

Enhancing Laboratory Communication to Reduce Extra-analytical Errors

What must entry-level Medical Laboratory Scientists Know About Diagnostic Errors?

George A. Fritsma, MLS

Director of Medical Laboratory Education
BioMedica Diagnostics Inc., Windsor, Nova Scotia
www.fritsmafactor.com~george@fritsmafactor.com



The Fritsma Factor

Chronic Cough with Chest Pain

- You see your primary care physician for a 2-week cough with mild chest pain. To diagnose, she...
 - Documents Hx, records vitals plus O₂ sat, performs physical exam with auscultation of chest and abdomen
 - Develops a preliminary differential diagnosis
 - Sends you for an ECG and chest x-ray
 - Sends you to the lab for "blood work"
 - Starts Rx while awaiting results
- 24-h diagnosis: bronchitis



The Fritsma Factor

2

What Tests Could Influence Diagnosis?

- ECG, troponin I or T: acute myocardial infarction
- Chest x-ray: R/O pneumonia (confirms auscultation), cancer, pulmonary embolus
- D-dimer, spiral tomography: R/O pulmonary embolus
- CBC, PT, PTT, UA, metabolic panel, liver panel: no indication-based information, ran anyway, "just to be sure"



Hallworth M. The (true) value of laboratory medicine. Thepathologist.com/issues/2015, accessed 12-31-16.
The Fritsma Factor

3

"Lab Results Are the Basis for 70% of Medical Decisions"

- Widely quoted myth from the "data-free zone"
- Mayo Clinic EHR per-patient data, 2000
 - 90% pathology, 3% radiology (pre-electronic images, now more), 1% "patient data," 1% surgery.
- Aurora Health Systems, Milwaukee, 2010
 - Lab data occupies 82% of EHR data bits
- Lab costs consume 5% of total medical costs
 - Documentation from Medicare billing database

Forsman RW. Why is laboratory an afterthought for managed care organizations? Clin Chem 1996;37:1244-48.
Forsman RW. The electronic health record: implications for the laboratory. Clin Leadership Manag Rev 2000;14:292-5.



The Fritsma Factor

4

The Effective Lab Test...

- Is selected to address clinical indications
- Confirms or rules out predicted outcomes
 - Helps establish diagnosis
 - Affects selection of therapy
 - Improves outcome
- Causes no harm



The Fritsma Factor

5

Survey of US Primary Care Physicians

- Estimated 500,000,000 PCP patient visits per year
- 1800 PCPs surveyed, mean age 51; years in practice, 21; avg patients seen per week, 81 each
- Averaged 25 diagnostic lab tests/week, 31% of pts
- Uncertain about what test (s) to order: 14.7% of pts who needed diagnostic tests
- Uncertain about how to interpret results: 8.3%
- Potential 23,000,000 incorrectly ordered or interpreted tests/year

Marques MB, Hickner J, Thompson PJ, Taylor JR. Primary care physicians and the laboratory; now and the future. Am J Clin Pathol 2014;142:738-40.



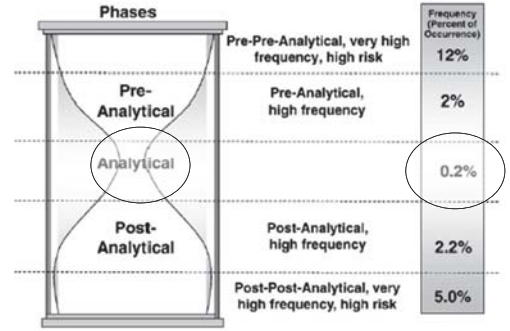
The Fritsma Factor

6

Post-analytical Diagnostic Errors

- Types of errors that occur after results are delivered
 - Incorrect interpretation, 37%; inappropriate or inadequate follow-up, 45%; failure to refer, 26%
- Factors contributing to errors
 - Inadequate judgment, 70%; vigilance or memory, 59%; knowledge, 48%; patient-related, 46%; handoffs, 20%
 - Multifactorial: 54% of errors involve 3 process breakdowns; 29%, 4 or more
 - Multi-clinician: 43% of errors involve 2 or more physicians; 16% 3 or more
- Wall Street Journal, 2013: *"Patients would be safer if doctors did not ...diagnose alone. Physicians should...bring pathologists and radiologists into the loop to make sure the correct test is ordered and the right diagnosis is offered."*

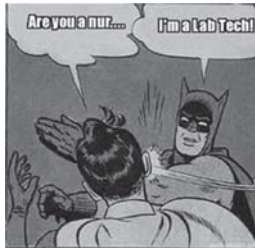
Where are the errors?



Stroobants AK, Goldschmidt HM, Piebani M. Error budget calculations in laboratory medicine: linking the concepts of biological variation and allowable medical errors. Clin Chim Acta 2003;333:169-76.

How do PCPs Deal with Lab Test Interpretation Uncertainty?

- Review patient history: 70%
- Follow up with patient: 66%
- Review e-references: 46%
- Order more lab tests: 34%
- Refer to a specialist: 29%
- Consult fellow PCP: 23%
- Check guidelines and references: 22%
- Repeat the same test: 19%
- Consult with lab professional: 6%
 - Helpful? 35%



What PCPs Hate about Labs

- Confusing test names
- Slow turnaround time
- Can't access prior results
- Reference interval variation: no harmony
- Report info and format variation
- Whom to call?



MB Marques, MD, "I know for certain that most of my relevance as a member of the medical staff stems from my direct relationships and collaboration with physicians from other departments."

Lab Scientist–Clinician Communication

- How does lab science improve patient experience?

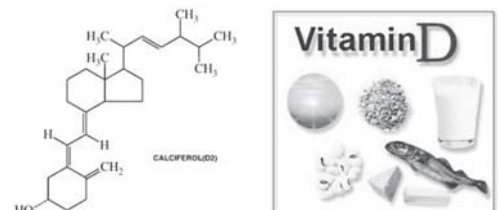


"This concludes my lecture on non-verbal communication. Any comments or questions?"

Rose AM. What have we learned about vitamin D? MLO 2017. pp 18-22

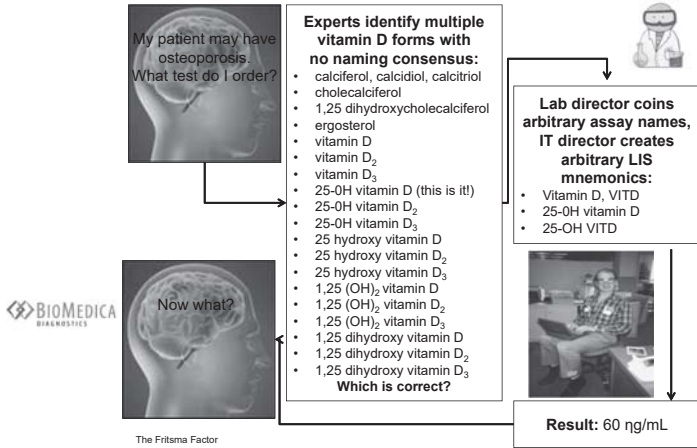
Test Names

An order arrives with a serum-separator tube requesting "Vitamin D." How do you log it?



- Kleerekoper M, Schleicher RL, Eisman J, et al. Clinical applications for vitamin D assays: what is known and what is wished for. Clin Chem 2011;57:1227-32.
- Passiment E, Meisel JL, Fontanisei J, Fritsma GA, Aleryani S, Marques, M. Decoding laboratory test names: a major challenge to appropriate patient care. J Gen Intern Med DOI 10.1007/s11606-012-2253-8

Test Names: The Vitamin D Puzzle



What's in a name?



More Pre-analytical Issues What to Do?

- PTT ordered for LMWH, fondaparinux, rivaroxaban, dabigatran, how to test for DOACs?
- Order PT and PTT when LA present?
- LA, LAC, DRVVT screen, DRVVT confirm, Sta-Clot LA; PTT-AL, what does it all mean?
- What is in a thrombophilia profile?
- What is VWF:RCo, VWF:act, VWF:ag, VWF:imm, VWF:coll, VWF multimers, VWF:etc?



Assistive Algorithm

- IOM says, "facilitate more effective teamwork in the diagnostic process among health care professionals, patients, and their families"
- Partner to produce robust laboratory test utilization
- Assistive algorithm: clinician selects or enters indications gathered from patient Hx and physical.
- Algorithm returns recommendations for tests and test profiles, from which physician makes choices.

Indication-based Laboratory Utilization

- Team of clinical and technical practitioners establishes algorithms
- Hemostasis indication examples
 - Current complaint—chest pain, shortness of breath, bruising, swollen leg
 - History of prior events, first-degree relatives
 - Age, sex, BMI, race, habits
- List applicable hemostasis assays: D-D, PT, PTT, TT, FG, PC, PS, factor assay, PLT count, PLT aggregometry
- List hemostasis assay profiles: thrombophilia, anatomic bleeding, systemic bleeding, arterial thrombosis
- Match selected lists of indications with hemostasis laboratory assays and profiles.

Example: Thrombophilia Profile

Assay	Patient	RI
Protein C activity	35%	>70%
Protein S activity	39%	>65%
Antithrombin activity	57%	78–126%
Factor VIII	125%	50–186%
APCR	2.4	>1.8
Factor II 20210	Wild-type	Wild-type
PTT-LA	39 s	30–40 s
Homocysteine	3.9 ηmol/L	<4.3 ηmol/L

60-YO man, DVT; Coumadin 3 W

- Triple heterozygote?
- Increase Coumadin?
- Start heparin?
- Consult with the lab?



Thrombophilia Profile Narrative Report

Assay	Patient	RI
Protein C activity	35%	>70%
Protein S activity	39%	>65%
Antithrombin activity	57%	78–126%
Factor VIII	125%	50–186%
APCR	2.4	>1.8
Factor II 20210	Wild-type	Wild-type
PTT-LA	39 s	30–40 s
Homocysteine	3.9 η mol/L	<4.3 η mol/L

Or: "Protein C, S, and AT appear deficient, probably Coumadin interference, reflex INR = 2.1, suggesting Coumadin is present. Other risk factor assay results are within reference interval. No evidence for thrombotic risk, repeat profile 2 weeks after discontinuing Coumadin."



The Fritsma Factor

19

Pre-op Screen

Assay	Patient	RI
HGB	14.2 g/dL	13.5–15.6 g/dL
PTT	59 s	25–35 s
PT	12.4 s	9.8–12.6 s
TT	18.2 s	<21 s
PLT count	310,000/ μ L	250–450,000/ μ L
Fibrinogen	270 mg/dL	150–400 mg/dL
No bleeding Hx, surgeon postpones		

- Heparin present?
- Risk: bleeding? Thrombosis?
- Repeat PTT until negative?
- Consult with laboratory?
- Laboratory immediate reflex to...



The Fritsma Factor

20

Pre-op Screen: How About This?

Assay	Patient	RI
HGB	14.2 g/dL	13.5–15.6 g/dL
PTT	59 s	25–35 s
PT	12.4 s	9.8–12.6 s
TT	18.2 s	<21 s
PLT count	310,000/ μ L	250–450,000/ μ L
Fibrinogen	270 mg/dL	150–400 mg/dL
No bleeding Hx, surgeon postpones procedure		

"Isolated prolonged PTT may indicate coagulation factor deficiency, coagulation factor inhibitor, or lupus anticoagulant. Normal TT indicates no heparin present. Laboratory reflex to PTT mixing study, results follow."



The Fritsma Factor

21

Mixing Study: New Specimen, Next Day

Assay	Result	RI	Comment
PTT	57 s	25–35 s	Confirms prior PTT
PTT/NP 1:1 immediate mix	38.5 s	NP 27.5 s	Mix is >10% prolonged over the normal plasma

- Uncorrected?
- Should lab have done incubated mix?
- Do you send this result to the surgeon?
- Continue to delay surgery?
- Consult with laboratory?
- Laboratory immediate reflex to...



The Fritsma Factor

22

Mixing Study: How About This?

Assay	Result	RI	Comment
PTT	57 s	25–35 s	Confirms prior PTT
PTT/NP 1:1 immediate mix	38.5 s	NP 27.5 s	Mix is >10% prolonged over the normal plasma

Interim report: "Patient plasma mixed 1:1 with normal plasma, PTT performed immediately after mix remains prolonged (uncorrected). Presumptive evidence of lupus anticoagulant. LA profile follows."



The Fritsma Factor

23

LA Profile: Third Day of Hospital Stay

Assay	Result	RI	Comment
PTT-LA	47.9 s	30–40 s	Confirms PTT
PTT-LA/control 1:1	38.5 s	Control 34.5 s	Possible LA
Staclot LA kit	12 s	> 8 s correction	Confirms LA
DRVVT	52.5 s	35–45 s	Possible LA
DRVVT confirm	1.4 ratio	> 1.2 correction	Confirms LA

- Send this result to the surgeon w/o comment?
- Delay surgery?
- Consult with laboratory?



The Fritsma Factor

24

LA Profile: How About This?

Assay	Result	RI	Comment
PTT-LA	47.9 s	30–40 s	Confirms PTT
PTT-LA/control 1:1	38.5 s	Control 34.5 s	Possible LA
Staclot LA kit	12 s	> 8s correction	Confirms LA
DRVVT	52.5 s	35–45 s	Possible LA
DRVVT confirm	1.4 ratio	> 1.2 correction	Confirms LA

Or: "Patient plasma tested using LA-sensitive PTT reagent and dilute Russell viper venom reagent, both prolonged, both corrected by high phospholipid neutralization reagent, confirming LA. No bleeding risk, may indicate thrombosis risk if LA is chronic. Repeat after 12 weeks to determine persistence."



Web-based Narrative Reports

- Reporting system with 119 coagulation & 38 thromboelastography synoptic templates.
 - HTML, made interactive through JavaScript
- Enter up to 29 coag findings: PT, PTT, TT, PLT count and aggs, VWD profile, LA profile, more
- Enter TEG findings: R, α , MA, Ly30, shake and bake
- "Baseline PTT is prolonged, corrected with mix, TT is normal. Impression: results intrinsic pathway factor deficiency: VIII, IX, XI, XII, VWF. CPT 85390."



Quesada AE, Jabuga CE, Nguyen A, et al. Interpretation of coagulation test results using a web-based reporting system. *Lab Medicine* 2014;45:343–56.

Am Board of Internal Medicine
& Consumer Reports: ASCP



An initiative of the ABIM Foundation

- Don't screen for 25-OH-vitamin D deficiency.
- Avoid routine preoperative testing for low risk surgeries without a clinical indication.
- Don't use the bleeding time test to guide patient care.
- Use C-reactive protein (CRP) for acute inflammation in patients with undiagnosed conditions.
- Don't test vitamin K levels unless the patient has an abnormal INR and doesn't respond to VK therapy.
- Use only troponin I or T in the diagnosis of acute myocardial infarction (AMI).



CEO Blair Holladay notes: every agency gave lab assay utilization comments.

Am Board of Internal Medicine
& Consumer Reports: ASH



An initiative of the ABIM Foundation

- Don't transfuse more than the minimum RBC units necessary to relieve symptoms of anemia or to return a patient to a safe HGB range—7–8 g/dL in stable, non-cardiac in-patients.
- Don't test for thrombophilia in adult patients with VTE who have major transient risk factors—surgery, trauma, immobility.
- Don't test or treat for heparin-induced thrombocytopenia (HIT) in patients with a low pre-test probability of HIT.



Am Board of Internal Medicine
& Consumer Reports: AABB



An initiative of the ABIM Foundation

- Don't transfuse red blood cells for iron deficiency without hemodynamic instability.
- Don't routinely use blood products to reverse warfarin.
- Don't perform serial blood counts on clinically stable patients.
- Don't transfuse O negative blood except to O negative patients and in emergencies for women of child bearing potential with unknown blood group.



Am Board of Internal Medicine
& Consumer Reports: More



An initiative of the ABIM Foundation

- American College of Chest Physicians
 - Don't order diagnostic tests at regular intervals (such as every day), but rather in response to specific clinical questions.
- Society for Maternal-Fetal Medicine
 - Don't do thrombophilia evaluation for women with histories of pregnancy loss, intrauterine growth restriction (IUGR), preeclampsia and abruption.
- Society for Vascular Medicine
 - Don't order hypercoagulable testing for patients who develop first episode of DVT in the setting of a known cause.

