CONNECTING FOR HEALTH
COMMON FRAMEWORK

Resources for Implementing Private and Secure Health Information Exchange

National Committee on Vital and Health Statistics

July 17th, 2007

Carol C Diamond MD, MPH
Managing Director, Health
Markle Foundation
Chair, Connecting for Health

Key Points

1. Time to reset our definitions and assumptions about health data
2. Need to articulate new, broadly accepted working principles
3. Need to develop an information policy framework that broadly addresses public hopes and concerns

Connecting for Health…*A Public Private Collaborative*

- Convened and operated by the Markle Foundation since 2002
- Works to accelerate the development of a health information-sharing environment to improve the quality and cost effectiveness of health care
- Brings together private, public, and not-for-profit groups
- http://www.connectingforhealth.org

Areas of Focus

1. Technology Standards and Adoption
2. Policy Framework for Successful Implementation
3. Role of the Consumer

They all matter and they are all necessary

Our Journey

- Connecting for Health Roadmap June 2004:
  - decentralized and open standards-based information network
  - proposed a “Common Framework” of privacy and technology attributes that accepts and encourages local variation and innovation while achieving interoperability and portability across geographic regions
  - based on a framework of privacy and built on a model of trust

- In April 2006, CFH Common Framework was fully documented and tested in a prototype implementation in Boston, Indianapolis and Mendocino County, California.

Connecting for Health Now Focusing on Population Health

- CFH recognizes vital role of data derived from populations for research, quality measurement, public health
- In extensive interviews, serious concerns about current approach in each sector
- Yet a shared vision ...

Common vision from diverse leaders

"Research should be a normative part of health care...every intervention with a patient is a chance to learn something"

"The data must be incorporated with decision support and re-measurement not an episodic hiccup of a data dump"

"I have been saying this for 20 years...where is the feedback loop folks?"

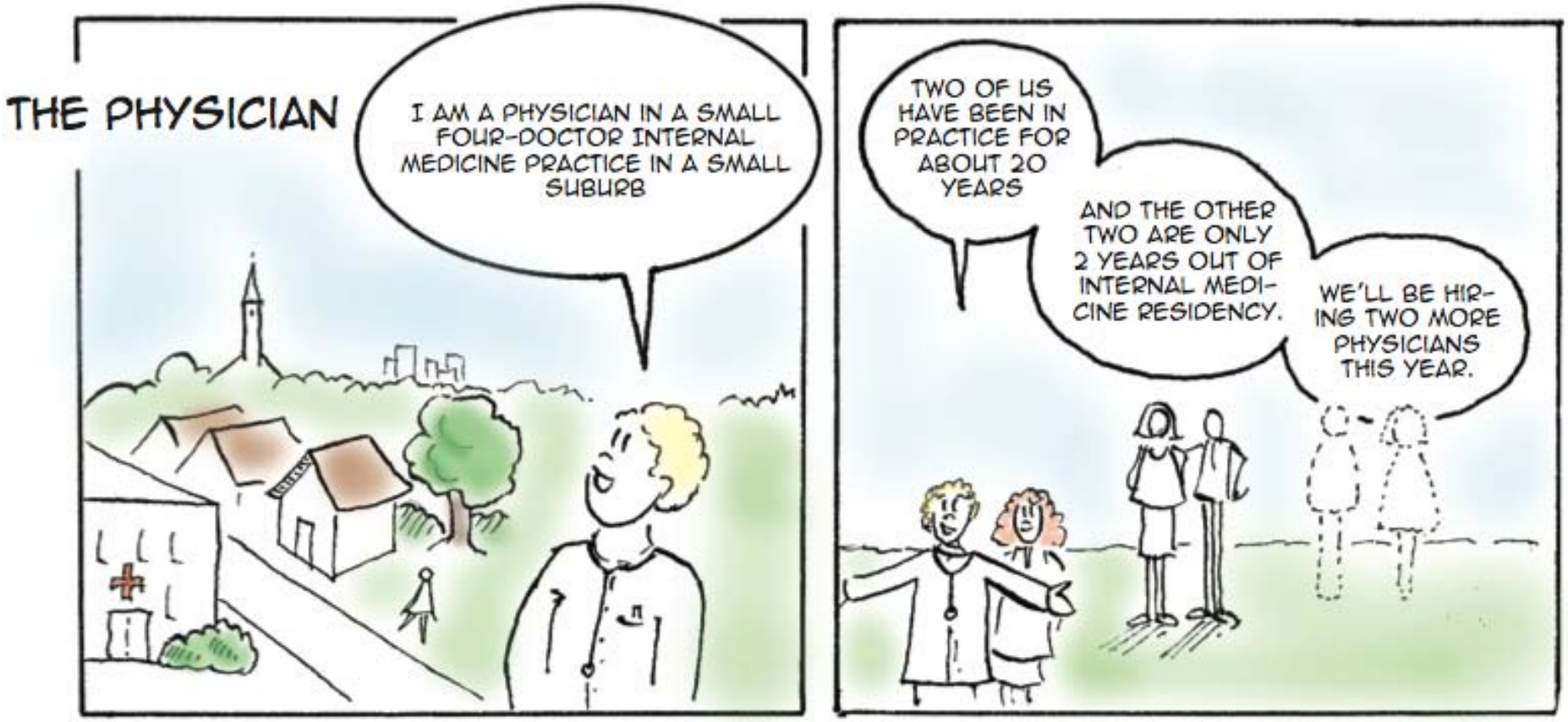
"The only way to improve a process is to extract information from that process and send it back to the person"

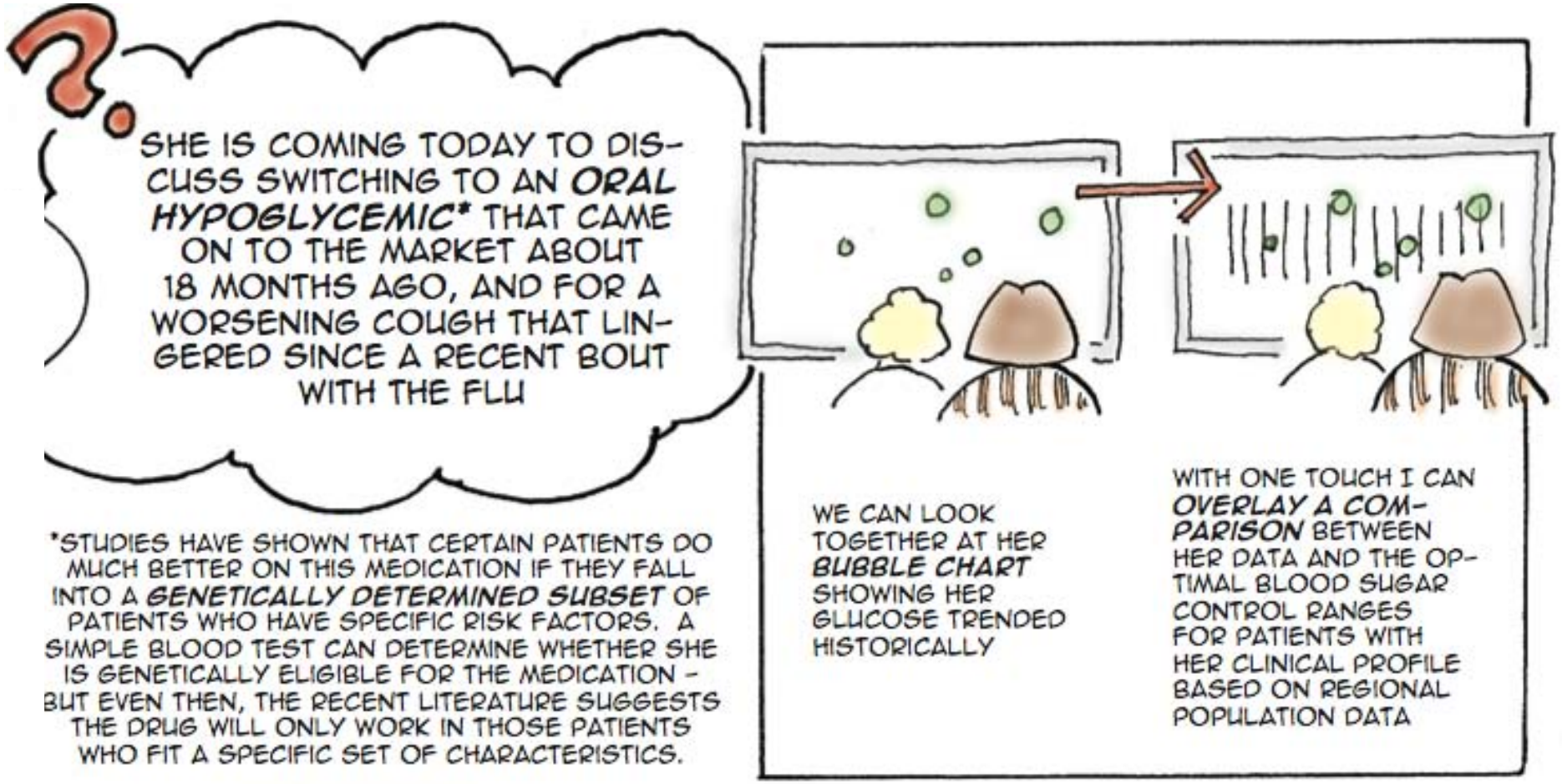
The point of population health is to make better clinical decisions at the point of care

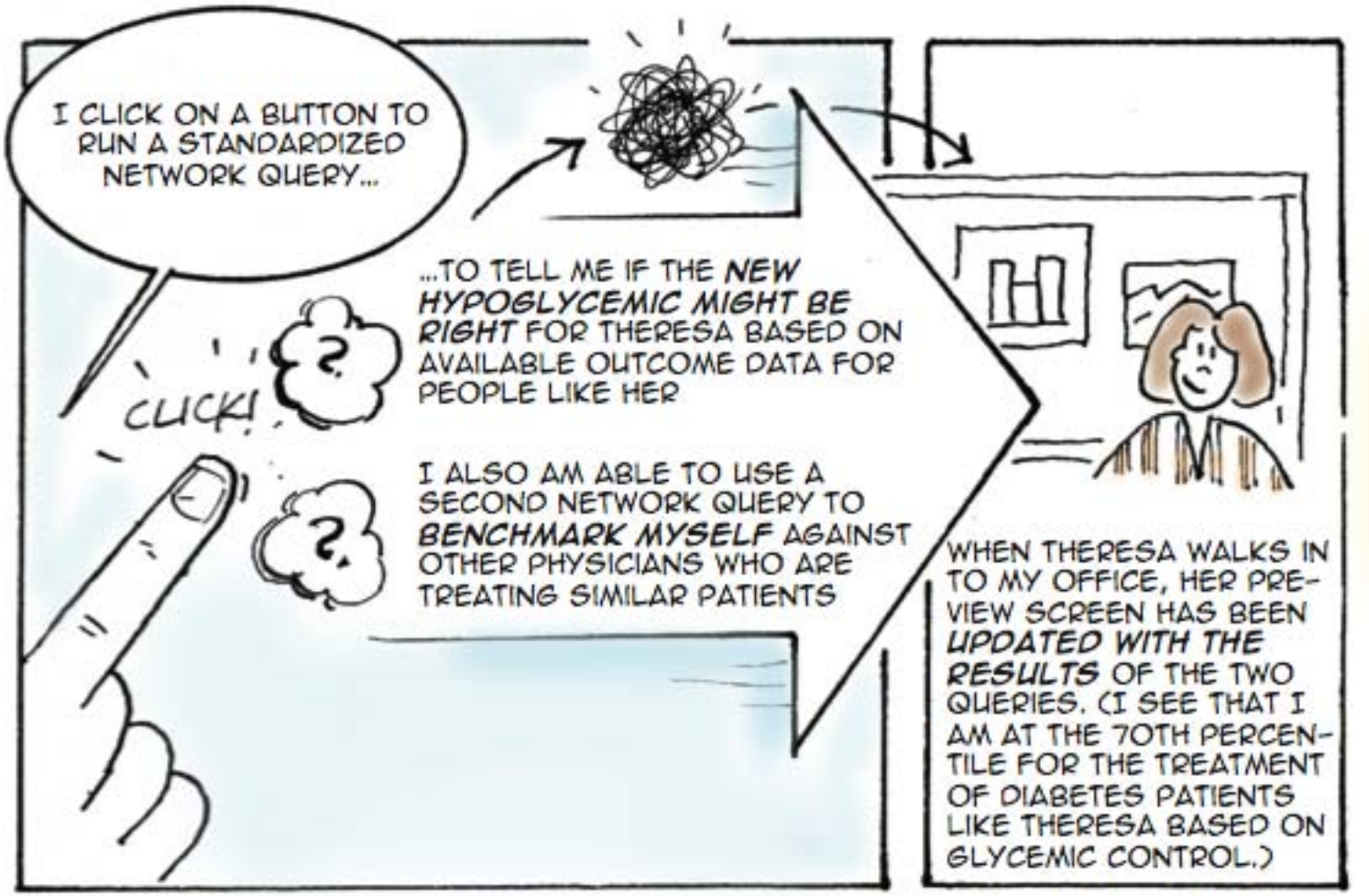
"In the past 50 years we have made substantial progress in understanding the biology of disease and in devising new ways to prevent or treat it. However, there has been a substantial lag in applying what we know to actual patient care."

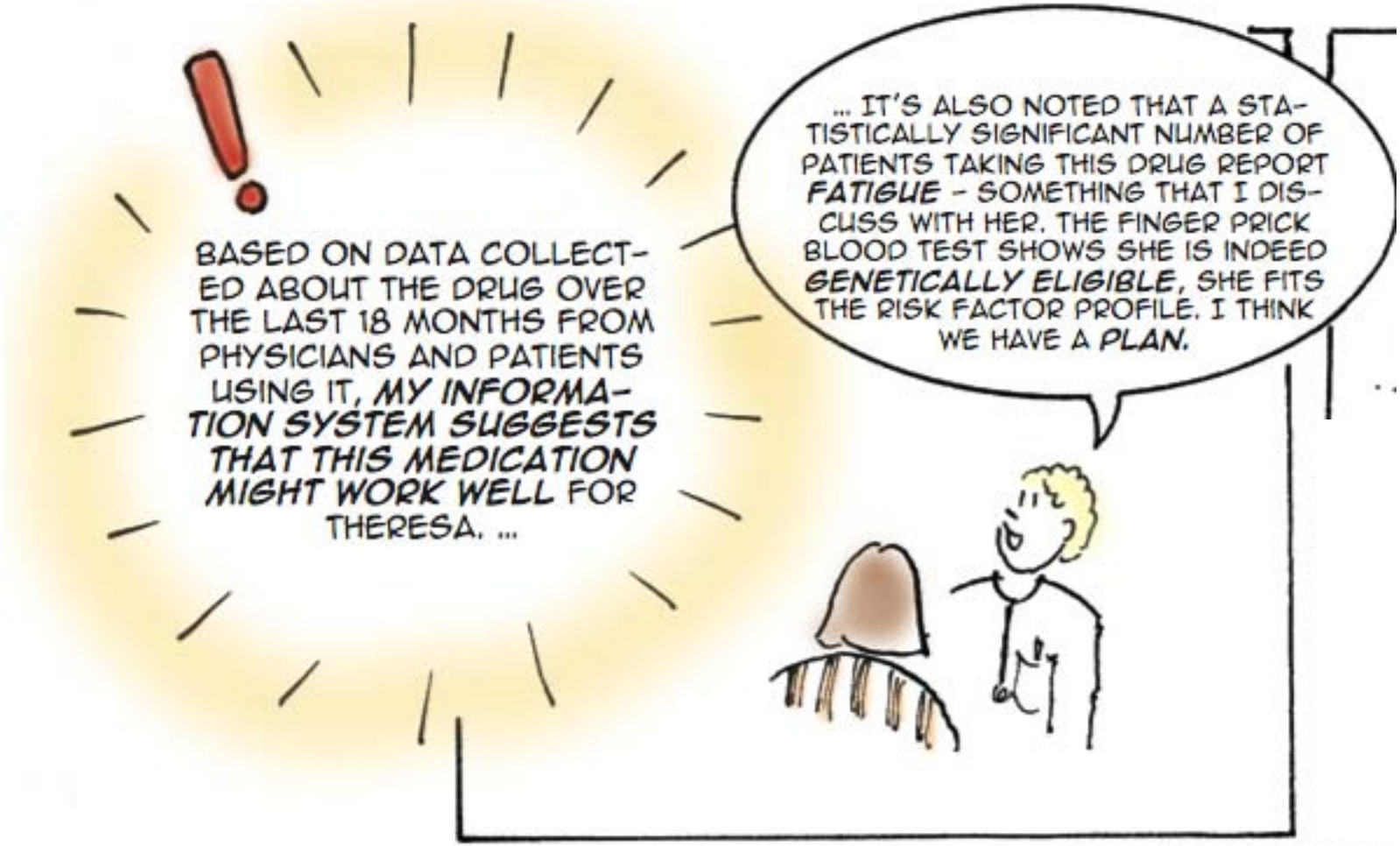
Claude Lenfant
Clinical Research to Clinical Practice -- Lost in Translation?

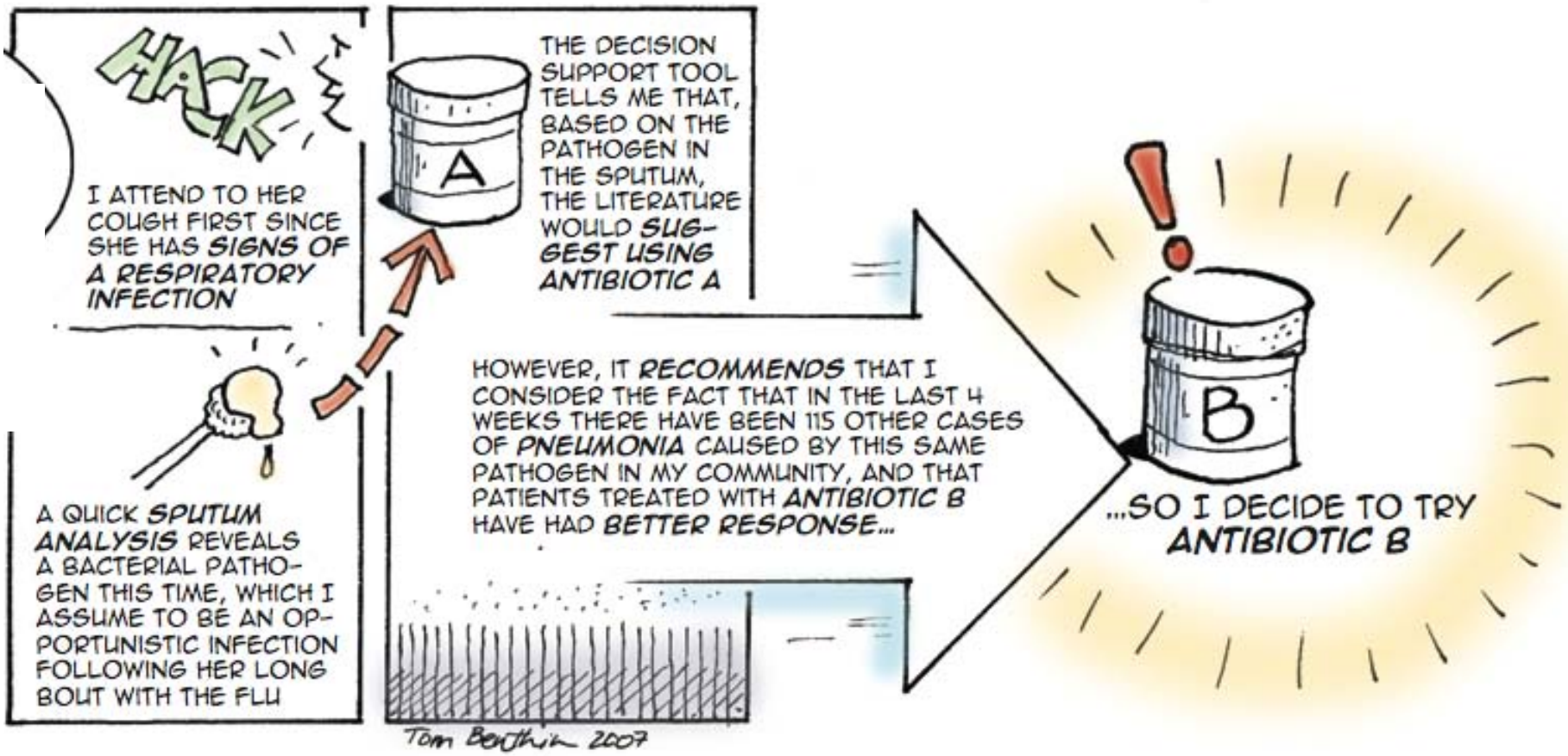
N Engl J Med 2003 349: 868-874


THE PHYSICIAN
I AM A PHYSICIAN IN A SMALL FOUR-DOCTOR INTERNAL MEDICINE PRACTICE IN A SMALL SUBURB
TWO OF US HAVE BEEN IN PRACTICE FOR ABOUT 20 YEARS
AND THE OTHER TWO ARE ONLY 2 YEARS OUT OF INTERNAL MEDICINE RESIDENCY.
WE'LL BE HIRING TWO MORE PHYSICIANS THIS YEAR.


SHE IS COMING TODAY TO DISCUSS SWITCHING TO AN ORAL HYPOGLYCEMIC* THAT CAME ON TO THE MARKET ABOUT 18 MONTHS AGO, AND FOR A WORSENING COUGH THAT LINGERED SINCE A RECENT BOUT WITH THE FLU
*STUDIES HAVE SHOWN THAT CERTAIN PATIENTS DO MUCH BETTER ON THIS MEDICATION IF THEY FALL INTO A GENETICALLY DETERMINED SUBSET OF PATIENTS WHO HAVE SPECIFIC RISK FACTORS. A SIMPLE BLOOD TEST CAN DETERMINE WHETHER SHE IS GENETICALLY ELIGIBLE FOR THE MEDICATION – BUT EVEN THEN, THE RECENT LITERATURE SUGGESTS THE DRUG WILL ONLY WORK IN THOSE PATIENTS WHO FIT A SPECIFIC SET OF CHARACTERISTICS.
WE CAN LOOK TOGETHER AT HER BUBBLE CHART SHOWING HER GLUCOSE TRENDED HISTORICALLY
WITH ONE TOUCH I CAN OVERLAY A COMPARISON BETWEEN HER DATA AND THE OPTIMAL BLOOD SUGAR CONTROL RANGES FOR PATIENTS WITH HER CLINICAL PROFILE BASED ON REGIONAL POPULATION DATA


I CLICK ON A BUTTON TO RUN A STANDARDIZED NETWORK QUERY...
...TO TELL ME IF THE NEW HYPOGLYCEMIC MIGHT BE RIGHT FOR THERESA BASED ON AVAILABLE OUTCOME DATA FOR PEOPLE LIKE HER
CLICK!
I ALSO AM ABLE TO USE A SECOND NETWORK QUERY TO BENCHMARK MYSELF AGAINST OTHER PHYSICIANS WHO ARE TREATING SIMILAR PATIENTS
WHEN THERESA WALKS IN TO MY OFFICE, HER PREVIEW SCREEN HAS BEEN UPDATED WITH THE RESULTS OF THE TWO QUERIES. (I SEE THAT I AM AT THE 70TH PERCENTILE FOR THE TREATMENT OF DIABETES PATIENTS LIKE THERESA BASED ON GLYCEMIC CONTROL.)

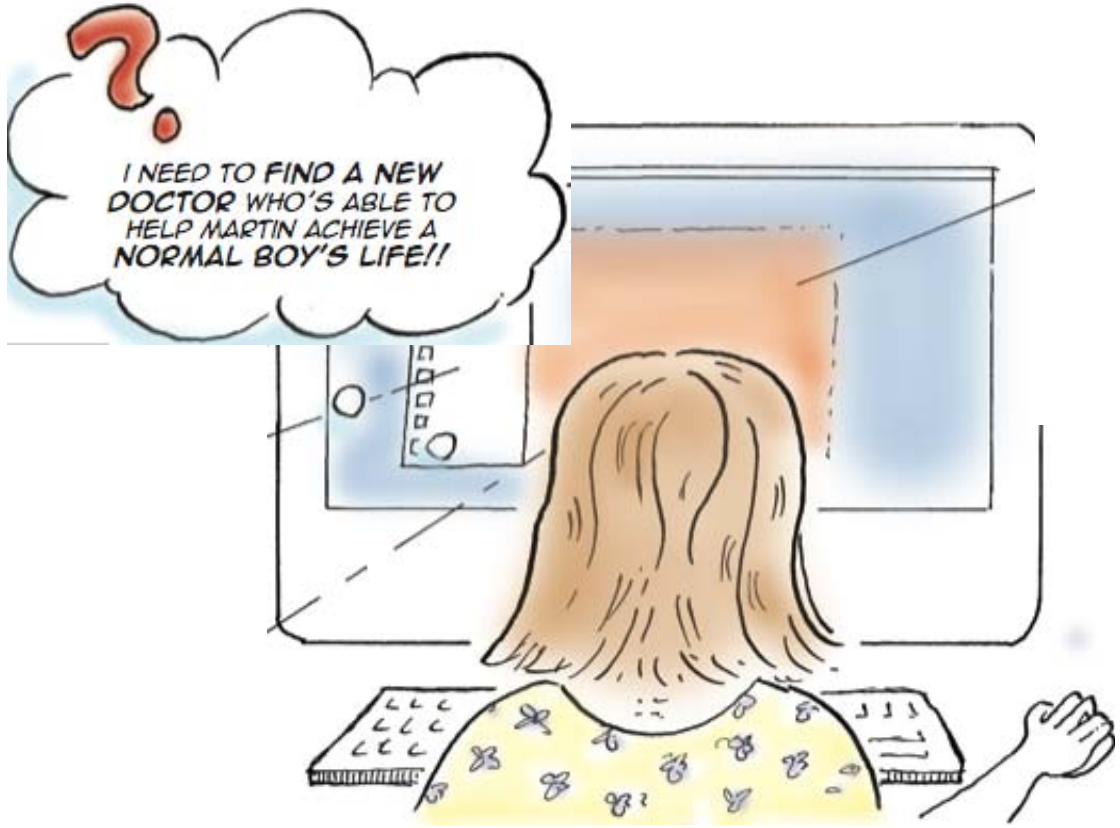

BASED ON DATA COLLECTED ABOUT THE DRUG OVER THE LAST 18 MONTHS FROM PHYSICIANS AND PATIENTS USING IT, MY INFORMATION SYSTEM SUGGESTS THAT THIS MEDICATION MIGHT WORK WELL FOR THERESA. ...
... IT'S ALSO NOTED THAT A STATISTICALLY SIGNIFICANT NUMBER OF PATIENTS TAKING THIS DRUG REPORT FATIGUE - SOMETHING THAT I DISCUSS WITH HER. THE FINGER PRICK BLOOD TEST SHOWS SHE IS INDEED GENETICALLY ELIGIBLE, SHE FITS THE RISK FACTOR PROFILE. I THINK WE HAVE A PLAN.

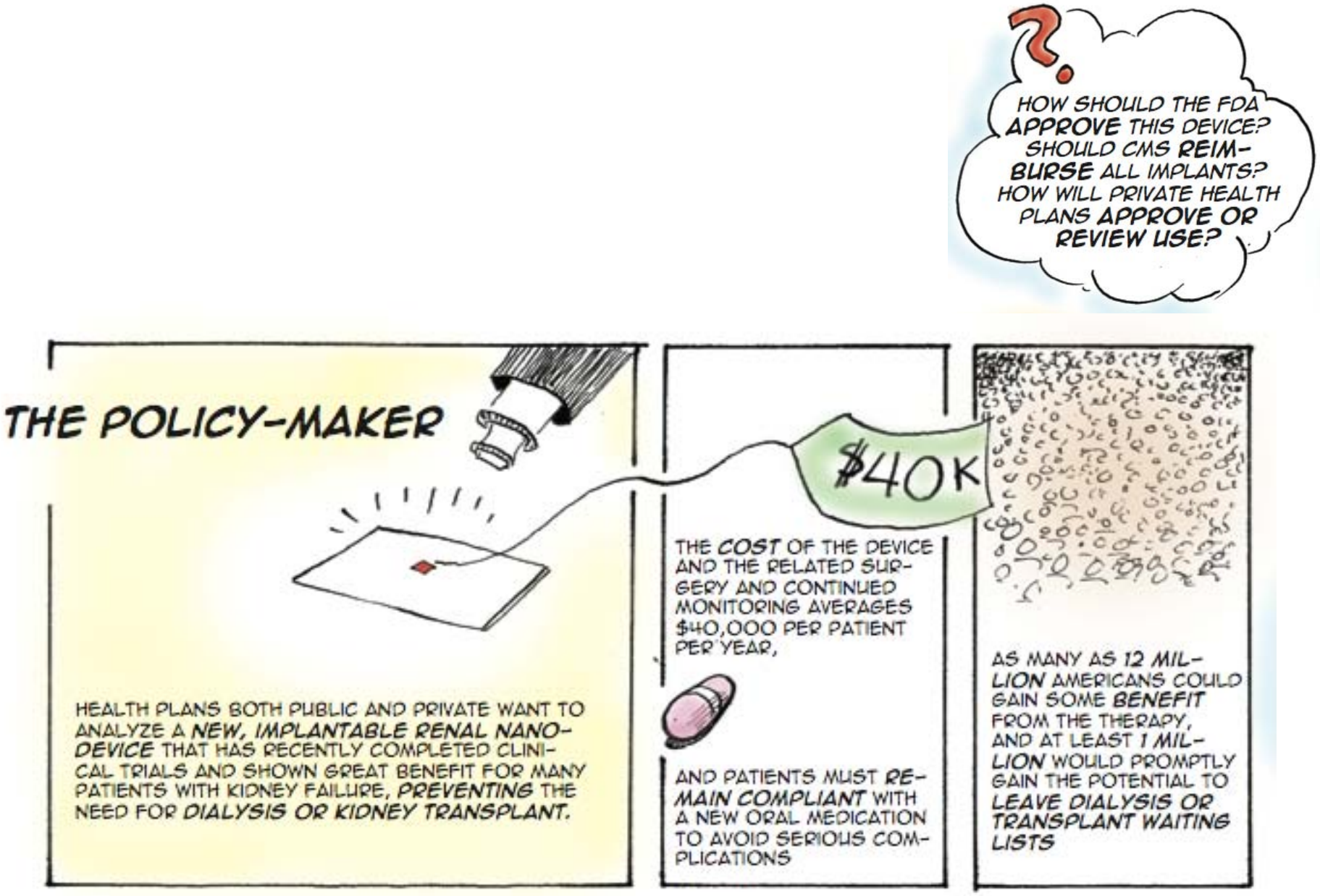

HACK
I ATTEND TO HER COUGH FIRST SINCE SHE HAS SIGNS OF A RESPIRATORY INFECTION
A QUICK SPUTUM ANALYSIS REVEALS A BACTERIAL PATHOGEN THIS TIME, WHICH I ASSUME TO BE AN OPPORTUNISTIC INFECTION FOLLOWING HER LONG BOUT WITH THE FLU
A
THE DECISION SUPPORT TOOL TELLS ME THAT, BASED ON THE PATHOGEN IN THE SPUTUM, THE LITERATURE WOULD SUGGEST USING ANTIBIOTIC A
HOWEVER, IT RECOMMENDS THAT I CONSIDER THE FACT THAT IN THE LAST 4 WEEKS THERE HAVE BEEN 115 OTHER CASES OF PNEUMONIA CAUSED BY THIS SAME PATHOGEN IN MY COMMUNITY, AND THAT PATIENTS TREATED WITH ANTIBIOTIC B HAVE HAD BETTER RESPONSE...
B
...SO I DECIDE TO TRY ANTIBIOTIC B
Tom Bouthiaux 2007

THE CONSUMER

ANGELA MORENO LIVES IN DAYTON, OHIO, WITH HER 9-YEAR OLD SON, MARTIN

MARTIN HAS MODERATE TO SEVERE **ASTHMA**, WHICH HAS BEEN HARD TO CONTROL. IT INTERFERES WITH HIS SCHOOL PERFORMANCE AND, OFTEN, HIS ABILITY TO SLEEP. HE SKIPS SPORTS




HOW SHOULD THE FDA APPROVE THIS DEVICE? SHOULD CMS REIMBURSE ALL IMPLANTS? HOW WILL PRIVATE HEALTH PLANS APPROVE OR REVIEW USE?
THE POLICY-MAKER
HEALTH PLANS BOTH PUBLIC AND PRIVATE WANT TO ANALYZE A NEW, IMPLANTABLE RENAL NANO-DEVICE THAT HAS RECENTLY COMPLETED CLINICAL TRIALS AND SHOWN GREAT BENEFIT FOR MANY PATIENTS WITH KIDNEY FAILURE, PREVENTING THE NEED FOR DIALYSIS OR KIDNEY TRANSPLANT.
$40K
THE COST OF THE DEVICE AND THE RELATED SURGERY AND CONTINUED MONITORING AVERAGES $40,000 PER PATIENT PER YEAR,
AND PATIENTS MUST REMAIN COMPLIANT WITH A NEW ORAL MEDICATION TO AVOID SERIOUS COMPLICATIONS
AS MANY AS 12 MILLION AMERICANS COULD GAIN SOME BENEFIT FROM THE THERAPY, AND AT LEAST 1 MILLION WOULD PROMPTLY GAIN THE POTENTIAL TO LEAVE DIALYSIS OR TRANSPLANT WAITING LISTS

Time to reset the paradigm?

- Primary vs. Secondary Use
- Consent and Opt-in vs. Opt-out
- The “Lock Box”

1. Primary and Secondary Use

- **Primary use** is data collected about and used for the direct care of an individual patient. Is this all we need for the high quality care of an individual patient?
- **Secondary use** is non-direct care use of personal health information including but not limited to analysis, research, quality/safety measurement, public health, payment, provider certification or accreditation, and marketing and other business including strictly commercial activities. (e.g. everything else) or "non-clinical" uses
- *Are we basing our policy discussions on broken assumptions that perpetuate historical gaps in the knowledge required to achieve high quality clinical care?*
- *This linear thinking may be an artifact of a paper world.*

Closing the Loop

- Health information should flow in a continuous virtuous circle
- Policy process should not create “camps” arguing clinical vs. population value of information.
- Policy framework should protect individual rights and society’s interests by articulating appropriate and inappropriate uses in a context of notification and control

2. Consent

- Not a magic bullet
- Consenting to what?
- Consent, alone, does not protect privacy
  - Rather, a suite of interdependent policy and technology tools
  - Subject to operational or “real-world” limitations
- Need to address consent in the context of a broad framework of information policies, privacy protections and consumer empowerment

Connecting for Health Common Framework

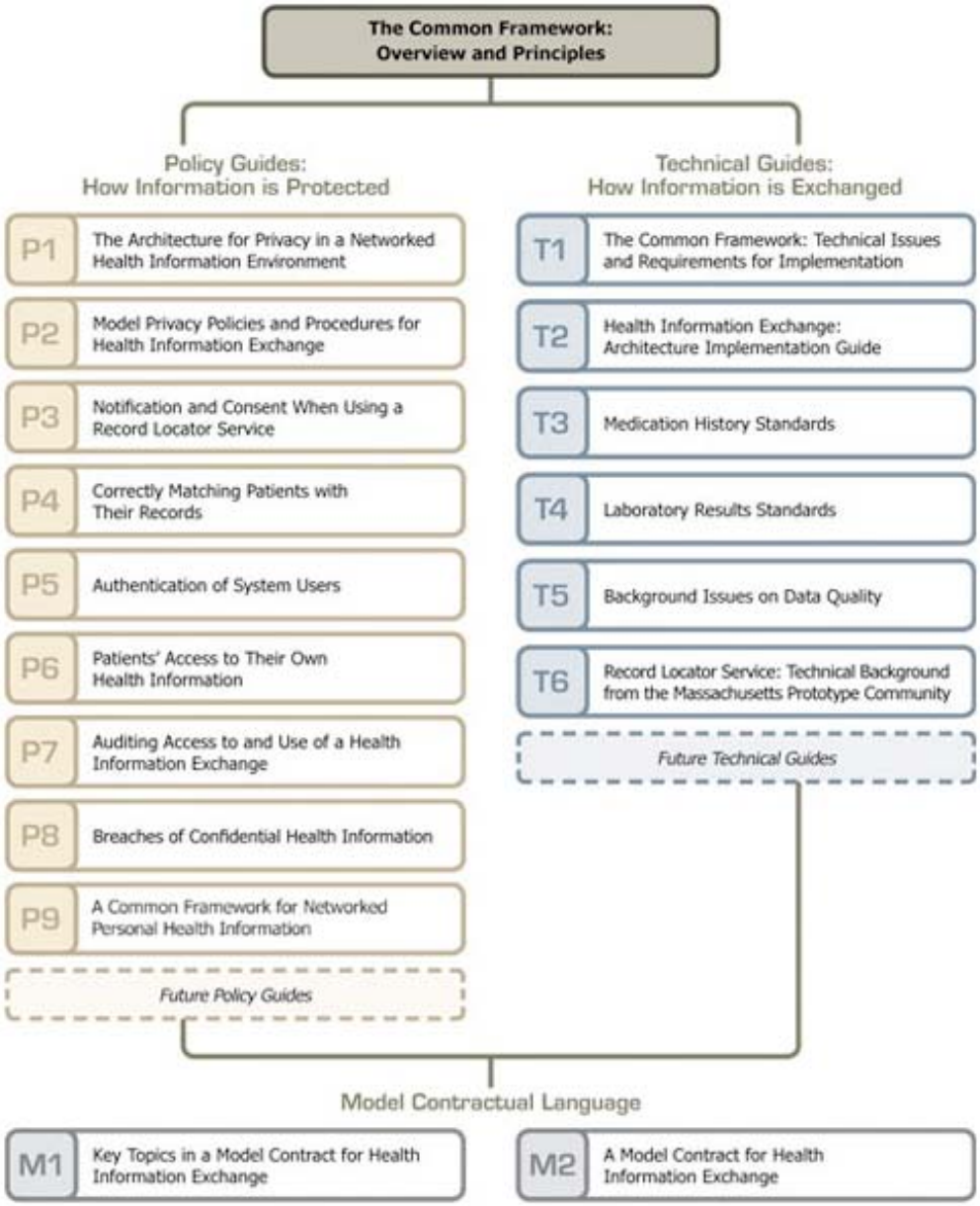
Technical Principles

1. Make it “Thin”
2. Avoid “Rip and Replace”
3. Separate Applications from the Network
4. Decentralization
5. Federation
6. Flexibility
7. Privacy and Security
8. Accuracy

Connecting for Health Common Framework

Privacy Principles

1. Openness and Transparency
2. Purpose Specification and Minimization
3. Collection Limitation
4. Use Limitation
5. Individual Participation and Control
6. Data Integrity and Quality
7. Security Safeguards and Controls
8. Accountability and Oversight
9. Remedies


The Common Framework:
Overview and Principles
Policy Guides:
How Information is Protected
P1
The Architecture for Privacy in a Networked Health Information Environment
P2
Model Privacy Policies and Procedures for Health Information Exchange
P3
Notification and Consent When Using a Record Locator Service
P4
Correctly Matching Patients with Their Records
P5
Authentication of System Users
P6
Patients' Access to Their Own Health Information
P7
Auditing Access to and Use of a Health Information Exchange
P8
Breaches of Confidential Health Information
P9
A Common Framework for Networked Personal Health Information
Future Policy Guides
Technical Guides:
How Information is Exchanged
T1
The Common Framework: Technical Issues and Requirements for Implementation
T2
Health Information Exchange: Architecture Implementation Guide
T3
Medication History Standards
T4
Laboratory Results Standards
T5
Background Issues on Data Quality
T6
Record Locator Service: Technical Background from the Massachusetts Prototype Community
Future Technical Guides
Model Contractual Language
M1
Key Topics in a Model Contract for Health Information Exchange
M2
A Model Contract for Health Information Exchange

Common Framework Attributes

1. A Decentralized, Distributed Architecture
2. Separate Demographic from Clinical Data on the Network
3. Maintain a Flexible Platform for Innovation to Enable Interoperability
4. Implement Privacy through Technology (Audit, Access, Authorization, Authentication, Accuracy)
5. Nine Foundational Privacy Principles

3. The “Lock Box”

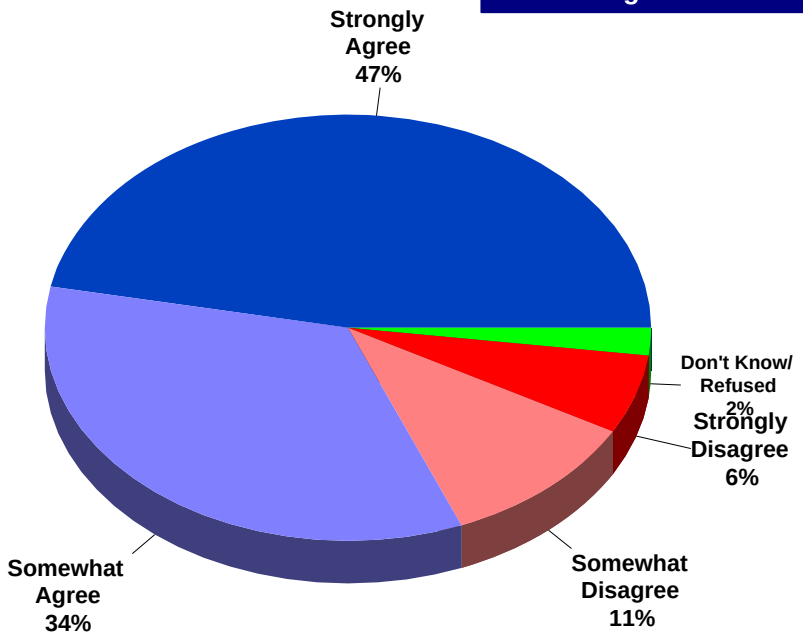
- Another artifact of paper-based or mainframe thinking.
- In a networked environment we are discussing copies of information.
- You can’t source delete.

Articulating New Foundational Principles

Four in five Americans believe if physicians kept electronic medical records on their patients, health care quality would improve and medical errors would be reduced.

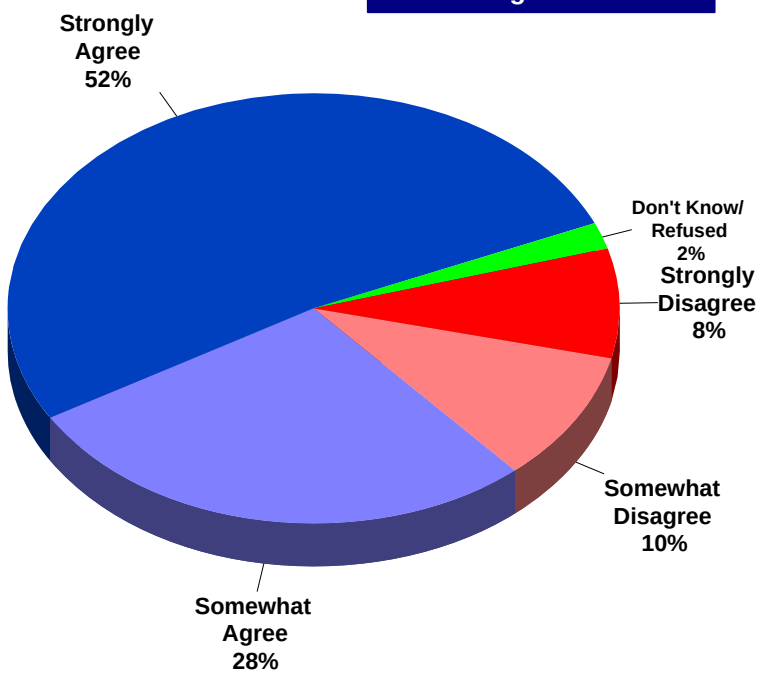
Allow medical experts to review millions of anonymous health records to determine what treatments work best for different diseases. This would allow your doctor to have the most up-to-date medical information and expand their knowledge about different treatments and diseases.

Total Agree	81%
Total Disagree	17%



Improve health care quality because it would help reduce medical errors because doctors would be able to retrieve a patient's complete medical history in a matter of seconds.

Total Agree	80%
Total Disagree	18%



Now let's imagine that doctors were required to keep electronic medical records of their patients. I am going to read you a list of statements you might hear about this, please tell me whether you agree or disagree with each statement.

Americans recognize the “upside”… and the “downside”…

- Significant concern about privacy and security
  - 85% say protecting confidentiality absolutely essential
  - FACCT survey: 91% “very concerned” (barrier for 1/4)
  - Strong desire to “control” who sees health information
- Fear of misuses
  - 52% believe employer uses medical info to affect personnel or insurance benefits (CHCF Survey 2005)
  - 85% believe if genetic test results known to insurers, would refuse policies or charge more (Genetics and Public Policy Center Survey 2007)
- Three-quarters of Americans are willing to share their personal information to help public officials look for disease outbreaks and research ways to improve the quality of health care if they have safeguards to protect their identity (Markle Survey 2006).

"Patients, privacy and trust: patients' willingness to allow researchers to access their medical records"

Laura J. Damschroder,, Joy L. Pritts, Michael A. Neblo, Rosemarie J. Kalarickal, John W. Creswell, Rodney A. Hayward

- Willingness to share ≠ willingness to cede control
- Veterans want a say in deciding how their medical records can be used for research

  ...and in *whether* their records are used
- Veterans were most willing to share their medical records with VA researchers and placed highest level of trust in them
  - Compared to other entities
- Higher trust means less stringent consent procedures

Social Science & Medicine 64 (2007) 223–235

Connecting for Health

Draft First Principles for Population Health

How were these pulled together ?

- *The Connecting for Health Common Framework* (2006),
- Population Health Visioning Scenarios (Cartoons),
- March 2007 Steering Group meeting,
- Steering Group Interviews conducted earlier this year,
- *Roadmap on Achieving Electronic Connectivity* (2004).

Connecting for Health: Draft First Principles for Population Health

1. Designed for Decisions

A 21st century health information environment will focus on improving the decision-making ability of the many actors in the health sector. Information technology provides value to health and health care by bringing timely, accurate, and appropriate information to a decision-maker at the right time and in the right way. Data collection alone does not lead to better decisions – indeed, too much or poorly organized data can distract us from filtering up to the most useful information upon which to base a given decision.

Connecting for Health: Draft First Principles for Population Health

2. Designed for Many

A 21st century health information environment should empower a rich variety of users. The network can feed analytic tools in many settings and provide value to millions of users – to consumers, families, health professionals, policy makers, public health officials, scientific investigators, and many others. The technical and policy framework for the network should anticipate the diverse requirements of this array of users – much like the Internet itself.

Connecting for Health: Draft First Principles for Population Health

3. Shaped by Public Policy Goals & Values

The 21st century health information environment should achieve society's goals and values – such as to improve the health of individuals; to make the care delivery system more effective, safe, and efficient; to reduce and manage threats to public health; to respect confidentiality; and to increase scientific knowledge. The network serves both the personal care setting and public needs and values. It is obliged to respect and further public values such as individuals' ability to control the use of their information. Such policy and public values must be made explicit and subjected to public discussion, and then architected into the technology at the outset.

Connecting for Health: Draft First Principles for Population Health

4. Boldly Led, Broadly Implemented

A 21st century health information environment should be guided both by bold leadership and strong user participation. The network's value expands dramatically with the number of needs it can meet and the number of participants it can satisfy. The network is not bound, for example, by a hospital's walls or the parameters of a research grant. A forward-looking generation of health care will know that they are not building information systems to keep data from competitors or to deprive others of the opportunity for insight, but that they are contributing to a diverse, flexible, and expansive body of knowledge. Value will be created by those who are most skilled at accessing the right information, applying the right intelligence, and solving the right problems. New health care leaders must come together with a common vision to develop an architecture and policy framework that facilitates this kind of information environment.

5. Possible, Responsive and Effective

A 21st century health information environment should grow through realistic steps. Overly complex or ambitious technology can exacerbate the problems we face, or introduce new ones. It is therefore essential to seek realistic steps towards the ultimate vision of a responsive, nimble system to enhance decision-making.

6. Distributed but Queriable

A 21st century health information environment should be comprised of a large network of distributed data sources. It should be possible to query across all of these sources without needing a central structure. We must avoid replicating (or even exacerbating) the current problem of uncoordinated health data silos, which result from duplicative efforts to build repositories and analytic systems, often from the same data sources.

Connecting for Health: Draft First Principles for Population Health

7. Trust through Safeguards and Transparency

A 21st century health information environment should earn and keep the trust of the public through policies that provide safeguards and transparency. Americans will support sharing their sensitive health information across the Internet if they trust in the security, privacy, and appropriate uses of the network. Such trust can be established through a combination of safeguards (including both technical and non-technical approaches) and transparency (of both decision-making process and practice). The technical architecture will include tools to protect data against break-ins and theft, to provide anonymization, and to prevent data corruption or errors. The policy architecture will develop clear rules and guidelines through an inclusive and transparent ongoing process.

8. Layers of Protection

The 21st century health information environment should protect patient confidentiality by emphasizing the easy movement of queries and responses, rather than of raw data. The level of protection should be scaled to the risks, with identifiable data achieving the highest levels of protections. Many classes of authorized users should be able to send standardized queries across the network, allowing appropriate data sources to respond with aggregated or anonymized "answers" without compromising personally identifiable data. When requirements for additional identifiers are appropriate, additional levels of protections should be applied.

9. Good Network Citizenship

A 21st century health information environment should encourage and enforce good network citizenship by all participants. Health sector leaders should take steps to increase the appropriate movement of health information and discourage those who pursue unauthorized uses. To receive public funding or to be welcome in various information exchange initiatives, participants must abide by both the technical and policy rules that permit the larger national network to function. There must be accountability and strong mechanisms for adequate enforcement associated with these requirements and commitments. These rules must provide for auditing and assignment of liability and mechanisms for redress.

Developing a New Information Framework

A starting point…(for a complex task)

- Reset the terminology to support the desired paradigm
- Emphasize that health and health care improvement depends upon information continuity and availability across health and health care in a climate of trust
- Engage stakeholders in constructive, forward-looking process towards a shared vision that addresses both the policy and technology framework
- Identify the risks and classes of information misuse and the classes of technology and policy protections available
- Urge that the framework establish the policy and technical requirements that any Federally-sponsored work on population health must achieve