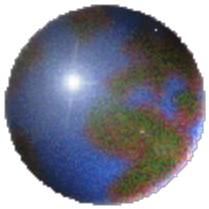


Applying a New Generation of Standardization for Clinical Care

eHealth 2016

Don Newsham and Neil Gardner

Covering in this presentation:

- Interoperability / Clinical Context / Drivers
- New Standards Approach
- Applied Service in Patient Summary and Clinical Imaging
- Applied Service in Health Software / Patient Safety

My clinical system / app / project

✓Standards Yes… But

- Many excellent standards
- Which ones ?
  - data format / message service / code set / security control / …
- Profiles help – not fully
- Bring it all together please…
  - Safely, coherently, with minimal clinical workflow disruption, within budget

Needed – real interoperability

- "ability …to exchange electronic health information …without special effort on the part of the user."
  - Office of the National Coordinator HIT presentation, A Shared Nationwide Interoperability Roadmap – Final Version 1.0

- Interoperability IS COMMUNICATION. "All you need to do is two things: 1. Deliver the message to the recipient and 2. Ensure the recipient can understand it."

Delivery of the message and ensuring understanding

  - Allscripts Chief Innovation Officer, Stanley Crane, in a blog post titled "Interoperability is as simple as good communication"

Information interoperability includes

Joint Initiative Council

JIC Standards Categorization

Using the framework (v5) identified & agreed to with the JIC

- Semantic interoperability standards
  - *Data* related standards (content, format, structure)
  - *Semantic* related standards (terminologies, vocabularies, code sets, terminology binding)
- Technical Interoperability standards
  - *Transport* related standards (Information exchange, technical, identifiers, exchange services)
  - *Security, privacy and safety* standards
- Functional Interoperability standards
  - *Functional* related standards (for business, information governance, systems, API's and other)
  - *Implementation specification* related standards (Includes guides, profiles, reference implementations, workflow practices)

NEW GENERATION of Standards

FOR CLINICAL DOMAINS, CLINICAL / PATIENT SAFETY USE

- ***Standards sets and portfolios of reference standards***
  - *encompass all of semantic, technical and functional interoperability*
  - *a new SDO standards service*

- ***Through ISO TC215 and the Joint Initiative Council of 8 SDO's***
  - *A greater engagement, real interoperability and wider adoption opportunity for vendors, clinicians and standards users at all levels*

NEW GENERATION of Standards is:

- A holistic view
  - digital health standards for specific use cases (patient summary, clinical imaging, software & patient safety, ...)
- Specific requirements / guidance
  - for development, implementation and use
- Conformity assessment
- Increased standards adoption at any level
- Standards harmonization
  - addressing gaps, overlaps and maintenance
  - selected standards work together seamlessly to support information sharing
  - architected/ coordinated view of needed standards
- Consolidated standards information

NEW GENERATION of Standards is:

- ***Value for vendor, clinician, hospital, region, government and ultimately PATIENT:***
  - ***one stop source,***
  - ***for a set of INTEROPERABLE standards***
  - ***for an important health business need,***
  - ***with conformance assessment specifications included.***

ISO/TC215 Standards Service

ISO, IEC, ITU - foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade

- 238 technical committees, 162 member countries (NMB's)
- 21,100 standards, 100,000 experts involved

- Delivers International Standards through
  - global openness and transparency, consensus and technical coherence.

- ISO/TC215, Health Informatics
  - 31 Participating, 28 Observing Countries

ISO/TC215 Standards Service

- **REFERENCE STANDARDS PORTFOLIO:**

- An assembly of health information communication and technology standards ("digital health" standards),
- For a domain, with guidance,
- [NORMATIVE]

- RSP – Clinical Imaging

the technique and process of creating visual representations of the body for clinical analysis and medical intervention

JOINT INITIATIVE COUNCIL OF

SDO's Standards Service

- ISO/TC215, HL7, CEN/TC251, IHTSDO, CDISC, GS1, IHE, DICOM
- Current Objective / Focus
  - better global patient health outcomes by providing strategic leadership in the specification of sets of implementable standards for health information sharing"

- **STANDARDS SET:**

- A coherent collection of standards and standards artefacts
- For a specific use case, with guidance
- [INFORMATIVE]

- PATIENT SUMMARY STANDARDS SET

minimum set of information needed to assure healthcare coordination and the continuity of care.

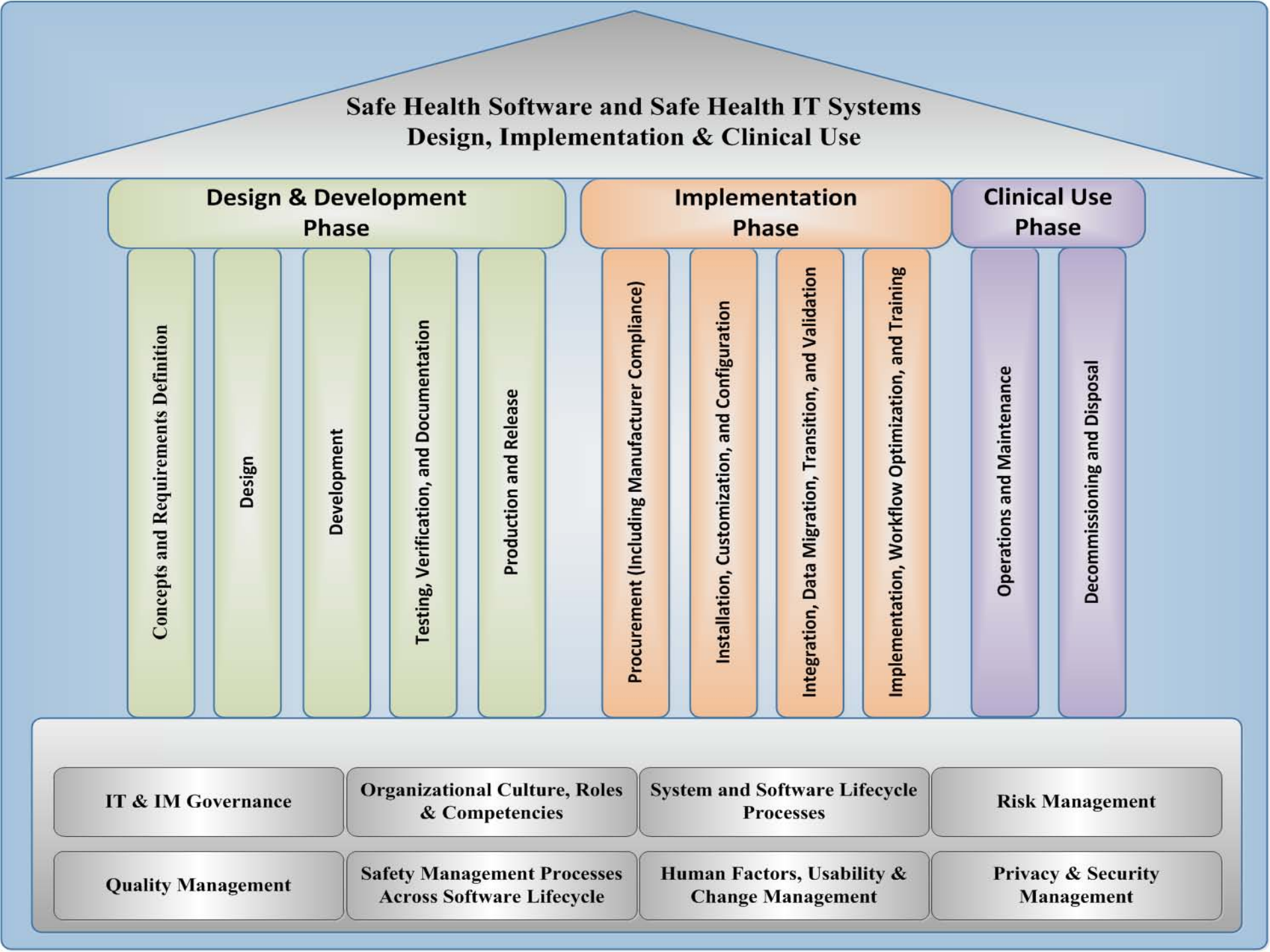
Sets and Portfolios provide

- data content standards from ISO/TC125, CEN/TC251, DICOM, GS1 and HL7, +
- semantic standards from IHTSDO, DICOM, +
- transport standards from HL7, +
- security and safety standards from ISO/TC215, IEC/SC62 +
- implementation specifications from IHE and other standards
- AND IMPLEMENTATION GUIDANCE

Patient Safety – a Critical Clinical Concern

- Our vision of fully inter-operable systems offers many benefits – improved patient safety being a key element
- At the same time, to quote the Institute of Medicine:

  'to fully capitalize on the potential that health IT may have on patient safety, a more comprehensive understanding of how health IT impacts potential harms, workflow, and safety is needed"
- Software is now highly configurable, integrated with other systems and part of a complex ecosystem where several factors affect safety and adoption
- As the following chart illustrates, many factors need to be managed and safety considerations must be managed throughout the software lifecycle


Safe Health Software and Safe Health IT Systems
Design, Implementation & Clinical Use
Design & Development Phase
Implementation Phase
Clinical Use Phase
Concepts and Requirements Definition
Design
Development
Testing, Verification, and Documentation
Production and Release
Procurement (Including Manufacturer Compliance)
Installation, Customization, and Configuration
Integration, Data Migration, Transition, and Validation
Implementation, Workflow Optimization, and Training
Operations and Maintenance
Decommissioning and Disposal
IT & IM Governance
Organizational Culture, Roles & Competencies
System and Software Lifecycle Processes
Risk Management
Quality Management
Safety Management Processes Across Software Lifecycle
Human Factors, Usability & Change Management
Privacy & Security Management

eSafety – 'It takes a Village'

Developers

- Development and support of eHealth products and services
- Focus on product quality, usability and support

Implementers

- Integration of products and services into a complex eHealth ecosystem
- Focus on configuration, integration and interoperability

Operators

- Real-world operation of integrated eHealth systems in technical & clinical environments
- Focus on clinical workflow integration, data quality, support

End-users

- Direct use by clinicians and patients at Point-of-Care
- Focus on clinical use, human factors, training, benefits optimization, adoption and any emerging safety risks

Patient Safety – New Approach was Needed

- Patient safety is a shared responsibility for all of involved in the development, implementation & use
- Patients & consumers will also be important end-users with apps, wearable devices, home monitoring, etc.
- Clinicians are increasingly reliant on the veracity of the information they are presented - the volume, velocity and complexity of the information is ramping up
- Traditional standards will not be sufficient in addressing the breath and scope of what is needed to assure we collectively manage the inherent risks appropriately
- The collaborative work of several countries, and existing standards, are now being harnessed through work now being led through Joint Working Group 7 of ISO & IEC.

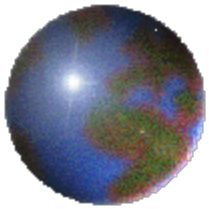
Patient Safety Standards - Innovation

- The new standards ‘architecture’ developed to address patient safety involves:
  - A new foundational standard currently being proposed to underpin and integrate new & revised standards
  - Altered scope and content for several existing standards that were originally developed to focus ion medical device safety
  - Major focus on developing a family of standards with best practice guidance to address the integration, implementation, operation and clinical use phases of the software lifecycle
- In parallel, collaborative work will continue to be fostered between several countries (including Canada, the US, Australia and the UK) active in the ISO/IEC work
- This will ‘fast-track’ domestic and international innovations and inform safer systems development, implementation and clinical use on the front-lines of health care innovation.

Your clinical system /app /project

✓Standards Yes… AND

- Target full information interoperability
- Use or help develop new standards sets
  - Participate in the collaboration efforts (national / international)
- Be a part of implementation guidance
- Use it all together
  - Safely, coherently, with minimal clinical workflow disruption, within your budget



Thank you

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