National Policy for Reuse of Person-specific Health Data
A perspective from the United States

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Declared Interests*

American College of Surgeons
University of Virginia
CHIME, University College London
NIH Clinical Translational Science Award National Advisory Groups: UW-Madison; U Michigan; U Minnesota
Dept. Biomedical Informatics: U Washington
Board, Corporation for National Research Initiatives
CSPlacement

*Comments in this talk are solely personal & not intended to reflect any related policies of the organizations or institutions listed above.
“Medicine is a social science, & politics is nothing else but medicine on a large scale. Medicine, as a social science, as the science of human beings, has the obligation to point out problems & to attempt their theoretical solution: the politician, the practical anthropologist, must find the means for their actual solution.”

- Rudolf Virchow
Policy making in democracies involves striking a balance among competing social goods & other desires that are in dynamic conflict.

Examples of these forces: Altruism, Equity, Greed, Health, Liberty, Opportunity, Privacy, Solidarity, Trust

Due to these inherent conflicts, enduring values in cultures are not to be assumed.*

Nothing is so contagious as opinion, especially on questions which, being susceptible of very different glosses, beget in the mind a distrust of itself.

James Madison

*Letter to Dr. Rush, March 7, 1790*
A people who would govern themselves must arm themselves with the power to which knowledge gives.

- James Madison, 1822
  Author of U.S. Constitution
Contemporary Theoretical (Virchow) Principles for Grand Scale Health Policy

• Public policy should be ‘nudged’* to favor social trust, altruism, happiness, & health (individual & population).
  • Health is the first wealth. Emerson

• Public policy protecting the privacy, security, & confidentiality of ‘publicly held’ person-specific health data is essential but it must allow functional access for critical social ‘goods’ & progress.

USA Specific Terms

IOM - Institute of Medicine - Part of US quasigovernmental National Academies devoted to Health Policy Studies; National Academies chartered by Abraham Lincoln; Offers sound advice to government & public

HIPAA - Health Insurance Portability & Accountability Act (Administrative Simplification Provisions) - Federal Law governing use of Person-specific Health Information managed by the Department of Health and Human Services (DHHS) - mandated in 1996

Common Rule - Federal Policy for Protection of Human Subjects (1991); Common Rule ANPRM (Advanced Notice of Proposed Rulemaking) - Publication seeking comment for proposed changes. Research protocols need prior approval through IRBs (Institutional Review Boards)

NCVHS - National Committee on Vital and Health Statistics - National Advisor to Secretary DHHS for Policy relating to Privacy and Security matters

ONC - Office of the National Coordinator for Health Information Technology (DHHS) - Provides oversight on Health Information & Communications Technology referred to as simply HIT in USA

PCAST - President’s Advisory Council on Science & Technology

SSA - Social Security Administration - Federal Agency responsible for post-retirement support and Medicare (Federal post 65 years of age health insurance program)
USA Policy & Trustworthy Reuse of Person-specific Health Data

• “Trustworthy Reuse” - Highly Commendable Language
• Origin of “Secondary Use” - 1991 & 1997 Institute of Medicine EHR Reports
  • May imply that other uses are less important
  • Over 130 uses & users - IOM study
  • HIPAA complicated this with Business Operations & Quality Review

• 2006 Definition of Secondary Use *

“Non-direct care use of personal health information (PHI) 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”  (Safran NCVHS 2006)

USA Policy & Trustworthy Reuse of Person-specific Health Data

• AMIA Data Reuse Policy Conferences
  • 2006 Secondary Data Use*
    • Concepts of Data Stewardship (encouraged) v. Data Ownership (disparaged)
  • 2007 Data Reuse**
    • Principles for Data Reuse via Trusted Stewardship
  • 2012 “Data Use” - this IMIA meeting?


AMIA Definition of Data Stewardship*

Data stewardship encompasses the responsibilities & 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 & processes engaging in health information.

*AMIA 2007 Health Policy Conference
Stewardship Principles for Data Reuse* ^

- **Accountability**, including governance, oversight, & the application of relevant regulations to the appropriate extent & level.
- **Transparency**, including clearly understood policies & procedures regarding data structure, processing, & delivery of data, & business processes & practices.
- **Notice** to patients & other legitimate users.
- **Technical issues**, e.g., data security, quality, de-identification, & costs of re-identification.
- **Patient consent** of appropriate granularity.
- **Permitted uses & disclosures**, including for data aggregation & analyses.
- **Enforcement & remedies**.


Today, US privacy law, regulatory structure, & federal system behavior seriously restrict flow of health data needed for a Learning Health Care System.*

Multiple studies show all levels of health related quality improvement & research are significantly limited by current structure & practice, e.g., public health, genetics, health services

http://nap.edu

IOM: Beyond the HIPAA Privacy Rule (2009)
http://nap.edu

Also, PCAST 2010

* Penfield, Anderson, Edmund, Belanger: Toward Health Information Liquidity: Realization of Better, More Efficient Care From the Free Flow of Health Information
US Health Privacy Efforts & Impact

The Laws

Neither does a very good job protecting personal data nor offering cost-effective access to data for researchers. Ex. No unique personal health identifier

  Confuses use of data for quality of care studies v. its use for research, e.g. discourages publication & sharing valuable insights.

  Preferentially favors Minimum Data Sets which limits value

  • Incentivizes Data Collection Centers to limit access to data in order to reduce legal exposure to fines if misuse were to occur

  • Confusing mixture of state & federal mandates

  • Under HIPAA, individuals are prohibited from consenting to future, unspecified uses of data
Discouraging Aspects of US Health Privacy Efforts for Care Improvement Efforts & Health-related Research

The Regulatory Structure
Legal Mandate of DHHS Privacy Office is to protect personal data without mention of balancing privacy with other important social uses of data
- Multiple federal oversight agencies - the duplication confuses users & raises costs

Behavior of Regulators
Research not valued highly as a national objective by privacy experts used by government despite $30B/year for National Institutes of Health research

Example: US Office of National Coordinator accepts Privacy Regulatory advice from its National Advisory Committee on privacy issues despite any analysis of impact of its recommendations on research

Example: US Social Security Administration’s (SSA) Death Master File (SSDMF), known as SSDI is no longer available (1 November 2011)* - makes trauma quality research much more costly
## Data Access for Information-based Research: Current Requirements, Barriers, & Privacy Vulnerabilities

<table>
<thead>
<tr>
<th>Type of Health Data</th>
<th>Current HIPAA Requirements</th>
<th>Barriers to Research/Access</th>
<th>Privacy Vulnerability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fully Identifiable Personal Health Information (PHI)</td>
<td>Individual consent OR Institutional Review Board waiver</td>
<td>• Costly, burdensome, often impossible for large data sets • Requiring consent may create selection bias • IRB waiver possible but inconsistent</td>
<td>• Consent does not mean protections are adequate • Use of fully identified PHI means any breach creates exposure</td>
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Adapted from Douglas Peddicord (2012)
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<td>Limited Data Set</td>
<td>• Remove 16 direct identifiers AND • Data Use Agreement, with prohibition of re-identification or contact of individuals</td>
<td>• IRBs often restrict use • Upcoming ban on sale of PHI creates uncertainty • State-based consent requirements may pose major obstacles</td>
<td>• Risk of inadequate data security &amp; breach • Residual risk of re-identification remains despite Data Use Agreement prohibition</td>
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| De-identified Data  | • Safe Harbor Method removes 18 direct identifiers & associated data  
                    | OR  
                    | • Statistician Method certifies “low risk” | • Removal of identifiers & data elements, especially all dates, makes for limited utility | • None proven, but there is a perception that increased computing power has rendered genuine de-identification nearly impossible (esp. with genomic data) |

Adapted from Douglas Peddicord (2012)
Some *Potentially* Good News about US Health Privacy Reforms Efforts

- While Current Regulations are under review, trends in regulation are not comforting in terms of cost-effective access to data for care delivery & other research uses.

- Common Rule ANPRM (July 2011) suggest individuals should give consent even for use of de-identified data.

- PCAST Report to President Obama (Dec 2010) “Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward” suggests Granular Consent for health data could go to level of individual data elements (p.46-47) [http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf](http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf)
For use by audience as later reference: Current Status of Federal Policy of Common Rule & HIPAA governing Research

DHHS considering Common Rule changes: see Advanced Notice of Proposed Rulemaking seeking early feedback. No further developments out yet on this.
. As of May 14, no specific recent change.

- GAO Record Linkage and Privacy GAO-01-126SP, April 2001

- Office of Civil Rights:


Source: Deven McGraw (24 April 2014)
Americans generally strongly support sharing personal health data with teaching centers for care & research. (90-95%)*

* Data available upon request
Current Policy Options in USA

to support dramatically better data access for Care Improvement & Research:

- Private Sector Approaches

- State Policy Reforms (50 states)

- Federal Policy Reform
Private Sector Approaches: Can/will they scale up?

- Vanderbilt (Paul Harris-REDcap, Dan Masys eMerge Network, Harvard (Murphy, Kohane i2b2) combine clinical & genomic data but detailed clinical information stays at the ‘parent’ institution.
- PatientsLikeMe (ALS data sharing) see
- George Church [http://www.personalgenomes.org/](http://www.personalgenomes.org/)
Reform State Policy
State Automobile Driver’s License Solution

• Add 4 more icons / options to the Organ Donor option
  – Use my automobile driver’s license # for electronic healthcare record authentication purposes
    • Suggested symbol – EHR# or EHR#
  – Allow my healthcare record information to be sent to me & my healthcare professionals
    • Suggested symbol
  – Allow my healthcare record information to be used for medical research (IRB approved research) & (option worth testing) to contact me for relevant research
    • Suggested symbol
  – Allow my DNA data to be used in IRB approved research protocols.
    • Suggested symbol
Prediction:
• By 2017, human genome sequencing will be routinely available in health care institutions at a very affordable cost
• Anonymization as we have known it will not be easily controlled

Conclusion: We don’t have time to wait!
Virchow public policy circa 2015
at do we need in the USA?

ADVOCACY  for an altruistic ‘nudge’
A coalition of health professional & disease advocacy
groups need to champion federal law that: 1) assigns a
unique health identifier for research purposes, 2) allows
access to unanonymized personal health information for
research & quality/safety improvement purposes, & 3)
supports unfettered permanent ‘citizen opt-out’ from
such data sharing with ‘no questions asked’.
Trustworthy Data Use would be strictly monitored through
International Standards incorporating Trusted Stewardship
Principles.
If you don’t like what the public thinks, inform their discretion.

- Thomas Jefferson
  author, US Declaration of Independence
  founder, University of Virginia
Most Critical Issues for US Population*

Arthur Levin
Director, Center for Medical Consumers, NYC

1) Totally transparent program management, e.g., all processes available on Website including those relating to opting out
2) Published Audits of Researchers accessing data
3) Published Audits of any wrongful disclosures
4) Focus groups used prior to going live

*He estimates few opt-outs if supported by public education, patient advocacy groups & health professions
As for the future, your task is not to foresee, but to enable it.

- de Saint-Exupery
Thank you for the invitation
and for your attention.

And, best wishes on this vital work.

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