May 4th, 12:00 PM

Clinical Research Informatics

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Clinical Research Informatics
Thomas Houston, MD, MPH
May 4, 2012

FINANCIAL DISCLOSURE:
Funding from NIH, AHRQ and VA
No industry funding
Unlabeled Use:
None to disclose
Informatics at UMMS/UMMHC

Bioinformatics and Integrative Biology

Health Informatics and Implementation Science

Academic and Research Computing

UMass Memorial Healthcare Health Information Systems

Worcester Polytechnic Institute Computer Sciences

Amherst Center for Intelligent Information Retrieval
BRIDG
Biomedical Research Informatics Development Group

- Tom Houston, MD, MPH, Chief, Division of Health Informatics and Implementation Science, Quantitative Health Sciences
- Rajani Sadasivam, PhD
- Thomas English, PhD
- Ralph Zottola, PhD
- Timothy Hogan, PhD
Informatics

- Discipline focused on the acquisition, storage, and **optimal use** of information for health and healthcare

  - “Informatics is more about information than technology, with the latter being a tool, albeit an important one, to make best use of information.”

    - Hersh BMC Medical Informatics 2009
Health IT

- HIT = the application of computers and technology in health care settings
  - Hersh BMC Medical Informatics 2009
Clinical research Informatics

“Development, application, and evaluation of theories, methods, and systems to optimize the design and conduct of clinical research and the analysis, interpretation, and dissemination of the information generated.”

Embí et al. Clinical research informatics: challenges, opportunities and definition for an emerging domain. J Am Med Inform Assoc 2009
Development

- Usability Assessments
  - Expert-driven evaluation
  - User-driven evaluation
    - Quantitative (time on task)
    - Qualitative (cognitive think-aloud)
“A set of computer-based tools that allow people to access and coordinate their lifelong health information and make appropriate parts of it available to those who need it.”

Markle Foundation, 2006
The Potential of PHRs:

- Enhanced Patient Satisfaction
- Patient Activation
- Enabled Self-Management
- Enhanced Communication
- Efficiency and Cost
- Quality and Safety

The Chronic Care Model

- Community
  - Resources and Policies
  - Self-Management Support
- Health Systems
  - eHealth Tools (PHR, SM)
  - Organization of Health Care
  - Delivery System Design
  - Decision Support
  - Clinical Information Systems

- Informed, Activated Patient
- Productive Interactions
- Prepared, Proactive Practice Team

Improved Outcomes
Disparities

Cumulative Proportion by Month of KPGA Enrollees Registered with KP.org from 10/1/05.

Roblin, Houston et al. JAMIA 2009;16:683–689

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Ecosystem of applications making use of a patient’s or a population’s PCHR data

- Disease-management tools
- Wellness applications
- Clinical research-management tools
- Social-networking tools

Interface to applications

PCHR platform

- Information access controls (personally controlled)
- Secure storage of lifelong persistent data across all sources

Interface for importing data (personally controlled)

Subscription agents for standards-based exchange

Data providers
- Hospital or health system
- Pharmacy
- Primary care practice or network
- Payer claims
- Laboratory

Mandl et al, NEJM 2008
<table>
<thead>
<tr>
<th>LEVEL</th>
<th>FUNCTIONALITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Collect patient information, such as self-reported demographic and risk factor information (health behaviors, symptoms, diagnoses, and medications)</td>
</tr>
<tr>
<td>2</td>
<td>Integrate patient information with clinical information through links to the electronic medical record and/or claims data</td>
</tr>
<tr>
<td>3</td>
<td>Interpret clinical information for the patient by translating clinical findings into lay language and delivering health information via a user-friendly interface</td>
</tr>
<tr>
<td>4</td>
<td>Provide individualized clinical recommendations to the patient, such as screening reminders, based on the patient's risk profile and on evidence-based guidelines</td>
</tr>
<tr>
<td>5</td>
<td>Facilitate informed patient action integrated with primary and specialty care through the provision of vetted health information resources, decision aids, risk calculators, personalized motivational messages, and logistical support for appointments and follow-up</td>
</tr>
</tbody>
</table>

Krist and Woolf, JAMA, 2011
eHealth QUERI

Leadership
- Tom Houston, MD, MPH (Director)
- Bonnie Wakefield, PhD, RN, FAAN (Clinical Coordinator)
- Timothy Hogan, PhD (Implementation Research Coordinator)

Field Sites
- Boston, Chicago, Salt Lake, Ann Arbor, Portland, Iowa City

Data Center (West Haven VAMC)
1) To augment access and meaningful use of eHealth tools

2) To enhance veteran self-management and participation in collaborative care through the design, evaluation, and implementation of appropriate eHealth tools
Using Allscripts Data at UMass for Clinical Research

Thomas English PhD
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Department of Quantitative Health Sciences Division of Health Informatics and Implementation Science
University of Massachusetts Medical School

Center for Clinical and Translational Science
Quantitative Methods Core: Bruce Barton PhD
Biomedical Informatics Core: Tom Houston MD

4/20/2011
Purpose

• Discuss the role Allscripts can play in your research

• Discuss how to access Allscripts data
Who am I?

• Health Informatics & Outcomes Researcher
• Former Allscripts Administrator
• Former Allscripts Analytics Administrator
• Design Studies
• Modify Systems
• Extract Data
• Analyze Data
How can Allscripts Help?

• Grant Preparation

• Cohort Discovery

• Data source

• Intervention
Grant Preparation
Grant Preparation

- Some data can be gathered prior to IRB approval
  - Power Calculations
  - Sample Size
  - Summary Statistics

- All research using Allscripts will be subject to IRB approval

- Individual data will not be gathered without prior IRB approval
Population Characteristics

- Race/Ethnicity
- Age
- Medications
- Lab results
- Immunizations
- Comorbidities

Data about individuals will not be available until the IRB has approved the study.
Cohort Discovery
New England Newborn Screening Program

• How many children have:
  • SCID, DiGeorge Syndrome, Velo-Cardio-Facial Syndrome etc...

• Pulled cohorts from Micard and Allscripts

• Challenges:
  • ICD9 Codes
  • Matching Terminology
Focused Recruitment

• Suppose we did need to recruit the patients for the study. How would we?

• With Allscripts we can extract patient demographics including contact info. Mail, call, email...

Or

• Query the system to find out when potential participants will be at the clinic and approach them individually.
Data Source Example
Metformin & B12

- Resident research with no funding
- Can you pull the number of subjects we follow with diabetes who:

1. Are treated with metformin

2. Had a vitamin B12 level drawn within 2 years prior to starting metformin.
Metformin & B12

• Explore the effect of Metformin on Vitamin B12 levels

• Initial Plan: Find patients on Metformin that had a B12 level checked within 24 months prior to the start of Metformin.

• Contact the patients and repeat the Serum B12 if they are willing

• We found 1700 patients meeting the criteria
Metformin & B12

• 1700 Potential Participants

• But I did some digging.

• I found 600 of those patients had a serum B12 level after the start of Metformin already documented.

• We now have IRB approval to extract the data from Allscripts to conduct the analysis

• Now we can do the study using data already in the system as part of standard care. No recruiting! No Specimen Management!
B12 (6386 Results) Issues

- What do you do with non numeric values?
  - <50
  - >1500

- Average B12
  - 665.9

- What do the different codes mean?
  - hB12  n=3963  Average: 643
  - h**B12  n=2415  Average: 704
ED Visits
Emergency Department Visits

- Investigate trends and predictors of ED use
- Claims data
- Allscripts data
  - Problems
  - Medications
  - Hospitalizations
  - # Visits
  - Lab Results
  - Etc.....

- Data about physician and clinic characteristics

- Create predictive model to determine who is most likely to use the ED
ED Visit and No Other Care.

- N=25844
- Male: 52%  Female: 48%

<table>
<thead>
<tr>
<th>Age Group</th>
<th>n</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>(&lt;1)</td>
<td>457</td>
<td>1.77%</td>
</tr>
<tr>
<td>(1-10)</td>
<td>5584</td>
<td>21.61%</td>
</tr>
<tr>
<td>(11-19)</td>
<td>3584</td>
<td>13.87%</td>
</tr>
<tr>
<td>(20-39)</td>
<td>6668</td>
<td>25.80%</td>
</tr>
<tr>
<td>(40-64)</td>
<td>5965</td>
<td>23.08%</td>
</tr>
<tr>
<td>(65+)</td>
<td>3586</td>
<td>13.88%</td>
</tr>
</tbody>
</table>
## ED Visit Race Data

<table>
<thead>
<tr>
<th>Race</th>
<th>n</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian or Alaskan Native</td>
<td>12</td>
<td>0.05%</td>
</tr>
<tr>
<td>Asian</td>
<td>296</td>
<td>1.15%</td>
</tr>
<tr>
<td>Asian or pacific</td>
<td>5</td>
<td>0.02%</td>
</tr>
<tr>
<td>Black or African American</td>
<td>929</td>
<td>3.59%</td>
</tr>
<tr>
<td>Hispanic-</td>
<td>25</td>
<td>0.10%</td>
</tr>
<tr>
<td>Multi Racial</td>
<td>2</td>
<td>0.01%</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>16</td>
<td>0.06%</td>
</tr>
<tr>
<td>Other Race</td>
<td>1805</td>
<td>6.98%</td>
</tr>
<tr>
<td>White</td>
<td>12749</td>
<td>49.33%</td>
</tr>
<tr>
<td>Unknown</td>
<td>10017</td>
<td>38.76%</td>
</tr>
</tbody>
</table>
ED Visit Count?

25,844 Patients had 39,265 ED Visits

Numbers represent the number of “Emergency Department” document items in Allscripts. May have duplicates and/or additional ED reports on the same visit.

<table>
<thead>
<tr>
<th># of Documents</th>
<th>% Population</th>
<th>% Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>73.19%</td>
<td>48.17%</td>
</tr>
<tr>
<td>2</td>
<td>16.51%</td>
<td>21.73%</td>
</tr>
<tr>
<td>3</td>
<td>5.36%</td>
<td>10.59%</td>
</tr>
<tr>
<td>4</td>
<td>2.24%</td>
<td>5.91%</td>
</tr>
<tr>
<td>&gt;=5</td>
<td>2.70%</td>
<td>13.60%</td>
</tr>
</tbody>
</table>

>5 shows 697 patients had 5,340 ED reports
Allscripts as Part of an Intervention
AAFP Foundation Childhood Immunizations Project

- Goal: Improve Childhood Immunization Rates

- Intervention involved patient education, physician education, and tools enable by Allscripts.

- Used IDX, the scheduling system, to remind nurses to review immunizations on patients 19-35 months old.

- Used Allscripts to create lists of patients not up to date for physician to review and for us to contact in bulk using mailers.

- Also gave quality scores to all physicians and benchmarked them against their peers.
Childhood Immunizations

- Immunization rate increases significantly

- Largely due to finding missing documentation of Hep B vaccine given at the hospital

- 2010 AAFP Foundation Pfizer Immunization Best Practice Award
Closing the Feedback Loop

- AHRQ Grant

- Made Follow-up calls to patients presenting with acute illness

- Compared Human Calls vs. Automated Calls

- Analysis is under way

- Extracted data from Allscripts to gather participant contact info

- Added specific task types in Allscripts to inform physicians about their patients we called and how the patient was doing
Allscripts Diabetes

- Natural Experiment around Allscripts Implementation

- Investigated Diabetes Care Pre/Post Allscripts Implementation

- Analyzed data using Orders, Results, and Lab Values

- Allows us to find patients that have tests ordered but do not have them performed.
Allscripts Diabetes

• Post EHR Implementation patients were more likely to have an:
  • HbA1c<7
  • LDL<100
  • A Microalbumin Ordered

• Data Collection 1 month vs. 4 hours
Intervention Ideas
CKD Report Card generated in Allscripts Analytics will be part of an intervention.

**Renal Medicine**

**Stage 1 Kidney Damage**
- Normal Function
  - GFR > 90

**Stage 2 Kidney Damage**
- Mild Function Decrease
  - GFR 60-90

**Stage 3 Kidney Damage**
- Moderate Function Decrease
  - GFR 60-30

**Stage 4 Kidney Damage**
- Severe Function Decrease
  - GFR 15-30

**Stage 5 Kidney Failure**
- GFR < 15

**Diet Instructions**
- Limit dietary sodium to 2 g/24 hrs. Avoid salty snacks, canned soups, processed and fast food.
- Limit dietary potassium to 2 g/24 hrs. Limit tomatoes and tomato sauce, oranges and orange juice, bananas, potatoes (boiled potato is OK), avocados and cantaloupes.

**Medications**
- **ACE Inhibitor**: Accupril 5 MG Oral Tablet
- **ARB**
- **Lipid Lowering**
  - Avoid Use of NSAID and other Nephrotoxic Medications

**Recommended Referrals**

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**Other Labs**

<table>
<thead>
<tr>
<th>Protein Urine</th>
<th>Results</th>
<th>Date</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microalbumin</td>
<td>1</td>
<td>3/5/09</td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td>9.0</td>
<td>4/16/09</td>
<td></td>
</tr>
<tr>
<td>Sodium Bicarbonate</td>
<td></td>
<td></td>
<td>&gt;21</td>
</tr>
<tr>
<td>Phosphorus</td>
<td>2.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PTH</td>
<td>40</td>
<td>3/5/09</td>
<td>&gt;30</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>5.0</td>
<td>4/17/09</td>
<td>3.5-5.4</td>
</tr>
<tr>
<td>Potassium</td>
<td>3.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serum Albumin</td>
<td>14.0</td>
<td>11:34:00</td>
<td>&gt;10</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>4.0</td>
<td>3/5/09</td>
<td>&lt;7%</td>
</tr>
</tbody>
</table>

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Developed by UMass Medical School Quantitative Health Science Department and the CCTS and UMass Memorial Hospital Medical Management and Renal Medicine. Treatment Guidelines: http://www.kidney.org/professionals/kdoqi_guidelines_complementary.cfm
Pragmatic Trial

• Grant Stipulates data must be a residual of usual care.

• Use Allscripts and patient portal to improve care

• Extract Allscripts data
  • Tasks
  • Documents
  • Orders
  • Patient reported outcomes

• Allscripts based tools

• Customize Allscripts workflows
Summary
Limitations

• Missing Data

• Noisy Data

• Linking Concepts to Data

• Confounding - by indication, by severity, etc Variations in data entry by provider and clinical setting

• Different Allscripts Functionality in UMass clinics
Strengths

• Real-world data

• Huge volumes of data
  • 622,254 Patients with an arrived visit since 1/1/2007
  • 2,396,711 Blood Pressures on 318418 patients

• Inexpensive to retrieve (relative to direct capture) Dually valuable for research and operations

• Access to grant opportunities calling for electronic data that is the residual of usual care
So, how does this work?
Services Available

- It is best to integrate Allscripts into your research from the beginning!!!
- Allscripts data and capabilities will affect:
  - Collect pilot data
  - Analysis of existing data
  - Study design
  - Intervention Design
  - Grant preparation (sample size/power, analysis plans, QA/QC, data management, DSMB)
  - Data management
  - Data Coordinating Center (DCC) activities
  - Analytic Approach
- In the near future we should be able to do similar work with Soarian
Cost

- Partially supported by the CTSA
- Junior investigators and short consults are generally at no cost (CTSA)
- Help with grant applications is generally at no cost
  - Adequate support must be in the grant budget
- Long-term analyses projects require support
  - There are various mechanisms, including P01 program/project grants
- Let’s talk
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  • Quantitative Methods Core
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  • QMC@UMassMed.edu