A Computable Guideline in FHIR: Opioid Prescribing Support

Maria Michaels and Bryn Rhodes
## Adapting Clinical Guidelines for the Digital Age

<table>
<thead>
<tr>
<th><strong>Problem:</strong> Long Lag Time, Inconsistencies, and Inaccuracies in Translation</th>
<th><strong>Reason:</strong> Playing the “Telephone Game”</th>
<th><strong>Solution:</strong> Developing Tools and Guidelines Together</th>
</tr>
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<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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Overview
The Data Lifecycle & Impacts to the Public’s Health

Delivering actionable knowledge

Analyzing data to advance evidence

Guidelines
Recommendations
Guidance
Public Health Policies or Mandates

Point of Care
Emergency Response
Public Health Departments
Community Services

DATA

EHRs
Registries
Public Health Info Systems
Community Info Systems
...many potential sources

UPDATING SCIENTIFIC EVIDENCE

INFORMATION

Data Science
Analytics
Data Linkages
Data Visualization

Action

HEALTH IMPACTS & OUTCOMES

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How FHIR Facilitates the Data Lifecycle (examples)

Representation of Clinical Practice Guideline Recommendations in FHIR (CPG-on-FHIR)

Representation of Evidence-Based Medicine in FHIR (EBM-on-FHIR)

Bidirectional Services eReferrals (BSeR)

Electronic Case Reporting (eCR)

Quality Measure Reporting

Data Access Framework (DAF) for Research

NOTE: This is not an exhaustive list of examples
The Data Lifecycle & Impacts to the Public’s Health

**Delivering actionable knowledge**

**Analyzing data to advance evidence**

Data
- Data Science
- Analytics
- Data Linkages
- Data Visualization

Knowledge
- Guidelines
- Recommendations
- Guidance
- Public Health Policies or Mandates

Updating Scientific Evidence

Action
- Point of Care
- Emergency Response
- Public Health Departments
- Community Services

Health Impacts & Outcomes

Data Sources
- EHRs
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- ...many potential sources

Updading Scientific Evidence

Information

Guidelines
- Recommendations
- Guidance
- Public Health Policies or Mandates
Today’s Guideline Development and Implementation

Develop guidelines

Research Results

Literature Review

Meta-analysis

Guideline Narrative

Interpret guidelines

Guideline released

Clinicians hear about guideline

Additional/conflicting guidelines?

Convene internal clinical workgroup

Determine which guideline (and which part(s)) to implement

Implemented CDS tool

Search existing CDS tools

Conduct workflow analysis

NOTE: This process is repeated for each guideline

Implemented CDS tool

Create CDS tool

Monitor CDS tool for issues & monitor for updates to guidelines

Release CDS tool into production system

Test within workflow with actual users

Multiple system tests

Implemented CDS tool in test system

Long Implementation Time

Performed by up to 95% of ~5500 hospitals

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

https://dashboard.healthit.gov/quickstats/quickstats.php
Adapting Clinical Guidelines for the Digital Age: Redesigning Guideline Development and Implementation

CURRENT STATE

Guidelines → CDS → Informatics → Implementation → Evaluation (maybe) → Patient Care → CQMs

- 10s-100s of translations
- 100s-1000s of translations
- Inconsistent (or nonexistent) feedback loop

PROPOSED FUTURE STATE

Guidelines, CDS, & CQMs → Concurrent guideline development and translation & upfront planning → Local Implementation

- Consistent feedback loop

Local Implementation → Patient Care

https://www.cdc.gov/ddphss临床-guidelines/index.html
# Translating Evidence to Executable CDS

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Formalizing into a Framework
Implementation Guide
Implementation Guide: Representation of Clinical Practice Guideline Recommendations in FHIR

Targeted for ballot: September 2019

http://build.fhir.org/ig/HL7/cqf-recommendations/
Shareable Computable Guidelines: CDS Connect Repository

Where to find Opioid Prescribing Support
The Origin Story: Towards Computable Opioid Guidelines
Opioid Overdose

CDC Guideline for Prescribing Opioids for Chronic Pain

Improving the way opioids are prescribed through clinical practice guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse, abuse, or overdose from these drugs.

CDC developed and published the CDC Guideline for Prescribing Opioids for Chronic Pain to provide recommendations for the prescribing of opioid pain medication for patients 18 and older in primary care settings. Recommendations focus on the use of opioids in treating chronic pain (pain...
The Running Example

• Patient is being prescribed opioids for chronic pain
• Patient does not appear to be at end of life
• If MME $\geq 50$ and $< 90$, provide a recommendation to taper
• If MME $\geq 90$, provide a recommendation to taper now
Implementation w/in a Health IT system

- Patient is being prescribed opioids for chronic pain
  - Quite difficult to infer, but could reasonably be something like “an opioid with primary care misuse potential for 80 out of 90 days” or “first prescription for an opioid with primary care misuse potential”

- Patient does not appear to be at end of life
  - Again, quite difficult to infer, but could reasonably be something like “Patient is not in hospice care” or “does not have metastatic or pancreatic cancer”
Morphine milligram equivalents (MME/day)

- If MME >= 50 and < 90, provide a recommendation to taper
- If MME >= 90, provide a recommendation to taper now
- Provider is presented with options:
  - Accept – Change dosage
  - Benefits outweigh risks – Snooze 3 months
  - Acute Pain – Snooze 1 month
  - Invalid/Not Applicable – Provides a reason
What is the implementation effort involved?

• Turns out to be quite involved, even assuming you can get the medication information in normalized (RxNorm) form

• Obviously subject to data availability with PDMP registries, dispensing information, accurate med rec information, etc.

• A reasonable go-forward is to base the recommendation on the EHRs current med list for the patient, not perfect, but a starting point

• Calculating MME from prescription information involves calculation dosage frequency and strength, considering things like PRN, ranges, etc.

• In addition, opioids are often combined with other pharmaceuticals, have to calculate based on component ingredients

• Can use RxNav, but calling for each calculation would be prohibitive, needs an offline cache that then needs to be maintained
Can’t someone else do it?

• Shouldn’t the health IT systems just provide these types of functionality?

• Well yes, and they do, but:
  • Pure volume, there are many more of these types of functionalities than can reasonably be provided by any one system
  • Settings-specific factors, leads to customization and complication

• Okay, but each major system also support customizations

• Well yes, and they do, but:
  • Requires “one-off” implementations at each site
  • Limited ability to share implementation experience and cost
Clinical Reasoning Module

• Allows decision support content to be shared as FHIR resources
• Artifacts that define the *structure* of content including rules, order sets, protocols, and questionnaires
• Libraries that define the *behavior* using logic in Clinical Quality Language
Key Resources in Sharing Decision Support

• ValueSet – To share standardized definitions of the concepts used
• Library – To share the logic (can also be used to "package")
• ActivityDefinition – To describe the recommended actions
• PlanDefinition – To describe the "rules"
Knowledge-based Implementation

• Patient is being prescribed opioids for chronic pain
  • Define a value set for “Opioids with primary care misuse potential”
  • If the medication being prescribed is in this set, we know we need to take the next step
• Patient does not appear to be at end of life
  • Again, use terminology to define conditions that are known to be terminal
An aside about Opioid ValueSets

• Valuesets are often distributed as enumerated lists
  • High maintenance/governance cost
• Valuesets are also often defined in terms of a terminology query
• How can we distribute the "definition" of the Valueset, not the "expansion"
  • ValueSet does have facilities for this, but did not support the definitions we had for the valuesets
  • Working with Terminology on that, but is there a way now?
An aside about “process decisions”

• Throughout the implementation process, decisions about how exactly a guideline or recommendation is best realized are being made
• These decisions won’t be the same for every setting, and that’s okay
• The decisions need to be *documented* and *surfaced*
• Ideally, repositories would support semantic indexing based on these types of decisions
Opioid Management Terminology Knowledge
Portable Opioid Management Terminology Knowledge

- CQL Expression of the data
- No run-time dependencies
- Needs maintenance, but can be automated
- Can be (and is being) shared with quality measure definitions
- Not an ideal solution, working on others
Portable MME Calculation

```python
define function CalculateMMEs(medications List<Tuple (rxNormCode Code, doseQuantity Quantity, dosesPerDay Decimal)):
Flatten(
    medications M
    let Ingredients: GetIngredients(M.rxNormCode)
    return
    Ingredients I
    let
        adjustedDoseQuantity: EnsureMicrogramQuantity(M.doseQuantity),
        dailyDose: GetDailyDose(I.ingredientCode, I.strength, I.doseFormCode, adjustedDoseQuantity, M.dosesPerDay),
        factor: GetConversionFactor(I.ingredientCode, dailyDose, I.doseFormCode)
    return {
        rxNormCode: M.rxNormCode,
        doseFormCode: I.doseFormCode,
        doseQuantity: adjustedDoseQuantity,
        dosesPerDay: M.dosesPerDay,
        ingredientCode: I.ingredientCode,
        ingredientName: I.ingredientName,
        strength: I.strength,
        dailyDose: dailyDose,
        dailyDoseDescription: GetDailyDoseDescription(I.ingredientCode, I.ingredientName, I.strength, I.doseFormCode, I.doseFormCode, factor),
        mme: Quantity {
            value: dailyDose.value * factor,
            unit: dailyDose.unit + '/d'
        }
    }
```

Note: Conversion factors used in this calculation are provided by the CDC Guideline MME table here: https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf
In STU3

```java
define MME:
  Prescriptions P
  let mme: SingletonFrom(OMTKLogic.CalculateMMEs({ rxNormCode: P.rxNormCode, doseQuantity: P.dose, dosesPerDay: P.dosesPerDay })
  return {
    rxNormCode: P.rxNormCode,
    isDraft: P.isDraft,
    isPRN: P.isPRN,
    prescription: P.prescription,
    dailyDose: mme.dailyDoseDescription,
    conversionFactor: mme.conversionFactor,
    mme: mme.mme
  }
  sort by if isDraft then 0 else 1, rxNormCode.code
```

Note: Conversion factors used in this calculation are provided by the CDC Guideline MME table here: https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf
And a PlanDefinition to describe the rule

```
<triggerDefinition>
  <type value="named-event"/>
  <eventName value="medication-prescribe"/>
</triggerDefinition>

<condition>
  <kind value="applicability"/>
  <description value="Is total MME \( \geq 50 \)?"/>
  <language value="text/cql"/>
  <expression value="IsMME50OrMore"/>
</condition>

<groupingBehavior value="visual-group"/>
<selectionBehavior value="exactly-one"/>

<!-- Will reduce dosage -->

&action>
  <description value="Will reduce dosage"/>
  <!-- Open Order Set, where available -->
</action>

<!-- Risk of overdose carefully considered and outweighed by benefit; snooze 3 mo -->

&action>
  <description value="Risk of overdose carefully considered and outweighed by benefit; snooze 3 mo"/>
</action>

<!-- Acute pain; snooze 1 mo -->

&action>
  <description value="Acute pain; snooze 1 mo"/>
</action>
```
Shareable definition, but is it executable?

- CQF Ruler – Clinical Reasoning implementation
- HAPI FHIR plugin for
  - Evaluating CQL
  - “Realizing” PlanDefinition and ActivityDefinition
  - CDS Hooks service support
CQL Evaluation Architecture

Clinical Quality Language (CQL)

Expression Logical Model (ELM)

Native  Java Script  Drools  SQL

Authors use CQL to produce libraries containing human-readable yet precise logic.

ELM XML documents contain machine-friendly rendering of the CQL logic. This is the intended mechanism for distribution of libraries.

Implementation environments will either directly execute the ELM, or perform translation from ELM to their target environment language.
Native CQL (ELM) Engine

**Logic** is the description of the conditions involved

**Model** is the structured representation of clinical information

**Data Access** is how instances of clinical information are retrieved

**Terminology** is concerned with membership testing and value set expansion

**Libraries** allow reuse of **Logic**

**Engine** is the runtime system that performs calculations
Java-Based CQL Engine

Java Environment

- Engine
- Model Impl
- FHIR RI
- FHIR Data Provider
- FHIR Term Provider
- Library Loader
- Library Load
- Data Access
- Terminology
- ELM

HAPI FHIR Structures

HAPI FHIR Client

FHIR Endpoint

FHIR Term Endpoint

HAPI FHIR Structures

HAPI FHIR Client

FHIR Endpoint

FHIR Term Endpoint

FHIR Term Endpoint
CDS Hooks Integration
Stepping Back
Generalizing the Implementation

• How do we generalize this across different guidelines?
• How do we put the patient at the center?
• Recognize common patterns across guidelines
• Use those patterns to organize the computable content

2013 AeHIN General Meeting, Operationalizing Guideline-based Care
http://www.aehin.org/Meetings/2013AeHINGeneralMeeting/AGM13Files3.aspx
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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.
Requirements -> Running Code

L1 – Narrative
- Narrative questions
- Guideline narrative
- Glossaries

L2 – Semi-Structured
- Paper forms
- Workflows
- Terminologies

L3 – Structured
- Questionnaire (SDC)
- Library (CQL)
- CodeSystem

L4 – Executable
- User-interface Forms
- Application Services
- Systems of Record

T1 – Data
- Use Cases
- Decision Trees
- Data Dictionary

T2 – Logic
- Personas
- Triggers
- StructureDefinition

T3 – Forms
- Narrative
- ActivityDefinition
- Measure

Application Services
Health Record Systems
Decision Services
Systems of Record
Registries and Exchanges
Data Services
Methods of Implementation

1. **Use CQL as a specification** *(manual development)*
   Developers will still need to hand code own code based off of that published “L3” CQL. Although, the most time consuming option, this is still faster than starting from the narrative artifacts “L1”

2. **Translate CQL** *(automated translation)*
   Translate “L3” CQL into the code base used in the current legacy system

3. **Consume CQL** *(native implementation)*
   Directly intake “L3” CQL artifacts natively
Recommendations in FHIR (CPG-on-FHIR)

• Multi-stakeholder international effort
• Coordinated with other projects in the space
  • Evidence-Based Medicine on FHIR (EBM-on-FHIR)
  • IHE Computable Care Guidelines (CCG) Profile
  • IHE Mobile Aggregate Data Exchange (mADX) Profile
  • IHE Dynamic Care Planning (DCP) Profile
• Focused on recommendations from representative use cases
  • Opioid Prescribing Support Guidelines (US & Canadian)
  • World Health Organization Antenatal Care (ANC) Guidelines
  • Chronic Kidney Disease (CKD) (VA, KDIGO)
  • Immunization Decision Support
  • HIV/HBV Screening, Prevention, and Followup
Resources

CDC Opioid Prescribing Support Implementation Guide:
• http://build.fhir.org/ig/cqframework/opioid-cds/

CQF Recommendations (CPG-on-FHIR):
• http://build.fhir.org/ig/HL7/cqf-recommendations

Publicly Available Clinical Reasoning Test Server (CQF Ruler) URL:
• http://measure.eval.kanvix.com/cqf-ruler/baseDstu3

Publicly Available CDS Hooks Server URL:
• http://measure.eval.kanvix.com/cqf-ruler/cds-services
Walkthroughs

Opioid Quick Start:
• http://build.fhir.org/ig/cqframework/opioid-cds/quick-start.html

CDS Hooks Request:
• https://github.com/DBCG/cqf-ruler/wiki/CDS-Hooks-Request-Processing

Activity Definition $apply
• https://github.com/DBCG/cqf-ruler/wiki/ActivityDefinition-$apply-Operation

Plan Definition $apply
• https://github.com/DBCG/cqf-ruler/wiki/PlanDefinition-$apply-Operation
For questions or more information please contact:

**Maria Michaels – maria.michaels@cdc.gov**

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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.