

Day one-Plenary session-B
Dan Russler

The National Health Information Network & its Implications for a National Rare Disease Patient Registry/case study
Dan Russler, M.D., (Oracle Health Sciences Strategy)

Building on alternative approaches to the governance of rare disease registries, this session will examine national infrastructures for communication of sensitive health information over the internet. Specifically, this session will briefly compare and contrast the national health communication architectures in the UK, Canada, and the US as examples of national initiatives and then will focus specifically on details of the US Nationwide Health Information Network (NHIN). Areas covered in more detail in the section on the NHIN will include the governance model for health communications, the “trust fabric,” a review of current participants in the NHIN along with their business goals, and the current and future types of communication support that are included in the architectural model for the NHIN. Finally, opportunities for working within these national health communication models in order to support national and international rare disease registries will be considered.



Uniting Rare Diseases

***Advancing Rare Disease Research:
The Intersection of Patient Registries, Biospecimen Repositories and Clinical Data***

***Plenary sessions B:
Dan Russler, M.D.
VP Clinical Informatics, Oracle Global Health Sciences Strategy***

***The US Nationwide Health Information Network:
its Implications for Rare Disease Patient Registries/case study***

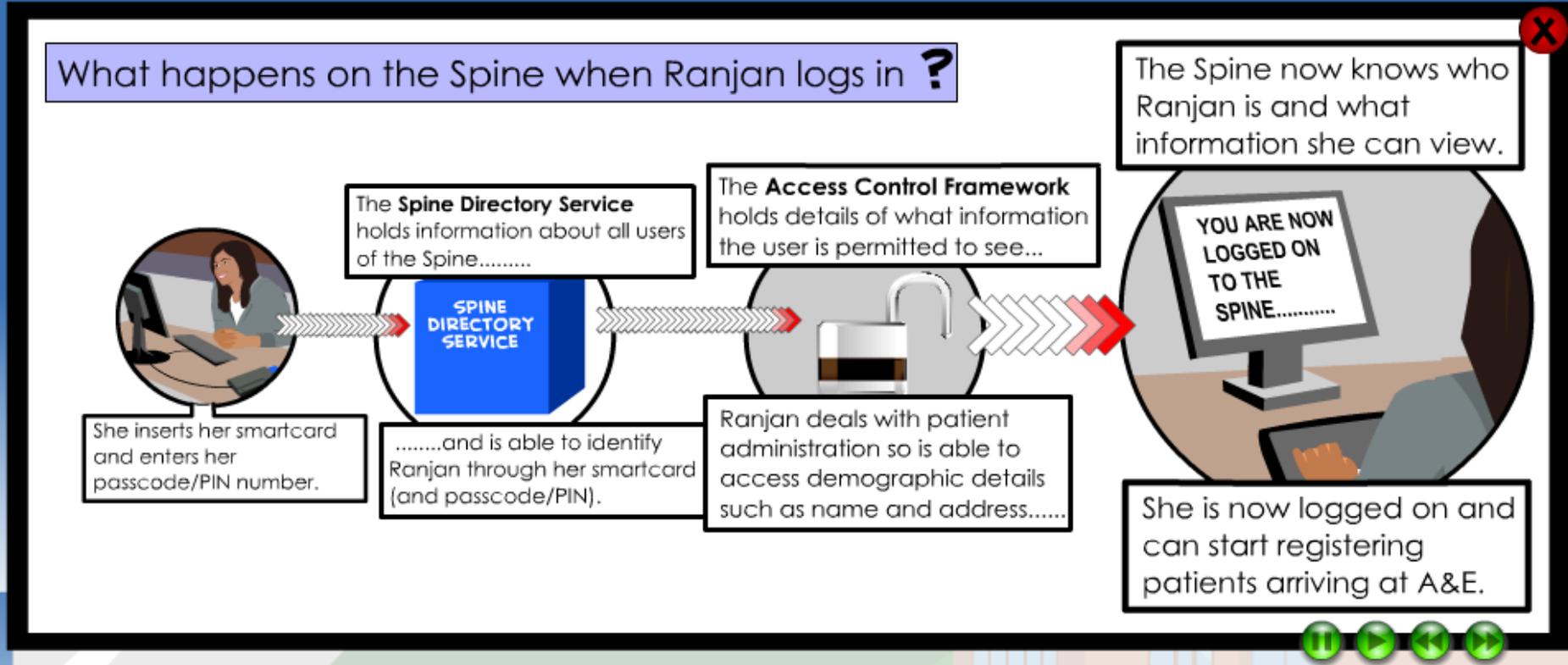
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HEALTH SCIENCES

Agenda

- Health Communication Models—National Initiatives
 - UK National Health Service “National Spine”
 - Canada Infoway “Provincial Reference Architecture”
 - US ONC “Nationwide Health Information Network (NHIN)”
- NHIN Case Study
 - Value propositions for the NHIN
 - Governance of the NHIN
 - Trust Fabric of the NHIN
 - Examples of Health Information Organization (HIO) projects
 - Communication architecture
- Disease Registries – National and International
 - Common disease registries
 - Rare disease registries
 - Collaborative registries

National Health Architectures



Centralized EHR Architecture

- User logs in to obtain central information
- UK – direct login to Spine (see above)
- Canada – login via EHR applications to centralized data (less direct than UK)

Decentralized EHR Architecture

- User logs into local EHR
- EHR retrieves data only from other HIOs
- US - No centralized data storage

National Initiatives

Compare Similarities

- Based on HL7 V3 Reference Information Model Standards
- Interfaces with local HIT systems that connect to the national infrastructure
- Ensures the security of these local systems that connect to the national infrastructure
- Provides access to a summary of the clinical record of each member
- Provides services for population data reporting

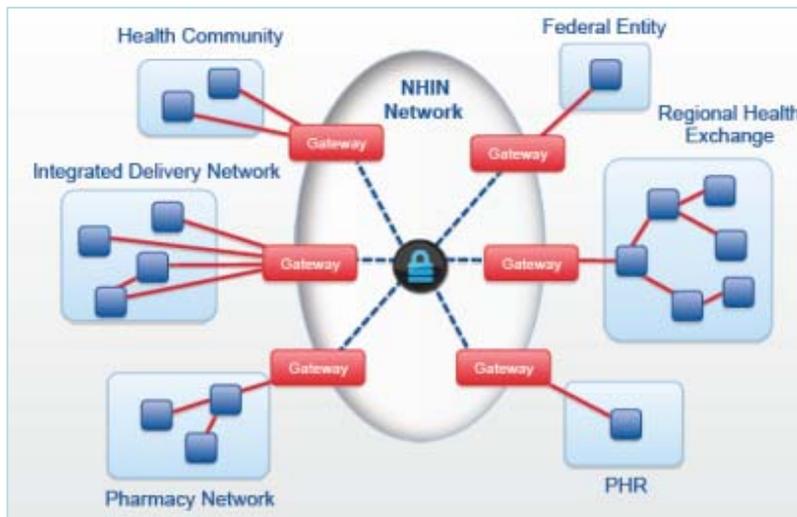
Contrast Differences

- **UK National Spine:**
 - **Stores** personal characteristics of patients, such as demographics
 - **Stores** summarised clinical information such as allergies, current medications and adverse reactions to drugs
 - Provides a [Secondary Uses Service \(SUS\)](#), using anonymised data for business reports and statistics for research and planning
 - Interfaces with all the local IT systems **within** the National Programme.
- **Canada Infoway Provincial Reference Architecture**
 - Stores personal characteristics of patient, Client Registry
 - Stores clinical information, Shared Health Record Repository
 - Provides Public Health Surveillance Solution
 - Interfaces with local IT systems and privacy legislation are provincial rather than national governance decisions
- **US Nationwide Health Information Network**
 - **No central storage** of personal characteristics; all person demographics are stored by Health Information Organizations (HIOs)
 - **No central storage** of clinical information; all clinical information is stored by HIOs
 - Provides web services for Secondary Use, but secondary use reports are provided only by HIOs, e.g. individual federal agencies or private reporting organizations
 - Interfaces with **any** public or private HIO that signs the NHIN contracts (DURSA) and passes NHIN Gateway implementation testing inspections; interfaces with local public and private IT systems and privacy policies are local decisions driven by local regulation

US NHIN – a Case Study

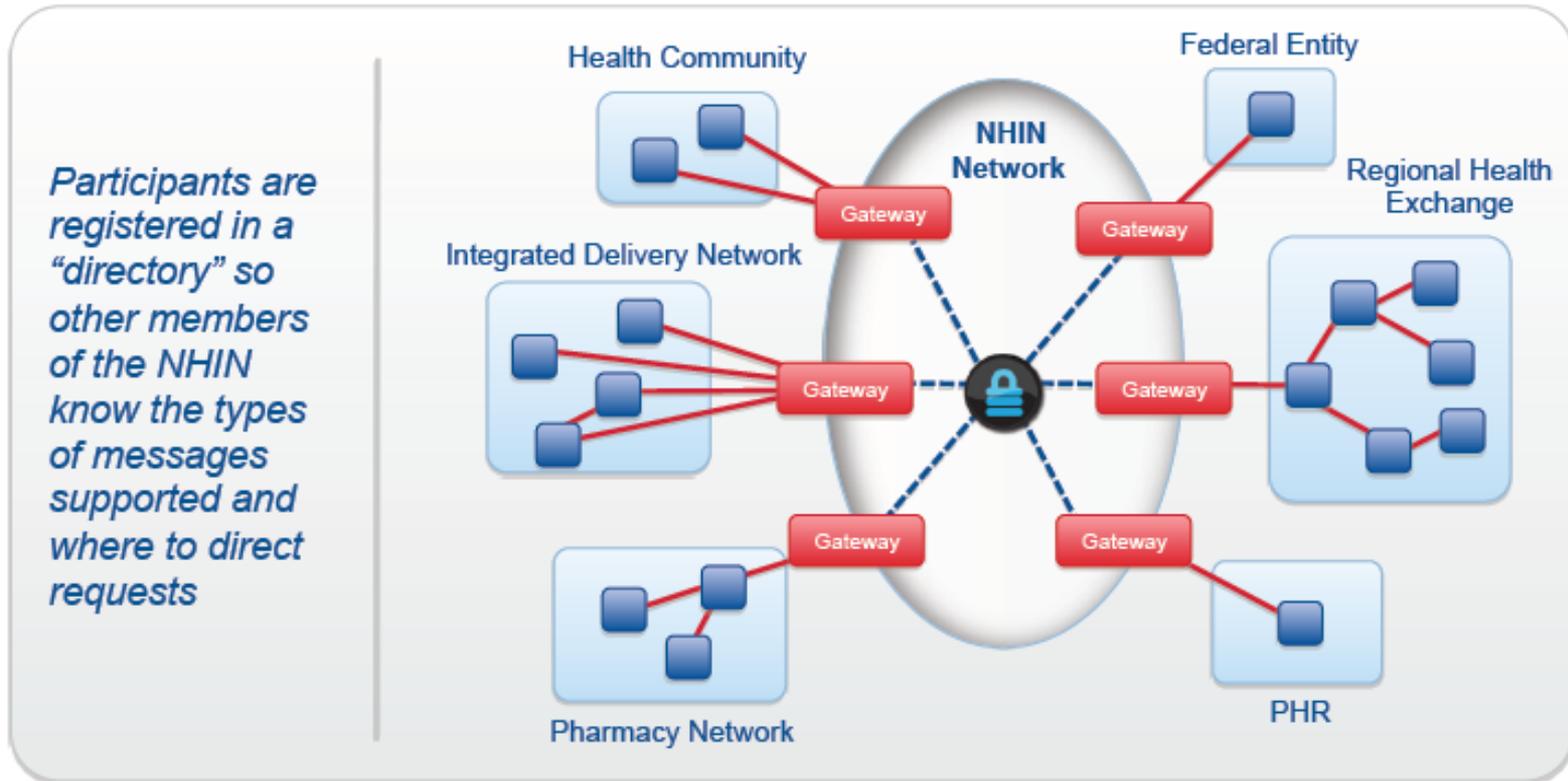
NHIN Value Propositions

- One legal network contract instead of multiple point-to-point legal contracts
 - One technical communication agreement instead of multiple point-to-point technical agreements
- The open source NHIN CONNECT tools enable health organizations to share information using standards designed to forge a nationwide health information network (NHIN)
 - “Given the federal investment in health IT, and the definition of meaningful use, it is clear there is a vibrant future for the NHIN.” “Our hope is that it will support health information exchange and meaningful use at the federal, state and local levels.” - Dr. David Blumenthal, The National Coordinator for Health Information Technology
 - “The more organizations using the NHIN, the more valuable the NHIN will become for everyone.” – a variation on Metcalfe’s Law



Governance and Trust

Participants support a gateway that conforms to NHIN requirements and enables its connected users/systems/networks/communities to exchange information among other NHIN participants.



Note: These “participants” are all now called Health Information Organizations (HIO)



- Built upon a foundation of policies
- Implemented in legal agreement, called Data Use and Reciprocal Support Agreement (DURSA)
- Architected to support trust technically
- Validated and tested as a condition of membership
- Controlled access among trusted participants
- Accountability through interim governance mechanisms

1. Sign DURSA after legal review

2. Pay for Gateway Testing Resources

Note: An HIO may be any public or private entity, for-profit or not-for-profit

The DURSA reaffirms each Participant's obligation to comply with "Applicable Law." As defined in the DURSA, "Applicable Law" is the law of the jurisdiction in which the Participant operates.

- For non-Federal Participants, this means the law in the state(s) in which the Participant operates and any applicable Federal law.
- For Federal Participants, this means applicable Federal law.

Participants Retain Local Control

-
- Each Participant can apply its own local access policies before requesting data from other Participants or releasing data to other Participants.
 - Responding Participants are responsible meeting all legal requirements before disclosing the data as required by their applicable law, including obtaining an individual's consent or authorization for treatment purposes.
 - HIPAA Privacy and Security Rules are minimum requirements.
 - When a request is based on a purpose for which authorization is required under HIPAA (e.g. for SSA benefits determination), the requesting Participant must send a copy of the authorization with the request for data.
-

Harmonization with Existing Law

The NHIN has been designed from its inception to provide secure information exchanges through:

- Encryption (to prevent interception)
- Digital signature (to prevent repudiation and protect message integrity)
- Authentication (to prevent impersonation)

Business Goals:

Privacy

Security

Trust

- **Authorization** – requestors of medical information must provide authentication and a purpose for use
- **Consumer control** – patients have the ability to articulate their preferences for the sharing of identifiable medical data
- **Auditing** – all requests for medical information are logged, auditable and ultimately accessible to the patients affected

NHIN Business Summary

Nationwide Health Information Network (NHIN) and CONNECT Architecture

Mission

To achieve better quality, value, and affordability of health and wellness services by establishing the Nationwide Health Information Network as the common, secure, nationwide, interoperable network for exchanging health information, and provide this infrastructure with low adoption barriers.

Provides

- Ability to look up, retrieve and securely exchange health information
- Ability to apply consumer preferences for sharing information
- Ability to apply and use the NHIN for other business capabilities as authorized by the health care consumer
- Interoperability Architecture

In short provides a single architecture/method for health care data exchange

Projects Testing the NHIN

“The more organizations using the NHIN, the more valuable the NHIN will become for disease registries.”

– a second variation on Metcalfe’s Law

See Appendix in slide deck for a more complete list of participants

Improving Disaster Medical Care

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CAPT USPHS

Director, QA

National Disaster Medical System

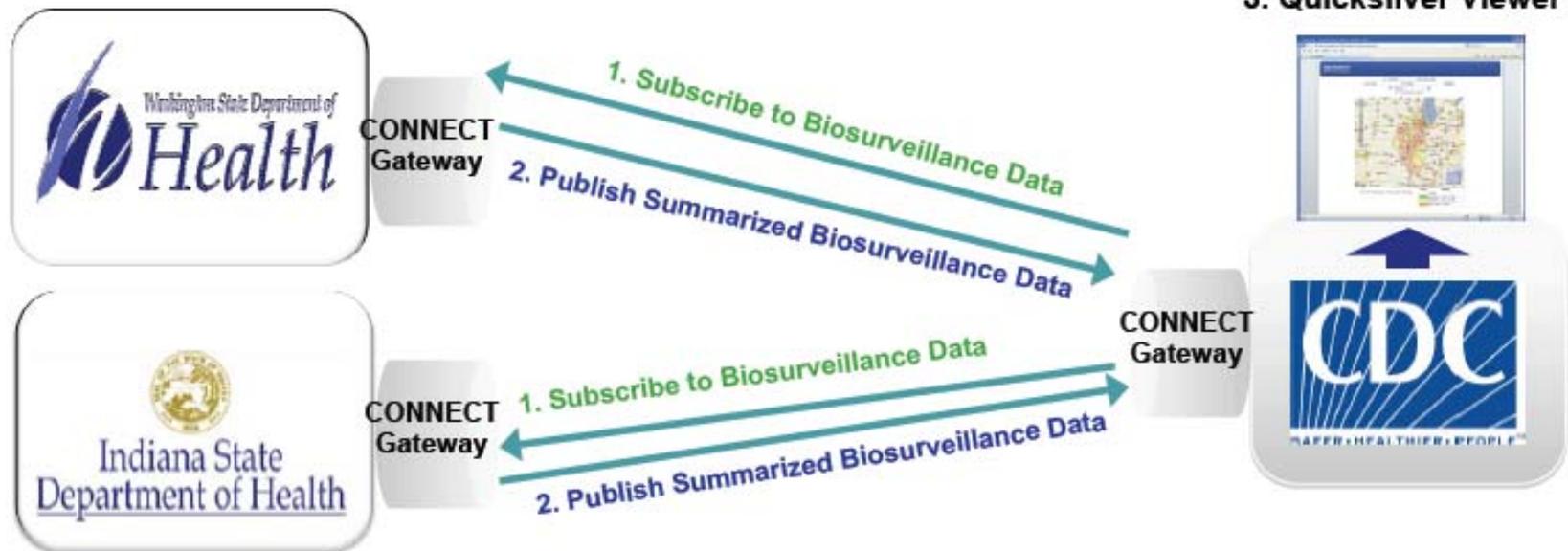


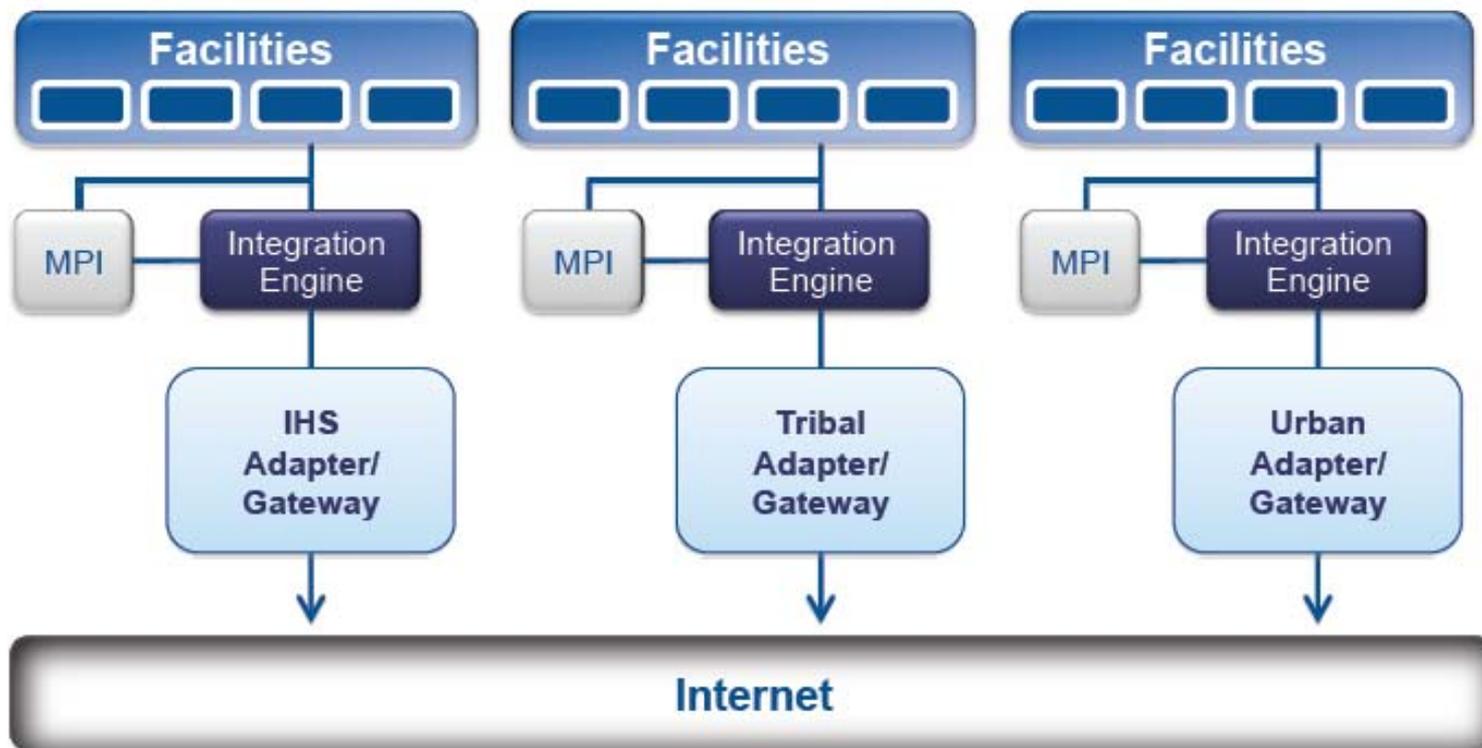
Federal Perspectives June 2009

- Access to medical data from other deployment locations
- Enable the acquisition of patient information from other federal departments (VA, CMS)
- Lay groundwork for future information sharing with non-federal government entities (hospitals, pharmacies, urgent care centers, and state programs)
- Enhance the usability of NDMS Disaster Medical Information System (DMIS)

➔ Biosurveillance using Summary Data Geocoded Interoperable Population Summary Exchange (GIPSE) Services

- CDC uses NHIN Gateway to subscribe to summarized Biosurveillance data from State Health Departments (SHD)
- SHD's publish summarized biosurveillance data via NHIN Gateway
- CDC aggregates and visualizes summarized data using Quicksilver or other summary data viewers





Disease Registry Concepts

- Common Disease Registries
 - Registries often planned at local, regional, national or international levels
 - May or may not use national communication architectures, especially at local levels, e.g. a disease “practice register” is a UK NHS quality measure; also now a US provider “meaningful use” measure (“lists of patients by specific conditions to use for...”)
- Rare Disease Registries
 - Adequate number of persons (denominator) may only be possible at national and international levels
 - Since more organizations must participate in order to generate more records, more likely to use national communication architectures for collaboration infrastructure
- International Disease Registries
 - More important for rare diseases than common diseases
 - Requires compliance with national laws and integration with national architectures (via international standards?)
- Collaborative Disease Registries — two concepts
 - Multi-organizational collaborative registry governance (including PHRs?)
 - Technical collaboration (data communication) between registries, e.g. data moving from PHR to local to national to international disease registries

UK Disease Registry Opportunities?

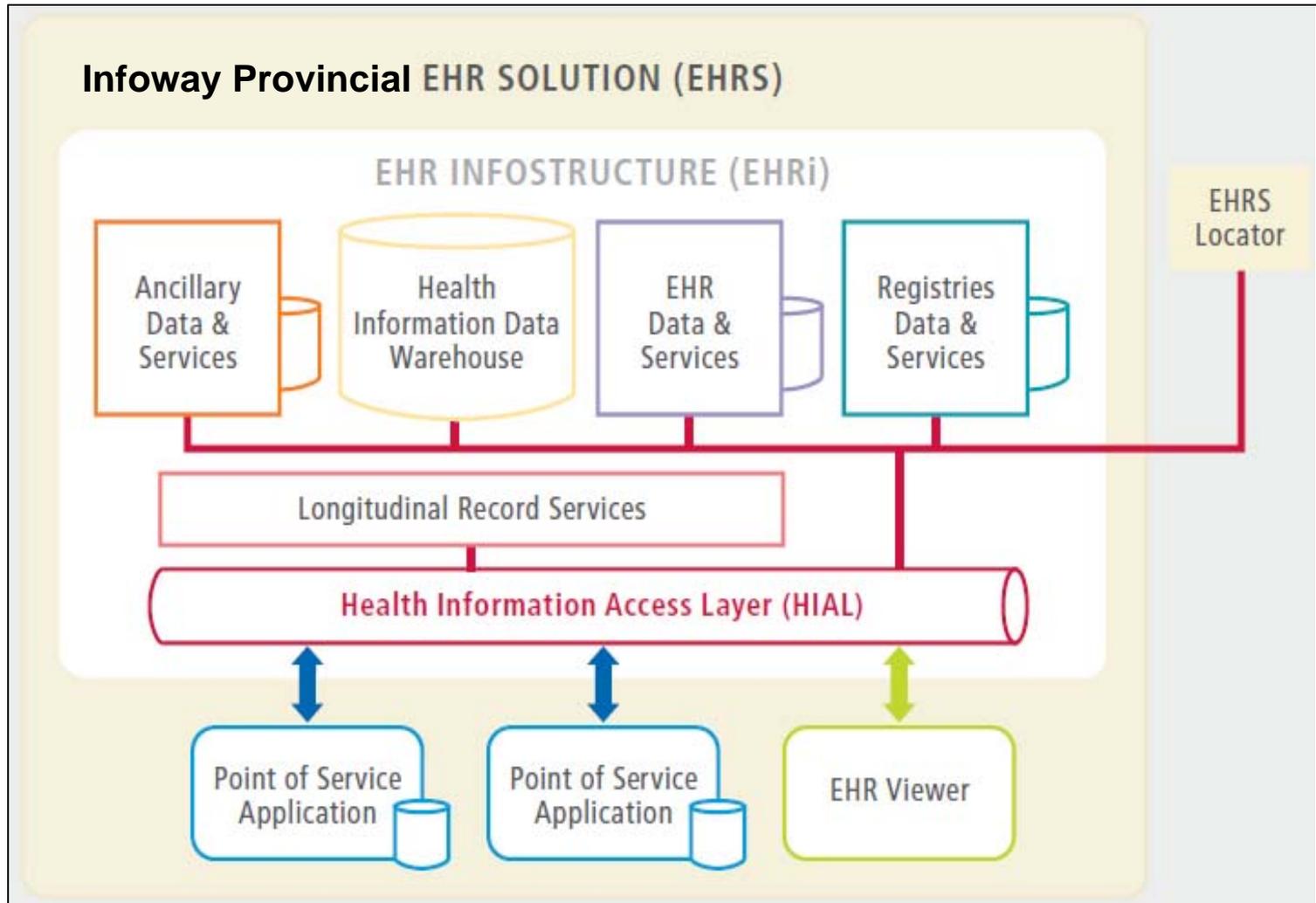
Negotiation with the NHS “Ethics and Confidentiality Committee”

When we might use or share information that names you without asking you

- Sometimes we have a legal duty to give information about people. Examples include:
 - births of children;
 - reporting some infectious diseases;
 - reporting gunshot wounds to the police; or
 - because a court orders us to do so.
- Sometimes special permission will be given to use your information without your consent. This may be for medical research, keeping registers of cancer patients or checking quality of care. This permission is given by the Ethics and Confidentiality Committee of the National Information Governance Board for Health and Social Care.

Canadian Disease Registry Opportunities?

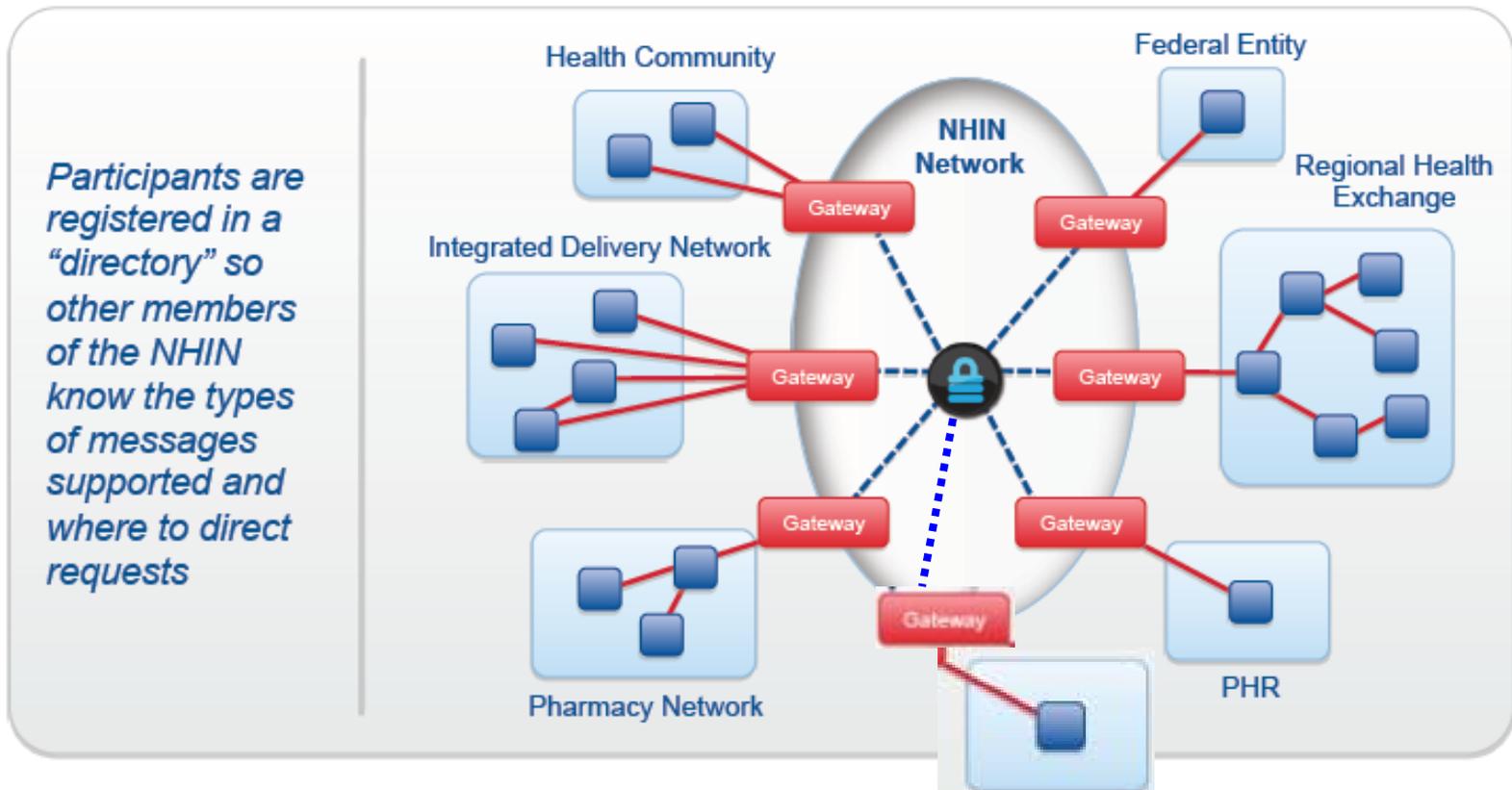
Negotiation with the each Province for inclusion in the Provincial Architecture



US Disease Registry Opportunities?

Sign the NHIN DURSA and Comply with Inspections

Participants support a gateway that conforms to NHIN requirements and enables its connected users/systems/networks/communities to exchange information among other NHIN participants.



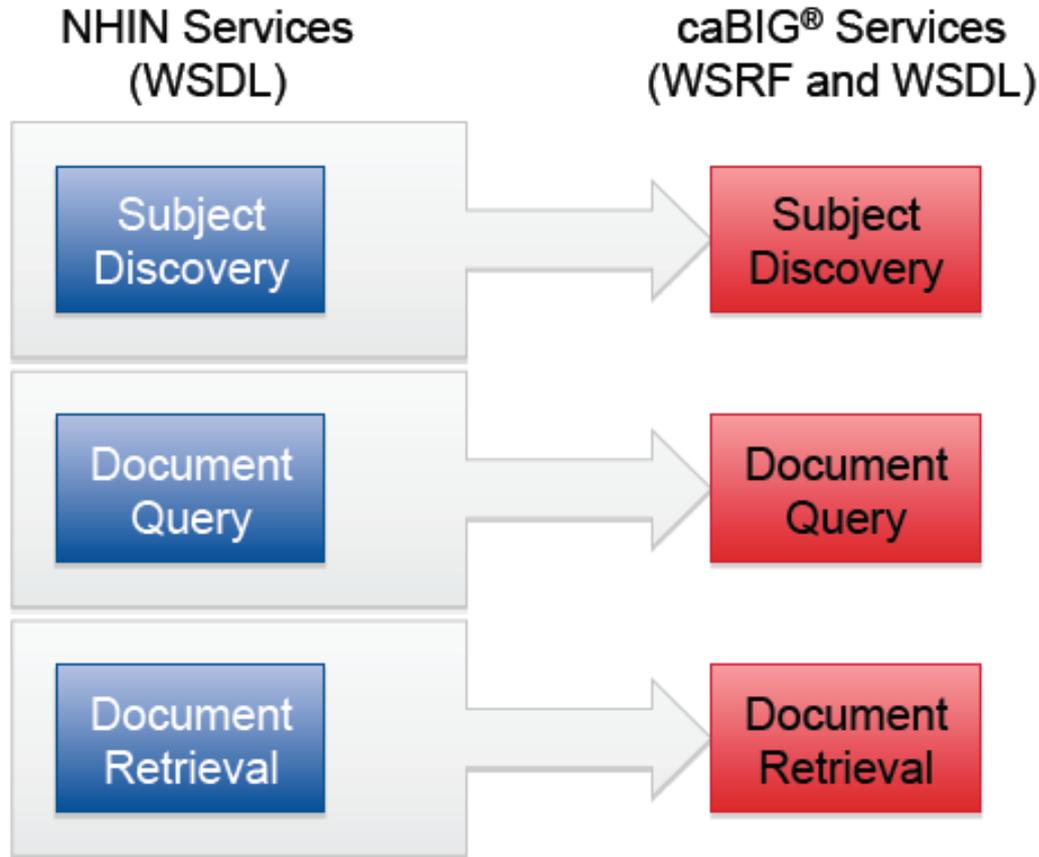
Participants are registered in a "directory" so other members of the NHIN know the types of messages supported and where to direct requests

Rare Disease Registry ?
(national or international)

Appendix

Other Projects Testing the NHIN

Clinical Trial Communications



INTRODUCE Generated caGrid Service Wrappers

Public Insurance and Quality Care

Following NHIN Interoperable standards and architecture around new technology areas, CMS believes that current methods of Quality Data collection could be simplified to *achieve better quality, value, and affordability*. As CMS and other organizations adopt the NHIN architecture it will help lessen the burden of data exchange to all stakeholders and help increase quality improvement. CMS is working on enabling change through its various Quality, Medicare, and Medicaid programs!

Military and Community Care



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VA and KP

HITSP C32 patient health summary

- Version 2.1 - Minimum data set
- Personal information
- Contacts
- Allergies
- Medications
- Problems
- Source of information

All required data elements in the specified HITSP terminologies to the extent possible, others optional (pending NHIN certification criteria)