Geisinger

An Introduction to the Clinical Pathology LIS

Jordan Olson MD FCAP

21 May 2018

Disclosures

Disclosures: None

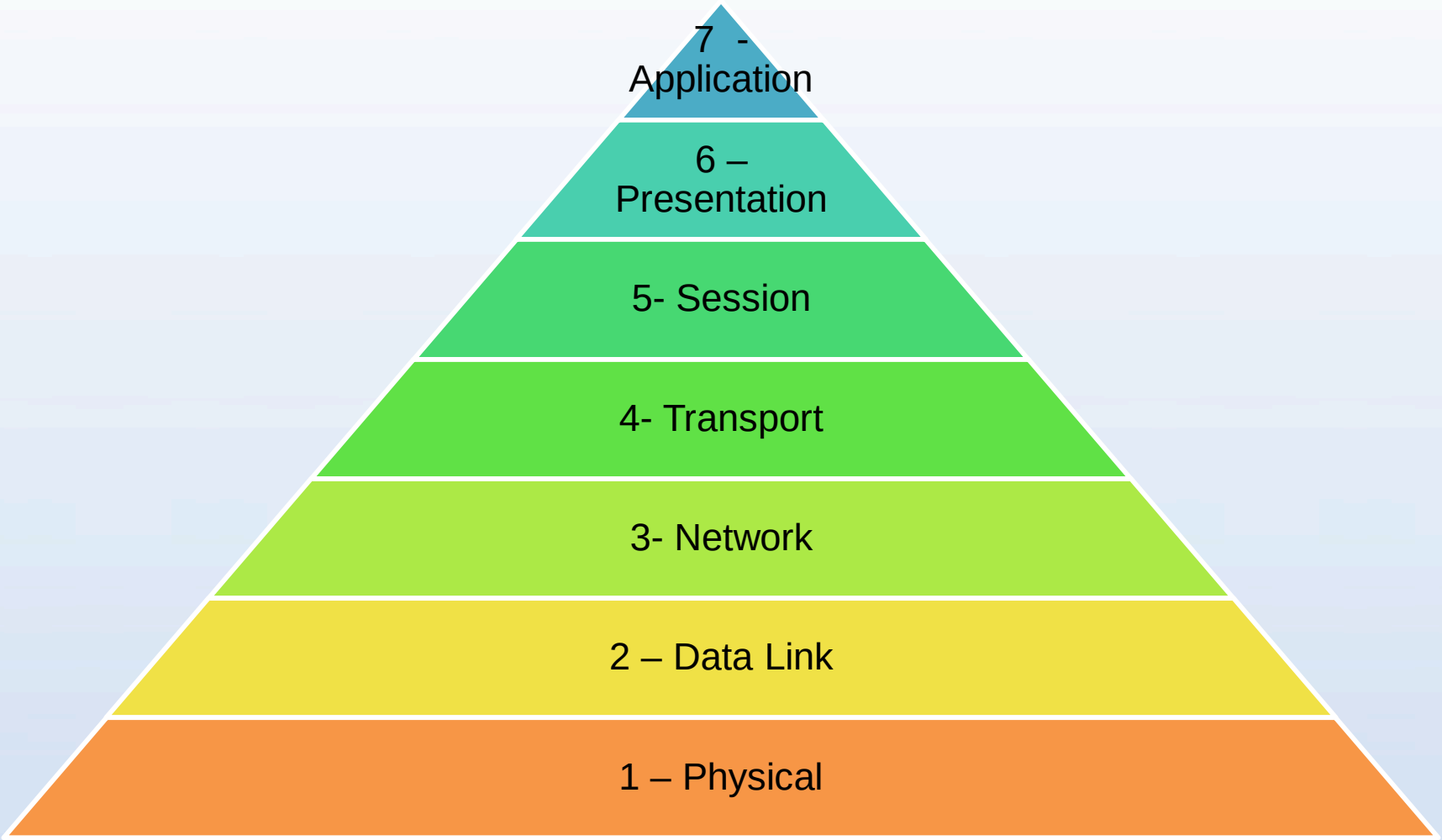
Goals/Objectives

1. Describe basic laboratory information system (LIS) architecture
2. Provide an overview of LIS functionality
3. Describe the LIS's role in laboratory workflow

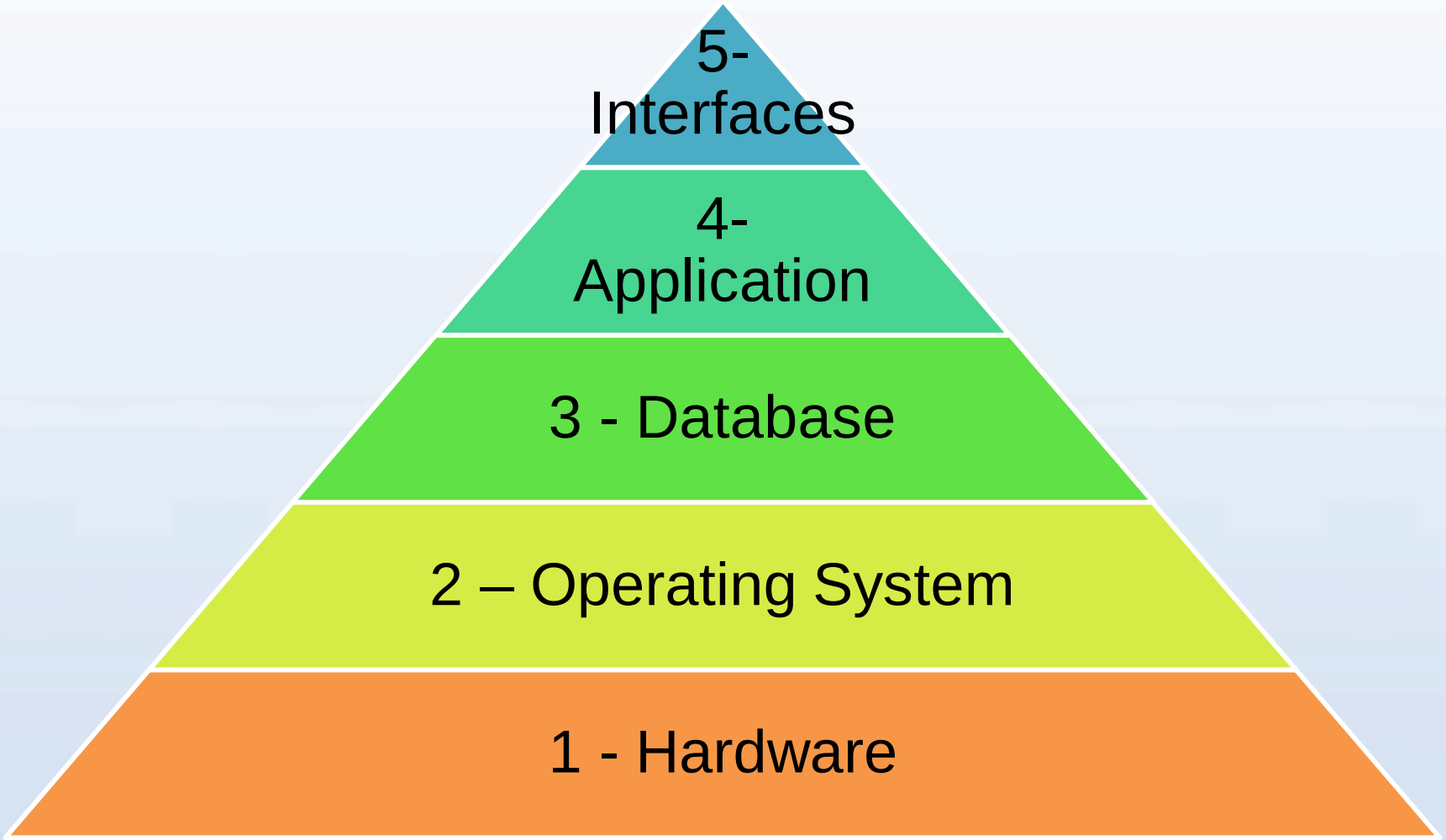
What is an LIS

- Laboratory Information System
  - Software that supports the laboratory
- Multiple different architectures
  - Multiple different pros and cons

OSI Model of Network Connectivity

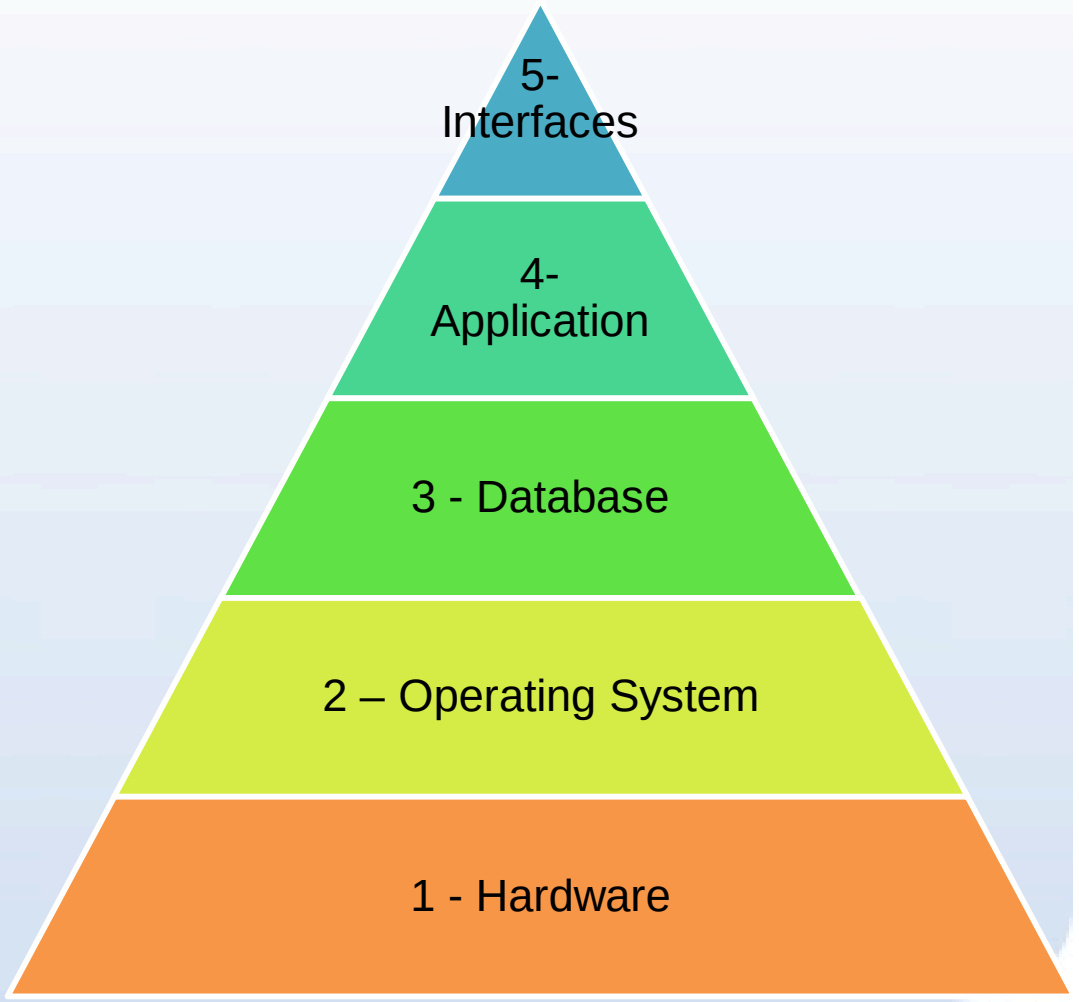


Analogous Model for LIS Architecture



Model for LIS Architecture

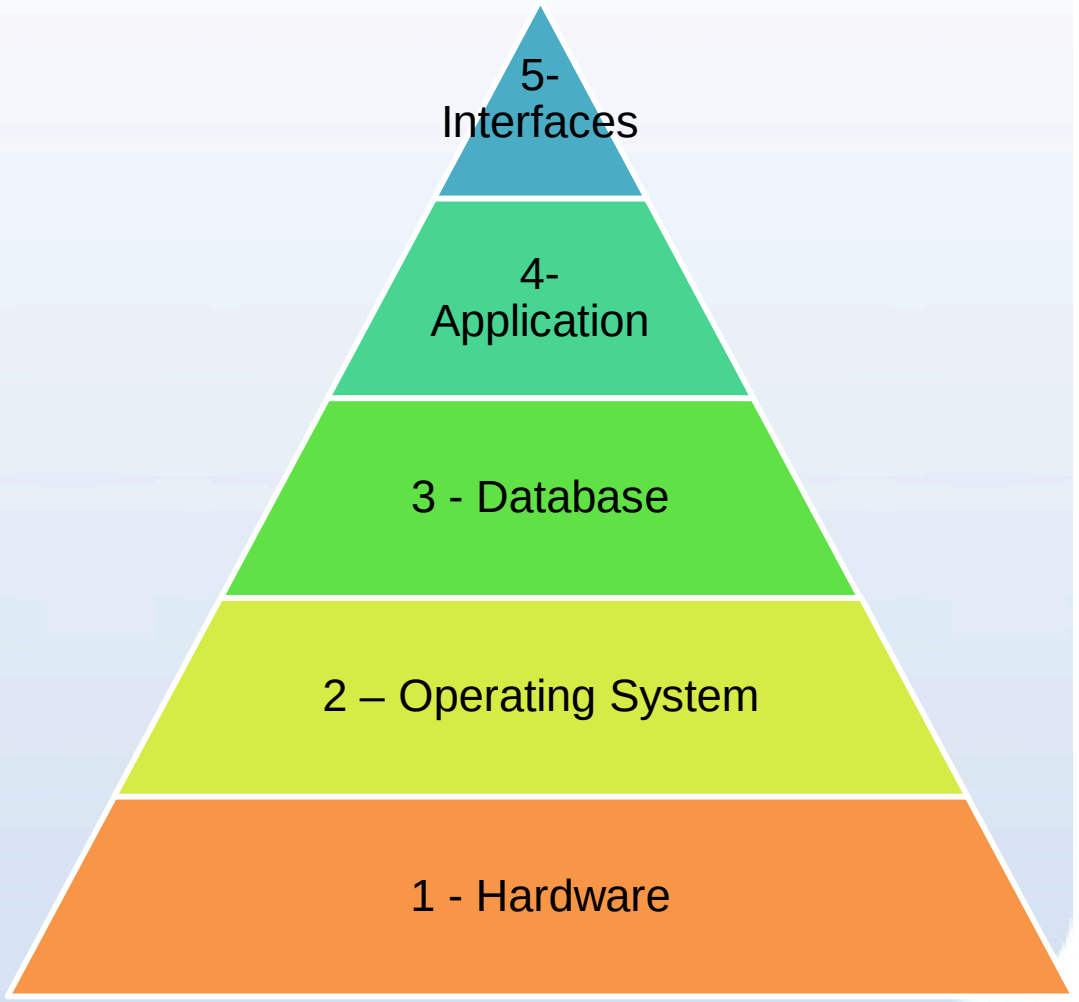
- Hardware
  - Physical Computer
  - Can be Hosted vs. Local
  - Generally an IT department Function
- Operating System
  - Software layer that Manages the Hardware



Model for LIS Architecture

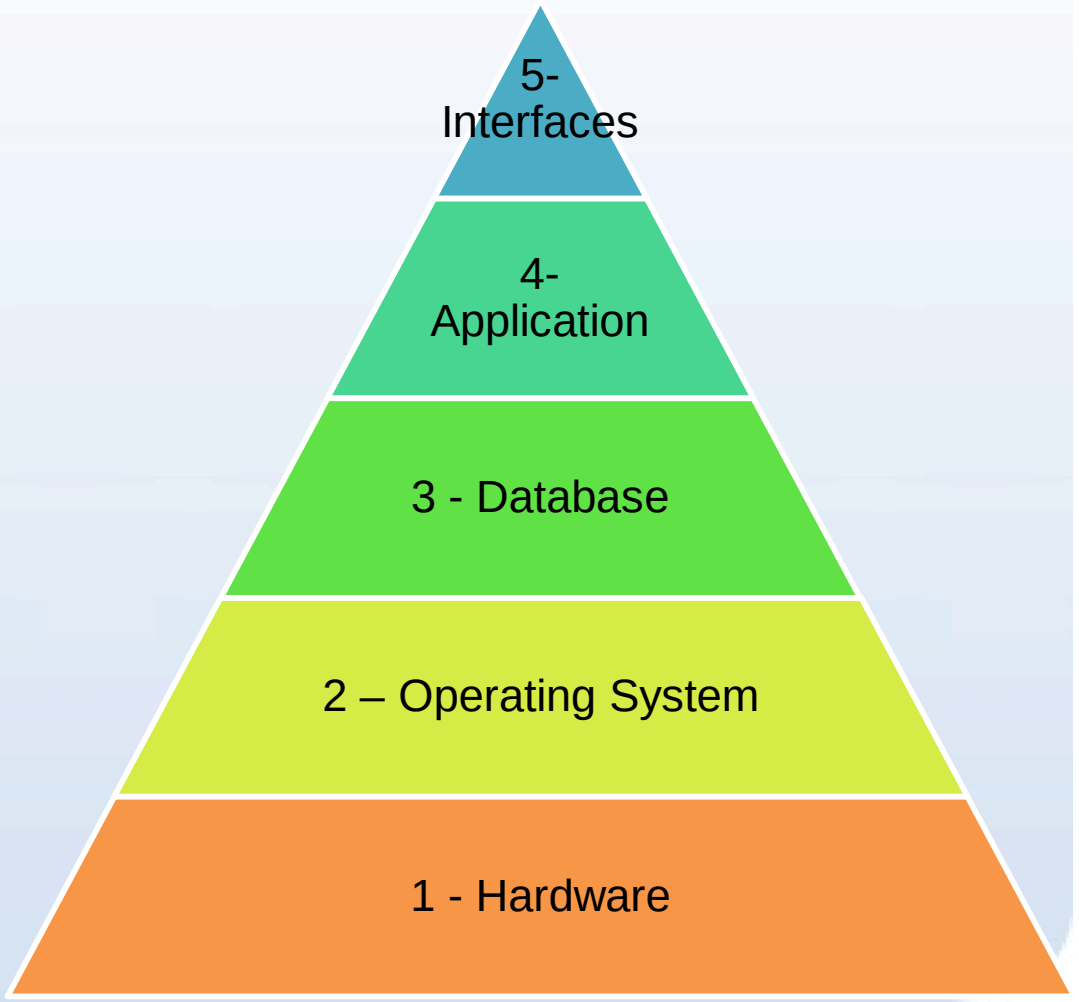
- Database
  - Software that manages the files the data is kept in
  - Data Definition
  - Update Function
  - Retrieval function
  - Administration Functions

  - Mumps
  - SQL

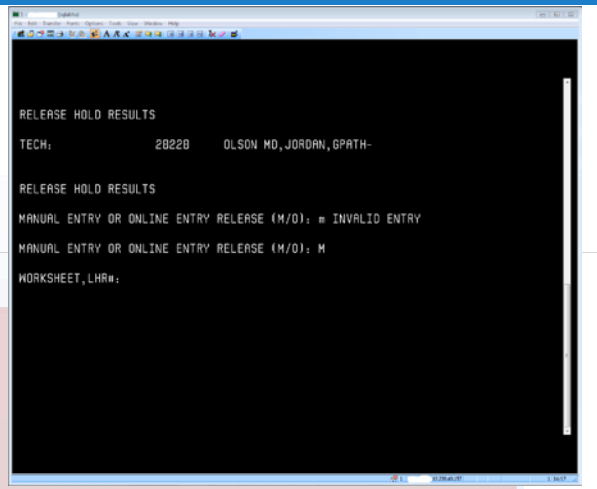


Model for LIS Architecture

- Application
  - LIS software that utilizes database
  - Administration function
  - Can have several architectures
- Interfaces
  - Connect LIS to other applications



LIS Architectures



Terminal - Server

- “Dumb” Terminals
- Browser based systems

Client-Server

- Thick
- Thin
- VDI / Zero Client

LIS Architecture

Dedicated LIS

- System(s) Interfaces with Clinician-facing systems
- “Best-of-Breed”

Integrated LIS

- EMR and LIS are one System, sharing common database(s)
- Fewer systems to maintain

Dedicated LIS

- Advantages
  - Purpose Built
    - Development centered on laboratory
    - Many diverse applications are required to support modern laboratory
  - Laboratory requirements for responsiveness
    - IT Governance usually different with stand-alone system
  - Adoption of New technology often requires the LIS to change

Integrated LIS

- Advantages
  - Fewer Vendors to deal with
  - Possible Cost savings
  - Simplified deployment
  - Consolidated Maintenance
  - Reduced Need for interfaces (with EMR)
  - More comprehensive patient portals
  - Improved coordination with EMR users

Interfaces - Why

- Data is rarely useful by itself, but when aggregated and combined with other types of data it becomes useful
- Systems working together more useful than being apart
- Discrete data much more useful for re-use than non-discrete

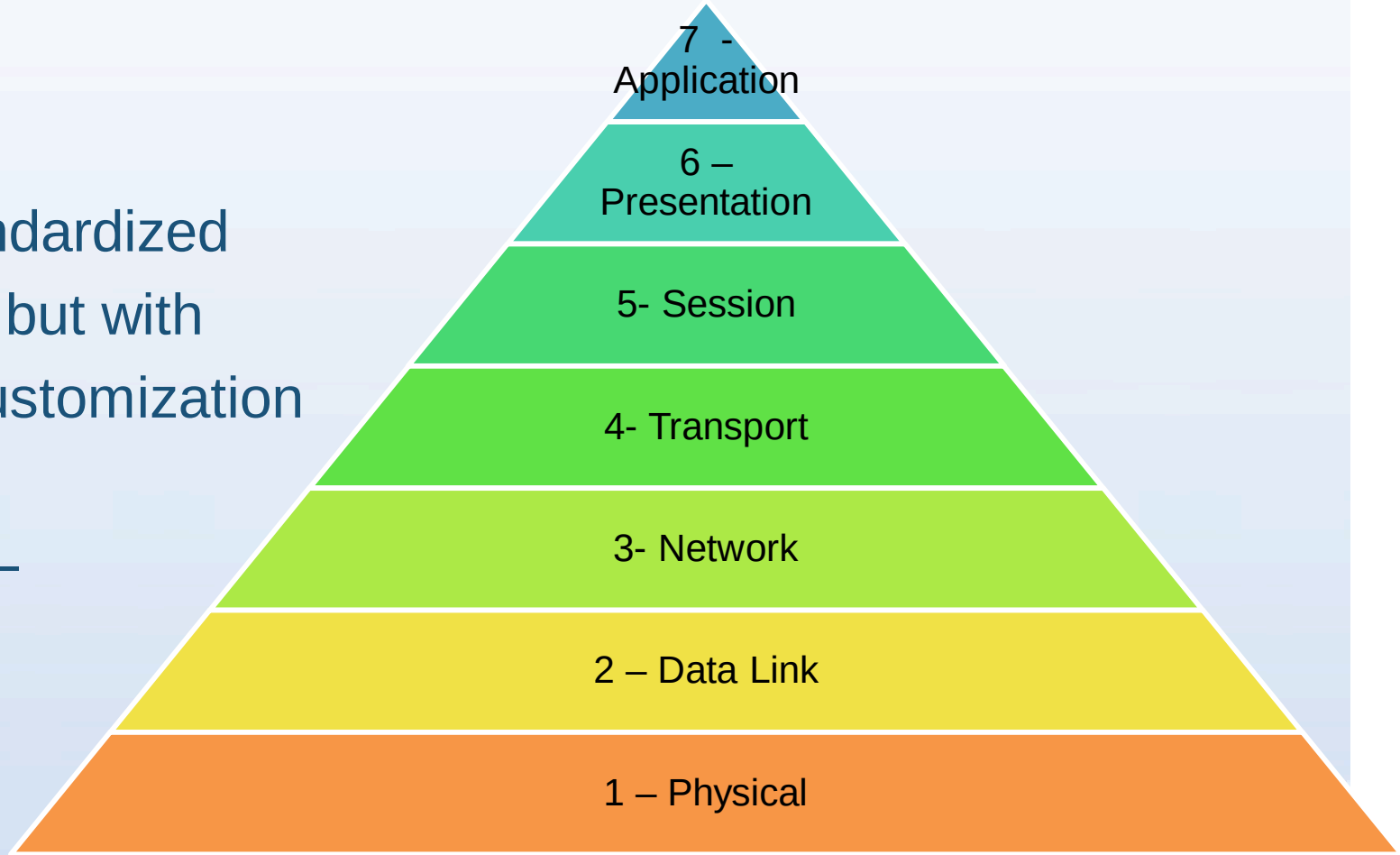
Interfaces - How

Physical – Hardware

Network – Often very standardized

Software – Standardized, but with some opportunity for customization

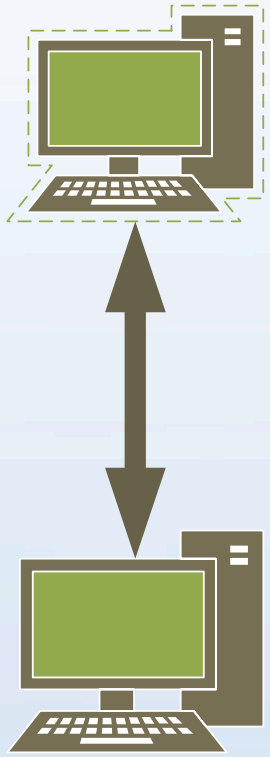
Communication Protocol – Hl7, XML



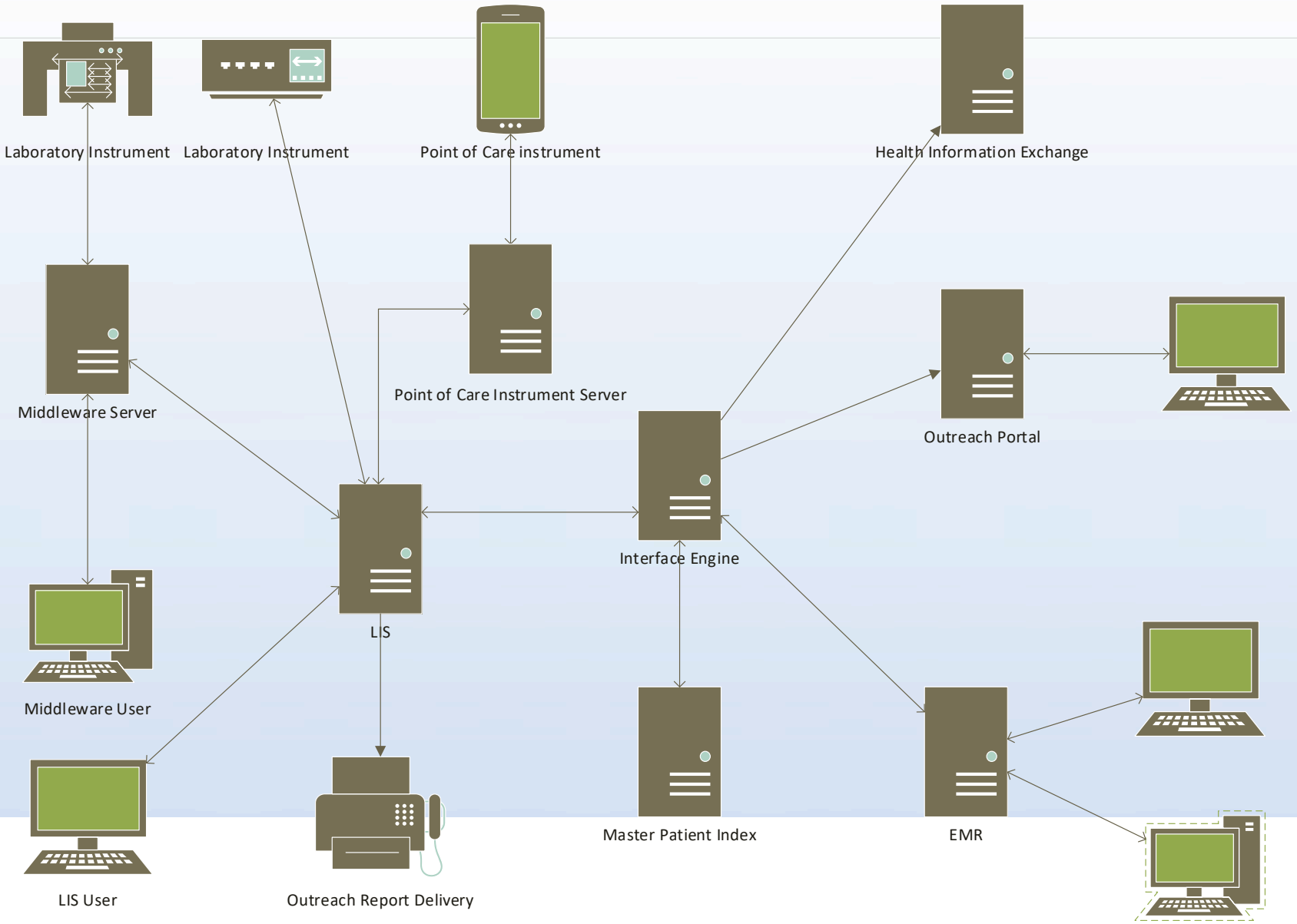
Interfaces

Types of common LIS Interfaces

- Admission/Discharge/Transfer – ADT
- Order Entry Interface
- Result Entry Interface
- Point-of-Care Testing Interface
- Billing Interface



Idealized Interface Diagram



HL7

- Health Level Seven International
- HL7.org
- HL7 2.0
- HL7 3.0
- CDA / CCD
- FHIR

HL7 2.0 Example

MSH|^~\&|MegaReg|XYZHospC|SuperOE|XYZImgCtr|20060529090131-0500||ADT^A01^ADT_A01|01052901|P|2.5

EVN||200605290901||||200605290900

PID|||56782445^^^UAReg^PI||KLEINSAMPLE^BARRY^Q^JR||19620910|M||2028-9^^HL70005^RA99113^^XYZ|260 GOODWIN CREST DRIVE^^BIRMINGHAM^AL^35209^^M~NICKELL'S PICKLES^10000 W 100TH AVE^BIRMINGHAM^AL^35200^^O|||||||0105I30001^^^99DEF^AN

PV1||I|W^389^1^UABH^^^^3||||12345^MORGAN^REX^J^^^MD^0010^UAMC^L||67890^GRAINGER^LUCY^X^^^MD^0010^UAMC^L|MED|||||A0||13579^POTTER^SHERMAN^T^^^MD^0010^UAMC^L|||||||||||||||||||||||200605290900

OBX|1|NM|^Body Height||1.80|m^Meter^ISO+|||||F

OBX|2|NM|^Body Weight||79|kg^Kilogram^ISO+|||||F

AL1|1||^ASPIRIN

DG1|1||786.50^CHEST PAIN, UNSPECIFIED^I9|||A

OBR – Observation Request, ORU – Observation Result NTE - Note

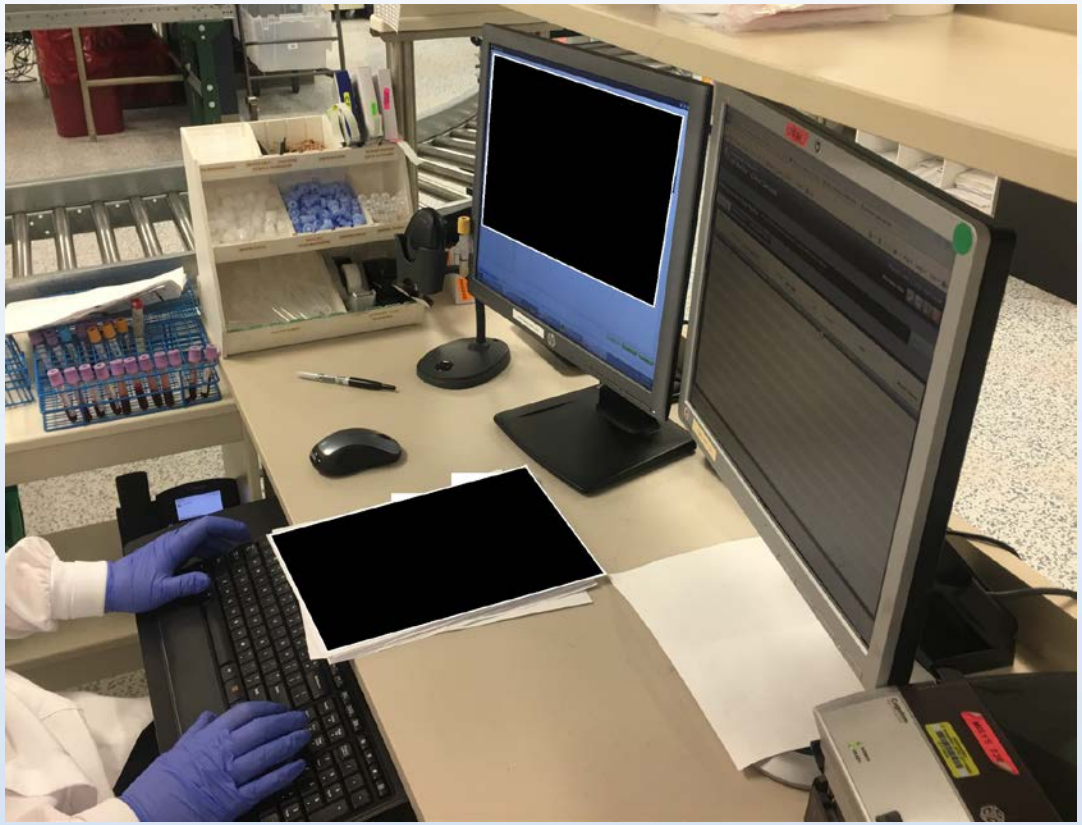
Example Courtesy https://en.wikipedia.org/wiki/Health_Level_7

The LIS and it’s function in workflows

- The laboratory information system is designed to improve the laboratory testing process
- Many different needs throughout the testing process

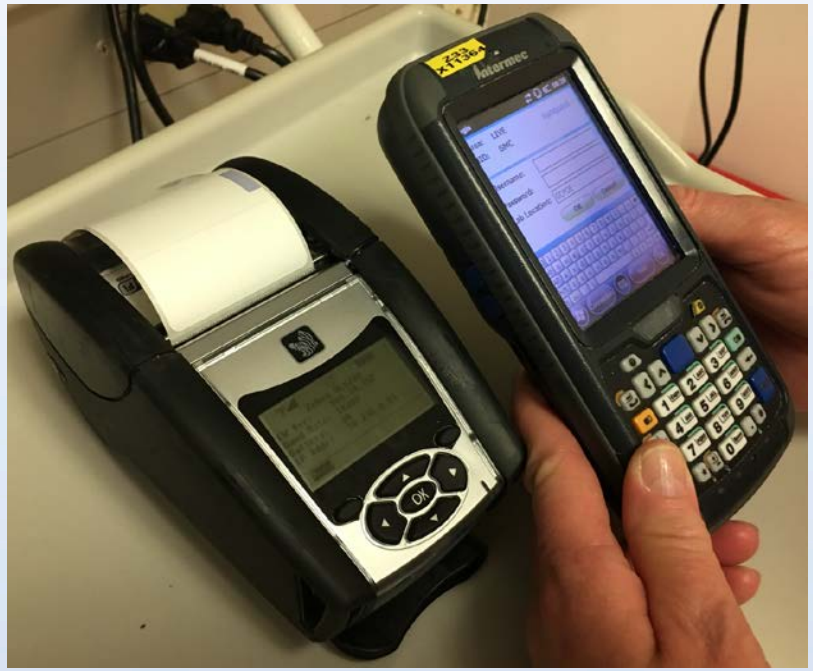
Pre-Analytic

- Order Creation
  - Order Entry
  - Receiving Orders from other systems
    - EMR
    - Other LIS
    - Portals
    - Outreach
  - Functions of Order Creation



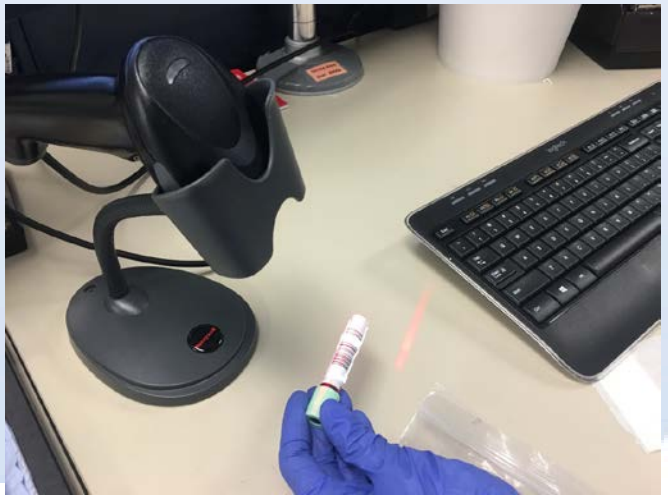
Pre-Analytic

- Specimen Collection
  - Processes may need to be co-managed with EMR
  - Positive Patient Identification
    - Specimen Labeling
  - Specimen and Test Requirements
  - Test Catalogue
  - Add-ons



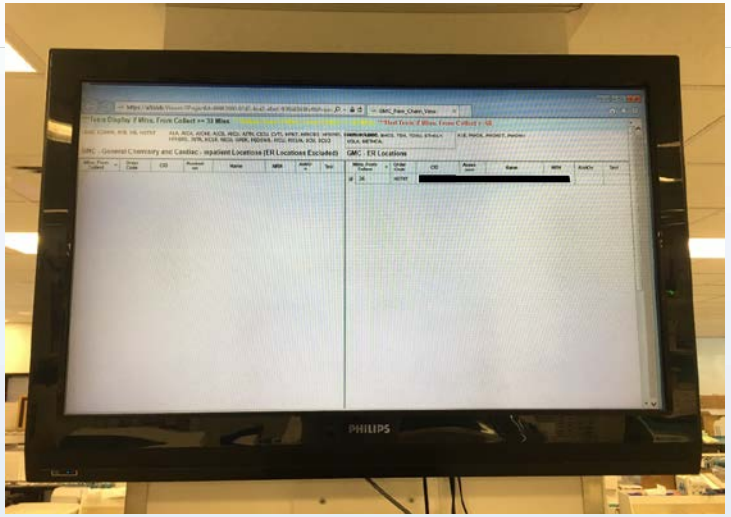
Pre-Analytic

- Specimen Tracking
  - Specimen tracking
    - Transport aids
    - Pneumatic tube systems
    - Couriers
  - Specimen Receipt
  - Reference Laboratories
    - Pending Logs
    - Reporting Considerations

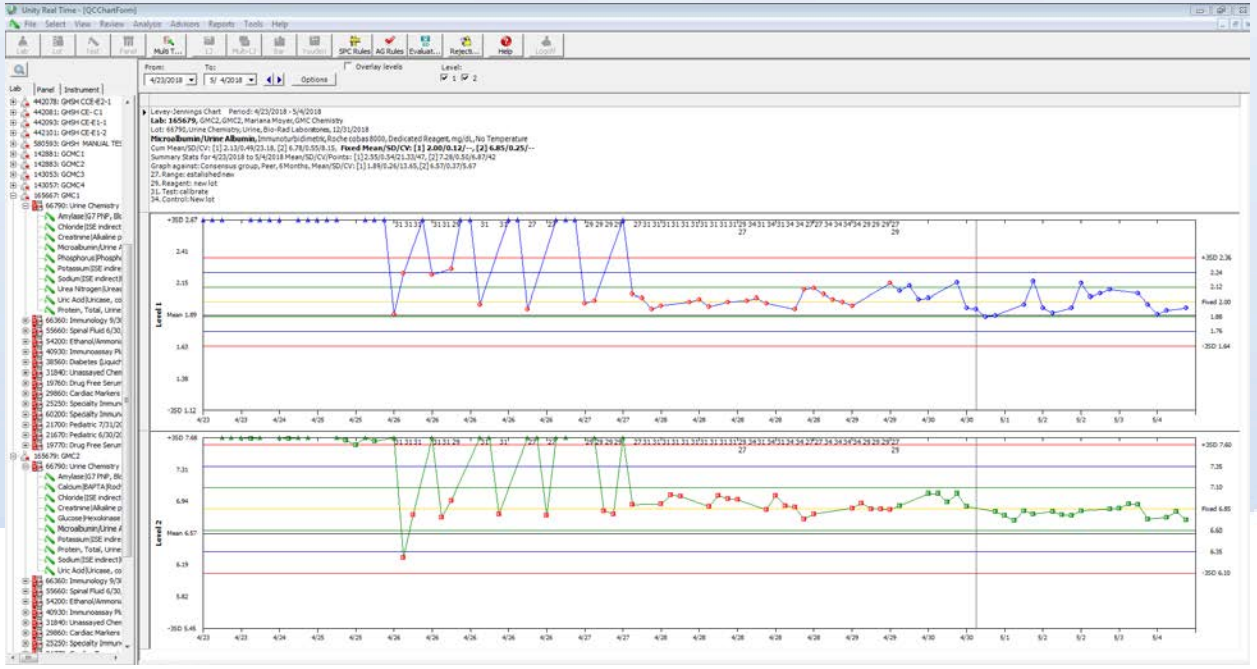


Analytic

- Work Distribution and Tracking
  - Aliquot Workflows
  - Pending Work Lists
  - Turn around time Monitoring

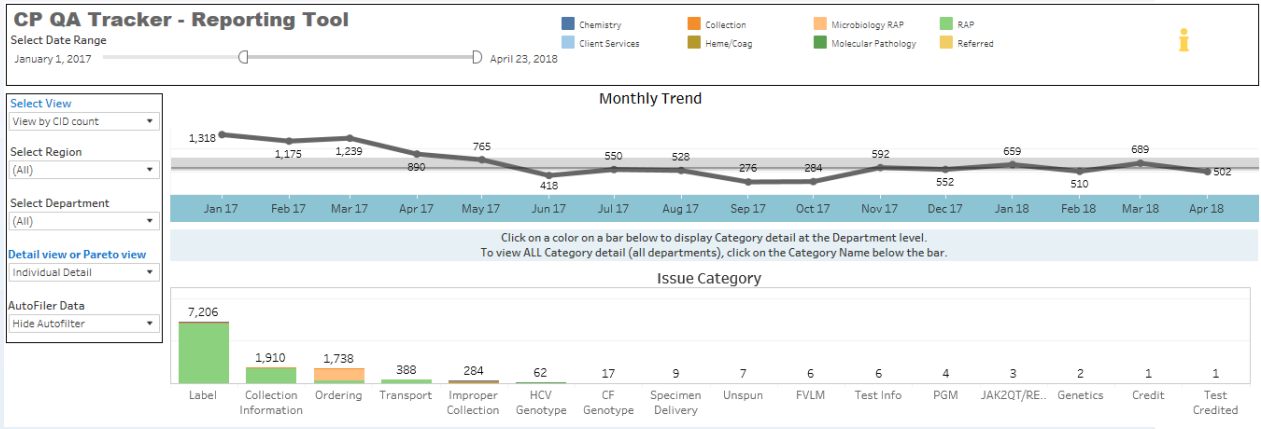


- Test Performance
  - QC
    - Westgard Rules
    - Moving Averages
    - Central Review
    - Peer Group comparisons



Analytic

- Work Distribution and Tracking
  - QA
    - Error tracking
    - Intervention Tracking



- Autoverification
  - Assists with reducing technologist workload
  - Should be dependent on many sample and patient factors

- Reflex Testing
  - Very powerful method for improving laboratory utilization
  - Very useful to clinicians, when deployed correctly

Analytic

- Middleware
  - Software that sits between two software systems
  - Originality designed to allow integration of new components to legacy systems
  - May be very robust
    - QC
    - Autoverification
    - Rules
    - Reflex testing
    - Instrument maintenance
  - LIS vs. Middleware – overlapping feature sets

Post-Analytic

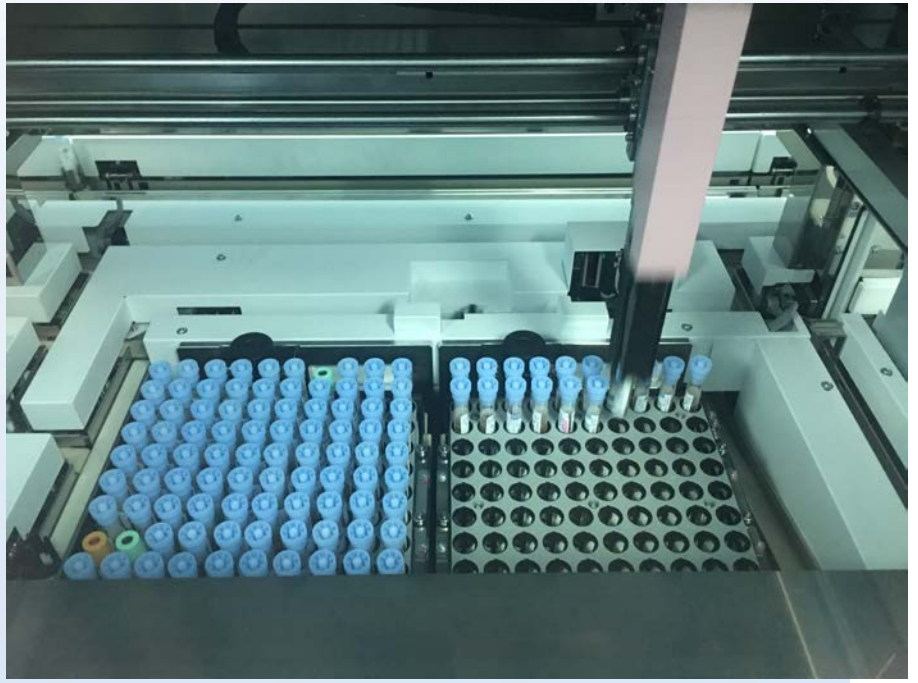
- Results Delivery
  - Interfaces, faxing, portals
  - Patient facing portals
- Results Formatting
  - HL7
  - Discrete vs. Non Discrete
  - PDF
- Integrated Reports

Post-Analytic

- Regulatory
  - CLIA
    - 42 CFR 493.1291(a)
      - “ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry to final report destination”
    - 42 CFR 493.1291 (c) and (d)
      - The test report must indicate the following:
        - (1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.
        - (2) The name and address of the laboratory location where the test was performed.
        - (3) The test report date.
        - (4) The test performed.
        - (5) Specimen source, when appropriate.
        - (6) The test result and, if applicable, the units of measurement or interpretation, or both.
        - (7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.
      - Pertinent “reference intervals” or “normal” values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

Post-Analytic

- Sample storage
  - Automation
  - Add-ons
- Report Retention
- Report Correction/Addenda/Amendment
- Business Intelligence
  - Tracks Key Performance Indicators

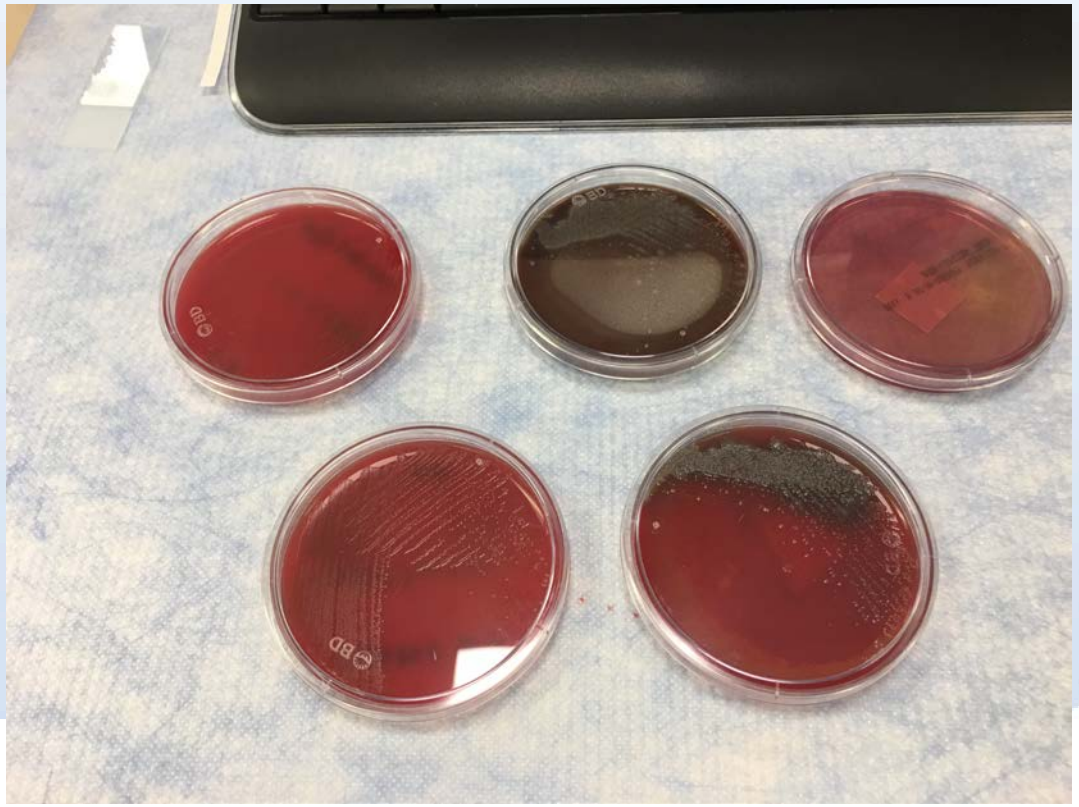


LIS - Special Considerations

- Transfusion Medicine
  - Significant variations based on services offered
  - Donor vs. Patient testing
  - FDA Regulation

LIS - Special Considerations

- Microbiology
  - Very different workflows compared to other sections of the laboratory
  - Multiple specimen types
  - New technology
  - Discrete Microbiology resulting
  - Automation



LIS - Special Considerations

- POCT
  - Distributed nature offers special challenges
  - Interfaced vs. Non-interfaces
  - Middleware
- CRM
  - Key for any laboratory to track calls
- Courier
  - Integration with LIS is ideal

Questions?

Thanks

Jordan Olson MD