The Intersection of HSR and IT: Opportunities and Challenges

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HIT to Improve Population Health

"The improvement of population health requires timely, accurate, and detailed clinical information to allow for evaluation of health care delivery. It may include reporting of critical findings to public health officials, clinical trials, and other research. Feedback to clinicians is also important for improvements in care delivery. However, collection of this information cannot impose an undue burden. This is of particular importance as assumptions are made about the ability of EHRs to support a new echelon of information needs for research and surveillance."

Thompson TG, Brailer DJ. The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care. Framework for Strategic Action. July 21, 2004.

Three Strategies for Using HIT to Improve Population Health

- **Unify public health surveillance architectures**
- **Streamline quality and health status monitoring**
- **Accelerate discovery and dissemination**

Thompson TG, Brailer DJ. The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care. Framework for Strategic Action. July 21, 2004.

HIT for Outcomes Research

Capture, use in real time to evaluate, guide patient care

- **Collect, pool, and analyze patient health status, progress report data via EHR/PHR**
- **Use to establish large databases of diagnostic, therapeutic, and outcome information**
- **Assess, improve the safety, effectiveness, cost-effectiveness of care**
- **Feed outcomes data to evidence base, develop and update guidelines**
- **Bring patient data, guidelines, other resources into real-time decision-support for clinicians and patients**

Assessing Quality of Care … The Hard Way?

"We telephoned a random sample of adults living in 12 metropolitan areas in the United States and asked them about selected health care experiences. We also received written consent to copy their medical records for the most recent two-year period and used this information to evaluate performance on 439 indicators of quality of care for 30 acute and chronic conditions as well as preventive care."

N= 6,712 participants

McGlynn EA, et al. The quality of health care delivered to adults in the United States. N Engl J Med 2003;348(26):2635-45.

NIH NECTAR

Part of NIH Roadmap

- **Feasibility testing of National Electronic Clinical Trials and Research (NECTAR) Network**
- **Toward rapidly conducting high-quality clinical studies and trials**
- **Allow community-based clinicians from the NIH National Clinical Research Associates to participate in important national studies**
- **Facilitate the sharing of data and resources**
- **Augment clinical research performance and analysis**

Study Data Tabulation Model

- New standard that drug sponsors can use to submit data from clinical trials to FDA
- Developed by FDA, NIH, Clinical Data Interchange Standards Consortium (CDISC: consortium of 40+ pharma companies and clinical research organizations)
- Facilitate automation of mostly paper-based process
- CDISC standard for exchange of clinical trial laboratory data is approved as HL7 Reference Information Model Version 3 message
- Data presented in a standard structure will improve FDA's ability to evaluate the data and help speed new discoveries
- FDA exploring making the standard a requirement for data submission

caBIG: Cancer Biomedical Informatics Grid

- NCI pilot, to be implemented across 50 academic centers in cancer research
- Voluntary network linking individuals and groups to form a world wide web of cancer research
- Open environment with common standards
- Operates in multiple workspaces and strategic level working groups via face-to-face meetings and open teleconferences
- FDA and NCI will use to support regulatory submissions

Comparative Clinical Effectiveness - PCTs

"The widespread gaps in evidence-based knowledge suggest that systematic flaws exist in the production of scientific evidence, in part because there is no consistent effort to conduct clinical trials designed to meet the needs of decision makers. Clinical trials for which the hypothesis and study design are developed specifically to answer the questions faced by decision makers are called pragmatic or practical clinical trials (PCTs) …. The supply of PCTs is limited primarily because the major funders of clinical research, the National Institutes of Health and the medical products industry, do not focus on supporting such trials."

Tunis S, Stryer DB, Clancy CM. JAMA 2003;290(14).

Comparative Clinical Effectiveness - PCTs

Characteristic features of PCTs:

1. **Select clinically relevant alternative interventions to compare**
2. **Include diverse population of study participants**
3. **Recruit participants from heterogeneous practice settings**
4. **Collect data on the broad range of health outcomes**

Tunis S, Stryer DB, Clancy CM. JAMA 2003;290(14).

MMA Sec. 1013. Research on Outcomes of Health Care Items and Services

To improve health care delivered through Medicare, Medicaid, and S-CHIP, $50M authorized in FY2004

Research and other activities may address:

1. Outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs)
2. Strategies for improving efficiency and effectiveness of such programs, including ways in which such items and services are organized, managed, and delivered under such programs

MEDICARE DRAFT NATIONAL COVERAGE FOR IMPLANTABLE CARDIOVERTER DEFIBRILLATORS INCLUDES REGISTRY OF RECIPIENTS TO TRACK PROGRESS. September 24, 2004

CMS today posted a draft national coverage determination (NCD) to expand coverage of implantable cardioverter defibrillators (ICD) based on new research showing that the devices can benefit a wider population of patients than first indicated in the product's original trials.

This expansion will increase the number of Medicare beneficiaries eligible for an ICD by one-third, to nearly 500,000. When this NCD becomes final, CMS expects to provide this therapy to an additional 25,000 patients in the first year of coverage, potentially saving up to 2,500 lives.

Medicare NCD for ICDs Includes Registry …

- **CMS will work closely with product manufacturers and clinical experts, including NIH, to develop a practical registry that can track the progress of patients who receive the devices and help develop additional evidence to better identify who is most likely to benefit from them.**
- **The feasibility and value of clinical registries has been demonstrated by several very large registry projects in cardiovascular disease device and drug therapy. Active registries are producing valuable data for patients undergoing implantation of ventricular assist devices, thrombolytic therapy for acute MI, heart failure, acute myocardial infarction, treatment for congestive heart failure, placement of coronary stents, and cardiac catheterization.**