

“Put your trust in God, my boys, and keep your powder dry.”
Colonel Blacker,
1800’s

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Quilted consent: patching the holes in the HIPAA blanket

By Michael L. Glickman, President, Computer Network Architects (an affiliate of CCI)

By any measure, the increasing cost of health care is worrisome and unsustainable. National health expenditures total about \$2 trillion each year. By 2015, they will double to \$4 trillion and represent one-fifth of the gross domestic product. Among the factors propelling the rise in costs are increases in life expectancy and the size of the aging Baby Boomer population.¹

Medical technology and care provided -- especially during the last six months of life -- contribute significantly to health care cost increases. However, technology also promises real improvements in both costs and quality that can be achieved by leveraging data and information.

It’s been 15 years since the landmark Institute of Medicine report, *The Computer-Based Patient Record*, prompted development of today’s electronic health record. The next new thing will be the revolutionary changes that will enable personalized medicine, or more significantly, personalized health.

Scientific breakthroughs inaugurate era of personalized health

A milestone scientific achievement of the 21st century has been the sequencing of the human genome, which has led to the new sciences of genomics and proteomics. The study of polymorphisms, or genomic changes associated with particular diseases, promises vast improvements in the efficacy and efficiency of health care delivery.

Glimpses of this quantum leap are already evident in the treatment of cancer. Genetic testing, coupled with the many choices of available chemotherapy drugs, has led to personalized drug regimens and treatment protocols that are becoming more effective by the month.

How does the electronic health record fit in?

A cornerstone of the important contributions to improvements in health care delivery will be the holy grail of health information technology (HIT), & the electronic health record (EHR).

¹ US Centers for Medicare & Medicaid Services: *National Health Care Expenditures Projections: 2005-2015*. Full text free here: <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2005.pdf> (accessed 11/11/06)



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As an industry, we have experienced the barriers to adoption for many years including such issues as hard to quantify provider benefits, high costs, limited technology effectiveness, and the very long implementation times.

But now the payback will be enormous, as HIT and EHRs become multi-dimensional and leverage data and information to yield knowledge. The uses of the electronic health record include the original notion of housing data about the individual patient receiving care in the physician's office, hospital, or other provider setting. However, another important use of the EHR is to provide aggregate data for clinical trials or other population-based studies. Related to this is the ability to contribute to public health surveillance of epidemic outbreaks. These uses of electronic health record data are intended primarily for health professionals, researchers, and public health officials.

Electronic health records versus *personal* health records

Another dimension of data use brings the electronic health record to life. This involves the concept of consumer empowerment, which places the patient at the center of – *and in charge of* – data collection, dissemination, and decision making. This type of personal health record information, although derived from similar data, is fundamentally different in form and content from EHR data. Implications of the implementation of PHRs require careful thought by HIT professionals.

Will the patients – *should* the patients -- trust the system?

A multidimensional, patient-centric personal health record will have to be controlled by the patient to be of any value. The implications are enormous. Before a patient can be expected to share data, trust must be established between the patient and the users of the data. This is a far cry from the state of affairs today. HIPAA protects against the improper use and disclosure of personal health information but provides a mile-wide waiver for data associated with the direct delivery of care. This has resulted in patients signing waivers that provide **blanket consent** authorizing the use of data and information for the delivery of medical care and for reimbursement.

Consumers may be surprised at the holes in the blanket

To the chagrin of many consumers, many secondary uses of these data have crept into the system. Highly personal data such as prescriptions, diagnoses, procedures, and test results -- including genetic tests -- are known to insurers, employers, and others lacking a clear, direct need to know.

Blanket consent will not work in the evolving, multidimensional environment of personal health records. For the patient to use the system, the patient must trust the system. And trust requires control. Thus, the practice of blanket consent must and will be replaced soon by what I call "*quilted consent*".

What is *quilted consent*?

More granular than blanket consent, quilted consent is the start of a chain of trusted end-to-end information flow. The patient must be able to control these facets of his or her own data:

- Who will use information about me?
- For what purpose will my information be used?
- How long will my information be available for this use?

Different rules will also apply for different conditions, such as when a patient has AIDS, a communicable disease, or a mental health ailment. A consumer must trust that his personal health information will be used properly. Otherwise, patients will neither opt in, or if not provided the choice, will opt out in volumes that will render conventional systems incomplete and useless. Implementing more



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granular quilted consent into the system is the tipping point that will instill trust in the user and begin the chain reaction that will certainly follow. Of course, there is a need to support the “break the glass” emergency. But that use of data will be the exception rather than the rule in the multidimensional personal health record/EHR setting.

How can we achieve quilted consent?

How to encrypt data transmitted over the Internet is well understood. Similarly, to support trusted uses of secondary population-based longitudinal personal health information, inherent anonymization of the data is required to maintain trust. Pseudonymization, a related but more sophisticated technique, is required in the case of “break the glass” uses of data. This technique allows personal health data to be stripped of personal identification fields, but the identity of the patient can be reverse-engineered for notifications and public health emergencies. Beyond the issues of confidentiality and privacy identity, development of a trusted end-to-end information flow must address:

- Authentication
- Authorization
- Audit
- Non-repudiation
- Persistence of records
- Completeness

If we don't adapt, few will buy and few will sign up to use our systems. Incomplete data, especially when you don't know what is missing, is worse than no data at all.

-- What's new in the literature? --

Small practices lag in IT adoption

Physicians in small practices are less likely to have access to a full range of clinical information technology than their counterparts in large practices, according to this national sample survey conducted periodically by the Center for Studying Health System Change. Physicians practicing in group/staff HMOs were found to be the most likely to have access to IT. One of the study's authors commented that the gap between large and small practices may reflect the “natural path of technology adoption where larger, savvier organizations adopt new technologies first.” Among the various IT applications studied, over half of all physicians surveyed reported the ability to obtain guidelines, exchange clinical data, and access patient notes. Less than one-third of all physicians reported having the ability to generate reminders or write prescriptions.

Sources: Center for Studying Health System Change: Clinical IT gaps persist – grow – between small and large physician practices. *News Release*, November 9, 2006. Full text free here:

http://www.rwjf.org/files/research/11-9-06_IB_106_IT_Gaps_Final_News_Release.doc and, Grossman JM, Reed MC: Clinical information technology gaps persist among physicians. *Issue Brief*, November 2006;106: pp 1-4. Full text free here: <http://www.hschange.org/CONTENT/891/891.pdf>

Competition spurs doctor portals

The extent of clinical data sharing was studied in 12 urban markets in 2005 as part of the ongoing Community Tracking Study. Nearly three-quarters of the hospitals in these markets were found to have operational physician portals or be in the process of implementing them. However, these portals are primarily targeted to meeting the needs of the hospitals' heavy admitters as a physician recruitment and retention tool. How competitive barriers may hamper the



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formation of regional health information organizations (RHIOS) between unaffiliated providers is discussed.

Source: Grossman JM, Bodenheimer TS, McKenzie K: Hospital-physician portals: the role of competition in driving clinical data exchange. *Health Affairs*, November/December 2006;25(6):pp 1629-1636. Full text free for a limited time here:

<http://content.healthaffairs.org/cgi/reprint/25/6/1629?ijkey=Dxdz1Z7dglf9o&keytype=ref&siteid=healthaff>

EDIS part of emergency redesign

CentraState Healthcare System (Freehold, NJ, 271 beds) undertook an emergency department expansion project that included an overhaul of the departmental workflow. Implementation of a Wellsoft emergency department information system has been a major part of the workflow redesign. The new 48-room ED, twice as large as the old department, features decentralized registration, and automated patient tracking and documentation.

Sources: McBride M: On track to improved workflow. *Health Management Technology*, December 2006;27(12):pp 26+. Full text free here:

http://www.healthmgttech.com/archives/1206/1206on_track.htm; and, Wellsoft goes live at CentraState Medical Center. *Press Release*, August 2004. Full text free here: http://www.wellsoft.com/news/press_releases/centrastate.php

Neurologists compare IT vendors

The American Academy of Neurology studied the electronic health record products offered for small to medium-sized medical practices and produced this ranked comparison of the leading vendors. Among the factors used in comparing the vendors were functionality, end-user satisfaction, client base, and price, among others.

Source: American Academy of Neurology: *Electronic Health Records Vendor Report*, September 2006. Full text free here: http://www.aan.com/professionals/patient/pdfs/ehr_report_091906.pdf

P4P implications for CIOs

An estimated 10 percent of employers are already involved with some type of pay-for-performance initiative. As the number of P4P programs increases, CIOs of health care provider organizations will need to think through the issues involved with providing data about the quality of patient care. Experiences of the Kettering Medical Center Network (OH) and Staten Island University Hospital (NY) are among those described in this cover story. Concerns about quality measurements – such as the need to develop a more comprehensive set of measures – are discussed.

Source: Hagland M: Catching the P4P wave. *Healthcare Informatics*, November 2006;23(11):pp 28+. Full text free here: <http://healthcare-informatics.com/issues/2006/11/028/>

PC replacement cycle = 2 years

Although hardware prices are dropping on a per-unit basis, health care providers are faced with increased numbers of clinicians who need access to PCs and a shorter useful life for the computers. Although the replacement cycle for servers is about 5 years, it is only about 2 years for PCs. Implications of these trends for health care providers' computer purchasing patterns are discussed in this cover story. Among the considerations is whether to handle purchasing in-house or through outsourcing.

Source: Briggs B: Hardware: when to hold 'em, when to fold 'em. *Health Data Management*, December 2006; 14(12). Full text free here:

<http://www.healthdatamanagement.com/html/current/CurrentIssueStory.cfm?articleId=14363>