

# Health Record Banking System Secondary Uses of Health Data

Ad Hoc Work Group on  
Secondary Uses of Health Data  
NCVHS

Jonathan D. Gold, MD  
P.O. Box 270249, Louisville, Colorado 80027  
e-mail: [drjgold@yahoo.com](mailto:drjgold@yahoo.com)

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Dr. Gold is a physician analyst for McKesson Provider Technologies. He recently completed a Master of Science degree as a National Library of Medicine post-doctoral fellow in health sciences informatics at Johns Hopkins University. He received an M.D. degree at Ben-Gurion University in Beer Sheva, Israel in 1990 and gained board certification in pediatrics in 1997. Subsequently, Dr. Gold served as a primary-care pediatrician and as the director of the medical quality-assurance unit for the Maccabi Health Service's Negev region. In 2001, he completed a Master of Health Administration degree at Ben-Gurion University. A pediatrician with close to a decade of primary-care practice and medical quality-assurance experience, Dr. Gold is focused on the development of the consumer-oriented, electronic Health Record Banking system, the practical needs of the health-care provider, and the considered goals of a comprehensive health-care strategy.

# Outline

- HRBS Overview
- HRBS Study: Critical Issues related to Secondary Use of Health Data
  - Results
- For Consideration
  - Questions
  - Analogies
  - Resources

“Is there a need for secondary  
use of data at all?”

# For New FDA Approved Drugs (Research and Development)

Trial Phase	Time Frame	Number of Participants	Total Annual U.S. Investment
Rx Discovery	5 yr		\$11.0 Billion
Pre-clinical	1.5 yr		
Phase I	6 yr	20-100	\$14.1 Billion
Phase II		100-500	
Phase III		1,000-5,000	
<b>NDA Submitted</b>			
FDA Review	2 yr	[10 <sup>4</sup> 's-10 <sup>5</sup> 's]	\$4.1 Billion
<b>FDA Approval</b>			
Phase IV/ Post-Market	2 yr	[10 <sup>6</sup> 's]	\$3.7 Billion

Adapted from: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2005.

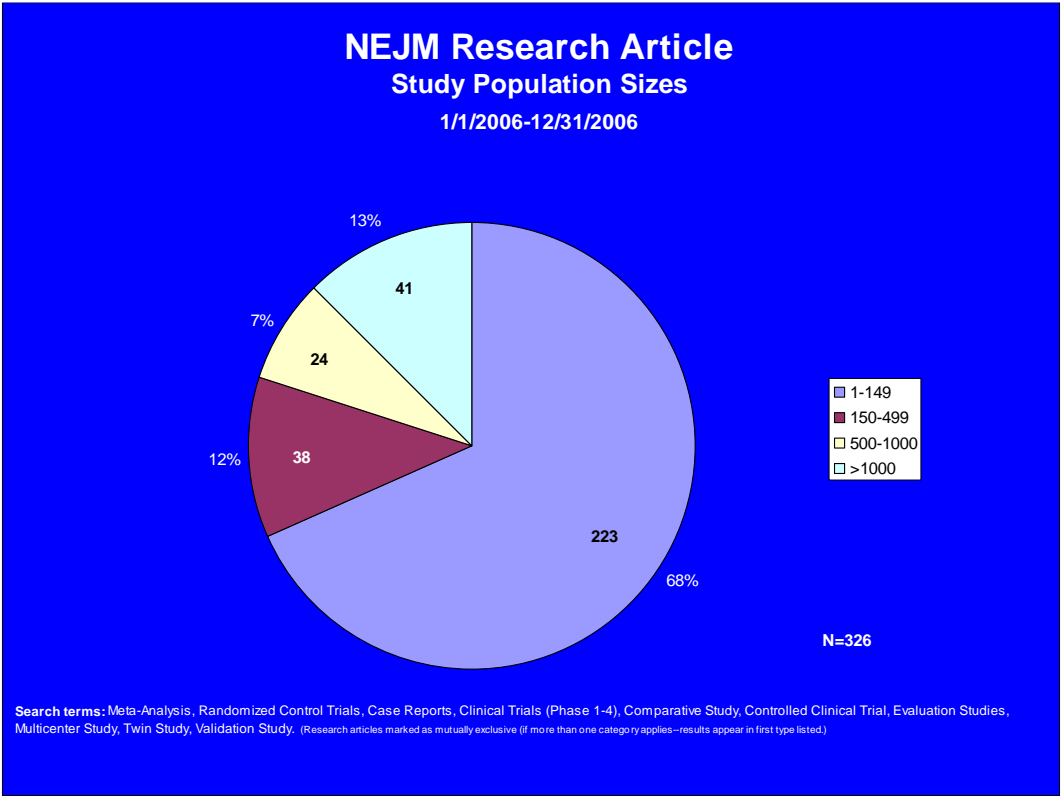
The medical research benefits for complete and accessible digital health records are obvious. Huge stores of de-identified data will be rapidly mined for information and knowledge regarding many research questions about diagnostics, therapy, and education. Instead of research limited to scores or hundreds of participants, millions of relevant files will become immediately accessible to the investigator. Questions which heretofore could not be approached because of the limited availability of subjects and the expense of compiling data will no longer be unsolvable.

# PubMed Search Criteria

- **Journal:** *New England Journal of Medicine*
- **Dates:** 1/1/2006-12/31/2006
- **Study Populations:** Humans, All Ages, Both Sexes
- **Types of Articles:**
  - Clinical Trials
  - Meta-Analysis
  - Randomized Control Trials
  - Case Reports
  - Clinical Trial (Phase 1-4)
  - Comparative Study
  - Controlled Clinical Trial
  - Evaluation Studies
  - Multicenter Study
  - Twin Study
  - Validation Study

Further evidence should be explored by reviewing the % of research articles on medical procedures/techniques/drugs published in the last five years in JAMA, Lancet, NEJM, and Pediatrics, which are based upon fewer than 150 participants (control group and test group), those based upon between 150-499 participants, those based upon between 500-1000 participants, and those with greater than 1000 participants.

When we are talking about secondary use of data, if we have a larger pool of potential (albeit anonymous) participants, smaller studies might be of less importance. We could also attempt to validate the findings of tightly controlled double blind studies with the real world.

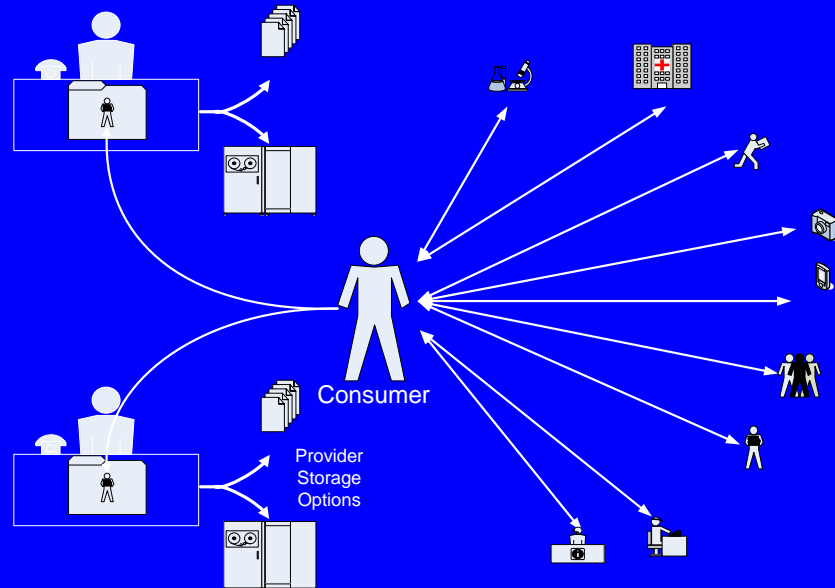


341 separate entries, including 15 comments or unavailable patient study size.

# Health Record Banking System 101

An Overview

# Information Flow 'As Is': Consumer View



Adapted from Gold JD, Bakalar RS, Ball MJ.  
"Dataflow Comparison of 'As Is' and 'To Be' in  
a Health Record Banking System". 2006

The flow and storage of health data: Represents the present day health record situation ('as is' case) from the consumer's perspectives.



# Comparing commercial banking and health record banking

		<b>Commercial Banking</b>	<b>Health Record Banking</b>
<b>Account Holders</b>	Small	Personal or Joint	Individual, Joint or Family personal health records
	Medium-sized	Small- and Medium-sized businesses	Solo Physicians, Group Practices, Pharmacies, etc.
	Large enterprise	Corporations	HMOs, Hospitals, etc.

Gold JD, Ball MJ. "The Health Record Banking Imperative". IBM Systems Journal, Vol 46, No 1., 43-55 (2007)

In general, the HRB system shall function similarly to commercial banking. If we overlay the HRB model on top of the commercial model, many of those features found in the commercial bank today are clearly paralleled. The diverse patron groups include small account holders (the individual consumer with a personal health record), medium sized clients (the physician or group practice, pharmacies, etc.) and the large enterprise customers (HMOs, hospitals, etc.). Distinct accounts will be used for storing different classes of health data (text, images).<sup>[1]</sup> Specialty banks might store only a particular type of data (e.g., genomic data) or only maintain a particular type of account (solo physician or group practice accounts). Comparable to commercial banking, the chief source of revenue will be through leasing de-identified data for re-use by commercial and research enterprises. Additional sources of revenue might include Information Disaster Recovery Plans (and/or Insurance) for individuals and enterprises, member service charges, health kiosks/ATMs, health record curation, and specialty service charges (e.g., Consumer Healthcare Financial Advisors).

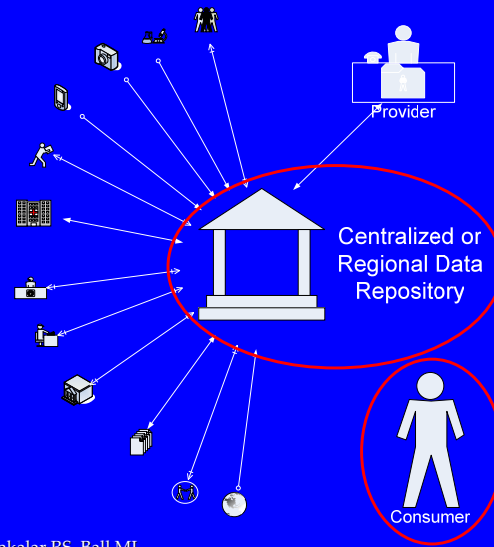
<sup>[1]</sup> Different health data classes require unique search engines, have diverse storage specifications, and possess different access time requirements.

# Comparing commercial banking and health record banking

		<b>Commercial Banking</b>	<b>Health Record Banking</b>
<b>Types of Accounts</b>		Savings, Checking, Safety Deposit services, IRA, etc.	Text health record, Imaging, AV/ Monitoring, Lab/Path, Genomic
<b>Bank Types</b>		Savings, S&L, Credit Union, Investment, etc.	Full Service Bank, Genomic Specialty Bank, Physician Services Bank, etc.
<b>Chief Revenue Sources</b>		Investment, Lending, etc.	Member services, Lease of De-ID'd data, Disaster Recovery Plans, Specialty Services, Health Kiosks, Health Record Curation, etc.

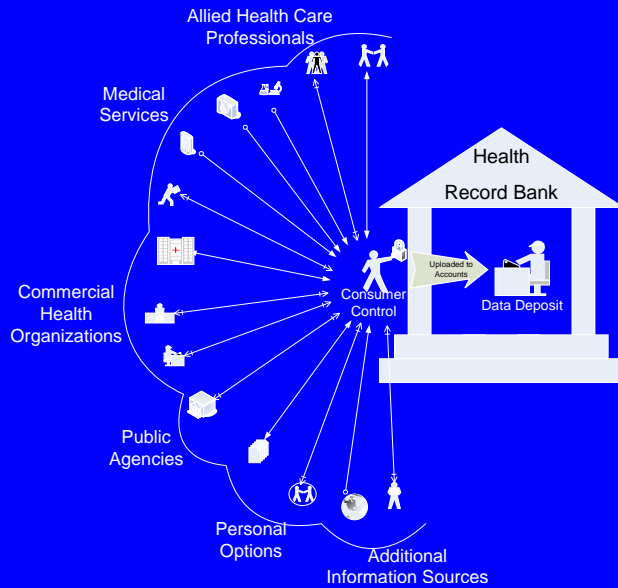
Gold JD, Ball MJ. "The Health Record Banking Imperative". IBM Systems Journal, Vol 46, No 1, 43-55 (2007)

# Information Flow 'To Be': Centralized Data Repository



Adapted from Gold JD, Bakalar RS, Ball MJ.  
"Dataflow Comparison of 'As Is' and 'To Be' in  
a Health Record Banking System". 2006

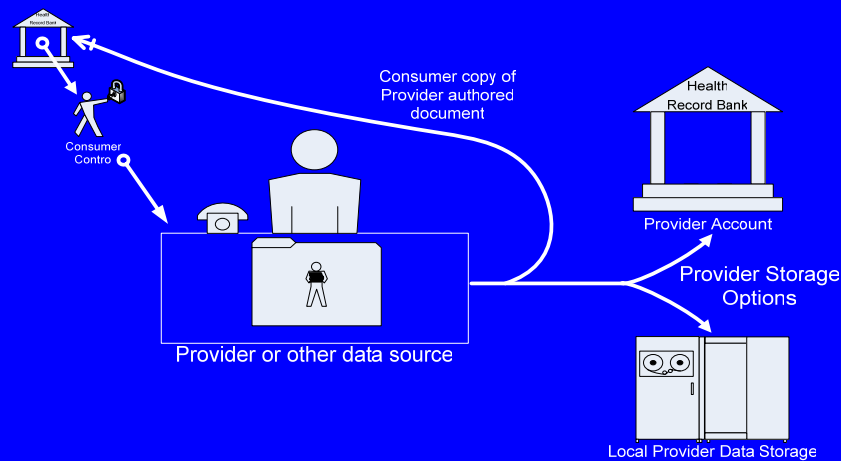
# Personal health record data sources



Gold JD, Ball MJ. "The Health Record Banking Imperative".  
IBM Systems Journal, Vol 46, No 1., 43-55 (2007)

The HRB will not only allow the consumer to store all personal health information in a secure virtual "account" (or ePHR), but, like in a commercial bank, will pay its owner a dividend for this. These records will be owned and controlled by the consumer. In much the same way that a bank depositor maintains a bank account, the consumer will determine who has access to which parts of the record over what period of time and who can deposit information in the record. The consumer will grant different providers and data sources different access and deposit rights to the health record account.

# Provider Storage Options



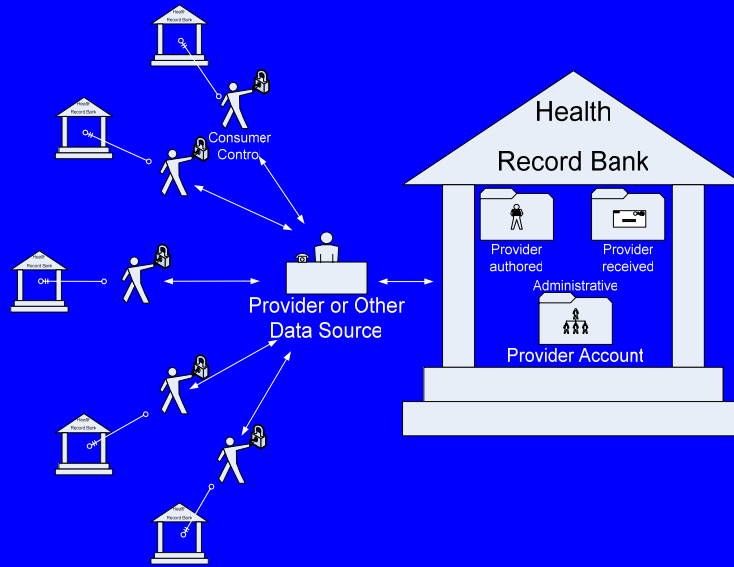
Gold JD, Ball MJ. "The Health Record Banking Imperative".  
IBM Systems Journal, Vol 46, No 1, 43-55 (2007)

To author an entry in a patient's file, the provider will receive initial record access permission from the consumer. This will allow the provider to view read-only files, create new entries, and upload them to the consumer's ePHR. Revising a new entry in the record will be time-limited. While write access to files will require current consumer permission<sup>[1]</sup>, the provider will permanently retain the right to read all components of a file which he/she has authored and to view all reports specifically addressed to him/her.

When the provider writes a medical record entry, a copy is deposited in the consumer's personal health record account while an identical copy is retained by the provider for storage either locally on the provider's computer or in the provider's health record account. The provider's account will contain all authored entries for multiple patients. A provider working in more than one setting, for more than a single group, or simply interested in maintaining more than one account, may have multiple provider accounts. A specific patient's records may only appear in one of the provider's accounts and may not span multiple accounts. Provider accounts may include all documents authored by the provider, those reports or correspondence addressed to him/her about a patient (including lab results), and all provider administrative data. Like PHR accounts, a bank log will preserve a legal record of all provider account transactions (including accesses, reads, and writes).

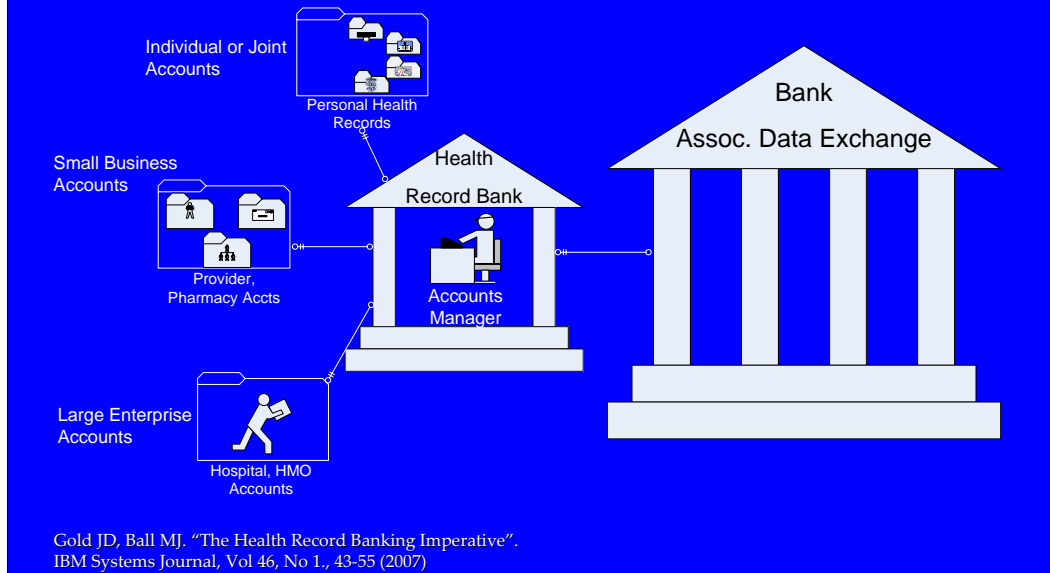
<sup>[1]</sup> Write access will always require two access codes (the consumer's and the provider's), verification of current authorization and identity authentication.

# Provider Health Record Accounts



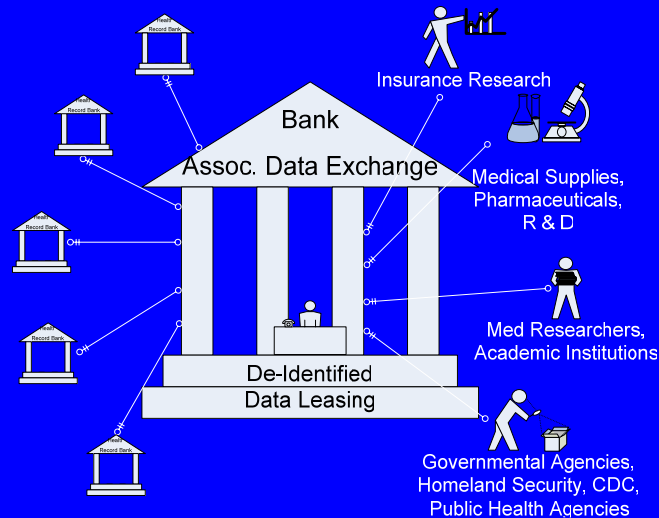
Gold JD, Ball MJ. "The Health Record Banking Imperative".  
IBM Systems Journal, Vol 46, No 1., 43-55 (2007)

# Sharing of data between Health Record Bank and affiliated Bank Association



The consumer may choose to sell his/her de-identified data in return for some dividend if he/she wishes (i.e., after removal of name, address, social security number, etc.). With the consumer's permission, the HRB will lease access to the de-identified data in databanks for use by pharmaceutical and medical technology companies, insurance companies, research institutions, universities, and government agencies. This databank will serve as an invaluable source for research purposes.

# Bank Association Data Exchange leasing data to 3rd parties



Gold JD, Ball MJ. "The Health Record Banking Imperative".  
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Through the 'Bank Association Data Exchange', a consumer's leased de-identified health data, will return a dividend to its owner. This dividend may be given each time the consumer's de-identified personal health record information is accessed, may be directly and only associated with the consumer's age, or may be awarded in some other manner.

Each ePHR will include 'envelope information' which will serve as a searchable index to the record. Envelope information will include both a stable data section (containing demographic information) and a labile data section (composed of UMLS terms, for capturing medical terminology entered in the record and appended after each new ePHR entry). Satellite HRBs will transmit lists of de-identified patient record envelope information to the central Bank Association for use in preparing leasing databases.

When the Bank Association receives a query from an interested third party, envelope indices will be compared to the query's term parameters. Records corresponding to a researcher's query specifications will be located. The de-identified records will then be copied into a temporary query file to the Bank Association's Data Exchange. The temporary query file will serve as an unabridged database customized for use by the leasing researcher. Leasing of this file may be time-limited, read access limited, or controlled in some other manner.

The choice of which account holder's files (consumer, provider, or other patron) should be accessed for a research question, ultimately will depend upon the question being asked and the aim of a study. For instance, if the question being investigated will be "How does the combination of drug A and drug B affect the libido?", the most likely approach would be to search patient data records (initially screening the files envelope headings). If, however, the question shall be simply "How often are drug A and drug B prescribed to the same person within a given time frame?", then reviewing the pharmacy health data accounts will be simpler, less time consuming and cheaper. Another study question might be "What types of physicians tend to prescribe drug A in combination with drug B?". This would most easily be answered by reviewing the provider health data accounts.



# Health Record Banking System 201

Critical Issues in the Development and  
Implementation of a Health Record Banking System

## Research Results

Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues  
in the Development and Implementation of a Health Record  
Banking System". 2007

# Ten critical issues to the development of an HRBS

1. Standardization of data entry, sharing, and interoperability
2. Information security and HIPAA standards  
(Privacy and Confidentiality, Accountability and Auditability)
3. Workflow and data transfer
4. Business incentives & the development of a banking model
5. Patient identification and record matching  
(also record de-identification and the re-use of data)

Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues in the Development and Implementation of a Health Record Banking System". 2007

To these, we have included additional challenges and defined nine issues critical to the development and implementation of a health record banking system and questions related to these areas. ([Table 6](#)). The success of the HRBS model is dependent upon addressing and solving these significant challenges.

Development of such a considerable infrastructure and enterprise demands both focus on the details and the vision. This system is not about the technology; it is aimed at providing timely access to the right information and its appropriate use by the right people. Developing the crucial standards and building the core structure—a network for health records—will shape the future of health, health research and health policy. A viable and sustainable health record network which allows for the sharing of data and knowledge discovery shall launch us into the new era of health care.

## Ten critical issues (continued)

6. Legal, ethical, and legislative concerns
7. Stakeholder acceptance & acceptance thresholds
8. Standardization of ePHR format/ UMLS health-record indexing
9. Architectural Design  
(Infrastructure, Database Development, Integrity Validation, Operating Speeds)
10. Determination of critical challenges and project implementation sequence

Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues in the Development and Implementation of a Health Record Banking System". 2007

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# Study Methodology

Purposive structured interview of  
stakeholder opinion leaders

Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues  
in the Development and Implementation of a Health Record  
Banking System". 2007

# Domain Experts

- Informaticians
- Infrastructure/Technology Engineers
- Health Policy Makers, Health Economists and Academics
- Government Representatives/ Public Officials
- Business Investors/ Insurers/ Bankers/ Pharma
- Financial Experts
- Health Services Organizations
- Medical Researchers
- Clinicians
- Healthcare Consumers ('Patients')

Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues in the Development and Implementation of a Health Record Banking System". 2007

# Survey Questions

## Three sections of questionnaire:

1. Challenges, information needs, recommendations (related to model and critical issue)
2. Interviewee's area of expertise
3. General analysis of model

Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues in the Development and Implementation of a Health Record Banking System". 2007

1. challenges ("What are problems related to this issue?"),
2. information needs ("What information needs to be known in planning how to address this challenge?"),
3. recommendations ("How would you recommend that we address this challenge?"),
4. expert knowledge (about the issue or related matters).

### **Challenges related to model and issue** (*Problem list. What need to know to address them? How solve them?*)

2. Regarding the model's «critical issue to be specified» aspect and what has been outlined, what are going to be the 3-4 crucial steps and hurdles to overcome in order to make this model work effectively?
3. Order these in terms of priorities, predecessors, successors, and dependencies.
4. How would you go about overcoming these obstacles?
5. What important numbers/ statistics/ information would you need to know to help design this section of the system, to help plan strategy, etc.?

### **Interviewee's area of expertise** (*What do you know? Who do you know?*)

6. What relevant numbers relating to the model do you, as an expert, feel secure in providing?
7. (optional) What other important numbers regarding costs (infrastructure, maintenance), potential revenue and expenditures, can you provide with relative confidence?
9. What important sources or references about these issues or technologies should be used?
11. What are the minimal functional requirements for developing and supporting a health record banking system?
12. Can you name other people in your field (or other fields) whose opinion/views about this issue should be sought?

### **General analysis of model** (*Other issues? Other fields? Perfect system description?*)

1. Having reviewed the Health Record Banking System model, do you see this as a reasonable and viable idea?
8. What are 2-3 other critical issues (beyond the nine presented) or technologies which must be addressed for the establishment of an HRB which have not been listed (above)?
10. What other domains/fields do you recommend we survey to get a better insight into issues related to the development and implementation of this model?
13. (optional) What would be a perfect HR Banking system?
14. Any additional comments, thoughts, suggestions.

## Research Process

- White paper distributed to diverse groups
- Upon recipient agreement to interview, 30-60 minute telephone call
- Structured interview with questionnaire
- Pilot
- Notes taken validated by participant
- Notes summarized by critical issues for consideration or change in model

Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues in the Development and Implementation of a Health Record Banking System". 2007

## Analysis Focus

- Common concerns
- Essential aspects of the issue
- Unique / interesting opinions or expert knowledge

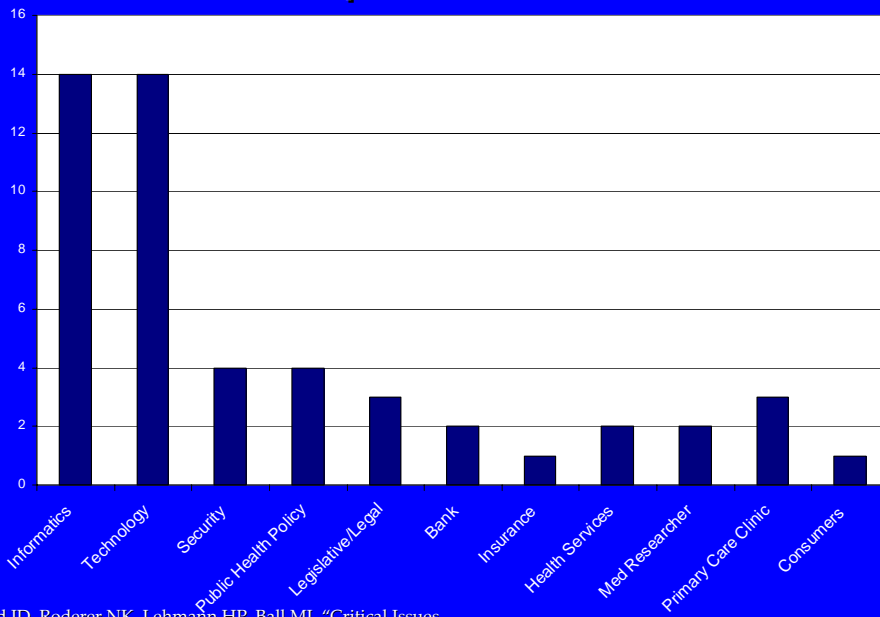
Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues in the Development and Implementation of a Health Record Banking System". 2007



# Results

Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues in the Development and Implementation of a Health Record Banking System". 2007

# Domain Experts/Stakeholders



Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues in the Development and Implementation of a Health Record Banking System". 2007

# 1. Info Security/HIPAA Standards

- Confidentiality/Security Paramount
- HIPAA for Non-Covered Entities; Enforcement
- Determining Security Limits
  - Stakeholder Trust
  - Acceptable limits to consumer, etc., for potential loss of confidentiality?
  - Price consumer and organization willing to pay to meet limits?
- Security Investment 20-40% Development Costs
- Future Technologies

Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues in the Development and Implementation of a Health Record Banking System". 2007

## Information Security and HIPAA Standards

### *Challenges*

Confidentiality, accountability, and auditability each play an important role in the security (and stakeholder acceptance) of a banking system. Enforcement of HIPAA rules is of key importance, but the health record bank would most likely be a non-covered entity by today's regulations. By adding the element of leasing de-identified personal data, questions are raised as to how to thwart its potential external re-identification and misuse. Will stakeholders be willing to trust private enterprise to lease out only that personal health data which the consumer permits?

### *Information Needs*

Determining the limits of security needs and understanding the extent of HIPAA play vital first steps in assuring a comprehensive grasp of this area. What will be acceptable limits to the consumer, provider, and HRB for potential loss of confidentiality? What price will the consumer and organization be willing to pay to meet these acceptable limits?

### *Recommendations*

Stakeholder trust in the security and integrity of personal information is of prime significance. Defining acceptable limits for security needs, provides a practical approach for developing functional requirements. Additionally, the opinions and concerns of privacy advocacy groups (and their political influence) must be addressed through public dialogue and enrollment during the planning stage.

### *Expert Opinion*

Information security is such a key element that one domain expert estimates that the security investment may reach 20-40% of the total development costs for this model. This said, new technology will affect this critical issue dramatically. Since HIPAA does not permit the transfer of personal healthcare information without specific patient authorization, consumer confidence in the security of the system will be a key step prior to considering the re-use of de-identified health data.

## 2. Pt. Identification, De-ID, Record Matching, Secondary Use of Data

- Definition of De-ID?
- Ensuring/Verifying Correct Data Linkage
- Preventing Fractionated Accounts. Handling Record Duplication
- Pt May Grant Limited or Full Permission or Opt Out
- ID's for Consumer, Provider, Institution, Locale. Must De-ID
- Selling Answers to Queries vs. Access to De-ID'd Records
- Audit Trail for Leased Data
- Possibly 20% of Population Hide Parts of Health Info
- Anonymity Possible with Phenotypic Data?
- EHR Keyword Index

Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues in the Development and Implementation of a Health Record Banking System". 2007

### Patient Identification and Record Matching; Record De-identification and the Re-use of Data

#### *Challenges*

Ensuring precise identification and matching the consumer to all parts of his or her health record remains one of the largest challenges facing the HRBS. What measures will need to be taken to ensure and verify that all data related to a particular consumer are linked accurately? How will fractionated accounts be prevented? Within any system where different points of entry into a record exist, mismatched data will arise. To what extent will mismatched or unmatched data be considered tolerable? What will be the financial cost for eliminating error rates? Record duplication by the consumer may be inadvertent or it may be purposeful (similarly to having multiple financial bank accounts). Will HRBS allow for multiple accounts for a single person? Determination of the parameters of "de-identification" may be a particularly problematic area. Truly de-identified data—those which lack temporal, contextual, and locale information—may be of little research value.

#### *Information Needs*

At present, the lack of a national patient/consumer identification system, with a single and unique identifier for each participant in the healthcare system (regardless of that individual's U.S. citizenship status) remains a key stumbling block. What will ensure retrieval of the correct patient's record?

Other questions relate to the process for data de-identification, the manner in which data are transferred to a bank, from the bank to the data exchange and on to the leasers of data.

#### *Recommendations*

It must be clear to consumers that they have the right to opt in or opt out of having their health data leased. Prior to the re-use of data for leasing, many potentially identifiable entities in the health record must be de-identified, including the providers, the delivering service to the patient and the healthcare institutions or organizations involved. These can be codified in such a way as to give them unique and consistent identifications for each patient, while maintaining their anonymity. Another possibility is for the bank association data exchange to sell answers to research queries without providing actual access to the de-identified records in the bank.

An accurate and precise audit trail for the leased data will provide one means of monitoring potential misconduct in the aggregation and leasing of de-identified data. It would be worthwhile to review how the publishing and digital media industries follow where copyrighted materials are transferred

### 3. Legal, Ethical, and Legislative Issues

- Pt not granted free access to all of health record on demand
- Legal basis for limited control of personal data by consumer & protection of data from unauthorized examination/use (HIPAA)
- Ownership vs. Control of Access to caregivers, secondary users
- Consumer may not desire sharing of data by different providers
- Data controlled by consumer may not be known by physician; erroneous decisions might be made
- Legal liability of provider and institution
- Legal regulations defining information abuse of system
- National legislation imperative to resolve legal issues
- Difficulty enacting healthcare legislation, e.g., national patient ID

Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues in the Development and Implementation of a Health Record Banking System". 2007

#### Legal, Ethical, and Legislative Issues

##### *Challenges*

Significant concerns about confidentiality and security by the consumer (discussed in Sections 2 and 6) and legal liability by the provider and institution require legislation and legal clarification. Today the custodian of health records is the provider's practice or the healthcare enterprise (HMO, hospital, etc.). The concept of the consumer owning (or at least, controlling) and freely accessing health data authored by his/her health care providers challenges present day convention. While there exists a legal basis allowing limited control of personal health data by the consumer (primarily, through HIPAA) and protection of this data from unauthorized examination and use, caretakers and organizations do not grant the consumer free access to review all parts of the health record on demand. Additionally, since not all healthcare consumers desire to have their health data shared by different providers (let alone organizations, such as insurance companies, employers, etc.), important data controlled by the consumer may not be known by the treating physician and erroneous decisions might be made by the provider.

##### *Information Needs*

Will the consumer own personal data and control those while the HRBS only provides a framework for the consumer to store and lease information? What will be the medico-legal issues related to the provider (who may or may not have full access to the consumer's data) and the provider's stored copy of a portion of the consumer's record? Who will own the HRBS? Who will be granted access to look at data within the HRBS (i.e., HR bank officials)? Who will be granted access to this for patient care (healthcare providers, healthcare institutions, and insurers) or completely outside of the HRBS (through data leasing) and what limitations will the consumer be able to place on this? What liability/malpractice costs will surface through the realization of health record banking (e.g., as a result of the consumer or provider not making available personal information when needed, making the wrong data available, or compromising confidentiality)? What will be the legal regulations defining the information abuse or fraud management capabilities of the system?

##### *Recommendations*

Legislation, particularly national, is imperative to resolve a multitude of legal issues. Since national, state, and local regulations regarding the transfer of data often do not exist or may conflict with each other, the most immediate need is for a federal legislative remedy for data transfer across state lines. These laws must

- protect the right of the individual to access and control personal health data,
- safeguard the confidentiality and security of each individual's health data,
- determine the HRBS mandate and its regulatory body,

## 4. Stakeholder Acceptance & Critical Mass

- De-ID'd Data Needs Critical Mass To Be Valuable
- Public Distrust: Centralized Systems, Commercializing Personal Info
- Engagement of Public In Dialogue
- Who Feels Threatened By System?
- Marketing to Stakeholders
- Stakeholder Incentives and Understanding of System
- Culture Change Necessary
- How Ensure Healthcare Providers Will Quickly Adopt?
- Workflow vs. Computer Time

Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues in the Development and Implementation of a Health Record Banking System". 2007

### Stakeholder Acceptance and Acceptance Thresholds

#### *Challenges*

Confidentiality and security are of paramount concern for the consumer.<sup>[1]</sup> (6) Resistance to a system which commercializes personal information and has the potential for misuse or access by undesired intruders duly alarms privacy advocates and consumer groups. The public may well be wary of placing its trust in centralized databases following recent, well-publicized major lapses in their security in both the financial and healthcare spheres.<sup>[2],[3],[4]</sup> (7,8,9) Overcoming the emotion and fear reinforced after such breaches of security and the aversion of consumer advocates to the leasing of personal data is no less important than the actual safeguarding of that information. For many, the notion of commercializing data heightens suspicion and distrust in an HRBS and these issues need to be addressed. Aside from healthcare consumers, additional stakeholders include physicians and healthcare organizations. They, too, require incentives to use electronic health records, as well as to agree to an external data repository such as an HRBS. (2) While researchers and some hospital departments (e.g., the emergency department) might embrace the idea of access to a patient's entire medical record earlier, private practitioners will be slower to adopt this. (One authority pointed out that it is a challenge to get individual physicians to adopt anything, period.) HMOs and hospitals which have implemented an electronic medical record already use local data repositories and proprietary software. For these to shift to an out-of-house data network and warehouse after investing in a local system, will require a clear and substantive financial benefit.

#### *Information Needs*

From the perspective of the investor, how many consumers need to be enlisted to join the HRBS for it to become economically viable is of prime concern. One component needed to answer this is what will be the critical mass cut off points—specifically, how many patrons will be necessary for the system to be launched, how many 'paying' patrons will be needed to make a bank financially stable (even if data is not leased), and how many records will need to be available for an HRBS to gain interest in potential leasers of information (e.g., the pharmaceutical industry)?

From the consumer perspective, if one pays money to store records or agrees to lease his/her de-identified data, what will the consumer receive in return? What, for the consumer, will be enough of an incentive (monetary or other) for him/her as an individual to subscribe to the system? What will ensure confidentiality and security of leased data? Will the system be able to guarantee that all sections of the medical record will be blocked from insurer or government access if the consumer requests this? What will insurers, law enforcement agencies and the government have access to in the PHR?

Regarding the healthcare professionals, how quickly will they adopt a new system for recording and sharing medical data?

# Conclusions

- Attend to ethical, legal and legislative issues
- Ensure the rights of the individual to personal health data confidentiality and security
- Engage stakeholders in process & address misgivings
- Identify champions and opponents to the proposal

Gold JD, Roderer NK, Lehmann HP, Ball MJ. "Critical Issues in the Development and Implementation of a Health Record Banking System". 2007

# Questions, Analogies, and Resource Recommendations



## Questions For Consideration

1. Definition of 'secondary use of health data'?
2. Acceptable secondary uses for health data?
3. Acceptable means for sharing?
4. Incentives for consumers to share data?
5. Guarantees of confidentiality/security?
6. How can we engage public in discussion?

### HRBS View:

- 1) Primary = direct patient care. Secondary = research
- 2) Limited by consumer (individual choice). Public (governmental) Agencies? Private Industry (only med research [Pharma, med eqpt, etc.] or also non-med businesses, like tobacco industry)? Med research in academic setting?
- 3) Query v. Raw Data: To be determined by legislation (query more secure, aid in confidence in the confidentiality of system, but limits how much information can be gleaned in a study).
- 4) Consumer should receive some form of compensation, i.e., health credits (e.g., reduced health insurance rates, etc.) or monetary (cash or tax incentives).
- 5) Technology, legislation and data sharing methods.
- 6) Go to advocacy groups, etc., commit percentage of budget to public engagement (ex: NHGRI).

# Analogies For Consideration

1. ATMs
2. Online Banking
3. Internet
4. Human Genome Project

Four notable network analogies repeatedly arose during the interviews. The first analogy, the adoption of automated teller machines (ATMs) required a cultural change in how people conducted the physical transfer of money to and from a bank. Questions which arose for the customer included 'Is the system secure? Confidential? Trustworthy?' Inhibitors to ATM adoption varied most dramatically by consumer demographics. A second analogy, the adoption of online banking dealt with many of the same issues as that of the ATM, but since no longer was there a physical transfer of cash, substantially larger amounts of the consumer's and bank's money were potentially at risk. Also, since the bank could exist in a remote (or even virtual) location, no physical contact was necessary for the consumer. This required the development of new standards for bank regulation (federal and state).

The third analogy, the proliferation and expansion of internet from the initial limited scope of DARPA (for the exchange of research data and information between the academic world and defense establishment) to our considerable reliance today on the internet in virtually all aspects of our lives, exemplifies how the initial intent and scope envisioned by the originators of this network might not have foreseen its later growth and ramifications upon our society. The fourth analogy, the decoding of the human genome (Human Genome Project or HGP), connecting researchers and institutions throughout the world, already affects our understanding of medicine today and is anticipated to change the way in which we will treat patients in the future. Notably, the HGP addresses ethical and legal questions routinely, and engages the public in an ongoing dialogue to determine the limits of its mandate.

All four of these analogies must be studied to understand how cultures shift and embrace (or reject) a new technology, what timelines may be involved, how are rights of individuals addressed and protected, and what stages might be necessary to ensure a reasonable transition phase. How did these enterprises begin? Most researchers initially looked at a problem and searched for a technical solution which then grew well beyond the initial intent. The challenge we face in health care has less to do with technology and consumer suspicions over personal health data being transmitted over a network, but rather how will our societal institutions, healthcare organizations and structure, aimed at protecting the health of its members, best serve the individual and the general public in the future. An equitable solution will need to leverage accessible technological tools, be acceptable to stakeholders, and be sustainable financially. What such a solution might achieve, we cannot even guess.

# Resources For Consideration

1. Representatives of those with potential to be harmed by sharing of health data
  - AARP
  - Syndrome/disease support organizations (Am Diabetes Assoc, CFF, etc.)
  - Citizen Rights Advocacy Groups
  - Minority groups, "Uninsurable", Illegal Aliens
2. Agencies with experience in medico-ethical issues and Citizen Rights organizations
  - NHGRI (ELSI)
  - NIH
  - CDC
3. Public and Private sectors most likely to benefit from secondary use
  - Government Health Agencies
  - Pharma/Medical Device Industry/Med Informatics Industry
  - Medical Researchers
4. Industries with copyrighting experience
  - Publishing and media industry

NHGRI (Ethical, Legal, Social Implications) receives 5% of NHGRI annual extramural budget by mandate

Industries with copyrighting experience

Publishing and media industry (transfer of copyrighted material from one party to another, tracing/auditing transmission)

## Questions, Comments, Discussion

