Convergence Informatics: The Future of Clinical Innovation

HST 921 Lecture

By Keith Strier, JD

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Deloitte.

The Big Picture

Innovators in Medicine
The Headline to Look For

Harvard sets new land-speed record translating HPCGG discoveries into Clinic Practices within 90 days!
The terms

• **Translational Medicine**
  – Definition #1: “The translation of scientific innovations into health gains.”
  – Definition #2: “A learning approach to medicine, bridging the lab to the bedside.”
  – Definition #3: “Bidirectional exchange between basic and clinical sciences to move research findings from the lab to applied settings involving patients and populations

• **Clinical Informatics**: Applying computer science to the delivery of care, developing novel information technology and knowledge management methodologies to prevent disease, deliver safer and more effective health care

• **Bioinformatics**: Collection, organization and computational analysis of large biological data sets from genomics, proteomics, drug screening and medicinal chemistry sequences.

• **Integrative Informatics**: Integration and ‘mining’ of ever-expanding databases of information (clinical to biomedical) across scientific and clinical disciplines

• **Clinical Data Collaboration**: A broad term incorporating the formation of alliances for the purpose of exploiting secondary use-cases for health data

• **Convergence Informatics** – TO BE DEFINED.
The Burning Platform

Photo of oil drilling platform on fire removed due to copyright restrictions.
What’s the burning platform?

For providers...

- Coronary heart disease* (7.2 million deaths per year)
- Cancer* - all sites (6.3 million deaths per year)
- Cerebrovascular disease* (4.6 million deaths per year)
- Acute lower respiratory infection (3.9 million deaths per year)
- Tuberculosis (3.0 million deaths per year)
- Chronic obstructive pulmonary disease* (2.9 million deaths per year)
- Diarrhea - including dysentery: 2.5 million deaths per year
- Malaria (2.1 million deaths per year)
- HIV/AIDS (1.5 million deaths per year)
- Hepatitis B (1.2 million deaths per year)

* = non-communicable diseases

Paragraph of text removed due to copyright restrictions. Highlighted text: “...success in the discovery arena is not being translated into new medicines...”
Translational science aims to remove the linear relationship between research and the clinic, and instead generate a symbiotic partnership, increasing cross-functional communication and collaboration with the goal of reducing attrition and enhancing the quality of compounds moving into clinical studies.

SOURCE: Bridging the Divide: the case for translational informatics; Andy Gaughan, Pharmacogenomics 2006 7(1)
High Level Informatics Overview

- Translational Medicine
  - Discovery Informatics
  - Clinical Informatics
  - Patient Informatics

Integrative Informatics

- Research Applications
- Clinical Systems
- Personal Health Records (PHR)

- Strategic Planning
- Population Health
Integrative informatics architecture
A Provider Perspective

**Transactional Systems**

- Clinical Information Systems
  - Administrative Transactions
  - Clinical Transactions
  - Financial Transactions
- Epidemiological Data
- Clinical Trials Management System
- Bio-bank Management
- Proteomic/Genomic Data
- Other Public Sources

**Data Repositories**

- Clinical Data Repository
  (stores clinical data from multiple systems to support the clinical mission)
- Research Data Repository
  (supports the research mission by integrating data from clinical and biomedical sources)
- Operational Data Warehouse
  (focuses on administrative, service planning)

**Data Mining and Analysis**

- Rules-based expert systems
- Statistical Analysis
- Bayesian Networks
- Neural Networks

**Clinical and Research Queries**

- What is the treatment for an episode of severe broncho-constriction?
- Which population group has the highest incidence of asthma?
- What key epidemiological factors contribute to an increase in the incidence of asthma in a particular ethnic population?
- Does the efficacy of a particular asthma treatment differ for various genetic variations?

SOURCE: Deloitte Analysis, Subject Matter Expert interviews

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The opportunity for life science firms

Improving data flows across bench-to-bedside-to-bench continuum will improve target validation, reduce the cost and risk of clinical trials, and improve the economics of drug discovery (maybe???)

SOURCE: Bridging the Divide: the case for translational informatics; Andy Gaughan, Pharmacogenomics 2006 7(1)
Through the integration of molecular-based technologies, systematic tissue procurement and medical informatics, we now have the ability to identify clinically applicable "genotype"-"phenotype" associations across cohorts of patients that can rapidly be translated into useful diagnostic and treatment strategies.

SOURCE: Translation research: from accurate diagnosis to appropriate treatment, Craig P Webb, and Harvey I Pass, Journal of Translational Medicine, 21 October 2004
Courtesy of Journal of Translational Medicine and BioMed Central.
## Partners - Registered patient data repository (RPDR)

<table>
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<tr>
<th>Description</th>
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<tr>
<td>• Purpose is to enable a Partners Healthcare research clinician to at least get a “first cut” of patient cohort to recruit for research studies</td>
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<td>• Unique tool mainly used for clinical research and improving clinical operations</td>
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<td>• Proven track record of usage with clinical investigators</td>
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<td>• Many person-years of embedded knowledge about the clinical domain</td>
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<td>• Clinicians can construct complex queries using its simple user interface</td>
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<td>• Data is anonymized at the Query Tool</td>
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<table>
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<tr>
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<tr>
<td>• Operational since 12/16/1999</td>
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<td>• 1,072 registered users, 308 new in 2005</td>
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<td>• 3.1 million Partners Healthcare patients</td>
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<tr>
<td>• 810 million diagnoses, medications, procedures, laboratories, and physical findings coupled to demographic and visit data</td>
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<td>• 95 teams preparing grants</td>
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<td>• 129 teams preparing patient cohorts for IRB approved research</td>
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<td>• 84 teams doing clinical studies</td>
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<tr>
<td>• 36 teams reviewing hospital operations</td>
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### Funding / Support

- Capital funding from Partners Research Council, operational funding from Partners Information Systems
- Total operational budget – $850 thousand/year
- Total capital budget – $900 thousand/year
- Operational team of 7 at Massachusetts General Hospital Laboratory of Computer Science

Source: RPDR Report
RPDR (2 of 4)

How Useful was RPDR for Grant Applications?

- Very useful: 58%
- Somewhat useful: 24%
- Not useful: 6%
- Critical: 12%

Time Saved by RPDR for Grant Applications

- Days: 65%
- Hours: 20%
- Same: 15%

Source: Henry Chueh, Director, Laboratory of Computer Science, Division of Clinical and Research Informatics, Department of Medicine Massachusetts General Hospital, presentation “Research Databases: The Research Patient Data Registry and Strategic Directions”
How Useful was RPDR for Cohorts?

<table>
<thead>
<tr>
<th>Useful</th>
<th>Critical</th>
<th>Somewhat useful</th>
<th>Not useful</th>
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<tbody>
<tr>
<td>Very useful</td>
<td>24%</td>
<td>16%</td>
<td>5%</td>
</tr>
<tr>
<td>Critical</td>
<td>55%</td>
<td>24%</td>
<td>-</td>
</tr>
<tr>
<td>Somewhat useful</td>
<td>16%</td>
<td>5%</td>
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<tr>
<td>Not useful</td>
<td>5%</td>
<td>-</td>
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Time Saved by RPDR for Cohorts

- 85% of RPDR Patients meeting Study Criteria
- 15% of patients did not meet study criteria

Cohorts; % of RPDR Patients meeting Study Criteria

- >50%: 40%
- 25-50%: 19%
- 10-25%: 19%
- <10%: 19%

Source: Henry Chueh, Director, Laboratory of Computer Science, Division of Clinical and Research Informatics, Department of Medicine Massachusetts General Hospital, presentation “Research Databases: The Research Patient Data Registry and Strategic Directions”
**How Useful was RPDR for Study Feasibility?**

- Very useful: 27%
- Somewhat useful: 45%
- Not useful: 23%
- Critical: 5%

**How Useful was RPDR for Operations?**

- Very useful: 50%
- Somewhat useful: 30%
- Not useful: 10%
- Critical: 10%

Source: Henry Chueh, Director, Laboratory of Computer Science, Division of Clinical and Research Informatics, Department of Medicine Massachusetts General Hospital, presentation “Research Databases: The Research Patient Data Registry and Strategic Directions”
Questions

• Is this enough to accelerate translation?
• What additional functionality/applications are needed?
• How else can they connect/collaborate with life science firms?
• What is the role, if any, of PHRs?
## Stanford translational research integrated database environment (STRIDE)

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<td>• A secure, HIPAA compliant, integrated data repository in the form of structured biomedical data, electronic documents and imaging data; linked to a common database model using a set of data representation standards and designed to support Stanford University Medical Center’s (SUMC) translational research mission</td>
<td>• Integrates clinical, research and imaging data within one standards–based data model</td>
</tr>
<tr>
<td>• An informatics project commissioned to create an integrated standards-based clinical research data repository for SUMC</td>
<td>• Provides a set of services to the Stanford research community: cohort identification, clinical data access, research data management, custom research applications</td>
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<td>• Facilitates sharing of clinical data between Lucile Packard Children’s Hospital (LPCH), Stanford Hospital and Clinics (SHC) and the School of Medicine</td>
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<td>• Several STRIDE applications are under development</td>
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### Technical Characteristics

- High performance, scalable database platform (Oracle)
- Entities Attribute Value (EAV) data model using the HL7 Reference Information Model (RIM) and Clinical Document Architecture (CDA)
- Supports HL7 and DICOM messaging standards
- Uses SNOMEDCT as its core concept encoding scheme
- A database and development platform for biomedical research applications, data management, reporting & exploration
- Secure, monitored, HIPAA-compliant, IRB-approved access to protected health information for research purposes

Source: Henry Lowe, MD, Associate Professor of Medicine, Director, Stanford Center for Clinical Informatics, presentation “STRIDE”
STRIDE (Cont’d.)

STRIDE Architecture Model: Data In-flow

- Cohort Identification
- Custom Research Applications
- Data Management and Reporting Tools
- Clinical Trials Support
- Virtual Tissue Bank
- Disease-Specific Registries
- Master Person Index

Selected data from Research Systems & IRB eProtocol System

HL7

DICOM

Wired & Wireless Network, Data Center Services, I.T. Security System & Software Development Services, Data Management Services

Source: Henry Lowe, MD, Associate Professor of Medicine, Director, Stanford Center for Clinical Informatics, presentation “STRIDE”
Kaiser: Genetic research program

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<td>• The goal of the genetic research program is to help Kaiser and other researchers explore how environmental factors and genes are linked to specific diseases such as asthma, Alzheimer’s, cancer, diabetes, autoimmune disorders and heart disease.</td>
<td>• 2 million adult Kaiser enrollees in Northern California have been asked to voluntarily donate blood or saliva as DNA samples.</td>
</tr>
<tr>
<td>• By combining genetic, health and other demographic information from potentially hundreds of thousands of Northern California enrollees into huge databases, researchers hope to gain a deeper understanding of the causes and potential treatments of complex diseases.</td>
<td>• Up to 500,000 Kaiser members are expected to volunteer.</td>
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<td>• $7 million in donations have been raised from several nonprofit foundations to initially fund the program.</td>
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<td>• Research division has more than 450 staffers, including 40 scientific investigators.</td>
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<td>• Medical record and insurance-related data is stored on more than 3.2 million enrollees.</td>
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<td>• Only when an adult enrollee agrees to participate in the new program will research data and medical record data be combined, “to discover patterns and relationships”.</td>
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<td>• Upcoming individual disease studies are expected to cost in the neighborhood of $5 million to $7 million each.</td>
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<td>• The databank will be available to researchers at Kaiser as well as outside collaborators.</td>
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Source: [http://sanfrancisco.bizjournals.com/sanfrancisco/stories/2007/02/12/daily34.html](http://sanfrancisco.bizjournals.com/sanfrancisco/stories/2007/02/12/daily34.html);
## Vanderbilt – Affymetrix

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<td>• Affymetrix Inc. and Vanderbilt-Ingram Cancer Center entered into a three-year translational research collaboration to analyze genomic information across a large number of patient samples.</td>
<td>• The partnership provides a mechanism to bring technology to the forefront of translational research in helping Vanderbilt understand not only the molecular basis for the disease but also the genetic disparities in various cancers and responses to therapy.</td>
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<tr>
<td>• Under terms of the agreement, researchers at Vanderbilt-Ingram and Vanderbilt University Medical Center will use Affymetrix GeneChip(R) microarray technology to develop new applications for translational research projects, focusing on disease areas such as cancer and HIV/AIDS.</td>
<td>• The HIV/AIDS translational research project will aim to help clinicians avoid the often irreversible and costly complications of therapy.</td>
</tr>
<tr>
<td>• The Affymetrix Human Mitochondrial Resequencing Array 2.0 will be used as a research tool to identify genetic variants that may make some patients more susceptible to adverse effects of certain drugs.</td>
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## Institutional Characteristics

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<td>• In 2003, The Vanderbilt Clinic had over 698,900 patient visits, and more than 33,800 patients were admitted to the Vanderbilt Hospital, with a substantial number of patients from outside Tennessee.</td>
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<td>• Five of the School’s departments were ranked in the top ten among comparable medical school departments in receipt of NIH funding in 2003.</td>
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<tr>
<td>• Support for competitive research grants from all external sources was almost $300 million in 2004.</td>
</tr>
<tr>
<td>• In FY 04 the entities that comprise the Medical Center received more than $59 million in philanthropic gifts.</td>
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</table>

Source: Business Wire – Press Release, “Affymetrix Signs Three-Year Translational Medicine Agreement With Vanderbilt-Ingram Cancer Center” 01.24.07, 8:00 AM ET
The Future

Advanced medical imaging screenshot removed due to copyright restrictions.
Where are we on the Gartner Hype Cycle

Figure by MIT OCW. After Gartner Dataquest, 2002.
In Canada

Leveraging clinical data collaborations to generate eminence and improve clinical outcomes, down to the PCP level

...[our] goal is to improve the quality of healthcare in Quebec by identifying opportunities where genomic and proteomic technologies can be integrated into both clinical trials and the physicians’ office.

Image removed due to copyright restrictions.

In Singapore

Leveraging clinical data collaborations to generate eminence and improve clinical outcomes, down to the PCP level

Image removed due to copyright restrictions.
The economics

Under the terms of the agreement, Pfizer will pay Scripps Research $100 million over a five year period, during which scientists from Pfizer and the Institute will work together to identify and perform specific projects of mutual interest.
The best way to predict the future is to create it.

Peter Drucker
professor of social science and management at Claremont Graduate University
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