Board Report: IHE PaLM Domain

Sponsors:

- College of American Pathologists (CAP) [http://www.cap.org]
- Japanese Association of Healthcare Information Systems Industry (JAHIS) [https://www.jahis.jp/]

Leadership:

- Secretariat: Mary Kennedy, CAP (email: mkennedy@cap.org)
- Board Representative: Mary Kennedy, CAP (email: mkennedy @cap.org)
- Plan Cmte Co-chair: Riki Merrick, Vernetzt, LLC, / APHL staff (email: rikimerrick@gmail.com)
- Plan Cmte Co-chair: Rajesh Chandra Dash, Duke / CAP (email: r.dash@duke.edu)
- Tech Cmte Co-chair: Alessandro Sulis (email:asulis@crs4.it)
- Tech Cmte Co-chair: Kenichi Takahashi - Hitachi Hightech (email: kenichi.takahashi.zu@hitachi-hightech.com)

Membership Rosters:

- Planning Cmte: (our planning and technical committees meet together and share a single roster)
- Technical Cmte: PaLM Committee Roster 2022

Activity:

- Domain Scope: The IHE Pathology and Laboratory Medicine Domain addresses information sharing and workflow related to in vitro diagnostic testing performed in anatomic and clinical pathology laboratories, or on point of care devices under a clinical laboratory supervision; this includes development of standards for digital pathology. The PaLM domain also covers representation of biologic specimen metadata in laboratories and in biobanks. And last, the domain covers information sharing and workflow related to transfusion medicine. See more: http://wiki.ihe.net/index.php/Pathology_and_Laboratory_Medicine_(PaLM)
- Current Cycle Timeline: https://wiki.ihe.net/index.php?title=Pathology_and_Laboratory_Medicine_(PaLM)&action=edit&section=9 – we need to update the publication dates, then I can update this webpage that we will use in the official report: https://wiki.ihe.net/index.php/Domain_Milestone_Dates#2021_Cycle (note that that is the latest table on that page – title is for Connectathon use after 2022)
- Background: IHE Laboratory was established in 2003 by GMSIH, IHE-Japan, JAHIS and SFIL. IHE Anatomic Pathology was established in 2006 by SEIS, SEAP and ADICAP.
  In January 2016 Anatomic Pathology and Laboratory merged to form The IHE Pathology and Laboratory Medicine Domain, covering the scope of both prior domains. That same year the scope of the domain was extended to transfusion medicine, after discussion in DCC.

Most Significant Profiles:

Title	# vendor (Cthon)	# product (Registry)	Description	Significance
Sharing Laboratory	14	19	A clinical laboratory	Austrian national ELGA policy / specifications (more than 0.5 M clinical lab reports monthly): http://www.elga.gv.at/index.php?id=28

Reports (XD-LAB)			report as a CDA document exchanged using one of the XD* profiles from ITI.	French ASIP Santé national interoperability framework: http://www.esante.gouv.fr/services/referentiels/referentiels-d-interoperabilite/cadre-d-interoperabilite-des-systemes-d-inform Swiss national eHealth implementation guide: https://www.e-health-suisse.ch/fileadmin/user_upload/Dokumente/2013/D/130822_Bericht_Austauschformate_meldepflichtige_Laborbefunde_D.pdf German Discharge Summary Implementation guide (Laboratory Addendum): http://wiki.hl7.org/images/8/84/Addendum-Lab-v100.pdf Adopted by the European Commission, for reference in public tenders: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015D1302 Incorporated into the health regulatory framework for France in January 2016: https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000031922237&categorieLien=id Implemented in the eastern Netherlands to share lab results from a regional lab to pharmacists: https://www.ihe-nl.org/uploads/bestanden/Success_story_ZNO_e_lab_okt17.pdf Implemented in Veneto, Italy: Clinical laboratory reports shared in the Regional Electronic Health Record http://www.consorzioarsenal.it/en/web/guest/progetti/fascicolo-sanitario-elettronico-regionale/il-progetto
Laboratory Analytical Workflow (LAW)	8	1	Analytical robotic devices in the laboratory	Has been tested at several connectathons lately and is the basis for Clinical Laboratory Standards Institute **(CLSI) AUTO16 standard** published in Spring 2019. Adopted by the European Commission, for reference in public tenders: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015D1302 Deployed in Japan and France
Laboratory Testing Workflow (LTW)	9	8	Intra hospital workflow of ordering and reporting lab tests	Covering acute care settings Adopted by the European Commission, for reference in public tenders: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015D1302 Implemented in Belgium (Filip.migom@mips.be) in 23 sites Implemented in France in over 50 sites: Hospitals of Assistance Publique – Hôpitaux de Paris (AP-HP), Lyon and Bordeaux (Filip.migom@mips.be) and Paris American Hospital (Thierry-Alain.KERVELLA@ahparis.org) Implemented in the Netherlands in 65 sites (Filip.migom@mips.be) Implemented in Spain at 1 site (Filip.migom@mips.be) Implemented in more than eight sites in Japan (IHE-Japan: http://www.ihe-j.org/en/ and JAHIS: https://www.jahis.jp/index_en/)
Laboratory Specimen Barcode Labeling (LBL)	5		Workflow of container preparation for lab automation	Implemented in more than six sites Italy (Inpeco - riccardo.castagna@inpeco.com) Implemented in more than six sites in Japan (IHE-Japan: http://www.ihe-j.org/en/ and JAHIS: https://www.jahis.jp/index_en/)
Laboratory Code Set Distribution (LCSD)			Workflow of exchanging information about available laboratory services	Implemented in France: 39 hospitals of Assistance Publique – Hôpitaux de Paris (AP-HP) (Sylvie.cormont@aphp.fr) National reference labs CERBA and BIOMNIS communicate their catalogs to hundreds of corresponding labs. Labo France is a group of more than 150 laboratories, sharing its catalog of a central specialized lab Eight additional sites (Filip.migom@mips.be)

				Implemented in two sites in Belgium (Filip.migom@mips.be)
Transfusion Medicine – Administration (TMA)			First in a set of profiles to support transfusion medicine – this covers the reporting of completion of transfusion and related adverse events	Implemented in a three sites in Belgium and one in the Netherlands (Filip.migom@mips.be) and the UK (Drutz@epic.com)
LDA				Roche is using in preanalytical systems
LPOCT				Roche is using

Note: *Japanese vendors don't register their products into the IHE International product registry – Japan: LTW = 11 vendors, LBL = 9 vendors, LAW = 5 vendors

Newly published profiles looking for implementers:

Laboratory Clinical Communications (LCC)	Supports ordering adjustments from the filler and follow up orders from the placer
Digital Pathology - Image Acquisition (DPIA)	Workflow for ordering digital images in Anatomic Pathology labs
Specimen Event Tracking (SET)	Requirements and data elements for tracking any kind of specimen movement and operations
Radiology Pathology Concordance (RPC)	Compares data alignment between radiological and Anatomic Pathology reports for same patient/case

Significant Deployment Activity:

- Uptake of the LAB domain by the major companies of the in vitro diagnostic industry, via the IVD Industry Connectivity Consortium (IICC). The LAW profile has become a Clinical Laboratory Standards Institute (CLSI) standard in April 2019 (AUTO-16) which should raise its visibility. Also the Federal Food and Drug Administration (FDA) in the US has a project that includes promotion of LAW implementation called Systematic Harmonization and Interoperability Enhancement for Lab Data (SHIELD) and CLSI published a guidance document / report that explains how LAW interconnects with other laboratory related standards in the US in May 2023 (CLSI. Semantic Interoperability for In Vitro Diagnostic Systems. 1st ed. CLSI report AUTO17. Clinical and Laboratory Standards Institute; 2023).
- France developed and published constraint on LCDS and combined LTW and ILW transactions, which will be tested at EU Connectathon 2023: http://www.interopsante.org/412_p_15688/documents-publics-de-reference.html

Demonstrations and Other Events:

- IHE Japan Connectathon – October 17-21, 2022 in Asakusa, Tokyo, Japan
  - LAB was canceled in the same manner as last year
- IHE Joint European/North American 2022 Connectathon – September 12 – 16, 2022 Montreux, France and Atlanta, GA
  - LTW was tested by 2 new vendors; XD-LAB was tested by tested LTW, 3 returning and one new vendors, no other profiles were tested
- Promotion Activities
  - Mr. Naomi Ishii and Ms. Megumi Kondo gave an IHE Tutorial session titled 'Let's become an IHE Certified Technician!' at the 26th JAMI – Japan Association for Medical Informatics Convention on 30 Jun. 2022
  - Ms. Megumi Kondo gave a presentation titled 'IHE PaLM Update' at the 20th Annual Meeting of Japanese Society of Digital Pathology on 26 Aug. 2022
  - Updated the US Interoperability Standards Advisory (ISA) with better descriptions of the IHE LAW profile and other IHE profiles (https://www.healthit.gov/isa/recent-isa-updates)

- Newly published documents
  - Digital Pathology Aid for Telemedicine (DP-AT): Providing access to digital images during Telemedicine consultations (Nov 18, 2022)

Trends:

- Working with IHE to promote participation in Connectathons by
  - Held webinar on March 30, 2023 with introduction to the PaLM domain and highlighting the profiles we hope to test at the September 2023 EU Connectathon in Rennes, France:
    - Laboratory Testing Workflow (LTW) with a 50% discount for testing it
    - Laboratory Analytical Workflow (LAW) with a 50% discount for testing it
    - Digital Pathology - Image Acquisition (DPIA)
    - Specimen Event Tracking (SET)
- Digital Pathology (DP) profile group
  - Close collaboration with DICOM WG26 continues and highlights need for
    - additions to the DPIA profile
    - finalization of DPIO to support fully populated DICOM metadata
- The PaLM domain brings its contribution to international projects specifying patient summaries, which include laboratory results: The HL7/CEN IPS project, and the European project Trillium II.
- The IVD Industry Connectivity Consortium (IICC) is helping promote uptake of PaLM Profiles by the major companies of the in vitro diagnostic industry.
- Intra-Laboratory Workflow (ILW)
  - Netherlands are implementing national network of laboratories – ILW for microbiology reference laboratory testing is being evaluated
  - France has launched IHE France WG with vendors and users to implement this for various connections between laboratories, including with the national blood transfusion service management

Summary of Future Plans:

- Work ongoing and planned for publication in 2023.
    - Updates to existing profiles:
        - PaLM Technical Framework to facilitate the uptake of its content, and to cover the issues and additional use cases coming back from the field (hospitals having deployed existing profiles), including Sharing Laboratory Reports (XD-Lab) to accommodate needs for document based lab report exchange in Europe (e-Xhealth) – should publish TF-v11 in July 2023
        - Laboratory Clinical Communications (LCC) – update to July 2023
        - Digital Pathology - Image Acquisition (DPIA) – update to August 2023
    - Continue to adapt PaLM profiles to support digital pathology in collaboration with DICOM WG 26. Support for additional steps after publication of the Image Acquisition (DPIA) Supplement for Trial Implementation in August 2020 will focus on Order Management (DPOM) and Digital Pathology and Structured Reporting (DPSR)
- Expand Laboratory Testing Workflow (LTW) and potentially also the Inter-Laboratory Workflow (ILW) to support proficiency testing (PT) in the US
- Transfusion Medicine – expand this suite to cover ordering next (LAB-1 and for result reporting LAB-3 are being used in the real world for this and while it is working, it is not ideal)
- Discussion about migration to FHIR for several profiles in the lab domain to ensure that work in several different countries does not diverge and we can provide a universal profile
    - Lab result reporting (LAB-3 in LTW) is in use in several European countries
    - XD-LAB is used in several European Countries; X-ehealth also created a FHIR IG based on this resource, IHE PaLM will review the IG and see, if we can adopt it into the offerings
    - Laboratory Code Set Distribution (LCSD) based on the FHIR standard (catalog resources) which relies on R5 artifacts; FHIR R5 was published March 2023, so the FHIR catalog IG can now be published