CONNECTING FOR HEALTH COMMON FRAMEWORK

Resources for Implementing Private and
Secure Health Information Exchange

Creating a Public Good for the Public's Health

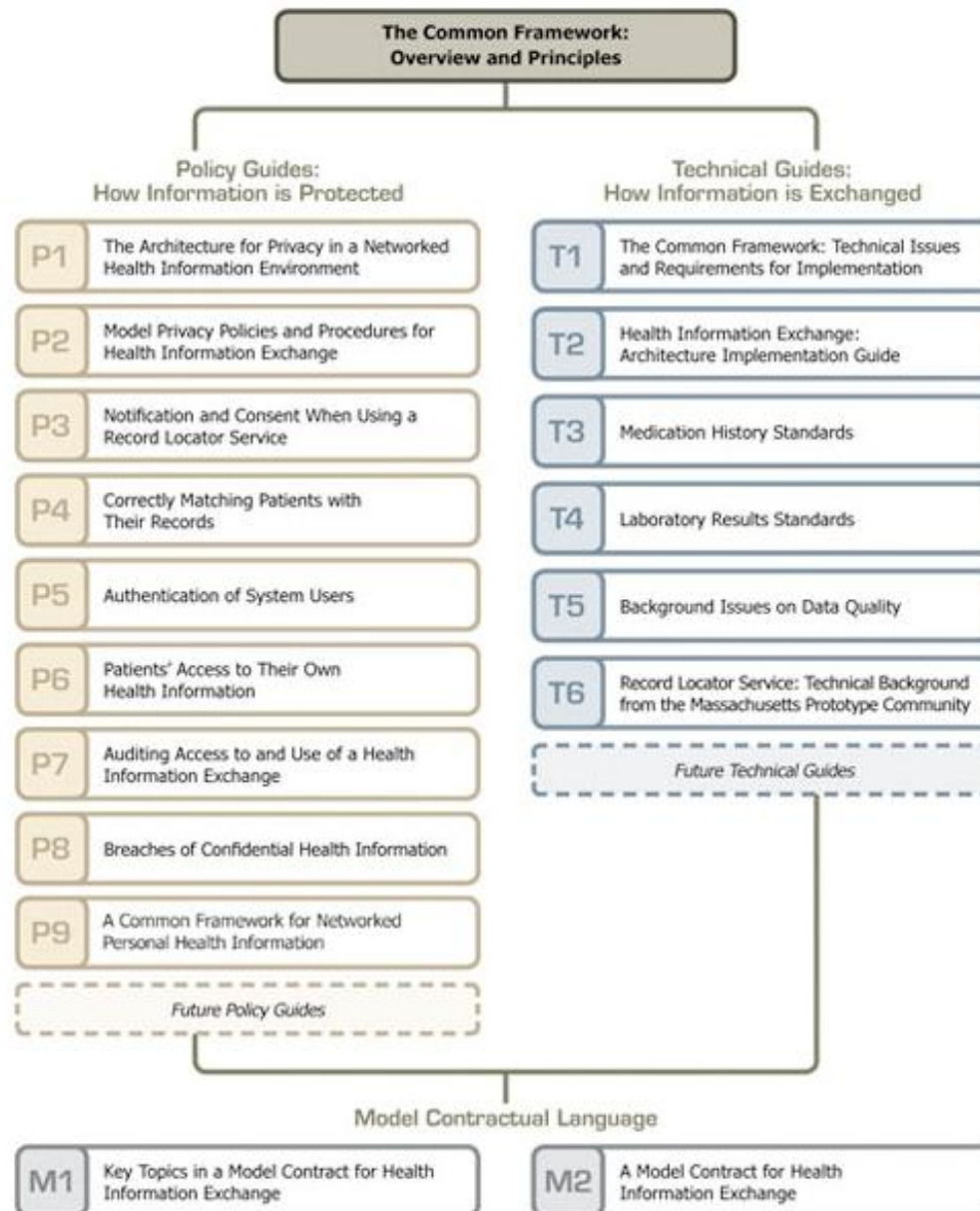*Carol C. Diamond MD, MPH*
Managing Director, Markle Foundation
Chair, Connecting for Health

Key Points for an <u>Action Agenda</u>

1. Be open to reset our definitions and assumptions about health data and research approaches

2. Articulate new, broadly accepted working principles based on 21st century information paradigms

3. 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, additional support from the RWJF

- Brings together private, public, and not-for-profit groups

- Works to accelerate the development of a health information-sharing environment to improve the quality and cost effectiveness of health care

- Our approach is rooted in looking at technical <u>AND</u> policy issues together!

- http://www.connectingforhealth.org

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

Connecting for Health

- **Connecting Professionals**: Common Framework for Health Information Exchange (released April 2006)

- **Connecting Consumers**: Common Framework for Networked Personal Health Information (full compendium to be released 2nd quarter 2008)

- **Connecting All Health Decision Makers**: Current work...how can the Common Framework support the nation's goals of improving the health of entire populations?
  - Bolstering **research** capabilities and enabling clinical practice to fully participate in and make use of scientific evidence
  - Increasing the effectiveness of our **public health system**
  - Empowering consumers and professionals with information about **cost, quality, and outcomes**

In extensive interviews with our leadership group serious concerns and frustrations with current approach to population health and data collection from each sector.

Yet a shared vision ...

What We Heard...

"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 Vision: What COULD it be like?

In this new vision, the decisions of providers, consumers, payers and policy-makers are grounded on reliable evidence.
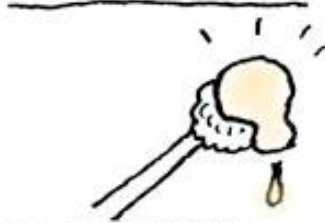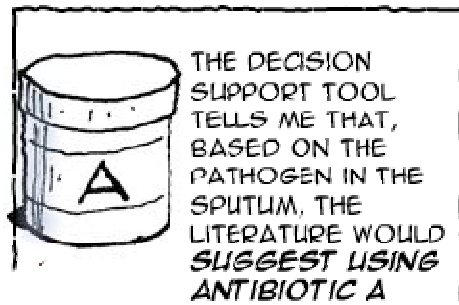
Imagine if.....
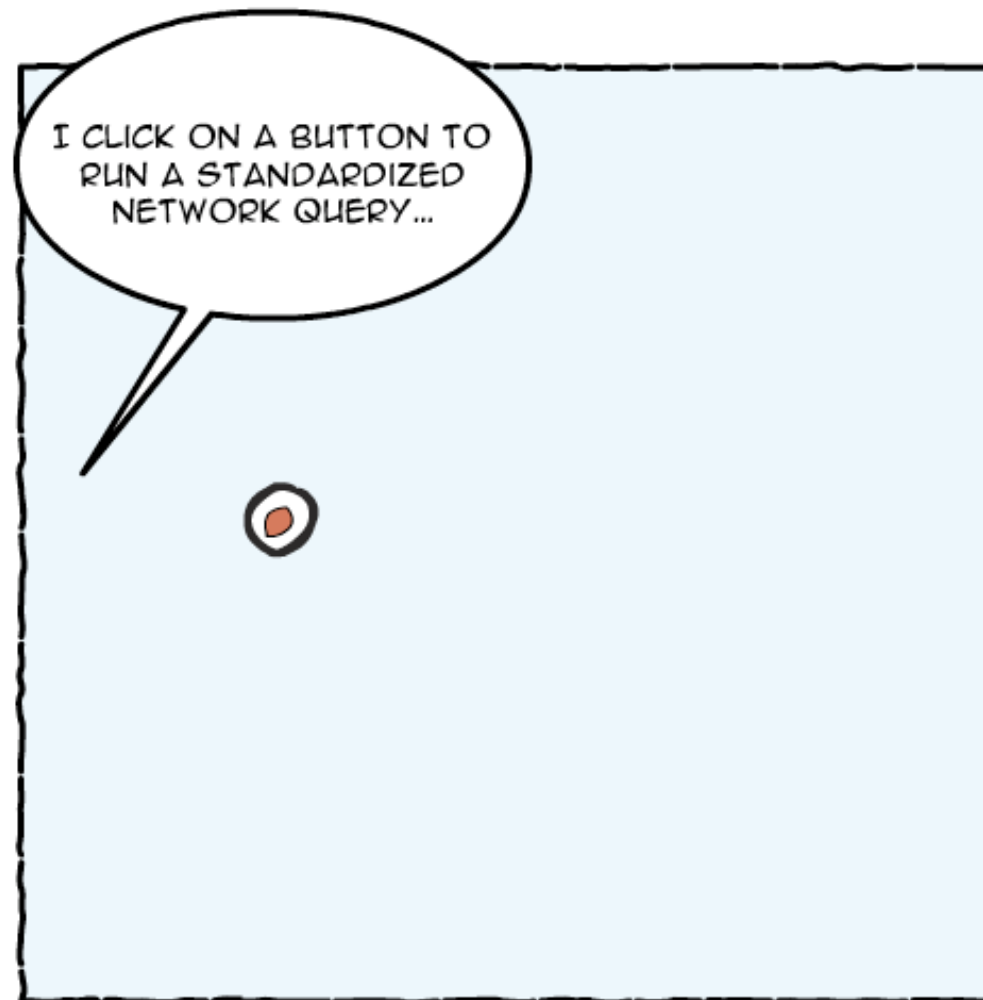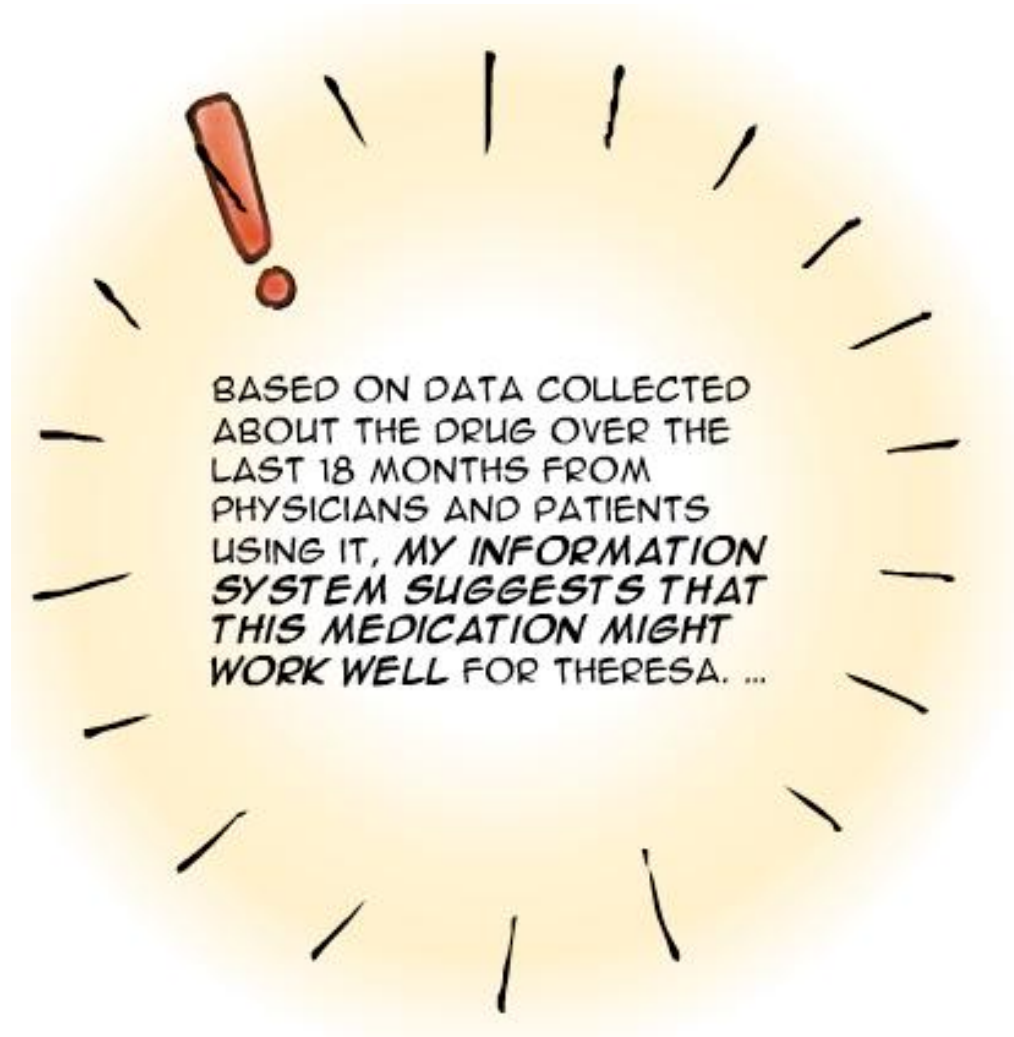
1. MORE EFFICIENT AND EFFECTIVE MEANS TO INTERACT WITH PATIENTS
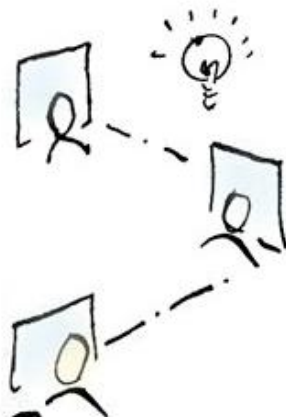
2. FRESH OPPORTUNITIES TO COLLABORATE AS PART OF THE SCIENTIFIC AND MEDICAL COMMUNITY
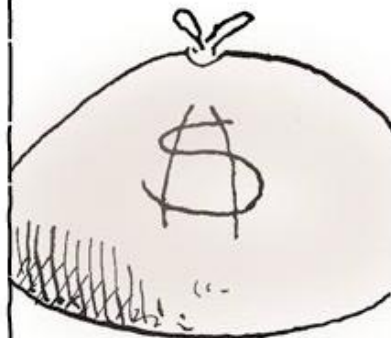
3. INNOVATIVE AND SUSTAINABLE FINANCIAL MODELS FOR OUR PRACTICE

4. A TRANSFORMED OFFICE WHERE WE WORK AS A TEAM, DRAMATICALLY IMPROVING CARE AND OUR OWN LIVES

BASED ON HER WEIGHTED PREFERENCES, THE SYSTEM PROVIDES HER WITH AN ORDERED LIST OF TEN PHYSICIANS AND A BUTTON TO *"SCHEDULE INITIAL APPOINTMENT."*

SHE *SELECTS A DOCTOR* WHO BEST MEETS MARTIN'S NEEDS, AND AFTER THEIR FIRST VISIT, IS INVITED TO RETURN TO THE WEBSITE TO RATE THE VISIT ON A VARIETY OF MEASUREMENTS. SHE CONSENTS TO ALLOWING MARTIN'S PEAK-FLOW READINGS TO BE POOLED WITH OTHER PATIENTS ON A DE-IDENTIFIED BASIS

THE POLICY-MAKER
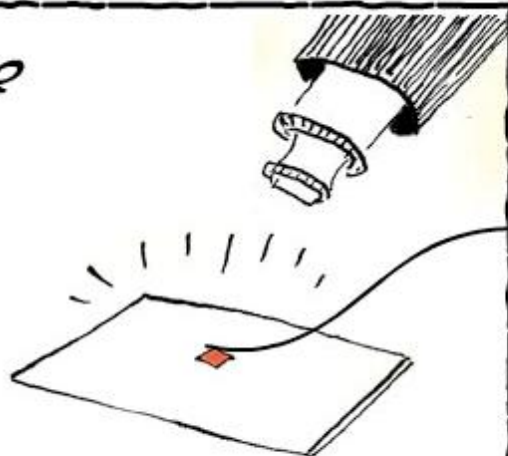
HEALTH PLANS BOTH PUBLIC AND PRIVATE WANT TO ANALYZE A *NEW, IMPLANTABLE RENAL NANO-DEVICE* THAT HAS RECENTLY COMPLETED CLINICAL TRIALS AND SHOWN GREAT BENEFIT FOR MANY PATIENTS WITH KIDNEY FAILURE, *PREVENTING* THE NEED FOR *DIALYSIS OR KIDNEY TRANSPLANT.*

$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
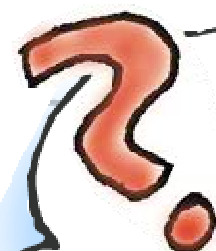
IT'S NOW COM-
MONPLACE FOR
THE NETWORK TO
ENABLE *QUERIES*
ACROSS
*MULTIPLE DATA
SOURCES* THAT
WERE ONCE
*IMPENETRABLE
SILOS*
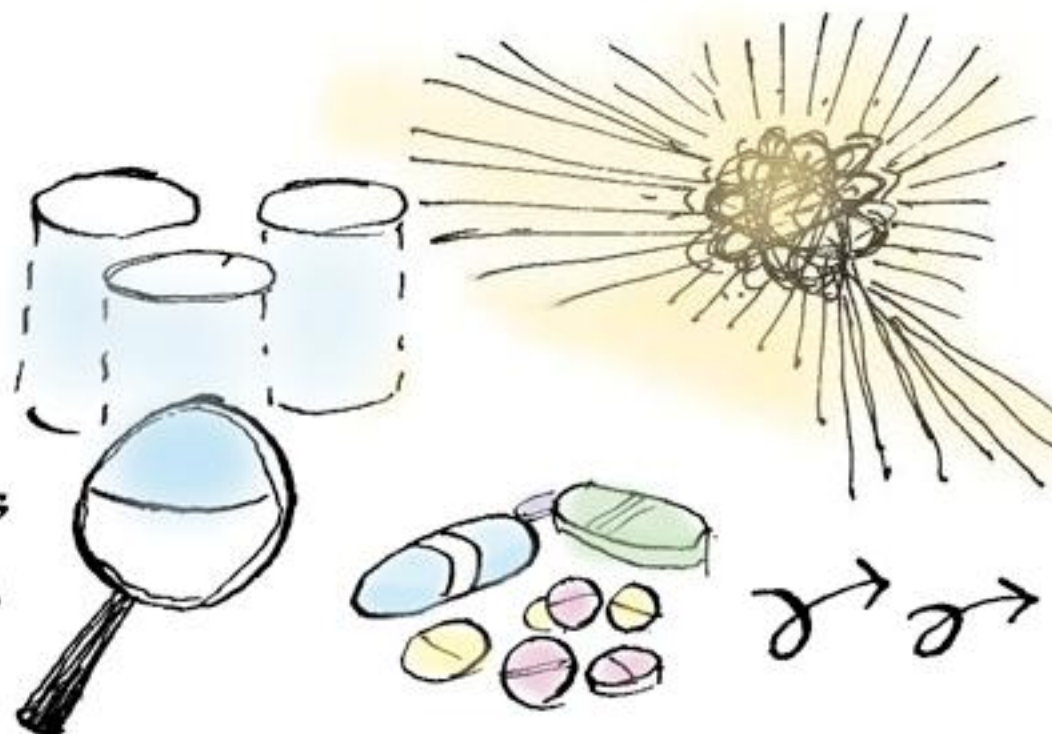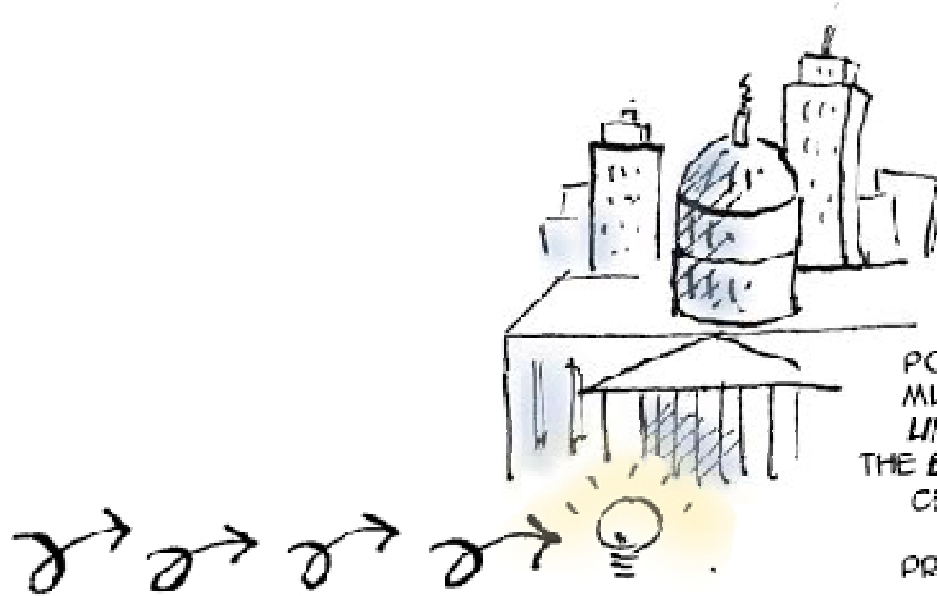
PAYERS AND PUBLIC POLICYMAKERS HAVE A MUCH MORE GRANULAR *UNDERSTANDING* OF THE *EFFECTIVENESS* OF CERTAIN TREATMENTS, AND CAN *TARGET* PROVIDER AND PATIENT EDUCATION *INTERVENTIONS* MUCH MORE *EFFECTIVELY*

THE *INNOVATION CYCLE* HAS QUICKENED - PROMISING NEW USES ARE QUICKLY DIFFUSED THROUGH THE REAL-TIME ONLINE CHANNELS. AT THE SAME TIME, WE QUICKLY STAMP OUT SPURIOUS AND UNFOUNDED OFF-LABEL USES. THE PHARMACEUTICAL AND DEVICE INDUSTRY, ALONG WITH THEIR CLINICAL PARTNERS, DEVELOP *FASTER, BETTER AND CHEAPER* NEW TECHNOLOGIES AND CREATIVE USES OF EXISTING TECHNOLOGIES.

This roundtable has outlined a vision for a learning healthcare system, in which clinical data are a staple resource

We share this vision

And recognize the critical importance of clinical data as a key resource

But it is unlikely that we can achieve this vision using our historical approaches for collecting and analyzing these data

"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

1. An <u>Action Agenda</u> should be open to reset our definitions and assumptions about health data and research approaches

The Way We Do it Today

- Most of the effort in trying to collect, clean and then "hoard" data.

- Places a huge burden on data "providers" to submit the (same) information repeatedly to different repositories

- Creates separate repositories for each specific purpose at great cost in money and time

- Poorly adaptable and therefore "success" is elusive

- Creates privacy and security vulnerabilities

- Lacks connectivity, feedback, and broad USE for better decision-making

- Does not include the consumer (and often not the provider) as a key and active participant

Swarms of Data Requests to a Single Care Delivery Organization

IRB Projects

JCAHO Reporting

IM reporting

CQ Reporting

Teaching requests

Commercial plans

Local Requests

Cancer registry

Quality/ AQA pilots

Genetic screening

Public Health

Peri-natal

UB92

State Requests

AHRQ

Leapfrog

CMS

NCQA

Biosense

PB Project

DAWN

NACRI

UHC

National Requests
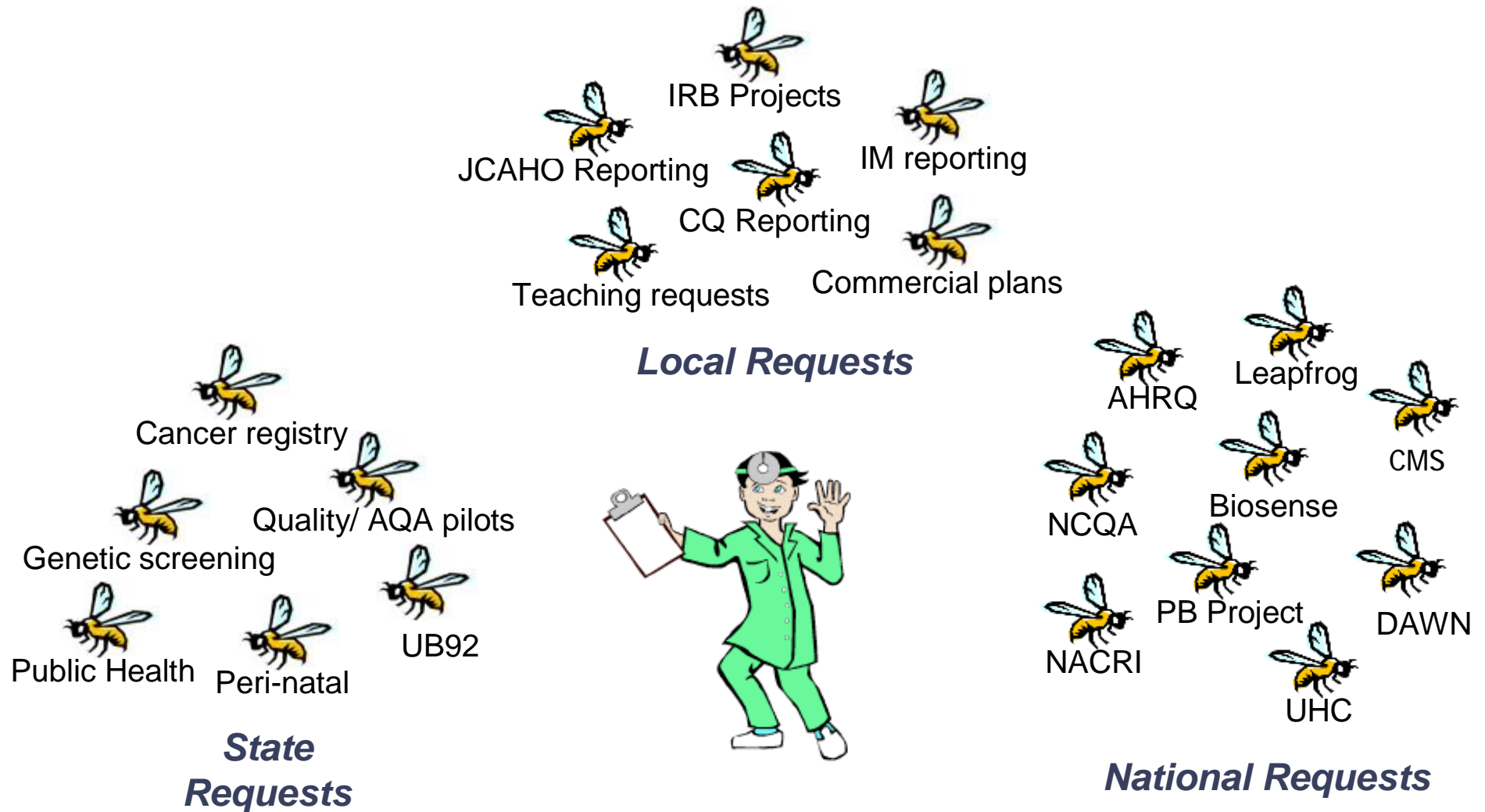
The Temptation

- Gaps in data, knowledge and evidence

- It is tempting to try to solve the problem by focusing on bigger centralized data collection repositories

- But this approach is not practical and has not proven to be effective to date

- Many reasons…

We can't replace the swarms with one 800-pound gorilla!
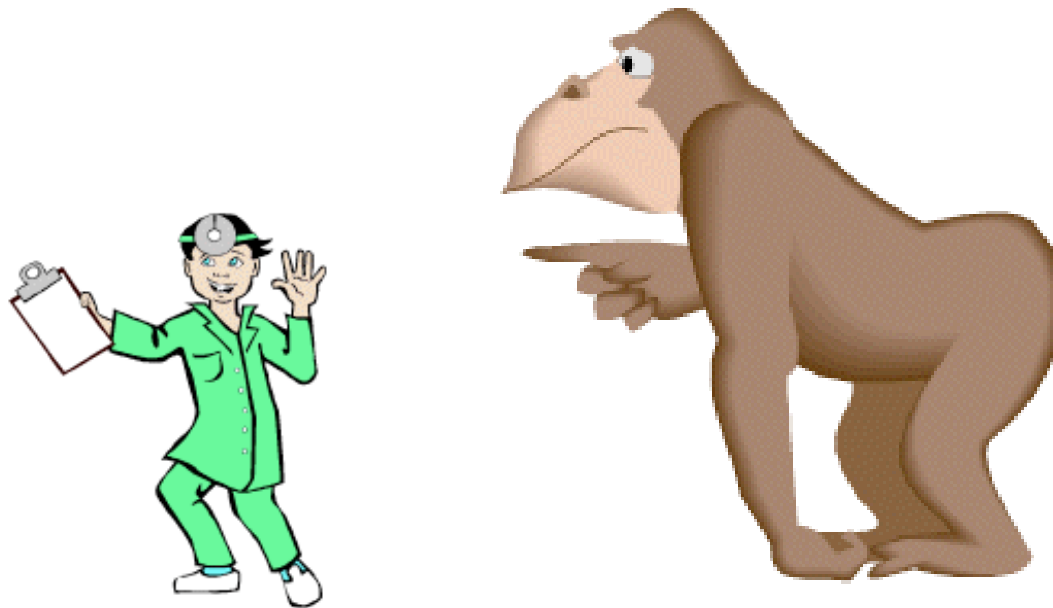
The goal is better decisions by many, not more data for the few

- It is tempting to focus our efforts on amassing data for better research

- But the thornier and more important question is how to truly improve decision-making – and what role information plays in this process

The "Mountain"

"You send your data to the mountain but the mountain rarely gives you something useful back"

2. An <u>Action Agenda</u> needs to articulate new, broadly accepted working principles based on 21st century information paradigms

21st Century *Thinking*

- Whereas businesses of earlier centuries thrived on command and control paradigms

- 21st century enterprises depend on the ideas and initiative of many

- They succeed by distributing decision-making authority, incentives, and information tools to the edges

The 21st century
Health care environment

Characterized by:

- Increasingly distributed needs for sharing and accessing information about what works best

- Increasingly sophisticated "nodes"

- Embracing consumers as key producers, users and potentially managers of clinical data and partners in the research process

- A networked and distributed approach to information sharing and evidence creation

Caveats

- This is not a matter of centralizing an analytic function

- There is a compelling need to embed analysis, decision-support, and feedback loops throughout the health care system

- We cannot predict exactly who the future information users will be, or what questions they will bring to the data – needs will change

Specific Information Needs
Breast cancer decision map

Prevention/ Early Detection → Diagnosis & Treatment → Recovery & Follow-Up

Risk Assessment → **Self Exam** → **Clinical Exam** → **Screening Mammogram** → **Diagnosis: Mammography Biopsy** → **Getting Treatment** → **Recovery** → **Adjuvant therapy** → **Long-Term Follow-up**

Key Decisions:
Should I be screened for BC?

Info. Needs:
What are the risks assoc. with BC?
Can I prevent breast cancer?
Am I at risk for BC?
Should I get genetic testing?
What are the warning signs of BC?
What will my insurance cover?

Key Decisions:
Should I see a doctor?

Info Needs:
What should I know about basic breast anatomy?
When should I start BSE?
How often should I perform a BSE?
How do I perform a BSE?
How do I notice changes?
What changes are important to notice/discuss with my doctor?

Key Decisions:
How do I choose a doctor?

Info Needs:
What kind of doctor should I look for?
What should I ask my doctor?
What will the exam be like?
How often should I have a clinical exam?

Key Decisions:
When should I start getting a screening mammogram?
How do I choose a mamm center?

Info Needs:
What is a mamm?
How often should I get one?
How do I prepare for a mamm?
Is it painful?
What will the procedure tell me?
How do I interpret the results of my tests?
How accurate are these tests?
Do I need ultrasound?
What should the dr./care team tell me about my cancer?
What other Drs. should I consult?

Key Decisions:
How do I choose a mamm center?
What do I do with my results?
Should I get a 2nd opinion?

Info Needs:
What is a mamm?
What is a biopsy?
What is ultrasound?
When will I get the results?
What will the procedure tell me?
How do I interpret the results of my tests?
How accurate are these tests?
What should my dr./care team tell me about my cancer?
What else could my condition be if it is not cancer?
What other doctors should I consult?

Key Decisions:
How do I choose a treatment?
What type of doctor/care team should I see?
How do I choose a hospital?

Info Needs:
What stage of BC do I have?
What are my treatment options?
Do I need radiation?
Do I need chemo?
Do I need hormonal treat?
What are the pros and cons of each option?
What are my risks?
What happens during treatment?
What are the side effects of treatment?
Where is the latest rsrch?
Are there any clinical trials?
Are there any alternative treatments available?
Which Drs./ care team members are best?
Which hosp is best?
How do I prepare for treatment?
Is there supportive counseling?

Key Decisions:
Should I have reconstructive surgery?
Should I use support services?

Info Needs:
What is the recovery process like?
Do I need to change my diet?
How do other people feel at this stage of BC?
What are my reconstr. options?
What other svcs can help with my recovery process (yoga, herbs, etc.)?
Where can my fam/friends get support?

Key Decisions:
Should I use adjuvant therapy?

Info Needs:
What is radiation?
What is chemo?
What is hormonal treatment?
What are the side effects?
How long will the treatment last?

Key Decisions:
How do I know if I am better/cured?
Should I join/remain in a support group?

Info Needs:
How often should I see a doctor/care team member?
How is my life going to be different?
How will I deal with these changes?
How do I cope?
How might my body feel?
How might my relationships change?
What might happen to my image of myself?

The challenge is to create alternative models that take into account…

A wide variety of distributed information <u>users</u>

Multiple and growing data sources

A new approach to research and evidence-creation taking advantage of 21st century information paradigms
 (the evolution of the global information economy as a whole vs. traditional exceptionalism of health care)

"We believe that the Internet can democratize patient data and accelerate research like never before"

"PatientsLikeMe was built to... accelerate the transfer of knowledge about what works and what does not. Today, PatientsLikeMe has data on the progression and history of more than 1600 ALS patients - twice the number in the largest ALS trial in history. Even before the trial results were published, 50 patients worldwide who had elected to start taking lithium, in collaboration with their doctors, have been tracking their progression and blood levels on PatientslikeMe. This is more than twice the number of patients participating in the trial itself! We have data on historical forced vital capacity, the ALS Functional Rating scale, and a full symptom battery for most of the patients who have started, as well as for all the other non-lithium users in our system."

(from http://blog.patientslikeme.com/)

All | ALS | MS | PD

👥 **Patients** | 📋 Treatments | 🤖 Symptoms | 📊❤️ Community

🔍 Search this site | **Search »** | ? Help

Patients Like You

📷 Patient Spotlight

actualized
Male, 59 years, Surry, ME

ALS: 2 yrs

I am living on the ocean, in the woods in Maine with best friend (wife) of 35 years, our two dogs and a cat. We have 2 sons and a daughter-in-love. My background is education and psychotherapy. My philosophy is to live each day to fullest with gratitude and a positive mental attitude. More

📷 Patient Spotlight

ZenArcher
Male, 39 years, McEwensville, PA

ALS: 2 yrs

I've been married to my wife Tammy for 15 years and we have two wonderful girls. We live in a small town just outside Williamsport, PA (the home of the little league baseball world series). More

🔍 Find Patients

Search over 6245 patients.

Location ▼ | Age | Username | Treatment | Symptom

Any ⌄ | | **Find Patients** | Advanced Search

🔍 Patients with most updates | See more ▷

Status	Updates ▼	Updates
MS: 26 yrs — thjuland	symptoms updated (1 day ago)	1090 updates
MS: 3 yrs — NIM	symptoms updated (less than 1 day ago)	921 updates
MS: 6 yrs — Cyprian1	symptoms updated (3 days ago)	658 updates
ALS: 3 yrs — john33	outcomes updated (about 1 months ago)	501 updates
ALS: 7 yrs — Jeannie	outcomes updated (1 day ago)	453 updates
PD: 3 yrs — ukelady	treatments updated (2 days ago)	491 updates
MS: 3 yrs — pinkbutterflies	outcomes updated (about 1 week ago)	414 updates
MS: 33 yrs		

🌐 Internet | 🔍 100% ▾

CONNECTING FOR HEALTH COMMON FRAMEWORK

Let's Start with First Principles...

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.

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. ...

2. Designed for Many

A 21st century health information environment should empower a rich variety of users.

2.

FRESH
OPPORTUNITIES TO
COLLABORATE AS
PART OF THE
SCIENTIFIC AND
MEDICAL
COMMUNITY

3. Shaped by Public Policy Goals and Values

A 21st century health information environment should achieve society's goals and values –
e.g.: improve the health, safety, and efficiency; reduce threats to public health, etc.

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.

5. Possible, Responsive and Effective

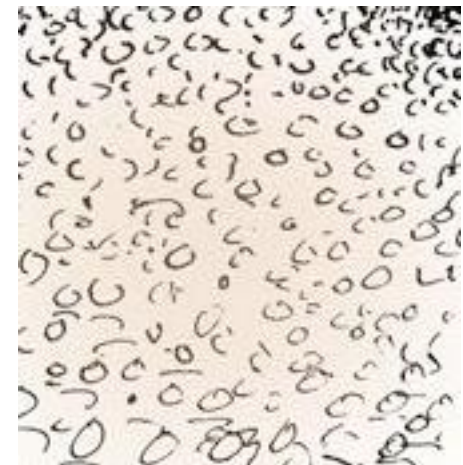**A 21st century health information environment should grow through realistic steps.**

6. Distributed but Queriable

A 21st century health information environment should be comprised of a large network of distributed data sources.

7. Trusted 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.

8. Layers of Protection

A 21st century health information environment should protect patient confidentiality by emphasizing the easy movement of queries and responses, rather than of raw data.

9. Accountability and Enforcement of Good Network Citizenship
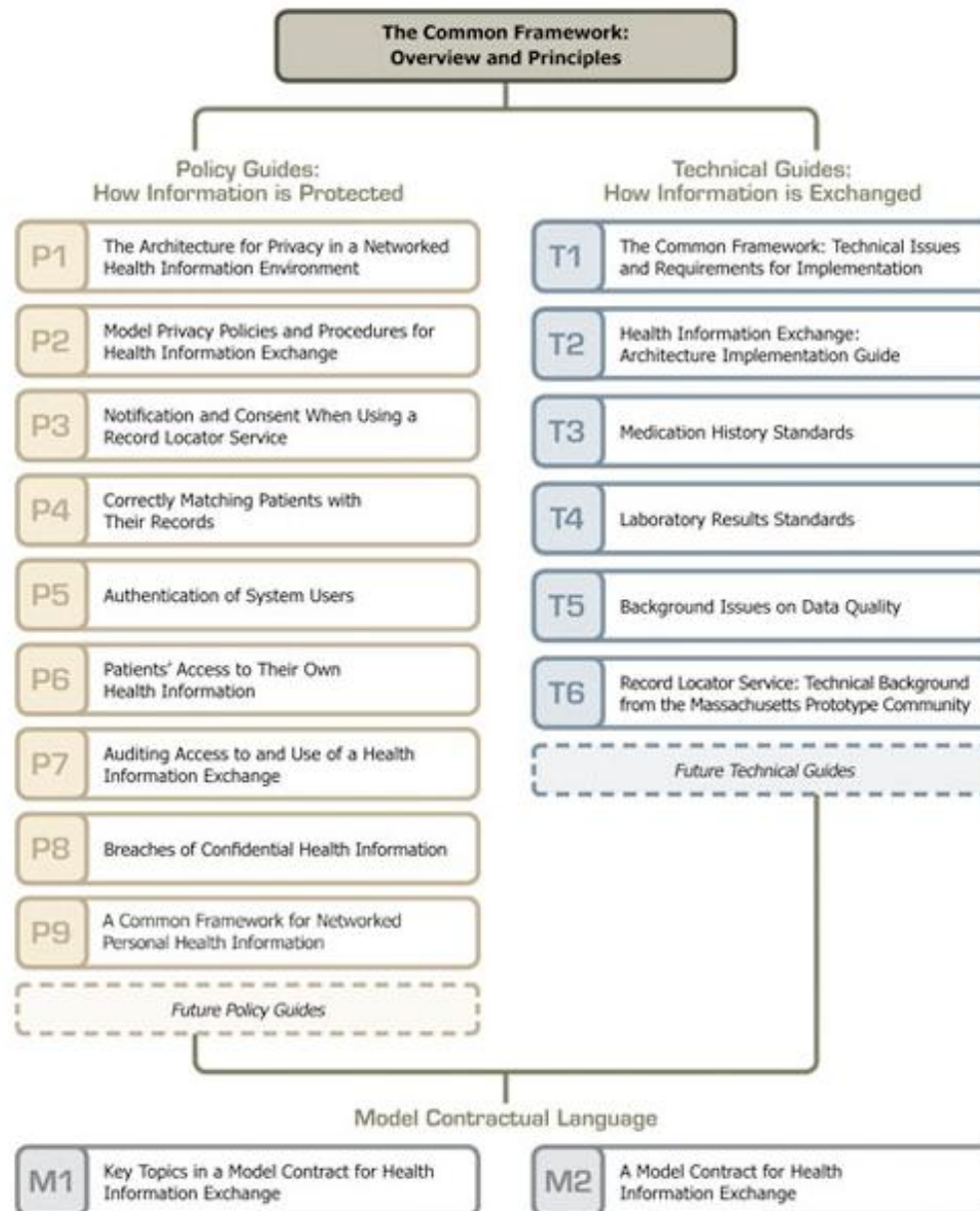
A 21st century health information environment should encourage and enforce good network citizenship by all participants.

3. An <u>Action Agenda</u> needs to develop an information policy framework that broadly addresses public hopes and concerns

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).

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Model Contractual Language

|	
M1	Key Topics in a Model Contract for Health Information Exchange
M2	A Model Contract for Health Information Exchange

CONNECTING FOR HEALTH COMMON FRAMEWORK

Architecture for Privacy in a Networked Health Information Environment

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

These Principles are Interdependent

Openness

Purpose Specification

Remedies

Accountability

Collection Limitation

Security

Data Integrity

Use Limitation

Individual Participation and Control
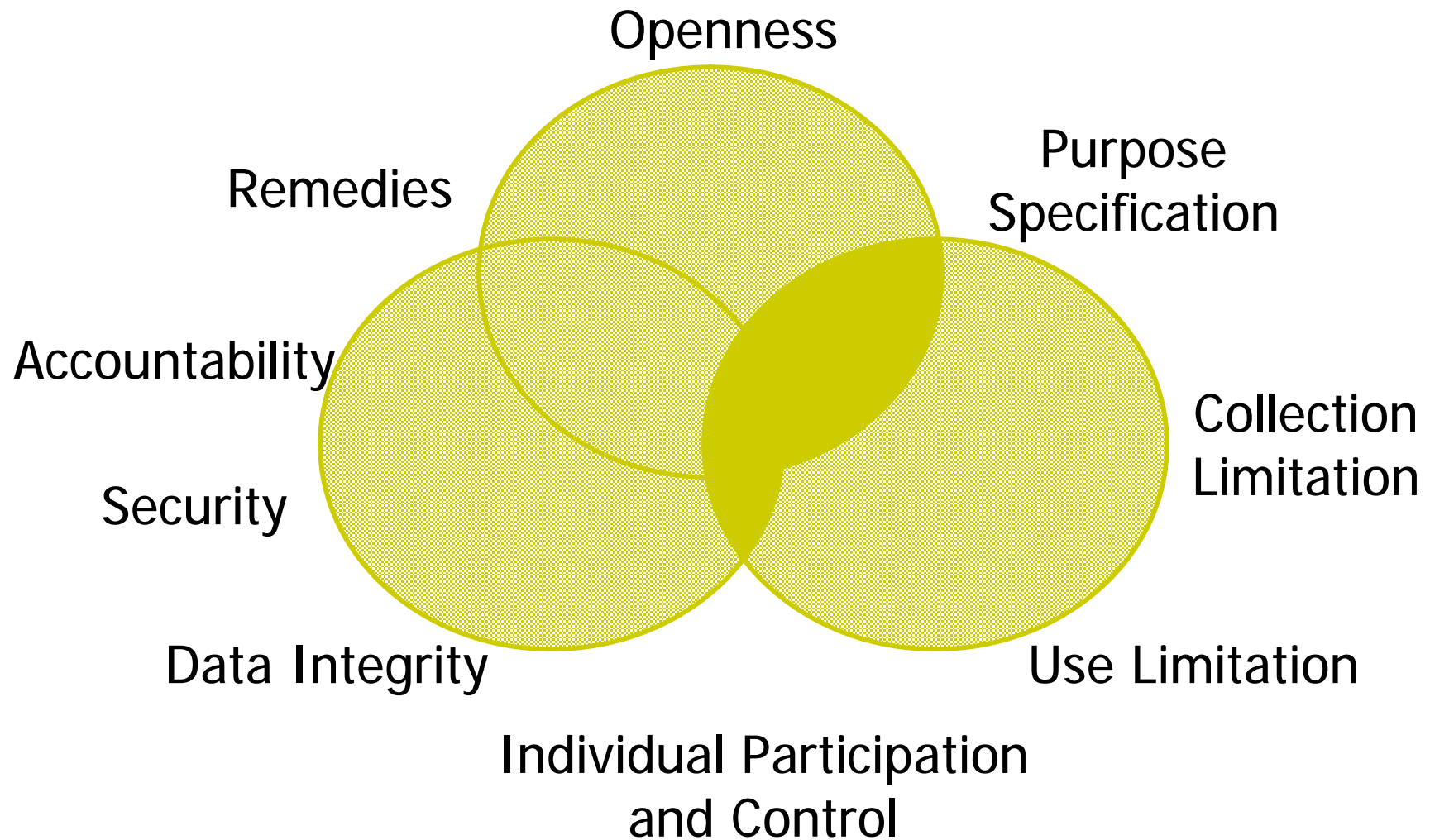
Why A Policy Framework Matters

- "Post-hoc" policy is rarely easy to implement technically and can only mitigate risk, never eliminate it.

- We create a comprehensive set of criteria as opposed to piece-meal "fixes" and we lower the likelihood of gaps (collection).

- We are less likely to take on unnecessary risks (better matching between risk and benefit)

- There is a lot at stake if we lose the trust of the public

DiSTRIBuTE for Flu Surveillance
http://www.syndromic.org

- Uses summarized counts of influenza-like-illness (ILI) syndrome reported by age group from existing syndromic surveillance systems.

- The data is visualized and used to provide public health practitioners with age-specific weekly trends in influenza morbidity.

- The DiSTRIBuTE approach changes the traditional surveillance paradigm from central data collection and analysis to one of distributed data collection and analysis with central monitoring of summary information.

- By limiting the data request to the information that is truly the minimum required (summarized counts), the system has retained the ability to demonstrate meaningful flu trending data quickly and cost effectively.
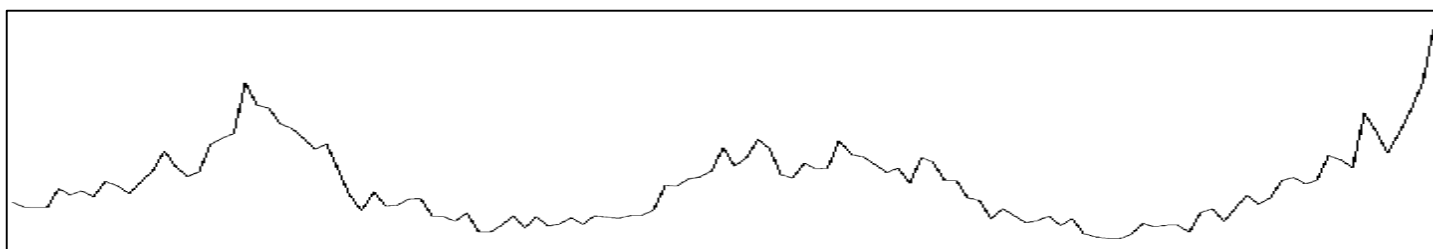
Draft DiSTRIBuTE Visualizations - week ending 02/09/08
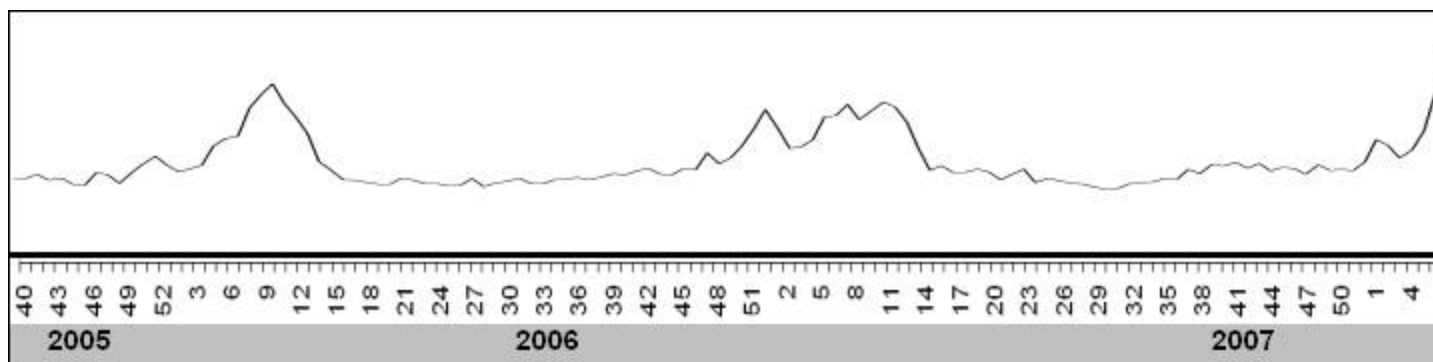Jurisdiction specific graphs depict ED visits (% fever/total)

USA: North East

USA: Midwest

Visualization accessed 2/22/08 at:
http://www.syndromic.org/projects/DiSTRIBuTE2008_02_09.doc

CONNECTING FOR HEALTH COMMON FRAMEWORK

What if..

- We created a climate of trust with a policy framework that enabled information liquidity

- We engaged stakeholders in constructive, forward-looking process towards a shared vision that prioritized creating value for all participants

- We embraced alternatives that involve and reward consumers

- We focused on the infrastructure requirements to push the questions to the data rather than trying to bring all the data to every question

- We set our sights on a collective effort to address a small set of high priority public good objectives using this new approach and enjoyed some rapid learning

The Economist, April 2005

"As the Markle Foundation puts it..............This goes to the very heart of the matter. For even though it is fine to start hoping for the day when interoperable electronic health records create vast pools of medical information that could be used to find new cures and battle epidemics in real time, their ultimate purpose is to make one simple and shockingly overdue change: to enable individuals, at last, to have access to, and possession of, information about their own health."

www.connectingforhealth.org