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

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Information Processing in the Laboratory Testing Process

Pre-analytic
- Ordering
  - Automated Specimen Collection Process
  - RFID/bar coding
- Collection

Analytic
- Processing/Analysis
  - Institutional Reflex Algorithms
- Middleware
  - Interference checking
  - Rules-based auto-dilution
  - Automated add-ons

Post-Analytic
- Reporting
  - Info Buttons
    - Guidelines
    - Literature
    - Online resources
  - Pathology Interpretative Services
- Interpretation
  - Enhanced Electronic Medical Record systems
  - Actionable result reporting
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
  o Patient developed widespread disease 2 years later

• Patient with acute cholecystitis with an “incidental” ovarian mass seen on CT scan and not followed up
  o 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
  o EMR use did not correlate with better performance

Archives of Internal Med (2009) 169: 1123

• Pending tests at transitions of care
  o Nearly 5% of patients have actionable test results post discharge from ED or inpatient care
  o 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 reduce process variation

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### 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

- **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**

Provider Order Entry

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

- Avoid reliance on memory
- Avoid reliance on vigilance
- Use constraints and forcing functions
- Simplify key processes
- Standardize work processes
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.
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
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
  o K > 8 is Level 1, positive MRSA swab level 2, pulmonary nodule is level 3

• Adopt a common set of timeframes for acknowledgement
  o 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

![MGH Care Team Detail](image)

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.

Clinical Action Taken

Result Acknowledgement
- **Y**
  - Acknowledgement Within Timeframe?
    - **Y**
      - Clinical Action Taken
    - **N**
      - Escalation

Alert Clinician

Determine Responding Clinician

PEPL

Test Ordered

Test Performed

Test Resulted

Level 1, 2, or 3 Result?
- **Y**
  - Flag Test Result as Level 1/2/3 in CDR or Local LIS
- **N**

Flagged result reported to CDR

Patient Notification

Patient Gateway

Determine Alert Type

N

Closing the Loop
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

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
  o Use forcing functions in order entry systems to improve utilization and reduce redundant testing

• Build result managers, not result viewers
  o Should be designed to support clinical and administrative processes
  o Integrated into daily workflow

• Standards/policies are essential
  o Define Level 1, 2, 3 alerts
  o 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

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BWH Medicine
• Chris Roy