Policy Reforms Essential for Robust PCOR Data Sharing

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Health is the first wealth.

- Ralph Waldo Emerson

1803-1882

Big Picture

HIPAA was passed into law in 1996, less than a year after the government *first* resolved to define the term **Internet.**

Bill Gates' 1995 famous memo, *"The Internet Tsunami"* roughly noted that 'the Internet changes everything'.

It hasn't worked out that way. Thirty-five years later, we still are trying to share information for healthcare & data research using pre-Internet thinking & largely ineffective regulatory tweeks.

Isn't it time to ask seriously,
'How's this working out for you?'

Sociotechnical Context for Current & Emerging Health Data Researchers

- Ubiquitous Internet plus Internet of Things,
  e.g., tons of new data alongside traditional data

- Ubiquitous 'Asocial' Media –
  Raucous Open Private Communications Environment

- Societal Goals:
  - Quest for "post-George Floyd" Equity
  - Engage Citizen-scientists, activated Patients & Related Care-givers
  - Support precision Medicine – Genome up for Medical Care of Individuals
  - Support Precision Health – Genome up through Social Determinants of Health for Population Health

Talking Truth to Power:

Therefore, IMO, anything you do within the current framework is certain to be quite suboptimal.

The basic structure needs a reset to allow informed public policy development addressing these societal desires with Citizen-scientists, Patients & Health Providers as **primary** players in the data system vis-a-vis Covered Entities & Business Associates.

Down to Earth

If President Biden can't include a HIP/AA Replacement In the National Infrastructure Plan, do the next best thing

Revive & enact the HIPAA Changes included in Section 1124 in H.R.6, the initial 21st Century Cures Act. H.R.6 passed the House 344-77 in July 2015 but which the Senate let die.

Is this change possible via regulation versus legislation?

- If so, please do it.
- If not, please get to legislating it.

Section 1124: “Accessing, Sharing, and Using Health Data for Research Purposes”

This section directed revisions to the HIPAA Privacy Rule of provisions that currently impede **access, use** & **sharing** of protected health information (PHI)
by HIPAA Covered Entities for **data research** purposes all within HIPAA.

That is, Section 1124 changes access to PHI **from** *treatment, payment, & healthcare operations* **to** *treatment, payment, healthcare operations & data research (TPOR)*.

This will allows us to discover the future.

In the Weeds

Current Prevailing Options:

All suboptimal to meet needs

- Registries with individuals (one by one) donating their PHI
  - Time consuming to build & maintain w/ limited range of data
- Aggregating limited data sets
  - Data sets are limited when diverse data is sought
- Using de-identified data
  - Authentication is difficult to impossible with diverse data sets

Even Better Options for Care & Data Research!/?

Two sets of Questions to conclude:

- For this Workshop

- For National Academies

Possible Workshop Options for Care & Data Research!/?

- **Question for Workshop:**

Could regulation allow texting & email of PHI for legitimate data research aka PCOR with emailed or texted approval from individuals.

Written consent is expensive, time-consuming & pre-Internet as well as post-mail service deterioration.

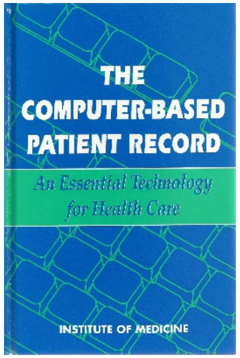
Even Better Options for Care & Data Research!/?

Questions for Workshop:

- Could authorization be created for specified entities like PCORI to allow aggregate secure access to individual PHIs for relevant databases being researched w/o individual consent?

- Might we also include a system for unique patient identifiers? (Secure options exist.)

Time for a new National Academies Study, **“Essential Policy Reforms for Internet-based Personal & Population-centered Longitudinal Health Records”**



THE COMPUTER-BASED PATIENT RECORD

An Essential Technology for Health Care

INSTITUTE OF MEDICINE

- The study would create a vision & plan for a sound functional replacement of HIPAA
- A few desired capabilities & goals:
  - Robust system security for all data
  - No-Questions-Asked Opt-in privacy for sharing personal data
  - Data sharing that assures:
    - System trust
    - Compassionate care
    - Scientific health care practice & evaluation for individuals & populations
    - Support for citizen-science & special populations
    - Secure unique personal identifiers
    - Pandemic data fitness & management
    - Automation of ***all*** business operations & other administrative functions, e.g. no involvement of caregivers time (cure clinican burn-out)

At the End of the Day (where we are now), America needs much better Data Access Policy to support both Individual *and* Population Health.

Thank you for the invitation & your attention.

Plus, my thanks to Doug Peddicord & Ann Waldo for their advice.

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Declared Interests

University of Virginia
American Medical Informatics Association
Blue Ridge Academic Health Group, Founder & Senior Member
Chair, Assessment Panel, Faculty of Clinical Informatics, UK
Corporation for National Research Initiatives, Board Member
International Academy of Health Sciences Informatics

Related Sources for this Talk

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