Inside IHE: Pathology and Laboratory Medicine
Webinar Series 2018

Presented by
• Raj Dash, MD, Duke - Planning Committee Co-Chair
• Riki Merrick, MPH – Vernetzt, LLC - Planning Committee Co-Chair
Agenda

- Intro to IHE Pathology and Laboratory Medicine (PaLM) / Mission and Scope
- Summary of all Integration profiles
- Highlighting of New Trial Implementation profiles
  - Anatomic Pathology Structured Report (APSR) 2.0
  - Laboratory Clinical Communications (LCC)
  - Transfusion Medicine Administration (TMA)
- Current Projects
  - Specimen Event Tracking (SET)
  - Digital Pathology (collaboration with DICOM WG 26 to update Anatomic Pathology Workflow (APW))
Why IHE?

International standards represent usually the state-of-the-art and the best-of-bread blocks to build safe, interoperable, reproducible solutions of healthcare data exchange.

IHE helps put those together for specific use cases (profiles)

- For a good introduction to IHE see this video: https://youtu.be/Cz5B5KOoDuw
IHE International joins healthcare professionals and IT vendors to build robust and relevant interoperability specifications.

IHE is organized per domains.

The integration profiles of a domain are assembled into the **domain Technical Framework**.

Each domain has a planning committee and a technical committee, or a single committee combining the two roles.
Connectathons

- Week-long testing sessions organized annually per continent (Japan, North-America, Europe ...).
- Enable IT vendors to test the interoperability of their solutions with their peers.
- Accelerate the refinement of the specifications (integration profiles).
- Once finalized, the status of an Integration Profile changes from "Trial Implementation" to "Final Text", and the specification is then integrated into the domain Technical Framework.

Next Dates:
Japan: Oct 15-19, 2018
US: Jan 21-25, 2019
Europe: Apr 8-12, 2019
PaLM scope covers:

- representation and exchange of digital documents, structured data, and images associated with services performed by clinical laboratories\(^{(1)}\) and pathology laboratories \(^{(1)}\) on in-vitro specimens collected from a patient or a non-living material;
- steering of analytical and peri-analytical automated devices;
- representation and exchange of structured data related to specimen management, long term storage (for instance in biobanks) and reuse;
- secondary use of in-vitro diagnostic observations and related clinical observations;
- representation and exchange of structured data related to the workflows of transfusion medicine around blood product receivers.

\(^{(1)}\): Laboratory specialties in scope: clinical chemistry, hematology, coagulation, blood gas, microbiology, immunology, transfusion medicine, HLA, fertility, AMP, cytogenetic, drug monitoring, toxicology, surgical pathology, autopsy, cytopathology, image cytometry, immunohistochemistry, clinical genomics
IT Systems in scope

- Electronic Healthcare Record Systems (EHR-S) in hospital and ambulatory care settings
- Clinical and/or anatomic pathology lab information systems (LIS)
- Public Health lab information management systems (LIMS)
- Electronic healthcare record shared infrastructures (PHR, HIE …)
- Robotic specimen container distributors
- Barcode labelers
- Robotic devices peri-analytical devices in the laboratory work area
- IVD analyzers in laboratory or on the point of care
- Middleware systems handling a set of analyzers and/or of peri-analytical devices, in laboratory or on the point of care
- Imaging modalities
- PACS and digital archive systems
- Biobank management systems
- Adverse Event tracking systems (if different from EHR-S)
IHE PaLM Technical Framework (IHE LAB TF)

- Volume 1: Profiles & Use Cases
  - Laboratory Testing Workflow (LTW)
  - Laboratory Device Automation (LDA)
  - Laboratory Analytical Workflow (LAW) Profile
  - Laboratory Point of Care Testing (LPOCT)
  - Laboratory Code Set Distribution (LCSD)
  - Sharing Laboratory Reports (XD-Lab)

- Volumes 2a, 2b, 2c: Transactions
- Volume 2x: Appendices - common material for Transactions
- Volume 3: Content Modules

http://www.ihe.net/Technical_Frameworks/#PaLM

IHE PaLM v9.0 was sent to publishing 6/21/2018
PaLM Domain Integration Profiles

- Supplements for Trial Implementation
  - in LAB domain:
    - Inter-Laboratory Workflow (ILW) Profile
    - "Graphics and simple Images in Results (GIR)" option on LTW Profile
  - In Anatomic Pathology Domain:
    - Anatomic Pathology Workflow (APW) in hospitals
    - Anatomic Pathology Structured Report (APSR)
    - Anatomic Pathology Report to Public Health (ARPH)

- Brief Description of Profiles developed by the PaLM Domain

  http://wiki.ihe.net/index.php/Profiles#IHE_Pathology_and_Laboratory_Medicine_28PaLM.29_Profiles
2018 cycle publication schedule for PaLM

- PaLM TF 9.0
- 2 supplements for Trial Implementation: LCC, TMA

Digital Pathology White Paper publish

- Nov 12 to 14, 2018

Face to Face (JAHIS) Tokyo (Japan)

CPs: 256 - 261

Supplements:
- APSR 2
- LCC

2018-06-30
2018-07-15
2018-09-17
2019-01-08
Newly Published Supplements
Laboratory Clinical Communication
LCC
Enhance Communications for Orders

- Works together with existing profiles:
  - Laboratory Testing Workflow (LTW)
  - Inter-Laboratory workflow (ILW)
- LAB-6:
  Filler can recommend to replace or supplement orders, placer can accept or reject recommendations
- LAB-7
  Placer can request specific results to be re-examined

Standards: HL7 v2.5.1 and HL7v2.9
LAB-6

LTW or ILW

Order Placer

1. Placement of a new order
   - OML New Order: ORC-1 = NW

Order Filler

2. ORL Order accepted: ORC-1 = OK
   - Unable to accept: ORC-1 = UA

3. OML Battery replaced: ORC-1 = RU
   - Battery canceled: ORC-1 = OC
   - ORL acknowledgement: ORC-1 = OK

4. Placer order checked with the related specimens. Some battery may be replaced or canceled

OML Recommendation for Order Replacement/Supplementation:
ORC-1 = RP/SU; RC

OML Recommendation response:
ORC-1 = RP/SU; RO, RA, RD
Unable to replace/supplement: ORC-1 = UM, CA

OML Recommendation response confirmation:
ORL ack: ORC-1 = RQ/SQ; RO, RA, RD, CA
Unable to replace: ORC-1 = UM

MSA ack

Patient or specimen information suggests need for order replacement requiring clinical input

Recommendation time window (order replacement only)

LCC

Replacement of an order. May be done independently, or as a response to a recommendation
Anatomic Pathology Structured Report
APSR 2.0
Generalize Anatomic Pathology Structured Report

- Create generic templates
- Enhance specimen collection section
- Created in Art-Décor tooling for better implementation experience (have conformance rule files (XML) as well as text)

Standards:
- HL7 v3 CDA R2,
- LOINC,
- DICOM
- SNOMED CT
### Art Décor view

#### Template Anatomic Pathology Structured Report Content Module 2014-05-13 11:57:57

<table>
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<th>DT</th>
<th>Card</th>
<th>Conf</th>
<th>Description</th>
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</thead>
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<tr>
<td>Art Décor view</td>
<td>cs</td>
<td>1..1</td>
<td>F</td>
<td>Description</td>
<td>APSR 2 (continued)</td>
</tr>
</tbody>
</table>
VOLUME 1 - PROFILES

10 Anatomic Pathology Structured Report (APSR) Profile

This content profile describes an anatomic pathology structured report (APSR) as a digital document to be shared or exchanged between pathology laboratories and other care providers and institutions. Anatomic pathology structured reports document the findings on specimens removed from patients for diagnostic or therapeutic reasons. This information can be used for patient care, clinical research, and epidemiology. Standardizing and computerizing anatomic pathology reports is expected to lower the exchange and reuse of the content of these reports.

This content profile describes a digital anatomic pathology report shared in a human-readable format, which may include images, and which also contains findings and observations in a machine-readable format, facilitating the integration of these into the database this content.

The scope of this IHE content profile covers all fields of anatomic pathology (cancers, benign neoplasms as well as non-neoplastic conditions) as well as cytopathology.

Goldsmith, J.D., et al., “Reporting guidelines for clinical laboratory reports in surgical pathology” Arch Pathol Lab Med, 2008; 132(10): p. 1608-16, is the first source of specification for this content profile. This article delineates the required, preferred, and optional content modules.

This source is complemented by the “cancer checklists” produced by the College of American Pathologists, and by the “comptes rendus d’anatomopathologie : données minimales à renseigner pour une tumeur primitive” produced by the French society of pathology.

German “Guideline Pathology / Neuropathology” (formerly TM-30) of the Sector Committee Pathology for the implementation of DIN EN ISO/EC 17020.

This profile has also benefited from the guidance on cancer AP reports provided by the North-American Association of Central Cancer Registries; some of the example snippets captured in the profile leverage the NAACCR Standards for Cancer Registries, Volume 2.

10.1 APSR Actors/Transactions

This section defines the actors, transactions, and content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A published here.

Figure 10.1-1 shows the actors directly involved in the APSR Profile and the direction that the content is exchanged.

A product implementation using this profile must group actors from this profile with actors from a workflow or transport profile to be functional. The grouping of the content module described in this profile to specific actors is described in more detail in the “Requirements and Conformance.”

Figure 10.1-1 APSR Actor Diagram

Table 10.1-1 lists the content module(s) defined in the APSR profile. To claim support with this profile, an actor shall support all required content modules (labeled “R”) and may support optional content modules (labeled “O”).

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<thead>
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<th>Content Modules</th>
<th>Optionality</th>
<th>Reference</th>
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<td>PfLM TF-3: 8.3.1.2</td>
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<tr>
<td>Content</td>
<td>Anatomic Pathology Structured Report 1.3.6.1.4.1.19370.1.8.1.1.1</td>
<td>R</td>
<td>PfLM TF-3: 8.3.1.2</td>
</tr>
<tr>
<td>Consumer</td>
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<td></td>
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</table>
Transfusion Medicine – Administration (TMA)
Tracking Adverse Events During Transfusion Administration

- First in family
- Event tracking during Administration (optional patient matching verification step) = green
- Future expansion: Assigning units to collecting units = orange

Standards: HL7 v2.x, LOINC, SNOMED CT
WE NEED YOUR HELP

• For more detail and to access the TMA as published for comment:

• We are looking for stakeholders interested in testing this in connectathons (applies to ALL PaLM profiles)

• We are planning more elements of the Transfusion Medicine life cycle and would like input from stakeholders
Current Work
Specimen Event Tracking (SET)
Manage Specimen Transport Tracking

• Provide common framework for IVD vendors to manage specimen passing in the laboratory in different settings (intra- and inter-organizations and facilities)

• Use cases:
  – #1 Specimen Collection Tracking
  – #2 Specimen Intra and Inter organization transfer
    • No/re-identification, reject by receiver
  – #3 Intra Laboratory IVD Specimen Tracking
  – #4 Biobank Specimen Tracking
    • Collection
    • Retrieve from biobank for testing (immediate or not)
  – #5 Specimen Derivation Tracking

• Reduce design burden for Laboratory Automation Systems (LAS) and Specimen Processing Devices (SPD)

Standards:
HL7 v2.5.1
(and pre-adopt v2.9)
Others TBD
WE NEED YOUR HELP

• For more detail and to access current work on SET [http://wiki.ihe.net/index.php/Specimen_Event_Tracking](http://wiki.ihe.net/index.php/Specimen_Event_Tracking)

• Working on data element matrix (defining all the elements for each of the different tracking steps)

• Working on defining message structure(s) for tracking steps with the same data requirements

• Verifying all tracking steps covered
Evolve Anatomic Pathology Workflow to Accommodate Digital Pathology

- DICOM WG26 and IHE PALM collaboration
- Anatomic pathology workflow reimagined with incorporation of image digitization
- Use cases established with initial effort focused on profile to support image acquisition
  - Primary diagnosis and secondary consultation use cases will take priority
- First white paper to be released Fall 2018 and first profile to be published December 2018
Example: actors, workflow, transactions in Digital Pathology

1. EHR sends case order with one or more specimens
2. LIS sends case results (diagnosis)
3. LIS requests stored image(s) for specimen
4. Archive returns image(s)
5. EHR requests all images for case (not likely?)
6. Archive returns image(s)
7. Creator sends images for storage
8. Archive acknowledges image(s) stored
9. LIS receives events as creator acquires, completes, modifies digital asset
10. LIS acknowledges / approves creator transaction
WE NEED YOUR HELP

- For more detail and to access current work on Digital Pathology
- Review use cases
- Review draft white paper, comment on focus of initial effort, and associated actors and transactions
- Identify how you would recommend prioritization of future efforts as part of a long term road map
- Identify which vendor partners in your organization would benefit from being involved and help us reach out to them!
If you want to contribute

• Apply for IHE International Organizational Membership
  Visit: [www.ihe.net/apply](www.ihe.net/apply) (note IP Policy)
  Approved monthly by IHE International Board
  Review IHE's 200+ Organizational Members:
  [http://www.ihe.net/governance/member_organizations.cfm](http://www.ihe.net/governance/member_organizations.cfm)

• Join IHE Laboratory Planning & Technical Committees
  Mailing list: [https://groups.google.com/a/ihe.net/forum/#!forum/palm](https://groups.google.com/a/ihe.net/forum/#!forum/palm)

• Non-members have limited participation:
  Review & comment during Supplement Public Comment period
  Implement IHE Profiles and test them at connectathons

Thank you

- IHE International - www.ihe.net
- IHE Europe - www.ihe-europe.net
- IHE North America/USA - http://www.iheusa.org/
- The complete program of educational webinars
  http://www.iheusa.org/resources-education-webinars.aspx#webseries
- Overview of over 100 existing IHE integration profiles
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ANAPATH</td>
<td>Anatomic Pathology domain</td>
</tr>
<tr>
<td>ASIP Sante</td>
<td>Agence des Systemes d’Information Partages de Sante</td>
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<tr>
<td>ATNA</td>
<td>Audit Trail and Node Authentication</td>
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<tr>
<td>AWOS</td>
<td>Analytical Work Order Step</td>
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<tr>
<td>CAP</td>
<td>College of American Pathologist</td>
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<tr>
<td>CDA R2</td>
<td>Clinical Document Architecture Revision 2</td>
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<tr>
<td>CEN</td>
<td>European Committee for Standardization</td>
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<td>CIS</td>
<td>Clinical Information System</td>
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<td>CLSI</td>
<td>Clinical and Laboratory Standards Institute</td>
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<td>CT</td>
<td>Consistent Time</td>
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<td>DICOM</td>
<td>Digital Imaging and COMmunications in Medicine</td>
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<td>eDOS</td>
<td>Electronic Directory of Services</td>
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<td>EHR</td>
<td>Electronic Health Record</td>
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<tr>
<td>EMR</td>
<td>Electronic Medical Record</td>
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<tr>
<td>ETSI</td>
<td>European Telecommunication Standards Institute</td>
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<td>Health Information Exchange</td>
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<td>Health Information System</td>
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<td>Health Level Seven</td>
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<td>IEEE</td>
<td>Institute of Electrical and Electronics Engineers</td>
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<td>Internet Engineering Taskforce</td>
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<td>In-Vitro Diagnostics Industry Connectivity Consortium</td>
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<td>International Organization for Standardization</td>
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<td>International Telecommunication Union</td>
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<td>IVD</td>
<td>In-Vitro Diagnostic</td>
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<td>Logical Observation Identifiers Names and Codes</td>
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<td>OASIS</td>
<td>Organization for the Advancement of Structured Information Standards</td>
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<td>Patient Demographics Query</td>
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<td>Personal Health Record</td>
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<td>Point Of Care Demographics Manager</td>
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<td>POCRG</td>
<td>Point Of Care Result Generator</td>
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<td>Systematized Nomenclature of MEDicine Clinical Terms</td>
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<td>Unified Codes for Units of Measure</td>
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<td>W3C</td>
<td>World Wide Web Consortium</td>
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<td>XD-Lab</td>
<td>Sharing Laboratory Reports</td>
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<td>XDM</td>
<td>Cross-Enterprise Document Media Exchange</td>
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<td>Cross-Enterprise Document Reliable Exchange</td>
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