eGuideline and Clinical Decision Support for STDs

June 28, 2017
Agenda

• Introductions (5 mins)
• Background and Context (5 mins)
• Project and Methodology Review (15 mins)
• Implementation Demonstration (45 mins)
• Questions & Answers (10 mins)
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.
At Apervita, we believe in... Open, industry-scale collaboration for health analytics & data
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**
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.

1. Build and distribute clinical eGuidelines to HCOs
2. Leverage real-time analytics to power CDS at point of care through desired engagement layer (e.g., EHR, SMART on FHIR, BI, others)
3. Enable automatic eGuideline surveillance to State and Public Health authorities
4. Support continuous improvement of Guidelines
The Big Problem
DELIVERING UBIQUITOUS ACCESS TO CLINICAL KNOWLEDGE

GUIDELINES AND MEASURES

BARRIERS TO IMPLEMENT AND ADAPT

MANY END POINTS

CONSTANT GROWTH & CHANGE

$MILLIONS COST & COMPLEXITY

MILLIONS OF DECISIONS

THE ERA OF INSIGHT

PAPER ERA  EHR ERA

2000  2010  TODAY

x100 Demand for Health Insight

THE CARE CONTINUUM

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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

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

- **Logic Expressions**

- **Value Sets**

- **Controlled Terminologies / Ontologies**

- 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
Project and Methodology Review
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

L3 Built standards-compliant CQL and FHIR Resources

L4 Implemented real-time CDS on 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

Going from L1 to L2 - Guidelines to Computable Logic Flow Diagram

1. Fully understand guideline context and scenarios
2. Create initial draft of logic flow diagram
3. Review with clinical SME advisory panel and build CQL
4. Finalize flowchart diagram based on feedback
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

<table>
<thead>
<tr>
<th><strong>FHIR QICore Data Profile</strong></th>
<th><strong>CQL (Clinical Quality Language)</strong></th>
<th><strong>VSAC and custom Value Sets</strong></th>
<th><strong>FHIR STU3 PlanDefinition</strong></th>
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<tbody>
<tr>
<td>• Based upon Quality Information and Clinical Knowledge (QUICK) data model</td>
<td>• CQL is designed to harmonize eCQMs and CDS</td>
<td>• Define high-level concepts in terms of applicable codes from standard terminologies</td>
<td>• FHIR STU3 resources are focused around reusability, performance, and data fidelity</td>
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<tr>
<td>• Specializes in clinical decision support and quality measures</td>
<td>• Provides for specification of interoperable expression logic</td>
<td>• Share standard definitions with eCQM specifications and measure developers</td>
<td>• PlanDefinition resource provides a template for recommendations and actions in treatment guidelines</td>
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<td>• Designed to be highly interoperable</td>
<td>• Both human-readable and machine-readable</td>
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[https://ecqi.healthit.gov/system/files/clinicalqualitylanguagebasicsv5_508.pdf](https://ecqi.healthit.gov/system/files/clinicalqualitylanguagebasicsv5_508.pdf)
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
Implementation and Application Overview

TODAY: Demonstration of Clinical Scenario

Analytics Engine

EHR

SMART on FHIR App

Apervita

Population Health

Strategic Reporting

APIs

SCM

Finance

EHR

EHR

Allscripts

Cerner

Epic

Meliorix

Meliorix Sapphire

SMART on FHIR
Live Demonstration

Standards Driven Implementation

Analytics Engine  EHR  SMART on FHIR App

apervita  Cerner  Meliorix
Demonstration Personas

**Users of eGuidelines**

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

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

- **Jackie**
  - Epidemiology Team
  - Sacred Heart Hospital
  - Evaluate Usage and Efficacy of the eGuideline across the State

**Builders of eGuidelines**

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

- **Robertta**
  - Guideline Provisioner
  - CDC
  - Publish eGuidelines and make available for use

- **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 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 a 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.
Live Demonstration
Using Population Analytics to Assess Clinical Quality

Simon, Chief Quality Officer at Sacred Heart Hospital

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?
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?
Live Demonstration
Demonstration Personas

**Users of eGuidelines**

- **Karen**
  - Informatics Implementor
  - Sacred Heart Hospital
  - Evaluate Usage and Efficacy of eGuideline within Sacred Heart Hospital

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

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

- **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

**Builders of eGuidelines**

- **Robertta**
  - Guideline Provisioner
  - @ CDC
  - Publish eGuidelines and make available for use

- **Jason & Team**
  - Guideline Builder
  - @ CDC
  - Build and convert eGuideline into CQL/FHIR

- **Simon**
  - Chief Quality Officer
  - Sacred Heart Hospital
  - Implement CDS using existing EHR infrastructure

- **Jackie**
  - Epidemiology Team
  - State Public Health
  - Implement CDS using a SMARTonFHIR application

- **Karen**
  - Informatics Implementor
  - Sacred Heart Hospital
  - Provision Guidelines to HCO Informatics Implementor

- **Dr. Weaver**
  - PCP
  - Sacred Heart Hospital
  - Make eGuideline CQL available on Apervita Platform
Uncomplicated Gonococcal Infections of the Pharynx

Most gonococcal infections of the pharynx are asymptomatic and can be relatively common in some populations [1, 2, 3]. Gonococcal infections of the pharynx are more difficult to eradicate than are infections at genitally and anorectal sites [4]. Few antimicrobial regimens, including those involving oral cephalosporins, can reliably cure >90% of gonococcal pharyngeal infection [5, 6]. Providers should ask their patients with urgent or rectal GC about oral sexual exposure; if reported, patients should be treated with a regimen with acceptable efficacy against pharyngeal gonorrhea infection.

**Recommended Regimen**
- **Ceftriaxone 250 mg IM in a single dose**
- PLUS
- **Ampicillin 1 g orally in a single dose**

**Other Management Considerations**
To maximize adherence with recommended therapies and reduce complications and transmission, medication for gonococcal infection should be provided on site and directly observed. If medications are not available when treatment is indicated, linkage to an STD treatment facility should be provided for same-day treatment. To minimize disease transmission, persons treated for gonorrhea should be instructed to abstain from sexual activity for 7 days after treatment, and until all sex partners are adequately treated (17 days after receiving treatment and resolution of symptoms, if present). All persons who receive a diagnosis of gonorrhea should be tested for other STIs, including chlamydia, syphilis, and HIV.

**Follow-Up**
A test-of-cure is not needed for persons who receive a diagnosis of uncomplicated urethral or rectal gonorrhea who are treated with any of the recommended or alternative regimens; however, any person with pharyngeal gonorrhea who is treated with an alternative regimen should return 10 days after treatment for a test-of-cure using either culture or NAAT. If the NAAT is positive, efforts should be made to perform a confirmatory culture before re-treatment. All positive cultures for test-of-cure should undergo antimicrobial susceptibility testing.
Live Demonstration
Clinical Decision Support Distribution

Distribute STD Guideline on Apervita

Roberta, Guideline Provisioner at CDC
Live Demonstration
Clinical Decision Support Implementation

Karen, Hospital Informatics Implementor at Sacred Heart
Live Demonstration
Clinical Decision Support is delivered to clinicians with no need to “click the button” or otherwise invoke the clinical reasoning module.

Provides information and suggestions for action to clinicians in the EHR user interface and in the patient context.

Links to SMART-on-FHIR apps when more extensive interaction is required.

Returns data and decisions for integration with the patient record.

Records and tracks accepted suggestions and decisions to support process improvement.
QA Session
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.

1. Build and distribute clinical eGuidelines to HCOs
2. Leverage real-time analytics to power CDS at point of care through desired engagement layer (e.g., EHR, SMART on FHIR, BI, others)
3. Enable automatic eGuideline surveillance to State and Public Health authorities
4. Support continuous improvement of Guidelines
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 recommendations

- 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
Questions & Answers
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