Rethinking Pathology Informatics in the Era of the EMR
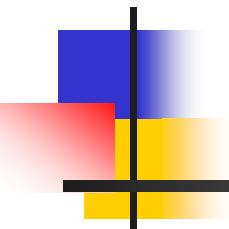
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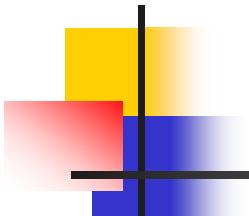
Major Topics and Ideas To Be Addressed in This Lecture

- Early history of lab computing; LISs flourished because of added value & HISs not well adapted for clinical support

- EMRs emerging as key hospital systems to provide OE/RR and integrated clinical data to hospital clinicians

- Classic LISs have failed to respond to changing lab mission; V-LISs have emerged with specialized SLAMs

- Hospital lab may lose "franchise" if reference labs permitted to set up two-way interfaces to EMRs

- Challenges & opportunities in new era for pathology informatics: emerging need for lab system integrators
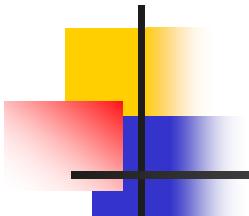
Brief Summary of Early Days of Laboratory Computing

- Lab computing and LISs began to be adopted in the 1970s; general labs were relatively easy to automate and came first

- Computing was a natural fit for lab professionals because comfortable with automated analyzers and technology

- Paper test requisitions submitted to lab central processing unit where orders entered manually into LIS using a terminal

- LISs generated complex color-coded sets of hard-copy reports: interim reports, "cum sums", & discharge reports

- LIS as an ancillary system; labs were profit centers & given great latitude to optimize operations & improve cash flow
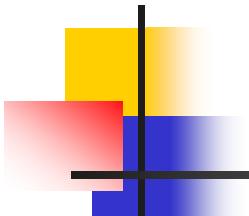
Brief Summary of Early Days of Hospital "Mainframe" Computing

- Major locus of 'hospital computing' was the HIS (hospital information system); primary functions were PA and PM

  - PA (patient accounting) focused on billing and other financial applications; primary *raison d'etre* for system

  - PM (patient management) focused on patient admitting, transfer, and discharge; critical support for billing

- Oversight over central computing provided by central IT manager or director who reported to the CFO of hospital

- Perception in 80s that, in time, all clinical applications would naturally folded into the mainframe application *repertoire*

- Challenges for mainframe clinical applications: (1) poor functionality (2) prolonged scheduled downs for backup
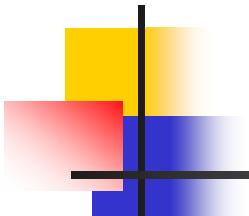
Reasons Why Lab Computing & LISs Flourished in the Early Days

- Clinical labs with intensive number processing were well suited to computerization using "mini-computers" like DEC

- More complex functionality – text-based apps for blood bank, microbiology, & AP -- developed later to complete suite

- Easy to find subset of med techs and MDs who gravitated toward LIS support unit; methodical & process-oriented

- LIS entrepreneurs who developed early LISs arose from inside clinical labs; deep understanding of lab work flow

- Profit margins for LISs were substantial; IBM set schedule for mainframe app cost; LISs viewed as comparative bargain
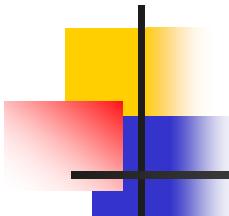
Early History of Pathology Informatics and Informaticians

- Since the earliest days of LIS, pathology informaticians who worked on the clinical side accustomed to pragmatic goals

- Worked collaboratively with LIS vendors to improve LIS functionality and to expand software into uncovered labs

- Continuous entry of new LIS vendors; worked initially with pathology department alpha sites to develop/refine software

- Few publication openings & little federal research funding: academic discipline of pathology informatics evolved slowly

- Research pathology informatics remained undeveloped; impetus later from research in genomics and proteomics
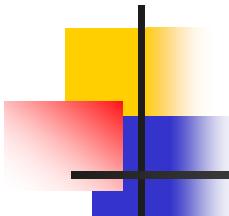
Architecture Model for Ancillary Clinical Systems Like the LIS and RIS

- Because LISs developed earlier than CDRs & EMRs, designed as customized, specialized, & autonomous

- Process continues today with added modules such as molecular diagnostics, cytogenetics, HLA/tissue typing

- LISs & AP-LISs did not gracefully integrate imaging; evolution of specialized pathology image servers/vendors

- Same approach in radiology with RIS evolving as patient scheduling/reporting system & PACS for imaging support

- PACS now evolving due to various pressures into institutional image servers serving multiple departments
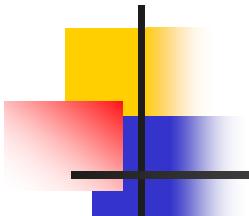
Functionality of the LIS vs. EMRs; Test Order Entry/Results Reporting

- Starting about ten years ago, lab test orders began to be placed in mainframe systems & transferred to LISs & labs

- In last few years, increasingly successful deployment of EMRs; provide clinicians with integrated clinical record

- Gradual weakening of concept of the LIS database as the "source of truth" -- permanent retrievable record of lab data

- Major task of the LISs in hospitals today is to replicate lab data to EMR which constitutes the permanent clinical record

- Perceived loss of political power and influence for the LIS; no longer supporting test OE/RR -- feeder system for the EMR
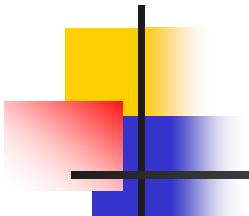
Continuing Struggle to Validate Lab Data Replicated to Multiple Systems

- One of major challenges for lab has been validation of lab data replicated from the LIS to other clinical systems

- At Michigan, we have assumed responsibility for lab data passed to CDR; soon going live with EMR & same rules apply

- We also have anesthesiology system that obtains lab results directly from the CDR and not directly from the LIS database
  - We have required validation of lab results against the LIS database but system managers comply only half-heartedly

- Results also being passed from CDR to data warehouse which was **not** designed for real-time patient care delivery
  - Slippery slope; MDs want to access this data warehouse for some clinical reports because includes billing data
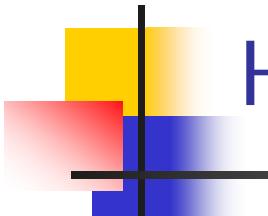
Changing Mission and Structure of Hospital Clinical Laboratories & LISs

- LISs developed in era when centralized hospital lab model dominated thinking; all specimens sent to lab & results out

- First crack in the façade with point-of-care-testing when analyzers moved from labs to decentralized patient venues

- Second crack in façade was growth of lab outreach; classic LIS were not flexible enough to provide this functionality

- Specialized lab portal vendors evolved to support reference labs; then systems were sold to hospital labs for outreach

- Next crack in façade & expansion of decentralized testing will be home care & sophisticated on-site home testing
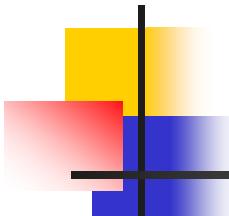
Changing Hospital Information Technology Political Landscape

- Hospital CIOs now exercising tighter political control over clinical systems like the LIS through the EMR

- Capital funding requests being vetted by committees populated by clinicians interested in system integration

- Historically, pathology informaticians tapped for central IT responsibilities because no other physicians available

- Clinicians now taking informatics fellowships & joining CIO staff as directors of clinical computing & EMRs

- Clinicians view the EMR as *their* system that meets *their* needs; lab data being squeezed into new mold
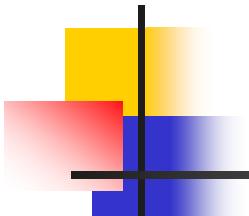
Middleware As New Assault on the Primacy of the Classic LIS

- Specialized instrument/LIS vendors emerging as providers of new category of lab software: *middleware*

- IVD vendors also entering fray with middleware to enhance analyzer sales and "finish" their test results

- Classic LISs as the major engine for lab rules now being challenges by middleware with proximity to instruments

- Middleware gaining traction in individual labs, allowing lab personnel greater control over *their own software*

- Can IVDs effectively compete in this middleware space; they often need to outsource software development
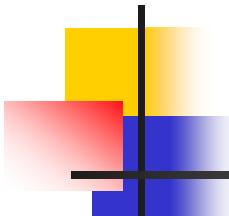
Emergence of the Virtual LIS (V-LIS) as a Replacement for the Classic LIS

- Due to increasing complexity of lab mission and focus on only hospital processes, classic LISs have less utility

- LISs supplemented by specialized modules (SLAMs) now coming to market like lab portals & middleware

- Some feel that classic LIS vendors could have avoided this product challenge by greater investment in R&D

- Paucity of skilled system integrators for hospital labs who could help architect V-LIS intra-lab networks

- Bottom line is that emerging cadre of pathology informaticians will function as these system integrators
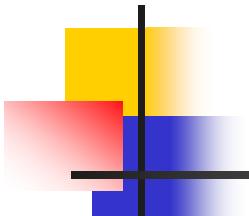
Defining the Nature of the Hospital Lab "Franchise"

- Hospital lab professionals assume that internal labs will perform all tests or contract for/manage lab outsourcing

- In exchange for this assumed or granted franchise, they perform the following services for hospital physicians
  - Quality oversight over local and outsourced specimens/results
  - Integrative functions to provide common look and feel
  - Manage contractual relationships with the outsourced labs
  - I&A responsibility for all lab data that flows through the LIS

- Hospital clinicians and administrators are beginning to examine this relationship in terms of ROI and utility

- Hospital administrators can talk a good game about quality but make many decisions on the basis of cost
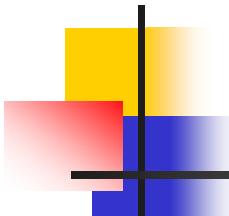
Pathology May Lose Grip on the Lab Testing Franchise in Hospitals

- Given that the LIS now replicate results to the EMR, outside reference labs could develop similar interfaces

- Paradigm of all test results in hospital flowing through the LIS & then replicated to EMR now being challenged

- Problem exacerbated by reference lab carve-outs; tests results for some hospital pts. only available in ref lab LISs

- Although problem today couched in terms of access to results, could morph into two-way interfaces in future

- One way to "protect" lab franchise might be using regional lab network for broad lab data exchange
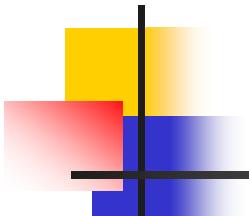
Attributes of an Idealized EMR but One That Is Rarely Executed in Practice

- In a properly architected EMR (which has only been deployed in the VA), the patient becomes the central data object

- All clinical data like lab, collected over time, is integrated together and attached directly to this central data object

- Like paper-based medical chart, the idealized EMR provides a single object containing all clinical information about a patient

- Information experts can refine this data model to eliminate data redundancy and enhance clinical data integration

- Model could replace traditional clinical reports with data output selected & assembled on-the-fly from within the EMR
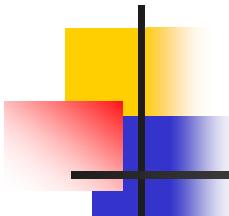
Advantages of This Idealized EMR Model for Pathology

- Pathology now being stressed by creating more complex test results --cannot be wedged into the EMR

- Ideally, pathology would be able to create a clinical lab object which could be attached to the pt. clinical object

- This would give pathology more latitude in terms of how lab data organized, formatted, and layered

- Also opportunity that the LIS could evolve beyond a test reporting tool to a learning tool for the clinicians

- Also need to move beyond obsolete concept that the EMR needs to run on a locally maintained set of servers
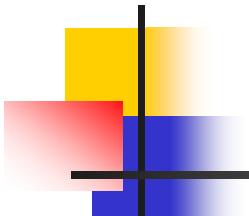
# First Lab Integration Challenge: Three Lab Data Domains

- Three lab data domains are (1) hospital/health system; (2) office EMR; and (3) research/controlled clinical trials

- Hospital-based labs + regional lab networks have been successful in competing for MD office outreach business

- Lab data unique in that it spans these three data domains; provides opportunity to integrate across them

- Clinical research lab database in academic centers overlaps service database; encompasses sick patients

- E-research apps being developed to support IRBs; clinical data like test results could be integrated into them
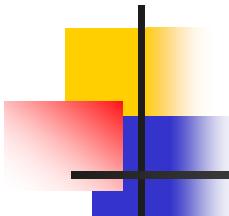
Second Integration Challenge: Exchange with Other Regional Entities

- May have heard terms RHIO & NHIN – regional health information organization, national health info network

- This is another attempt to exchange health information on a regional and national basis; similar to CHINs

- Pet project of David Brailer who is National Coordinator for Health Information Technology (health info. czar)

- Hints that he wants a Cisco or IBM to manage technical infrastructure; RHIOs manage politics & coordination

- I believe that most health systems view data as proprietary to them; few incentives to share data
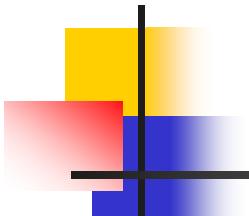
Summary of <u>Challenges</u> Facing Pathology and Pathology Informatics

- Key LIS functionality (OE/RR) moving to the EMR
- Clinicians view the integrated EMR as *their* system
- Diminishing status of LIS database as "source of truth"
- Trained informaticians joining EMR support team
- Capital funding for LIS improvements under CIO control
- Lab data needs to be "dumbed down" for the EMR
- Decentralization of lab testing + integration challenges
- More complex data generated in "new biology" labs
- LISs aging; new systems not radically improved
- Government clamping down on healthcare expenditures
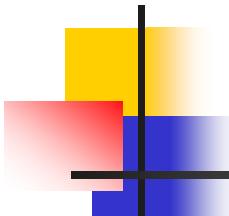
Summary of <u>Opportunities</u> Facing Pathology and Pathology Informatics

- Movement away from the central lab paradigm & toward new venues allows the labs to follow customers

- The V-LIS provides opportunity for informaticians to architect a laboratory network with multiple modules

- Complex results from new genomic/proteomic testing makes previous lab reporting solutions obsolete

- Pathology leadership recognizing that most lab testing is commoditized; IT is the major value-adding factor

- *In-vitro* diagnostic companies with global reach now restructuring to both create and manage lab information
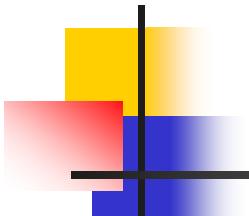
A New More Global Value-Adding Paradigm for Pathology Informatics

- Health system wide IT functionality (OE/RR, integrated clinical data reporting) has now migrated to the EMR
- Set agenda for hospital clinical pathology informatics
  - Integrate lab data streams from multiple decentralized testing venues into coherent organized lab data object
  - Lobby health system and third party payor executives for compensation for their value-adding activities
  - Develop coherent response to the assault on the hospital lab franchise by national reference labs
  - Capitalize on inherent local advantages within health systems to compete in this new information-rich era