An Introduction to Informatics Standards in Pathology

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Topics

- Importance of standards
- Standards relevant to Pathology
  - HL7
  - LOINC
  - SNOMED
  - DICOM
  - IHE
- Standards Development
- Role of Pathologists

Standards in Everyday Life

- Railroad gauge

- Shipping containers

A Standard is…

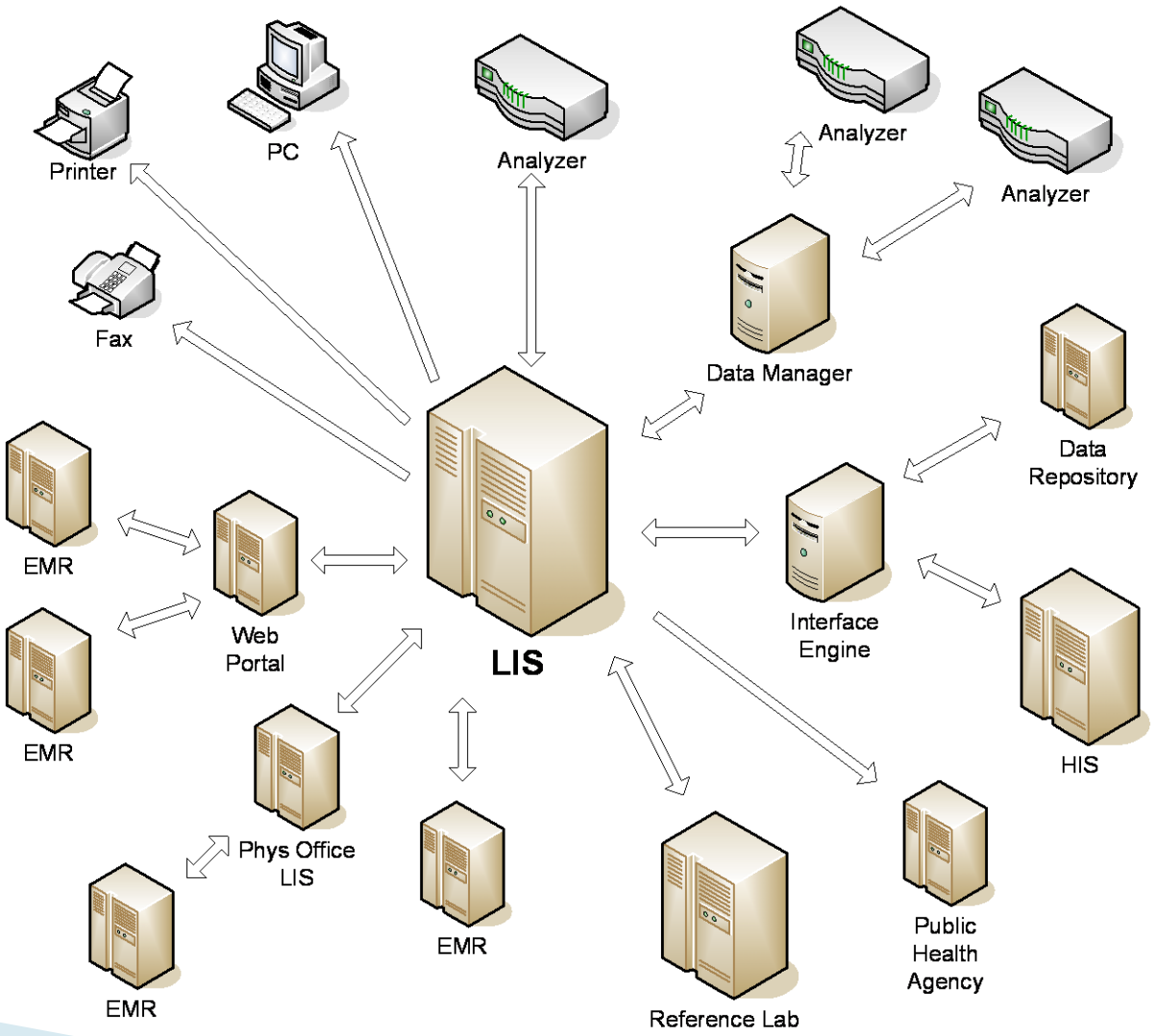
a document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Source: International Organization for Standardization (ISO)

Role of Informatics Standards

- Facilitate electronic exchange of information
- Rely upon a shared understanding between sending and receiving systems
- Ideally, use an underlying data model
- Replace idiosyncratic local schemes

LIS Environment



Barriers to Communication

- Incompatible acquisition or storage formats
- Differing data models
- Standards or vocabularies incomplete
- Many current interfaces need local customization

Medical Informatics Standards

- Vocabulary
  - SNOMED, UMLS
- Billing
  - CPT
  - HCPCS
  - 5010
- Diseases
  - ICD-9-CM, ICD-10-CM
- Observations and test results
  - LOINC
  - UCUM
- Image exchange
  - DICOM

Medical Informatics Standards

- Clinical messages
  - HL7
- Medical Reports
  - Clinical Document Architecture (CDA)
  - Continuity of Care Document (CCD)
- Pathology report content
  - CAP electronic cancer checklists (eCC)
- Instrument interfaces
  - ASTM 1394 / CLSI LIS-2
  - POCT-1
- Labeling of blood products
  - ISBT 128
- Specimen labeling
  - CLSI AUTO12-A

Structure vs. Content

Messaging	Content
HL7	SNOMED-CT, LOINC, CPT, ICD9-CM
DICOM	JPEG, TIFF, SNOMED-CT
5010 (billing transactions)	CPT, ICD9-CM
CDA	CAP electronic Cancer Checklists
Code 128	ISBT 128

Health Level 7 (HL7)

- Clinical and administrative messaging standard for healthcare
- Most widely used medical information standard worldwide
- Developed by the international standards development organization HL7
- 30+ volunteer working groups devoted to improving the standard

HL7

- Handles many administrative messages
  - Admit/discharge/transfer
  - Test orders and results
  - Clinical notes and documents
- Current versions are 2.x
  - Character delimited text
- Very flexible

  “If you have seen one HL7 interface, you have seen one HL7 interface”

Example HL7 v2.x message

MSH|^~\&|APEX.ICE|ANYTOWN MEDICAL CENTER LAB||DIMC|200304100859||ORU^R01|12|D|2.4

PID|||T000001^^^^MRN||Marge^Simpson^^^^^L||19441117|F|||1 MAIN STREET^^ANYTOWN^MICHIGAN|PC1 1CP|

PV1||O|^^^AMC|

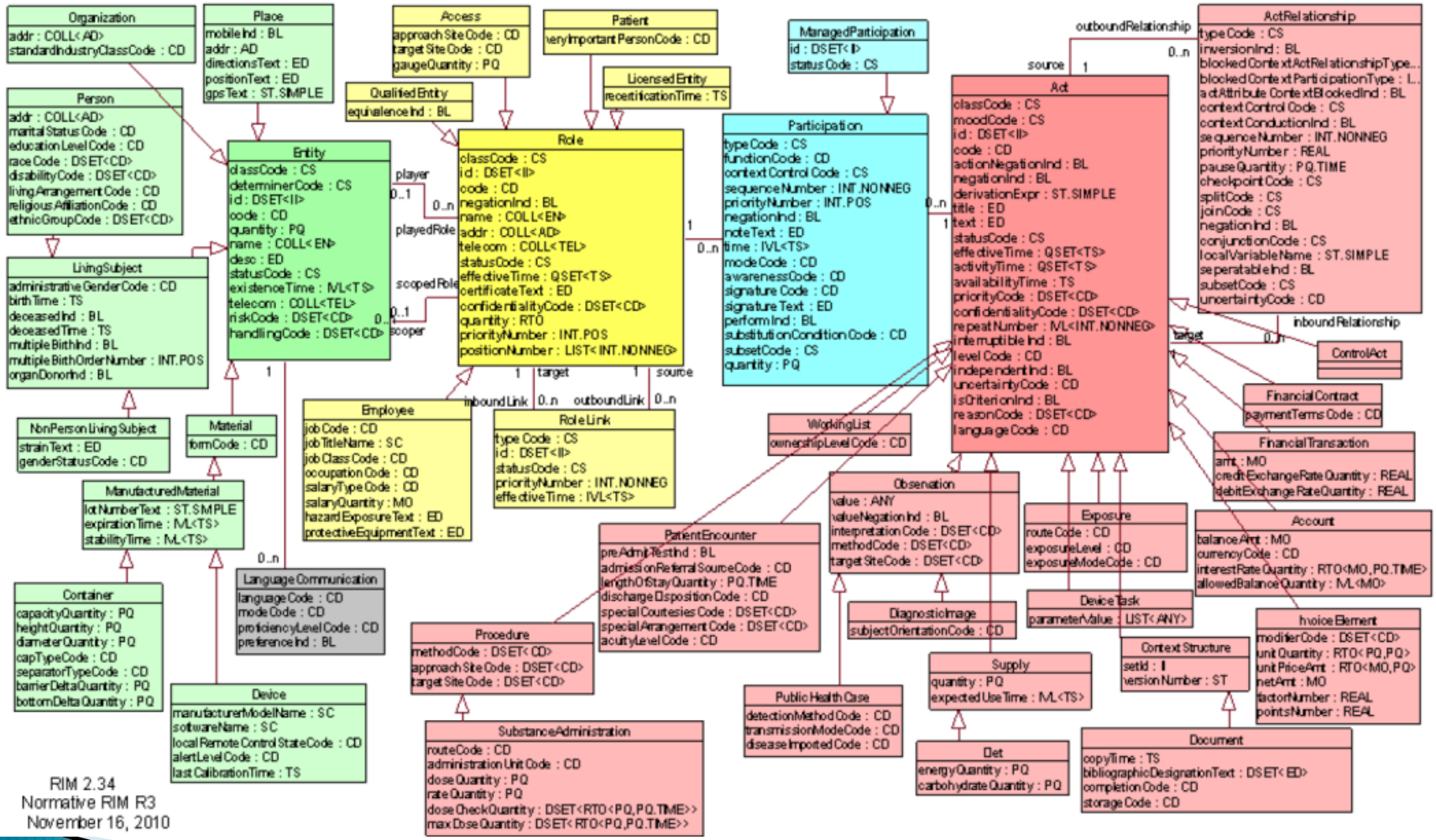
OBR|1||HT082071Y^Chemistry Lab|B12^Vitamin B12^LC|||200304050000||||||200304071543|T034^BLOOD|0001^Dr. Homer Smith||||||200304100856||HM|

OBX|1|NM|B12^Vitamin B12^LC||373|ng/l|150-700||||F|||200304100856|

HL7 v3

- XML based
- Not widely used in US
- Version 3 uses an explicit, very detailed, information model, called the RIM

HL7 Reference Information Model



RIM 2.34
Normative RIM R3
November 16, 2010

Clinical Document Architecture

- XML based standard for clinical documents, such as discharge summary, pathology report, etc.
- Envisioned as a method for inter-enterprise information exchange
- CCD (Continuity of Care Document) is a specific use case for CDA
  - Likely to be the most common use of CDA since it is one of the ways to meet certain Meaningful Use requirements

Logical Observation Identifiers, Names and Codes (LOINC)

- Unambiguously identifies clinical observations, orders and results
- Specifies the question being asked or answered
- >70,000 codes defined, most are lab related
- Regularly add new codes
- Replaces local codes in messages
- Uses a multi-axial data model
- Has hierarchical relationships
- Required for MU stage 2 in some cases

Current Scenario

LAB
GLU
K
Na

LAB	EMR
GLU	Glucose
K	Potassium
Na	Sodium

EMR
Glucose
Potassium
Sodium

Using LOINC

LAB

Test	LOINC
GLU	2345-7
K	2823-3
Na	2951-2

EMR

LOINC	Test
2345-7	Glucose
2823-3	Potassium
2951-2	Sodium

…|2345-7|100|mg/dL|…

EMR Display of Results from Multiple Labs

Test	7/1/12	6/1/11	3/1/10
Gluc (lab A)	100		
Glu Rnd (lab B)			200
Glucose (lab C)		300	

(with LOINC)

Test	7/1/12	6/1/11	3/1/10
Glucose	100	300	200

LOINC Example

Axis	Value
LOINC Code	2345-7
Component	Glucose
Property	Mass concentration
Time	Point in time
System	Serum/plasma
Scale	Quantitative
Method	(blank)

A typical serum glucose reported in mg/dL

LOINC

PROS	CONS
Large set of codes	Complex to understand and use
Easy to request new codes	Difficult to choose correct codes
Specified in federal interoperability standards and M.U.	LIS/EHR support is variable but improving

SNOMED-CT

- Systematized Nomenclature of Medicine – Clinical Terms
- Based on SNOP system developed by CAP in 1965
- Latest version is result of merger of SNOMED RT and United Kingdom developed Clinical Terms
- Continuing development managed by IHTSDO

SNOMED-CT

- > 300,000 concepts
- > 1 million semantic relationships
- Multi-axial system
- Hierarchical organization
- Allows for very detailed coding of medical information

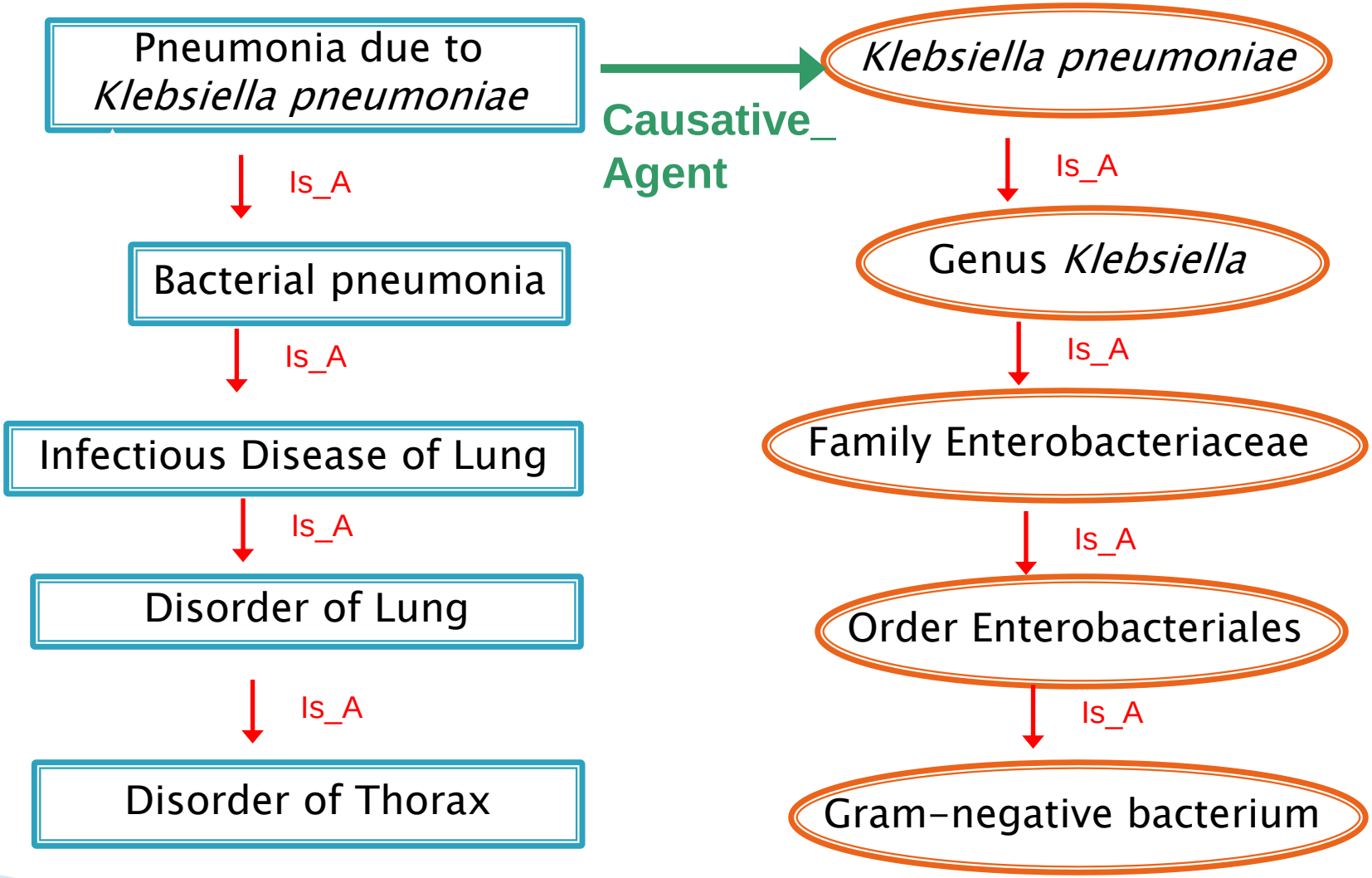
SNOMED CT AXES

Hierarchy	Examples
Clinical Finding/Disorder	Normal breath sounds, Diabetes mellitus
Procedure/Intervention	Influenza (H1N1) vaccination, hysterectomy
Observable Entity	Primary tumor size, gender
Body Structure	Liver, diverticulum
Organism	*Staphylococcus aureus*, *Giardia lamblia*
Substance	Parathyroid hormone, hematoxylin stain
Pharmaceutical/Biologic Product	Digoxin, growth hormone preparation
Specimen	24 hour urine, hysterectomy specimen

SNOMED CT AXES

Hierarchy	Examples
Physical Object	Book, syringe
Physical Force	Gravity, fire
Event	Blizzard, tripping
Environment or Geographical Location	Stairs, Asia
Social Context	Occupation, lifestyle, religion
Staging and Scales	Glasgow coma scale, International Federation of Gynecology and Obstetrics ovary tumor staging
Special Concept	Concepts that have been retired from use

SNOMED Example



Medical Image Standards

- Digital Imaging and Communications in Medicine
- Voluntary standards organization
- Image exchange standard for CLINICAL images
- 30 working groups currently
- Anyone with a material interest may participate
- Version 3 of standard released 1992

DICOM Overview

- Communication standard
- High level standard, conceptual
- Facilitates interchange, doesn't mandate internal storage formats
- Image object definitions are central
- Widely adopted in radiology
- Addresses workflow as well as images

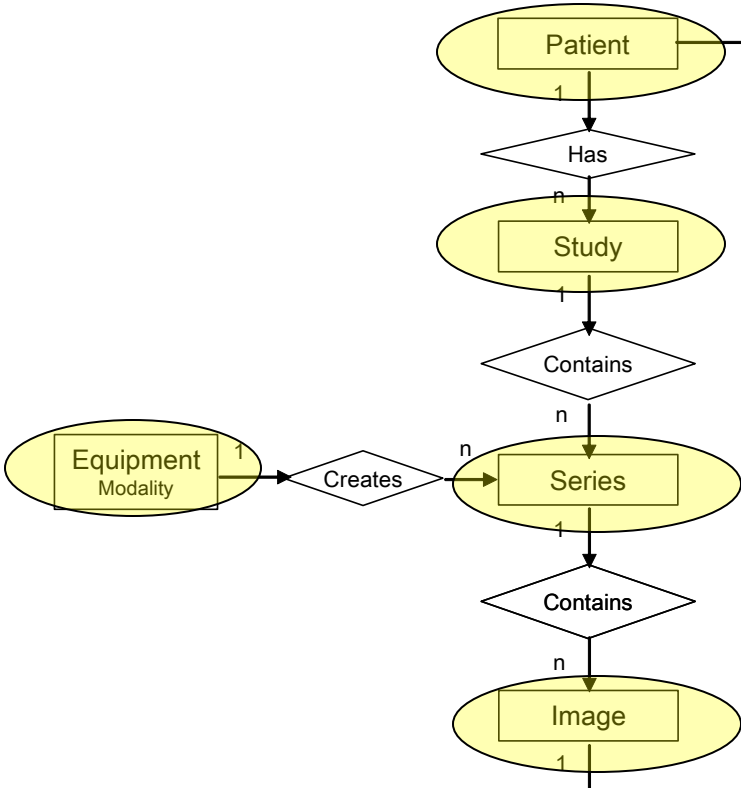
Pathology in DICOM

- Visible light supplement approved 1999
  - Incomplete and rarely used
  - Doesn't support the complexity of Pathology practice
- Pathology WG needed
  - Created WG-26 Fall 2005
  - Meets 3-4 times per year
  - Representatives from most major pathology imaging vendors
  - Also pathologists, consultants and researchers

WG-26 Goals

- Initial goals:
  - Extend minimal capabilities to describe specimens in DICOM
  - Create a mechanism to allow exchange and use of whole slide microscopic images within DICOM
- Long term goals:
  - Other imaging modalities, such as multi-spectral images, electron microscopy, flow cytometry, clinical lab images

Pathology Imaging in DICOM



Base Std

Supp 122

Supplement 122

- Specifies a specimen description model which allows description of:
  - Type of specimen
  - Procurement and processing steps
  - Sampling methods
  - Physical attributes of slides
- Approved 2008

Supp 145 – Whole Slide Images

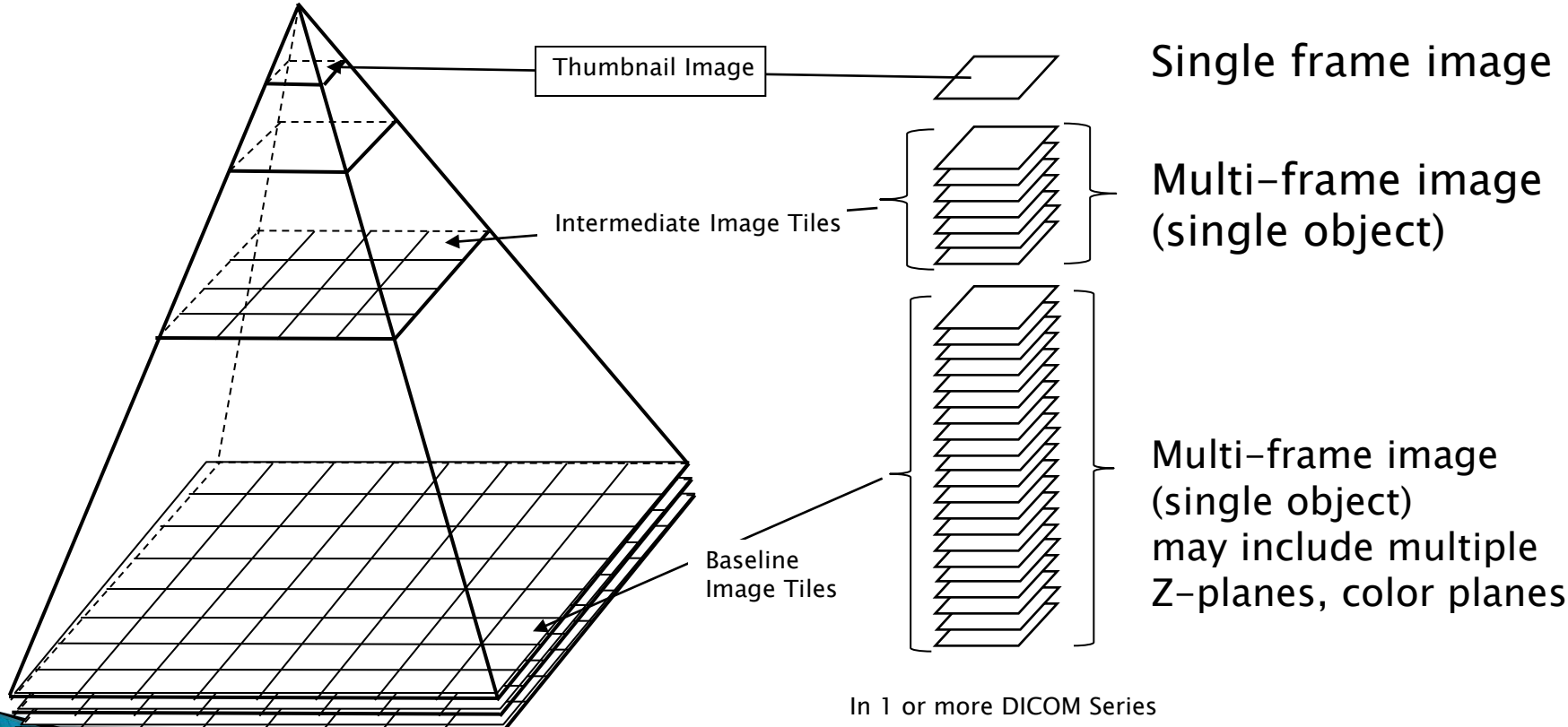
- Needed a new DICOM Image Object Definition
- Challenges
  - Vast size
  - Need for intuitive and fast viewing interface
- DICOM specific issues
  - Image pixel dimensions limited to 64k x 64k
  - Image size description limited to 4GB
  - Desirable to be backwards compatible
  - Efficient sub-region access
  - Most DICOM services assume entire image transmission

Supp. 145

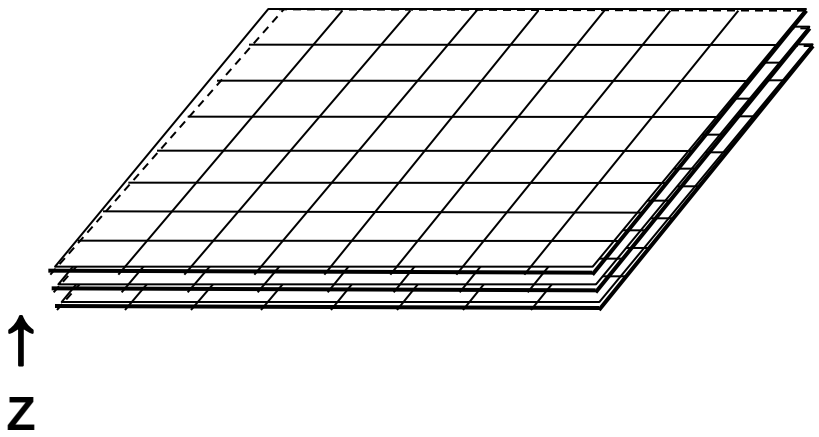
- Specifies how to incorporate WSI images into DICOM
- Approved Fall 2010
- DICOM is now able to handle most pathology and lab images!

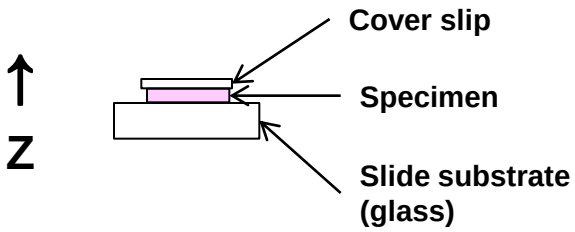
Supp. 145 Concept

Use multi-frame image objects



Z-planes

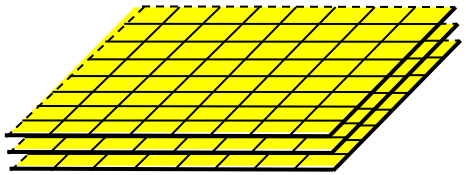


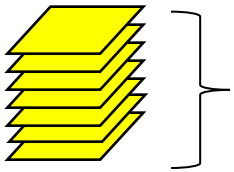


- Z-planes are identified as nominal physical height of image focal plane above reference surface (μm)
- Z-plane information is used for relative spatial positioning of image planes, and *nominal* inter-plane distance
- An image plane may track variable specimen thickness / surface contour, but only one Z-value used

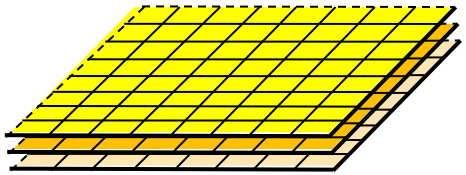
Organization of tiles into objects

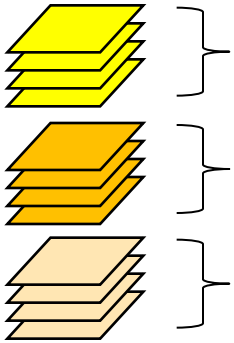
All Valid:



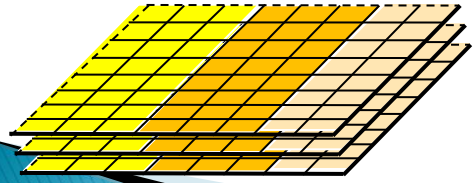


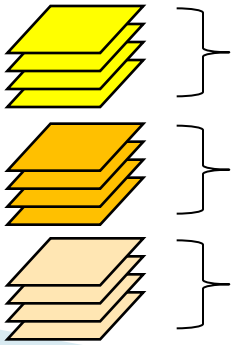
Single Multi-frame image





Multi-frame image per Z-plane





Multi-frame image per spatial region

Implementation Issues

- Supp. 122 has the needed data elements, BUT most AP LIS Systems don't have these data at the SPECIMEN level, if at all
  - Unique slide ID may not be explicitly present
  - No ability to identify subregions of a slide/block
  - Staining and fixation information often co-mingled
  - Specimen descriptions difficult to parse out from large text blocks
  - Dictionaries may be poorly implemented

WSI Implementation Issues

- Need to have slide scanner and PACS vendors implement support for Supp. 145 in their products
- Need to have real world testing to identify issues

IHE - Integrating the Healthcare Enterprise

- Doesn't develop standards
- Creates integration profiles with suggestions for ways to best use standards in practice
- Holds "connectathons" to allow vendors to demonstrate interoperability

Connectathon

IHE Pathology/Lab

- IHE-Pathology
  - Pathology Technical Framework
  - Includes integration profiles that target specific clinical situations in Anatomic Pathology

- IHE-Lab
  - Works on issues related to lab testing
  - Lab device automation profile – interfaces between LIS and instruments including pre-analytic automation

Standards Development Process

Have an Idea

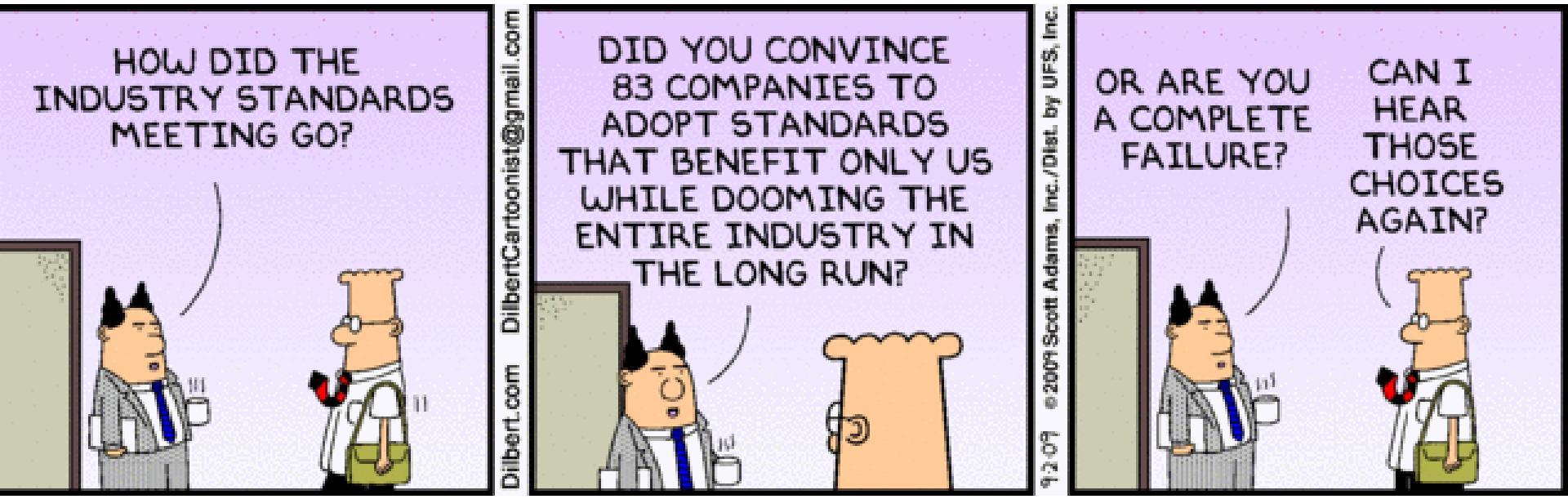
- Identify a gap in a current standard
  - Can an existing standard be modified?
  - Join an existing working group
- Identify a need for a new standard
  - Create a new working group
  - Create a new standards organization

Define the problem

- Be able to write a succinct statement of the issue
- Identify the relevant use case of example that illustrates the need
- Think about possible technical solutions (especially ones that are already in use by vendors)

Coalesce Support

- Users
- Vendors
- Standards Organization
- Find a sponsoring organization


HOW DID THE INDUSTRY STANDARDS MEETING GO?
DID YOU CONVINCE 83 COMPANIES TO ADOPT STANDARDS THAT BENEFIT ONLY US WHILE DOOMING THE ENTIRE INDUSTRY IN THE LONG RUN?
OR ARE YOU A COMPLETE FAILURE?
CAN I HEAR THOSE CHOICES AGAIN?
Dilbert.com DilbertCartoonist@gmail.com
9-2-09 © 2009 Scott Adams, Inc./Dist. by UFS, Inc.

Vendors

- Generally understand the benefits of standardization versus lock in
- Radiology market is a good example where the benefit of DICOM is that the market is very much larger than before standardization
- Need to be aware of intellectual property constraints/issues

Figure out resources needed

- Development costs
  - ? Consultants for technical issues
- Travel, conference calls or webinars
- Publicity

Role of Pathologists

- Standards Development
  - Identify gaps or needs
  - Provide domain expertise
- Adoption and Implementation
  - Champion use within home institutions
  - Educate trainees
  - Lobby vendors to support
  - Publicize relevant standards

Possible Future Areas to Address

- Pathology/lab result display
  - Ensure complete and logical display of results
- Container labeling
  - Layout and content – AP
  - UUID on tube?
  - RFID content
- Histology equipment communication

Summary

- Interconnectivity is becoming essential and ubiquitous
- Without standards, achieving interconnectivity would be almost impossible
- There are many existing healthcare standards that we can leverage
- Pathologists can play an important role in the adoption and extension of standards
- Pathology Informaticists are particularly valuable participants!

References

- HL7:
  - http://www.hl7.org/
- LOINC:
  - http://loinc.org/
- SNOMED CT
  - http://www.ihtsdo.org/

References Cont.

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- IHE Laboratory
  - http://wiki.ihe.net/index.php?title=Laboratory