Information Technology as a Key Enabler for Enhanced Automation in the Core Laboratory

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“The future will be better tomorrow.”

-Dan Quayle

- System level thinking is no longer optional
- The time to prepare is now (“it wasn’t raining when Noah built the ark”)
- We have a lot to learn from industrial process engineering
- Creating high quality, low cost laboratory testing processes
  - Role of automation
  - Role of information technology

Core Laboratories

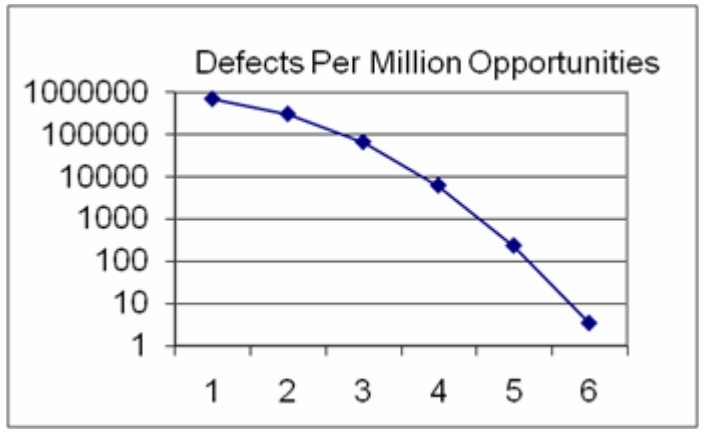
- Core laboratories typically combine all laboratory medicine specialties with the exception of blood banking
  - Combine Chemistry, Hematology, Coagulation, Immunology, Molecular Diagnostics, may or not include microbiology
- Core laboratories will become essential as laboratory medicine increases in complexity
- Core laboratories provide the critical mass for specialization within the laboratory:
  - Business analyst: billing, contracting, RFP management, project organization
  - Customer service specialist: call center, critical value reporting, compliance
  - IT specialist: LIS, reports, dashboards, POE, automation

Automation

- Automation is often a strong driver for core laboratory formation
- Laboratory medicine is complex and does not lend itself to “assembly line” type automation
- Information flows and data analytics are essential to success
- Medicine is decades behind modern manufacturing practices but we have the tools to make rapid progress

Six Sigma

- Emphasis in six sigma is hitting the target (specification)
- Primary goal is to reduce variation



Sigma level	% within spec	# defects per million
1	30.23%	697,672
2	69.15%	308,537
3	93.32%	66,807
4	99.38%	6,210
5	99.977%	233
6	99.9997%	3.4

Six Sigma and Healthcare

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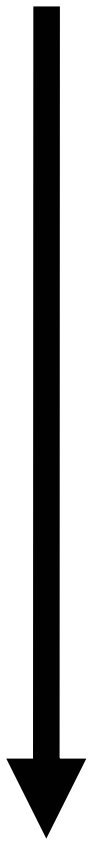
- Most healthcare processes operate at 2 sigma
- Anesthesia 5.2 sigma
- Getting to 4 sigma requires protocols and checklists
- Getting to 5 sigma requires **automation**

A Brief History of Industrial Automation

- Craft style production
- Mass production
- Total quality production, mass customization



Craft Style Production

- A single craftsperson creates a product from start to finish
- In industries employing craft style production there is generally an apprenticeship due to the complexity of the work
- Medicine is still referred to as the “craft of medicine”
- In industry craft style production all but died out in the early 1900s

Paul Revere

Scientific Management ("Taylorism")

Frederick Taylor 1856-1915

Ford Assembly Line, 1916

- American mechanical engineer considered to be the father of scientific management
- Taylor saw production as a series of linked processes
- Defined mass production methods (assembly lines) in the early 1900s
- Prior to Taylor most of the world's production was craft style production
- Within 2 decades craft style production was obsolete

“Taylorism”

"It is only through the enforced standardization of methods, enforced adoption of the best implements and working conditions, and enforced cooperation that this faster work can be assured. And the duty of enforcing the adoption of standards and of enforcing this cooperation rests with management alone....

However…

The Limits of Taylorism

- The highly standardized assembly line approach fails in the face of complexity
- Industry evolved process management tools to handle complexity:
  - Front line worker participation
  - Statistical process control, PDCA (Shewhart, 1940s)
  - Quality improvement (Deming, 1950s)
  - Lean or TPS or “pull through” (1980s-1990s)
- Widely adopted in Japanese industry in the 1950s and 60s

“We will win and you will lose.”

-- Konosuke Matsushita, founder of Matsushita Electric Industrial Co (1988)

"**We will win and you will lose.** You cannot do anything about it because your failure is an internal disease. Your companies are based on Taylor's principles.

We have measured - better than you - the new technological and economic challenges. We have passed the Taylor stage. We are aware that business has become terribly complex. **Therefore, a company must have the commitment of the minds of all of its employees to survive.”**

“I'm not going to have monkeys running the zoo”

Frank Borman, president of Eastern Airlines, discussing worker participation

- Although most of the major quality improvement tools were developed in the U.S. in the 1940s and 1950s they were slow to be adopted in the U.S. due to post war complacency, lack of competition
- Japanese fully embraced worker participation and quality improvement tools
  - Statistical process control, PDCA cycles (Shewhart, 1940s)
  - Quality improvement (Deming, 1950s)
  - Lean or TPS or “pull through” (1990s)

Quality Controls Cost

- Japanese industries in 1960s understood that assembly lines are only one part of the solution
- QI tools and front line worker participation were other key ingredients to success
- The major conclusion was that **higher quality products are cheaper to produce** (build it right the first time; less rework and scrap)

Why Hasn't U.S. Healthcare Adopted Quality Improvement Tools?

- High cost, variable quality
- Most developed nations outperform the U.S. on measures of total health
- Total process quality using quality improvement tools has been **required for survival** in competitive industries for decades
- The major reason for lack of use of QI tools in Medicine is **incentives**

Misaligned Incentives

("Quality improvement can be a path to financial ruin")

- Currently incentives in healthcare are poorly aligned with quality outcomes
- For outpatient testing in particular the incentives encourage overutilization
- Healthcare financing is undoubtedly going to undergo reform that will change this

Healthcare Reform

- Incentives for “quality” (Pay for performance II)
- Two tiered system (Oregon model)
  - Full payment for certain procedures; less for others
- Bundled payments for patient cohorts
  - A set payment to **provide an individual’s inpatient and outpatient care**
  - Removes incentive for the overutilization of outpatient care and provides incentive for preventative care
- Market driven reform

Why Focus on Quality Improvement?

- Financial incentives will begin to favor organizations that provide high quality (low cost) care across the continuum of care
- Focus on quality improvement massively improves our professional roles
- Traditional management approaches for laboratories have emphasized expense management
- Quality controls cost. Focus on quality improves our expenses (without gutting our labs)
- How to get there…

What's the Role of a Leader in an Organization?

- Hiring the right people?
- Employee motivation?
- Setting management targets or goals?
- Managing front line operations?
- Managing the operating budget?

Leadership Role

- The primary role of leaders is to **have a vision and build infrastructure**
- Infrastructure choices should be in support of your front line value added work processes

What Should We Be Measuring?

- "Organize everything around **front line value added work processes**" (Deming)
  - "The monkeys should be running the zoo"
- Identify your key value adding processes
- Build your data system based on the front line
- Top down data will not give you the data you need to manage your organization
  - Don't manage for CAP/JC/CMS/finance office
  - Expense variance reports say very little about how you are doing and do not provide areas to focus on
  - Most expense variation is non-assignable (random) and managing it is counterproductive (tampering)

Laboratory Key Value Adding Processes

- Order entry/decision support
- Patient identification
- Specimen collection
- Customer service metrics (communication of refusals, etc.)
- Result reporting
- Critical value reporting

Design your infrastructure and data systems with your front line value adding processes in mind

Infrastructure

- Build systems buy applications
- Interoperability is a key decision point when deciding upon the purchase of an application to add to your system
- True interoperability is still mostly a fantasy
  - Most of our standards are syntactic standards not semantic standards (the terms in each field are loosely defined)
  - Managing interfaces and interoperability consume a large percentage of the operations of an organization

Data Automation (Applications)

- Data is very expensive
- Principle: Automation/applications must improve productivity
- Thou shalt not destroy clinical productivity.
- Central issues
  - Issue 1: Paper vs. electronic storage
  - Issue 2: Freetext vs. encoded data
- Any complex yet still useable system combines freetext and encoded data

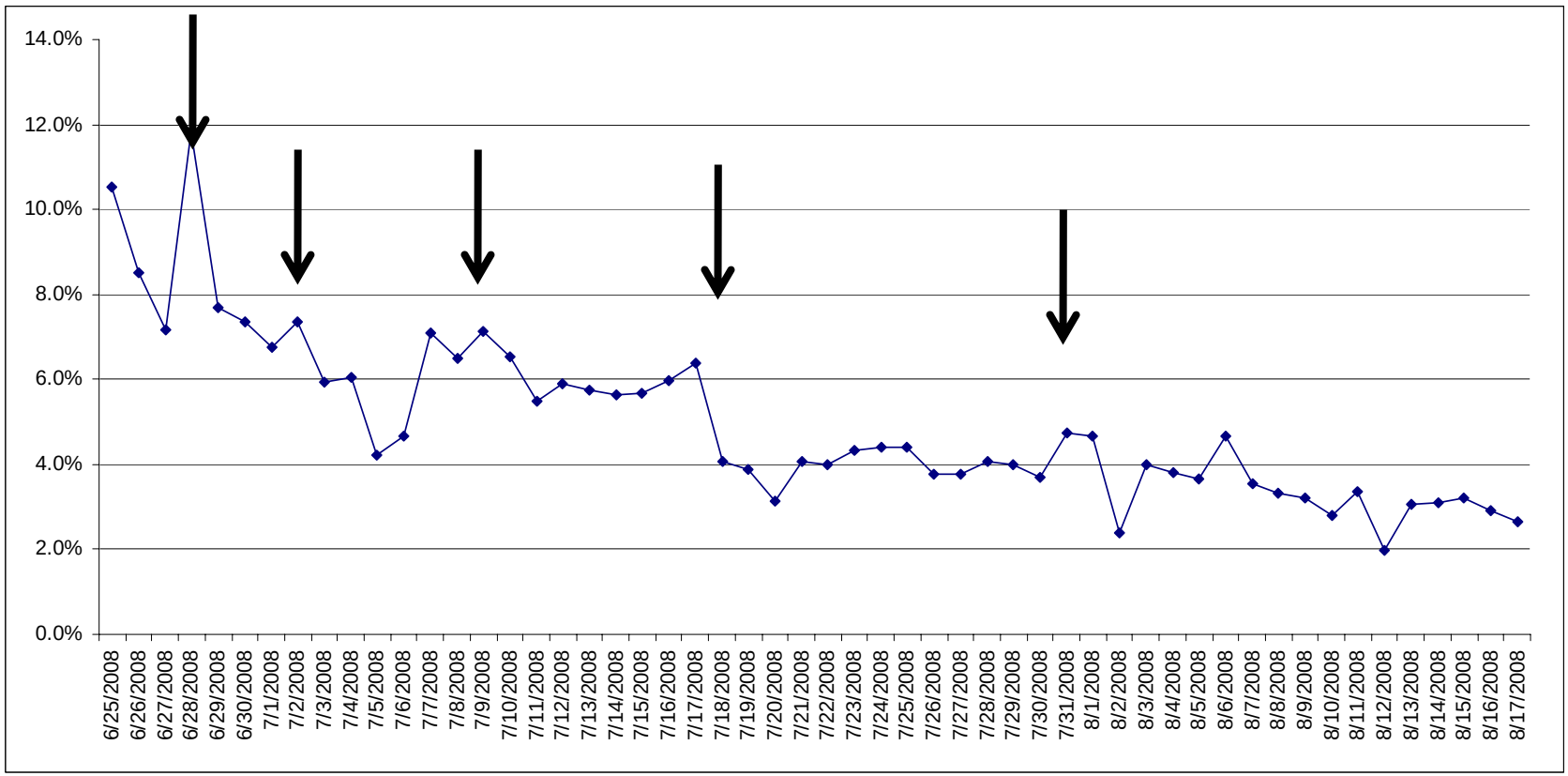
Encoded Data vs. Freetext

- Freetext is a necessary evil. No clinical vocabulary can be all inclusive and still be useful
- SNOMED has 1 million codes
- Apply the Pareto principle:
  - Design your system for the common, use other methods (such as freetext) for the uncommon

Seek Simple but Useful Monitors

Percentage of Free Text Orders in New Lab Order Entry System

- Correlates with providers using system appropriately
- Permits near real time intervention with non-compliant physicians and system changes
- Has dropped free text orders to < 1% (4 sigma)



System Level Thinking

Identifying Processes of Care in a Hospital

- "Information generating processes of care"
  - All Pathology services except blood bank (core laboratory, microbiology, anatomic pathology)
  - Radiology
  - Diagnostic cardiology
- "Consumptive processes of care"
  - Pharmacy, blood bank, dietary
- "Procedure/protocol driven processes of care"
  - Surgery
  - Inpatient care

Information Generating Processes of Care (Labs/Radiology/Cardiology)

- Currently all 3 are major sources of revenue in many healthcare systems due to the present reimbursement system
- **In future all 3 will likely be pure cost centers**
- Each of these areas has similar needs and it makes sense to consider them together when designing information flows (and next generation EMRs)

Information Generating Processes of Care (Labs/Radiology/Cardiology)

- Each of these areas has similar needs:
  - Order entry and decision support
  - Patient identification
  - Results generation
  - Results management:
    - Communication of critical results
    - Acknowledgement of results
    - Communication to patients
    - Follow-up plan for testing
  - Interpretive support for results

Error prone

Medicolegal Implications

- Communication is the number one root cause of medical error
- **Diagnosis related error is consistently in the top 3 categories of malpractice**
- 30% of cases are specifically related to the receipt and transmission of test results
- Most errors occur in the ambulatory setting
- Errors rooted in the lack of robust systems to support clinicians in managing whether the ordered test was completed, reviewed, communicated to the patient, and a follow-up plan executed.

Diagnosis Related Errors

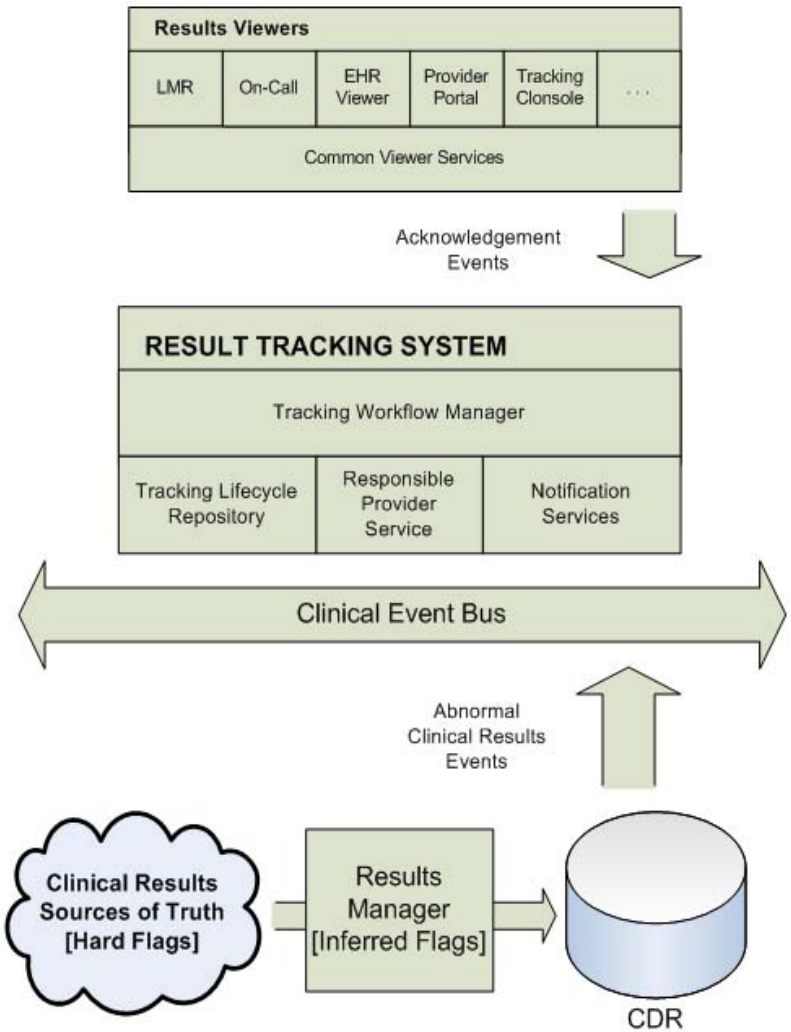
- “Incidental” ovarian mass seen on CT scan that showed acute cholecystitis
  - 12 months later patient diagnosed with ovarian cancer
- Elevated PSA that was never reviewed
  - Patient developed widespread disease 2 years later
- A 64-year-old man died from lung cancer two years after X-rays in the ED revealed an incidental finding of a lung nodule that was never followed up

Better safety reporting systems will improve this?

Patient Safety

- Voluntary error reporting systems are completely inadequate
  - Capture less than 1% of actual errors
  - May even be counterproductive
    - Sentinel events get huge priority that may not be justified
- Diagnostic testing errors should be proactively screened for using all available data
  - Order entry data, freetext percentage, mislabeled specimens, amended reports, cancelled tests, refused tests, wrong tube type, unreceived orders, testing delays
- Core laboratories have sufficient scope to pursue data analytics and create the infrastructure necessary to improve safety

Results Have a Lifecycle and Need to Be Actively Tracked and Managed



(1) Test ordered

(2) Analysis performed

(3) Result reported

(4) Result acknowledged by provider

(5) Result interpreted correctly by provider

(6) Result communicated to patient

(7) Clinical action taken

(8) Follow-up testing pursued

Results tracking systems should be developed to improve steps 4-8

Involving the Patient (“Nothing without me”)

- Patients should have online access to their test results (labs/radiology/cardiology) in addition to their meds/allergies/problem lists
- “No news is not good news”
- Patients provide a backstop for medical errors
- Basic interpretive information should be provided with test results
- National plans for PHRs will not be successful without interoperability/standards for data exchange

How to Survive/Thrive as a Cost Center

Attack quality and efficiency waste

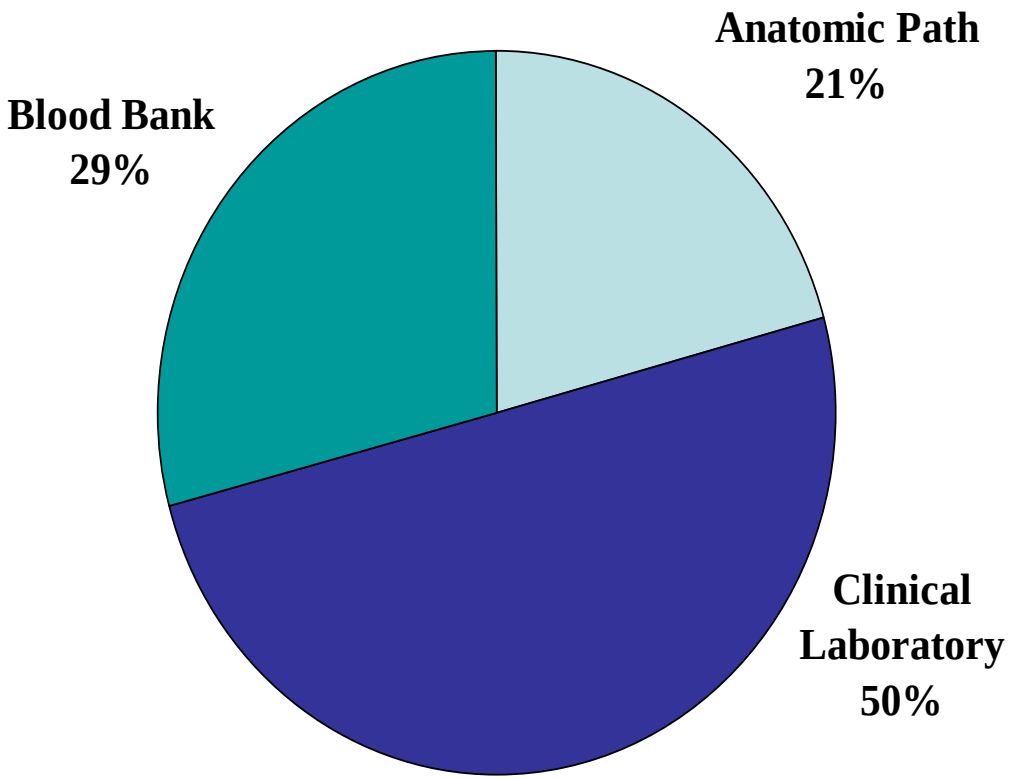
- Pay attention to front line operations and develop metrics based on front line value added work processes
- Automate and make process changes based on data:

  → Less scrap and rework will lower your costs and raise your quality

The harder sell (cost/benefit)

- Controlling laboratory test utilization

Cost Control: Typical Budget for a Large Pathology Department ($60 Million)



Focus effort on areas with:

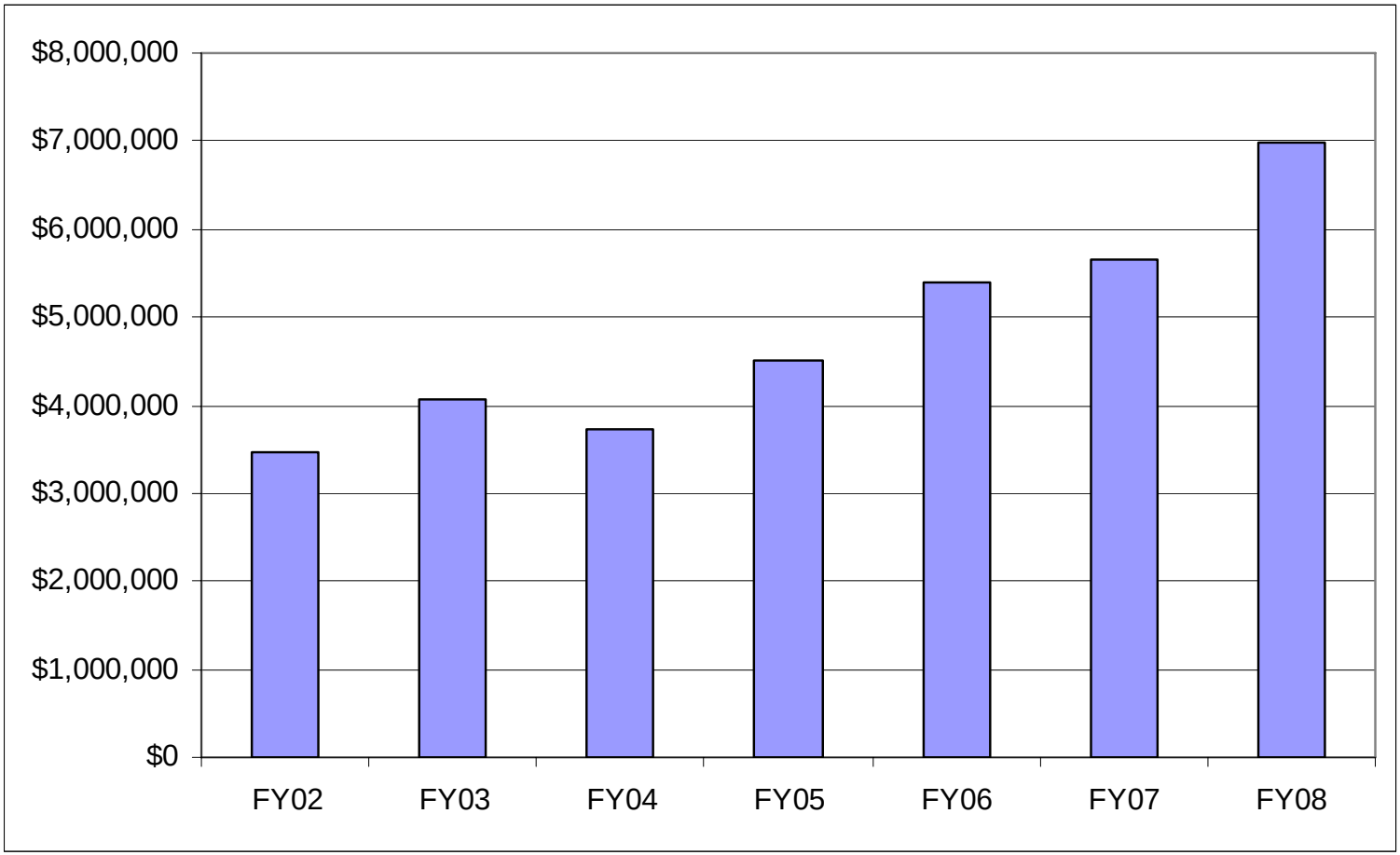
1) Large contributions to bottom line
2) High variability in clinical practice
3) Large amounts of non-fixed costs (e.g. high level of variable costs)

→ Clinical lab testing and blood banking

Utilization

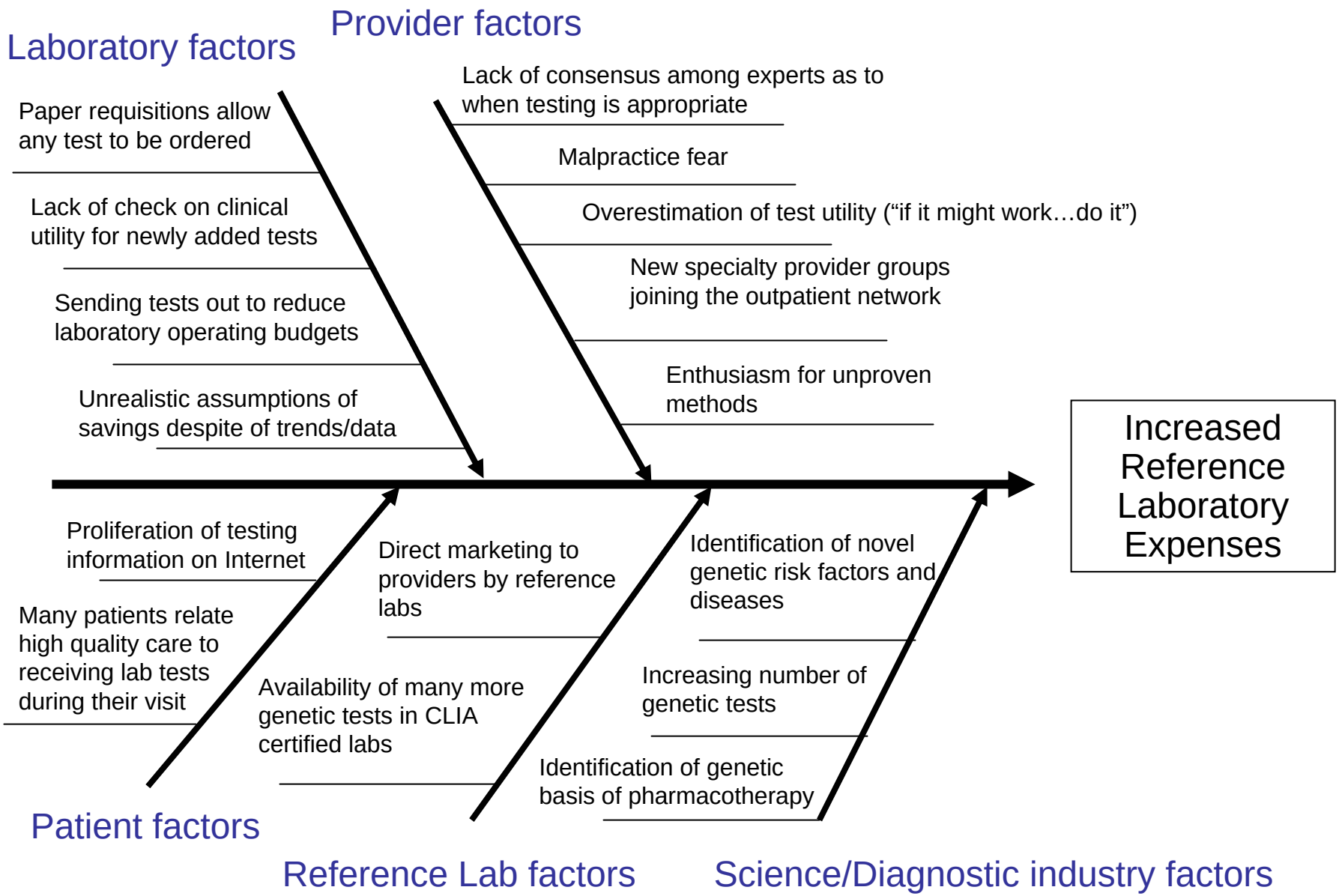
- Increasingly laboratory directors are being asked to address utilization issues
- Evidence based laboratory medicine?
  - Level 1 evidence does not exist for most of what we do and even expert consensus (level 3) is all over the map
  - “If it might work, do it”
  - “If you can’t show me level 1 evidence then I’m free to practice at level 4 (e.g. personal anecdotes…”in my experience”…)

MGH Reference Lab Expenses

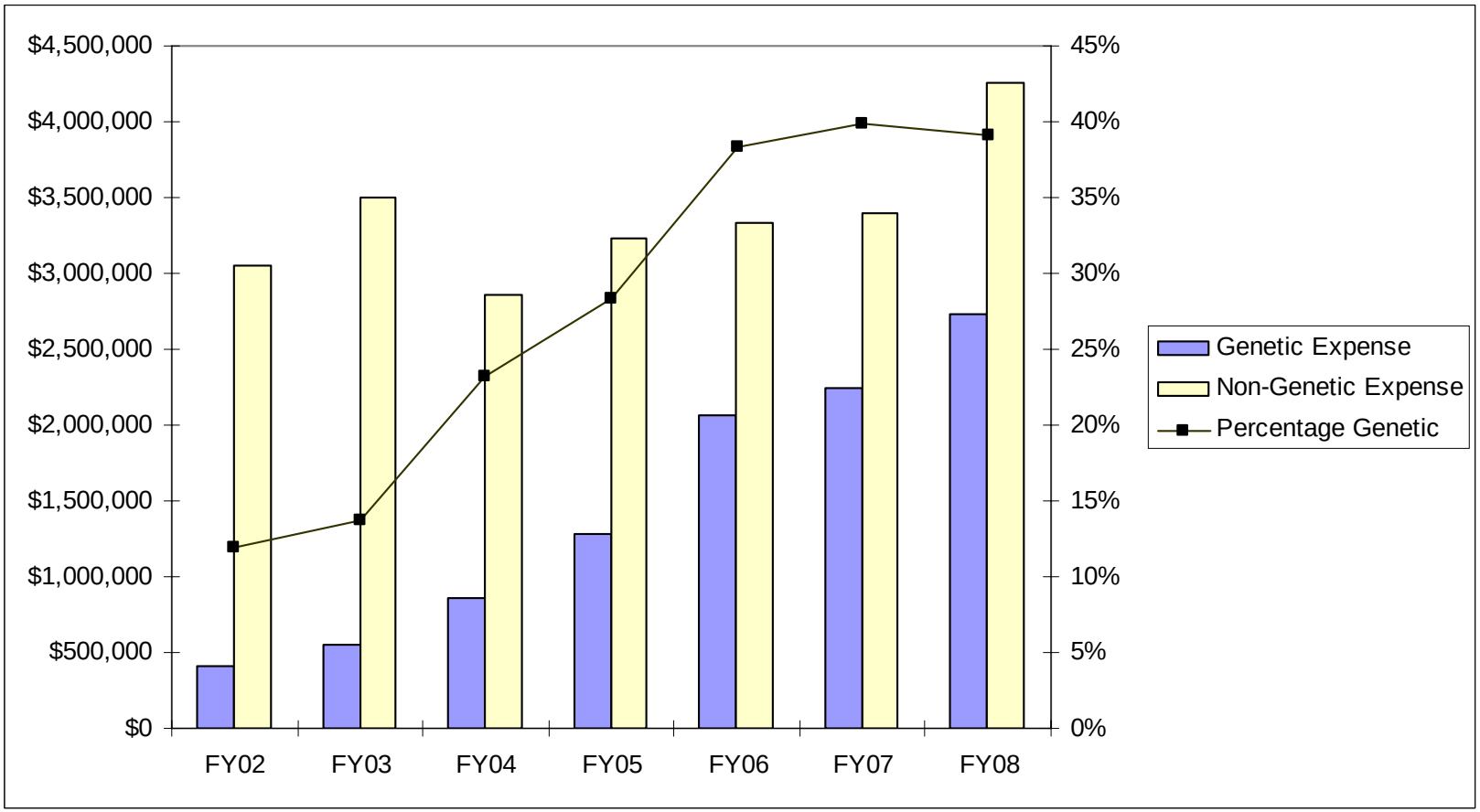


12-15% annual growth rate for overall reference lab testing expenses

Factors Leading to Increased Reference Lab Testing



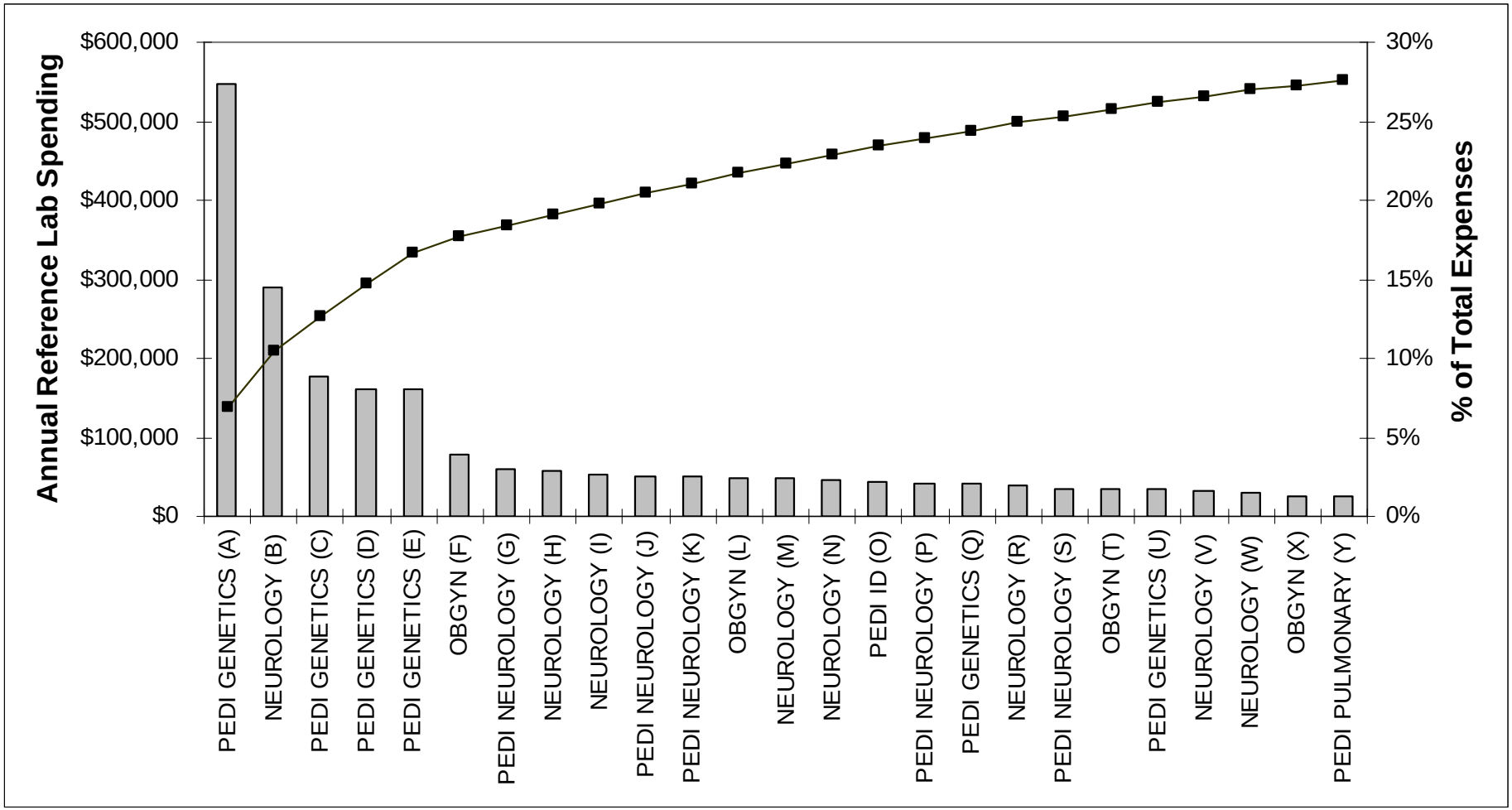
Contribution of Genetic Testing to Reference Lab Expenditures



Genetic testing expense has been rising an average of 26% per year since FY2002

Non-genetic testing expense has been rising an average of 6.5% per year since FY2002

Genetic Testing: Top 25 Providers



Genetic tests ordered by top 25 providers account for 27% of entire reference lab expense

Healthcare Variability

- Geography is the number one cause of variability in health care processes
- "Who you see is what you get"
- **Variability in a process is almost always a sure sign of waste**
- Process improvement in industry is all about reducing variability (hitting the target specification)
- How to reduce utilization variability…

Apply Psych 101 to Lab Test Utilization

Select interventions that…

→ Exploit human nature

- Make it easy to do the right thing
- Make it a nuisance to do the wrong thing

→ Reduce decision making

→ Provide real time, accurate test information in the context of clinician workflow (how?)

What Do We Need?

- Need a different type of middleware
  - Not in the middle between the LIS and analyzers
  - Sits in between the LIS and rest of the enterprise information systems
- Need to incorporate the Lean concepts of eliminating waste (store data once) and maximizing information flow to the various data consumers:
    - Enterprise decision support
    - Inpatient and ED order entry
    - Outpatient order entry
    - Online laboratory handbook
    - Pharmacy decision support

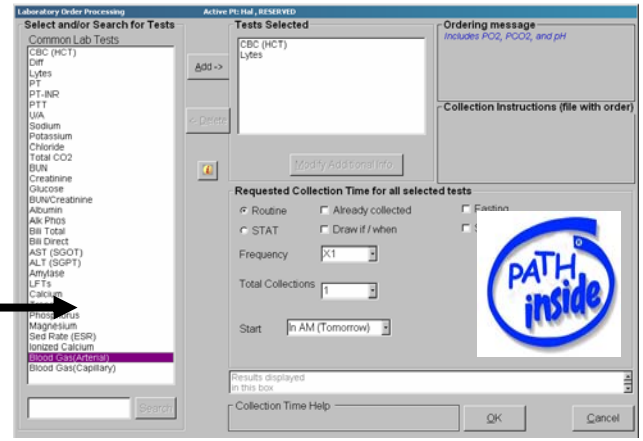
“Pathology Inside”

- “PathConnect” middle layer permits Pathology to maintain control over the content, presentation, and maintenance of laboratory tests
- Allows Pathology data to be aggregated, augmented, and shared with other applications via a service oriented architecture

Outpatient Order Entry
“End of Visit” Module

Enterprise Decision Support (Lab Order Catalog)

Inpatient Provider Order Entry



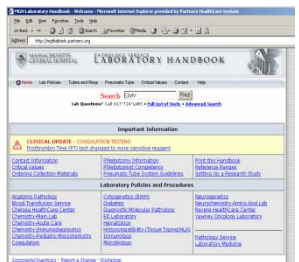
Clinical Information System
(KnowledgeLink)

PathConnect Middleware

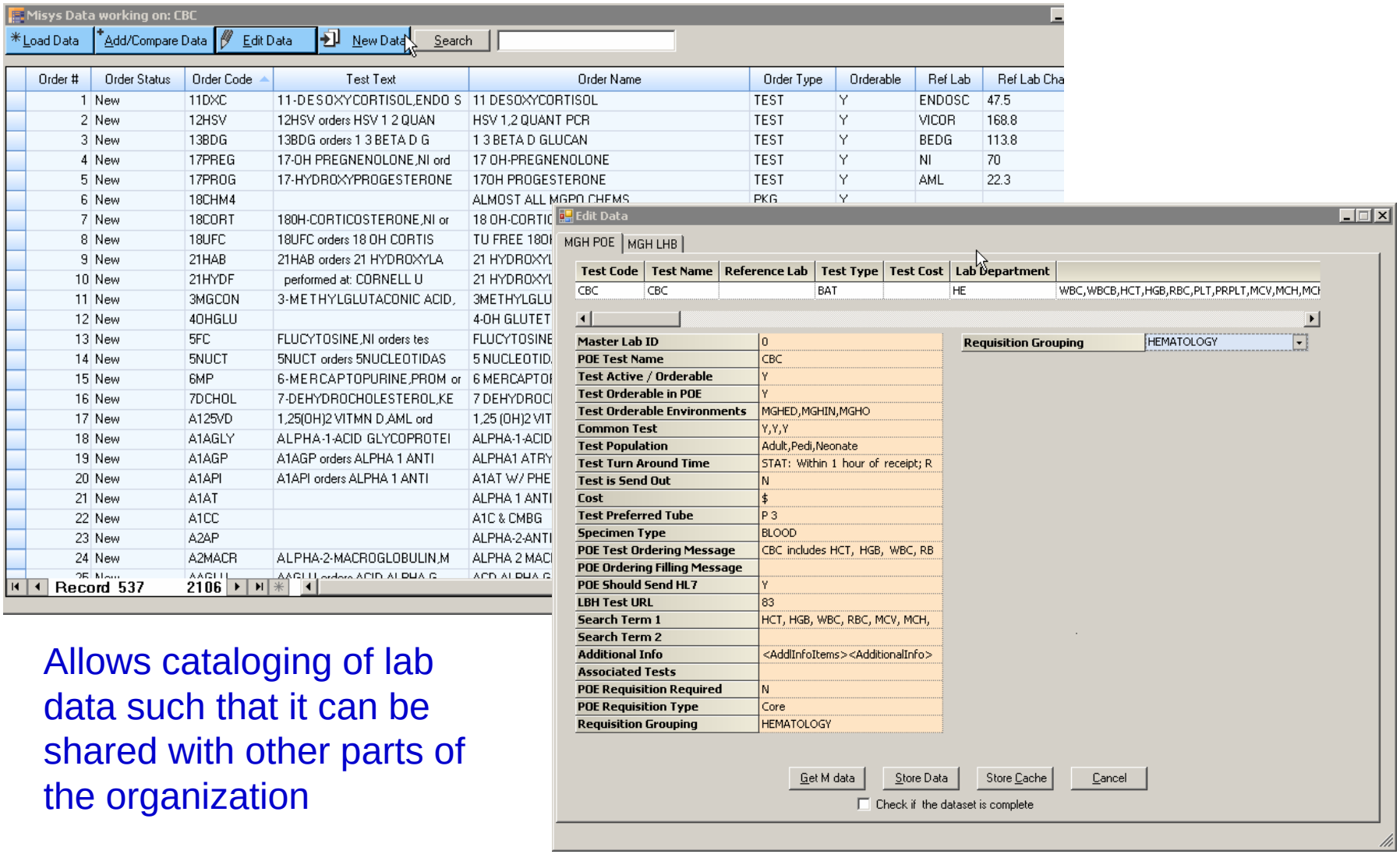
Sunquest CP LIS

PowerPath AP LIS

Laboratory Handbook



PathConnect Middleware



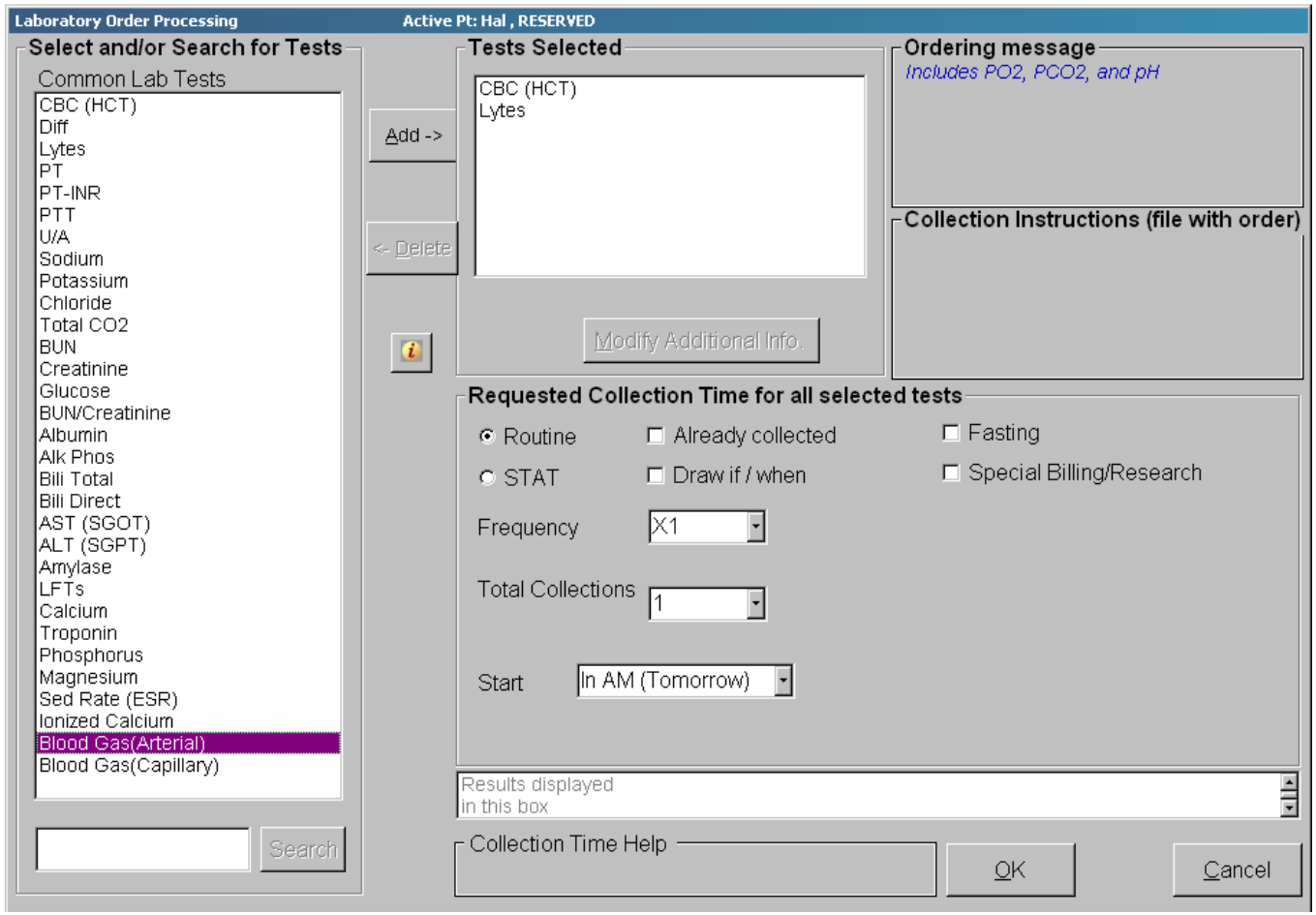
Allows cataloging of lab data such that it can be shared with other parts of the organization

Lab Ordering Screen

The order entry group leaves us “white space” that the lab fills in.

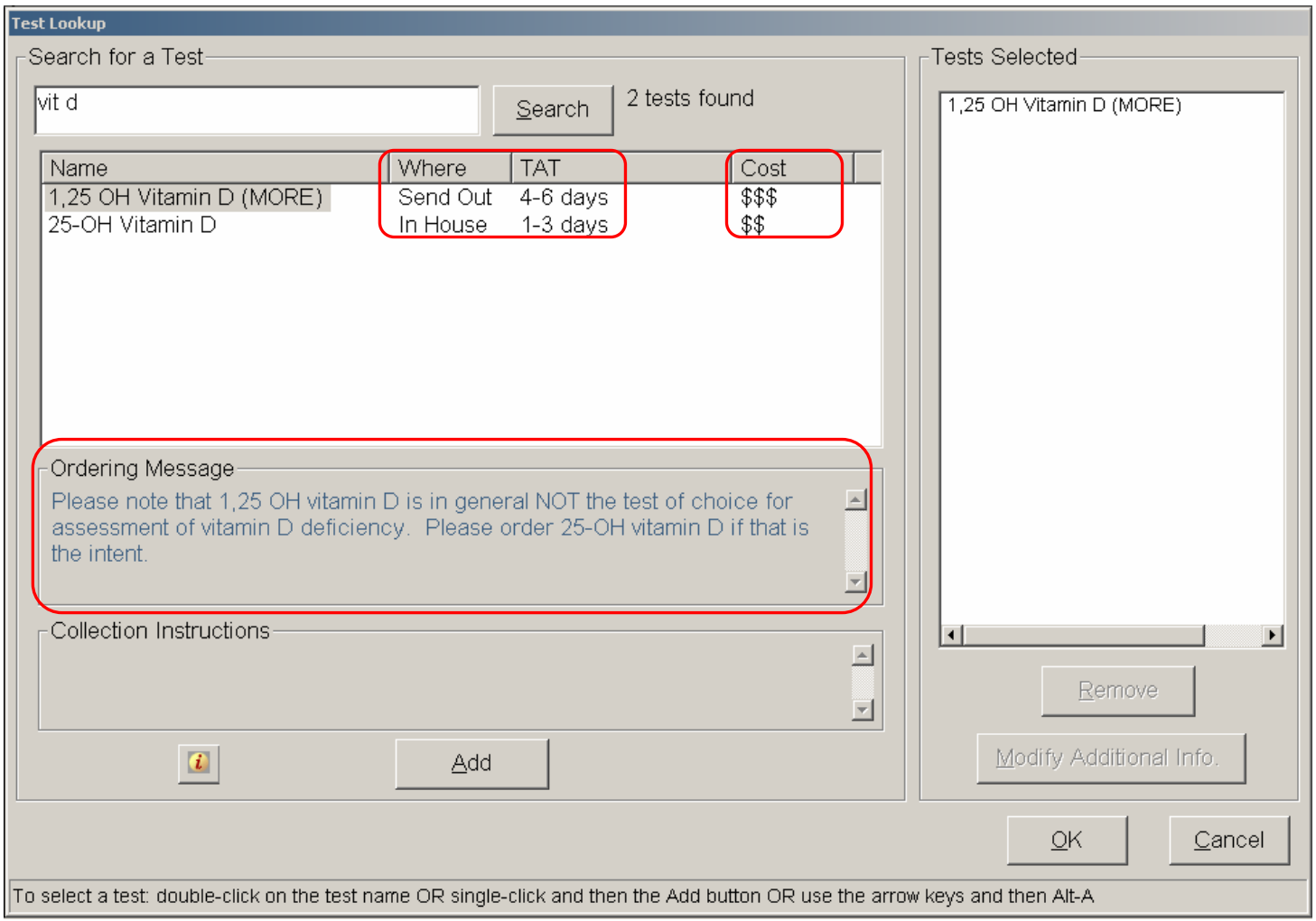
User Interface Built Entirely from MGH PathConnect Data

- Provider order entry calls middleware web service to build test dictionaries in a “just in time” manner
- Data behind the interface can be readily updated via the web service



MGH Inpatient Order Entry: the Importance of Search

With 1,000 tests on the menu a robust search engine must be a part of all test order entry applications.



All laboratory information in the order entry system is provided and maintained in real time by the Dept of Pathology

Provide information requested by users to guide appropriate utilization

Utilization Control

- Build/buy infrastructure and data systems to:
  - Catalog and share laboratory knowledge
  - Gather encoded data at the point of order entry to reduce errors/waste and simplify analysis
- Establish a “shared baseline” (e.g. practice standards) with your key providers and measure deviation from the baseline
  - Utilization report cards for inpatient teams and outpatient providers
  - Regular meetings with key provider groups

“The future will be better tomorrow.”

-Dan Quayle

- Focus on front line processes and information flow will be essential in the next chapter of healthcare
- Core laboratories permit the execution of integrated information management strategies which incorporate both machine and data automation
- It will be important to start considering the **Result Generating Areas** of healthcare together and focus on the entire lifecycle of a test result

Thanks

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