Toward a National Framework on Secondary Use of Health Data

National Committee on Vital and Health Statistics

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Agenda

- Definitions
- Overview of 2006 Deliverables and Findings
- Overview of 2007 Conference
  – Pre-conference Working Groups
    - Data Stewardship
    - Taxonomy
    - Identification/De-identification
  – Review of major themes
  – Proposed principles
- Expected 2007 Deliverables
- Next Steps

What is Primary Use of Health Data?

Data collected about and used for the direct care of an individual patient.

What is Secondary Use of Health Data?

- Non-direct care use of personal health information including but not limited to analysis, research, quality/safety measurement, public health, payment, provider certification or accreditation, and marketing and other business including strictly commercial activities. (e.g. everything else)

- Secondary use of health data occurs when data are used for purposes other than those for which they were originally collected

Major Findings from 2006 AMIA Meeting

- Secondary uses of healthcare data are widespread

- Patient privacy issues dominate the public trust

- Technological capabilities to merge, link, re-use, and exchange data are outpacing the establishment of policies, procedures, and processes.

- Need for additional attention and leadership at the national and state levels.

"Toward a National Framework for the Secondary Use of Health Data". Safran C, Bloomrosen M, Hammond WE, Labkoff S, Markel-Fox S, Tang PC, Detmer DE, Expert Panel. *J Am Med Inform Assoc*. 2007 Jan-Feb;14(1):1-9. Epub 2006 Oct 31.

2006 Proposed Components of a National Framework for Secondary Use of Health Data

- Transparent policies and practices for the secondary use of health data
- Focus on data control rather than data ownership (e.g. stewardship)
- Consensus on privacy policy and security
- Public awareness
- Comprehensive scope (beginning with a taxonomy)
- National leadership

Overview of AMIA 2007 Conference

- Major Themes
  - Vetting work products of pre-work groups
    - Taxonomy
    - Stewardship
    - Identification/De-identification
  - Finding agreement on framework in 4 domains
    - Research
    - Public Health
    - Quality
    - Commercial
  - Proposal of Principles for Stewardship

  - Preliminary meeting materials posted on AMIA web site
    http://www.amia.org/inside/initiatives/healthdata/2007/index.asp

What is Data Stewardship

- Data stewardship encompasses the responsibilities and accountabilities associated with managing, collecting, viewing, storing, sharing, disclosing, or otherwise making use of personal health information.

- Principles of data stewardship apply to all the personnel, systems and processes engaging in health information storage and exchange within and across organizations.

- Provides guidance for all discussions about secondary data use and lays the groundwork for the principles.

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Why Establish Data Stewardship Principles

- Provides the rationale and safeguards for the legitimate secondary uses

- Describes the enforcement mechanisms that provide reassurance of appropriate usage

- Describes the benefit to the field of having "trusted data stewards" who adhere to these principles
    - These stewards would potentially be able to share data without having to create ad hoc data handling guidelines for each transaction.

Proposed Data Stewardship Principles

– Accountability (including governance, oversight, and the extent and level of applicable regulations)

– Openness and transparency (including structure, processing and delivery of data, and business processes and practices)

– Notice to patients

– Privacy and security (including data quality, de-identification, and costs of re-identification)

– Granularity of patient consent

– Permitted uses and disclosures (including data aggregation and analyses)

– Enforcement and remedies

A Consumer Guide Regarding Personal Health Information

- Does the organization prominently post a privacy policy with an effective date?

- Is the privacy policy written in clear and understandable language with definitions of terms?

- Will you be notified in advance of any changes to the privacy policy, and can you terminate any agreements, without penalty, if you do not agree to the change?

- Does the privacy policy describe how your data are handled if the organization is sold, merges with another organization, or files for bankruptcy?

- Does the privacy policy clearly list any and all uses of your data, whether or not you can be identified?

- Does the privacy policy describe how your data are protected?

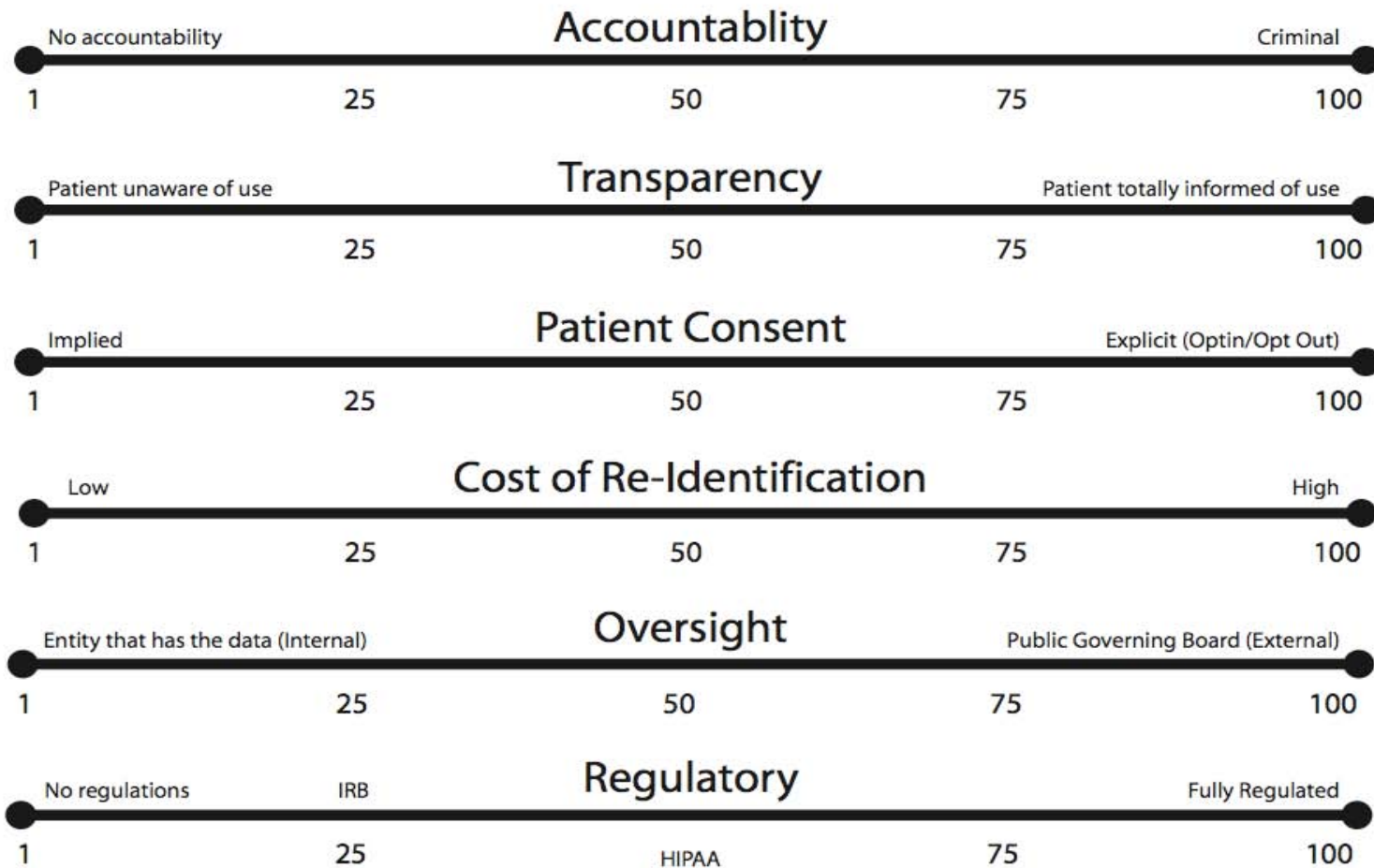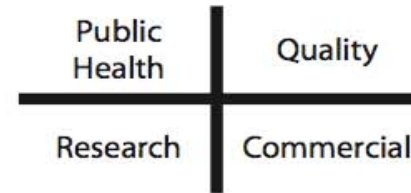# A Consumer Guide Regarding Personal Health Information (con't)

- Does the privacy policy clearly list any and all sharing of your data with other organizations, whether or not they are affiliates or business partners, and whether or not you can be identified?

- Does the privacy policy describe whether your permission is required to share your data and, if so, how your permission is obtained?

- Does the privacy policy describe how you can contact a privacy official with questions or complaints about the organization's privacy policy or behaviors, and receive a timely response?

- Does your decision to deny permission result in any adverse actions against you (for example, denial of services)?

- Can you obtain a free report at any time of who has accessed your data and when?

- If you terminate an agreement, will the organization remove (and no longer use or disclose) your data, whether identifiable as yours or as part of a group?

Taxonomy

- Workgroup convened
- Created a taxonomy (work in progress)
- The taxonomy identifies possible non-clinical uses of personal health information to clarify societal, public policy, legal, and technical issues.
- The taxonomy supports more focused, productive discussions regarding health data and their use.

- Axes of the taxonomy
  - What are the categories or classes of secondary use?
  - How are the data used?
  - What are the existing or potential sources of secondary data?
  - Who are the users?

Towards a Framework for Secondary Uses of Healthcare Data

Public Health	Quality
Research	Commercial

Accountablity

No accountability | | | | Criminal

| 1 | 25 | 50 | 75 | 100 |

Transparency

Patient unaware of use | | | | Patient totally informed of use

| 1 | 25 | 50 | 75 | 100 |

Patient Consent

Implied | | | | Explicit (Optin/Opt Out)

| 1 | 25 | 50 | 75 | 100 |

Cost of Re-Identification

Low | | | | High

| 1 | 25 | 50 | 75 | 100 |

Oversight

Entity that has the data (Internal) | | | | Public Governing Board (External)

| 1 | 25 | 50 | 75 | 100 |

Regulatory

No regulations | IRB | | | Fully Regulated

| 1 | 25 | HIPAA | 75 | 100 |

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Components of the Framework

- **Accountability**- level of sanctions or penalties for disclosures or inappropriate use of patients' health data
  - **End Points**: 0 = No accountability; 100 = Criminal sanctions

- **Transparency**- the extent to which the practices governing the use of patients' health data are known and understood by those who disclose or use data and to the patients whose data are subject to use
  - **End points**: 0 = Patient is completely unaware of secondary uses of health data; 100 Patient is informed of every use of health data at the time of its occurrence

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Components of the Framework (con't)

- **Patient consent/notification:** the opportunity offered to patients to allow/permit the use of their health data. Notification refers to the mechanism by which patients are informed of their right to consent
  - **End points**: 0= No Choice; 100= "Opt in"

- **Cost (resources required for) of re-identification** – is a proxy for the nature, complexity, and extent to which patients can be re-identified in a data base(s)
  - **End points**: 0 = low/relatively straightforward; 100 = high/complex and difficult

Components of the Framework (con't)

- **Oversight-** the extent to which the entity is subject to governance or supervision; includes the ability to impose remedies for breaches
  - **End points**: 0 = Internal, residing with the entity that has the data; 100 = External, residing with a public governing board

- **Regulatory/Law**: framework of regulations and laws that govern secondary uses of health data, including penalties and enforcement guidelines
  - **End points**: 0 = No regulations or laws; 100 = fully regulated

Data Analytic Principles Background

- A statistically sound approach is necessary for secondary analysis of large clinical practice data sets

- Random analysis or unstructured data mining could yield associative conclusions and potentially introduce false positive associations

- Standard data analysis principles provide a framework for sound studies with credible and reproducible results, and for minimizing errors possibly introduced during analysis

- Data analysis principles mitigate the risk of false positives that could cause misidentification of a safety problem

- Provide a grounding for multiple parties such that analyses can be more readily compared

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Proposed Data Analytic Principles

- Agreement to use principles
  - Users commit to using standard data analysis principles
- Establishment of local data access committees
  - Serve as gatekeepers and provide governance to data sets and analytic projects
- Hypothesis needed
  - A prospectively defined scientific hypothesis or defined purpose for hypothesis testing is required prior to analysis
  - If hypothesis testing the goal, no changes to medical practice until hypothesis validation
- Sound experimental design
  - A clear statistical experimental design is necessary to undertake study
- Close the loop
  - Data access committees receive results of the hypothesis testing

Key Take-aways from the
AMIA 2007 Conference

- Secondary use of health data is important and valuable, although value may be in the eyes of the user
  - includes not just economic value to commercial entities that use the data, but economic and other benefits to individuals and society

- Need to broadly educate various audiences on the value of secondary use of health data

- Issues are very complex and ongoing work is needed – the environment is dynamic and fluid

- Consumers have an important role, although there were various opinions on what that role

- Taxonomy is an important tool to help inform the greater community and will need expansion and maintenance
  - Users and associated uses are not always clear cut

Key Take-aways from the
AMIA 2007 Conference (con't)

- There is still confusion about:
  - the HIPAA Privacy Rule, FDA's human subject protection regulations, and the Common Rule
  - *none of which may be applicable or adequate to address secondary data issues*

- Data stewardship principles needed
  - Must address the implicit chain of trust as data changes hands

- Data must be of a minimum quality
  - Accurate; reproducible; complete; timely; and credible
  - Data limitations should be acknowledged and described (data analytic principles)

Planned Work Products and Outputs
From 2007 Meeting: Secondary Uses Framework Toolkit

- **White Papers/Commentaries/Recommendations**
  - Value of Secondary Use
  - Health Data Stewardship
  - Framework and Principles for Secondary Use of Data
  - Framework Instrument

- **Data Stewardship Definitions & Principles**
  - A Consumer Guide Regarding Personal Health Information
  - Data Analytic Principles

- **Taxonomy of Users and Uses**

AMIA Next Steps

- Synthesize and distill AMIA conference discussions
- Reconvene working groups
- Refine interim work products and meeting outputs
- Continue public discussion at AMIA Annual Symposium, November 2007
- Develop white papers for publications
- Participate in ongoing discussions with AHIC, NCVHS, Connecting for Health, eHI and others

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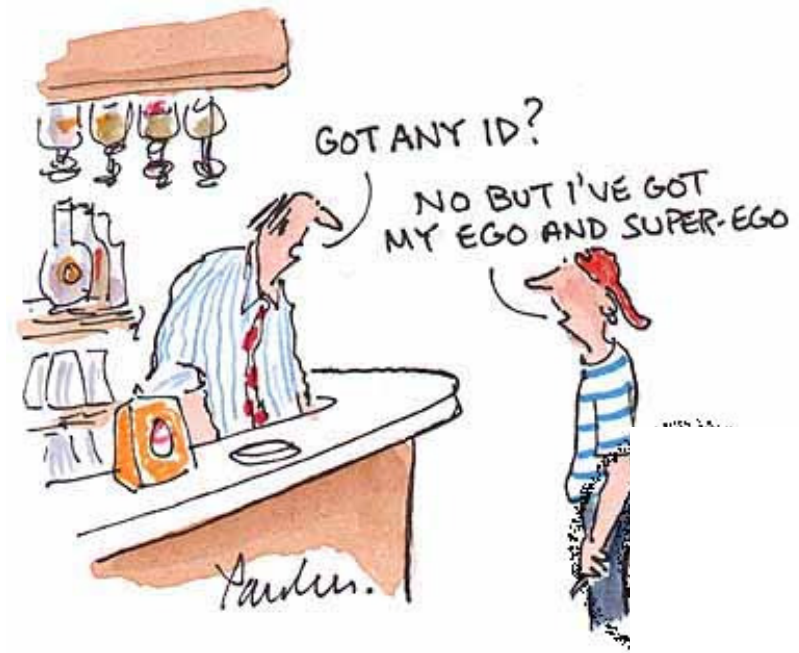- Charles Safran, MD
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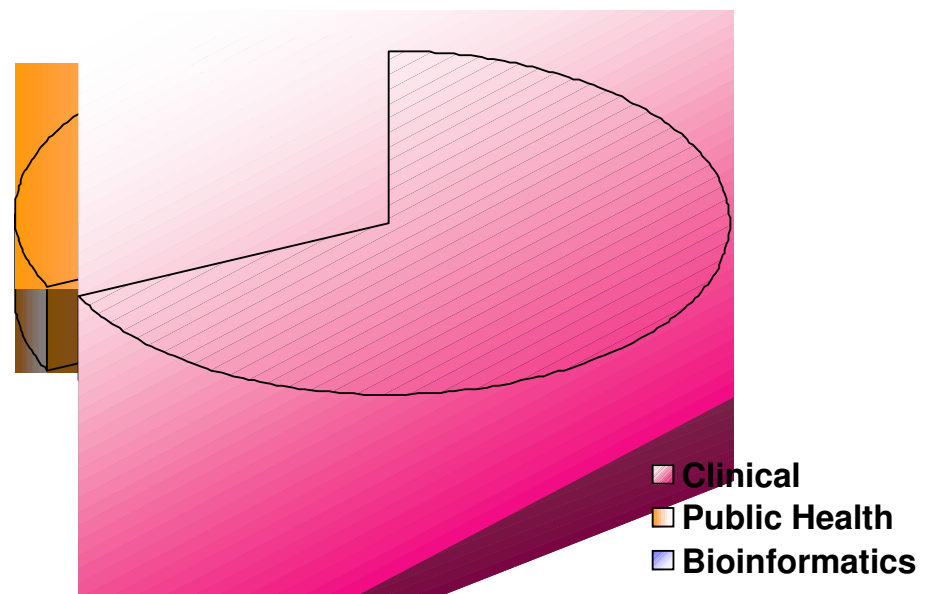- Bradley Malin, Ph.D.
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AMIA Membership

- 4000 members in 53 nations

- Of those indicating an area of interest

  - 68% clinical or health care (including personal health management)

  - 24% public health/population

  - 8% bioinformatics

Clinical
Public Health
Bioinformatics

Annual Symposium
- a 30 year history

- ## Features include:

- State-of-the-art overviews by acknowledged experts
- Panels exploring critical issues of the day
- Demonstrations of some of the most advanced information resources in the world
- Scientific & applied papers and posters
- Dozens of in-depth educational sessions, ranging from fundamental to advanced, from conceptual to applied, taught by leading informatics experts

November meeting of AHIC in conjunction with
AMIA 2007 Annual Symposium in Chicago

AMIA
2007
CHICAGO

AMIA 2007
Annual Symposium

November 10-14
Sheraton Chicago Hotel & Towers
Chicago, IL

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AMIA Initiatives

10x10 Goal

- Train 10,000 health care professionals in applied clinical informatics by 2010.
- An initiative of AMIA in partnership with participating informatics training programs.
- AMIA's depth of expertise across bioinformatics, clinical informatics, & public health/population informatics sets us apart.
- http://www.amia.org/10x10/

- *got**EHR?*** is based on two premises
  - EHRs can enable high quality, safe, cost-effective health care with data security
  - EHRs can strengthen the relationship between patients & clinicians
- *got**EHR?*** targets three key audiences for widespread adoption of EHRs
  - Patients in 'clicks & mortar' care localities
  - Policy makers to reduce policy barriers & ⬆$ support
  - Clinicians, especially small office practices

A Roadmap for National Action on Clinical Decision Support

- Provides an overview of current state of CDS-enabled systems, describes barriers of adoption, & offers potential solutions to barriers

- Provides a national action plan & series of short & longer term recommendations for growth, adoption & value of clinical decision support in improving quality, & safety of health care

- Developed at the request of the Office of the National Coordinator for Health Information Technology (ONC) & supported by the Agency for Healthcare Research and Quality (AHRQ).

- http://www.amia.org/inside/initiatives/cds/

THANK YOU

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