

IMPACT OF LABORATORY SERVICES ON DIAGNOSTIC ERRORS

Diagnostic Errors in Medicine
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THE LABORATORY ROLE IN DIAGNOSIS IS UNCLEAR

- In a study* of 248 hospitalized patients, 246 had definitive diagnosis within 3 months of hospitalization.
- The primary determinant of diagnosis for 215 with “exact” in-hospital diagnosis was:
 - History and Physical – 48.4%
 - Radiologic exam – 33.5%
 - Blood test or culture – 9.8%
- Study limitations
 - did not examine diagnostic error
 - did not examine time to diagnosis
 - did not examine appropriate use of diagnostic tools

*Wahner-Roedler, D. L. et al. (2007). Who makes the diagnosis? The role of clinical skills and diagnostic test results. *Journal of evaluation in clinical practice*, 13(3)

EVIDENCE SUGGESTS THERE’S A PROBLEM

- There exists substantial regional variability in test ordering practices that cannot be explained by case mix¹
- A study of 583 diagnostic errors indicated that 44% occurred in the testing phase (lab and imaging)²
- Lab turnaround time remains a primary source of ED clinician dissatisfaction³ and is the second most cited cause of delayed treatment in Joint Commission Sentinel Event data (misdiagnosis is first)⁴

¹Song, Y. et al. (2010). Regional Variations in Diagnostic Practices. *New England Journal of Medicine*
²Schiff, G. D. et al. (2009). Diagnostic error in medicine: analysis of 583 physician-reported errors. *Archives of internal medicine*, 169(20)
³Hawkins, R. C. (2007). Laboratory turnaround time. *The Clinical biochemist. Reviews / Australian Association of Clinical Biochemists*, 28(4).
⁴Joint Commission Sentinel Event Alert (2002) Issue 26

FURTHER EVIDENCE WAS FOUND IN A ONE WEEK UNPUBLISHED STUDY*

- Vanderbilt University Medical Center
- Reviewed one week of consultation requests
- Involved 53 cases
 - 29 cases had appropriate test orders
 - 19 cases had incomplete test orders (36%)
 - 5 cases had inappropriate test orders (9%)
- Of 24 cases where tests were added or deleted following consultation, the diagnosis was impacted in 2 cases. The timing of the diagnosis in the other cases was not impacted only because of the near real-time addition of tests.

*Information and analysis provided by Jennifer M. Giltane, MD, PhD and Michael Laposata, MD, PhD, Vanderbilt University Medical Center

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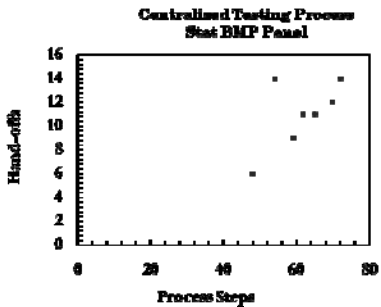
EXAMPLE: CASE REPORT

- 2 y/o presents with a history of one severe nosebleed
- Family history +VWD
- OSH labs show:
 - PTT 56 sec
 - Factor VIII act: 33%
- MD ordered platelet function study to confirm VWD
- DMT consult requested
- Abnormal Coagulation Interpretation (ACI) panel with reflex testing added
- Revealed lupus anticoagulant as alternative diagnosis, explaining both abnormal labs
- Bleeding episode likely unrelated to labs

*Information and analysis provided by Jennifer M. Giltane, MD, PhD and Michael Laposata, MD, PhD, Vanderbilt University Medical Center

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THE TESTING PROCESS IS MORE COMPLEX THAN THE “HICKNER MODEL” SUGGESTS*



*unpublished study of orders originating in ED

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**TEST SELECTION COMPLEXITY:
NOMENCLATURE**

- High Sensitivity CRP synonyms
 - Ultrasensitive CRP
 - Cardiac CRP
 - Test abbreviations: hsCRP, CRH, HSC
 - Alkaline Phosphatase synonyms
 - Alkaline Phos blood
 - Alkaline phosphomonoesterase
 - Alkaline phosphohydrolase
 - Alkaline phenyl phosphatase
 - Test abbreviations: ALP,Alk Phos, AP, AKP
 - Within single physician office, multiple test synonyms are used driven by multiple payers
- "If I want Panel A it should look like Panel A in another lab and maybe you've ordered the right panel but now they've changed insurance and you're ordering from a different lab. How [do you] identify what you're getting?"*

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NOMENCLATURE OPTIONS FOR VITAMIN D

Vitamin D2	1,25 dihydroxy vitamin D2
Vitamin D3	1,25 dihydroxy vitamin D3
25-OH vitamin D2	1,25 dihydroxy vitamin D
25-OH vitamin D3	Vitamin D 25 Hydroxy D2
25-OH vitamin D	Vitamin D 25 Hydroxy D3
25 hydroxy vitamin D2	Vitamin D 1,25 Dihydroxy
25 hydroxy vitamin D3	Calcifdiol
25 hydroxy vitamin D	Calcidiol
1,25 (OH)2 vitamin D2	Calcidiol
1,25 (OH)2 vitamin D3	Cholecalciferol
1,25 (OH)2 vitamin D	

"I was forced to look through all these panels and frankly I had no idea which one it was ...I was totally frustrated. They had 6 different things that all looked the same to me. And if you called them to find out...that would be hopeless."

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**THE LITERATURE CONTAINS
INTERVENTIONS THAT REDUCE TEST
ORDER AND RESULT INTERPRETATION
ERRORS**

- Guidelines/Clinical Pathways
 - National and locally developed
 - With or without electronic decision support
- Structured requisitions
- Reflex testing
- Consultations
- Interpretive comments

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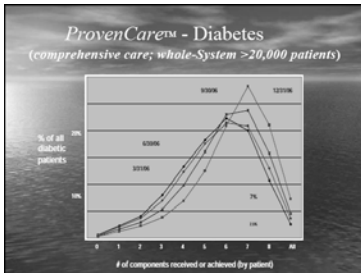
GEISINGER USES LOCALLY DEVELOPED GUIDELINES WITH CLINICAL DECISION SUPPORT*



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* Jones, Jay, "Lab Enterprise Analytics," Executive War College 2009

ORDERING PATTERNS HAVE CHANGED*



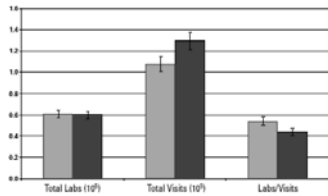
* Jones, Jay, "Lab Enterprise Analytics," Executive War College 2009

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"I can't tell you that I routinely pull those [guidelines] out and follow through... rarely, don't have enough time."

REQUISITION DESIGN*

- o Design changes focused on medical necessity, reduction in panels, test groupings linked to specialty, etc.
- o Reduction in tests per visit occurred
- o No assessment of impact on Dx errors was made



*J.F. Emerson and S.S. Emerson, "The impact of requisition design on laboratory utilization," *American Journal of Clinical Pathology*, vol. 116, Dec. 2001.

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INTERPRETIVE COMMENTS

- Criteria for providing interpretive comments have been described¹
 - a decision on treatment is indicated by the results in combination with the clinical details provided
 - a result is unexpected
 - a specific question has been posed but it is not obvious whether the results provide the answer
 - a clinician has requested a test with which he/she is not likely to be familiar
- Seventy percent of clinicians surveyed report the use of interpretive comments reduced misdiagnosis or sped up diagnosis²

¹E. Piva and M. Plebani, "Interpretative reports and critical values," *Clinica chimica acta; international journal of clinical chemistry*, vol. 404, 2009.
²M.E. Laposata, M. Laposata, E.M. Van Cott, D.S. Buchner, M.S. Kashalo, and A.S. Dighe, "Physician survey of a laboratory medicine interpretive service and evaluation of the influence of interpretations on laboratory test ordering," *Archives of pathology & laboratory medicine*, vol. 128, Dec. 2004.

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WHAT WE DON'T KNOW

- What is the prevalence of cognitive diagnostic errors triggered or impacted by the testing process?
 - Failure to order necessary tests
 - Ordering of unnecessary tests
 - Inappropriate utilization of test results
- What are effective interventions that reduce cognitive diagnostic errors and could be initiated by laboratory professionals?
 - What settings are appropriate for these interventions?
 - What limitations exist in the use of these interventions?
 - What new sources of errors are created by the interventions?

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THE PATH FORWARD: CLIHC™

- A survey of medical schools to understand curricular changes since 1992 involving labs
- A survey of primary care clinicians to quantify the barriers to appropriate laboratory utilization
- An initiative to define nomenclature issues and develop a thesaurus in the absence of standardization
- An initiative that will develop and publish algorithms to guide clinicians in the use of complex tests
- An initiative that will seek research funds to experimentally determine the effectiveness of laboratory interventions on diagnostic error reduction (ITSRI)

*CLIHC: Clinical Laboratory Integration into Healthcare Collaborative

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