Connecting for Health Common Framework: Resources for Implementing Secure Health Information Exchange

AHRQ Resource Center for Health Information Technology
National Teleconference, July 25th 2006

Presented by Lygeia Ricciardi and Melissa Goldstein, of the Markle Foundation, Vicki Estrin from the Vanderbilt Center for Better Health and Marc Overhage from Indiana University on behalf of Connecting for Health, and moderated by Susan Christensen, Senior Advisor at AHRQ, as part of the AHRQ HIT Web Teleconference Series.

Overview of the Common Framework
AHRQ National Resource Center HIT Webconference
July 25, 2006

**Lygeia Ricciardi
Director, Health
Markle Foundation**

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Markle Foundation, Vicki Estrin from the Vanderbilit Center for
Better Health and Marc Overhage from Indiana University on
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What is Connecting for Health?

- A public-private collaborative of 100+ organizations representing all the points of view in healthcare.

- A neutral forum.

- Founded & supported by the Markle Foundation

- Additional support from the Robert Wood Johnson Foundation

What is the Purpose of Connecting for Health?

To catalyze changes on a national basis to create an interconnected, electronic health information infrastructure to support better health and healthcare

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Healthcare is Unique

- The healthcare system is very diverse
- Health information is especially sensitive—and privacy spills can't be "fixed"
- Patients/consumers are traditionally less involved than in some other areas

Some Barriers to Electronic Information Sharing in Health

- **Technical** (e.g. lack of standards)

- **Policy** (e.g. lack or incompatibility of rules about who is allowed to see information and why)

- **Financial** (e.g. misalignment of incentives for IT adoption)

- **Educational** (e.g. lack of understanding of the benefits and risks of IT)

… and the technology is the *easy* part!

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Sharing Health Information = Linking Existing Sources

- Health information can *stay where it is*—with the doctors and others who created it
- Specific information is shared *only* when and where it is needed.
- Sharing *does not* require an all new "network" or infrastructure
- Sharing *does not* require a central database or a national ID
- Sharing *does* require a Common Framework

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A Common Framework Is Needed

- The Common Framework is the minimum necessary set of rules or protocols for *everyone* who shares health information to follow.

- Helps organizations overcome the barriers without "reinventing the wheel"

- Enables nationwide interoperability…avoiding isolated islands of information

- Builds *trust*

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The Common Framework

Is like a nationwide set of traffic rules that enable specific pieces of health information to travel when and where they are needed…

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The Common Framework

…and that put patients and the doctors they trust in the drivers' seat.

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FIND

Source sends index information

LOCATOR

Provider asks if there are records for his/her patient

Index sends location of any records

Patient Index

GET

Patients
Providers
Hospitals
Diagnostic Services
Payors
Public Health Providers

Individual Care Providers

Message Transfer

Provider asks for and receives records

Records are sent to Provider

Patients
Providers
Hospitals
Diagnostic Services
Payors
Public Health Providers

Data Sources

SEND

De-Identified Data

Source may push data for reporting

REPORTING DATA

Public Health

Reporting Router

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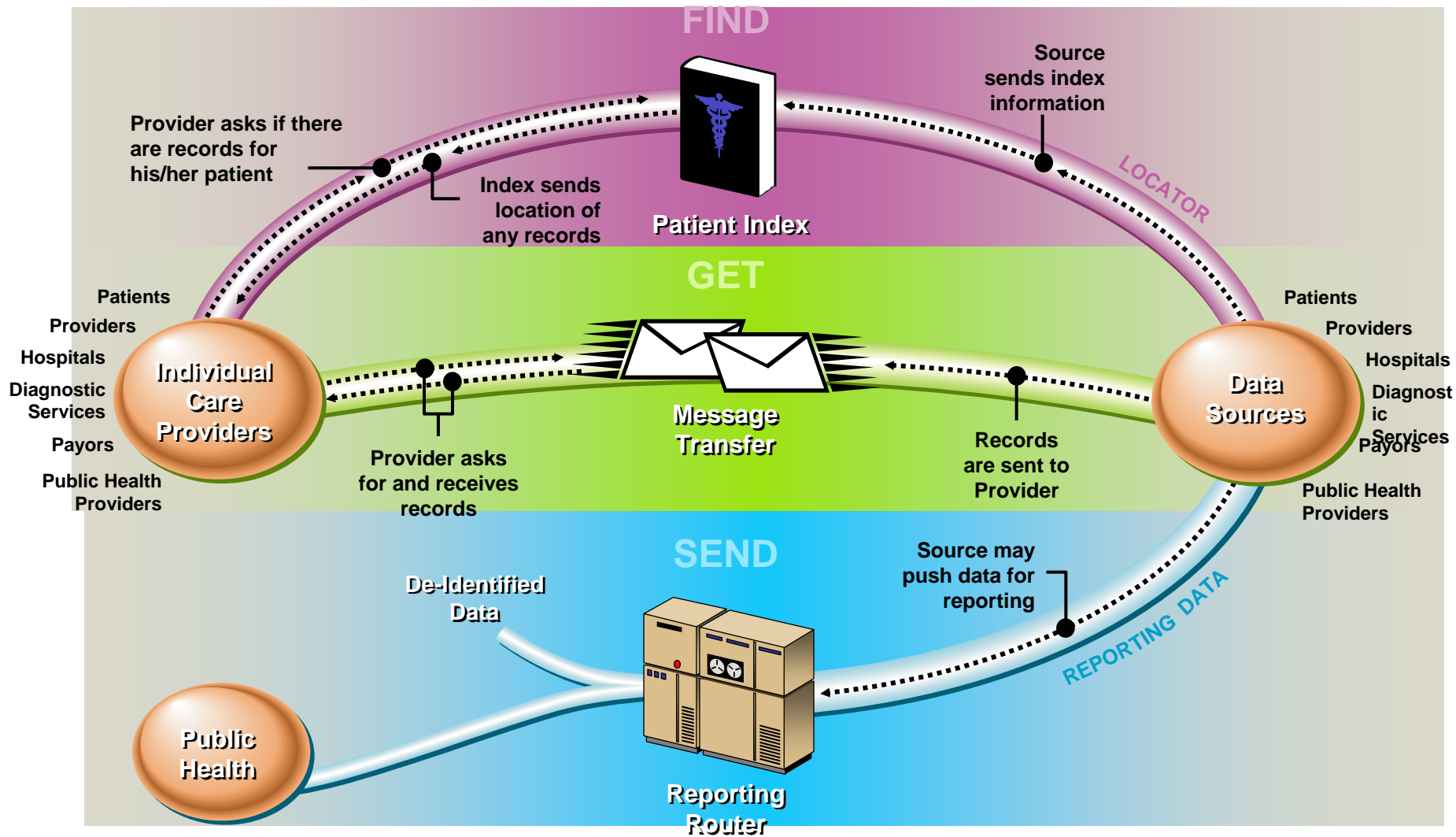
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What Do the Common Framework Resources Consist of?

- Technical rules and standards—that allow systems to "talk to" each other

- Policies on how to handle information– that build *trust*

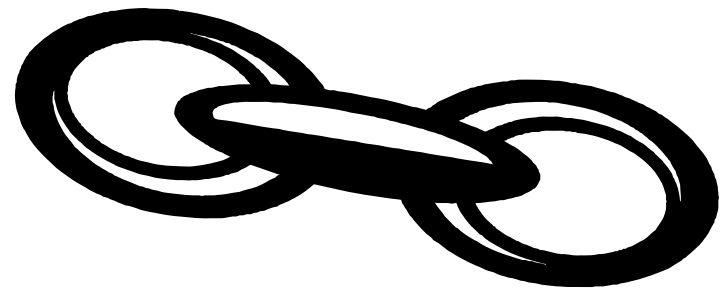- Model contractual language—that holds it all together

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Technology and Policy are Intertwined

- Choices about one necessarily shape the other.

- To build trust, you have to put policy decisions first.

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

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

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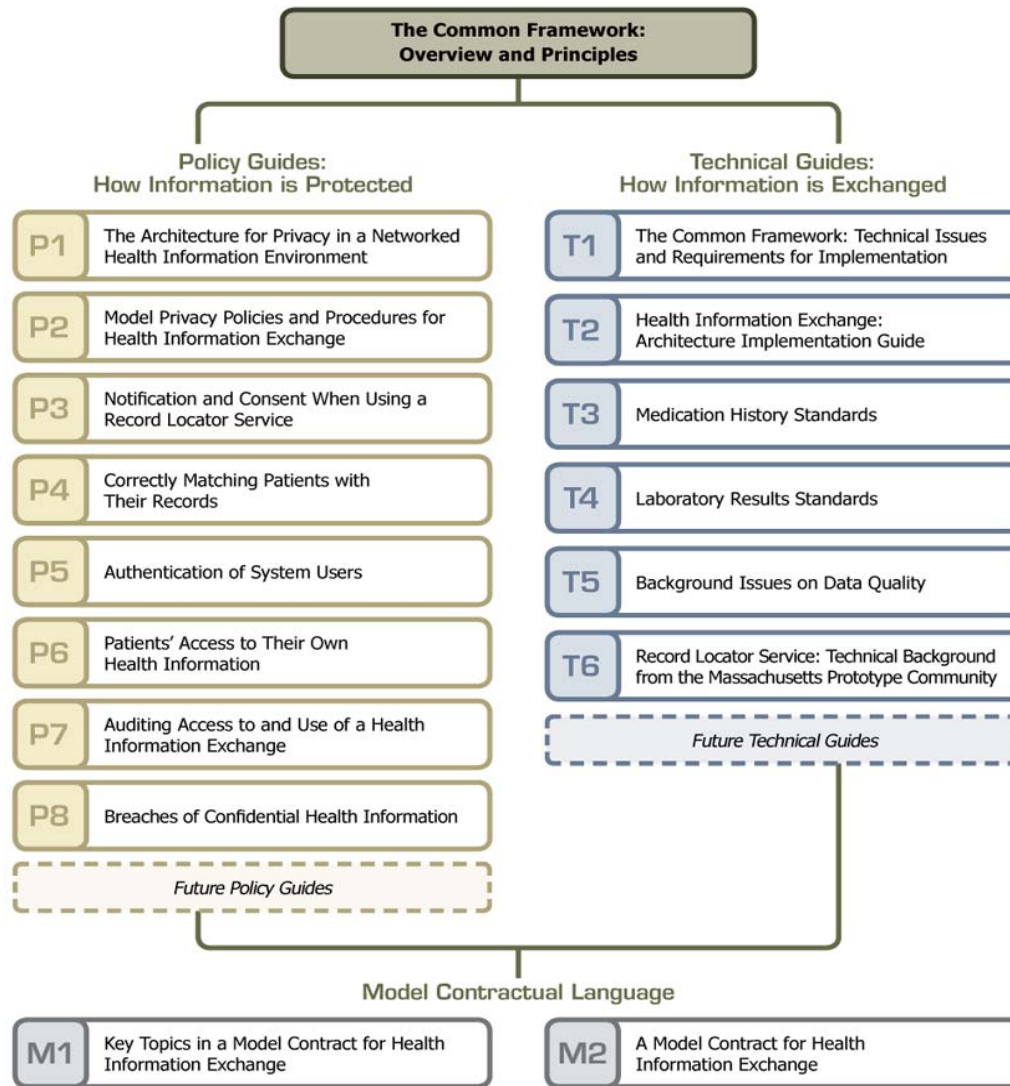
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Sample Policy Documents

Sample policy language

CFH Recommended policy

Incidents to the covered entity.[13] *See relevant sample contract excerpts below:* [14]

Section 8.03 Report of Improper Use or Disclosure. [The SNO] agrees promptly to report to a [Participant] any use or disclosure of the [Participant's] PHI not provided for by this Agreement of which [the SNO] becomes aware.

and

Section 8.14 HIPAA Security Rule Provisions.

(a) ...
(b) [The SNO] agrees promptly to report to a [Participant] any Security Incident related to the [Participant's] ePHI of which [the SNO] becomes aware.

Similarly, each Participant must agree to inform the SNO of any <u>serious</u> breach of confidentiality. It is not necessary for a Participant to inform the SNO of minor breaches of confidentiality (unless there is otherwise a legal duty to disclose such breaches to the SNO). While it is difficult to define what would rise to the level of a "serious" breach, SNOs and Participants might decide that the breaches of

From P8 – Breaches, p. 4

Model Terms and Conditions	Notes
4.7 Participant's Other Rights to Terminate Registration Agreement. *How a Participant may cease to be a Participant, generally.* **Alternative One: Participant may terminate at any time without cause.** A Participant may terminate its Registration Agreement at any time without cause by giving notice of that termination to [SNO Name]. **OR** **Alternative Two: Participant may terminate without cause with prior written notice.** A Participant may terminate its Registration Agreement at any time without cause by giving not less than _____ days prior notice to [SNO Name]. **OR** **Alternative Three: Participant may terminate as of the next anniversary of having entered into the Registration Agreement.** A Participant may terminate its Registration Agreement at any time without cause effective as of the next anniversary of the effective date of the Participant's Registration Agreement, by giving not less than _____ days prior notice to [SNO Name]. **OR** **Alternative Four: Participant may terminate for cause (may be combined with Alternatives Two or Three and/or Five).** A Participant may terminate its Registration Agreement upon [SNO Name]'s failure to perform a material responsibility arising out of the Participant's Registration Agreement, and that failure continues uncured for a period of sixty (60) days after the Participant has given [SNO Name] notice of that failure and requested that [SNO Name] cure that failure. **OR** **Alternative Five: Participant may terminate for specified cause (may be combined with Alternatives Two or Three and/or Four).** A Participant may terminate its Registration Agreement upon a Serious Breach of Confidentiality or Security, as described in Section 9.3 (Reporting of Serious Breaches), when such Serious Breach of Confidentiality or Security continues uncured for a period of sixty (60) days after the Participant has given [SNO Name] notice of that failure and requested that [SNO Name] cure that breach.	The SNO may wish to allow Participants to terminate their participation freely at any time, or to require that termination be preceded by a substantial period of advance notice, or to require that Participants maintain their participation for a year (or longer) at a time. If the SNO wishes to limit further certain Participants' (e.g., certain data providers) rights to terminate their participation, the SNO may provide for such special terms in written Registration Agreements described in Section 4.2 (Registration by Agreement). If the SNO places limits upon the Participant's right to terminate, the SNO may wish to provide for the Participant's right to terminate based on the SNO's failure to perform. The Model provides a simple "termination for cause" provision. The SNO may wish to qualify a Participant's right to terminate, e.g., by providing in addition that if the SNO's failure to perform is one that the SNO cannot reasonably cure within the specified period, then the termination will not take effect so long as the SNO commences and diligently pursues work to cure the failure.

From M2 – Model Contract, p. 10
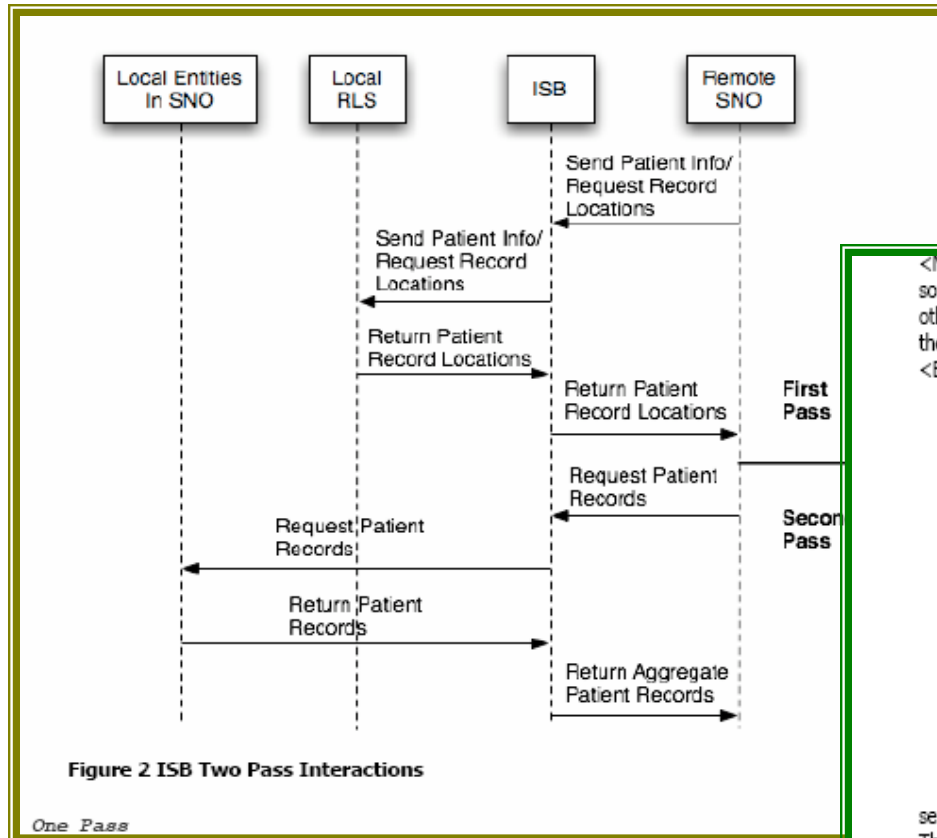
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Sample Technical Documents (T2)

Figure 2 ISB Two Pass Interactions

One Pass

<NHINQuery> node. The WS-Basic Profile 1.0 requires a single node within the SOAP <BODY>, so there will never be a second node at this level. Within the <NHINQuery> node, we find two other nodes. One contains control information about the query settings and the other contains the actual query. For example, the topmost level of the *PatientDataQuery* SOAP message <BODY> looks like:

```
<soapenv:Body>
    <nhin:NHINQuery>
        <nhin:EvaluationSettings>
            <nhin:MaxResponseInterval>60</nhin:MaxResponseInterval>
            <nhin:ResponseStyle>I</nhin:ResponseStyle>
        </nhin:EvaluationSettings>
        <nhin:Query format="HL7" version="2.4">
            <QBP_Z01 xmlns="urn:hl7-org:v2xml">
                ...
            </ QBP_Z01 >
        </nhin:Query>
    </nhin:NHINQuery>
</soapenv:Body>
```

The <Query> node defines the information that is actually being requested. The SOAP service and operation are merely wrappers in which to pass this generic "query" specification. The *format* and *version* attributes define the format in which the query is expressed. Currently, only HL7 version 2.4 queries are supported. NHIN is considering support of HL7 version 3.0 as its use becomes more widespread.

At the topmost level of the SOAP message <BODY>, each response message also contains a single node. The <NHINResponse> node contains two data-bearing nodes, just like the
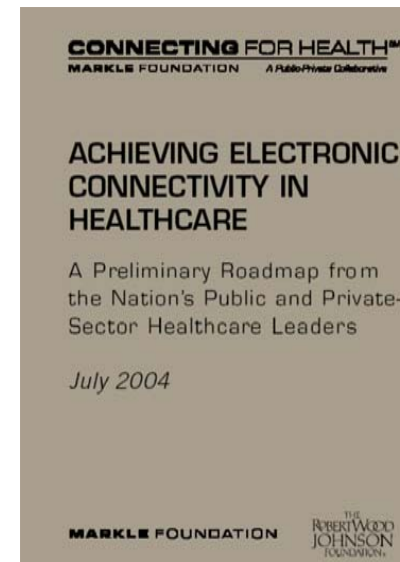
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The Common Framework is Not a "RHIO in a box"

- It provides different models to consider—not one "right answer."

- It is intended as a partial solution. It does not address finance, governance, etc.

- There are topics (like how to aggregate data for research and public health) that Connecting for Health is still working on…

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How Was the Common Framework Developed?

Connecting for Health…

- Started with Design Principles

- Wrote a Roadmap

- Built a Prototype

- Developed the Common Framework through field experience and the collaboration of experts

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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

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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

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The Roadmap Report

- Laid out the vision in 2004
- More than 60K copies in circulation

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ACHIEVING ELECTRONIC CONNECTIVITY IN HEALTHCARE

A Preliminary Roadmap from the Nation's Public and Private-Sector Healthcare Leaders

July 2004

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The Prototype

- Three sites
  - Boston
  - Indianapolis
  - Mendocino County, CA
- Diverse architectures
- Diverse structures

If these 3 can all use the Common Framework…anyone can!

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Who Developed the Prototype and the Common Framework?

- Connecting for Health Steering Group
- Policy Subcommittee: Co-Chairs Bill Braithwaite and Mark Frisse
- Technical Subcommittee: Chair: Clay Shirky
- Three communities and teams:
  - **Boston**: MA-SHARE and technical partner CSC
  - **Indianapolis**: Regenstrief Institute and Indianapolis Health Information Exchange (IHIE)
  - **Mendocino**: Mendocino HRE and technical partner Browsersoft, Inc.

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What is Available?

Technical Documentation: 3 Categories

1. <u>Background Documents</u>

   – T6: Record Locator Service Design

   – T5: Data "Cleanliness" and Quality

2. <u>Specific Technical Documents</u>

   – T1: Technical Overview and Implementation Requirements

   – T2: NHIN Message Implementation Guide (Record Locator Service/Inter-SNO Bridge)

   – T3-T4: Standards Guides

     • Medication History: Adapted NCPDP SCRIPT

     • Laboratory Results: ELINCS 2.0, with modifications

3. <u>Technical Code and Interfaces</u>

   – Test Interfaces: CA, IN, MA

   – Code base: CA, IN, MA

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What is Available?

Policy Documents: 3 Categories

1. <u>Background Document</u>
    –   P1: Privacy Architecture for a Networked Health Care Environment

2. <u>Specific Policy Documents</u>
    –   P2-P8: Model privacy policies, notification and consent, correctly matching, authentication, patient access, audits, and breaches

3. <u>Sample Contract Language</u>
    –   M1: Contact Topic List
    –   M2: Model Contract

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The Common Framework is Still Evolving

- Improving the resources to better meet the needs of communities

- Exploring how patients/consumers can access their own information

- Exploring how researchers and public health can benefit from health data

- Connecting for Health needs the input of organizations nationwide….
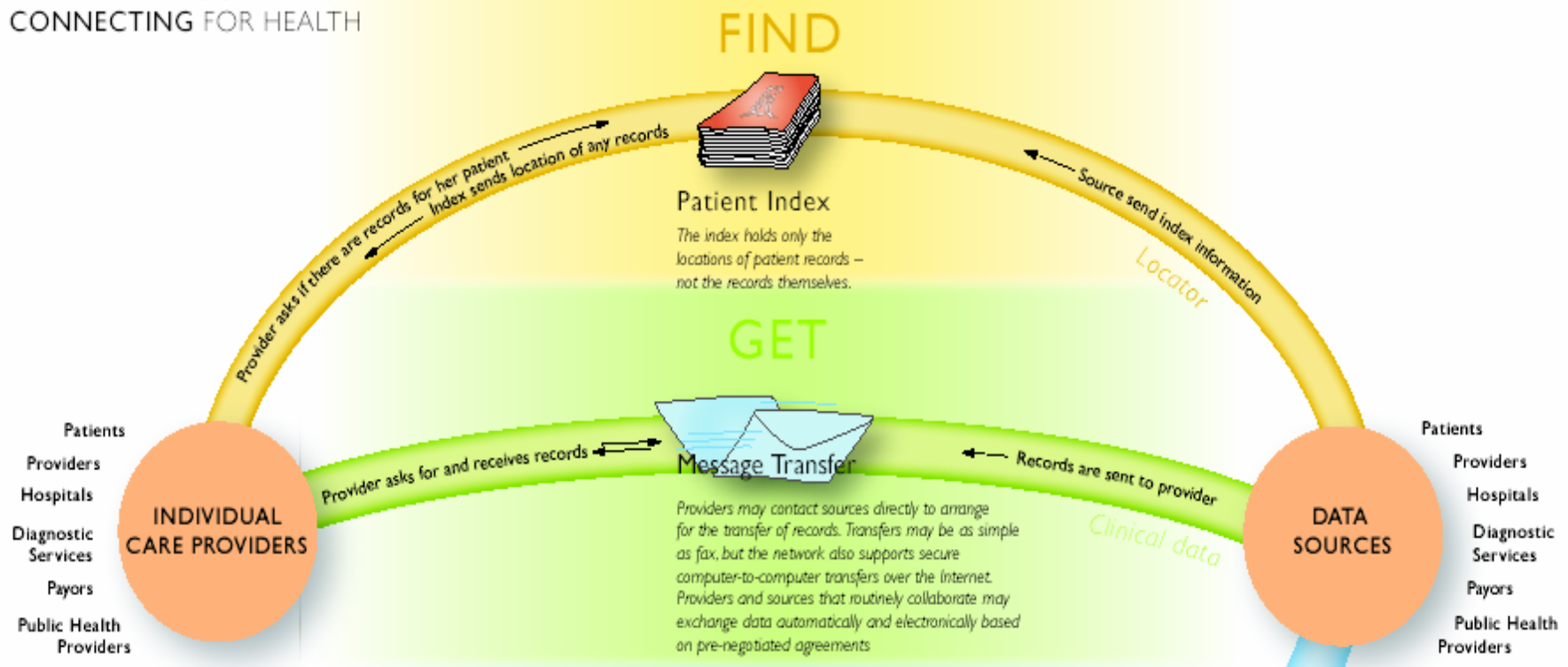
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Common Framework Resources

- All available free at
  www.connectingforhealth.org
- Policy and technical guides, model contractual language
- Registration for AHRQ/NORC Common Framework discussion forum
- Software code from regional prototype sites: Regenstrief, MAShare, OpenHRE
- Email to info@markle.org

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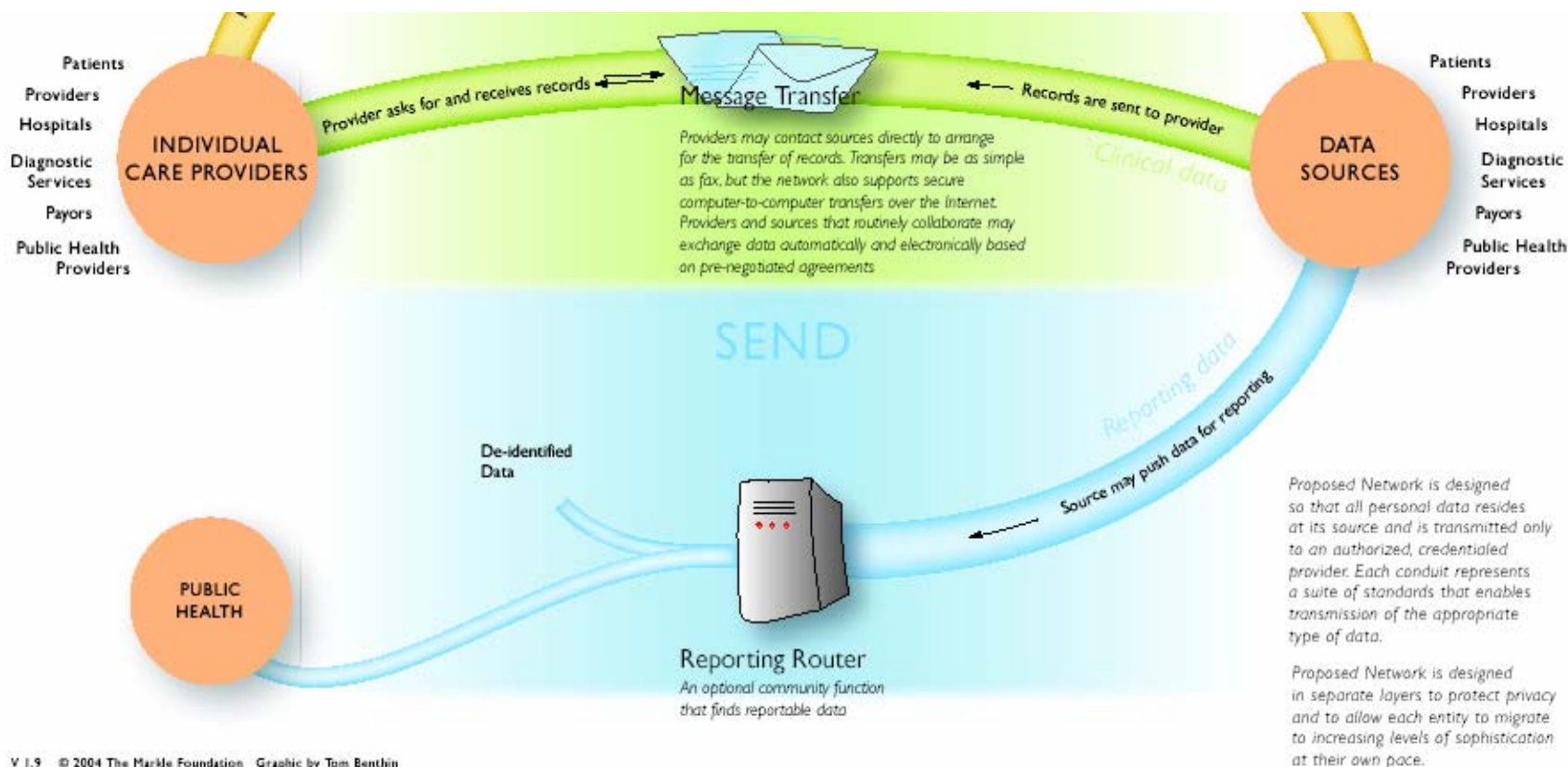MARKLE FOUNDATION

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Technical Overview of the Common Framework
National Resource Center
Agency for Healthcare Research and Quality

J. Marc Overhage, MD, PhD
Regenstrief Institute
Indiana University School of Medicine
Indiana Health Information Exchange

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Architecture is Federated and Decentralized: Once records are located, the health information flows peer-to-peer – with patient's authorization

The architecture supports point of care information sharing and population-based reporting

Patients
Providers
Hospitals
Diagnostic Services
Payors
Public Health Providers

INDIVIDUAL CARE PROVIDERS

Provider asks for and receives records

Message Transfer

Records are sent to provider

Providers may contact sources directly to arrange for the transfer of records. Transfers may be as simple as fax, but the network also supports secure computer-to-computer transfers over the Internet. Providers and sources that routinely collaborate may exchange data automatically and electronically based on pre-negotiated agreements

Clinical data

Patients
Providers
Hospitals
Diagnostic Services
Payors
Public Health Providers

DATA SOURCES

SEND

Reporting data

Source may push data for reporting

De-identified Data

PUBLIC HEALTH

Reporting Router
An optional community function that finds reportable data

Proposed Network is designed so that all personal data resides at its source and is transmitted only to an authorized, credentialed provider. Each conduit represents a suite of standards that enables transmission of the appropriate type of data.

Proposed Network is designed in separate layers to protect privacy and to allow each entity to migrate to increasing levels of sophistication at their own pace.

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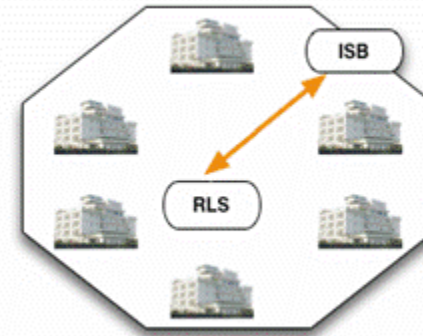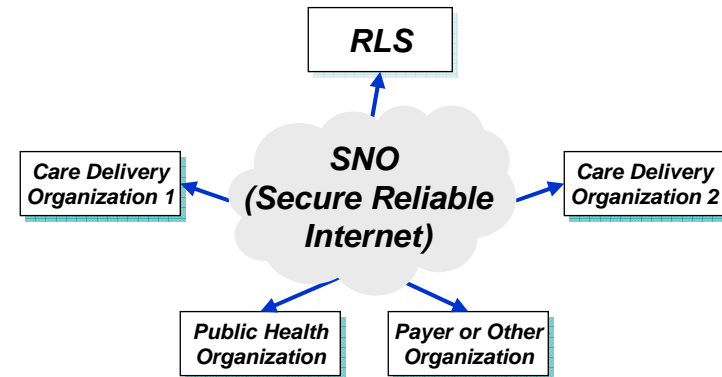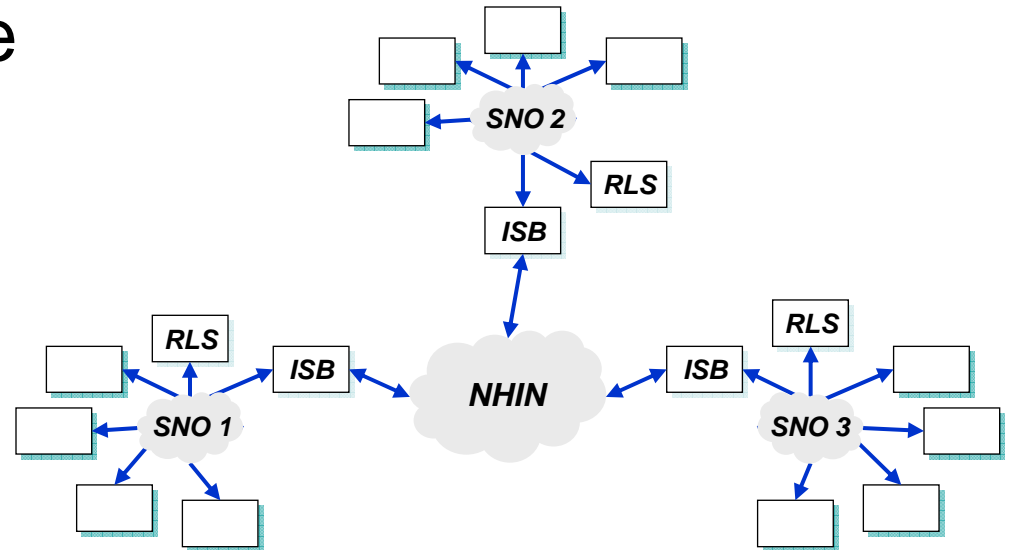
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The Connecting for Health Model for Health Information Sharing

- Sharing occurs via a network of networks (National Health Information Network) — not a completely new architecture
- The nationwide "network" is made up of smaller community networks or SNOs (Sub Network Organizations)
- Each SNO has an RLS (Record Locator Service) to locate patient records
- SNOs are interconnected through ISBs (Inter-SNO Bridges)

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NHIN: Network of Networks

- National Health Information *Network*, not National Health Information *Database*
- Bad Tradeoff: 1000x Searches for 0.1 to 0.01 increase
- No "Top Level" Query
  - Privacy
  - Security
  - Patient Trust
  - Source of Truth
  - Data Cleanliness
- Queries Must Be Targeted/No Fishing
- Built On Lines of Actual Human Trust

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What is a SNO?

- A group of entities (regional or non-regional) that agree to share information with each other
- Implements the Common Framework
- Provides an ISB for all external traffic
- Runs an RLS internally

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What is a Record Locator Service (RLS)?

- Like a phone book listing locations of information
- Contains no clinical information
- Only authorized participants can access it
- Obtaining the actual clinical record is a separate transaction not involving RLS

RLS

Care Delivery Organization 1

SNO (Secure Reliable Internet)

Care Delivery Organization 2

Public Health Organization

Payer or Other Organization

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What is a Inter-SNO Bridge (ISB)?

- Software that provides the interfaces that define a SNO
- Provides essential services

How Multiple SNOs Connect to Form NHIN

- A SNO queries other SNOs when it knows:
  - An institution where the patient received care
  - A region where the patient received care
- Same query formatted for all remote SNOs
- Only need location of ISBs
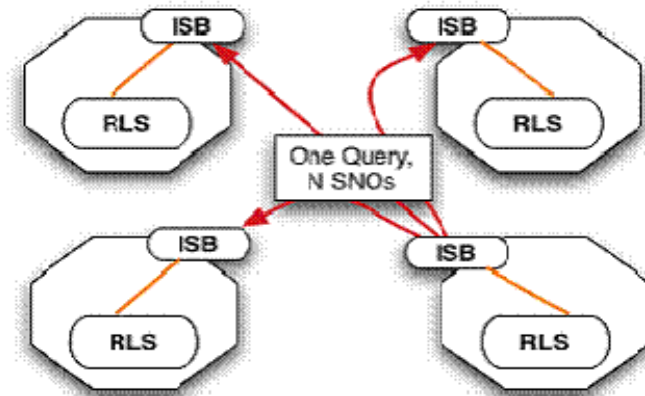
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Underlying Technologies

- TCP/IP
- SOAP
- Web Services
- HL7/NCPDP messaging standards
- LOINC codes
- NDC codes

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Security / Confidentiality

- Server-to-server (ISB-to-ISB) authentication via X.509 certificates

- Communication protected by SSL/TLS

- Federated identity based on single token authentication in edge systems

- Role based/level based access control

Prototype SNOs reflect the realities of existing market and health IT variation

	IHIE	MA-SHARE	Mendocino HRE
Market	Mixed urban and rural; dominant academic anchor (IU)	Urban mix of academic, community and commercial influences	Rural and underserved community medicine and health centers
RHIO-related history	35+ years	25+ years	7 years
Technology partner	Regenstrief (academic not-for-profit)	CSC (large commercial)	Browsersoft (small commercial)
Development preference	J2EE	Microsoft .NET	Mixed Open Source
Overall architecture	Central data repository with standardized data	Federated, with shared Record Locator Service	Brokered through mirrored data at central HRE
Standards	Significant investment in HL7 2.x	Implementing HL7 3.0; investigating XDS	"Bi-lingual" (HL7 2.x and 3.0)

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Prototype Approaches

Supported by Browsersoft, Inc. (OpenHRE)

Record Exchange Service (RES)

Mirrored Clinical Data

RLS

InterSNO Bridge

Auth / Access Control Service (AACS)

Registries, Audit, etc.

IHIE / INPC (at Regenstrief)

Clinical Data

HL7 Update Services

MPI / RLS Service

INPC Disburser / Aggregator (serving as InterSNO Bridge)

IHIE
Indiana Health Information Exchange

Indiana
- Developed Disburser / Aggregator for ISB
- Adapted existing MPI for RLS
- Source systems send data to hosted HL7 Update Services for transformation and hosting in standard form

Hosted by CSC

RLS

Community-level registries

CDX Gateway (serving as InterSNO Bridge)

MA-SHARE

MENDOCINO HEALTH RECORDS EXCHANGE
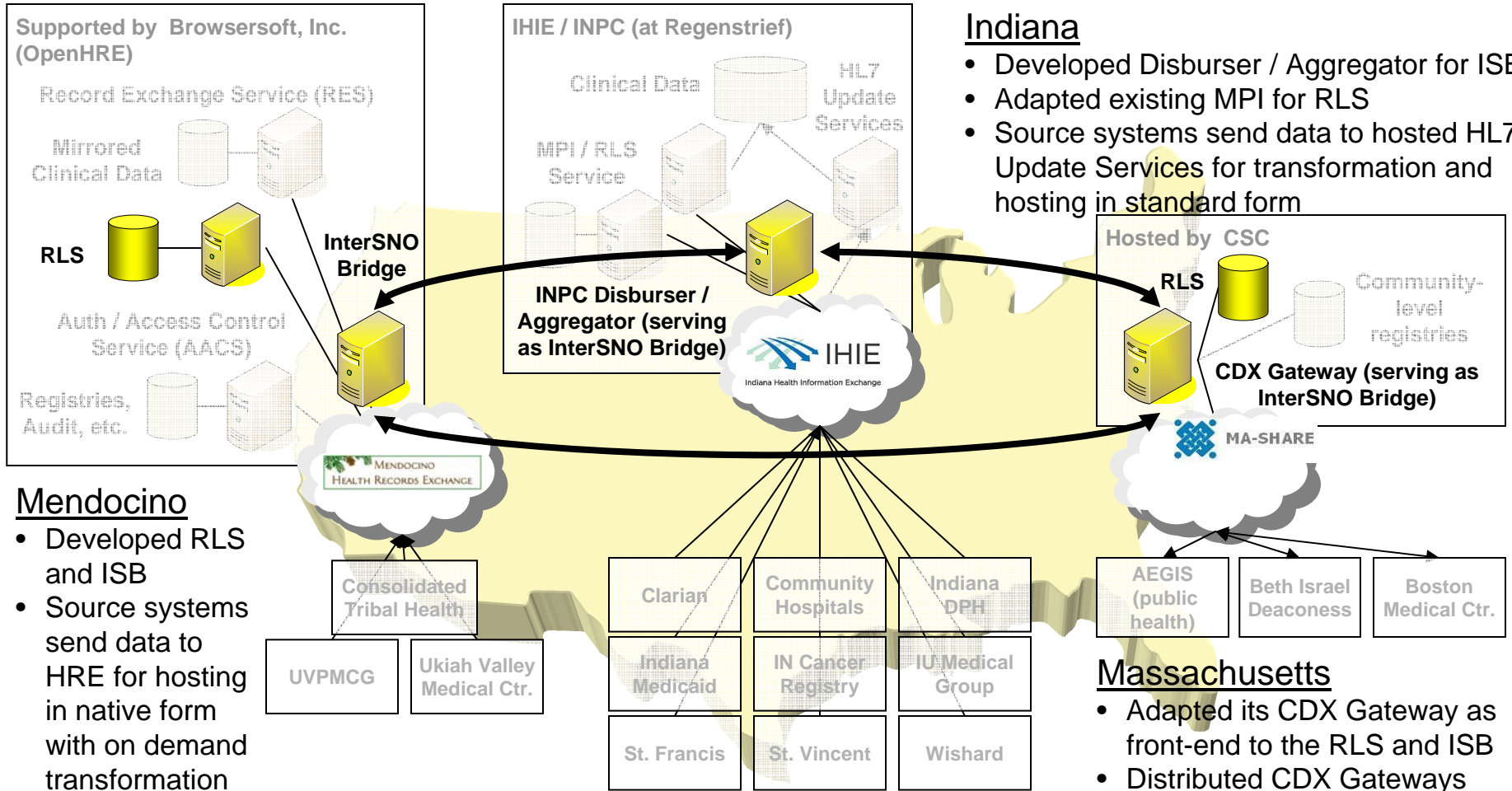
Mendocino
- Developed RLS and ISB
- Source systems send data to HRE for hosting in native form with on demand transformation

Consolidated Tribal Health

UVPMCG

Ukiah Valley Medical Ctr.

Clarian

Indiana Medicaid

St. Francis

Community Hospitals

IN Cancer Registry

St. Vincent

Indiana DPH

IU Medical Group

Wishard

AEGIS (public health)

Beth Israel Deaconess

Boston Medical Ctr.

Massachusetts
- Adapted its CDX Gateway as front-end to the RLS and ISB
- Distributed CDX Gateways fetch source data on demand from participant sites

■ = New "NHIN" functionality

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Policies for Information Sharing
AHRQ National Resource Center HIT Webconference
July 25, 2006

Melissa M. Goldstein
Director, Health
Markle Foundation

Presented by Lygeia Ricciardi and Melissa Goldstein, of the Markle Foundation, Vicki Estrin from the Vanderbilt Center for Better Health and Marc Overhage from Indiana University on behalf of Connecting for Health, and moderated by Susan Christensen, Senior Advisor at AHRQ, as part of the AHRQ HIT Web Teleconference Series.

Connecting for Health
Policy Subcommittee

- **About 40 experts in**
  - Law

  - Health privacy and ethics

  - Health care delivery

  - Administration

  - Technology

  - Local network development (RHIOs)

Connecting for Health
Policy Subcommittee

- Looked at HIE in the context of HIPAA and existing state laws

- Developed a list of significant topics from

  - Members' experience with early information exchange networks

  - Members' own expertise

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Challenges

- Who has access to what, under what circumstances, and with what protections?

- Who shares what and who bears the liability?

- How can you control access to your information?

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Connecting for Health Goals

- Develop a <u>policy framework</u>
- Identify <u>what needs to be</u> common for interoperability and what does not
- Design and develop a working guide

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What is the Common Framework?

- A set of critical tools, including technical standards and policies for how information is handled, whose general adoption will enable secure nationwide health information sharing

- Contractual arrangements among members of communities (or SNOs) are a key to implementation

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Overview of Connecting for Health Architecture

- A sub-network organization (SNO) brings together a number of providers and other health information sources
- They are linked together by contract
- Agree to follow common policies and procedures
- Agree to create and use a shared index to where patient records are located (RLS)
- Agree to create and use a common gateway to share information with other networks (ISB)

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What is a Record Locator Service (RLS)?

- An index containing patient demographic information and the <u>location</u> of a patient's medical records

- Contains <u>no</u> clinical information – obtaining the clinical record is a separate transaction NOT involving the RLS

- Participating entities decide whether or not to put record locations into the RLS

- Designed to take a query in the form of demographic details and return only the <u>location</u> of matching records

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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

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
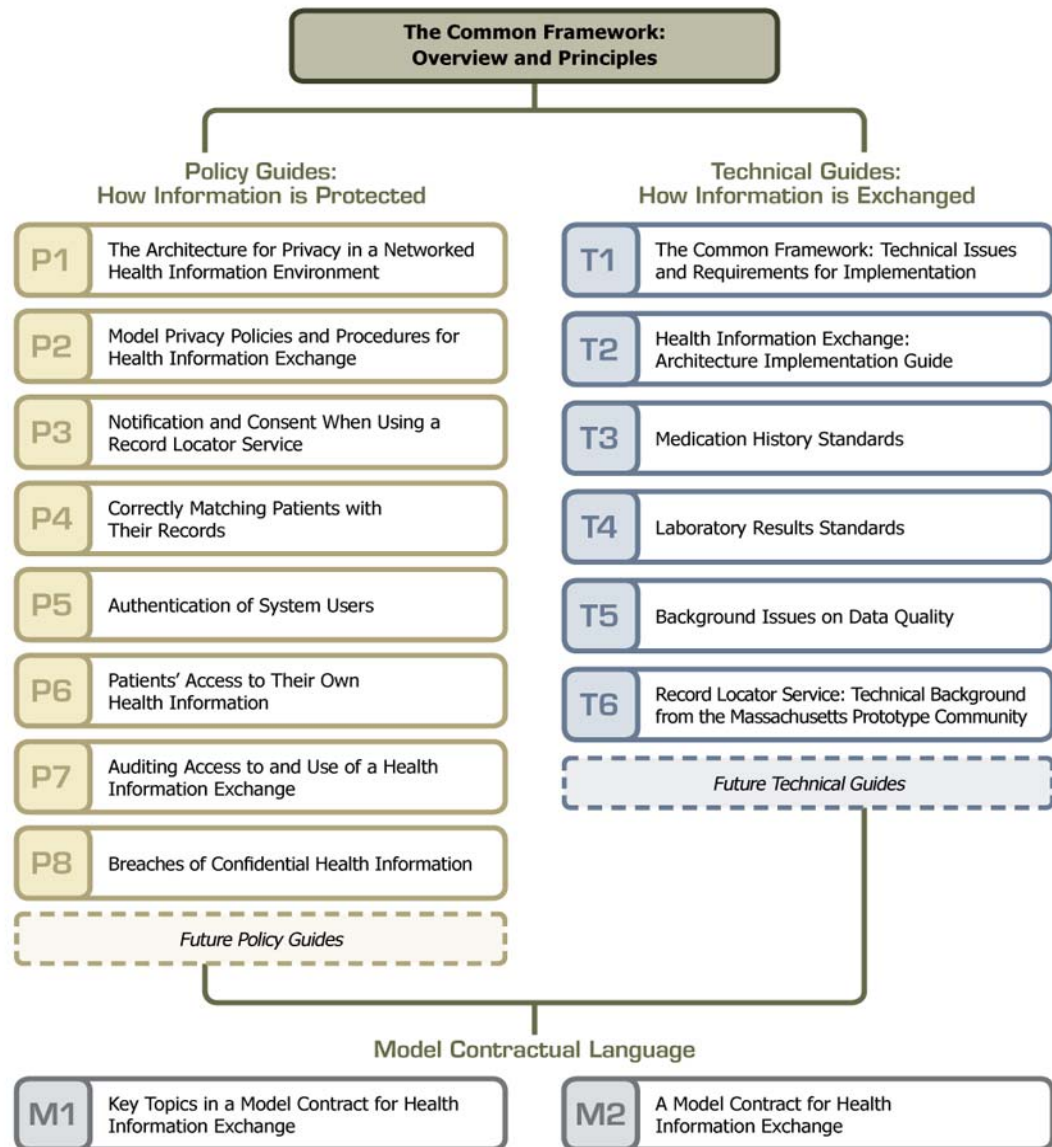
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Connecting for Health: Privacy Principles

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

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The Privacy Principles are Interdependent
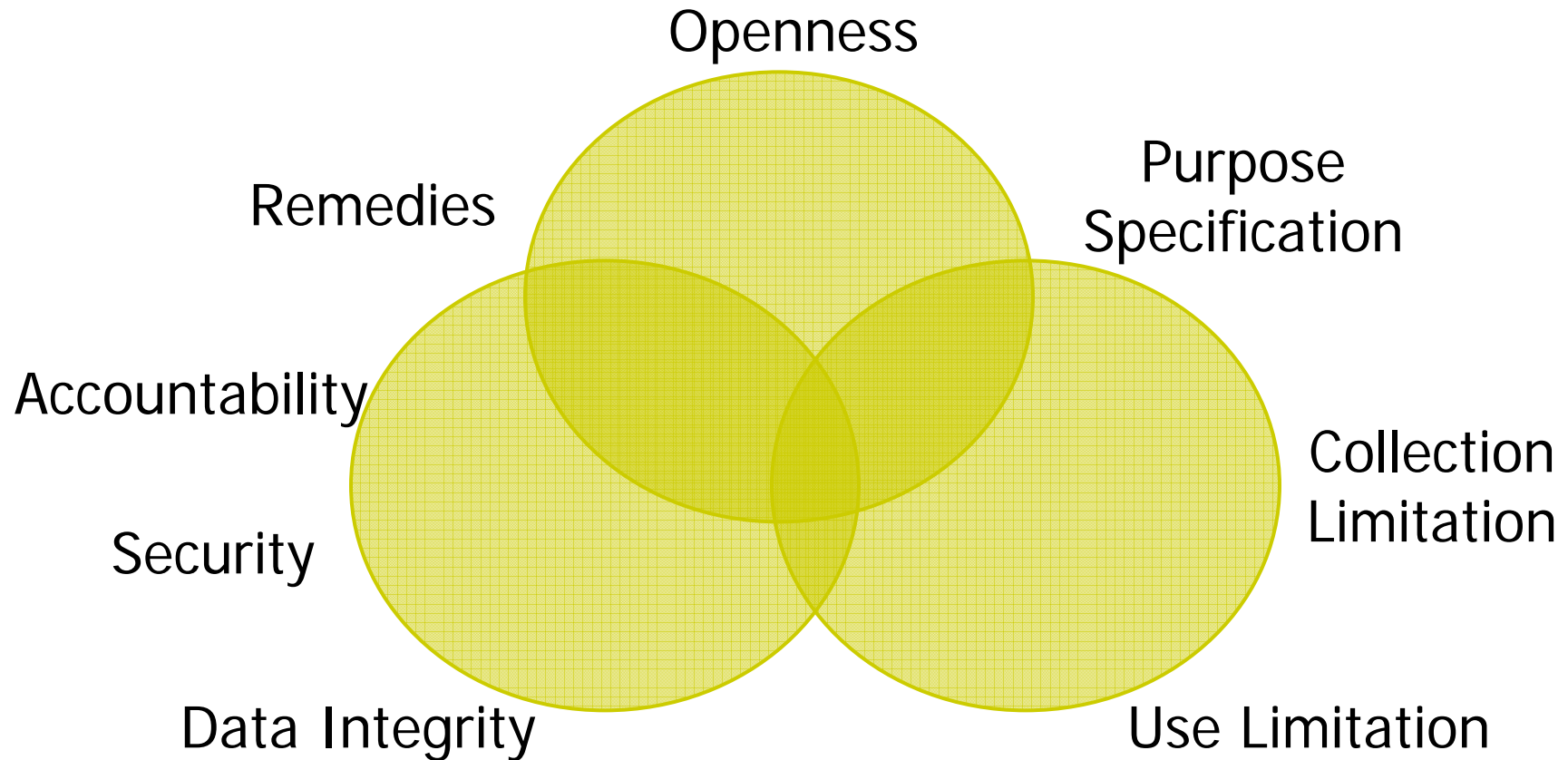
Openness

Purpose Specification

Remedies

Accountability

Collection Limitation

Security

Data Integrity

Use Limitation

Individual Participation and Control

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

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Model Privacy Policies and Procedures

- To be used in conjunction with the *Model Contract for Health Information Exchange*
- Establish baseline privacy protections – participants can follow more protective practices
- Based on HIPAA, although some policies offer greater privacy protections
- Rooted in nine privacy principles
- Should be customized to reflect participants' circumstances and state laws

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Model Contract for
Health Information Exchange

- Purpose of Model SNO Terms and Conditions
  - To assist SNOs prepare their own Terms and Conditions
  - 60-40 solution
  - Identify issues and alternatives
  - Raise questions

Model Contract:
Essential Components

- Incorporates applicable terms of Common Framework Policies and Procedures
- Provides specific terms that the individual SNO may determine are appropriate for its unique needs
- Includes mechanism for making and implementing changes

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Common Framework
Policy Topics Addressed

- Notification and consent
- Patient access to their own information
- Breaches of confidential information

Sample Policy Documents

Sample policy language

Incidents to the covered entity.[13] *See relevant sample contract excerpts below:* [14]

Section 8.03 Report of Improper Use or Disclosure. [The SNO] agrees promptly to report to a [Participant] any use or disclosure of the [Participant's] PHI not provided for by this Agreement of which [the SNO] becomes aware.

and

Section 8.14 HIPAA Security Rule Provisions.

(a) ...
(b) [The SNO] agrees promptly to report to a [Participant] any Security Incident related to the [Participant's] ePHI of which [the SNO] becomes aware.

CFH Recommended policy

Similarly, each Participant must agree to inform the SNO of any serious breach of confidentiality. It is not necessary for a Participant to inform the SNO of minor breaches of confidentiality (unless there is otherwise a legal duty to disclose such breaches to the SNO). While it is difficult to define what would rise to the level of a "serious" breach, SNOs and Participants might decide that the breaches of

From P8 – Breaches, p. 4

Model Terms and Conditions	Notes
4.7 Participant's Other Rights to Terminate Registration Agreement. *How a Participant may cease to be a Participant, generally.* **Alternative One: Participant may terminate at any time without cause.** A Participant may terminate its Registration Agreement at any time without cause by giving notice of that termination to [SNO Name]. **OR** **Alternative Two: Participant may terminate without cause with prior written notice.** A Participant may terminate its Registration Agreement at any time without cause by giving not less than _____ days prior notice to [SNO Name]. **OR** **Alternative Three: Participant may terminate as of the next anniversary of having entered into the Registration Agreement.** A Participant may terminate its Registration Agreement at any time without cause effective as of the next anniversary of the effective date of the Participant's Registration Agreement, by giving not less than _____ days prior notice to [SNO Name]. **OR** **Alternative Four: Participant may terminate for cause (may be combined with Alternatives Two or Three and/or Five).** A Participant may terminate its Registration Agreement upon [SNO Name]'s failure to perform a material responsibility arising out of the Participant's Registration Agreement, and that failure continues uncured for a period of sixty (60) days after the Participant has given [SNO Name] notice of that failure and requested that [SNO Name] cure that failure. **OR** **Alternative Five: Participant may terminate for specified cause (may be combined with Alternatives Two or Three and/or Four).** A Participant may terminate its Registration Agreement upon a Serious Breach of Confidentiality or Security, as described in Section 9.3 (Reporting of Serious Breaches), when such Serious Breach of Confidentiality or Security continues uncured for a period of sixty (60) days after the Participant has given [SNO Name] notice of that failure and requested that [SNO Name] cure that breach.	The SNO may wish to allow Participants to terminate their participation freely at any time, or to require that termination be preceded by a substantial period of advance notice, or to require that Participants maintain their participation for a year (or longer) at a time. If the SNO wishes to limit further certain Participants' (e.g., certain data providers) rights to terminate their participation, the SNO may provide for such special terms in written Registration Agreements described in Section 4.2 (Registration by Agreement). If the SNO places limits upon the Participant's right to terminate, the SNO may wish to provide for the Participant's right to terminate based on the SNO's failure to perform. The Model provides a simple "termination for cause" provision. The SNO may wish to qualify a Participant's right to terminate, e.g., by providing in addition that if the SNO's failure to perform is one that the SNO cannot reasonably cure within the specified period, then the termination will not take effect so long as the SNO commences and diligently pursues work to cure the failure.

From M2 – Model Contract, p. 10

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Notification and Consent

- Inclusion of a person's demographic information and the location of her medical records in the RLS raises privacy issues and issues regarding personal choice

- What should an institution participating in the RLS be required to do to inform patients and give them the ability to decide not to be listed in the RLS index?

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Notification and Consent

- Involves issues of openness and transparency, and individuals' participation and control over their own health information

- Easy to fall into trap of opt-in/opt-out debate, but question is really about enabling individual choice

Notification and Consent: recommendations

- Subcommittee recommendations are more protective of privacy than HIPAA – HIPAA is a floor but not always sufficient in this environment

- Patient must be given notice that institution participates in RLS and provided opportunity to remove information from index

- Revision of HIPAA Notice of Privacy Practices should reflect participation in RLS

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Notification and Consent

- Recommendations strike balance between burden on SNO participants, individual patient choice and control, and maximizing the benefits of a networked health information environment

- Encourages participation in system by engendering patient trust

- Separation of clinical record from locations included in the RLS add layer of privacy protection

Patient Access

- Patients have a vital interest in accessing sensitive information about their own health care
    - Enables informed choices about who should get such information, under what circumstances
    - Facilitates awareness of errors that the records my contain
- Ability to effectively access personal health information could be significantly enhanced with the use of new technologies

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Patient Access

- How can we facilitate patients' access to their own health information in health information exchange networks?

- Involves issues of openness and transparency and individual control of health information

Patient Access

- HIPAA – the baseline
  - Right to See, Copy, and Amend own health information
  - Accounting for Disclosures
  - Covered entities required to follow both Privacy Rule and related state laws
  - Allows stronger privacy safeguards at state level

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Patient Access

- As a matter of principle, patients should be able to access the RLS.

  - Access will empower patients to be more informed and active in their care

- However, significant privacy and security concerns exist regarding giving patients direct access at this stage

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Patient Access: recommendations

- Patient access to the information in the RLS
  - Each SNO should have a formal process through which information in the RLS can be requested by a patient or on a patient's behalf
  - Participants and SNOs shall consider and work towards providing patients direct, secure access to the information about them in the RLS

Presented by Lygeia Ricciardi and Melissa Goldstein, of the Markle Foundation, Vicki Estrin from the Vanderbilt Center for Better Health and Marc Overhage from Indiana University on behalf of Connecting for Health, and moderated by Susan Christensen, Senior Advisor at AHRQ, as part of the AHRQ HIT Web Teleconference Series.

Patient Access

- Recommendations strike balance between current security and authentication challenges and principle that patients should have same access to their own information as health care providers do

- RLS could ultimately empower patients to access a reliable list of where their personal health information is stored

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Breaches of Confidential Health Information

- Networked health information environments include higher volumes of easily collected and shared health data – thereby increasing privacy risks

- Security experts assure us that breaches will occur in even the most secure environments

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Breaches of Confidential Health Information

- What policies should a SNO have regarding breaches of confidentiality of patient data?
- Involves issues of purpose specification, collection, and use of health information, accountability, and remedies
- Who should be notified of breaches, and when?
- Is breach a reason for a participant to withdraw from the SNO? Should special rules for indemnification apply in the case of a breach?

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Breaches of Confidential Health Information: recommendations

- SNO should comply with HIPAA Security Rule. SNO Participants should comply with applicable federal, state, and local laws

- Responsibility of Participants to train personnel and enforce institutional confidentiality policies and disciplinary procedures

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Breaches of Confidential Health Information: recommendations

- SNO must report any breaches and/or security incidents. SNO Participants must inform SNO of serious breaches of confidentiality

- Participants and SNOs should work towards system that ensures affected patients are notified in the event of a breach

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Breaches of Confidential Health Information: recommendations

- SNO contract could include provision allowing participant withdrawal from SNO in case of serious breach of patient data

- SNO contract could include indemnification provisions pertaining to breach of confidentiality of protected health information

Breaches of Confidential Health Information

- Recommendations strike balance between levels of institutional and SNO responsibility for breaches and goal of notifying patients in the event of a breach

- Model language for SNO policies regarding breach is provided

Common Framework Resources

- All available free at www.connectingforhealth.org
- Policy and technical guides, model contractual language
- Registration for AHRQ/NORC Common Framework discussion forum
- Software code from regional prototype sites: Regenstrief, MAShare, OpenHRE
- Email to info@markle.org

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SW Tennessee's experience in Using the Connecting for Health Framework Model Contract
## AHRQ National Resource Center HIT Webconference
July 25, 2006

Vicki Estrin
Program Manager
Vanderbilt University

Presented by Lygeia Ricciardi and Melissa Goldstein, of the Markle Foundation, Vicki Estrin from the Vanderbilt Center for Better Health and Marc Overhage from Indiana University on behalf of Connecting for Health, and moderated by Susan Christensen, Senior Advisor at AHRQ, as part of the AHRQ HIT Web Teleconference Series.

Where are we talking about?
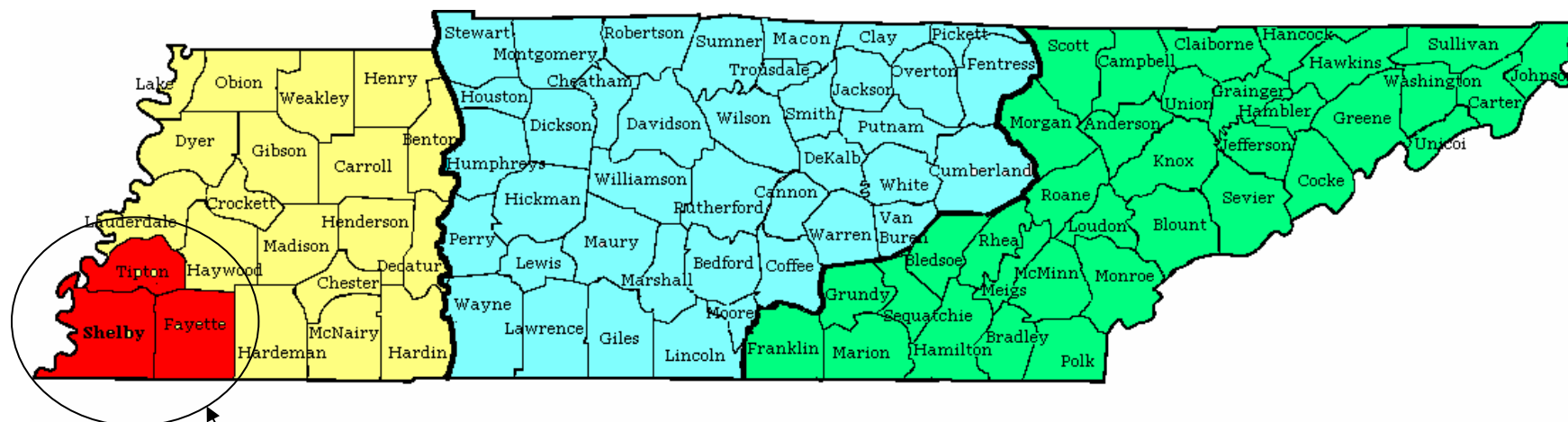
All parties recognize that health care is regional and that a significant number of individuals seeking care in Tennessee are residents of one of the 8 bordering states
Note – There are other regional initiatives and state-wide HIT initiatives funded by HHS, AHRQ and HRSA in the state

Project Summary

Funding Sources

September 21, 2004, Tennessee received a 5 year contract/grant from Agency for Healthcare Research and Quality (AHRQ) - total award is $4.8 million

State of Tennessee provided additional funds in the amount of $7.2 million for the same 5 year period

MidSouth eHealth Alliance will receive additional funding from the state to fund operations (e.g. Executive Director and local support staff)

Vanderbilt's Role

"Donated" the use of its technology for the project

Serves the functions of Project Management Office and Health Information Service Provider

Responsible for compliance with the AHRQ contract

Also supports as requested other HIT activities across the state at a planning level

Initial Participating Organizations

- Baptist Memorial Health Care Corporation – 4 facilities

- Christ Community Health – (3 primary care clinics)

- Methodist Healthcare – 7 facilities including Le Bonheur Children's Hospital

- The Regional Medical Center (The MED)

- Saint Francis Hospital & St. Francis Bartlett

- St. Jude Children's Research Hospital

- Shelby County/Health Loop Clinics (11 primary care clinics)

- UT Medical Group (200+ clinicians)

- Memphis Managed Care-TLC (MCO)

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Project Summary

- ## Planning August 2004 – January 2005
  - Governor initiated planning effort in August 2004 to explore the effect of HIT on healthcare in Tennessee
  - September 2004 awarded AHRQ Contract to be a State Regional Demonstration (SRD) project
  - Planning effort re-focused primarily in the demonstration area of Shelby, Fayette and Tipton counties

- ## Detail Design and Implementation February 2005 – present
  - Memorandum of Understanding and Business Associate Agreements
  - Data feeds through secure VPN connection
  - Test data started June 2005. Switch to production data August 2005
  - October 1, 2005 demonstrated the ability to exchange 25% of core data elements. System was not in use.
  - Limited initial use in 1 emergency department (The MED) during weekday day shifts on May 23rd. Shifted to 24/7 use on June 21st.
  - Next site for initial use is targeted for August 22nd

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Organization and Governance

- The MidSouth eHealth Alliance (MSeHA) – Organization responsible for the operations of a RHIO in the three counties
  - Board was formed in February 2005
  - Incorporated in August 2005- not-for-profit status in March 2006
  - Plan to hire an executive director
- Board makes all final decisions on policy
  - Current Structure: Work groups make recommendations to the board
    - Privacy and Security
    - Technical
    - Clinical
    - Financial
  - Future Structure: Operations Committee (a.k.a. Management Committee in Connecting for Health Framework) will be formed in August 2006 – initial membership will be the Privacy and Security Work Group.
    - Function will be to review, educate, and advise the board on Policy and Procedure
    - Board will continue to make all final decisions on policy

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Privacy and Security
Where the conflict began

- Technology was hard work but early on, one of the project principles was that policy would drive technology whenever possible
- In the planning effort we generated more questions than answers
  - HIPAA was the easy part
  - Never considered the legal fees in our budget
  - Did not understand the magnitude of what we were attempting
- Privacy and Security Work group charted in June 2005 to support implementation efforts
  - Members were told it was a 6 – 8 month commitment – *Now we see no end in sight*
    - Group has grown to approximately 25 members and meets monthly for half a day with work done via conference call and e-mail in between
- First meeting, listed all the issues to tackle among them was the creation of a regional data exchange agreement AND everyone wanted to start there but…

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Our Approach to a
Regional Data Exchange Agreement

- Mark Frisse was the co-chair of the Connecting for Health Policy for Information Sharing Sub-committee. He promised me that a model contract was in the works for a regional data sharing agreement
  - We all agreed it made sense to wait for the model
- The Privacy and Security workgroup tackled a number of issues while we waited…turns out these needed to be tackled sooner than later anyway
  - Who would have access to the MidSouth eHealth Alliance data?
  - Would we allow a patient to "opt out" of the RHIO (or "RHIO Out" as we now call it)?
  - Would we notify the patient in some way that their data was being shared?
  - What would we audit and track?
  - What policies do we need to have in place?
  - Who will write policies?
  - Etc.
- The dialogue and debate around these issues laid the foundation for an environment of trust where all views are considered viable and discussed openly

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Our Approach to a
Regional Data Exchange Agreement

Note: June through August the workgroup focused on key policy issues. This laid a foundation for trust and open dialogue. When we began working on the Regional Data Exchange agreement, our overall approach was to do as much work as we possibly could without incurring legal fees

September	October - November		January - February	March	May
Received Model Contract Draft version. Distributed to P&S work group	P&S work group identified a leader and interested members agreed to meet to walk through the model contract	Distributed the start of a MSeHA framework based upon the model to larger group. Met to review questions and concerns	Distributed a redline document for each organization to review and give feedback	Attorney engaged to represent MSeHA. Reviewed all the feedback. Created the "final" draft for organizations to review	All Participants agreed on the language on May 10th and document was fully executed by May 19th for initial use on May 23rd

Total of 8 people participated in this work representing 6 organizations. Group met several times for 2+ hours each time

Review was done by 30+ people representing all the organizations that are considered to be in the MSeHA – several sought advice from their own counsel

Review was facilitated by the work group and board members. Involved 10 attorneys representing the 9 organizations

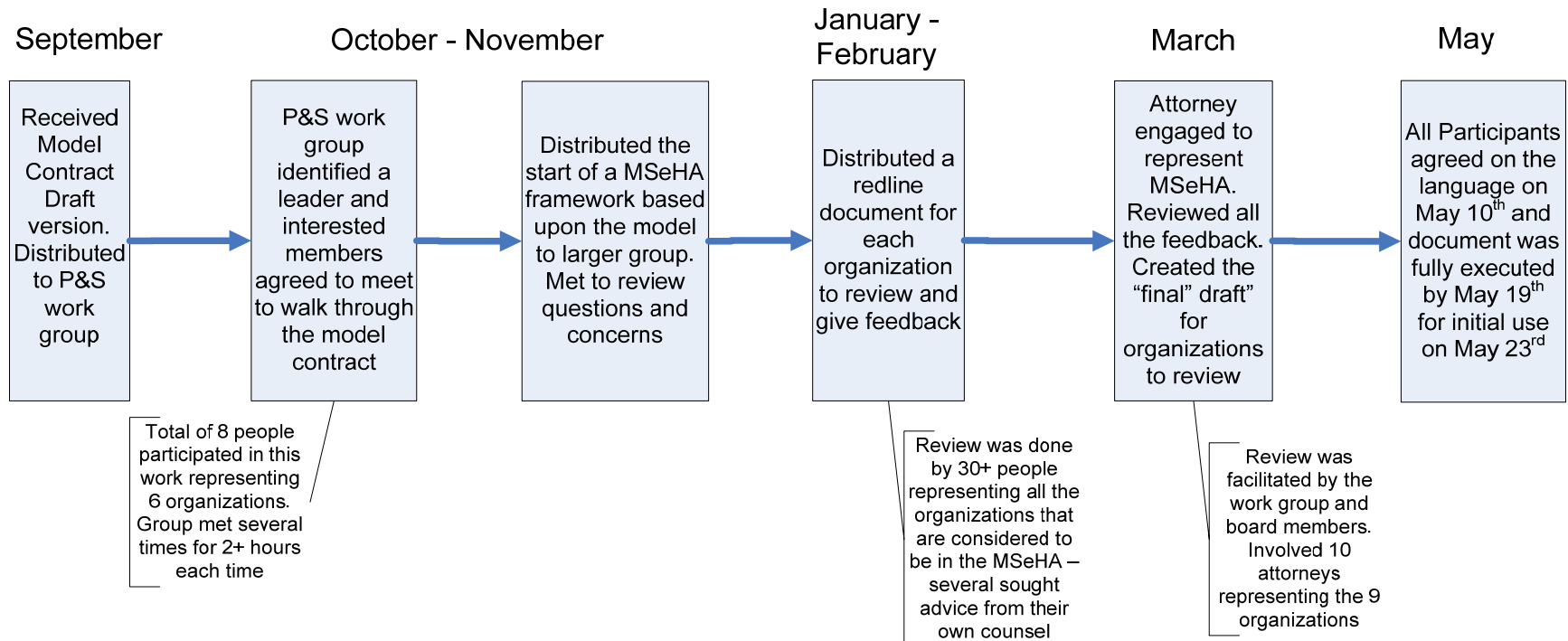CONNECTING FOR HEALTH
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Once the Regional Data Exchange Agreement Draft was completed we thought we could relax …

- WRONG!
- <u>All</u> of the attorneys requested at a minimum a draft of the policies and procedures
  - Not an unreasonable request given that the agreement makes a number of references to policies
- We immediately turned to the recently released Markle Framework…
  - We created a minimum list of policies that the agreement required
  - Used the Framework as a reference guide
  - While the agreement was being reviewed, the work group spent two full days together working through policies. In addition each organization had at least one person and usually two people working for several hours a week on the policies prior to the day long working meetings.

Did the Connecting for Health Framework Help – You Bet It Did!

- Model Contract gave us framework to start work from
  - It identified areas we needed to address in our agreement
  - The language didn't always flow for the members but it gave them an idea of what was intended
  - It took several readings to digest the format, terms, etc.
  - Initially, wrestled with the terms and definitions
  - Model forced MSeHA board and work group to discuss all parties' assumptions
- We kept most of the construct from the model although made a few deliberate changes
  - Example: We have reference the license agreement but the MSeHA will sign a separate license agreement with Vanderbilt for software access
- The model did about 50 – 60 percent of the work for us by giving us the framework and example language in many cases from which to work
  - It supported our goal/approach of engaging counsel later in the process
- The Model Policies gave us a benchmark to start with and sample language to start from

Our Challenges

- Achieving agreement between all parties
  - The model raises questions that only the community working through the agreement will be able to answer – *it doesn't have all the answers – it has most of the questions*
  - It is an educational process that requires deep understanding of the issues and the positions of all involved
  - Getting 9+ attorneys to agree on one single document is never easy
    - The framework once understood actually facilitated the agreement much quicker than anyone dared to believe was possible
- Time
  - The agreement and policies were our last milestones to bringing the system up in a live environment
  - All of the organizations donated a significant amount of resource time to work on the agreement and policies/procedures that support the agreement
- Money
  - Never predicted the amount of legal fees we would incur
  - Consciously brought the lawyers in only after we had discussed the areas of conflict and come to a common conclusion/decision

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Next Steps

- Document what we actually did using the Markle Model Contract and Framework as a benchmark
  - Policies were written for initial use in the Emergency Department to keep focus and get the policies done; however, they need to be reviewed in a more methodical manner with a larger scope of use in mind.
- Have identified a set of Participant policies that need to be reviewed by each Participant before bringing the system live in the next organization
- Identify and bring up the next emergency department in August. (The goal is to have five emergency departments using the system by first quarter of 2007.)

Questions & Answers

- For additional Common Framework resources, visit:
  www.connectingforhealth.org

- For more information, visit AHRQ's National Resource Center, which boasts links to more than 6,000 health IT tools, best practices, and published evidence online at http:healthit.ahrq.gov.

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