Memorial Sloan Kettering Cancer Center

The LIS - Anatomic Pathology (AP-LIS)

Monday, May 21, 2018
S. Joseph Sirintrapun, M.D.
Director of Pathology Informatics
sirintrs@mskcc.org

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Outline

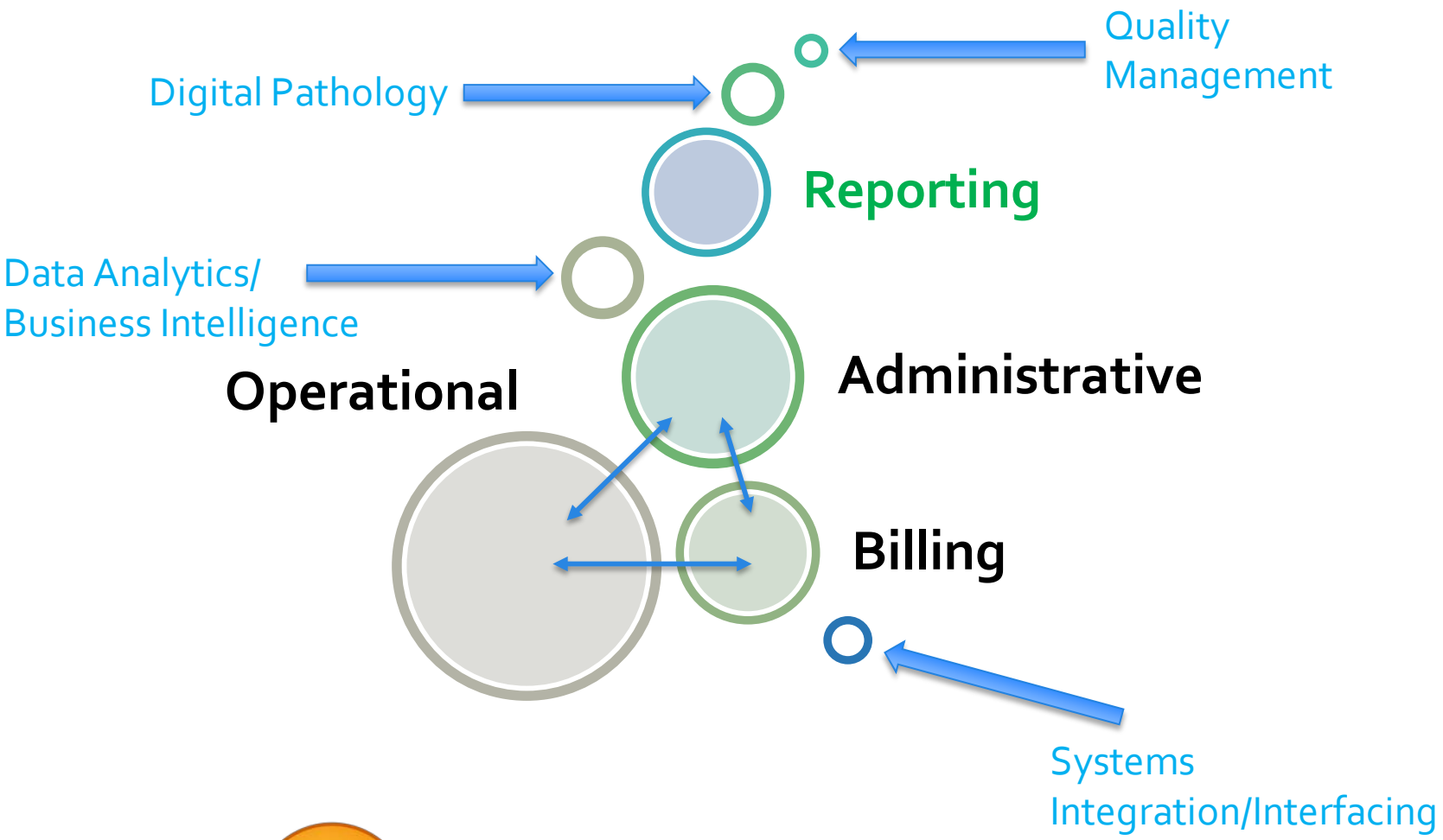
Functionalities of AP-LISs:

- *What they do today*
- *Functionality gaps and opportunities missed*
- *Emerging needs*
  - Integrated reporting
  - Data analytics/business intelligence
  - Quality management
  - Digital pathology

Categories of AP-LIS Users

- Laboratory Staff
- Laboratory Managers
- Pathologists
- Laboratory Directors
- Information Technology Staff
- **Administration**
- Patients

Anatomic Pathology Laboratory Information System (AP-LIS) Functionalities



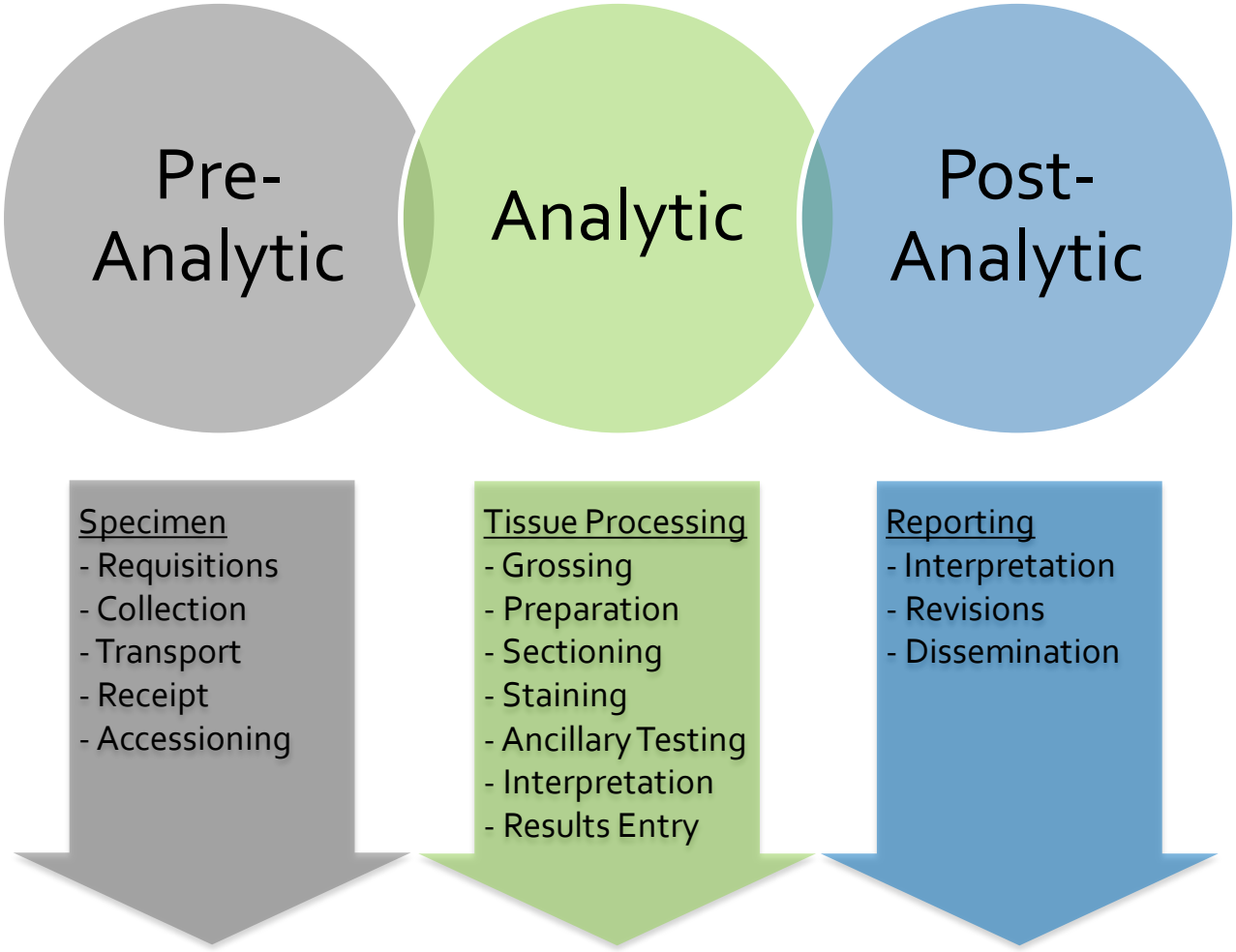
User Friendly Interfaces/Automation

Gaps in Functionalities = Cost ($$ & Safety)

"if the workhorse LIS of a pathology department lacks certain functionalities, there can be substantial up-front capital and long-term maintenance costs to purchase, install, and incrementally operate the additional software modules needed to compensate for the identified functionality gaps."

Dr. Bruce Friedman – CAP Today August 12, 2013

Laboratory Testing Cycle
Anatomic Pathology



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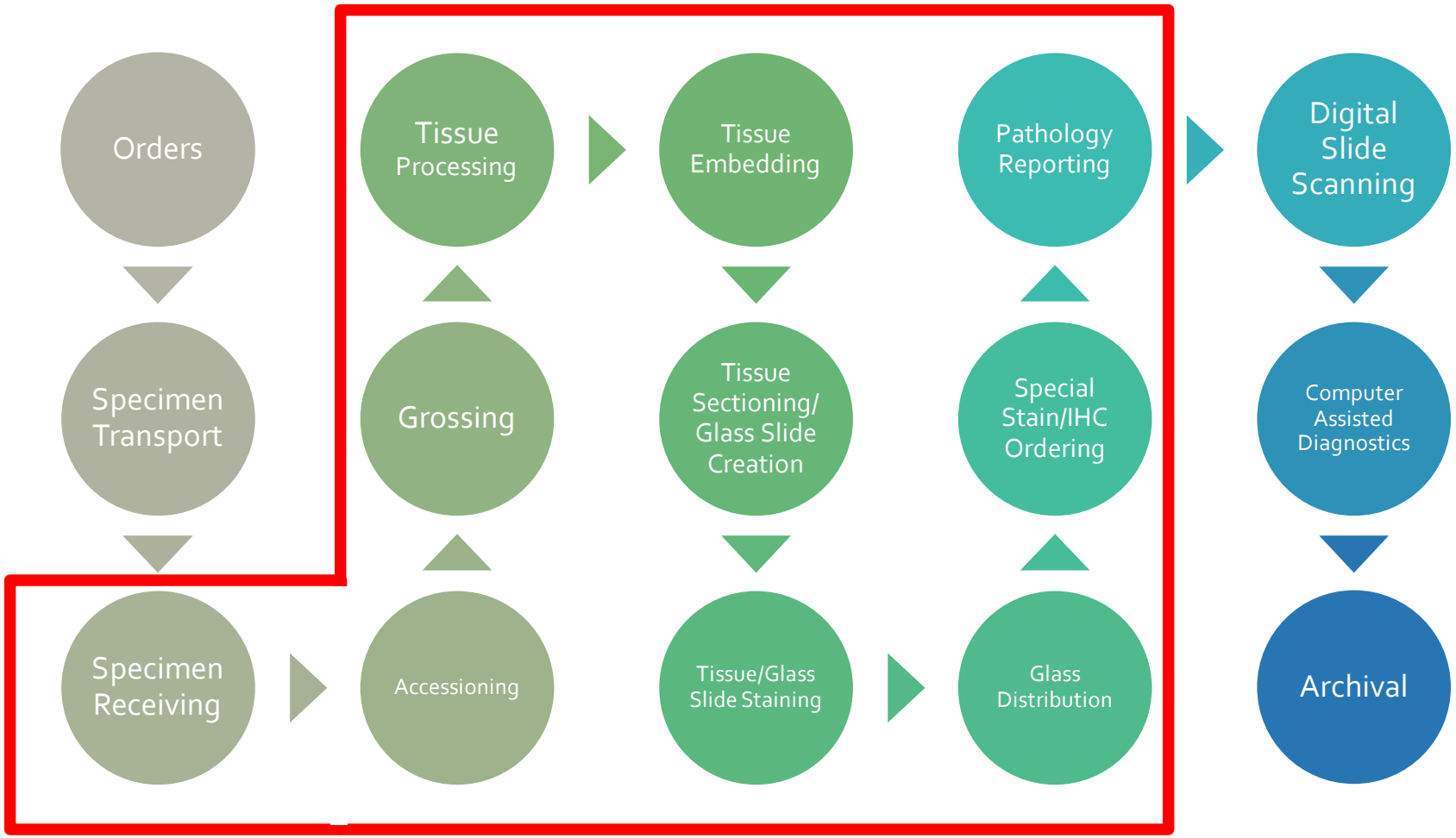
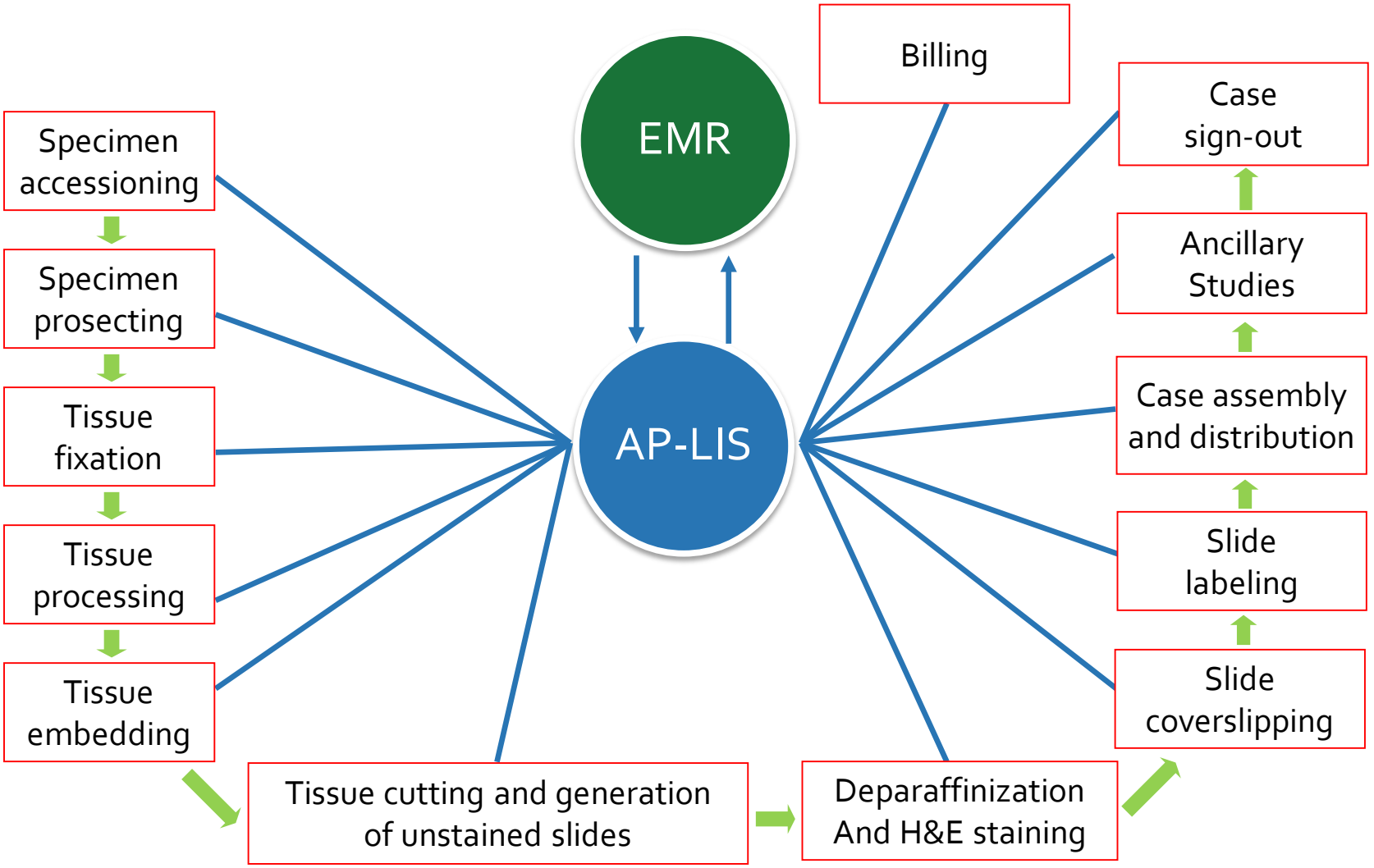
"Comfort Zone" in the Laboratory Testing Cycle for AP-LISs



Anatomic Pathology Workflow and AP-LIS



Specimen Receipt in Lab & Specimen Accessioning

Paper Requisitions or Non-Interfaced Orders

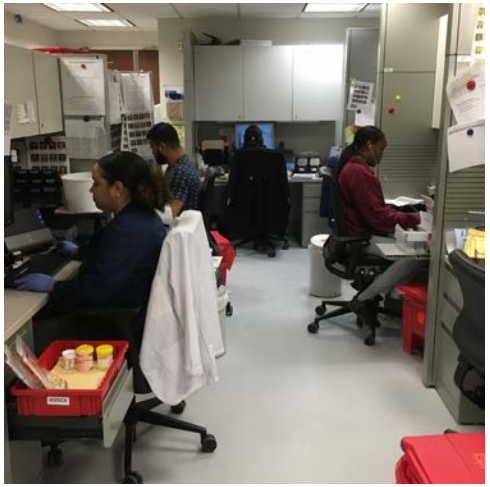
- *AP-LIS assigns unique accession number(s) to specimen(s)*
  - Different "number wheels", distinguish different classes of specimens
  - Accession numbers accommodate multiple specimen parts

Late Pre-Analytic to Analytic

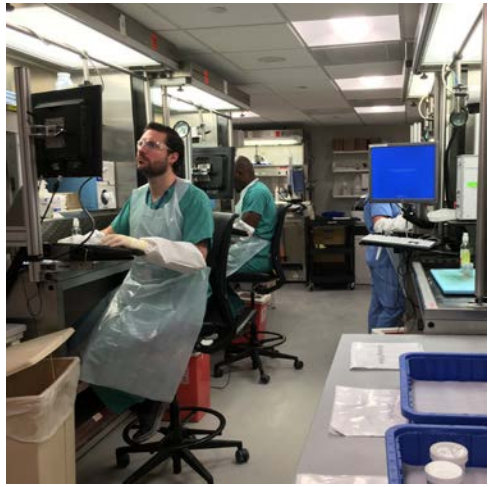
AP-LIS vendors should demonstrate processes for:

- Accessioning
- Grossing

Accessioning



Grossing



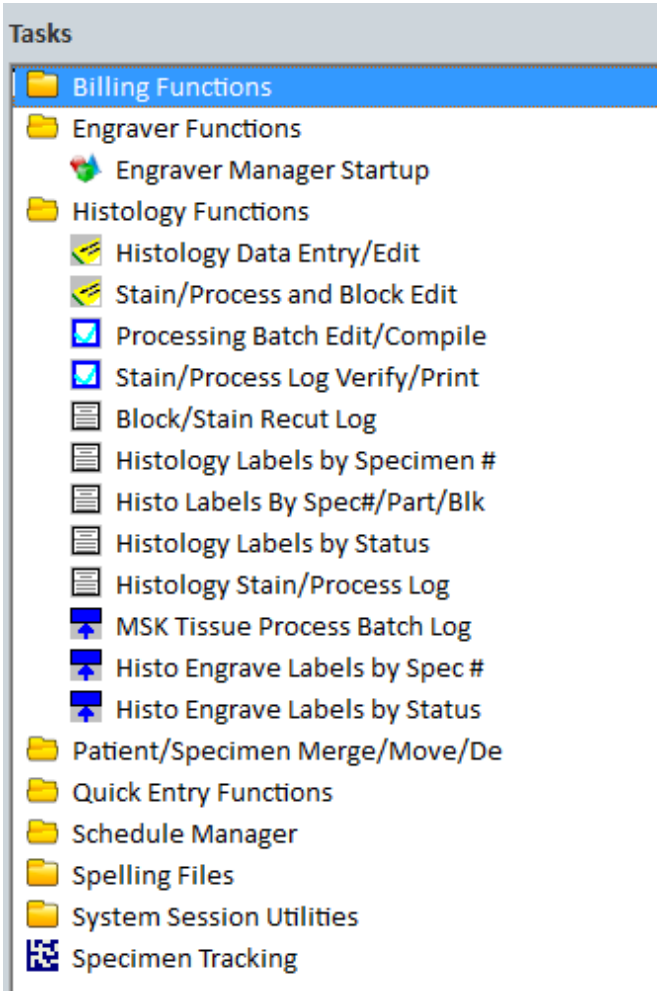
AP-LISs direct slide preparation workflow,
defining worklists of cases and blocks from grossing step

Operational/Administrative Functionalities
Specimen Asset Tracking

AP-LIS vendors should demonstrate processes for:

- Pathology orders (i.e. specimen tracking and pathologist assignment)

Histology Lab



AP-LIS directs slide preparation workflow

"Asset" tracking

- Occurs through bar code labels and defined points of scanning

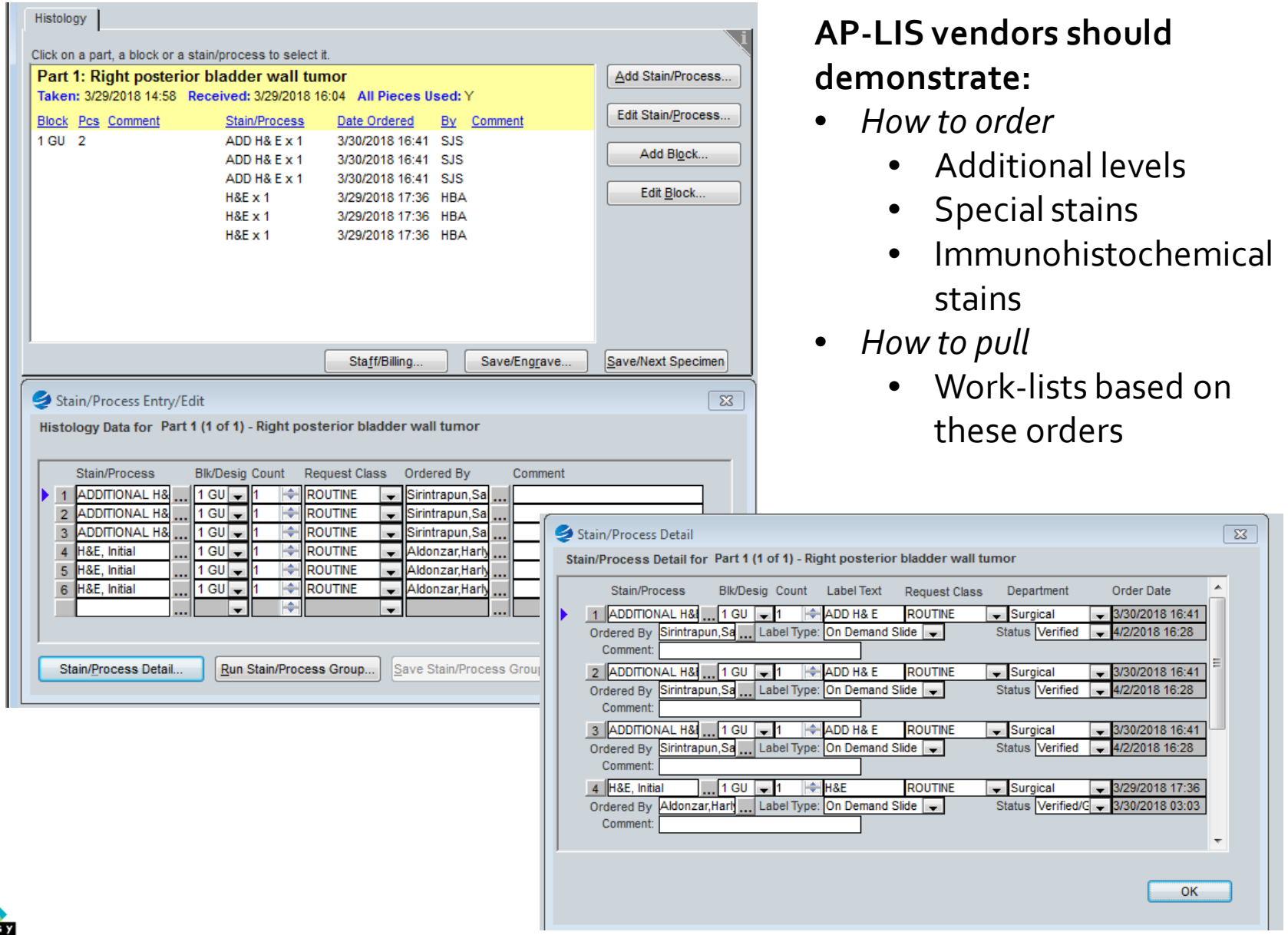
AP-LIS histology module

- Houses protocols for levels and staining definitions

Embedding/Sectioning

Slide Organization/ Case Preparation

Operational/Administrative Functionalities



AP-LIS vendors should demonstrate:

- *How to order*
  - Additional levels
  - Special stains
  - Immunohistochemical stains
- *How to pull*
  - Work-lists based on these orders

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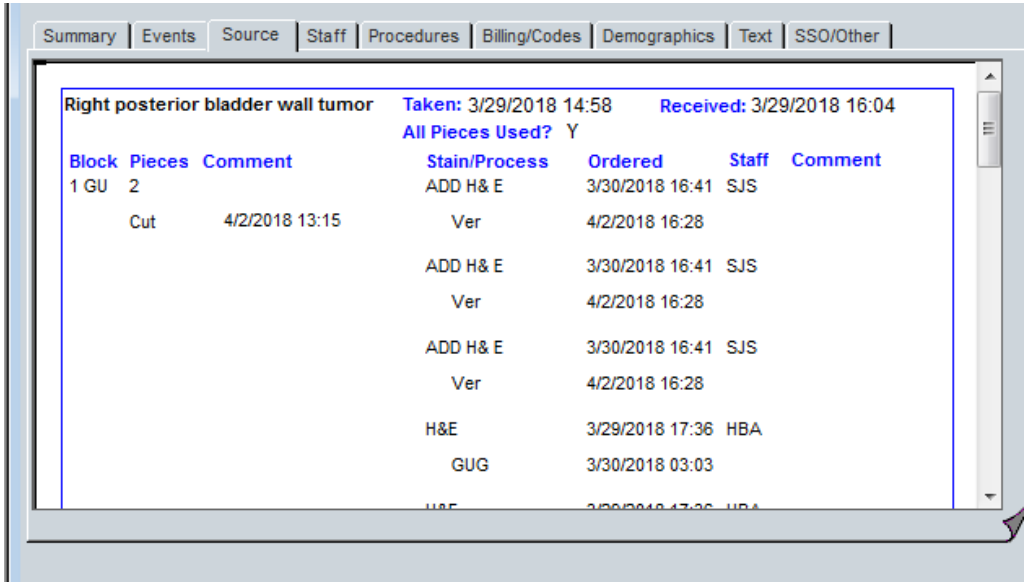
AP-LIS create histology laboratory logs

Example of section level log

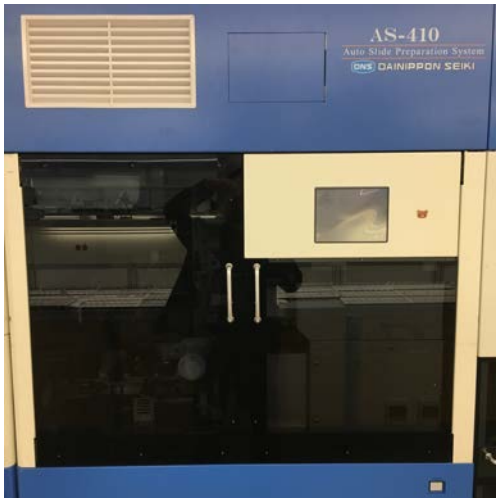


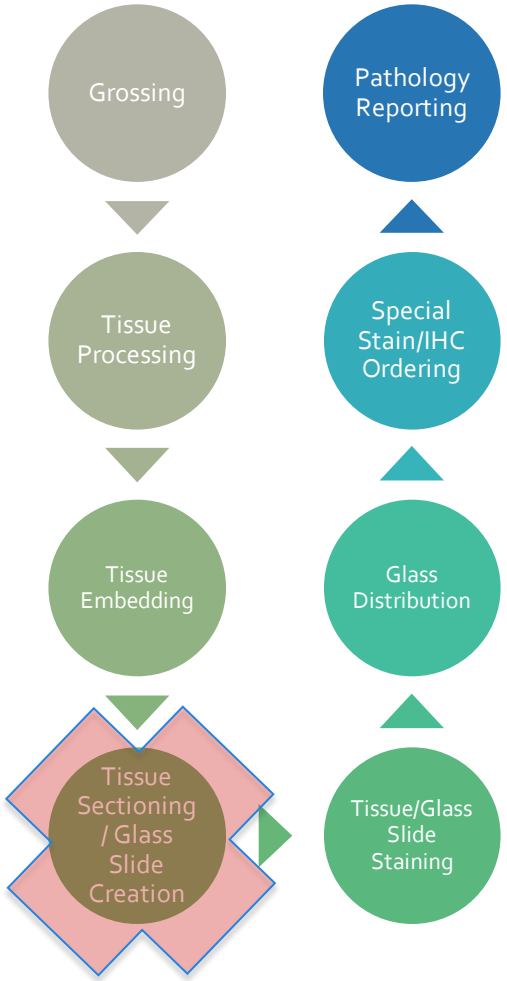
Additional specific logs include:

- Special stains
- IHC

Analytic
Future Opportunities for Disruption

Automated Tissue Sectioners





AP-LIS Dictionary Set-Up/Design

Dictionaries and maintenance tables

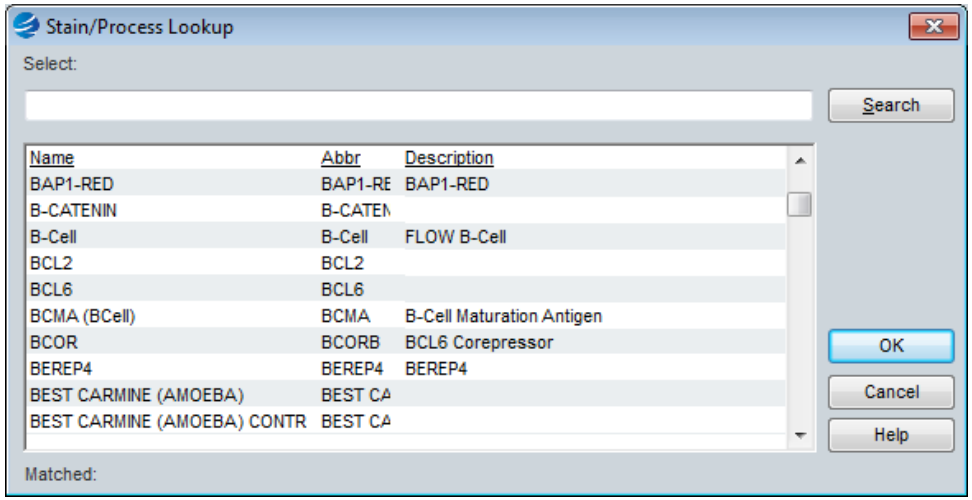
- *Tailor the AP-LIS to YOUR laboratory*

- *To effectively construct/maintain:*
  - Perform by experts in information management
  - Involve users (i.e. pathologist and technical staff)
  - Iteratively test before "putting changes into production"

Defining dictionaries and maintenance tables is critical to successful LIS implementation and lab operation

AP-LIS Dictionary Examples

- Specimen class dictionary
- Part type dictionary
- Person dictionary ((e.g., ordering physician, pathologist, technologist)
- Permission group dictionary
- Billing fee code dictionary
- Quick text dictionary
- Synoptic worksheet dictionary
- SNOMED II code Dictionary
- Procedure dictionary
- Block category dictionary
- Block status dictionary
- Special stain/ immunohistochemistry process dictionary



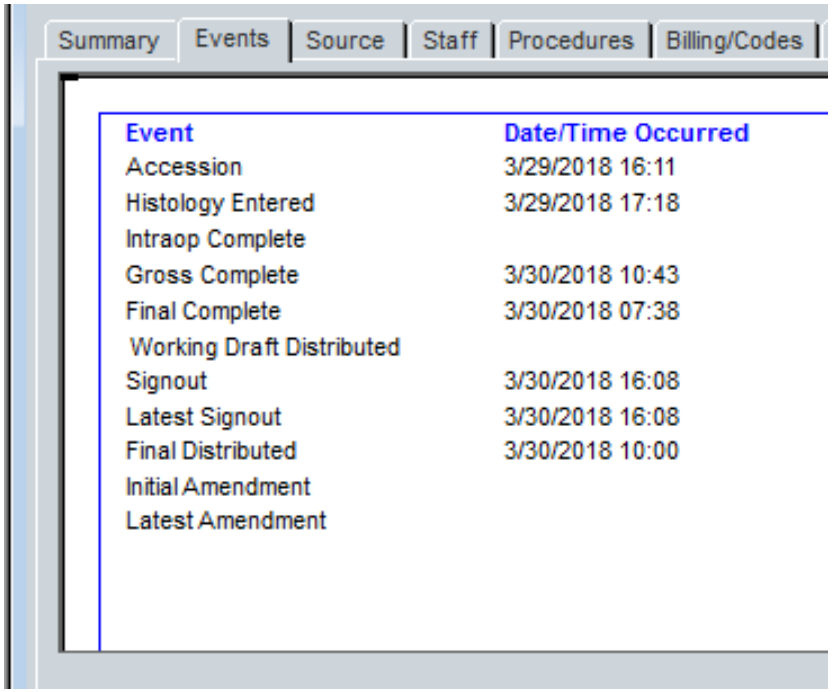
Standards for dictionary setup are lacking

Challenging issue:
Criteria for data definition in different fields and in different dictionaries

- When to create a specimen class?
- When to create a part type?
- Acceptable number for specimen classes or part types?

Specimen Asset and Reporting Tracking Gaps

AP-LISs handle specimen/asset tracking more so during late pre-analytic and analytic phases



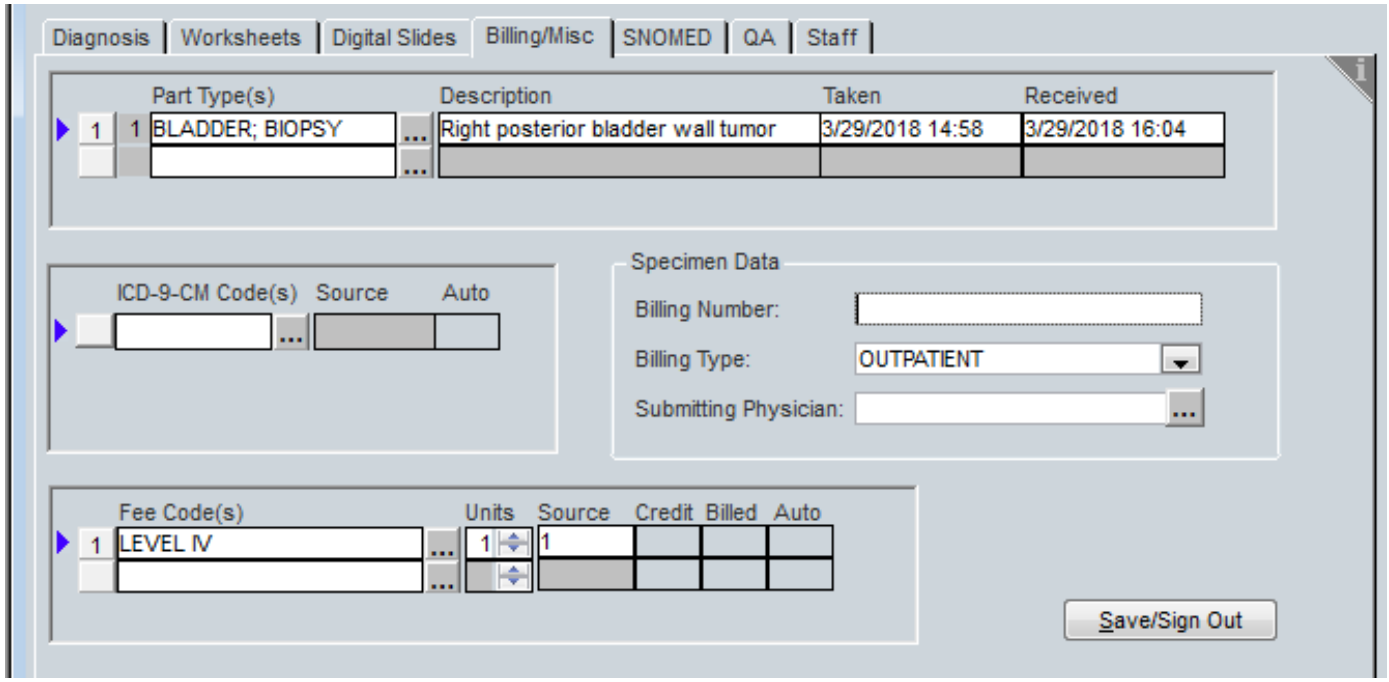
AP-LISs NOT as good

- *Tracking specimen/assets throughout:*
  - Early pre-analytic phase
    - Location - Clinics, ORs, outreach
    - Pre-analytic variables - ischemic time, specimen quality, etc.
  - Post-analytic phase
    - Off-site storage location management
    - Slide scanning processes - retrospective digital slide scanning
  - Analytic phase
    - Transport to various sections within laboratory
    - Slide scanning processes - prospective digital slide scanning

Administrative/Billing Functionalities

AP-LIS vendors should:

- Demonstrate how charges are placed on cases
- Interface with institutional-wide billing systems



User Friendly Interfaces/Automation

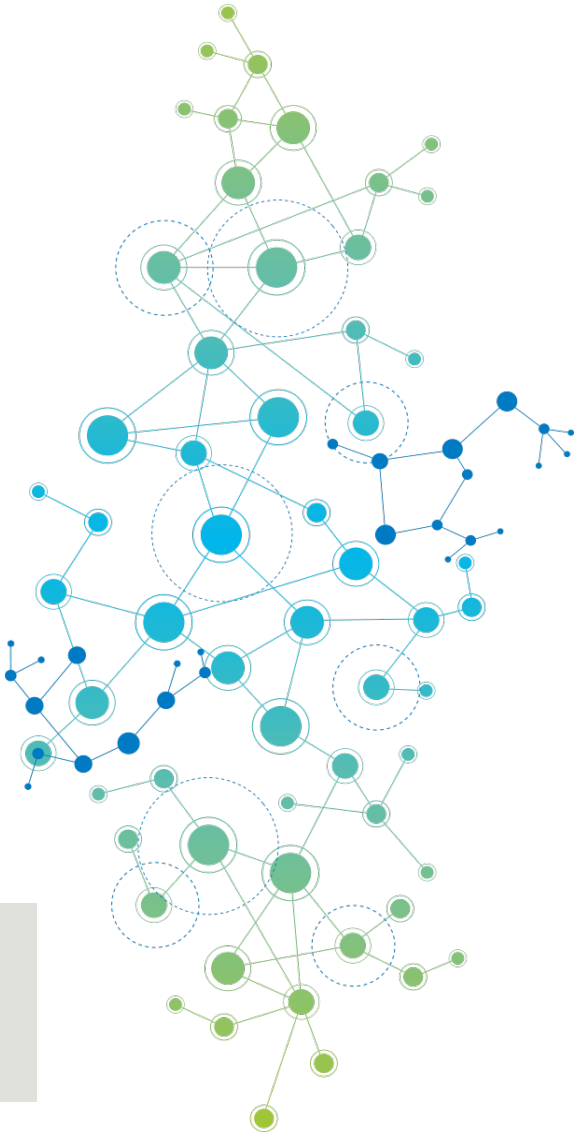
Wishlist for better human and AP-LIS interaction:

- *User interface and navigation should be:*
  - Intuitive and user friendly
  - Lean approach designed
    - Optimizing efficiency and maximizing productivity
  - Minimizing keystrokes, wasted effort and time where manual processes involved
    - Without AP-LIS performance degradation regardless of workload

Sepulveda JL et al. *The Ideal Laboratory Information System.*

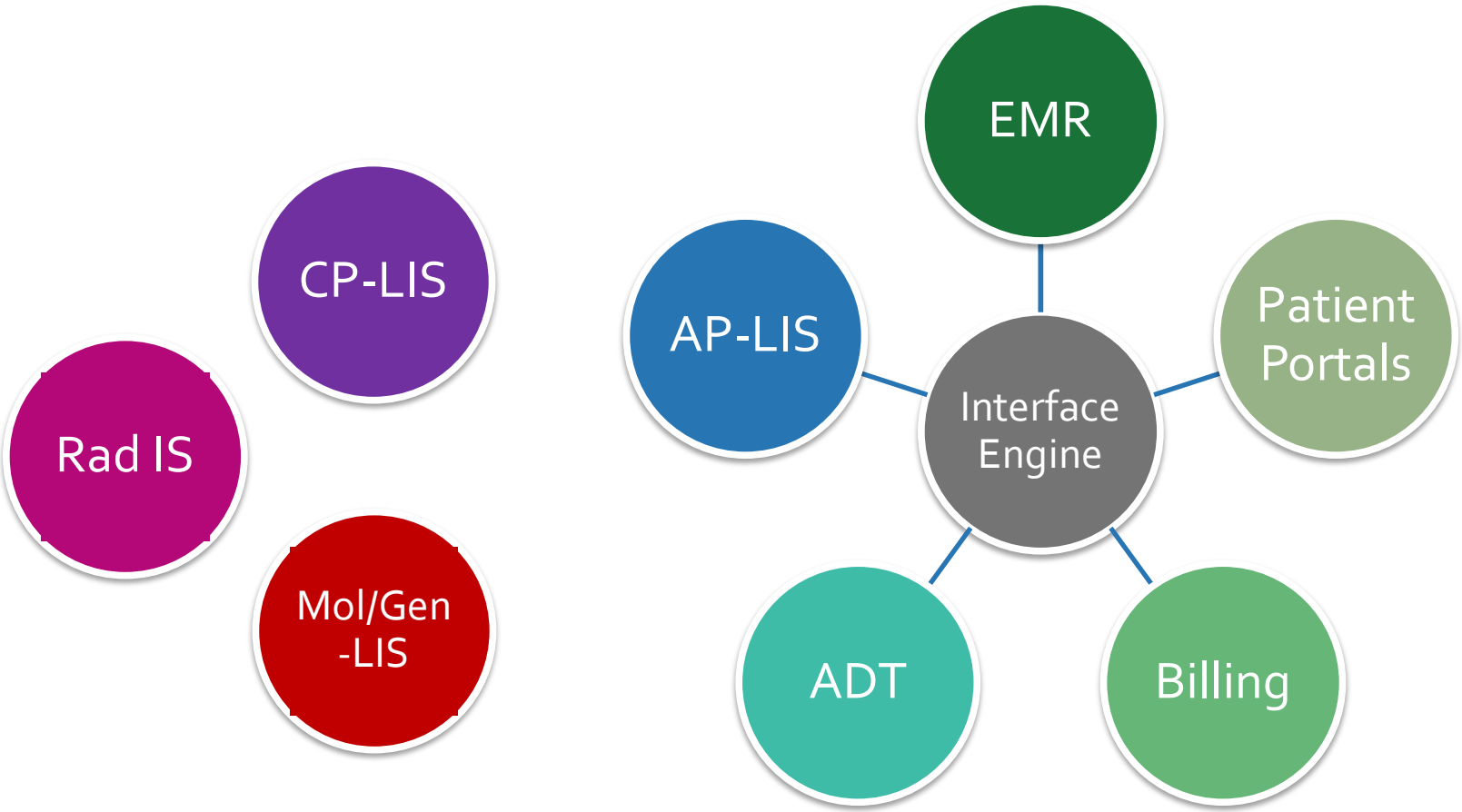
IS interfaces are software and connections

- Unidirectional vs bidirectional
- Translate electronic messages
  - *Exchange* data between otherwise incompatible systems



Critical to laboratory success
(i.e. test order receipt, results reporting)

IS Ecosystem
Interface Architectures



Common Interfaces

Application (System)

- EMR
- ADT
- Order entry
- Results reporting
- Billing
- Other clinical system
- Pharmacy
- Operating room
- Tumor registry
- Interface engine

Instruments

- Automated analyzer
- Middleware
- Lab automation system
- Point of care testing devices
- Tissue cassette and slide engraver
- Immunohistochemistry strainers
- Printers
- Fax machines

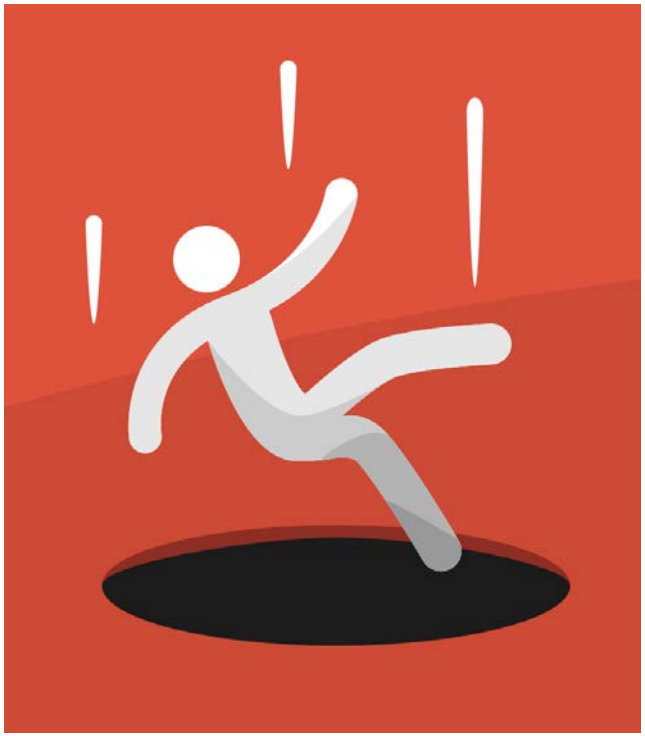
HL7 (Health Level 7) is a syntactic data exchange standard

- Defines format (syntax, structure)
  - Not specific content of messages
- Defines for systems "how to say it"
  - Not "what to say"

HL7 does NOT eliminate difficulties of implementing interfaces

NOT being "plug & play" difficulties

- *Mismatch:*
  - HL7 interface specifications typically do not match other vendors/systems
- *Harmonization:*
  - Dictionaries between systems must be "in sync"
  - Translation tables may be necessary to cross-reference different test codes in different systems.
- *Rigorous testing:*
  - Required along with validation and documentation for interface deployment

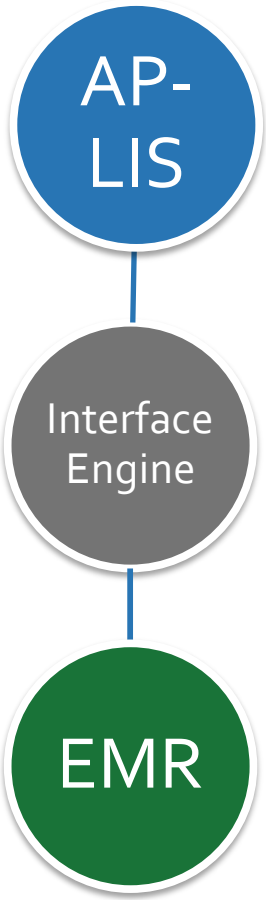


More Pitfalls of HL7 to Come

Systems Integration/Interfacing
Computerized Order Entry (CPOE)

Clinical, laboratory, and IS teams should:

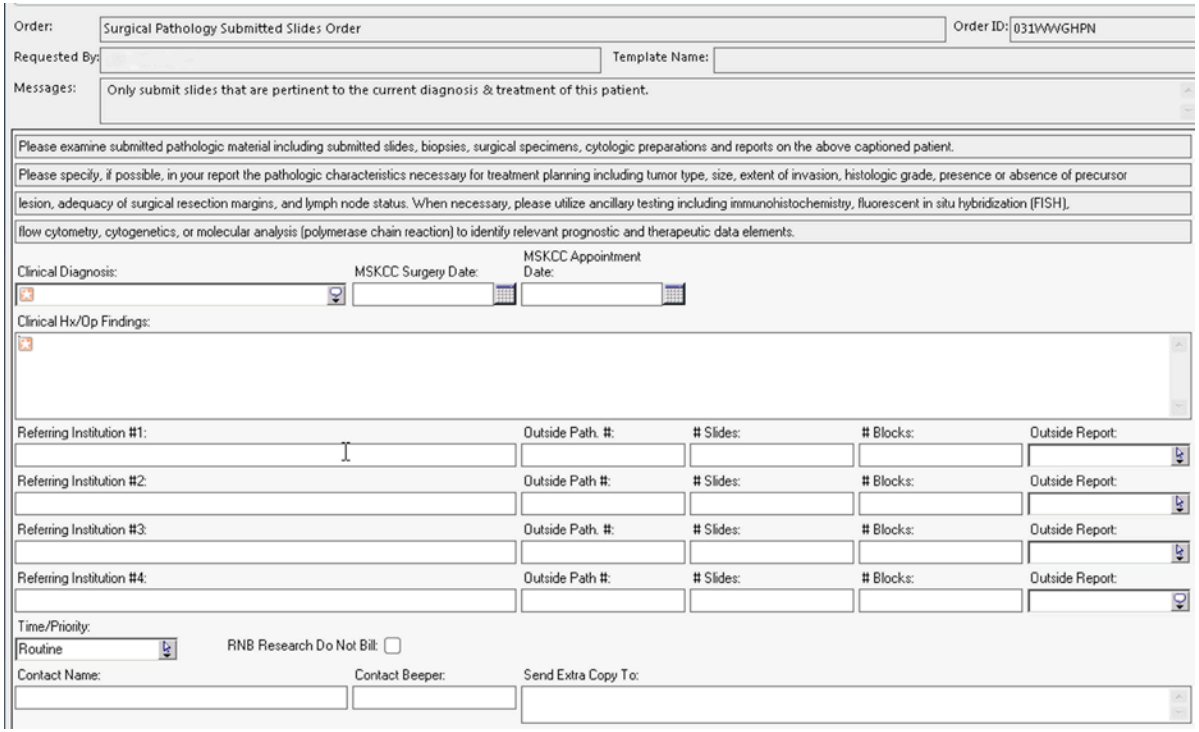
- Design and customize for deployment
- Expect considerable testing and adjustment for both clinical and laboratory workflows



CPOE Example
Request for Outside Pathology Review

Assigned to each order:
- Unique order number
- Printed labels and/or requisition

Data entry fields:
- Ordering provider with attributes
- Patient information with attributes
- Order information with attributes (i.e. date, time, urgency)



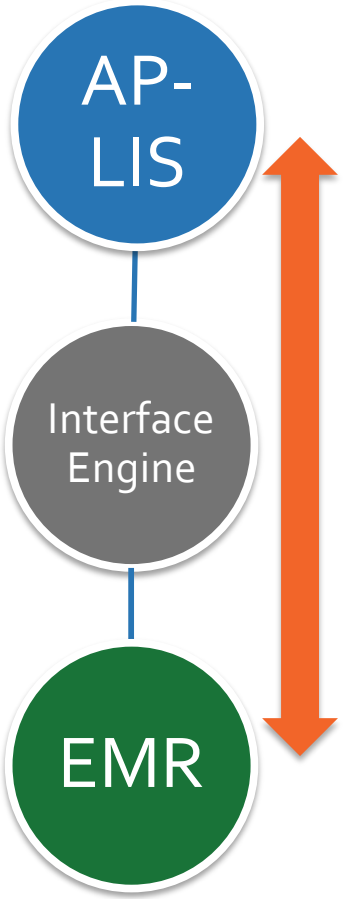
CPOE Gaps

Real-time feedback notifying order acknowledgement/status

- *From AP-LIS to ordering system (i.e. EMR)*
  - Specimen(s) collected
  - Specimen(s) accessioned
  - Analytic processes in-process/completed
  - Results in-process/completed

Order splitting

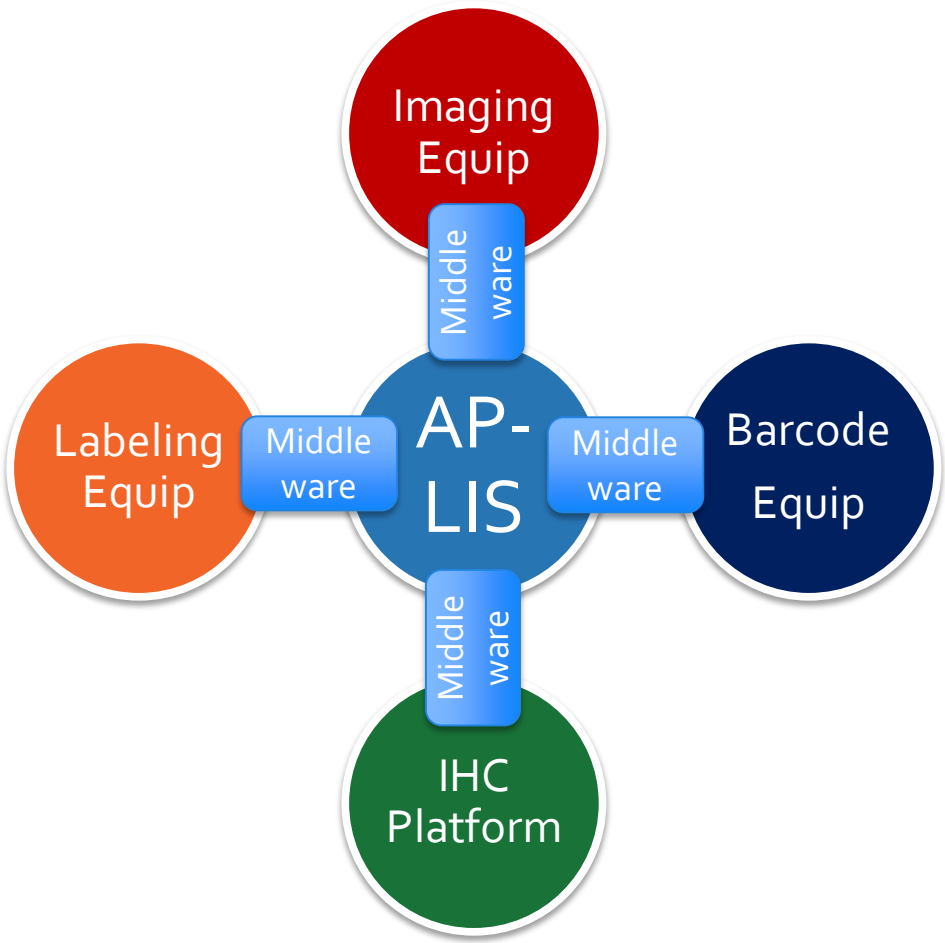
- *Single order requiring:*
  - Separating to multiple component specimens/accessions with multiple tests
  - Tracking progress and reporting status of component specimens/accessions



Systems Integration/Interfacing Within Pathology

Middleware

- Rules-based processing
- "Sits between" the AP-LIS and equipment/platform
- Provided by equipment/platform vendor or third party

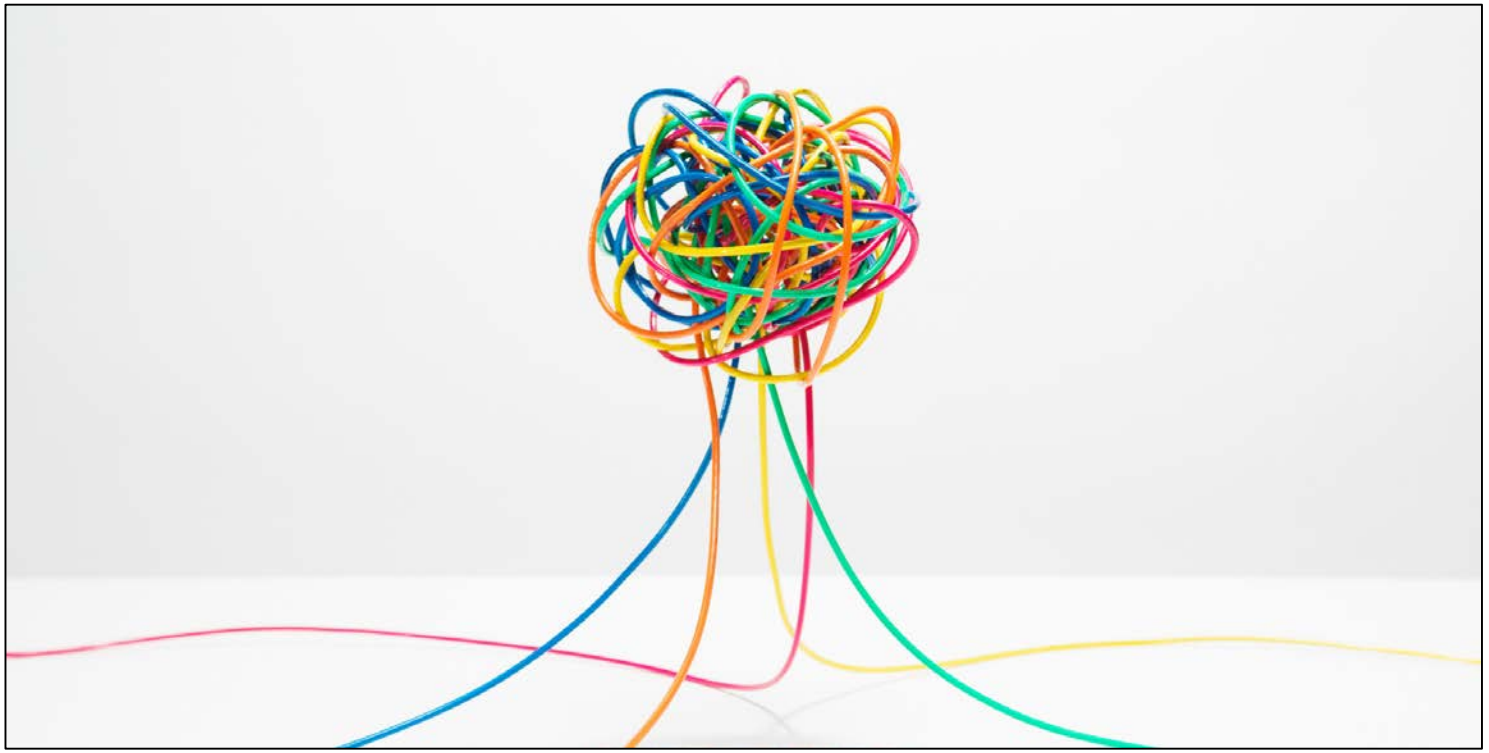


Cautionary Message for Middleware

"Middleware products have been and continue to be employed as an integral component of overall configurations to meet functionality gaps in enterprise-wide LIS offerings"

"But an assemblage of multiple middleware vendors with the core product **increases its overall COMPLEXITY** to reach the same goals as a more sophisticated standalone LIS product might allow."

Dr. Ule Balis CAP Today August 12, 2013



AP-LIS Report Generation

AP-LIS produce "working draft" reports for pathologists

Working draft format and content

- *Based on template configuration in AP-LIS*
  - Clinical information
  - Gross description
  - Frozen section report (if performed)
  - Summary of patient's previous results
    - Based on search of AP-LIS database

AP-LIS report generation should be flexible and configurable by users

AP-LIS facilitation of final diagnosis entry

- Pre-defined templates, checklists, and formats
- Speech to text conversion capability
- Automatic entry of billing (CPT) and diagnosis (ICD) codes, based on dictionary definitions

Synoptic AP-LIS modules

- Structured report generation
- Enabled entry of discrete data elements

Finalized case (pathologist signs out)

- Electronic signature affixes to report, locking case
- Unalterable without creating amendment or addendum

AP-LIS Report Distribution

Physical copy reporting:

- *Based on AP-LIS configurable templates*
  - Printing (scheduled batches, on-demand)
  - Automated secure faxing (based on fax number dictionary)

Electronic reporting:

- *AP-LIS reports pass through interfaces to downstream receiving systems*
  - Format and display of interfaced reports, dictated by screen design in receiving system
- *PDF and RTF interfaces preserve formatting*
  - Accommodated by receiving system

HL7 Pitfalls of AP-LIS Reporting

IMMUNOHISTOCHEMISTRY, BONE MARROW: Immunostains highlight rare scattered CD20+ PAX-5+ B-cells and few scattered CD3+ T-cells.

FLOW CYTOMETRIC IMMUNOPHENOTYPING, BONE MARROW: No monotypic B-cell or phenotypically aberrant T-cell population is detected.

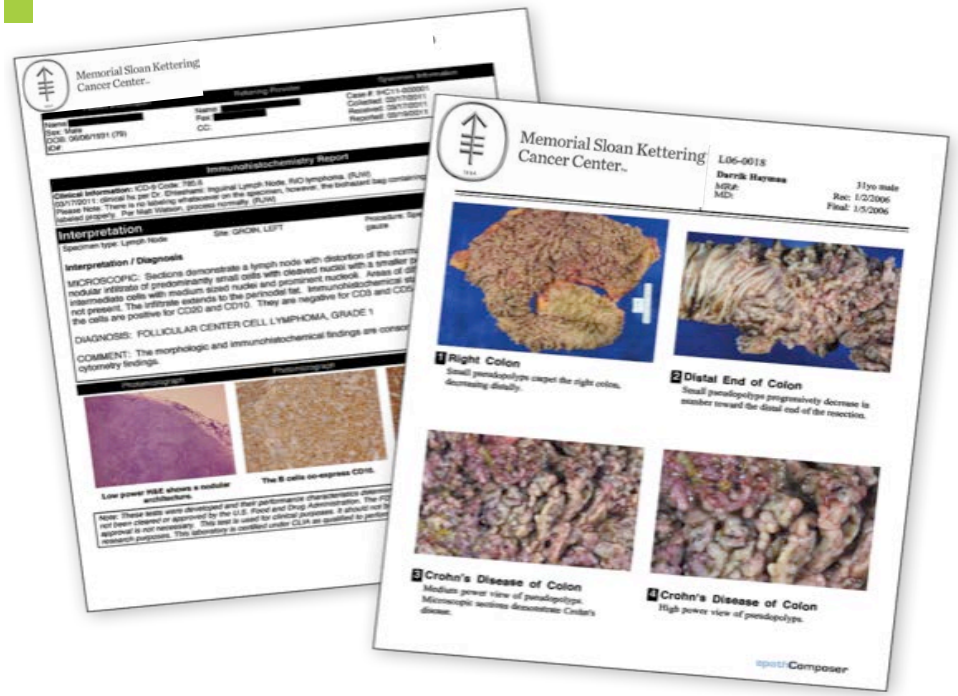
GENETIC STUDIES: Results will be reported separately

HL7 cannot accommodate:

- *Conditional formatting*
- *Color coding*
- *Sophisticated graphing or visualizations*
  - Integration of multidimensional data for intuitive and ingestible display

Continuing Decision Support Gaps in Reporting

Media Rich Reports



Help providers interpret results and use information in clinical care

- *Incorporation of hyperlinks containing further information including:*
  - Nomograms
  - Literature references
  - Clinical guidelines
  - Knowledge engines

Acknowledgement for graphics: Matthew Hanna, MD.

RTF and PDF interface enabled systems preserve formatting, making visualizations possible

DIAGNOSTIC INTERPRETATION:
POSITIVE FOR THE FOLLOWING SOMATIC ALTERATIONS IN THE CLINICALLY VALIDATED
PANEL:
1. TP53 (NM_000546) exon10 p.R337C (c.1009C>T)

POSITIVE FOR THE FOLLOWING SOMATIC ALTERATIONS IN THE INVESTIGATIONAL PANEL:
2. AXIN2 (NM_004655 - 17q24.1) Amplification (Fold Change: 3.8)
3. MYC (NM_002467 - 8q24.21) Amplification (Fold Change: 2.9)
4. PIK3CB (NM_006219 - 3q22.3) Amplification (Fold Change: 2.4)
5. FOXL2 (NM_023067 - 3q22.3) Amplification (Fold Change: 2.4)
6. ATR (NM_001184 - 3q23) Amplification (Fold Change: 2.4)
7. RNF43 (NM_017763 - 17q22) Amplification (Fold Change: 2.3)
8. RAD51C (NM_058216 - 17q22) Amplification (Fold Change: 2.3)
9. CD79B (NM_001039933 - 17q23.3) Amplification (Fold Change: 2.2)
10. PPM1D (NM_003620 - 17q23.2) Gain (Fold Change: 1.8) (Note 1)
11. BRIP1 (NM_032043 - 17q23.2) Gain (Fold Change: 1.8) (Note 1)
12. MAP3K1 (NM_005921 - 5q11.2) Deletion (Fold Change: -6.1)
13. PTEN (NM_000314 - 10q23.31) Deletion (Fold Change: -4.4)
14. PLK2 (NM_006622 - 5q11.2) Deletion (Fold Change: -2.3)
15. PIK3R1 (NM_181523 - 5q13.1) Loss (Fold Change: -1.8) (Note 2)

16. AR (NM_000044) exon5 p.L745I (c.2233C>A)
17. CTNNB1 (NM_001904) exon3 p.D32Y (c.94G>T)
18. FGF3 (NM_005247) exon1 p.E13Q (c.37G>C)
19. RB1 (NM_000321) exon6 p.W195* (c.585G>A)
20. RFWD2 (NM_022457) exon17 p.R634H (c.1901G>A)

21. TMPRSS2 (NM_001135099) - ERG (NM_182918) fusion (TMPRSS2 exon 1 fused to
ERG exons 2-10): c.56-3633:TMPRSS2_c.18+24406:ERGdel

Note 1: The PPM1D and BRIP1 copy number gains fall slightly below the cut
off criteria for amplification. Confirmatory testing by an alternate method
is suggested, if clinically indicated.
Note 2: The PIK3R1 copy number loss falls slightly below the cut off
criteria for deletion. Confirmatory testing by an alternate method is
suggested, if clinically indicated.
Note 3: Copy number profile is suggestive of broad copy number gain on
Chromosome arm 5p.
Note 4: Copy number profile is suggestive of broad copy number losses on
Chromosome arms 3p11-21, 3q27-28, 9p, 13q, and 18q.

MEAN OVERALL COVERAGE (SEQUENCING DEPTH) IN THIS SAMPLE: 1194X
Unless specified, all exons tested had minimum depth of coverage of 100X.

Summary	6 mutations, 14 copy number alterations, 1 structural variant detected
Comments	Copy number profile is suggestive of broad copy number gain on Chromosome arm 5p. Copy number profile is suggestive of broad copy number losses on Chromosome arms 3p11-21, 3q27-28, 9p, 13q, and 18q.

Somatic alterations detected in this sample:

Gene	Type	Annotation	Location	Additional Information+	
Mutations					
TP53	Missense Mutation	R337C (c.1009C>T)	exon10	MAF: 85%, COSMIC: 20	a
CTNNB1	Missense Mutation	D32Y (c.94G>T)	exon3	MAF: 40%, COSMIC: 135	
RB1	Nonsense Mutation	W195* (c.585G>A)	exon6	MAF: 70%, COSMIC: 1	
RFWD2	Missense Mutation	R634H (c.1901G>A)	exon17	MAF: 5%	
FGF3	Missense Mutation	E13Q (c.37G>C)	exon1	MAF: 18%	
AR	Missense Mutation	L745I (c.2233C>A)	exon5	MAF: 12%	
Copy Number Alterations					
MAP3K1	Whole gene	Deletion	5q11.2	FC: -6.1	
PTEN	Whole gene	Deletion	10q23.31	FC: -4.4	
PLK2	Whole gene	Deletion	5q11.2	FC: -2.3	
PIK3R1	Whole gene	Loss	5q13.1	FC: -1.8	a
PPM1D	Whole gene	Gain	17q23.2	FC: 1.8	b
BRIP1	Whole gene	Gain	17q23.2	FC: 1.8	c
CD79B	Whole gene	Amplification	17q23.3	FC: 2.2	
RNF43	Whole gene	Amplification	17q22	FC: 2.3	
RAD51C	Whole gene	Amplification	17q22	FC: 2.3	
PIK3CB	Whole gene	Amplification	3q22.3	FC: 2.4	
FOXL2	Whole gene	Amplification	3q22.3	FC: 2.4	
ATR	Whole gene	Amplification	3q23	FC: 2.4	
MYC	Whole gene	Amplification	8q24.21	FC: 2.9	

Zhao T el al. *An Enterprise Approach for Pathology Reporting Utilizing PDF Functionality for the Electronic Medical Record.*

AP-LIS should demonstrate handling of report revisions (amendments versus addendums)

Not acceptable:

- Correcting and re-issuing reports without changes identifiable

Report revision formats should be configured, so that identification of report status of amendments or addendums is obvious

Report addendums

- *Issued when information is additive (i.e. special stain and IHC results)*
- *Added to end of finalized reports*

Amendment reports

- *Finalized with new electronic signature*
- *AP-LIS:*
  - Automatically labels new report as amended report
  - Transmits across interface to EMR, same manner as routine reports
  - Replaces and overlays original report with new amendment report

Original reports accessible in:

- *AP-LIS and EMR*
  - Through audit-trail type functions

Operational/Administative Functionalities *Notifications*

"Critical test results":

- *As defined through Joint Commission and College of American Pathologists (CAP)*
  - Mandate direct notification of health care providers with ability to intervene in patient care
  - Not specifically defined in anatomic pathology

Changes or corrections to laboratory results:

- *Be communicated and reported rapidly to providers*
- *Be accurately and completely updated to downstream interfaced systems*

Synoptic Reporting Definition by CAP

Antiquated Definitions

Definition of Synoptic Reporting

The CAP has developed this list of specific features that define synoptic reporting formatting:

1. All required cancer data from an applicable cancer protocol must be included in the report and must be displayed using a format consisting of the required checklist item (required data element), followed by its answer (response), e. g. "Tumor size: 5.5 cm". Outline format without the paired required data element (RDE): response format is not considered synoptic.
2. Each diagnostic parameter pair (checklist RDE: response) is listed on a separate line or in a tabular format, to achieve visual separation.

   Note: the following are allowed to be combined on the same line:
   a. Anatomic site or specimen, laterality and procedure
   b. Pathologic Staging Tumor Node Metastasis (pTNM) staging elements
   c. Negative margins, as long as all negative margins are specifically enumerated

      For example:
      - Headers may be used to separate or group data elements
      - Any line may be indented to visually group related data elements or indicate a subordinate relationship
      - Text attributes (e.g., color, bold, font, size, capitalization/case, or animations) are optional

Synoptic Reporting and Structured Data Capture

Synoptic reports:

- Constrains reports to individual data elements
- Structure and clarify findings for clinicians

Structured data:

- "Clarifies findings" for computers
- Not all synoptic reports contain structured data

Gaps exists in synoptic data interoperability and data exchange with many vendor AP-LIS synoptic reporting modules

Interoperability and Exchange of Data Gap

Transmission of "codified"/computational information

AP-LISs capture industry standards for:

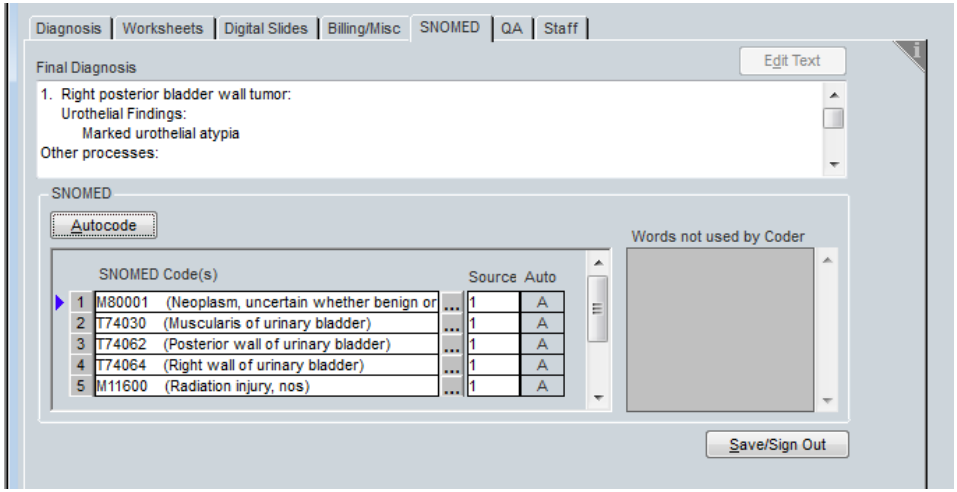
- Coding with billing and interfacing
- Test codes (Current Procedural Terminology[CPT]

AP-LISs not as good at capturing accurately and even worse at transmission for:

- Systematized Nomenclature of Medicine [SNOMED-CT]
- ICD-9 or ICD-10

AP-LISs have poorly developed (if non-existent) capture and transmission of:

- XML/JSON/SDC
- HL7 FHIR (accommodating CDA)



Mapping dictionaries ("Rosetta Stones") for interconversion between different standards is far from robust

Upcoming sessions that address synoptic data interoperability and data exchange

Tuesday Morning Track Presentations

Mary Edgerton, MD, PhD

- *The California Cancer Reporting Revolution: Making Population Health Relevant to Everyday Patient Care*
- 11:20 am - 12:00 pm

Wednesday Afternoon Plenary Presentations

J. Mark Tuthill, MD

- *Deploying the 2018 CAP/AJCC ECC's and Externalizing Resultant Data to 3rd Party Systems*
- 2:10 pm - 2:50 pm

Thursday Plenary Lectures Implementation of Best Practices: AP, CP, and Molecular

Richard Moldwin, MD, PhD

- *Next-Generation CAP eCC: Improved Functionality and Interoperability in Pathology Cancer Reporting with SDC-XML*
- 9:00 am - 9:40 am

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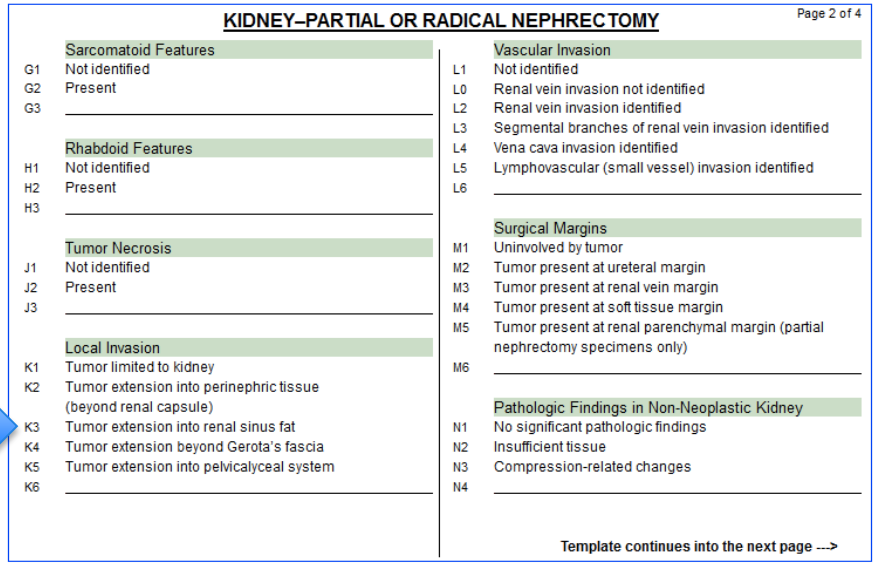
Usability gap of synoptic modules

Lack of rules-based support to simplify data entry and avoid errors in synoptic reporting



KIDNEY–PARTIAL OR RADICAL NEPHRECTOMY Page 2 of 4

Sarcomatoid Features
- G1 Not identified
- G2 Present
- G3 _____

Rhabdoid Features
- H1 Not identified
- H2 Present
- H3 _____

Tumor Necrosis
- J1 Not identified
- J2 Present
- J3 _____

Local Invasion
- K1 Tumor limited to kidney
- K2 Tumor extension into perinephric tissue (beyond renal capsule)
- K3 Tumor extension into renal sinus fat
- K4 Tumor extension beyond Gerota's fascia
- K5 Tumor extension into pelvicalyceal system
- K6 _____

Vascular Invasion
- L1 Not identified
- L0 Renal vein invasion not identified
- L2 Renal vein invasion identified
- L3 Segmental branches of renal vein invasion identified
- L4 Vena cava invasion identified
- L5 Lymphovascular (small vessel) invasion identified
- L6 _____

Surgical Margins
- M1 Uninvolved by tumor
- M2 Tumor present at ureteral margin
- M3 Tumor present at renal vein margin
- M4 Tumor present at soft tissue margin
- M5 Tumor present at renal parenchymal margin (partial nephrectomy specimens only)
- M6 _____

Pathologic Findings in Non-Neoplastic Kidney
- N1 No significant pathologic findings
- N2 Insufficient tissue
- N3 Compression-related changes
- N4 _____

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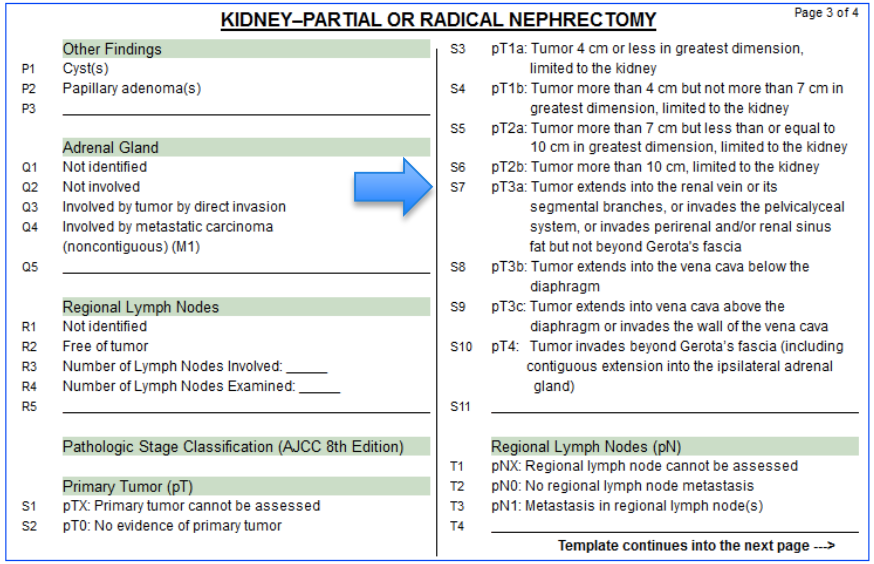

KIDNEY–PARTIAL OR RADICAL NEPHRECTOMY Page 3 of 4

Other Findings
- P1 Cyst(s)
- P2 Papillary adenoma(s)
- P3 _____

Adrenal Gland
- Q1 Not identified
- Q2 Not involved
- Q3 Involved by tumor by direct invasion
- Q4 Involved by metastatic carcinoma (noncontiguous) (M1)
- Q5 _____

Regional Lymph Nodes
- R1 Not identified
- R2 Free of tumor
- R3 Number of Lymph Nodes Involved: _____
- R4 Number of Lymph Nodes Examined: _____
- R5 _____

Pathologic Stage Classification (AJCC 8th Edition)

Primary Tumor (pT)
- S1 pTX: Primary tumor cannot be assessed
- S2 pT0: No evidence of primary tumor
- S3 pT1a: Tumor 4 cm or less in greatest dimension, limited to the kidney
- S4 pT1b: Tumor more than 4 cm but not more than 7 cm in greatest dimension, limited to the kidney
- S5 pT2a: Tumor more than 7 cm but less than or equal to 10 cm in greatest dimension, limited to the kidney
- S6 pT2b: Tumor more than 10 cm, limited to the kidney
- S7 pT3a: Tumor extends into the renal vein or its segmental branches, or invades the pelvicalyceal system, or invades perirenal and/or renal sinus fat but not beyond Gerota's fascia
- S8 pT3b: Tumor extends into the vena cava below the diaphragm
- S9 pT3c: Tumor extends into vena cava above the diaphragm or invades the wall of the vena cava
- S10 pT4: Tumor invades beyond Gerota's fascia (including contiguous extension into the ipsilateral adrenal gland)
- S11 _____

Regional Lymph Nodes (pN)
- T1 pNX: Regional lymph node cannot be assessed
- T2 pN0: No regional lymph node metastasis
- T3 pN1: Metastasis in regional lymph node(s)
- T4 _____

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Upcoming sessions that address usability of synoptic reporting modules

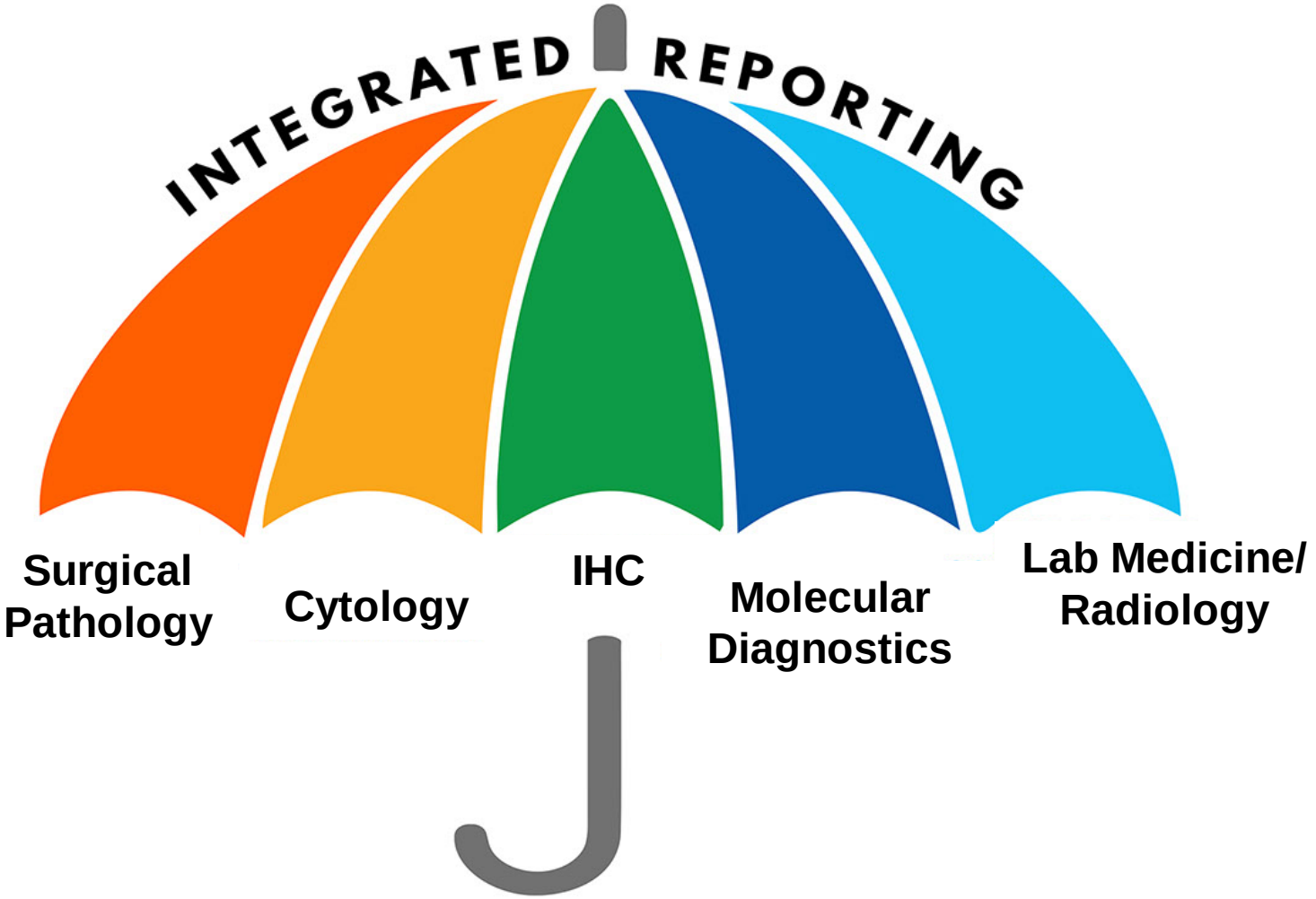
Wednesday Morning Track Presentations

Veronica Klepeis, MD, PhD

- *Moving to a Single Source Product for the CAP Cancer Protocols and CAP eCC*
- 9:45 am - 10:20 am

Jason R Pettus, MD

- *Cancer reporting with the CAP Cancer Protocols/ eCC in your LIS: Challenges and Solutions*
- 11:20 am - 12:00 pm



Demonstrate ability of the reporting module/system to generate a more meaningful comprehensive report:

- Integrates results from other systems
- "Interpretation of interpretations"

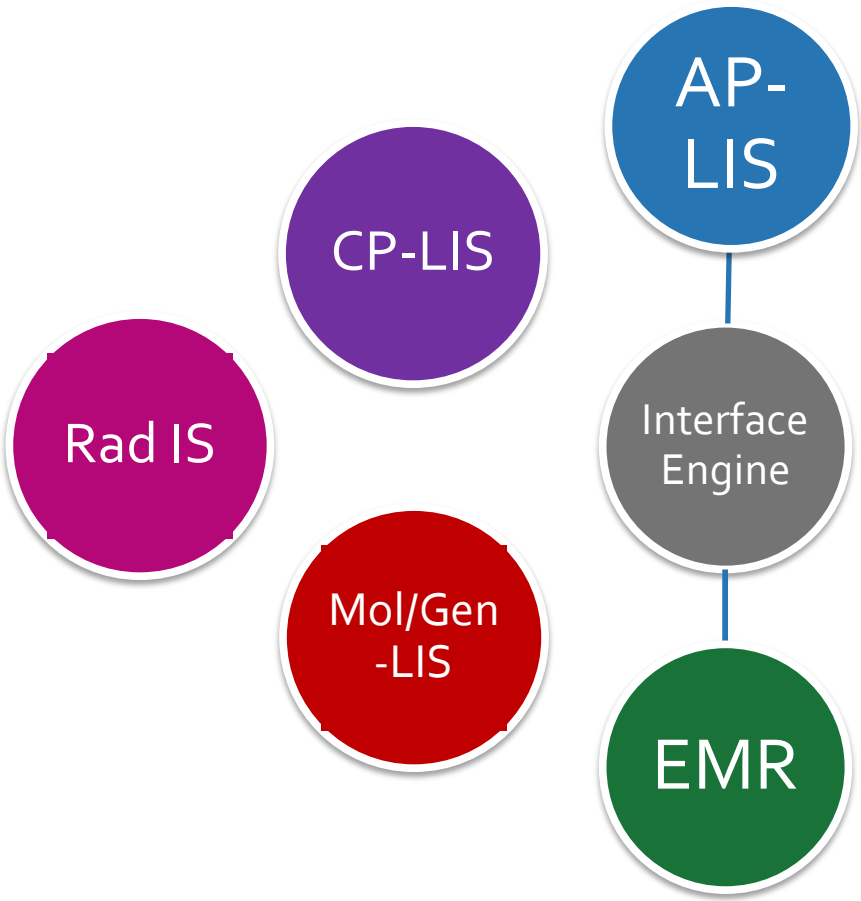
Systems Integration/Interfacing

Example:

- *Leukemia Dx dependent on integration of:*
  - Clinical information
  - Hematology
  - Hematopathology
  - Flow data
  - Molecular

Reporting module/system should receive:

- Results in a variety of formats (i.e. tables and graphs)
- From other systems and even external reference laboratories



Data Analytics (Queries/Searches)

Ability to perform queries into laboratory and clinical databases:

- Paramount to maximize the efficiency and quality of the laboratory operation

Reports of user activity should be:

- Available to laboratory managers for process improvement
- Exportable to spreadsheet programs for further data aggregation and analysis for common statistical functions

AP-LIS should demonstrate:

- How to pull the number of blocks and slides produced during a work day
- How to retrieve cases by diagnosis, key words, synoptic data element
- How to search for cases by ordering physician during a specific time frame

AP-LIS should demonstrate how to pull Turn Around Times (TATs)

Based on signing pathologists:

- Frozen sections
- Surgicals/biopsies
- Cytologies
- Autopsies

Surgical Routine Turn-Around Time (in days)

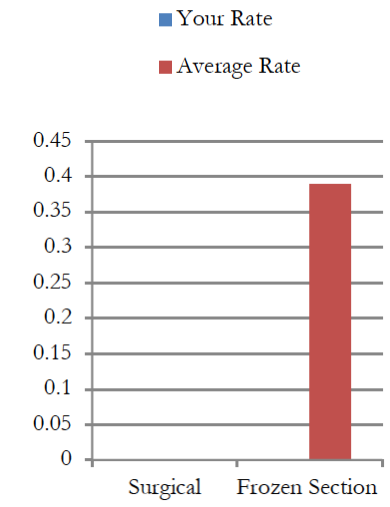
	You	Team
Average Total TAT	3	4
% Routine Cases S/O by Threshold	91%	77%
% Total Cases S/O by Threshold	58%	39%
Threshold: Sign-out 80% of Routine cases within 3 days		

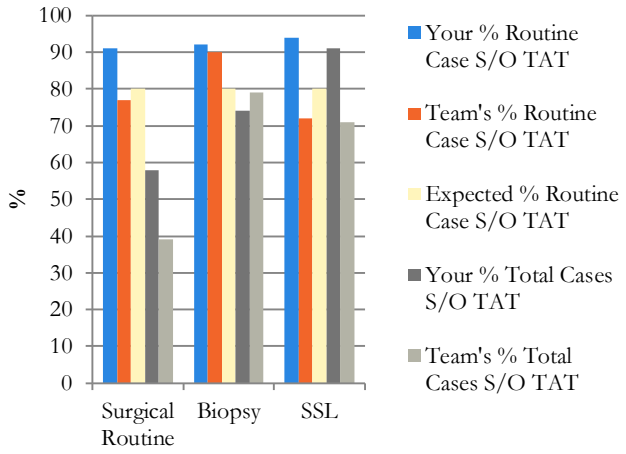
Surgical Biopsy Turn-Around Time (in days)

	You	Team
Average Total TAT	2	2
% Routine Cases S/O by Threshold	92%	90%
% Total Cases S/O by Threshold	74%	79%
Threshold: Sign-out 80% of Routine cases within 2 days		

Frozen Discrepancies and Amendments in 2017 Quarter 3
(Change in Primary Diagnosis)

	Total	Rate
Your Amendments in Surgical	0	0.00%
Average Amendments in Surgical	0	0.00%
Frozen Section Errors	0	0.00%
Average Frozen Section Errors	0.23	0.39%





Such benchmarking ties with quality management

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Business Intelligence through Dashboards

Dashboards allow continuous on demand reporting through:

- *Visualizations (i.e. color coding and sorting)*
  - Displays unfulfilled processes with ability to pinpoint points of failure
- *Incomplete "lists" of processes/specimen assets in process, or not completed*
- *Alerts to staff*
  - To investigate and processes/specimen assets at risk of exceeding acceptable turnaround time thresholds

Block Dashboard							
	Ready for pickup	Need to be put on processor batch	Ready to process	In processor	Need embedding	Need to be cut	Need to be filed
In process	20	25	70	150	200	200	200
Completed	100	100	100	0	10	200	500

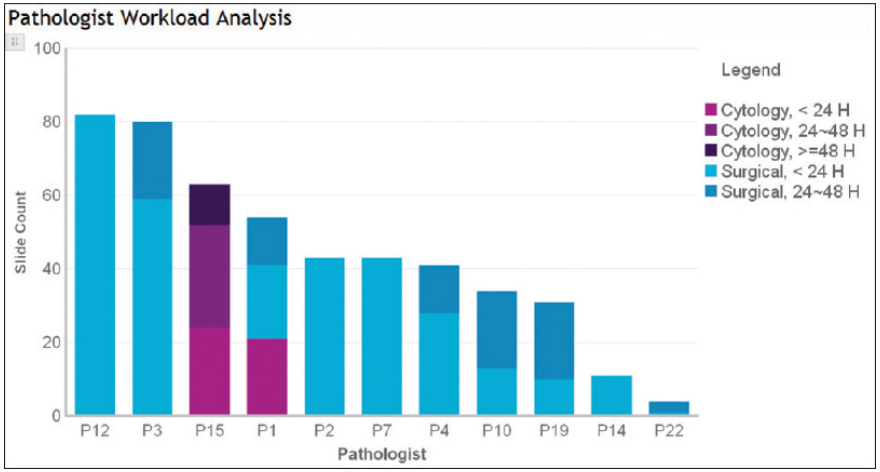
Strong Case for Robust Business Intelligence Solutions

Allows laboratory to record, track and manage key performance indicators

- Molecular test request/utilization by client and by physician

Provides insights into opportunities for revenue growth, quality improvement and operational efficiencies

- Identify trends and perform root-cause analyses into performance variation (TAT outliers, order entry errors)
- Dynamically provide detailed work load data to better align staffing levels
- Manage and grow outreach



Halwani F, Li WC, Banerjee D, Lessard L, Amyot D, Michalowski W, Giffen R. A real-time dashboard for managing pathology processes. J Pathol Inform. 2016 May 4;7:24.

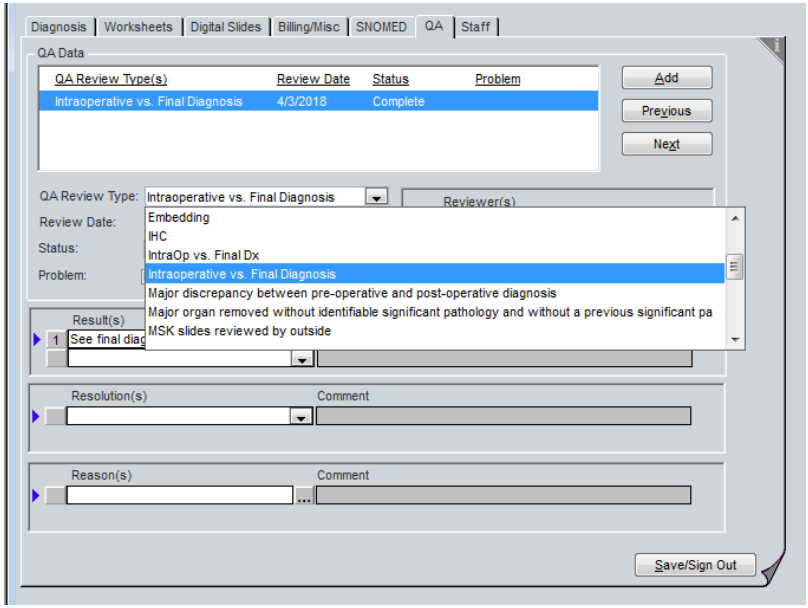
Data Analysis/Business Intelligence Gap

Advanced AP-LIS should have:

- *Advanced data warehouse and mining capabilities*
- *Ability to de-identify and codify specimens*
  - Research purposes including database management capabilities for biobanks
- *State-of-the-art search engine technologies*
  - Allowing for synonyms, misspellings, and advanced Boolean combinations of search terms

AP-LIS vendors are far from that future

Quality Management



AP-LISs should demonstrate:

- How to place markers/flags for later retrieval (QA/QC cases, interesting cases, tumor board)
- How to retrieve anatomic pathology history/reports

AP-LISs capture data for analysts to do:

- Peer comparison statistics (i.e. range, mean, median, standard deviations, standard deviation index)
- Ability to produce periodic reports of laboratory productivity and management efficiency

The long term goal of quality management is more encompassing

Institutions are increasingly focusing on improved quality and outcomes of patient care

- To enhance financial situation and gain competitive advantages

Quality management for laboratories involves:

- Program to ensure quality throughout all aspects of laboratory operation

Quality Management Gaps

Automated reporting of quality management data to public health registries

- *Using required formats and appropriate standards*

Correlative analysis with patient outcomes

- *Using AP-LIS data-mining capabilities and clinical data extracted from EMRs/enterprise datawarehouses*
- *Using outcome parameters (i.e. mortality, morbidity, complications, care costs) correlated to:*
  - Pre-analytic and analytic variables (acquisition/processing times)
  - Synoptic data elements (i.e. histology type, margin status, stage, etc)
  - Genomic results

National Efforts Benchmarking Quality Management

ASCP NPQR
NATIONAL PATHOLOGY QUALITY REGISTRY

Harness Your Lab Data to Improve Patient Care and Fulfill CMS Requirements

Launching Fall 2017

MONITORING
appropriate utilization of laboratory testing

IMPROVING
pre-analytical processes

ESTABLISHING
best practices through national and peer group comparisons

OPTIMIZING
turnaround time and critical value reporting

ASSESSING
analytical and diagnostic accuracy

PARTICIPATING
in pay-for-performance programs to meet CMS requirements

Provides pathologists and laboratory professionals with:

- Guidelines-driven performance measurement, benchmarking, and quality improvement capabilities
- Enables laboratories to identify areas for improvement
- Participate in government-required pay for performance programs
- Integrate results into educational programs
- Measure adherence to appropriate use criteria

Digital Pathology

ARMS

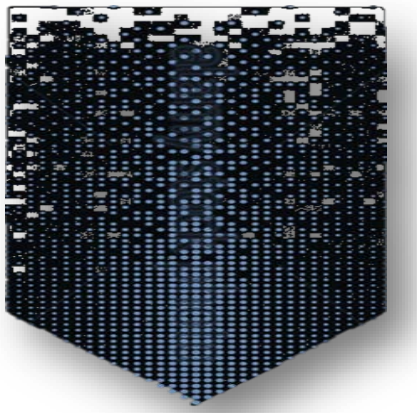
Acquisition

Retrieval/Storage

Manipulation

Sharing

Acknowledgement for graphics: Matthew Hanna, MD.

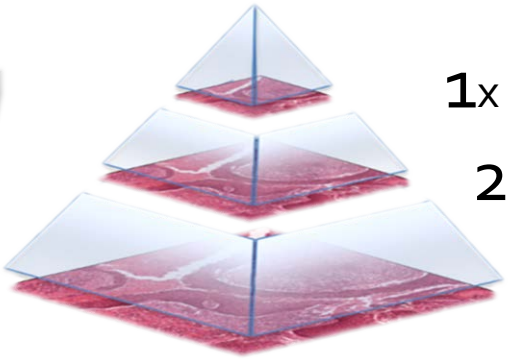


AP-LISs should demonstrate:

- How the system captures and incorporates/reports images
- How to scan documents into the system and into pathology reports

Digital Pathology Ecosystem

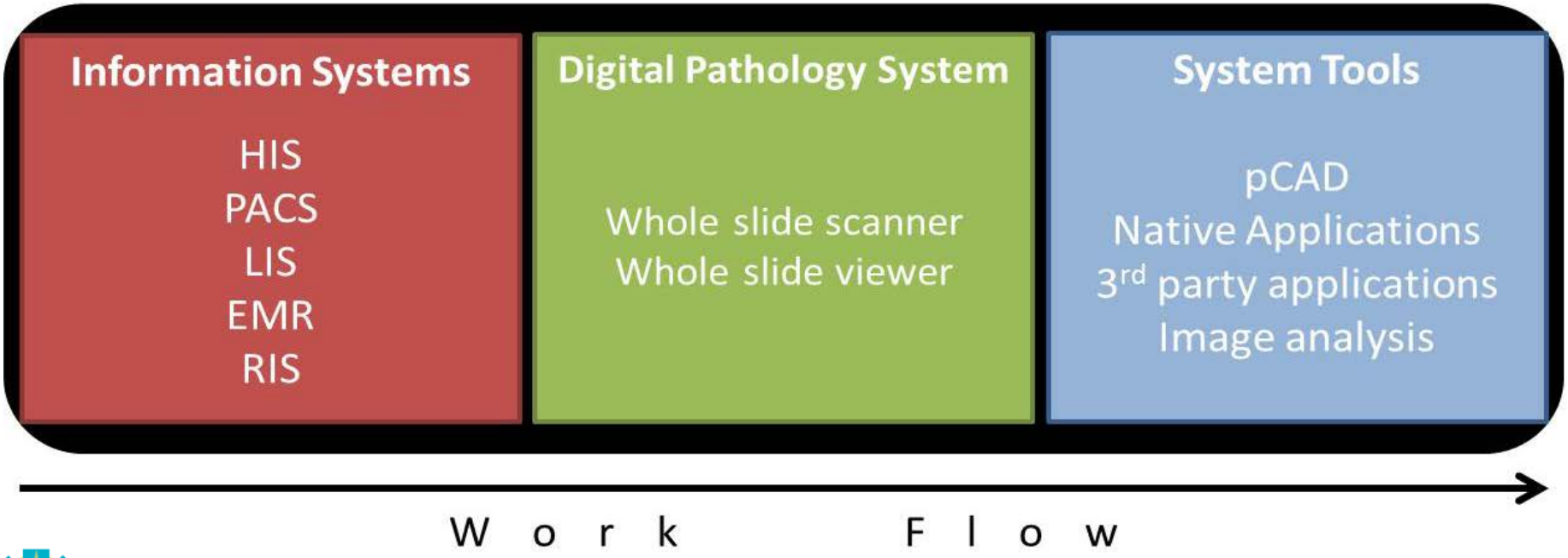
Acknowledgement for graphics: Matthew Hanna, MD.



1x magnification

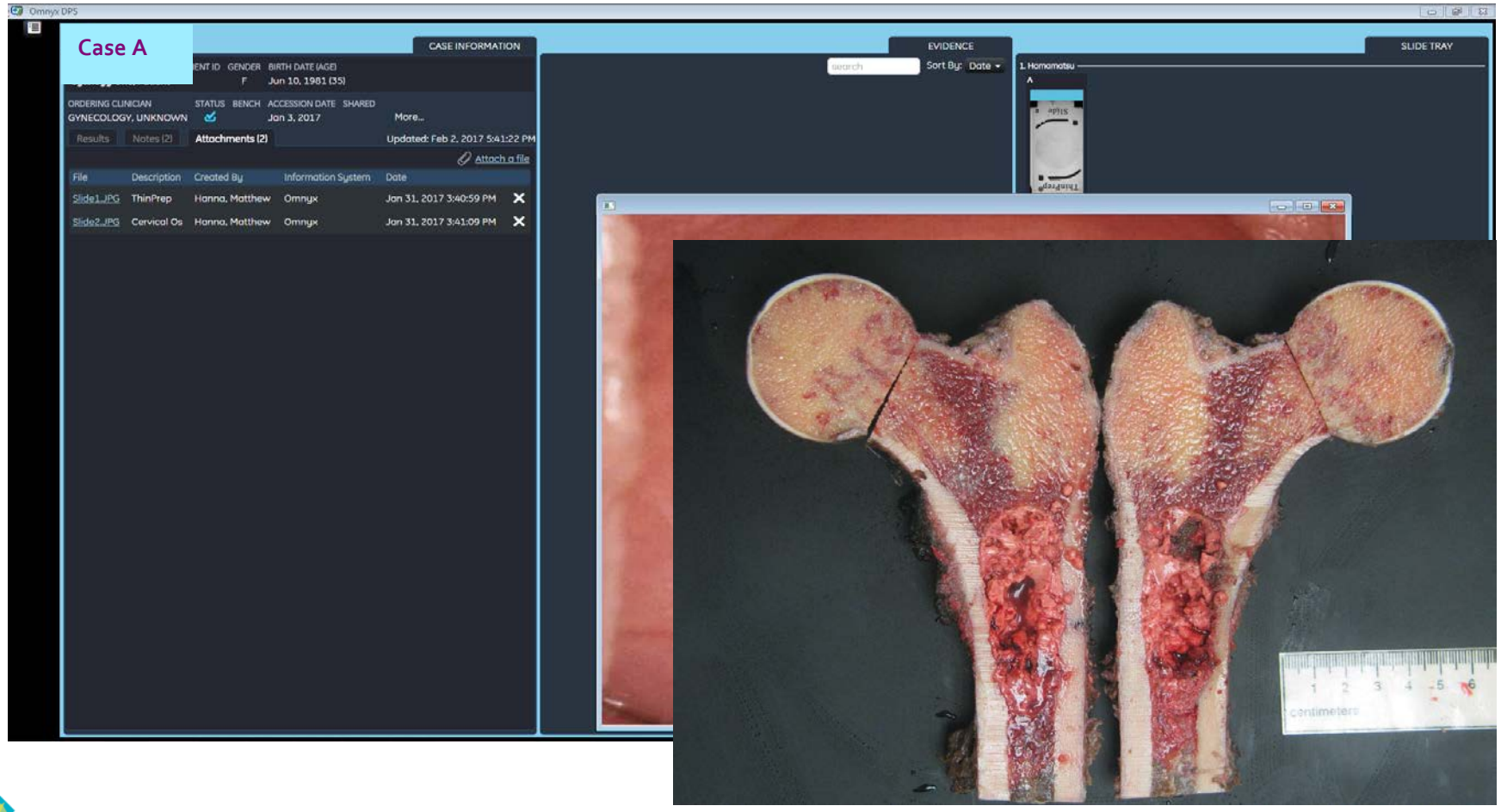
20x magnification

40x magnification



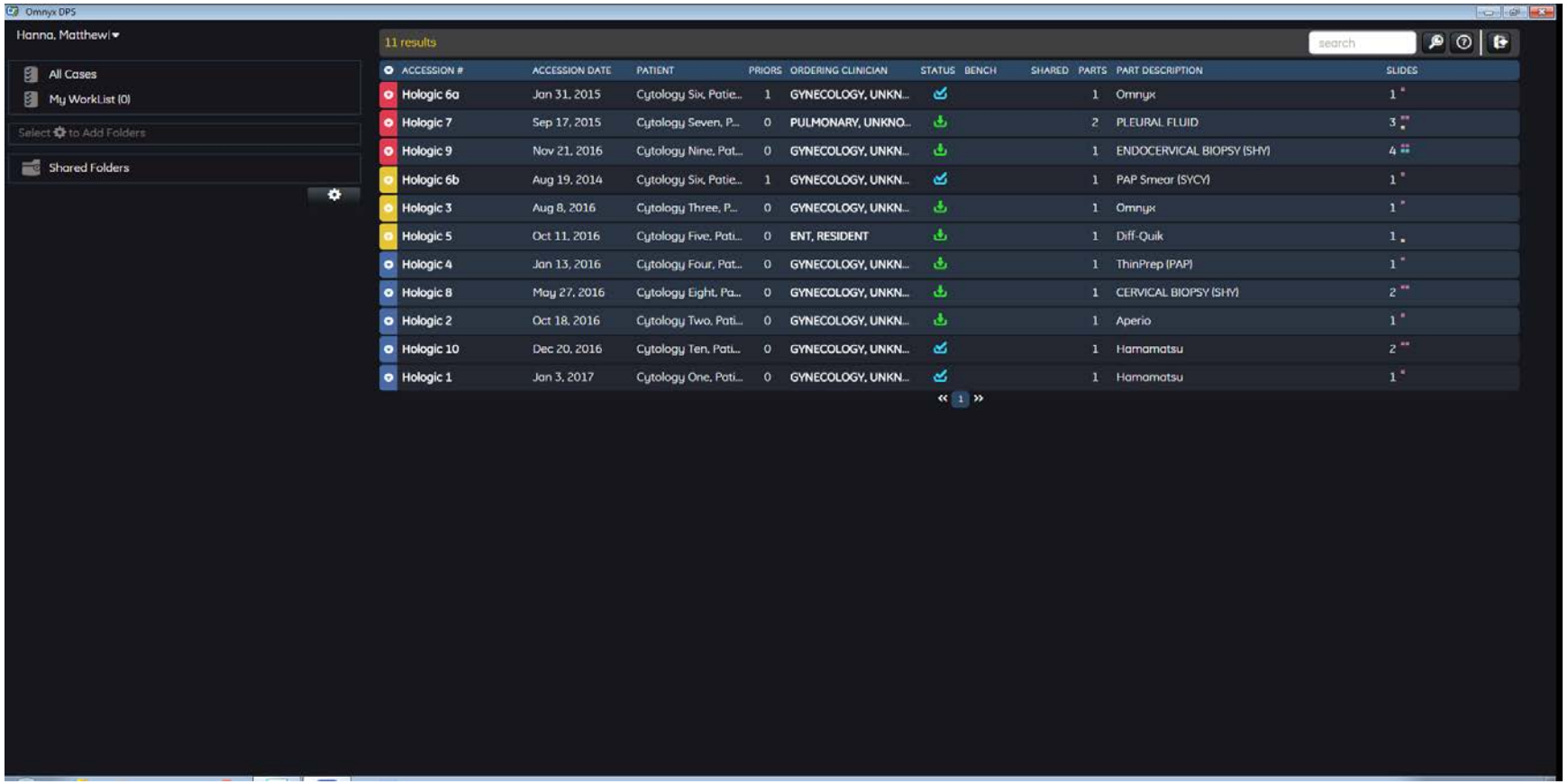
Hanna MG, Pantanowitz L. Digital Pathology. The Encyclopedia of Biomedical Engineering

Desired is incorporation of gross images but also clinical information



Acknowledgement for graphics: Matthew Hanna, MD.

Desired is on-demand archive/case management

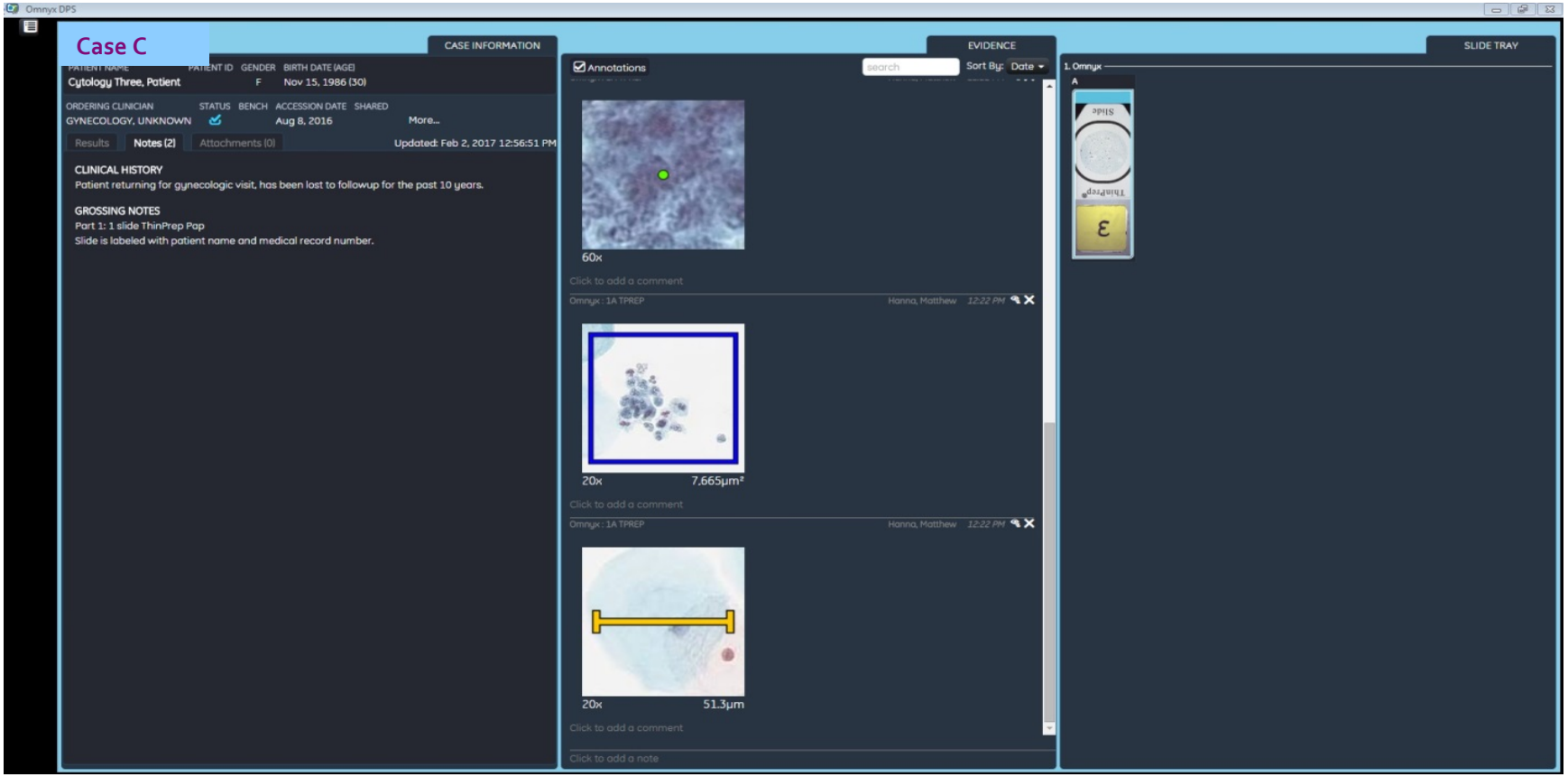


Acknowledgement for graphics: Matthew Hanna, MD.

Desired is delivery of computational pathology tools

Computer-assisted diagnostics

(pre-selected ROIs and searchable annotations)



Acknowledgement for graphics: Matthew Hanna, MD.

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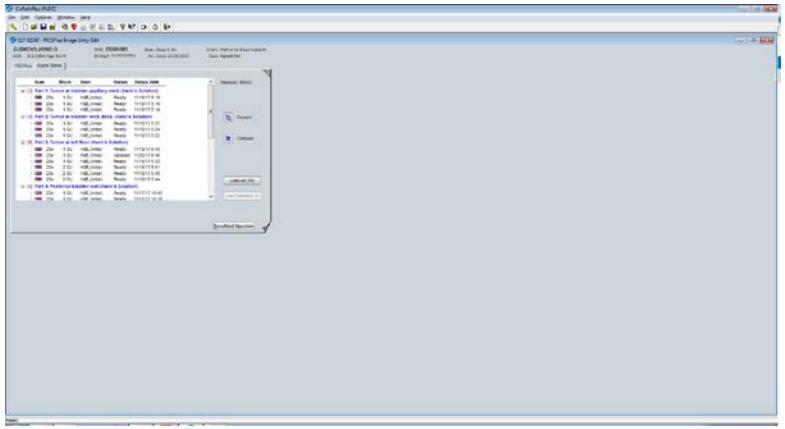
Digital Pathology Gap

Digital pathology ecosystem integration with the AP-LIS is lagging



Interoperability challenges

- Between systems and platforms
- AP-LISs, EMRs, digital scanner imaging platforms

Digital pathology ecosystem and AP-LIS integration is anecdotal

Original Article

Digital pathology and anatomic pathology laboratory information system integration to support digital pathology sign-out

Huazhang Guo[1], Joe Birsa[2], Navid Farahani[1], Douglas J. Hartman[1], Anthony Piccoli[3], Matthew O'Leary[3], Jeffrey McHugh[3], Mark Nyman[2], Curtis Stratman[2], Vanja Kvarnstrom[2], Samuel Yousem[1], Liron Pantanowitz[1]

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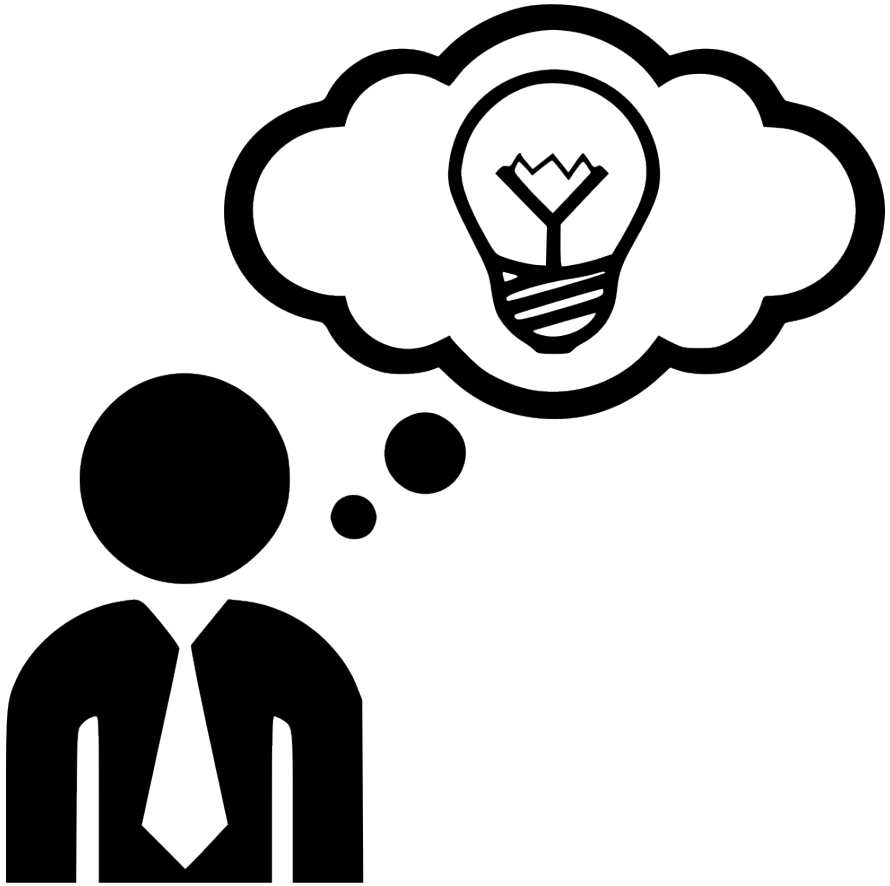
Parting thoughts:

"a specific workflow that may be easy to perform in one system" "requires many steps or is extremely cumbersome in another."

"Just because they say they can support the workflow doesn't mean it provides an optimized solution."

Andrew Splitz - CAP Today August 12, 2013



References:

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- Henricks WH. *Laboratory Information Systems Overview: Structure and Function.* In: Pathology Informatics: Theory and Practice. Pantanowitz L, Tuthill JM, Balis UGJ (eds.) 2012. ASCP Press, Chicago, IL.
- Sepulveda JL, Young DS *The Ideal Laboratory Information System.* Arch Pathol Lab Med. 2013;137:1129–1140
- API toolkit (https://www.pathologyinformatics.org/lis_toolkit.php)

- Acknowledgement:
  - Walter H. Henricks, M.D.
  - Mehrvash Haghighi, M.D.