IBM

eHealth Initiative

Case Study on Sharing Health Information: Creating a Healthcare Collaborative Network and Addressing HIPAA Issues

The Seventh National HIPAA Summit
September 16, 2003

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Agenda

- Overview of the Healthcare Collaborative Network Project
  - Purpose
  - Participants
  - Architecture
  - Current status
- Addressing HIPAA
  - Issues and challenges
  - Approaches
- Lessons Learned for Future Data Sharing Projects

A National Alert on Bioterrorism

Daschle: 'They were trying to kill someone'

October 16, 2001 Posted: 10:25 PM EDT (0225 GMT)

WASHINGTON (CNN) -- Parts of eight floors of the Hart Senate Office Building were closed Tuesday as authorities searched for anthrax. The move comes a day after a letter sent to Senate Majority Leader Tom Daschle's office in that building field-tested positive for the potentially deadly bacterium.

CBSNEWS.com

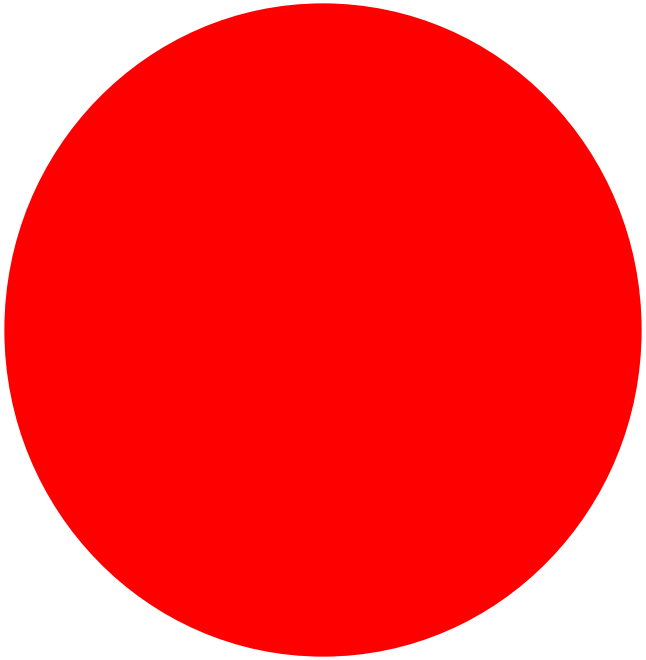
Drug Errors Plague Hospitals

CHICAGO, Sept. 9, 2002

(AP) More than 40 potentially harmful drug errors daily were found on average in hospitals in a new study, yet another report on a worrisome problem regulators are working to remedy.

Quality of Care is Poor

31% of Medicare Patients with Myocardial Infarction were not Administered β –blockers within 24 hours of admission.



IT Solutions Rise on National Political Agenda

- **HHS Sec. Thompson**: "I want to create a financial assistance program to help health care organizations modernize and upgrade to interoperable health information technology"

- **FDA Commissioner McClellan**: "Our goal is to have in place an electronically-based monitoring system that allows us to link into medical records and monitor in real time, or near real time, for signals such as trends on blood tests that could alert us to a potential problem with a new medication. This is a two way street as well. . . We will also have more confidence during our own review processes that potential problems can be identified and communicated to doctors and patients quickly after a drug is approved.

- **William D. Novelli, Executive Director and CEO, AARP:** I believe AARP can help [create a national health information infrastructure]. As a consumer organization with 35 million members, many thousands of volunteers, and offices in every state, we can play a role. We can help create consumer demand for a national system and for better care and better information. We can educate our members, their families and the public about using the system . . . So, by working together, we can save lives, by avoiding errors. We can save money by eliminating inefficiencies. We can give patients power by giving them information. We can give physicians and hospitals greater capability through better information, and more of it when they need it.

HCN is a Coalition Effort to Drive a National Health Information Infrastructure

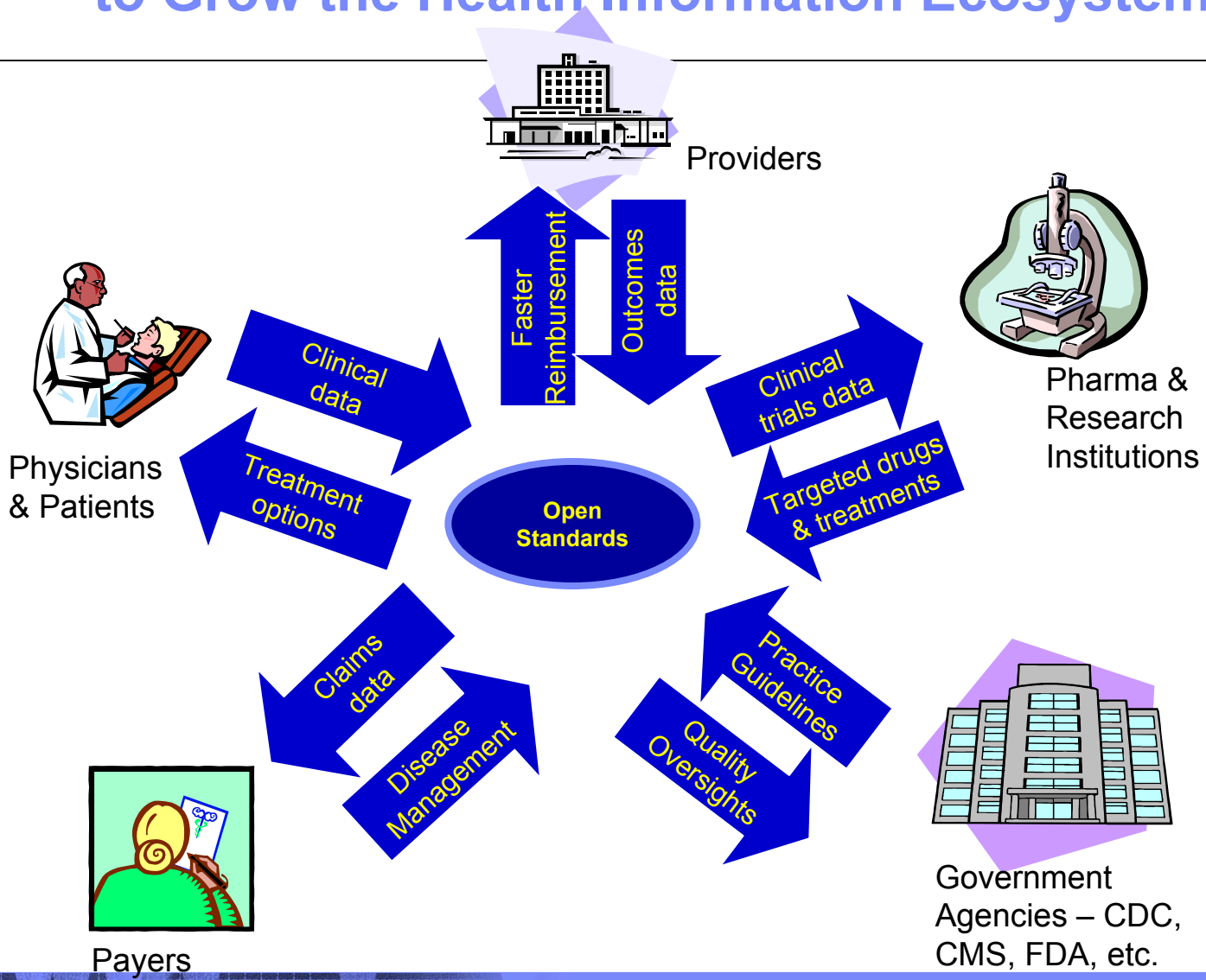
MARKLE FOUNDATION

CONNECTING FOR HEALTH

A Public-Private Collaborative

eHealth Initiative

Federal Partnerships are an Initial Step to Grow the Health Information Ecosystem



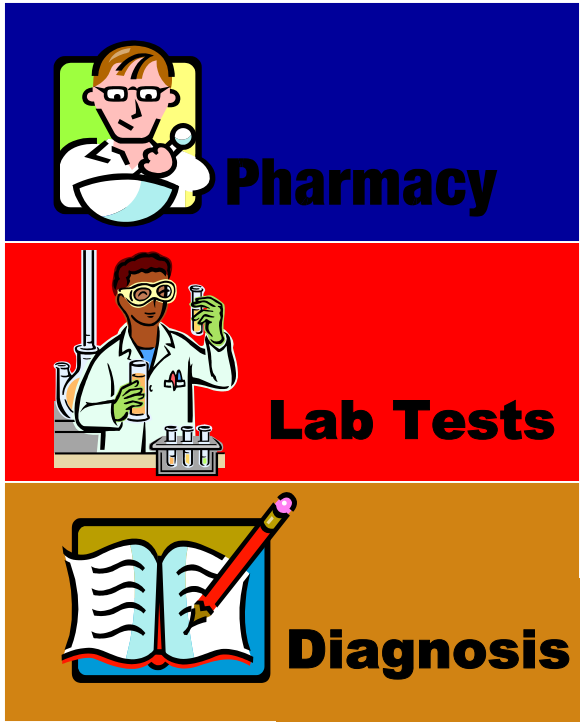
Certain Electronic Clinical Information Widely Present in Hospitals

HL7 Messages

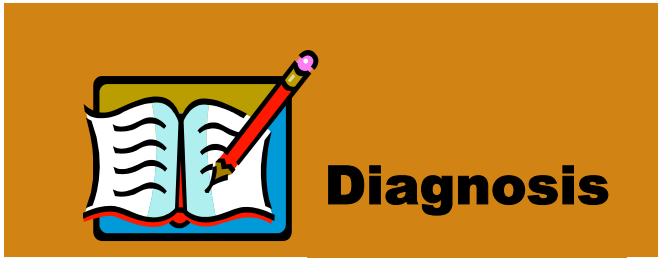
NDC

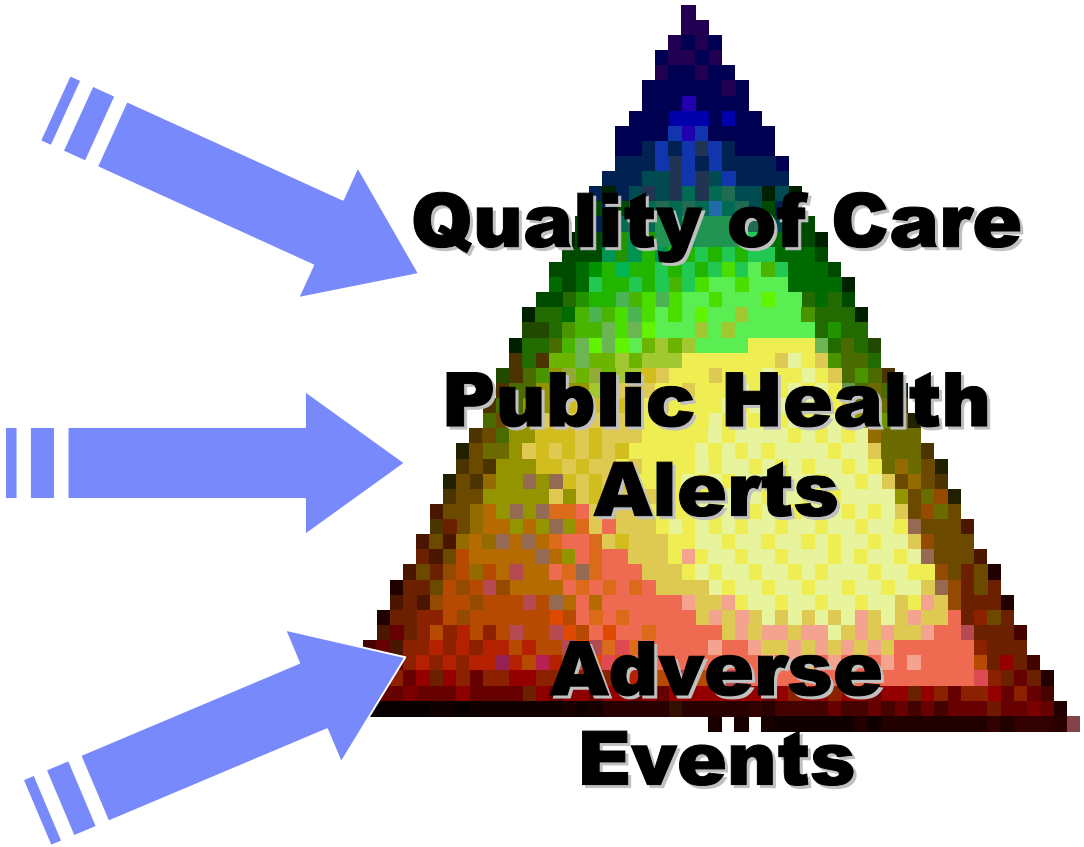
LOINC

ICD-9



Integrating Available Clinical Information Can Solve Spectrum of Health Reporting Needs





Integrating Medicare Healthcare Quality Data

Lab **Pharmacy** **Diagnosis**

- 31% of Medicare Patients with **Acute Myocardial Infarction** were not administered β –blockers within 24 hours of admission
- 26% of Medicare Patients with **AMI and** left ventricular ejection fraction<0.40 were not given ACE Inhibitor

Sample HCN Message for Stroke Patient (partial)

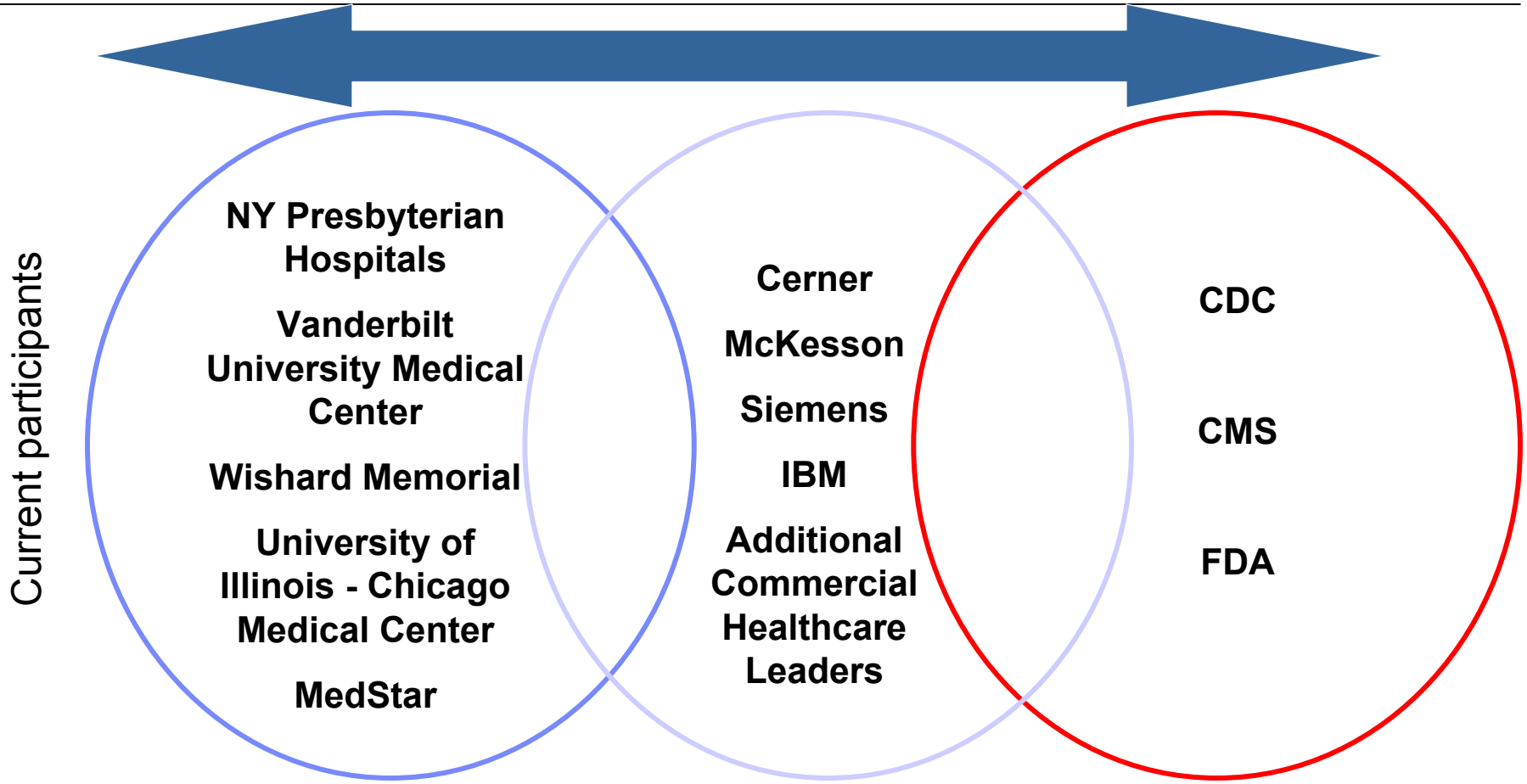
Message submitted successfully for publication:
Submission time: 2003-08-08 12:25:09.921
Publisher ID: 'Provider 1'
Publish Topic: 'Stroke Diagnosis'
Rule Name: 'Stroke Diagnosis'
Patient ID: '123153'
Message Timestamp: '2003-08-08T12:26:17-07:00'
Message:

'MSH|^~\&|<XXX>||<XXX>||200307190843||RDE^O11||<XXX>|2.4|
PID|||123153^^^&Provider 1|<XXX>|<XXX>||<XXX>|F|||||||||<XXX>|<XXX>|
PV1||I|<XXX>|||<XXX>|<XXX>|<XXX>|||||HNA|||<XXX>|<XXX>|||||||||||||||||<XXX>|||||||<XXX>|
ORC|NW|100|18491559||SC||^QD&0900^INDEF^200307190900^^R^0||200307190839|<XXX>|<XXX>|<XXX>|<XXX>|
RXE||0000429160^PANTOPRAZOLE EC TAB 40 MG^L|40||^MG|TABLET EC||||1|EA|
RXR|^ORAL| ',

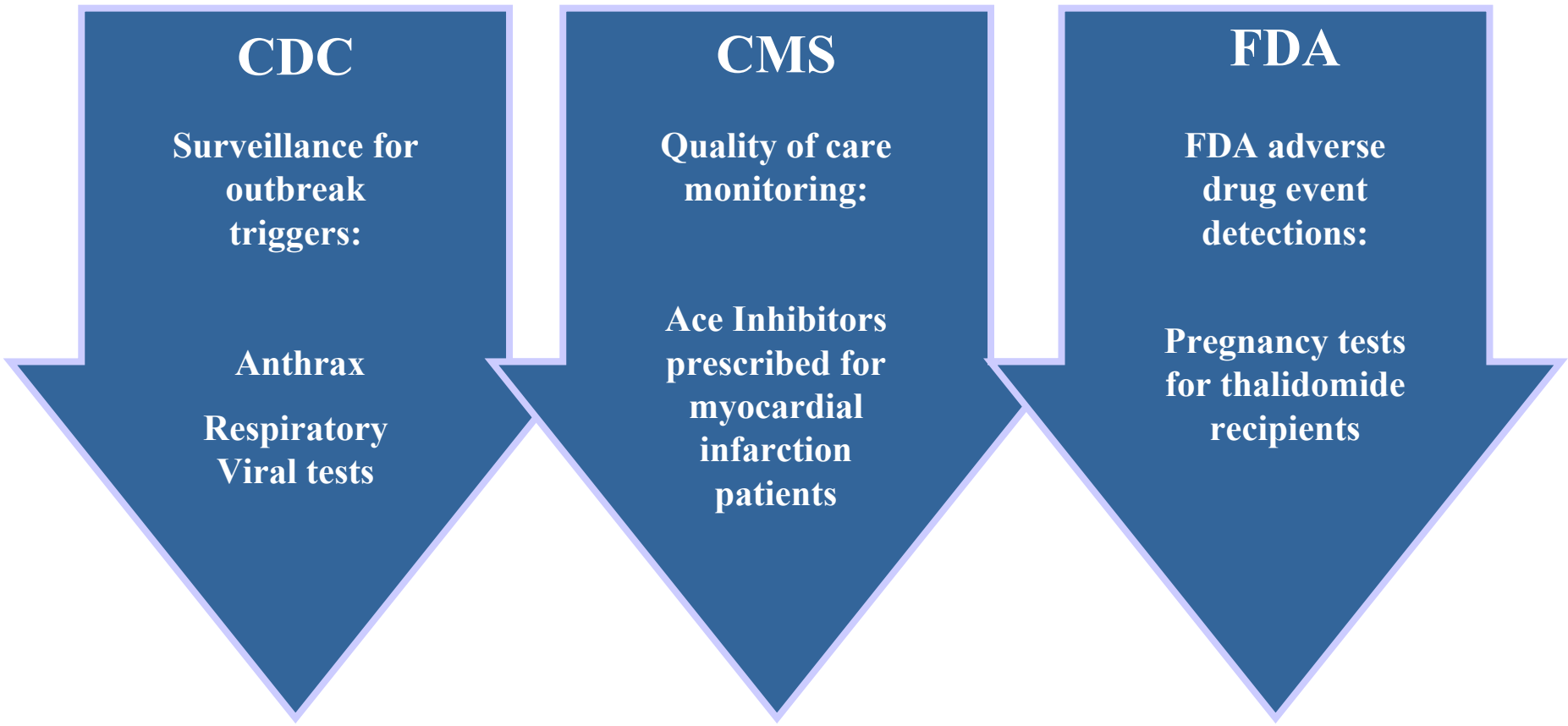
'MSH|^~\&|<XXX>||<XXX>|<XXX>|20030719084337||ORU^R01|<XXX>|<XXX>|2.4|
PID|||123153^^^&Provider 1||<XXX>||<XXX>|F|||||||||<XXX>|
PV1|||<XXX>|
ORC|RE|||||||||<XXX>|<XXX>|<XXX>|<XXX>|<XXX>|||<XXX>|
OBR|||T44676BCBLUD037F^1|600-7^LOINC^BLOOD
CULTURE|||20030715160000||||||<XXX>|<XXX>|<XXX>|<XXX>|<XXX>|||||||<XXX>|P||^^^^^R|<XXX>|
OBX|1|TX|36484^BLUD^MED|0|SPECIMEN DESCRIPTION: BLOOD||||||F|
OBX|2|TX|60187^NGB4^MED|0|CULTURE: NO GROWTH OF BACTERIA OR FUNGI AFTER 4 DAYS||||||F|

'MSH|^~\&|HIHLS21-215259|EAGLE 2000|||20030731200333||ADT^A08|203072702400179832O1|P|2.3|||NE|NE|
EVN|A08|<XXX>||<XXX>|<XXX>|
PID|<XXX>||123153^^^&Provider 1||<XXX>|<XXX>|<XXX>|F|<XXX>|||<XXX>|<XXX>|<XXX>|<XXX>|<XXX>|<XXX>|<XXX>|<XXX>|
PV1|<XXX>|I|<XXX>||||<XXX>|<XXX>|<XXX>|<XXX>|||<XXX>||<XXX>|<XXX>|<XXX>|<XXX>|<XXX>|<XXX>|<XXX>|||||||||||||||<XXX>|<XXX>||<XXX>|
DG1|<XXX>|I9|430^SUBARACHNOID HEMORRHAGE^I9|<XXX>|<XXX>|A|<XXX>|<XXX>|||||<XXX>|
DG1|<XXX>|I9|430^SUBARACHNOID HEMORRHAGE^I9|<XXX>|<XXX>|P|
DG1|<XXX>|I9|401.9^HYPERTENSION NOS^I9|<XXX>|<XXX>|S|
DG1|<XXX>|I9|307.9^SPECIAL SYMPTOM NEC/NOS^I9|<XXX>|<XXX>|S|
', 'MSH|^~\&|<XXX>|<XXX>|||20030723190145||ADT^A03|<XXX>|<XXX>|2.3|||<XXX>|<XXX>|
EVN|A03|<XXX>||<XXX>|<XXX>|
PID|<XXX>||123153^^^&Provider 1||<XXX>|<XXX>|<XXX>|F|<XXX>|||<XXX>|<XXX>|<XXX>|<XXX>|<XXX>|<XXX>|<XXX>|<XXX>|
PV1|<XXX>|I|<XXX>||||<XXX>|||<XXX>|||||||||<XXX>|<XXX>|||||||||||||||<XXX>|<XXX>||<XXX>||<XXX>|||<XXX>|<XXX>|

Federal healthcare agencies and industry leaders are the initial participants in HCN

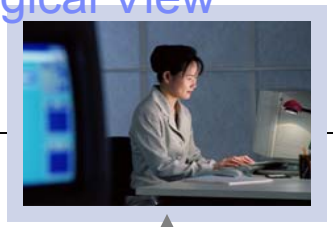


Agencies have identified data elements to test during the demonstration that enable fast detection of health risks, and that, ultimately, enable improved care delivery



HHS has recently issued requirements for all federal agencies to follow health information exchange standards, which are already in use by most healthcare providers

Architecture
Logical View



HCN Federated Web Portal

Participants
- Manage Healthcare Business Rules
- Select data to share and who to share with
- Monitor, Alerts, Notifications, Reports, Account Activity

Monitoring

Participant's Existing Clinical IT Systems

Lab
ADT
Pharmacy
LAN
Firewall
HCN Gateway
HL7 Messages
- Diagnosis
- Lab Results
- Pharmacy Orders
- Alerts

HCN Data Integration Broker

Firewall

CDC
CMS
FDA

Key Gateway Functions
- Business Rules
- Mapping Codes (LOINC, ICD9, etc.)
- Message Normalization
- Message Parsing
- Caching
- Anonymization

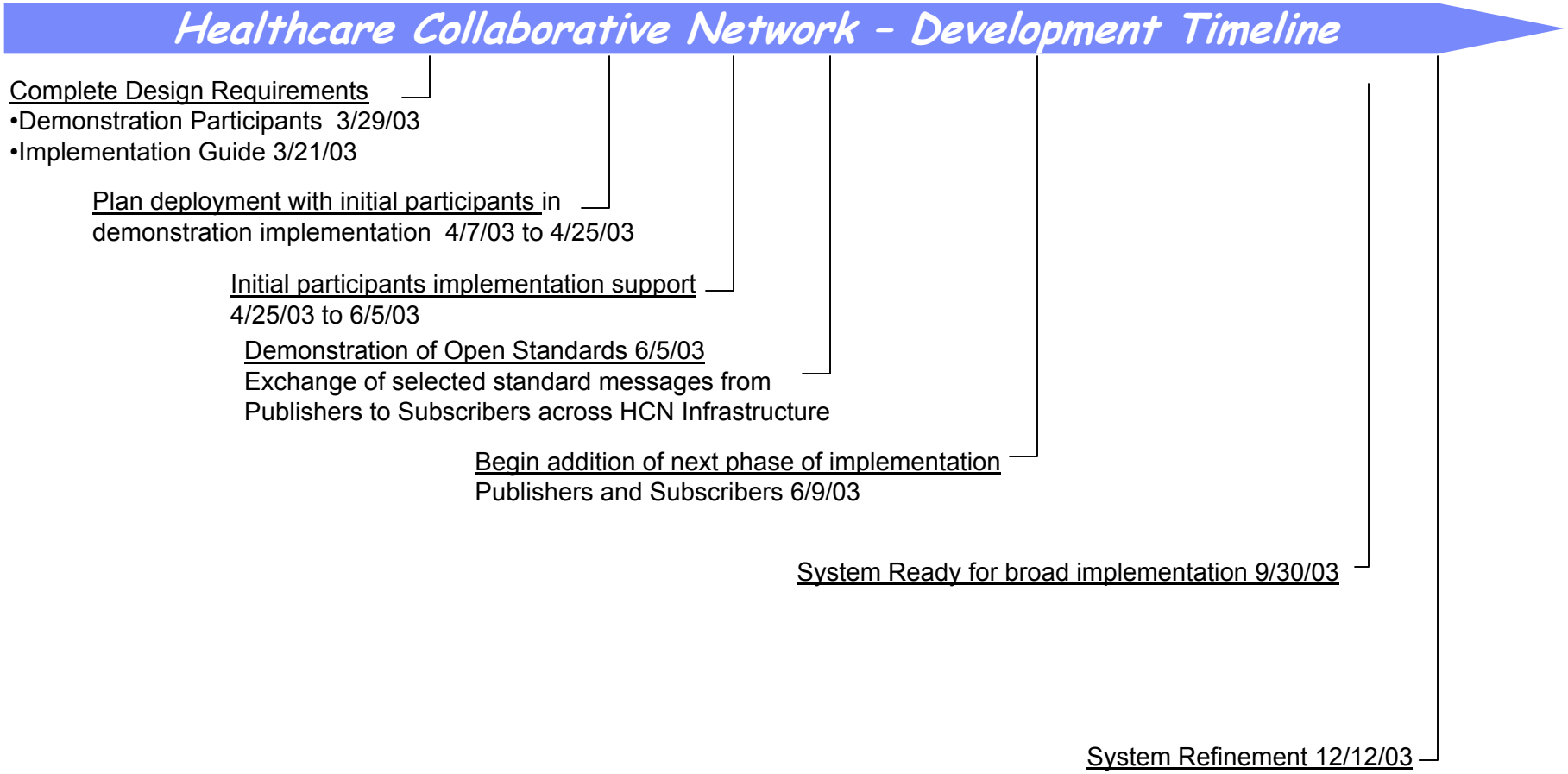
Summary of Healthcare Collaborative Network

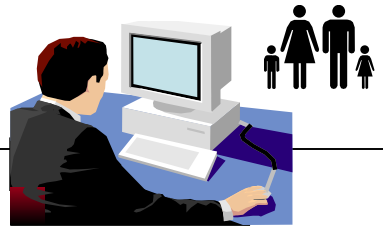
- Data comes from existing clinical systems and is not stored externally.
- Data coded and transmitted using open standards making that critical data set accessible, efficient and usable by various data consumers
- Data elements are existing priorities for agencies, providers, payors, and others (current quality reporting measures, key drugs with associated clinical lab results, public health requirements)
- Privacy, security, and business rule functionality to identify key health events included in design requirements and processed information will be passed back to provider at the same time as it is sent to agencies.
- Openness to participation: any provider, vendor, or federal agency that wishes to participate can because the open standards provide a common basis for exchange of information.
- Resulting health information linkages for standards based reporting from clinical information systems is step on critical path toward national health information infrastructure

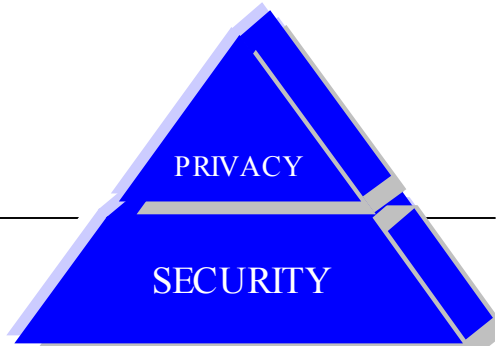
Benefits of HCN Solution

- Improves response time for bio-surveillance, adverse drug reactions, quality of care, and disease outbreaks
- Reduces administrative burden of mandatory reporting
- Enables rapid ability to aggregate and share data
- Puts clinical data in hands of reviewers faster to improve quality of care
- Provides a secure environment for clinical data transmission
- Leverages existing applications minimizing barriers to participation

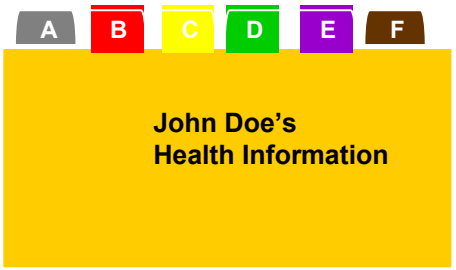
The HCN demonstration launched on June 5 but additional steps are planned beyond October 2003







Addressing HIPAA: Issues and Challenges



HIPAA Issues in Creating a Health Data Sharing Project

- Type of data to use (e.g., identifiable)
- Necessary legal protections/agreements
- Analysis of regulatory exceptions
- Requirements gathering and input to design team
- Type of security controls to protect data integrity, confidentiality, and availability
- Use of patient identifiers
- Privacy and security policies and procedures
- Disclosure accounting
- Maintaining audits

HCN HIPAA Approaches

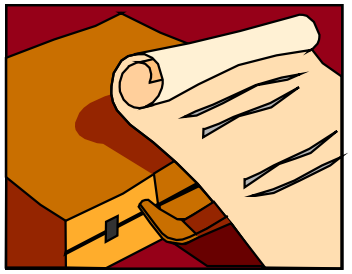
- Requirements/Design – utilize advisory group made up of experts and members of Privacy and Security Working Group
- Data
  - Utilize Limited Data Set including 5-digit zip code, admission and discharge dates
  - Anonymization – patient identifier replaced by a dummy identifier
    - Maintain identifier synchronization inside the sender's firewall
  - Data transmitted in form of HL7 messages wrapped in XML message that identifies the topic of the message and the publisher
  - Use of standards (ICD, CPT, HL7, ANSI)
  - Focus on particular data requested by subscribers and approved by publishers

HCN HIPAA Approaches

- Security controls
  - **Integrity** – use of SSL encryption and signed digital certificates
    - HL7 message inside the XML wrapper encrypted using symmetric key encryption (3-DES)
  - **Authorization** – role based access control at the web portal
    - Users can only see information relevant to their own subscriptions or publications
    - Participants must secure the Gateway systems to prevent unauthorized access
    - Participants determine their users for access
  - **Authentication** – users required to log on to the Portal (Tivoli Access Manager)
    - MQ Series mutual authentication to ensure only HCN Gateway machines can connect to the Integration Broker
  - **Non-repudiation** – maintenance of a log in the Portal of each action performed by an authenticated user

HCN HIPAA Approaches

- Legal protections
  - Business Associate Agreements – IBM and hospitals
  - Special Projects SOW – IBM and hospitals; IBM and agencies; IBM and payers
  - Confidentiality Agreements – IBM and payers
  - Data Use Agreements – hospitals and payers
  - Demand Letters – agencies and hospitals
    - Public health oversight agency authority
    - Disclosures required by law



A Good First Step – CMS mandates Hospitals to send data to QIOs through HCN as part of a Demonstration Project

"As part of a special study to determine the extent to which a hospital's electronically available information can be used to produce CMS quality measures CMS is directing the Iowa Foundation for Medical Care (IFMC) to request information from providers participating in the National Healthcare Network. This information will not be shared with any other entity…"

- QIOs acting as a public health oversight agency -- patient permission not needed for disclosure

- Covered entities must report certain data to QIOs as required by law – patient permission not needed for disclosure

FDA and CDC Follow Suit with Permission Letters

- Disclosure permitted to agencies acting in health oversight agency capacity [§164.512(b)(i)]
  - Covered entities may disclose PHI to public health oversight agencies "authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to . . . the conduct of public health surveillance, public health investigations, and public health interventions . . . "
  - Other regulations applicable to each agency, for example
    - Federal Food, Drug, and Cosmetic Act
    - Public Health Service Act

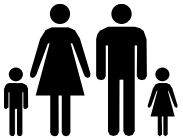
Patient Authorization Not Required for Disclosures

Lessons Learned for Future Sharing Projects

- Need executive leadership and commitment
- Involve legal early on
  - HIPAA, state law analysis, anti-trust issues, agreements, accounting of disclosures, etc.
  - Time intensive
- Determine where solution falls under HIPAA
  - exception, treatment, research, public health, etc.

- Include privacy and security requirements in the design phase of the solution
- Utilize standards and/or necessary mapping tools (HL7, ICD)
- Don't forget about the users (i.e. acceptance testing)
  - obtain requirements up front or solution won't succeed
- Determine scalability of solution
  - can I roll out the solution state-wide, agency-wide, hospital-wide, etc.?

Lessons Learned for Future Sharing Projects



- Determine if utilizing patient identifiers and/or de-identification
  - MPI; use of social security number fading
- Obtain agreement from stakeholders (clinical, technical, operational, researcher) on scope and outcomes
- Address challenge of interoperability
- Address challenge of integrating disparate systems and data sources
- Must have strong project management and communication channels
- Involve researchers to help identify study/outcome indicators
- Allow lag time in development, integration, and testing phases
- Utilize project management and communication skills




APPENDICIES

eHealth Initiative Profile: a public-private partnership aiming to improve Healthcare through the use of information technology

Mission *To drive improvement in the quality, safety, and cost-effectiveness of health care through information technology.* (www.ehealthinitiative.org)

Vision Consumers, providers and those responsible for population health will have ready access to timely, relevant, reliable and secure health care information through an interconnected, electronic health information infrastructure.

… with the broad participation necessary for success

- **Practicing Clinicians**
- **Hospitals, Academic Medical Centers**
- **Payers**
- **Pharmaceutical companies**
- **Quality Improvement Organizations**
- **Government – CDC, CMS, FDA, State Organizations**
- **Researchers**
- **ISV's**
- **Application Vendors**

MARKLE FOUNDATION
CONNECTING FOR HEALTH
A Public-Private Collaborative

Connecting for Health Profile:
A collaborative focused on improving healthcare through sharing of information to impact health and the delivery system

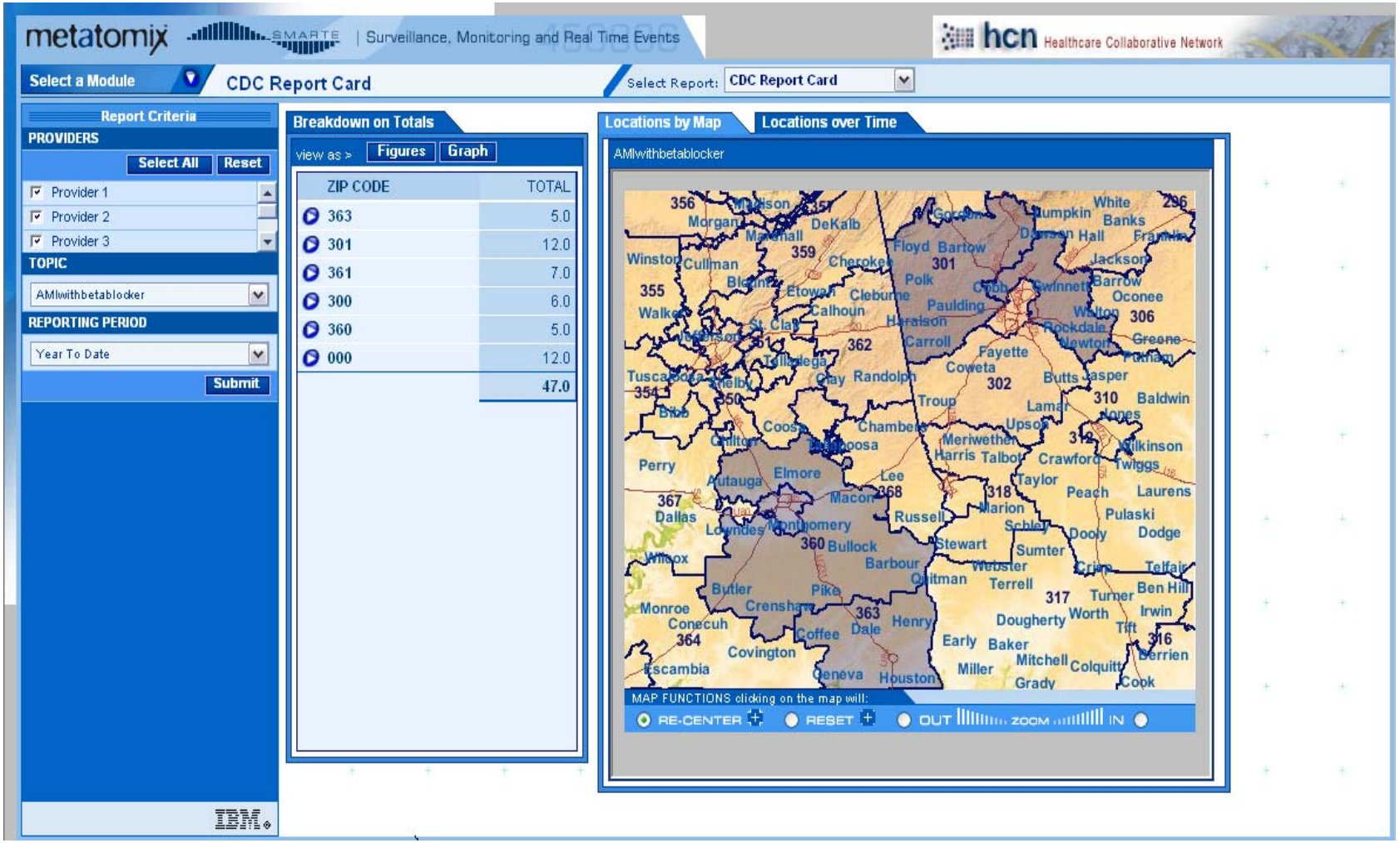
- **Connecting for Health** consists of over 100 stakeholders representing every part of the health care system – healthcare organizations and clinicians, patients, payers, accreditors, government agencies, researchers and health care information systems suppliers – supported through the Markle Foundation (www.connectingforhealth.org)

Mission *Connecting for Health is working to transform how information flows through all segments of the health care system in order to improve the health and health care of every American*

Three key organizational objectives:

- Accelerating the rate of adoption of national clinical data standards in order to facilitate true interoperability. (Data Standards Working Group)
- Identifying practical strategies and solutions for ensuring the secure and private transmission of medical information. (Privacy and Security Working Group)
- Actively working to understand what consumers will need and expect from an interconnected health information system. (Personal Health Working Group)

AMI with Beta Blocker



CMS QIO Report Card (AMI)