INJECTING DIGITAL PATHOLOGY INTO DIAGNOSTIC LABORATORY

IS IT POSSIBLE TO INTEGRATE PAIN(LESS)LY?

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Beds: 1,597  
Staff Strength: 9,888  
Annual Patient Discharges: 78,651  
Annual Outpatient Attendances: 687,242  
Annual Emergency Attendances: 146,899  
Annual Inpatient and Elective Operations: 80,859  

Note: FY2013 Figures (year ended 31 Mar 2014)  

SGH Campus:  
Includes 4 specialist centres (NHCS, NCC, NDC, SNEC)
Largest pathology department in Singapore
Supports SGH, specialist centres in SGH Campus and affiliated institutions

Staff Pathologists: 27
Residents and Trainees: 16
Surgical pathology cases: ~46,100
Frozen Section cases: ~1,900
Immunohistochemistry Tests: ~58,600
Gynaecology Cytology Cases: ~20,200
Non-Gynaecology Cytology Cases: ~14,700

Note: 2013 Figures
SGH Digital Pathology Expansion Project
- Background

- 2009 – Pilot whole slide imaging (WSI) implementation; supports predominantly education and research
- 2011 – Planning for expansion of WSI into diagnostic workflow
- 2013 – Implementation of new WSI solution to support expanded use
- 2014 – Deployment of new WSI solution
SGH Digital Pathology Expansion Project
- Background

- 2009 – Pilot whole slide imaging (WSI) implementation; supports predominantly education and research
- 2011 – Planning for expansion of WSI into diagnostic workflow
- 2013 – Implementation of new WSI solution to support expanded use
- 2014 – Deployment of new WSI solution

- Initial study of workflow and requirements
- Pre-emptive introduction of workflow alterations
SGH Digital Pathology Expansion Project
- Objectives

- Ability to integrate WSI into diagnostic workflow, including integration with laboratory information system (LIS)
- Ability to support remote consultation between frozen section laboratory in operating theatre and main laboratory in Academia
- Ability to support collaboration and remote access to images beyond SGH campus
SGH Digital Pathology Expansion Project
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- Ability to integrate WSI into diagnostic workflow, including integration with laboratory information system (LIS)
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DIAGNOSTIC WORKFLOW - INTEGRATION WITH LIS
Why Integrate with LIS?

- Reduce separate double entry of information into WSI system
  - Even if key patient and case information can be incorporated into 2-D barcode in slide label for consumption by WSI system at the point of scanning, there is still limitation to the amount of information possible

- Changes of patient and case information in LIS are automatically updated into WSI system
  - Continuous update of case information through the diagnostic workflow is the norm
  - In standalone WSI system implementations, with time, there will be increasing discrepancy of information between most up-to-date information in LIS and old information in WSI system

- Allow ready scale up of slide scanning and sustainable information management
  - LIS will likely remain central to information management in diagnostic setting and duplication of information management efforts in multiple system may not be sustainable

- If properly done, allow synergy to be built between WSI system and LIS in terms of functionality and business rules, and novel approaches to overcome system limitations
Integrating with the LIS - Challenges

- Many users of LIS and many existing system flows even if focusing on specific modules. Need to ensure that other modules are also not affected in the course of implementation.
- Approach needs to be fairly comprehensive, with ability to address exceptions even if these are relatively less common.
- Integration can be potentially cumbersome if not well designed or thought out. It may not be easy to reverse or reign back a “bad” design decision, especially post “go-live”.
- Need to ensure your LIS vendor is willing to go through this digital pathology journey with the users, including coming up with solutions and creative ideas.
SGH Digital Pathology Expansion Project - Diagnostic Workflow and LIS Integration

Hospital Information System (HIS) and Electronic Medical Records (EMR)

LIS

WSI

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SGH Digital Pathology Expansion Project - Diagnostic Workflow and LIS Integration

Linked via barcode with slide ID

Hospital Information System (HIS) and Electronic Medical Records (EMR)
SGH Digital Pathology Expansion Project
- Diagnostic Workflow and LIS Integration

Patient Creation/Update
Case Creation/Update
Slide Creation/Update
Image Import Notification
Image Delete Notification

Hospital Information System (HIS) and Electronic Medical Records (EMR)

LIS

WSI

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SGH Digital Pathology Expansion Project - Diagnostic Workflow and LIS Integration

Actual and Potential Users of LIS and WSI – Comprehensive Department Level Involvement

Hospital Information System (HIS) and Electronic Medical Records (EMR)

LIS

WSI

- Patient Creation/Update
- Case Creation/Update
- Slide Creation/Update
- Image Import Notification
- Image Delete Notification

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SGH Digital Pathology Expansion Project - Diagnostic Workflow and LIS Integration

Actual and Potential Users of LIS and WSI – Comprehensive Department Level Involvement

Patient Accountability
Case Accountability
Specimen Accountability
Slide Accountability

LIS
WSI

Hospital Information System (HIS) and Electronic Medical Records (EMR)

Patient Creation/Update
Case Creation/Update
Slide Creation/Update
Image Import Notification
Image Delete Notification
Implementation Overview

0 mth
- Project kick off
- Set up DPS staging environment

1 mth
- User Champion training
- Lab workflow review

2 mth
- DPS awareness session in pathology department
- Trial prospective scanning in lab on DPS staging environment
- Initial study of lab workflow

3 mth
- DP workflow study and review
- Finalisation of requirements and design

4 mth
- DPS Production Technical Go-Live
- Clinical Validation (CAP recommendations)
- LIS Readiness

5 mth
- Integration Testing (including User Acceptance Testing)
- End-users Training
- Go-live preparations

6 mth
- Business Verification
- Clinical Go-Live
- Diagnostic Scanning Ramp Up

7 mth
- Finalisation of requirements and design

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5 mth: Integration Testing (including User Acceptance Testing)
- End-users Training
- Go-live preparations
Resources and inputs
- Wide coverage…do not forget support staff

Actual and Potential Users of LIS and WSI – Comprehensive Department Level Involvement

- Head of Pathology Department
- Head of Histopathology Section
- Clinical Champion
- IT Project Lead

Core Project Team
- Clinical Champion
- Clinician Support
- Laboratory IT/Admin Manager
- IT Project Manager
- Senior Medical Tech
- DP Med/Lab Techs

Extended Project Team
- Med Techs and Lab Techs
- Clerical
- Pathologists - Early Adopters
- Education Reps
- Research Reps

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7 mth
Workflow Studies
- Identifying workflow that matters now and future

Do not just think about now….ensure future proofing

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<td>Accessioning &amp; Processing</td>
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<tr>
<td>2</td>
<td>Routine lab workflow</td>
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Provides a checklist and scope for use in requirements, design and testing

Priority based on what will affect requirements and design most
## Workflow Studies
- Identifying workflow that matters now and future

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Next…….

Examples of how we address these…..
WSI systems must be kept up-to-date of patient information changes and updates.

LIS remains the “source of truth” for WSI system as there might be patient information sources other than HIS.

This key premise remains one of the most intricate piece to implement as other upstream systems are involved; trigger need to be as automated as possible.

Extending the “patient” concept to research and education scenario; require a department level naming convention:
  - Research – Project Name
  - Education – Education Set Name (e.g. mock exam sets, conference sets etc.)
Case Accountability – Frozen Section (1)

- Case type is based on prefixes (e.g. “PB” for surgical pathology, “NG” for non-gynaecological cytology)
- Frozen section (FS) laboratory is located remotely within the campus from the main laboratory
- Pre-assignment of biopsy numbers in frozen section (using pre-printed labels) as practiced in main laboratory was not possible as both used the same prefixes (i.e. “PB”)
- Hence upfront case assessment of frozen section specimen into LIS was not possible
- Review of this issue occurred 1 year prior to actual new WSI system implementation
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Review of this issue occurred 1 year prior to actual new WSI system implementation
One of the aims of the project is for remote consultation between FS laboratory and main laboratory (e.g. subspecialty opinion), which requires scanning of FS slide upfront.

Although it is possible to handle scanning and entry of patient information manually into WSI system without LIS accessioning and labelling, this is not favoured in view of the following:

- Possible discrepancy with subsequent LIS accessioning
- Combining with frozen follow up specimen is likely going to be a manual process in WSI system and possibility of error (e.g. mismatch) increases
Case Accountability – Frozen Section (4)

- Working principle: Need to ensure that case already exist (i.e. case must be accountable) in LIS and WSI system at the point in time of scanning and not later.
- Solution: Introduction of a new prefix “PF” unique for frozen section cases that can be assigned directly in the FS laboratory
  - Prefix introduced 1 year prior to introduction of new WSI system
  - Ensure logistics (e.g. pre-printed labels) issue are sorted out and department is familiar with the concept
New procedures introduced in LIS to distinguish between FS slide and subsequent paraffin block slides

- High acuity nature of FS laboratory demand quick LIS accessioning and slide ID entry and “quick method” was introduced during actual WSI expansion project

- Other benefits of unique “PF” prefix
  - Clear identification of FS cases
  - Ease of tracking of FS workload
  - Ease of retrieving FS cases for audit
Previously: when IF and EM specimens were received, these were noted in the request forms and reports, but were all grouped under specimen/part “A” in the LIS, with separate manual tracking by special laboratory teams.

Single part approach was also in view of single microscopic description generated against all the materials rather than separate parts.

Issues with such approach:
- If we scan or incorporate WSI or other images from IF and EM specimens, or should they be subsequently used as paraffin materials, the blocks and slides thus generated may not be reflective of their origin (i.e. no specimen accountability).
Solution: Assign different parts to each of specimens (e.g. formalin, IF and EM)
- Allow downstream accountability of blocks and slides with clear specimen “parent”
- Future proofing of solution even if current solution address routine surgical pathology only

Issues to address:
- Change in reporting practice to generate a single microscopic description incorporating multiple parts
- IF and EM teams need to incorporate practice to update LIS

Other benefits of separate part assignments
- Ease of identifying presence of IF and EM specimens directly from LIS
- Potential of tracking IF and EM workload from LIS prior to report completion
Similar issues were addressed for materials received from external institutions for consultation.
Focus of LIS data entry previously was on blocks and specific procedures for generating slide labels; there was no slide ID concept as slides with same procedure and from same block used the same slide label print out.

Immunohistochemistry (IHC) procedures were documented in LIS but not coded as specific procedures as the slides generated directly from the automated stainers were submitted “as is” with the original label.

- No slide ID concept for IHC slides in LIS
- Case accession and block numbers were keyed in as text data in automated stainers
- Tracking of stain orders were done manually and via automated stainers
Introduction of WSI scanning in diagnostic workflow require comprehensive slide ID concept (i.e. slide accountability)

- Require relatively broad consideration and is one of the most major change for the laboratory if not previously introduced

Exceptions, including double colour IHC stains need to be rationalised (e.g. coded procedure “DUAL-IHC” and qualifying text “CD3bCD2r” for CD3 in brown, CD2 in red)
Extensive discussions took place to ensure various “exceptions” (though not altogether rare), like double colour IHC stains, two blocks in single slides and repeat stains are considered.

Actual practice of slide ID require strict discipline within laboratory, as there can only be one slide ID for a single physical slide submitted (i.e. NO reprint for a different physical slide).

- Education and change management for technical staff.

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All procedures, including IHC, need to be coded and specified in LIS per slide ID.

Other benefits from introduction of LIS slide management:
- More accurate tracking of workload by actual number of slides generated
- Potential to automate tracking of IHC and other specific procedure orders
Diagnostic Workflow and LIS Integration with WSI system – Reviewing guiding concepts and principles

Actual and Potential Users of LIS and WSI – Comprehensive Department Level Involvement

Hospital Information System (HIS) and Electronic Medical Records (EMR)

LIS

WSI

Patient Creation/Update

Case Creation/Update

Slide Creation/Update

Image Import Notification

Image Delete Notification

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Integration of WSI system into diagnostic workflow is possible with careful planning and discipline.
LIS integration is an integral component of incorporating WSI system into diagnostic workflow.
Formation of core project team with representative members and early involvement of the department with extensive participation across different roles and functions is essential to ensure key considerations are captured while designing LIS integration with WSI system.
Identification and prioritization of workflows to be addressed provides an important checklist for the various stages/phases of implementation.
Ensuring accountability of patient, case, specimen and slide is a key guiding principle for workflow enhancements to successfully integrate WSI system into diagnostic workflow.
Workflow review and enhancement before and during implementation of WSI system with LIS integration provides a good opportunity for process improvements and tightening of governance as well as better workload tracking.
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