

Ordering the Right Lab Test: It all begins with the Right Test Name

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Professor, Baylor College of Medicine

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Medicine

No Conflicts of Interest

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Objectives

1. Recognize that many Lab Test Utilization Management programs utilize **Lab Test Name Change as a major tool**
2. Recognize that the **names of lab tests** lead to considerable confusion in ordering
3. Analyze and participate in a **process to create lab test names that are easy** to understand, use and make widely available

Patient Harm Related to Lab Services

1. Ordering the wrong test
2. Failing to retrieve a result
3. Misinterpreting a result

Dickerson *et al*, 2017, JALM, 02:02:259-68

One of out Eight malpractice claims feature failures to order or correctly interpret test results

1. Failure to order the right test (55%)
2. Misinterpret a result (37%)
3. Failure to retrieve/receive result (13%)

Gandhi TK et al, Ann Intern Med. 2006;145:488-496

Inappropriate Test Orders are Common

- 10%–30% of lab tests performed in the US are either unnecessary or incorrect
- ~ 30% of genetic test orders are inappropriate
- ~ 5% of genetic test orders are frank medical errors

Zhi M et al. PLoS ONE 2013, 8:1– 8

Miller CE et al, Am J Med Genet A 2014, 164:1094 – 101

Mathias PC et al, Am J Clin Pathol 2016, 146:221– 6

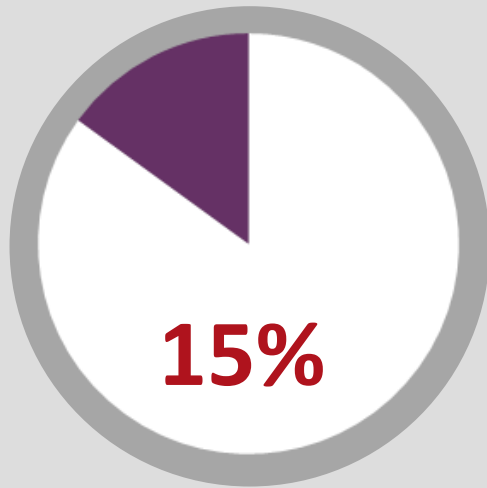
National Academy of Medicine (IOM) Study

Unnecessary lab tests cost an
average hospital **\$1.7 million a year**

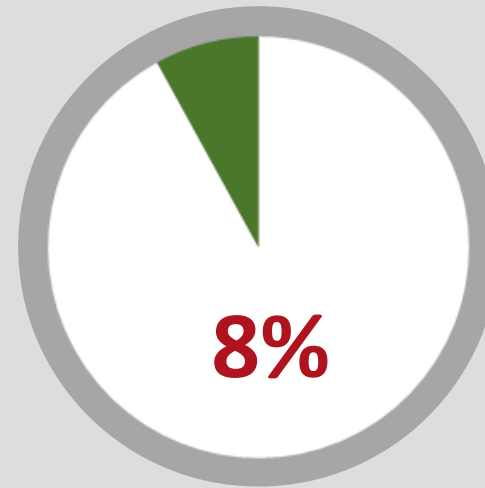
For a 800 bed hospital system = \$8.5 million/year

Uncertainty in Ordering Lab Tests

Study of 1,768 US primary care physicians ¹



Uncertain about **which test**
to order



Uncertain about **interpreting**
the results

¹. Primary Care Physicians' Challenges in Ordering Clinical Laboratory Tests and Interpreting Results, Journal of the American Board of Family Medicine, Mar-Apr, 2014

Why the Uncertainty?

- Laboratory tests **Increased > 4000**
- Test names are confusing *
- Lab Medicine teaching **Reduced**
hours in medical school **Sometimes to zero**

* Passiment et al, Decoding laboratory test names: a major challenge to appropriate patient care, J Gen Intern Med. 2013;28:453-8.

Why the Uncertainty?

Vitamin D

25 hydroxy Vitamin D

1, 25 dihydroxy Vitamin D

How do Clinicians Compensate for this Uncertainty?

Order more tests

Use the 'H' and 'L' approach

Laboratory Test ~~Utilization Management~~

Ordering
fewer tests

It could, in some cases,
mean **more testing**

Ordering
the *right test*
at the *right time*
for the *right price*

Stewardship

Andrew Fletcher

Dickerson *et al*, 2017, JALM, 02:02:259-68 (PLUGS)

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Hospitals all over the US are Setting Up Stewardship Programs



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CLSI GP49-ED1:2017 Developing and Managing a Medical Laboratory (Test) Utilization Management Program, 1st Edition

Introduction

This report provides guidance for initiating, developing, and maintaining an effective test utilization program.

A CLSI report for US application.

GP49, 1st ed. July 2017

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Strategies of Different Stewardship Programs Vary...

Scant basis in evidence-based outcomes

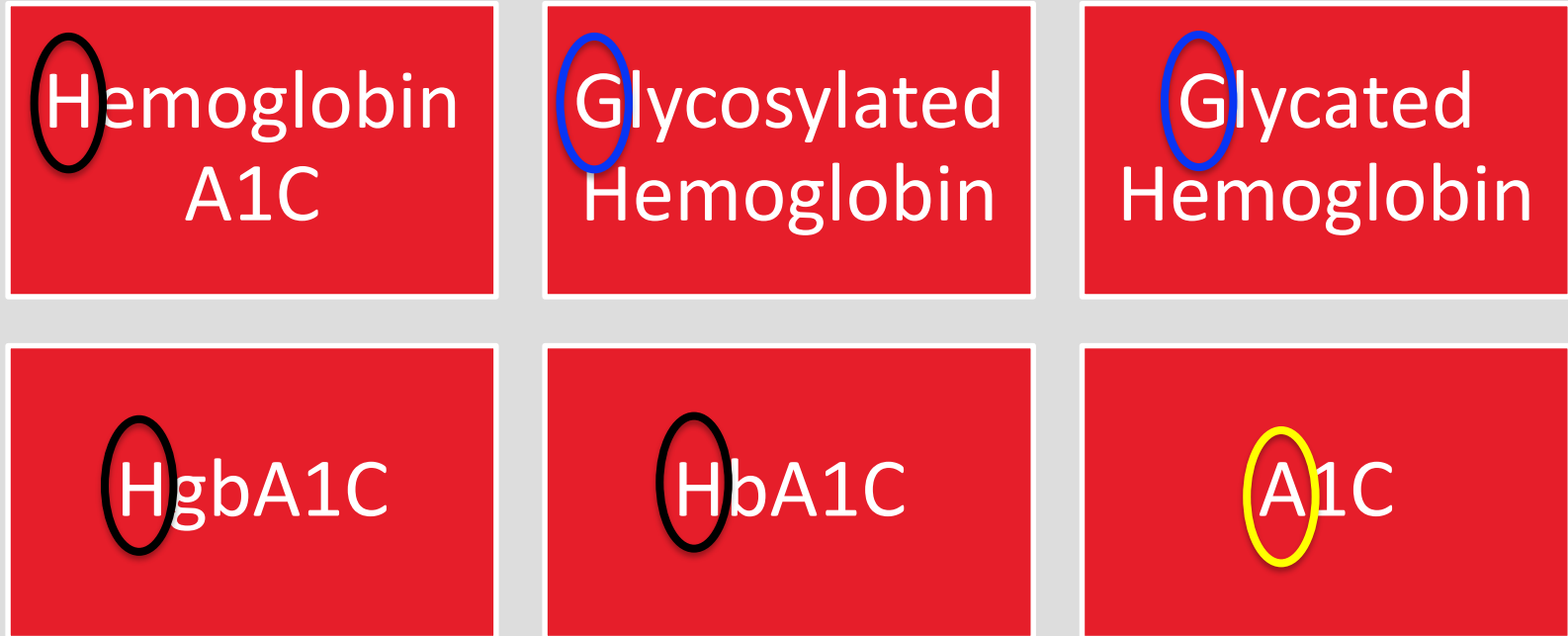
Few tests have defined parameters for testing intervals

- More information about tests
- Making tests invisible to clinicians
- Setting up a Lab formulary
- Clinical Decision Support Algorithms
- Lab-Run Algorithms/ reflexive testing
- **Renaming tests**

Scenario 1

Test names are well known, but
Lack of standardization and clarity

Lack of Standardization



Makes it hard to find the test

Some Standardization...

Basic Metabolic
Profile

BMP

Chem7/8

Because there are CPT codes for these panels,
their components are standardized

Hepatic
Function Panel

No Standardization

Liver Function
Panel

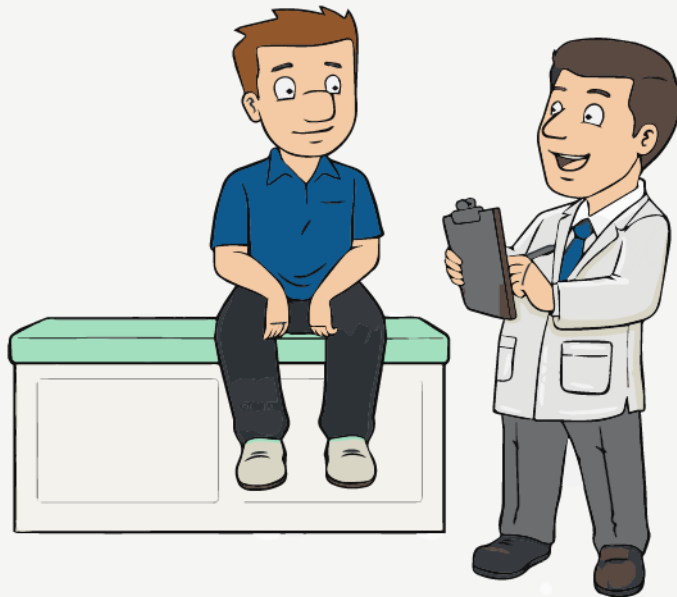
Respiratory
Virus Panel

Lactate Dehydrogenase?
Gamma Glutamyl transferase?

Panel depends on the
manufacturer

This will be a technical fix someday
Hovering over the name  explode to components

A Clinical Pathologist Joke...



I am not sure why you are feeling so ill. But I am ordering some comprehensive test panels. One of them should show something.

If you want everyone to order a test, call it "the **COMPREHENSIVE**" panel

Whole Exome Sequencing

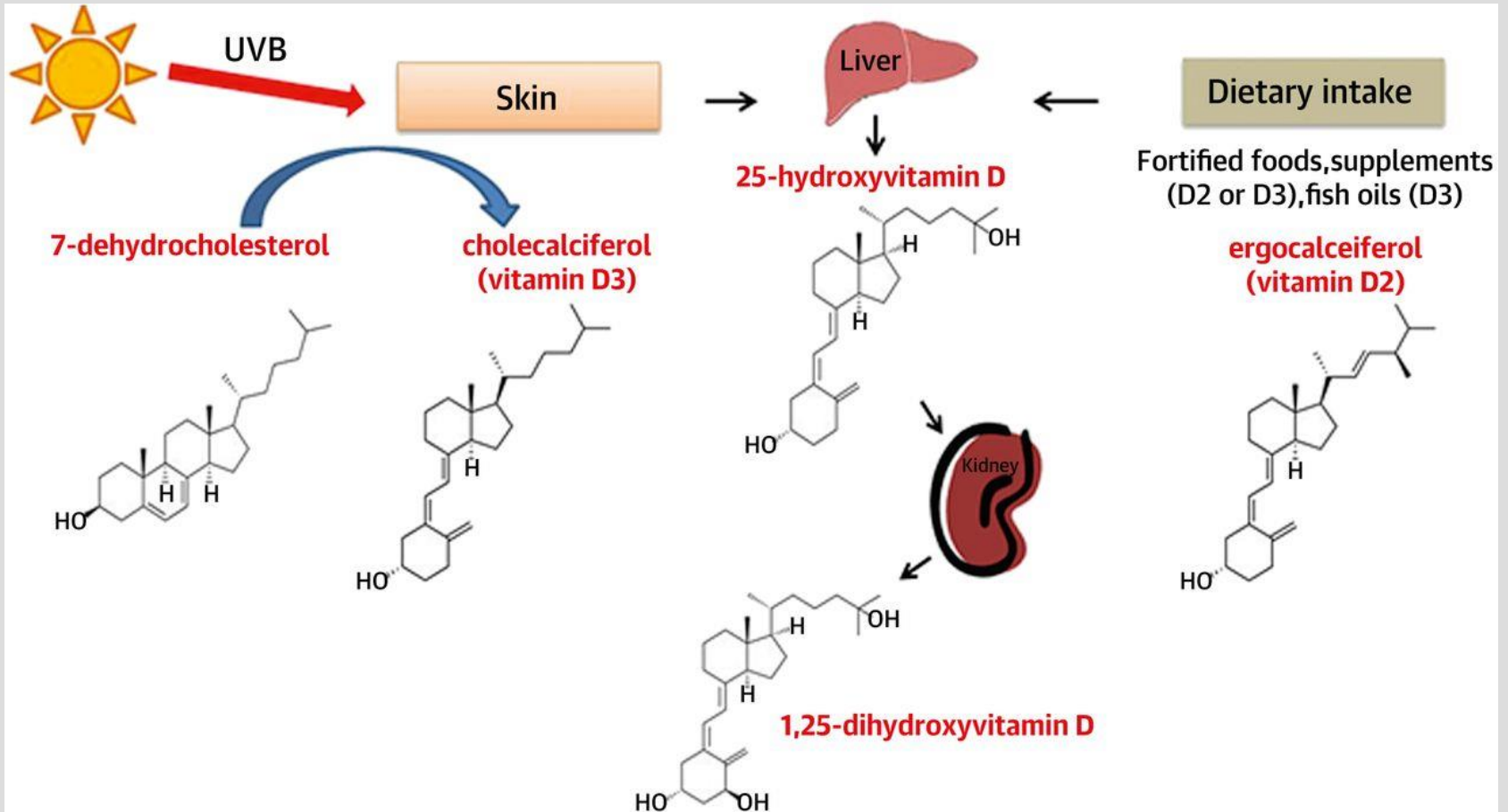
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Scenario 2

Test Names are Difficult

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The Vitamin D Problem



It all sounds so complicated ...

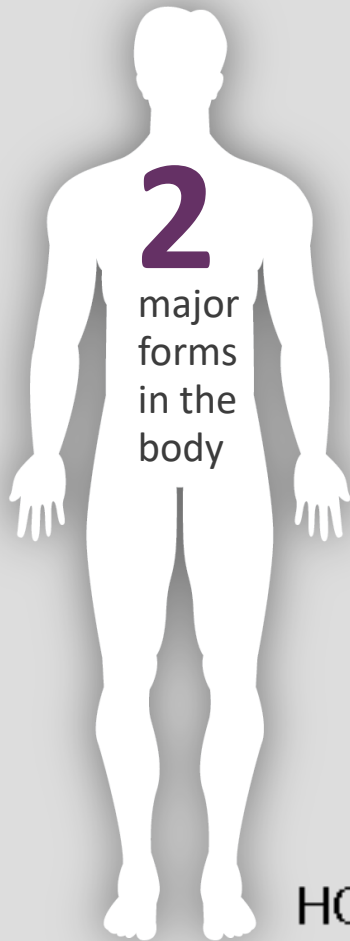
डॉ० शैलेन्द्र प्रसाद
BAMS (PAT), M.A.I.A.C. (Delhi)
MRCP Vit D₃ (U.K.)
चर्म रोग विशेषज्ञ

समय : सुबह 8 बजे से 12 बजे

नाम (A) 45

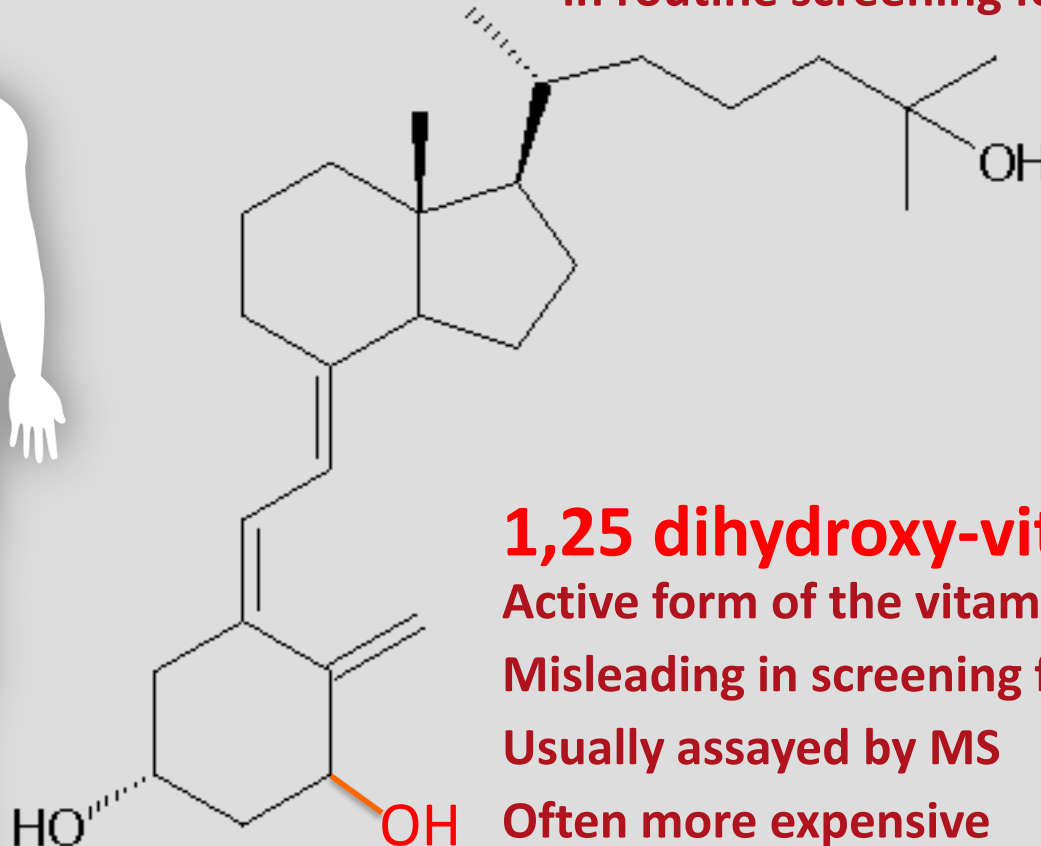
① Respiration - 27

Two Major Forms of Vit D



25 hydroxy-vitamin D ●

the best indicator of Vitamin D status
in routine screening for deficiency



1,25 dihydroxy-vitamin D ●

Active form of the vitamin

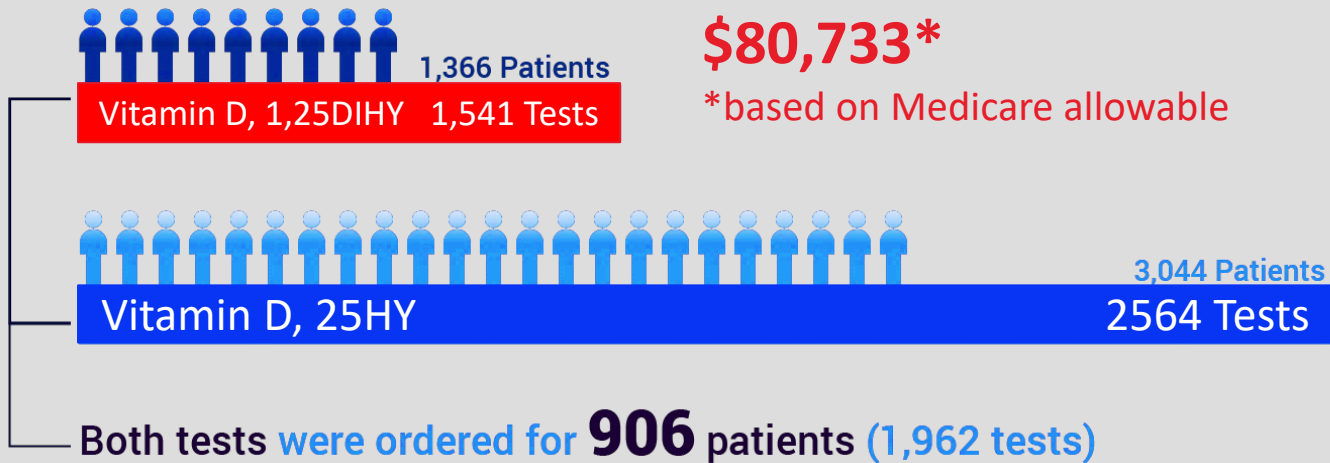
Misleading in screening for deficiency

Usually assayed by MS

Often more expensive

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The Vitamin D Problem



Three Hospitals with the Same Problem

Three Different Solutions

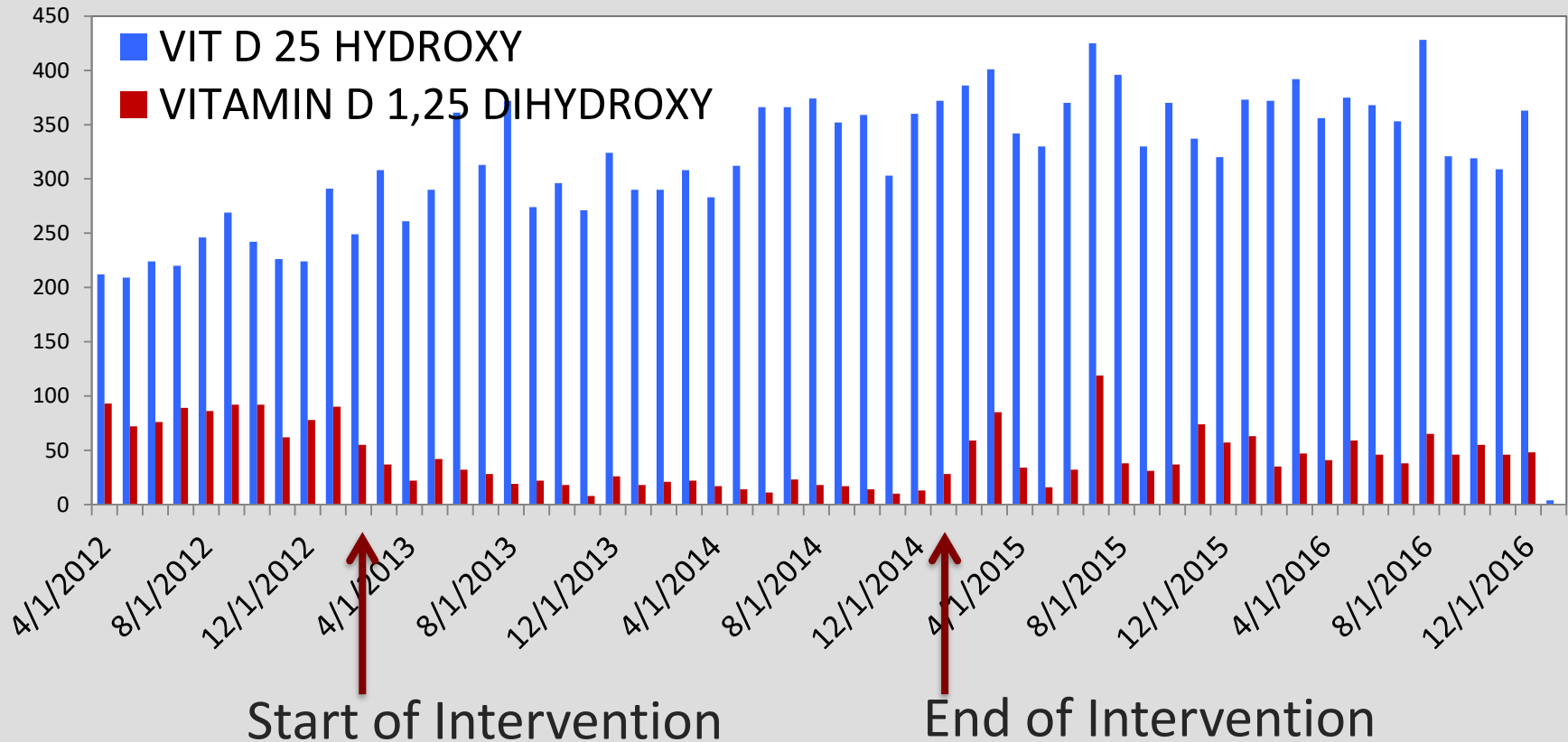
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Solution 1: Call the Ordering Clinician

March 2013 - Feb 2015



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Solution 2: Change Test Names in CPOE

25- hydroxy vit D → Vitamin D for Deficiency Screen

1,25-dihydroxy vit D → Vitamin D Bone/Renal Disorder



Resulted in increase in the 'wrong' test!

Solution: To hide the 'wrong' test

Solution 3: Provide Clarification to Names

Provide *Clarification* to test names without completely changing them

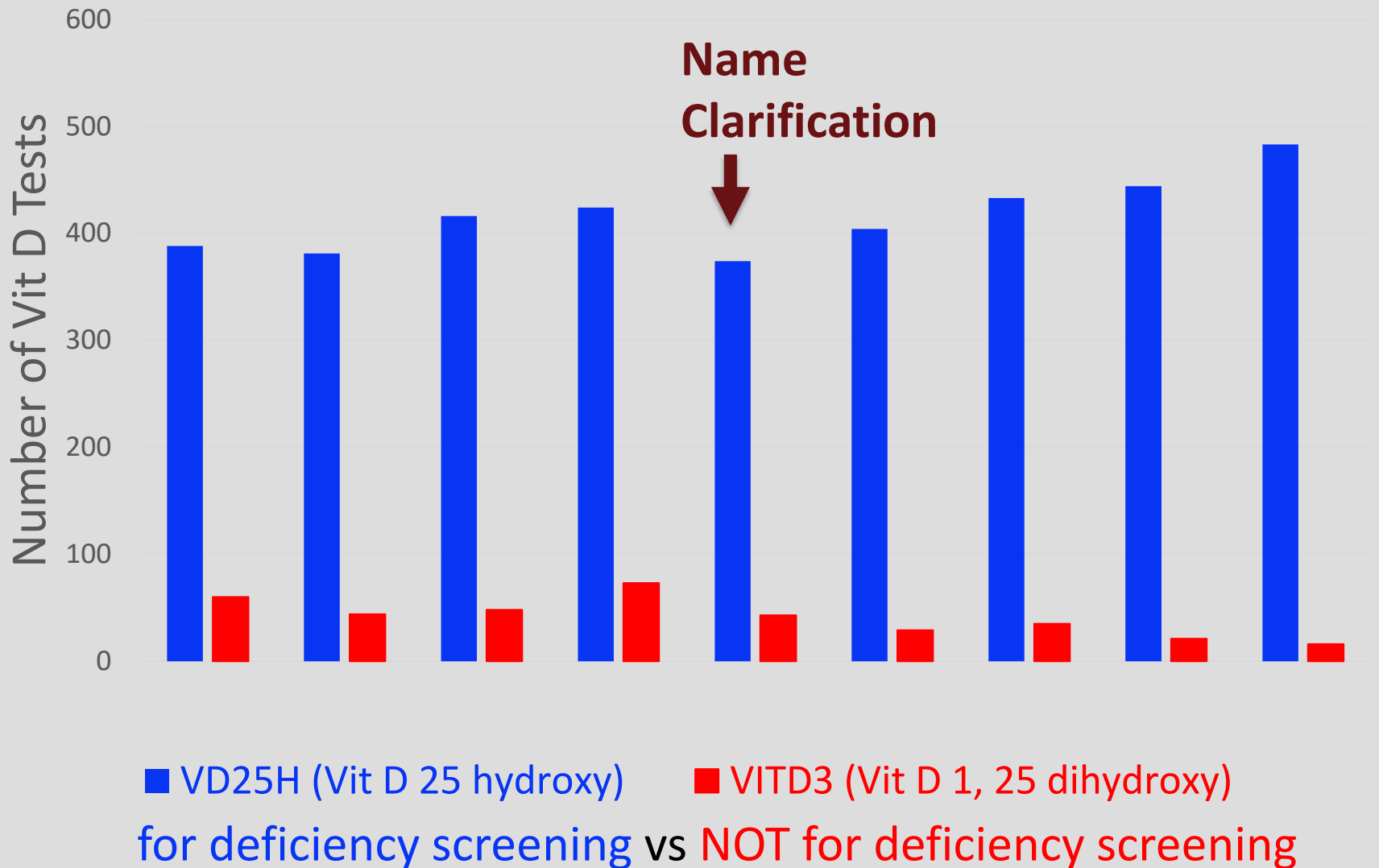
25- hydroxy vitamin D

- (for deficiency screening)

1,25 dihydroxy vitamin D

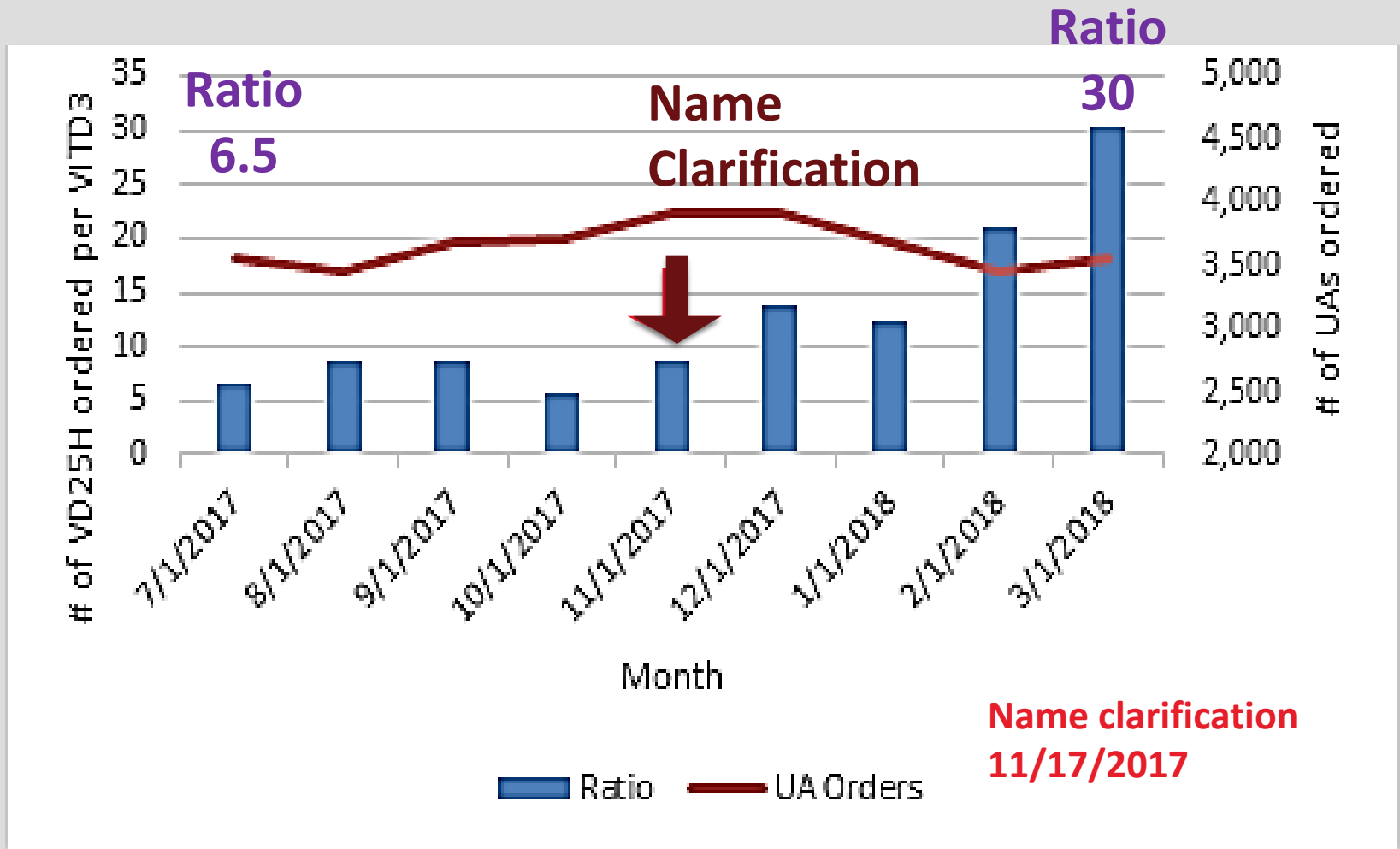
- (NOT for deficiency screening)

Results with Solution 3



Results with Solution 3

RATIO between for deficiency screening & **NOT** for deficiency screening



Even so-called 'Simple' Interventions are not so simple

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Testosterone Test Utilization

Consolidated Order Name (group)		% of Total Unique Orders
TESTOSTERONE, FREE (<u>DIALYSIS</u>) AND TOTAL(LC/MS/MS)	Cost 1X	40.2%
TESTOSTERONE, TOTAL, LC/MS/MS		34.1%
TESTOSTERONE, FREE, <u>BIOAVAILABLE</u> AND TOTAL, <u>LC/MS/MS</u>	Cost 12X	22.7%
TESTOSTERONE, FREE (IMMUNOASSAY)		2.3%
TESTOSTERONE, TOTAL, MALES (ADULT), IMMUNOASSAY		0.7%

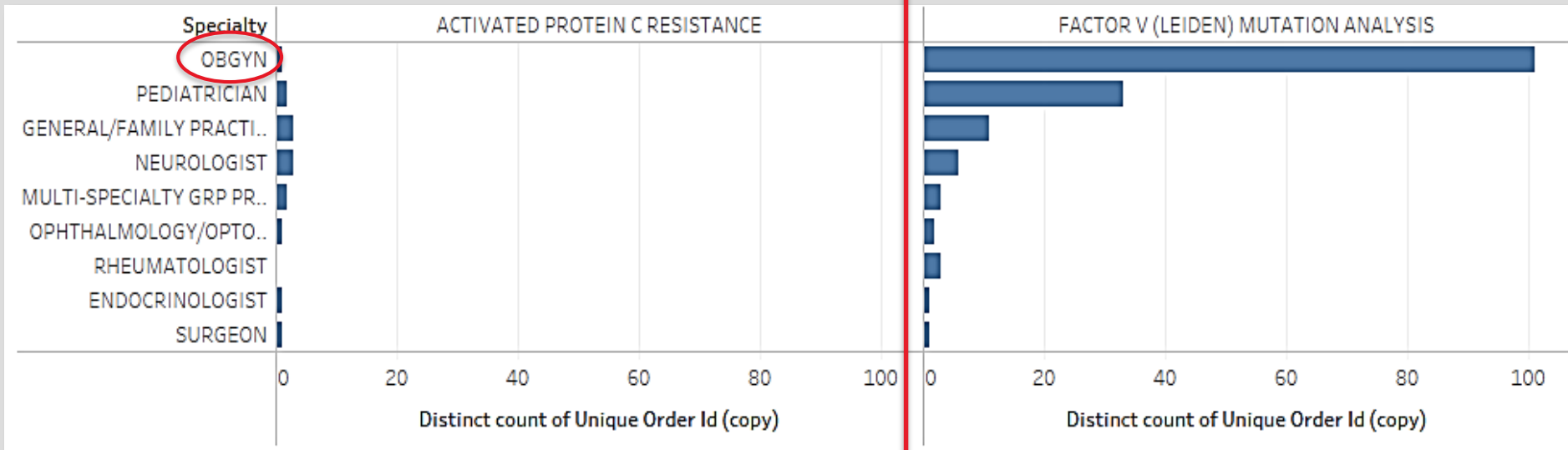
Scenario 3

The clinically superior and cheaper test has a poorly-recognized name

Under-recognized APC resistance vs. Over-recognized Factor V Leiden testing

Activated Protein C resistance

Factor V (Leiden) Mutational Analysis



\$5

\$60

Prices from NEJM, 2014

APCR will pick up 10% more cases than just the FV Leiden mutation

Algorithm - APCR screen followed by factor V Leiden mutational analysis

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Many Test Names are Confusing

- Lupus Anticoagulant
- Measles
- HSV 1/2
- eGFR vs EGFR Many EMRs convert all names to Uppercase
- Panels
 - for Celiac Disease
 - for Leukemia Flow Cytometry
 - Viruses
 - Allergies
- LYMPH LEUK FLW CYT = 18 characters
- Free PSA

Considerable Confusion

Even with common, 'easy' to understand test names

How did we end up here?

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Traditionally Test Names are Chosen by

- Pathologists and Clinical Scientists at *each institution*
- Without a **Style Guide**
- Without consulting with **clinicians**

SOURCES OF NAMES

1. **Analyte:** Sodium
2. **Reagent:** Anti-Cardiolipin Abs
3. **Etiologic Agent:** EBV PCR
4. **Patient:** Hageman factor (XII)
5. **Physician:** von Willebrand factor
6. **Vendor chosen:** Quantiferon Gold
7. **??:** RPR, Rapid Plasma Reagin

How do we fix this?

Local fixes

National Fix

Stewardship Committees

Pathologist or
Clinician-led

Physicians

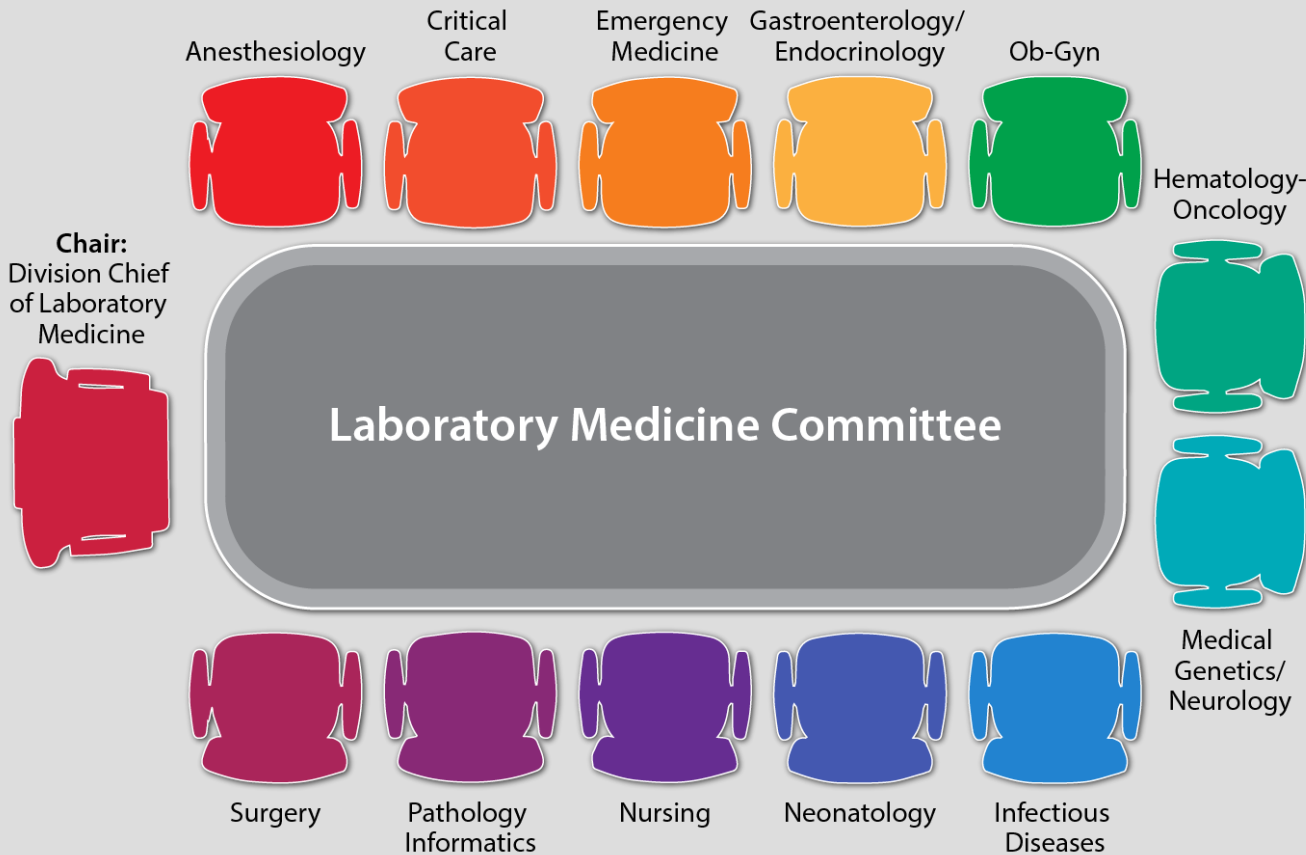
Chief Residents

Nurses

Informaticians

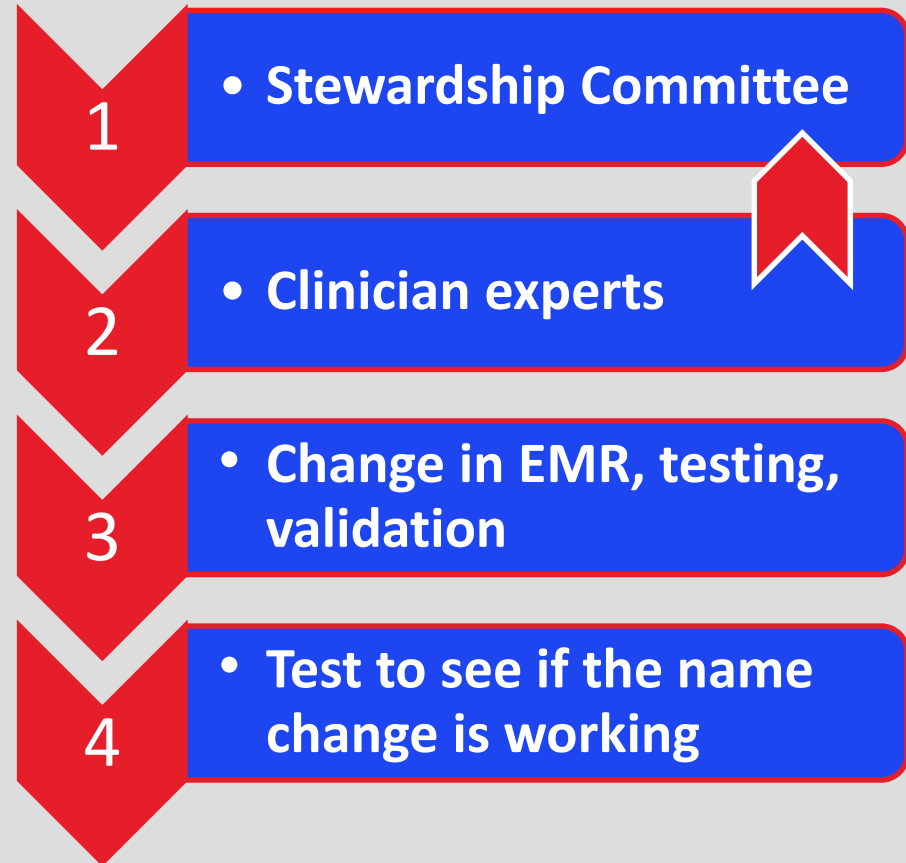
Evidence-based
Outcomes team

IS



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Process for Name Change



- The process can take several months for **ONE** test

What if we could do this at a National Level?

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Previous Attempts at Renaming Tests

1. Identifying the Naming Problem, CLIHC, CDC

Passiment et al, Decoding laboratory test names: a major challenge to appropriate patient care, J Gen Intern Med. 2013;28:453-8.

2. Creating an alternative list of names, linked to Regenstrief Institute's LOINC

Why begin another Test Naming Initiative?

- **Timing...**

- Many hospitals have Stewardship committees
 - slow process for each test in each hospital
- Unprecedented numbers of Hospital and Lab M & As
 - different names for same tests
- Greater awareness that this is a Safety and Quality issue
- EMRs have relaxed character limits for test names
- Machine Learning Studies will need standardized test names across institutions to get the large, useful datasets

TRUU-Lab



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TRUU-Lab aims to

Bring together health care providers, professional societies, and industry groups to address problems caused by ambiguous, incomplete, and non-standard laboratory test names, by

- Generating a consensus guideline for test naming
- Generating consensus names for existing lab tests
- Promoting the adoption and implementation of consensus lab test names and guidelines

TRUU-Lab Members

AACC

- Patti Jones, PhD
- Sridevi Devaraj, PhD

ACLPS

- Neal Lindeman, MD

AMP

- Rick Nolte, PhD
- Mary Williams
- Robin Temple-Smolkin

API

- Monica de Baca, MD
- David McClintock, MD

ASCP Choosing Wisely

- Lee Hillborne, MD
- Iman Kundu, Edna Garcia

ASM

- Paula Revell, PhD
- Dona Wigetunge, PhD

CAP

- Peter Perotta, MD

CDC

- Reynolds Salerno, MD
- Jasmine Chaitram, MPH
- Maribeth Gagnon, MS CT

EMR/LIS/Terminology Groups

- Jigar Patel, MD (Cerner)
- Jeff Watson (Sunquest)
- Amanda Caudle (Atlas/Sunquest)
- Holly van Kleeck JD (Health Language)
- Dale Davidson (Health Language)
- Nancy Sokol (UpToDate)
- Cheryl Mason

FDA

- Michael Waters, PhD

Nudge Unit

- Mitesh Patel MD, PhD, MBA

PLUGS

- Mike Astion, MD, PhD
- Jane Dickerson, PhD

Reference Labs

- Brian Jackson, MD, MS (ARUP)
- Andrew Fletcher, MD (ARUP)
- Jon Nakamoto, MD, PhD (Quest)
- Mohamed Salama MD (Mayo)

Instrumentation Makers

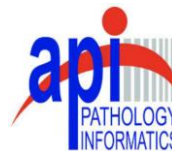
- Ross Molinaro MD (Siemens)

Clinical Pathologists and Scientists

- Ila Singh, MD, PhD (Texas Chil/Baylor)
- Gary Procop MD (Cleveland Clinic)
- Charlene Bierl, MD, PhD (Cooper)
- Swapna Abhayankar MD (Regenstrief)
- Elissa Passiment, PhD
- Michael Laposata MD, PhD (UTMB)
- Chris Zahner, MD (UTMB)
- Anand Dighe, MD, PhD (MGH/Harvard)

Trainees & Students

- Julia Wang, MD PHD student (Baylor)
- Delia Garcia RN, DNP student (UT)
- Emily Garnett PhD, Chemistry fellow (Baylor)
- Judy Trieu MD, MPH (UTMB)



How does TRUU-Lab Work?

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Steering Committee

AACC

CAP

PLUGS

ACLPS

CDC

Reference Labs

AMP

EMR/LIS/Terminology Groups

Instrumentation

API

ology Groups

Makers

ASCP Choosing

FDA

Clinical Pathologists

Wisely

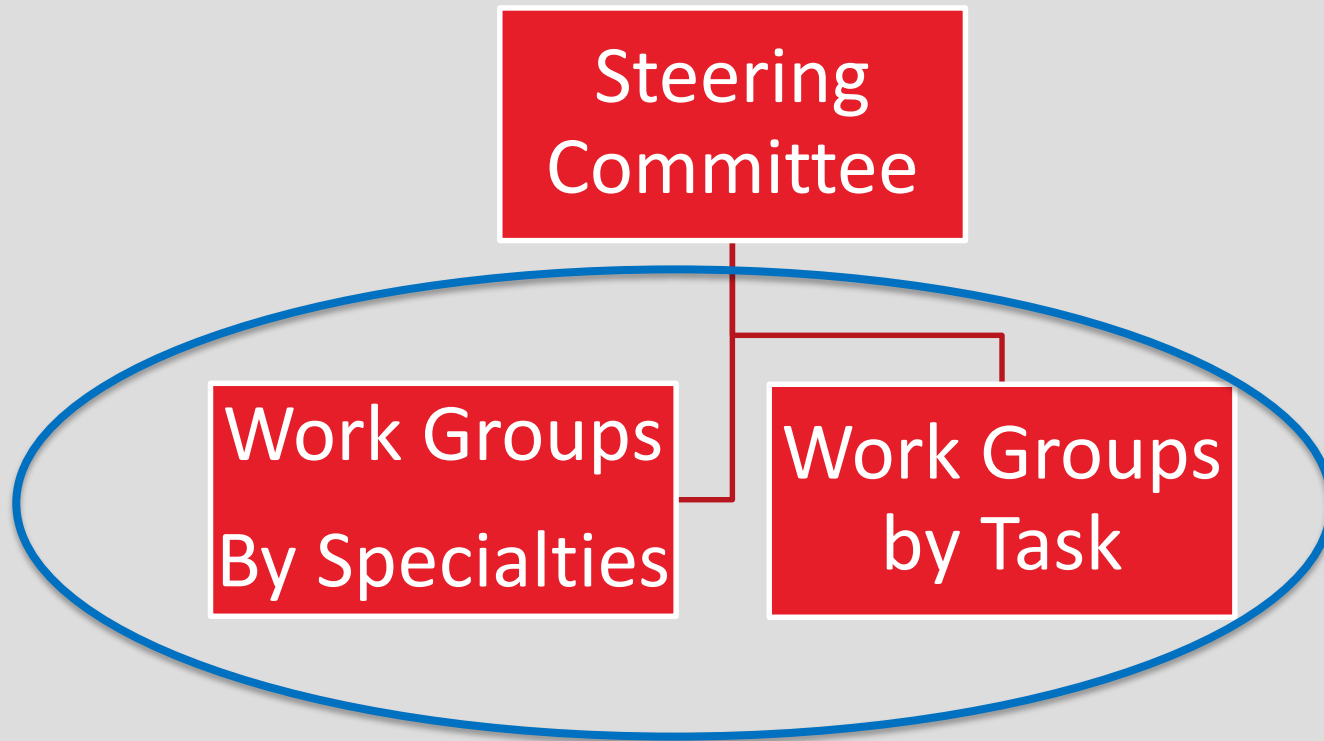
Nudge Unit

and Scientists

ASM

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Governance



Structure with project lead and project manager

Current TRUU-Lab Subcommittees

1. Developing guidelines

- Brian Jackson

2. Selecting perplexing names to pressure test

- Gary Procop

3. Whitepaper

- Ila Singh

4. Developing guidelines for action (~NDA)

- Nancy van Kleeck

ASCP Choosing Wisely Lab Test Stewardship Project

The ASCP Effective Test Utilization Steering Committee plans to conduct a survey on laboratory test naming conventions that cause issues or are problematic in laboratories. This survey will help identify problematic laboratory test name and offer recommendations for clearer and more understandable test names.

Have you experienced issues in test naming conventions in your laboratory?

- Yes
 No

Please name the test(s) that have been problematic in your laboratory as well as suggestions for renaming the test.

	Current name of test	Suggestion for renaming the test
#1	<input type="text"/>	<input type="text"/>
#2	<input type="text"/>	<input type="text"/>
#3	<input type="text"/>	<input type="text"/>
#4	<input type="text"/>	<input type="text"/>
#5	<input type="text"/>	<input type="text"/>

Which best describes you?

- Pathologist
 Laboratory Professional (other than Pathologist)
 Other (please specify):

Please provide your contact information so we may follow up if we have any questions.

Name:
Email Address:
Institution:

Save

Submit

<https://app.keysurvey.com/f/1287048/33eb/>

Survey for Confusing Test Names

ASCP Choosing Wisely/TRUU-Lab Survey: Responses on > 252 test names, with suggestions for renaming

Heparin/ Anti-Xa Assays

1. anti Xa level
2. Antifactor Xa assay
3. anti Xa
4. Anti-XA LMW vs Anti-XA UM
5. Heparin activity level
6. Heparin assay, LMW Heparin assay
7. Unfractionated heparin
8. Factor 10 with factor 10A
9. Rivaroxaban
10. Apixaban

Other Coagulation tests

1. Factor II
2. Factor V
3. Activated Protein C Resistance

Cancer Genetics tests

1. BCR-ABL tests
2. Multiplex gene expression analysis/
Pancancer NGS panel
3. t(15;17) PML-RARA - qualitative
gets confused with FISH

Choose a small set of tests to rename

1. Use the survey to choose a small set of problematic names
2. Rename using new guidelines, “pressure test”

Develop Rules for Naming

- Most labs/EMRs do not follow specific guidelines
- Examine existing Guidelines or Preferred list of names
 - ARUP Style Guidelines
 - ONC Tiger Team's guidelines
 - LOINC's list of names
 - Standards for Pathology Informatics in Australia Guidelines
 - RCPA Pathology Units and Terminology Standardization Project (Australasia)
 - Canadian guidelines

ARUP Guidelines

<p>Substance analyzed by the test (compound, drug)</p>	<p>Always</p>	
<p>Form of analyte measured (Free, Fractionation, Total, Quantitative, Qualitative, Quantitation, Level, Functional, Enzymatic)</p>	<p>When it is necessary to clarify the exact nature of the test to assist in ordering the correct test.</p>	<p>Carbamazepine, Free and Total Carnitine, Free Protein, Total, Plasma or Serum</p>
	<p>Quantitative and qualitative are required when there are 2 tests for the same analyte and 1 is qualitative while the other is quantitative. Highly recommended that they be used whenever possible for applicable tests.</p>	<p>Adrenal Steroid Quantitative Panel by LC-MS/MS Glutaryl carnitine Quantitative Bence Jones Protein, Quant. Free Lambda Light Chains BCR-ABL1, T315I Mutation Detection, Quantitative Bence Jones Protein, Qualitative Free Kappa and Lambda Light Chains Drug Screen (Non forensic), Qualitative Malaria Detection & Speciation, Qualitative by RT PCR Cryoglobulin, Qualitative w/ Reflex to Quant. IgA, IgG, & IgM</p>
	<p>Quantitation is generally reserved for Drugs of Abuse</p>	<p>Drugs of Abuse Confirmation/Quantitation - Opiates - Meconium Confirmation/Quantitation - Serum or Plasma</p>
	<p>Level is generally reserved for antimicrobial drug level testing</p>	<p>Ticarcillin, Antibiotic trough and peak Level Vancomycin, Antibiotic Peak Level</p>
	<p>Functional and Enzymatic Activity are generally reserved for coagulation-type test (Protein C)</p>	<p>Protein C, Functional Antithrombin, Enzymatic Activity Galactosemia, (GALT) Enzyme Activity and 9 Mutations</p>

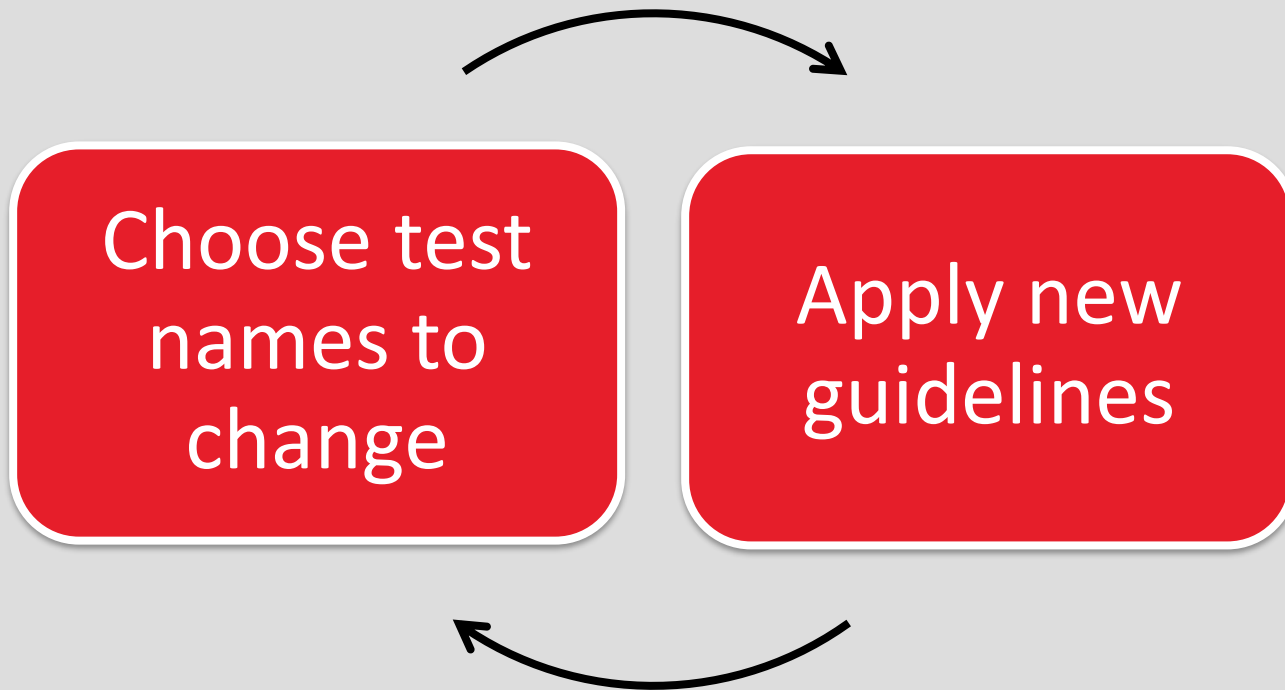
ONC Tiger Team Guidelines

ANALYTE IDENTIFICATION	<ol style="list-style-type: none"> 1. The identifier of the substance (analyte) being measured must come first. 2. Use the more common name rather than scientific name where possible, except as tradition dictates or clinical experts believe it is required to avoid confusion. 3. Do not use double names, pick only one name for the analyte. 4. First letter of a test name shall be upper case, use mixed case. 	<p>Identification of organisms, use the scientific name</p>
ANIONIC NAME FOR CHEMICALS	<p>Use anionic name</p>	<p>Use the acid name when it is more commonly accepted and space is not an issue</p>
ANTIBODY/ANTIGEN	<ol style="list-style-type: none"> 1. Distinguish between antigens and antibodies. For immunologic test: Use Ab for Antibody and Ag for antigen 2. The noun form of the target antibody should be used. 3. The word anti should not be used for naming antibodies. 4. Preferred convention for measurement of parent immunoglobulin is "Total IgG" or "IgG level" 5. Delete redundant identifiers, example Apple IgE Ab should be Apple IgE because it is measuring an immunoglobulin, it is an Ab 	<p>Antinuclear Ab and Anti D Quantitative Assay; Use of Anti for inhibitory activity e.g. Anti Xa.</p> <p>If this an immunoglobulin level, then include "level" at the end (e.g. IgG level) -- to differentiate it from IgG given as a therapeutic</p>

Generate draft consensus guidelines

Look at various existing guidelines to create a working draft

Iterative Process



- 1 • Implement on a small scale
- 2 • Disseminate for widespread adoption
- 3 • Foundation Build of EMR, LIS
- 4 • Basis for sharing lab results between systems

Whitepaper

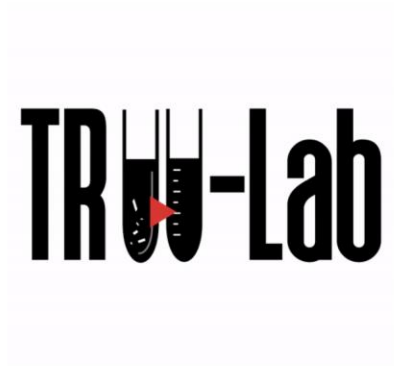
Describe the problem, and our approach to solve it

Secure funding

What have we done so far?

1. Recruited Members – officially agreed to be a part of TRUU-Lab
2. Chose Skype as a way to meet
3. Had 5 meetings – one each month
4. Developed a Mission statement, Scope, Goals, Workflow
5. Selected a name (TRUU-Lab was chosen out of 10 possibilities)
6. Secured a domain, twitter handle, gmail address
7. Developing a website and logo - truulab.org
8. Sent out a survey (with ASCP Choosing Wisely)
9. Reviewed existing guidelines worldwide
10. Sub-committees: Guidelines, ‘bad’ test names, whitepaper
11. Ways to work together – Basecamp, Slack, Google doc





The mission of TRUU-Lab is to bring together health care providers, professional societies, and industry groups to address problems caused by ambiguous, incomplete, and non-standard laboratory test names.

The objectives of TRUU-Lab are:

- Generate a consensus guideline for lab test naming
- Generate consensus names for existing lab tests
- Promote the adoption and implementation of consensus lab test names and guidelines



Why TRUU-Lab?

The problem with laboratory test names

Names for lab tests have traditionally been chosen by clinical pathologists and scientists. While these test names make perfect sense to anyone in the clinical laboratories, that is not always the case with clinicians. Clinicians often order the wrong test or a sub-optimal test, or more tests than necessary, because the relevant test names are unclear, abbreviated, obscure, or inconsistent across institutions. Often the wrong orders lead to safety and quality issues.

Three root issues can be identified when naming a laboratory test in electronic ordering systems:

- One test may have multiple names (e.g. Hemoglobin A1c/glycosylated hemoglobin/Hgb A1c) or abbreviations (e.g. FBS/FGLU/FGLUC/FG for "fasting blood glucose"). This redundancy may lead to confusion and inefficiencies in ordering laboratory tests.
- Tests that are different but carry similar variations of the name (e.g. 25-hydroxy vitamin D and 1,25-dihydroxy vitamin D) may result in choosing suboptimal or multiple tests for patients.
- Names that include the methods by which the laboratory performs the test may confuse clinicians (e.g. dialysis or LC/MS/MS).

TRUU-Lab is a collaborative effort among pathologists, clinicians, professional organizations, accreditation agencies, large reference labs and terminology groups to create a consensus guideline for giving laboratory test more rational and consistent names.

The ultimate goal is to bring these consistent and easy-to-understand lab test names into electronic health records (EHR) and laboratory information systems (LIS) everywhere.



JOIN US

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ASCP Choosing Wisely Lab Test Stewardship Project

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Have you experienced issues in test naming conventions in your laboratory?

- Yes
 No

Which best describes you?

- Pathologist
 Laboratory Professional (other than Pathologist)
 Other (please specify):

Please provide your contact information so we may follow up if we have any questions.

Name:

Email Address:

Institution:

Join As A Sponsor

TRUU-Lab is looking for sponsors to bring our members together for an annual conference. Please contact truulab@gmail.com if you have an interest in sponsoring at any level.

Join As A Participant

Our initiative is organized by a steering committee and multiple sub-committees for specific tasks and goals. When you send us an email (truulab@gmail.com) or a feedback form, please note the following information: your name, degree(s), job title, institution, and describe in 1-2 sentence your interest in our initiative so we can move forward with the appropriate next steps.

Contact Us

Contact us at truulab@gmail.com

Your Name (required)

Your Email (required)

Your Message

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How you can participate in TRUU-Lab...



Truulab.org

Learn More about TRUU Lab

Take the ASCP Choosing Wisely/TRUU-Lab Survey for perplexing Test Names

[Join Us](#)

[Sponsor Us](#)

Send us an email:
truulab@gmail.com