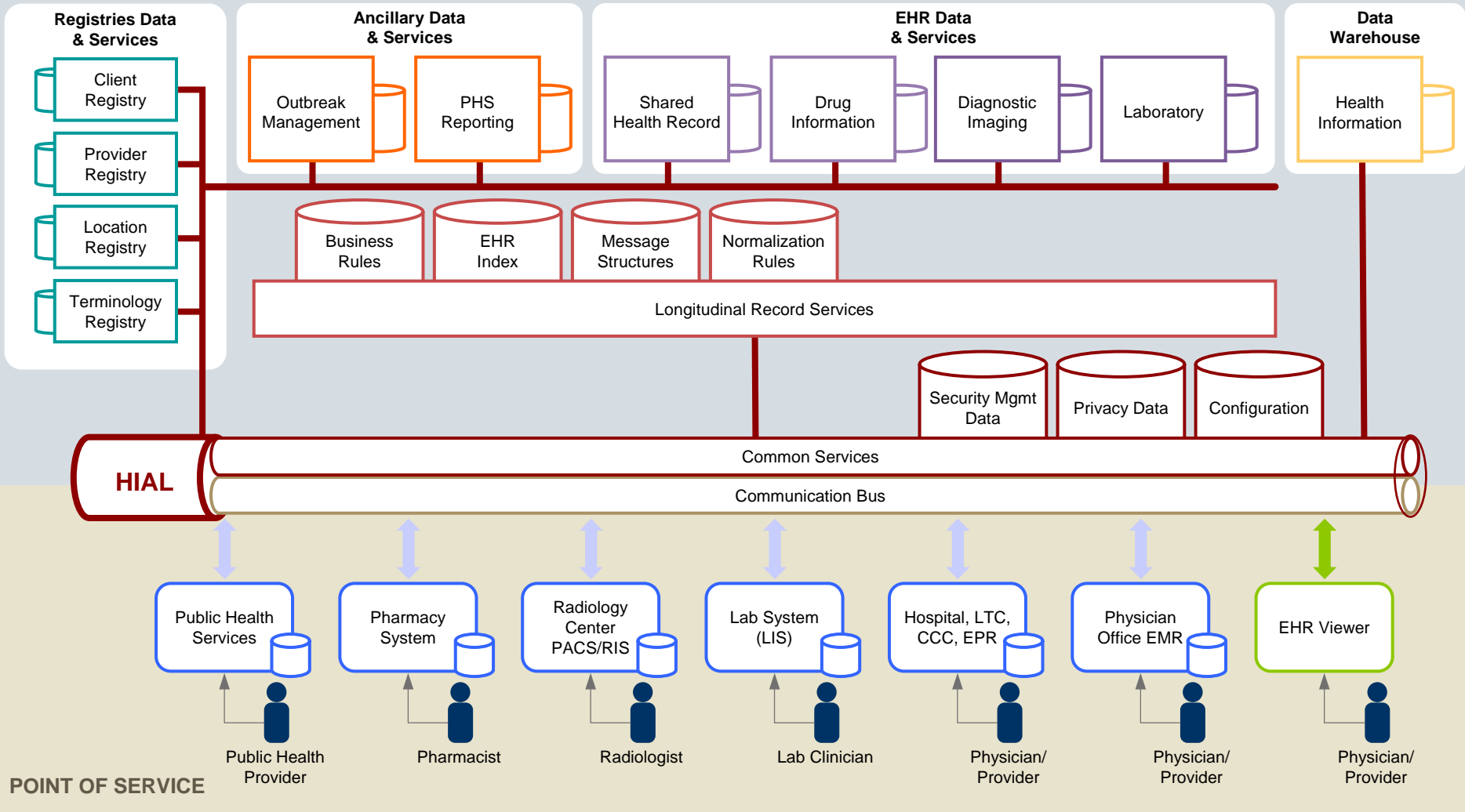




# International Healthcare Information Standards and relevance to E-health

# JURISDICTIONAL INFOSTRUCTURE



# Integrating Health Information Systems: Key Challenges (Canada health info way)

- Protecting Privacy
  - Governance, accountability & data custodianship
  - Controlling access
  - Managing & applying consent directives
  - Controlling feeds and queries to the data
  - Trust relationships & contracts
- Existence & availability of data
  - Discovery capability
  - Availability in electronic format
  - Timeliness
- Harmonization
  - Data structures (format)
  - Vocabularies (encoding, normalization)
  - Semantics
- Heterogeneous technology environments
- Number of organizations, connection points & systems
- Costs inherent to integration

## Key Principles of the Standards Development Framework as prerequisite for E-health

- Data are captured at source as a by-product of actual health care provisioning (and other) events
- An agreed data set is established (e.g. Minimal Data Set, Core Data Set, or similar) to contain sufficient information to identify the patient, support the diagnosis, justify the treatment, document the course and results of treatment, and promote continuity of care among health care providers.
- Data are properly managed for reporting
  - Agreed data set is used for any communication and reporting between providers and other agencies
  - This agreed set is transferred to a common location (Data Center) for subsequent information retrieval by any authorized user
- Transmission/communication methods are selected to support the above and provide for proper level of privacy and security

## Different reasons to want standards for different actors

- **Health care providers (hospitals, doctors and other professionals)**
  - Enable interoperability between different units and systems to increase the efficiency of care
  - Lower costs for buying systems by having a large competitive (international) market
  - Protected investments
- **Systems suppliers (software companies)**
  - Enable the provision of modular systems where one product can tie into the total needs of the customers
  - Large market for their "standard" product – less maintenance problems than with customer specific special solutions
  - Guaranteed long term product strategy
- **Public healthcare authorities**
  - Standards are seen in many countries as an important way of increasing the efficiency of the sector, leading to better quality with minimum resources
  - Standards enable the collection of statistical information for surveillance and planning purposes
  - Standards enable the effective and proactive management of health care organizations – reliable information
  - Standards for Informatics may help the authorities to exert quality control of health care information systems and medical devices.
  - We are moving towards certification

## Code Sets

Definition	Examples	Usage	Usage
<p>Representation assigned to a term so that it may more readily be processed; code sets are lists of codes and their associated terms.</p>	<p><b>LOINC</b></p>	<p>The Logical Observations, Identifiers, Names, and Codes (LOINC) code sets or terminology standards are widely used by public health or clinical laboratories that support electronic reporting. LOINC includes a set of universal names and identification codes for identifying <b>laboratory and clinical observations</b> developed by the Regenstrief Institute.</p>	<p>US, EU, CAN, AUS, NZ</p>
	<p><b>CPT</b></p>	<p>The Current Procedural Terminology (CPT) is used for <b>professional services billing and analyses.</b></p>	<p>US mainly</p>
	<p><b>ICPC2</b></p>	<p><b>International Classification of Primary Care – 2nd revision.</b> ICPC-2 was originally created as a paper based classification for general practice. It is now almost universally used in computer systems. It was kept small and simple to facilitate use and data analysis. Like most classifications, the granularity was coarse by design. It absorbs the variation in language, opinions, beliefs and documentation found in clinical practice. ICPC is widely used in general practice in over 30 countries around the world.  <b>ICPC-2 Plus = code set + classification system.</b></p>	<p>US, EU, CAN, AUS, NZ</p>
	<p><b>ATC</b></p>	<p><b>Coding of Drugs,</b> The main use of ATC is as a tool for producing drug use statistics. The system may be used in the registration process of drugs and collection of utilization statistics in various settings and at different levels.</p>	<p>WHO standard used in US, EU, CAN, AUS  Used in SK</p>

# Classification Systems

Definition	Examples	Usage	Usage
<p>Classification systems organize terms for easy use of information for retrieval, analysis and decision support.</p>	<p><b>ICD 10</b></p>	<p>The <b>International Statistical Classification of Diseases and Health Related Problems (ICD)</b> is used widely for hospital billing and statistical analyses.</p>	<p>WHO standard Universal use Used in SK</p>
	<p><b>SNOMED CT</b></p>	<p>SNOMED CT (clinical terms) is a <b>very large</b> terminology that aspires to contain all the concepts used in healthcare. It is designed primarily for computer use. SNOMED retains its traditional identifiers and can still be used in those unusual circumstances where people may want to code manually. However, manual coding is not recommended.</p>	<p>US mainly</p>
	<p><b>ICD-10AM</b></p>	<p>International Classification of Diseases, 10th revision, Australian Modification. ICD10AM was designed for hospital inpatient care.</p> <p>The ICD-10-AM <b>disease component</b> is based on the WHO ICD-10. It uses an alphanumeric coding scheme for diseases. It is structured by body system and aetiology, and comprises three, four and five character categories.</p> <p>The ICD-10-AM <b>procedures component</b> is based on the Medicare Benefits Schedule (MBS). The classification is structured by body system, site and procedure type. Procedures not currently listed in MBS have also been included (eg allied health interventions, cosmetic surgery).</p>	<p>AUS, NZ, US, EU</p>
	<p><b>ICNP</b></p>	<p>The ICNP® is a combinatorial terminology for nursing practice that facilitates cross mapping of local terms and existing vocabularies and classifications. Elements of the ICNP®</p> <ul style="list-style-type: none"> <li>Nursing Phenomena (nursing diagnoses)</li> <li>Nursing Actions (nursing interventions)</li> <li>Nursing Outcomes</li> </ul>	<p>US, UK</p>

## Nomenclatures

Definition	Examples	Usage	Usage
<p>“... a set of specialized terms that facilitates precise communication by minimizing or eliminating ambiguity.”</p>	<p><b>SNOMED</b></p>	<p>The Systemized Nomenclature of Medicine (SNOMED) is a structured nomenclature and classification of the terminology used in human and veterinary medicine. VERY COMPLEX</p>	<p>Originally USA, recent opening of international body in Copenhagen</p>
	<p><b>UMLS</b></p>	<p>The Unified Medical Language System (UMLS) is a system maintained by the National Library of Medicine (NLM) made up of hundreds of thousands of search concepts and terms which links medical classification systems (e.g., ICD) to NLM’s medical index subject headings (MeSH codes) and to each other. These linkages increase the use of UMLS by the clinical and public health communities.</p>	<p>US mainly</p>

## Messaging standards

### ■ Clinical Messaging

- HL7 v2.x
- HL7 v3.x
- DICOM
- CORBAmed
- EDIFACT



*Clinical and Laboratory  
Service Utilization or Encounter*

### ■ Non-clinical Messaging

- EDIFACT
- ANSI X12
- HL7
- ebXML
- WebServices



*Registry/Statistical  
Screening  
Financial/Administrative  
Facility*

“**Health Level Seven (HL7)** recently announced that two **Version 3 (V3) transport specifications - Web Services and ebXML** - have passed the ballot stage and have been approved as Draft Standards for Trial Use“  
 (Press Release. Ann Arbor, Mich. --- Health Level Seven, Inc.)

#### ▪XML

▪Extensible Markup Language (XML) is a simple, very flexible text format derived from SGML ([ISO 8879](#)). Originally designed to meet the challenges of large-scale electronic publishing, XML is also playing an increasingly important role in the exchange of a wide variety of data on the Web and elsewhere. XML was designed to describe data and to focus on what data is. HTML was designed to display data and to focus on how data looks.

▪**Web Services** – is a protocol/technology of choice for application integration

▪There are many definitions of Web Service, but almost all definitions have these things in common:

- Web Services expose useful functionality to users through the Web Services protocols
- Web services provide a way to describe their interfaces in enough detail to allow a user to build a client application to talk to them. This description is usually provided in an XML document called a Web Services Description Language (WSDL) document
- Web services are registered so that potential users can find them easily. This is done with Universal Discovery Description and Integration (UDDI)

#### ▪ebXML

▪The primary goal for ebXML was to "provide an open technical framework to enable XML to be utilized in a consistent and uniform manner for the exchange of Electronic Business data in application to application, application to person and person to application environments."

▪ebXML - ebXML™ is a specification for message communication in XML developed by the OASIS consortium ([www.oasis-open.org](http://www.oasis-open.org)). The **purpose** of the **HL7 ebXML** transport specification is **to provide secure, flexible transport for exchanging HL7 messages between message handling interfaces** or ebXML Message Service Handlers (ebXML MSH). It specifies an HL7-specific implementation of the ebXML Message Service as described in "Message Service Specification Version 2.0 1 April 2002". The transport will move HL7 content, messages and documents, as well as legacy standards over a variety of lower level transports, such as TCP/IP, HTML, and SMTP. This protocol optionally supports important features such as Duplicate Message handling, Reliable Messaging, Message Routing, Sequencing, and Digital Signatures. When using this protocol in combination with a certificate based TLS (Transport Layer Security) or SSL (Secure Sockets Layer) TCP/IP lower level transport it provides a robust, secure and authenticated communications infrastructure for exchanging HL7 V2 and V3 messages and content between organizations. It may also be used within organizations to exchange HL7 content, as well as legacy content, over internal networks.

## Security and Privacy

### ■ Security:

■ **HL7 transport specification:** *it will enable moving HL7 content, messages and documents, as well as legacy standards over a variety of lower level transports, such as TCP/IP, HTML, and SMTP. This protocol optionally supports important features such as Duplicate Message handling, Reliable Messaging, Message Routing, Sequencing, and Digital Signatures. When using this protocol in combination with a certificate based TLS (Transport Layer Security) or SSL (Secure Sockets Layer) TCP/IP lower level transport it **provides a robust, secure and authenticated communications infrastructure** for exchanging HL7 V2 and V3 messages and content between organizations.*

- PKI: NBU has built Root Certification Authority
  - 2 Certification Authorities accredited (EVPÚ, D. Trust) + (CA's of VUB, Dexia, PSCA)
- Appropriate legislation needs to be in place for the minimal technological requirements to provide for identification, authentication & authorization
- EN 12251:2004: Secure user identification for healthcare - Identification and authentication by passwords - Management and security

### ■ Privacy:

- The EU data protection directive (95/46/EC)
- Law on Personal Data Protection (Zákon o ochrane osobných údajov)

## Electronic Health Record (EHR)

- **CEN EN13606** - 4-part EHR standard is expected to be completed and balloted in the first half of 2005 (to be adopted by Australia upon completion)
    - Reference Model,
    - Archetype Interchange Specification,
    - Reference Archetypes and
    - Term Lists, Security Features and Exchange Models.
  - Memorandum of understanding between CEN and HL7 on harmonisation and, where possible, convergence. Currently applicable to data types, the HL7 CDA and CEN 13606 Reference Models and CEN/*openEHR* archetypes with HL7 Templates.
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- **CEN 12967** "Health Informatics Service Architecture" (HISA) (in development)
  - It is a high-level service-based architecture
  - "sits above" CEN 13606 and similar lower-level standards such as HL7 CDA.
    - Enterprise viewpoint,
    - Information viewpoint and
    - Computational viewpoint
- The HISA standard will provide a reference model for health care IT services, facilitating the building and purchasing of interoperable systems.

▪ <http://www.enigma.co.nz/hcro/website/index.cfm?fuseaction=articledisplay&FeatureID=020904#7.2>

▪ <http://www.enigma.co.nz/hcro/website/index.cfm?fuseaction=articledisplay&FeatureID=010904#4>

## An approach to introducing Electronic Health Record (EHR)

- These data sets will be the base for and components of the future EHR:
  - Continuous treatment (e.g. Core Data Set)
  - Financial & Quality Justification (e.g. Minimal Data Set)
  - Statistical Reporting
  - other types of required data sets to be carefully considered
- 
- There are other data to be added to EHR not related to specific treatment
    - E.g. health profile: vaccination, blood type, allergies,
    - E.g. family health history, addictions, ....

## Standards relevant to E-health

- *Identifier standards*
- *Vocabulary standards*
- *Content and structure standards*
- *Electronic patient record architecture standards*
- *Data interchange (messaging) standards*
- *Confidentiality, data security, and authentication standards*
- *Data sets, quality indicators, and guidelines*

## Standards relevant to E-health

### *Identifier standards*

- Patient / person ID: health care organizations, health insurance, population registry
- Equipment ID: all instruments, laboratory and radiology devices in national registries
- Organization ID: hospitals, clinics, family physicians,..
- Health provider ID: doctors, nurses, laboratory technicians,..

## Standards relevant to E-health

### *Vocabulary standards*

- terminology for medical expressions consistent in all reports and documents which are candidates for national E-health repository

Includes: Symptoms, History, Physical findings, Diagnostic tests including clinical chemistry, hematology, imaging, pathology, microbiology, physiological function laboratory, Diagnoses, syndromes, and conditions, Vaccines, Medications and drug related terminologies, Surgical procedures, Anesthesia and Medical supplies and equipment

## Standards relevant to E-health

### *Content and structure standards*

- Content relevant to data to be stored in national E-health repository

Standards for structure and content are needed to give a clear description of the data elements that will be included in electronic patient records. This involves identifying essential data elements such as temperature and blood pressure, and standardizing the field lengths, data type, and acceptable content of each data field.

## Standards relevant to E-health

### *Electronic patient record architecture standards*

- In short, to be defined as national standard in all future tenders addressing the needs of information solutions for providers
- Consider CEN EN13606, CEN 12967 (HISA) – only as guideline

## Standards relevant to E-health

### *Data interchange (messaging) standards and Data Sets*

- In addition to common HL/7 , EDIFACT and ebXML protocols, define standards for:
  - Core Data set – minimal clinical content sufficient to next clinician to determine the course and outcome of previous treatment. It includes discharge summary, laboratory results, medication prescribed, radiology observations,..
  - Minimal Data set – claim attachment to DRG
  - Person Demographic Data set: standardized content describing a person. It includes names, addresses, relatives, insurance, telephone nrs.
  - Person Health Profile – it includes allergies, blood type, vaccinations, medication prescribed, family health history,...

## Information Management

- Information Management standards is media independent
  - Though managing certain medical documentation in paper form may become practically impossible
- EU still have not agreed on European accreditation standards delivering pragmatic results
  - They are considering JCIA as a base
- Some leading hospitals in EU countries implement JCIA in the meantime
  - Sweden, Turkey, Germany, Denmark, UK, ...
  
- JCIA provides sufficient framework for the HC provider organizations for Management of Information
  - *We recommend considering JCIA as a very pragmatic and safe approach.*
  
- Other standards which may be a guidance for specific parts of the info/records management
  - A standard for designing forms - AS2828-1999 paper based health records
  - A standard for dossier keeping and management - ISO 15489-1 Information and documentation - records management

## Standards Development Frameworks

### ■ Organizational/Institutional

- Central organizational infrastructure, responsible & authorized for
  - establishing initial version/s (nomination, selection, accreditation where appropriate, localization, ...)
  - continuous maintenance (updates, development, extensions, ...),
  - Communication (publication)
  - Support for implementation
  - Auditing/Quality Assurance
- Organizational infrastructure at individual HCP/agencies
  - Records Management departments
  - New job profiles (management of information) + revised curricula in educational structure
  - Change management (to support the implementation)

### ■ Legislative

- Establishing proper legislative support for the introduction and further maintenance of the standards

### ■ Process & Timing

- Stakeholders: identification, selection, involvement & management
- Standards: introduction, maintenance, adherence control
  - (See e.g.: <http://www.fmrc.org.au/atc/maintenance.htm> for ATC maintenance/updating process example)
- Implementation: methodologies & support, change management
- Communication/Publication
- Time plan

### ■ Technical/Technology

- Supporting IT infrastructure definition, set-up and operations (wherever appropriate and needed)
- Set of mandatory requirements for certain parts of the current IT systems
- Guidelines for building future IS and acquiring technical equipment

Based on Slovakian Example

## Suggested phasing to develop National Standards Plan

- **STEP 1: Conduct a "strategic planning session" to agree and document**
  - A. goals and objectives to be achieved by implementing the standards
    - these objectives (measurable) will be derived from original MOH / WB documentation and more specific for standards like:
      - "standards to meet the needs of future Quality standards in slovakian health care", or
      - "slovakian health care providers to achieve the level of information management as practiced in EU countries", or
      - "any information generated for external reporting has to be from the same business cycle as used for the creation and management of original data, and any information submitted to external agencies has to be in such form and shape that is practical to perform any relevant audits and verifications"... or
      - "slovakian health care providers to implement JCIA guidelines..."
  - B. Critical Success Factors, required to enable achievement of defined objectives
  - C. Identification of (current) Obstacles (resources, agreements, specificity of new six laws, funding, conflict of interest between different stakeholders groups,..) which prevent realization of Critical Success factors, and
  - D. Action Plan how to remove Obstacles and prepare the "National Standards Implementation Plan"
- **STEP 2: Execute the agreed Action Plan**
- **STEP 3: Prepare the legislative framework**
- **STEP 4: Finalize the "National Standards Implementation Plan"**

