National Institute of Standards and Technology
Technology Administration, U.S. Department of Commerce

NIST Collaborations to further Healthcare Informatics Standards & Interoperability

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Healthcare IT Program Focus Areas

- **Electronic Health Record** - Electronic health record standards (EHRs) that provide patients and clinicians with all relevant patient information
  - Project: EHR Conformance
- **Interoperability** - Standards and technologies that support the ability for NHIN users to find, access and retrieve all appropriate information available through the NHIN
  - Messaging Conformance
  - Standards Integration & Implementation
  - Medical Device Communication
- **Security & Reliability** - Standards, guidelines and technologies that promote a secure and reliable healthcare environment
- **Awareness** - Awareness efforts that focus on both security and interoperability
  - Telemedicine Guidelines
  - Standards Landscape

NIST has... strong partnerships

NIST Participation with Industry

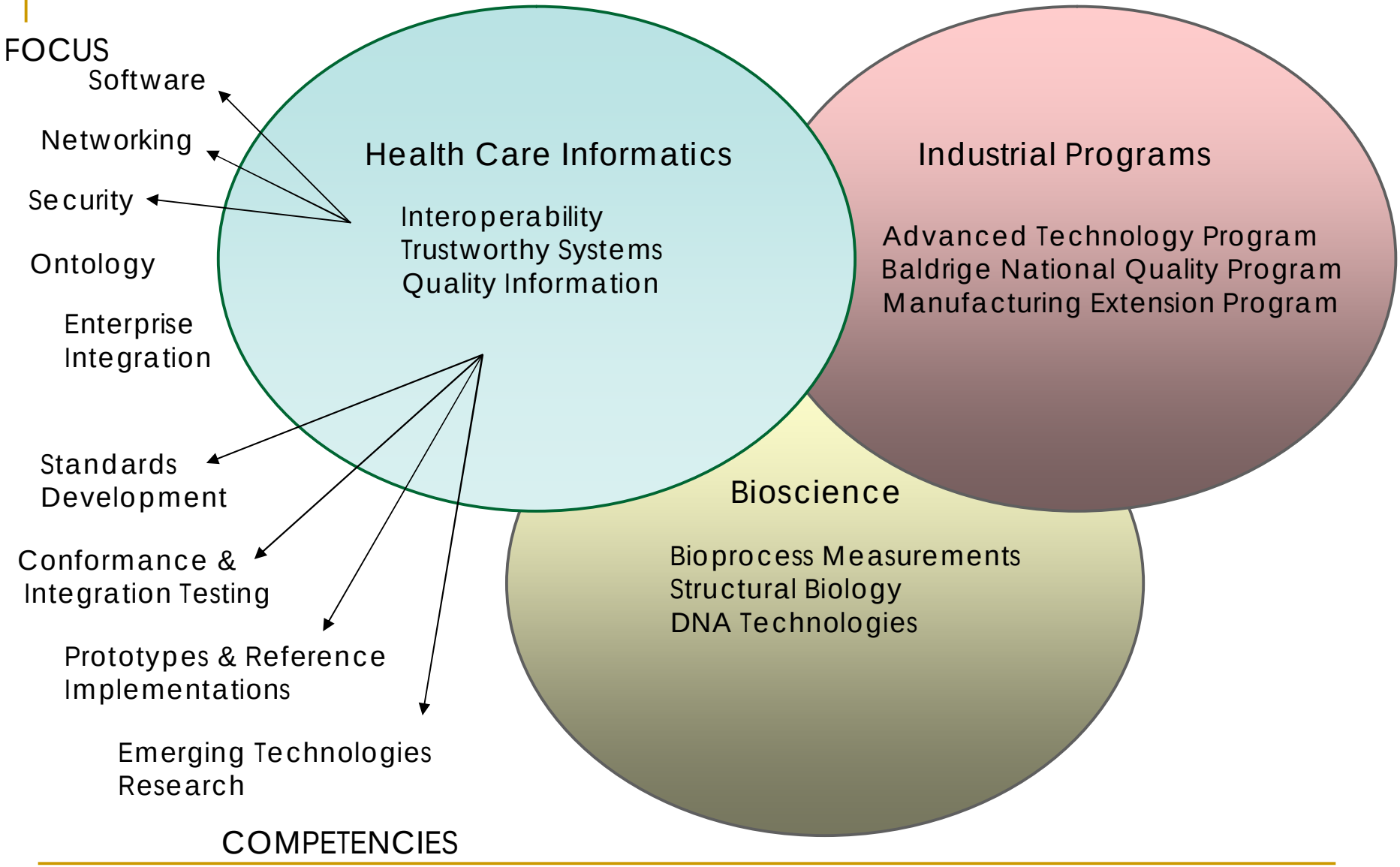
- ANSI HISB - Healthcare Informatics Standards Board
- ASTM – ASTM International
- Markle Foundation's Connecting for Health
- ATA – American Telemedicine Association
- IEEE 1073 Medical Device Communications
- HIMSS/IHE - Healthcare Information and Management Systems Society / Integrating the Health Enterprise
- HL7 – Health Level Seven
- OASIS – Organization for the Advancement of Structured Information Standards
- URAC – (not an acronym)
- Wedi – Workgroup for Electronic Data Interchange

- NIST participation:
  - Organizational members usually with technical/conformance lead role
    - HL7 Conformance SIG Co-Chair, IHE IT Infrastructure Committee Co-chair
  - Technical level collaboration with private-industry member organizations
    - IHE Open Source effort, Medical Device Testing effort
  - Co-sponsor awareness activities
    - Co-sponsor of HIMSS Summer Summit, New York City, June 2005

Federal Agency Collaborations

- FHA/CHI – Federal Health Architecture/Consolidated Health Informatics (egov)
- HHS/AHRQ – Agency for Healthcare Research Quality
- HHS/ONC – Office of the National Coordinator for Healthcare IT
- Co-participants in industry participations
  - VA, CDC, DOD, FDA, NIH,…

Overview of NIST Health Care Activities



NIST Current Role

- Electronic Health Records
- Messaging Conformance
- Infrastructure Integration
- Integrating Emerging Technology
- Security Guidance for Healthcare Systems
- Telemedicine
- Standards Landscape

- Engage constituents
  - Gather requirements
  - Validate our approach through workshops & discussions
- Leadership and participation in standards and conformance efforts
  - Partners with industry standards groups
  - Consultant to federal agencies with healthcare missions
- Development of conformance tests, tools and prototypes
  - Based on industry priorities
  - Prototypes fill in industry gaps
  - Chair industry conformance efforts

Electronic Health Record (EHR)

- **Longitudinal collection of electronic, patient-centric health information, available across providers, care settings, and time**
  - Enhance the quality, safety, and efficiency of patient care
  - Yields data for public health, homeland security, clinical research

- **Current industry efforts**
  - HL7 EHR System Functional Spec.
  - Certification Commission for Healthcare IT (CCHIT)
- **NIST collaborations:**
  - Co-lead of HL7 EHR Conformance effort
  - Developed conformance approach for HL7
    - Profiles of HC domains
    - Conformance criteria model
  - CCHIT approach based on HL7 effort
- **Impact**
  - Certification efforts based on objective measurement
  - Helps move adoption of EHRs forward

HL7 – Health Level Seven
CCHIT – Certification Commission for Healthcare Information Technology

Messaging Conformance

- Messaging - ability to share information among diverse health care (HC) systems
- Health Level Seven (HL7) standards used for the exchange, mgmt and integration of data for clinical care
  - Deployed in 90% of US hospitals, international use growing
  - Moving to other care settings – labs, imaging, pharmacy, long-term care
  - Currently, plug-n-play interoperability is cost-prohibitive for many participants
- NIST Collaborations with HL7
  - Define conformance and measurement definitions for HL7 standards
  - Build conformance tests & tools to determine system conformance
- Impact
  - Cost-effective implementation of HC messaging systems
  - Seamless movement of HC information among/between HC organizations

Partial List of Messaging Areas

Patient Administration	Admit, Discharge, Transfer, and Demographics.
Order Entry	Orders for Clinical Services, Pharmacy, Dietary, and Supplies.
Query	Rules applying to queries and to their responses.
Financial Management	Patient Accounting and Charges.
Observation Reporting	Observation Report Messages.
Scheduling	Appointment Scheduling and Resources.
Patient Referral	Primary Care Referral Messages.

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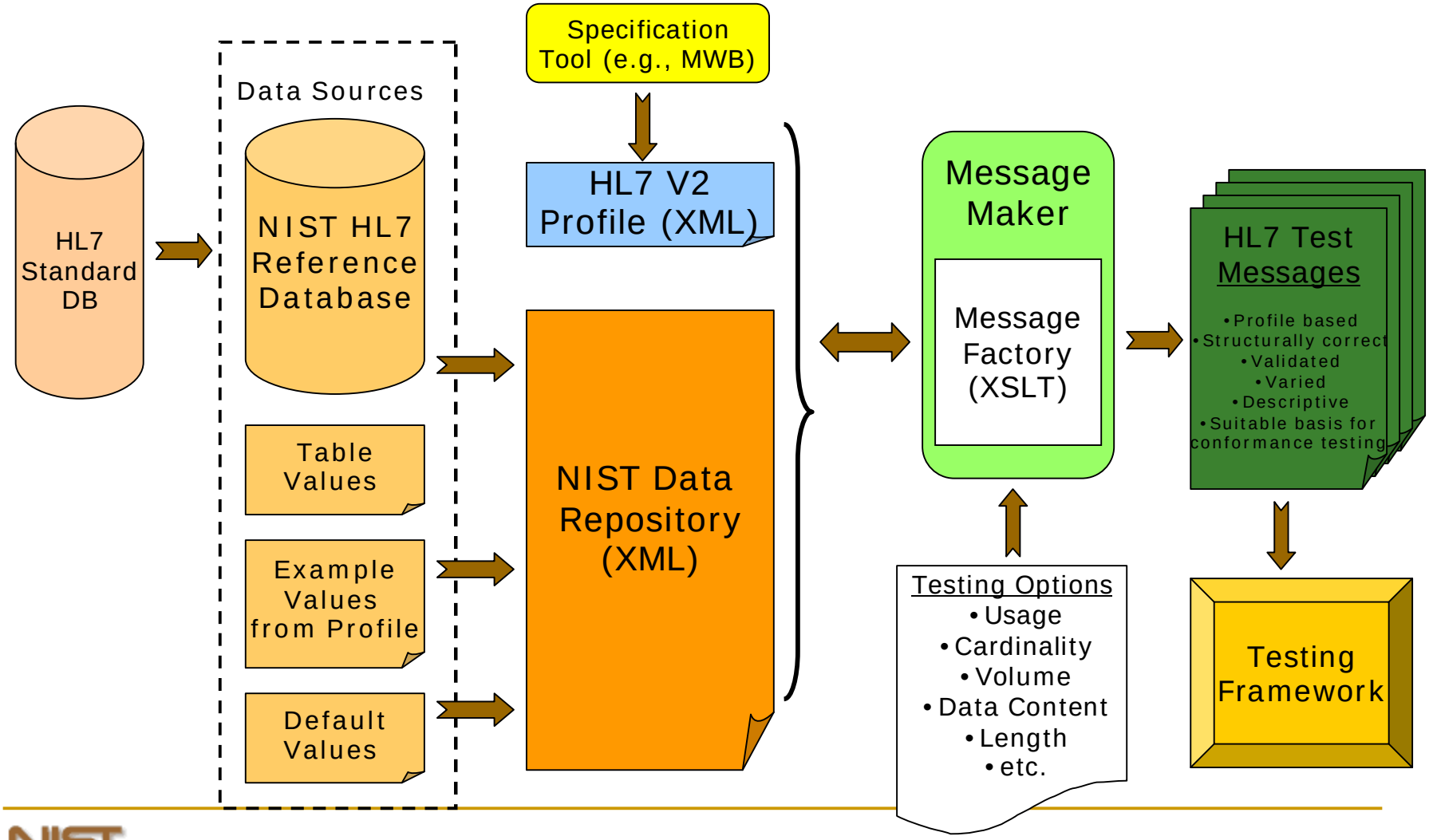
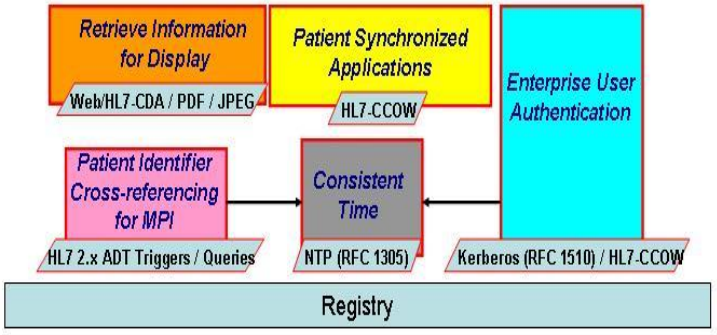
Message Maker Design



Standards Infrastructure Integration

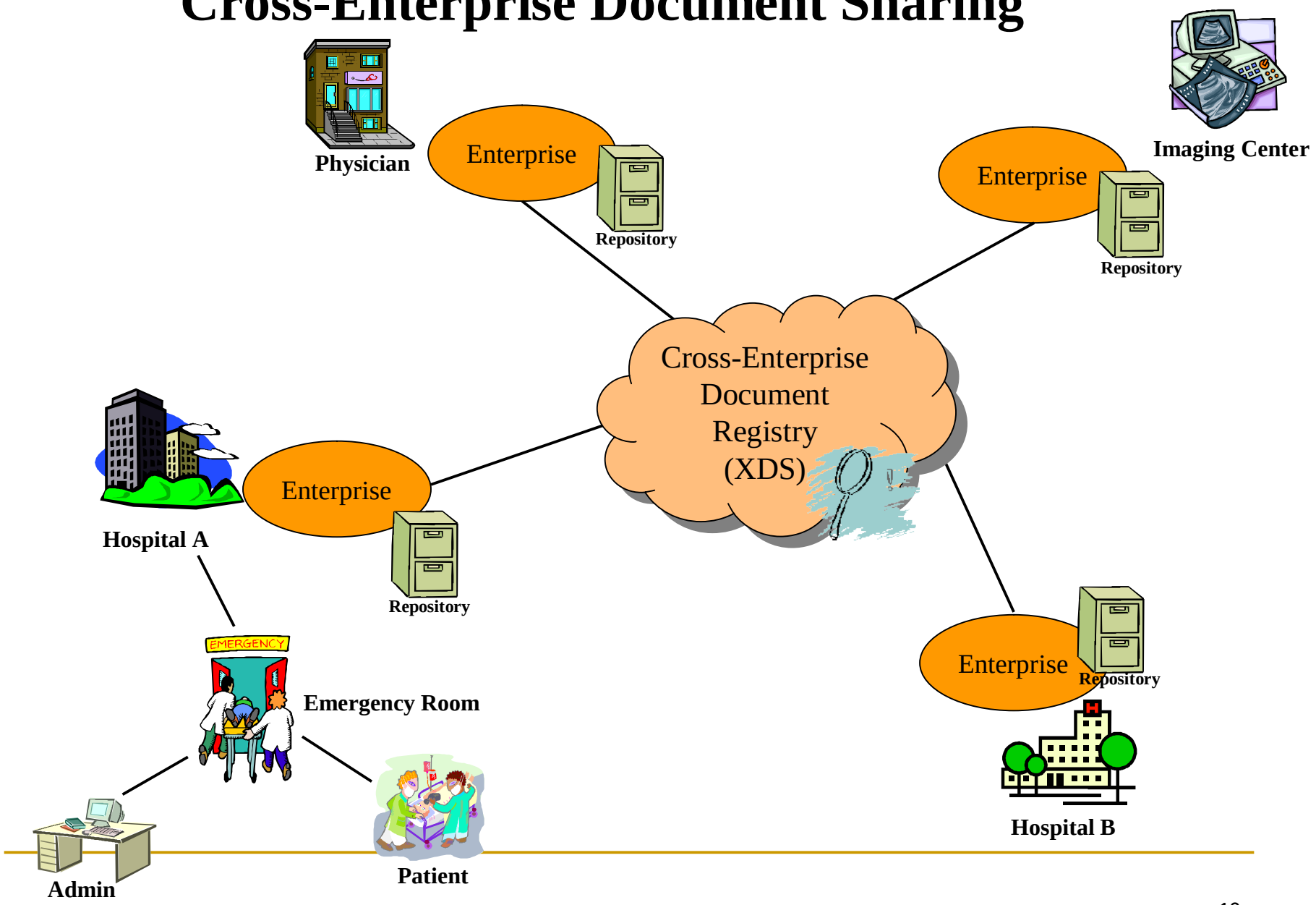
- Standards-based integration allows vital health information to be seamlessly passed from application to application across and between HC enterprises
- HIMSS IHE Project
  - Use-case driven to focus on specific clinical informatics need
  - Industry consensus-based profile of HC and IT standards
  - Reference implementation
  - Interoperability tests for implementers



IHE Profile Environment

- NIST Collaboration with HIMSS Integrating the Healthcare Enterprise (IHE) Project
- Define, test, and implement integration profiles
  - Co-authored *IHE Cross Enterprise Document Sharing Profile* (XDS)
  - Developed XDS reference implementation and test tool
  - NIST implementation featured at HIMSS Showcases (2004, 2005)
  - Industry implementations of XDS featured at HIMSS Showcase 2006
- Impact
  - Fully integrated stds-based solutions available
  - XDS helps ensure the availability of longitudinal healthcare records

Cross-Enterprise Document Sharing



Medical Device Communication

- Acute care devices can't communicate
  - Expensive custom-connectivity equipment is expensive
  - Manual data capture is labor intensive, done infrequently, prone to error
- Need info to be electronically captured and recorded in real-time, from multiple devices

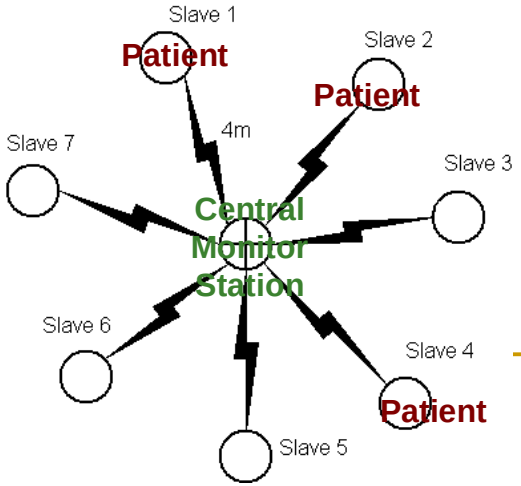
- NIST collaborating with IEEE Medical Device Communications Working Group (IEEE 1073) & Integrating the Healthcare Enterprise (IHE)
  - Facilitate the efficient exchange of medical device data throughout the HC enterprise
  - Ensure standards are well-defined
  - Define conformance tests to ensure correct implementation of critical devices
- Impact
  - Hasten the industry's ability to deploy devices
  - Higher quality of device output leads to higher quality medical decisions

Summary

- *We develop measurements, tools, and prototypes, and contribute to voluntary standards to advance the use of information technologies in healthcare systems and achieve an interconnected electronic health information infrastructure.*
  - Collaborate with industry to develop clear, testable public specifications
  - Based on industry priority we develop conformance test suites to ensure correct, robust interoperable software
  - Develop prototypes of emerging HC standards to fill in the gaps that are identified by industry

Integrating Emerging Technology – Wireless Patient Rooms

- Development of a universal & interoperable wireless interface for medical devices
- Quality of Service (QOS) is significant requirement
- Determine wireless technology use based on unique HC application requirements - performance, coexistence, interoperability & security requirements



- NIST collaboration with IEEE 1073 Medical Device Communications Working Group
  - Define relevant performance evaluation metrics – throughput, delay, jitter & packet loss
  - Conduct performance evaluation based on analysis & simulation for medical scenarios of interest.
- Impact
  - Plug-n-play for medical devices to wireless network
  - QOS guarantees
  - Informed choices for purchase

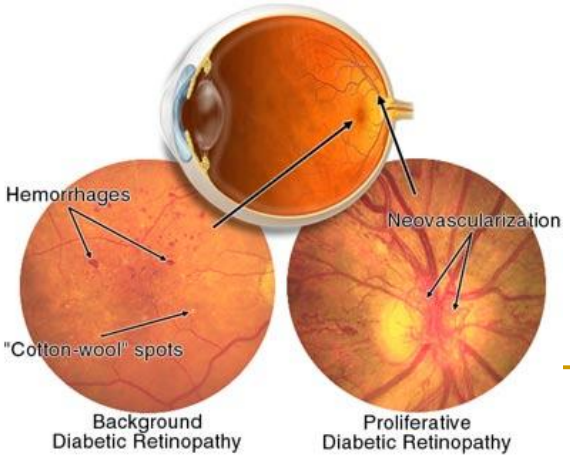
Security Guidance in HC systems

- Clinicians and patients must have confidence that HC systems maintain the privacy and integrity of patient information, and that the information is always available
- Trust is a show-stopper in building the NHIN
- Quality medical decisions depend on the quality of medical information
- Integrate established security standards and practices into HC environments

- *An Introductory Resource Guide for Implementing the HIPAA Security Rule* (NIST Special Publication 800-66)
  - Crosswalk from Security Rule to NIST Security Guidance
  - Provides situational examples for small/medium HC enterprises
- Impact
  - Provide HC organizations with common-sense, easy-to-understand approach to security
  - Reduce duplicative efforts in meeting security requirements
  - Help ensure patient trust wrt their healthcare information

Telemedicine Standards & Validation

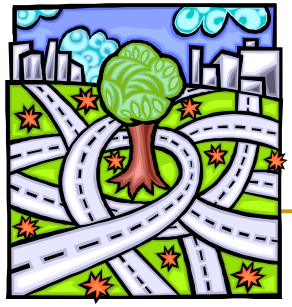
- Telemedicine is the use of medical information exchanged from one site to another via electronic communications for the health & education of the patient or healthcare provider and for the purposes of improving patient care
- Telemedicine provides significantly improved and cost effective access to quality HC regardless of geographic area or socioeconomic status
- Used in radiology, dermatology, pathology, ocular health & home healthcare (not inclusive)



- NIST collaboration with the American Telemedicine Association (ATA)
- Area of focus: Use of teleophthamalogy for diabetic retinopathy (DR) screening and treatment
- Developed *Telehealth Practice Recommendations for DR,* a standards profile that includes IT standards, clinical guidelines and business rules standards
- Ensure measurement and conformance are defined where possible
- Collaboration underway to develop validation and quality assurance approaches
- Impact
  - Improved and Consistent Medical Services
  - Technical and Clinical Interoperability
  - Business Model and Yardstick for Reimbursement

Standards Landscape

- The HC informatics domain has a plethora of standards
- Monitoring relevant standards is arduous and labor-intensive
  - Relationships of standards
  - Overlapping context
  - Duplication of scope
- HC Standards Landscape
  - A web-based repository to capture standards knowledge
  - Emerging and existing HC standards, organizations, and initiatives
- NIST collaborates with ANSI HISB & AHRQ to develop Standards Landscape
  - Facilitates collaborative standards work
  - Minimize overlap and duplication of stds. effort
  - Knowledge of Who's implementing What stds.
- Impact:
  - Foster coordination among standards developers
  - Helps determine best-of-breed among standards based on implementation
  - Foster use of/adherence to standards



Health Care Standards Landscape

http://hcsl.sdct.nist.gov

NIST is Called Out...

- Towards achieving correct implementations of HISs, an IOM report suggests that "**The National Institute of Standards and Technology (NIST) could perhaps serve as the body supporting the implementation process as the developer of protocols for conformance tests,** … to verify vendors' compliance with the standards *(Patient Safety, Achieving a New Standards of Care, p.118*).
- The Connecting for Health Collaborative recommends "To ensure interoperability there is an immediate need for certifying interface conformance … **Organizations that fund regional health information projects should foment a collaboration between NIST …and others to establish a methodology for interface certification** …" *(Achieving Electronic Connectivity in Healthcare, pps.41-43, July 2004).*
- The PITAC report recommends "Where possible, R&D efforts should be shared. …Possible models, in particular **regarding computer infrastructure, privacy, and security, may be found where there is a long history of research, such as … NIST** and other agencies." *(Revolutionizing Health Care Through Information Technology, PITAC, June 2004).*

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- HL7 – Health Level Seven
- PITAC - President's Information Technology Advisory Committee
- OASIS – Organization for the Advancement of Structured Information Standards
- URAC
- Wedi – Workgroup for EDI

NIST Successes

- HL7 Conformance activities
  - Co-chair conformance committee
  - Developing conformance definitions for HL7 standards
  - Experimental Registry facilitates conformance
  - Developed initial prototype of dynamic configuration conformance tool
- Developed initial conformance tests for IEEE Medical Device standard
- Infrastructure integration advanced with standard, prototype, and tests
  - NIST XDS reference implementation sole registry in HIMSS/IHE demonstration
  - Multiple vendors implementing NIST co-authored XDS profile
- EHR Conformance activities
  - Lead effort to define conformance requirements
  - NIST work provides the basis for private-industry certification (CCHIT*)
- Standards Landscape chosen as public view for HISB business.
- NIST asked to collaborate with ATA on validation and quality assurance approaches to Diabetic Retinopathy Practice Recommendations

*CCHIT – Certification Commission for Healthcare Information Technology

Reminder: Motivation

- **$1.7 trillion** – National Healthcare Spending (CMS, 2004)
- **44,000 – 98,000** – Americans die each year from inpatient medical errors (IOM)
- **770,000** – Americans injured or die each year from adverse drug events (ADE)
- **$300 billion**– treatments that may not improve health, may be redundant, or may be inappropriate (Wennberg 2002, 2004; Fisher, 2003)

- **$78 billion - $112 billion** annually – savings from ambulatory EHRs and the interoperability of those EHRs (Johnson 2003; Pan, 2004)
- LDS Hospital (Salt Lake City) – CPOE system reduced ADEs by **75%**

Moving the Industry Forward

- National Coordinator for Health IT established (April 2004)
- President's goal: Most Americans use interoperable EHRs in 10 years (April 2004)
- ***The Decade of Health Information Technology: Delivering Consumer-centric and Information-Rich Health Care*** (HHS, July 2004)
  - **Inform Clinical Practice**
  - **Interconnect Clinicians**
  - **Personalize Care**
  - **Improve Population Health**
- Healthcare and IT industries have embraced these goals and appear willing to move forward collaboratively.
- HHS announces contracts to help move industry forward (June 2005)
  - Development of NHIN prototypes
  - Development of an EHR certification program
  - Development of an HC standards harmonization process
  - Analysis of security/privacy state laws and organization policies as barriers to interoperability

Interoperable Health Information Exchange

Standards include content, vocabulary, communications, security, business rules, etc.

Conformance to standards is necessary but not sufficient to achieve interoperability