Adapting Clinical Guidelines for the Digital Age

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OUR HOLISTIC GOAL

Make it easy for clinicians to do the right thing by applying guidelines in practice more easily, quickly, accurately, and consistently
WANTED: Complete Feedback Loop

CLINICAL DECISION SUPPORT

DO

STUDY

PLAN

ACT

CLINICAL QUALITY MEASUREMENT

DESIRED HEALTH ACTIONS & OUTCOMES

CLINICAL GUIDELINES DEVELOPMENT

MIND

BODY

SPIRIT
Today’s Guideline Development and Implementation

Develop guidelines
- Research Results
- Literature Review
- Meta-analysis

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

Implement guidelines
- 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
- NOTE: This process is repeated for EACH guideline

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

https://dashboard.healthit.gov/quickstats/quickstats.php
Participating 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

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Leads to an average of 17 years for scientific evidence to apply in patient care</td>
<td>Multiple translations of guidelines add complexity, opportunity for error, and variation across sites/providers</td>
<td>Can help evidence apply to patient care more easily, quickly, accurately, and consistently</td>
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https://www.cdc.gov/ddphss/clinical-guidelines/index.html
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>
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<tr>
<td>L2</td>
<td>Semi-structured</td>
<td>Flow diagram, decision tree, or other similar format that describes recommendations for implementation</td>
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<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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Redesigning Guideline Development and Implementation

**CURRENT STATE**

- Guidelines
- CDS
- Informatics
- Implementation
- Evaluation (maybe)

**PROPOSED FUTURE STATE**

- Guidelines
- Informatics
- Communications
- Implementation
- Evaluation

**KEY POINTS**

- 10s-100s of translations
- 100s-1000s of translations
- Concurrent guideline development and translation & upfront planning
- Consistent feedback loop

**LOCAL IMPLEMENTATION**

- Patient Care
- Inconsistent (or nonexistent) feedback loop
- Concurrent guideline development and translation & upfront planning
Clinical Guidelines of the Future

- Clinical Decision Support Community
  - Clinical Guideline Producers
  - Researchers
- Clinical Guideline Management
  - Governance
  - Tools and Repositories
- Clinical Decision Support Consumers
  - Health IT System
  - Provider
  - Patients

- Guidelines implemented in hours
- Complement guideline narratives with computable guidelines
- Build repositories of reusable guideline components
- Automate the evaluation of guidelines
Learning from the 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

Level 2 (L2) Development
- Narrative Guideline(s)
- Semi-Structured Logic
- Value Sets

Level 3 (L3) Development
- Structured Code
- Internal Validation Testing
- Implementation Guide

Level 4 (L4) Development
- Implement Artifact

Test Artifact
- Pilot with synthetic data
- Conduct clinical pilot

Health IT System
Provider
Patients
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

What if each clinical organization had to do this work?
Level 3: Iterative Development and Testing

- Based on L2 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)
Final Anthrax CDS for Anthrax Post-exposure Prophylaxis

Complex CDS artifact with:

- 8 value sets
- 105 CQL expressions
- 232 dependencies
- 1215 lines of code
Anthrax CDS Published

Clinical Decision Support
Accelerating Evidence into Practice through CDS

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
Multimodal

Creation Date
Thu, 10/25/2018 - 12:00

Version
0.1

Status
Draft

Experimental
True

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

- Metadata
- CQL
- Built-in synthetic test patients
- Implementation guide
- Validation report
Adapting Clinical Guidelines for the Digital Age: Where are we now?
Implementation Guide: Representation of Clinical Practice Guideline Recommendations in FHIR (”CPGonFHIR”)

Project Scope Statement approved at San Antonio HL7 meeting (Jan 2019)

http://build.fhir.org/ig/cqframework/cdc-acg/index.html

HL7 Balloting planned for September 2019 Ballot Cycle
Considering several potential pilot guidelines

- Includes CDC’s & medical societies’ guidelines

- Guidelines at various starting points
  - *Already published*: structure recommendations using standards
  - *Starting at the beginning of the process*: will have parallel development of guideline narrative & CDS

- Pilots will include a multi-stakeholder matrixed approach
  - Guideline authors
  - Partner implementers (via HL7 process)
  - Adapting Clinical Guidelines Workgroups:
    - Guideline Creation
    - Informatics
    - Translation and Implementation
    - Dissemination and Communication
    - Evaluation
Applying guidelines in patient care more easily, quickly, accurately, and consistently

The case for shareable interoperable CDS via CDS Connect
Clinical Guidelines of the Future

- Complement guideline narratives with computable guidelines
- Clinical Decision Support Community
- Clinical Guideline Producers
- Researchers
- Build repositories of reusable guideline components
- Governance
- Tools and Repositories
- Automate the evaluation of guidelines
- Clinical Decision Support Consumers
- Health IT System
- Provider
- Patients
- Guidelines implemented in hours
Complete Feedback Loop

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For questions or more information, please contact:

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More Slides: Development of CDS for Anthrax Emergencies
1. Generated 100 synthetic patient records using 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
# L2 & L3 Challenges and Recommendations

<table>
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<tr>
<th>Issue</th>
<th>Recommendation</th>
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<tr>
<td>Uncertainty of or conflicting guidance</td>
<td>&gt;Involve guideline developers with the L2 team</td>
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<tr>
<td>Multiple overlapping guidelines</td>
<td>&gt;Define a systematic process for evaluating each guideline and recommendation</td>
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<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>
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<tr>
<td>L2/L3 must align</td>
<td>&gt;Have a robust ongoing mechanism for communicating between L2 and L3 teams</td>
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<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>
</tr>
<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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</table>
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 System

- 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