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Adapting Guidelines for Emergencies in the Digital Age

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Conflict of Interest

Maria Michaels MBA, PMP, Public Health Advisor Centers for Disease Control & Prevention

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.



Conflict of Interest

Sharon Pacchiana, FNP, MSN, MHA, MMI, Principal Health Systems Analyst, Health Informaticist The MITRE Corporation

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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

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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)



Scenario

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



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Clinical Guidelines of the Future





Adapting Clinical Guidelines for the Digital Age



Today's Guideline Development and Implementation H2MSS19 Long Implementation Time **Develop Guidelines** Interpret & Implement Guidelines: Interpret & Implement Local Level Guidelines: Across Health Systems Research Guideline Clinicians hear Additional/ Convene Determine which Health IT Health IT Health IT_{Svstem} System Health ITSystem Health ITSystem about guideline conflicting internal clinical guideline (and which released Results System guidelines? workgroup part(s)) to implement Search Conduct Adjust Test within Multiple Implement Guideline Literature workflow CDS as workflow with CDS tool in existing system CDS tools analysis needed actual users test system tests Narrative Review Not NOTE: This Release CDS Monitor CDS tool process is repeated tool into for issues & A Meta-Create for EACH monitor for updates production quideline CDS tool to guidelines PDF system analysis Performed by up to 95% of ~5500 hospitals Performed by up to 82% of ~355,000 clinics https://dashboard.healthit.gov/guickstats/guickstats.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

Himssip Adapting Clinical Guidelines for the Digital Age

Reason: Playing the "Telephone Game"

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



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

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





Himssip Translating Evidence to Executable CDS

Knowledge	Description	Example
Level		
L1	Narrative	Guideline for a specific disease that is written in the format of a
	guideline	peer-reviewed journal article
L2	Semi-	Flow diagram, decision tree, or other similar format that describes
	structured	recommendations for implementation
L3	Structured	Standards-compliant specification encoding logic with data
		model(s), terminology/code sets, value sets that is ready to be
		implemented
L4	Executable	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

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Use Case: Development of CDS for Anthrax Emergencies

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Overarching CDS Development Approach

Develop Clinical Decision Support Artifact



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Level 2 Semi-structured Representation



1. Identified Pertinent Guidelines (17 total)

4. Assessed Recommendation Statement(s) to Derive Artifact Anthrax Post-Exposure Prophylaxis (PEP) for Asymptomatic Patients

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



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

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



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Level 3 Iterative Development and Testing



* Not the same as those used in synthetic pilot

- 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) 2019 The MITRE Corporation. ALL RIGHTS RESERVED. Approved for Public Release: 19-0459. Distribution Unlimited.

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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

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- 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

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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



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Anthrax CDS Published



Anthrax Post-Exposure Prophylaxis

Provides information for treating patients greater than or equal to 18 years old exposed to anthrax within the past 60 days, who do not have anthrax. It is divided into two parts:

Part #1- For patients that may be symptomatic to flag the need to conduct a full diagnostic evaluation to rule out anthrax before proceeding with post-exposure prophylaxis (PEP)

Part #2 - For patients who are asymptomatic (not displaying signs and symptoms of anthrax), it provides recommended PEP regimen

Artifact Type		
Treation Date Thu, 10/25/2018 - 12:00		
/ersion	Status	Experimental
0.1	Draft	True

Metadata

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

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

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L2 & L3 Challenges & Recommendations

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

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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

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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







Questions



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Guidelines Related to Anthrax Considered

Prevention

- CDC Guidance: Anthrax Vaccine Adsorbed (AVA) Post-Exposure Prioritization (2013)
- Use of Anthrax Vaccine in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) (2010)

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)
- Identifying Meningitis During an Anthrax Mass Casualty Incident: Systematic Review of Systemic Anthrax Since 1880 (2016)

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)
- Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007)
- Medical Examiners, Coroners, and Biologic Terrorism: A Guidebook for Surveillance and Case Management (2004)

Laboratory

- Recommended Specimens for Microbiology and Pathology for Diagnosis of Anthrax (2017)
- Biosafety in Microbiological and Biomedical Laboratories (2009)
- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories (2012)

Yellow highlights = those guidelines used (5 total)



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