Section B

Standards Harmonization: Standards Selection
Standards Selection

- Identify available candidate standards
- Weighting
- Constraints
- Gap analysis
Candidate Standards: HI Standards Bodies

- **ASTM**: American Standards for Testing and Materials
  - E31.15: Healthcare Information Capture and Documentation
  - E31.35: Healthcare Data Analysis
  - E31.90 Executive
Candidate Standards: HI Standards Bodies

- ISO TC215: Health Informatics
  - WG 1 Data Structure
  - WG 2 Data Messaging
  - WG 3 Semantics Content
  - WG 4 Security, Safety, and Privacy
  - WG 5 Health Cards
  - WG 6 Pharmacy and Medication Business
  - WG 7 Devices
  - WG 8 Business Requirements for an EHR
  - WG 9 Joint Initiative Council
  - Operations, Harmonization, Executive Council
Candidate Standards: HI Standards Bodies

- HL-7 - Health Level 7
  - CCOW
  - Clinical decision support
  - Control/query
  - Education (admin.)
  - Financial mgmt.
  - Electronic health records
  - Implementation (admin.)
  - Marketing (admin.)
  - Medical records
  - Modeling and methodology
  - Orders/observations
  - Personnel management

- Patient administration
- Patient care
- Process improvement (admin.)
- Public health and emergency response
- Publishing (admin.)
- Regulated clinical research info mgmt.
- Security
- Scheduling and logistics
- Structured documents
- Tooling (admin.)
- Vocabulary
Candidate Standards: HI Standards Bodies

- NCPDP: National Council for Prescription Drug Programs
  - WG1 Telecommunication
  - WG2 Product Identification
  - WG3 Standard Identifiers
  - WG4 Provider/Member Enrollment
  - WG5 Payment Reconciliation
  - WG7 Manufacturer Rebates
  - WG9 Government Programs
  - WG10 Professional Pharmacy Services
  - WG11 Prescriber/Pharmacist Interface
  - WG12 Education—Legislation and Regulation
  - WG14 Long-Term Care
  - MC Maintenance and Control
Candidate Standards: HI Standards Bodies

- ASC X12N: Insurance/TG02-HEALTHCARE
  - WG1 Health Care Eligibility
  - WG2 Healthcare Claims
  - WG3 Claim Payments
  - WG4 Enrollments
  - WG5 Claims Status
  - WG9 Patient Information
  - WG10 Health Care Services Review
  - WG12 Interactive Healthcare Claims
  - WG15 Provider Information
  - WG20 Insurance Transaction Acknowledgement
Candidate Standards: HI Standards Bodies

- DICOM: digital imaging and communications in medicine
  - WG-01: cardiac and vascular information
  - WG-02: projection radiography and angiography
  - WG-03: nuclear medicine
  - WG-04: compression
  - WG-05: exchange media
  - WG-06: base standard
  - WG-07: radiotherapy
  - WG-08: structured reporting
  - WG-09: ophthalmology
  - WG-10: strategic advisory
  - WG-11: display function standard
  - WG-12: ultrasound
  - WG-13: visible light
  - WG-14: security
  - WG-15: digital mammography and CAD
  - WG-16: magnetic resonance
  - Wg-17: 3d
  - WG-18: clinical trials and education
  - WG-19: dermatologic standards
  - WG-20: integration of imaging and information systems
  - WG-21: computed tomography
  - WG-22: dentistry
  - WG-23: application hosting
Candidate Standards: HI Standards Bodies

- IHE: Interconnecting the Health Care Enterprise
  - IT infrastructure
  - Radiology
  - Laboratory
  - Cardiology
  - Discussing pharmacy
  - Patient care coordination (content)
  - Quality public health and research
  - Pharmacy
  - Anatomic pathology
  - Eye care
Candidate Standards: HI Standards Bodies

- SCDI: Standards Committee on Dental Informatics
- National, regional standards (e.g., European: CEN; Canadian: COACH; ...)
- USP: United States Pharmacopeia
Candidate Vocabulary Standards: HI Standards Bodies

- International classification of disease (ICD: ICD-9, ICD-10)
  - Procedures
  - Diagnoses

- Current procedural terminology (CPT)
  - Procedures

- Systematized nomenclature of medicine-clinical terms (SNOMED-CT)
  - Diseases, findings, procedures, microorganisms, pharmaceuticals
Candidate Vocabulary Standards: HI Standards Bodies

- National Council for Prescription Drug Programs (NCPDP)
  - Drug products

- RxNorm
  - Clinical drugs
  - Drug delivery devices

- LOINC
  - Laboratory orders
  - Laboratory results
Weighting Considerations

- **Suitability**
  - For the program or community
  - For the use case business requirements
  - Compliant with jurisdiction laws

- **Compatibility**
  - Within program or community
  - Supporting information reuse
Weighting Considerations

- Readiness
  - First level—review standards development organization (SDO)
  - Second level—review within SDO

- Ease of access
  - Lack of dominance (vendor neutrality)
  - Open/transparent (ability to influence standard)
  - Intellectual property/licensing terms (cost)
  - Consensus-based
  - Availability
Weighting Considerations

- Code sets
  - Used with other selected standards
  - How often are terms updated
  - Versioning of updates
  - Mapping to other domain, jurisdictional, or selected standards
  - Robustness or deficiencies in the code set
Standards are flexible and may need specific constraints to support the use case to attain interoperability

- Message segment optionality
- Document (XML) content module optionality
- Security constraint options
- Transport options
- Vocabulary options

- Interoperability specification (HITSP)
- Profile (IHE)
- Implementation guide (HL7)
Constraints: Example

- Biosurveillance
  - Message segment optionality
    - Require support for segments containing surveillance data
  - Document (XML) content module optionality
    - Require support for content modules containing surveillance data
    - Specified support for pseudo-identifiers
- Security constraint options
  - Support pseudonymized and multi-patient access to shared information resources
- Transport options
  - Support both message and document sharing to maximize availability of surveillance data
- Vocabulary options
  - Require structured vocabularies from selected vocabulary domain (SNOMED-CT, LOINC)
Gap Analysis

- Identification of standards not available to fulfill the use case

- Specification scoping to exclude functionality where gap is identified

- Gap resolution plans
  - Provisional selections for standards in progress
  - Plans to update existing standards
  - Plans to request new standards
  - Plans to provide resources to develop new standards
  - Plans to update specification once gap is resolved
Gap Analysis: Example

- Biosurveillance gaps
- Identification of standards not available to fulfill use case
  - Subscription mechanism was not available
    - Requested new work from IHE IT-infrastructure
    - Document subscription (DSUB) profile developed
  - Document sharing was restricted to one-patient-at-a-time query
    - Initial specification removed constraint
    - Provided IHE IT-infrastructure committee feedback
    - Multipatient query was developed
  - Unable to express lab orders
    - Specification removed this from scope
    - LOINC subset requested
  - Unable to express reporting criteria
    - Specification removed this from scope
    - HL7 standardization request