

How do you introduce metadata to clinicians and researchers in health?

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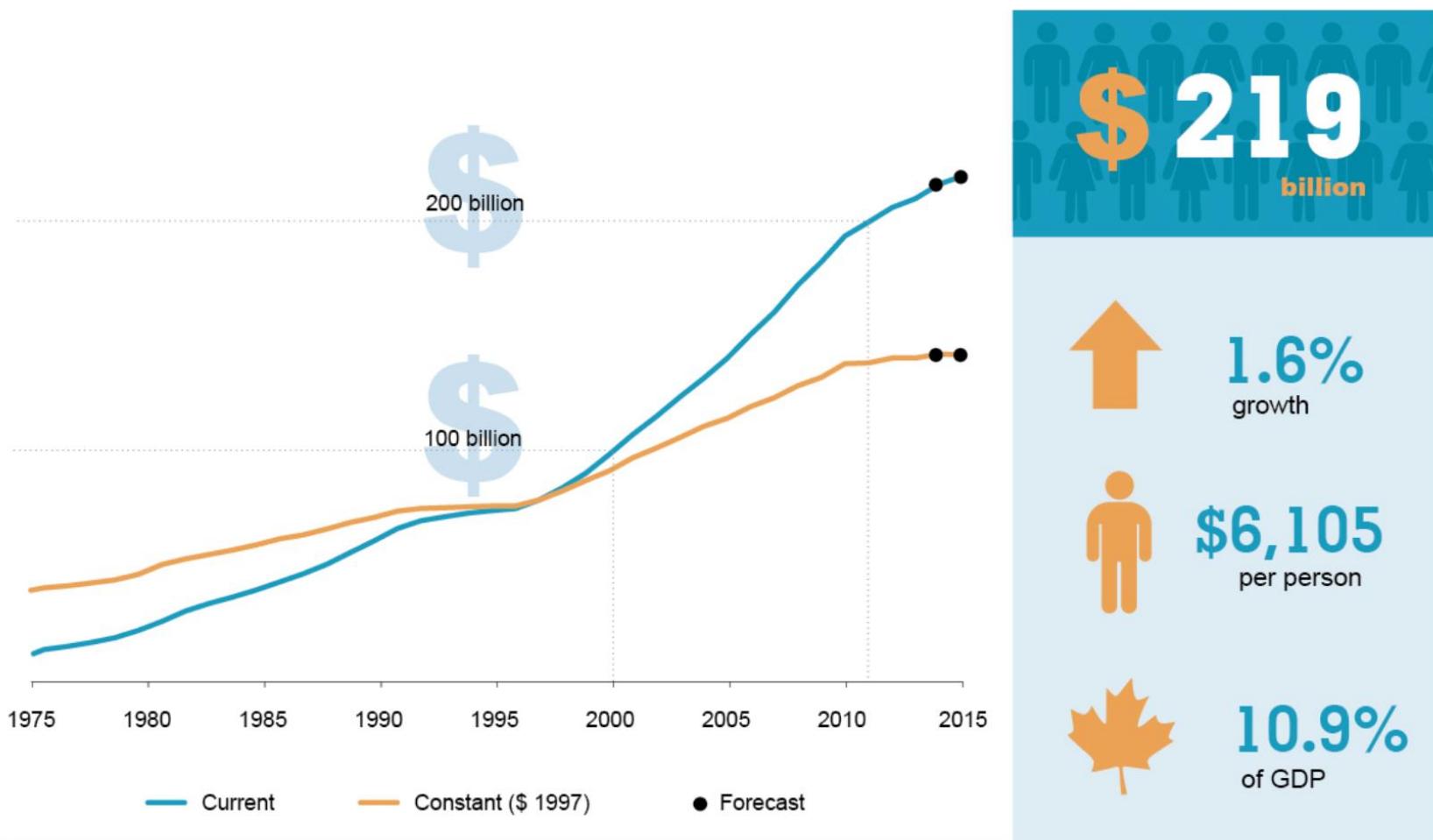
Disclosures

- I have no financial associations to disclose related to the presentation.

Objectives

- Explore current directions in health care and research that are requiring increasing degrees of data interoperability
- Explore the challenge of data ‘interoperability’
- Review opportunities to engage with clinicians and health researchers regarding the importance of metadata / data documentation

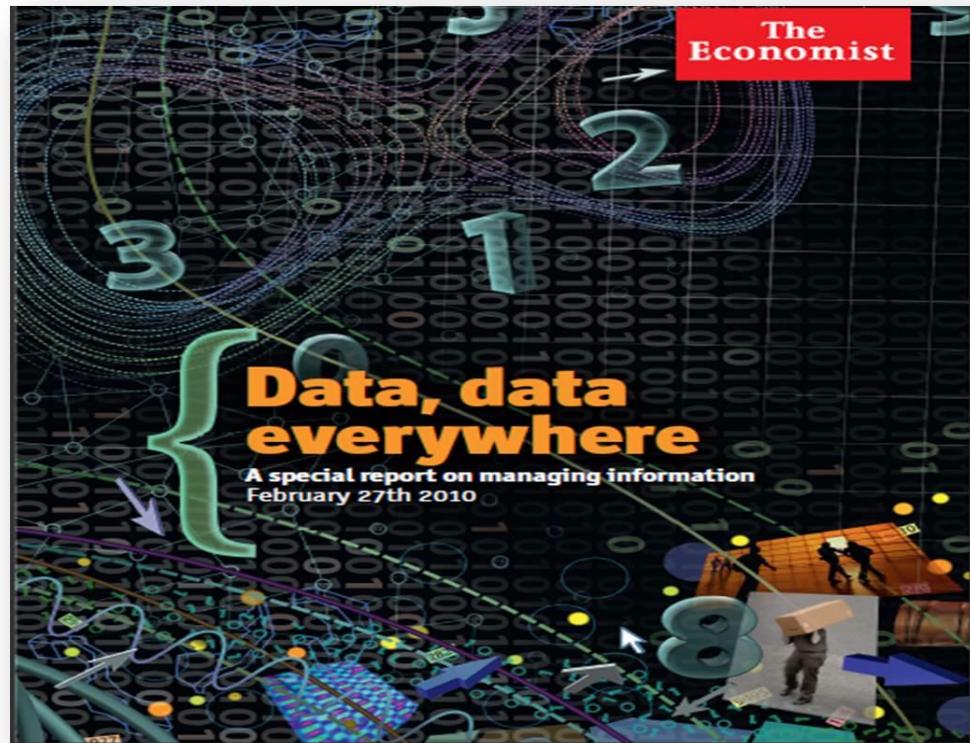
How much will we spend on health in 2015?



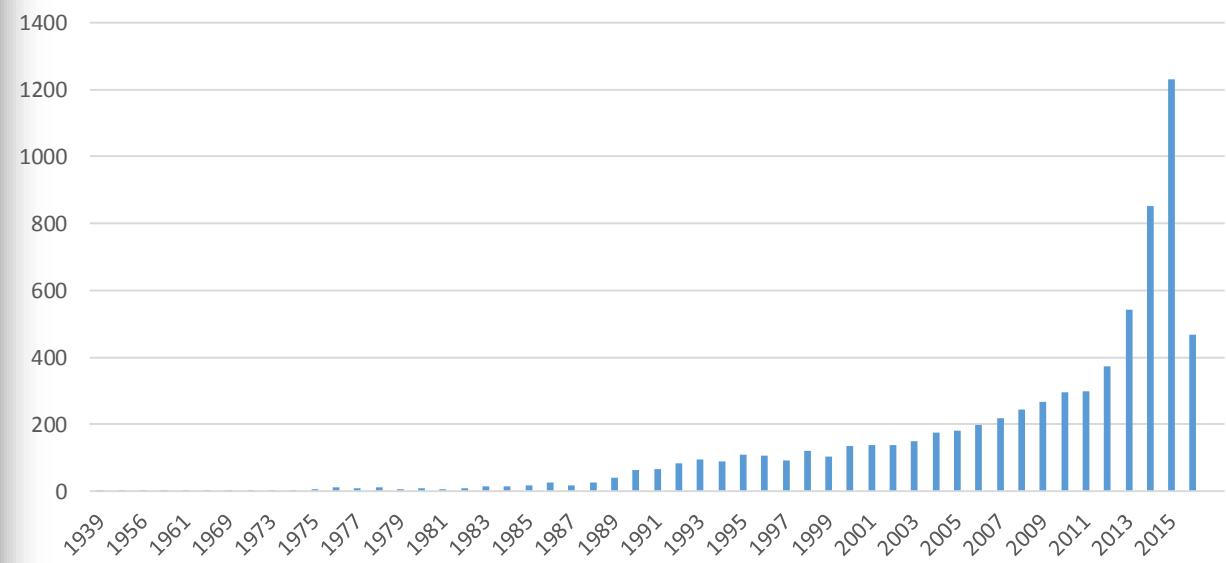
Source

National Health Expenditure Database, Canadian Institute for Health Information.





Number of published articles mentioning 'big data' in the title, abstract, or keywords over time



<http://www.ncbi-nlm-nih.gov.login.ezproxy.library.ualberta.ca/pubmed/?term=big+data>

Since 2001, **Canada Health Infoway** has received
\$2.1 billion

77% of primary care physicians now use an EMR

99.9% of diagnostic x-rays, MRIs, CTs in hospitals are digital

88% of lab test results are now digital

\$1.5 billion
an estimate of the cost of implementing an EMR province wide in Alberta

Health Information Technology for Economic and Clinical Health (HITECH) Act in the US spent more than **\$27 billion** to encourage hospitals and providers to adopt EHRs

Health data in Alberta – is it big data?

- Sum total health data in AHSDRR (including vital stats and claims)
 - 2.3 billion records
 - 800 GB



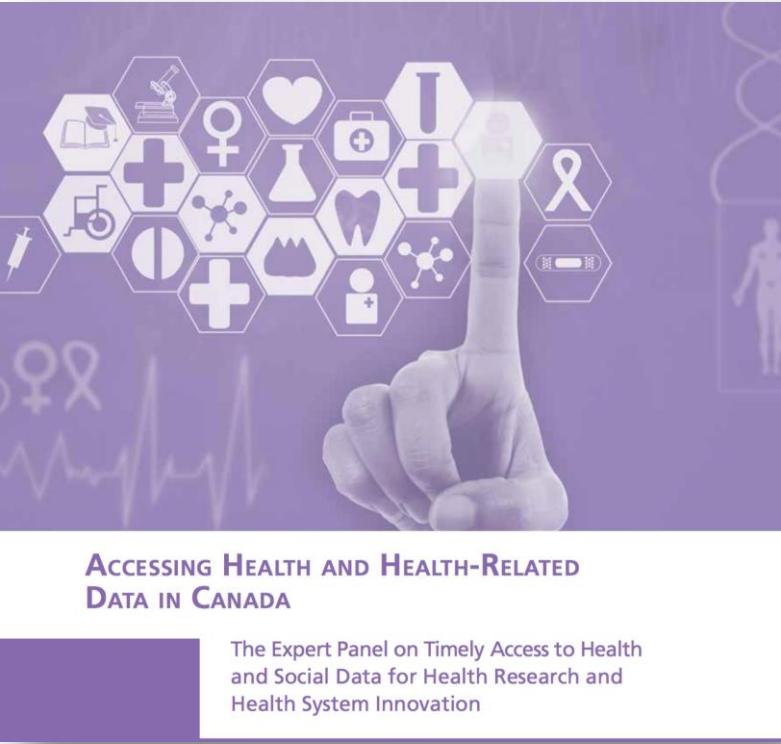
Personal communication from DIMR, Oct 2015

There is a certain and urgent need for standards and best practices in the implementation of EMRs and planning for the capture, management, and use of health data not only to document care delivery, but also to improve care and advance knowledge.

‘Steps’ to secondary use of health data

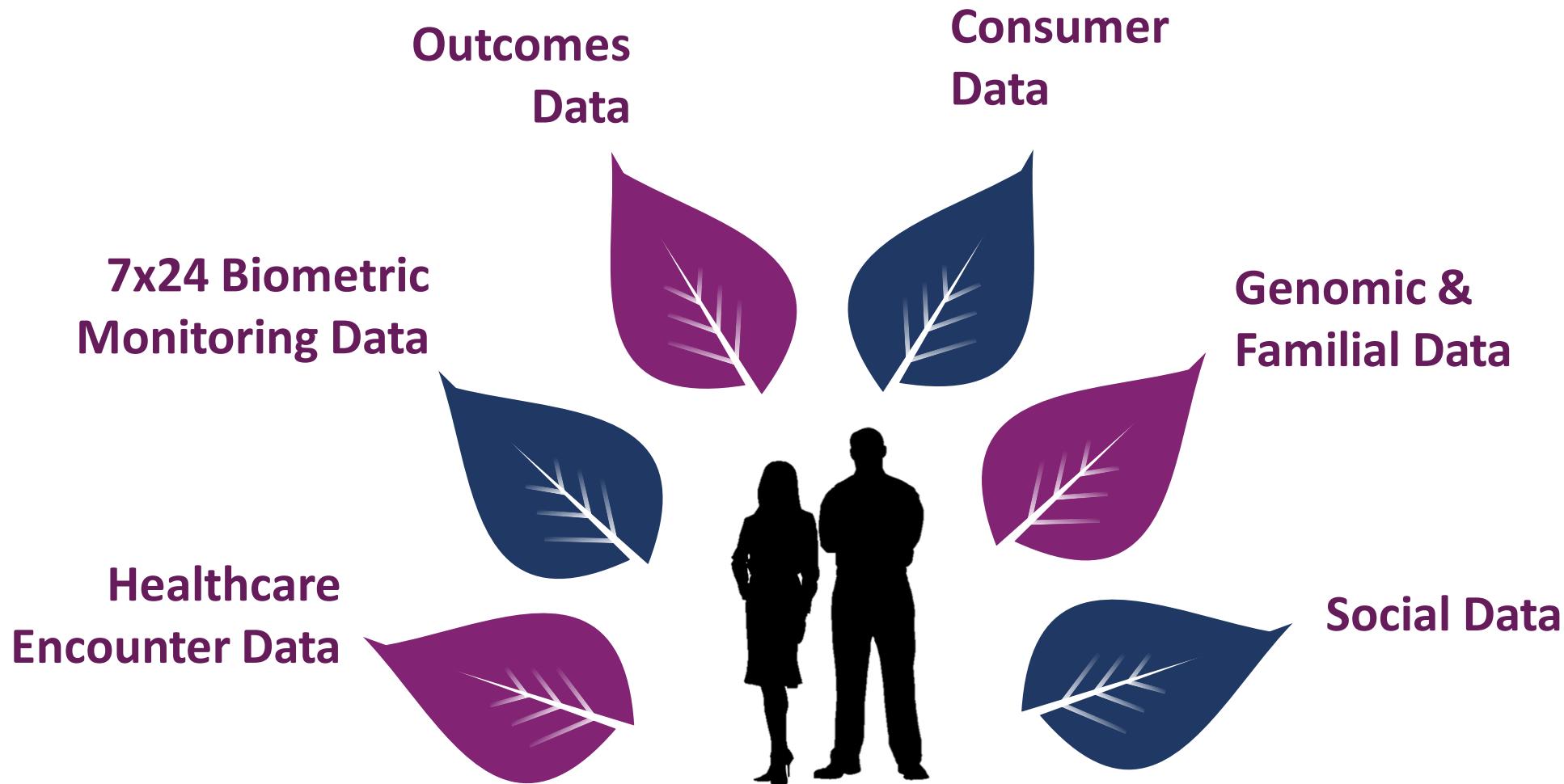
1. Access to the data
2. Understand the data
3. Integrate the data
 1. Across systems
 2. Across jurisdictions
4. Use the data to create information, insight, and knowledge
 1. By mixing it with more data
 2. Using it in new research paradigms

Access to health and health-related data

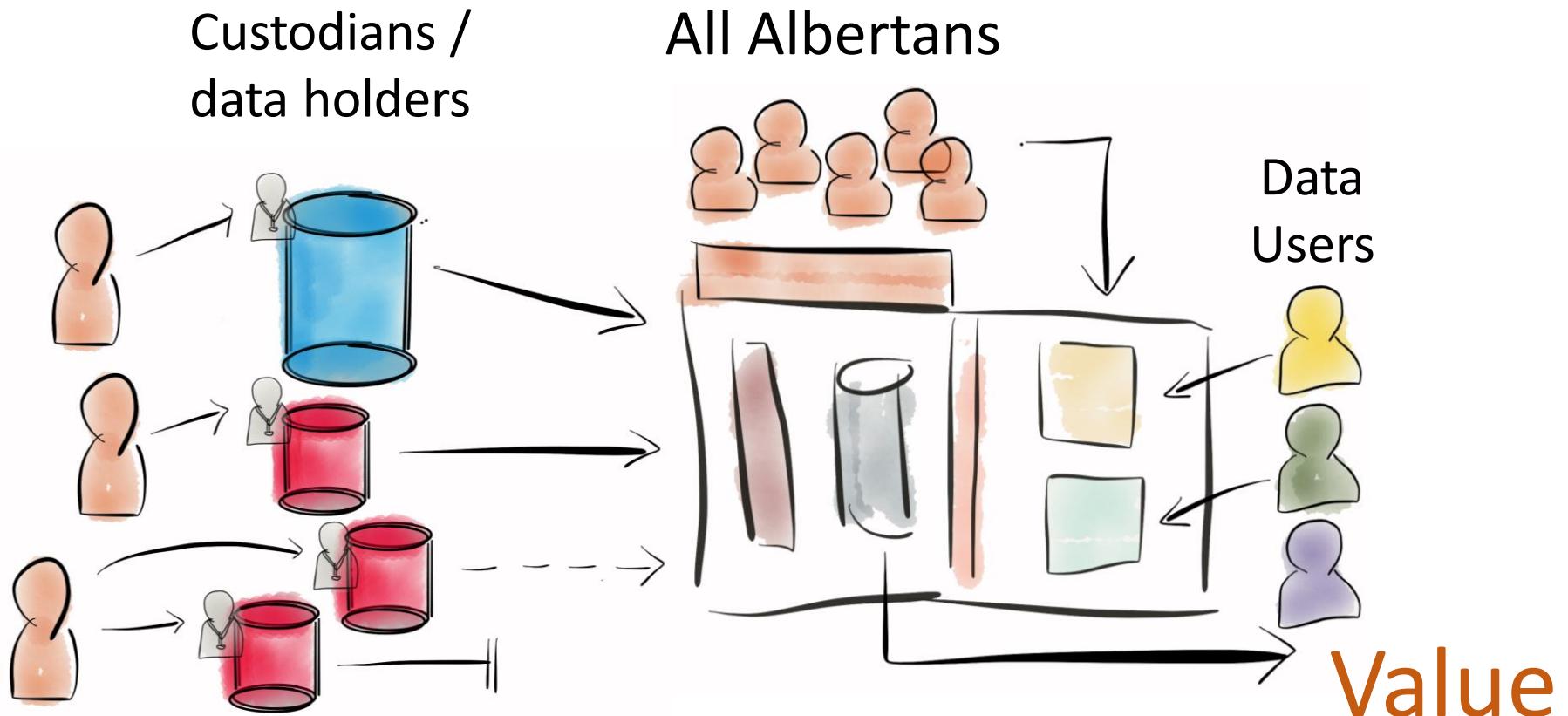


- For effective research with health and health-related data, disparate sources of data must be brought together. Providing these data in an “analysis-ready” format, thereby allowing statistical relationships or patterns to be derived, is a central methodological challenge.
- Evidence shows that timely access to data enables significant high-quality research that can have far-reaching effects for health care and the overall health of Canadians.
- The risk of potential harm resulting from access to data is tangible but low. The level of risk can be further lowered through effective governance mechanisms.
- Timely access to data is hindered by variable legal structures and differing interpretations of the terms identifiable and de-identified across jurisdictions. Instead of rigidly classifying data as either identifiable or non-identifiable, it is useful to view de-identification as a continuum and to adjust access controls accordingly.
- Evidence demonstrates that a shift is occurring among leading entities from a “data custodianship” model to a “data stewardship” model. Central to the success of this shift is the adoption of good governance practices, specifically in privacy governance, research governance, information governance, and network governance.

Alberta Secondary Use Data Project



Individual Albertans interacting
with health and other systems



Understand the data

Health care data is different

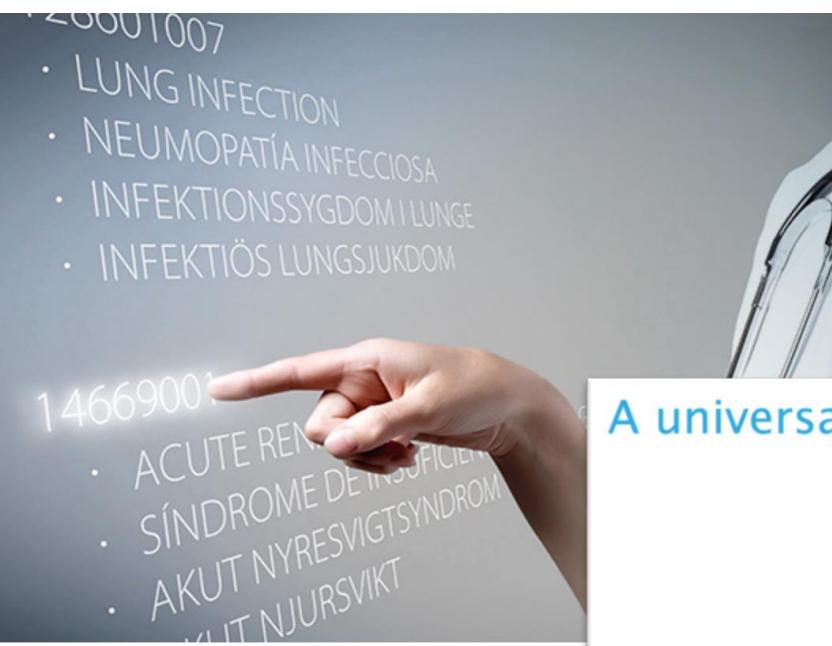
- Privacy and the regulatory environment
- Multiple sources
 - Collected at point of care
- Structured and unstructured
 - ‘Rigid’ data collection systems vs. ‘free form’ text
- Terminology and data definitions vary
 - Continually evolving standards
- Data is complex and will only become more complex
 - New technology → new data sources

WHY HEALTHCARE DATA IS DIFFICULT



SNOMED CT
The global language
of healthcare

ihtsdo
Delivering
SNOMED CT



A universal code system for tests, measurements,
and observations.

How do you say glucose?



Clinical terminology is one of the keys to true
interoperability between systems and integrating data

How to explain this to a clinician?

- Data documentation and management strategies employed in research should be used in the implementation of EMRs

*Begin with
the end in
mind*

*Meaningful
use*

Meaningful Use (as defined in the US)

- Improve care coordination
- Reduce healthcare disparities
- Engage patients and their families
- Improve population and public health
- Ensure adequate privacy and security

What are we trying to achieve?

Integrate disparate data to:

1

Improve the quality of care provided to every patient, on a personal level

2

Reduce the cost of delivering high quality care

3

Improve the overall health of the community while reducing the overall economic drain of poor health on the community

4

Accelerate the pace of clinical research

Integrate data across systems
(and jurisdictions)

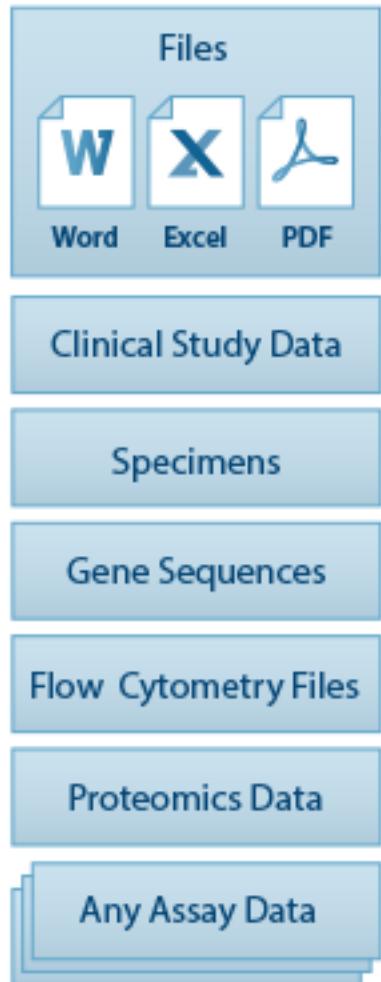
Data integration and interoperability are critical to the evolving need to use ‘big data’ and real-world evidence to inform and improve practice and enable cost effective research to close the evidence gap.

Make it easy!



- Easy to use web-based electronic data collection system
- Simple interface to develop online forms
- Data dictionary created as data collection forms are designed
- Data and metadata may be ‘consumed’ by other systems through the API

Integrate



Analyze

LabKey Server

Data Repository

Data Integration

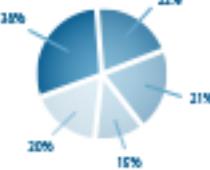
Security

Auditing

Visualizations



Reports / Data



API

R
Javascript
SQL
SAS
Perl
Java

Collaborate



Scientists



Collaborators



Statisticians,
Programmers

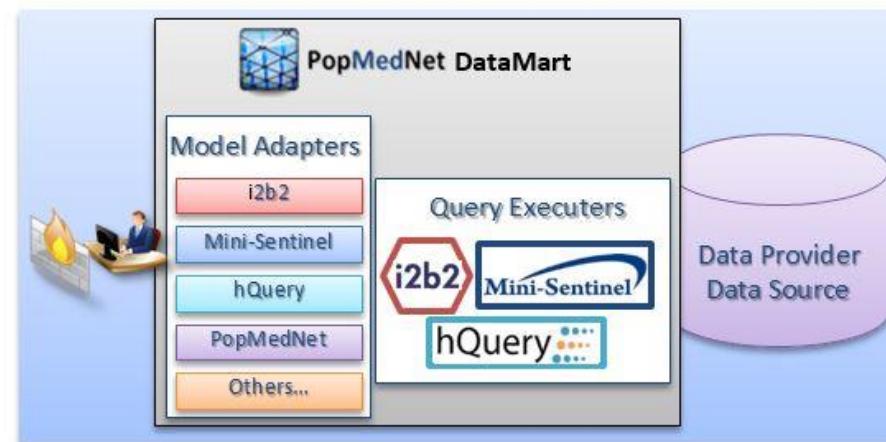
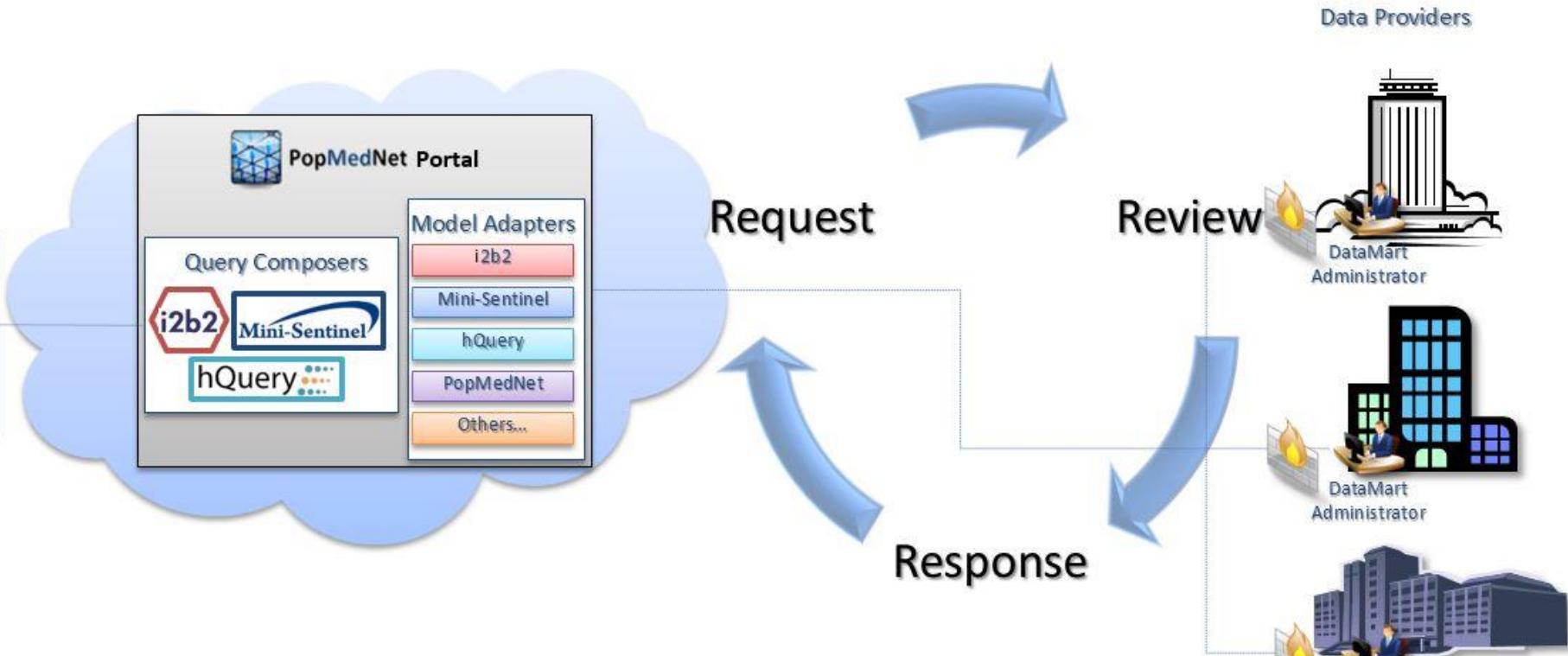


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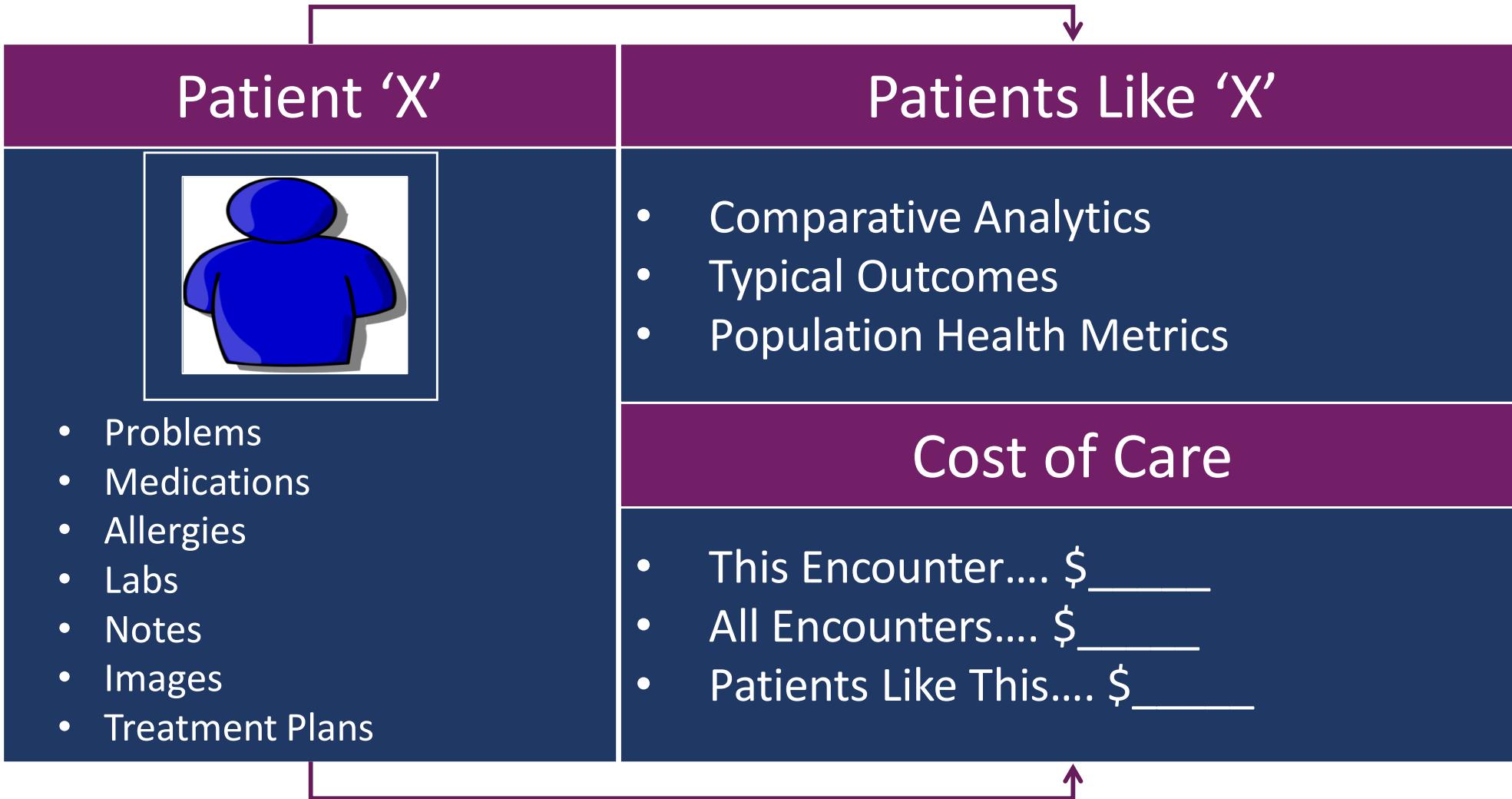
- Investigator
- Enhanced Investigator
- Observer



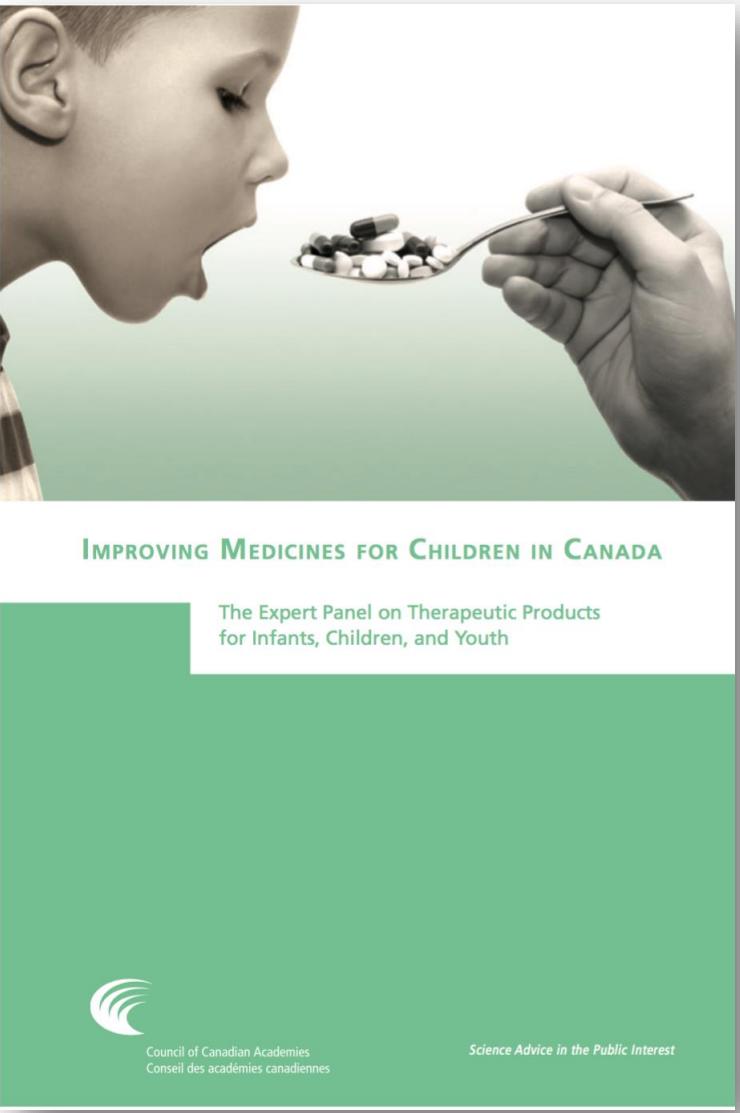


... a vision of the future with completely data-integrated and informed care delivery

Closed Loop Analytics: Next Gen EMR



Use the data



IMPROVING MEDICINES FOR CHILDREN IN CANADA

The Expert Panel on Therapeutic Products
for Infants, Children, and Youth



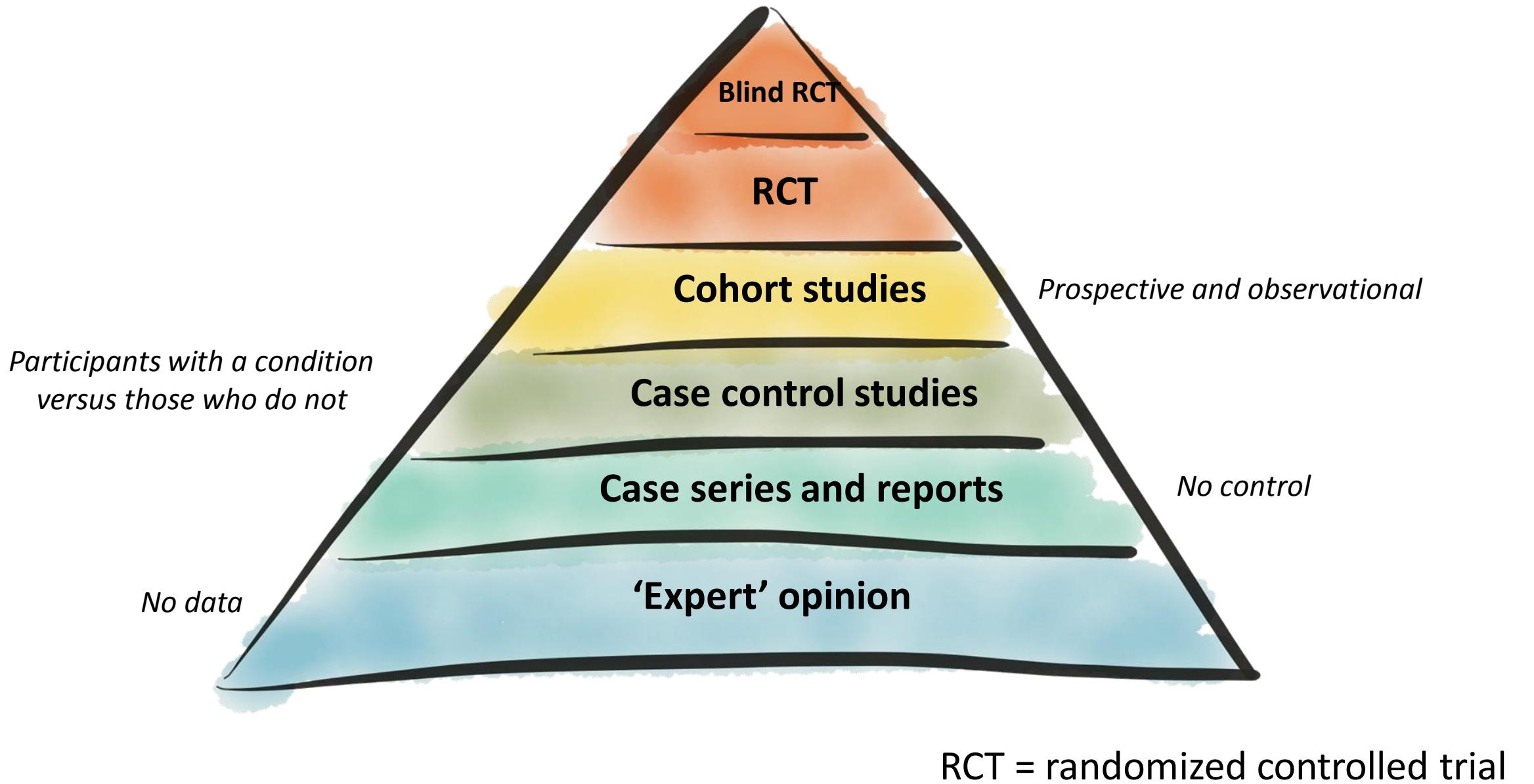
Council of Canadian Academies
Conseil des académies canadiennes

Science Advice in the Public Interest

*Up to 80% of medications used
in children have not been tested
in children*

*Less than 25% of guidelines in
cardiology have high level
evidence to support the
guideline*

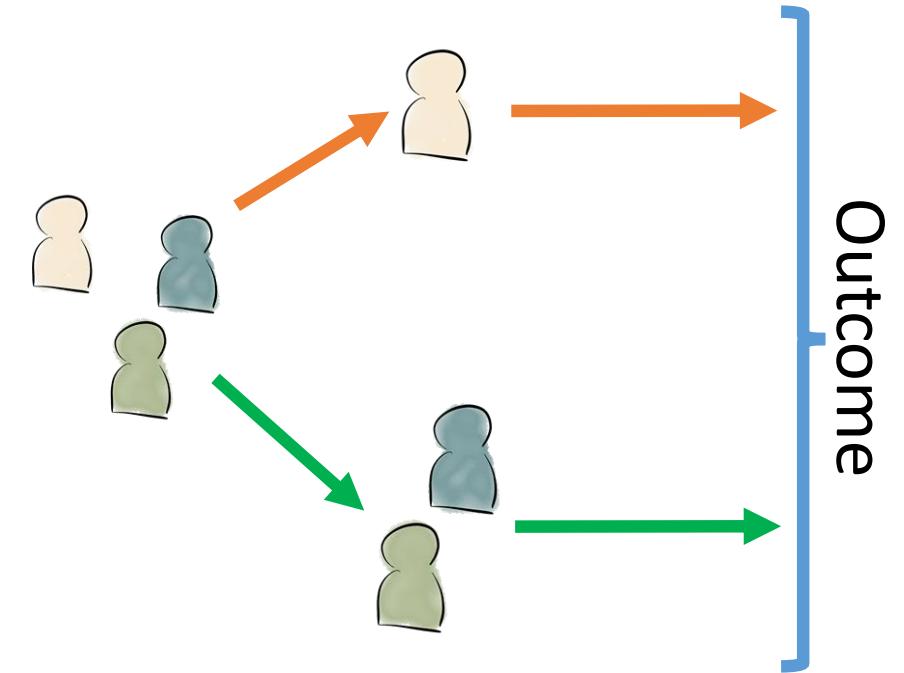
*Drug safety monitoring relies
entirely on voluntary reporting*

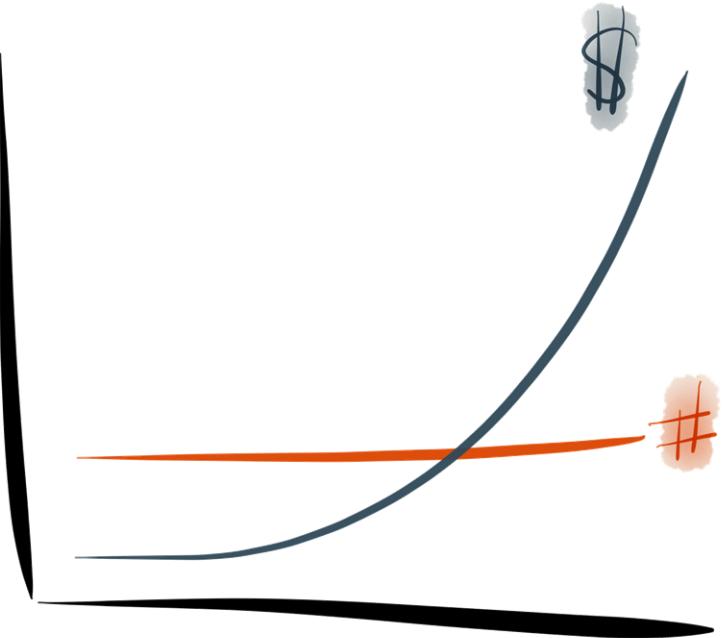




Randomized controlled trials

- Gold standard method to assess efficacy
 - Select patient population
 - Limited duration of follow-up
- Often ‘ideal’ conditions
 - Actual prescribing practice much more variable





*In 2015 – the cost of
developing a new drug was
\$2.5 billion dollars*



Tufts Center for
the
Study of Drug Development

TUFTS UNIVERSITY

Tufts
UNIVERSITY

School of
Medicine

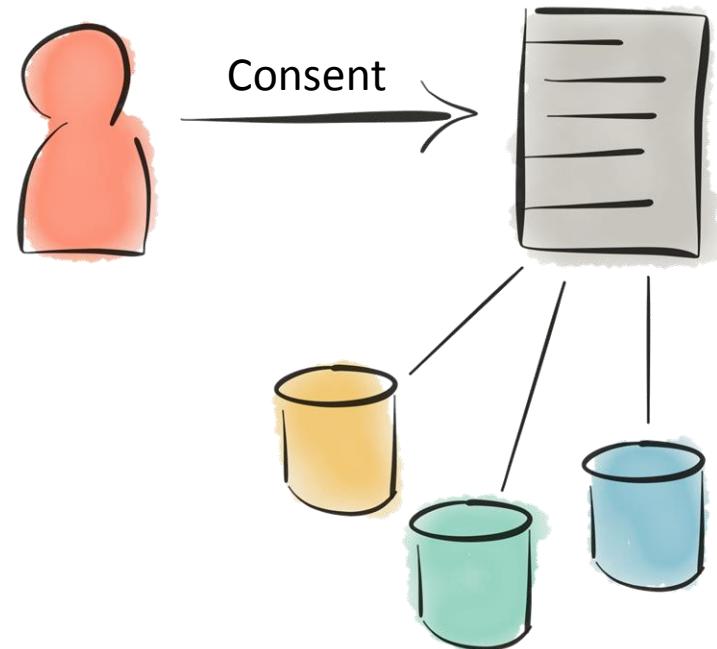
New directions in health research

- Real world evidence, registries, and pragmatic clinical trials
- Big data - the reuse of data to provide audit and practice feedback
- Precision medicine and deep phenotyping

Pragmatic Clinical Trials and Real World Evidence

How can existing data be used in trials?

- Cohort identification
 - Permission to contact
- Safety surveillance beyond the trial
- Enriched baseline and outcome assessment
 - Actual costs of care, social determinants
 - How does the study population relate to the ‘real’ population of interest?
- Modelling ‘what if’ scenarios on ‘real world’ data





Adaptable

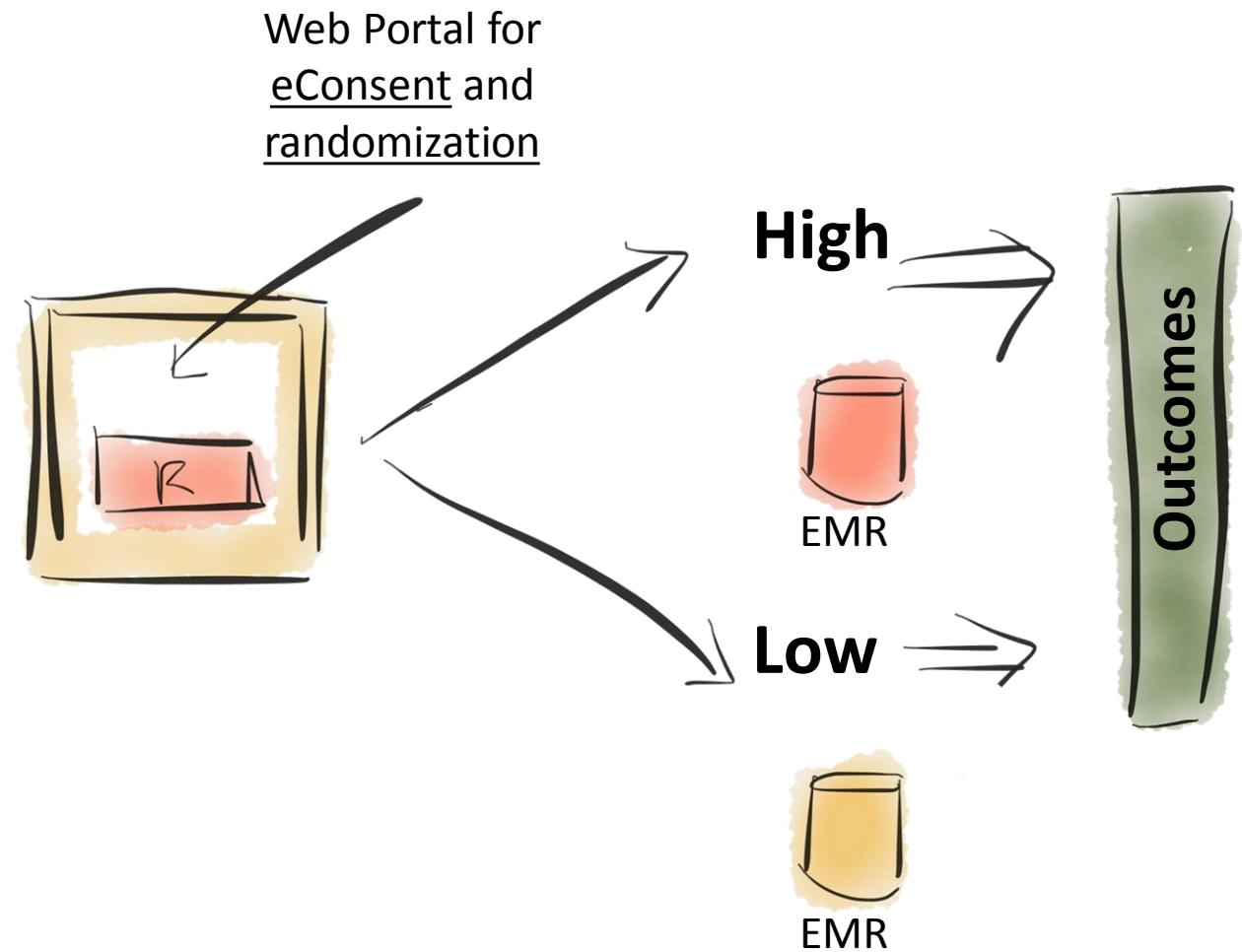
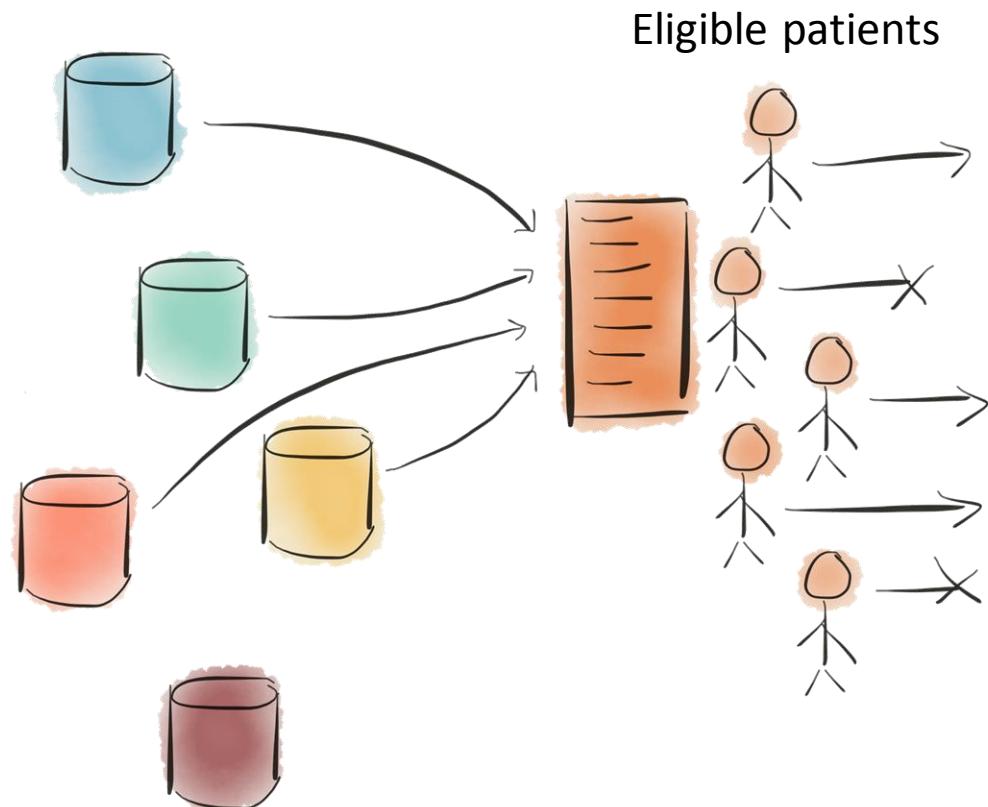
The Aspirin Study

- ADAPTABLE (Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness)
 - compare the effectiveness of two daily doses of aspirin
 - could prevent as many as 88,800 deaths per year around the world
- Adaptable is considered a pragmatic trial.
 - Pragmatic trials are designed to reflect “real-world” medical practice, with the actual work of the study taking place in a variety of clinical settings and amongst a broad patient population.
 - Pragmatic trials use input from health systems and produce results that can be readily used to improve patient care.
 - Pragmatic trials have been benefiting health care for decades. The polio vaccine studies in the 1950s and early aspirin studies for the treatment of acute heart attacks in the 1980s and 1990s are examples of pragmatic research.



Adaptable

The Aspirin Study



230 million vs. 17 million

‘Real World’ Outcomes



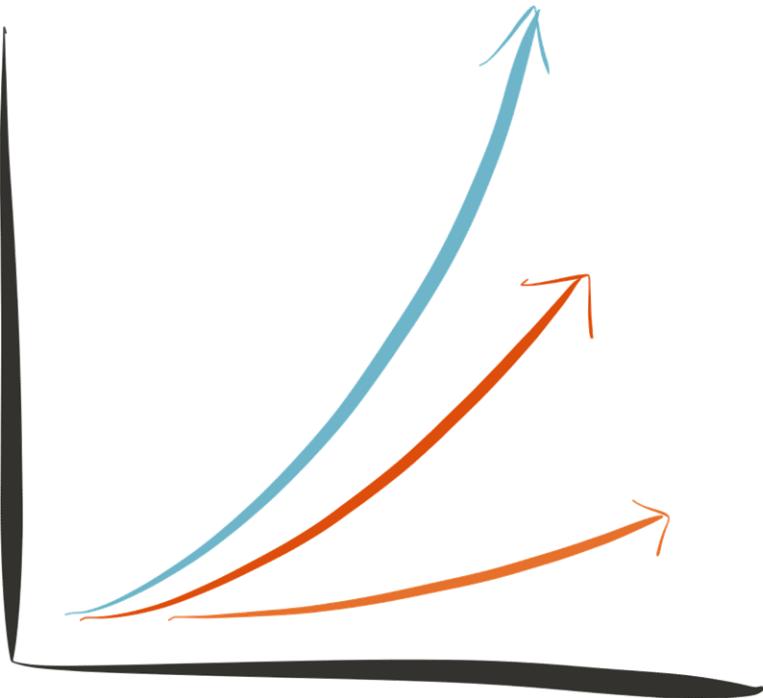
- Studies (messy) real world experience
- Faster and much less expensive than experimental studies
 - Data accrued in other research (e.g. clinical trials) can be re-examined
 - Often can be performed when controlled trials are simply not possible
- May detect unexpected phenomena or subpopulations
- Even when not statistically definitive
 - Can refine questions and hypotheses
 - Identify potential recruits
 - Inform the design of future experimental research



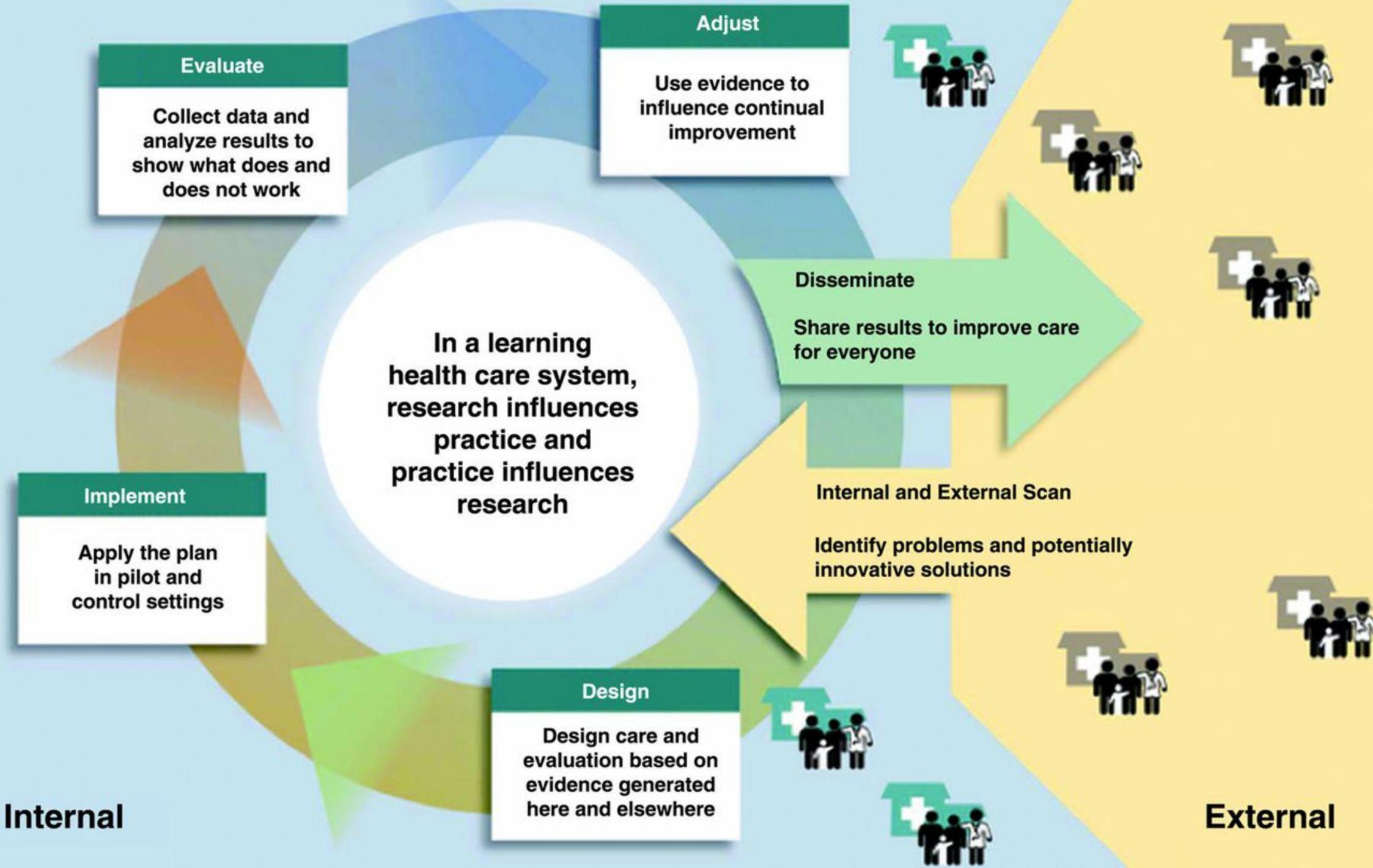
- Active surveillance system for monitoring drugs, using electronic data from healthcare information holders.
- FDA has used administrative and insurance claims databases to investigate safety questions about Agency-regulated products, but generally it has only worked with one particular healthcare system at a time to evaluate a given safety issue.
- Its goal now is to create a linked, sustainable system--which FDA calls the Sentinel System--that will draw on existing automated healthcare data from multiple sources to actively monitor the safety of medical products continuously and in real-time.
- Establishing a long-term, sustainable system raises many questions of great public interest, including issues about governance, privacy, data standards and public availability of results. For this reason, Sentinel's development will require considerable stakeholder participation.

Quality Care = Reduction in Variation

Ability to create data > capacity to use data



- Research and analytics
 - Statistical analysis and modelling
 - Mid level of “data and analytic maturity”
- Data integrated culture
 - All administrative, clinical, and operational decisions are informed by data
 - High level of “data and analytic maturity”

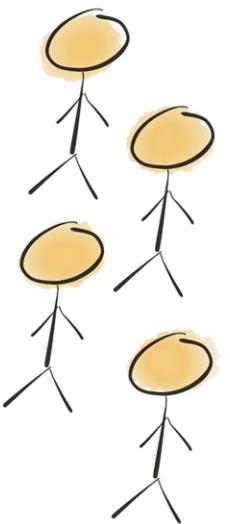
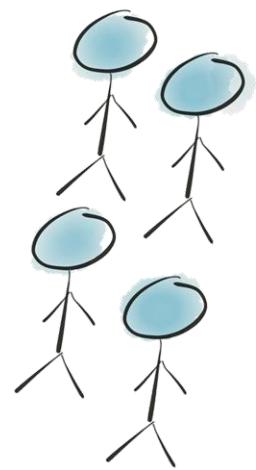
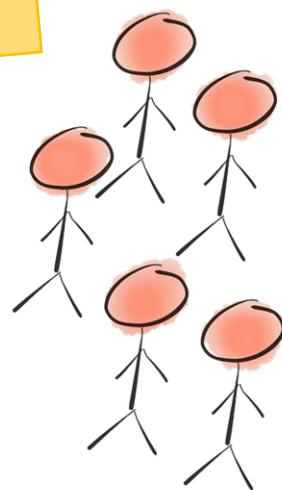
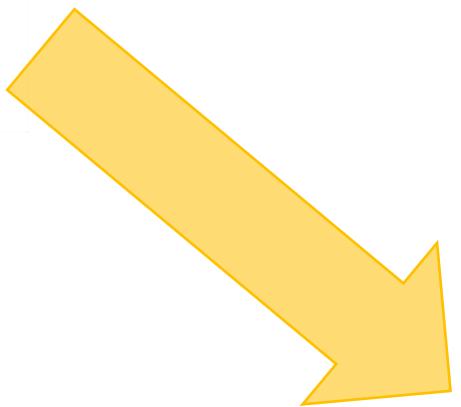
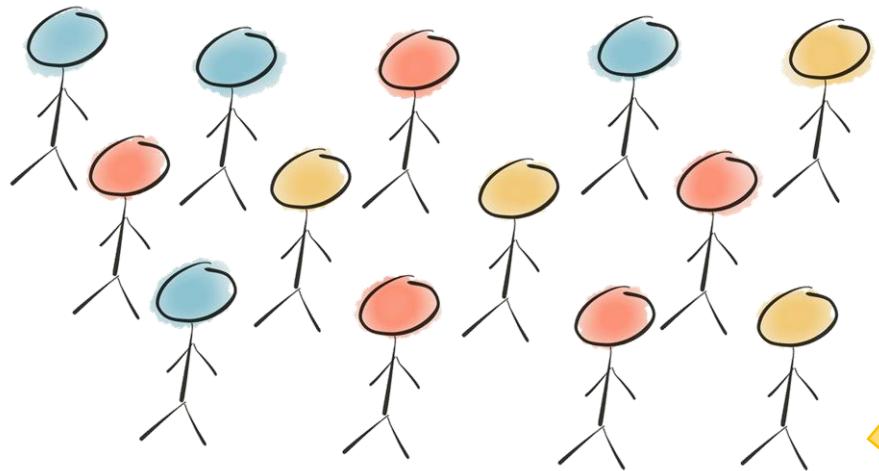


Aspirational Healthcare

Imagine if your physician could say this to you:

"I can make a health optimization recommendation to you, informed not only by the latest clinical trials, but also by our local and regional data about patients like you; the real-world health outcomes over time of every patient like you who has had your illness, and over time of every patient every patient like you who has had your illness, and the level of your interest in the real-world health outcomes, the level of your interest own care -- and in turn I can tell you within a specified range of confidence, which treatment has the greatest chance of success for a patient specifically like you like you and how much that treatment will cost."

Source – Dale Sanders, Health Analytics



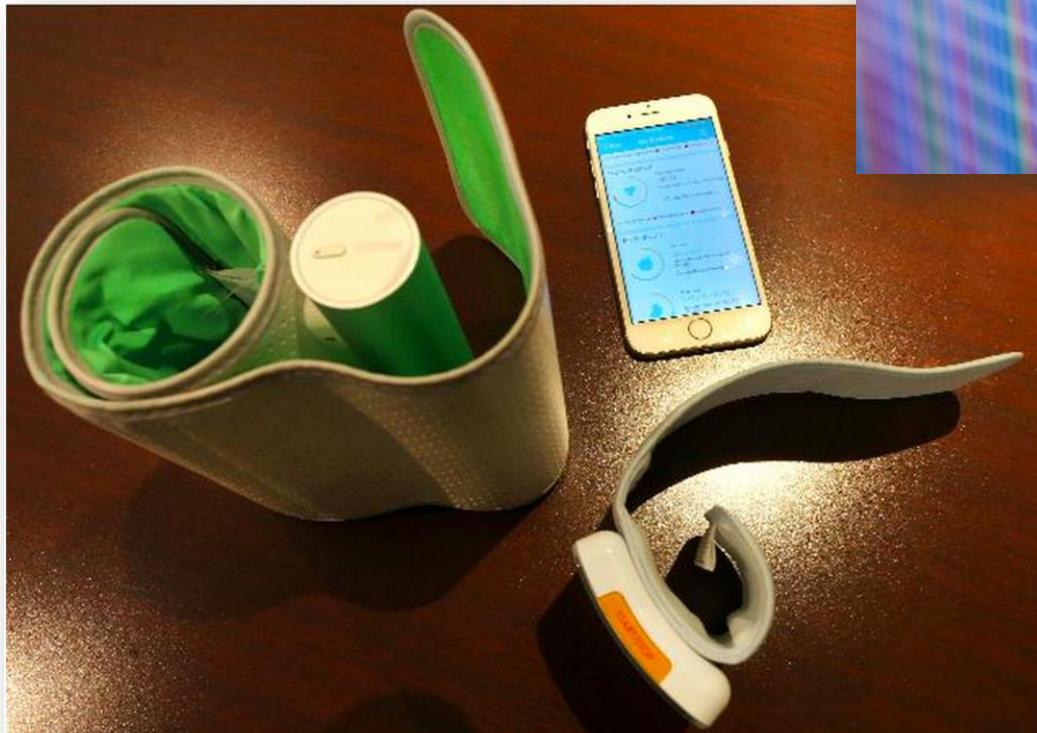
Personalized, Precision Medicine



Genotype associations

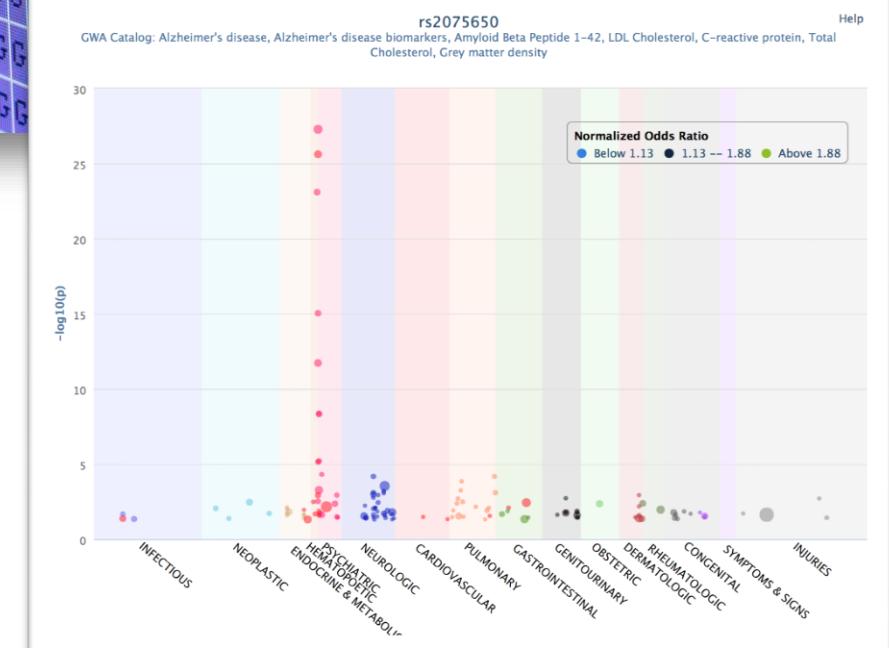


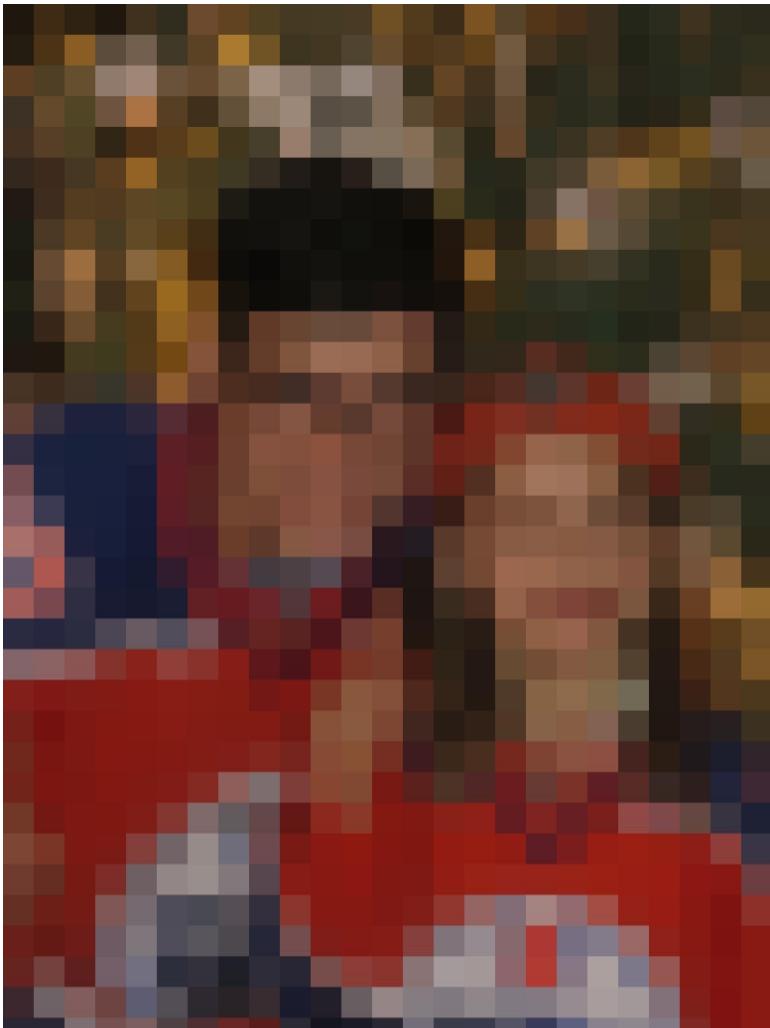
Ambulatory monitoring



Wearable blood pressure monitors send data to a smartphone app, then off to the doctor. (Photo by John Thumacki/The Boston Globe via Getty Images)

Phenotype associations





Summary

- Data is at the heart and only hope to reduce the cost of health care and improve health outcomes
- Data integration and interoperability across formats, sources, and systems is critical to realizing the potential for the secondary use of health data to transform health care
- New paradigms in research rely on existing data and allow for more cost effective designs
- The aspirational goal of treating individuals (not the average) is at the heart of precision medicine and dependent on rich and diverse data sources for ‘deep’ phenotyping