Challenges in Clinical Communication

James H. Harrison, Jr., MD, PhD
Associate Professor
Public Health Sciences and Pathology
University of Virginia School of Medicine
Charlottesville, VA

Key Issues

1. Evolution of CIS and communicating with physicians through CIS
2. Inadequate/outmoded data model for test information
3. Management and communication of test “meta-data”
4. Management of test information change

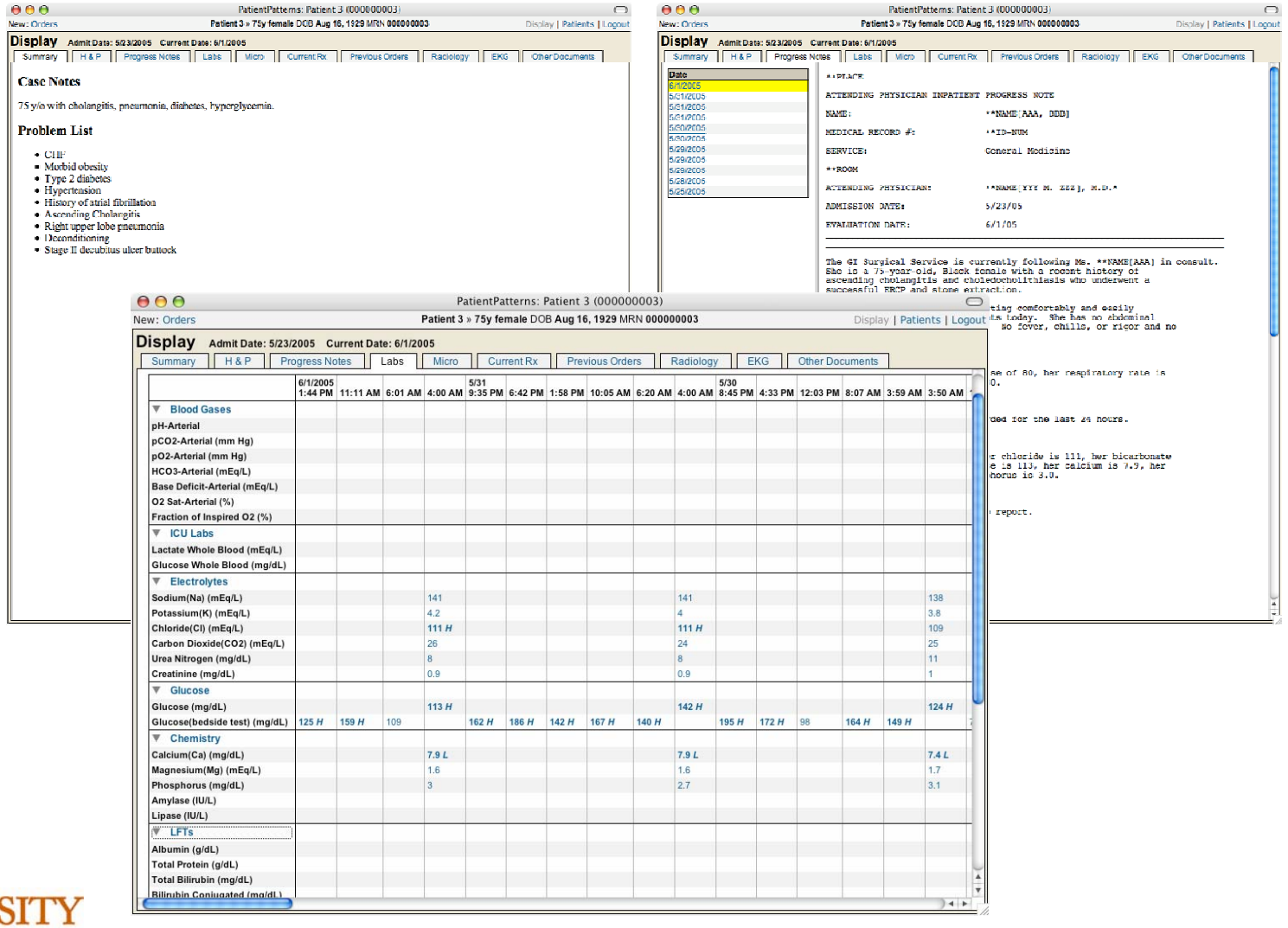
1. Clinical Information Systems

- Manage test ordering and results review
  - Unified physician workstation
  - Potential for decision- and context-oriented displays
  - Decision support
  - Decline of the separate Pathology Report
  - Variable laboratory/pathologist involvement with system design, implementation and validation
- CIS/LIS interface
  - Exchange of order and results data with CIS
  - LIS manages in-lab operations and data flow

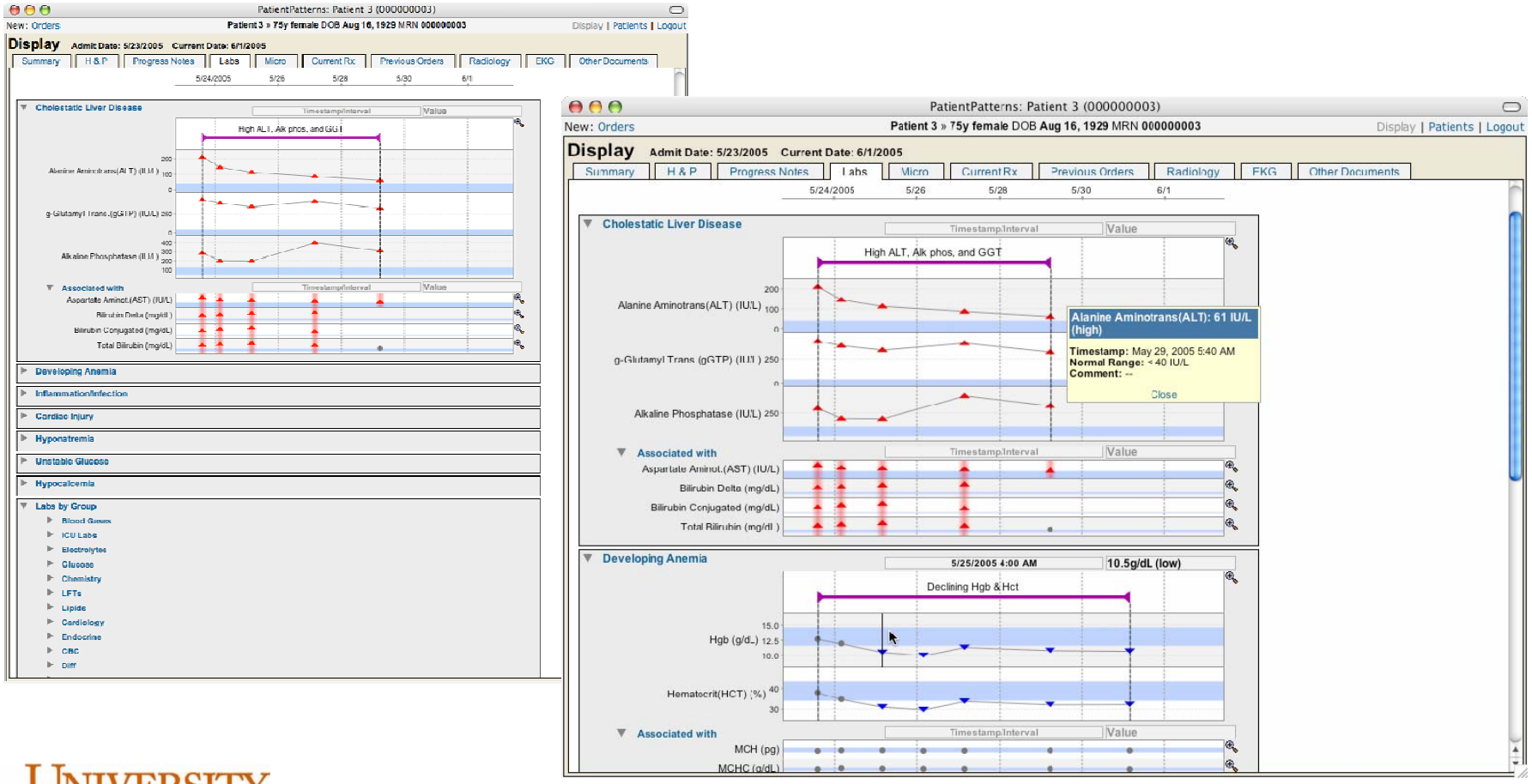
CIS/LIS Limitations

- Review/validation of order entry and result displays
  - Potential for error
- System communication may occur only at the ends of the process
  - Very limited or no interactivity between LIS and CIS
  - Intermediate results and triggers problematic
- Decision support operation and display
  - Decision support for lab data outside of lab management
- Ambiguous authority for lab-related system problems
- Need for lab/pathologist participation, approval, signoff

“Standard” Display



Pattern Detection with Information Aggregation and Display



2. Laboratory Test Data Models

- Traditional code-result-reference-comments inadequate
  - Identity of tests and analytes across locations and instruments (overloading test codes)
  - Categorization of comments
    - Interpretive, administrative, reference range, other
  - “Tests” that contain subtests
  - Calculated/derived vs. measured results
- “Middleware” systems are limited by the LIS data model
- CIS systems are influenced by the LIS data model
- Limits ability to represent tests, communicate additional information with results, and display result data

caBIG CTMS Lab SIG Data Model

- Patient
  - Specimen Collection
    - Specimen
      - Lab Test(s)

- Lab Test
  - Test identity
  - Lab Test(s)
  - Lab Result
    - Laboratory
    - Result (num/text)
    - Units/scale/precision
    - Result comment
    - Reference range
    - Ref range comment
    - General comment
  - Interpretation/codes
  - Administrative comment

3. Laboratory Test Metadata

- Labs are in both the *result information* and *test information* business
  - Test identity, lab identity, analyte, reference range, interpretive comments, administrative comments, specimen condition
  - Physicians Reference Manual content
  - Procedure Manual content
- In aggregate, substantial utility for groups within and served by labs
- Management is currently time-consuming
- Communication and use as reference material poor
  - Access to metadata in CIS results displays
  - Synchrony of and access to reference/procedure manuals

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Laboratory Management

Definition of an XML Markup Language for Clinical Laboratory Procedures and Comparison with Generic XML Markup

GILAN M. SAADAWI,[1†] and JAMES H. HARRISON, JR.[2‡*]

Background: **Clinical procedure manuals are typically maintained as word processor files and are inefficient to store and search, require substantial effort for review and updating, and integrate poorly with other laboratory information. Electronic document management systems could improve procedure management and utility. As a first step toward building such systems, we have developed a prototype electronic format for laboratory procedures using Extensible Markup Language (XML). ratory procedures from a central repository, decreasing procedure maintenance effort and, increasing the utility of procedure information. A standard electronic procedure format could also allow laboratories and vendors to share procedures and procedure layouts, minimizing duplicative word processor editing. Our results suggest that laboratory-specific markup such as CLP-ML will provide greater benefit for such systems than generic markup.**

Procedure Document Sections

labProcedure *(document root, attributes for document identification and type of procedure)*
- title *(title of the procedure)*
- synonym *(may be multiple)*
- abbrev *(may be multiple)*
- identifier *(method identifier code, e.g., Logical Observation Identifiers Names and Codes, LOINC)*
- assayMethod *(text or identifier)*
- analyte *(may be multiple)*
- usage *(scope of application of the method, start and end dates, local order codes)*
- history *(completion, revision, acceptance, current version)*
- introduction *(useSetting, principle, clinicalSignificance, interpretation, patientGuide)*
- schedule *(testing schedule and turnaround times)*
- referral *(send-out and downtime backup information)*
- specimenRequirements *(per specimen: specimenType, container, volume, stability, storage, patientPrep, rejection)*
- reagents *(per reagent: identity, description, value, prep, stability, storage)*
- materials *(per item: identity, description, location, storage)*
- instruments *(per instrument: identity, location, setup, maintenance)*
- qualityControl *(control, prep, stability, storage, verification)*
- calibration *(calibrator, prep, stability, storage, verification)*
- standards *(standard, prep, stability, storage, verification)*
- mainProcedures *(per procedure: steps, per step: text or substeps, conditions and actions)*
- calculations *(may contain multiple calculations with multiple steps per calculation)*
- results *(verification, report, referenceValue, turnaround time)*
- validation *(detection limit, linearity, precision, accuracy, carryover)*
- limitations *(per limitation: text description)*
- interferences *(per interference: text description)*
- proceduralNotes *(may contain multiple notes)*
- crossReferences
- citations *(per citation: author, title, source, publisher, vol, pages, year)*

Clinical Content Management Systems for Laboratories

- Unify reference materials and procedure manuals
  - Update and review all testing information in one process
  - Electronic signoff
- Location-independent access
- Electronic searching
- Tailored content and format views by personnel role
- “Help” content based on workflow
- Sharing document content and display formats between laboratories and with vendors

4. Changes in Testing

- Changes necessitated by national or local business requirements
- Changes resulting from new knowledge
  - Application of existing tests in new ways
  - New tests
- Lifecycle of test information communication
  - Ordering and results interpretation
  - Unfamiliarity - familiarity - new uses - methodology changes - replacement

Communication of Test Change Information

- Supplemental information in test order and result displays
  - Poorly integrated, need to respect workflow
- Printed laboratory newsletters, other mailings
- Email mailing lists
- Centralized laboratory information resources
- Currently poorly coordinated, uneven coverage
  - More effort dedicated to teaching correct billing than correct lab use

Summary

- Rise of CIS have increased physician-lab separation
  - CIS needs laboratory review and management contribution
  - CIS do not yet do a good job of communicating laboratory data or integrating lab with other data
- Outmoded laboratory test data models limit the communication of test information
- Laboratories “own” substantial data about tests but do not communicate it well
- The communication of test change information needs to be more standardized and robust
  - Can be addressed with current technologies (mailing lists, blogs, etc.) but requires institutional discipline to enforce use