Public Policy around "Real" Big Data

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“Big Data”

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Big Data ...
and the Next Wave of InfraStress

John R. Mashey
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Technology Waves:
NOT technology for technology’s sake
IT’S WHAT YOU DO WITH IT

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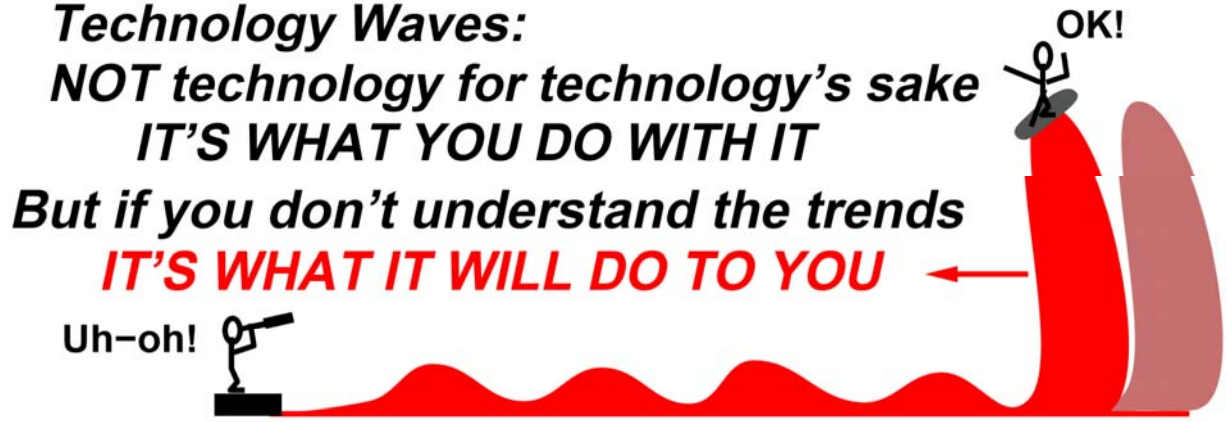
Technology Waves:
NOT technology for technology’s sake
IT’S WHAT YOU DO WITH IT

But if you don’t understand the trends
IT’S WHAT IT WILL DO TO YOU



Real World Data as the Next Wave of Health Technology

- Lots of discussions around it!
- 21st Century Cures Act mentions it
- FDA draft Guidance issues around RWD

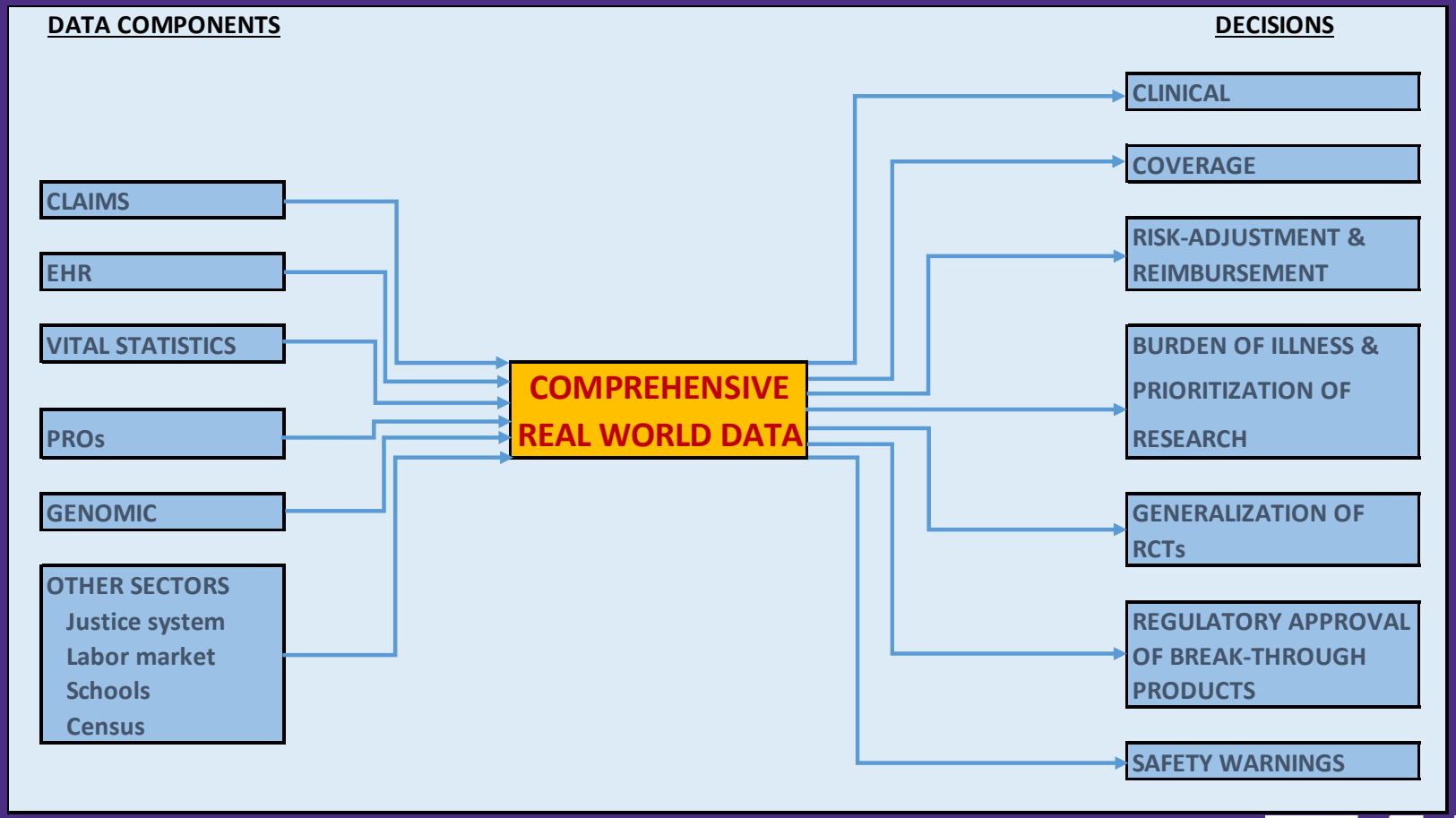
RWD are …

> *"Data used for clinical, coverage, and payment decision-making that are not collected in conventional randomized controlled trials (RCTs)"* - Garrison et al. 2007

RWD are data that do not consist of

> *"Any data collected from human subjects that follow protocols, including randomization, which do not mirror actual clinical practice for the treatment or disease"* – Basu et al. 2016

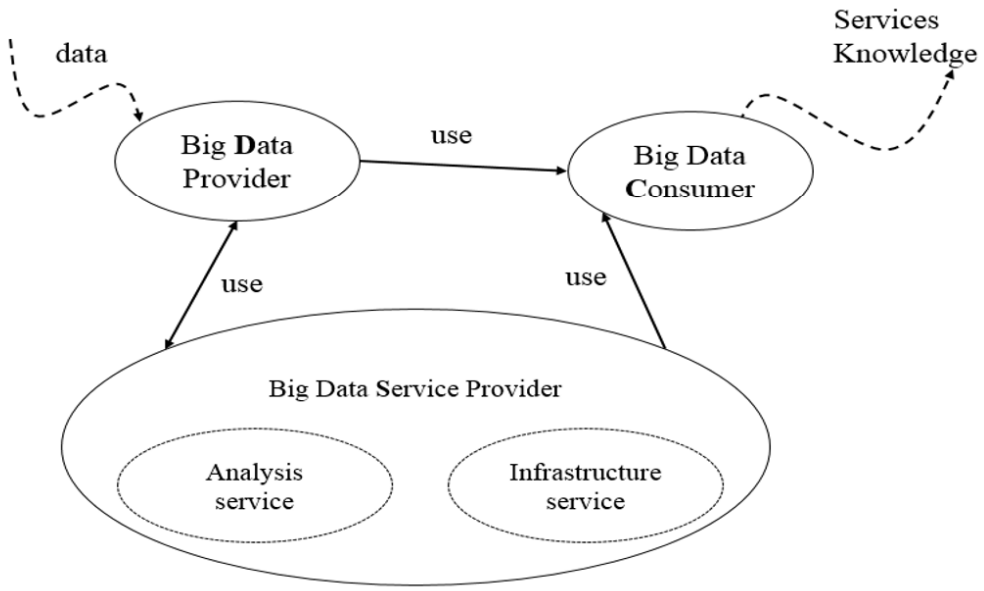
Real World Data entering Big data realms



Big Data Ecosystem

Ha et al.

International Journal of Software Engineering and Its Applications
Vol. 8, No. 11 (2014)



Three policy Issues with Big RWD … and government's role in it

> Challenges in portability issues for RWD components

> Investments in RWD

> Quality standards for information from RWD

Portability Issues for RWD Components

- Different entities are often the custodians of different components of RWD
- Interoperability Issues and Standardization Policies
- Government could and should play an important role

Portability Issues for RWD Components

- Government could and should play an important role
  - Uniform implementation of HIPAA regulations
  - Data structure standardization (e.g. metadata standards)
  - NLP standards for EMR data
  - Data standardization in other sectors

- Critical for the successful implementation of the HITECH Act (2009)

Portability Issues for RWD Components

- **RxNORM** ("normalized" notations for clinical drugs)
  - Collaboration between National Library of Medicine and the Veterans Health Administration
  - semantic normal form for a clinical drug

- **Unique Ingredient Identifier** (UNII)
  - Developed by the Food and Drug Administration (FDA)
  - Code molecular entities through their active and inactive ingredients

- **The Standards and Interoperability (S&I) Framework**
  - establish standards, specifications and other implementation guidance that facilitate effective healthcare information exchange

Investments in RWD

- Access to RWD assets is often a problem
  - Price is too high
  - Regulations restricting access
  - Monopolistic sharing

- Leads to an inefficient investments in developing RWD assets
  - Public seed funding often does not require a business case to be developed.
  - Restricting access to public RWD for for-profit entities
  - No scope for developing a competitive market on RWD assets that could bring down price.

Investments in RWD

- CMS FFS data
  - Restrictions to for-profit access
  - Recently relaxed
  - No such restriction on CMS Managed Care data

- SEER-Medicare

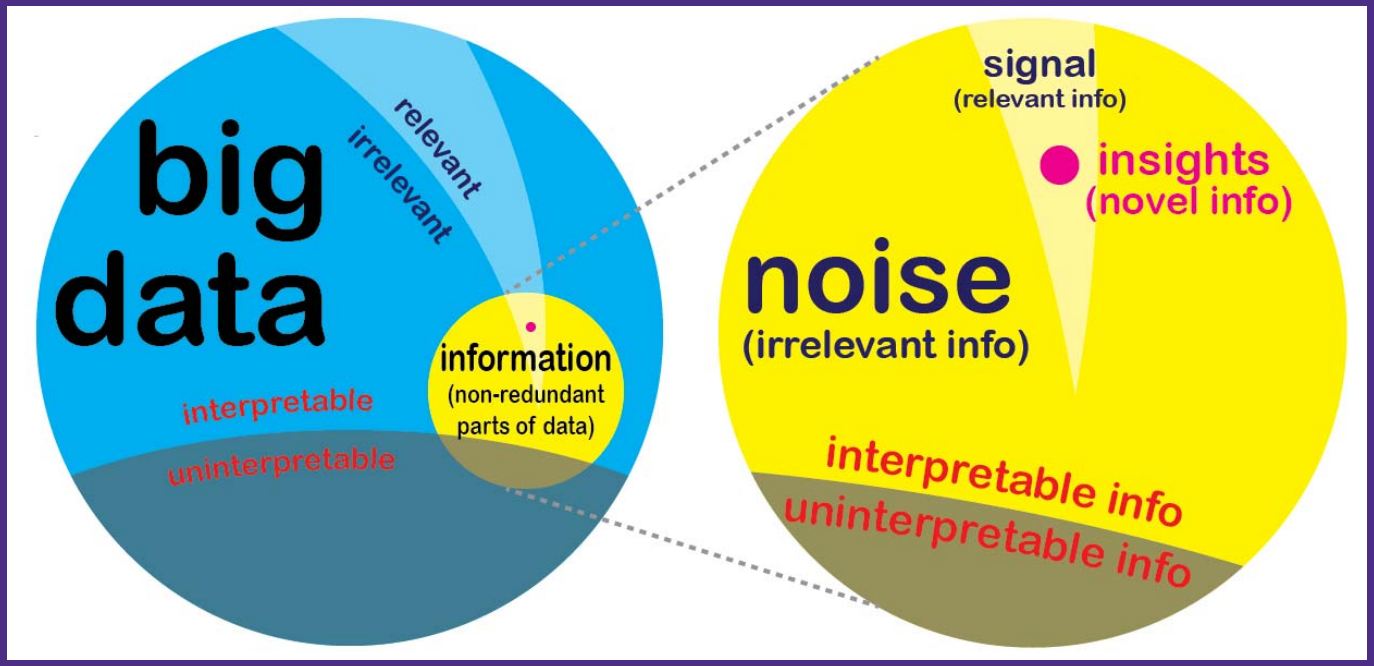
"If your organization is a consulting firm, contractor, or pharmaceutical company, then your proposal must include information about the funding source and a letter from the funder indicating that you are free to work and publish your findings without limitations by the funder"

Investments in RWD

- EMR-linked claims data
  - Some local efforts
  - Very few databases with multi-state scope (e.g. Optum, Truven)
  - Extremely high price

- Government can and should seed development of RWD assets
- Allowing business cases to develop for these assets is important
- We need competition in the RWD space

Quality Standards



- **General concerns:**
  - **Sell noise as signal by parties with vested interests**
  - **Information overload**
  - **Insufficient training by consumers**

Value of a Quality Score for RWD studies

- **BENEFITS**
  - **all stakeholders, especially those who could have difficulty assessing the technical aspects of these studies.**
  - **Everyone's studies would be held to the same standards as others.**
- **COSTS**
  - **Costs of developing such an index. Can IOM help?**
  - **Costs of applying this score to every RWD study**
    - **peer-reviewers' time commitments for these reviewers.**
    - **Clearinghouses could be developed that score published studies based on these standards.**

Market for a Quality Scoring Entity

- Are payers and other users of these studies value such ratings?
- Are they willing to pay clearinghouses for their services?
- In case such markets fail to develop, public payers may establish centralized clearinghouses to ascertain RWD study qualities, which could be disseminated as public goods.

Conclusions

- RWD are crossing into the space of Big Data.
  - appropriate use can generate precise and valid evidence on the value of both clinical and policy decisions in health care
- Reliance on RWD is growing (e.g. 21st Century Cures Act)
- Costs of producing RWD assets should be reduced
- Greater accessibility of these assets are required
- A competitive market should be fostered to bring down price.
- Creates potential for growth in biased and uninformative studies
- Quality standards to assess RW study results will be useful