Open-Source Clinical Decision Support Models

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Disclosures

• I am or have recently been a consultant to Partners HealthCare, Inflexxion, and RAND Corporation.

• I was formerly a consultant for Religent, Inc. and formerly a co-owner and consultant for Clinica Software, Inc.

• I have no financial competing interests related to OpenCDS.
Presentation Objectives

• Describe clinical decision support (CDS) and how it could help bridge the translation gap for personalized medicine

• Identify requirements for scaling CDS for personalized medicine (PM) on a national scale

• Describe an open-source, standards-based CDS platform (OpenCDS) that could enable CDS for PM at scale
Clinical Decision Support (CDS)

• Definition
  – The provision of pertinent knowledge and/or person-specific information to clinical decision makers to enhance health and health care (Osheroff et al., *JAMIA*, 2006)

• Supports translation of evidence into practice
  – CDS systems that provide patient-specific care recommendations automatically and within clinical workflows have significantly improved care quality in >90% of RCTs (Kawamoto et al., *BMJ*, 2005)
## CDS Example: Disease Mgmt. Dashboard

**Source:** Lobach DF, Kawamoto K, et al. Medinfo. 2007;861-5.

### Diabetes

<table>
<thead>
<tr>
<th>Focus</th>
<th>Status</th>
<th>Relevant Data</th>
<th>Last Done</th>
<th>Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>Not Due</td>
<td>Height: 154.9 (61.0 in)</td>
<td>12/15/08 (age 61y 3m)</td>
<td>21+yo: once after age 21</td>
</tr>
<tr>
<td>Weight/BMI</td>
<td>DUE NOW</td>
<td>Weight: 77.1 kg (170.0 lb) BMI: 32.1</td>
<td>01/08/09 (0m 4d ago)</td>
<td>21+yo: q visit. Goal: BMI &lt;25</td>
</tr>
<tr>
<td>B.P.</td>
<td>DUE NOW</td>
<td>BP: 120/69 mm Hg Patient has diabetes or GFR &lt;60</td>
<td>01/08/09 (0m 4d ago)</td>
<td>18+yo: annual; if diabetic or HTN q visit. Goal &lt;140/90, 130/80 if diabetic or GFR &lt;60</td>
</tr>
<tr>
<td>Alcohol Screen</td>
<td>Not Due</td>
<td>Abstains</td>
<td>01/08/09 (0m 4d ago)</td>
<td>10+yo: check alcohol use yearly (excessive: males &gt;2/d, females &gt;1/d) q visit</td>
</tr>
<tr>
<td>Visual Foot Exam</td>
<td>DUE NOW</td>
<td></td>
<td>01/08/09 (0m 4d ago)</td>
<td>q visit</td>
</tr>
<tr>
<td>Foot Monofilament</td>
<td>Not Due</td>
<td></td>
<td>01/08/09 (0m 4d ago)</td>
<td>q visit</td>
</tr>
<tr>
<td>HgbA1C</td>
<td>Not Due</td>
<td>HgbA1C: 6.2%</td>
<td>01/08/09 (0m 4d ago)</td>
<td>21+yo: q6mo if &lt;7%, q3mo if &gt;= 7%. Goal: &lt;7%.</td>
</tr>
<tr>
<td>Urine Micro alb/cr</td>
<td>Not Due</td>
<td>alb/cr ratio: * mg/g</td>
<td>10/08/08 (3m 4d ago)</td>
<td>10+yo: annual</td>
</tr>
<tr>
<td>Total Chol.</td>
<td>Not Due</td>
<td>Total-C: 151 mg/dL</td>
<td>12/15/08 (0m 28d ago)</td>
<td>annual, goal &lt;200</td>
</tr>
<tr>
<td>LDL Chol.</td>
<td>Not Due</td>
<td>LDL-C: 94 mg/dL</td>
<td>12/15/08 (0m 28d ago)</td>
<td>annual, goal &lt;100</td>
</tr>
<tr>
<td>Eye Exam</td>
<td>DUE NOW</td>
<td>Intervention considered but not delivered on 01/08/09. Reason: Scheduled</td>
<td></td>
<td>10+yo: annual</td>
</tr>
<tr>
<td>Flu Vacc.</td>
<td>CONSIDER</td>
<td>&gt;2y ago</td>
<td></td>
<td>annual, unless egg allergic</td>
</tr>
<tr>
<td>Pneum. Vacc.</td>
<td>Not due</td>
<td></td>
<td>01/06/06 (3y 0m ago)</td>
<td>once; revacc if &gt;=65 and last 5+ yrs ago when &lt;65</td>
</tr>
<tr>
<td>ASA (81 mg)</td>
<td>Not Due</td>
<td>Not known to be allergic to aspirin Aspirin listed as prescribed</td>
<td></td>
<td>40+yo: no contraindications</td>
</tr>
<tr>
<td>Education</td>
<td>Not Due</td>
<td>Completed</td>
<td>01/08/09 (0m 4d ago)</td>
<td>once; repeat annually if HgbA1C &gt;=7%</td>
</tr>
</tbody>
</table>
Potential CDS Applications Areas for PM

• **Test ordering**
  – Recommend indicated test
  – Recommend against test with dubious clinical utility

• **Personalized test interpretation**
  – Combine genetic test result with clinical data to provide personalized risk assessment and care guidance

• **Family history analysis**
  – Tailor preventive care guidance based on family history

• **Therapy**
  – Provide genetically-informed drug therapy guidance
# CDS Example: Warfarin PGx Dosing

<table>
<thead>
<tr>
<th>Baseline INR</th>
<th>Current Smoker</th>
<th>Liver Disease</th>
<th>Current or recent NPO</th>
<th>Estimated blood loss from recent surgery</th>
<th>Calculated body surface area</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes or No</td>
<td>0 mL</td>
<td>1.492 m²</td>
</tr>
</tbody>
</table>

**On Direct Thrombin Inhibitor (e.g., hirudin, bivalirudin):**
- Yes
- No

**On Azole Antifungal (e.g., ketoconazole, fluconazole):**
- Yes
- No

**On Carbamazepine:**
- Yes
- No

**On Fluoroquinolone (e.g., moxiﬂoxacin, ciprofloxacin):**
- Yes
- No

**Statin use:** Pravastatin/Pravachol®

**Amiodarone use:** 0 mg/day

**On Metronidazole:**
- Yes
- No

**On Propafenone:**
- Yes
- No

**On Phenytoin (e.g., Dilantin):**
- Yes
- No

**On Rifampin:**
- Yes
- No

**On Steroid:**
- Yes
- No

**On Sulfonamide:**
- Yes
- No

**CYP2C9 genotyp:** *2/*3

**VKORC1-1639/3873 genotyp:** AA

### Prior Doses and Recent Labs:
- **Prior doses (past week):**
  - 7/13 (Tue) mg
  - 7/14 (Wed) mg
  - 7/15 (Thu) mg
  - 7/16 (Fri) mg
  - 7/17 (Sat) mg
  - 7/18 (Sun) mg
  - 7/19 (Mon) mg

Unless manually entered, above doses do not reflect held doses or outside doses. Edit as needed to ensure validity of dosing guidance provided below.

### Most Recent Labs:
- **PTT:** 37 07/20/2010 13:56:33
- **INR:** 1.5 07/20/2010 13:56:33
- **Platelets:** 180 07/20/2010 13:56:33
- **Hemoglobin:** 14.9 07/20/2010 13:56:33
- **Hematocrit:** 0.42 07/20/2010 13:56:33

### Warfarin Order

#### Dosing Guidance:
- Dosing guidance received from [http://www.warfarindosing.org](http://www.warfarindosing.org)
- Consider following dosing:
  - Dose 1: 2.9 mg/day
  - Dose 2: 1.6 mg/day
  - Dose 3: 1.6 mg/day

**Consistent:** mg PO QHS x 3 days

**Custom QHS:**
- 7/20 (Tue) mg
- 7/21 (Wed) mg
- 7/22 (Thu) mg
- 7/23 (Fri) mg
- 7/24 (Sat) mg
- 7/25 (Sun) mg
- 7/26 (Mon) mg
Achilles’ Heel of CDS: Limited Scalability

• Despite demonstrated effectiveness, CDS is not widely available
  – Most CDS capabilities only work within specific institutions and health IT systems
• We are still trying to scale up “traditional” CDS capabilities that have been validated for decades
  – Unless we focus on scalability, CDS will have a limited impact on PM for decades to come
What is Needed to Scale CDS for PM?

• Standardized representation of relevant patient data

• Centrally managed repositories of high-quality, computer-processable medical knowledge

• Standard approaches for leveraging the encoded knowledge to provide patient-specific advice

OpenCDS

- An open-source, standards-based CDS platform designed to enable CDS at scale
- Addresses core requirements of a national CDS infrastructure for PM
  - Uses standard data models
  - Can leverage various knowledge resources, both externally and internally developed
  - Provides a standard approach for EHR systems to leverage CDS resources over the Internet to obtain patient-specific advice
Collaborators

- University of Utah
- HP Advanced Federal Healthcare Innovation Lab
- HLN Consulting, LLC
- Apelon, Inc.
- Intermountain Healthcare
- New York Citywide Immunization Registry
- Alabama Department of Public Health
- Veterans Health Administration
- Wolters Kluwer Health
- EBSCO
- Univ. of NC at Chapel Hill
- Main Line Health
- Hospital Universitario Virgen del Rocío, Spain
- Keona Health
- Mass. General Hospital
- Stanford University
- MaRS Innovation, Canada
- SmartCare, Africa
- Emetra AS, Norway
- Visumpoint, LLC
- Genesys, LLC
- df8health
- IsoDynamic, Inc.
- Calcudos.com, Inc.
- CogniTech Corporation
## WarfarinDosing.org Integration via OpenCDS

<table>
<thead>
<tr>
<th>Baseline INR: 1.2</th>
<th>Current Smoker: Yes</th>
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<th>Current or recent NPO: Yes</th>
<th>Estimated blood loss from recent surgery: 0 mL</th>
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</tr>
</thead>
<tbody>
<tr>
<td>On Direct Thrombin Inhibitor (e.g., hirudin, bivalirudin): Yes</td>
<td>Statin use: Pravastatin/Pravachol®</td>
<td>Amiodarone use: 0 mg/day</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>On Azole Antifungal (e.g., ketoconazole, fluconazole): Yes</td>
<td>On Metronidazole: Yes</td>
<td>On Rifampin: Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>On Carbamazepine: Yes</td>
<td>On Propafenone: Yes</td>
<td>On Steroid: Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>On Fluoroquinolone (e.g., moxifloxacin, ciprofloxacin): Yes</td>
<td>On Phenytoin (e.g., Dilantin): Yes</td>
<td>On Sulfonamide: Yes</td>
<td></td>
<td></td>
<td></td>
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<td>CYP2C9 genotype: *2/*3</td>
<td>VKORC1-1639/3673 genotype: AA</td>
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<th>7/18 (Sun)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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### Most Recent Labs:

<table>
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<tr>
<th>Test</th>
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<th>Date/Time</th>
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<tr>
<td>PTT</td>
<td>37</td>
<td>07/20/2010 13:56:33</td>
</tr>
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  - dose 3: 1.6 mg/day

- Consistent: mg PO QHS x 3 day(s)
- Custom QHS:
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<tbody>
<tr>
<td>mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Web-based Authoring – Decision Rules

**WHEN**

1. Initialize - Note that all criteria below must be met for the rule to fire.
2. Pt.Age.Low - Patient age is greater than or equal to **42** years
3. Pt.Age.High - Patient age is less than or equal to **69** years
4. Pt.Gender - Patient gender is **Female**
5. Pt.Enc.Past.Count - Patient has had a **Outpatient encounter** **1** or more times in the past **2** year(s)
6. not ( )
7. Pt.Proc.Past - Patient has had a **Bilateral mastectomy**
8. or
9. Pt.Proc.Past.Lat - Patient has had a **Mastectomy** with a laterality of **Bilateral**
10. or
11. Pt.Proc.Past.Count - Patient has had a **Unilateral mastectomy** **2** or more times in the past **200** year(s)
12. )

**THEN**

1. Assert that **NQF 0031 denominator criteria met**
<table>
<thead>
<tr>
<th>#</th>
<th>Desc</th>
<th>Vaccine</th>
<th>Gender</th>
<th>Dose #</th>
<th>Min Age</th>
<th>Units1</th>
<th>Max Age</th>
<th>Units2</th>
<th>Index Dose #</th>
<th>Min Interval</th>
<th>Units3</th>
<th>Rec Interval</th>
<th>Units4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>HPV</td>
<td>Female</td>
<td>1</td>
<td>9 Yr</td>
<td>26 Yr</td>
<td></td>
<td></td>
<td>1</td>
<td>24 Day</td>
<td>61 Day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td>80 Day</td>
<td>121 Day</td>
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<td>3</td>
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<td>1</td>
<td>164 Day</td>
<td>182 Day</td>
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<td>4</td>
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<tr>
<td>5</td>
<td></td>
<td></td>
<td>Male</td>
<td>1</td>
<td>11 Yr</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>24 Day</td>
<td>61 Day</td>
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<td>6</td>
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<td>2</td>
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<td>7</td>
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</tr>
</tbody>
</table>
Web-Based Authoring – Decision Diagram

Is Ashkenazi Jew?

Yes

Male relative with breast cancer?

2 first-degree relatives with breast cancer, one dx <= age 50?

3 or more first or second-degree relatives with breast cancer?

Both breast and ovarian cancer among first and second-degree relatives?

First-degree relative with bilateral breast cancer?

2 or more first or second-degree relatives with ovarian cancer?

First or second-degree relative with both breast and ovarian cancer?

No

FHx indicates increased risk for deleterious BRCA mutation.

FHx does not indicate increased risk for deleterious BRCA mutation.
OpenCDS Status

- 1.0 release scheduled December 2011
- Multiple ongoing initiatives within University of Utah and partner organizations
Recommendations

• Make CDS a core component of the PM vision
• Consider and prioritize **scalability** for CDS
• Leverage **relevant resources**
  – OpenCDS
  – Multiple CDS efforts focused on “traditional” medicine
• Align with, and influence, EHR **Meaningful Use** regulations
• Start building national CDS infrastructure **now**
  – Divergent, incompatible approaches will develop without coordination and standardization
Acknowledgements

• Financial support
  – NHGRI K01 HG004645 (PI: K. Kawamoto)
  – University of Utah Dept. of Biomedical Informatics
  – ONC Beacon Community Program subcontract (PI: Bruce Bray)

• Numerous OpenCDS collaborators
  – https://sites.google.com/site/opencdspublic/collaborators
What is OpenCDS?

OpenCDS is a multi-institutional, collaborative effort to develop open-source, standards-based clinical decision support (CDS) tools and resources that can be widely adopted to enable CDS at scale.

Who is Involved?

OpenCDS was founded by Dr. Kensaku Kawamoto, MD, PhD, who is a faculty member at the Duke Center for Health Informatics and a co-chair of the HL7 CDS Work Group. OpenCDS collaborators include the University of Utah, Intermountain Healthcare, the Veterans Health Administration, the University of North Carolina at Chapel Hill, and Apelon, Inc.
Thank You!

Kensaku Kawamoto, MD, PhD

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Assistant Professor, Department of Biomedical Informatics
University of Utah

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