Standards and Terminology

in Health Informatics

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N256 – Clinical Informatics

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http://jenders.bol.ucla.edu -> Documents and Presentations

"Outline"

HL7 HIMSS CCHIT Arden RIM HSSP SOA DSS SNOMED ICD9 HCPCS NIC NOC NDC RxNorm SQL GEM ProFORMA ASTM CCR CDA CCD EDIFACT LOINC CPT NANDA BIRADS DICOM ICPC UMLS CEN HITSP HISB ANSI ISO CTS AHIC ONC CHI NCVHS HIPAA NDF-RT HUGN CDISC ASC ICPC NCPDP IHE ARRA HITECH ONC

The Good, The Bad and The Ugly

- **Rationale for standardization: Use**

- **State of standardization**
  - **Process: Development + harmonization + certification**
  - **SDOs and standards**
  - **Focus of standards activities: Terminologies**
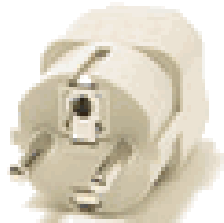 - **Practical application: CDSS**

- **Advantages and challenges**
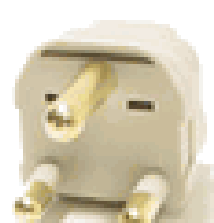
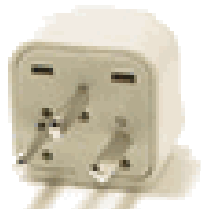# Rationales for Standardization
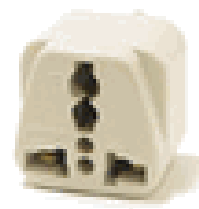
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WA-14   WA-15   WA-16   WA-20   GROUNDED BACK   UNGROUNDED BACK
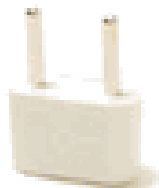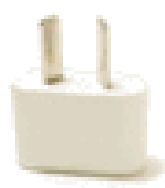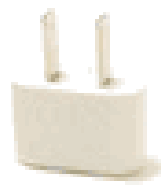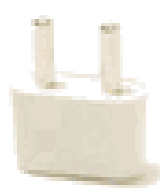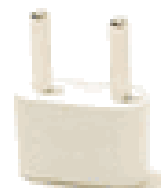
1   # 2   # 3   # 4   # 5   # 6

Rationales for Standardization

- **<u>Communication</u>**
  - **Understand the transmitted data element**

- **<u>Interpretation</u>**
  - **Quality improvement: Data analysis & reporting**
  - **Clinical decision support**

- **<u>Computability</u>**
  - **Knowledge sharing and reuse**
  - **Knowledge management: Tools**

Rationales for Standardization (continued)

- **<u>Conformance / Certification</u>**
  - **System performance: A CIS that does what it is supposed to do**
  - **System usability**

Rationales for Standardization

A Roadmap for National Action
on
Clinical Decision Support

June 13, 2006

Prepared by:
Jerome A. Osheroff, MD
Jonathan M. Teich, MD, PhD
Blackford F. Middleton, MD, MPH, MSc
Elaine B. Steen, MA
Adam Wright
Don E. Detmer, MD, MA

Osheroff JA, Teich JM, Middleton B et al. A roadmap for national action on clinical decision support. J Am Med Inform Assoc. 2007 Mar-Apr;14(2):141-5.

CDS National Roadmap: Three Pillars
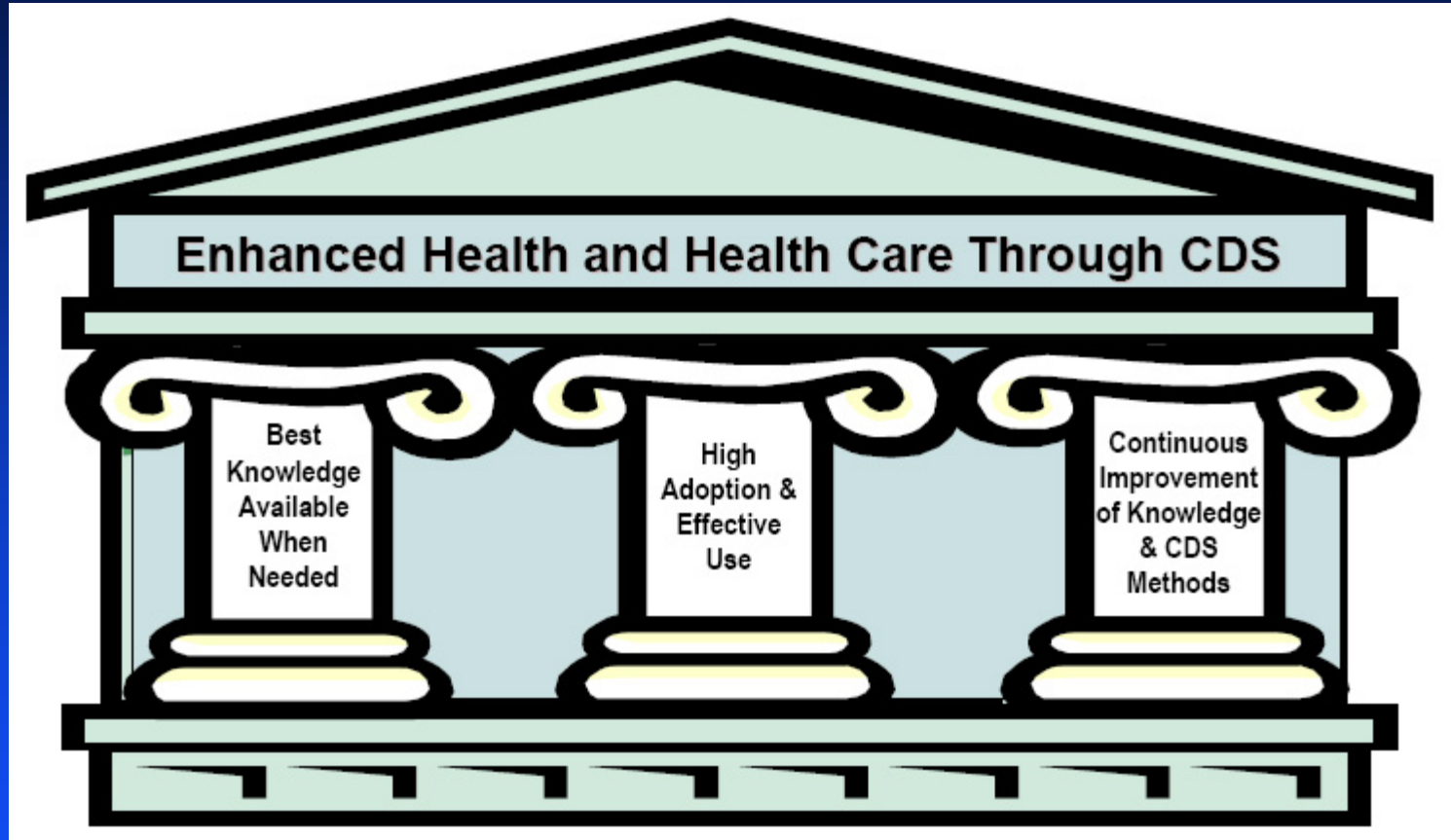
Jenders RA, Morgan M, Barnett GO. Use of open standards to implement health maintenance guidelines in a clinical workstation. Comput Biol Med 1994;24:385-390.

Rationales for Standardization: CDS

Focus on e-Prescribing

JAMIA

AMIA Position Paper ■

Clinical Decision Support in Electronic Prescribing: Recommendations and an Action Plan

Report of the Joint Clinical Decision Support Workgroup

JONATHAN M. TEICH, MD, PHD, JEROME A. OSHEROFF, MD, ERIC A. PIFER, MD, DEAN F. SITTIG, PHD, ROBERT A. JENDERS, MD, MS, THE CDS EXPERT REVIEW PANEL

Standardization Process

- **Development**

- **Too Much Development: Harmonization & Selection**

- **Conformance: Certification**

Standards Development: Key Methods

- **<u>De facto</u>: Think Redmond, WA**

- **<u>Government</u>**
  - **Use of regulatory and financial power to force development**

- **<u>Ad hoc</u>: Consortia, etc**
  - **DICOM**

- **<u>Standards Development Organization</u> (SDO)**

Standards Development: SDOs

- **<u>ASC X12</u>: Accredited Standards Committee**
  - **General EDI (e.g., CICA for XML exchange)**

- **<u>ASTM (E31)</u>: American Society for Testing and Materials**
  - **GEM, CCR**
  - **And many more**

- **<u>CDISC</u>: Clinical Data Interchange Standards Consortium**
  - **Clinical trials reporting**

Standards Development: SDOs

- <u>CEN (TC 251)</u>: Comité Européen de Normalisation

- <u>Health Level Seven</u>: Messaging standard (v2.x, v3), CDA, CCD (with ASTM), GELLO, Arden Syntax, DSS, RIM, EHR Functional Model/Specification
    - Partnering with <u>Object Management Group</u> (OMG) in Healthcare Services Specification Project (HSSP)

- <u>IHTSDO</u>: International Health Terminology Standards Development Organization
    - SNOMED

Standards Development: Other Organizations

- **<u>AMA</u>: American Medical Association (CPT-4)**

- **<u>WHO (OMS)</u>: ICD-9, ICD-10**

- **<u>UN/CEFACT</u>: Center for Trade Administration and Electronic Business**
  - **UN/EDIFACT (Electronic Data Interchange For Administration Commerce and Transport)**

- **<u>IEEE</u>: Institute of Electrical and Electronics Engineers**
  - **Medical Information Bus**

Standards Development: Other Organizations

- **<u>WICC</u>: WONCA (World Organization of National Colleges, Academies = World Organization of Family Doctors) International Classification Committee**
  - **ICPC (International Classification of Primary Care)**

- **<u>NANDA</u>: North American Nursing Diagnosis Association**
  - **NIC / NOC**

- **<u>NCPDP</u>: National Council of Prescription Drug Plans**
  - **SCRIPT (Rx transmission standard)**
  - **And many more…**

SDO Process: HL7

- **North America with 20+ international affiliates**
- **Subdivided into technical committees that work on standards**
  - **Conference calls + thrice annual meetings**
- **Mostly volunteer workers**
- **Heavily consensus-based, multilayer voting approval process**
- **Certification of adherence to process by external authority that charters SDO (e.g., ANSI)**

Standardization Process: Harmonization & Selection

- **<u>Problems</u>**
  - **Too many standards (and maybe SDOs) in some domains: Vendors, HCOs don't know which one to use**
  - **Overlapping content**
  - **Need for local specialization**
    - **May not be easy to accommodate**
  - **Especially challenging with terminology (code sets)**

- **<u>Addressing the challenge</u>: Selection and harmonization**
  - **Before the fact: JIC = HL7 + CEN/TC 251 + ISO/TC 251 + CDISC**
  - **After the fact: HITSP**

Main Focus of HIT Standards: What is a vocabulary?

- **<u>Terminology</u>**: Controlled list of concepts

- **<u>Vocabulary</u>**: 1+ terminologies with additional information (relationships, definitions, etc)

- **<u>Controlled</u>**: limited list of terms (clinician may not use any old term to express a concept)

- **<u>Structured</u>**: Concepts have explicit relationships (ISA, PART-OF, etc) that create a hierarchy with classes & subclasses of related concepts

- **<u>Nosology</u>**: Classification of diseases

Vocabulary Structure
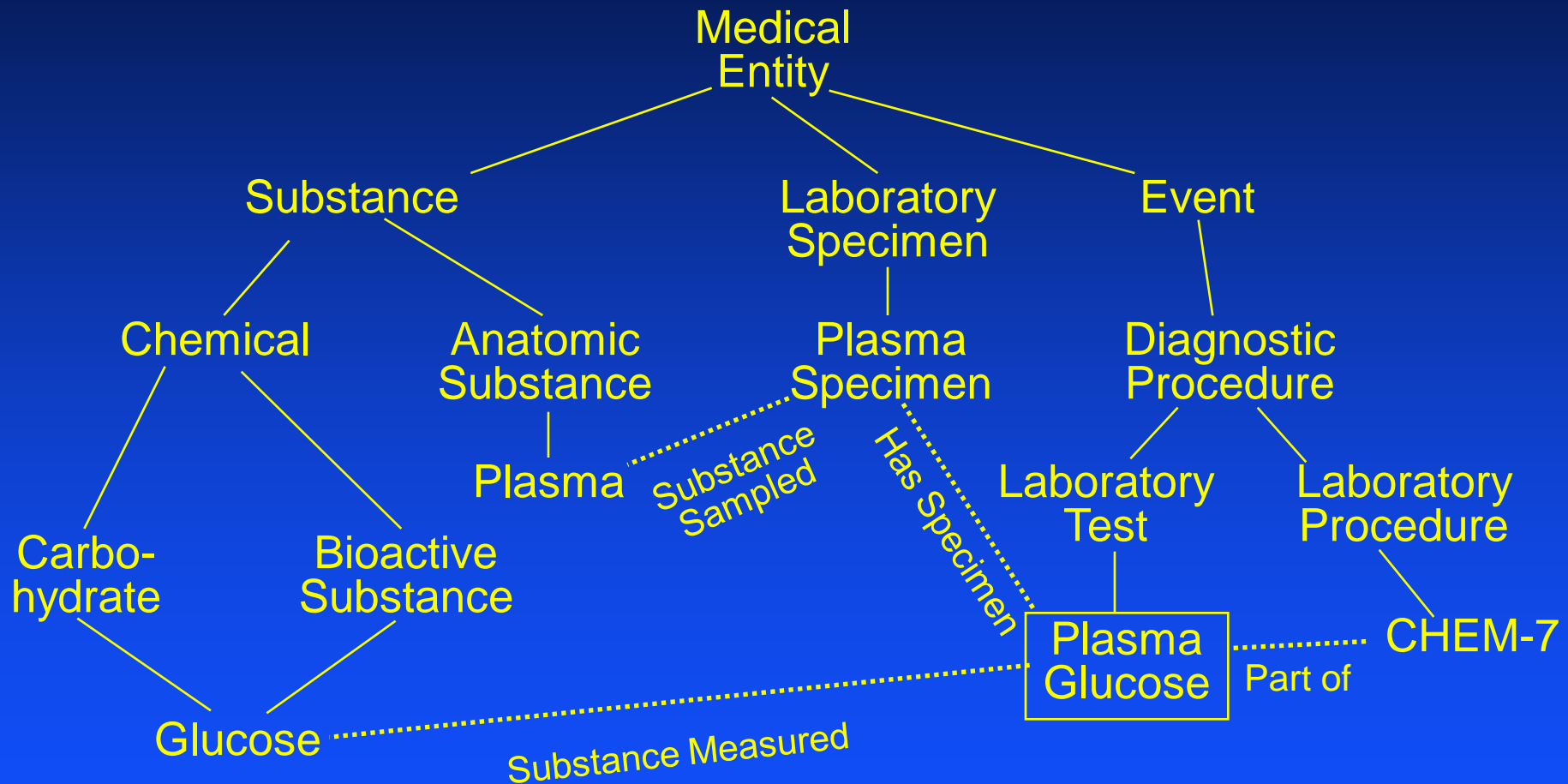
Concept Structure

- **Plasma Glucose**
  - **CSMC code**
  - **SNOMED code**
  - **Misys code**
  - **Reference range lower limit**
  - **Reference range upper limit**
  - **Units**
  - **Analyte**
  - **…**

Why do we need terminologies? Uses

- **Comprehensive data dictionary: Describe data collected electronically**

- **Different names for the same thing**
    - **Data stored using one coding scheme can be translated to another**
    - **Data from different sources can be stored using a consistent set of concepts**

- **Uniform representation of data**
    - **Queries for the CDR, data warehouse**

Retrieving Results by Class
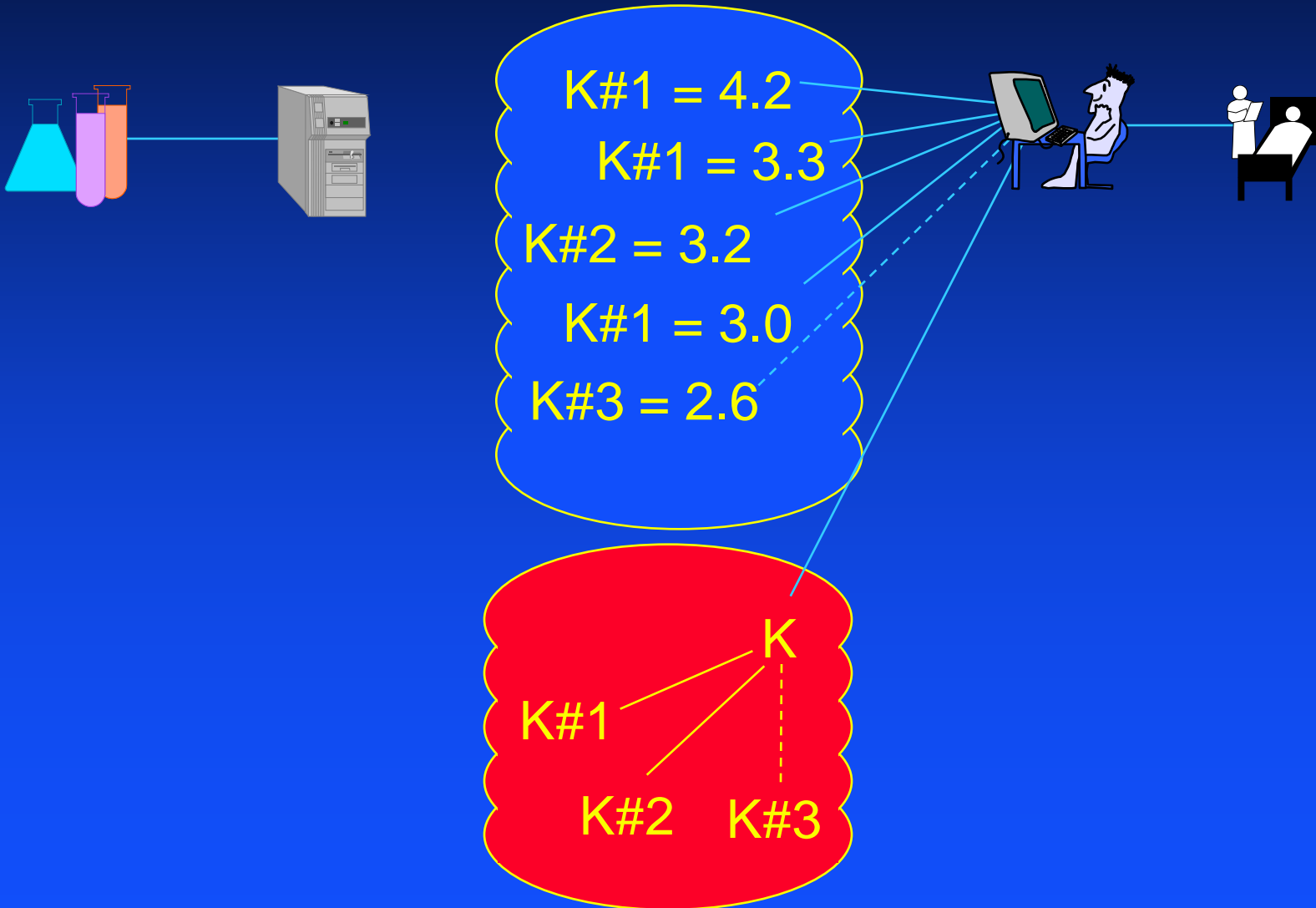
Mapping Terminologies: UMLS

- **<u>UMLS = Unified Medical Language System</u>**
  - **Effort by NLM to map different coding schemes**
  - **Goal: Improve lookup in the Library's bibliographic resources**
  - **Alternative use: Clinical information systems**
- **<u>Parts</u>**
  - **Metathesaurus**
  - **Information Sources Map**
  - **Semantic Network**

Standards Selection: CHI

- **Consolidated Health Informatics initiative = health care portion of eGov**
  - **Select from potentially overlapping standards**

- **Coalition of HHS (CMS, NLM, AHRQ, etc), DoD, VA, GSA, SSA, NIST + others**
  - **Will influence others wanting to do business with these agencies**

- **<u>Endorsed common standards (3/2003)</u>**
  - **HL7: messages**
  - **NCPDP: ordering from pharmacies**
  - **IEEE 1073: Medical Information Bus (devices)**
  - **DICOM: imaging**
  - **LOINC: laboratory, vital signs**

CHI:
Endorsed Common Standards (6 May 2004)

- **HL7**: Vocabulary (demographics, units of measure, immunizations, clinical encounters), CDA

- **SNOMED CT**: lab results contents, non-lab intervention/procedures, anatomy, dx/problems, nursing

- **LOINC**: lab test orders and drug label headers

- **HIPAA**: transactions/code sets for billing & admin

- **Federal med terminologies**: FDA (ingredients, manufactured forms, packages), NLM RxNorm (clinical drugs), VA NDF-RT (classification)

- **HUGN**: Genes in biomedical research

- **EPA Substance Registry System**: non-medicinal chemicals

Standards Selection: Other Units

- <u>NCVHS</u>: Acting under its HIPAA authority to define standards for electronic transactions in 2000
    - IEEE 1073, NCPDP SCRIPT, HL7 v2.x and some v3
    - Amended in 2002
    - Further amendments under consideration now

- <u>ONC</u>: Stimulate and coordinate standards work

- <u>IHE</u>: Interconnecting the Healthcare Enterprise
    - "Connectathons" using conformance profiles, helping to define system interactions

05 13 2003

Standardization: Harmonization

- **<u>AHIC (American Health Information Community)</u>: Advised HHS (2005 – 2008) about HIT**
  - **Use cases for standards that influence their development**

- **<u>Healthcare Information Technology Standards Panel</u> (formed by ANSI in 2005)**
  - **Public/private partnership**
  - **Identify best-of-breed standards for various domains**
  - **If no single best standard, foster merger or development**

Standardization: Harmonization

- **<u>Health IT Standards Committee</u>**
  - **Formed via ARRA in 2009**
  - **Advises ONC**
    - **Standards**
    - **Implementation specifications**
    - **Certification criteria**
  - **Paired with Health IT Policy Committee**

  http://healthit.hhs.gov

Standardization: Certification Commission for Health Information Technology

- <u>**Workgroups**</u>: **Inpatient, ambulatory, emergency department, health information networks, foundation**
- <u>**Expert panels**</u>: **Advise on security, interoperability, etc**
- <u>**Process**</u>
  - **Identify relevant standards to assure proper operation of health IT in these domains and timelines for compliance**
  - **Create a vetting process to assess an application's compliance with standards**

Alternative Certification: Developers

- **Provide training courses**

- **Certify programmers and other developers as knowledgeable about a standard**

- **Example: HL7**

- **Still other certification: Certifying (chartering) the SDOs**
  - **ANSI**

Standardization: Benefits of Certification

- **Reduce barriers for EHR implementation**
  - **Provides assurance for clinicians that they are getting compliant software even though they lack resources to evaluate it fully**
  - **Minimize concern that a CIS will be a "silo" system**

- **Possibly tied to monetary incentives for EHR implementation**
  - **Reimbursement / rebate in other countries based on purchase of certified systems**

Standardization Process: Summary

- **Creation: SDOs and others**

- **Selection and Harmonization: CHI, NCVHS, AHIC, HITSP, Health IT Standards Committee**

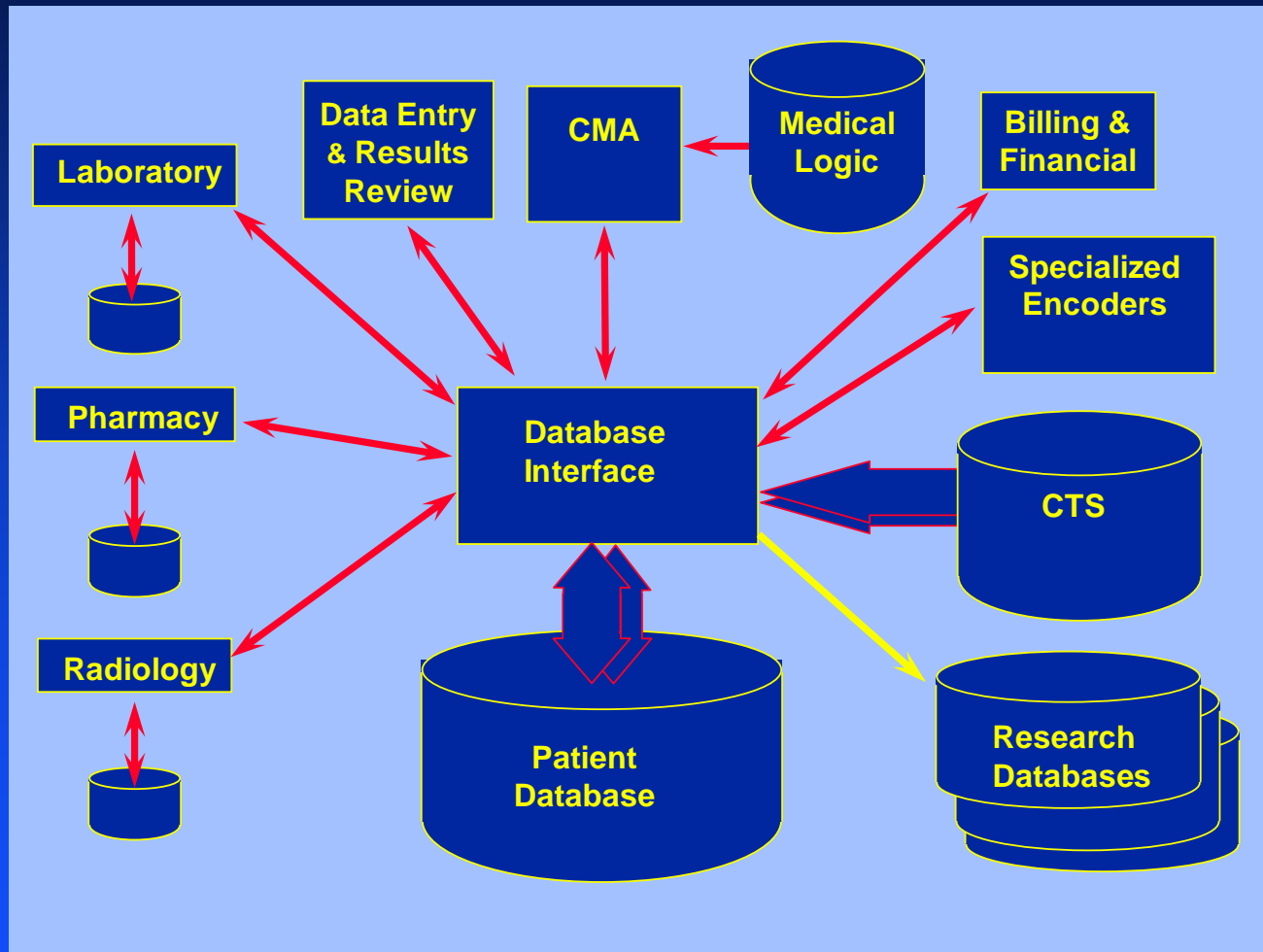- **Certification: CCHIT**

Aspects of Standardization

- **<u>Messaging</u>: Format, terminology**
  - **Enable interoperability**

- **<u>Function</u>: Services**

- **<u>Structure</u>: Knowledge representation**
  - **Enable sharing + reuse**

- **Clinical practice: Guidelines**

Practical Application of Standards: Deploying Clinical Decision Support (CDS)

CDS: Key Architectural Elements

- **Data capture/display/storage**
  - **EMR**
  - **Central data repository**

- **Controlled, structured vocabulary**

- **Knowledge representation + knowledge acquisition**

- **Clinical event monitor: integrate the pieces for many different uses (clinical, research, administrative)**

CDS: Standards

- **<u>Data Capture / Use</u>**
  - **Transmission: Medical Information Bus**
  - **EHR Functional Model & Specification**
  - **Terminology: Many**
    - **LOINC: Lab**
    - **SNOMED, ICD9/10, ICPC: Diagnoses**
    - **RxNORM, NDC: Medications**
    - **CPT-4: Procedures**

- **<u>Data Availability</u>**
  - **Data model: RIM**
  - **Data message: HL7 v2.x/v3; EDIFACT**

- **<u>Knowledge Representation</u>**

Arden Syntax

- **ASTM v1 1992, HL7 v2 1999, v2.1 (ANSI) 2002, v2.5 2005, v2.6 2007, v2.7 2008**
- **Formalism for procedural medical knowledge**

- **Unit of representation = Medical Logic Module (MLM)**
  - **Enough logic + data to make a single decision**
  - **Generate alerts/reminders**

- **Adopted by several major vendors**

Jenders RA, Dasgupta B. Challenges in implementing a knowledge editor for the Arden Syntax: knowledge base maintenance and standardization of database linkages. Proc AMIA Symp 2002;:355-359.

Arden as Exemplar Standard: Analysis

- **Incorporated in vendors' products, but…**
  - **Limited sharing occurs, mainly among install sites of the same vendor**

- **Installed in many places, but…**
  - **Still not widespread after 15 years**

- **Provides a standard formalism, but…**
  - **Incomplete standardization obtains => "Curly braces problem": No standardization of database linkages**
  - **A standard that is not fully a standard**
    - **Messaging example: HL7 v2.x "Z" segment**

Arden as Exemplar Standard: Analysis

- **Robust, but insufficient according to some**
  - **GEM (guideline markup), GELLO (common expression language) to represent complex clinical guidelines**
  - **DSS: Standardize the interface, not the knowledge formalism**
    - **Part of an overall SOA**
  - **Many, many alternatives: Confusing for vendors and customers**

- **Challenging business case for knowledge sharing**
  - **Intellectual property, liability concerns**
  - **No compulsion toward a standard**

Bringing It All Together: "Meaningful Use"

- **<u>ARRA HITECH authority</u>** (PL 111-5, 2/2009)
  - **Released 30 Dec 2009, published 13 Jan 2010**
  - **Goal: Provide incentives for eligible hospitals and providers to become "meaningful users" of certified HIT**
  - **Now in the 60-day comment period**
- **<u>ONC IFR</u>: Adoption of an initial set of standards, implementation specifications & certification criteria**
- **<u>CMS NPRM</u>: Define "meaningful use" & create incentive programs**

HITECH New Programs

- **<u>Regional extension centers</u>** (REC): Help users become meaningful users ($643M)

- **<u>Health information exchanges</u>** (HIE): Move health data across jurisdictions ($564M)

- **<u>Workforce training programs</u>** ($118M)

- **<u>Beacon communities</u>:** Demonstration sites for HIT in a geographic area ($235M)

- **<u>SHARP</u>:** Additional research ($60M)

- **<u>NHIN</u>:** Reference system architecture

Blumenthal D. Launching HITECH. 2010 Feb 4;362(5):382-5.

HITECH Framework
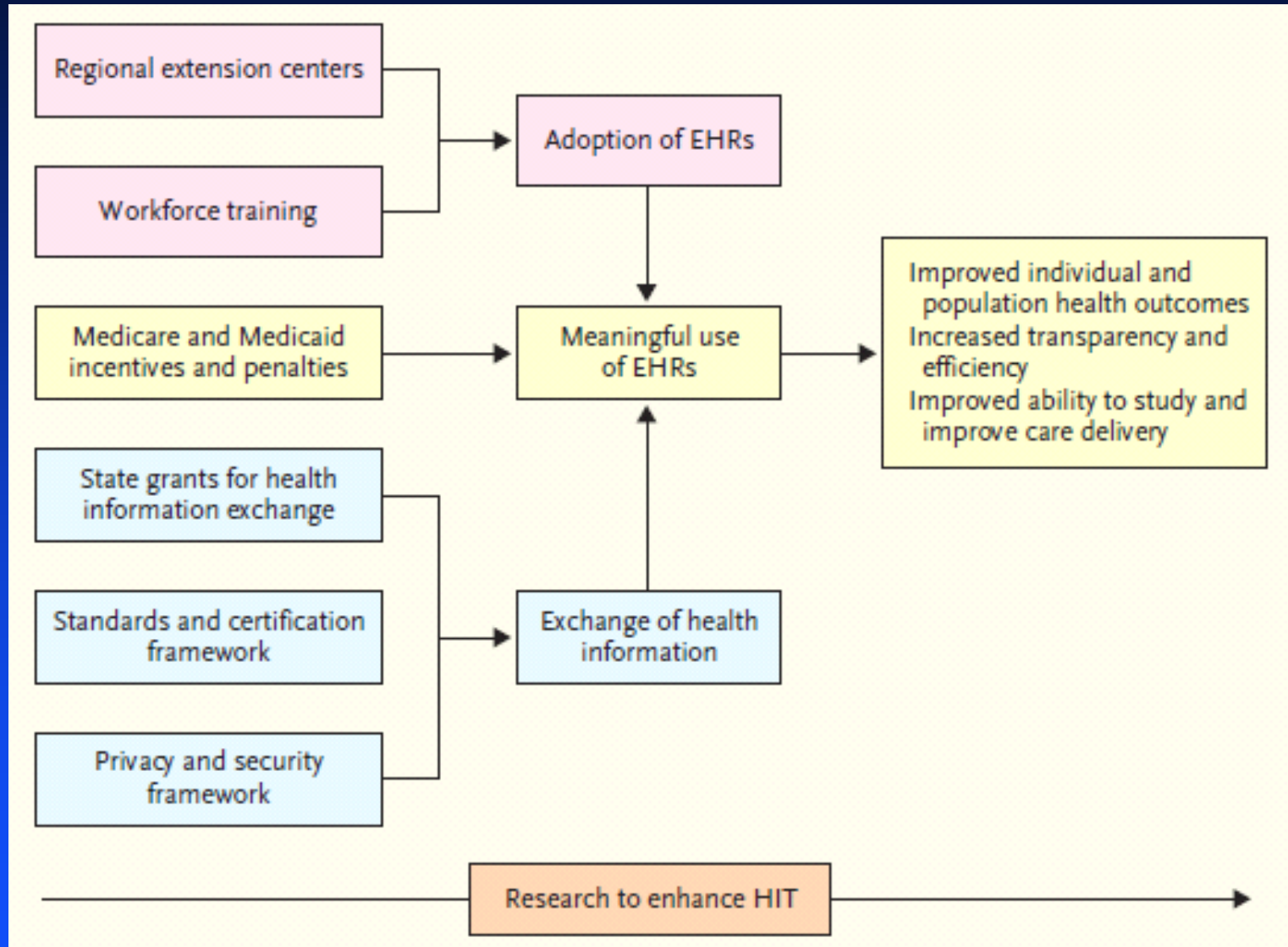
Advantages of Standardization

- **<u>Interoperability</u>**
  - **Sharing of data to coordinate care**
  - **Simplicity of interface implementation (reduced need for customization)**

- **<u>Interpretation</u>: Query multiple data sources to assess and improve quality**

Advantages of Standardization (continued)

- **<u>Reduce cost</u>: Minimize need to reinvent the wheel**
  - Ease of training personnel
  - Ease of system maintenance

- **<u>Improved commercial potential</u>: Easier to sell interoperable systems because customers' fears of a silo system are reduced**

Disadvantages of Standardization

- **<u>Development duration = lengthy</u>**
  - **Volunteer-based process**
  - **Consensus-based process: Inclusive, but minorities can retard innovation**

- **<u>Least-common-denominator effect</u>: Do only that for which consensus is possible**
  - **Vendors have to leapfrog the standard in order to respond to customers' business needs**
  - **Feedback to the standards development process occurs, but it is slow**

Disadvantages of Standardization

- **<u>Possibility of bias</u>**
  - **Organizations using the standards development process to their commercial advantage**
  - **Can be beneficial: Make innovation widely available, simplify development**
  - **HL7 and others have rules to protect against disproportionate influence in the process**

- **<u>Victims of our own success</u>: Having too many standards requires costly selection and harmonization**

Barriers to Standardization

- **<u>Cost</u>**
  - **Licensing the standard**
    - **Overcoming this: Free access to SNOMED in the USA**
  - **Training developers**

- **<u>Complexity</u>**
  - **Possibly significant change to product offerings**
  - **Overcoming this: Constraining a standard (e.g., ELINCS for lab data using HL7 messaging v2.4)**

Barriers to Standardization (continued)

- **<u>Market uncertainty</u>: Too many standards, inability to discern which will prevail**
  - **Overcoming this: Selection and harmonization**

- **<u>Time</u>: Developing a standard can take a long time**
  - **Overcoming this: Funding to reduce reliance on volunteers**
    - **Example: HL7 EHR Functional Model**

Advantages of *Not* Standardizing

- **<u>Vendors</u>: Create a market niche**

- **<u>Users</u>: Preserve local flexibility**

Synthesis:
The Good, The Bad and The Ugly

- **<u>Standards are valuable</u>**
  - **Reduce barriers to HIT deployment**
  - **Improved assessment leading to improved care**

- **<u>Standards have costs</u>**
  - **Time, money, retardation of innovation**

- **<u>Overall</u>: Directed development + application of certification will help preserve benefits while minimizing costs**
  - **Stay tuned for HITECH!**

Thank you!

- **AHRQ / NLM**

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