Closing the Loop: Improving Quality and Reducing Risk for Actionable Test Results

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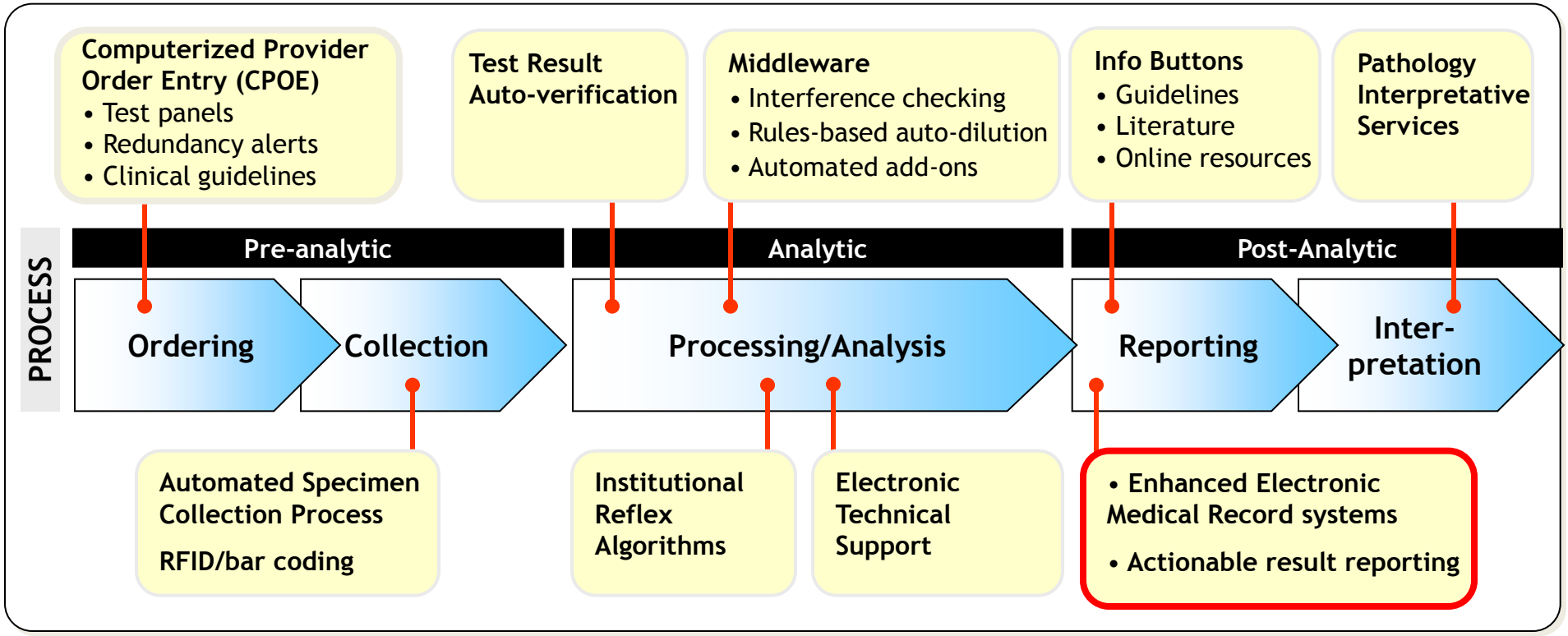
October 5, 2011

MASSACHUSETTS GENERAL HOSPITAL
1811 - 2011

Information Processing in the Laboratory Testing Process



Outline

- Failure in test result management is common
- Pathology is well positioned to take on a leadership role to ensure that our test results translate into action
- Requires attention to the entire testing process (pre-ordering to action taken)
- A multi-disciplinary approach is required to address this issue

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

What Are "Actionable" Test Results?

- Includes not only critical values but also results that do not pose immediate risk, but require action to avoid potential morbidity/mortality
- Examples of actionable (but not critical) results: highly elevated TSH, positive HCV antibody, pulmonary nodule, abnormal pap smear
- Actionable, non-critical results may be at highest risk of falling through the cracks due to the heightened awareness and external regulatory attention on critical values

A Few Examples of "Dropped Balls"

- Elevated PSA in a 54 year-old man that was never reviewed
  - Patient developed widespread disease 2 years later
- Patient with acute cholecystitis with an "incidental" ovarian mass seen on CT scan and not followed up
  - 12 months later patient diagnosed with ovarian cancer
- 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
- 45-year old male admitted with fever, discharged with pending blood cultures. Culture turned positive for MRSA but not followed up, readmitted 4 weeks later with septic shoulder and spinal osteomyelitis

Anecdotes or a Reflection of the Norm?

- **In a wide variety of outpatient settings 7% of actionable test results are never communicated to the patient**
  - **EMR use did not correlate with better performance**

Archives of Internal Med (2009) 169: 1123

- **Pending tests at transitions of care**
  - **Nearly 5% of patients have actionable test results post discharge from ED or inpatient care**
  - **Follow-up is poor for these results**

Annals of Internal Med (2005) 143: 121

Partners Healthcare Malpractice Experience

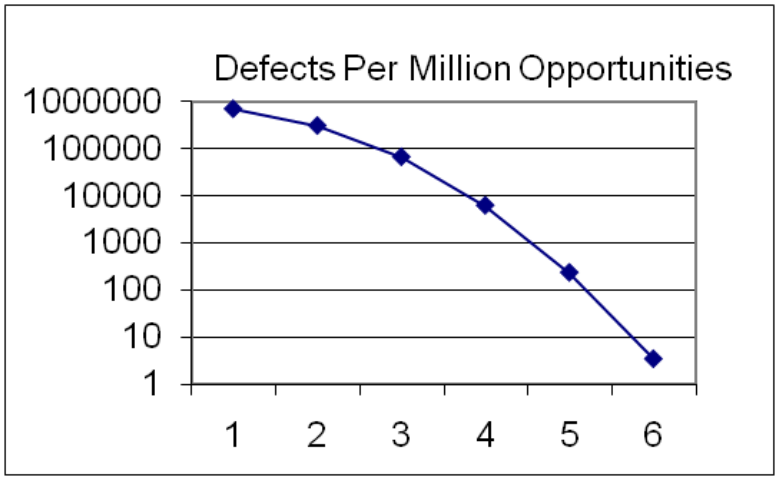
- From 2004-2008, 151 malpractice claims cited a diagnosis-related error as the major allegation
- 22 were related to receipt and transmittal of test results, accounting for nearly $16 million in incurred costs
- Errors related to lab test results (14 cases, $8.9 million) were most common, followed by radiology (9 cases, $6.8 million)
- The vast majority of the diagnosis-related cases (92%) occurred in the ambulatory setting and involved actionable, but not critical results

Safety Reporting Systems

- Voluntary error reporting systems are completely inadequate
  - Capture less than 1% of actual errors
  - May even be counterproductive, with sentinel events receiving priority that may not be justified
- Diagnostic testing errors should be proactively screened for using all available front line data
  - Order entry data, mislabeled specimens, amended reports, cancelled tests, refused tests, unreceived orders, testing delays
- Laboratories have sufficient scope to pursue data analytics and create the infrastructure necessary to improve result management

Six Sigma

- **Emphasis in six sigma is hitting the target (specification)**
- **Primary goal is to continually improve the process and <u>reduce process variation</u>**



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 (machine and/or data)

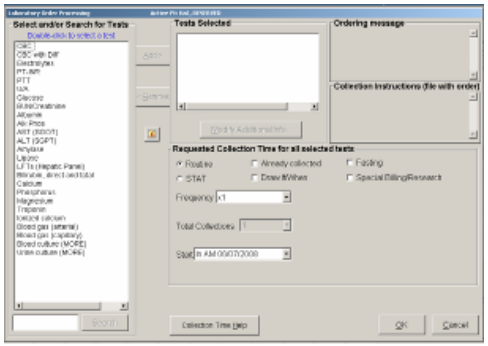
Automation

- Automation is a useful tool for improving quality
- Pathology 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

Error-Free, Paperless Pathology

Laboratory Order Communication and Core Laboratory Automation

Provider Order Entry



- Electronic order communication from Provider Order Entry to the laboratory information system
- Bar coded tubes to go directly onto automation line
- On automation line, tubes automatically processed, analyzed, resulted, auto-verified, and results sent to EMR with no human intervention

Bar coded specimen

MGH Core Laboratory Automation Line

Medical Error = Communication Failure

- **Single most common error cited in high-risk professions from aviation to medicine: *the failure to share key pieces of information***
- **30% of diagnosis related malpractice cases specifically involve the receipt and transmission of test results**
- **Errors are rooted in the lack of robust systems to support clinicians in test result management**
  - **Systems to ensure ordered test was indicated, completed, reviewed, communicated to the patient, and a follow-up plan executed**
  - **Must address the entire process**

Quality Controls Cost

- Applying Quality Improvement tools to the entire process is now required for survival in industry
- The major insight used by the Japanese to dominate numerous industries in the 1960's was that higher quality products are cheaper to produce (build it right the first time; less rework, QA, and scrap)
- In healthcare there are few current incentives for high quality
- How do you design for safety and quality?

Respect Human Limits in Process Design

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- **Avoid reliance on vigilance**
- **Use constraints and forcing functions**
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Misaligned Incentives

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

- 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

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 adding work processes

Pathology Key Value Adding Processes

- Test ordering
- Patient identification
- Specimen collection
- Processing, analysis
- Result reporting
  - Actionable test result reporting

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

System Level Thinking

Identifying Processes of Care in a Hospital

- "Consumptive processes of care"
  - Pharmacy, blood bank (products), dietary
- "Procedure/protocol driven processes of care"
  - Surgery, inpatient care
- "Information generating processes of care"
  - Pathology
  - Radiology
  - Diagnostic cardiology

Information Generating Processes of Care

(Pathology/Radiology/Cardiology)

Each of these areas has similar needs:

- Order entry and decision support
- Patient identification
- Result generation
- Result management:
  - Communication of actionable results
  - Acknowledgement of results
  - Communication to patients
  - Follow-up plan for testing

Actionable Test Results Taskforce

- Co-chaired by a Pathologist and a Hospitalist
- Membership from all member hospitals
  - Result generating areas (RGAs): Pathology, Cardiology, Radiology
  - Medicine, PCPs, Information Systems, RMF
- Refined mission, scope and vision
- Reached consensus on key recommendations
- Formed permanent cross-specialty, multi-institutional team to implement key recommendations

Vision

100% reliable communication, acknowledgment, and follow up of all actionable test results for all Result Generating Areas in all settings (IP/OP/ED)

Task Force Recommendations

1. Standardize actionable test result policies and definitions across PHS
2. Create systems that foster robust identification of the patient's care team
3. Enhance results management/tracking systems for both providers and patients
4. Promote centralized quality reporting and metrics

Recommendation 1:

Standardization of Policies and Definitions

- **Standardize lists of actionable test results across result generating areas (labs, radiology, cardiology)**
- **Adopt Level 1, 2, 3 result categories to indicate the urgency of actionable test results**
  - **K > 8 is Level 1, positive MRSA swab level 2, pulmonary nodule is level 3**
- **Adopt a common set of timeframes for acknowledgement**
  - **60 min for level 1 results, 6 hours for level 2's, and 6 days for level 3's**

Recommendation 2:

Robust Identification of the Patient's Care Team

- A key building block is the reliable identification of the provider who can and should take action on an actionable test result.
- Maintain and update in real-time all members of a patient's care team, regardless of the patient's location (e.g. inpatient, outpatient, emergency department).
- Require each service, unit, or practice to create coverage and escalation hierarchies

Recommendation 2:

Robust Identification of the Patient's Care Team

Partners Responsible Provider Application

Recommendation 3:

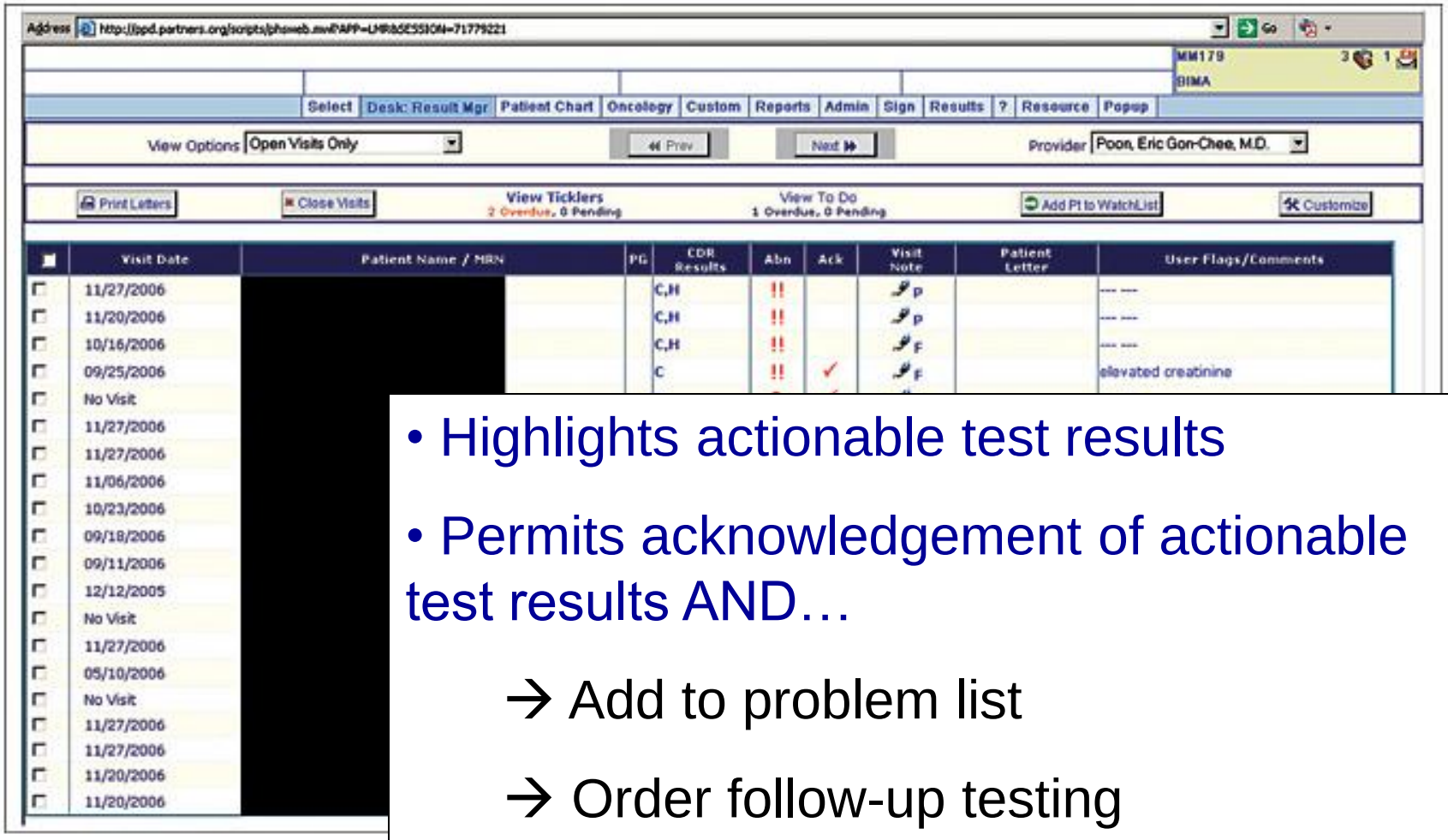
Enhanced Result Management/Tracking Systems

Enhance existing information systems utilized by Result Generating Areas (RGAs), providers, and patients

- Create functionality in the Clinical Data Repository (CDR) to flag results with levels 1/2/3
- Certain RGA systems upgraded to code results with the three recommended levels of flagging (levels 1, 2, 3)

GOAL: Permanently affix a flag to the test result to enable tracking and delivery of the flagged result to the responsible provider

Results Managers, Not Result Viewers



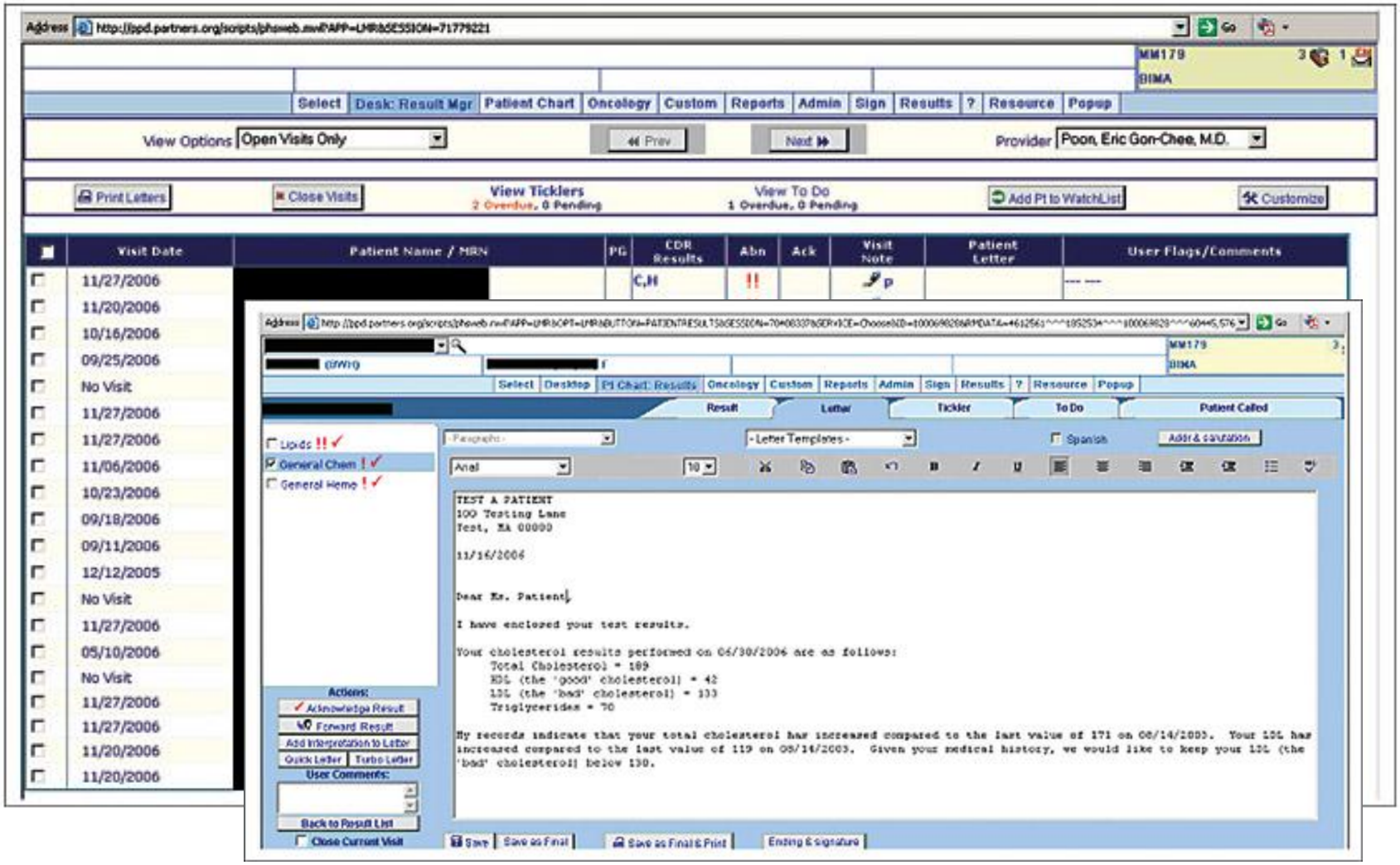
- Highlights actionable test results
- Permits acknowledgement of actionable test results AND…

→ Add to problem list

→ Order follow-up testing

→ Send patient letter

Results Managers, Not Result Viewers

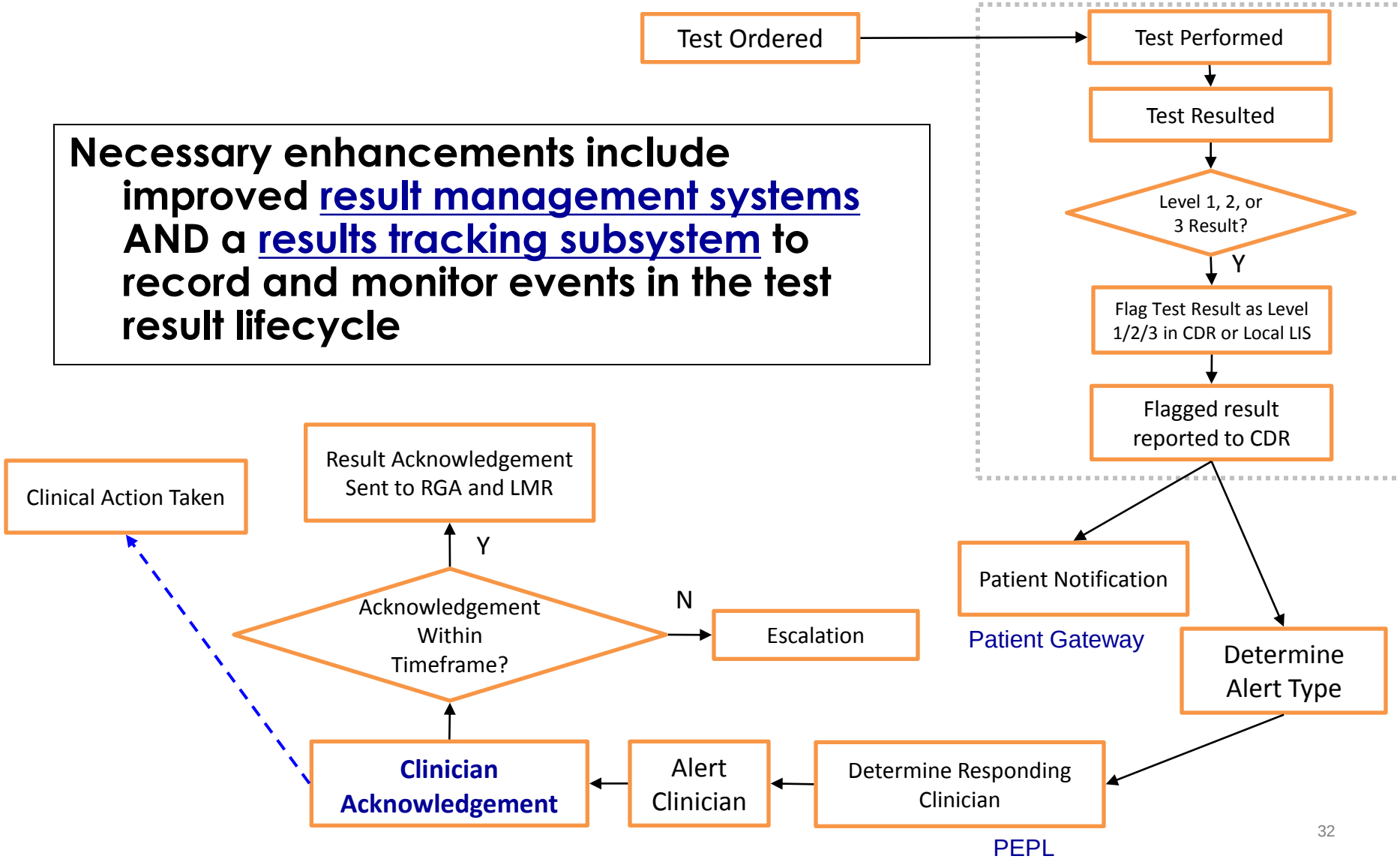


Involving the Patient ("Nothing about me without me")

- Patients should have online access to their test results (labs/radiology/cardiology) in addition to their meds/allergies/problem lists/clinical notes
  - "No news is NOT good news"
- Currently 13 States expressly prohibit release of lab results to patients but a proposed amendment to Federal Privacy Rule would require all states to provide access upon request
- Basic interpretive information should be provided with test results
- Patients may provide a backstop for medical errors
  - Improved satisfaction, better follow-up in some instances
- National plans for PHRs will not be successful without interoperability/standards for data exchange

Closing the Loop

Necessary enhancements include improved result management systems AND a results tracking subsystem to record and monitor events in the test result lifecycle



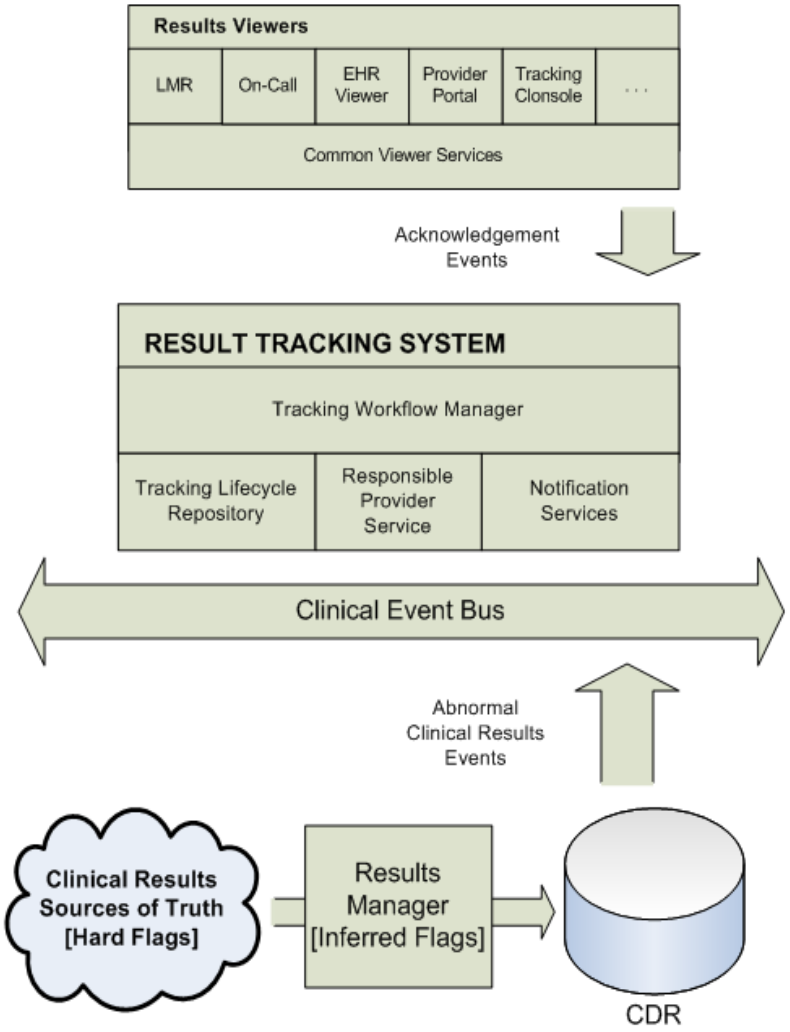
Acknowledgement May Not Be Enough

- **In one system with an advanced notification system (VA) timely follow-up was not significantly different for an acknowledged result versus an unacknowledged result**
- **Many providers were unaware of system features; workarounds were abundant**
- **Need to link acknowledgement to clinical action**
  - **→ Add to problem list**
  - **→ Create patient letter**
  - **→ Order follow-up study**
  - **→ Create referral**

Amer J. of Medicine (2009) 123: 238.

JAMIA (2010) 17:71.

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 communicated to patient

(6) Clinical action taken

(7) Follow-up testing pursued

Creating results tracking system to enable measurement of steps 4-7

Recommendation 4:

Centralized Quality Reporting and Metrics

- **The process of test result management must be measurable and quantifiable**
- **The attachment of permanent flags to results is a prerequisite for centralized analysis**
- **Metrics regularly provided to result-generating areas and quality and safety offices**
- **Actionable test result tracking metrics for all Partners sites added to the Partners quality dashboard with system wide performance goals set**
  - **e.g. % of new pulmonary nodules communicated, acknowledged, and with follow-up plans within 90 days**

Lessons Learned

- **Assess the entire process of result management**
  - **Use forcing functions in order entry systems to improve utilization and reduce redundant testing**
- **Build result managers, not result viewers**
  - **Should be designed to support clinical and administrative processes**
  - **Integrated into daily workflow**
- **Standards/policies are essential**
  - **Define Level 1, 2, 3 alerts**
  - **Create policies for result acknowledgment, handoffs, escalation**
- **Communicate results to the patient**
- **Create tracking systems that capture the relevant data for analysis/metrics and provide visibility**

Thank You

MGH Pathology

- Kent Lewandrowski

Partners

- Irina Kamis
- Erin Graydon Baker

MGH Medicine

- Andy Karson

BWH Medicine

- Chris Roy

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