Adapting Clinical Guidelines for the Digital Age

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OUR HOLISTIC GOAL

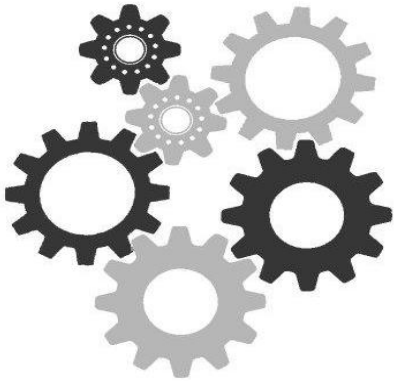
Make it easy for clinicians to do the right thing

by applying guidelines in practice

more easily, quickly, accurately, and consistently

WANTED:

Complete Feedback Loop

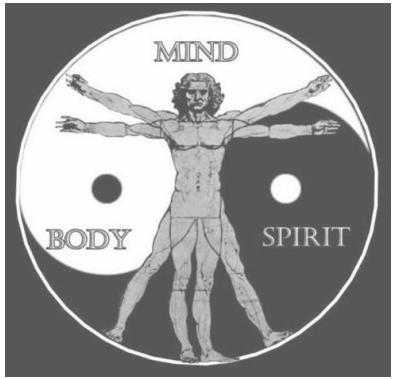


CLINICAL DECISION SUPPORT

CLINICAL QUALITY MEASUREMENT

CLINICAL GUIDELINES DEVELOPMENT

DESIRED HEALTH ACTIONS & OUTCOMES



Today's Guideline Development and Implementation

Long Implementation Time

Develop guidelines

Research Results

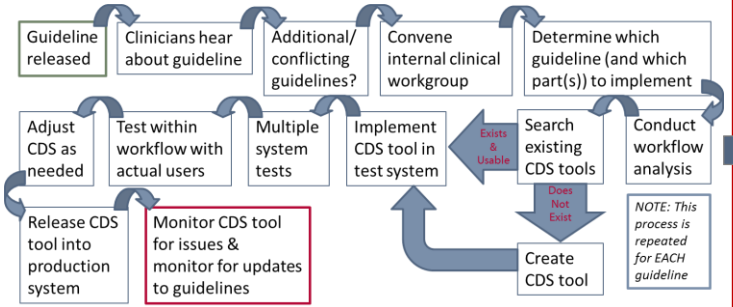
Literature Review

Meta-analysis

Guideline Narrative

PDF

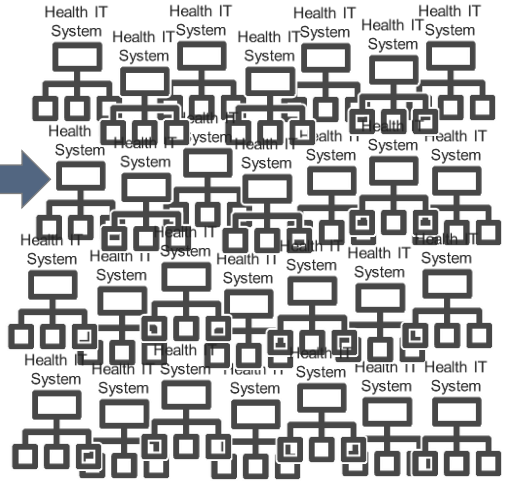
Interpret guidelines



Performed by up to 95% of ~5500 hospitals

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

Implement guidelines



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

Participating Stakeholder Groups

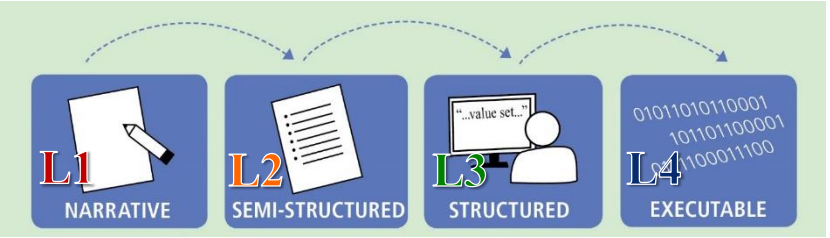
- Guideline authors
- Health IT developers
- Communicators
- Clinicians
- Patients / Patient Advocates
- Medical Societies
- Public Health Organizations
- Evaluation experts
- Standards experts
- Clinical decision support developers
- Clinical quality measure developers
- Policy or technical support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

Adapting Clinical Guidelines for the Digital Age

Problem: Long Lag Time, Inconsistencies, and Inaccuracies in Translation	**Reason**: Playing the "Telephone Game"	**Solution**: Developing Tools and Guidelines Together
		
Leads 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	Can help evidence apply to patient care more easily, quickly, accurately, and consistently

https://www.cdc.gov/ddphss/clinical-guidelines/index.html

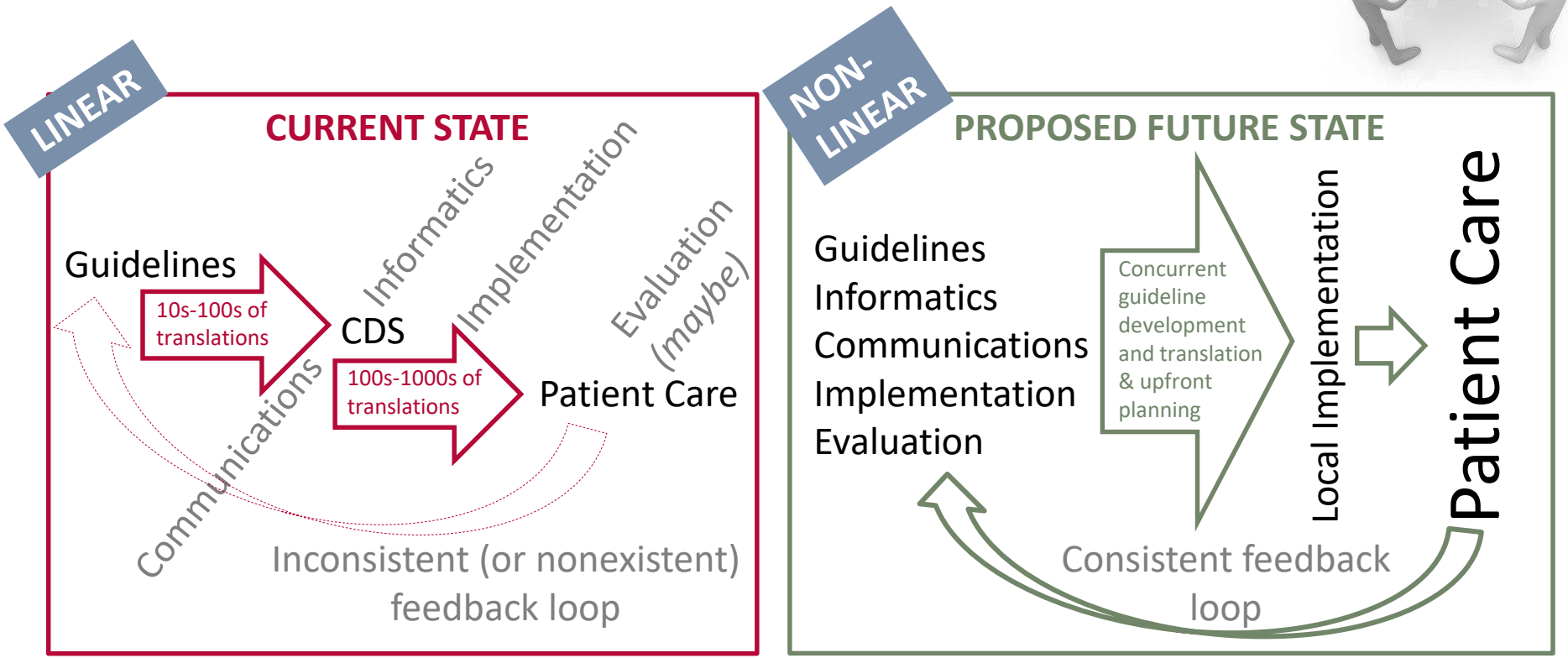
Translating Evidence to Executable CDS



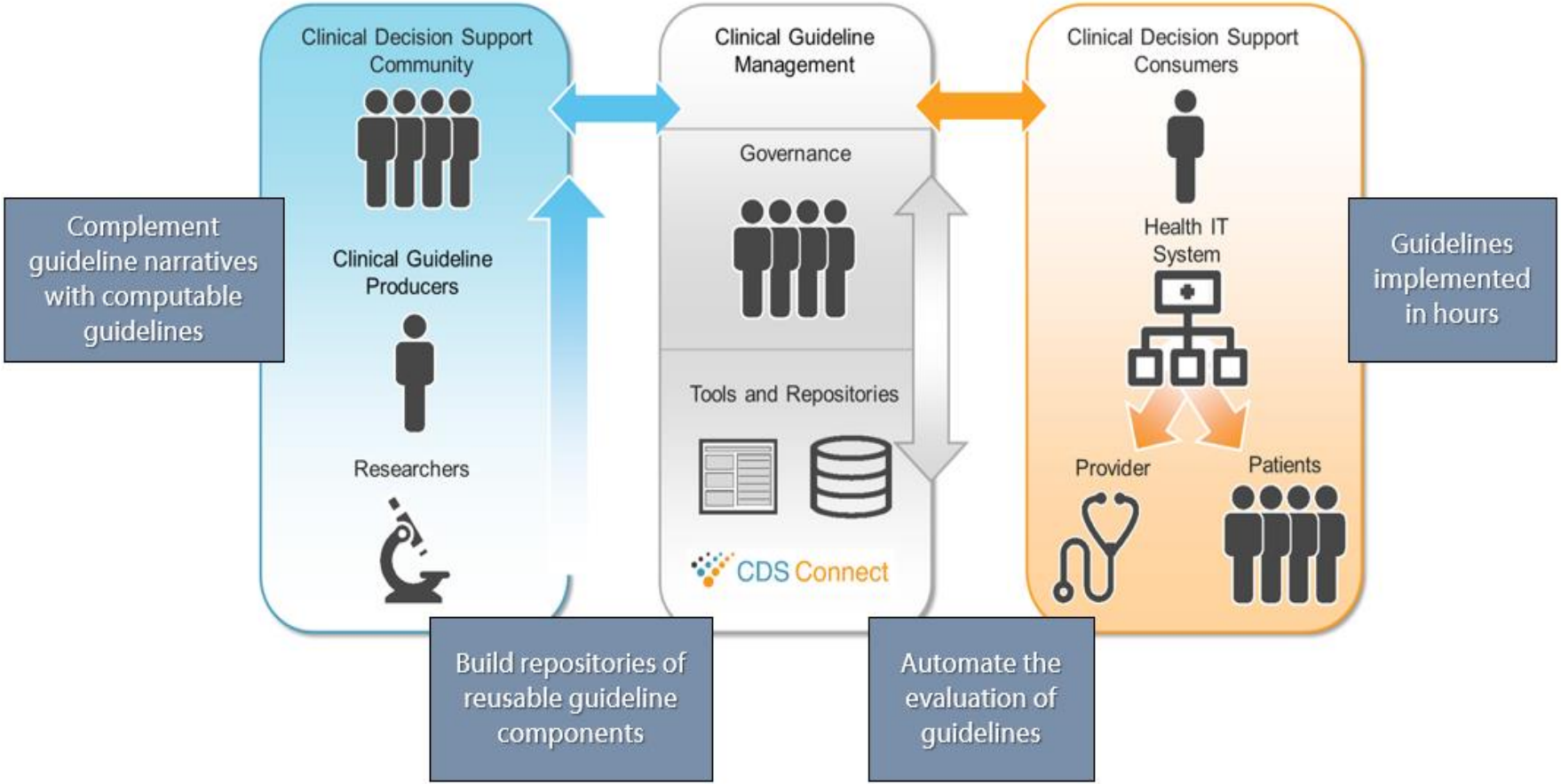
Knowledge Level	Description	Example
L1	Narrative guideline	Guideline for a specific disease that is written in the format of a peer-reviewed journal article
L2	Semi-structured	Flow diagram, decision tree, or other similar format that describes recommendations for implementation
L3	Structured	Standards-compliant 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

Adapted from: Boxwala, AA, et al.. A multi-layered framework for disseminating knowledge for computer-based decision support. *J Am Med Inform Assoc* 2011(18) i132-i139.

Redesigning Guideline Development and Implementation

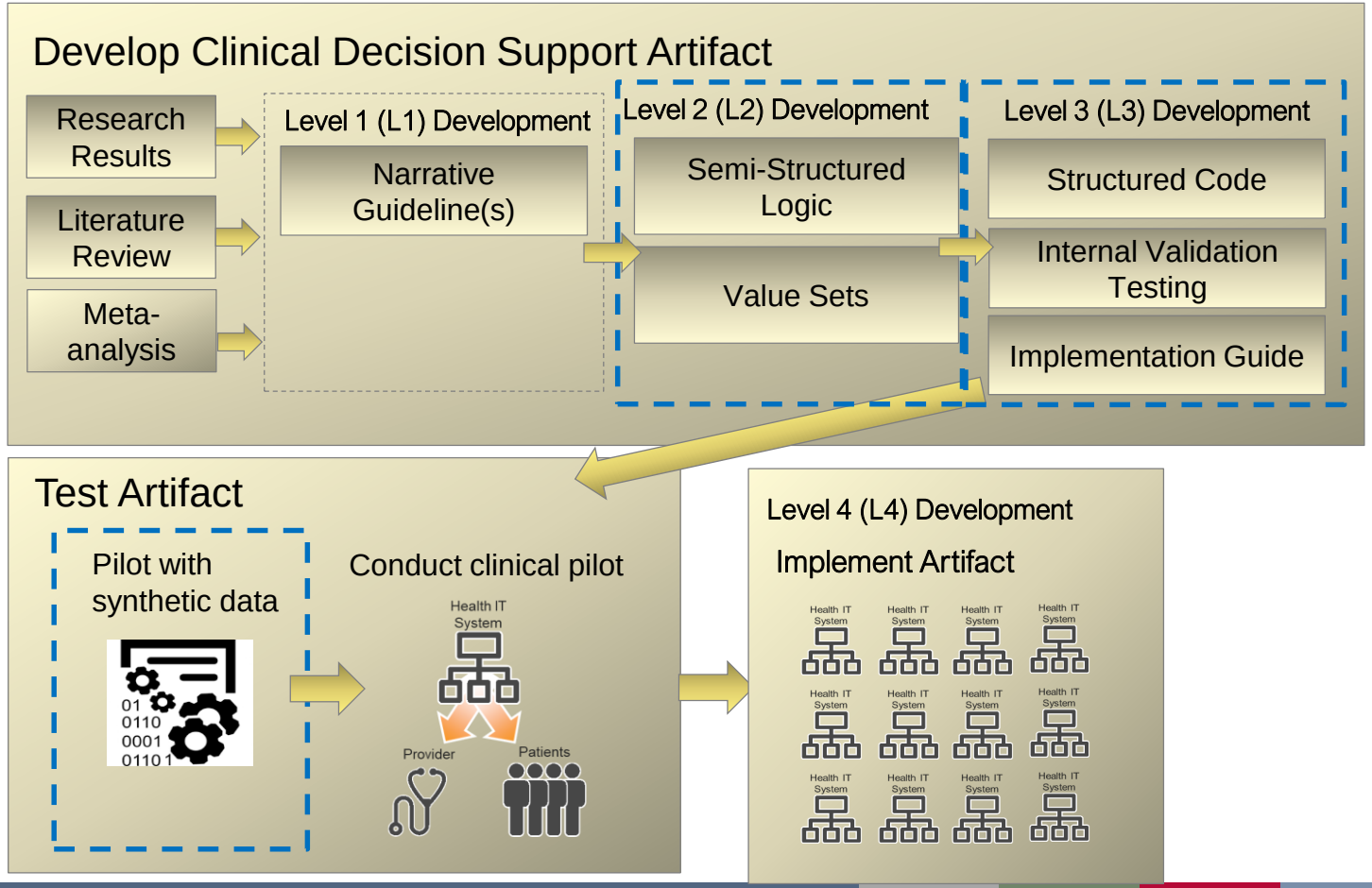


Clinical Guidelines of the Future

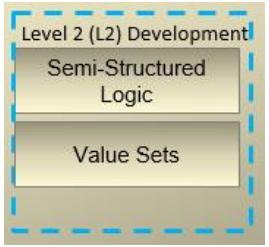


Learning from the Development of CDS for Anthrax Emergencies

Overarching CDS Development Approach



Level 2: Semi-structured Representation



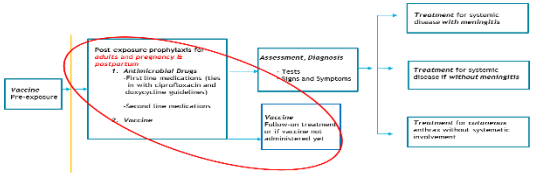
1. Identified Pertinent Guidelines

(17 total)

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

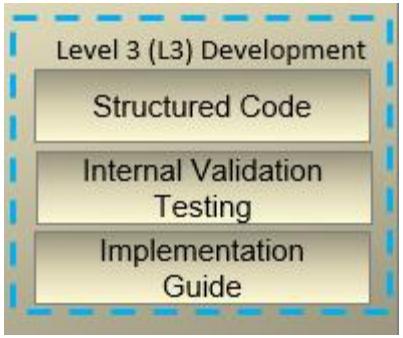
(selected 5 guidelines)

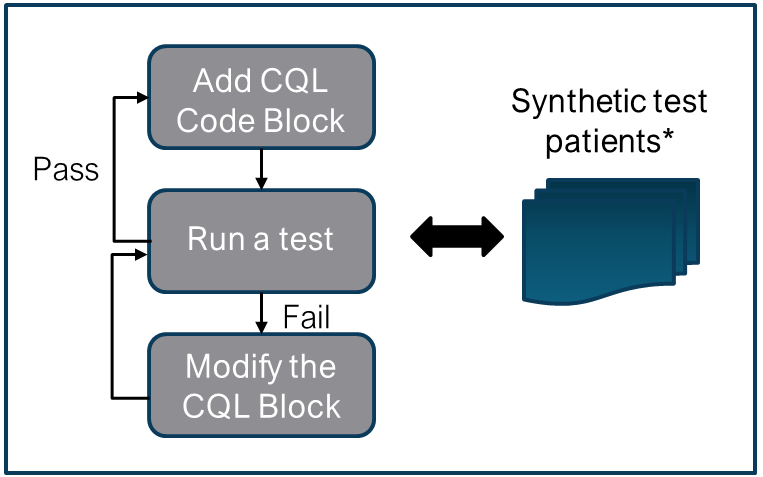
4. Assessed Recommendation Statement(s) to Derive Artifact

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



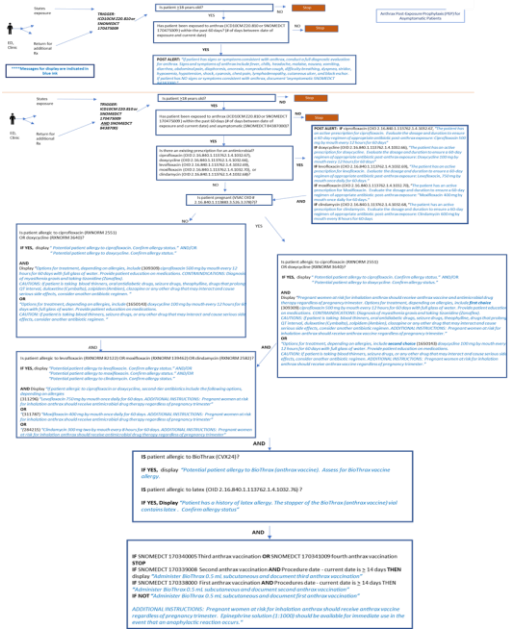


* Not the same as those used in synthetic pilot

- **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

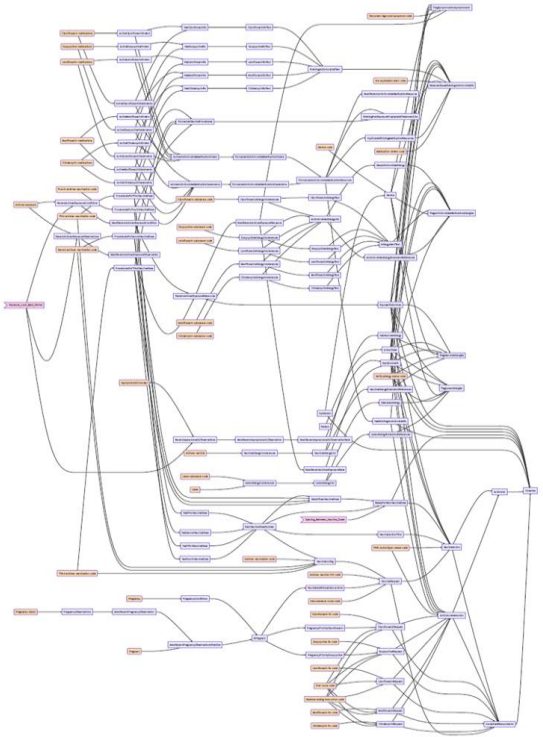
Detailed L2



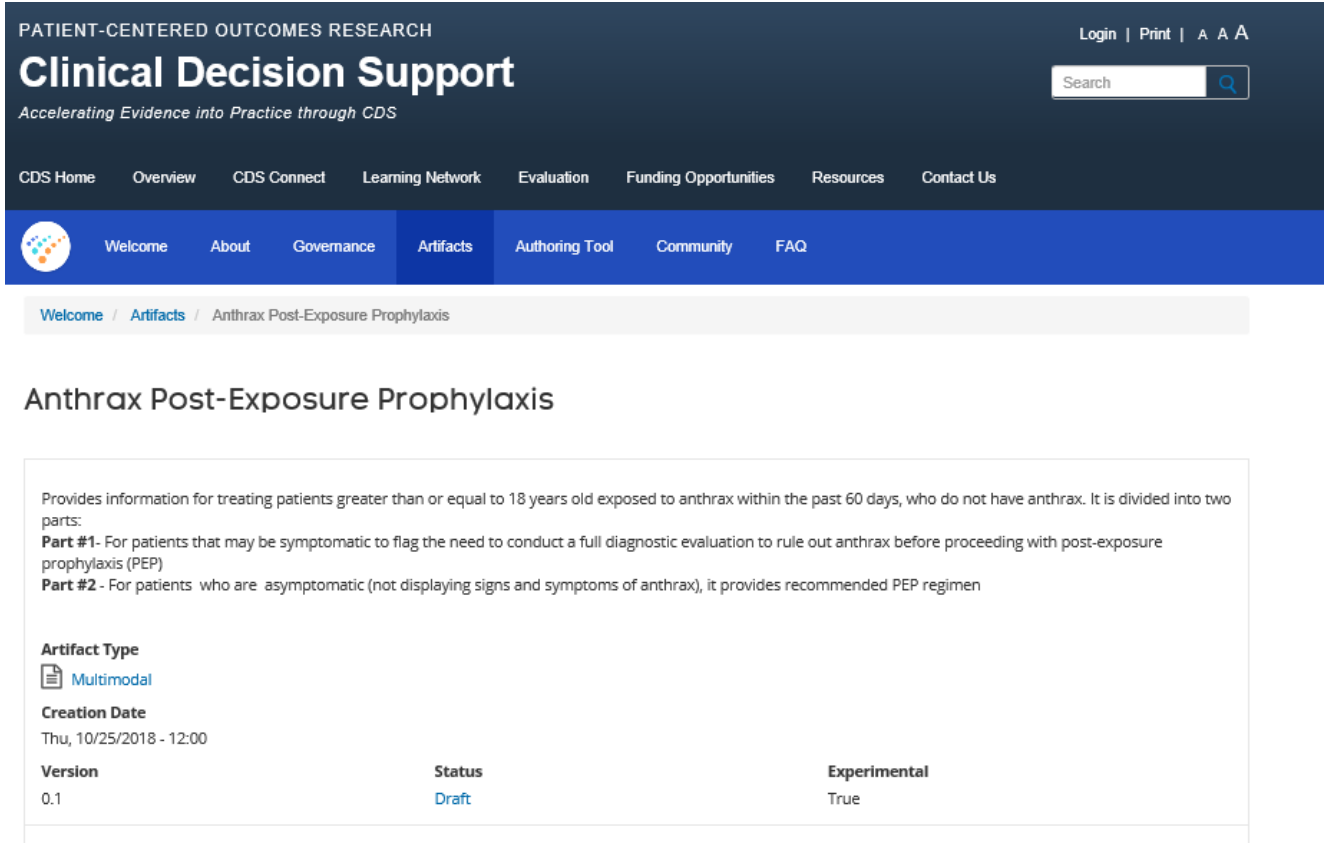
***Complex* CDS artifact with:**

- **8 value sets**
- **105 CQL expressions**
- **232 dependencies**
- **1215 lines of code**

Detailed L3



Anthrax CDS Published



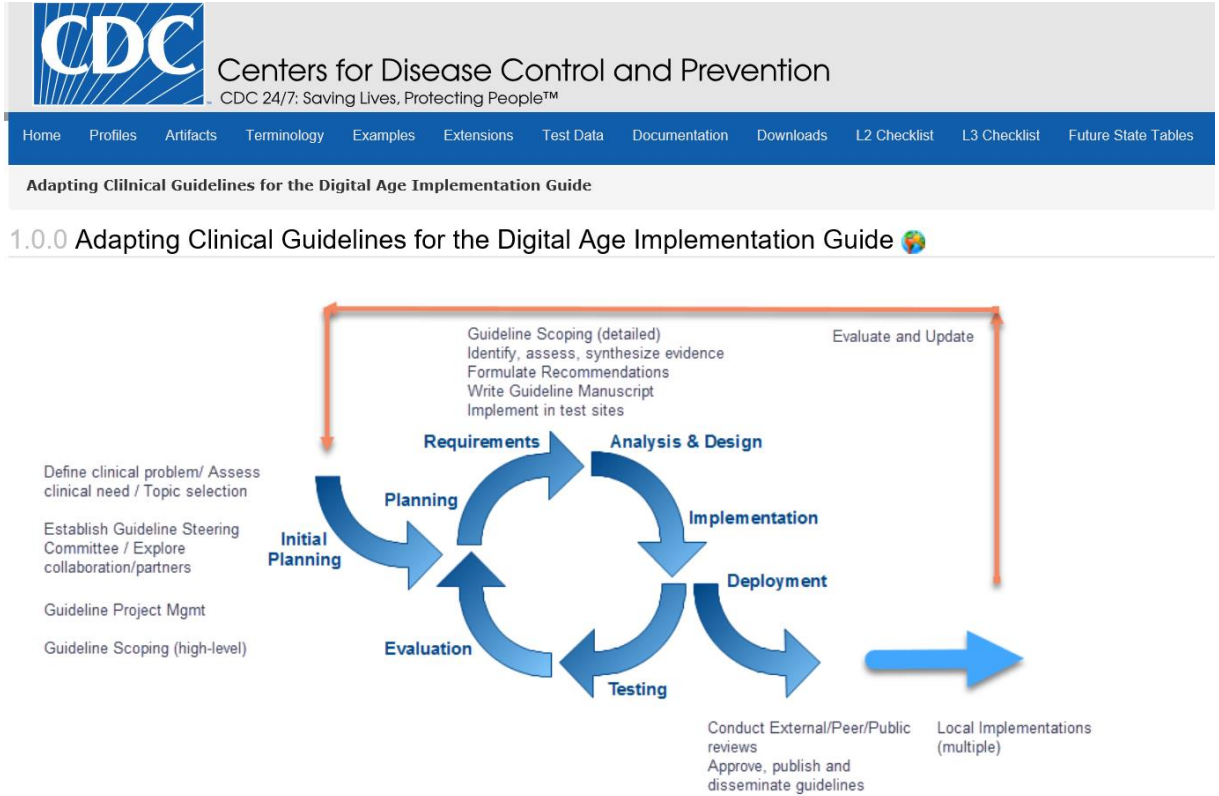
- **Metadata**
- **CQL**
- **Built-in synthetic test patients**
- **Implementation guide**
- **Validation report**

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

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)



HL7 Balloting planned for September 2019 Ballot Cycle

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

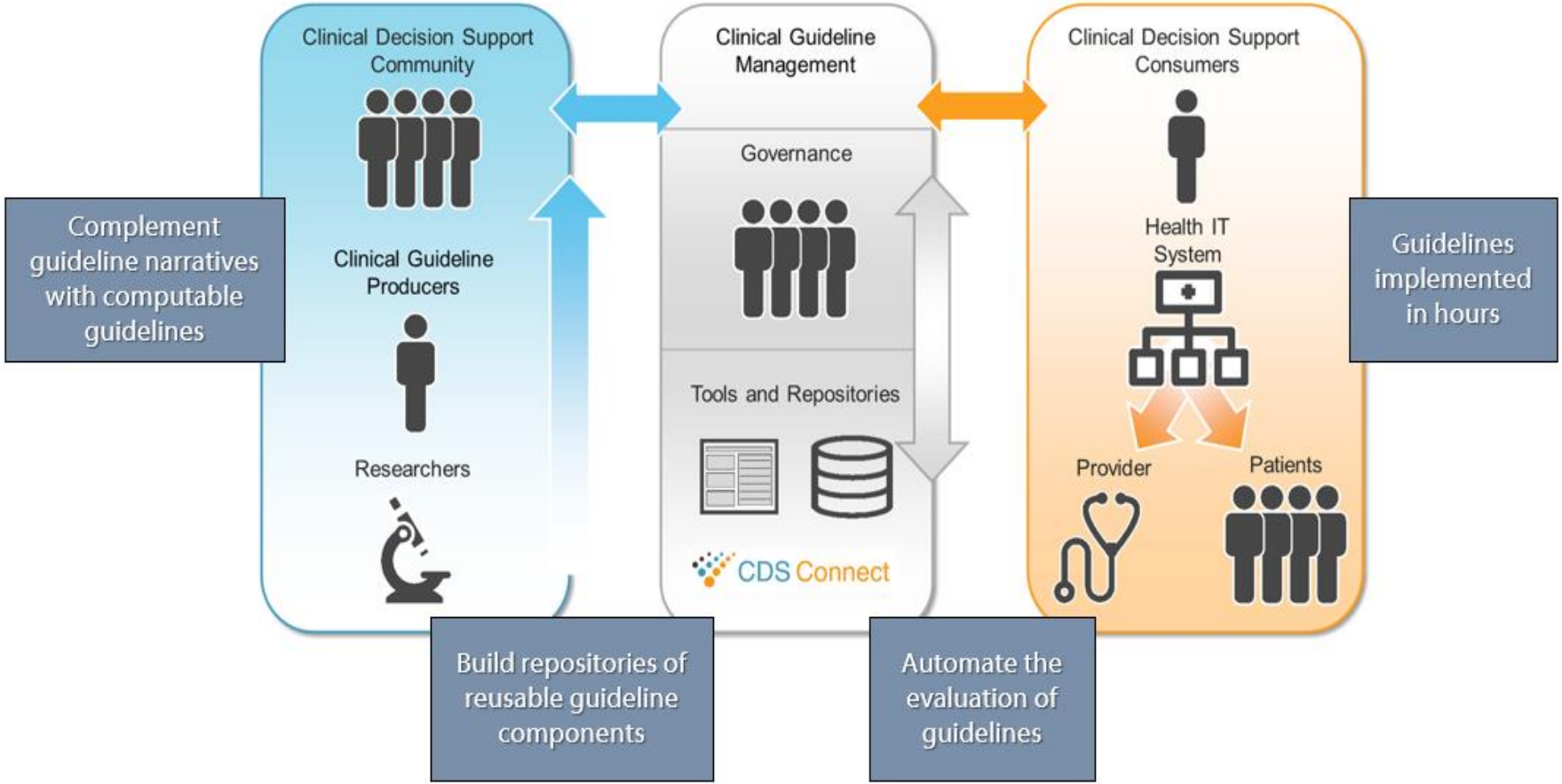
Considering several potential pilot guidelines

- **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

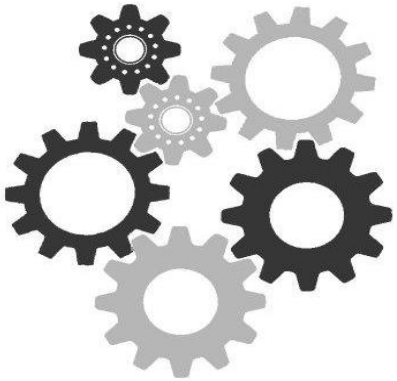
Applying guidelines in patient care more easily, quickly, accurately, and consistently

The case for shareable interoperable CDS via CDS Connect

Clinical Guidelines of the Future



Complete Feedback Loop



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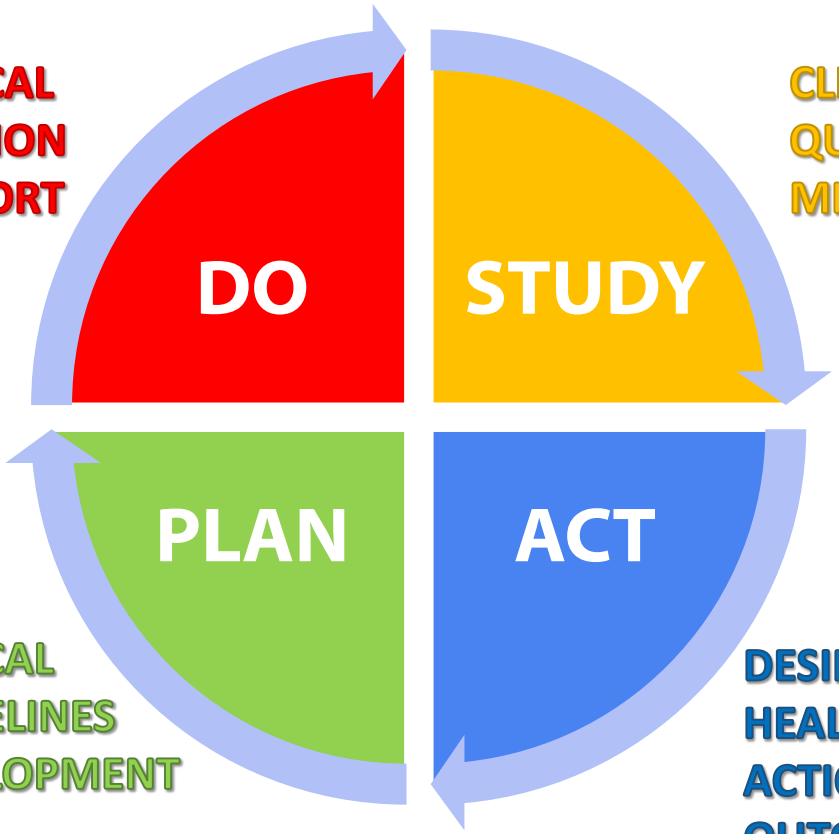

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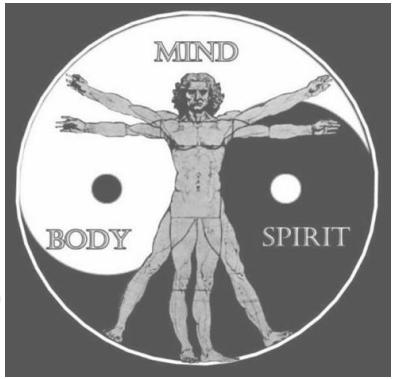

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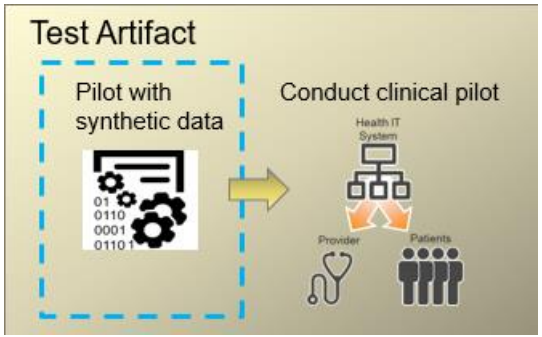
For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.

More Slides: Development of CDS for Anthrax Emergencies

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

L2 & L3 Challenges and 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

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