Scaling Patient-Centered CDS for Disseminating Guidelines in Public Health: A Case Example

September 14, 2017

Grant #: CDC-RFA-OT13-130203CONT16
Funding #: U38OT000216
Introductions

Dr. Middleton first envisioned electronic health records while a medical student in 1984. He has been engaged in clinical informatics research and development ever since, focusing on Clinical Decision Support, knowledge engineering, and knowledge sharing technologies at Stanford, MedicaLogic, Partners Healthcare, Harvard, and Vanderbilt. At Apervita, he provides leadership and guidance for informatics at Apervita and supports customers on clinical informatics issues.

Jim Jellison serves as the director of Practice Support and as the senior informatics analyst for the Public Health Informatics Institute (PHII). As director, Jim supervises staff and manages the Practice Support portfolio of projects. As the senior informatics analyst, Jim provides informatics and policy analysis expertise to a number of projects, either as project director or as a member of a project team.
Agenda

• Background and Context (5 mins)
• Implementation Overview (15 mins)
• Functional Overview (30 mins)
• Questions & Answers (10 mins)
Clinical decision support (CDS) is a term used to describe the use of information technology to encourage health care providers' adherence to clinical guidelines. These clinical guidelines can include recommended treatment regimens for health conditions of public health concern. The Public Health Informatics Institute (PHII), working under cooperative agreement with the Centers for Disease Control and Prevention (CDC), has partnered with Apervita to advance CDS for STIs. This webinar will demonstrate how CDC's gonorrhea treatment recommendations were converted into an electronic CDS knowledge artifact that conforms to current interoperability standards, is executable in standards-based CDS engines, is encoded in Clinical Quality Language (CQL), and conforms with appropriate terminology standards.
At Apervita, we believe in...
Open, industry-scale collaboration for health analytics & data
The Big Problem

DELIVERING UBIQUITOUS ACCESS TO CLINICAL KNOWLEDGE

GUIDELINES AND MEASURES

CONSTANT GROWTH & CHANGE

BARRIERS TO IMPLEMENT AND ADAPT

$MILLIONS COST & COMPLEXITY

MANY END POINTS

MILLIONS OF DECISIONS

THE ERA OF INSIGHT

x100 Demand for Health Insight

PAPER ERA	EHR ERA

2000	2010	TODAY

THE CARE CONTINUUM
Background and Context

In the US we are experiencing a near epidemic of STDs and growing patterns of antibiotic resistance among infecting agents.

Antibiotic-resistant gonorrhea is particularly concerning:

• **There are about 820,000 new gonorrhea infections each year in the U.S**

• **Gonorrhea is the 2nd most commonly reported infectious disease**

• **We are down 1 recommended effective class of antibiotics to treat it**

Antibiotic-Resistant Gonorrhea

Gonorrhea is developing resistance to the antibiotics we use to treat it.

- There are about 820,000 new gonorrhea infections each year in the U.S.
- Gonorrhea is the 2nd most commonly reported infectious disease.
- We are down to 1 recommended effective class of antibiotics to treat it.

The public health and medical communities must work together to:

- Monitor antibiotic resistance
- Develop new treatment options

With only one recommended treatment option remaining, it’s time to take action.

Learn more at [www.cdc.gov/std/gonorrhea/arg](http://www.cdc.gov/std/gonorrhea/arg)
The Vision

To address this challenge, the CDC needs a new approach and capabilities to distribute and operationalize computable clinical Guidelines & CDS and monitor their effectiveness.
Where are We?

**YESTERDAY**

- Paper Guidelines
- Limited standards to represent knowledge and to access data
- High-cost, resource intensive one-off Guideline & CDS implementations
- Costly to maintain as Guideline evolves
- Difficult to assess efficacy

**TODAY**

✓ Computable Guidelines
✓ Completely standards based and interoperable Guideline implementation
✓ Tools and infrastructure are available to deliver Guideline across multiple applications (e.g., EHR, Business Intelligence)
✓ Full lifecycle capabilities allow for knowledge asset maintenance

Few CDS in national use

Standards-based, interoperable eGuidelines & eCDS
How do we get There?
COMMON BUILDING BLOCKS FOR INTEROPERABLE CLINICAL REASONING

Reusable Building Blocks

- **Logic Expressions**
- **Value Sets**
- **Controlled Terminologies / Ontologies**

Presentation Layer - Deployable into Standardized Workflow in EHR, Quality/Safety apps, PHR

- eCQM, eCase Reporting, eCase Detection, and Clinical Decision Support share many common building blocks

- An integrated architecture with common and shared set of specifications for key components and delivered applications reduces friction and enhances interoperability
Implementation Overview
Project Scope

• The purpose of this project is to convert CDC’s gonorrhea treatment recommendations into an electronic clinical decision support (CDS) knowledge artifact that is:
  - conformant with **current CDS interoperability standards**
  - executable in **standards based CDS engines**
  - compliant with appropriate **terminology standards**

• The project was completed in 6 months and divided into three parts:
  - **Part 1**: Build logic flow diagram from 2015 STD guideline treatment and management recommendations
  - **Part 2**: Convert logic flow diagram to interoperable, standards-based representation using CQL Expression Language and FHIR Clinical Reasoning resources
  - **Part 3**: Implement and demonstrate the delivery of real-time clinical decision support using the Apervita computing platform
Methodology and Application Overview

L1  Started with paper CDS STI Guideline

L2  Converted Guideline to a logic flow diagram with CDC SME input

L3  Built standards-compliant CQL and FHIR Resources; specifying and encoding the logic with data model(s), terminology/code sets, value sets

L4  Implemented real-time CDS in an execution environment (Apervita)

2015 STD Treatment Guidelines

Systemic Infection Scenarios
- Disseminated NG Infection
- NG Arthritis/Arthritis Dermatitis Syndrome
- NG Endocarditis
- NG Meningitis

Non-Systemic Infection Scenarios
- Conjunctival NG Infection
- Oropharyngeal NG Infection
- Urogenital & Anorectal NG Infection
- Suspected Cephalosporin Treatment Failure

Gonorrhea Logic Flow Diagrams

Non-Systemic Infection Expanded Scenarios

- Oropharyngeal NG Infection
- Azithromycin Allergy
- Cephalosporin Allergy
- Urogenital & Anorectal NG Infection
- Azithromycin Allergy
- Cephalosporin Allergy
- Pregnancy
- Suspected Cephalosporin Treatment Failure
- Test for Cure
## Going from L2 to L3 - Applying Current Informatics Standards to the Translation and Specification Process

**FHIR QICore Data Profile**
- Based upon Quality Information and Clinical Knowledge (QUICK) data model
- Specializes in clinical decision support and quality measures
- Designed to be highly interoperable

**CQL (Clinical Quality Language)**
- CQL is designed to harmonize eCQMs and CDS
- Provides for specification of interoperable expression logic
- Both human-readable and machine-readable

**VSAC and custom Value Sets**
- Define high-level concepts in terms of applicable codes from standard terminologies
- Share standard definitions with eCQM specifications and measure developers

**FHIR STU3 PlanDefinition**
- FHIR STU3 resources are focused around reusability, performance, and data fidelity
- PlanDefinition resource provides a template for recommendations and actions in treatment guidelines

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[https://ecqi.healthit.gov/system/files/clinicalqualitylanguagebasicsv5_508.pdf](https://ecqi.healthit.gov/system/files/clinicalqualitylanguagebasicsv5_508.pdf)
L3 - Standards Used to Represent the Guidelines

**Data Model Standards**
- FHIR QICore v1.6
- FHIR Helpers v1.8.0

**Guideline Representation**
- Clinical Quality Language (CQL)
- FHIR STU3 v1.8.0 Clinical Reasoning Resources

**Value Set Code Systems**
- LOINC
- SNOMEDCT
- RXNORM
- NDF-RT

**Completely Standards-Based!**
Customizable Plan Definitions

**Plan Definitions for Treatment Scenarios**
- Adult Standard Treatment Recommendation
- Adult STD Coinfection Testing Recommendations
- Adult Retest Recommendation
- Adult Treatment Associated Recommendations
- Azithromycin Allergy Treatment Recommendation
- Cephalosporin Allergy Treatment Recommendation
- Pregnant Adult With Allergy Treatment Recommendation
- NGi With Allergy Consult Recommendation
- Adult Suspected Cephalosporin Treatment Failure
- Adult Oropharyngeal Test Of Cure Recommendation At Dx
- Adult Oropharyngeal Test Of Cure Due Recommendation

**FHIR PlanDefinition Resources**
- Rules for selection of applicable plan
- Rules for customization
- Definition of required provider communications
- Detailed action requests
  - medications
  - procedures
  - referrals
Going from L3 to L4 - Implementing the Standards Based CDS

Standards Based Implementation

- Standard Data Structure
- Customizable Careplans

- Assess Clinical Scenarios

- Customizable Value Sets
- HTML
- CDS Hooks
- EHR Integration

On-Demand Data Pull - Assess Qualification for Treatment - Treatment Guideline FHIR Resources - Customize Careplan - Render Care Plan

Apervita API
Web Services Interactions - EHR and SMART on FHIR

1. Send Request
2. Request Patient Data
3. Return Data
4. Execute Clinical Calculations
5. Return Content for Display

EHR User Interface (Browser Window or IFrame)

EHR Data Service (FHIR or Proprietary API)

Apervita Cloud

CQL

Generate FHIR Care Plan

FHIR Plan Definitions

Render as HTML
<table>
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<tr>
<th>WORKFLOW TRIGGERED</th>
<th>Clinical Decision Support is delivered to clinicians with no need to “click the button” or otherwise invoke the clinical reasoning module.</th>
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<tbody>
<tr>
<td>INFORMATION IN CONTEXT</td>
<td>Provides information and suggestions for action to clinicians in the EHR user interface and in the patient context.</td>
</tr>
<tr>
<td>SMART ON FHIR</td>
<td>Links to SMART-on-FHIR apps when more extensive interaction is required.</td>
</tr>
<tr>
<td>DATA INTEGRATION</td>
<td>Returns data and decisions for integration with the patient record.</td>
</tr>
<tr>
<td>RESULTS TRACKING</td>
<td>Records and tracks accepted suggestions and decisions to support process improvement.</td>
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Web Services Interactions - CDS Hooks, Apervita, and Meliorix Sapphire

1. Send Request
2. CDS-Hooks Post
3. (Get Data)
4. Info Cards Returned
5. Process Info Card Content

Create Dashboard
Create Filter Rules
Render Card Content

Clinical Calculations
Generate FHIR Care Plan
Render as CDS Hooks Cards

Meliorix Sapphire Client
Meliorix Server
Apervita Cloud

CDS-Hooks, Apervita, and Meliorix Sapphire
Functional Overview
### Demonstration Personas

#### Users of eGuidelines

- **Dr. Weaver**  
  PCP  
  Sacred Heart Hospital  
  Sees a patient in need of a standard NG treatment  
  Sees a patient in need of a complicated NG treatment

- **Simon**  
  Chief Quality Officer  
  Sacred Heart Hospital  
  Evaluate usage and efficacy of the eGuideline within Sacred Heart Hospital

- **Jackie**  
  Epidemiology Team @ State Public Health  
  Evaluate Usage and Efficacy of eGuideline across the State

#### Builders of eGuidelines

- **Karen**  
  Informatics Implementor  
  Sacred Heart Hospital  
  Implement eGuideline/CDS using existing EHR infrastructure  
  Implement CDS using a SMARTonFHIR application

- **Robertta**  
  Guideline Provisioner @ CDC  
  Publish eGuidelines and make available for use  
  Provision Guidelines to HCO Informatics Implementor

- **Jason & Team**  
  Guideline Builder @ CDC  
  Build and convert eGuideline into CQL/FHIR  
  Make eGuideline CQL available on Apervita Platform
### Demonstration Clinical Scenarios (Standard NG Treatment) - Part A

**Ambulatory Care Routine Screening Reveals Urogenital Infection in a 30 y/o Male**

**PROFILE**

Paul was reminded to schedule his routine annual visit automatically by a scheduling alert
- He also filled out an online questionnaire detailing his current condition, interval history, and any new complaints.

**DOCTOR’S VISIT**

Dr. Weaver uses the CDC STD Guideline plan of care for her patient:
- Paul is sexually active with a history of an STD. Clinical Decision Support recommends STD screening. Paul completes NAAT prior to clinical encounter.
- Dr. Weaver conducts an H&P examination and confirms STD diagnosis and positive NAAT.
- CDS (CDC STD Guideline) suggests a care plan for treatment, education, and follow-up.

**MANAGEMENT AND TREATMENT**

- **Management**: Patient care handout automatically sent to patient and posted to the patient portal, follow up testing order done, follow up clinic visit scheduled, partner testing and treatment if applicable.
- **Treatment**: Ceftriaxone 250 mg IM x 1 in clinic and Azithromycin 1g orally observed

**REPORTING**

Electronic Case Reporting to Public Health authorities
- All diagnosed cases and relevant data (evaluated by CDC Guideline) abstracted as a report to submit automatically to appropriate Public Health authorities.
Ambulatory Summary

This page is not a complete source of visit information.

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Recommendations

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2015 CDC Guidelines for Sexually Transmitted Diseases

Treatment for NG Infections

- Standard Treatment Recommendation for Adult with New Untreated Gonorrhea
- Evaluation for STD Co-infections in Adults with Gonorrhea
- Treatment-associated Recommendations for New Gonorrhea
2015 CDC Guidelines for Sexually Transmitted Diseases

Treatment for NG Infections

**Standard Treatment Recommendation for Adult with New Untreated Gonorrhea**

This patient has a new test result suggesting untreated gonorrhea and has no known allergies to the standard treatment regimen. Consider treatment with azithromycin 1g PO x 1 dose and cefixime 250mg IM x 1 dose.

Propose order for azithromycin 1g PO x 1 dose
Propose order for cefixime 250mg IM x 1 dose

**Evaluation for STD Co-infections in Adults with Gonorrhea**

If an adolescent or adult has evidence of gonorrhea and has not received simultaneous or subsequent evaluation for co-infection with chlamydia, syphilis, and HIV, then the missing tests should be performed.

Propose an order for a chlamydia test.
Propose an order for a syphilis test.
Propose an order for an HIV test.

**Treatment-associated Recommendations for New Gonorrhea**

If this patient has a new test result suggesting gonorrhea, then the patient’s sexual partners during the last 60 days should receive evaluation and presumptive treatment for gonorrhea. The partner should be retested for gonorrhea 3 months after treatment, and patient...
Ambulatory Care Routine Screening Reveals Urogenital Infection in a 27 y/o Female

PROFILE

Mary is coming in for a follow-up visit after lab work. She was first diagnosed with gonorrhea 6 months ago by another health provider but treatment is unclear.

DOCTOR’S VISIT

Dr. Weaver triggers the CDC STD decision support given her clinical concern regarding Mary’s history of symptoms and discovery of a new partner also exhibiting symptoms:

- Mary is sexually active with a history of an STD and has a new partner in the past 60 days. Mary has an azithromycin allergy and a cephalosporin allergy.
- Dr. Weaver confirms Chlamydia and NG diagnosis, urogenital location, and no pregnancy. It is uncertain if Mary has a recurrent infection or a new infection from her partner.
- CDS (CDC STD Guideline) suggests a care plan for treatment, education, and follow-up.

MANAGEMENT AND TREATMENT

- **Management:** Order ID consult, patient referral, Linkage to STD Treatment Facility, Culture to CDC, STD Testing Regimen, Partner Treatment Regimen, Retesting Regimen, Patient Education Regimen.
- **Treatment:** Given Azithromycin and cephalosporin allergy; She is given an ID consult recommendation for gonorrhea complicated by allergies to recommended antibiotics.

REPORTING

Electronic Case Reporting to Public Health authorities

- All diagnosed cases and relevant data (evaluated by CDC Guideline) abstracted as a report to potentially submit to appropriate Public Health authorities.
2015 CDC Guidelines for Sexually Transmitted Diseases

Treatment for NG Infections

- Recommended Treatment for Adult with New Untreated Urogenital/Anorectal NG infection and Allergy to Azithromycin
- Recommendations for Recurrent Gonorrhea When Cephalosporin Treatment Failure Is Suspected
- Evaluation for STD Co-infections in Adults with Gonorrhea
- Treatment-associated Recommendations for New Gonorrhea
Recommended Treatment for Adult with New Untreated Urogenital/Anorectal NG Infection and Allergy to Azithromycin

This patient appears to have recurrent gonorrhea after prior treatment with a cephalosporin. If cephalosporin treatment failure is suspected, consider microbial testing (C&S for N. gonorrhoeae, if not done), and consider testing for eradication and cure with both a NAAT and C&S for N. gonorrhoeae 14 days after re-treatment.

Propose an order for a culture before re-treatment in the setting of recurrent gonorrhea with suspected cephalosporin treatment failure.

Propose an order for a test of antibiotic susceptibilities for any Neisseria gonorrhoeae organisms that may be identified by a culture test obtained in the setting of recurrent gonorrhea with suspected cephalosporin treatment failure.

Propose an order for a NAAT to detect the persistent presence of Neisseria gonorrhoeae 14 days after treatment in the setting of suspected cephalosporin treatment failure.

Propose an order for a culture to detect the persistent presence of Neisseria gonorrhoeae 14 days after treatment in the setting of suspected cephalosporin treatment failure.

Propose an order for a test of antibiotic susceptibilities for any Neisseria gonorrhoeae organisms that may be identified by a culture test obtained 14 days after re-treatment in the setting of suspected cephalosporin treatment failure.
N. gonorrhoeae treatment CDS - Clinical decision support for N. Gonorrhea

Ms. Mary Contrary
DOB: 1989-10-29
Age: 27
Gender: Female
Address: 108 Florence Street, Springfield, IL, USA
Contact:
Mobile: 708-555-1234
Home: 708-555-6666

Recent results

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Treatment recommendations

Evaluation for STD Co-infections in Adults with Gonorrhea

Treatment-associated Recommendations for New Gonorrhea

Recommended Treatment for Adult with New Untreated Urogenital/Anorectal NG infection and Allergy to Azithromycin

Recommended for Recurrent Gonorrhea When Cephalosporin Treatment Failure Is Suspected

This patient appears to have recurrent gonorrhea after prior treatment with a

Related medications

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<th>Medication</th>
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<td>2016-08-01 12:30 PM</td>
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<tr>
<td>Doxycycline Monohydrate 100 MG Oral Capsule 100 mg, by Mouth, two times a day</td>
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Related allergies

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<tr>
<td>Azithromycin</td>
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Related diagnoses

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<tr>
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<th>Onset</th>
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<tr>
<td>Gonococcal infection, unspecified (ICD10CM: A54.9)</td>
<td>2017-03-01</td>
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Resources

- Gonorrhea also called: The clap
- Understanding Gonorrhea tests
Evaluation for STD Co-Infections in Adults with Gonorrhea

Treatment-associated Recommendations for New Gonorrhea

Recommended Treatment for Adult with New Untreated Urogenital/Anorectal NG Infection and Allergy to Azithromycin

Recommendations for Recurrent Gonorrhea When Cephalosporin Treatment Failure Is Suspected

This patient appears to have recurrent gonorrhea after prior treatment with a cephalosporin. If cephalosporin treatment failure is suspected, consider microbial testing (CFS, DST, microscopy) if possible. If treatment failure is confirmed, select an alternative treatment.

Related medications:
- Ceftriaxone 250 MG Injection 250 mg, Intramuscular, once
- Doxycycline Monohydrate 100 MG Oral Capsule 100 mg, By Mouth, twice a day

Related allergies:
- Azithromycin

Related diagnoses:
- Gonococcal infection, unspecified (ICD10CM: A54.9)

Resources:
- Gonorrhea also called: The clap
- Understanding Gonorrhea tests
Using Population Analytics to Assess Clinical Quality

SIMON WANTS TO KNOW....

• What percentage of diagnosed STD patients are treated at the point-of-care?

• How often are partners prescribed treatment?

• What resistance patterns are emerging?

• Are all untreated but diagnosed cases contacted for follow-up?
STD Cases at Sacred Heart Norfolk Clinics, 2017 YTD

SH Gonorrhea Cases: 558
SH Gonorrhea Follow Ups: 168
STD Case Count in Norfolk, VA: 15,313

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<tr>
<th>STD</th>
<th>Sacred Heart Case Count</th>
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<td>HPV</td>
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<tr>
<td>Trichomoniasis</td>
<td>290</td>
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SH NG Guideline Followed

Share of STD Cases

STD Case Distribution - Sacred Heart

STD Case Distribution - National

Illustrative purposes only. Not real patient data
Using Population Analytics to Assess STD Trends

JACKIE WANTS TO KNOW....

- What are the incidence and prevalence patterns for STDs?
- What clusters are emerging?
- What resistance patterns are emerging across the region?
- Are treatment patterns following Guidelines across healthcare systems?
Illustrative purposes only. Not real patient data
In Summary

The infrastructure is here that will allow the CDC to build, distribute and operationalize computable clinical Guidelines & CDS and monitor their effectiveness using open standards that are scalable nationally.
Lessons Learned

• Broadly accepted standards are in place today to accomplish representation and delivery of interoperable Guidelines and Clinical Decision Support

• Going from paper Guidelines to logic flow diagram (L1 to L2) was not a straight forward translation and required domain expertise and input from clinical SMEs

• Going from L2 to L3 also required significant clinical informatics expertise to identify Value Sets and Plan Definitions for treatment recommendation
  - Publicly available value sets from VCAC required editing

• Information required to drive clinical decision choices may not exist, proxies are needed for true data enablement
Standards and Applications Used

Standards Used:
- HL7 FHIR STU3 for data exchange & template plan definition
- HL7 FHIR QICore data model for use with CQL
- HL7 CQL for expressing clinical logic
- HL7 SMART on FHIR for CDS workflow applications
- CDS Hooks for CDS workflow integration

Applications Used:
- Apervita
- Cerner
- Allscripts
- Meliorix Sapphire
Acknowledgements

- Ninad Mishra, MS, MD
- Bob Kirkcaldy, MD, MPH
- Emily Weston, MPH
- Aziz Boxwala, MD, PhD, FACMI
- Randolph Barrows, MD
- Lana Tsurikova, MSc, MA
- Jim Jellison, MPH
- Michael DeMayo, MPH
- Natalie Viator, MPH
- Blackford Middleton, MD, MPH, MSc, FACMI
- Matthew Burton, MD
- SiSi Shen, MBA
- Andy Schriever
- Tony Thai, MBA
- Kenji Wong
Questions & Answers