Systematic Risk Assessment and Clinical Decision Support with a Patient-Facing FHIR-enabled web service
Abstract

Initiating widespread systematic risk assessment for disease prevention and risk management in primary care is one key to promoting population health; however, there are a significant number of barriers to implementation. One is that family health history is a critical data element that is hard to capture and use effectively. The other is the complexity of risk assessment guidelines. To facilitate systematic risk assessment in primary care, we developed and tested a web-service that positioned patients as the drivers of the risk assessment process – including family health history data collection- and integrated clinical decision support for patients and providers to enhance shared decision making around risk management and disease prevention. This talk will describe our approach, the SMART-FHIR components, and some of the outcomes we’ve achieved to date.
Value of Systematic Risk Assessment

**Clinical**
- Facilitates uptake of guidelines
- Risk stratification enables precision and population medicine
- Improves quality of care
- Encourages learning and shared decision making

**Research**
- Inform/refine guidelines
- Discover disease co-inheritance patterns
- Identify modifiers of disease penetrance by FHH x gene interactions
- Enables behavioral interventions
An Example of Clinical Value

- Increasingly, clinical practice guidelines are based on risk level.
- Risk stratification allows targeting of the right strategies to the right patient to maximize benefits over risks.
  - For example, breast MRI increases detection of cancers but also frequency of biopsies. To decrease likelihood of an unnecessary biopsy, risk of breast cancer should be >20%.
An Example of Research Value

PALB2

The absolute breast-cancer risk for PALB2 ranged from 33% (95% CI, 25 to 44) for those with no family history of breast cancer to 58% (95% CI, 50 to 66) for those with two or more first-degree relatives with breast cancer...
Risk assessment is essential for optimizing disease prevention and risk management (i.e. “keeping healthy people healthy”)

*Family Health History (FHH) is one of the strongest predictors of disease and is the first step in risk assessment*

*But…*

It is frequently overlooked and undervalued in clinical practice
Barriers by Stakeholder

**Patient**
- Education
- Accuracy

**Provider**
- Time
- Awareness
- Complexity

**Health System**
- Inadequate systems for data collection & providing actionable information
- Awareness of population impact

The Logistic Function:

\[ \log \left( \frac{Y}{1-Y} \right) = b_0 + b_1X_1 + b_2X_2 + b_3X_3 + \ldots + b_nX_n \]
Technology solution: MeTree

A patient-facing risk assessment and clinical decision support program

For the Patient:

✓ Educates patients on what information to collect and how
✓ Can update anytime
✓ Real-time tailored clinical decision support
✓ English and Spanish versions

For the Provider:

✓ Saves provider time (no data collection)
✓ Creates pedigree for 88 medical conditions
✓ Automated risk assessment for 30 conditions
✓ Risk calculators for CAD and Breast cancer
✓ Provides action-oriented clinical decision support tied to just in time education

For the Health System:

✓ Improves data quality
✓ Delivers evidence-based recommendations and resource utilization triggers
✓ Directs resources to the right patient at the right time
How does the information flow?

Patient receives referral to complete MeTree or accesses link in patient portal *For example...*

New Message in Duke MyChart
MESSAGES@dukemychart.org

Appointment reminder: 12/08/2014 with Dr. Smith

Before your appointment, please go to [www.MeTree.com](http://www.MeTree.com) and complete your family health history.

MeTree™ generates a personal risk profile for the patient, tailors a report for the patient and a report for the provider.

At the visit, the provider and patient are empowered for a more productive discussion of health risks and can focus on a personalized plan.

Patient reads the ‘how to’ information at MeTree™, confers with family and completes his FHH online.
Technology

- Tablet/Touch screen functions (drag/drop/swipe..)
- American Health Information Community standards for high-quality FHH
- Data storage standards
  - HL7
  - SNOMED
  - ICD9
- SMART on FHIR® for plug and play compatibility with EHRs
Clinical Trials

- Cone Health study
  - Assess value for clinical care
  - 5 pilot clinical decision support conditions
  - 2 Intervention and 1 control primary care clinics
  - 1184 adult patients with upcoming appointments with their providers
  - Wide spectrum of data collection: acceptability, accuracy, clinical impact

- Implementing Genomics in Practice (IGNITE) network
  - Current version of MeTree
  - Clinical utility and parameters critical to implementation success across diverse healthcare settings
  - 5 national (very diverse) healthcare settings’ primary care clinics
  - Adult patients with upcoming appointments with their providers
  - Mixed methods assessing: acceptability, accuracy, clinical impact
Proportion of High-quality Pedigrees vs. Proportion of High-quality Relatives Required
Types of Pedigree Changes After Patient Education

<table>
<thead>
<tr>
<th>Change Type</th>
<th>N</th>
<th>Percent of Total Pedigrees</th>
<th>Mean (Per Pedigree)</th>
<th>Standard Deviation</th>
<th>Total Number of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>% With Any Changes</td>
<td>49</td>
<td></td>
<td>8.41</td>
<td>6.72</td>
<td>412</td>
</tr>
<tr>
<td>% Added/Removed Relative</td>
<td>6</td>
<td></td>
<td>4.00</td>
<td>3.10</td>
<td>24</td>
</tr>
<tr>
<td>% Changed Relative Age</td>
<td>27</td>
<td></td>
<td>7.70</td>
<td>6.10</td>
<td>208</td>
</tr>
<tr>
<td>% Changed Relative Alive/Dead Status</td>
<td>10</td>
<td></td>
<td>3.00</td>
<td>4.42</td>
<td>30</td>
</tr>
<tr>
<td>% Changed Cause of Death</td>
<td>23</td>
<td></td>
<td>3.00</td>
<td>1.86</td>
<td>69</td>
</tr>
<tr>
<td>% Changed Relative Disease</td>
<td>42</td>
<td></td>
<td>4.62</td>
<td>3.48</td>
<td>194</td>
</tr>
<tr>
<td>% Changed Relative Age of Onset</td>
<td>18</td>
<td></td>
<td>1.72</td>
<td>1.23</td>
<td>31</td>
</tr>
</tbody>
</table>
### Recommendations

44% (523/1184) received at least one non-routine recommendation

<table>
<thead>
<tr>
<th>Disease</th>
<th>Recommendation</th>
<th>Frequency Among All Participants</th>
<th>Frequency Among Eligible Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hereditary Syndrome Risk</td>
<td>Genetic Counseling</td>
<td>308 (26.0%)</td>
<td>308/1184 (26.0%)</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>Breast MRI</td>
<td>10 (0.8%)</td>
<td>10/694 (1.4%)</td>
</tr>
<tr>
<td></td>
<td>Chemoprophylaxis</td>
<td>58 (4.9%)</td>
<td>58/694 (8.3%)</td>
</tr>
<tr>
<td>Colon Cancer</td>
<td>Start colon screening early</td>
<td>114 (9.6%)</td>
<td>114/1178 (9.7%)</td>
</tr>
<tr>
<td></td>
<td>More frequent colonoscopies</td>
<td>107 (9.0%)</td>
<td>107/1178 (9.1%)</td>
</tr>
<tr>
<td>Ovarian Cancer</td>
<td>Referral to gynecology</td>
<td>14 (1.2%)</td>
<td>14/694 (2.0%)</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>Genetic Testing</td>
<td>42 (3.5%)</td>
<td>42/1184 (3.5%)</td>
</tr>
<tr>
<td></td>
<td>Genetic Counseling</td>
<td>29 (2.4%)</td>
<td>29/1184 (2.4%)</td>
</tr>
</tbody>
</table>
Cone Health Results

Of 488 patients with a chart review:

- **Before using MeTree™**
  - 93 patients were receiving high risk management/services
    - 82 (88%) were **not** assigned high risk status by MeTree™ (overutilization/waste)
  - 203 patients met MeTree™ criteria for high risk and high risk management
    - **only 12 (5.9%)** of these patients had previously received the appropriate high risk management (missed opportunity/low quality)

- **After using MeTree™**
  - Of the 203 patients who met MeTree™ criteria for high risk and high risk management
    - **160 (78.8%)** were receiving the appropriate high risk management/services (improved care/quality)
    - Of the 82 patients not at high risk but receiving services, **only 11 (7%)** were still receiving high risk management/services (reduced waste)
Cone Health Results

- Broadly positive physician and patient user experiences with no differences by race, ethnicity, education, or income (Wu et al. BMC Fam Pract. 2013 6;14:111.)


- Helps physicians direct resources to the right patients – reduces overutilization and prompts guideline-driven risk management

- Improves patient uptake of physician risk management recommendations
Health Systems
- Duke University (Academic)
- Essentia Institute of Rural Health (Rural)
- Medical College of Wisconsin (Inner city)
- University of North Texas (Hispanic)
- David Grant Medical Center (Military)

Data
- Implementation
  - Qualitative interviews
  - Surveys providers and patients
- MeTree data
  - Frequencies of increased risk status
  - Family histories
- Outcomes
  - Disease incidence
  - Changes in care
Summary

1. Reduces burden on providers
2. Improves quality of data collection
3. Improves quality of care
4. Promotes patient participation in care
5. Optimizes healthcare utilization, reduces waste
6. Generates population risk data
7. Enables research
METREE SCREENSHOTS
Web entry point to MeTree™

The patient can download a worksheet that explains FHH and helps them collect information from family members.
Patient information...

Additional MedlinePlus information is available with a mouse-over to help the patient enter high quality data.
Three generations are required for an informative family history
Patient information – extended family…

MeTree™ can also collect information on aunts, uncles, cousins…

Family members are added with by dragging/dropping and are linked to patients’ paternal or maternal sides.
Family pedigree report – with less or more info
Most providers prefer a grid
Talk to your doctor about having a coronary artery calcium test. Because your risk for heart disease may be higher than it seems due to:
- Your having had one or more relatives with heart disease at age <60.
- Your heart disease risk level is low.

More Information
Since calcium scores use a CT scanner to measure how much calcium has settled in the wall of the coronary arteries (instead of remaining in the blood inside the artery), it is a more direct measure of early damage to the heart’s blood vessels (which leads to heart attacks). If your score is high, you may need to start a medication to lower your risk.

Talk to your doctor about testing for a genetic cause of blood clots (inherited thrombophilia). There’s an increased chance that blood clots run in your family due to:
- Your having had a blood clot at age <30.

More Information
Genetic counseling will help determine if you have a hereditary condition. It is important to know this because:
- You may pass it on to your children and other family members may be affected
- You may need to consider different screening and prevention options to lower your risk
- You may need genetic testing to confirm whether you have the condition or not

For more information, visit Frequently Asked Questions About Genetic Counseling or download the genetic alliance guide Making Sense of Your Genes

Talk to your doctor about breast cancer screening by breast MRI (magnetic resonance imaging) and mammograms due to:
- Your having a family history of cancer that increases your chance of getting breast cancer.

More Information
MRIs use strong magnets to make very detailed images of the breast. When added to mammograms they may pick up cancers earlier, than mammograms alone; however, you may also end up with more breast biopsies. The American Cancer Society recommends breast MRI for some women with an increased chance of breast cancer. Talk with your doctor about whether yearly breast MRI is right for you.

Talk to your doctor about being screened for Hemochromatosis since it can run in families

More Information
Hemochromatosis is a condition where too much iron is stored in the body. This can lead to organ damage over time. Early diagnosis and treatment can prevent complications such as liver disease, heart disease, and diabetes.

More information
Patient risk profile – report for the provider

- Provider Risk Assessment, Prevention, and Screening Report
  - If the patient has a condition, prevention recommendations are not provided for that condition.
  - Cancer addresses breast, ovarian, colon, and hereditary syndromes.

- Cancer
  - Recommend referral for genetic counseling for risk of hereditary cancer syndrome due to:
    - At least 1 first degree relative with breast cancer at age <50.
    - At least 1 first degree relative with ovarian cancer.
  - Recommend breast cancer surveillance via annual breast MRI and mammography due to:
    - Tyzer-Cuzick lifetime breast cancer risk = 20.1%, patient meets criteria to add breast MRI to annual mammography (>20%)9,10.
    - Breast MRI NNT (number of women needed to screen one breast cancer undetected by mammography) is $8 in increased risk women.11
  - Gall score 5-year breast cancer risk = 0.01657, patient meets criteria (>1.65%) for chemoprophylaxis with tamoxifen or raloxifene.3,4
  - Pharmacogenomic testing for efficacy and risk of adverse events with tamoxifen is available.
  - Tamoxifen NNT (number of women needed to treat to prevent one breast cancer) is 49 in increased risk women.12
  - Possible contraindication, patient is pregnant or breastfeeding.
  - Recommend starting routine colon cancer screening at age 45 due to African American race.

- Cardiovascular Disease
  - 10 yr risk of atherothrombotic cardiovascular events:
    - Framingham = 8%
    - Reynolds = NA
    - ATP IV = 10%
  - Refer to genetic counseling for risk of inherited cardiovascular disease due to:
    - At least one first degree relative with unexpected sudden cardiac death at age <60.
  - Consider starting or switching to a moderate or high intensity statin due to19:
    - Diabetic aged 40-60
    - At least one Cardiovascular risk score above and one below 7.5% 10 yr risk of atherothrombotic CVD events
Smart-on-FHIR

MORE THAN JUST A DATA STANDARD…
What exactly is SMART-on-FHIR

**SMART**
- Substitutable medical apps, Reusable Technology
- Authentication through OAuth2
- HTML5 and Javascript permits views in an “app window”
- Microinteractions which allows wrapping of data into different “views”

**FHIR**
- Fast health interoperability resource
- ReSTful API (resource oriented)
  - Bi-directional data transfer
- FHIR profiles
  - include a growing list of defined resources
  - Permits plug and play interoperability
  - Leverages standardized nomenclatures (snomed, rxnorm, loinc, CVX, etc..)
- Extensions for data not already defined
Key Features of SMART on FHIR

- Takes advantage of standards-based modern technology expanding accessibility, scalability, and interoperability.
  - HL7 now considers FHIR to be the next generation .api
  - These tools are already in use by systems like facebook and google so widely familiar to programmers outside the healthcare space
- SMART and FHIR combine authentication and data transmission in a single plug and play app
- Open source with no license fees
  - Prior to 2013 HL7 charged licensing fees and even now in some cases fees apply
- Narrowly defined data for plug and play capacity
  - The Argonaut project supported by all major stakeholders developed narrowly defined data to avoid the use of "optionality" as much as possible
  - Extension permit optionality when needed and once built by early adopters submitted to help establish a new data standard
- Widely supported by major EMR vendors
Patient Flow

**STEP 1**
Log into EMR patient portal

**STEP 2**
Data Query - Relevant data pull

**STEP 3**
Enter FHH data

**STEP 4**
Third party web-service (e.g. FHH Tool)

**STEP 5**
(Optional)
Patient-oriented report

**STEP 6**
Data Push - to relevant data fields

EMR
For MeTree:

- Authentication - information about who the person is
- Demographics
- Laboratory Studies
- Medical Conditions
- Family Health History
- Medications

For Data Analysis:

- Costs
- Medical Visits
- Providers
Provider Flow

**STEP 1**

Log into EMR

New Access Link to Web-Service creates an “applet” view in EMR window

EMR contains updated information

Interactive Graphical Interface with web-service
Supporting “multiple” views
Multiple views
Multiple Views: Patient-oriented

CARRIE DEMORA | sex female | dob 21Nov2005 | age 8y 3m

- Underweight
- Healthy
- Overweight
- Obese

CARRIE DEMORA is overweight at 34.4 kg (75 lb 13 oz). Compared to her last weight assessment, she is at risk for becoming obese.