



Memorial Sloan Kettering
Cancer Center™



The LIS - Anatomic Pathology (AP-LIS)

Monday, May 21, 2018

S. Joseph Sirintrapun, M.D.

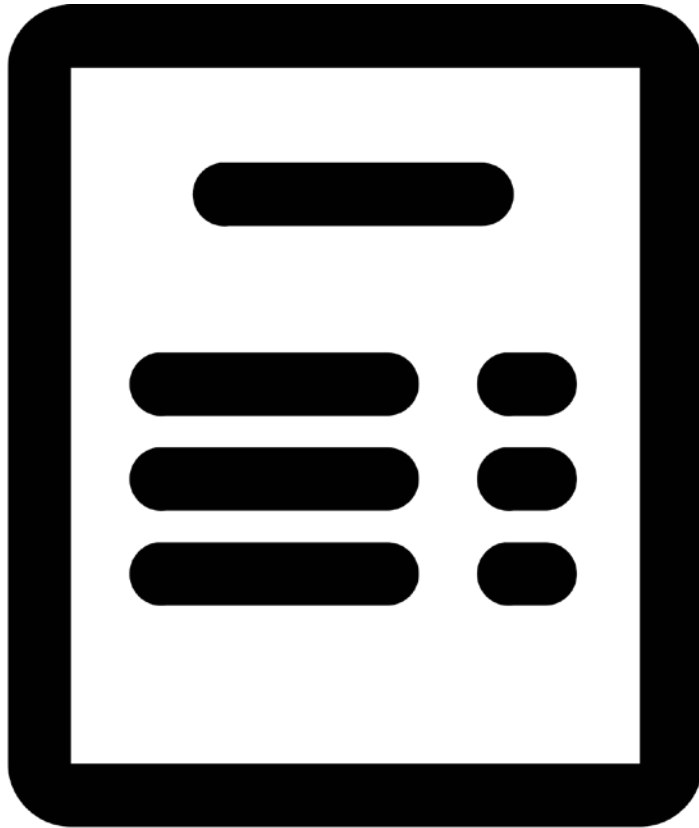
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Outline



Functionalities of AP-LISs:

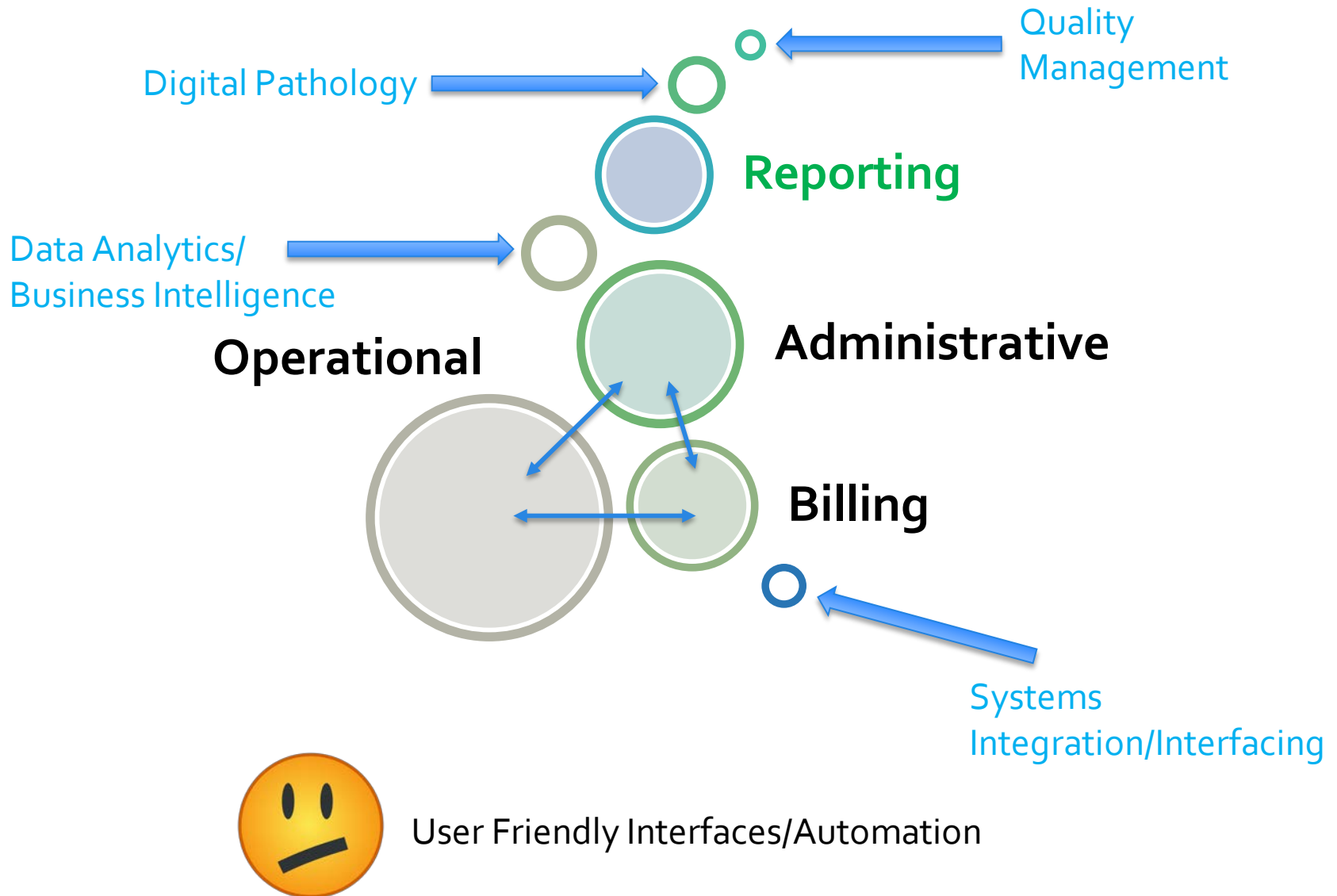
- *What they do today*
- *Functionality gaps and opportunities missed*
- *Emerging needs*
 - Integrated reporting
 - Data analytics/business intelligence
 - Quality management
 - Digital pathology

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



Gaps in Functionalities = Cost (\$\$ & Safety)

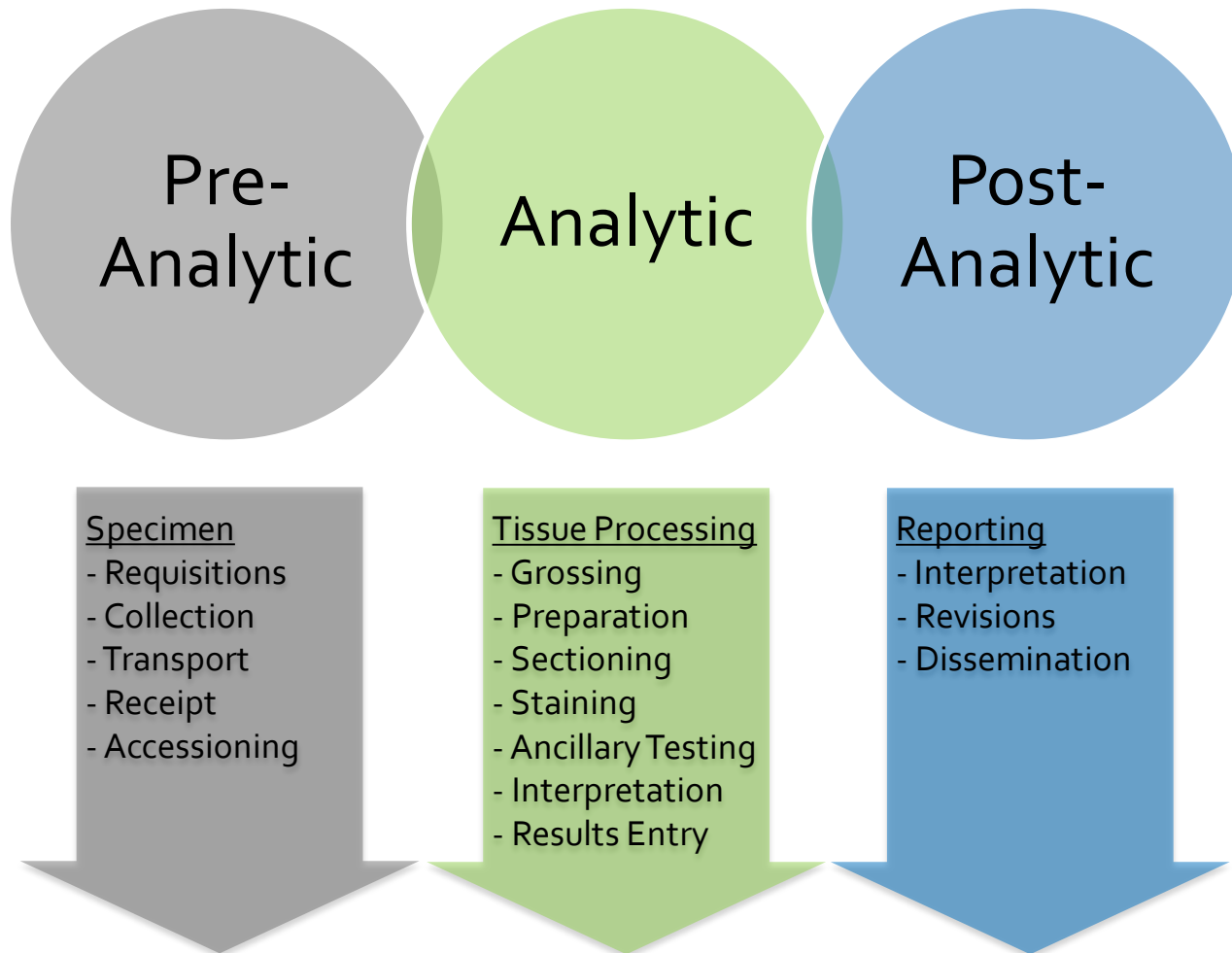
“if the workhorse LIS of a pathology department lacks certain functionalities, there can be substantial up-front capital and long-term maintenance costs to purchase, install, and incrementally operate the additional software modules needed to compensate for the identified functionality gaps.”

Dr. Bruce Friedman – CAP Today August 12, 2013

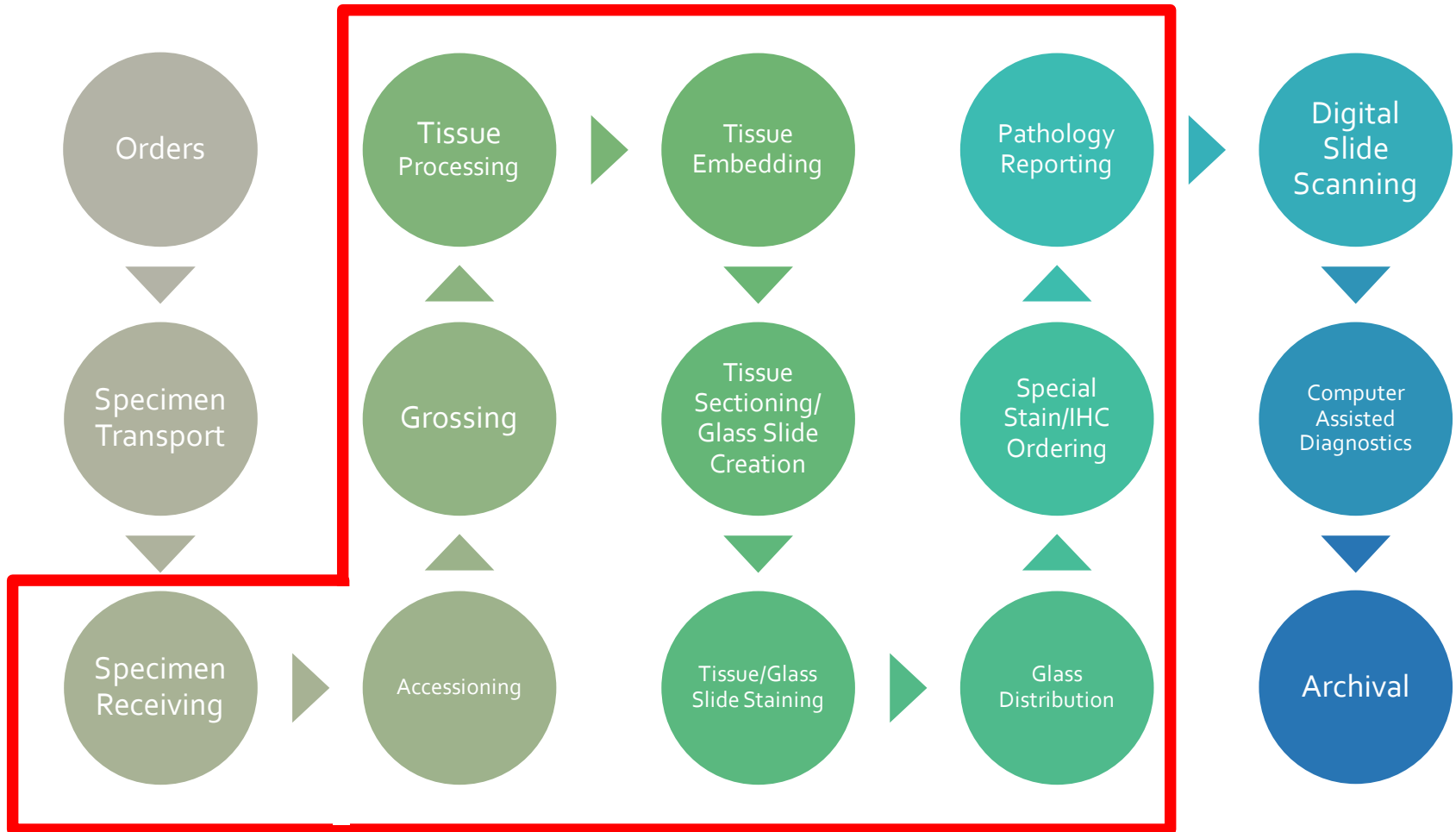


Laboratory Testing Cycle

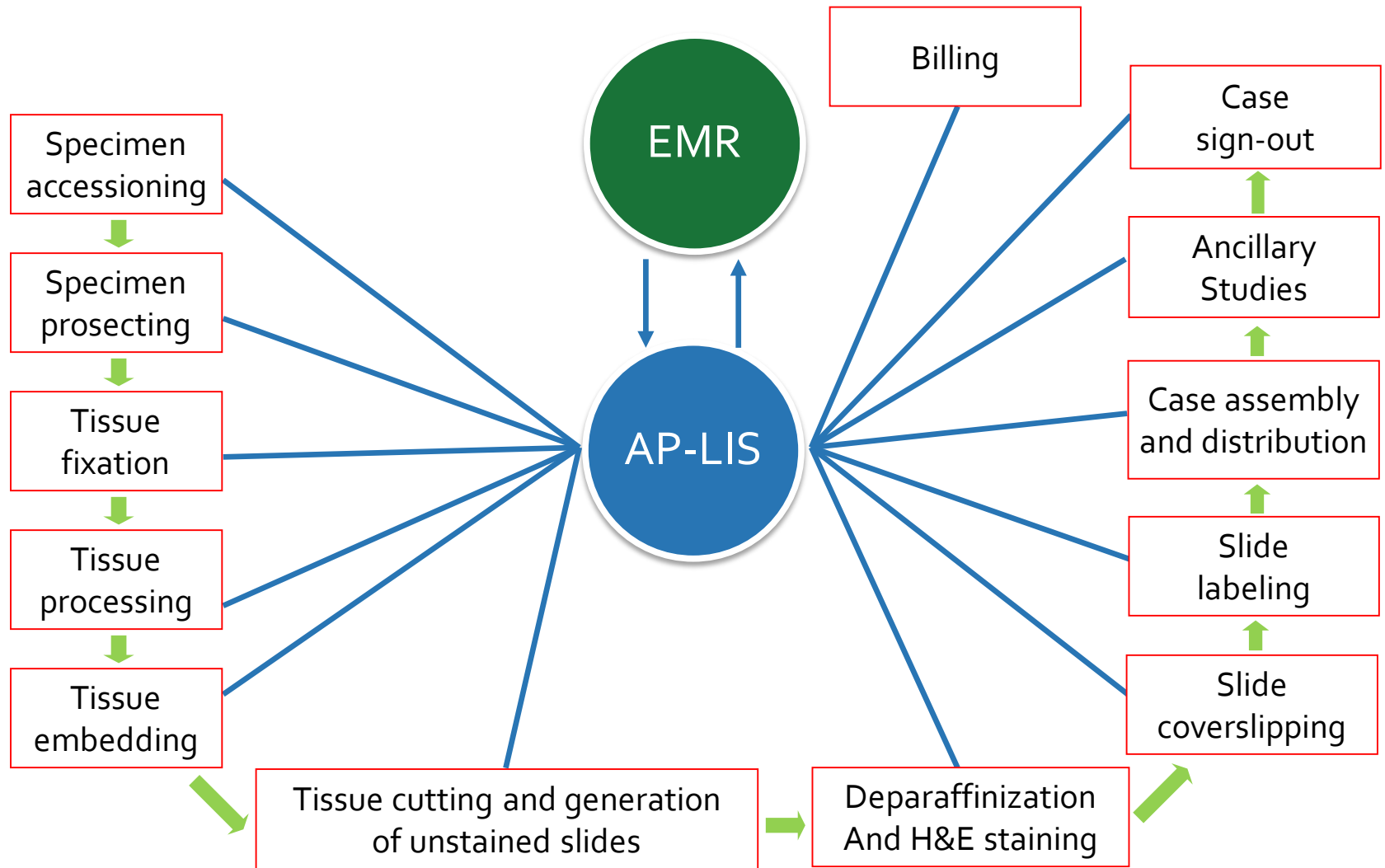
Anatomic Pathology



"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

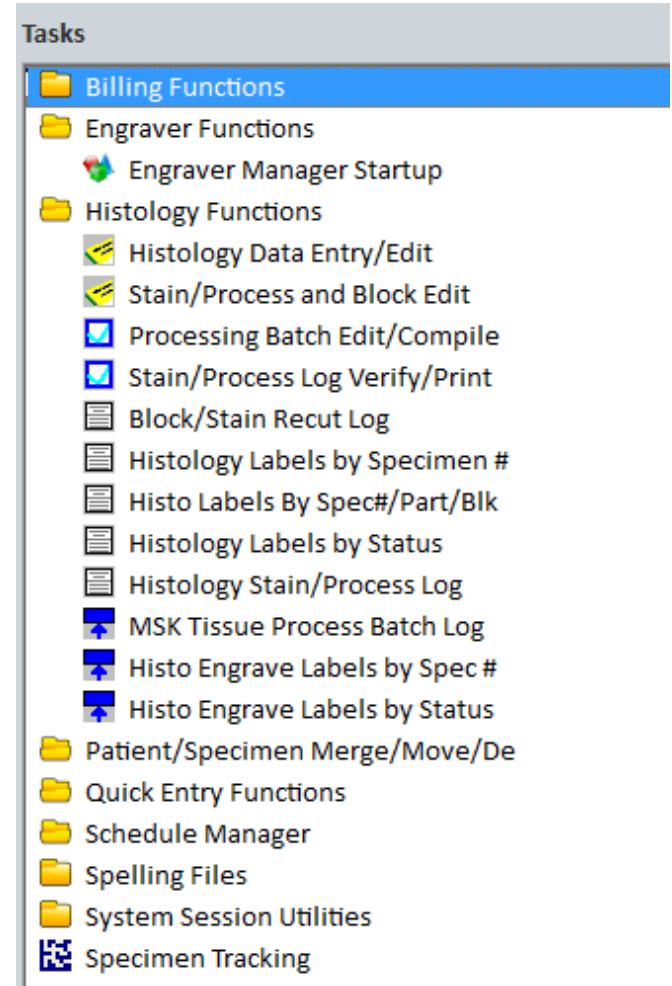
Operational/Administrative Functionalities

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

Histology

Click on a part, a block or a stain/process to select it.

Part 1: Right posterior bladder wall tumor
Taken: 3/29/2018 14:58 Received: 3/29/2018 16:04 All Pieces Used: Y

Block	Pcs	Comment	Stain/Process	Date Ordered	By	Comment
1 GU	2		ADD H&E x 1	3/30/2018 16:41	SJS	
			ADD H&E x 1	3/30/2018 16:41	SJS	
			ADD H&E x 1	3/30/2018 16:41	SJS	
			H&E x 1	3/29/2018 17:36	HBA	
			H&E x 1	3/29/2018 17:36	HBA	
			H&E x 1	3/29/2018 17:36	HBA	

Buttons: Add Stain/Process..., Edit Stain/Process..., Add Block..., Edit Block..., Staff/Billing..., Save/Engrave..., Save/Next Specimen

Stain/Process Entry/Edit

Histology Data for Part 1 (1 of 1) - Right posterior bladder wall tumor

	Stain/Process	Blk/Design	Count	Request Class	Ordered By	Comment
1	ADDITIONAL H&E	1 GU	1	ROUTINE	Sirintrapun,Sa	
2	ADDITIONAL H&E	1 GU	1	ROUTINE	Sirintrapun,Sa	
3	ADDITIONAL H&E	1 GU	1	ROUTINE	Sirintrapun,Sa	
4	H&E, Initial	1 GU	1	ROUTINE	Aldonzar,Harly	
5	H&E, Initial	1 GU	1	ROUTINE	Aldonzar,Harly	
6	H&E, Initial	1 GU	1	ROUTINE	Aldonzar,Harly	

Buttons: Stain/Process Detail..., Run Stain/Process Group..., Save Stain/Process Group

AP-LIS vendors should demonstrate:

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

Stain/Process Detail

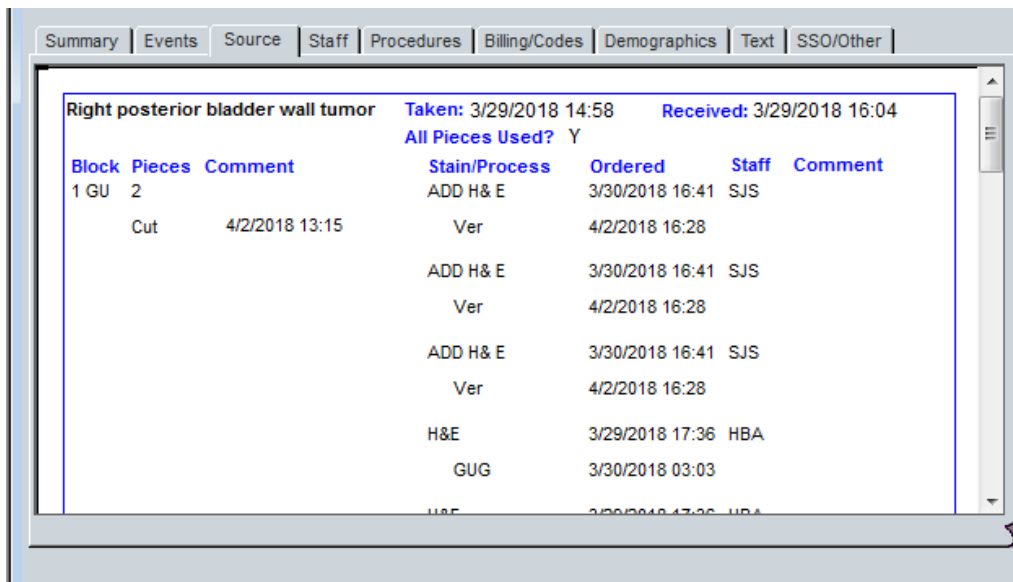
Stain/Process Detail for Part 1 (1 of 1) - Right posterior bladder wall tumor

	Stain/Process	Blk/Design	Count	Label Text	Request Class	Department	Order Date
1	ADDITIONAL H&E	1 GU	1	ADD H&E	ROUTINE	Surgical	3/30/2018 16:41
	Ordered By	Sirintrapun,Sa		Label Type: On Demand Slide	Status	Verified	4/2/2018 16:28
	Comment:						
2	ADDITIONAL H&E	1 GU	1	ADD H&E	ROUTINE	Surgical	3/30/2018 16:41
	Ordered By	Sirintrapun,Sa		Label Type: On Demand Slide	Status	Verified	4/2/2018 16:28
	Comment:						
3	ADDITIONAL H&E	1 GU	1	ADD H&E	ROUTINE	Surgical	3/30/2018 16:41
	Ordered By	Sirintrapun,Sa		Label Type: On Demand Slide	Status	Verified	4/2/2018 16:28
	Comment:						
4	H&E, Initial	1 GU	1	H&E	ROUTINE	Surgical	3/29/2018 17:36
	Ordered By	Aldonzar,Harly		Label Type: On Demand Slide	Status	Verified/C	3/30/2018 03:03
	Comment:						

OK

AP-LIS create histology laboratory logs

Example of section level log



The screenshot displays a software interface for a histology laboratory log. At the top, there is a navigation bar with tabs: Summary, Events, Source, Staff, Procedures, Billing/Codes, Demographics, Text, and SSO/Other. The main content area shows a log entry for a specimen labeled 'Right posterior bladder wall tumor'. It includes timestamps for 'Taken: 3/29/2018 14:58' and 'Received: 3/29/2018 16:04', and a status 'All Pieces Used? Y'. Below this, a table lists processing details for 'Block 1 GU' and 'Pieces 2'. The table has columns for 'Block', 'Pieces', 'Comment', 'Stain/Process', 'Ordered', 'Staff', and 'Comment'. The data rows show a sequence of processing steps: 'Cut' at 4/2/2018 13:15, followed by multiple 'ADD H&E' and 'Ver' steps on 3/30/2018 and 4/2/2018, and finally 'H&E' and 'GUG' steps on 3/29/2018 and 3/30/2018.

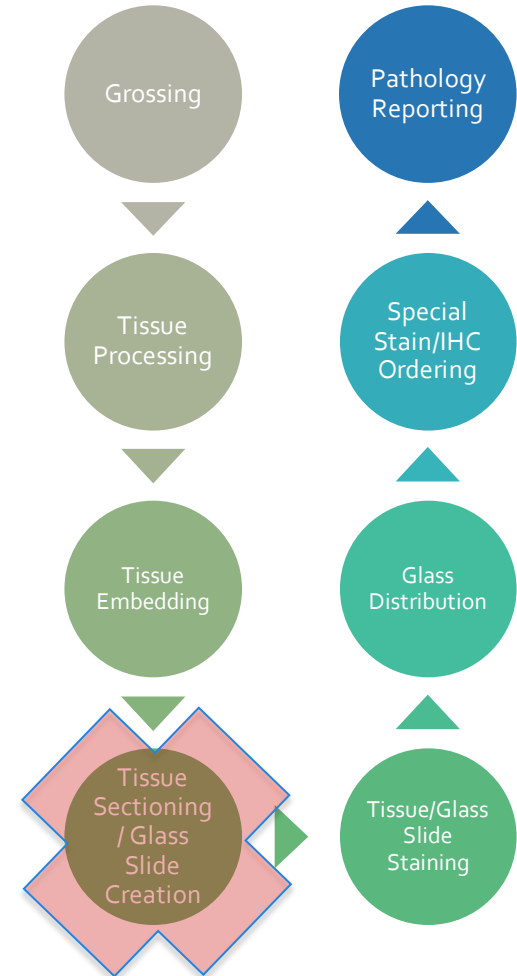
Block	Pieces	Comment	Stain/Process	Ordered	Staff	Comment
1 GU	2		ADD H&E	3/30/2018 16:41	SJS	
	Cut	4/2/2018 13:15	Ver	4/2/2018 16:28		
			ADD H&E	3/30/2018 16:41	SJS	
			Ver	4/2/2018 16:28		
			ADD H&E	3/30/2018 16:41	SJS	
			Ver	4/2/2018 16:28		
			H&E	3/29/2018 17:36	HBA	
			GUG	3/30/2018 03:03		

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

Stain/Process Lookup

Select:

Search

Name	Abbr	Description
BAP1-RED	BAP1-RE	BAP1-RED
B-CATENIN	B-CATEN	
B-Cell	B-Cell	FLOW B-Cell
BCL2	BCL2	
BCL6	BCL6	
BCMA (BCell)	BCMA	B-Cell Maturation Antigen
BCOR	BCORB	BCL6 Corepressor
BEREP4	BEREP4	BEREP4
BEST CARMINE (AMOEBA)	BEST CA	
BEST CARMINE (AMOEBA) CONTR	BEST CA	

Matched:

OK

Cancel

Help

Standards for dictionary setup are lacking

Challenging issue:

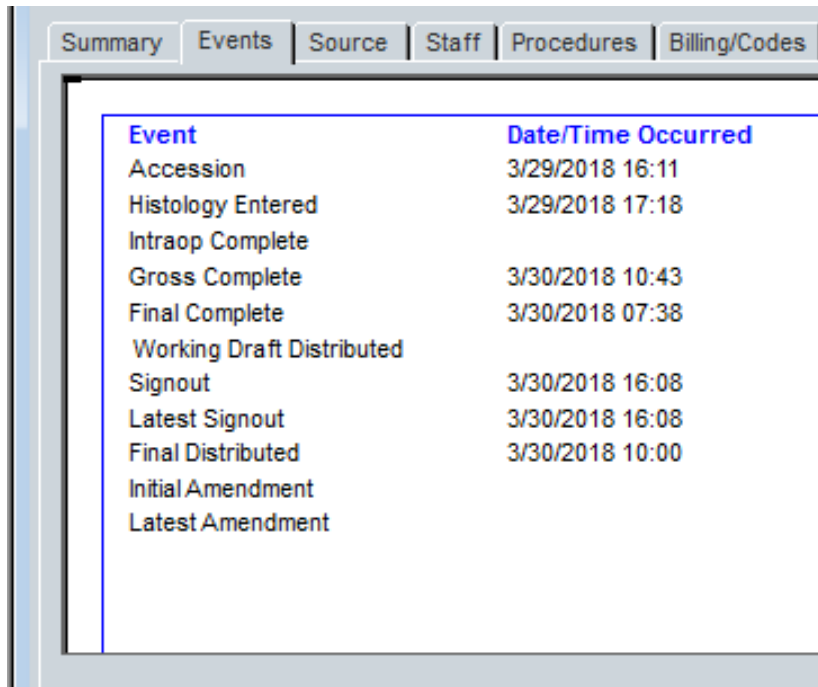
Criteria for data definition in different fields and in different dictionaries



- 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



The screenshot shows a web-based interface with a tabbed menu at the top containing 'Summary', 'Events', 'Source', 'Staff', 'Procedures', and 'Billing/Codes'. The 'Events' tab is selected, displaying a table with two columns: 'Event' and 'Date/Time Occurred'. The table lists various laboratory events and their corresponding timestamps.

Event	Date/Time Occurred
Accession	3/29/2018 16:11
Histology Entered	3/29/2018 17:18
Intraop Complete	
Gross Complete	3/30/2018 10:43
Final Complete	3/30/2018 07:38
Working Draft Distributed	
Signout	3/30/2018 16:08
Latest Signout	3/30/2018 16:08
Final Distributed	3/30/2018 10:00
Initial Amendment	
Latest Amendment	

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

The screenshot displays a software interface with a top navigation bar containing tabs: Diagnosis, Worksheets, Digital Slides, Billing/Misc (selected), SNOMED, QA, and Staff. The main content area is divided into several sections:

- Table 1:** A table with columns: Part Type(s), Description, Taken, and Received. It contains one data row.

Part Type(s)	Description	Taken	Received
1 BLADDER; BIOPSY	Right posterior bladder wall tumor	3/29/2018 14:58	3/29/2018 16:04
- ICD-9-CM Code(s) Section:** Includes input fields for ICD-9-CM Code(s), Source, and Auto.
- Specimen Data Section:** Includes input fields for Billing Number, Billing Type (set to OUTPATIENT), and Submitting Physician.
- Table 2:** A table with columns: Fee Code(s), Units, Source, Credit, Billed, and Auto. It contains one data row.

Fee Code(s)	Units	Source	Credit	Billed	Auto
1 LEVEL IV	1	1			

A "Save/Sign Out" button is located at the bottom right of the interface.



User Friendly Interfaces/Automation

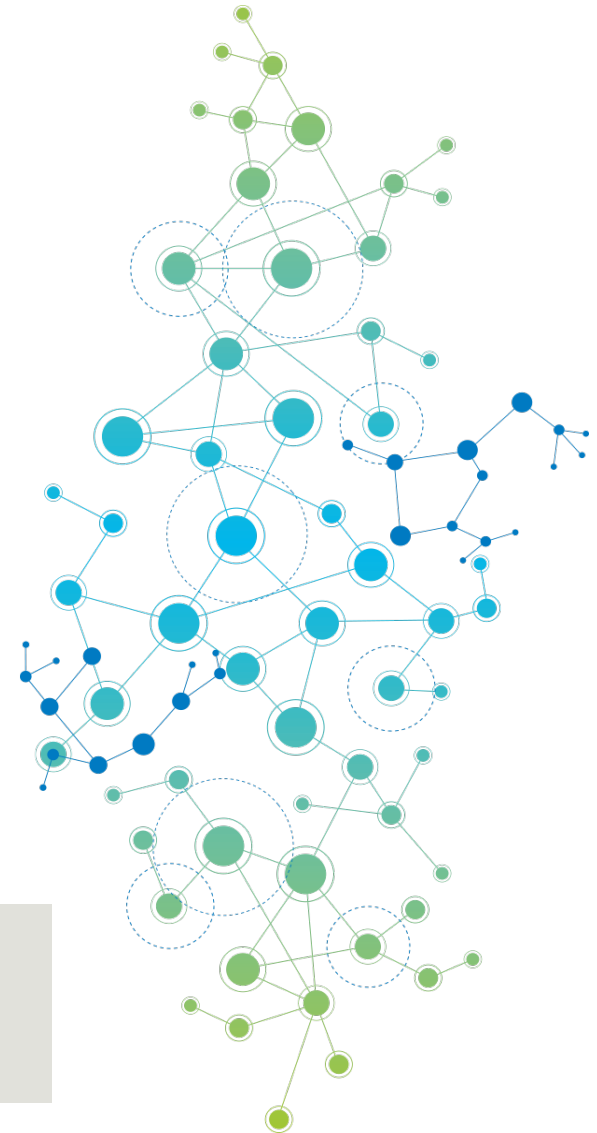
Wishlist for better human and AP-LIS interaction:

- *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

IS interfaces are software and connections

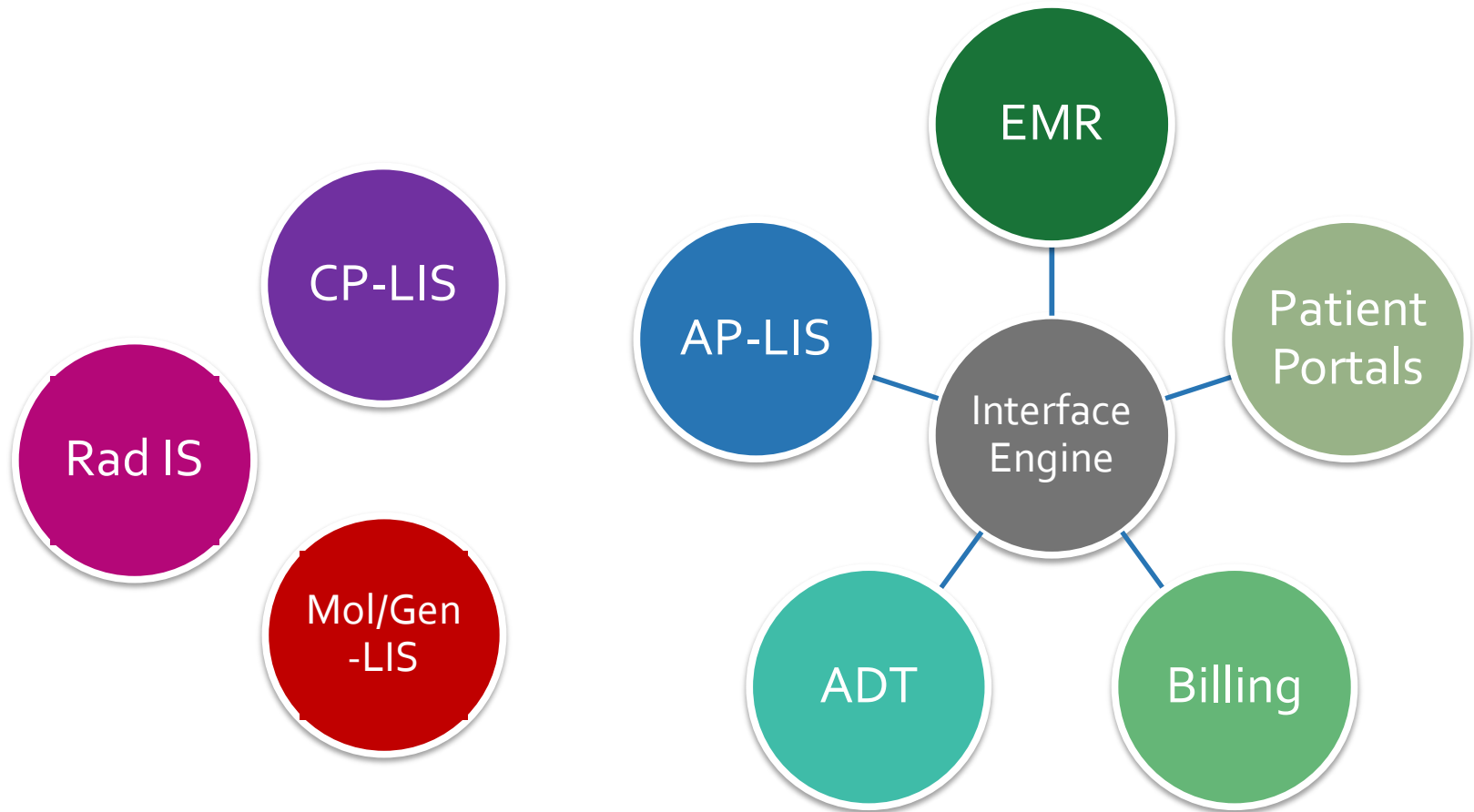
- Unidirectional vs bidirectional
- Translate electronic messages
 - *Exchange* data between otherwise incompatible systems

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

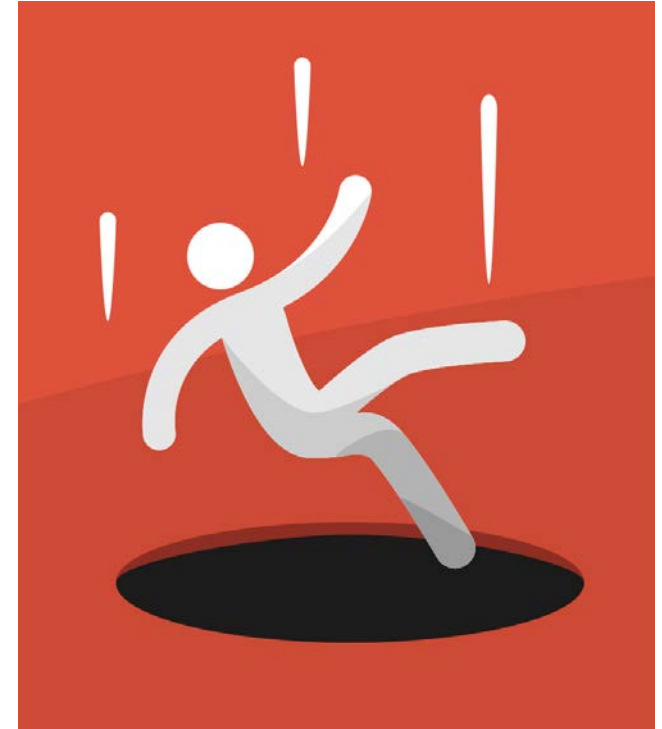
- Defines format (syntax, structure)
 - Not specific content of messages
- Defines for systems “how to say it”
 - Not “what to say”



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

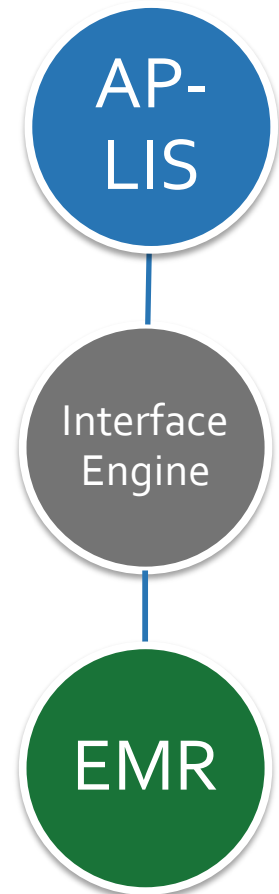


More Pitfalls of
HL7 to Come

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)

Order:	Surgical Pathology Submitted Slides Order			Order ID:	031VWVGHPN
Requested By:				Template Name:	
Messages:	Only submit slides that are pertinent to the current diagnosis & treatment of this patient.				
Please examine submitted pathologic material including submitted slides, biopsies, surgical specimens, cytologic preparations and reports on the above captioned patient.					
Please specify, if possible, in your report the pathologic characteristics necessary for treatment planning including tumor type, size, extent of invasion, histologic grade, presence or absence of precursor lesion, adequacy of surgical resection margins, and lymph node status. When necessary, please utilize ancillary testing including immunohistochemistry, fluorescent in situ hybridization (FISH), flow cytometry, cytogenetics, or molecular analysis (polymerase chain reaction) to identify relevant prognostic and therapeutic data elements.					
Clinical Diagnosis:	MSKCC Surgery Date:	MSKCC Appointment Date:			
<input type="text"/>	<input type="text"/>	<input type="text"/>			
Clinical Hx/Op Findings:					
<input type="text"/>					
Referring Institution #1:	Outside Path. #:	# Slides:	# Blocks:	Outside Report:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Referring Institution #2:	Outside Path. #:	# Slides:	# Blocks:	Outside Report:	
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Referring Institution #3:	Outside Path. #:	# Slides:	# Blocks:	Outside Report:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Referring Institution #4:	Outside Path. #:	# Slides:	# Blocks:	Outside Report:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Time/Priority:					
<input type="text"/>		RNB Research Do Not Bill: <input type="checkbox"/>			
Contact Name:	Contact Beeper:	Send Extra Copy To:			
<input type="text"/>	<input type="text"/>	<input type="text"/>			

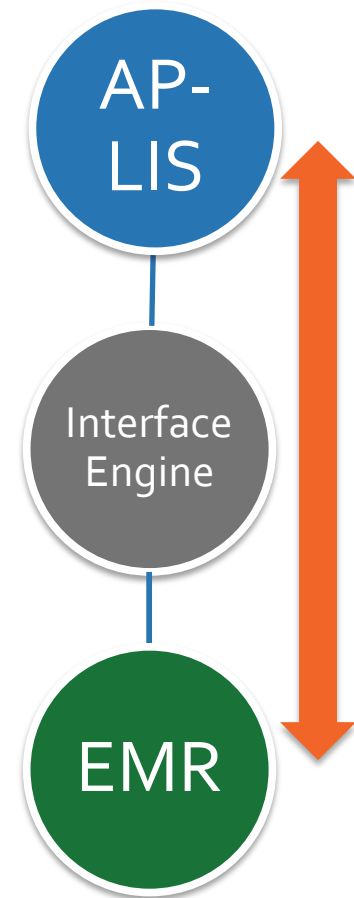
CPOE Gaps

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

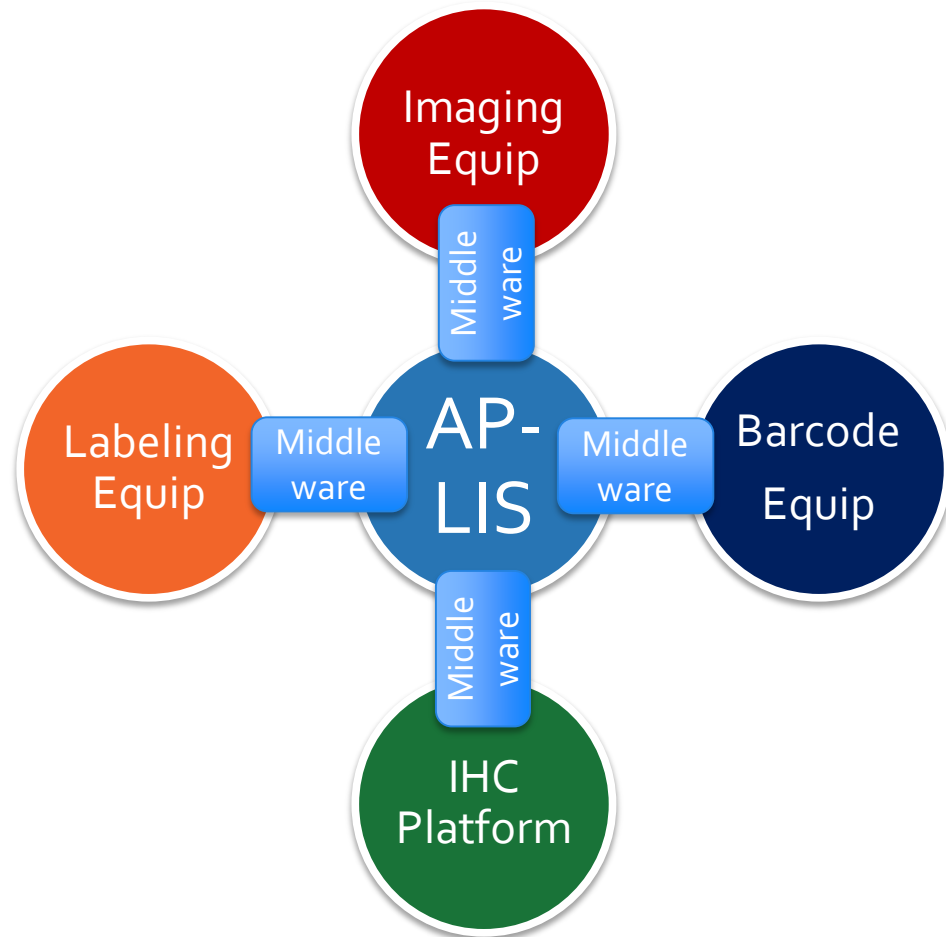
- *Single order requiring:*
 - Separating to multiple component specimens/accessions with multiple tests
 - Tracking progress and reporting status of component specimens/accessions



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

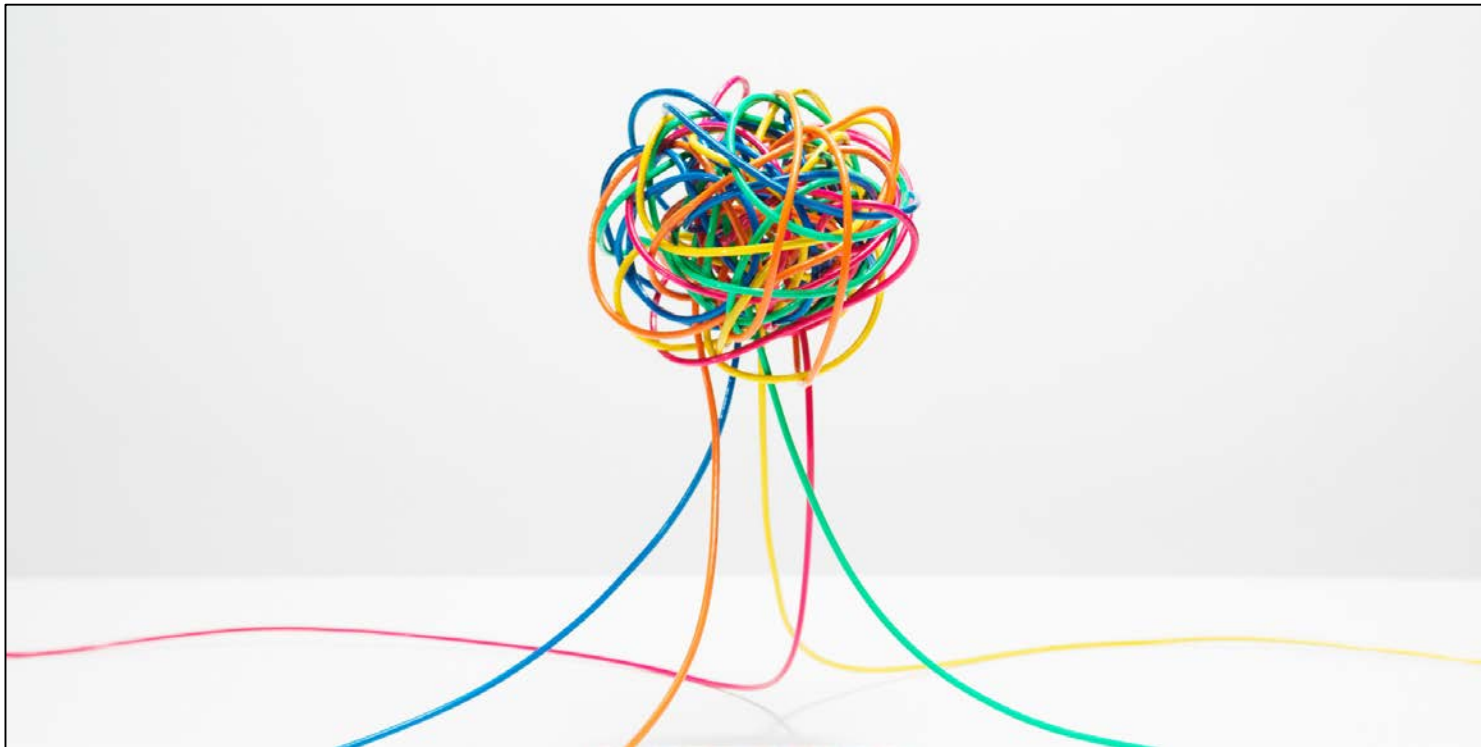


Cautionary Message for Middleware

“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 monoclonal 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

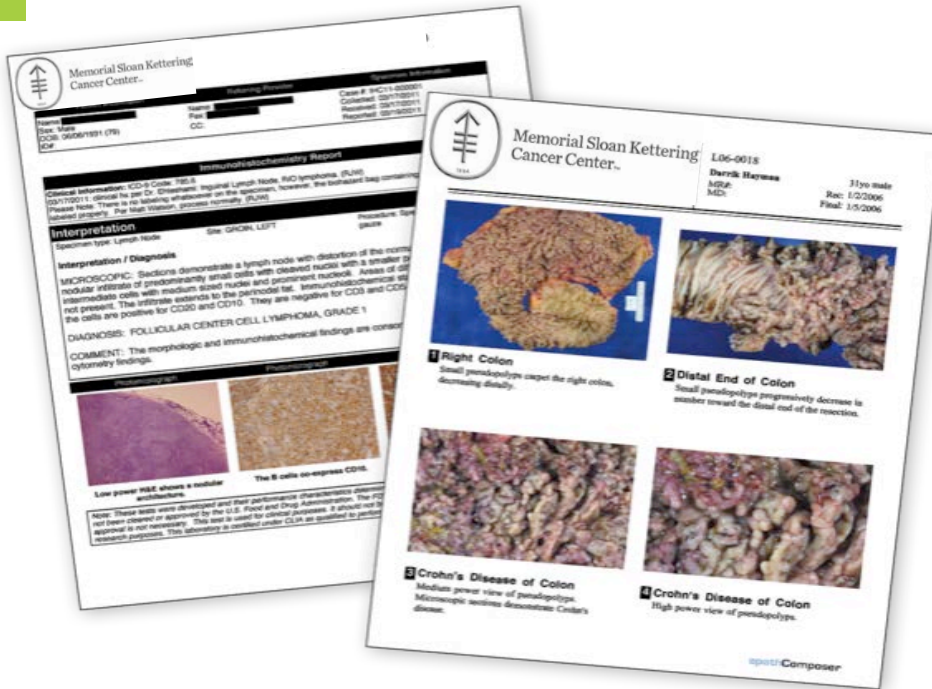
Continuing Decision Support Gaps in Reporting

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. RFW2 (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				
	Copy number profile is suggestive of broad copy number gain on Chromosome arm 5p.				
Comments	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	

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/Administrative 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)

The screenshot shows a medical coding software interface. At the top, there are tabs: Diagnosis, Worksheets, Digital Slides, Billing/Misc, SNOMED, QA, and Staff. The 'Diagnosis' tab is active. Below the tabs, there is a 'Final Diagnosis' section with a text area containing: '1. Right posterior bladder wall tumor. Urothelial Findings: Marked urothelial atypia. Other processes:'. To the right of this text area is an 'Edit Text' button. Below the 'Final Diagnosis' section is a 'SNOMED' section. It has an 'Autocode' button. Below this is a table with columns 'SNOMED Code(s)', 'Source', and 'Auto'. The table contains five rows of codes: M80001, T74030, T74062, T74064, and M11600, each with a description and corresponding values in the 'Source' and 'Auto' columns. To the right of the table is a 'Words not used by Coder' section with a text area. At the bottom right of the interface is a 'Save/Sign Out' button.

SNOMED Code(s)	Source	Auto
1 M80001 (Neoplasm, uncertain whether benign or malignant)	1	A
2 T74030 (Muscularis of urinary bladder)	1	A
3 T74062 (Posterior wall of urinary bladder)	1	A
4 T74064 (Right wall of urinary bladder)	1	A
5 M11600 (Radiation injury, nos)	1	A

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

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		Vascular Invasion	
G1	Not identified	L1	Not identified
G2	Present	L0	Renal vein invasion not identified
G3		L2	Renal vein invasion identified
Rhabdoid Features		L3	Segmental branches of renal vein invasion identified
H1	Not identified	L4	Vena cava invasion identified
H2	Present	L5	Lymphovascular (small vessel) invasion identified
H3		L6	
Tumor Necrosis		Surgical Margins	
J1	Not identified	M1	Uninvolved by tumor
J2	Present	M2	Tumor present at ureteral margin
J3		M3	Tumor present at renal vein margin
Local Invasion		M4	Tumor present at soft tissue margin
K1	Tumor limited to kidney	M5	Tumor present at renal parenchymal margin (partial nephrectomy specimens only)
K2	Tumor extension into perinephric tissue (beyond renal capsule)	M6	
K3	Tumor extension into renal sinus fat	Pathologic Findings in Non-Neoplastic Kidney	
K4	Tumor extension beyond Gerota's fascia	N1	No significant pathologic findings
K5	Tumor extension into pelvicalyceal system	N2	Insufficient tissue
K6		N4	Compression-related changes

Template continues into the next page ---->

KIDNEY-PARTIAL OR RADICAL NEPHRECTOMY Page 3 of 4

Other Findings		S3	pT1a: Tumor 4 cm or less in greatest dimension, limited to the kidney
P1	Cyst(s)	S4	pT1b: Tumor more than 4 cm but not more than 7 cm in greatest dimension, limited to the kidney
P2	Papillary adenoma(s)	S5	pT2a: Tumor more than 7 cm but less than or equal to 10 cm in greatest dimension, limited to the kidney
P3		S6	pT2b: Tumor more than 10 cm, limited to the kidney
Adrenal Gland		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
Q1	Not identified	S8	pT3b: Tumor extends into the vena cava below the diaphragm
Q2	Not involved	S9	pT3c: Tumor extends into vena cava above the diaphragm or invades the wall of the vena cava
Q3	Involved by tumor by direct invasion	S10	pT4: Tumor invades beyond Gerota's fascia (including contiguous extension into the ipsilateral adrenal gland)
Q4	Involved by metastatic carcinoma (noncontiguous) (M1)	S11	
Q5		Regional Lymph Nodes (pN)	
Regional Lymph Nodes		T1	pNX: Regional lymph node cannot be assessed
R1	Not identified	T2	pN0: No regional lymph node metastasis
R2	Free of tumor	T3	pN1: Metastasis in regional lymph node(s)
R3	Number of Lymph Nodes Involved: _____	T4	
R4	Number of Lymph Nodes Examined: _____	Pathologic Stage Classification (AJCC 8th Edition)	
R5		Primary Tumor (pT)	
S1	pTX: Primary tumor cannot be assessed	S1	
S2	pT0: No evidence of primary tumor	S2	

Template continues into the next page ---->

Upcoming sessions that address usability of synoptic reporting modules

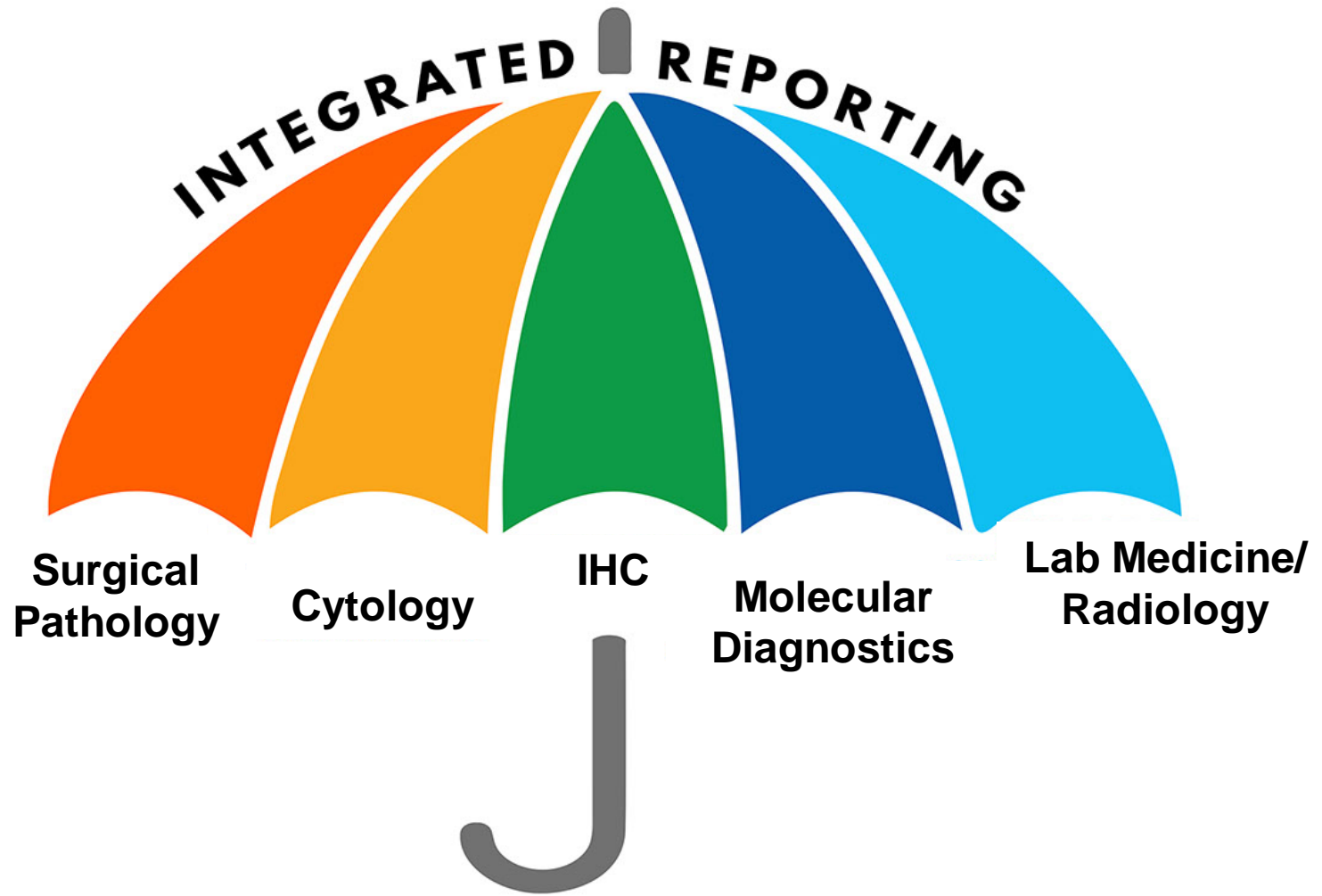
Wednesday Morning Track Presentations

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”

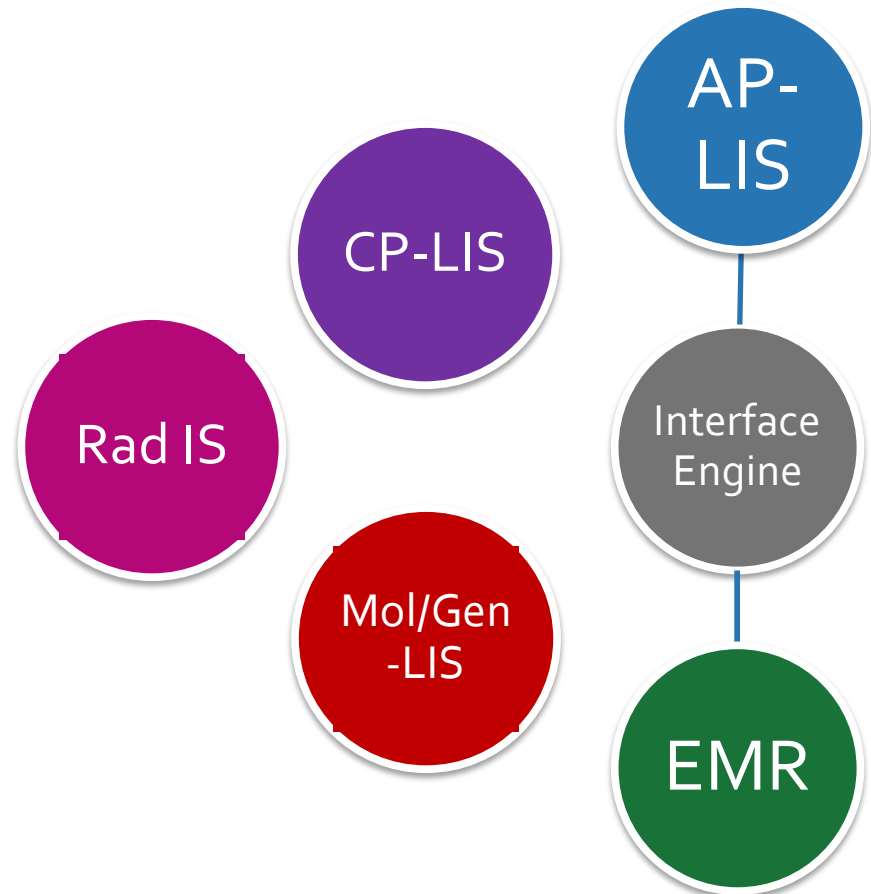
Systems Integration/Interfacing

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

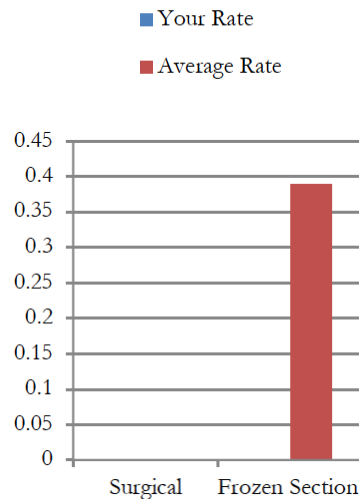
AP-LIS should demonstrate how to pull Turn Around Times (TATs)

Based on signing pathologists:

- Frozen sections
- Surgical/biopsies
- Cytologies
- Autopsies

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%

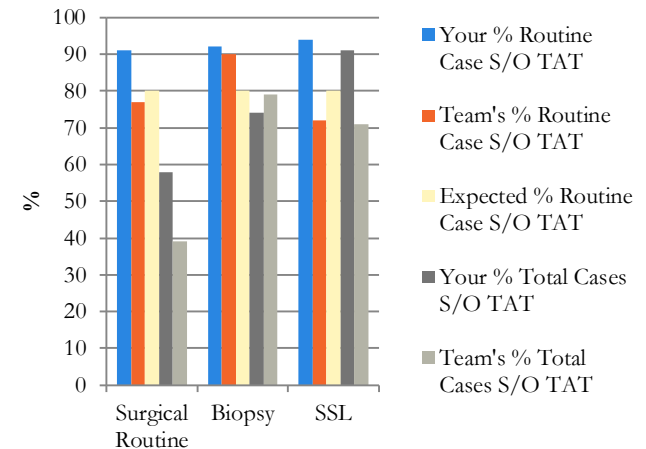


Surgical Routine Turn-Around Time (in days)

	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		



Such benchmarking ties with quality management

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

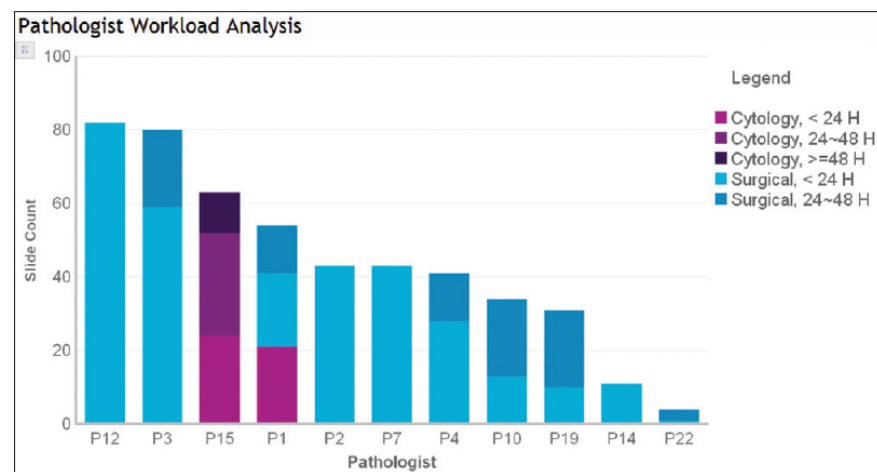
Strong Case for Robust Business Intelligence Solutions

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 workload 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

The screenshot displays a software interface for Quality Management. At the top, there are tabs: Diagnosis, Worksheets, Digital Slides, Billing/Misc, SNOMED, QA, and Staff. The QA tab is active. Below the tabs is a section titled 'QA Data' containing a table with columns: QA Review Type(s), Review Date, Status, and Problem. The table has one row: 'Intraoperative vs. Final Diagnosis', '4/3/2018', 'Complete', and an empty Problem field. To the right of the table are buttons: Add, Previous, and Next. Below the table is a form with fields for QA Review Type, Review Date, Status, and Problem. The QA Review Type dropdown is open, showing options: Embedding, IHC, IntraOp vs. Final Dx (highlighted), Intraoperative vs. Final Diagnosis, Major discrepancy between pre-operative and post-operative diagnosis, Major organ removed without identifiable significant pathology and without a previous significant pa, and MSK slides reviewed by outside. Below the dropdown is a Result(s) section with a dropdown showing 'See final diag'. At the bottom are Resolution(s) and Reason(s) sections, each with a dropdown and a Comment field. A Save/Sign Out button is at the bottom right.

QA Review Type(s)	Review Date	Status	Problem
Intraoperative vs. Final Diagnosis	4/3/2018	Complete	

QA Review Type: Intraoperative vs. Final Diagnosis
Review Date: Embedding
Status: IHC
Problem: IntraOp vs. Final Dx
Intraoperative vs. Final Diagnosis
Major discrepancy between pre-operative and post-operative diagnosis
Major organ removed without identifiable significant pathology and without a previous significant pa
MSK slides reviewed by outside

Result(s)
1 See final diag

Resolution(s) Comment

Reason(s) Comment

Save/Sign Out

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

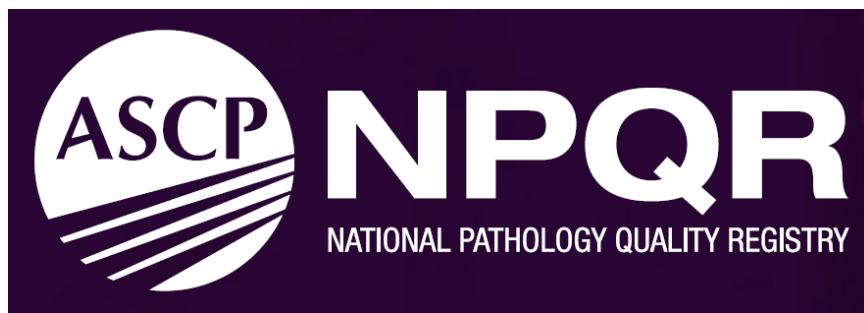
Automated reporting of quality management data to public health registries

- *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



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:

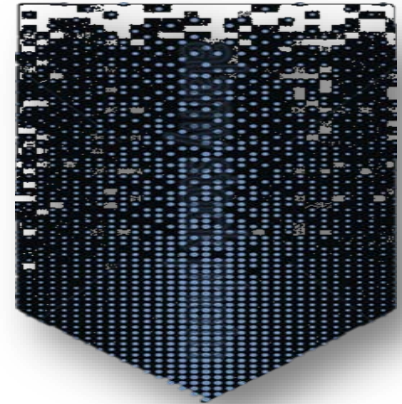
- Guidelines-driven performance measurement, benchmarking, and quality improvement capabilities
- Enables laboratories to identify areas for improvement
- Participate in government-required pay for performance programs
- Integrate results into educational programs
- Measure adherence to appropriate use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

Digital Pathology



ARMS
Acquisition
Retrieval/Storage
Manipulation
Sharing

Acknowledgement for graphics: Matthew Hanna, MD.



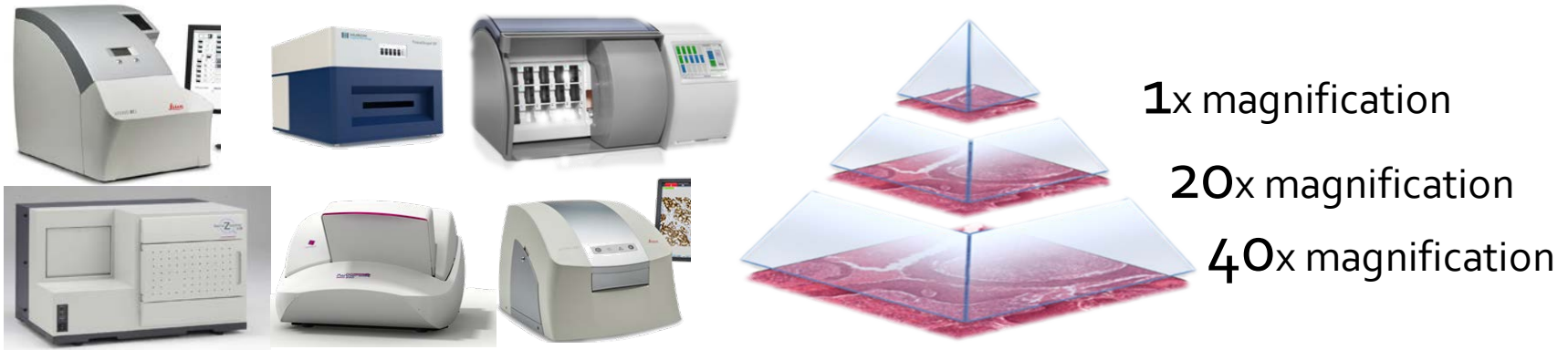
AP-LISs should demonstrate:

- 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.



Information Systems

HIS
PACS
LIS
EMR
RIS

Digital Pathology System

Whole slide scanner
Whole slide viewer

System Tools

pCAD
Native Applications
3rd party applications
Image analysis

W o r k F l o w

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

Desired is incorporation of gross images but also clinical information

The screenshot displays the Omnyx DPS software interface. On the left, the 'Case A' tab is active, showing patient information: Patient ID, Gender (F), Birth Date (Age) (Jun 10, 1981 (35)), Ordering Clinician (GYNECOLOGY, UNKNOWN), Status (BENCH), Accession Date (Jan 3, 2017), and Shared (More...). Below this, there are tabs for Results, Notes (2), and Attachments (2). The Attachments tab is selected, showing a table of files:

File	Description	Created By	Information System	Date
Slide1.JPG	ThinPrep	Hanna, Matthew	Omnyx	Jan 31, 2017 3:40:59 PM
Slide2.JPG	Cervical Os	Hanna, Matthew	Omnyx	Jan 31, 2017 3:41:09 PM

On the right, the 'EVIDENCE' tab is active, showing a search bar and a 'Sort By: Date' dropdown. Below this, a 'SLIDE TRAY' section displays a thumbnail of a slide. The main area of the interface shows a large, high-resolution image of a gross specimen, which appears to be a pair of human femurs. A ruler is visible in the bottom right corner of the image, indicating a scale in centimeters.

Desired is on-demand archive/case management

Omnyx DPS

Hanna, Matthew |

11 results

search

ACCESSION #	ACCESSION DATE	PATIENT	PRIORS	ORDERING CLINICIAN	STATUS	BENCH	SHARED	PARTS	PART DESCRIPTION	SLIDES
Hologic 6a	Jan 31, 2015	Cytology Six, Patie...	1	GYNECOLOGY, UNKN...	✓			1	Omnyx	1 *
Hologic 7	Sep 17, 2015	Cytology Seven, P...	0	PULMONARY, UNKN...	✓			2	PLEURAL FLUID	3 **
Hologic 9	Nov 21, 2016	Cytology Nine, Pat...	0	GYNECOLOGY, UNKN...	✓			1	ENDOCERVICAL BIOPSY (SHY)	4 **
Hologic 6b	Aug 19, 2014	Cytology Six, Patie...	1	GYNECOLOGY, UNKN...	✓			1	PAP Smear (SVCY)	1 *
Hologic 3	Aug 8, 2016	Cytology Three, P...	0	GYNECOLOGY, UNKN...	✓			1	Omnyx	1 *
Hologic 5	Oct 11, 2016	Cytology Five, Pati...	0	ENT, RESIDENT	✓			1	Diff-Quik	1 *
Hologic 4	Jan 13, 2016	Cytology Four, Pat...	0	GYNECOLOGY, UNKN...	✓			1	ThinPrep (PAP)	1 *
Hologic 8	May 27, 2016	Cytology Eight, Pa...	0	GYNECOLOGY, UNKN...	✓			1	CERVICAL BIOPSY (SHY)	2 **
Hologic 2	Oct 18, 2016	Cytology Two, Pati...	0	GYNECOLOGY, UNKN...	✓			1	Aperio	1 *
Hologic 10	Dec 20, 2016	Cytology Ten, Pati...	0	GYNECOLOGY, UNKN...	✓			1	Hamamatsu	2 **
Hologic 1	Jan 3, 2017	Cytology One, Pati...	0	GYNECOLOGY, UNKN...	✓			1	Hamamatsu	1 *

« 1 »

Acknowledgement for graphics: Matthew Hanna, MD.

Desired is delivery of computational pathology tools

Computer-assisted diagnostics

(pre-selected ROIs and searchable annotations)

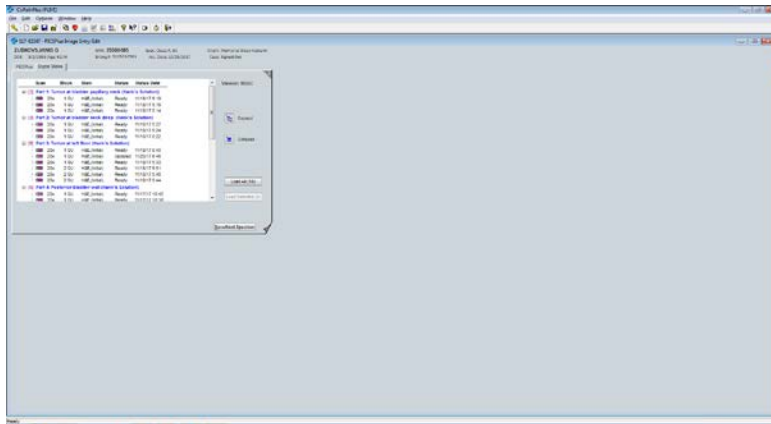
The screenshot displays the Omnyx DPS software interface for 'Case C'. The interface is divided into several panels:

- Case Information Panel:** Displays patient details for 'Cytology Three, Patient', including Patient ID, Gender (F), Birth Date (Nov 15, 1986), and Accession Date (Aug 8, 2016). It also shows clinical history and grossing notes.
- Evidence Panel:** Contains a list of annotations. The first annotation is a 60x magnification image with a green dot, labeled 'Omnyx: 1A TPREP' and 'Hanna, Matthew 12:22 PM'. The second annotation is a 20x magnification image with a blue bounding box, labeled 'Omnyx: 1A TPREP' and 'Hanna, Matthew 12:22 PM', with a measurement of 7.665µm². The third annotation is a 20x magnification image with a yellow scale bar, labeled 'Omnyx: 1A TPREP' and 'Hanna, Matthew 12:22 PM', with a measurement of 51.3µm.
- Slide Tray Panel:** Shows a list of slides, including '1. Omnyx' and '2. Omnyx'.

Acknowledgement for graphics: Matthew Hanna, MD.

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 Guo¹, Joe Birsá², Navid Farahani¹, Douglas J. Hartman¹, Anthony Piccoli³, Matthew O'Leary³, Jeffrey McHugh³, Mark Nyman², Curtis Stratman², Vanja Kvarnstrom², Samuel Yousem¹, Liron Pantanowitz¹

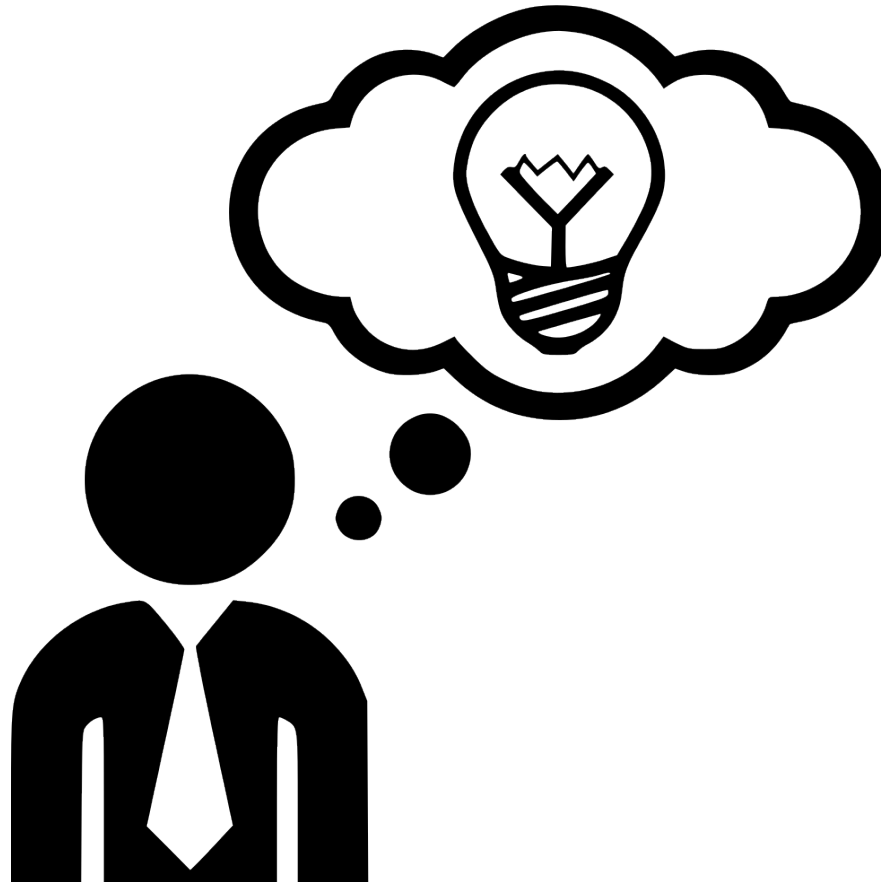


Parting thoughts:

“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.