Information Technology for the Health Care Enterprise



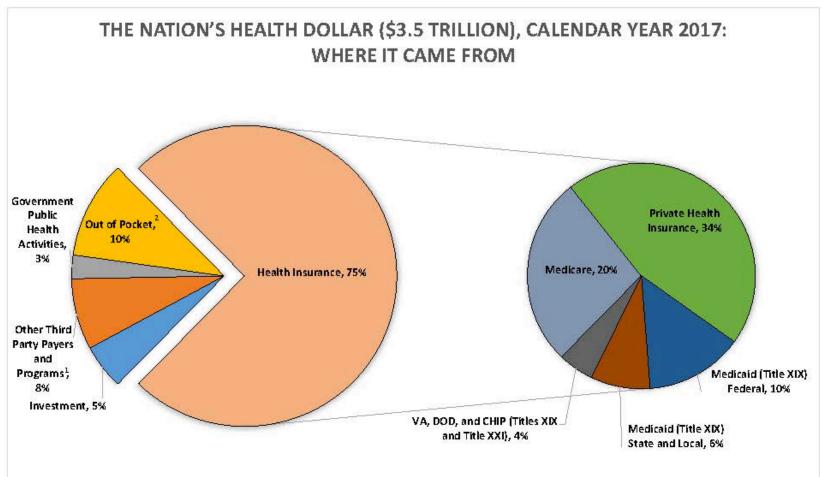
Ram D. Sriram, Ph.D. Chief, Software and Systems Division URL: http://www.nist.gov/itl/ssd/ sriram@nist.gov

Outline

- Healthcare Vision
- Health IT at NIST
- Standards & Testing
- Security
- Biomedical Imaging
- Bioinformatics
- Summary

Healthcare Facts

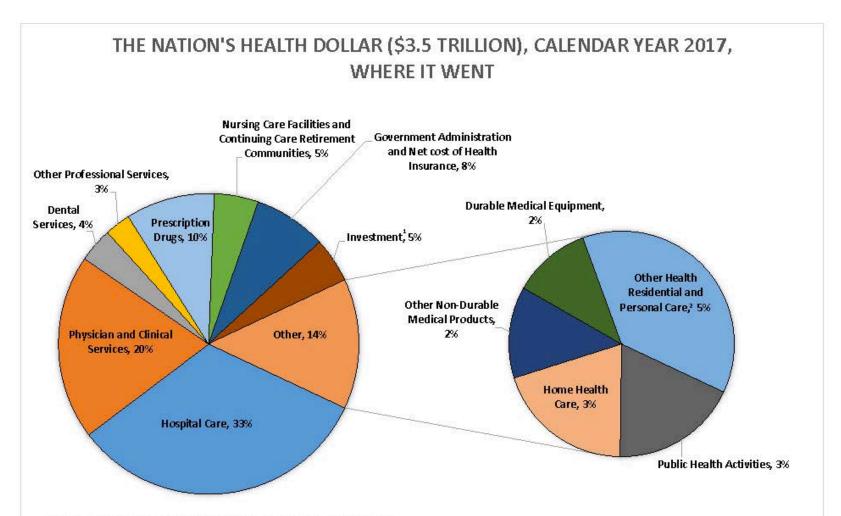
\$3.5 Trillion dollars spent in 2017 on healthcare in the U.S. (http://www.cms.gov)
It is estimated that approximately \$750billion is lost due to inefficiencies in the system – Effective use of IT may help reduce these costs
Multiple parties playing different roles



¹Includes worksite health care, other private revenues, Indian Health Service, workers' compensation, general assistance, maternal and child health, vocational rehabilitation, Substance Abuse and Mental Health Services Administration, school health, and other federal and state local programs.

² Includes co-payments, deductibles, and any amounts not covered by health insurance. Note: Sum of pieces may not equal 100% due to rounding.

SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.



¹ Includes Noncommercial Research and Structures and Equipment.

²Includes expenditures for residential care facilities, ambulance providers, medical care delivered in non-traditional settings (such as community centers, senior citizens centers, schools, and military field stations), and expenditures for Home and Community Waiver programs under Medicaid. Note: Sum of pieces may not equal 100% due to rounding.

SO URCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

Levels of Biological Information

HEALTH CARE

BIOSCIENCES

Ecologies

Societies/Populations

Individuals

Organs

Tissues

Cells

Protein and gene networks

Protein interaction networks

Protein

mRNA

DNA



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Hood

Advances Making Future Health Vision Attainable Software (Internet,

Advances in Data Analytics, Etc.) Computing, Imaging, and Information Technology



Speed and Storage



Networking Communications and Imaging **mPCD**



& Body

Advances in Healthcare **Practice**





Advances in **Healthcare** Technology



Courtesy: Jack Corley

Future

Health

The P7 Concept

- 1. Personalized
- 2. Predictive
- 3. Participatory
- 4. Precise (recommendation, decision analytics)
- 5. Preventive
- 6. Pervasive (including point of care)
- 7. Protective (Privacy and security)

Information Technology Laboratory, National Institute of Standards and Technology 8 Based on discussions with Leroy Hood and Bamesh Ja

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Key Activities in Health IT

- NIST enables interoperability and adoption by:
 - Accelerating standards development and harmonization
 - Developing a conformance testing infrastructure
 - Expanding R&D and deployment of security protocols



mage: Shutterstock, ©Jenny Horne

- Leveraging testing infrastructure to assist with certification process
- Leading to an emerging health IT network that is correct, complete, secure and testable.
- In addition to exploring standards and measurements for emerging technologies in health care.

NIST Health Care: IT Projects

- Health Information Technology: Standards & Testing
- Medical Devices: Interoperability
- Biomedical Imaging
- Bioinformatics
- Text Retrieval (Past)
- Usability (Past)
- Security

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Standards and Testing

Provide technical expertise to leverage industry-led, consensus-based standards development and harmonization as well as develop a conformance testing infrastructure to enable interoperability and adoption.

Key activities include:

Developed the conformance test method (test procedures, test data, and test tools) to ensure compliance with the Stage 1 and Stage 2 Meaningful Use technical requirements and standards

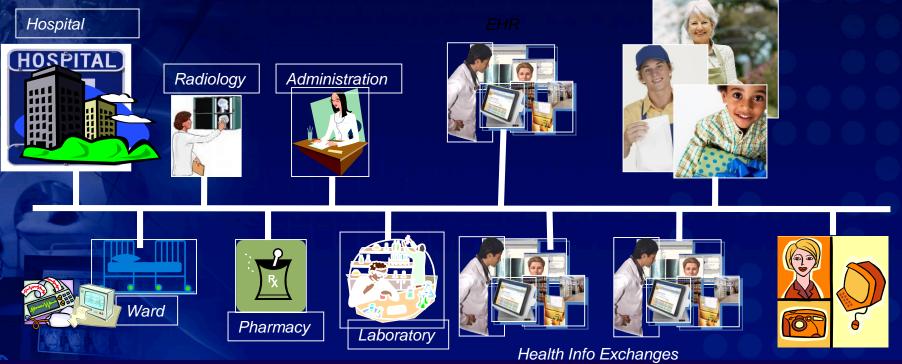
Under HITECH, developing a health IT standards testing infrastructure to provide a scalable, multi-partner, automated capability for current and future testing needs within the healthcare domain.

Developing conformance test tools for fully integrated health IT systems to assure that the standards are implemented consistently.

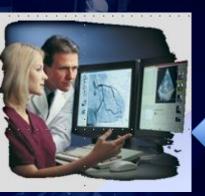
Collaborating with industry including Health Level Seven (HL7), IEEE, and Integrating the Healthcare Enterprise (IHE).

Health IT Interoperability

Personal Health Record



Homecare devices



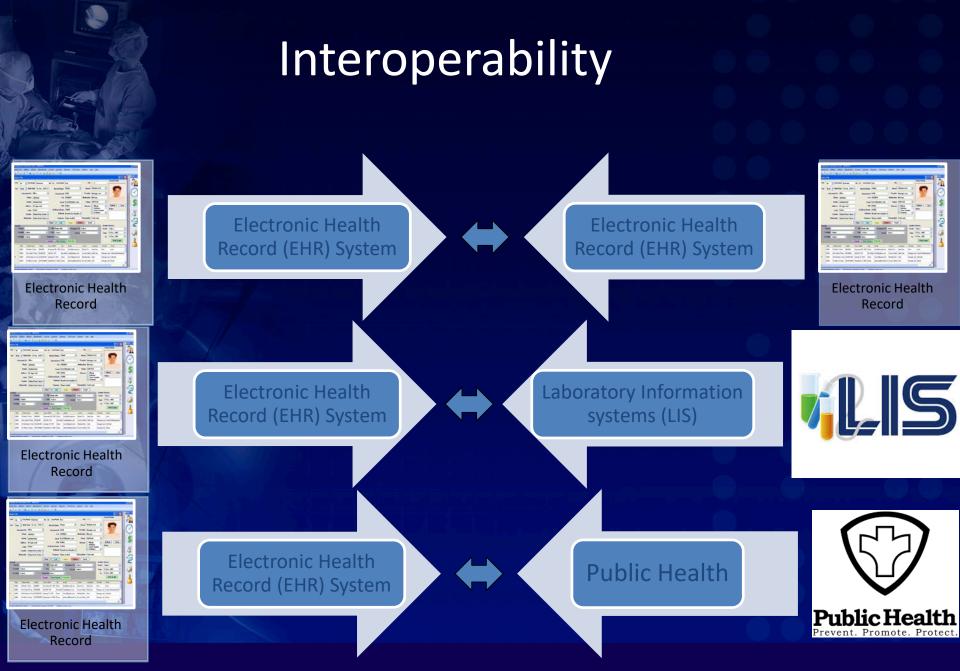
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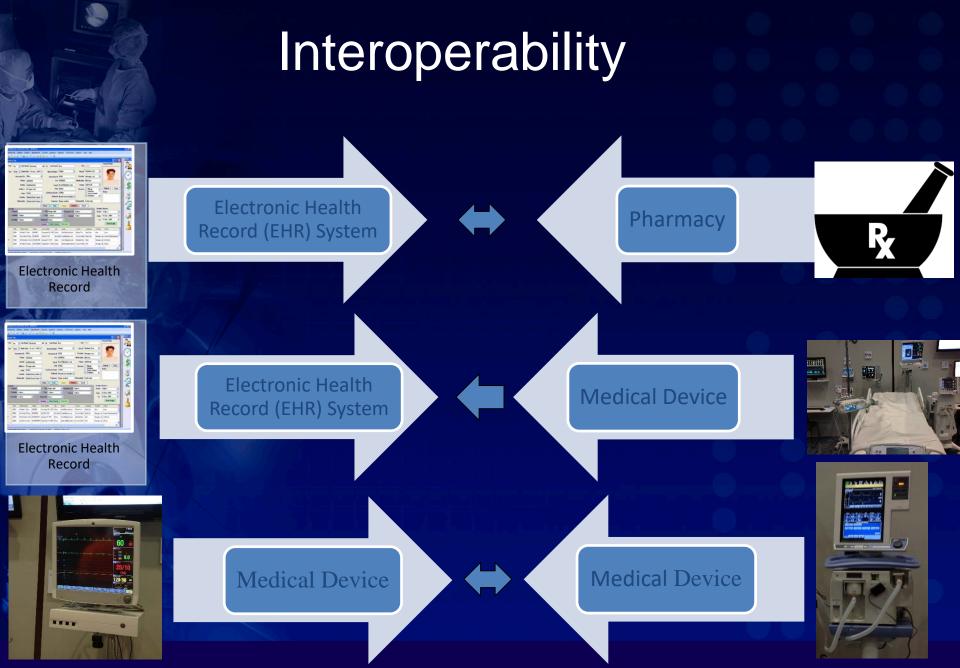
SECURITY

EHRs: Key Issues



- Input (user interfaces)
- Store (representation and persistency)
 - Manipulate (search, mining, knowledge creation)
- Exchange (syntactic and semantic interoperability)





Semantic Mapping Techniques The Medical "Tower of Babel"

Some terms for "Hypersomatotropic Gigantism":

A STATE OF THE REAL PROPERTY AND A STATE OF THE REAL PROPERTY	
Vocabulary	Term
UMLS Metathesaurus	Hypersomatotropic Gigantism
ICD-9-CM	No direct translation
MeSH	No direct translation
DXplain	Pituitary Gigantism
Read Codes	No direct translation
SNOMED	Hypersomatotropic Gigantism

True EHR Interoperability

Conformance to raw message specifications in the Standard

Syntax

Conformance to Specific Clinically Relevant Test data to exercise all options

Semantics

Context

Conformance to Specified Vocabularies in clinically relevant test data

Syntax

Context

Semantics

Interoperability

- <u>Standards</u> are essential to achieving conformance and interoperability
- Rigorous testing is critical to achieving <u>conformance</u> and enabling interoperability
- Conformance CAN NOT be definitively determined* but gives a level of confidence based on quality and quantity of test(s) performed (*unless specification is very basic)

Conformance

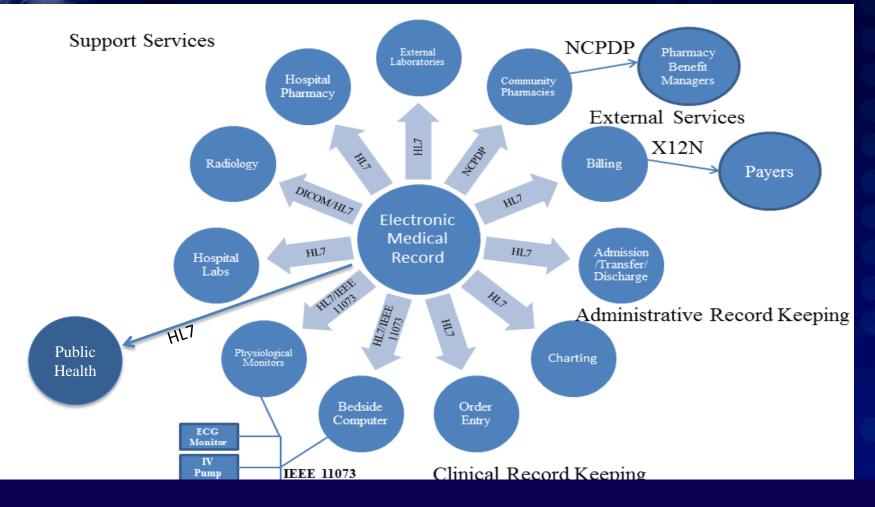


Interoperability

- A is Conformant, B is Conformant

The above does not say anything about interoperability between A and B

Standards That Link to an EHR



Standards in HealthCare

- Terminology
 SNOMED, LOINC
- Classification Systems
 - ICD9 & 10, CPT
- Devices
 - IEEE 11073
- EHR-Related
 - DICOM, HL7 (CDA)
- Interoperability
 - DICOM, HL7 Messaging, HIPAA Transactions, NCPDP
- Language Formats
 - XML, X12
- Internet Protocols
 − HTTP/HTTPS → TCP/IP

Four Levels of HIT Interoperability

automatic

manual

Organizational Interoperability

Standardized process (workflow) elements using business process modeling tools

Semantic Interoperability

Standardized meaning (model element) and terms / vocabulary for data interpretation, e.g., LOINC, ICD-10CM

Syntactic Interoperability

Standardized data exchange formats, e.g., HL7, XML

Technical Interoperability

Signals using standard protocols for technically secure data transfer, e.g., TCP/IP

Standards

Based on

Oemig F, Snelick R, <u>Healthcare Interoperability Standards Compliance Handbook</u>. Springer International Publishing Switzerland. 2016. Page 13, Figure 1.3.

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ow

high



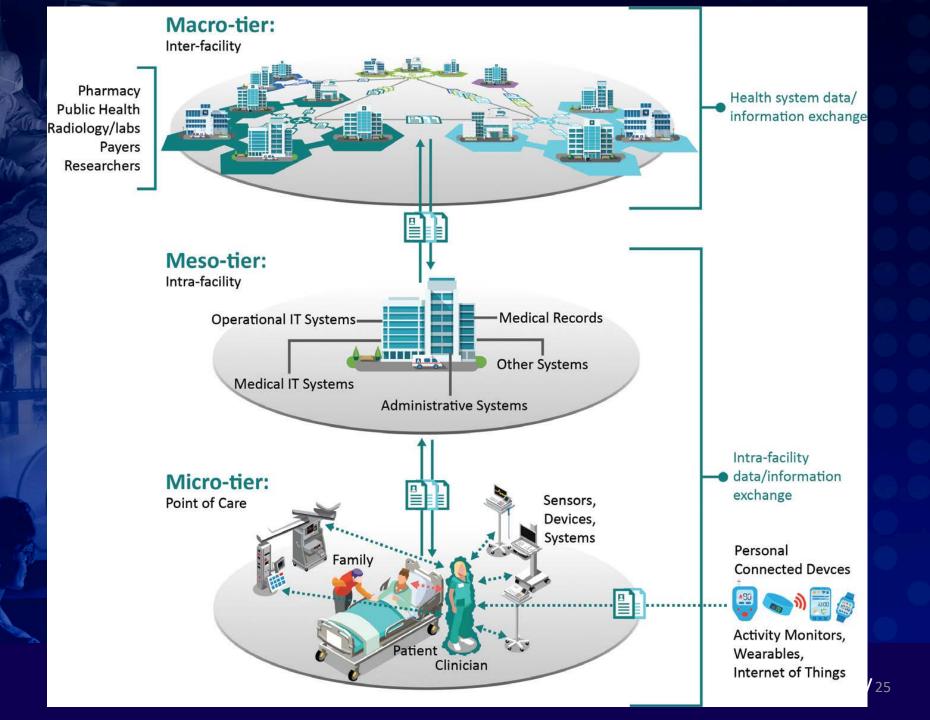
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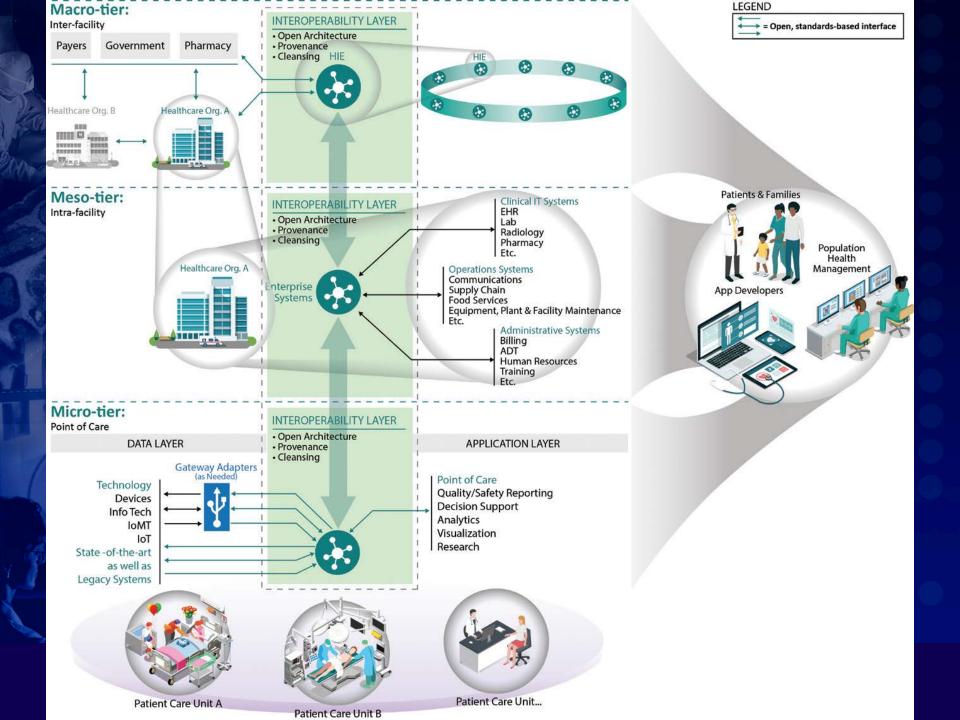
PROCURING INTEROPERABILITY

ACHIEVING HIGH-QUALITY, CONNECTED, AND PERSON-CENTERED CARE

Peter Pronovost, Michael M. E. Johns, Sezin Palmer, Raquel C. Bono, Douglas B. Fridsma, Andrew Gettinger, Julian Goldman, William Johnson, Meredith Karney, Craig Samitt, Ram D. Sriram, Ashwini Zenooz, and Y. Claire Wang, *Editors*

rds and Technology₂₄





Challenges with HIT Interoperability Standards

- Standards can be non-existent for certain doma
- Existing standards can be poorly defined
- Poorly-defined standards can be poorly implemented
- Well-defined standards can be poorly implement
- Well-defined standards can be ignored (i.e., not adopted)
- Standards can compete with each other (too many standards)
- Standards can be complex

Use of Standards doesn't guarantee Interoperability



Common Issues with HIT Standards

- Under specified
- Multiple solutions (occurs at all levels)
- Conflation of requirements (requirement scoping
- Document current state—not desired state
- Not specific enough—e.g., code system binding
- Too specific
- Poor documentation and typos
- Lack of a consistency
- Conditions w/o Condition Predicates
- Absence of harmonized requirement specification methodology
- Insufficient requirement specification mechanisms
- Lack of reference and pilot implementations
- Lack of testing
- Improper scoping

ACME AUTO PARTS

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"We are now in the Electronic Health Record business. We found a teenage hacker in ——— who can build us an EHR system on the cheap. Start the marketing campaign."

NIST Standard Activities/Working Group Participation



The American Recovery and Reinvestment Act (ARRA) identifies NIST to lead the development of a health IT testing infrastructure

- ARRA (2009) emphasizes the need to move toward electronic health records
- The legislation calls for National Institute of Standards and Technology (NIST) to contribute:
 - Ensure health IT standards are complete and robust
 - Establish a health IT standards testing infrastructure that supports industry consensus standards development and provides robust conformance and interoperability testing capabilities
 - Deploy those technologies to promote interoperable health IT adoption

Proposed Stages of Meaningful Use

Stage 1

- · Electronically capturing health information in a coded format
- · Using that information to track key clinical conditions
- · Communicating that information for care coordination purposes
- · Initiating the reporting of clinical quality measures and public health information

Stage 2

- Stage 1 objectives
- Disease management
- Clinical decision support
- Medication management
- · Support for patient access to their health information
- · Quality measurement and research
- · Bi-directional communication with public health agencies

Stage 3

- Stage 1 and 2 objectives
- · Improvement in quality, safety and efficiency
- · Decision support for national high priority conditions
- Access to self management tools
- · Access to comprehensive patient data and improving population health outcomes

NIST And MU

• NIST developed the tests for compliance with the MU criteria.

NIST Role in ARRA MU EHR Certification Stage 1

MU Recommendations from ARRA HIT Policy and Standards Committees

> CMS Final Rule – Meaningful Use Objectives and Measures

> > ONC Final Rule – Certification Criteria and Standards

Based on the requirements in the ONC Final Rule, NIST published 45 test procedures which are in use by the accredited testing laboratories to test and certify EHR products for the Meaningful Use Program

ONC-Approved Test Method

Accredited Testing and Certification Bodies**

Drummond Group, Inc. Complete EHR and EHR Modules. InfoGard Laboratories, Inc. –Complete EHR and EHR Modules.

<u>ICSA Labs</u> - Complete EHR and EHR Modules. <u>SLI Global Solutions</u> Complete EHR and EHR Modules. <u>Surescripts LLC</u> - EHR Modules: E-Prescribing, Security

** Set up by NVLAP

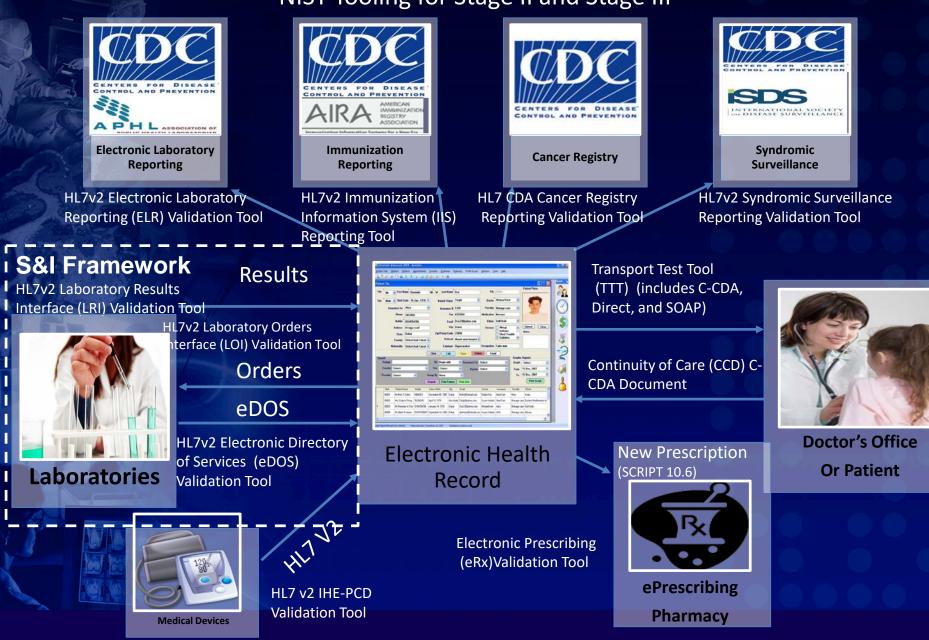
ATCB Test Scripts

Test Procedures Test Data Conformance Tools

ATCB Testing of EHRs

ONC Certified Products List

NIST Tooling for Stage II and Stage III



How we accomplished MU 2

HL7 CDA Cancer Registry Reporting Validation Tool

HL7v2 Immunization Information System (IIS) Reporting Validation Tool

HL7v2 Syndromic Surveillance Reporting Validation Tool

HL7v2 Electronic Laboratory Reporting (ELR) Validation Tool

Transport Test Tool (TTT) (includes C-CDA, Direct, and SOAP)

Electronic Prescribing (eRx)

HL7v2 Laboratory Results Interface (LRI) Validation Tool

Partner with CDC Four separate divisions

Partner with DIRECT Project/NwHIN

Partner with NCPDP Established MU WG

Partner with S&I

Framework

ory, National Institute of Standards and Technology 35

NIST's Tools are foundations for MU implementations

Improved Quality, Access, and Cost of Healthcare

Meaningful Use (MU) Attestation by Eligible Entities

Meaningful use of CEHRT by Eligible Entitics

CEHRT Configuration and Implementation at Eligible Entities' Sites

EHR Certification Testing using Test Toolstandards

Development of Conformance Test Tools by NIST

Development of IG Standards & Other Specifications by Work Groups (with **NIST** participation)

Information Technology Laboratory, National Institute of Standards and Technology CEHRT = Certified EHR Technology

\ \$10's of Billions

Quality of the CEHRT implementations and the installed sites is directly related to the quality of the Conformance Test Tools and the underlying

28 Billion Dollars CMS MU Incentive Payments to Eligible Entities

> Resolving interoperability problems is much less expensive during standards development and testing; after CEHRT deployment these problems would need to be resolved at numerous locations

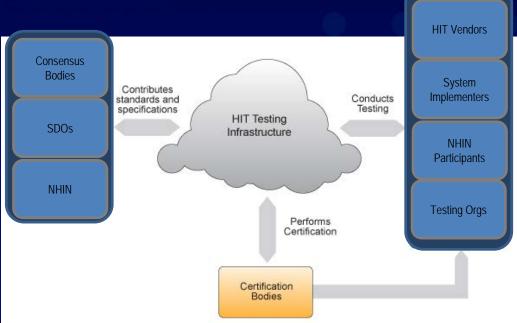


21st Century Cures Act (Dec. 2016) Sec. 4003. Interoperability

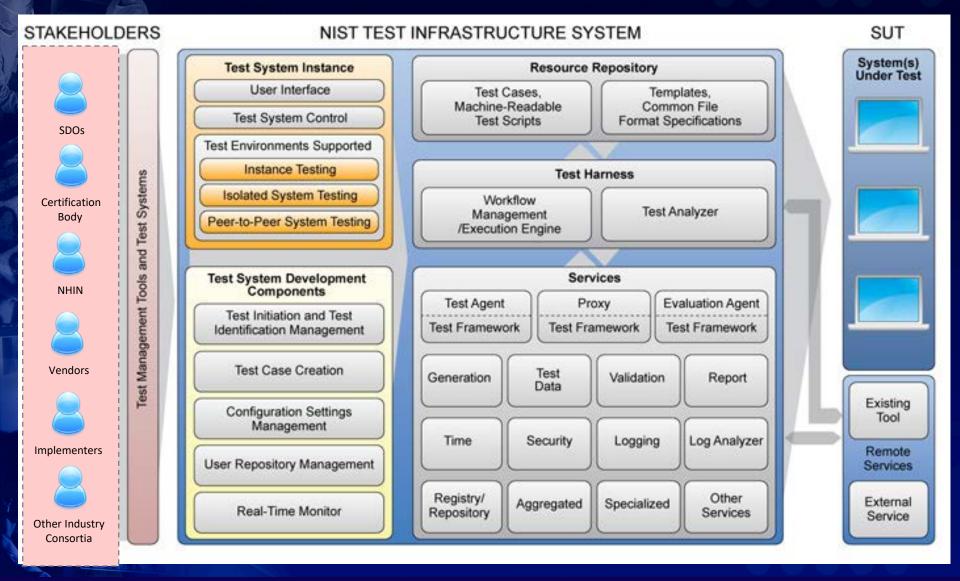
The National Coordinator shall, in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-tonetwork exchange of health information, convene publicprivate and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally. Such convention may occur at a frequency determined appropriate by the Secretary.

The NIST Testing Infrastructure will provide a scalable, automated environment for current and future testing needs

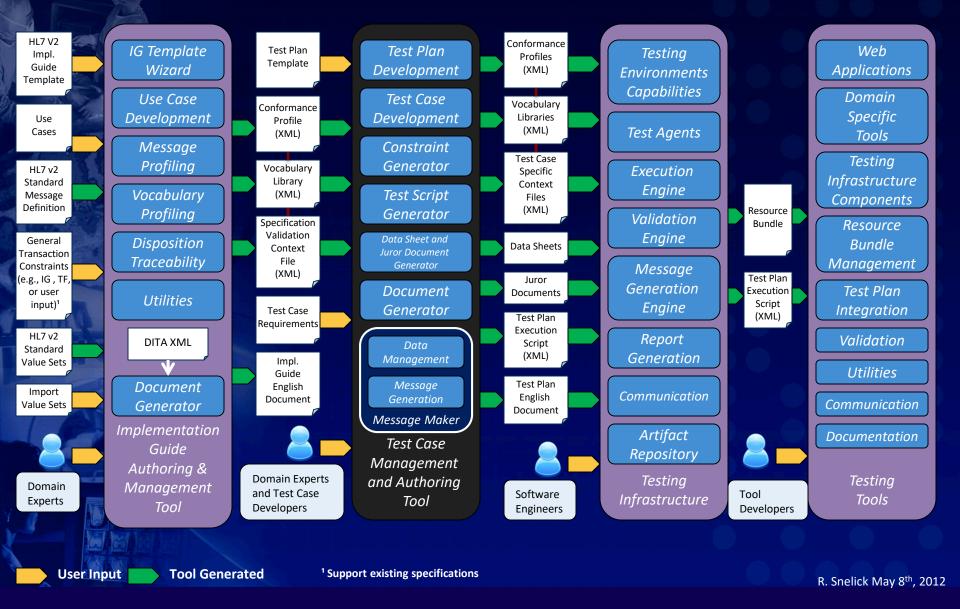
- NIST will collaborate with health IT stakeholders to harmonize healthcare standards test development and delivery to ensure conformance and interoperability within the healthcare domain
- NIST will leverage existing tools and work with health IT stakeholders including:
 - Certification Bodies
 - Testing Organizations
 - NwHIN
 - Vendors
 - Implementers
 - SDOs
 - Other Industry Consortia

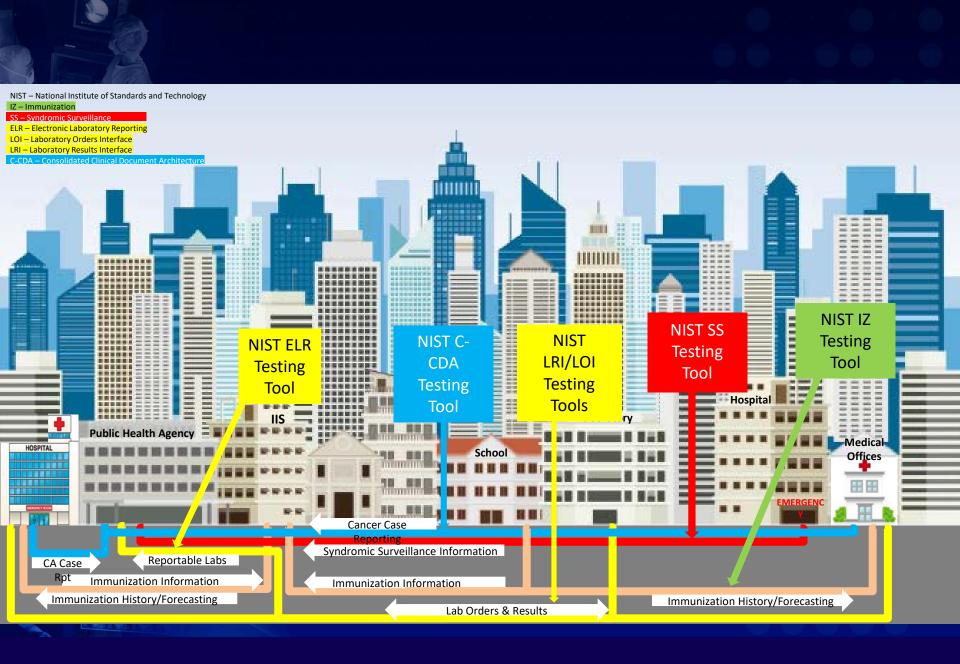


Conceptual View of HIT Testing Infrastructure



The Big Picture: HL7 V2 End-to-end Testing Support





Medical Devices

- Interoperability
- Body Area Network Standards
- Security

NIST Medical Device Communication Testing

Semantic interoperability of Medical Devices

Introduction - Need

As hospitals deploy EMRs into their most critical care areas, the need to acquire data directly from medical devices becomes increasingly evident.

- Device data capture is "real-time"
 - Data is up-to-date
 - Decision support algorithms can run on more timely data
- Device data capture is "automatic"
 - Reduce nursing workload
 - Device data capture is "accurate"
 - Automated data capture is less error prone than manual charting

Patient Care Health Device Connectivity

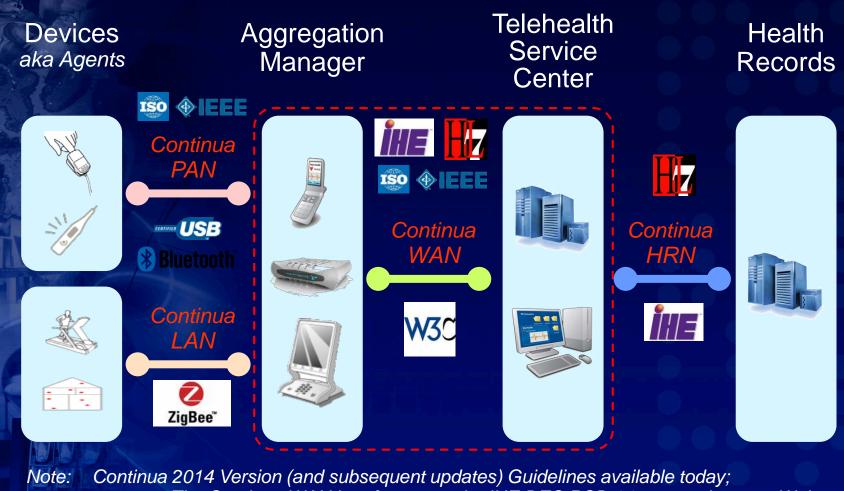
Departmental Hospital Hospital Remote **Devices and Mgmt** Device Health EHRs Systems Gateway(s) Records Acute care Internal Health Hospital Information Cardiology Network Exchange **IHE DEC** IHE Surgery **Profiles:** Content Profiles, PCD+RTM, XDS, XDR ER, ICU, PIB, SPD, ACM, PIV, others ... WCM, IDCO..

 Note:
 IHE Profiles shown above were recently (March 2016) demonstrated at HIMSS16;

 IHE DEC PCD-01 Technical Framework "Final Text" version first became available in Q3

 2011.

Personal Health Device Connectivity



The Continua WAN interface uses the IHE DEC PCD-01 transaction over Web

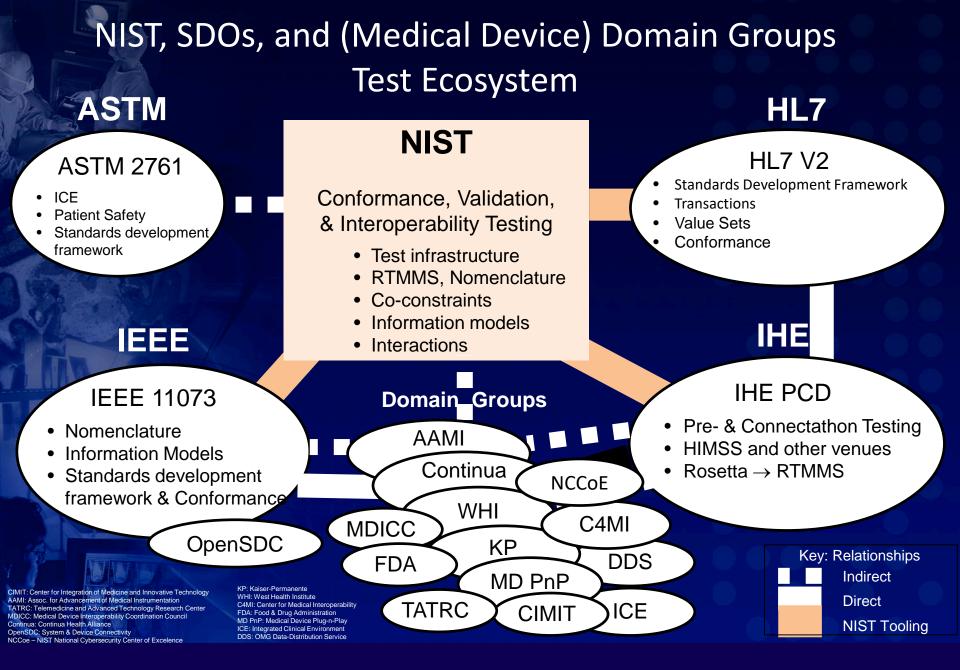
Services.

Slide developed and provided by Paul Schluter, GE Healthcare

Problem Space Addressed through test methods How can we Improve Interoperability?

The NIST Approach...

- Use standards to provide more economically effective solutions by amortizing the cost of design over many implementations.
- **Profile standards** to reduce optionality and simplify implementation and testing.
- Provide computable definitions of message syntax and semantics as well as information models.
- Use rigorous conformance (which in turn, used for certification and conformity assessment testing).
- Use other incentives to promote acceptance ...



WORK Products: Standards, Domains & NIST Test Medical Device Domain Tools NIST Tools

- IHE-PCD
- HL7 Health Level 7 Device-to-EHR/EMR

- Pre-Connectathon
- Connectathon
- RTMMS hRTM

 ISO/IEEE 11073 Medical Device Communication -Family of Standards

Device-to-Device

Model: Manager <-> Agent (Receives Data) (Provides data)

- RTMMS Nomenclature
- 'DIM Modeling 'DIM Editor -DeviceEditor'
- ICSGenerator' sunsetted
- 'ValidatePDU' on hold

Medical Devices

- Interoperability
- Body Area Network Standards
- Security

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National Cybersecurity Center of Excellence Healthcare Sector

National Institute of Standards and Technology

August 2019

National Institute of Standards and Technology U.S. Department of Omerication



Healthcare Sector



Projects

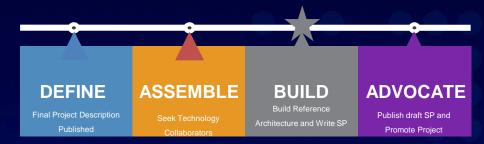
- <u>Securing Telehealth Remote Patient Monitoring</u>
 <u>Ecosystem Project Description</u>
- <u>Securing Picture Archiving and Communication</u> <u>Systems Project Description</u>
- Securing Wireless Infusion Pumps in Healthcare Delivery Organizations <u>(SP 1800-8)</u>
- Securing Electronic Health Records on Mobile Devices (SP 1800-1)
- Join our Community of Interest
- Email us at <u>hit_nccoe@nist.gov</u>

Securing Picture Archiving and Communication System (PACS)

Cybersecurity for the healthcare sector

Overview

- PACS is nearly ubiquitous in hospitals, prompting the Healthcare Sector Community of Interest (COI) to identify securing PACS as a critical need.
- This project will provide a reference architecture and an example solution for demonstrating the capabilities to address the cybersecurity challenges of a PACS ecosystem



Project Status

Build Phase - Currently building example solution in the NCCoE lab and drafting the NIST Special Publication 1800-series Practice Guide with expected publication date of 09/2019/2019 **Collaborate with us**

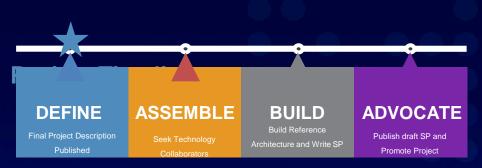
- Read <u>Securing Picture Archiving and Communication</u> (PACS) Project Description
- Email <u>hit_nccoe@nist.gov</u> to join the Community of Interest for healthcare projects

Telehealth Remote Patient Monitoring (RPM)

Cybersecurity for the Healthcare Sector

Overview

 Telehealth is one of the fastest growing sectors within healthcare. It leverages network-connected devices to monitor and treat patients outside of a healthcare delivery organization's (HDOs) closed environment. This project was driven by the NCCoE healthcare Community of Interest (COI) and will demonstrate an example solution with the capabilities to address the cybersecurity challenges of a telehealth RPM ecosystem.



Project Status

 Define Phase –The final project description was published in May 2019. A federal register notice seeking technology collaborators will be published soon.

Learn more:

- Read <u>Securing Telehealth RPM</u> Project Description
- Email <u>HIT_nccoe@nist.gov</u> to join the Community of Interest for healthcare projects

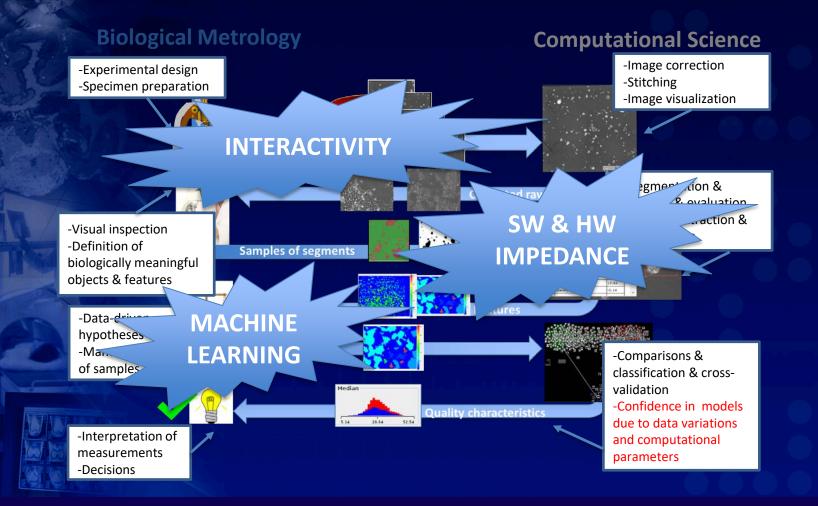
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Medical Imaging

- Change Analysis Lung Cancer
- NIST/QIBA Activities
- Iterative Reconstruction
- Interpreting Wireless Capsule Endoscopy Images
- From Images to Diagnosis through Ontologies
- Image Quality for Healthcare Applications
- Computational Metrology for Biomedical Imaging
- Performance of Scalabale Systems

Confidence in CS Metrology & Big Data Measurements



Use Case: Age–Related Macular Degeneration (AMD)

- **11 million** affected people in the US. Leading cause of vision loss in adults.
- Estimates of the global cost is \$343 billion, including \$255 billion in direct health care costs.
- Stem cell engineering of retinal pigment epithelium to treat macular degeneration (collaboration with NIH)



AMD vision



20/20 Vision

Stem Cell Therapy + Images → Quality Ieasurement

Use Case: Age–Related Macular **Degeneration** (AMD)



AMD blurred vision



20/20 Vision

Scale

Single Microscope FOV (10X) = 0.034% of 10 cm diameter dish ~1 MB

Complexity

- Phase Contrast
- Fluorescent imaging
- Bright-field imaging

Speed

- Identify & count healthy cells/colonies
- **Distribution of cells**



<1 TB image of total dish over time





Imaging instruments



Therapy Failed



Therapy Worked



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Bioinformatics: Projects

- Cellular Markers that Report Microenvironment
- Dynamic Measurements in Live Cells
- Computational Geometry
- Protein-Protein Interaction Networks
- Precision Medicine
- Performance of Scalabale Systems

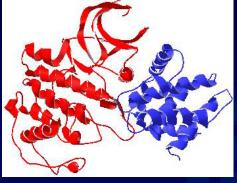
Motivation

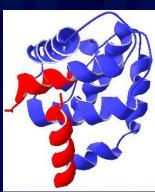
Cyclin-dependent kinase 5 (*Cdk5*) operates in human brain

- Involved in cell development, cancer and neurodegeneration
- P25 is a pathological cdk5 activator
 - Cdk5/p25 causes phosphorylation of brain protein tau (Alzheimer's disease)
- An experimental study of the effects of truncated fragments of p25 on Cdk5 activity is carried out in the Neurochemistry Lab, NINDS
- Inhibitory fragments inhibit cdk5/p25 pathology, but inhibition mechanisms are unknown
- Small fragments are needed for effective clinical trials
 - No side effects, can cross blood brain barrier Information Technology Laboratory, National Institute b

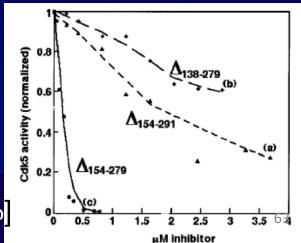


Amino acids in red are removed from p25 to obtain CIP





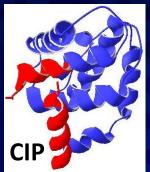
Cdk5 activity .vs. inhibitor concentration



Problem Formulation

- Fragments are randomly obtained from p25 and tested (years of work)
 - First inhibitor tested, CIP, consisted of 124 amino acids (too big!)
 - Smaller inhibitor tested so far, p5, consists of 24 AAs
 - Can cross the blood brain barrier
 - It is still big, so high probability of side effects





Computer-based studies should be used to provide insights into Cdk5-inhibitor bindings

Binding prediction and simulation

No more random truncations of p25 fragments, but computer-aided peptide design

Proposed approach

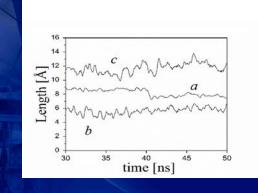
- A method to predict protein-protein association in solution has been defined [1,2]
- Basic idea: in the early stages of complexation, proteins form metastable preferential first-encounter complexes, from which stable binding modes evolve. The main steps are:
- 1. Protein conformers are obtained using a Monte Carlo (MC) method
- 2. For each pair of conformers, MC optimizations yield a set of firstencounter modes, defining a probability distribution
- 3. First-encounter modes are combined into a generalized probability function to simulate protein-protein systems using self-adaptive configurational bias-MC simulations.

4.

The binding modes thus obtained are refined using Molecular Dynamics (MD) simulations

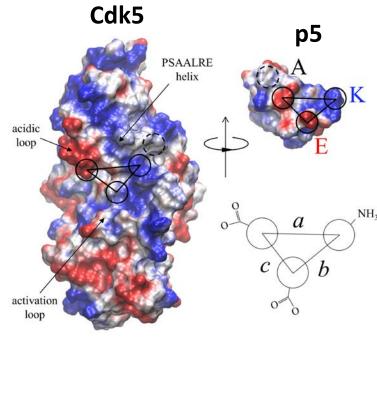
Results

Cdk5-p5 pharmacophore was characterized
 Strong electrostatic interactions identified
 Spatial arrangement and



critical AAs known

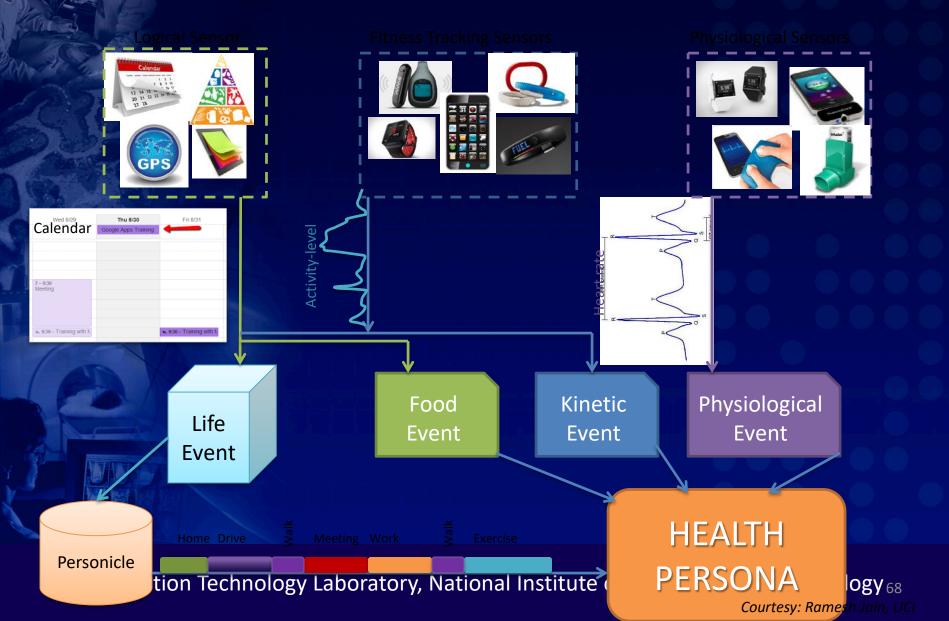
Dynamic stability tested

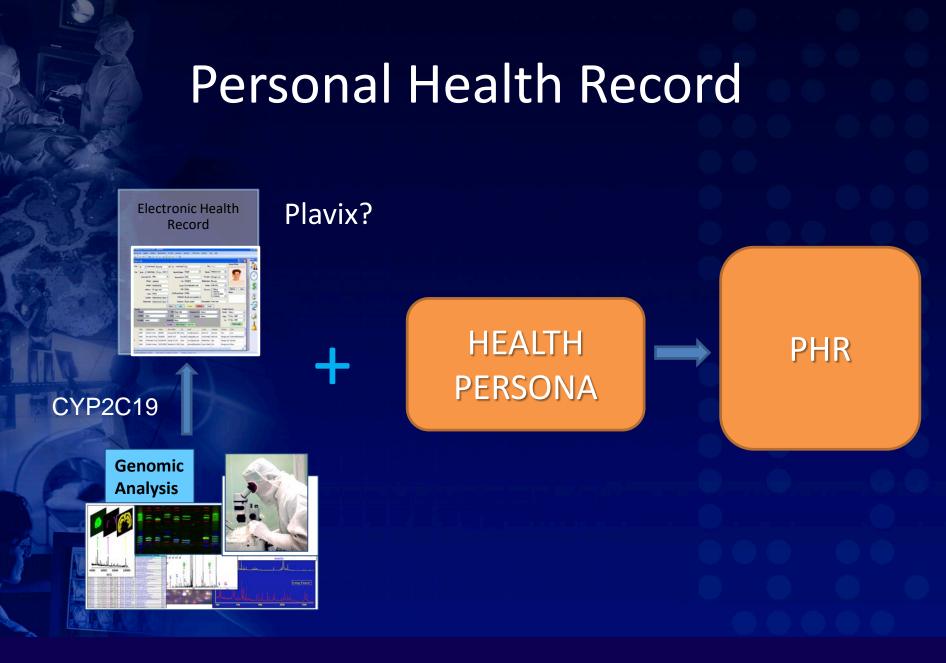


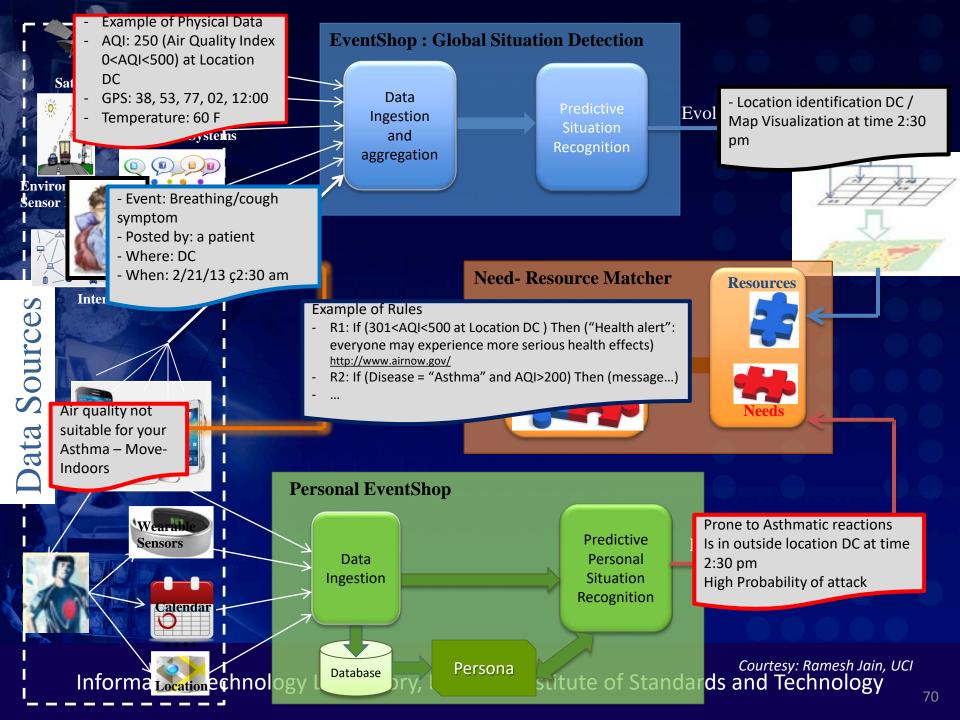
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Defining Health Persona











Smart Healthcare

- Smart Devices
- Smart Networks
- Smart Processes
- Smart EMRs
- Smart Medicine
- Smart Organizations
- Smart Collaborations
- Smart Society
- Smart Planet

Courtesy: Fred Hosea, Ture. Program Director Clinical Technology

fred.w.hosea@kp.org

Smart Doctor



Information Technology Laboratory, National Institute of Standards and Technology 72

Courtesy: Rod Grupen & Tihomir Latinovic

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
 - Develop the Health IT Testing Infrastructure
 - Research into standards, measurements, and testing methodologies for emerging technologies

Acknowledgments

- Testing (EHR & Medical Devices): Kevin Brady, John Garguilo (medical devices), Michael Indovina, William Majurski, Sandra Martinez, Andrew McCaffrey, Robert Snelick, Sheryl Taylor, Kevin Stine and NCCOE, and several contractors
- Biomedical Imaging & Bioinformatics: Mary Brady (PI), Peter Bajcsy, Paul Boynton [telehealth], Joe Chalfoun (GR), Antonio Cardone (GR), Marcin Kociolek (GR), Adele Peskin, Piotr M. Szczypinski (GR), Walid Keirouz, and other others
- Smart Health Care: E. Subrahamanian (IPA)
- Collaborators: MML, NIH, UMCP, UMBC, UCI, Etc.

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