Translational Research: The Essential Role of Biomedical Informatics

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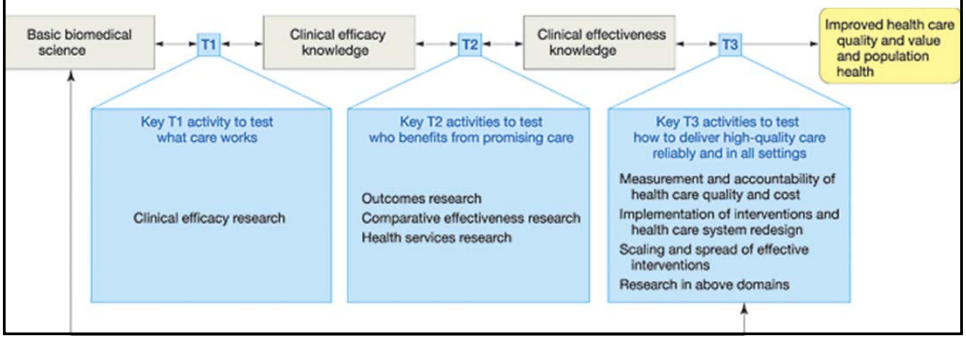
Topics to be covered

- Definitions
- Biomedical research environment
- Opportunities
- Challenges
- Solutions
- Conclusions

Translational research (Zerhouni, 2007)

- Accelerating research results from laboratory to clinical environment to community along T1/T2/T3 axis (Dougherty, 2008)
- Benefits require collaboration and partnerships, facilitated by informatics (Portilla, 2010)



Clinical research informatics (CRI)

- Overview of emerging domain within informatics (Embi, 2009)
  - "Clinical Research Informatics (CRI) is the sub-domain of biomedical informatics concerned with the development, use and evaluation of standards, models, processes and systems to optimize the design and conduct of clinical and translational research and disseminate the knowledge generated."
- Historical focus on management of research protocols and data capture and analysis, but increasingly focuses on integration of clinical systems and secondary use of clinical data (Payne, 2009)

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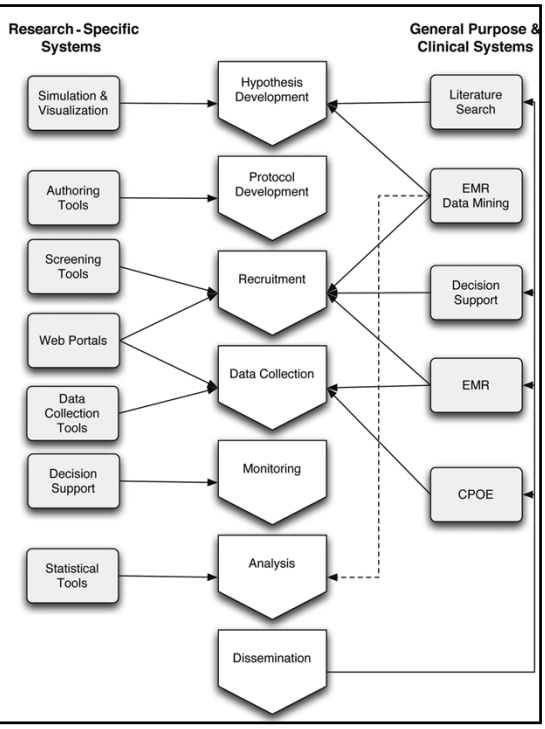
Informatics can help achieve integration of
- Research systems
- Research activities
- Clinical systems

(Payne, 2005)



Biomedical research environment

- Who performs it and where?
  - Academic medical centers – researchers, usually faculty, at universities and other medical centers
  - Government research laboratories
  - Private industry – usually focused on product research and development
- Who funds it?
  - Government – In US, National Institutes of Health (NIH) is main funder in US, but also comes from other agencies, such as National Science Foundation (NSF), Department of Defense (DOD), etc.
    - Other countries have similar agencies that fund research
  - Private industry – usually focused on product development

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Major US NIH initiative for translational research

- Clinical & Translational Science Award (CTSA)
  - www.ctsaweb.org
  - Goal is to accelerate translation of research into clinical care and community
  - Funds 60 centers around US in pursuit of goal
  - "Key function committees" focus on major areas, including informatics
  - Distinction of informatics from other disciplines well borne out in CTSA informatics program (Bernstam, 2009)

CTSA Clinical & Translational Science Awards ®

Many opportunities for CRI due to biomedical informatics

- Increased digitization of clinical data provides new opportunities for its secondary use (Safran, 2007)
- A growing "cyberinfrastructure" of distributed, standards-based systems for all biomedical research is enabling progress (Buetow, 2005)
- Practice-based research networks can more closely address pertinent research questions and are enabled by informatics (Westfall, 2007)
- Informatics can enable the "learning health care system" – learning from data collected in care (Eden, 2008), leveraging HITECH investment (Friedman, 2010)

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Opportunities (cont.)

- Convergence of technologies in informatics, genomics, imaging, and other areas provide great opportunity, e.g.,
  - Registries (Wright, 2009; Backus, 2009; Fleurant, 2011; Navaneethan, 2011) to support research (Dreyer, 2009), converging into national data networks (Maro, 2009)
  - Biorepositories, aka biolibraries, that facilitate retrieval of biological specimens and link to clinical data (Ginsburg, 2009; Prokosch, 2010)
  - Development of "federated" query mechanisms across distributed databases (e.g., SHRINE – see next slide; Weber, 2009)

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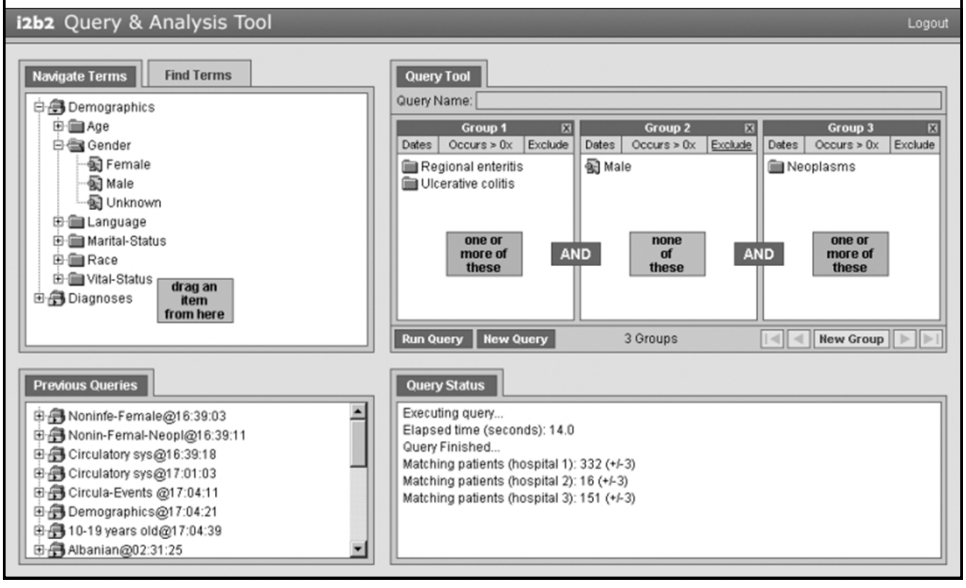
SHRINE i2b2 query tool (Weber, 2009)



Challenges for CRI

- Data capture and analysis
- Trust and privacy

Data capture and analysis

- Just because data is electronic does not mean it is adequate for research
  - Clinical documentation is often not a priority for clinicians (de Lusignan, 2005)
  - The functions and data structures in EHRs are designed for clinical care and transactions (Kahn, 2007)
    - Also do not want to overload operational systems with research queries
  - Data is sparse, multi-dimensional, derived, and highly personal (Eggebraaten, 2007)
    - Not to mention the usual problems of lack of standards (Richesson, 2008; McCourt, 2007)

Trust and privacy

- Patients must have trust that their best interests will be looked after – must manage relationships among researchers, institutions, and industry (Yarborough, 2002)
- HIPAA Privacy Rule may be impeding research without improving privacy for the patient
  - In a survey of epidemiologists, three-quarters reported it made research more difficult without benefit to subjects (Ness, 2007)
  - IOM has suggested revisions to HIPAA Privacy Rule to make it more "research-friendly" (Nass, 2009)

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Some solutions for CRI

- Cancer Bioinformatics Grid (caBIG) and related projects
- Clinical trials and studies management
- Research data warehousing
- Other informatics innovations to support clinical research

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Cancer Bioinformatics Grid (caBIG, cabig.nci.nih.gov)

- Aims to provide an infrastructure for research and collaboration in cancer research (MITRE, 2006)
  - Recent report criticized project management, scope, and (in some instances) competition with commercial sector (NCI, 2011)
- Based on four "cornerstones"
  - Federated software and resources widely distributed, interlinked, available to entire cancer research community
    - Institutions maintain local control over their own resources and data
  - Open-development – tools and infrastructure developed through an open, participatory process
  - Open-access resources freely obtainable by cancer community
  - Open-source – source code is available to view, alter, and redistribute

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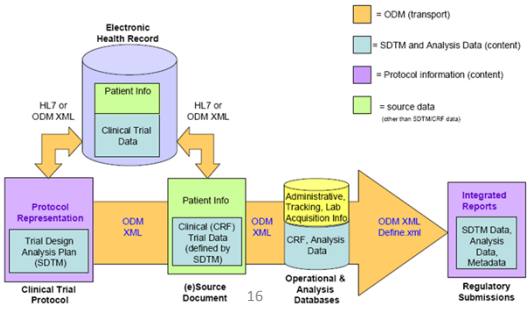
Clinical trials and studies management

- Clinical Data Interchange Standards Consortium (CDISC, www.cdisc.org) – standards to support electronic acquisition, exchange, submission, and archiving of clinical and non-clinical study data and metadata (Kush, 2008)



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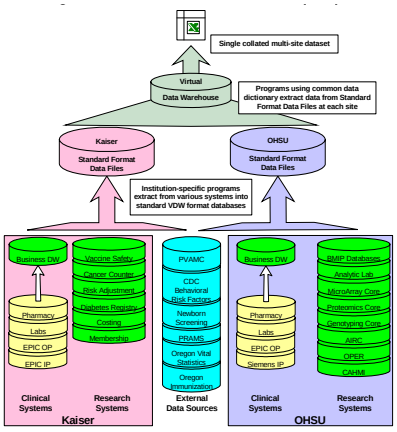
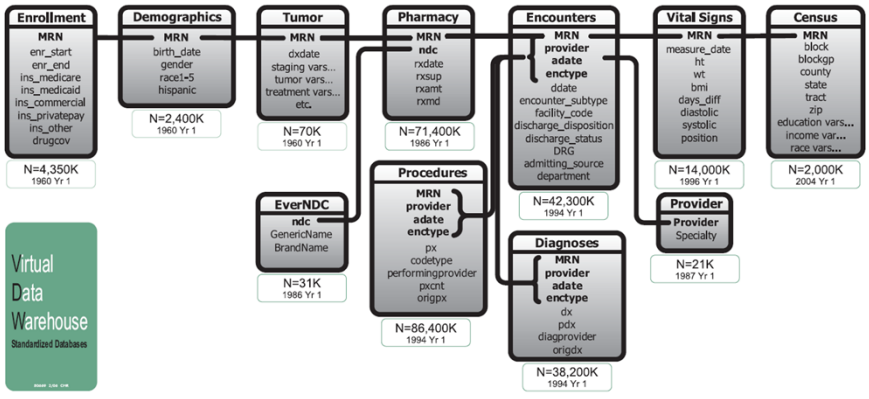
Research data warehousing

- HMO Research Network Virtual Data Warehouse (VDW)
  - Brings HIE-like capabilities to research systems (Hornbrook, 2005)
- Use cases include
  - Data analysis preparatory to research
  - Disease counters
- Accepts non-interoperability of inter-institutional data
  - Does not mean lack of advocacy for semantic interoperability
- Human layer adds additional value with respect to security, IRB, etc.



Elements of VDW



Other informatics innovations to support clinical research

- Research Electronic Data Capture (REDCap) uses metadata to create simple data capture forms and stores data securely for researchers (Harris, 2009)
- Mobile technologies to support data capture and use, especially in developing countries (Lang, 2011)
- "Point of care" clinical trials embedding research in clinical care process, demonstrated in VA system assessing sliding scale vs. weight-based regimen for insulin administration (Fiore, 2011)

Common themes emerging among CTSA informatics programs

- Web portal to integrate research activities, people, etc.
- Informatics services and consultation for investigators
- Data warehousing for clinical, laboratory, and/or specimen data
  - Long-term but difficult goal: data sharing
  - Also difficult but being undertaken by many: clinical data warehouses from EHRs and other systems
- Facilitating collaboration and translation
- Educational programs for translational researchers
  - Some programs also focused on education for informaticians

Conclusions and future directions

- Clinical and translational research offers the promise of improved human health through accelerated progress of research findings into practice
- Informatics is an essential tool and science for effective clinical and translational research
- Translational research programs present major opportunities for informatics research and education