LIS Design and Operations

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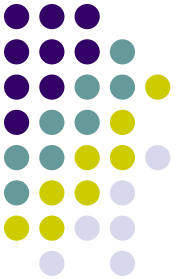
Mehrvash Haghighi, MD

Introduction to Laboratory Information Systems (LISs) Learning Objectives



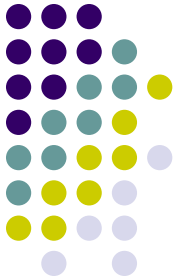
Define terms and jargon related to LISs

Describe central importance of dictionaries and interfaces to LIS function and laboratory operations

Identify LIS functions as they relate to laboratory workflow in CP and AP

Describe design anomalies and how they affect functionalities

Building Blocks of Laboratory Information Systems



LIS application software

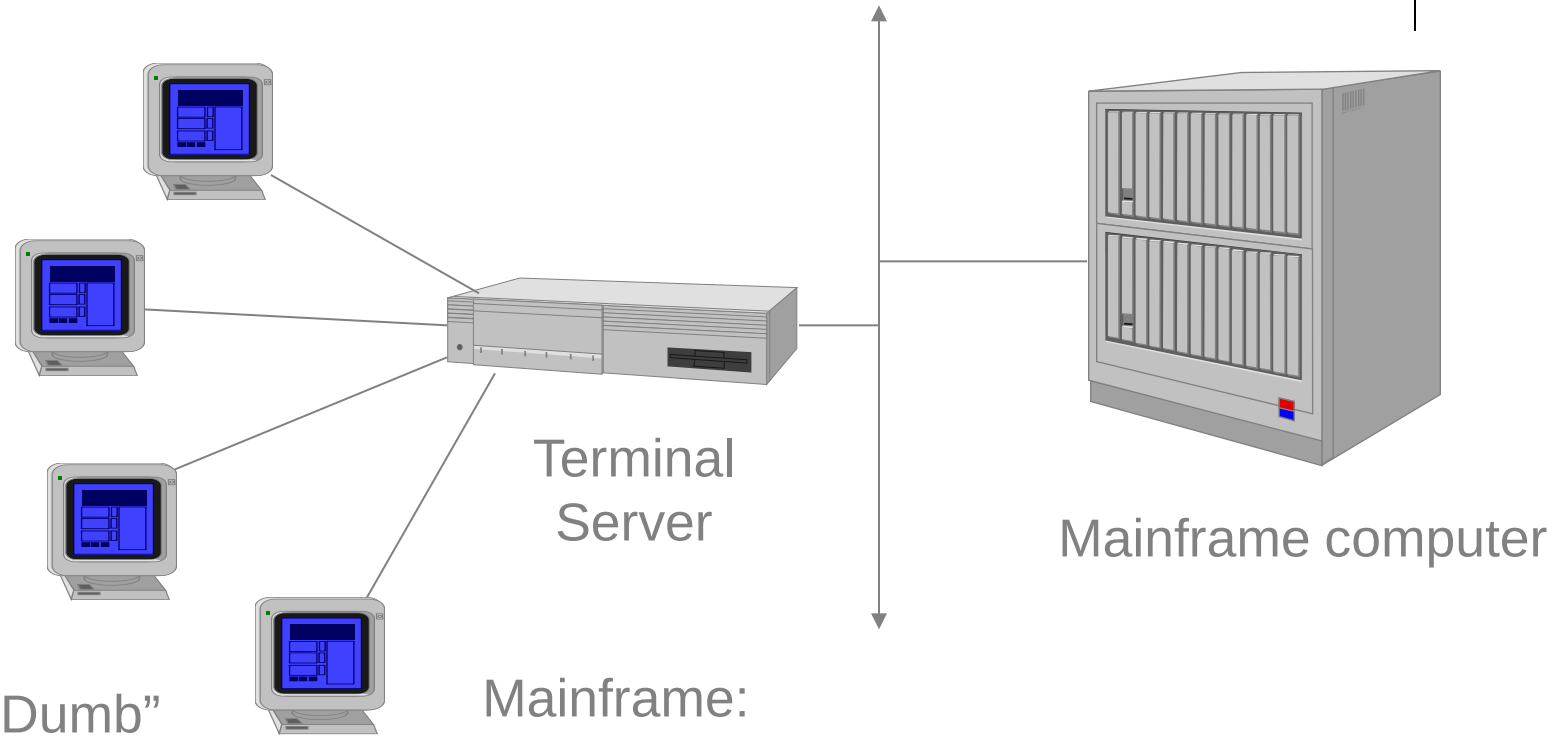
Database Management System (DBMS)

Operating System

Hardware

LIS Architecture

Mainframe (Host-based)



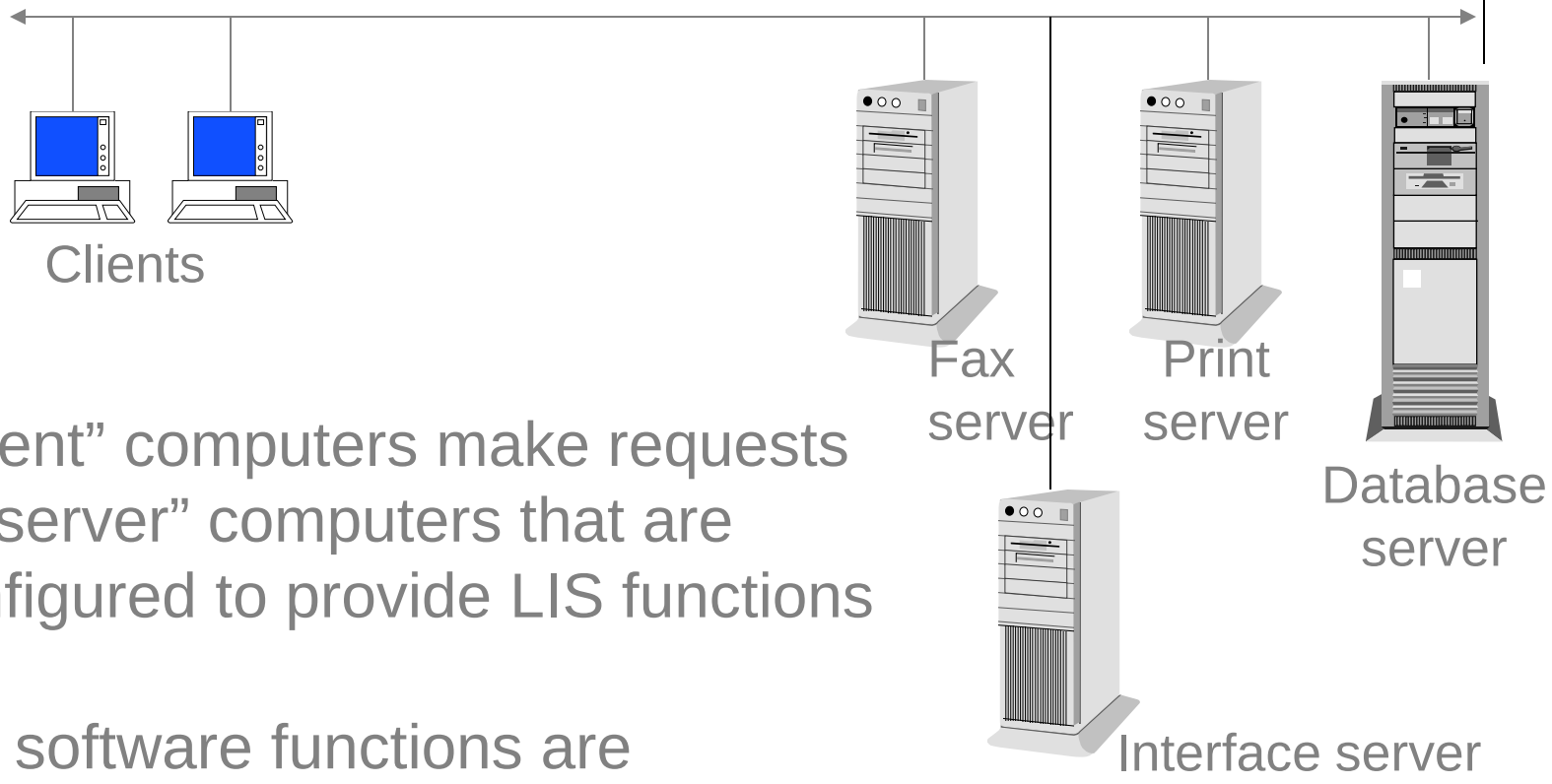
Mainframe:

- holds database and all LIS software
- manages all LIS functions and transactions

Terminals:

- data display and input only
- PCs can connect using "terminal emulation"

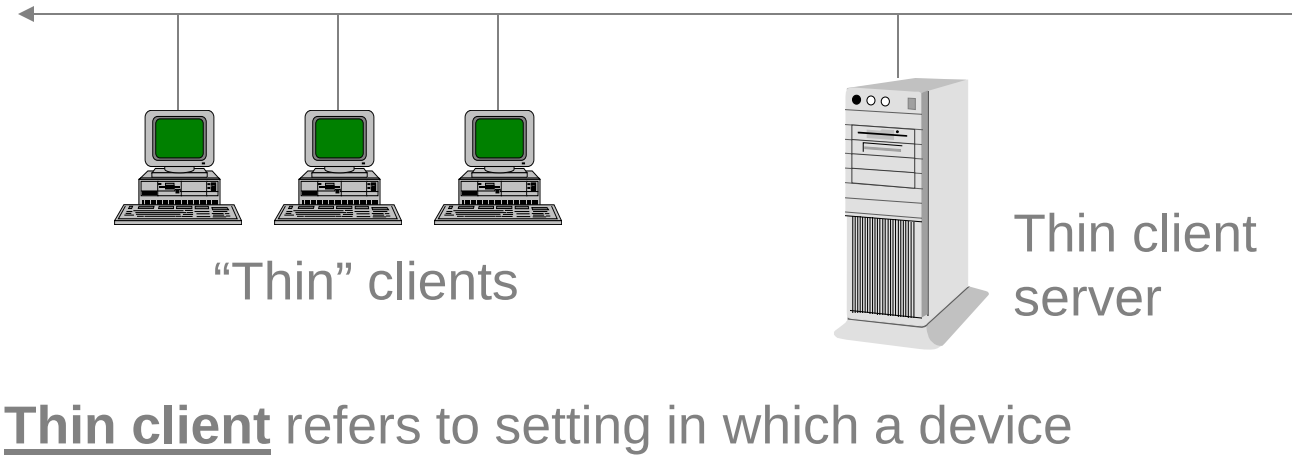
Client/Server LIS



"Client" computers make requests of "server" computers that are configured to provide LIS functions

LIS software functions are **distributed** across all clients and servers

Thin Client Architecture in LIS



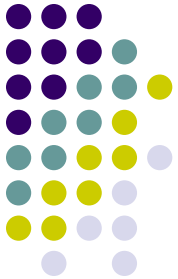
- **Thin client** refers to setting in which a device (e.g. PC) runs software that is relatively simple (="thin") and requires less computer power and resources

- Application logic executes on *thin client server*

- Resembles host-based/mainframe model in some respects (connection through intermediate server)

Thin Client Computing for the LIS

How it may benefit YOUR laboratory



Easier administration

- Standardized application/programs controlled centrally
- Easier to implement software updates in a complex environment

Cross-platform (PC, Mac)

Lower hardware requirements and costs

Remote access

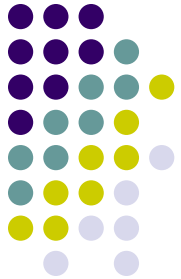
Less network traffic

Thin Client Computing for the LIS

Why YOUR laboratory may think twice

- Hardware and license costs
- Single point of failure for all workstations connected to thin client server
- Effectiveness of vendor's implementation of thin client
- Potential inability to do specialized functions on thin client workstation, e.g. imaging, voice recognition

Looking towards smart clients



Support work offline

Deployed and updated in real-time

Support multiple platform and languages

Run on almost any device

Offer rich GUI

Higher development and maintenance costs

Require installation

Introduction to LISs – Outline

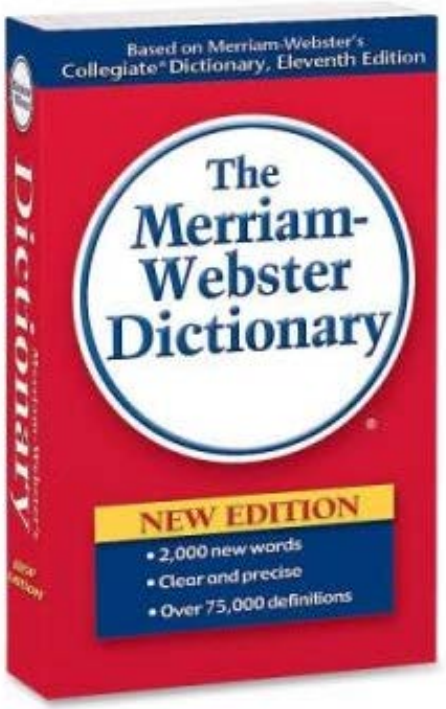
LIS architecture

➢

LIS functions in laboratory workflow

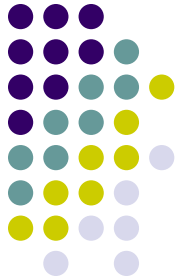
- Clinical laboratory (CP)
- Anatomic pathology (AP)

What do dictionaries contain?



DEFINITIONS!

LIS Dictionaries *Define* Your Laboratory's Information Framework



Standardize naming conventions and procedures

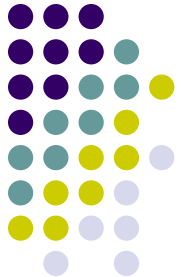
Standardize laboratory terminology and definitions

Constrain choices for data fields to ensure valid data entry

Define content and format of reports (e.g. units of measure)

Define rules and calculations

LIS Dictionaries Define *People, Places, Things*



- Test and test battery/profile definitions
- Test worksheets / worklists
- Person dictionaries (e.g., ordering physician, pathologist, technologist)
- Security/access level privileges for user types
- Patient locations
- Laboratory locations (e.g. sections, “areas”)
- Specimen types
- Histologic stain protocols (e.g. Giemsa on gastric bx)
- Analyzer/instrument interfaces
- Autoverification parameters
- Many others…

TEST DEFINITION DICTIONARY

TEST NAME: Hemoglobin

TEST CODE: HGB

LAB. DEPT: CORE

CONTAINER TYPES: LAV

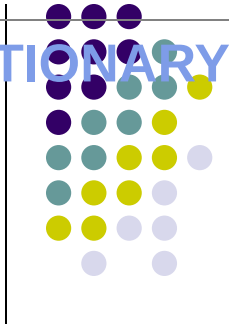
WORKSHEET(S): CELCOUNTR

IN BATTERIES: CBC, CBCDIF, HGBHCT

AUTOVERIFY RANGE: 6.1-19.9

LAB DEPT DICTIONARY

- CORE
- CLINIC
- GASLAB
- Etc.



CONTAINER TYPE DICTIONARY

- LAV
- BLUE
- RED
- Etc.

TEST BATTERY DICTIONARY

- CBC
- CBCDIF
- HGBHCT
- PTINR
- BMP
- Etc.

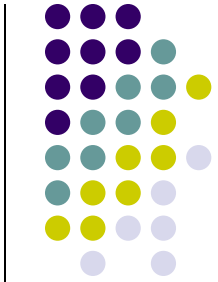
AUTOVERIFICATION DICTIONARY

- RULES FOR HGB
- Etc.

INSTRUMENT INTERFACE TABLE

- BLDCTR INTERFACE MAINTENANCE
- CHEM INTERFACE MAINTENANCE
- Etc.

LIS Dictionaries AP LIS



Specimen class dictionary

Part type dictionary

Person dictionary

Permission group dictionary

Autopsy reason dictionary

Billing fee code dictionary

Quick text dictionary

Interpretation dictionary

Synoptic worksheet dictionary

SNOMED II code Dictionary

Text type Dictionary

Menstrual /Pregnancy Dictionary

Infection History Dictionary

Cancer History Dictionary

Procedure dictionary

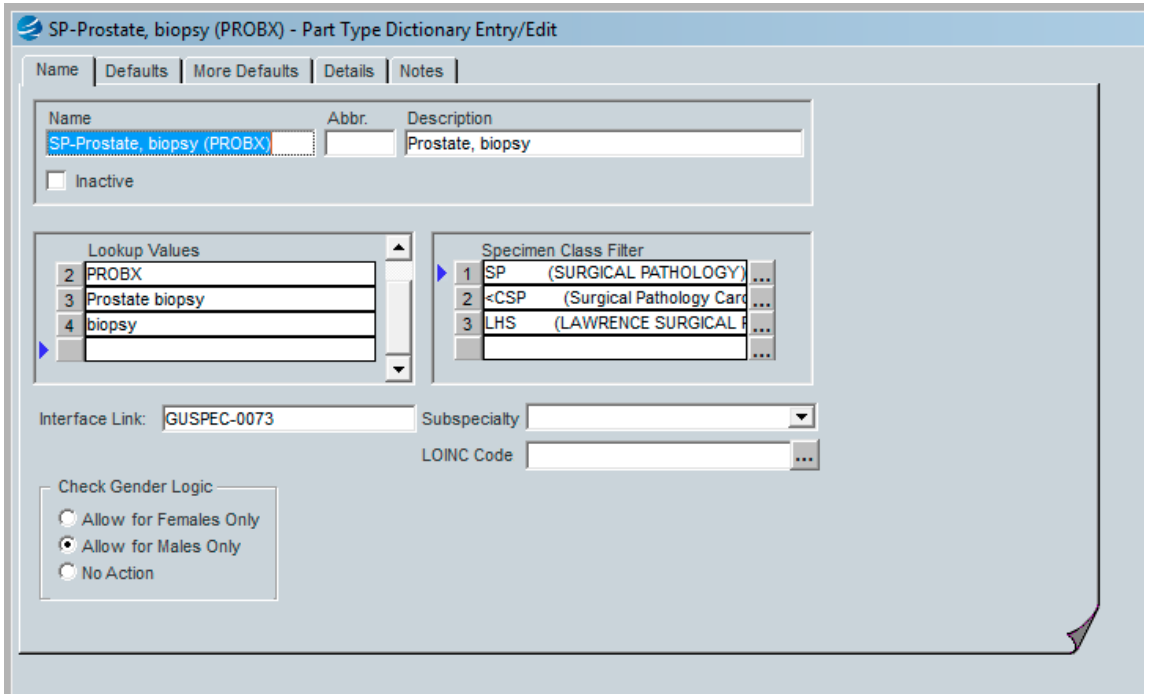
Protocol dictionary

Stain/process dictionary

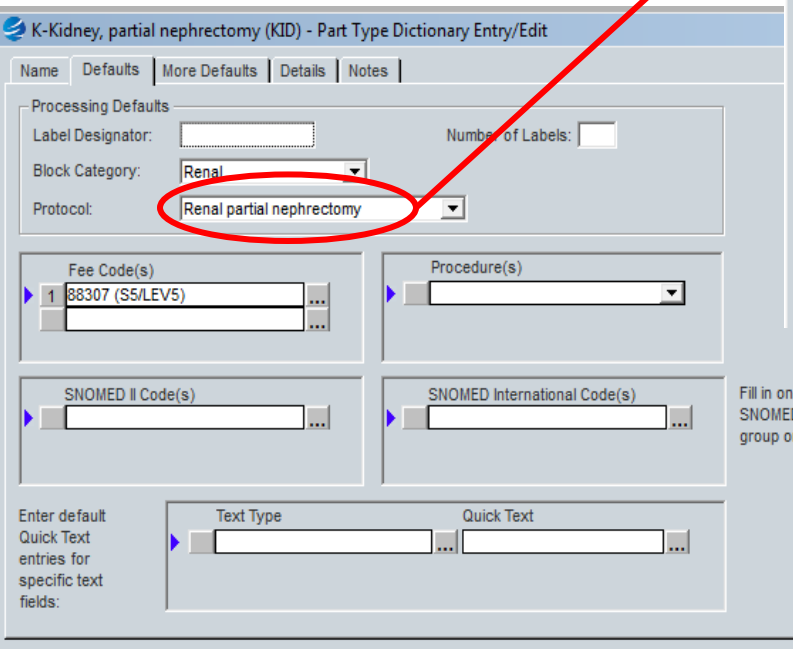
Block category dictionary

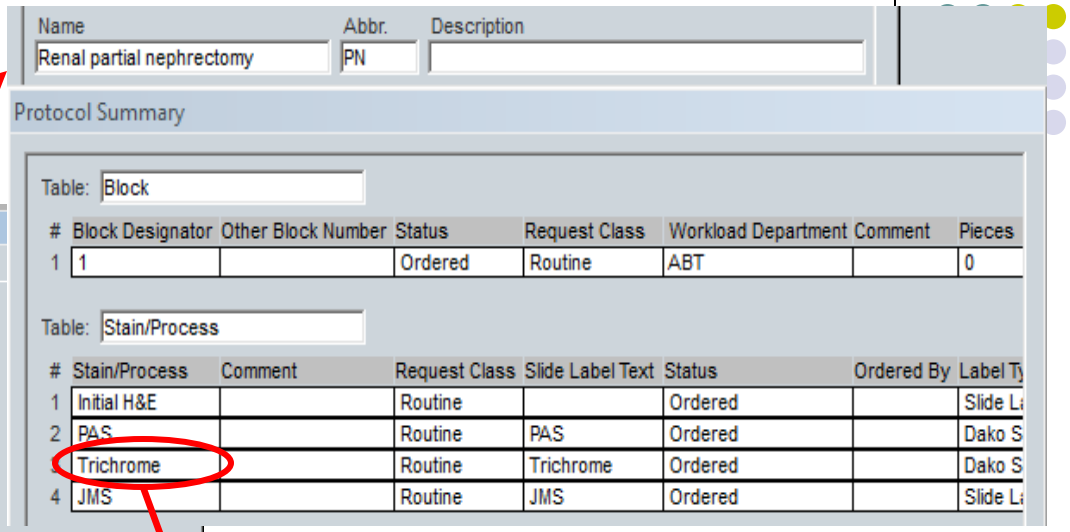
Block status dictionary

Example AP LIS Dictionary: Specimen Part Type

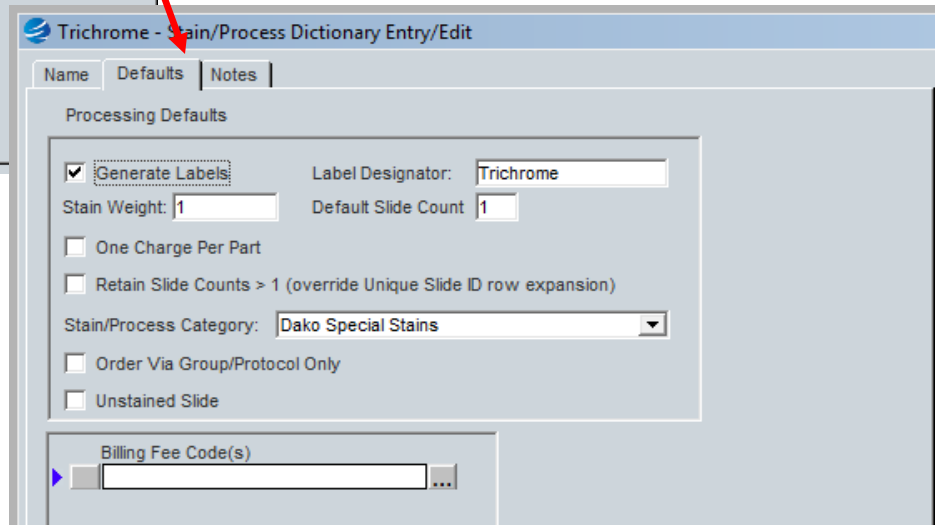


Protocol dictionary

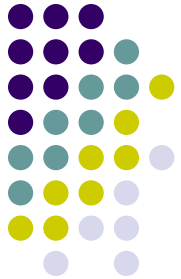




Stain dictionary



Dictionary set up/ LIS design



Dictionaries and maintenance tables *tailor* the LIS to YOUR laboratory

Table definition is critical to successful LIS implementation and lab operation.

It should be done by experts in information management

Users (pathologist and technician) involvement is essential.

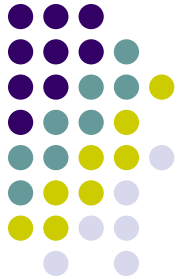
Changes must be tested before being “put into production”.

LIS Interfaces

Interface – software and connections that translate electronic messages so that otherwise incompatible systems can *exchange* data

LIS interfaces are critical to laboratory success (e.g. test order receipt, results reporting)

Common interfaces

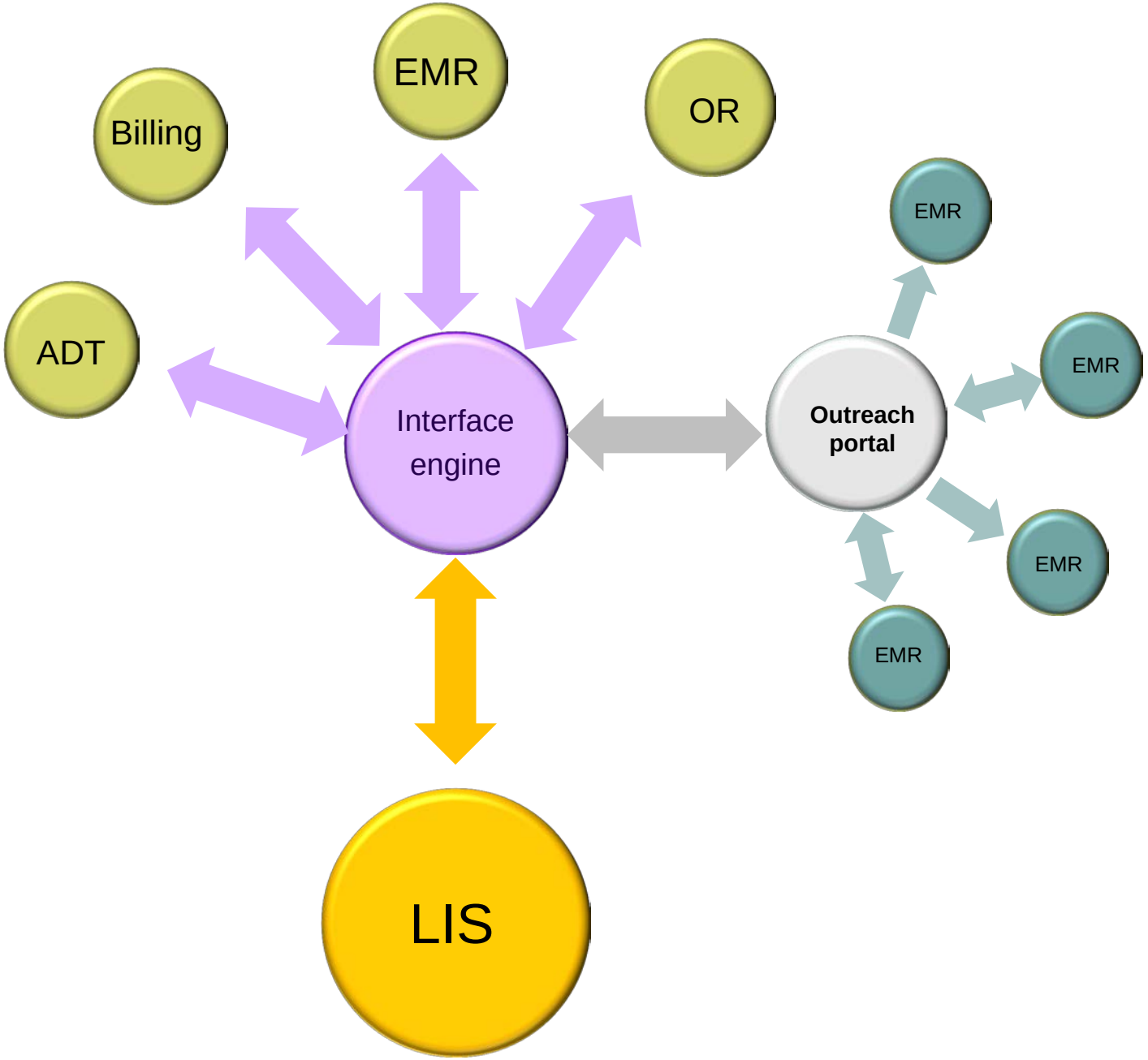


Application (system)

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

Instrument

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


Billing
EMR
OR
ADT
Interface engine
Outreach portal
EMR
EMR
EMR
EMR
LIS

Application interface

LIS vendors have some “off-the-shelf” interfaces for most common applications.

Most CPOEs should be designed and customized by lab.

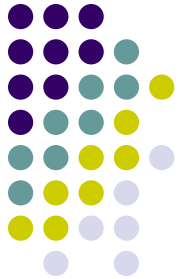
Unidirectional vs Bidirectional

Rigorous testing and validation prior to use and with changes.

Test plan

		Test Name	Order Entry Questions	Answers	TW	mh3373	CM#	MB#	CT	CT Dx	Path	Path Dx
1	CROWN, AAA	Pap test (E)	Last Menstrual Period Date	2/12/2015	TW450004520	OCG15-110			ES	ASCUS	MH	LSIL
	Louis Bigliani		Menstrual History	Normal								
			HPV test	N								
			GC/CT test	N								
			Trichomonas test	N								
			Specimen Source	E								
			Is this test a screening Pap test?	Yes								
			Current Contraceptive Use	IUD								
			History of Abnormal pap smear /HPV	Blank								
			History of treatment	Chemotherapy								
			History of Gyn malignancy	None								
			Other pertinent clinical information	Blank								
2	CROWN, CCC	Pap test (V)	Last Menstrual Period Date	Blank	TW450004590	OCG15-111			EG	LSIL	MH	HSIL
	Christopher Ahmad		Menstrual History	Abnormal bleeding								
			HPV test	N								
			GC/CT test	N								
			Trichomonas test	N								
			Specimen Source	V								
			Is this test a screening Pap test?	Yes								
			Current Contraceptive Use	Hormonal contraceptive								
			History of Abnormal pap smear /HPV	Pap								
			History of treatment	Pelvic Radiation								
			History of Gyn malignancy	Squamous cell carcinoma								
			Other pertinent clinical information	Cervical cancer, History of ASC-H								
3	CROWN, EEE	Pap test / (Cotesting) HPV (E)	Last Menstrual Period Date	1/15/2015	TW450004620	OCG15-112	HPV16		DK	HSIL	AS	HSIL
	Louis Bigliani		Menstrual History	Unknown			CM15-13					
			HPV test	C								
			GC/CT test	N								
			Trichomonas test	N								
			Specimen Source	E								
			Is this test a screening Pap test?	Yes								
			Current Contraceptive Use	Other								
			History of Abnormal pap smear /HPV	Neither								
			History of treatment	Cone Bx/Leep								
			History of Gyn malignancy	Adenocarcinoma								
			Other pertinent clinical information	urinary incontinence								

LIS-Instrument Interfaces



Download = direct transfer of patient identification and test order data from LIS to instrument

Upload = direct transfer of results back to LIS

Uni-directional vs. Bi-directional

Broadcast vs. query

LIS-Instrument Interface Implementation

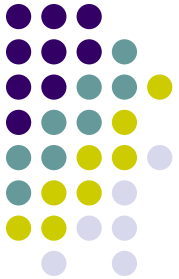
LIS vendors have “off-the-shelf” interfaces for most common instruments (revenue source).

Installation of a new interface is not “plug and play.”

Interface software must be installed in LIS dictionaries.

- Definition of data and sequence in the manner expected in the relevant worksheet(s).
- Rigorous testing and validation prior to use and with changes.

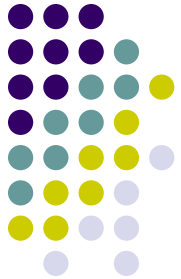
HL7 (Health Level 7) – Most Important Data Exchange Standard In Healthcare



HL7 defines the format (syntax, structure) but not the specific content of messages

HL7 tells computer systems “how to say it” to each other but not “what to say”.

HL7 does not eliminate the difficulties of implementing interfaces



- HL7 interface specifications for LIS typically do not match other vendors/systems.
- Translation tables are necessary to cross-reference different test codes in different systems.
- **LOINC** is a standardized vocabulary of lab test names with goal of interoperability
- Interface deployment requires testing, validation, documentation

Translation table

Downtown Womens		Columbia University Pathologists						
Test Code	Test Name	Test Code	Test Name	Question	AOE Question Text	AOE Required?	Default Response	
GYNCYTOLOGY	Thin Prep	GYNCYTOLOGY	ThinPrep Pap Test					
				Q1	Perform HPV DNA (Not part of standing order) (Y) or (N)	Y	?	
				Q2	Perform STI test (Chlamydia/Gonorrhoeae only)? (Y) or (N)	Y	?	
				Q3	Perform STI test (Chlamydia/Gonorrhoeae/Trichomonas)? (Y) or (N)	N	?	
				Q4	Perform STI test (Trichomonas only)? (Y) or (N)	N	?	
				Q5	Specimen Source (cervical (C)/vaginal(V) (If other specify type)	Y	<from EMR>	Cervical
				Q6	Is this test for screening (S) or diagnostic (D)?	Y	<from EMR>	Screening
				Q7	Date of LMP:	Y	<from EMR>	
				Q8	Prior history of cervical neoplasia?	N	<from EMR>	
				Q9	Other clinical information:	N	<from EMR>	
GYNCYTOLOGY2	Thin Prep / HPV	GYNCYTOLOGY	ThinPrep Pap Test					
				Q1	Perform HPV DNA (Not part of standing order) (Y) or (N)	Y	?	
				Q2	Perform STI test (Chlamydia/Gonorrhoeae only)? (Y) or (N)	Y	?	
				Q3	Perform STI test (Chlamydia/Gonorrhoeae/Trichomonas)? (Y) or (N)	N	?	
				Q4	Perform STI test (Trichomonas only)? (Y) or (N)	N	?	
				Q5	Specimen Source (cervical (C)/vaginal(V) (If other specify type)	Y	<from EMR>	Cervical
				Q6	Is this test for screening (S) or diagnostic (D)?	Y	<from EMR>	Screening
				Q7	Date of LMP:	Y	<from EMR>	
				Q8	Prior history of cervical neoplasia?	N	<from EMR>	
				Q9	Other clinical information:	N	<from EMR>	
GYNCYTOLOGY3	Thin Prep / Reflex HPV	GYNCYTOLOGY	ThinPrep Pap Test					
				Q1	Perform HPV DNA (Not part of standing order) (Y) or (N)	Y	?	
				Q2	Perform STI test (Chlamydia/Gonorrhoeae only)? (Y) or (N)	Y	?	
				Q3	Perform STI test (Chlamydia/Gonorrhoeae/Trichomonas)? (Y) or (N)	N	?	
				Q4	Perform STI test (Trichomonas only)? (Y) or (N)	N	?	
				Q5	Specimen Source (cervical (C)/vaginal(V) (If other specify type)	Y	<from EMR>	Cervical
				Q6	Is this test for screening (S) or diagnostic (D)?	Y	<from EMR>	Screening
				Q7	Date of LMP:	Y	<from EMR>	
				Q8	Prior history of cervical neoplasia?	N	<from EMR>	
				Q9	Other clinical information:	N	<from EMR>	
GYNCYTOLOGY4	Thin Prep / HPV / CT/GC	GYNCYTOLOGY	ThinPrep Pap Test					
				Q1	Perform HPV DNA (Not part of standing order) (Y) or (N)	Y	?	
				Q2	Perform STI test (Chlamydia/Gonorrhoeae only)? (Y) or (N)	Y	?	
				Q3	Perform STI test (Chlamydia/Gonorrhoeae/Trichomonas)? (Y) or (N)	N	?	
				Q4	Perform STI test (Trichomonas only)? (Y) or (N)	N	?	

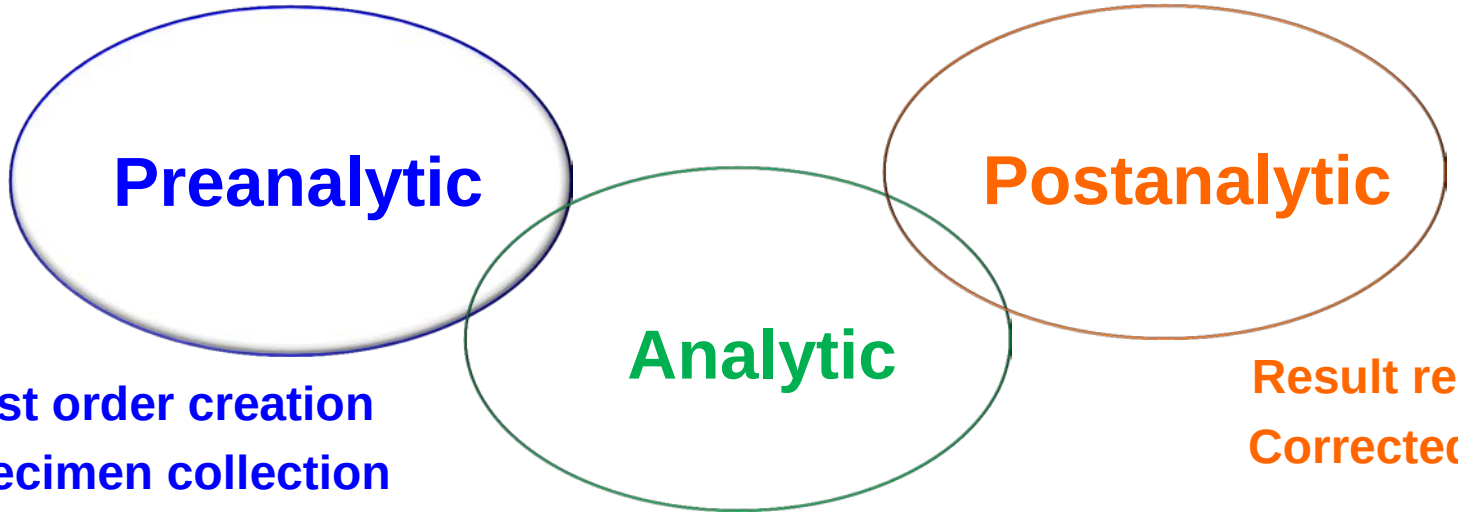
Introduction to LISs – Outline

LIS architecture

LIS dictionaries (a.k.a. maintenance tables)

- LIS functions in laboratory workflow
  - Clinical laboratory (CP)
  - Anatomic pathology
-

Lab testing cycle



Test order creation
Specimen collection
Specimen receipt

Specimen &test distribution
Analysis/interpretation
Additional testing
Result entry

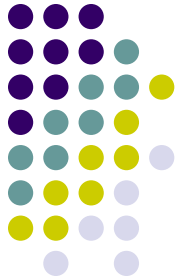
Result reporting
Corrected report

Order Creation and Test Selection – CP LIS

Orders interfaced from HER (HL7)

Non-interfaced test requisition order entry (hard copy)

Specimen Collection and Order Creation and Labeling – AP LIS



Clinician collect specimen

Order is created in EHR

A unique order number is assigned to each order

Labels and requisition are printed

Specimen Receipt in lab and specimen accession - AP LIS

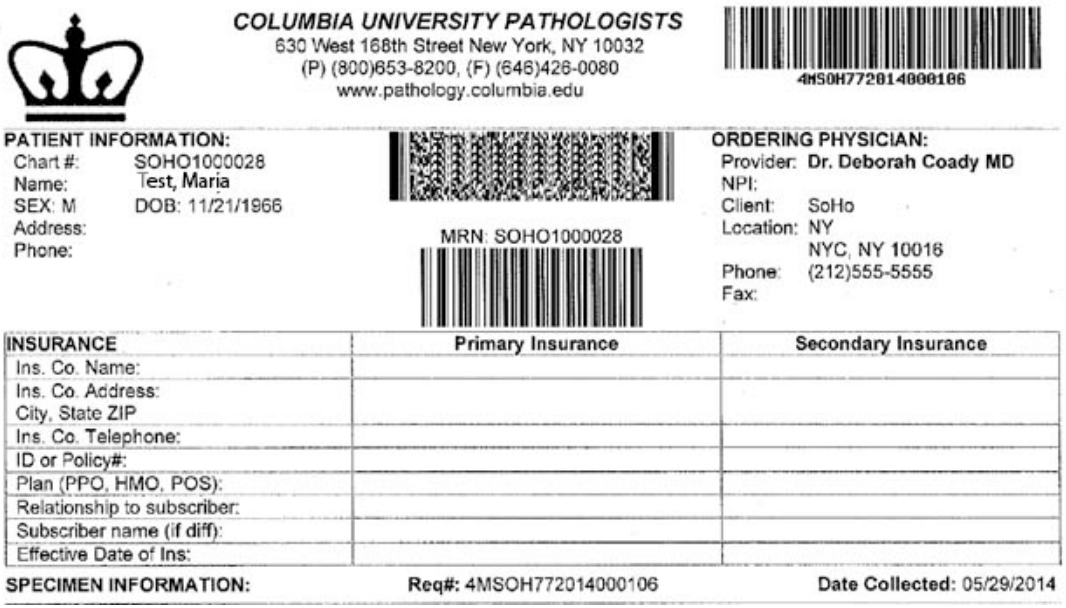
EHR-interfaced orders

Requisition unique number (barcode) is scanned in corresponding field in LIS (order entry number).

Patient demographic data and all other information will be pre-populated in LIS from ADT interface data.

Multiple specimen p
accession numbe

In 100% mapping al
populated via ord



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www.pathology.columbia.edu

4MSOH772014000106

PATIENT INFORMATION:
Chart #: SOHO1000028
Name: Test, Maria
SEX: M DOB: 11/21/1966
Address:
Phone:

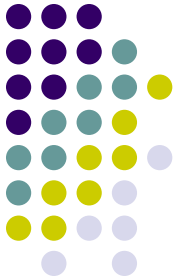
MRN: SOHO1000028

ORDERING PHYSICIAN:
Provider: Dr. Deborah Coady MD
NPI:
Client: SoHo
Location: NY
NYC, NY 10016
Phone: (212)555-5555
Fax:

INSURANCE	Primary Insurance	Secondary Insurance
Ins. Co. Name:		
Ins. Co. Address: City, State ZIP		
Ins. Co. Telephone:		
ID or Policy#:		
Plan (PPO, HMO, POS):		
Relationship to subscriber:		
Subscriber name (if diff):		
Effective Date of Ins:		

SPECIMEN INFORMATION: Req#: 4MSOH772014000106 Date Collected: 05/29/2014

Specimen Receipt in lab and specimen accession - AP LIS



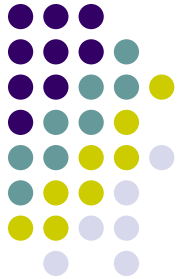
Non-interfaced orders

LIS assigns specimen a unique accession number (“accessioning”).

Different “number wheels” can be used to distinguish different classes of specimens

Multiple specimen parts are identified under one accession number.

Specimen Receipt and Order Creation – AP LIS



Two field types in LIS identify each part:

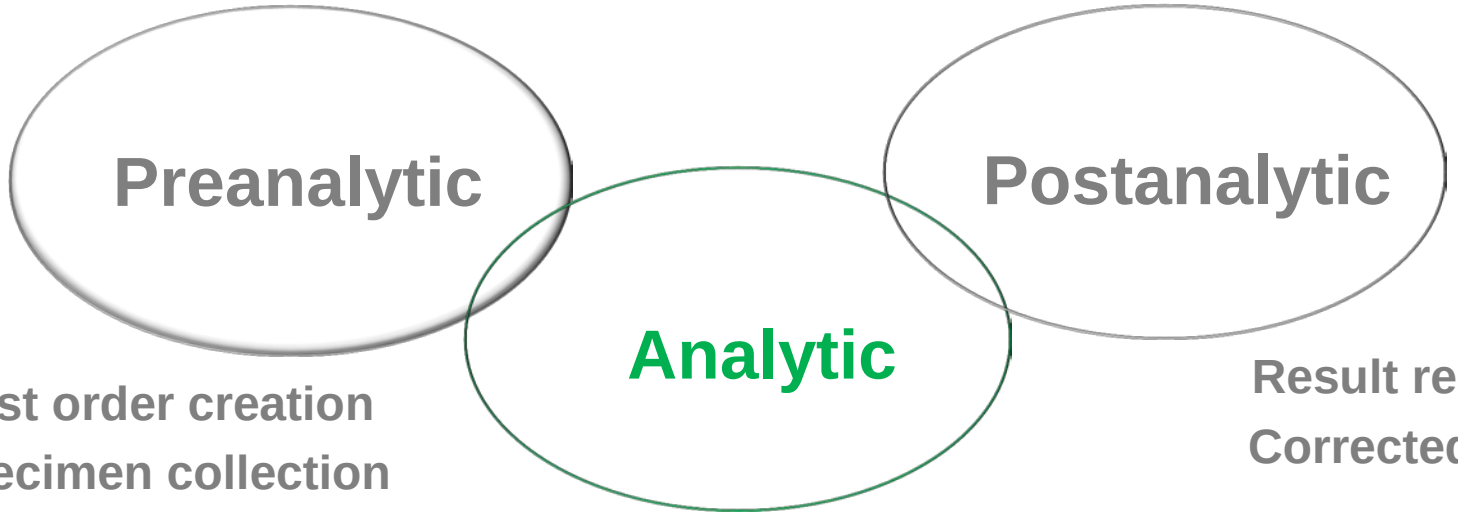
- Part type – selected from a dictionary; categories of specimen types, e.g. colon, polyp
- Part description – free text additional description provided with specimen, e.g. “large colon polyp at 50 cm”

Part types may be linked in LIS to histology protocols or special stains.

LIS may print specimen label with bar code.

Specimen status is updated, e.g. to “Accessioned”.

Lab testing cycle- CP LIS

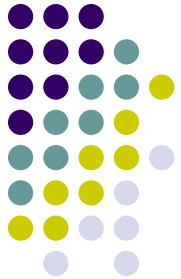


Test order creation
Specimen collection
Specimen receipt

Specimen &test distribution
Analysis/interpretation
Additional testing
Result entry

Result reporting
Corrected report

Analytic Phase Information Management



Work distribution and specimen preparation

Test performance and analysis

Test interpretation

Additional testing based on initial results

Results entry

Test Performance and Result Entry – CP LIS

For interfaced instruments:

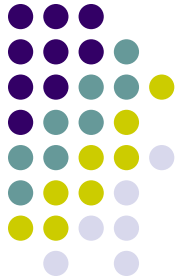
- Instrument software reads bar code specimen number and performs the tests per downloaded orders (from LIS) linked to that specimen number.
- Results are uploaded back to LIS, tied to specimen number
- Interface specifications shared between LIS and instrument software ensure data transfer in expected sequence and format.
- LIS worksheets linked to the instrument maintenance ensure that test results are filed correctly in the LIS.

Test Performance and Result Entry – CP LIS

For tests performed on non-interfaced analyzers or manually, technologists enter results into LIS worksheets using the LIS resulting function.

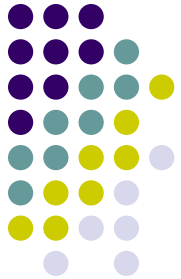
Footnotes or *comments* may be required to add additional information – free text vs. coded template from LIS dictionary

Rules and Additional Testing – CP LIS



- Simple calculation
- **Auto verification**
- Reflex testing

Possible auto-verification criteria



Reference ranges

Auto-verify ranges

Assay technical ranges

Critical values

Delta checks

Instrument-defined ranges

Instrument message flags

Failed single test vs failed entire cup

Dilution needs or manual processes

Patient location or age

Lab review process

Rules and Additional Testing – CP LIS

- Simple calculation
- Auto verification
- **Reflex testing**

Middleware

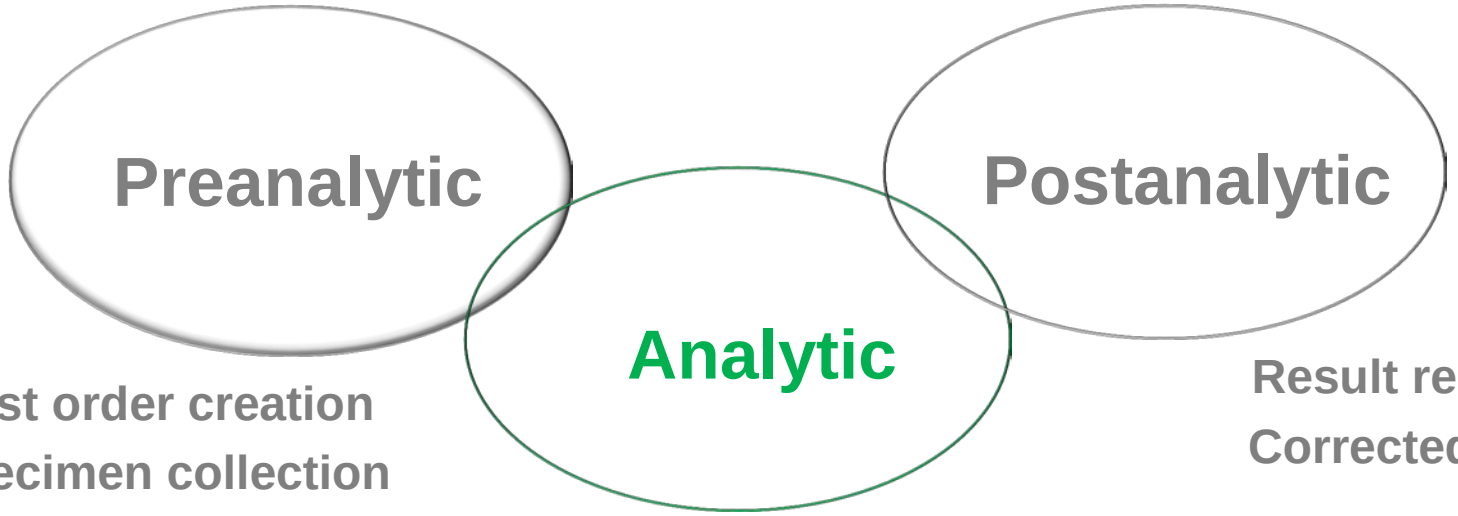
Middleware: rules-based processing provided by instrument vendor or third party that “sits between” the LIS and instrument

- Autoverification
- Reflexive test ordering based on result
- Automatic dilutions, repeats, smear creation
- Other aspects of instrument management, e.g. maintenance alerts

Business Intelligence Solutions

- Allows lab to record, track and mange almost very key performance indicators within the organizations.
- Provides insights into opportunities for revenue growth, quality improvement and operational efficiencies
- Some features are the ability to:
  1. Analyze and track lab test utilization by client and by physician
  2. Manage and grow laboratory testing outreach business
  3. Perform root-cause analyses into performance variation in areas such as Turnaround Time Outliers
  4. Provide detailed work load data in a dynamic manner to better align staffing levels
  5. Identify trends in order entry errors

Lab testing cycle-AP LIS



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Grossing and Specimen Preparation – AP LIS

Main information outputs in LIS of “grossing” phase are:

- Text entry in LIS “Gross Description” field
- Use of pre-defined templates for some specimen types
- Designation of tissue sections in Histology module
- Status updated, e.g. “Gross Complete”

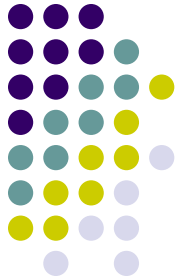
Slide Preparation and Work Distribution – AP LIS

LIS directs slide preparation workflow

- Pre-defined protocols for levels and stains
- Histology logs defining worklists of cases and blocks from grossing step
- Slide labels (+/- bar codes) based on data entered in histology module and protocol/stain definitions
- Special stains appear on specified logs (e.g. immunohistochemistry log)

"Asset" tracking based on bar code labels and points of scanning defined

Slide Preparation and Work Distribution – AP LIS



LIS produces “working draft” report for pathologist – paper vs. paperless

Working draft format and content are based on template configuration in LIS, e.g.

- Clinical information
- Gross description
- Frozen section report (if performed)
- Summary of patient’s previous results, based on LIS search of database

Report Generation – AP LIS

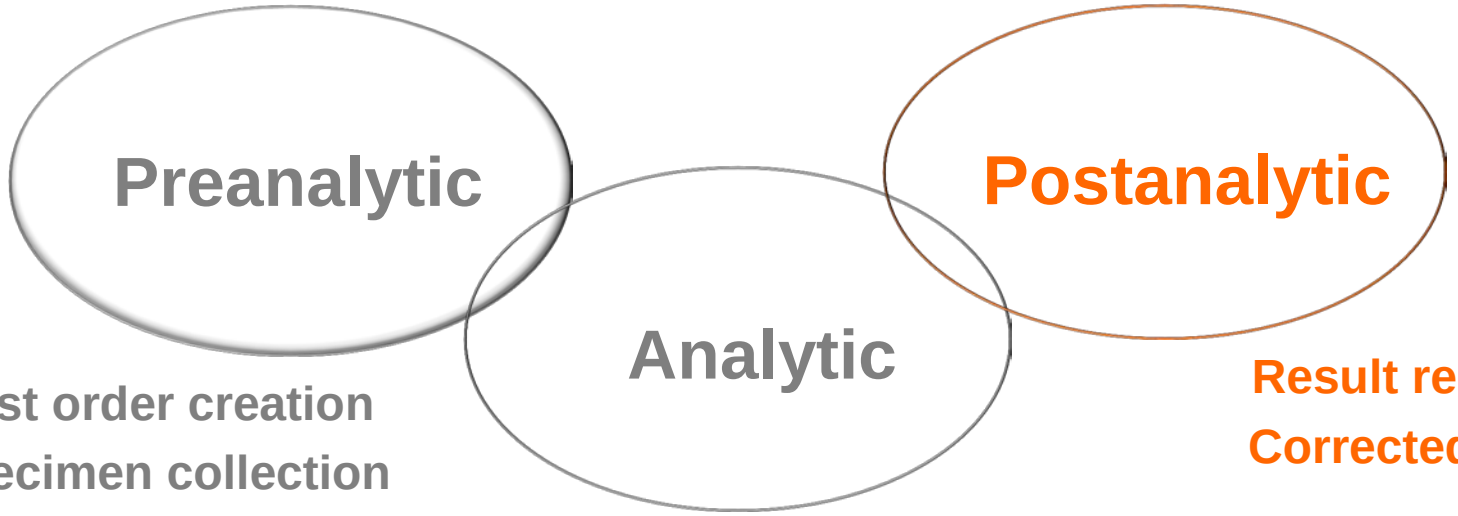
Entry of Final Diagnosis in LIS facilitated by:

- 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" LIS modules enable entry of *discrete data elements.*

Pathologist signs out cases with electronic signature that locks the case.

Lab testing cycle



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Report Distribution

Hard copy report format is based on configurable template in LIS.

- Printing – scheduled batches, on demand
- Faxing – automated if fax numbers in dictionary

For electronic reporting, reports pass from the LIS to receiving system via an interface

PDF and RTF interfaces preserve formatting; receiving system must accommodate.

Corrected Results – CP LIS

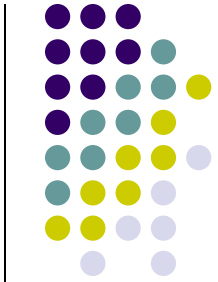
LIS report must clearly identify the corrected result as corrected.

Corrected result must also include the original result.

Corrected result typically also includes documentation of the person correcting the result and a record of any communications (e.g. “corrected result called to …”).

Corrected report typically replaces (overlays) previous result in EHR; original kept in audit trail.

Amendments and Addenda – AP LIS

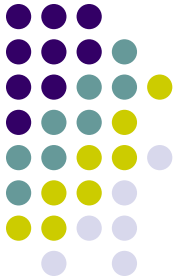


Report formats should be configured so that amended or addended status is obvious.

Entire report is re-printed or re-transmitted across the interface with the new addendum identified as such

In the EHR, the new report overlays the previous report.

Current issue



No standard for standardization

Part type

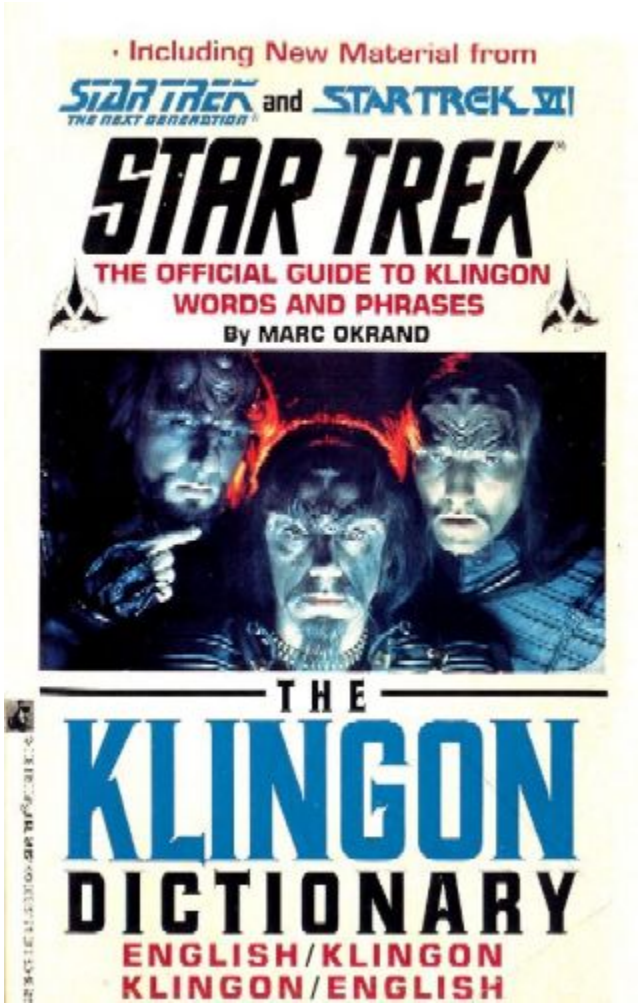
GP-BBX	Breast biopsy
OGP-BBX	Breast biopsy
CN-BR	Breast, fine needle aspiration
OCN-F-BR	Breast, fine needle aspiration biopsy
Breast, fna, right	Breast, fna, right
OSP-Breast, Lt, bx (LBBX)	Breast, left, biopsy
OSP-Breast, LT, capsule-04 (LCAP)	Breast, left, capsule resection
SP-Breast, LT, capsule-04 (LCAP)	Breast, left, capsule resection
Consultation slides	Consultation slides #

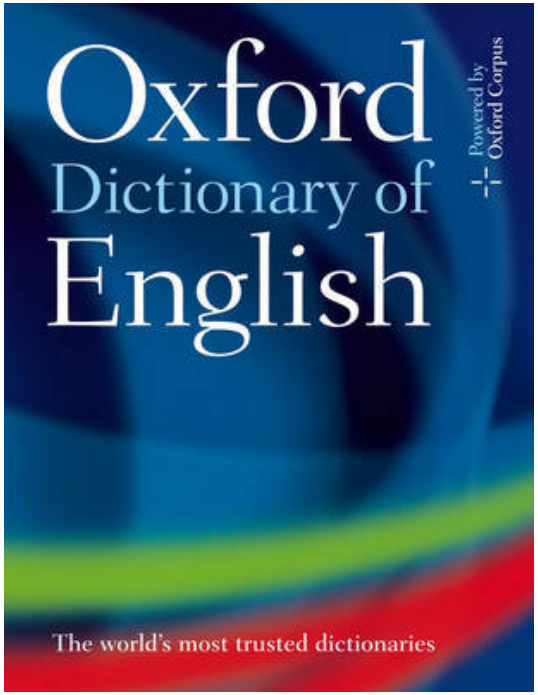
Name	Name	Description	Name	Description
CN-BDA	OCN-BDA	Bile duct aspirate	Liver, fna, bile duct	Liver, bile duct, aspirate
CN-BDB	OCN-BDB	Bile duct brushing	Liver, brushing, bile duct	Liver, bile duct, brushing
CN-BDL	OCN-BDL	Breast ductal lavage		Breast, ductal lavage
CN-BDS	OCN-BDS	Bile duct stent	Liver, stent, bile duct	Liver, bile duct, stent
CN-BIL	OCN-BIL	Biliary tree		
CN-BNA	OCN-BNA	Breast, nipple aspirate fluid		
CN-BR	OCN-F-BR	Breast, fine needle aspiration biopsy		
CN-CB	OCN-CB	Cell block		
CN-CSF	OCN-CSF	Cerebrospinal fluid		Cerebrospinal fluid
CN-F-KID	OCN-F-KID	Kidney, fine needle aspiration biopsy	Kidney, fna, left	Kidney, left, fine needle aspiration
CN-FL	OCN-FL	Fluid		
CN-F-LBR	OCN-F-LBR	Breast, left, fine needle aspiration biopsy	Breast, fna, left	Breast, left, fine needle aspiration

Organ, procedure, laterality

Organ, laterality, procedure

Anomalies





DEFINITIONS!

Customization vs Design Anomalies

Customization: LIMS can save vast amounts of time and dramatically improve productivity within the workplace

Design anomalies:

1. limit the expressive power of queries and lead to unnecessary complexity in queries.
2. Interfere with other QA /automation modules
3. Hinder LIS maintenance in general
4. Disrupt data extraction, interoperability and patient safety

There is no standard for dictionary set up:

- When should we create a specimen class/
- When should we create a part type?
- What are the criteria for data definition in different fields in different dictionaries?
- What is the acceptable number for specimen class or part types

Why is it important to follow standard/guideline for LIS design?

LIS poor design will affect:

- Data extraction (research result)
- Interoperability
- Patient safety

LARGE INTESTINAL/COLORECTAL CARCINOMA WORKSHEET (revised on 11/24/15)

CASE#:_____ PT. NAME:_____ UNIT#_____ DATE:_____

PATHOLOGIST'S NAME: _____

X. CIRCUMFERENTIAL RESECTION MARGINS (CRM) *Applies only to rectal tumors)*

(B36) Negative
(B37) Positive edge of mesentery - positive CRM
(B38) Distance of tumor to CRM: _____ mm
(B39) < 1.0 mm – positive CRM
(B40) > 1.0 mm – negative CRM
(B65) Not applicable (*use for all non-rectal tumors)*

XI. COEXISTING PATHOLOGY

(B41) Adenoma identified at tumor edge
(B42) Adenoma(s) identified separate from tumor (# of _____)
(B43) Hyperplastic polyp(s) identified (# of _____)
(B44) Other (Specify _____)

XII. TREATMENT EFFECT *(Primary tumor only, acellular mucin pools not counted)*

(B79) No prior treatment
(B80) No response identified
(B81) No residual tumor
(B82) Moderate response (single or small groups of cells only)
(B83) Minimal response (tumor with fibrosis)

XIII. PATHOLOGIC STAGING (pTNM) *AJCC 7TH Edition: Reflects staging only of the current specimen. Ultimate staging responsibility rests with the primary physician.*

Primary Tumor (pT)

(B45) pTX: Cannot be assessed.
(B46) pT0: No evidence of primary tumor.
(B47) pTis: Carcinoma in situ, intraepithelial (no invasion).
(B48) pTis: Intramucosal; invasion of lamina propria.
(B49) pT1: Tumor invades submucosa
(B50) pT2: Tumor invades muscularis propria
(B51) pT3: Tumor invades through the muscularis propria into pericolorectal tissue
(B52) pT4a: Tumor penetrates to the surface of the visceral peritoneum
(B53) pT4b: Tumor directly invades other organs or structures

Regional Lymph Nodes (pN)

(B54) pNX: Cannot be assessed
(B55) pN0: No regional lymph node metastasis
(B64) pN0(i+) Isolated tumor cells identified
(B56) pN1a: Metastasis in 1 regional lymph node
(B57) pN1b: Metastasis in 2-3 regional lymph nodes
(B58) pN1c: Tumor deposit(s) in subserosa, mesentery or pericolic/perirectal tissues without regional nodal metastasis
(B59) pN2a: Metastasis in 4 - 6 regional lymph nodes
(B60) pN2b: Metastasis in 7 or more regional lymph nodes

Distant Metastasis (pM)

(B62) pM1a: Distant metastasis - single site
(B63) pM1b: Distant metastasis - multiple sites

Reminder: Colorectal Molecular Testing

1) ***Did you order IHC for mismatch repair (MMR) enzymes (MLH1, MSH2, PMS2, MSH6) on all cases with invasive carcinoma?MMR IHC should be ordered on the resection specimen only if it was not done in a prior biopsy and/or if it was inadequate in the biopsy.***
2) ***Please order SP-M and select colorectal cancer panel if it has not been done in any other colon cancer specimen for the patient.***

Synoptic reporting definition by CAP

Definition of Synoptic Reporting

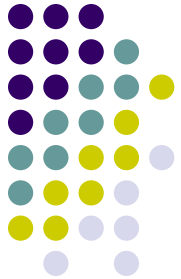
The CAP has developed this list of specific features that define synoptic reporting formatting:

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



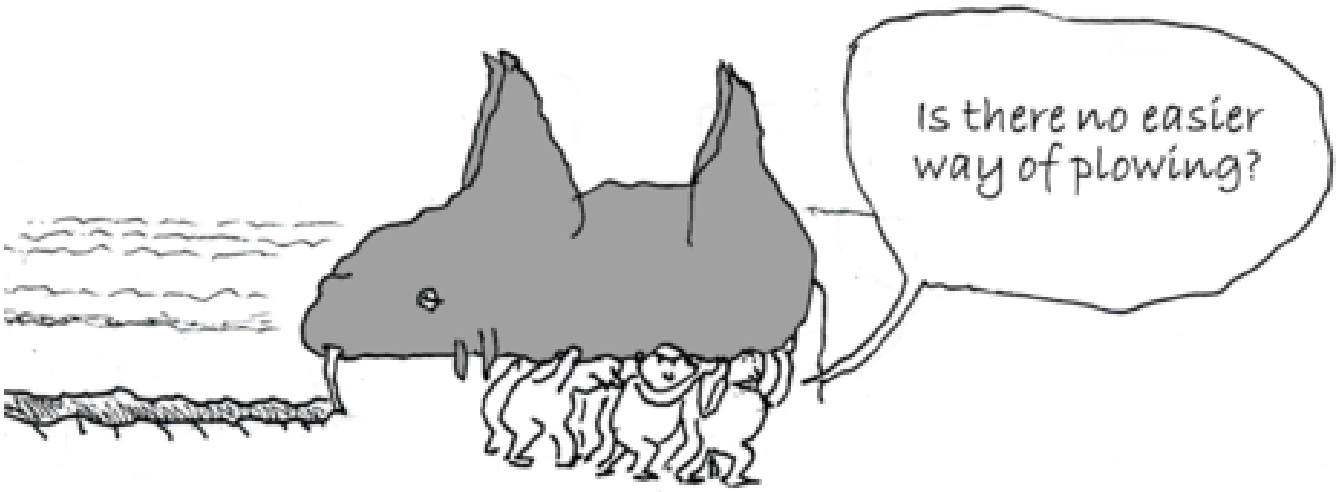
- Constraining the report to individual data elements
- Not all synoptic reports contain structured data
- Synoptic reports structure and clarify findings for clinicians
- Structured data clarifies findings for computers

- Using the wrong LIS for a specialized lab operation
- Incomplete real-time labeling
- Implemented tracking system with defective status set up and missing worklist report

Who knows, and knows that he knows,
Makes the horse of intelligence jump over the vault of heaven.
Who does not know, yet knows he does not know,
Can nevertheless bring his lame little donkey to its destination.
Who does not know, and does not know that he does not know,
Remains mired forever in double ignorance.

Naser od-Din Tusi (1201-1274)

Why should we care?



Suggestion

- Esatablishing standard/guideline for LIS set up
- Determining criteria for quality assurance of LIS design +/- functionality.
- Developing checklist to evaluate LIS performance in data extraction (research, operational and QC).

Reference

Walter H Henricks: Laboratory Information Systems Overview. In: Pathology Informatics: Theory and Practice. ASCP Press; 2012

Acknowledgement:

John Skinta