Innovation in Health Care Delivery Systems

Patient Concerns in Health Care

Patient Control of Health Records

April 30, 2010

McCombs School of Business
Patient expectations
Pop Quiz: Who said this?

• “Medical records would belong to patients. Clinicians, rather than patients, would need to have permission to gain access to them.”

• “Individuals have the right to control – and must have the ability to control – who can access their personal health information. All health information technology should be deployed to improve individual health, not to protect the status quo of proprietary claims to data.”

• “One thing is the federal government has got to make sure the privacy rules are strong. You're going to hear us talk about medical -- electronic medical records. And that's exciting. But it's not so exciting if you're a patient who thinks somebody could snoop on your records, to put it bluntly. I'm not interested in having my -- well, it's too late for me. (Laughter.) My medical records are pretty well known. But for those people -- there's a lot of people in America who say, good, I want there to be good information technology in the health care field, I just don't want somebody looking at my records unless I give them permission to do so.”

• “Congress had a chance to look at this issue [national privacy policy] and made a very conscious decision not to preempt the state privacy and security regulations.” ….. “We have to find ways to engineer the exchange of information across state boundaries so that patients can benefit when they move across state boundaries. And I think one of the solutions to that will be to give increasing amounts of control to patients over their health information.”
Answers

• **Don Berwick MD, nominee to lead CMS**: “*What ‘Patient-Centered’ Should Mean: Confessions Of An Extremist, A seasoned clinician and expert fears the loss of his humanity if he should become a patient*”
  
  *In Health Affairs* 28, no. 4 (2009): w555–w565

• **Newt Gingrich, Former Speaker of the House**, testimony March 15, 2006 before the House Subcommittee on the Federal Workforce and Agency Organization

• **President Bush** April 27, 2004, VA Medical Center, Baltimore
  

• **David Blumenthal MD**, National Coordinator for Health IT
  
  *In Health Affairs* 29, no. 4 (2010) w 591
Americans expect control over personal health data, but........
Where did this slide come from? The Medical Information Bureau, which sells
your health data to insurers and employers.
Health Research Data for the Real World: the MarketScan Data Bases

David M. Adamson, PhD
Stella Chang, MPH
Leigh G. Hanson, MS, MBA

Research and Pharmaceutical Division
Thomson Medstat
January 2006
Medicare and Medicaid data is for sale

To address the need for better data on privately insured Americans, Thomson Medstat created the MarketScan® data collection. Since its creation, MarketScan has been expanded to include data on Medicare and Medicaid populations as well, making it one of the largest collections of claims-based patient data in the nation. MarketScan data reflect the real world of treatment patterns and costs by tracking millions of patients as they travel through the healthcare system, offering detailed information about all aspects of care. Data from individual patients are integrated from all providers of care, maintaining all healthcare utilization and cost record connections at the patient level.
Table 1: Sample Data Elements for Commercial and Medicare Databases

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Medical Information (Inpatient and Outpatient)</th>
<th>Health Plan Features</th>
<th>Financial Information</th>
<th>Drug Information</th>
<th>Enrollment Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ID</td>
<td>Admission date and type</td>
<td>Coordination of benefits amount</td>
<td>Total payments</td>
<td>Generic product ID</td>
<td>Date of enrollment</td>
</tr>
<tr>
<td>Age</td>
<td>Principal diagnosis code</td>
<td>Deductible amount</td>
<td>Net payments</td>
<td>Average wholesale price</td>
<td>Member days</td>
</tr>
<tr>
<td>Gender</td>
<td>Discharge status</td>
<td>Copayment amount</td>
<td>Payments to physician</td>
<td>Prescription drug payment</td>
<td>Date of disenrollment</td>
</tr>
<tr>
<td>Employment status and classification (hourly, etc.)</td>
<td>Major diagnostic category</td>
<td>Plan type</td>
<td>Payment to hospital</td>
<td>Therapeutic class</td>
<td></td>
</tr>
<tr>
<td>Relationship of patient to beneficiary</td>
<td>Principal procedure code</td>
<td>Payments—total admission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Geographic location (state, ZIP Code)</td>
<td>Secondary diagnosis codes (up to 14)</td>
<td>National drug code</td>
<td></td>
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</tr>
<tr>
<td>Industry</td>
<td>Secondary procedure codes (up to 14)</td>
<td>Refill number</td>
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<td></td>
<td>DRG</td>
<td>Therapeutic group</td>
<td></td>
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<td></td>
<td>Length of stay</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Place of service</td>
<td></td>
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<tr>
<td></td>
<td>Provider ID</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Quantity of services</td>
<td></td>
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</tr>
</tbody>
</table>
“They Know What's in Your Medicine Cabinet, How insurance companies dig up applicants' prescriptions—and use them to deny coverage”

http://www.businessweek.com/magazine/content/08_31/b4094000643943.htm?chan=magazine+channel_in+depth

## DATA ON DEMAND
Two companies dominate the field of selling prescription information to insurance companies:

<table>
<thead>
<tr>
<th>MEDPOINT</th>
<th>INTELLISCRPT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parent</strong></td>
<td>UnitedHealth Group’s Ingenix</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td>Eden Prairie, Minn.</td>
</tr>
<tr>
<td><strong>History</strong></td>
<td>Milliman</td>
</tr>
<tr>
<td></td>
<td>Brookfield, Wis.</td>
</tr>
<tr>
<td>UnitedHealth acquired MedPoint in 2002 from a small, Utah-based health-technology company, Nex2</td>
<td>Milliman, a Seattle consulting firm, acquired IntelRx and its IntelliScript product in 2005</td>
</tr>
<tr>
<td><strong>Fine print</strong></td>
<td>Delivers five-year history of drug purchases, dosages, refills, and possible medical conditions</td>
</tr>
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<td></td>
<td>Similarly provides five-year purchase history, which includes information on pharmacies and treating physicians</td>
</tr>
<tr>
<td><strong>Pitch to insurers</strong></td>
<td>“Identify high-risk individuals, reduce costs, lower loss ratios, and increase revenue”</td>
</tr>
<tr>
<td></td>
<td>“Clients report financial returns of 5:1, 10:1, even 20:1”</td>
</tr>
</tbody>
</table>

Data: MedPoint and IntelliScript
Americans expect control over personal health data, but........
President Bush implemented the HHS HIPAA “Privacy Rule” which recognized the “right of consent”.

Congress passed HIPAA, but did not pass a federal medical privacy statute, so the Dept. of Health and Human Services (HHS) was required to develop regulations that specified patients’ rights to health privacy.

President Bush implemented the HHS HIPAA “Privacy Rule” which recognized the “right of consent”.

HHS amended the HIPAA “Privacy Rule”, eliminating the “right of consent”.

“… the Secretary of Health and Human Services shall submit to [Congress]… detailed recommendations on standards with respect to the privacy of individually identifiable health information.”

“….a covered health care provider must obtain the individual’s consent, in accordance with this section, prior to using or disclosing protected health information to carry out treatment, payment, or healthcare operations.”

“The consent provisions…are replaced with a new provision…that provides regulatory permission for covered entities to use and disclose protected health information for treatment, payment, healthcare operations.”
AHRQ: 2009
20 focus groups

A majority want to “own” their health data, and to decide what goes into and who has access to their medical records

(AHRQ p. 6)
• A majority believe their medical data is “no one else’s business” and should not be shared without their permission. This belief was expressed not necessarily because they want to prevent some specific use of data but as a matter of principle. (AHRQ p. 18)

• Participants overwhelmingly want to be able to communicate directly with their providers with respect to how their PHI is handled, including with whom it may be shared and for what purposes. Most believe they should automatically be granted the right to correct misinformation. (AHRQ p.33)
“there was no support for the establishment of general rules that apply to all health care consumers. Participants thought that health care consumers should be able to exert control over their own health information individually, rather than collectively.”

(AHRQ p. 29)


http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_1248_888520_0_0_18/09-0081-EF.pdf
NPR/Kaiser/Harvard 2009 Poll

The Public and the Health Care Delivery System

59% are NOT confident that if their medical records and PHI were stored electronically and shared online, that those records would remain confidential
NPR/Kaiser/Harvard 2009 Poll

76% believe it likely that an unauthorized person would get access to their medical records if the US adopts a system where medical records are kept electronically and shared online.

Research without consent
Westin/Harris Survey for the Institute of Medicine

Results of a National Survey
Commissioned by the IOM Committee on
“Health Research and the Privacy of Health Information: The HIPAA Privacy Rule”

Original Report - November 2007; Revised and expanded - March 2008
IOM Survey: People Won’t Participate in Research Without Privacy

• Only 1% agreed that researchers would be free to use personal medical and health information without consent

• Only 19% agreed that personal medical and health information could be used as long as the study “never revealed my personal identity” and it was supervised by an Institutional Review Board.
Research on Consent and NBS Programs

From Public Health Genomics
When Asked, Consumers Support Use of Their Data

"How willing are you to have your child's blood sample (from newborn screening) used for future research studies, with (or without) your permission?"

Four choices were:

• Very willing
• Somewhat willing
• Somewhat unwilling
• Very unwilling

Over 75% would share their data!

Source: Dr. Aaron Goldenberg (Case Western Reserve), Public Health Genomics, July 9, 2009 (as reported at Genetic Alliance Conference on Newborn Screening, December 2009).
"How willing are you to have your child's blood sample (from newborn screening) used for future research studies, with (or without) your permission?"

WITHOUT CONSENT  Only 28% were OK with research use and 72% were NOT OK with research use.

Four choices were:
- Very willing
- Somewhat willing
- Somewhat unwilling
- Very unwilling

Source: Dr. Aaron Goldenberg (Case Western Reserve), *Public Health Genomics*, July 9, 2009 (as reported at Genetic Alliance Conference on Newborn Screening, December 2009).
Patients rights
The right of privacy is a personal and fundamental right in the United States

The opportunities to secure employment, insurance, and credit, to obtain medical services and the rights of due process may be jeopardized by the misuse of personal information.

Fed. Trade Comm’n, Consumer Sentinel Network Data Book 11 (2009) (charts describing how identity theft victims’ information have been misused).
As the Supreme Court has made clear, and the DC Circuit Court of Appeals recently held, “both the common law and the literal understanding of privacy encompass the individual’s control of information concerning his or her person.”

Ethical rights
legal privileges
common law
The ethical codes of all health professions require informed consent

Since the time of Hippocrates physicians have pledged to maintain the secrecy of information they learn about their patients, disclosing information only with the authorization or the patient or when necessary to protect an overriding public interest, such as public health. Comparable provisions are now contained in the codes of ethics of virtually all health professionals.”

Report to HHS, NCVHS (June 22, 2006)
A. INTRODUCTION

5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the needs and interests of society.

B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.

21. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patients information, and to minimize the impact of the study on the subject’s physical and mental integrity and on the personality of the subject.
Legal Privileges

A physician-patient privilege is recognized in the laws of 43 states and the District of Columbia.

The State of Health Privacy, Health Privacy Project (2000)

A psychotherapist-patient privilege is recognized in the laws of all 50 states and the District of Columbia.

All 50 states and the District of Columbia recognize in tort law a common law or statutory right to privacy of personal information.  

HHS finding 65 Fed. Reg. at 82,464

Ten states have a right to privacy expressly recognized in their state constitutions.

The Texas Supreme Court has determined that Texans have a right to privacy.
Reality
EHRs without consent
PHRs without consent
HIEs without consent
NHIN without consent
Research without consent
**Key References:**

**EHRs**  “Your Medical Records Aren't Secure” by Deborah C. Peel  in the WSJ, March 23, 2010  
http://online.wsj.com/article/SB10001424052748703580904575132111888664060.html

**PHRs**  “Who can snoop in your PHR? A Personal Health Record Report Card”  
http://patientprivacyrights.org/personal-health-records/

**HIEs and NHIN**  “Designing a Trustworthy Nationwide Health Information Network (NHIN) Promises Americans Privacy and Utility, Rather than Falsely Choosing Between Privacy or Utility” by Latanya Sweeney, PhD,  April 22, 2010, Congressional Briefing on the “Implementation of Health Information Technologies in a Healthcare Environment”  

Liability
April 21, 2010

Indian Tribe Wins Fight to Limit Research of Its DNA

By AMY HARMON

In the weeks before state health officials destroyed more than 5 million newborn blood samples they had stored without consent, privacy advocates, parents and lawmakers reached a last-ditch accord to save them — but couldn’t convince the Department of State Health Services to sign on.

Solutions
ARRA—new privacy rights and MU

Old rights under HIPAA:

• Providers may offer consent (Original HIPAA Privacy Rule), so patients can restrict disclosures—*not addressed in MU*
• Psychotherapy Notes require consent to disclose—*not addressed in MU*

New rights under ARRA:

• Ban on sales of PHI (Protected Health Information)—*2010*
• Segmentation—*delayed*
• Audit trails x 3 years—*2011 or later*
• Breach notice—*2010*
• Encryption
• Patient can prevent disclosures of PHI for ‘payment and healthcare operations’ if pays out-of-pocket—*not addressed*
• Consent Technologies—*2014 or later*
Do Not Disclose

Register on the National Do Not Disclose List

Let Congress know that you want a Do Not Disclose list.

Do you want:

• To choose who can see and use your personal information, from prescriptions to DNA?
• To protect your children’s health information, so it won’t be used against them in the future for jobs or credit?
• To get a clear explanation of how your information will be used before you decide to share it?

Then sign up to support the “Do Not Disclose” campaign!

Sign Up Today!  Tell–A–Friend
Consent Solutions So Far for Research Biobanks

Each person grants “private access” to all or selected parts of their personal information based on their particular needs and interests.
ABRC Biospecimen Locator Service

... consent can be integrated into cutting-edge applications such as services for locating biospecimens for use in qualified research projects.
Open Source Consent Solutions

1. Adapt/use the National Data Infrastructure Improvement Consortium (NDIIC) open source electronic consent module as the minimum standard for consent tools in PHRs and for all HIT

2. Require the strong privacy protections in 43 CFR Part 2 be extended to cover all personal health information (PHI), wherever it is held.
Audit trails based on authentication

Mar 01, 2010

Imprivata's New Product Helps Hospitals Proactively Investigate and Audit Access to Patient Health Information

PrivacyAlert™ Quickly Detects Snooping and Identity Theft of Medical Records

Imprivata PrivacyAlert quickly detects snooping, identity theft and general inappropriate access of medical records through its automated pattern recognition, which delivers alerts on more than 100 patient privacy scenarios. Users can deploy automated and scalable privacy monitoring policies that assist in investigating and reporting on patient data privacy breaches.

Imprivata PrivacyAlert enables information security officers and privacy officers to deploy automated and scalable privacy monitoring solutions that assist them in investigating and reporting on patient data privacy breaches.

Ability to set and focus investigation criteria on employee, patient or combination of both. Out-of-the-box support for all leading healthcare applications including Eclipsys, GE Centricity Enterprise, MEDITECH Magic, Siemens Invision and others.

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