinfection problem

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The Seattle Times

600 UW patients told of cleaning lapse

By Warren King
Seattle Times medical reporter

Nearly 600 University of Washington Medical Center patients have been notified that tubular devices used to diagnose diseases of the intestinal tract were not completely cleaned for several months.
UW officials and outside experts said the risk of infection from the incomplete cleaning process, which involves several steps, was very low.
"The risk ... is essentially zero, it is negligible," said Dr. Ed Walker, medical director of the UW Medical Center.
The medical center performed an extensive review of the cleaning lapse and filed reports with the federal Food and Drug Administration (FDA) and the Washington state Department of Health.
Patients who were examined with the devices, called endoscopes, were notified by letter of the problem during the past few weeks.

Survey of UW endoscopy patients

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- Surveys returned by 127/266 (48%) of eligible respondents
- 98% agreed UW was right to notify them of the problem
- 64% somewhat/very concerned that endoscope cleaning breakdown might cause health problems for them
- Impact on perception of UW's honesty/integrity
  - 60% "increased"
  - 34% "unchanged"
- Impact on perception of quality of care provided by UW
  - 30% "increased"
  - 48% "no change"

Case 2: ENT fungal contamination

- 2000 patients potentially exposed to Acremonium due to contaminated endoscopes used for ENT procedures
  - Low risk to immunocompetent patients
  - Immunocompromised patients at risk of invasive infection
- Immediate patient notification
  - Personal contact from clinician for patients with positive cultures
  - Written notification for other patients
- Hotline, dedicated Acremomium clinic set up. Close collaboration with local public health officials.
- Press release issued on same day as notifications sent

Exercise 1: Written notification

- Read the written notification about the Acremoniun case as if you were a patient at that care site who had been potentially exposed
- Consider:
  - What did you like about the letter
  - What would you have phrased differently?

Notification--best practices

- High harm events/patients
  - Personal notification by clinician, followed by written notification
    - Clinicians need to be prepped to conduct these discussions effectively
- Low harm events
  - Written notification
- Devote resources needed for robust support post-notification
  - Hotline for patients with questions
  - Rapid access to testing
  - Anticipate small proportion of patients will have PTSD-like response
- For very large notifications, expect that testing will uncover "new" cases of Hep C/HIV
- Proactive media strategy
  - Assume written notification will become public

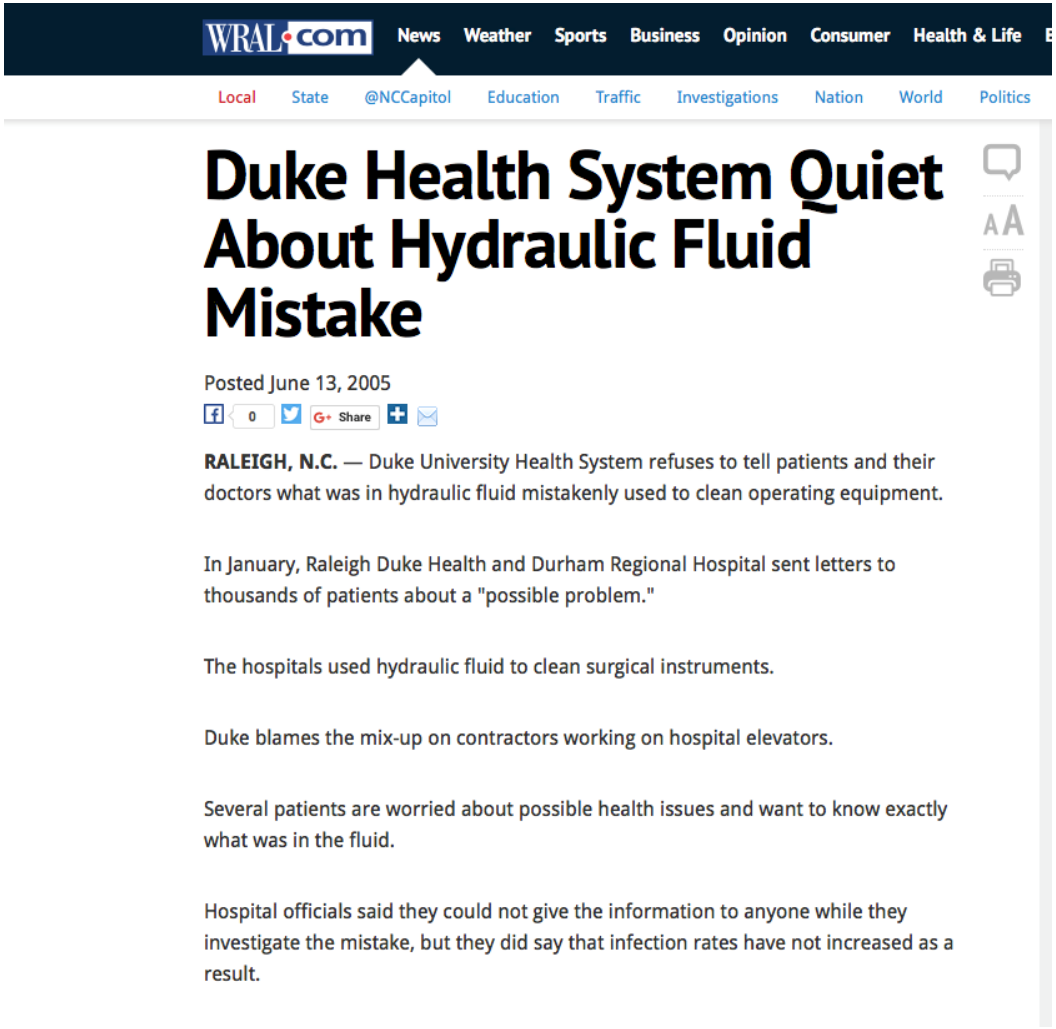
Written notification

- Use clear, direct language
- Apologize explicitly and more than once
- Discuss plans to prevent recurrences
- Make an explicit recommendation regarding testing

Exercise 2: Press release

- Read press release in your packet
- Consider
  - What did you like about the press release?
  - What would you have phrased differently?

Case 3: Hydraulic fluid



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Case 4: Drive-by colonoscopy

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You are a risk manager at a large, multi-specialty group practice. You are reviewing a lawsuit filed by a clinic patient claiming delayed diagnosis of colon cancer. The patient had been complaining of rectal bleeding and abdominal pain for 6 months, which prompted one of your GI physicians to undertake a colonoscopy which showed only hemorrhoids. The GI physician recommended a high-fiber diet. The symptoms persisted and the patient began to lose weight. She went to a different medical group, where the colonoscopy was repeated and revealed colon cancer (determined to be metastatic). As you review the chart, you realize that the time from insertion to removal of the colonoscope was only 8 minutes. A random sampling of other charts from this physician, one of the clinic's biggest revenue generators, showed that all of his screening colonoscopies were much shorter in duration than recommended.

Case 5: Diversion

You are the risk manager assigned to the interventional radiology suite at a large community hospital. A tech was observed on at least two occasions swapping fentanyl syringes that were intended to be used on patients. In one instance, the swapped syringe was tested and found to contain saline. On three occasions, empty syringes labeled “fentanyl” were discovered in the staff bathrooms or changing rooms for this unit. The tech was also noted on several occasions to be in procedure rooms she was not assigned to and to take frequent breaks. She received formal counseling, and following the most recent episode was terminated. She did voluntarily submit to testing for blood-borne pathogens, which was negative. Throughout, she denied any wrongdoing. A review of the injection procedures in this suite concluded that the chances of cross-contamination from one patient to another were thought to be virtually impossible.

Case 6: Incorrect breast cancer hormone receptor testing

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In Eastern Canada, it was determined that over 1000 patients had been affected by systematic errors in breast cancer specimen hormone-receptor tests between May 1997 and August 2005, with patients who actually had hormone receptor positive tumors given results that their tumors were receptor negative. Over 300 patients had not received recommended treatment, and 100 had died before the error was uncovered. There were long delays and inconsistent attempts at contacting women who were at risk for having incorrect results. Some women only learned of their risk through the media.

Tips for Managing LSAEs

- Establish a “command center” to handle emerging issues related to the disclosure
- Establish an escalation pathway for calls requiring feedback or mitigation
- Provide advance notice to boards and leadership
- Create a site to easily store and share documents
  - Scripts and resources for call center staff
  - Update “blog” with emerging news, call volumes, helpful info
  - Tracking follow-up calls
- For public entities, provide the press with copies of internal communications if regularly updating staff about the event

Credit: Marcia Rhodes

Summary

- LSAE have many similarities and some important differences compared to adverse events affecting individual patients
  - Same CRP principles generally apply
- Proactivity, both in advance and following LSAEs is key
  - Use the cases presented today as a “stress test” for your organization
- Considerable tools, resources, and expert advice are available to support your LSAE response
  - CDC toolkit
  - Journal articles
  - Use “large scale adverse event” topic filter in our Resource Library