

**Healthcare Quality**  
*and the challenges of medical devices and technology*

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National Center for Emerging and Zoonotic Infectious Diseases  
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**Evolution of US Healthcare Quality**

*Key events –*

**Transparency**  
– public reporting laws and public demand

**Preventability**  
– demonstrated success with adherence to recommended practices

**Incentives**  
– CMS reimbursement tied to reporting and outcomes

**National Expansion**  
– antimicrobial resistance initiative

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**Evolution of US Healthcare Quality**

*Key capacities supporting progress -*

**Partnership:**  
– CMS, other payors  
– State health departments  
– Hospital associations  
– Patient advocates  
– Information technology industry

**Communication:**  
– relevant to non-medical audiences  
– simple, high-impact

**Data:**  
– burden, mortality, cost, return on investment, impact

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## Evolution of US Healthcare Quality

*Key challenges in healthcare technology and environment -*

**Technology:**

- Procedures that are faster or safer
- Greater cost-effectiveness
- Better access to care
- More information available for care delivery

**Unintended Consequences:**

- Device design issues
- Environmental real-world issues
- Human factors issues
- Opportunity costs

**Opportunities for Improvements ...?**

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The image shows a screenshot of a news article from the Los Angeles Times. The headline reads "Dirty scopes needlessly infected scores of patients, investigation finds". Below the headline is a photograph of a hospital parking lot filled with motorcycles. The article's date is February 4, 2016. Navigation links for "MOST POPULAR", "LEGAL", "SPORTS", "ENTERTAINMENT", "POLITICS", "EDUCATION", "OPINION", and "PLACE AN AD" are visible at the top. A "Related Coverage" section is partially visible at the bottom of the article preview.

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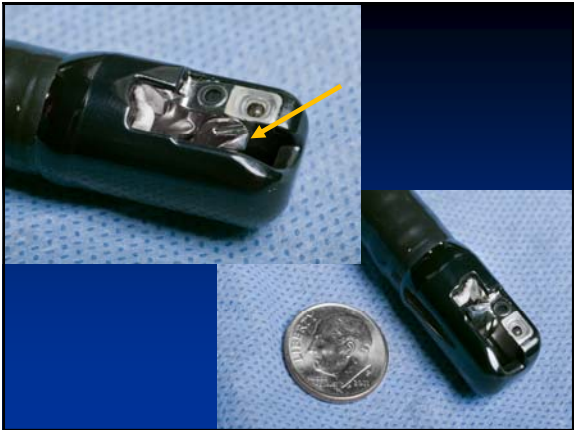
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**TIME**

PUBLIC HEALTH


### Meningitis Outbreak Grows, Highlighting Dangers of Compounding Pharmacies

By Alice Park @aliceparkny | Oct. 04, 2012 | 6 Comments

[I Share](#) [Pin It](#) [Read Later](#)

Health officials are hunting for the source of a meningitis outbreak among dozens of people who received steroid injections to treat back pain.

So far, 35 people have fallen ill with fungal meningitis and five have died after receiving shots in the spine. Health officials expect the case count to rise, warning that hundreds, if not thousands of patients who received epidural steroid injections could be at risk. The fungus, *Aspergillus*, causing



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### Methylprednisolone Acetate (MPA) from NECC

- Three lots associated with infections (all preservative-free)
- Implicated lots distributed to 75 facilities in 23 states
- ~ 14,000 patients exposed
- 257 cases of infection (3 joints)
- 20 Deaths



States that received implicated MPA



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- Sentinel detection
- Fast action
  - Notification
  - Remediation
  - Regulation
- Other opportunities...?



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Non-tuberculous Mycobacterium (NTM) Infections and Heater-Cooler Devices  
Interim Practical Guidance: Updated October 27, 2015

**Purpose:**

CDC has identified a need for increased vigilance for NTM infections by health departments, healthcare facilities, and individual healthcare providers. [FDA recently issued a Safety Communication on Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices](#) that addresses issues regarding the proper use and maintenance of these devices. CDC has been working with the FDA and local and state health departments to investigate heater-cooler units associated with NTM infections and/or found to be contaminated with NTM. This CDC communication is to (a) raise awareness among health departments, healthcare facilities, and healthcare providers of the possible association between NTM infections and use of heater-cooler devices and (b) to provide guidance on identifying patients with infection.



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- Risk recognition *(not just for clinical staff)*
  - Materials management
  - Purchasing
  - Environmental Services

CDC

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## Issues to consider

*For devices that require reprocessing:*

### **Cleanability**

- Surface textures, seams, etc.
- Materials – chemical compatibility/interactions, porosity
- Design elements/parts – e.g., modular, disposable elements

### **Assessability**

- Ease of visual inspection
- Colors/contrast
- Novel indicators for cleaning and disinfection

### **Similarity?**

- Consistency of processes, tools, timing, etc.

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## Issues to consider

*For equipment used in high-risk locations:*

### **Air current generation**

### **Moisture retention/reservoirs**

- Condensation
- Biofilm formation
- Conduits or reservoirs that opens directly to environment/patient

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## Issues to consider

*Other potential issues:*

### **Porous surfaces and materials**

- e.g., textile, wood elements in ORs and ICUs
- foam insulation panels

### **Innovative options to promote? e.g.:**

- fanless cooling
- biofilm retardant
- microbicidal/static characteristics
- self-cleaning nano-coatings

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# DRAFT

### Elements to Avoid

- Fans
- Motors/vibration sources
- Condensation sites
- Seams and porous surfaces
- other...?

### Elements of Concern

- Water reservoirs
- Moisture retention
- Re-usable tubing
- Splash potential
- Inaccessible compartments open to environment
- Complex cleaning procedures

### Extra Scrutiny Needed for devices and equipment used in:

- NICU/ICU
- Oncology
- Transplant
- Burn
- OR
- Sterile Processing

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## PERFECT CARE - EVERY TIME



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### Attaining perfect care:

- Optimally staffed, highly trained, competency-certified care delivery... plus:
- Effective oversight
- Environmental interventions
- Innovations in materials and design
- Optimal use of electronic health records

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## Thank you

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333  
Telephone: 1-800-CDC-INFO (232-4656)/TTY: 1-888-232-6348  
E-mail: [cdcinfo@cdc.gov](mailto:cdcinfo@cdc.gov) Web: [www.cdc.gov](http://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.

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## Applied Research

- Emerging Infections Program
  - Assessing pathogens
    - Burden, epidemiology, risk factors
  - Multiple settings (e.g., community, nursing homes)
  - Annual surveys
    - Non-ventilator associated pneumonia
  - Sepsis

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## Applied Research

Academic and public health partnerships  
to identify & scale up effective interventions:

- Develop healthcare facility networking tools to implement coordinated approach to stop spread of AR in connected facilities
- Improve sepsis recognition and prevention approaches
- Use electronic health record data to define appropriate antibiotic use
- Further assess healthcare environments as sources of AR transmission
- Explore impact of microbiome on AR risk

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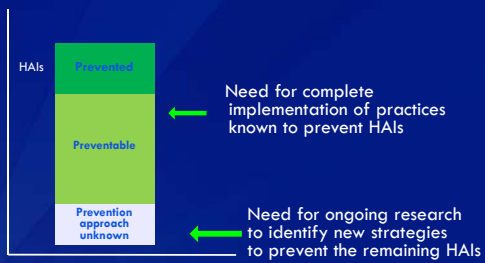
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## HAI Prevention Implementation and Research



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