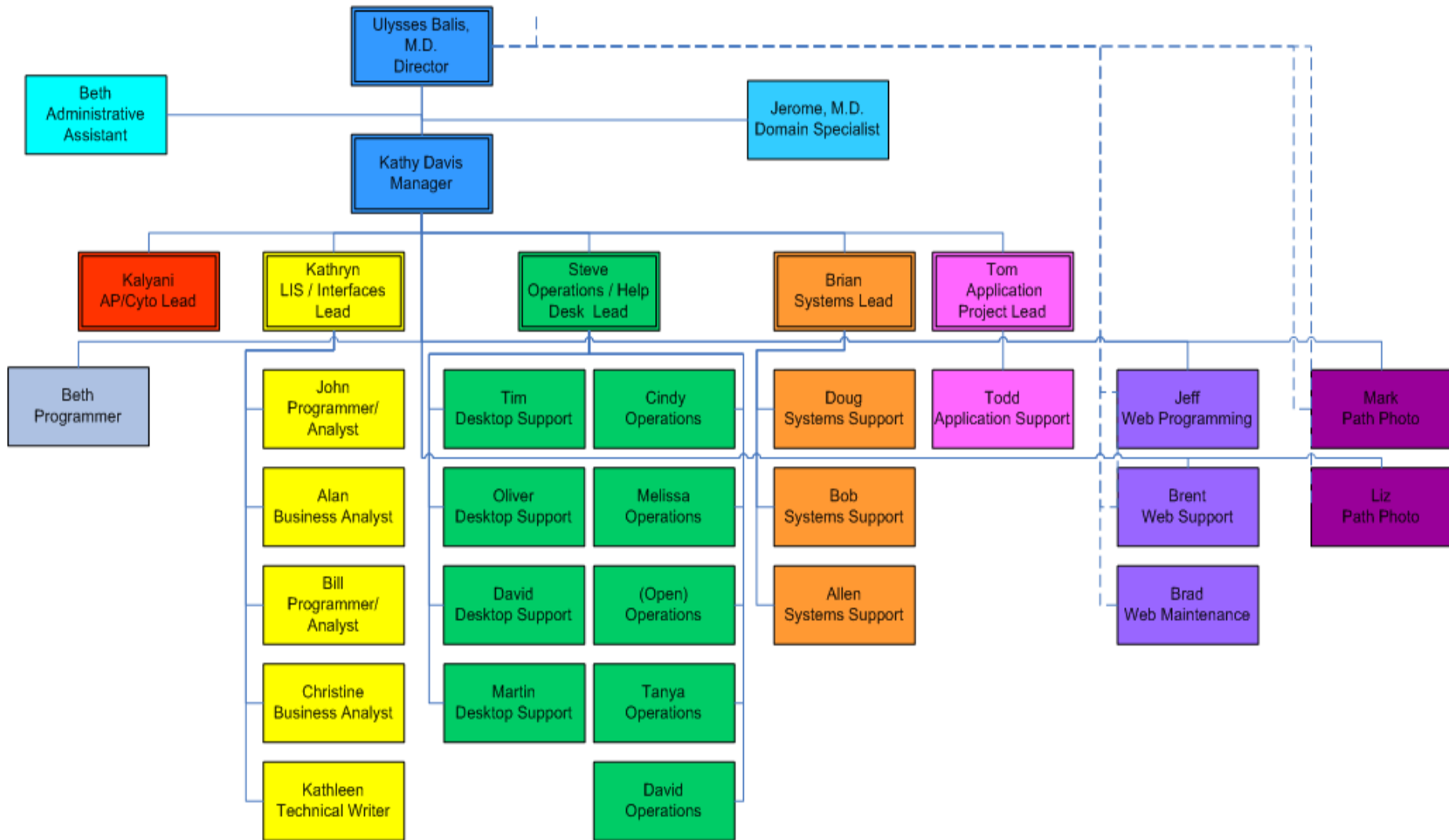


# LIS Implementation and Work Flow Design: Getting the Most Out of Your LIS

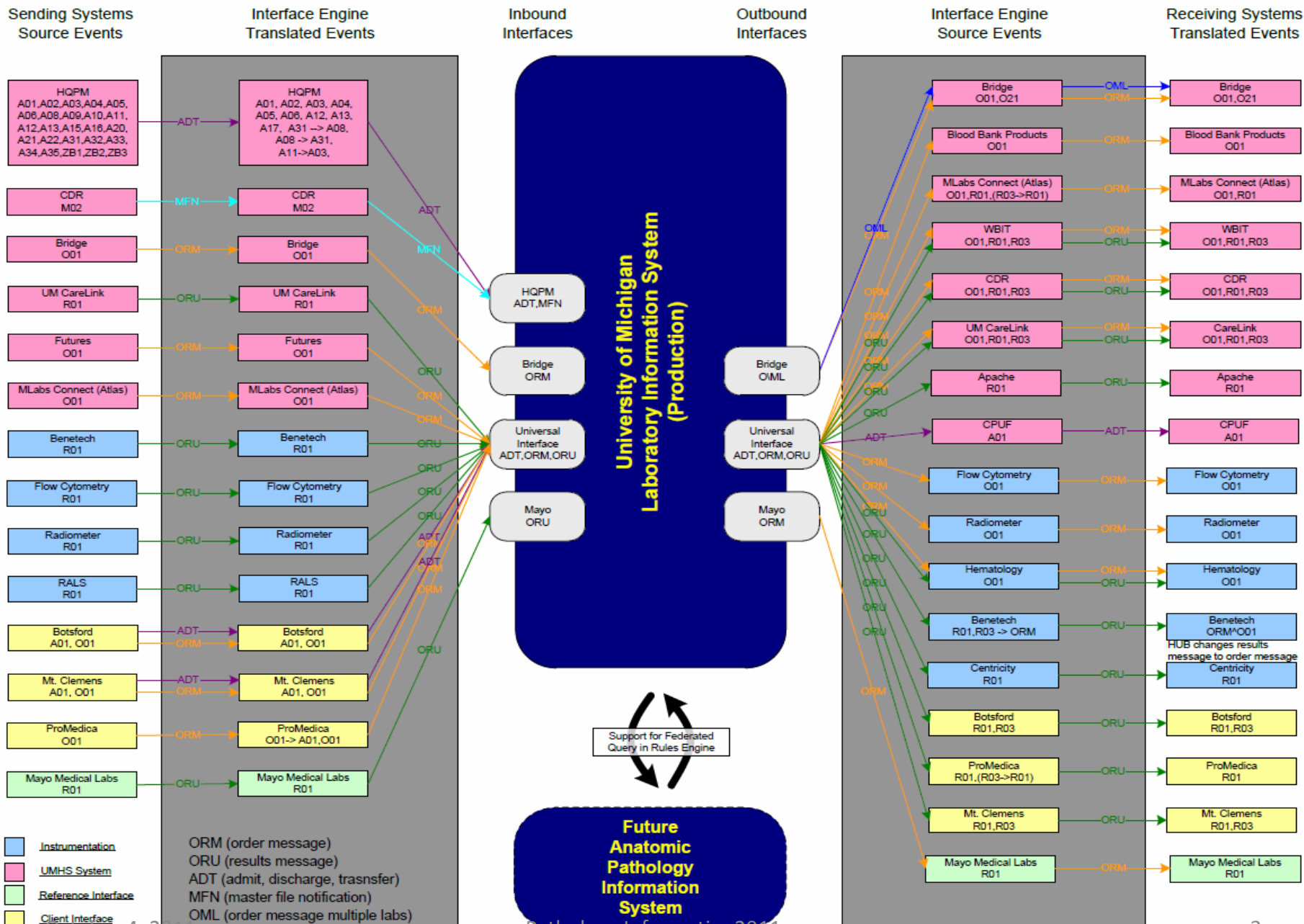
Kathy M. Davis, B.S., MT(ASCP)

Tuesday, October 4, 2011

# Pathology Informatics



# University of Michigan Laboratory Information System HL7 Interface Current and Near Future



# Overview

- Project planning considerations for implementing a replacement laboratory information system
  - Impact on clinical laboratories
  - Institutional integration requirements
- Implementation work plans and workflow design considerations
- Strategies for maintaining existing systems while implementing replacement systems
- Unexpected priorities

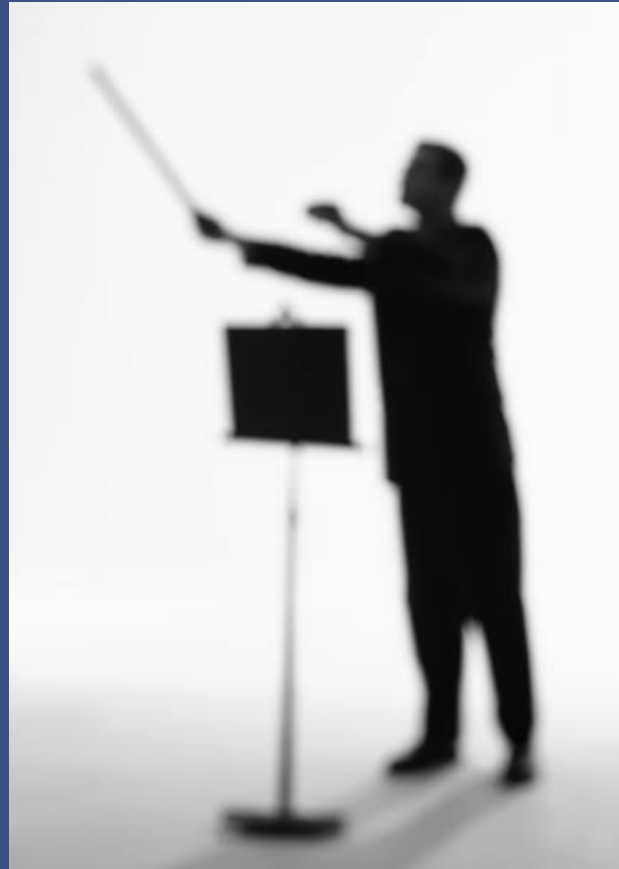
# What's the Big Deal?

- Laboratory systems are very integrated
- Interface hubs reduce the impact of change on other systems, but they do not eliminate it
- Every hospital department and division has their own agendas and priorities
- Priorities are constantly shifting, especially during long implementations that are typical for LIS's
- HR issues – sabotage, nitpickers, slackers

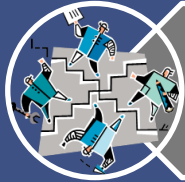
# The Big Deal continued ...

- The LIS functionality you purchased may not be exactly what you expected
- The development efforts may take a bit longer than expected
- Resources for the project may become diluted with operational responsibilities and other priorities
- Vendors always want to sell additional solutions
- Hospitals are on tight budgets and constantly need additional IT solutions to remain competitive

# Get Ready to Lead



# Securing the Resources



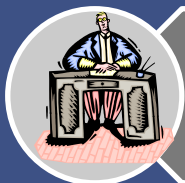
People



Work space



Hardware/software



Commitment from top  
management

# The People

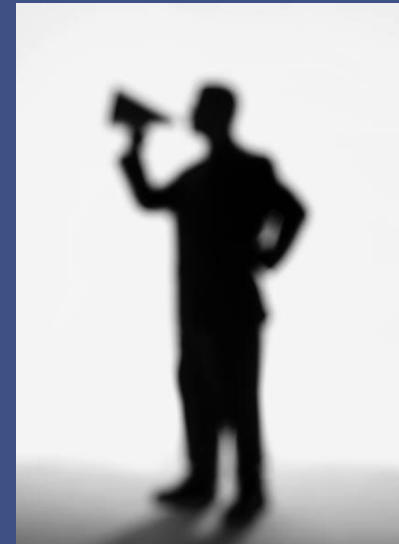


# The Project Director

- MD - Pathologist and/or Pathology Resident
- Manages the politics and pressures and provides the clout at the institutional level to resolve major issues
- Provides MD representation at high level executive IT committees in the hospital
- Communicates progress or concerns at departmental AP and CP faculty meetings
- Engages the LIS vendor leadership to resolve complex implementation issues and to kindle development relationships when appropriate

# The Project Manager

- Works to ensure top management commitment for the project
- Forms the project teams
- Coordinates all project activities
  - Overall project planning
  - Internal operational meetings
  - Manages the project plan
  - Training schedules
  - Database build activities
  - Problem and issue tracking
  - Testing and validation activities
  - Implementation schedules
- Ensures the project is delivered with the functionality and workflow required, on time, and within the budget.
- Communicates



# The Teams

- Laboratory Core team
  - Medical Technologists
  - Lab IT support staff
  - Desktop support
  - Systems support
- Interface team
  - HIS, CPOE, Outreach portals, etc.
- Laboratory Leadership team
  - Laboratory directors
  - Laboratory managers



# Forming the Teams

- Medical technologists with an aptitude for information management
  - Horizontal integration into the laboratories
- Central IT staff with desire to change job roles
- Internal vs. external candidates
- Experienced vs. inexperienced
- Full time project staff vs. staff with existing operational responsibilities

# Team Leads

- Coordinate the subprojects of the implementation
  - CP – general lab, blood bank, microbiology
  - AP – Anatomical pathology, cytology, genetics, flow
  - Data cross load
  - Desktop and peripherals
  - Patient and management reports
  - Outreach
  - Specimen management
  - System management
  - Testing and validation

# Consultants

- Consultants
  - Extra lead time
  - On boarding and off boarding
  - Risk that the operational support staff will lack the depth of knowledge necessary to maintain the systems post implementation
  - Dedicated staff that can focus on the project
  - May become eligible candidates for permanent employment

# Directors, Managers, and Top Leadership

- Must ensure that the project is visible at the highest level of the hospital
- Must ensure that upper management supports, embraces, and is made aware of the degree of effort required to implement an LIS
- Must include MD leadership because many of the business decisions and priorities are established by MDs in the healthcare environment

# The Work Room

- A separate work space is recommended for the project team
- Configuring and building a new LIS is often frustrating and those frustrations are confined within the room
- Teams working together promotes rapid communication and problem resolution
- Room configuration takes time – multiple desktops, networking, communications

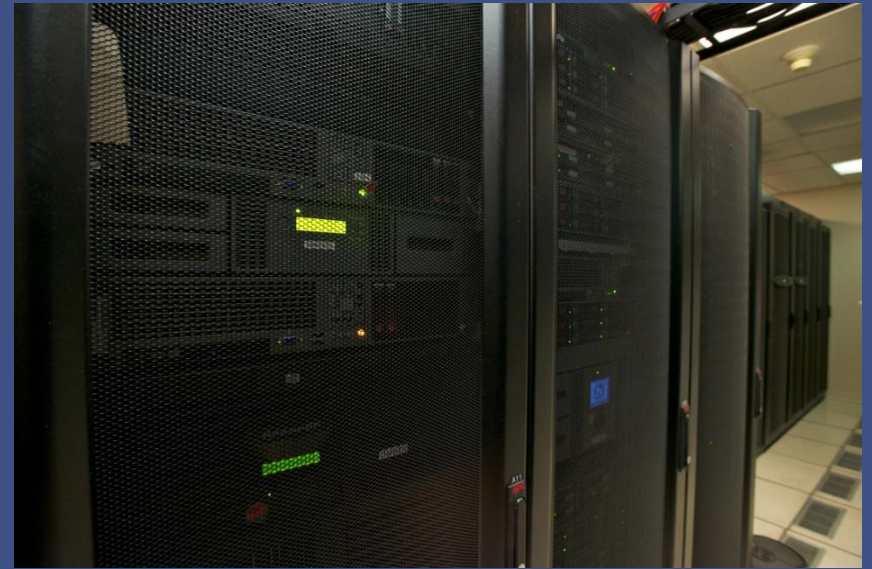
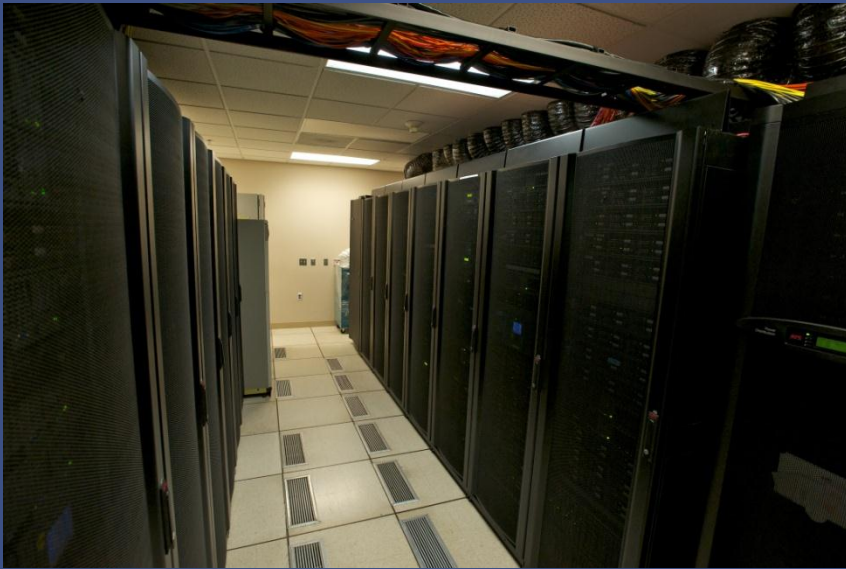
# Workspace



# Hardware, Software, and Environments

- Where will the servers be located?
  - Centralized IT vs Pathology Machine room
- Who manages the servers?
  - Central IT staff or Pathology IT support team
- Plans for redundancy; disaster plans
- How many “environments”
  - LIVE
  - TEST
  - Development
  - Others

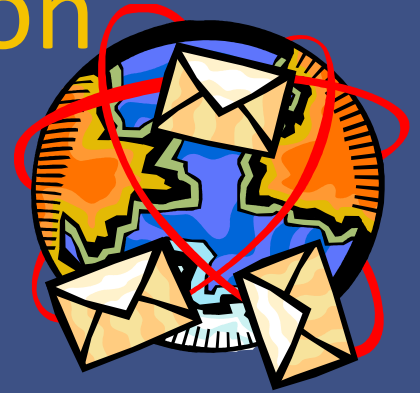
# Server Room



# Project Components



# Effective Communication



- Vendor communication
  - Overall project management checkpoints
  - Project development checkpoints
  - Weekly checkpoints for each module
  - Monthly on site sessions
  - Weekly file builds and workflow planning using on line collaboration tools
- Hospital leadership communication
  - Representation on hospital IT committee meetings
- Laboratory communication
  - Staff meetings
  - Periodic IT forums
  - Laboratory committee meetings or operational meetings
  - Project website
  - Newsletters
- IT communication
  - Staff meetings
  - Email

# Project Management Tools

- Comprehensive project plan
- Time lines
- Weekly or bi-weekly work plans
- Status reports
- Issue tracking
  - Enhancement requests
  - Defect management
- Keep the process simple

# Managing Multiple Projects



# The Co-Development Culture

- Whether or not your site engages in development initiatives with the LIS vendor is an important decision
- Success depends on the “culture” of an institution
- Some institutions are not prepared to meet the demands of co-development initiatives
- Development efforts require staff resources and kindling the development relationship with the vendor can be challenging
- The goal of co-development efforts should reflect satisfaction at your site and improved marketability for the vendor

# A Bit About Keeping the Lights On

- Not a trivial pursuit
- LIS systems are complex and typically with many value added applications that also require care and feeding
- The business of healthcare today is very competitive and the need for IT solutions is continuous in our quest to improve patient safety and to add efficiencies to our workflow, all while reducing our FTEs
- There is a constant flow of requests that range from process improvement initiatives for existing workflow to the development of custom solutions or incremental systems required to support the outreach programs
- Almost every change in healthcare involves IT, even if it's just rearranging office space or moving across town

# A Word About Prioritization

- EXTREMELY difficult job
- Should be the responsibility of an oversight leadership team, but often is not
- Addressing patient safety risks should always be a priority
- Addressing requests for features and functionality that compete in the healthcare marketplace are strongly driving project priorities
- Meaningful use



# Time Lines and Shifting Priorities

- Time lines – be prepared to be flexible
  - LIS implementations are complex and projected time lines typically require adjustments
  - 50% increase for high confidence factor
  - 100% increase for low confidence factor
  - 200% increase for high risk projects
  - Double the time recommended by the vendor

# Time Lines and Shifting Priorities

- Departmental mandates
  - Frequent laboratory instrumentation changes
  - Validation activities for updates to other interfaced systems
  - Requirements to support outreach program initiatives

# Time Lines and Shifting Priorities

- External mandates
  - During your LIS implementation the hospital implements EPIC at a rapid pace
  - LIS implementation at the hospital is postponed
  - Current LIS must be extended and version upgrade is required

# Ripple Effect

- Additional project time can be an advantage
  - Later versions of software with more enhancements at go live
  - Extended time for development initiatives
- Extended timelines are not always bad
- *“When things go wrong, you’ll find they usually go on getting worse for some time; but when things once start going right they often go on getting better and better.”*

*C.S. Lewis*

# Interfaces



- Review specifications for each interface
  - Do you have an interface integration engine?
  - Controls in application or interface engine
  - Eclipsys, EPIC, Atlas, etc.
  - Custom value added applications
- Assess the impact of new LIS to existing systems
  - Internal hospital systems
  - Outreach systems
  - Others

# Executing the project



# File Build Training



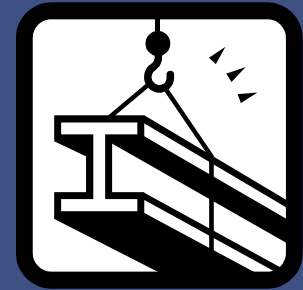
- Often takes place at vendor site
- Takes several weeks / months to cover all aspects of the system
- Ensure system is ready for use when the build team returns from training
- Make sure training is scheduled for current release or that arrangements are made to receive training documentation once available by the vendor

# Operational Assessments and Gap Analysis

- Vendor on site to review laboratory workflow before file builds begin
- Identify possible challenges for the vendor to support current workflow
- Identify possible laboratory workflows that may be required for new LIS
- Identify plans to reconcile differences in lab expectations and vendor capabilities
- Customizations vs. Enhancements vs. Product Defects

# Database build considerations

- Build the common files
  - Usernames / passwords
  - Location files (nursing units, clinics, etc.)
  - Specimen types
  - Specimen containers
  - Reporting units (standardized)
- Build the tests
  - Upper case/ lower case
  - Order codes naming conventions
  - Instrument interfaces
- Configure interfaces to other systems
  - Hopefully the customers are known and are in the loop
  - Controlling timelines and validation efforts is a challenge



# Workflow Design

- Opportunities to implement LEAN processing
  - Current state workflow vs. future state workflow
  - Reduce processing waste
- Complex workflows
  - Research accounts
  - Research specimen collection tubes
  - Sendout tests
  - Call back and fax back requests
  - Shared specimens
  - Integration between modules
  - Integrated reports

# Integrated Reports Workflow

- The integrated report
  - Interpretation summary for the bone marrow biopsy, cytogenetics report, molecular report, and flow report
- Which reports get integrated and how is this flagged?
- Which pathologist is responsible to produce the interpretation summary?
- How is billing handled – or is it?

# End User Training



- Technical writer role to prepare customized end user training materials
- Training the trainer approach
- On line training modules
- Keep end user training close to Go Live

# Validation and Test Plans

- Sub-committee
  - Blood Bankers are good choice to lead this work group
- Technical writer provides expertise
- Unit testing, Integrated testing
- Documentation requirements
  - Paper
  - Electronic

# Computer Validation Plan

- Purpose
- System Description and Scope
- Criticality and Complexity
- Validation Approach
  - Validation plan and documentation
  - System documentation
  - Test plan and scripts
  - Security
  - Change control
- Review and approval signatures

# Don't Forget about Regulatory Requirements!

# CAP GEN.43022

- GEN.43022
- There is documentation that programs are adequately tested for proper functioning when first installed and after any modifications, and that the laboratory director or designee has approved the use of all new programs and modifications.

# CAP GEN.43055

- GEN.43055
- There is documentation that all users of the computer system receive adequate training initially, after system modification and after installation of a new system.

# CAP GEN.48500

- GEN.48500
- There is a procedure to verify that patient results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to patient reports (whether paper or electronic).

# Implementation

- Implementation plans
- Go Live Readiness Assessment
- Conversion / cutover plans
- Downtime planning
- Staffing for conversion
- Staffing for post go live

# Thank You!

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