



# Laboratory Management of a Quality System

Module 8: Information  
Management





# ACKNOWLEDGEMENT

- Ministry of Health and Social Welfare - Tanzania
- Muhimbili University of Health and Allied Science
- World Bank
- ECSA- HC





# Learning Objectives

- Describe the basic elements of information management
- Describe the laboratory information system hardware and software components
- Provide the laboratory information system capabilities
- Describe the benefits of using printed barcode labels generated from the LIS for specimen labeling





# Learning Objectives

(Continued)

- Describe the difference between the types of reports that can be generated from the LIS
- Describe the purpose of a documented audit trail within the LIS
- Describe the purpose of performing a laboratory information system back-up process





# Today's Agenda

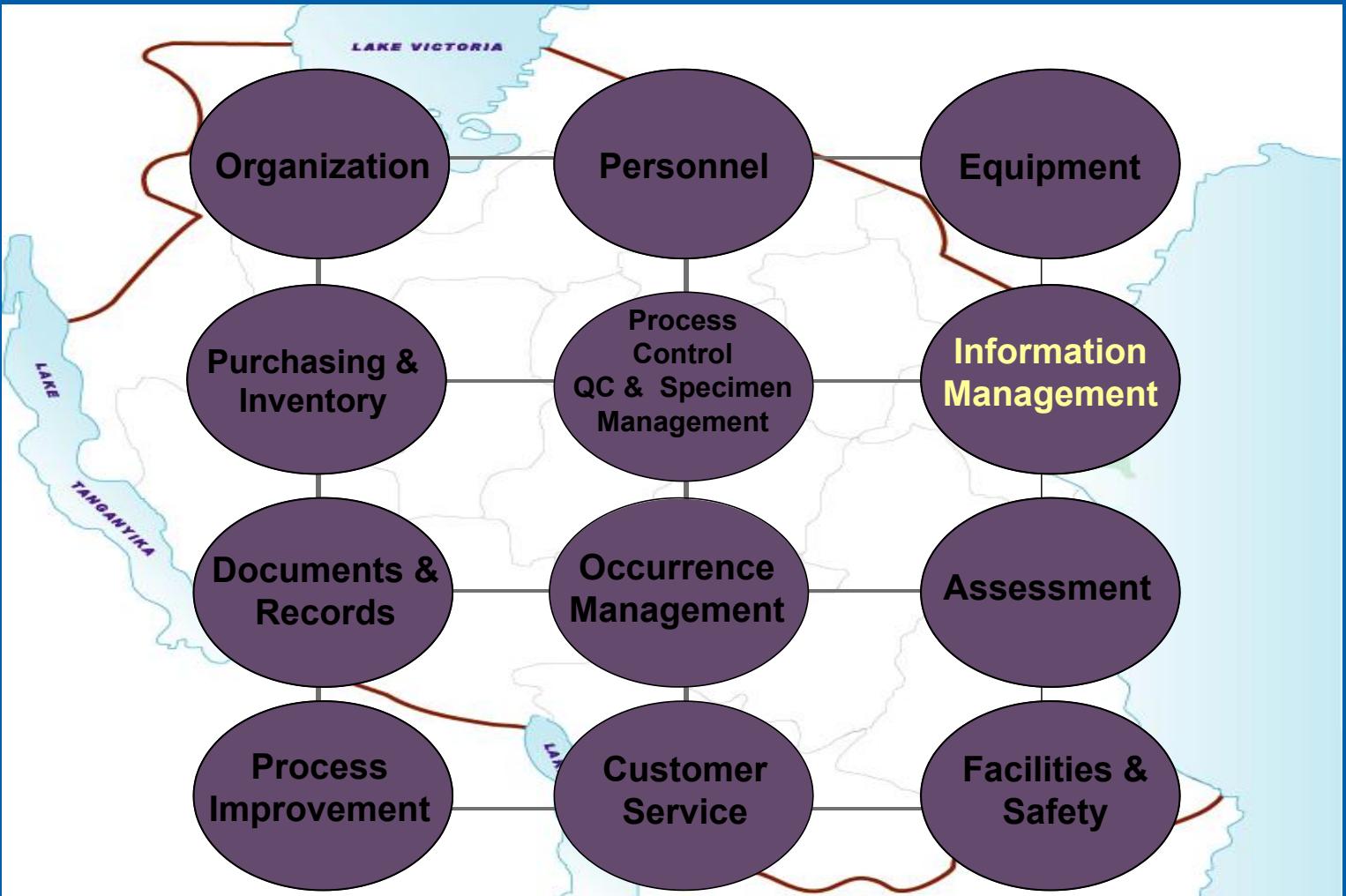
## Quality Systems

- Information Management Options
  - Paper-based
  - Automated
  - Laboratory Information System (LIS)
- LIS Components and Architecture
- LIS Capabilities
- Module Summary





# The Quality System





# The Laboratory Information

- The product produced by the laboratory is information
- Laboratory information within a quality system produces increased knowledge and better patient care
  - The quality of incoming information has an impact on the quality of outgoing information





# Examples of Laboratory Information

- Test orders/investigation forms with patient information
- Specimen receiving logs/specimen receipt information
- Specimen Transfer Forms
- Result and reception registers
- Specimen collection lists/labels





# Examples of Laboratory Information

- Laboratory reports
- Quality control data and charts
- Maintenance and service records
- Instrument function checks and calibration records
- Occurrence forms/logs
- QA logs





# Incoming Laboratory Requests

- Information on requests must be complete and standardized.
- Requests must document the order and provide:
  - What needs to be done; what tubes need to be drawn
  - How fast it needs to be done (Urgent)
  - Relevant patient and specimen information (patient on ART)
  - Information the lab needs to provide proper patient care





# Outgoing Patient Reports

- Laboratory reports must:
  - Contain patient and clinician demographics
  - Contain test order information
  - Have legible easily read results with correct units of measure
  - Have an appropriate reference range reported by the results
  - Have information on who released the report and when
  - Contain comments on specimen quality or other important notes to the caregiver





# Quarterly Laboratory Reports

- Summary of patient investigations performed
- Infrastructure
- Staff
- Equipment and Supplies
- Other QA, occurrence information





# Information Management Issues

- Missing reports, logs, or information
- Storage and archiving problems
- Inadequate control of documents and records
- No consistent numbering system
- Information lacks critical identifiers
- Information not standardized
- Lack of traceability
- Transcription errors; lack of readable records





# Managing Laboratory Information

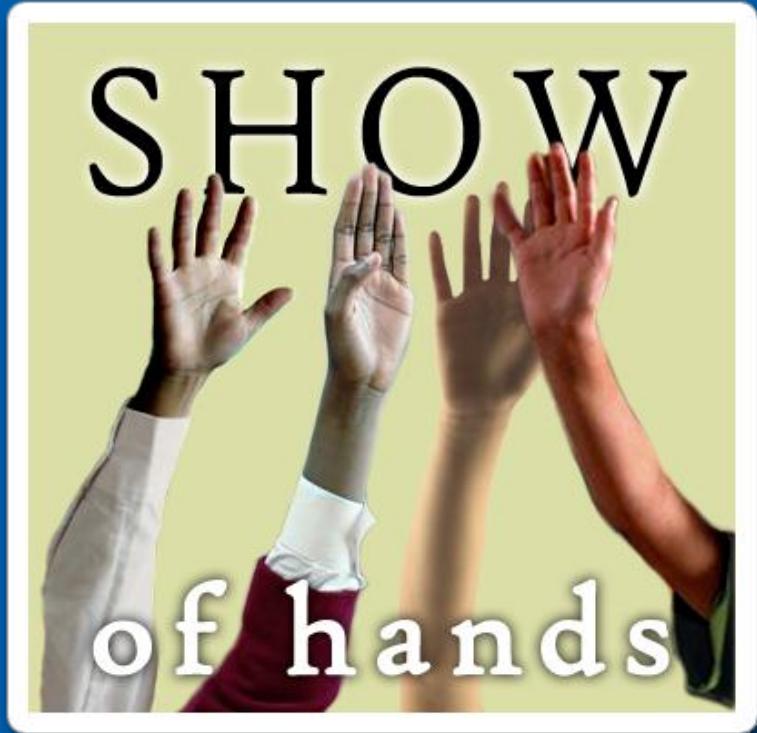


- Design processes for managing incoming and outgoing laboratory information
- Assure information management processes include:
  - Confidentiality controls
  - Quality controls for legibility and accuracy
  - Permanent and secure storage
  - Easy retrieval





What questions do  
you have on  
information  
management  
so far?





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# Information Management Options



- Paper-based Systems
- Automated Systems (non-LIS)
- Laboratory Information Systems (LIS)





# Paper-based Systems

- Comprised of manual logs, worksheets, QC charts, occurrence reports, laboratory reports, laboratory investigation forms, and general lab administration reports and records.





# Paper-based Systems (Continued)

- Requirements for paper systems:
  - Assure complete data entry
  - Assure legibility by writing as little as possible
  - Assure unique specimen ID number (accession logs, requests, and reports)
  - Assure proper storage and retention for





# Goal of Paper-based Systems

- Able to trace/reconstruct what occurred at each step during the testing process
- Easily find laboratory requests and reports as needed
- Assure confidentiality of laboratory information





# Organization of Paper-based Systems



- Labs must have an organized system to retain and readily access important paper information
- Options include log books, file cabinets, and binders
- Organize information sequentially by month, date, year or alphabetically by month, date, year (Laboratory Reports)
- Need system for copying and archiving records





# Organization of Paper-based Systems

(Continued)

- Determine what information is needed and where it is located
  - Organize related information in the same location - QC with QC, laboratory reports with laboratory reports
  - Organize the information so that related data can be reviewed together - for example, QC results and corrective actions





# Today's Agenda

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# Automated Systems (Non-LIS)

- Instrument software
  - Information is stored on-line in instrument computers for QC functions
- Personal computers/software programs
  - Excel and other programs can be used for recording and charting QC
- In-house developed system using commercial database software





# Exercise

- In your laboratory, you have daily QC information for chemistry, hematology, and flow cytometry instruments.
- How do you document and manage your QC information?





# Advantages of Computerized System



- Permanence, easy long-term storage
- Security and confidentiality
- Easy access to all patient results and data
- Reduction in errors due to legibility issues
- Rapid turnaround time for reporting
- Access to large volume of QC data and statistics
- Traceability





# Disadvantages of Computerized System



- Cost of equipment
- Need for equipment maintenance
- Consistent power requirements
- Need for special skills and training
- Time consuming to implement and train staff
- Back-up system and disaster recovery plan must exist





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- Quality Systems
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# Laboratory Information System (LIS)



- A laboratory information system (LIS) will enable laboratories to:
  - Manage their data
  - Maintain quality
  - Improve efficiency while focusing limited labor resources
- An LIS has tools and a database structure specific to the laboratory workflow.
  - Manual entry procedures and errors are minimized and data flow is automated by LIS software.





# Laboratory Information Systems (LIS)



- Multiple sizes and functionality
- General or specialized applications (i.e. clinical lab, blood banking)
- Hardware and software components
- Storage capacity requirements





**What questions do  
you have on the  
various options for  
laboratory  
information  
management?**





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# Components of LIS

- Network
- Computer Hardware
  - Servers
  - Cables
  - Workstations
  - Printers
- Computer Software
  - Programs (applications)
  - Databases





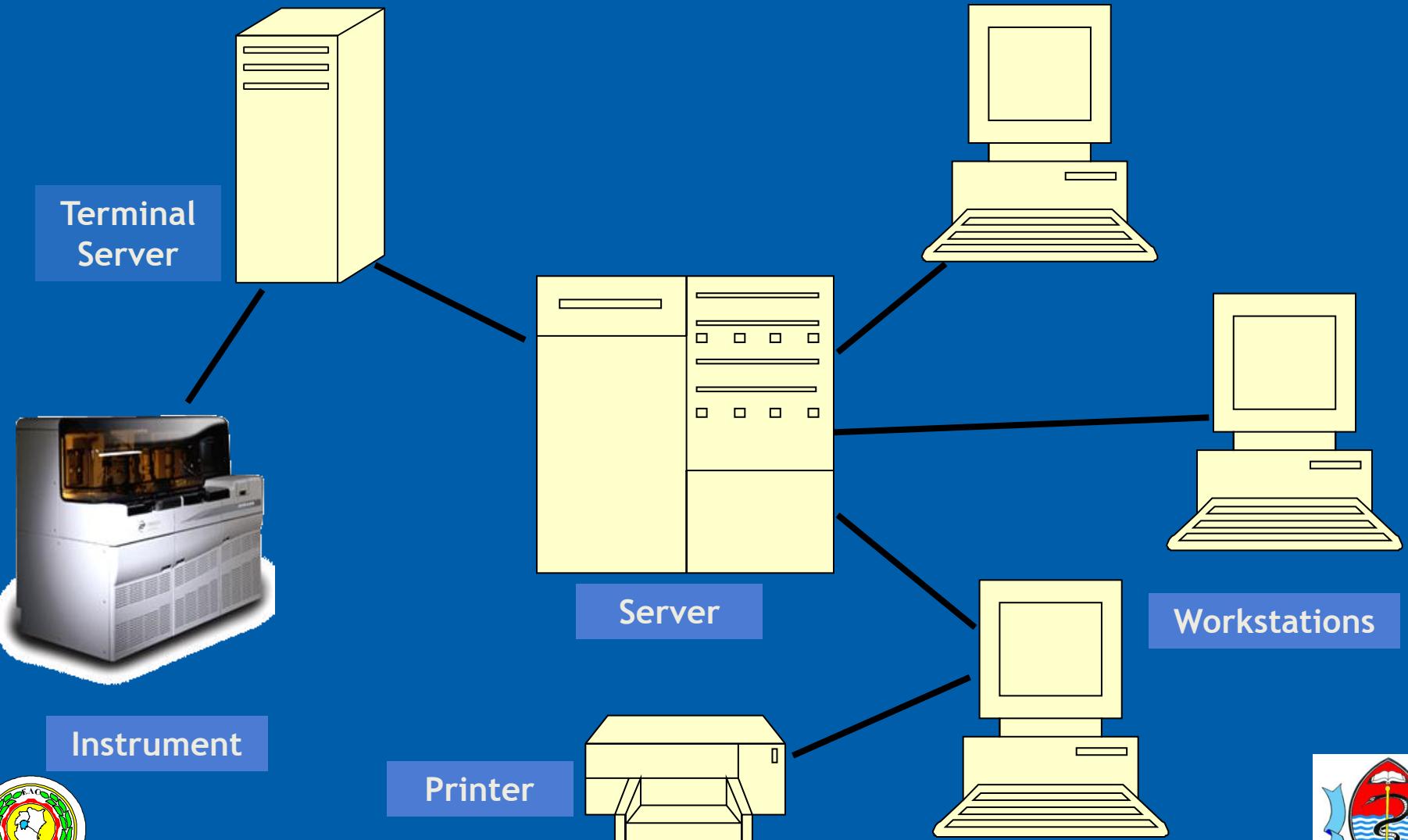
# Computer Hardware

- Servers
  - Physical “boxes” that control operations of the system and house databases
- Cables
  - Lines that connect remote workstations to the servers or other hardware (i.e. printers, instruments)
- Workstations
  - Physical components generally considered to be the computers (local hard drives, monitors, and keyboards)





# LIS System Architecture





# LIS Computer Software

- Programs (applications)
  - Contain the system instructions for performing operations and functions
  - Written in various programming “languages”
  - Most often reside on the servers
- Databases
  - Usually stored on the servers
  - Contain the data entered via the programs (i.e. patient data, test directories)





**What questions do  
you have on  
components and  
architecture  
of a laboratory  
information  
system?**





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# LIS Essential Capabilities

- Ease of Use
- Interfaces
  - instruments, hospital system, other systems
- Order entry, registration/acquisition, and receiving
- Result processing and reporting
- Data storage and retrieval
- System security, back-up, maintenance
- Audit trails and management reports





# Ease of Use

- Screens should be easy to read and allow for smooth movement between functions
- Automatic abnormal result flagging
- Sample identification number generation





# Ease of Use (Continued)

- Generation of bar codes enhances workflow and reduces chance of error
- Previous test results on a patient can be viewed along with new results
- Hospital computer download of patient data eliminates redundant typing and errors

Batch result (s) entry for quick accurate





# Interfaces

- The LIS interfaces laboratory analyzers, allowing laboratory staff to order test data from any workstation
- When testing is completed, results are uploaded to the system automatically, or manually entered through data entry user interface

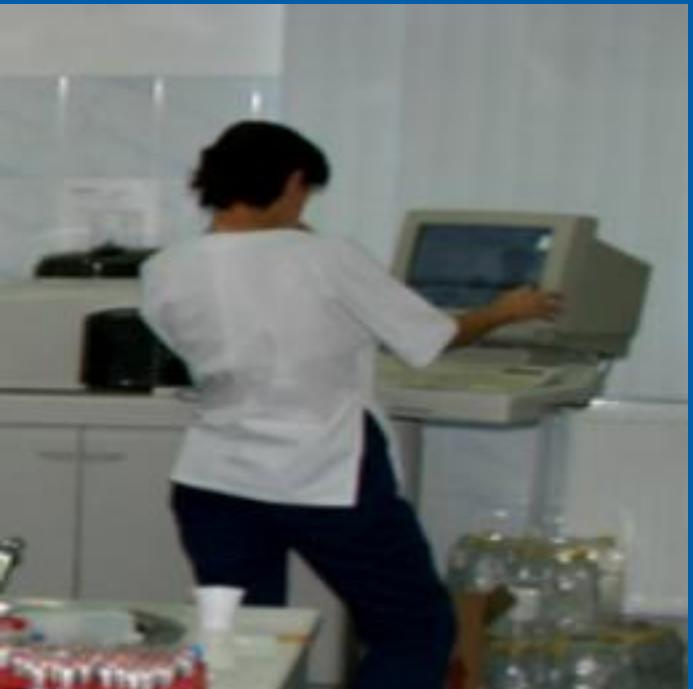




# Interfaces

(Continued)

- A technologist evaluates the results and releases them for reporting
- Need to understand interface requirements
  - Connectivity
  - Electronic message format





What questions do you have on ease of use and interfaces LIS capabilities?





# LIS Essential Capabilities

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# Order Entry

- An order is placed in the system usually by a clinician, nurse, lab assistant or technologist
- The order contains the tests to be performed
- Orders may be tracked with a unique identifier
- The identifier (which is usually a number) is most commonly referred to as an accession, specimen, or sample number





# Order Entry (Continued)

- The barcode labels with the unique patient accession number for the draw tubes are printed by the LIS. This provides the ability to track the specimen from the point it is taken from the patient to the point that it gets discarded.
- Using the barcode labels, a phlebotomist will collect the appropriate specimen(s) from the patient. Following collection, the specimens are labeled with the printed bar code labels and returned to the laboratory.





# Order Entry (Continued)

- Duplicate Order Checking
- The LIS will cancel duplicate tests ordered on the same accession number
- Depending on the LIS, the duplicate tests may show as cancelled on the final report, or may not show up at all





# Specimen Receiving

- After the specimen is collected, it is sent/brought to the lab for processing. This event is recorded in the LIS as specimen receipt.
- Upon receipt, either manual or automated testing begins. Most LIS systems are configured to download the specimen data to an analyzer either after the order is placed or when a specimen is received in the lab.





# Specimen Receiving

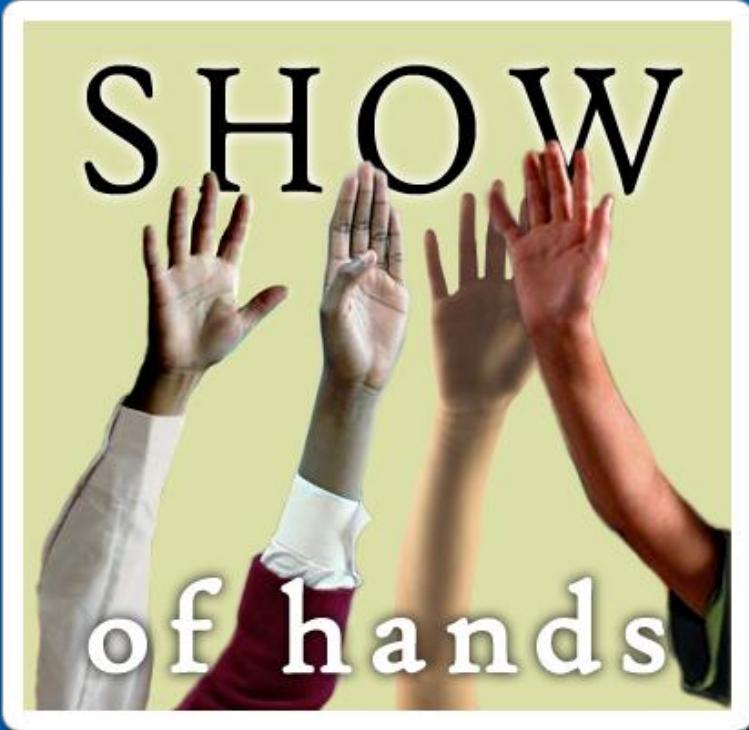
(Continued)

- When the specimen is placed on the instrument, the unique ID is read from the barcoded label and matched with the order previously downloaded to the instrument.





**What questions do  
you have on order  
entry and  
specimen  
receiving LIS  
capabilities so far?**





# LIS Essential Capabilities

- Ease of use and interfaces
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# Results Entry

- When results of lab tests are available, they are entered into the system manually or automatically downloaded from an instrument
- Once the results are double checked by the medical technologist, they are released to the patient record
- Released results are often automatically printed on lab reports which are delivered to the attending physician





# Results Processing

- Auto verification of results within the defined normal ranges
- Manual review of results outside of preset criteria
- Result edit capability; edits recorded in audit trail
- Automatic delta checking capability





# Results Processing (Continued)

- High, low and panic value flagging
- Automatic display of previous results obtained within defined timeframe
- Coded comments may be attached for consistency
- Manual entry of offline results





# Results Reporting

- Lab reports containing patient results are the final output of all LIS systems, and in many cases, the primary LIS interaction with healthcare providers outside of the lab
- Reports can be printed locally, printed remotely, autofaxed or delivered electronically
- The degree to which an LIS supports customizable lab reports and flexibility in result delivery methods should be considered when purchasing a new laboratory information system





# Results Reporting Formats

Types of report formats:

- Individual reports per accession number or occurrence
- Cumulative reports for multiple days or occurrences (i.e. all results for a hospital stay)
- LIS may have ability to create user-defined patient report formats





# Results Reporting Requirements

- Calculation verification at periodic intervals
  - Compare manual calculation to system calculation
- Detection of unbelievable or illogical results
- Reportable range limit flagging





# Results Reporting Requirements

(Continued)



- Allows for comments on specimen quality that might compromise the accuracy of analytic results (i.e. hemolyzed, lipemic)
- Manual and automated result entries are verified before final acceptance and reporting by the computer
- Corrections to report are clearly identified
  - What change was made and when
  - Record of what values were originally reported





# Results Reporting Requirements

(Continued)



- Ability to deliver reports at different status levels
  - Preliminary reports - Some results on the order have been completed but others are still pending
  - Final - All tests on an order are completed
  - Amended - A test result value has been changed after a report has been delivered
  - Corrected - Patient demographic information has been changed (i.e. patient age) after a report has been delivered





**What questions do  
you have on result  
entry, result  
processing, and  
result reporting  
LIS capabilities?**





# LIS Essential Capabilities

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# Data Storage and Retrieval

- A complete copy of archived patient test results can be reprinted, including original reference ranges and interpretive comments, any flags or footnotes that were present in the original report, and the date of the original report
- When multiple identical analyzers are used, they should be uniquely identified such that a test result may be appropriately traced back to the instrument performing the test





# Data Storage and Retrieval

(Continued)

- A process should be developed to ensure that the data storage capacity and performance of the system are sufficient to meet the patient needs of the organization
- Procedures should be in place for the preservation of data and equipment in case of an unexpected destructive event (e.g., fire, flood), software failure and/or hardware failure
- Procedures must allow for the timely restoration of service





# Data Storage and Retrieval

(Continued)

- Storage data media, such as tape reels or disk cartridges must be properly labeled, stored and protected from damage and unauthorized use
  - Off-site storage
  - Retrieval within specified timeframe
  - Documentation that the process has been tested and works as expected





**What questions do  
you have on data  
storage and data  
retrieval LIS  
capabilities?**





# LIS Essential Capabilities

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# System Security

- Policies that specify who may use the computer system to enter or access patient data, change results, change billing or alter programs
- Computer access codes (security codes, user codes) must be in place to limit user access to those functions they are authorized to use ( some more privileges than others)
- Security of access codes is maintained (i.e. inactivated when employees leave, not posted on terminals)
- Assure proper log in and log off





# System Security

(Continued)

- Establish user specific security access
  - Changes authorized by manager
- Required periodic change of passwords by users
- Password complexity requirements (i.e. combination of alpha numeric codes)
- Record of failed log-on attempts; automatic lockout after a defined number of unsuccessful attempts





# System Security

(Continued)

- If multiple use computers are in place (i.e. LIS applications plus internet access)
  - Restricted access for installation of unauthorized software
    - Prevent system instability
    - Prevent introduction of viruses
- Public network (internet) use must protect patient data





# System Function and Back-Up

- A copy of the database information should be made at regular intervals (i.e. nightly) so data can be restored in case of primary system failure
- Computer error messages should be generated that alert computer users of imminent problems
  - Disk space limitation
  - Network problems
  - Server location climate controls



Error messages should be monitored and



# System Function and Back-Up

(Continued)

- Responses to error messages that occurred during the system backup are documented
  - Review of nightly back-up process
- Record is maintained of unscheduled downtime, system degradation (response time), or other computer problems that includes reasons for failure and corrective actions taken
  - Troubleshooting logs





# System Maintenance

- Downtime for maintenance is scheduled to minimize interruption of service
- Develop schedule and procedure for regular maintenance of hardware and software either by maintenance contracts with vendors or in-house procedures
- Prepare service and repair records for all hardware components and software programs





# System Downtime

- Procedures to ensure reporting of patient results in a prompt and useful fashion during partial or complete downtime and recovery of the system
  - System should be tested to ensure it works
  - Policy for entry of results after system is brought back on-line
- Emergency service for both computer hardware and software available
  - Internal service (hospital IT department)
  - External service (vendor support)





# Network Performance

- Periodic monitoring of network performance
  - Use of packaged or custom monitoring systems
- Network equipment is accessible, well-maintained, adequately labeled
- Identification of which devices are using a specific port
  - Device names are necessary for immediate identification of location in case of network failure





**What questions do  
you have on  
system security,  
system back-up,  
and system  
maintenance LIS  
capabilities?**





# LIS Essential Capabilities

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  - instruments, hospital system, other systems
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# Audit Trails

- Manual and automated results should be verified before being released, and the person performing verification identified in the audit trail
- Autoverification should also be tracked as to when it was completed





# Audit Trails

(Continued)

- Document identification of users who have entered results
- Documentation is tracked by test (when multiple tests are ordered together)
- Should include who performed testing and who released the results
- Documentation of amended or corrected results
  - By whom
  - When





# Management Reports

- Test ordering patterns available by clinician and location
- Workload reports by category, clinician, laboratory and more
- Lab time efficiency reports (turnaround time statistics)





# Exercise

- Work in pairs
- Assess your current information management system describing its strengths and weaknesses.
- Which aspects would be desirable to automate? How?





**What questions do  
you have on audit  
trails and  
management  
reports LIS  
capabilities?**





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# Module Summary

- Described the basic elements of information management
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- Provided essential laboratory information system capabilities
- Described the benefits of using printed barcode labels generated from the LIS for specimen labeling





# Module Summary (Continued)

- Described the difference between the types reports that can be generated from the LIS
- Described the purpose of a documented audit trail within the LIS
- Described the purpose of performing a laboratory information system back-up process





**What questions do  
you have on  
Information  
Management?**





# Thank you

