DRIVING IMPROVED PATIENT OUTCOMES FROM THE CLINICAL LABORATORY

Seeding Knowledge for Tomorrow’s Labs
Paul L Epner
November 17, 2013
What is the lab’s mission?

To provide accurate, timely test results at the lowest possible cost

Where is the “patient?”
Operational efficiency is focused on reducing cost and systematic errors.

Clinical effectiveness is focused on improving patient outcomes.

Is our priority efficiency or effectiveness?
WHERE DO WE FOCUS OUR QUALITY AND PRODUCTIVITY IMPROVEMENT EFFORTS?

The nine steps in the performance of any laboratory Test. The brain-to-brain turnaround time loop.

Source: Lundberg, 1981
OWNERSHIP HAS BEEN NARROWLY FOCUSED

The nine steps in the performance of any laboratory Test. The brain-to-brain turnaround time loop.

Source: Lundberg, 1981
So what’s the problem?

OUR MEASURES IMPACT OUR MANAGEMENT?

- **Laboratory Turnaround Time (LTAT)** – starts when the sample arrives in the lab until the result is released in the LIS.

- **Sample Turnaround Time (STAT)** – starts when the sample is drawn and ends when the result is released in the LIS (complicated by Analyte Turnaround Time).

- **Order Turnaround Time (OTAT)** – starts when the order is entered into the first system or the requisition is generated and ends when the result is delivered to the ordering location.

- **Clinical Turnaround Time (CTAT)** – starts when the clinician asks for specific tests to be run or when a nurse institutes a clinical pathway and ends when the result is delivered to the clinician.
WHY NOT STAY LAB-CENTRIC?

Summary of ER Turnaround Time

<table>
<thead>
<tr>
<th>Patient</th>
<th>Diagnosis</th>
<th>Start Sample</th>
<th>Draw</th>
<th>Lab Receipt</th>
<th>Result Returned</th>
<th>MD Views Result</th>
<th>% Outside Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pt 1:</td>
<td>Chest Pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>73%</td>
</tr>
<tr>
<td>Pt 2:</td>
<td>Chest Pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>53%</td>
</tr>
<tr>
<td>Pt 3:</td>
<td>Chest Pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>46%</td>
</tr>
<tr>
<td>Pt 4:</td>
<td>Abdml/Rainbow</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>79%</td>
</tr>
<tr>
<td>Pt 5:</td>
<td>Lytes/CBC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>65%</td>
</tr>
<tr>
<td>Pt 6:</td>
<td>Hi Acuity ABG</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>66%</td>
</tr>
</tbody>
</table>

Minutes

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EXAMPLES OF TESTING IMPACT ON ER LOS ARE COMMON

- Patient on Coumadin having presented at the ER with vomiting and nausea was to be transferred to another hospital
- Desire for prudence put laboratory on the critical path to discharge

<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:39pm</td>
<td>Patient “Admitted” to ER</td>
</tr>
<tr>
<td>3:00pm</td>
<td>Labs Ordered and Collected</td>
</tr>
<tr>
<td>5:14pm</td>
<td>Samples Received in Lab</td>
</tr>
<tr>
<td>7:26pm</td>
<td>PT/INR* Result Requested by Physician</td>
</tr>
<tr>
<td>Approx. 9:30pm</td>
<td>PT/INR* Result Received</td>
</tr>
<tr>
<td>11:59pm</td>
<td>Patient transferred to another Hospital</td>
</tr>
</tbody>
</table>

Testing Process Impact on LOS

Note (*): PT/INR result was required prior to transportation of patient to another facility.
The problem with lab-centric

Shorter is not always better, but longer is “never” better!
THE VALUE CHAIN IS RELATIVELY SIMPLE

Clinical Question with Test Orders
- Clinician-driven
- Orders increasingly by CPOE with limited CDS added

Total Testing Process
- Multiple departments
- Sample collection through result release

Result Retrieval and Interpretation
- Clinician-driven
- Increasingly electronic
- Drives treatment and other procedures

The laboratory’s value will always be constrained by the appropriateness of the order and the utilization of the result
BREAKDOWNS HAPPEN AWAY FROM THE LAB
"It’s a simple stress test—I do your blood work, send it to the lab, and never get back to you with the results."

The New Yorker, February 4, 2013, p. 56
# USA Physician Survey: Dealing with Uncertainty in Test Ordering

<table>
<thead>
<tr>
<th>Activity</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review e-references</td>
<td>Utilized most often*</td>
</tr>
<tr>
<td>Review paper references</td>
<td></td>
</tr>
<tr>
<td>Refer to a specialist</td>
<td></td>
</tr>
<tr>
<td>See how patient evolves</td>
<td>Utilized often</td>
</tr>
<tr>
<td>Review practice guideline</td>
<td></td>
</tr>
<tr>
<td>Ask a laboratory professional</td>
<td>Utilized least often</td>
</tr>
</tbody>
</table>

*based on percent reporting that the activity occurred daily or at least once per week

Source: CDC Survey of 1200 primary care physicians, 2010
**USA Physician Survey**: 
**Dealing with Uncertainty in Result Interpretation**

<table>
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<tr>
<th>Activity</th>
<th>Utilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review patient history</td>
<td>Utilized most often*</td>
</tr>
<tr>
<td>Follow-up with patient</td>
<td></td>
</tr>
<tr>
<td>Review e-references</td>
<td></td>
</tr>
<tr>
<td>Order more tests</td>
<td>Utilized often</td>
</tr>
<tr>
<td>Refer to a specialist</td>
<td></td>
</tr>
<tr>
<td>Ask PCP or specialist</td>
<td></td>
</tr>
<tr>
<td>Review practice guideline or paper references</td>
<td>Utilized less often</td>
</tr>
<tr>
<td>Repeat the test</td>
<td></td>
</tr>
<tr>
<td>Ask a laboratory professional</td>
<td>Utilized least often</td>
</tr>
</tbody>
</table>

*based on percent reporting that the activity occurred daily or at least once per week

Source: CDC Survey of 1200 primary care physicians, 2010
Our value to patients falls into one of two domains.

**Diagnosis**
- Get Data
- Synthesize

**Monitoring**
- Get Data
- Synthesize
THE MEANING OF DIAGNOSIS IS EXPANDING

- Identifying the cause of symptoms (traditional)
- Predicting the risk of developing a problem
- Determining the best treatment
  - Antimicrobial susceptibility testing
  - Tumor typing
- Assessing the ability of the body to respond to treatments

Failures in diagnosis can have important consequences
Diagnostic errors are defined as misdiagnosis, missed diagnosis, or delayed diagnosis\(^1\)

Diagnostic errors occur in 10-15% of cases,\(^2\) with more than 50,000 DxE in primary care and 40-80,000 annual deaths in hospitals\(^3\)

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\(^3\)Newman-Toker DE. Measuring Diagnostic Errors in Primary Care - Invited Commentary. *JAMA Internal Medicine* 2013 February 25
MALPRACTICE CASES HIGHLIGHT THE PROBLEM

- 350,706 paid claims over 25 years
- Diagnostic errors were leading cause (28.6%) and highest proportion of total payments (35.2%)
- More often resulted in death than any other allegation groups (40.9%)
- Outpatient/Inpatient split was 68.8%/31.2%
- Failure to diagnose was largest proportion (54%) followed by delay in diagnosis (20%) and wrong diagnosis (10%)

Diagnostic errors are classified into one of three types

- **Cognitive Errors (74% in this study):**
  - Faulty knowledge
  - Faulty data gathering
  - Faulty synthesis

- **Systematic Errors (65%):**
  - Technical failures and equipment problems
  - Organizational flaws

- **No Fault Errors (7%)**
  - Masked or unusual presentation of disease
  - Patient-related error (uncooperative, deceptive)

THEY OCCUR ACROSS THE DIAGNOSTIC PROCESS

N= 583 Cases

“I may order 20 tests commonly and I may order an additional 10-20 tests [occasionally], so I may be using 40 tests that I feel comfortable that I’m not wasting time or money or resources.”
CAUSATIVE FACTOR: NOMENCLATURE

Vitamin D2
Vitamin D3
25-0H vitamin D2
25-0H vitamin D3
25-0H vitamin D
25 hydroxy vitamin D2
25 hydroxy vitamin D3
25 hydroxy vitamin D
1,25 (OH)2 vitamin D2
1,25 (OH)2 vitamin D3
1,25 (OH)2 vitamin D
1,25 dihydroxy vitamin D2
1,25 dihydroxy vitamin D3
1,25 dihydroxy vitamin D
Vitamin D 25 Hydroxy D2
Vitamin D 25 Hydroxy D3
Vitamin D 1,25 Dihydroxy
Calcifidiol
Calcidiol
Cholecalciferol
CAUSATIVE FACTOR: “ORPHAN” TEST RESULTS

- Study\(^1\) of 2644 patients at 2 tertiary care hospitals of which 1095 had 2033 test results (lab, radiology) return after discharge
- 191 of results were potentially actionable (9%)
- 61% of respondents with potentially actionable results were unaware of results
- A systematic review\(^2\) found failure to follow-up was a significant problem for in-patients, for in-patients being discharged and for ED patients.

The nine steps in the performance of any laboratory Test. The brain-to-brain turnaround time loop.

THE NEED FOR A NEW MODEL

- QI in laboratory has been heavily anchored to the B2B model
- Invites a process (TTP) focus; counting defects
- Measures are sensitive, but not specific for problems that impact patient outcomes
- Astion, O’Kane, Plebani, Schiff have all sought to shift to outcomes or specific causes
- An optimum approach would link outcomes to specific measures associated with root causes
**Five Causes Taxonomy of Testing-Related Diagnostic Error (TDE)**

<table>
<thead>
<tr>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>An inappropriate test is ordered</td>
</tr>
<tr>
<td>An appropriate test is not ordered</td>
</tr>
<tr>
<td>An appropriate test result is misapplied</td>
</tr>
<tr>
<td>An appropriate test is ordered, but a delay occurs</td>
</tr>
<tr>
<td>somewhere in the total testing process</td>
</tr>
<tr>
<td>The result of an appropriately ordered test is inaccurate</td>
</tr>
</tbody>
</table>

*Epner PL, Gans JE, Graber ML. When diagnostic testing leads to harm: a new outcomes-based approach for laboratory medicine. BMJ Quality & Safety. 2013 August 16 http://qualitysafety.bmj.com/content/22/Suppl_2/ii6.full.pdf+html*
**MEASURES ARE NEEDED**

<table>
<thead>
<tr>
<th></th>
<th>Diagnosis (new complaint)</th>
<th>Monitoring (Screening, Care Effectiveness)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order inappropriately</td>
<td>CK-MB</td>
<td>HPV</td>
</tr>
<tr>
<td>Fail to order appropriately</td>
<td>Algorithm compliance?</td>
<td>No TDM</td>
</tr>
<tr>
<td>Delays</td>
<td>TAT (order to action)</td>
<td>TAT (order to action)</td>
</tr>
<tr>
<td>Fail to apply appropriately</td>
<td>Change in diagnosis</td>
<td>Absence of follow-up</td>
</tr>
<tr>
<td>Inaccurate results</td>
<td>Corrected results</td>
<td>Corrected results</td>
</tr>
</tbody>
</table>
Diagnosis Detection: Repeat Serum Creatinine Results (2009-2011)

5,324 lab orders placed for patients with an abnormal creatinine not repeated within 90 days

2,565 total labs repeated within 90 days (48%)

1,311 abnormal results (51%)

1,078 New CKDs identified

Kanter – 2012 – “Reducing Diagnostic Errors By Closing The Loop On Outpatient Care”
INTerventions that **MAY** Improve diagnostic performance and bring value

- Inappropriate test ordered or appropriate test not ordered
  - CPOE design and monitoring
  - Algorithms, clinical pathways, guidelines
  - Reflex testing
  - Data mining
  - Inter-physician variance analysis
- Test result not utilized properly or fully
  - Interpretive comments
  - EMR interface
  - Trigger tools
- Test result delayed or not retrieved
  - Process monitor
  - Discharge monitor
KEY MESSAGES

- Diagnostic error is a major patient safety problem
- The total testing process is a significant source of diagnostic errors
- Effective laboratory-directed interventions are available
- Prioritization based on outcomes is needed
- Laboratory physicians and scientists have an opportunity to
  - Improve patient outcomes
  - Strengthen relationships with clinicians
  - Reduce the level of risk in the health system
  - Become indispensable stewards of clinical data
**Final Thought: The Goal**

The clinical lab’s mission **should not just be:**

To provide accurate, timely, low cost test results

**Although necessary, it is not sufficient**

The clinical lab’s mission **should be:**

To rapidly and efficiently enable the accurate **diagnosis** of conditions, the selection of appropriate **treatments** and the effective **monitoring** of health status*

* Epner, Paul, “Impact of Laboratory Services on Diagnostic Errors,” ThinkLab ‘11