Dramatic Reform of National Policy
Supporting Secure Access to
Person-specific Health Data
for Quality Life-giving Research

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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 Minnesota Board, Corporation for National Research Initiatives

*Comments in this talk are solely personal & not intended to reflect any related policies of the organizations or institutions listed above.
Policy making in democracies involves striking a balance among competing social goods & other desires that are in dynamic conflict.

Examples of these forces: Equity, Greed, Health, Learning, Liberty, Opportunity, Privacy, Security, Trust, Love, Charity, Duty, Patriotism, Citizenship, Responsibility

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

A people who would govern themselves must arm themselves with the power to which knowledge gives.

- James Madison, 1822
Author of U.S. Constitution
This Talk

• Greater data access for Health & Research today is a compassionate, patriotic & financial imperative

• Privacy regulations today are too [single focused & imbalanced] [dysfunctional & ‘cold hearted’] for our society
  • All types of biomedical & health research are hurt
  • Publication of Quality & Safety Research is limited
  • Social inequities via HICT use are increased

• What might health professionals do about it?
Unanonymized Data Access for Health & Research today should be a national imperative. Why?

• National debt unsustainable & healthcare is big part.
• Rising healthcare costs alone are unsustainable.
• Jobs are needed; health research creates good jobs.
• Biomedical research expenses keep rising, as good ideas go unexplored & budgets tighten.
• Rising research strictures discourage young scholars.
• Baby boomers want & will need care services.
• Mostly, because today biomedical research works!
“What makes America exceptional are the bonds that hold together the most diverse nation on earth. The belief that our destiny is shared; that this country only works when we accept certain obligations to one another & to future generations. The freedom which so many Americans have fought for & died for come with responsibilities as well as rights. And among those are love & charity & duty & patriotism. That's what makes America great.”

– President Obama’s election night 2012
Compassion & Charity:  
The Case for better Health through  
Cures due to Evidence-based Research  
A track record of research success –  
With good policy & resources, it really works!

• Life expectancy gains
• Reduced morbidity (pain & suffering)
• Far fewer halfway technologies (Lewis Thomas)

Pim Kolff – Renal Dialysis/Artificial Heart

Joe Murray – Kidney Transplantation
Compassion & Charity: Cures due to Evidence-based Research using patient data

Far fewer halfway technologies (Lewis Thomas)

Th. Billroth – Gastric resection for Peptic Ulcer

Barry Marshall – H. pylori
Duty: Sharing Personal Data for Quicker Cures through ‘Big Data’ & Translational Bioinformatics

Ex. Single Case Study - Identifying RETSAT as an important regulator of insulin sensitivity

Lazar – Global 5 year, multi-institutional study
Kohane – weekend data crunching for gene most commonly dysregulated in diabetics

Mitchell Lazar
Zak Kohane
Just how much privacy regulation can the nation justifiably afford in terms of:

...people otherwise living longer, healthier lives.
...less healthcare & greater inequities for the poor
...lost savings resulting from much more effective, less costly health care.
...lost benefits of high income research jobs.
...loss of international competitiveness.
...the reality that the entire world depends heavily on US research for its cures as well.
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*
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


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

Also, PCAST 2010

All at http://nap.edu

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>
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</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 • 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, limits data 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)
Blind Drive for Greater Privacy overrides Compassion, Equity, & Healthcare for Least Fortunate

• mHealth - Text messaging for appointment reminders & motivating behavior change is increasingly well-studied & evidence-based. Texting helps smoking cessation in UK (Lancet 2011)

But, in Dr. Houston’s clinical system, policy doesn’t allow texting, as it is not secure. Thus, even if patients ask for and even consent to texts as reminders for visits or tailored messages for information, security officers override use regardless of how much it enhances quality.

Over 85% of adults have access to a text-enabled phone, including the lowest income patients, including Homeless Veterans in the VA. Smart Phones are more secure & increasing in use but most poorer adults don’t have this technology today, e.g., the homeless patients or other highly vulnerable populations.

Source: Tom Houston, MD MPH (AMIA Clinical Symposium, 2012)
Professor and Chief, Division of Health Informatics and Implementation Science
UMass Medical School and Director, VA eHealth Quality Enhancement Research Initiative
Chronic Data Use Policy Problems not getting better elsewhere... *

• Uncertainties & disagreements around construct of ‘personal data’
• Debate about ethical & legal appropriateness of consent to complicated research and sharing data via research platforms
• Dispute over acceptability of broad consent to unspecified, perhaps unspecifiable, future research
• Lack of clarity about how to deal with privacy & confidentiality implications for relatives of people involved in research
• Public & researcher apprehension about legal power of researchers to resist forcible access to research data by police, courts, etc.
• Inconsistencies & redundancies in laws & regs, often out of step w/ times
• Onerous, inefficient, & costly procedural requirements for complying with all the regulatory structure

Conclusion: Current Federal & State Health Data Structure is harmful to your health & the health of future generations

- Neither protects personal data well nor offers cost-effective access to data for research. Ex. No unique personal health identifier for privacy or research to support authentication

- 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, changing admixture of state & federal mandates

- Under HIPAA, individuals prohibited from consenting to future, unspecified uses of data.
What can health professionals do?

1. Advocate for our Cure & Care Dreams for Informatics
2. Build on Presidential aspirations with a clear vision & Federal strategy
   • Executive Branch
   • Legislative Branch
   • All relevant influential players
3. Craft state strategy, e.g., “Copy Hawaii’s 5 0”
4. Develop opinion pieces & a public campaign
President Obama on 2nd Term Top Priorities & Regulatory Reform

**Priorities:** “...taxes, health care, education, energy policy & immigration. ...health care reform”

**Regulatory Reform** “...executive action to weed out regulations that aren't contributing to the health & public safety of our people. And we've made a commitment to look back & see if there are regulations out there that aren't working, then let's get rid of them & see if we can clear out some of the underbrush on that. Again, that's something that should be non-ideological.

- Des Moines Register Interview – October 2012
Action #2.1. The Federal Government should identify and achieve regulatory policy reforms, particularly relating to the regulatory burdens on research universities.
Patient Advocacy Groups, AAAS, Researchers, AMIA & Others should advocate for Federal Policy Reform

Proposed Campaign Slogan:

**Hope & Life come from Medical Research: Share Your Health Data, Not Your Privacy Fears**

We need a federal action to:
1) assign a citizen a unique health identifier for research purposes,
2) allow access to unanonymized personal health information for research & quality/safety improvement purposes
3) support unfettered permanent or subsequent ‘citizen opt-out’ from such data sharing with ‘no questions asked’.
4) remove all regulations on health-related research that have no clear public benefit

Trustworthy Data Use would be strictly monitored through National & International Standards incorporating Trusted Stewardship Principles.

Most Critical Issues to US Population regarding personal health data sharing*

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 who access data
3) Published Audits of any wrongful disclosures
4) Focus groups used prior to going live

*Levin estimates few opt-outs if supported by public education, patient advocacy groups & health professions
“You cannot put an idea into someone’s head. Media’s job is to touch what is already there.”

- Tony Schwartz
PR Example 1:

Data Sharing for Biomedical Research:
Which will be the American Spirit for 2013?

Privacy? or Cures?
“Hummmm. Facebook just hit 1 billion. Meanwhile, the government won’t let me get complete health data to help more sick children. Why must we let even one of them die unnecessarily?”
Patriotism: The Overall Big Data Message

- Cures can occur & the national health budget can be impacted by reducing ‘halfway technologies’
- Cures will come sooner if more personal health data is easily accessible
- Today, progress in health research is tied directly to sharing large sets of personal health data, e.g., clean, authenticated data
- Compassion requires greater liquidity of personal health data!
Policy making in democracies involves striking a balance among competing social goods & other desires that are in dynamic conflict.

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

Has America already changed too much?

Four Executive & Legislative ‘Asks’
1 - Amend HIPAA & subsequent regulations to treat research like quality, care, & business apps
2 - Enact a unique personal health identifier solely for research use to support authentication
3 - Get all states to copy Hawaii (Federal rules only)
4 - Rescind regulations & decisions that raise research costs w/o demonstrable public benefit
Thank you for the invitation & for your attention.

detmer@virginia.edu
Privacy Vulnerability of Health Data in the Genomic Era

None proven, but there is a perception that increased computing power will render genuine de-identification nearly impossible (esp. with genomic data)

True, or False?
Health Policy should be transparent, honest to the facts, & help instill trust through integrity. If in the genomic era, privacy of personal health data is genuinely at great risk due to progress in medical research, the health research community must square with the public & make the case that research is still in the public interest despite this vulnerability, or it will face even greater loss of public support.