Adapting Guidelines for Emergencies in the Digital Age

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Conflict of Interest

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Has no real or apparent conflicts of interest to report.

The findings and conclusions in this presentation 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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Agenda

• Adapting Clinical Guidelines for the Digital Age
  – Today’s Guideline Development and Implementation
  – A Multi-stakeholder Approach for a Future State That Helps Overcome Current Challenges

• Use Case: Development of Clinical Decisions Support (CDS) for Anthrax Emergencies
  – Overarching Anthrax Clinical Decision Support Development Approach
  – Anthrax CDS Development and Lessons Learned

• Role of Local Health Care Systems
• Summary
Learning Objectives

• Discuss the efforts led by CDC on Adapting Clinical Guidelines for the Digital Age
  – Explore a new process for sharing guidelines that translate scientific evidence into practice more easily, quickly, accurately, and consistently
  – Enable rapid translation in support of emergency preparedness and response

• Describe the process, challenges, opportunities, and lessons learned in developing CDS for anthrax

• Identify the role of local health systems in integrating CDS for non-routine biological exposures with their clinical workflows and electronic health records (EHRs)
Imagine you are a health care worker in a community hospital and have just been advised that you will be receiving patients exposed to anthrax in a mass casualty event.

How would you respond as patients started showing up in your emergency department?

You reached out to public health authorities to get guidance and recommendations in real-time…

…but the recommendations are dozens of pages long, in prose.

How do you ensure treatment consistent with clinical guidelines?
Now Imagine a Future...

- Clinical guidelines are expressed as executable code-based clinical decision support (CDS) that can be integrated into EHR systems in **real time**
  - Guidelines expressed **consistently** across implementation sites
  - Executability forces **precision** in guideline implementation
  - **Reduced (or eliminated) redundant** implementation efforts across sites
Clinical Guidelines of the Future

- Complement guideline narratives with computable guidelines
- Clinical Decision Support Community
  - Clinical Guideline Producers
  - Researchers
- Clinical Guideline Management
  - Governance
  - Tools and Repositories
  - CDS Connect
- Clinical Decision Support Consumers
  - Health IT System
  - Provider
  - Patients
- Build repositories of reusable guideline components
- Automate the evaluation of guidelines
- Guidelines implemented in hours
Adapting Clinical Guidelines for the Digital Age
Ensure clinical guidelines are followed consistently to improve public health outcomes.
Develop Guidelines

- Research Results
- Literature Review
- Meta-analysis

Guideline Narrative

- Guideline released
- Clinicians hear about guideline
- Additional/conflicting guidelines?
- Convene internal clinical workgroup
- Determine which guideline (and which part(s)) to implement

Interpret & Implement Guidelines: Local Level

- Adjust CDS as needed
- Test within workflow with actual users
- Multiple system tests
- Implement CDS tool in test system
- Search existing CDS tools
- Conduct workflow analysis

- Release CDS tool into production system
- Monitor CDS tool for issues & monitor for updates to guidelines

Performed by up to 95% of ~5500 hospitals
Performed by up to 82% of ~355,000 clinics

Interpret & Implement Guidelines: Across Health Systems

https://dashboard.healthit.gov/quickstats/quickstats.php
Integrating Stakeholder Groups

- Guideline authors
- Health IT developers
- Communicators
- Clinicians
- Patients / Patient Advocates
- Medical Societies
- Public Health Organizations
- Evaluation experts
- Standards experts
- Clinical decision support developers
- Clinical quality measure developers
- Policy or technical support for implementation
Adapting Clinical Guidelines for the Digital Age

**Problem:** Long Lag Time, Inconsistencies, and Inaccuracies in Translation

Contributes to an average of 17 years for scientific evidence to apply in patient care.

**Reason:** Playing the “Telephone Game”

Multiple translations of guidelines add complexity, opportunity for error, and variation across sites/providers.

**Solution:** Developing Tools and Guidelines Together

Can help evidence apply to patient care more easily, quickly, accurately, and consistently.

https://www.cdc.gov/ophss/WhatWeDoACG.html
Redesigning Guideline Development and Implementation

**CURRENT STATE**
- Guidelines
- Informatics
- Implementation
- Evaluation (maybe)
- CDS
- Patient Care

- 10s-100s of translations
- Inconsistent (or nonexistent) feedback loop

**PROPOSED FUTURE STATE**
- Concurrent guideline development and translation & upfront planning
- Local implementation
- Consistent feedback loop

- Guidelines
- Informatics
- Communications
- Implementation
- Evaluation

- Patient Care
- 100s-1000s of translations

#HIMSS19
## Translating Evidence to Executable CDS

<table>
<thead>
<tr>
<th>Knowledge Level</th>
<th>Description</th>
<th>Example</th>
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<tbody>
<tr>
<td>L1</td>
<td>Narrative guideline</td>
<td>Guideline for a specific disease that is written in the format of a peer-reviewed journal article</td>
</tr>
<tr>
<td>L2</td>
<td>Semi-structured</td>
<td>Flow diagram, decision tree, or other similar format that describes recommendations for implementation</td>
</tr>
<tr>
<td>L3</td>
<td>Structured</td>
<td>Standards-compliant specification encoding logic with data model(s), terminology/code sets, value sets that is ready to be implemented</td>
</tr>
<tr>
<td>L4</td>
<td>Executable</td>
<td>CDS implemented and used in a local execution environment (e.g., CDS that is live in an electronic health record (EHR) production system) or available via web services</td>
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Use Case: Development of CDS for Anthrax Emergencies
Overarching CDS Development Approach

Develop Clinical Decision Support Artifact

Level 1 (L1) Development
- Research Results
- Literature Review
- Meta-analysis

Narrative Guideline(s)

Level 2 (L2) Development
- Structured Code
- Internal Validation Testing
- Implementation Guide

Semi-Structured Logic
Value Sets

Level 3 (L3) Development

Test Artifact

Pilot with synthetic data

Conduct clinical pilot

Level 4 (L4) Development

Implement Artifact

Level 2 Semi-structured Representation

1. Identified Pertinent Guidelines (17 total)

2. Developed Skeletal Clinical Flow to Visualize Guidelines & Focal Areas
   (initially narrowed to 7 guidelines)

3. Assessed Guidelines per Defined Criteria (selected 5 guidelines)

4. Assessed Recommendation Statement(s) to Derive Artifact

5. Documented Detailed Clinical Workflow with Semi-structured Representation of CDS

Level 3 Iterative Development and Testing

- Based on L2 semi-structured logic and value sets,
  - Developed CDS code in the Clinical Quality Language (CQL) representation for clinical concepts), such as order sets and alerts
  - Incrementally tested (test-driven development)

* Not the same as those used in synthetic pilot
Level 3 Synthetic Pilot

1. Generated 100 synthetic patient records using Synthea
   - Synthea
     • Synthea™ is an open-source tool for generating synthetic patient records
     • Provides statistically and demographically accurate patient medical history records that are free from cost, privacy, and security concerns

2. Executed CDS CQL against patient records and record outputs
   - Main output was a potential order set plus potential alerts
   - All formatted as appropriate FHIR resources

3. Clinical SMEs evaluated CDS outputs
   - Compared treatment and alerts generated by CDS to the documented clinical recommendations
Final Anthrax CDS for Anthrax Post-Exposure Prophylaxis

Detailed L2

Complex CDS artifact with:
- 8 value sets
- 105 CQL expressions
- 232 dependencies
- 1215 lines of code

Detailed L3
Anthrax CDS Published

- Metadata
- CQL
- Built-in synthetic test patients
- Implementation guide
- Validation report

https://cds.ahrq.gov/cdsconnect/artifact/anthrax-post-exposure-prophylaxis

## L2 & L3 Challenges & Recommendations

<table>
<thead>
<tr>
<th>Issue</th>
<th>Recommendation</th>
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</thead>
<tbody>
<tr>
<td>Uncertainty of or conflicting guidance</td>
<td>&gt; Involve guideline developers with the L2 team</td>
</tr>
<tr>
<td>Multiple overlapping guidelines</td>
<td>&gt; Define a systematic process for evaluating each guideline and recommendation</td>
</tr>
<tr>
<td></td>
<td>&gt; Develop a skeletal clinical workflow chart to visualize the interrelationships</td>
</tr>
<tr>
<td>Complex clinical guidance</td>
<td>&gt; Develop detailed clinical flow chart with semi-structured representation</td>
</tr>
<tr>
<td>L2/L3 must align</td>
<td>&gt; Have a robust ongoing mechanism for communicating between L2 and L3 teams</td>
</tr>
<tr>
<td>Appropriate model to represent clinical concepts</td>
<td>&gt; Use proper FHIR resources so that the L3 accurately represents clinical concepts</td>
</tr>
<tr>
<td>Inability to use actual patient data for testing</td>
<td>&gt; Use methodology (e.g. Synthea) to generate random patient records to test logic</td>
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<tr>
<td>Proper error tracking</td>
<td>&gt; Have a sequential iterative process for development and the ability to trace errors</td>
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Critical Success Factors in Developing Clinical Decision Support

Critical elements for developing guidance into semi-structured and structured guidance, then executing it in clinical systems

1. **Continual involvement throughout the process as a team**
   - Guideline creators
   - Clinical artifact developers
   - Technical artifact developers
   - Health care system personnel implementing artifact

2. **Education** to each on all aspects of the process to ensure a foundational understanding of the entire CDS development process
Role of Local Health Care Systems

• Identify population health threats and prioritize CDS to address these threats
• Include multiple facilities in developing or selecting CDS for population health emergencies
• Follow a standardized method of implementing guidelines into clinical workflows.
• Incorporate artifact implementation for disaster responses into an integrated delivery network
• Pilot in a large-scale emergency preparedness exercise using a simulation built into the test environments at a variety of sites with multiple EHR platforms in order to determine if there are any challenges to resolve for local implementation
Clinical Guidelines of the Future


Complement guideline narratives with computable guidelines

Build repositories of reusable guideline components

Automate the evaluation of guidelines

Guidelines implemented in hours
Questions

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Guidelines Related to Anthrax Considered

### Prevention

### Treatment
- Prevention and Treatment of Anthrax in Adults: Results of CDC Expert Panels (2014)
- Special Considerations for Pregnant and Postpartum Women (2014)
- Pediatric Anthrax Management (2014)
- Emergency Use Instructions (EUI) for Doxycycline for Post-exposure Prophylaxis (PEP) of Anthrax (2017)
- Emergency Use Instructions (EUI) for Ciprofloxacin for Post-exposure Prophylaxis (PEP) of Anthrax (2017)

### Mass Casualty
- Clinical Framework and Medical Countermeasure Use During an Anthrax Mass-Casualty Incident (2015)

### Infection Control
- Guidance for Protecting Responders’ Health During the First Week Following A Wide-Area Aerosol Anthrax Attack (2012)
- Occupational Health Guidelines for Remediation Workers at *Bacillus anthracis*-Contaminated Sites (2002)
- Clearance Strategy for Environments Contaminated with *Bacillus anthracis* (2012)

### Laboratory
- Recommended Specimens for Microbiology and Pathology for Diagnosis of Anthrax (2017)
- Biosafety in Microbiological and Biomedical Laboratories (2009)

Yellow highlights = those guidelines used (5 total)