

# Clinical Laboratory Informatics: Building an Infrastructure for Improving Quality and Enhancing Value

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Anand S. Dighe, MD, PhD

October 5, 2011



# Outline

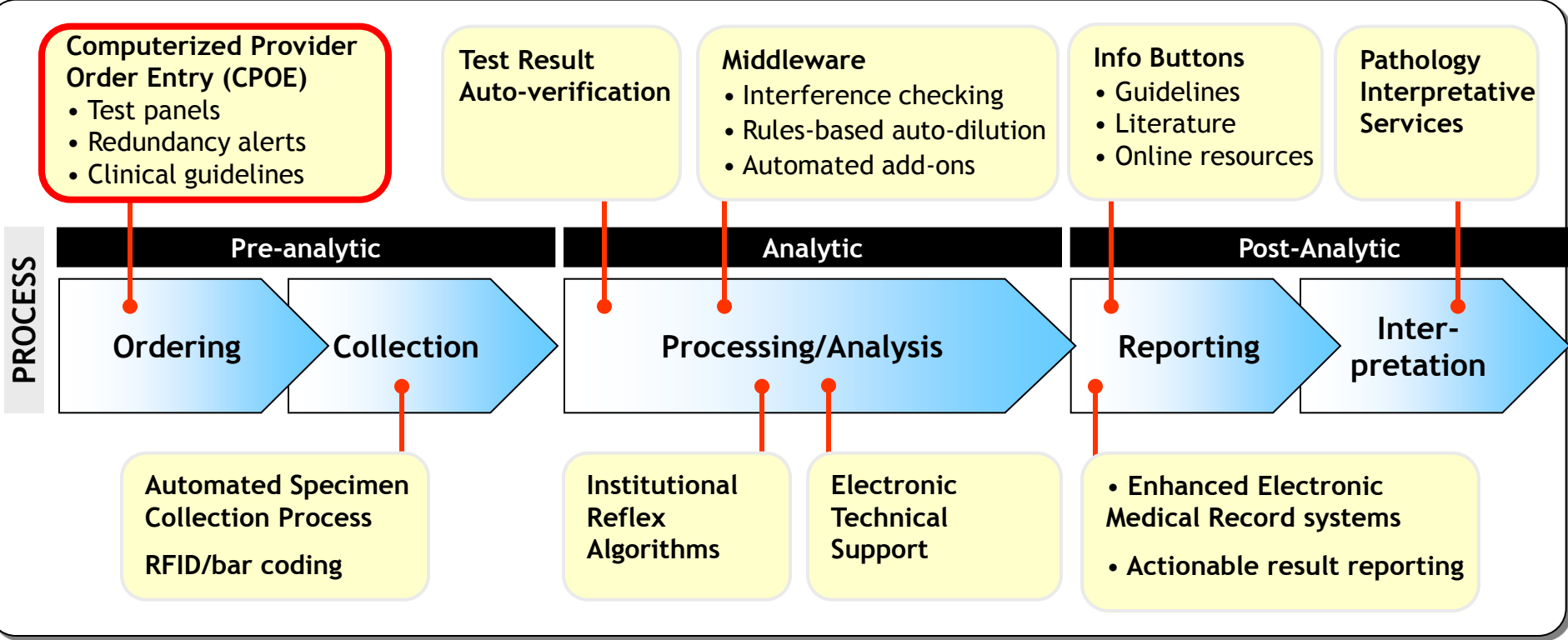
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Role of informatics in the redesign of key laboratory/healthcare processes:

1. Provider order entry and utilization management
2. Test result management

# Information Processing in the Laboratory Testing Process

CPOE is a key step for Pathology since orders set up the entire lab testing cascade



# Designing for Quality and Safety in Health Care

IOM Committee on Quality of Health Care in America

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## Respect Human Limits in Process Design

- Avoid reliance on memory
- Avoid reliance on vigilance
- Use constraints and forcing functions
- Simplify key processes
- Standardize work processes

# Order Entry vs. Order Communication

“Why are you doing this....We already have a lab order entry system. It works fine.”

4.4.4 Friday Feb 17, 2006 12:26 PM User: Anand S. Dighe, M.D.

Select pt: CLAUS, SANTA C MGH 0000004 29y M BC OUT OF STATE PCP: CONN, ALASDAIR

Laboratory Order Processing Active Pt: CLAUS, SANTA C

Orders

Results

List Mgmt

Options

Handbook

Phone Dir

Help

Feedback

Exit

Active App RESULTS

Common Lab Procedures

<input checked="" type="checkbox"/> A CBC (HCT)	<input type="checkbox"/> J Potassium	<input type="checkbox"/> R Alk Phos	<input type="checkbox"/> Z Troponin
<input type="checkbox"/> B Diff	<input type="checkbox"/> K Chloride	<input type="checkbox"/> S Bili Total	<input type="checkbox"/> 1 Aspartate Aminophosphatase
<input checked="" type="checkbox"/> C Lytes	<input type="checkbox"/> L Total CO2	<input type="checkbox"/> T Bili Direct	<input type="checkbox"/> 2 Magnesium
<input type="checkbox"/> E PT	<input type="checkbox"/> M BUN	<input type="checkbox"/> U AST (SGOT)	<input type="checkbox"/> 3 Sed Rate (ESR)
<input type="checkbox"/> F PT-INR	<input type="checkbox"/> N Creatinine	<input type="checkbox"/> V ALT (SGPT)	<input type="checkbox"/> 4 Ionized Calcium
<input type="checkbox"/> G PTT	<input type="checkbox"/> O Glucose	<input type="checkbox"/> W Amylase	<input type="checkbox"/> 5 Blood Gas(Arterial)
<input type="checkbox"/> H U/A	<input type="checkbox"/> P BUN/Creatinine	<input type="checkbox"/> X LFTs	<input type="checkbox"/> 6 Blood Gas(Capillary)
<input type="checkbox"/> I Sodium	<input type="checkbox"/> Q Albumin	<input type="checkbox"/> Y Calcium	

Other lab test names (separated by commas)

Ordering message  
CBC (HCT) includes: HCT, HGB, WBC, RBC, MCV, MCH, MCHC and PLT.

"Q Day" lab orders are NOT indicated in most cases. Please order Q Day ONLY when clinically necessary. Q Day ordering contributes to iatrogenic anemia, may compromise quality of patient care and increases lab turnaround time.

Collection time: In AM - (on Sat 2/13/2006)

Instructions:

HLA Testing Toxicology Cytology Microbiology OK Cancel

Enter additional instructions

4.4.4 Friday Feb 17, 2006 12:26 PM User: Anand S. Dighe, M.D.

Select pt: CLAUS, SANTA C MGH 0000004 29y M BC OUT OF STATE PCP: CONN, ALASDAIR

Laboratory Order Processing Active Pt: Hal, RESERVED

Select and/or Search for Tests

Common Lab Tests

Tests Selected

Ordering message  
Includes PO2, PCO2, and pH

Collection Instructions (file with order)

Requested Collection Time for all selected tests

Routine  Already collected  Fasting

STAT  Draw if / when  Special Billing/Research

Frequency: X1

Total Collections: 1

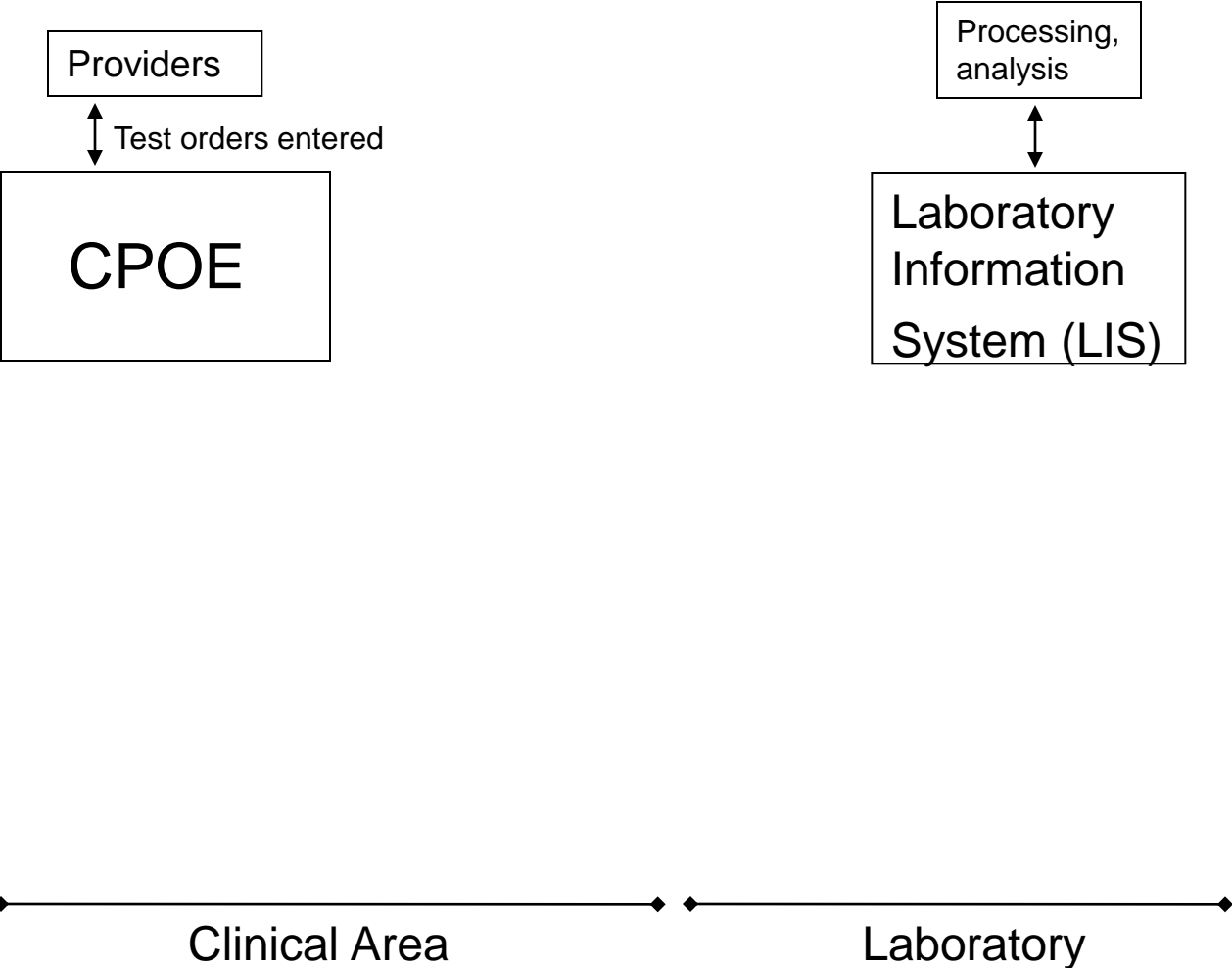
Start: In AM (Tomorrow)

Results displayed in this box

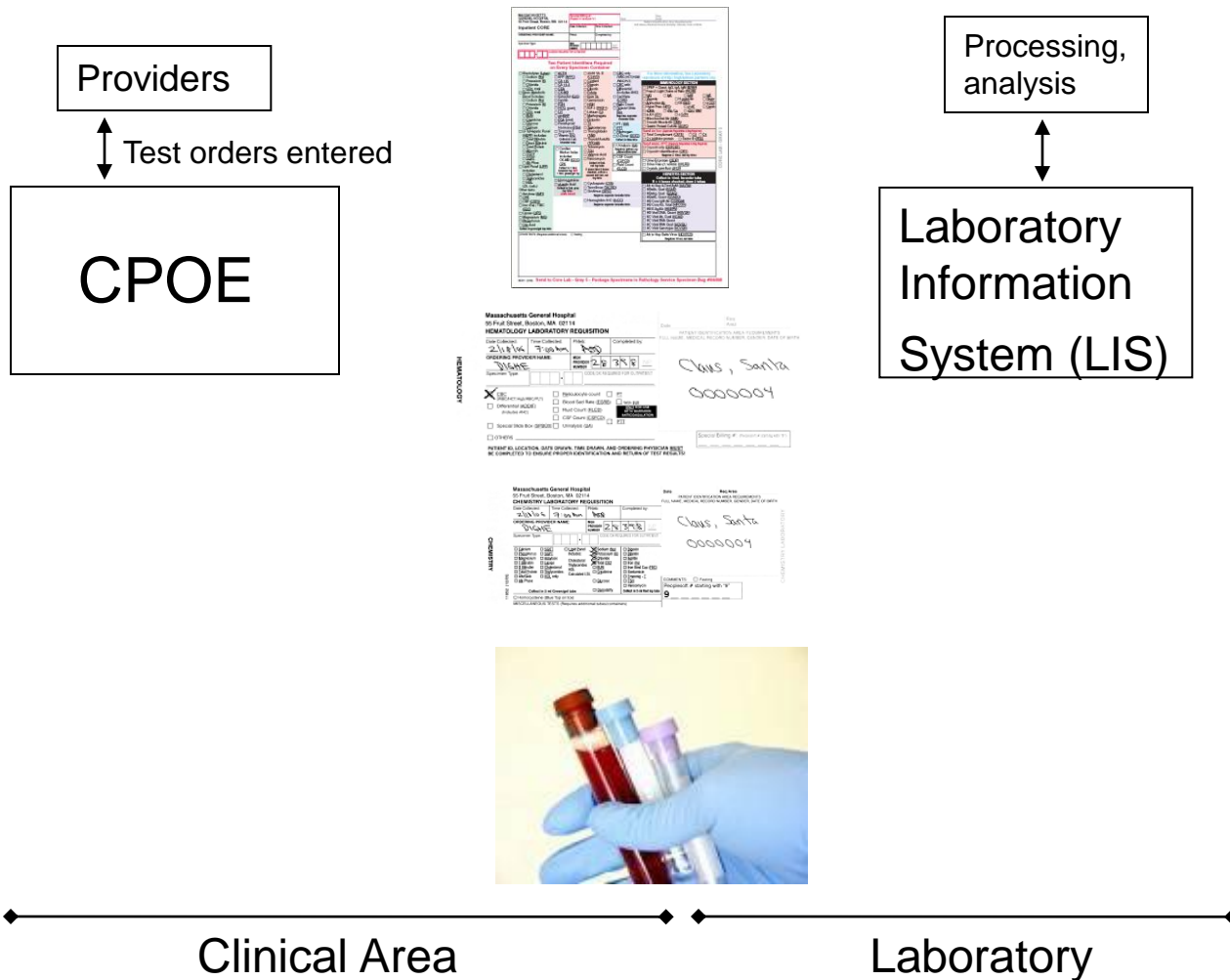
Collection Time Help OK Cancel

# Computerized Provider Order Entry (CPOE)

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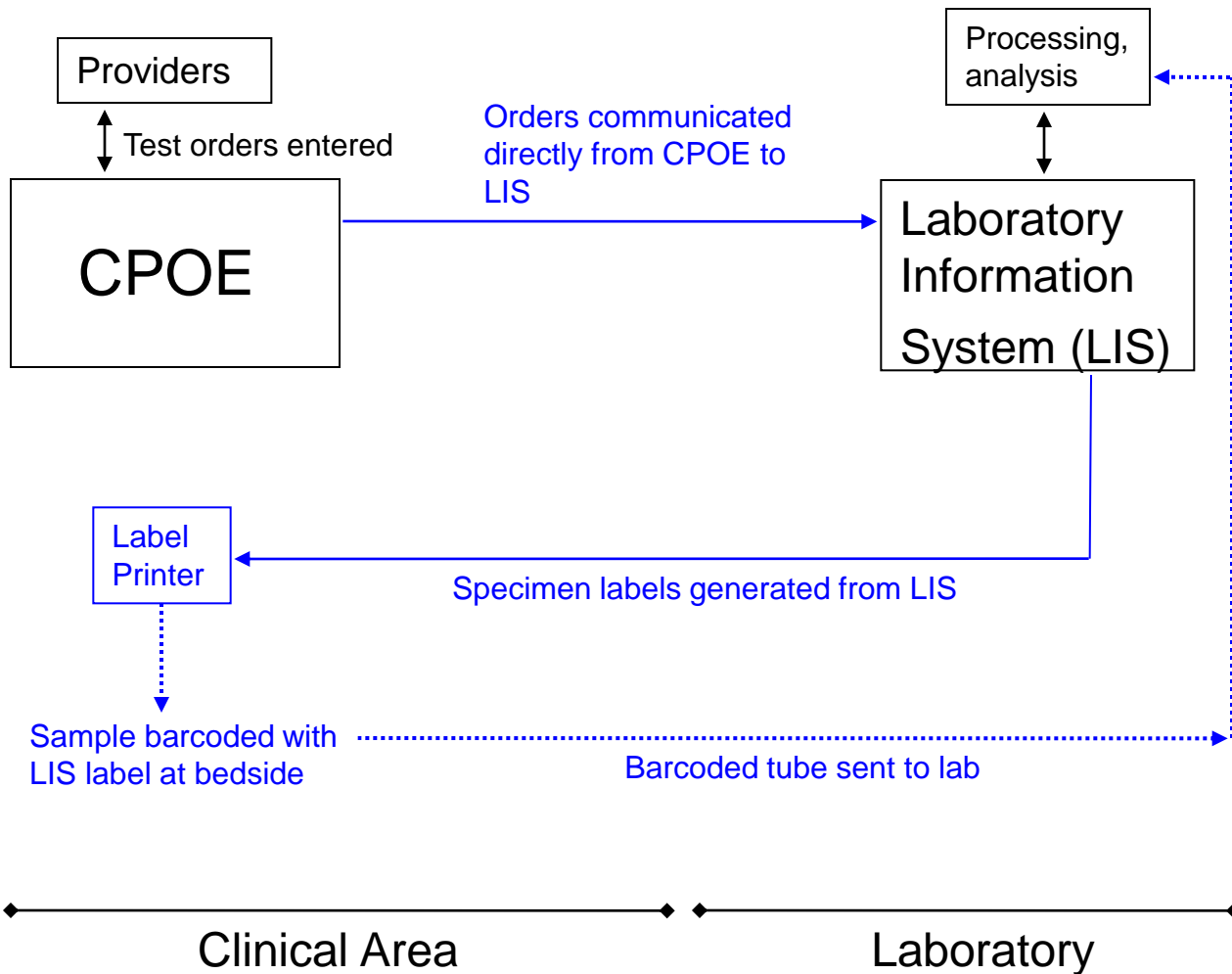
# Computerized Provider Order Entry (CPOE)



- No communication to laboratory system
- Huge amounts of wasted effort filling out requisitions, triplicate order entry
- Thousands of wrong tube errors per year
- 30% of orders were free text (“take as typed”); poor search function
- Pathology had minimal influence in CPOE group

# Computerized Provider Order Entry (CPOE) AND Order Communication

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## WISH LIST:

- Pathology has control of menu, templates, order entry rules
- Must be able to make changes to system in real time without IS involvement
- Real time data must be available for QI, auditing and follow-up

# Building Software That Gets Smarter

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**“I’ve been at MGH for 30 years and I have yet to see a project get to phase two.”**

**-- Dick Emrich, MGH LIS Director**

**1) A strong vocabulary and data model can make getting to phase two unnecessary**

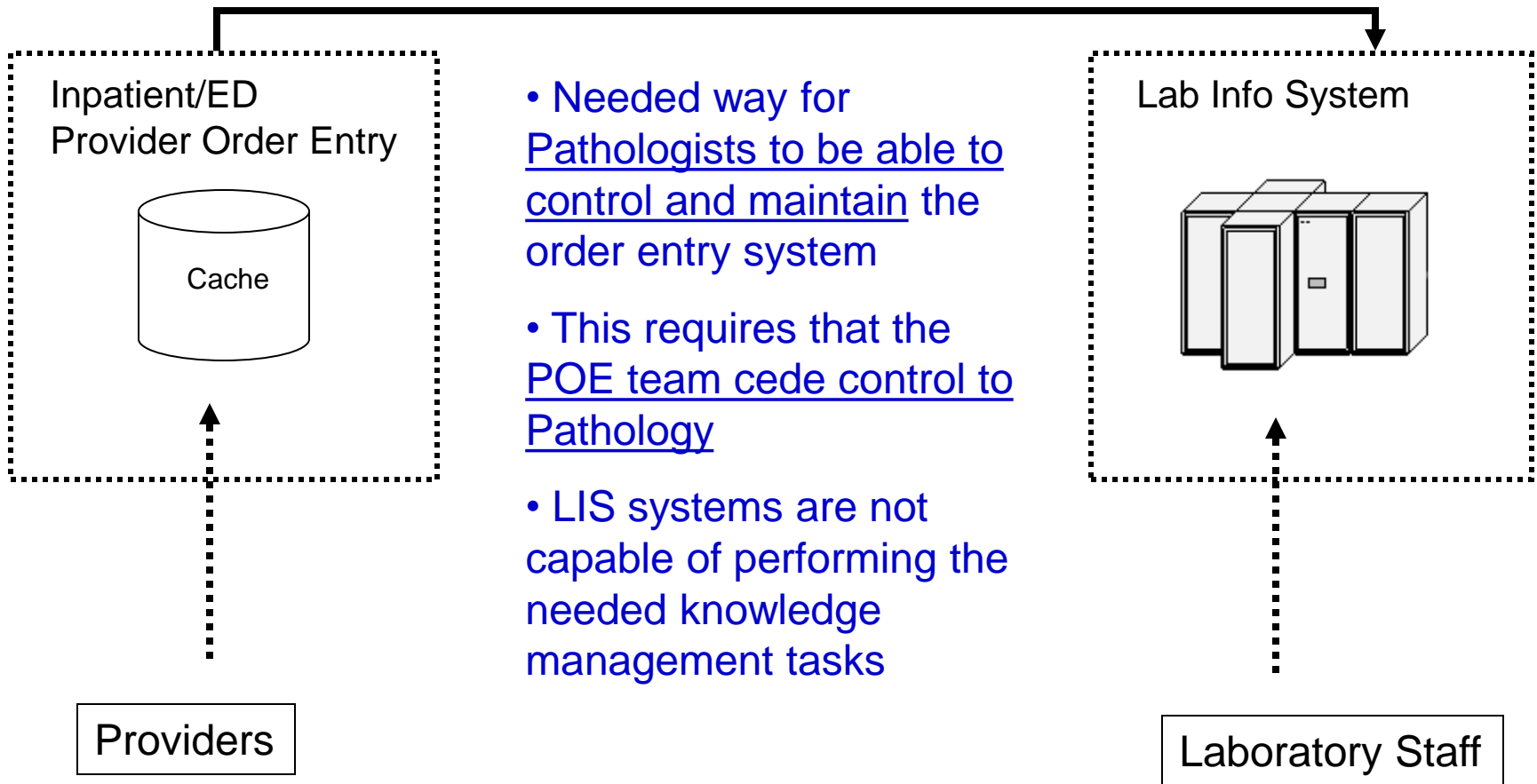
**2) Monitoring actual use is critical to understanding how to improve the underlying data model**

- If you have a system that can learn you need a teacher
- Don’t wait for complaints/user feedback
- Create monitoring reports for use on Day 1
- Expect and embrace failure!

# Inpatient/ED Provider Order Communication

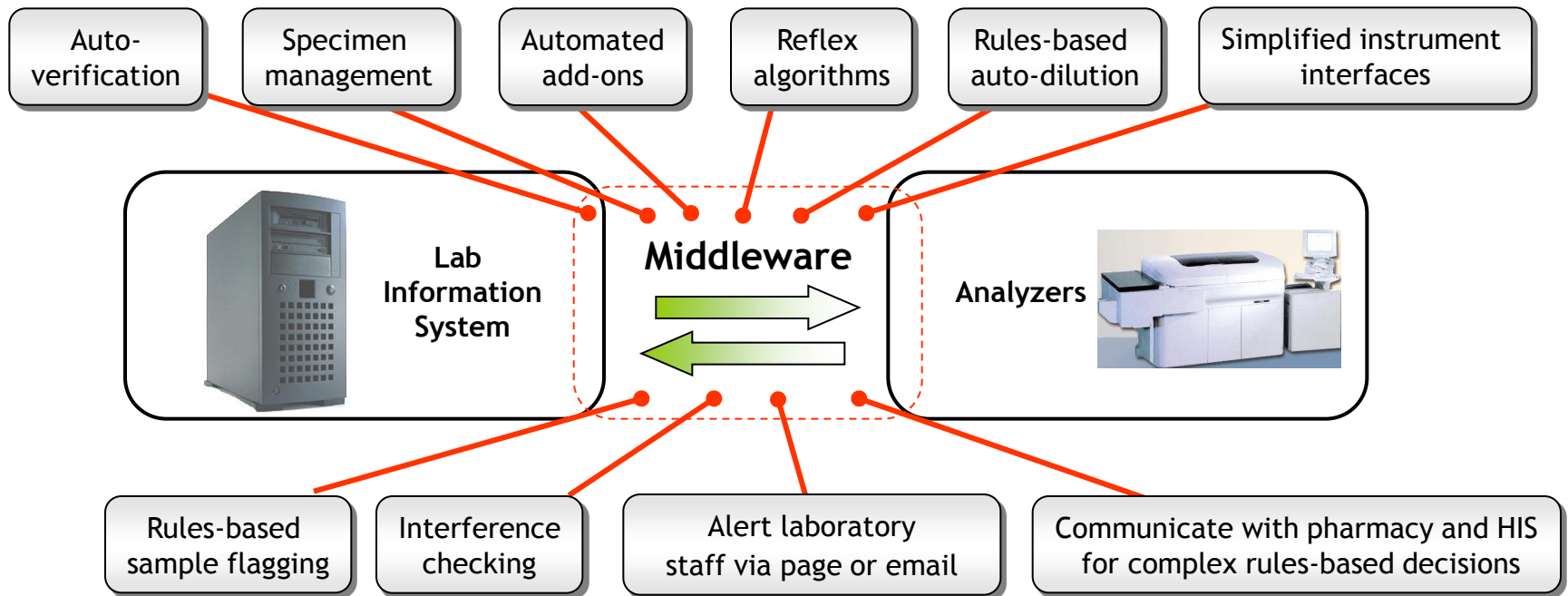
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*Lab Orders*



# How to “fix” the LIS: Middleware

- Middleware products specialize in one function or another (pre-analytic automation, autoverification, analysis rules, template reporting, digital image management, interpretive reporting, result reporting)
- Increasingly taking over functions of the core LIS products



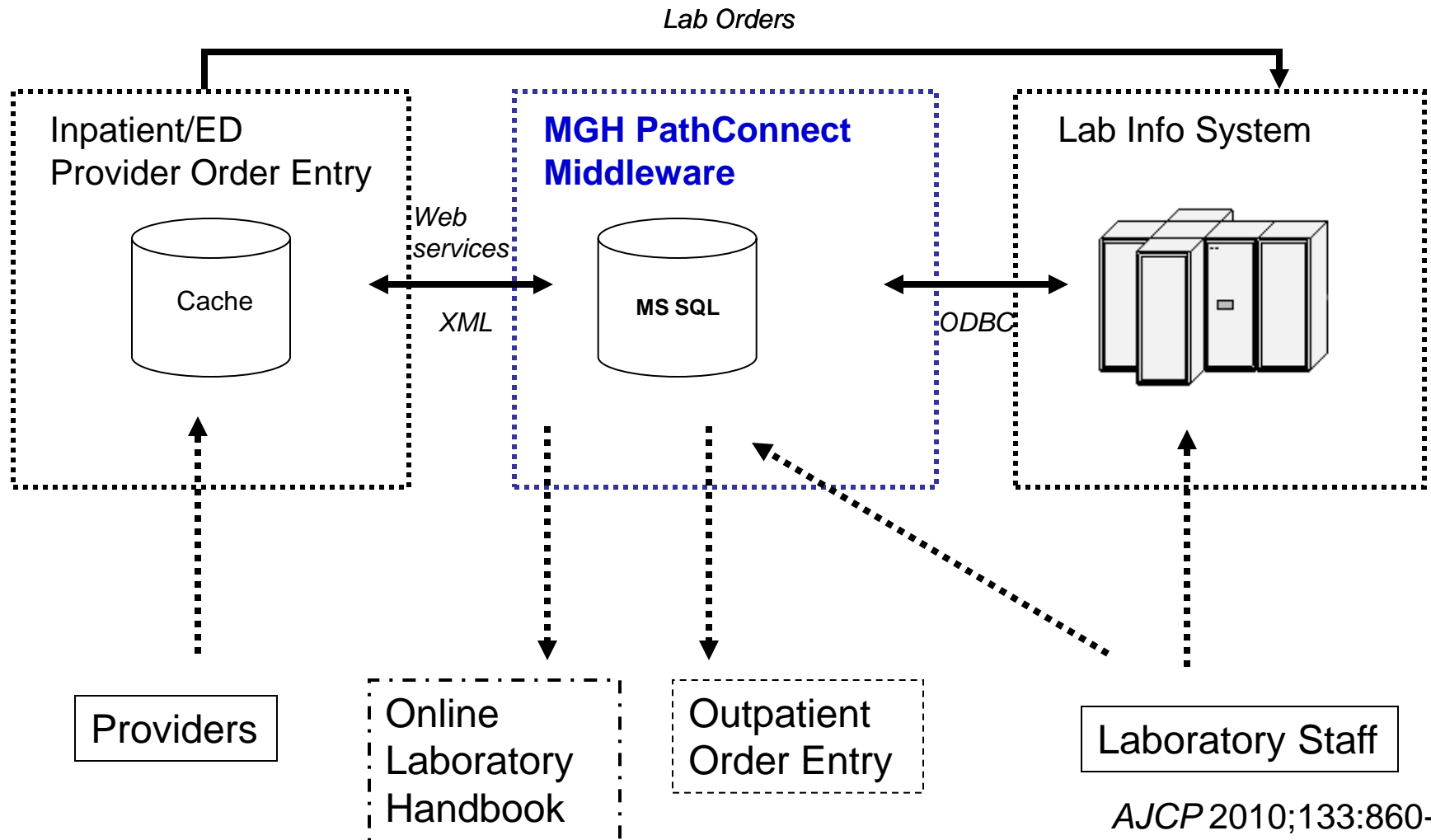
# What do we need?

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- 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** and **maximizing information flow** to the various data consumers:
  - Enterprise decision support
  - Inpatient order entry
  - ED order entry
  - Outpatient order entry
  - Online laboratory handbook

# MGH PathConnect Middleware

MISSION: Catalog, enhance, and share laboratory knowledge



# MGH PathConnect Middleware

The screenshot displays the MGH PathConnect Middleware interface. On the left is a table of test orders, and on the right is an 'Edit Data' window for a CBC test.

Order #	Order Status	Order Code	Test Text	Order Name	Order Type	Orderable
1	New	11DXC	11-DESOXYCORTISOLENDOS	11 DESOXYCORTISOL	TEST	Y
2	New	12HSV	12HSV orders HSV 1 2 QUAN	HSV 1.2 QUANT PCR	TEST	Y
3	New	13BDG	13BDG orders 1 3 BETA D G	1 3 BETA D GLUCAN	TEST	Y
4	New	17PPREG	17-OH PREGNENOLONE,NI ord	17 OH-PREGN		
5	New	17PROG	17-HYDROXYPROGESTERONE	17OH PROGES		
6	New	18CHM4		ALMOST ALL I		
7	New	18CORT	180H-CORTICOSTERONE,NI or	18 OH-CORTIC		
8	New	18UFC	18UFC orders 18 OH CORTIS	TU FREE 180H		
9	New	21HAB	21HAB orders 21 HYDROXYLA	21 HYDROXYL		
10	New	21HYDF	performed at: CORNELL U	21 HYDROXYL		
11	New	3MGCON	3-METHYLG LUTACONIC ACID,	3METHYLGLU		
12	New	4DHGLU		4-OH GLUTET		
13	New	5FC	FLUCYTOSINE,NI orders tes	FLUCYTOSINE		
14	New	5NUCT	5NUCT orders 5NUCLEOTIDAS	5 NUCLEOTID.		
15	New	6MP	6-MERCAPTUPURINE,PROM or	6 MERCAPTOI		
16	New	7DCHOL	7-DEHYDROCHOLESTEROL,KE	7 DEHYDROCI		
17	New	A125VD	1,25(OH)2 VITMN D,AML ord	1,25 (OH)2 VIT		
18	New	A1AGLY	ALPHA-1-ACID GLYCOPROTEI	ALPHA-1-ACID		
19	New	A1AGP	A1AGP orders ALPHA 1 ANTI	ALPHA1 ATRY		
20	New	A1API	A1API orders ALPHA 1 ANTI	A1AT W/ PHE		
21	New	A1AT		ALPHA 1 ANTI		
22	New	A1CC		A1C & CMBG		
23	New	A2AP		ALPHA-2-ANTI		
24	New	A2MACR	ALPHA-2-MACROGLOBULIN,M	ALPHA 2 MACI		

Test Code	Test Name	Reference Lab	Test Type
CBC	CBC		BAT

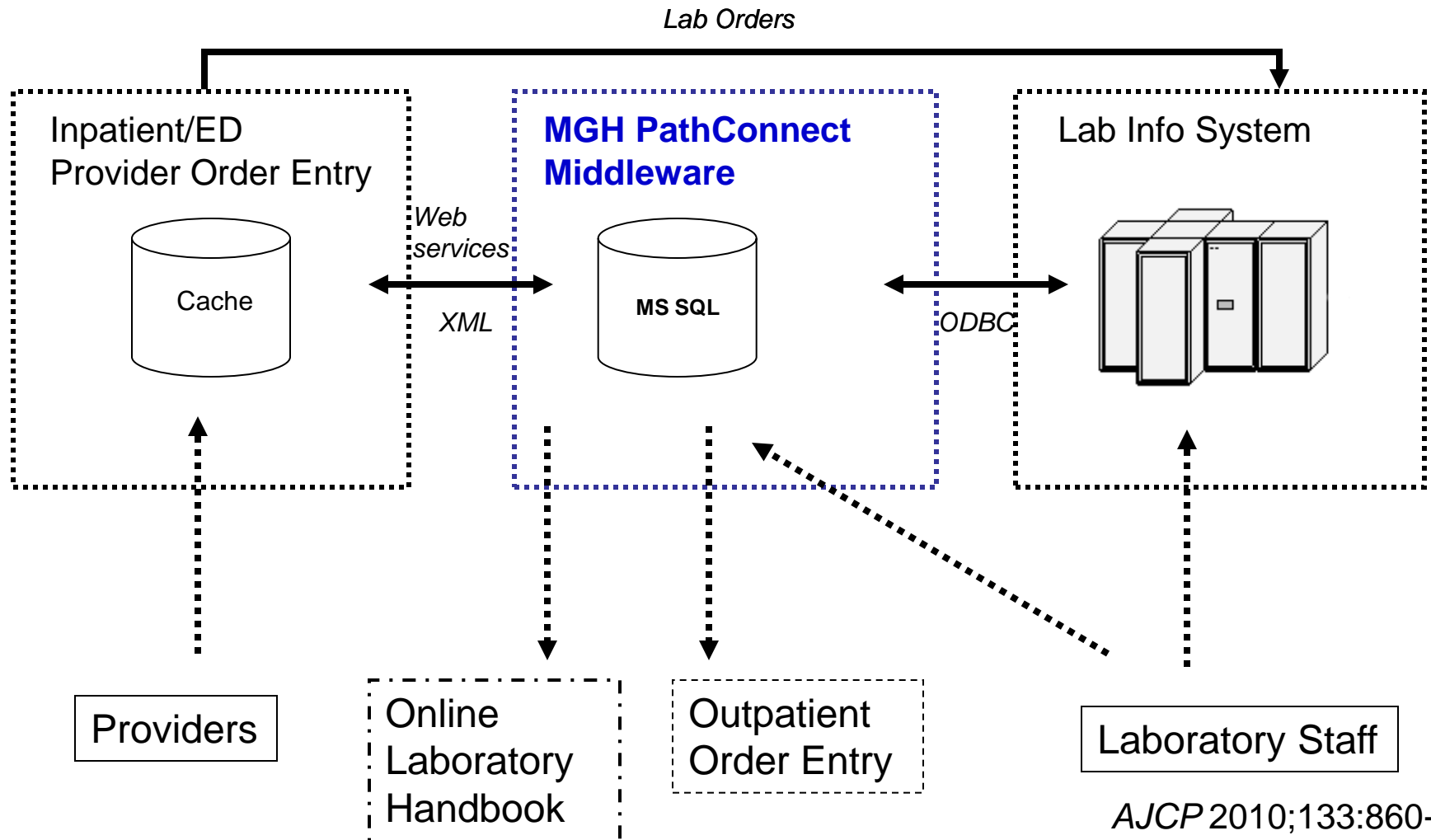
  

Master Lab ID	0
POE Test Name	CBC
Test Active / Orderable	Y
Test Orderable in POE	Y
Test Orderable Environments	MGHED,MGHIN,MGHO
Common Test	Y,Y,Y
Test Population	Adult,Pedi,Neonate
Test Turn Around Time	STAT: Within 1 hour of rec
Test is Send Out	N
Cost	\$
Test Preferred Tube	P 3
Specimen Type	BLOOD
POE Test Ordering Message	CBC includes HCT, HGB, W
POE Ordering Filling Message	
POE Should Send HL7	Y
LBH Test URL	83
Search Term 1	HCT, HGB, WBC, RBC, MCV
Search Term 2	
Additional Info	<AddlInfoItems> <AddlInfo
Associated Tests	
POE Requisition Required	N
POE Requisition Type	Core
Requisition Grouping	HEMATOLOGY

- Synchronizes with Laboratory Information System (LIS)
- Receives data from LIS regarding each test
- LIS test data can be augmented with ordering messages, alerts, search terms, related tests
- Allows cataloging of Pathology data such that it can be shared with other parts of the organization

# MGH PathConnect Middleware

Permits Pathology to have total control over Provider Order Entry screens



# POE 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 updated in real time **by Pathology** via the web service

Laboratory Order Processing Active Pt: CLAUS, SANTA P

**Select and/or Search for Tests**  
Double-click to select a test

- CBC
- CBC with Diff
- PT-INR
- PTT
- U/A (urinalysis)
- Electrolytes
- Glucose
- BUN/Creatinine
- Calcium
- Magnesium
- Phosphorus
- Albumin
- Alk Phos
- Bilirubin (direct and total)
- AST/ALT
- Amylase/Lipase (plasma)
- LFTs (hepatic panel)
- Troponin T
- Sed rate (ESR)
- Ionized calcium
- Arterial blood gas (MORE)
- Capillary blood gas (MORE)
- Blood culture/sensitivity (MORE)
- Urine culture/sensitivity (MORE)
- Respiratory culture/sensitivity (MOF)

Add >

< Remove

Modify Additional Info.

**Tests Selected**

- CBC
- PT-INR

**Ordering message**

Blood gases include pH, pO<sub>2</sub>, pCO<sub>2</sub>, and base excess.

**Collection Instructions (file with order)**

**Requested Collection Time for all selected tests**

- Routine  Already collected  Fasting
- STAT  Draw If/When  Special Billing/Research

Frequency x1

Total Collections 1

Start In AM 09/04/2010

Search

Help

OK

Cancel

# Lab Ordering Screen

Complex Decision Trees Built Entirely from Database

- Complex decision trees can be represented in the middleware and be readily updated by Pathology
- Permits rapid responses to utilization issues

Additional information for : Blood culture/sensitivity

**Test : Blood culture/sensitivity**

PLEASE NOTE: It is NOT necessary to add fungal blood cultures for most clinical scenarios. Candida and related yeasts are adequately detected in standard blood cultures.

Additional Information :

Number of Sets  
Specific Organism Sought?  
Special Requests

\* Required fields

\* Number of sets (Blood culture)  
2

Additional Tests for this Specimen :

Fungal blood culture  
 Mycobacterial (TB/AFB) cx bld

Click on each Additional Information item to enter specific information.

OK Cancel

# Improving Vitamin D Utilization with CPOE

Middleware enables rapid (minutes, to author and update test) responses to utilization issues

Search provides more than a list of possible matches →

Provides information to guide appropriate utilization

**Test Lookup**

Search for a Test

vit d Search 2 tests found

Name	Where	TAT	Cost
1,25 OH Vitamin D (MORE)	Send Out	4-6 days	\$\$\$
25-OH Vitamin D	In House	1-3 days	\$\$

Tests Selected

1,25 OH Vitamin D (MORE)

Ordering Message

Please note that 1,25 OH vitamin D is in general NOT the test of choice for assessment of vitamin D deficiency. Please order 25-OH vitamin D if that is the intent.

Collection Instructions

Add

To select a test: double-click on the test name OR single-click and then the Add button OR use the arrow keys and then Alt-A

**• Adding non-interruptive ordering message dropped 1,25 OH vitamin D orders by 70% (p < 0.001)**

**• Cost savings = \$20K/yr**

# Creatine Kinase MB

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- CK-MB: cardiac specific isoform used in the diagnosis of ACS and related conditions
- Largely obsolete test yet still ordered over 36,000 times per year on MGH inpatients
  - Cost \$38,000 per year
- Obtained cardiology, medicine, and ED approval to restrict use solely to the post-PCI setting
- Removed CK-MB from POE templates and created ordering message and pop-up screen to capture indication

# MGH Order Entry Screen

The screenshot displays the 'Test Lookup' window. At the top, there is a search bar containing 'ckmb' and a 'Search' button. To the right, it indicates '1 tests found' and provides a link: 'Double-click to select a test'. Below this is a table with the following data:

Name	Where	TAT	Cost
CK isoenzymes (CKMB+CPK) ...	In House	2 hours	\$


Below the table, there is an 'Ordering Message' section, which is highlighted with a red dashed border. The message reads: 'UPDATED R/O MI protocol: Troponin T q8h x 3. Routine measurement of CK isoenzymes (CKMB+CPK) is no longer recommended. The use of CKMB should be restricted to the following exception: Post percutaneous coronary'. Below the message is a 'Collection Instructions' section: 'Requires 3 ml Purple and 3 ml Green'. At the bottom of the window, there is an 'Add' button and an information icon. To the right of the main window is a 'Tests Selected' panel, which is currently empty. A red box with a white background and a red border contains the text 'Passive, non-interruptive ordering message', with an arrow pointing to the 'Ordering Message' section.

To select a test: double-click on the test name OR single-click and then the Add button OR use the arrow keys and then Alt-A

# CK-MB Additional Info Screen (Interruptive Alert)

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Additional information for : CK isoenzymes (CKMB+CPK)

 Test : CK isoenzymes (CKMB+CPK)

UPDATED R/O MI protocol: Troponin T q8h x3. Routine measurement of CK isoenzymes (CKMB+CPK) is no longer recommended. The use of CKMB should be restricted to the following exception: Post percutaneous coronary intervention.

Additional Information :

**\* Required fields**

\* Please review NOTE above and Cancel if not needed.  
Indication for CK-MB testing (REQUIRED):

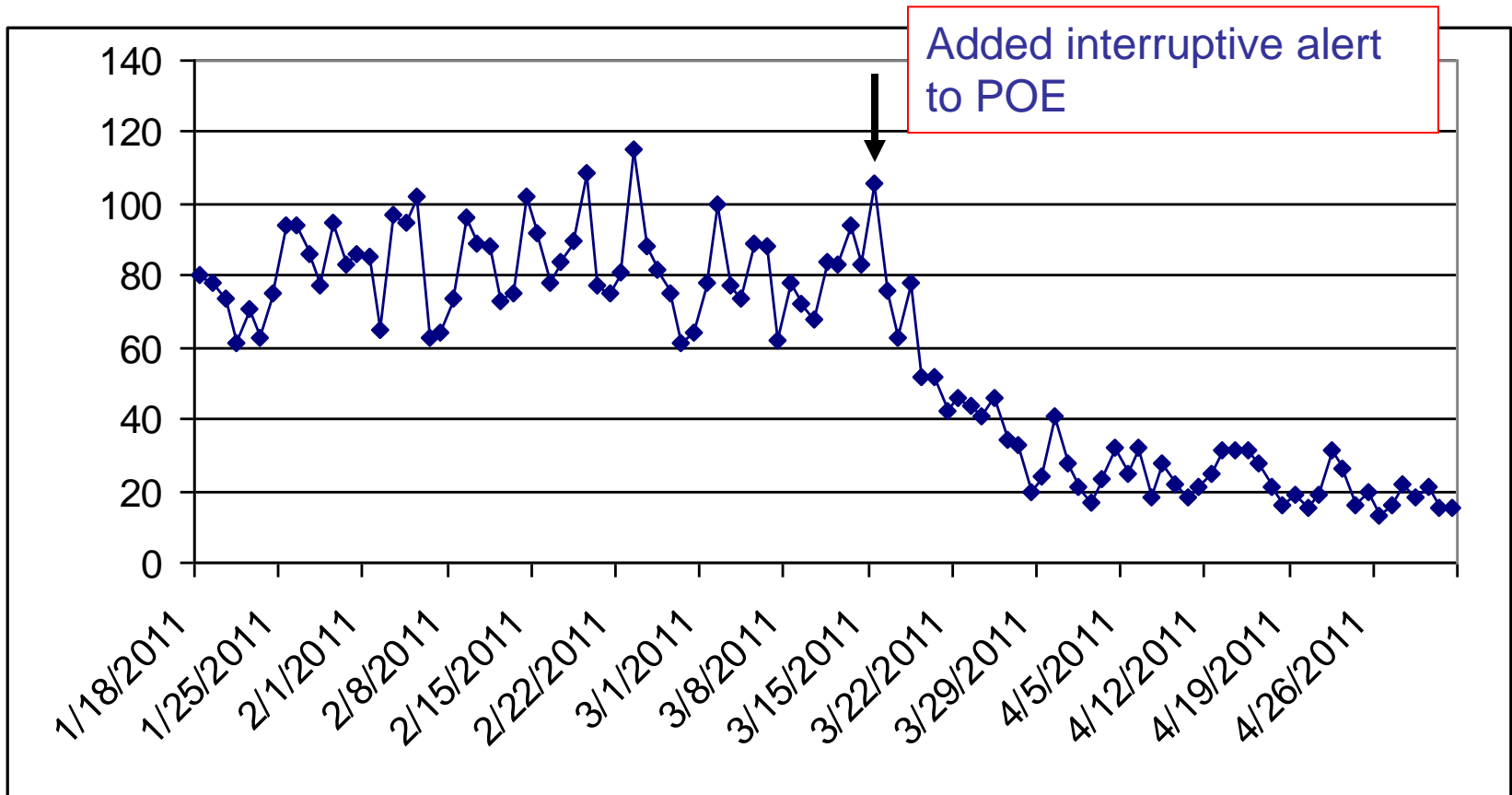
Additional Tests for this Specimen :

Click on each Additional Information item to enter specific information.

OK Cancel

- Middleware updates took 5 minutes to author, test, and implement
- No IS involvement required

# Inpatient CK-MB Results Per Day



- Sustained 80% reduction in CK-MB orders within 3 weeks
- Cost savings of \$30 K/year

# Building Software That Gets Smarter

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“I’ve been at MGH for 30 years and I have yet to see a project get to phase two.”

– Dick Emrich, MGH LIS Director

1) A strong vocabulary and data model can make getting to version two unnecessary

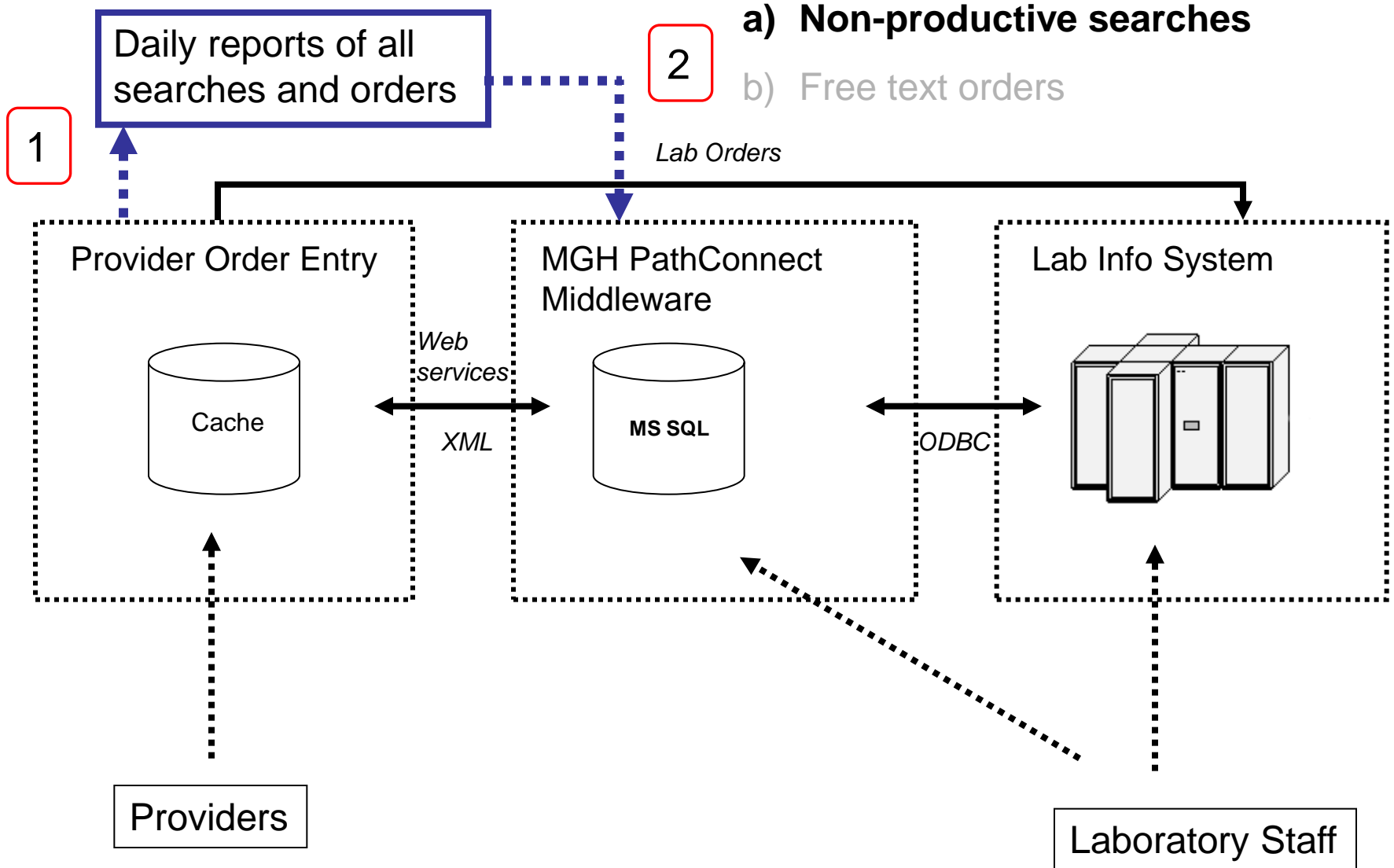
**2) Monitoring actual use** is critical to understanding how to improve the underlying data model

– Create monitoring reports for use on Day 1

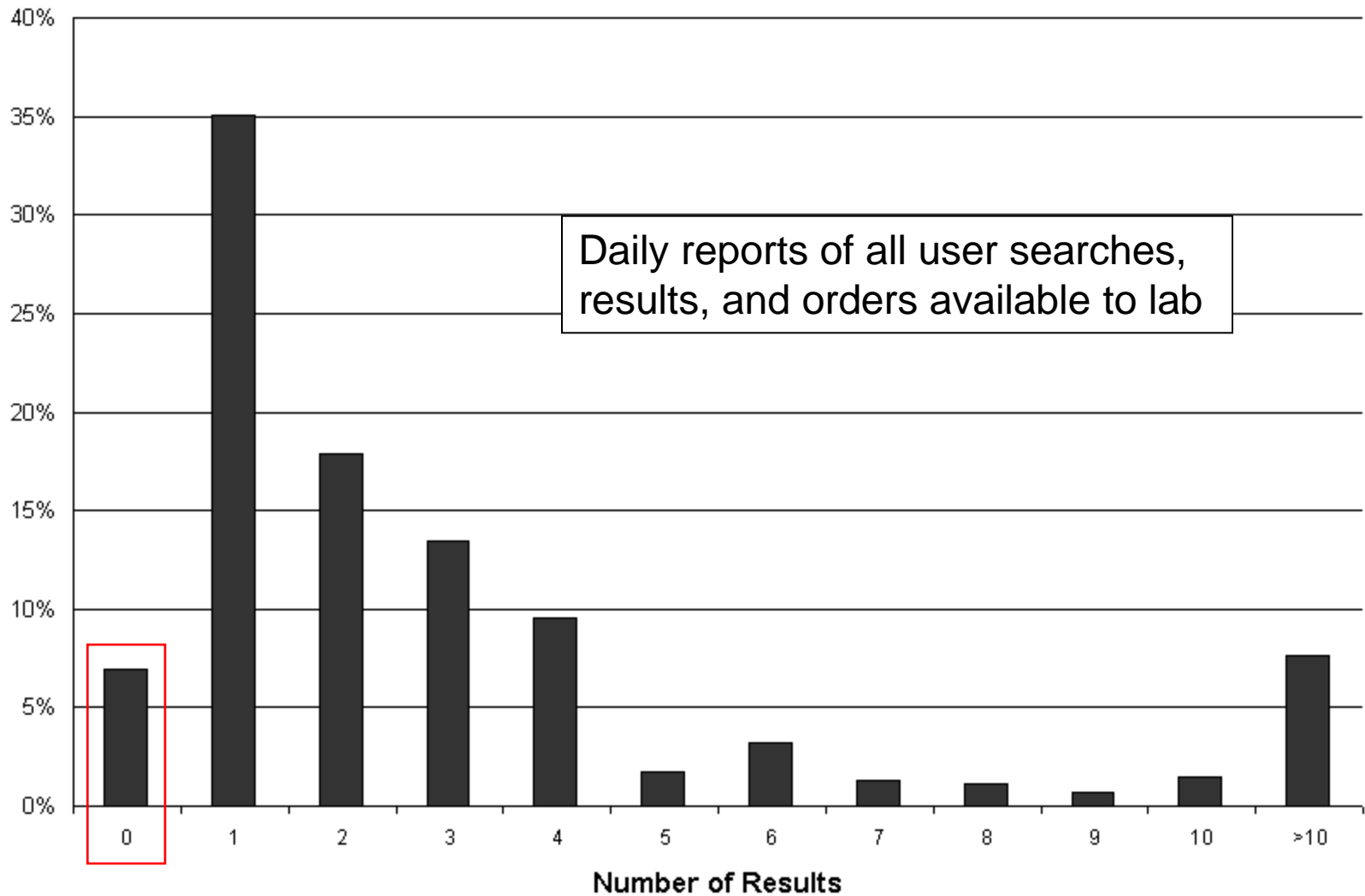
– Expect and embrace failure!

– If you have a system that can learn you need content

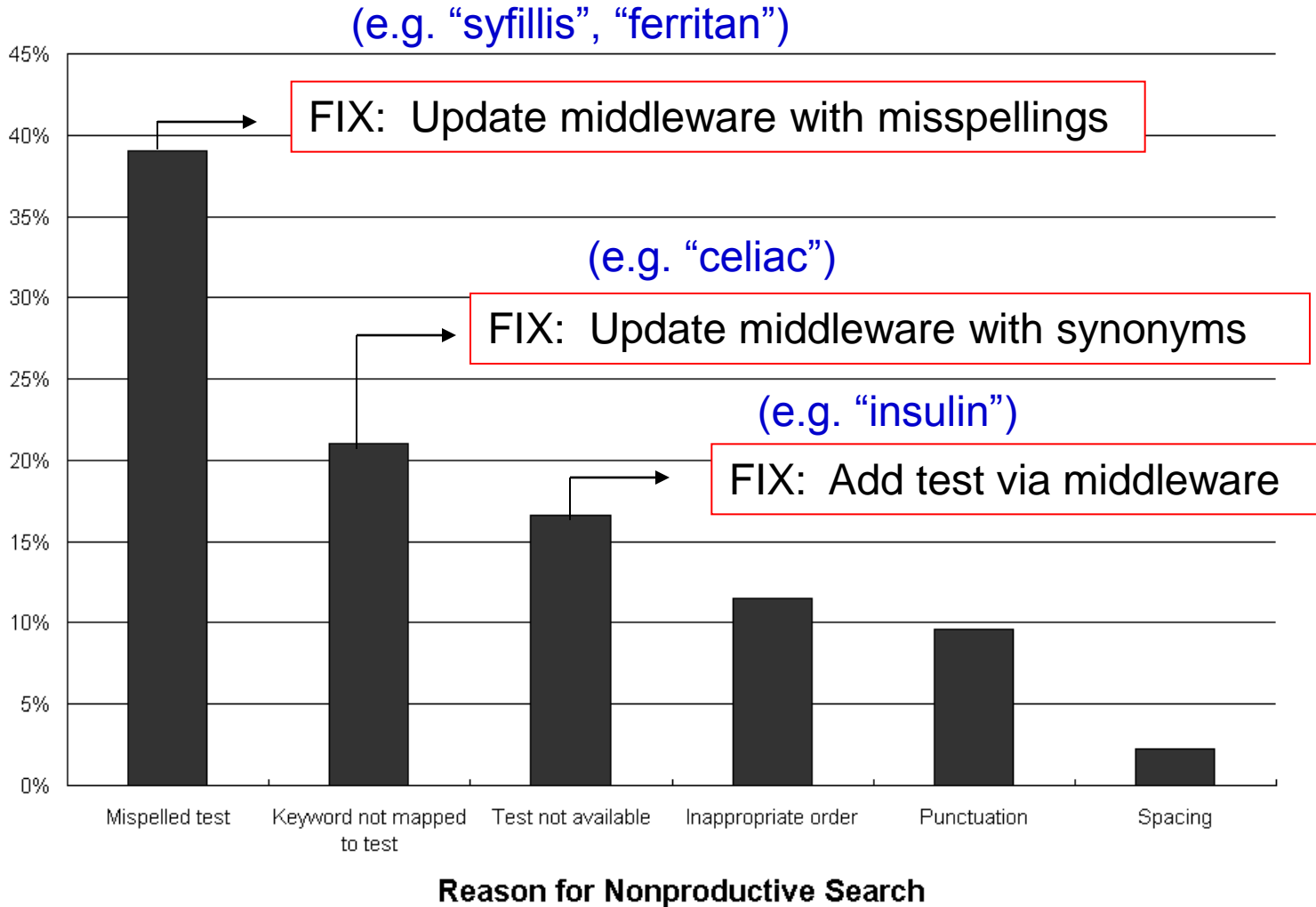
# Expect Failure: Monitoring Reports for Orders and Search



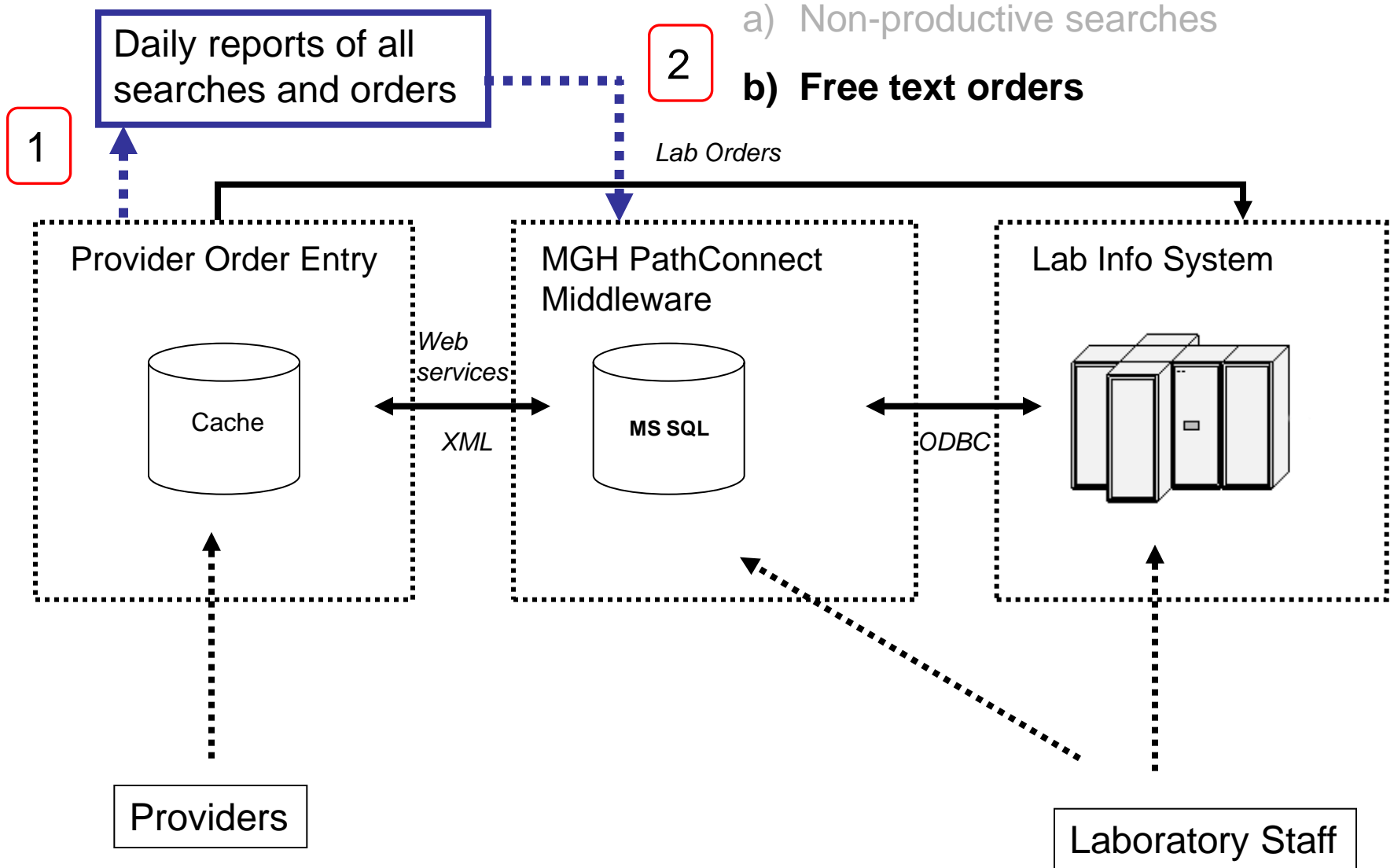
# Analysis of User Search Productivity



# Reasons for Nonproductive Searches



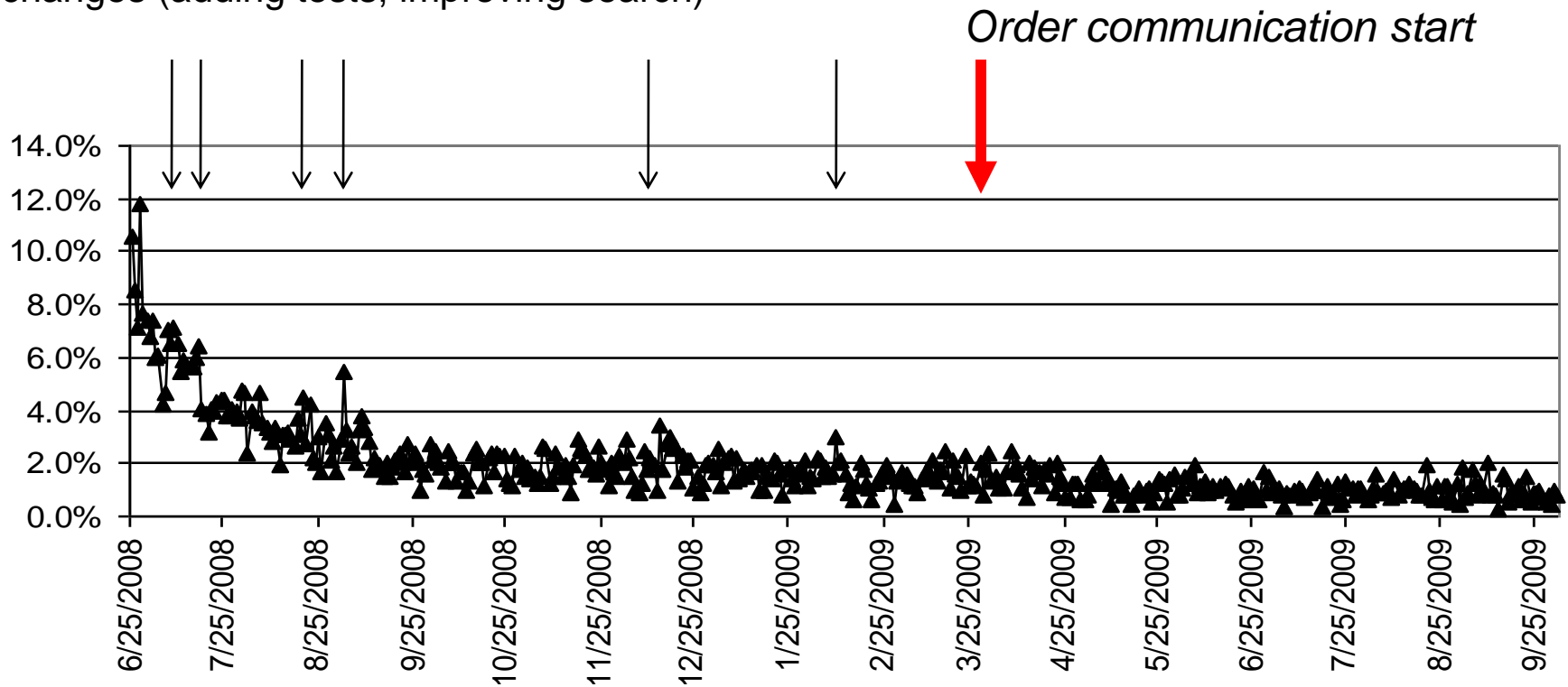
# Expect Failure: Monitoring Reports for Orders and Search



# Free Text Orders (e.g. “workarounds”)

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- Free text (directly typed) orders monitored on a daily basis
- Free text is essential to eliminate before orders are communicated to the LIS
- Report permits near real time intervention with non-compliant physicians and/or system changes (adding tests, improving search)



- Current free text percentage 0.32% (4 sigma)

# Provider Order Entry

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- Provider Order Entry is a **key leverage point** for Pathology to improve ordering practices, prevent ordering errors, and avoid pre-analytic error
- Pathology should have control over all laboratory order entry modules (IP/ED/OP) to permit rapid responses to ordering issues
- Centralization of laboratory knowledge and understanding ordering behavior is essential to improve **utilization**

# Misaligned Incentives

(“Quality improvement can be a path to financial ruin”)

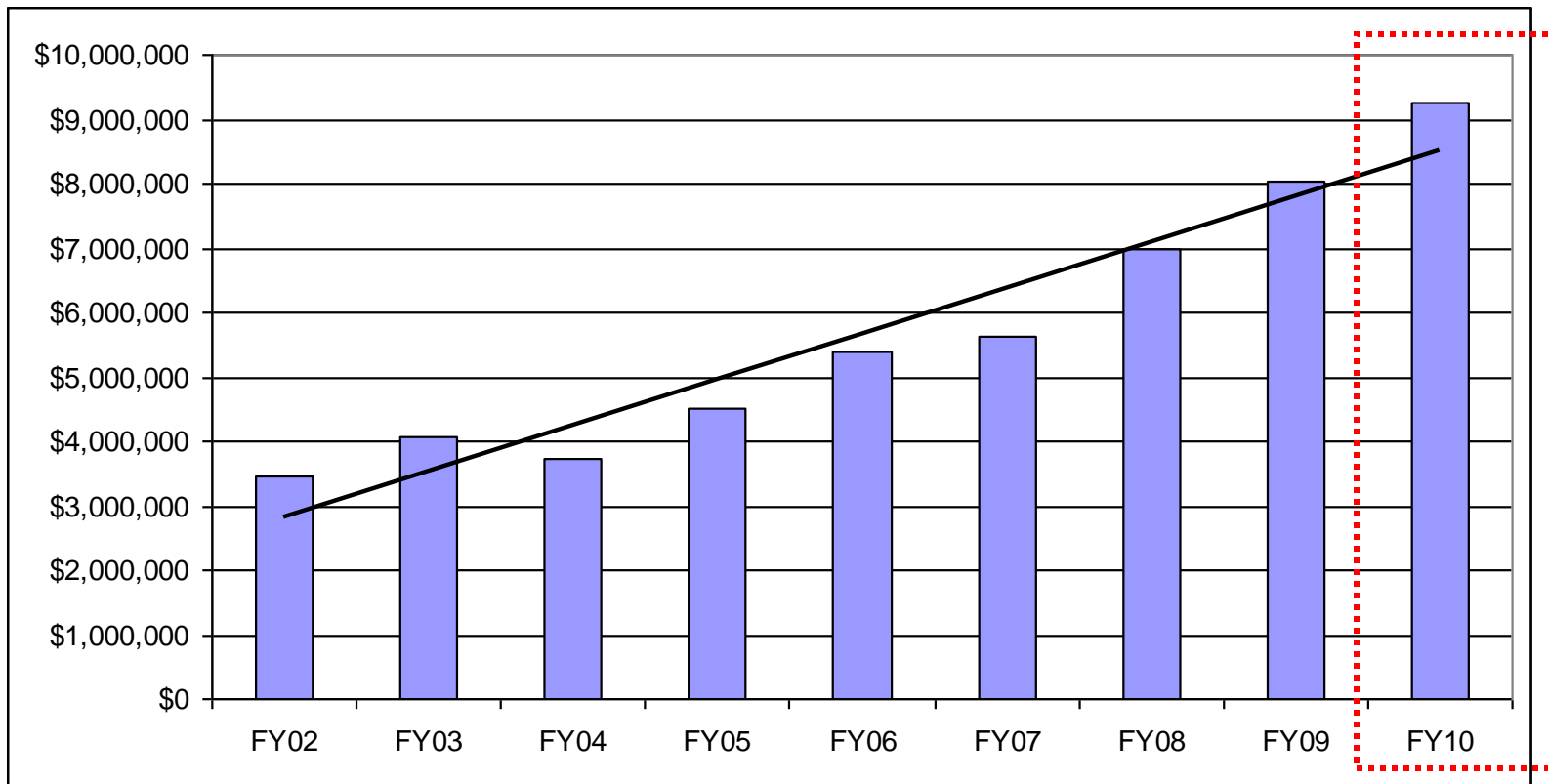
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- Currently most incentives in healthcare are poorly aligned with quality outcomes
- Incentives encourage overutilization and do not reward “process quality”
- Healthcare finance reform is already starting to change this
- Leadership is required to effect change

# Projected MGH Reference Lab Expenses FY10

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15% annual growth rate for overall  
reference lab testing expenses



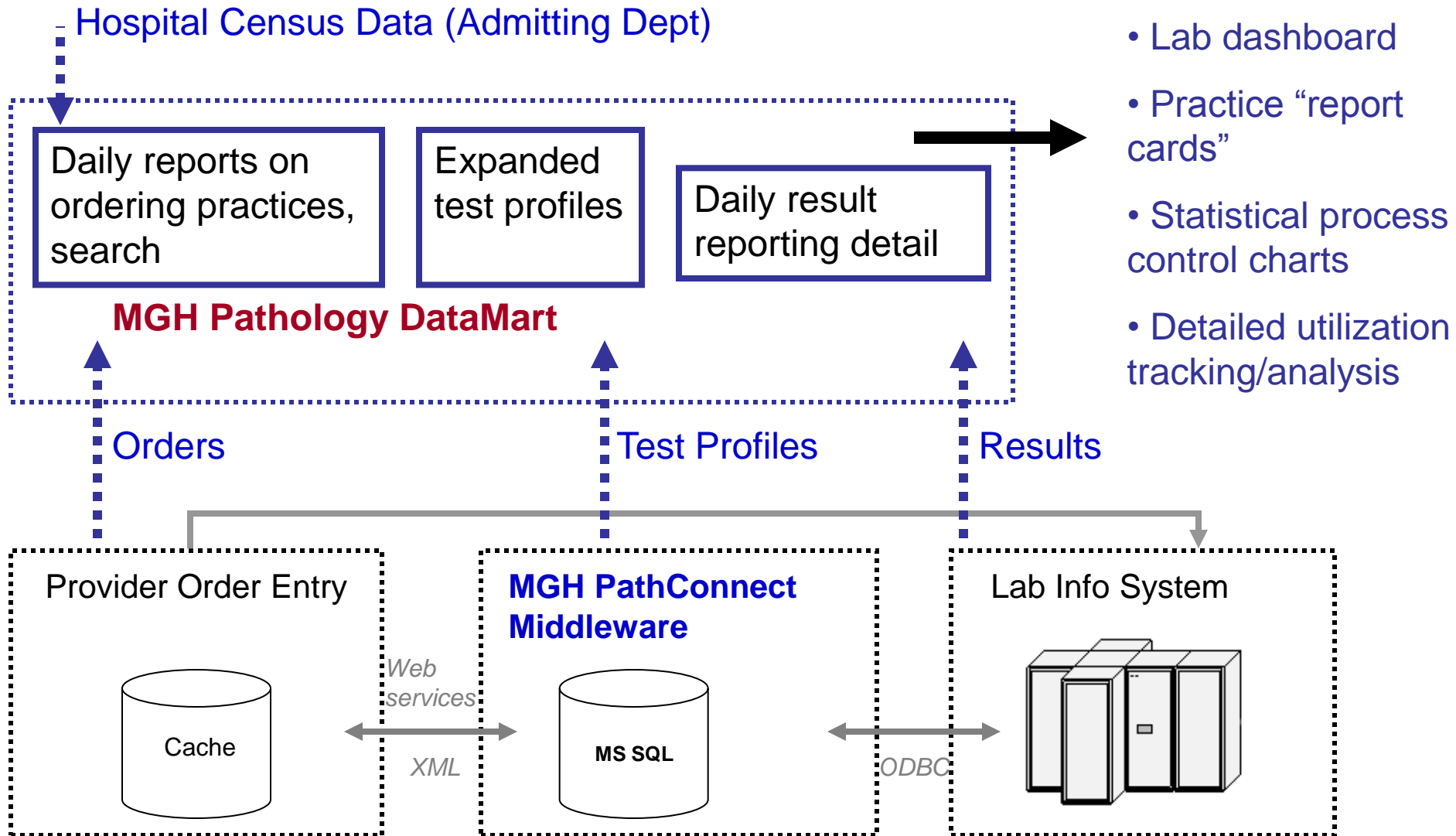
How can we head off this impending crisis?

# Building a Data Infrastructure

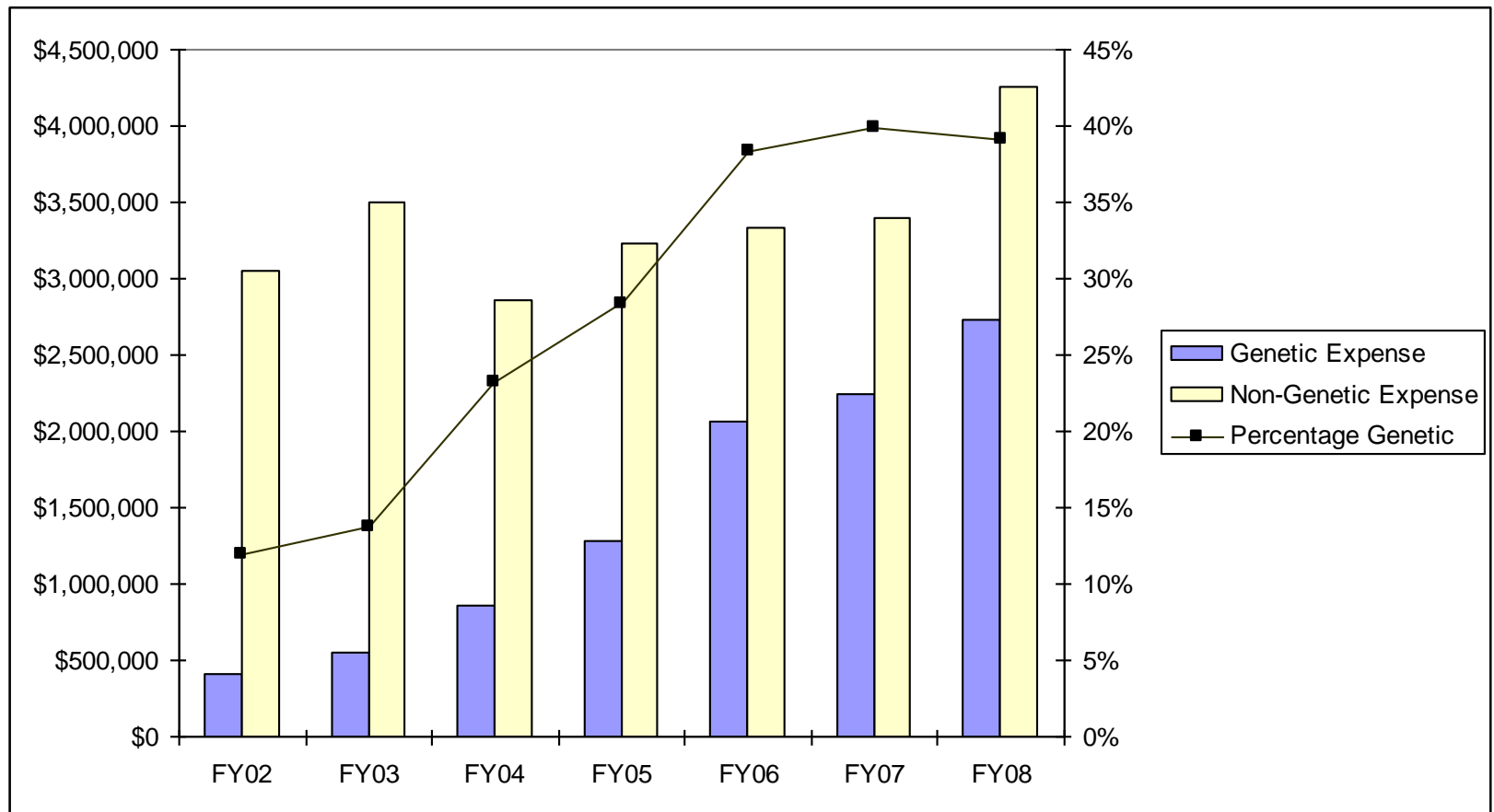
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- Needed real time data on reference laboratory test usage to facilitate monitoring
  - Test data, provider data, patient data, location data
- Enhanced middleware to add key fields for each of 2,100 reference laboratory tests:
  - Cost, performing laboratory, type of test, provider type
- Automatically digest daily feed from the Lab Information System (LIS), POE, admitting (daily census data) to provide integrated, clean data source for reporting and analysis
  - **MGH Pathology DataMart**

# MGH Pathology DataMart



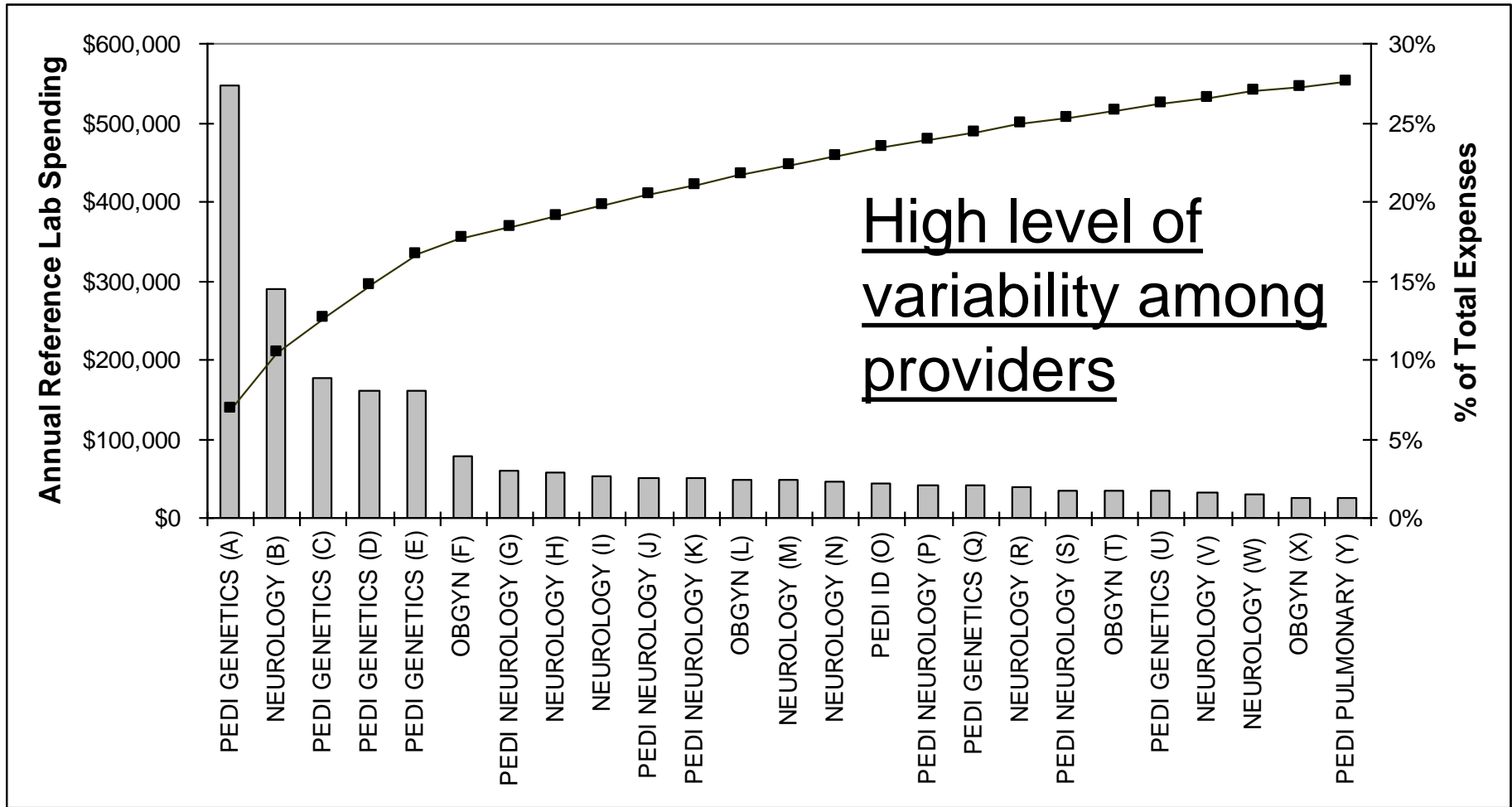
# Contribution of Genetic Testing to Reference Lab Expenditures



***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***

# Reference Lab Testing: Top 25 Providers



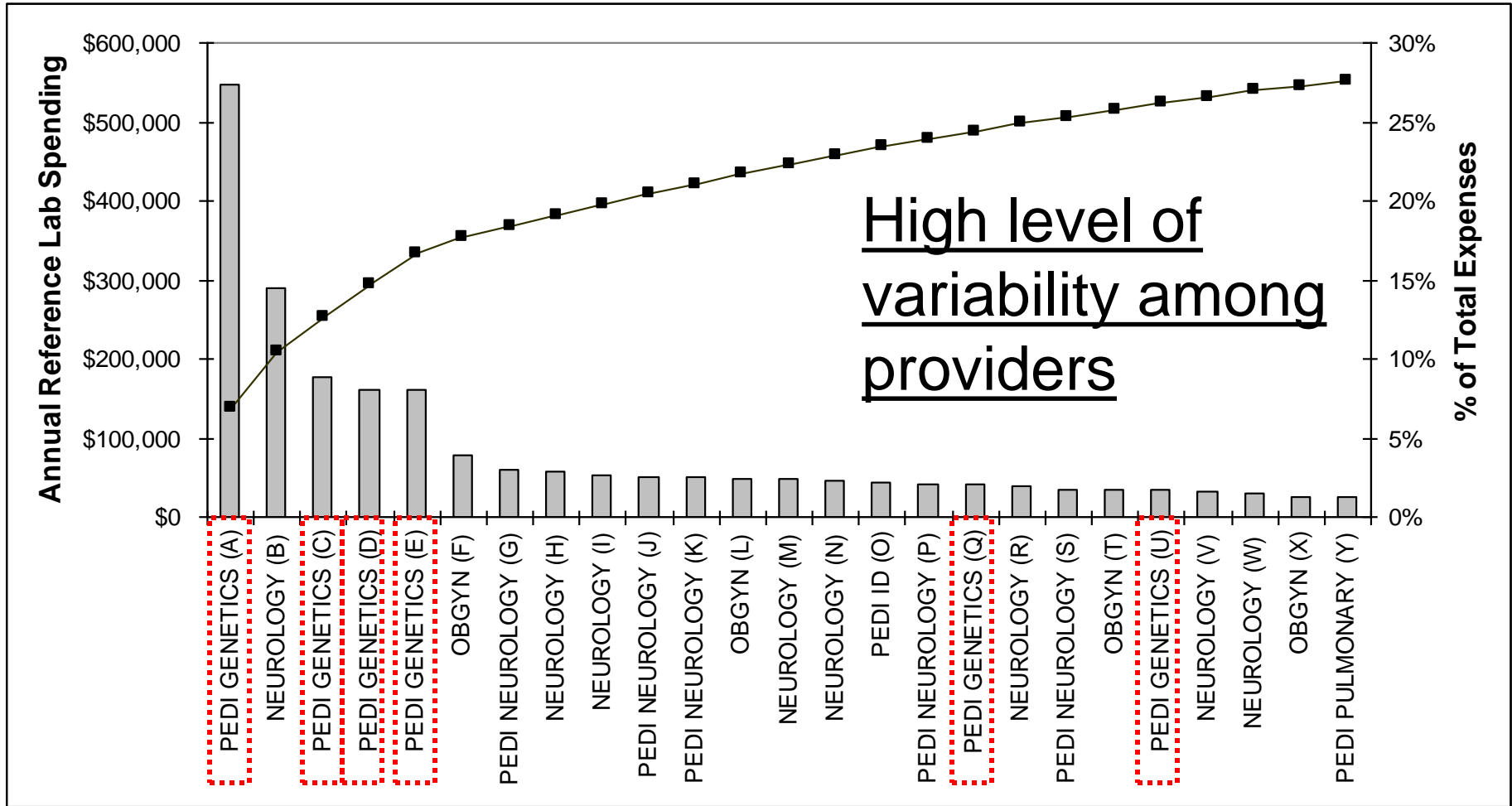
Genetic tests ordered by top 25 providers account for 27% of entire reference lab expense

# Healthcare Variability

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

# Reference Lab Testing: Pediatric Genetics



Genetic tests ordered by 6 providers account for 15-20% of all reference lab expenses

# Approach for Pediatric Genetics

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There is a high level of variability which likely represents inefficient utilization

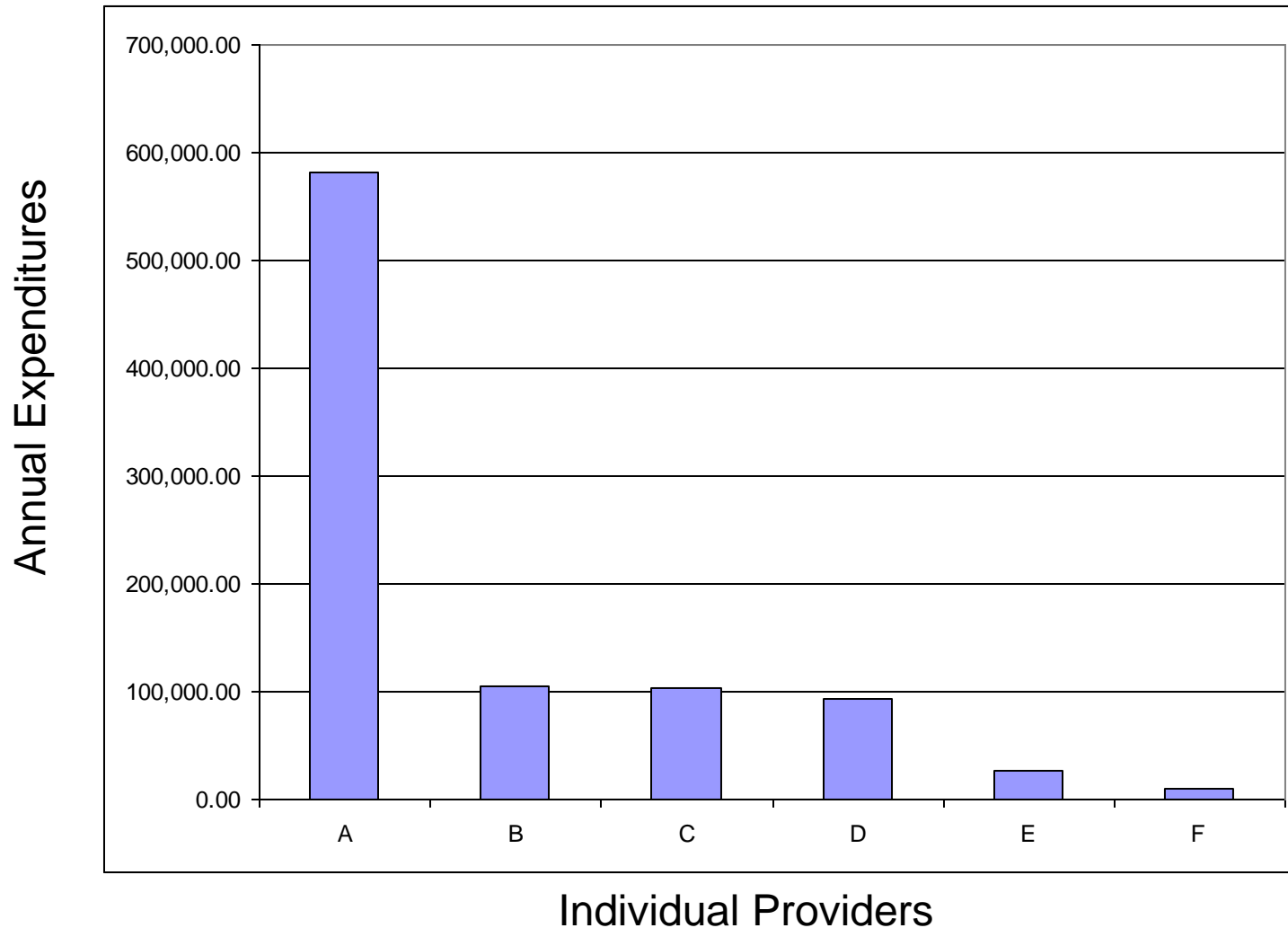
1. Creation of a reference laboratory formulary will improve utilization
  - Green: **Anyone** can order (aldosterone)
  - Yellow: **Staff specialists in that field** ONLY can order (Trofile assay for ID; Complete Hereditary Ataxia panel for neurology). Requires order or approval by Specialist in that field.
  - Red: **Not Recommended** for clinical use. Requires approval by Pathology based gatekeeper (Leptin).
2. Regular reporting of reference lab utilization to providers will improve utilization.
3. Development of practice standards will improve utilization.

# Pediatric Genetics Providers

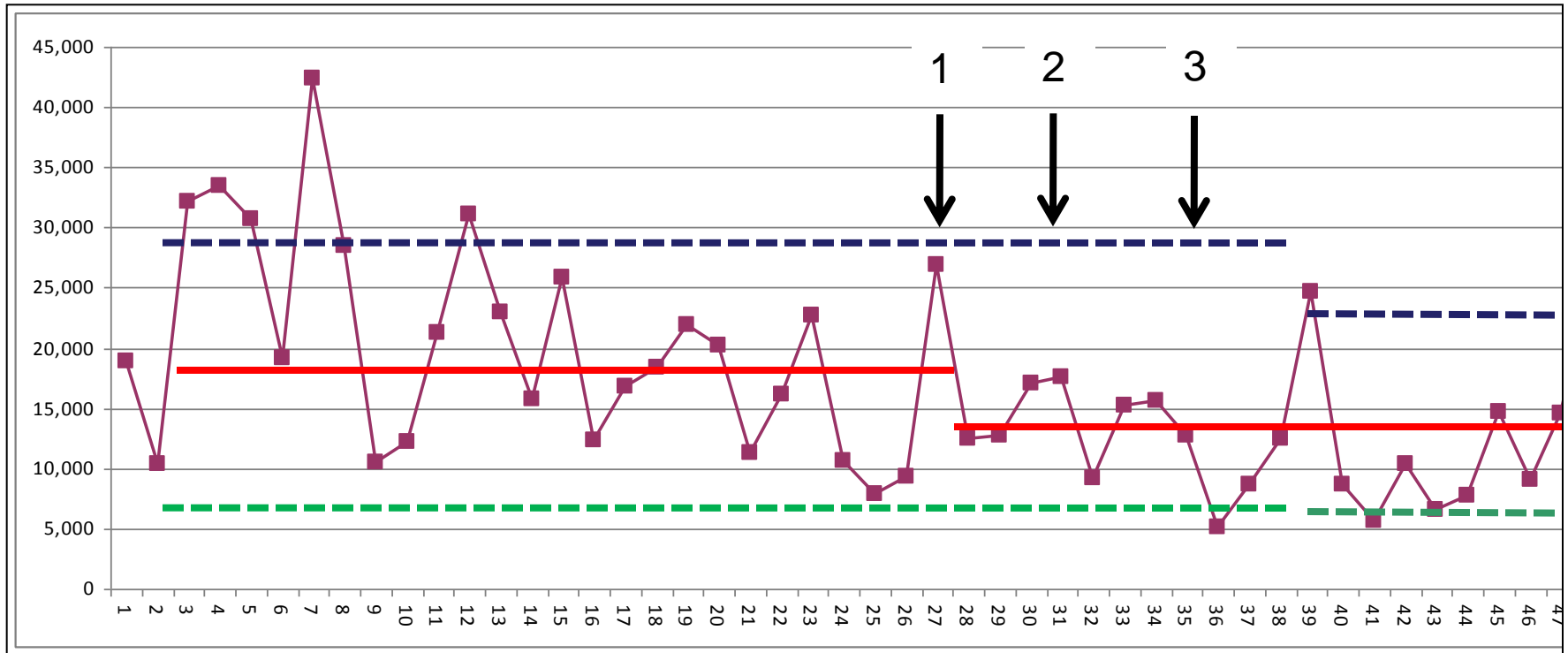
(4/5 Top Ordering Physicians, 15-20% of all sendout expenses)

(e.g. “who you see is what you get”)

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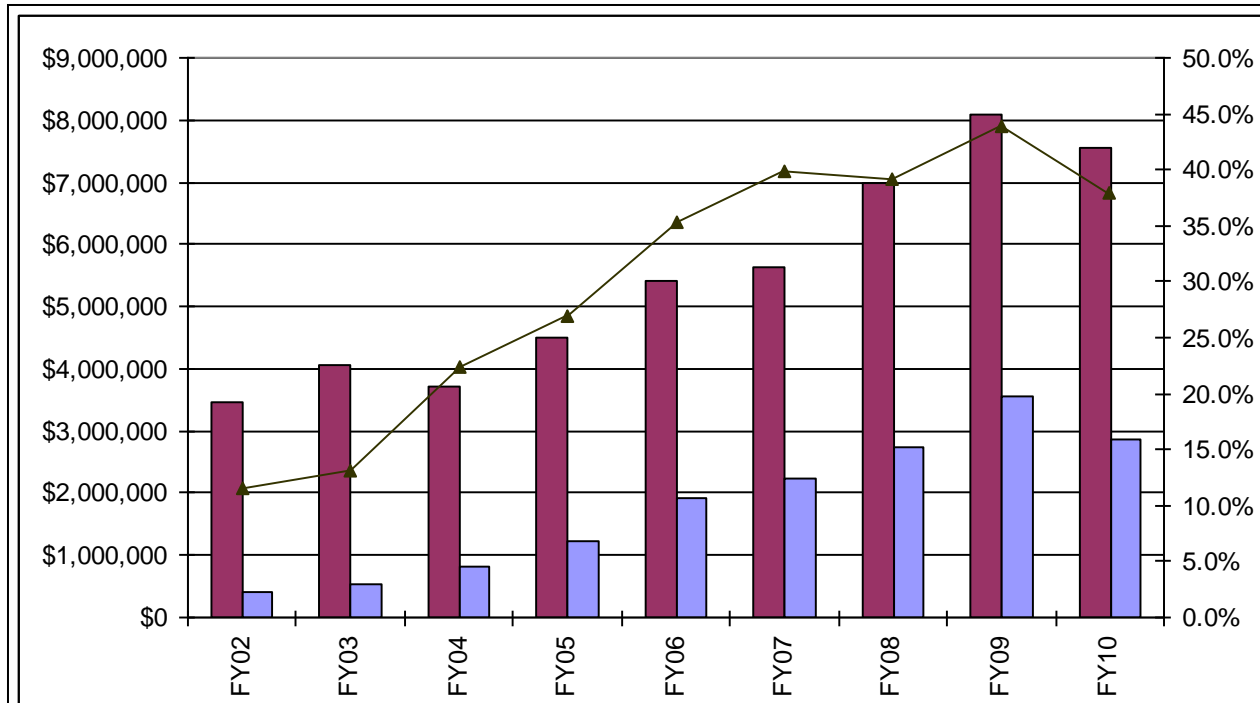


# SPC: Weekly Pediatric Genetics Reference Laboratory Expense



- 1: Meeting with Chief of Service, sent data to providers
- 2: Meeting with entire team, "report cards" reviewed
- 3: Review developed practice guidelines, monitoring data

# MGH Reference Lab Expenses



- First year in a decade that below budget (by \$1.6 M)
- First year on record that genetic testing costs declined
- Over \$500,000 in costs directly avoided via practice guidelines
- Project would not have been successful without highly detailed, real time data

# Lessons Learned

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- Focus on front line processes and information flow will be essential in the next chapter of healthcare
- Pathologist/Infomaticians are well positioned to occupy key roles in the organization to create system level solutions and increase the value of the diagnostic process
- Assess the entire testing process
  - Use forcing functions in order entry systems to improve utilization and reduce redundant testing
- Pathology should maintain control of laboratory ordering modules of order entry system
- Create tracking systems that capture the relevant data for analysis/metrics and system improvements

# Thank You

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## MGH Pathology

- Ricky Grisson
- Ji Yeon Kim
- Jason Baron
- Kent Lewandrowski
- Victor Brodsky
- Chris Nero

## Partners

- Irina Kamis
- Erin Graydon Baker
- Balaji Singh
- Shalini Batra
- Sidi Belkziz
- Hal Myers
- Alex Demyanov

## MGH Medicine

- Andy Karson