Digital Pathology and Interoperability Framework 5-Layer Model

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KEY LEARNINGS

1. What is digital pathology?
2. What is interoperability?
3. How to implement the interoperability framework model
4. Aspects of interoperability within and between institutions
5. Interoperability best practices
6. Example: Dutch National WSI exchange Project PIE

WHAT IS DIGITAL PATHOLOGY?

"Digital pathology is a dynamic, image-based environment that enables the acquisition, management and interpretation of pathology information generated from a digitized glass slide."[1]

"Healthcare applications include primary diagnosis, diagnostic consultation, intraoperative diagnosis, medical student and resident training, manual and semi-quantitative review of immunohistochemistry (IHC), clinical research, diagnostic decision support, peer review, and tumor boards."[1]

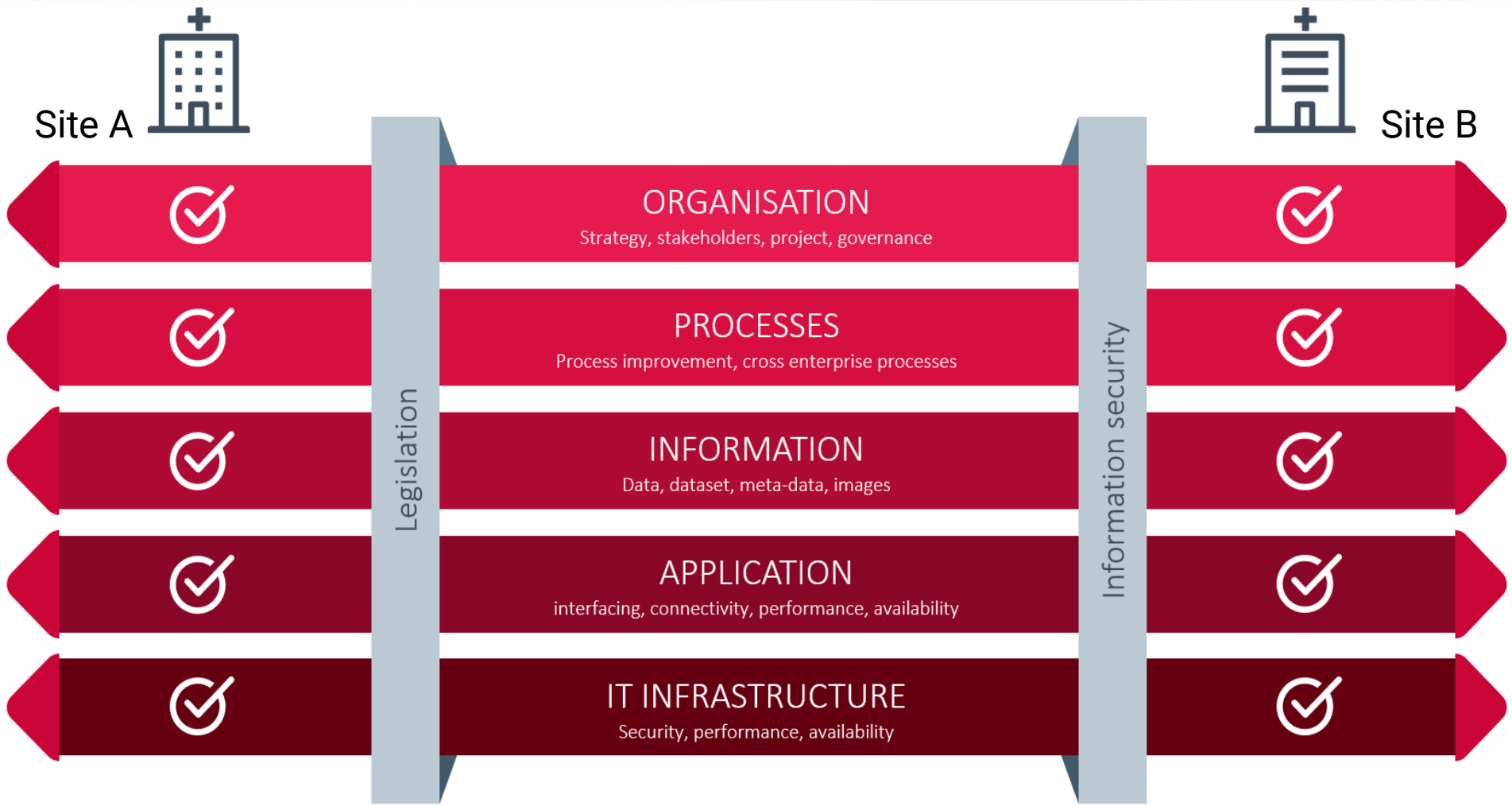
WHAT IS INTEROPERABILITY?

"..the ability of different information systems, devices and applications ('systems') to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally."[2]

INTEROPERABILITY RELEVANCE FOR DIGITAL PATHOLOGY

- Applications include:
  1. Primary diagnosis
  2. Computational pathology
  3. Second opinion/diagnostic consultation
  4. Interoperative procedures
  5. Patient referrals to other hospitals
  6. Tumor boards
  7. Research
  8. Education
- By scanning conventional glass slides into digital images, Whole Slide Images (WSI) are created. These images have the capacity to interact with multiple applications
- Applications can be internal within the lab and/or hospital (including multiple sites) or external to outside organizations

INTEROPERABILITY FRAMEWORK 5-LAYER MODEL



INTEROPERABILITY FRAMEWORK – KEY TAKEAWAYS

- For a successful project outcome, each layer needs to be addressed, and systems need to work together for a seamless integration
- Often projects focus on some but not all layers; this often results in avoidable issues in the short or long term
- Involve all relevant stakeholders, representing the different layers in the project, early and often throughout the deployment

ASPECTS OF INTEROPERABILITY – WITHIN AN INSTITUTION

- These components are part of a digital pathology solution design:
  - Slide scanners
  - Storage/Image Management System (IMS)
  - Display system
  - Algorithms for computational pathology
- The digital pathology solution is connected to a Laboratory Information System (LIS) and requires a barcode labeling system
- The patient Electronic Health Record (EHR) plays an important role in the workflow
- Some of the components are part of an enterprise (hospital) infrastructure
- The IMS may be connected to a Vendor Neutral Archive (VNA) solution which acts as a source for sharing images with a Health Information Exchange (HIE)

ASPECTS OF INTEROPERABILITY – BETWEEN INSTITUTIONS

- Formalize agreement among networked laboratories regarding financial/invoicing requirements and other needed contractual clauses
- Design and implement cross-enterprise workflows including:
  - Patient safety and security (Europe: GDPR legislation; USA: HIPAA compliant)
  - Reporting case results
  - Digital order and result (including possible synoptic reports)
  - Combine requests (e.g., second opinion), patient data, and images in a consistent view
- Standardization of the required information between laboratories streamlines operations and eases implementation
- Interfaces are needed because different applications are involved: LIS, IMS, and/or Picture Archiving and Communication Systems (PACS)
- Ensure local and federal guidelines are followed to create a secure infrastructure

INTEROPERABILITY BEST PRACTICES

- Involve all relevant stakeholders based on the 5-layer interoperability framework
- Make cross-enterprise and collaborative use cases part of the initial design
- To select a LIS or digital pathology vendor, implement a selection process that includes interoperability criteria
- Use international standards when possible - Integrating the Healthcare Enterprise (IHE), Digital Imaging and Communications in Medicine (DICOM)

Download International Healthcare IT Standards here.

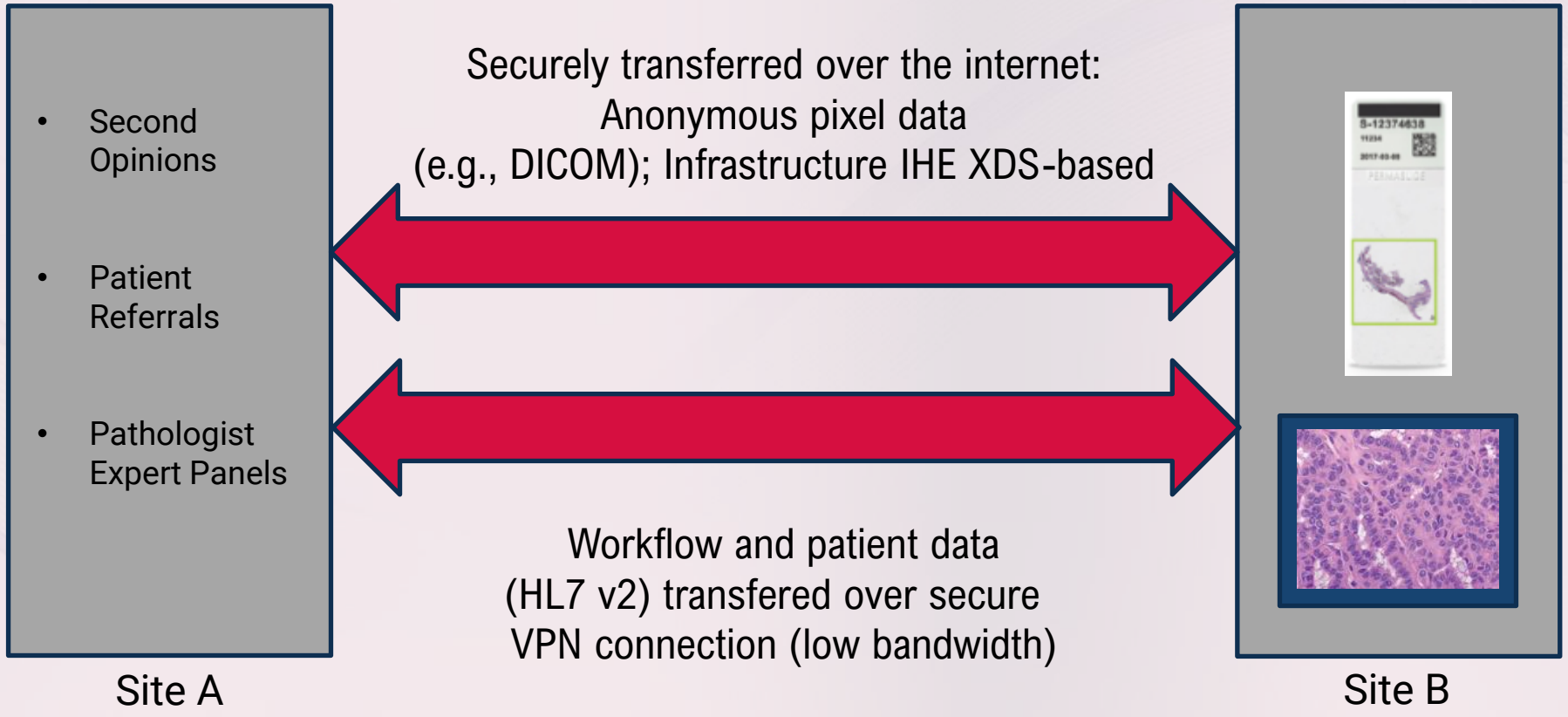
EXAMPLE - DUTCH NATIONAL WSI EXCHANGE

Project PIE: Pathology Image Exchange

- National infrastructure to exchange WSI between (potentially) all pathology laboratories for:
  - Second opinions
  - Patient referrals to other hospitals
  - Pathologist expert panels
- Provides a solution for process, information, application, and infrastructure parts of the interoperability framework
- Exchange information and data following all regional data privacy laws

EXAMPLE - DUTCH NATIONAL WSI EXCHANGE (CONTINUED)

PATHOLOGY IMAGE EXCHANGE (PIE) IS DEVELOPED BASED ON INTERNATIONAL HEALTHCARE IT STANDARDS



SUMMARY

- Interoperability is essential for a successful collaboration between laboratories
- Use Interoperability Framework 5-Layer Model:
  - Organization – strategy, stakeholders, project, governance
  - Process – process improvement, cross-enterprise processes
  - Information – data, dataset, meta-data, images
  - Application – interfacing, connectivity, performance, availability
  - Infrastructure – security, performance, availability
- Involve and align all relevant stakeholders
- Evaluate multiple vendors, including interoperability aspects – before signing a contract
- Make use of international healthcare IT standards, which are emerging for digital pathology

REFERENCES

1. About Digital Pathology. DPA. https://digitalpathologyassociation.org/about-digital-pathology
2. What is Interoperability? Himss.org. Published March 9, 2016. https://www.himss.org/what-interoperability