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.


- 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
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
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 challenged 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 **Challenges** 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 Opportunities 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