

Health Data as a Public Good for Discovery:

Public Policy to Protect Privacy
while Supporting Choice, Research, & Altruism

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Social Context

The first wealth is health.

- Ralph Waldo Emerson

A people who mean to be their own Government, must arm themselves with the power to which knowledge gives.

- James Madison

The key to benefiting from change will be in ensuring that health care decision makers are guided by science and research.

- Kathleen Sebelius



AMIA 2008 Policy Conference: Informatics, Evidence-based Care, & Research; Implications for National Policy

Recs:

- Support a 'Learning Health Care System'
- Improve & secure data integrity
- Attend to data security & privacy
- Facilitate research through a refocus
of public policy

Bloomrosen M and Detmer DE: Informatics, evidence-based care, and research; implications for national policy: a report of the American Medical Informatics health policy conference. *JAMIA* 2010 17:115-123.



Assertion:

A learning health care system requires broad access to personal health data. Citizens should be facilitated in supporting legitimate biomedical & health research.

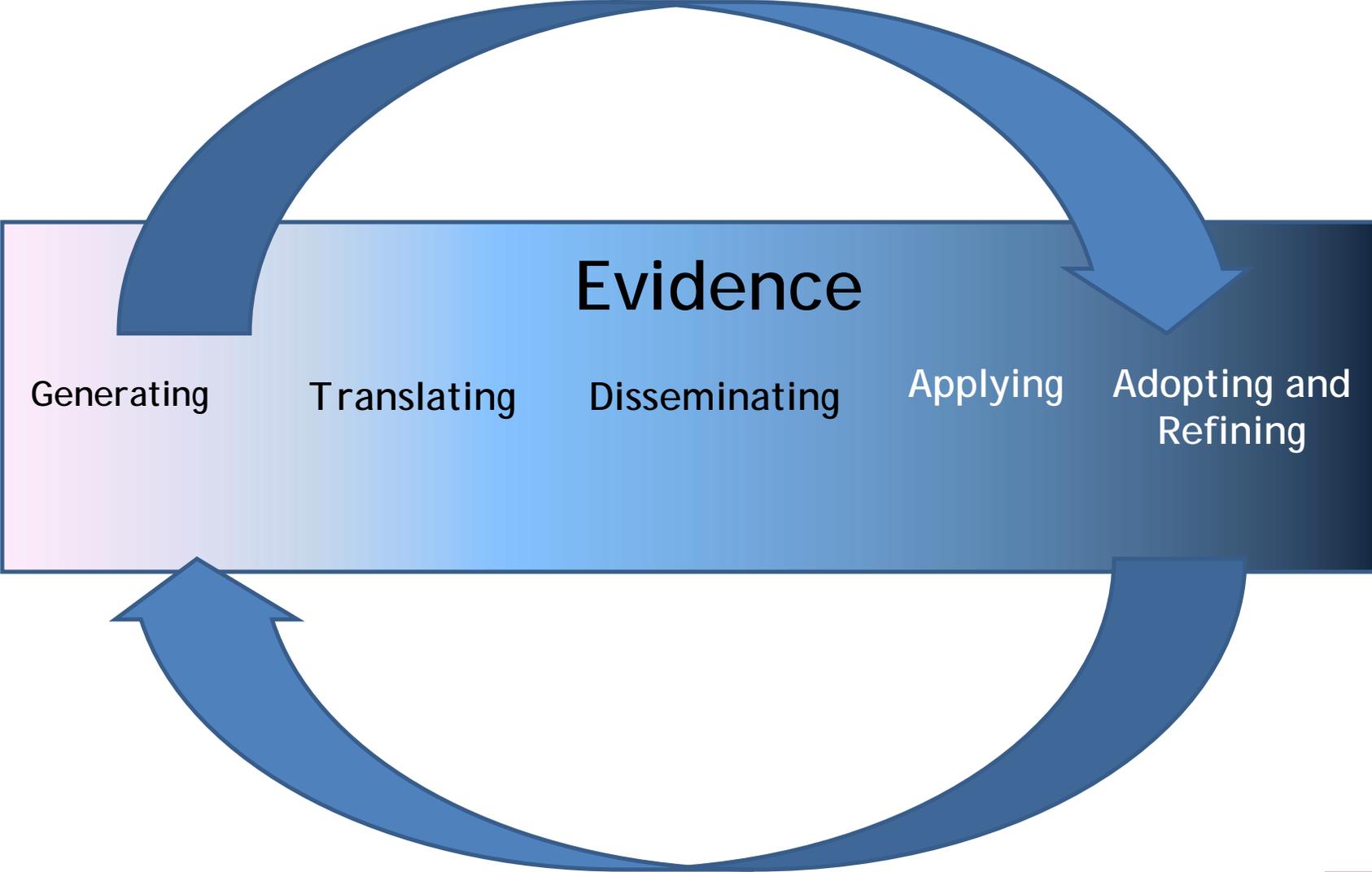
Today, federal policy impacts adversely legitimate biomedical & health research by restrictions to data access.*

This is in spite of high value put upon discovery & the improvements to health that have come from research.

* Nass SJ, Levit LA, Gostin LO, Eds.; Committee on Health Research and the Privacy of Health Information: The HIPAA Privacy Rule; Institute of Medicine, 2009, Washington, DC.; AAHC; AAMC; others



Today's View of the Evidence Continuum



We think in the abstract; we live in the concrete. Lawrence Weed

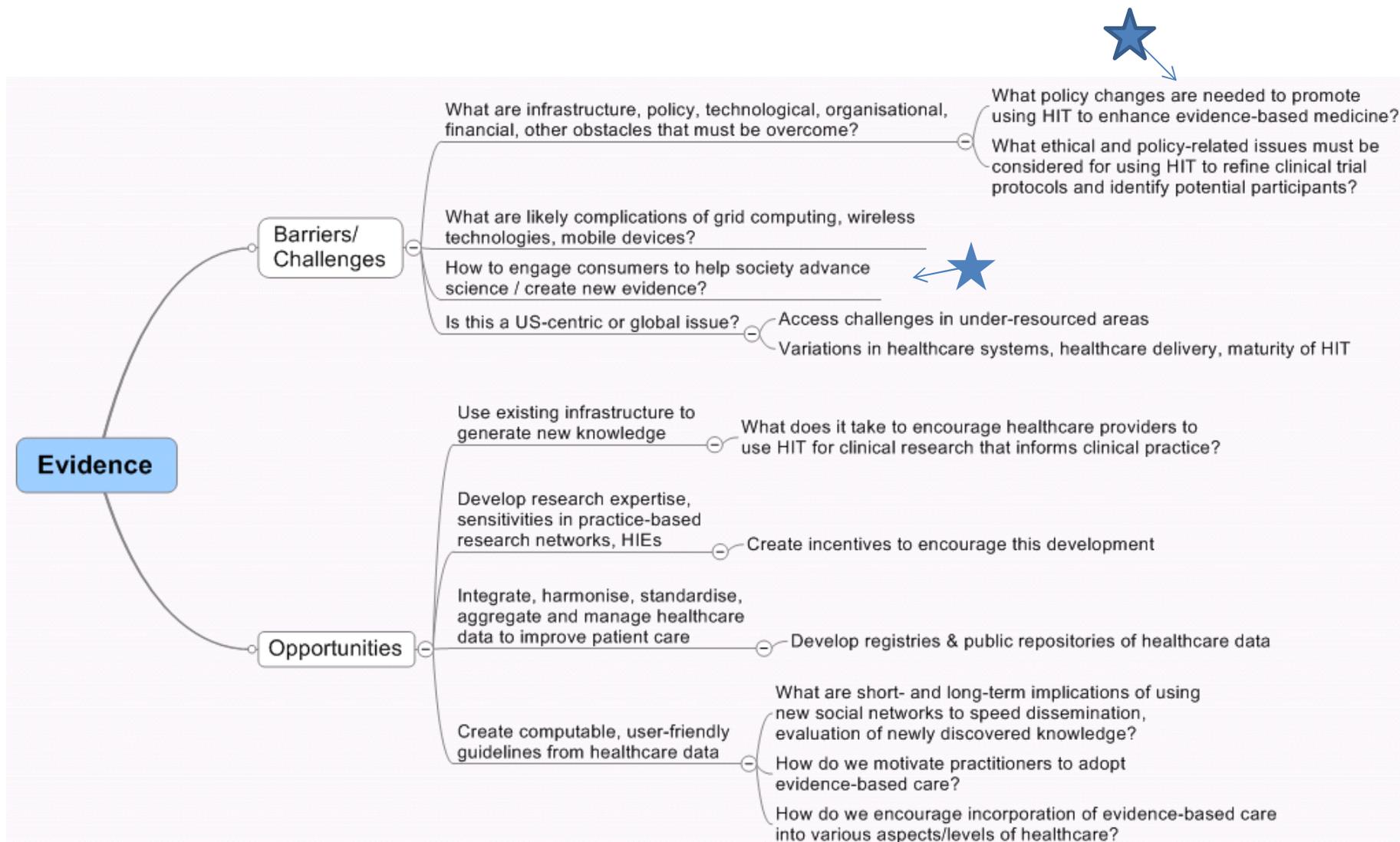


Well done is better than well said.

- Benjamin Franklin



The Future State of the Evidence Continuum



Today policy is focused disproportionately on privacy protection of personal health information, that is,

- Increasing federally enforced 'protections'*
- No freedom nor support for alternative action by citizens
- No behavioral policies that "nudge" us to accessing patient data

*Anonymization, minimum necessary, limited data set requirement, extended breach reporting, extended PHR definitions, increased penalties for unauthorized uses (unintended consequence is reduced data sharing to limit potential exposure & reduce risk)



Key Data Requirements for a Learning Health Care System

Data Integrity

- Patient ***authentication*** to assure data are in the right records
 - “Mary Smith” problem
- Patient identification when needed for research validity , etc.
- Smooth transition b/n quality management & clinical / health services research



The Issue of Incomplete Data

Example: Limited data sets (ARRA 2009)

- Inhibits identification of confounding medical conditions &/or therapies
- Limits identification of appropriate patients for potential participation in studies



UK Research Capability Program - Department of Health - 2007

21 Data-sets for researchers to access,
including the pharmaceutical industry

NHS CRS Personal Demographics Service (PDS); Death Registration; Birth Notification Dataset (BND); Commissioning Data Set (CDS) / Hospital Episode Statistics(HES); Cancer Register; NHS CRS Electronic Prescribing Service (EPS) and NPS; The General Practice Research Database (GPRD); The Health Improvement Network (THIN); EMIS Primary Care (QResearch); IMS-Mediplus; GPES (GP Extraction Service); Cardiac Register (CCAD); The National Diabetes Audit (NDA); National Congenital Anomaly System (NCAS); UK Renal Registry; The Townsend Material Deprivation Score; The Jarman Underprivileged Area Score; ONS Demographic indexes; The National Statistics Postcode Directory (NSPD); NHS HealthSpace; Mental Health Minimum Data Set (MHMDS)



UK Research Capability Program

Specific recommendations :

- "Safe Havens" for population-based research in which the protection of confidentiality is paramount
- Systems of approving & accrediting researchers allowed to work in such environments
- Involvement of academic & other partners in safe havens
- Development of systems to allow researchers to identify potential participants, who may then be approached to take part in clinical studies for which consent is needed.



HIPAA, ARRA, GINA & now PPACA:

A New Era for American Health Information Policy

“When one could lose insurability, etc. from access to personal record data...”



Refocusing Health Information Policy to support

“ ..decision makers..guided by science and
research” .
- Sebelius



Policy Option for 2010-2012
“Patient Choice, Research & Safety Bill”

Bill would give citizens the opportunity to:

- 1) Opt-out of selection of a unique personal health identifier ,
- 2) Opt-out of use of the PHI to share EHR data among care-givers,
- 3) Opt-out of a consent to share personal health data for IRB approved research (without data anonymization),
- 4) Opt-out of a consent to share personal genetic data, when available, for IRB approved research (without data anonymization).

- Use of anonymized data would be available without explicit personal consent.
- Opt-out would be justified by cost-effectiveness & better health treatments.*

*Allcott H and Mullainathan S: Behavior and Energy Policy . *Science* 2010, 327:1204-5.



Alternative Policy Option for 2010-2012

State by state strategy



The Driver's License 80% Solution - "Nothing's Perfect"

- Add 4 more icons / options to the Organ Donor option 
 - Do / Do not use my VA driver's license # for electronic healthcare record authentication purposes
 - Suggested symbol – EHR# or ~~EHR#~~
 - Do / Do not allow my healthcare record information to be sent to me & my healthcare professionals
 - Suggested symbol  or ~~~~
 - Do / Do not 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  or ~~~~
 - Do / Do not allow my DNA data to be used in IRB approved research protocols.
 - Suggested symbol  or ~~~~

Proposal for Pilot Testing beginning in 2010 - 2012

- Create multistate pilot & demonstration project(s) to test various models for ultimate national implementation.
- Citizens would be allowed to select among the icons. Their choices would be shown on their driver's licenses & a model IT infrastructure would tested best approach to manage the program securely & efficiently.
- Opt-in & opt-out options could be explored.
- Careful planning & evaluation would be pursued.



State partners sought

- Don Detmer , lead on policy dimensions of pilots
(see www.amia.org)
- Robert Kahn, National Corporation for Research Initiatives (NCRI)
lead on secure communications aspects of pilots
(see www.cnri.org)



The right to be left alone
is not a right to remain unknown.

And, your right to be left alone should not come at
the expense of the health of your neighbors.

In Massachusetts, 90% opt-in to sharing their data among health care professionals.

In Utah, less than 10% of parents opt their children out of statewide sharing of immunization records to care-givers throughout the state.



In the American context, a worthy society is exemplified by a healthy citizenry pursuing happiness through the beneficence of sound governance and positive expressions of personal freedom.

(Useful) knowledge is power .
- Thomas Jefferson

