

# Anatomic Pathology Middleware: A Pathway to the Merger of AP with CP

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# Topics to be covered

- A rationale; Why this talk?
- Historical differences between AP and CP informatics deployment strategy and capability
- Current high-level gap analysis of AP Information technology (cultural and workflow deficits, too)
- Temporizing and Permanent aspects of the Middleware Proposition
- Project APMER
  - *Anatomic Pathology Middleware Electronic Repository*

...a not entirely unfamiliar quote...

- “You’re the first prospective customer to ask for that particular feature. If we build it, it will probably represent an incremental contract line-item cost.”

# A rationale...

- No single prospective vendor currently offers the full repertoire of locally-perceived needs and no current (new or legacy) AP LIS system offers all possible functionality in the setting of a stand-alone system.
- Middleware, while well-known to CP is but an emerging presence in the AP continuum
- This need not remain the status quo....

# Historical differences between AP and CP informatics deployment strategy and capability

## *Differences in Workflow*

- CP

- Items are largely the same
- Items are often in a form factor amenable to automation and single-piece workflow
- Historical volumes have been high for a long time, necessitating use of informatics solutions
- Quantitative reporting model
- IT effort and IT capability equally distributed between pre-, analytic, and post-analytic areas

- AP

- Items have some variability in form factor and handling requirements
- Manual handling is often required
- Until recently, volumes were low enough for paper-based workflow, tracking and reporting.
- Qualitative reporting model
- Most effort focused at the report generation level; other areas underrepresented

# Historical differences between AP and CP informatics deployment strategy and capability

## *Differences in Culture*

- CP

- Long history of utilization of informatics tools and information technology
- IT is now considered the standard of practice

- AP

- No historical need for computer skills
- Proposed IT implementation can be met with caution, resistance or outright rebellion

# Historical differences between AP and CP informatics deployment strategy and capability

## *Differences in Repertoire of Tools*

- CP

- Rich, with many vendor and “home-grown” solutions available
- Significant peer-reviewed literature
- Solutions now in second and third-generation levels of sophistication
- Standard model for CP results reporting

- AP

- Relative paucity of drop-in tools, from any source.
- Limited anecdotal information
- Solutions often of a basic nature
- No standard model for AP results reporting (free-text conundrum)

# How Middleware Helps Extant Infrastructure

- As a temporizing measure:
  - Gain local functionality while waiting for the “next system”
  - Address urgent workflow and patient care needs while waiting for version patches, upgrades or platform transitions.
  - Allow for flexible and iteratively modifiable workflow in support of Lean Initiatives, without requiring costly and time-consuming vendor customizations.
- Permanent or semi-permanent roles:
  - Gain local functionality for a stable local system with constrained or unavailable extensibility capabilities
  - Integrate local systems to other devices and information systems that are out of scope for vendor consideration

# Functional Classes of Tools & Solutions

- “Screen Scrapers”
- Interceptors
- Shadow Repositories
- Stand-alone applications and turnkey solutions
- Total Integration Solutions
- Custom interfaces and drivers for specialized hardware

# Enabling Technologies that Now Make Simplified AP Middleware Development Possible

- Scalable enterprise databases that run on commonly available and modest hardware.
- Simplified Web services tool and the emergence of Service-Oriented Architectures.
- Natural Language Parsing (NLP) and sophisticated rules engines
- AP-centric Peripherals & AP-centric Media
- Lean / Six Sigma as applied to AP
- Human Factors Engineering

# High Level Gaps in Current AP Informatics Utilization; Where value is needed

- Recognize that the combined fields of AP represent more than merely a need for glorified text generation and workflow management of that text.
- Recognition of AP-style lab workflow as being equally meritorious for automation and tracking tools
- Recognition that a lack of automation in AP represents the same set of patient risks as already well-known to Clinical Pathology workflow

# Lab Worklist Management

- In the absence of electronic worklist management, if a site has high volume → guaranteed loss of control of one's workflow → utter chaos when compounded with a busy day and a short-staff situation
- AP for many sites has crossed the critical volume threshold and is not operating at a level of irreducible error rates (0.3% for all assets)

# Lab Electronic Order Entry

- Vendor Solutions are either absent or riddled with arcane interfaces that are slow
- Even upgraded version exhibit these similar traits.
- Middleware allows local control of a workflow area that is often idiosyncratic for locale
- Highly effective for enhancing staff satisfaction and productivity, while reducing orders

# External System Integration

- Vendor implementations are often expensive and can be the source for repeated missed implementation go-live dates
- Middleware allows the uncoupling of AP LIS development from external data integration initiatives.
- Middleware, in concert with the use of Federation, allows for an elegant use of “Best-of-breed” solutions to augment local repertoire of capability without becoming mired in an unsustainable geometric expansion of disparate interfaces and formats.



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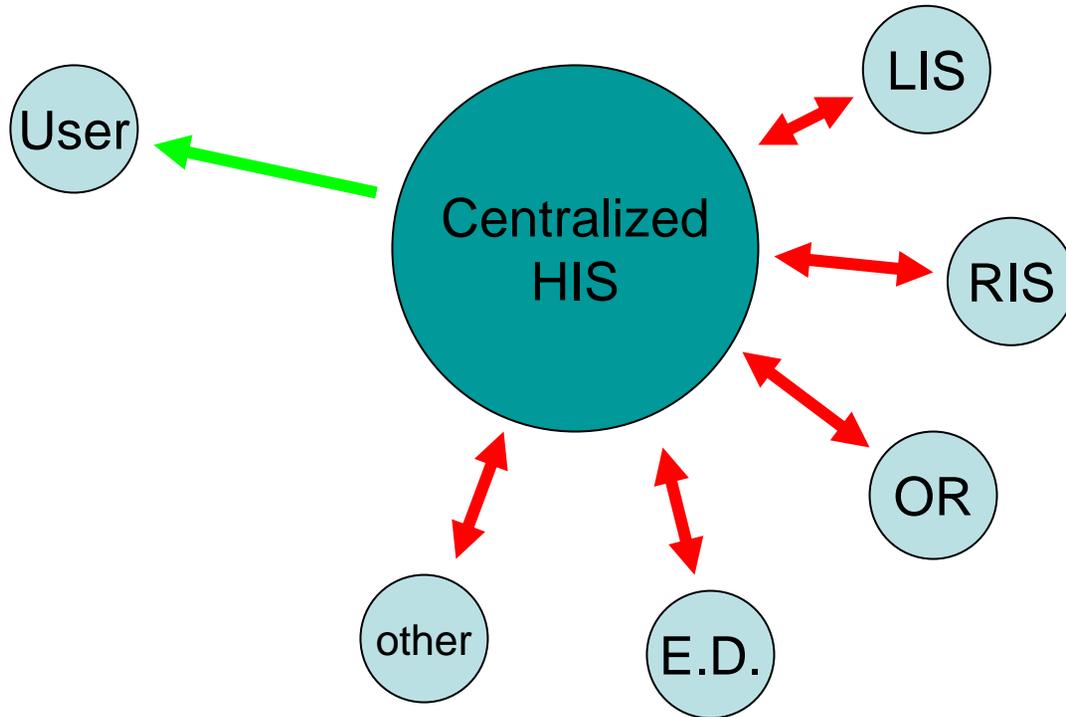
# The Promise of Federation

- Recognize that central IT departments have increasing demands and often diminishing composite resources to meet such demands
- Recognize that ancillary departments are usually the *most qualified* domain experts in terms of appropriate stewardship of data.
- Recognize that it takes less effort and imparts less risk to store every data element once and no more than just once (affirming the use of SSOT principles)
- Reduce time-consuming rework associated with cascaded interface changes, in the setting of evolution in both workflow and data model practices.

*Use of AP Middleware enables the provisioning for all of the above*

# What is Federation?

Conventional Data Model

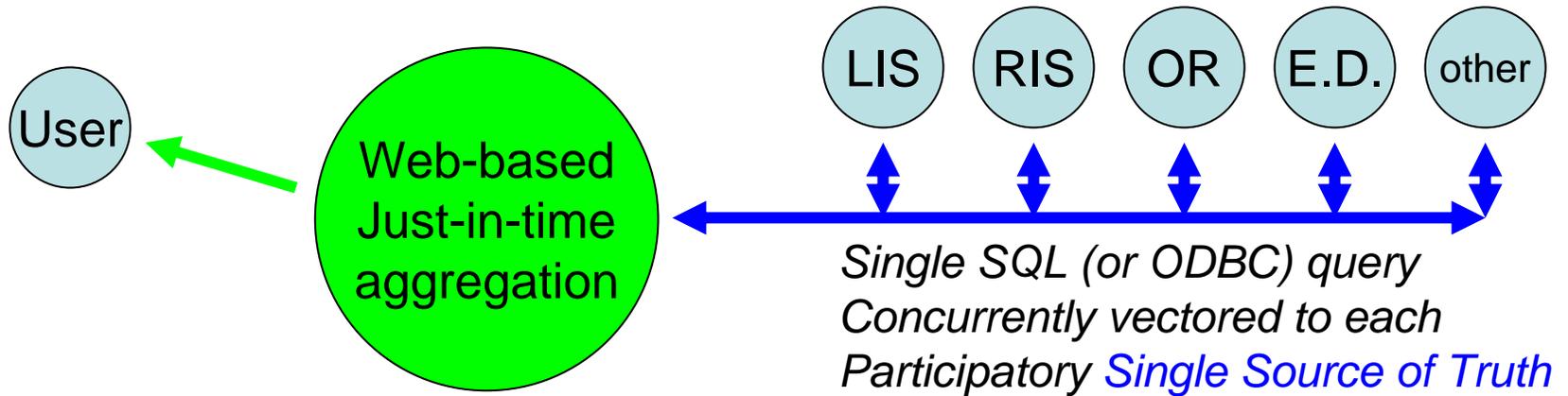


■ Conventional HL7 interface

# What is Federation?

(at the hospital level)

Potential Revised Data Model



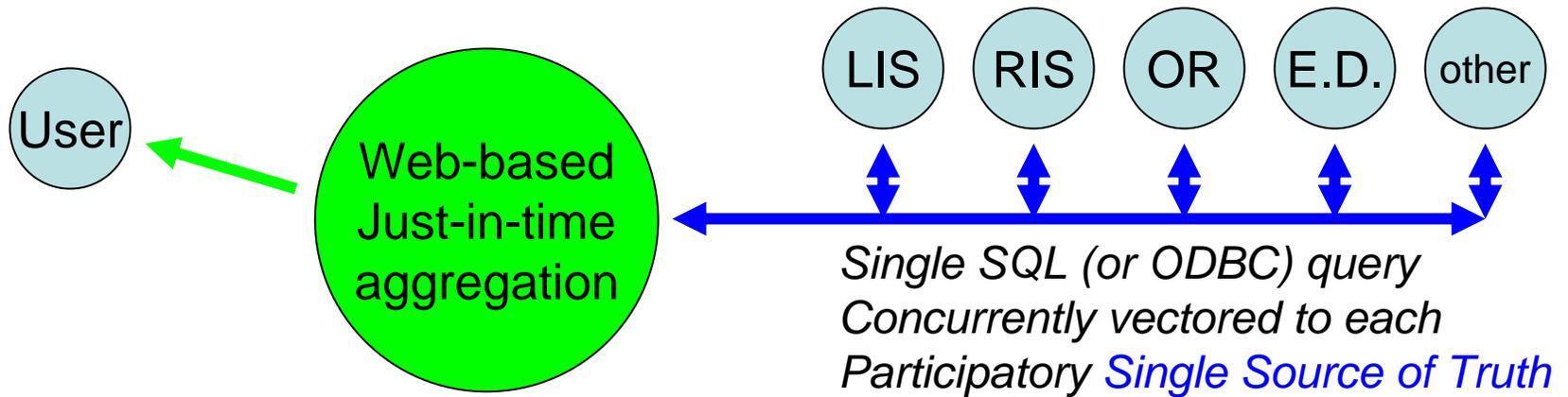
SSOT shifted to the appropriate domain-specific stewards of data from the HIS domain

■ Participatory SQL servers

# What is Federation?

*(at the hospital level)*

Potential Revised Data Model



Consequences of shifting to a SQL-based SSOT model:

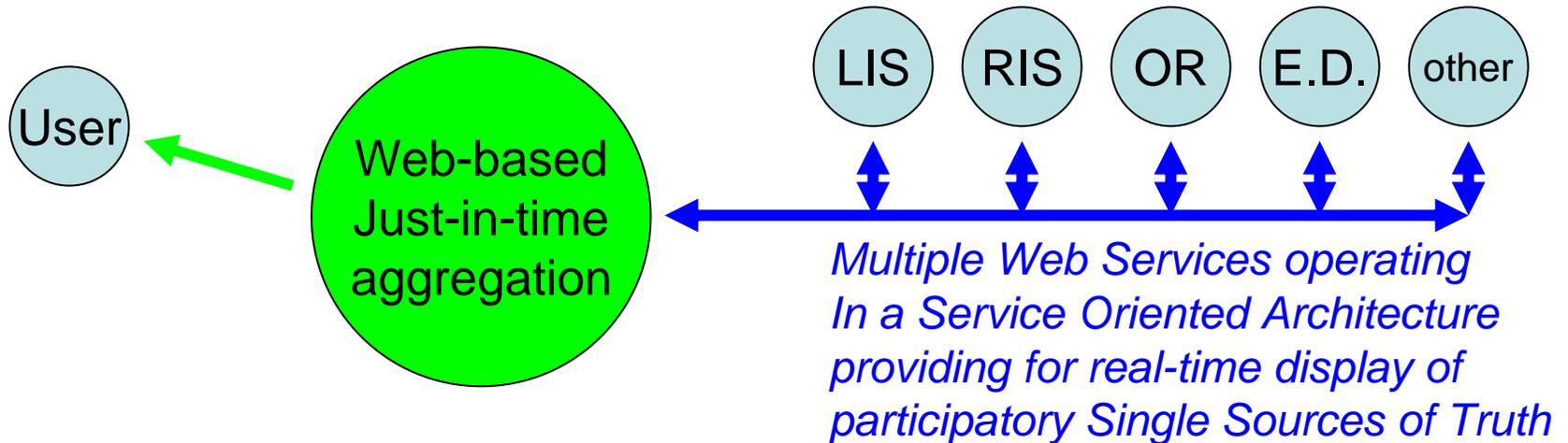
- Data only represented once in overall enterprise model
- Reduction in number of interfaces requiring support
- Potential to transfer classes information other than text
- Reduction in support responsibilities of central hospital IT.

■ Participatory SQL servers

# What is Federation?

*(at the hospital level)*

Potential Revised Data Model



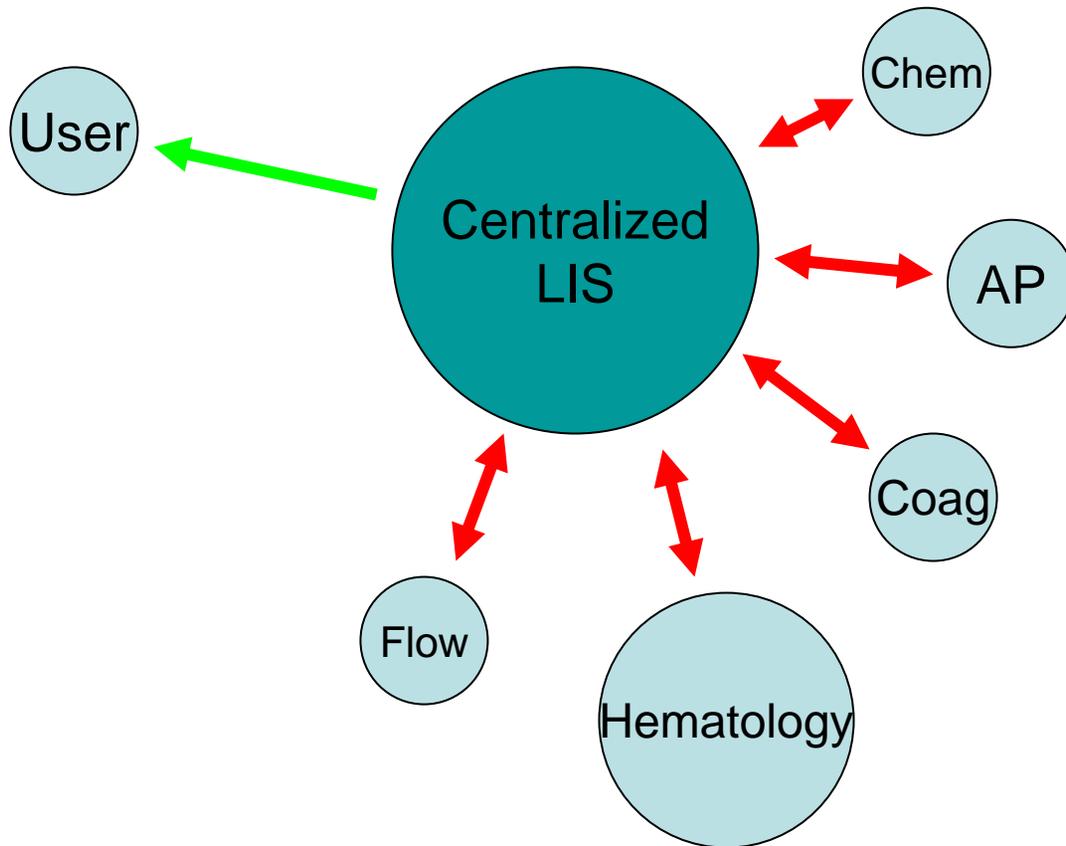
Consequences of shifting to a Web-based SSOT model:

- Simplified transfer and display of complex data types
- Simplified exchange of information via Web-based standards, supporting intra- and inter- institutional needs

■ Participatory SOA-Web servers

# Federation at the LIS level

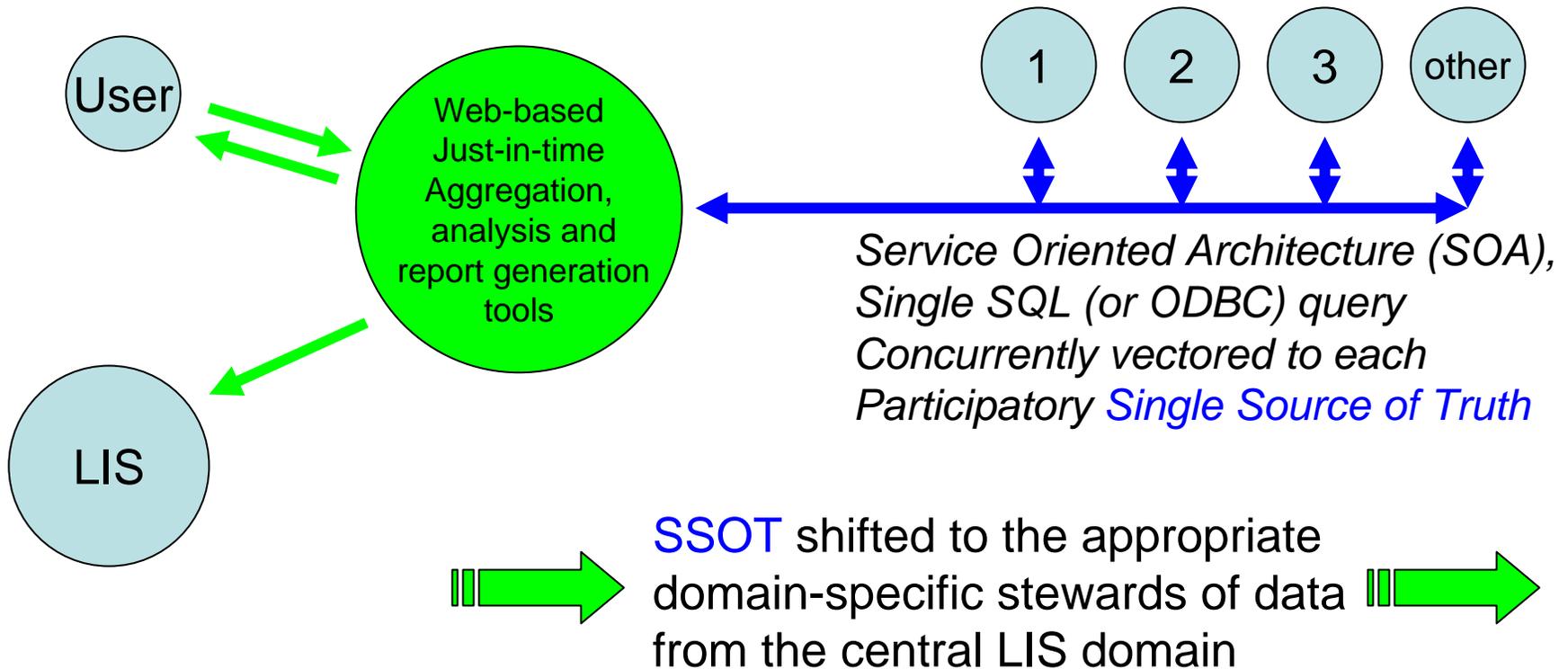
Conventional Data Model



■ Real-time interfaces

# Federation at the LIS level

Potential Revised Data Model



■ Participatory SQL servers

# Billing Decision Support

- Most AP systems have only partial billing solutions
- There is a need for higher levels of error state detection
  - Duplicate billing
  - Unsubstantiated stains (no comment in report)
  - Incorrect code totals
  - Wrong Fee Schedule

**Billing RollUp ©UJB 2006**

Accession #

Patient Name

Unit Number Date of Birth

Tiny Age Sex

CPT Codes

Specimen: Code	Quantity
--<NO DATA>--	-----

Duplicate Charges

Specimen: Proc.	Quantity
--<NO DATA>--	-----

L1 Total IO-I Total Flow (T/P)

--	--	--
----	----	----

L2 Total IO-S Total IMF

--	--	--
----	----	----

L3 Total IO-G Total EM

--	--	--
----	----	----

L4 Total Decals ICD 9 a

--	--	--
----	----	----

L5 Total Stains - I ICD 9 b

--	--	--
----	----	----

L6 Total Stains - II ICD 9 c

--	--	--
----	----	----

Consults Impox ICD 9 d

--	--	--
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Fee Schedule

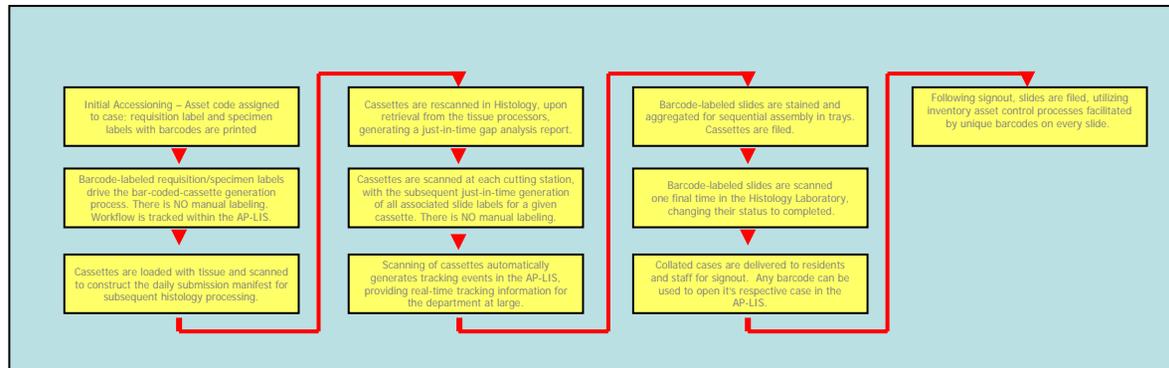
**None Specified**

Refresh Data Exit

# Closed Loop Clinical Communication of AP Results

- Printing the report / sending the report to a downstream interface is no longer a minimum standard, if we are to provide true patient care.
- Need to “close the loop” with the clinician; NOT with the EMR
- Patients DIE every day due to this lack of capability; AP Middleware allows this feature instantiation without the need to resort to vendor upgrades or platform exchanges
- Dr. Jeff Myers will lecture on this area extensively a little later this meeting.

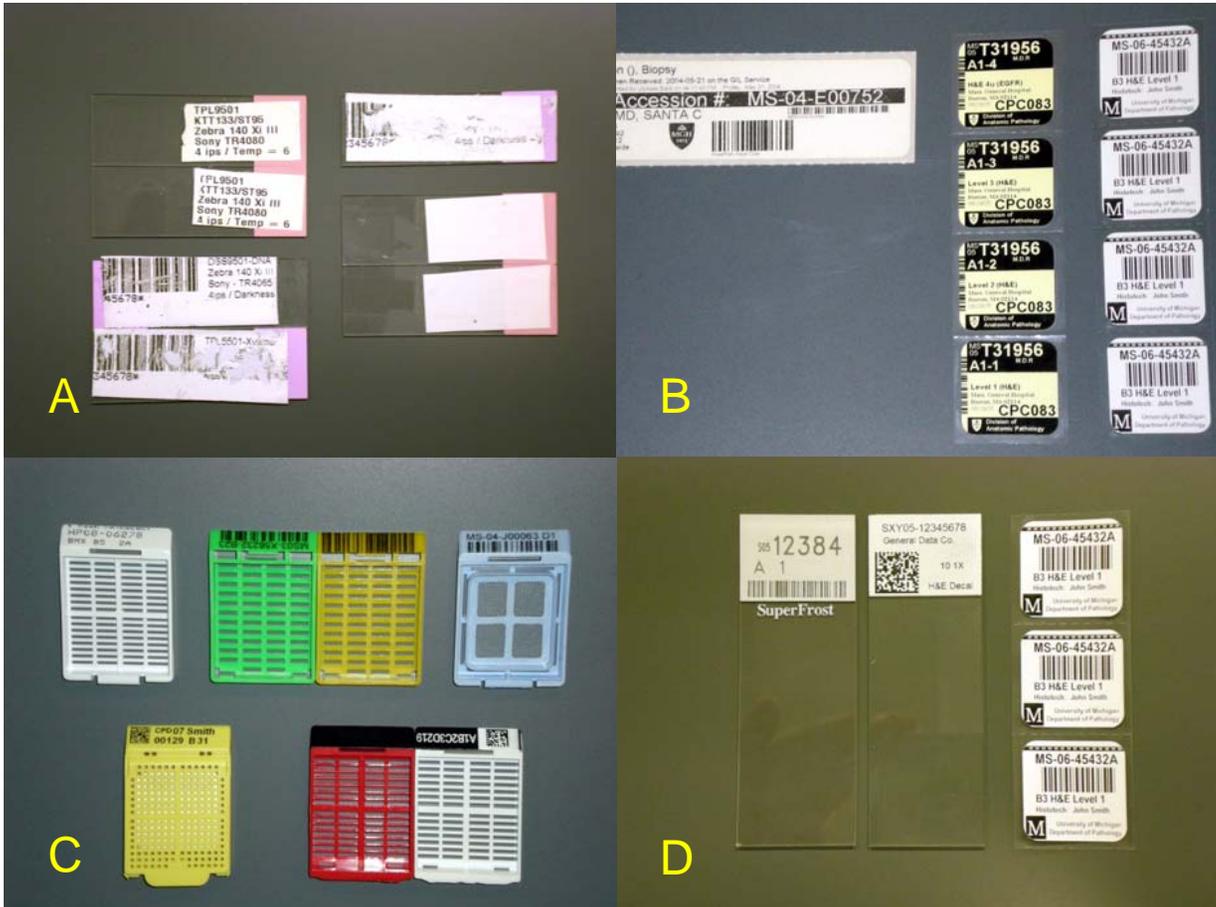
# Real-time tracking of workflow;



## Single Piece Workflow as an Overall Process Map:

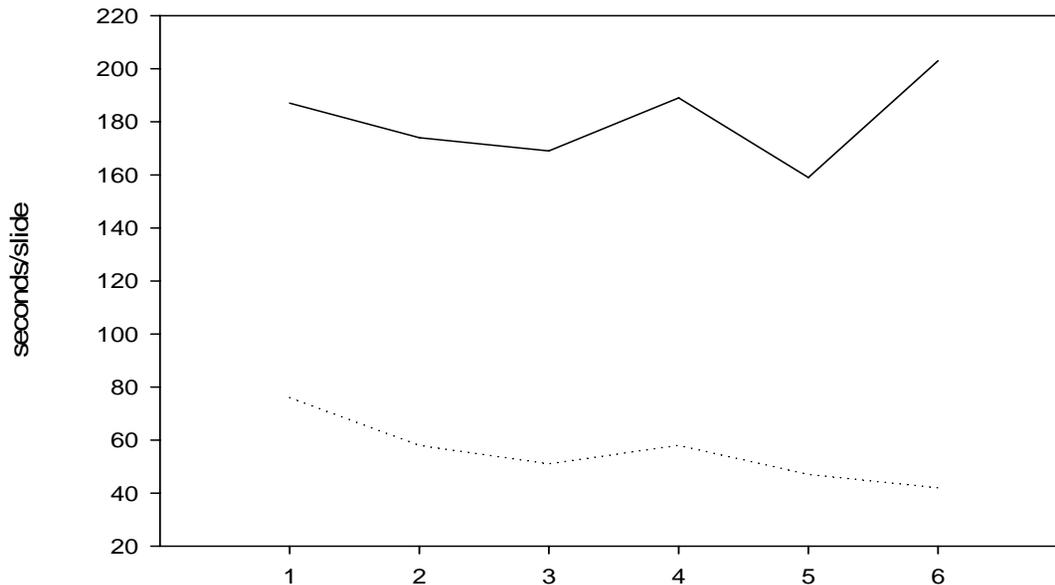
When applying single-piece workflow solutions to the entire value stream process, it becomes possible to concurrently drive all sources of error to near zero incidence. An essential key of this transformation is eliminating all manual or clerical steps, and rather, replacing them with barcode/information technology-driven solutions.

# Comprehensive asset tracking



## Evolution of Enabling Technologies:

Many of the present-state batch-based practices in use are in place as a logical result of historical limitations with respect to labeling and asset tracking technology. In early test-deployments of multilayer direct thermal label stock (A) seven major classes of so-called high performance formulations failed following a thirty minute xylene immersion. Newer formulations, such as General Data Stainer Shield labels (B), are able to withstand both xylene immersion as well as exposure to the far majority of routine histochemical staining protocols, thus providing for the first time the opportunity to leverage just-in-time single piece workflow in the histology suite. Similarly in the case of cassette printing technology (C), first and second generation based printing systems, which were dependent on thermal carbon or ink jet transfer (upper row), lacked both spatial resolution and consistency to provide for a consistently machine-readable barcodes, whereas newer platforms, based on laser-ablative reduction of a black polymeric coating, provide precise and highly consistent barcodes of very high resolution (lower row). Two dimensional barcodes, which have *intrinsic error correction*, are made possible by this higher rendered resolution. While it is possible to leverage laser-based printing approaches for direct slide annotation (D), the expense associated with the current generation of these printers makes them unapproachable for just-in-time generation of annotated slides at individual workstations. For this reason, the label-based approach, which allows for printing of slides at every cutting station (see figure to right), is a superior solution for maintaining single-piece workflow.



### **Effect of Single Piece Workflow with use of Middleware Barcode Tracking upon Productivity:**

A six month average estimate of time to section each slide is depicted by the solid line. Significant variability is noted. Following the deployment of just-in-time slide label printing (dotted line) there is both a significant reduction in overall processing time per slide ( $p < 0.00001$ ) and concurrently, a decreasing trend line (near statistical significance). More importantly, conversion to a barcode-based approach for this workflow step essentially removed all inter-slide label transposition errors.

# Rare Event Detection & Enhancement of Patient Safety

- Real-time tracking of every aspect of asset inventory and workflow progression
- Use of rules engines to identify when a low incidence event is not detected as humans are just pathetic (at best) at executing exception workflow practices based upon low incidence events. Moreover, the threat of punishment (or even bodily harm) does not work, in terms of alleviating subsequent errors.
- Again, Dr. Jeff Myers will extensively lecture our experience with this at Michigan.

# Decision Support at Signout (text tools)

- Cancer Checklists
- Protocols which require consistency
- Integrated consensus validation
  - e.g. Ishak Chronic Hepatitis tool

# Image Management

- Gross-Microscopic Correlation
- Longitudinal evaluation of chronic disease
- Similar Case retrieval, based upon Image morphology itself – Content-based Image retrieval (not text / metadata- based)

# Data Mining Tools and Clinical Repository Integration

The screenshot shows a web-based medical interface with the following sections:

- Patient Demographics:** Patient: Ms. XX, Reg #: 0112358, Date of Birth: 06/12/52, Age: 56, Gender: F.
- Active Problems:**
  - Type 2 Diabetes (ICD-9 Code):** 1972, Specialist: Dr. Wyckoff, Date of Diagnosis: 1972.
  - Retinopathy (ICD-9 Code):** 2003, Specialist: [blank], Date of Diagnosis: 2003, Last Visit: 12/18/07.
- History of Present Illness:**
  - Glucose Records:**

Date	B	2H	L	2H	D	2H	HS
1/1/08	127	275	200	205	255	200	165
1/2/08	127	275	200	195	255	200	165
1/3/08	127	275	200	200	255	200	165
  - History of DKA:**  History of Dangerous Hypoglycemia
  - Details:** Diagnosed at age 26 during her first pregnancy. She states that she rarely misses a dose of medication. Her primary care doctor has referred her to the endocrinologist for initiation of
- Physical Exam:**
  - Eyes:**  Fundi
  - Mouth:**  Carotids,  Lymph Nodes
  - Chest:**  Breath Sounds,  Rate,  Rhythm,  Heart Sounds,  Carotids,  Bowel Sounds
  - Neuro:**  Monofilament,  Vibration,  Alertness,  Orientation,  Affect,  DP Pulses,  PT Pulses
- Medications:**
  - Allergies:**  No Drug Allergies
  - Type 2 Diabetes:**
    - Glimeperide 4mg Once a day
    - Metformin 1000mg Twice a day

# Middleware-Based Research Tools

The screenshot shows a Mozilla Firefox browser window titled "Research Interface - Mozilla Firefox". The address bar contains "http://141.214.4.32/ctsa/#". The page header features the text "EMR (re)Search Engine" in yellow on a green background, and "Jeffrey Sica | Log Out" and "58740 Subjects On File" in white on the right. The main content area is a light green background with a central rounded rectangle titled "Inclusion/Exclusion Criteria". This rectangle has three tabs: "Inclusion", "Exclusion", and "Sites", with "Exclusion" selected. Below the tabs, there is a text input field and an "Add" button. A table below lists criteria with columns for "Definition", "Operator", and "Critical Value".

Definition	Operator	Critical Value	
Cystic Fibrosis	m		<a href="#">Remove</a>
Triglycerides	>	350	<a href="#">Remove</a>
anti-GAD	Positive		<a href="#">Remove</a>

Research Interface - Mozilla Firefox

File Edit View History Bookmarks Tools Help

http://141.214.4.32/ctsa/#

Google

Disable Cookies CSS Forms Images Information Miscellaneous Outline Resize Tools View Source Options

# EMR (re)Search Engine

Jeffrey Sica | Log Out  
58740 Subjects On File

## Inclusion/Exclusion Criteria

Inclusion Exclusion Sites

Select searchable sites:

- University of Michigan
- University of Pittsburgh
- University of Southern California
- University of Chicago
- Boston Children's Hospital
- Vanderbilt University
- Mayo Clinic
- ARUP
- Cleveland Clinic

http://141.214.4.32/ctsa/#site\_data

YSlow 18.51s

Research Interface - Mozilla Firefox

File Edit View History Bookmarks Tools Help

http://141.214.4.32/ctsa/#

Getting Started Latest Headlines

Disable Cookies CSS Forms Images Information Miscellaneous Outline Resize Tools View Source Options

# EMR (re)Search Engine

Jeffrey Sica | Log Out  
58740 Subjects On File

## Results Summary & File Format

### Summary

Results Summary

- 5000 patients have met your inclusion criteria ([Select this subset](#))
- 2000 patients have been excluded based on your exclusion criteria ([Select this subset](#))
- Of the 3000 remaining subjects:
  - Age is available for 2999 subjects ([Select this subset](#))
  - Medication data is available for 2563 subjects ([Select this subset](#))
  - C Peptide levels are available for 234 subjects ([Select this subset](#))
- A complete set of data elements is present for 234 subjects

To download your results:

Select a File Format

Finish

Done

# Other AP Middleware Venues...

- Sophisticated Management Reporting
- Education Support
- Consultation Tools for Intramural and Extramural Practice Needs
- Regulatory Compliance
- Lean / Six Sigma / Five S Support

# Project APMER

*Anatomic Pathology Middleware Electronic Repository*

- Goal: Create a repository of publicly-available tools for general use, under the terms of the GNU Public License
- Create a public forum by which the state of the art in AP Middleware can be extended
- Look to the Lab Infotech Summit Website in the coming days for the resource link