Digital Pathology in Europe: Coordinating Patient Care and Research Efforts

Informatics Standards in Anatomic Pathology

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Agenda

- What is anatomic pathology (AP)?
- Informatics Standards in Anatomic Pathology
  - “Interoperability framework”
- Results of recent efforts
  - IHE anatomic pathology
    - DICOM, HL7
    - “Specimen tracking”
- Further steps
  - IHE, DICOM, HL7
  - IHTSDO
  - jpeg2000
What is anatomic pathology?

*It is not clinical pathology*

- **Diagnostic process in anatomic pathology**
  - Mainly based on image interpretation
  - Little use of automatons
What is anatomic pathology?

*It is not radiology*

**Diagnostic process in anatomic pathology**
- Specimen-driven.
  - Images of the same study corresponding to the same order may be related to different specimen (parts and/or slides) from the patient.
  - Images of the same study may be related to different specimen even from different patients (e.g. in anatomic pathology imaging for research e.g in case of digital Tissue Micro Array).
  - Unlike patients in radiology, in AP, slides are always available to acquire more images, if needed.
- Involves multiple acquisition modalities
  - Gross imaging
  - Microscopic imaging
    - Microscopic still imaging
    - Whole slide imaging
    - Multispectral imaging
Informatics Standards in Anatomic Pathology

**Objective**
- Providing an interoperability framework to enhance patient care & research
  - “Integrating digital pathology to healthcare & research enterprise”
  - Sharing formats of AP reports & images (“virtual slides”)
- Defining “relevant, useful & coherent standards”
  - Corresponding to clearly defined user needs
    - Business analysis: process models, use cases
  - **Implementable** by vendors in real-life environments
  - Defined according to a clear international healthcare IT infrastructure development governance (ISO, HL7, CEN – OMG, W3C)
Informatics Standards in Anatomic Pathology

- **First step: business analysis**
  - Research in general business process modeling
  - Modeling AP processes & defining the road map
    - Business processes to implement (using standards) for both patient care and research

- **Second step: implementation guides**
  - Best use of existing standards to implement processes
    - IHE integration profile & profile contents

- **Facultative step: defining/changing standards**
  - DICOM, HL7, SNOMED CT etc
Integrating the Healthcare Enterprise

Both a process and a forum for encouraging integration efforts

- **“Technical framework”**
  - Users’ needs & Implementation guide
- **“Connectathons”**
  - Rigorous testing process
- **“Demos”**
  - Educational sessions & exhibits (RSNA, HIMSS)

Noordwijkerhout 2005: 300 participants, 100 systems, 62 vendors
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IHE: the grows
Informatics Standards in Anatomic Pathology

IHE
(ITI, Laboratory, Laboratory, PCC, etc)

IHE Anatomic Pathology
Integration Profiles
Content profiles

HL7 Pathology SIG

HL7
(Oders, RCRIM, etc)

DICOM WG26

DICOM
(WG6, WG13)

CDISC

OMG, W3C

MIE 2009 – Sarajevo - Tuesday, 1 September
Informatics Standards in AP
HL7 web site (http://www.hl7.org)
Informatics Standards in AP
HL7: standards for patient care

- Standards for interoperability among computerized information systems in healthcare.
  - A key aspect of the HL7 methodology is the HL7 Reference Information Model (HL7 RIM).
- HL7 version 2 messaging standards for
  - Patient administration, Order Entry, Results
- HL7 version 3 specifications for
  - Reference Information Model (RIM) for Healthcare
  - Data Type Specification for health care
  - XML Data Formats for Medical Information
  - Controlled Vocabulary
  - Clinical Document Architecture
Informatics Standards in AP
HL7 v3: Refined Models for XML observation on patient (messages & documents)

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Created in January 2006
- Specimen model, orders and reports aspects of the anatomic pathology workflow
Informatics Standards in AP
DICOM

- **DICOM**: Digital Imaging and COmmunication in Medicine
  - Create standards for integration of electronic healthcare information in medical imaging
  - Network communication protocols between informatic modules in medical imaging
Informatics Standards in AP DICOM WG26 for pathology

- Created in October 2005
- Specific challenges
  - Some pathology-related image formats do not as yet have applicable DICOM Information Object Definitions
    - whole slide images, high-order multi-spectral images, flow cytometry, electron microscopy and others
  - Imaging studies are of specimens and not of patients
    - revision and extension of specimen specification
  - Images are closely associated with tissue processing (i.e. fixing, staining, etc.) image metadata may need to include tissue processing information
Informatics Standards in AP
CDISC website (www.cdisc.org)
Informatics Standards in AP
CDISC : standards for clinical research

- Clinical Data Interchange Standards Consortium
- Open multi-disciplinary non-profit organization
  - Founded in 1997, liaison with ISO TC 215, agreement with HL7 since 2001
  - Over 200 member organizations: US, Europe, Japan, Australia, India, S. America and Africa
- Platform-independent data standards to support the electronic acquisition, exchange, submission and archiving of data to support regulated clinical research.
  - Freely available on the CDISC website (www.cdisc.org)
  - Developed through open, consensus-based approach
Results of recent efforts

- **Patient care**
  - Intra hospital integration profile: Anatomic Pathology Workflow (APW)
    - Ordering and performing anatomic pathology exams

- **Public health, research**
  - Anatomic Reporting for Public Health (ARPH)
Organization of Anatomic Pathology Technical Framework
Anatomic Pathology Workflow (APW)

- **Addressed by the 2008-09 cycle**
- **Scope**
  - Establishes the continuity and integrity of basic pathology data
  - Ordering and reporting aspects of the workflow
    - Transactions maintaining the consistency of ordering information, specimen management information and anatomic pathology reports.
  - Imaging aspects of the workflow
    - Acquisition, storage and distribution processes of images among multiple systems, enterprises and remote workstations.
Anatomic Pathology Workflow (APW)

Patient mgmt.

Care Ward

Anatomic Pathology Laboratory

ADT Registration

Order Placer Orders Placed

Order Filler Orders accepted Report created

Modality worklist

Acquisition Modality (gross imaging/microscopic imaging) Acquisition completed

PACS (Image Archive/ Image Manager) Images stored

Report Mgmt

Image Mgmt

Report/result Repository Reports stored
Anatomic Pathology Workflow (APW)

- Surgical Pathology
  - Surgical specimen
  - Biopsies
- Cytopathology
- Clinical Autopsy
- Research (TMA)
Figure 2.1-1: Anatomic Pathology Workflow (APW)
APW profile dependencies

- **Security**
  - CT: Consistent Time

- **Patient mgmt.**
  - PAM: Patient Administration Management

- **Care Ward**
  - APW: Anatomic Pathology Workflow
  - Order & Report mgmt.

- **Anatomic Pathology Department**
  - Image mgmt.

- **IT Infrastructure profiles**

- **Anatomic Pathology profiles**

- **Radiology profiles**

- **ED**: Evidence document
- **CPI**: Consistent Presentation of Images
HL7 & DICOM standard versions used

- **HL7 v2.5**
  - PAT-1, 2 & 4: OML^O21/ORL^O22
  - PAT 3: ORU^R01 + report

- **DICOM**
  - PAT 5: DICOM 2003 PS 3.4: Modality Worklist SOP Class (PAT-5)
  - RAD 8, 10, 43
    - DICOM 2007 PS 3.4: Storage Service Class
    - DICOM 2007 PS 3.4: Storage Commitment Push Model SOP Class
  - RAD 14, 16: DICOM 2007 PS 3.4: Query/Retrieve Service Class
  - Supplément 122: Specimen Identification and Revised Pathology SOP Classes
Specimen tracking across the sampling process
Specimen tracking

- **DICOM supp122 (public comments version)**
  - IHE, HL7
- **Specimen tracking across systems**
- **Applicable to each use case**
  - Specimen can be identified by containers’ ID

**Gross imaging**

**Virtual slide**
Specimen tracking

- Specimen can **NOT** be identified by containers’ ID
  - TMA: More than one tissue from different blocks and **different patients** tissue item (spots) per slide.
Specimen tracking across standards

- Three parallel efforts: IHE-pathology, DICOM WG 26, HL7 Anatomic Pathology Special Interest Group
  - Yet distinct, each with its own purpose and organizational context

- Aligned
  - One specimen model established in common across both standards.
IHE/HL7/DICOM Specimen imaging model

DICOM Sup 122 Specimen Identification

- Disambiguates specimen and container
- **Container** is target of image
- Container may have more than one specimen
- Specimens have a physical derivation (preparation) from parent specimens
- When more than one specimen in an imaged container, each specimen is distinguished (e.g., by position or color-coding)
Final Text adoption 2008

Support for pathology lab workflow, specimen-based imaging
- Gross specimens, blocks, vials, slides
- Image-guided biopsy samples

Robust new Specimen Module at image level of hierarchy
- Identification, processing history
- May be used with current Visible Light image object definitions

Update to Modality Worklist to allow Specimen Module
- Enables automated slide scanning devices to fully populate header

Update to Modality Performed Procedure Step to identify imaged specimen
- Allows LIS to track images for specimens

45 new concepts added to SNOMED
IHE/HL7/DICOM Specimen model

- R_Specimen universal (COCT_HD080000UV) / R_Specimen minimal (COCT_HD080100UV)
Reporting Anatomic pathology to public health repositories (ARPH)

- **Addressed by the 2009-10 cycle**

- **Scope**
  - defines the actors and transactions involved in anatomic pathology reporting to public health organizations.

- **Expected outcomes**
  - *make it easier for anatomic pathology laboratories, public health agencies, and software vendors to adopt a uniform method for report or data transmission and processing*
  - *facilitate international electronic reporting of anatomic pathology data in public health domain.*
Reporting Anatomic pathology to public health repositories (ARPH)
ARPH actors & transactions

Report Sender

Public Health Reporting [PAT-10]

Report Receiver
Standards Used

- **HL7 v2.5**
  - ORU^R01 message (PAT-10)

- **Reference terminologies**
  - LOINC, SNOMED CT, ICD-10

- **Inputs from**
  - NAACCR* Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting v3.0
  - NAACCR Search Term List

*NAACCR - North American Association of Central Cancer Registries (www.naaccr.org)
Further steps
Structured reporting in AP

**Objective**
- Analysis of national initiatives for standardizing Anatomic Pathology structured reports
  - e.g CAP Cancer Checklists (US), SFP templates (France)
  - Choice of the IT format to store and share structured reports in anatomic pathology

**Standards & Systems**
- HL7 v2;5
- HL7 CDA
- HL7 v3 : Domains Laboratory, Specimen, Observation
- DICOM SR

**Implementation guides**
Further steps

- **Structured reporting in AP**
  - **Objective**
    - Analysis of national initiatives for standardizing Anatomic Pathology structured reports
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    - Choice of the IT format to store and share structured reports in anatomic pathology
  - **Standards & Systems**
    - HL7 v2.5
    - HL7 CDA
    - HL7 v3: Domains Laboratory, Specimen, Observation
    - DICOM SR
  - **Implementation guides**
    - IHE content profile (XDS integration profile)
Further step

- **Enhanced imaging workflow**
  - Whole slide image
  - DICOM worklist
  - Image display
    - Specific specimen-based image queries & browsing processes in PACS/Image
Further step
Enhanced imaging workflow
Further steps

- **Patient care**
  - Connection to automatons
  - Integrating pathology information systems & biobanking

- **Research**
  - Integrating digital pathology to networked research (HL7/CDISC)
  - Image repositories & tissue banks
More information
IHE Anatomic Pathology - Users

- **France**
  - ADICAP (Association for the Development of Informatics in Cytology and Pathology), SFP (French Society of Pathology)

- **Spain**
  - SEIS (Spanish Society of Health Informatics), SEAP (Spanish Society of Pathology), SESCAM, Servicio de Salud de Castilla-La Mancha

- **Germany**
  - Charité Universitätsmedizin Berlin

- **Italy**
  - Udine University

- **US/Canada**
  - CAP, NAACCR (North American Association of Central Cancer Registries)

- **Japan**
  - IHE-Japan
More information
IHE Anatomic Pathology - Vendors

- **Acquisition modalities**
  - Tribvn/Aperio, Zeiss, VMScope, Hamamatsu, Aurora

- **LIS**
  - Technidata, Infologic, Satec, Isoft, Nexus, Paschmann GMBH

- **PACS Vendors**
  - Agfa, GE, ETIAM

- **EHR**
  - Medasys
More information

- **Googlegroup**: ihe-anatomic-pathology-committee@googlegroups.com
- **Road map & change proposals**
• Thank you for your attention

• Any questions?

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