

Standardizing Lab Test Names: the TRUU-Lab Initiative

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Professor, Baylor College of Medicine

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Objectives

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

No Conflicts of Interest

One out of 8 Malpractice Claims ...

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

Total of ~ 13 Billion tests performed each year in the US

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

Steindel SJ et al, Arch Pathol Lab Med, 2000, 124:1201-8

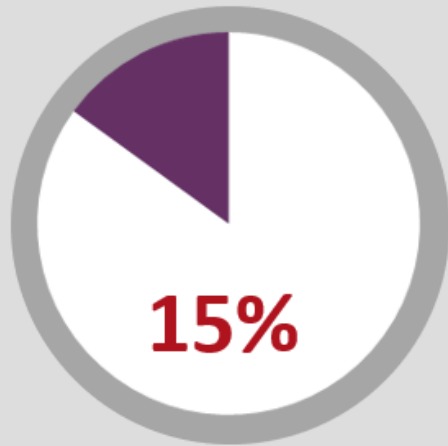
National Academy of Medicine (IOM) Study

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

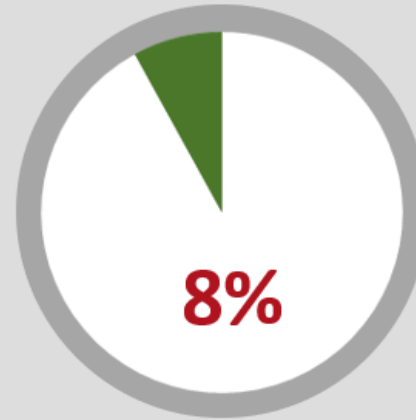
For a 800 bed hospital system
= \$8.5 million/year

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 this Uncertainty?

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

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

Confusing?

Vitamin D

25 hydroxy Vitamin D

1, 25 dihydroxy Vitamin D

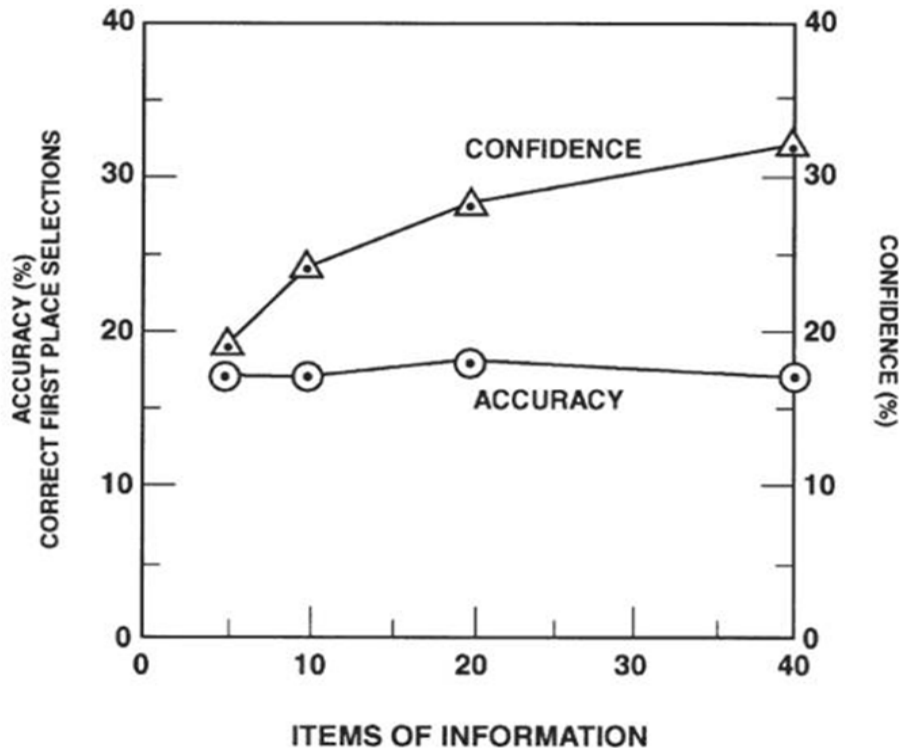
How do Clinicians Compensate for this Uncertainty?

Order more tests

Use the 'H' and 'L' approach

Is more testing better?

Horseracing Handicappers



Graph courtesy of
Brian Jackson, MD
CMIO, ARUP Laboratories

Paul Slovic, cited in
Hueur R.J.,
Psychology of Intelligence
Analysis

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Scenario 1

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

Lack of Standardization

Hemoglobin
A1C

Glycosylated
Hemoglobin

Glycated
Hemoglobin

HgbA1C

HbA1C

A1C

Makes it hard to find the test

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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?
Screens for Viral Hepatitis

Panel components depend
on the manufacturer

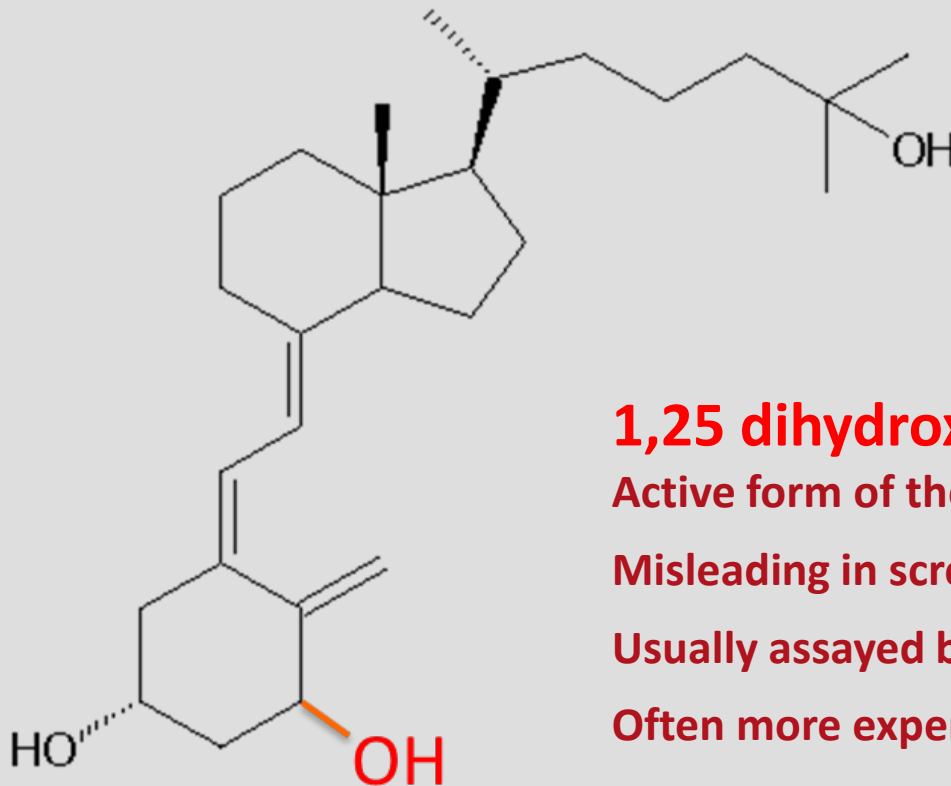
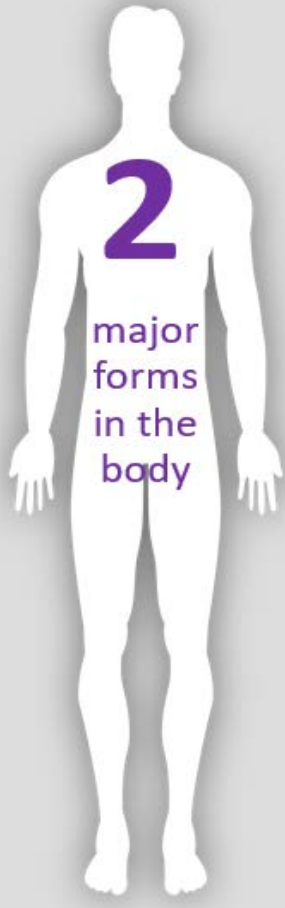
This will be a technical fix someday
Hovering over the name ➡ explode to components

Scenario 2

Test Names are Difficult

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The Vitamin D Problem



25 hydroxy-vitamin D

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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Three Hospitals with the Same Problem

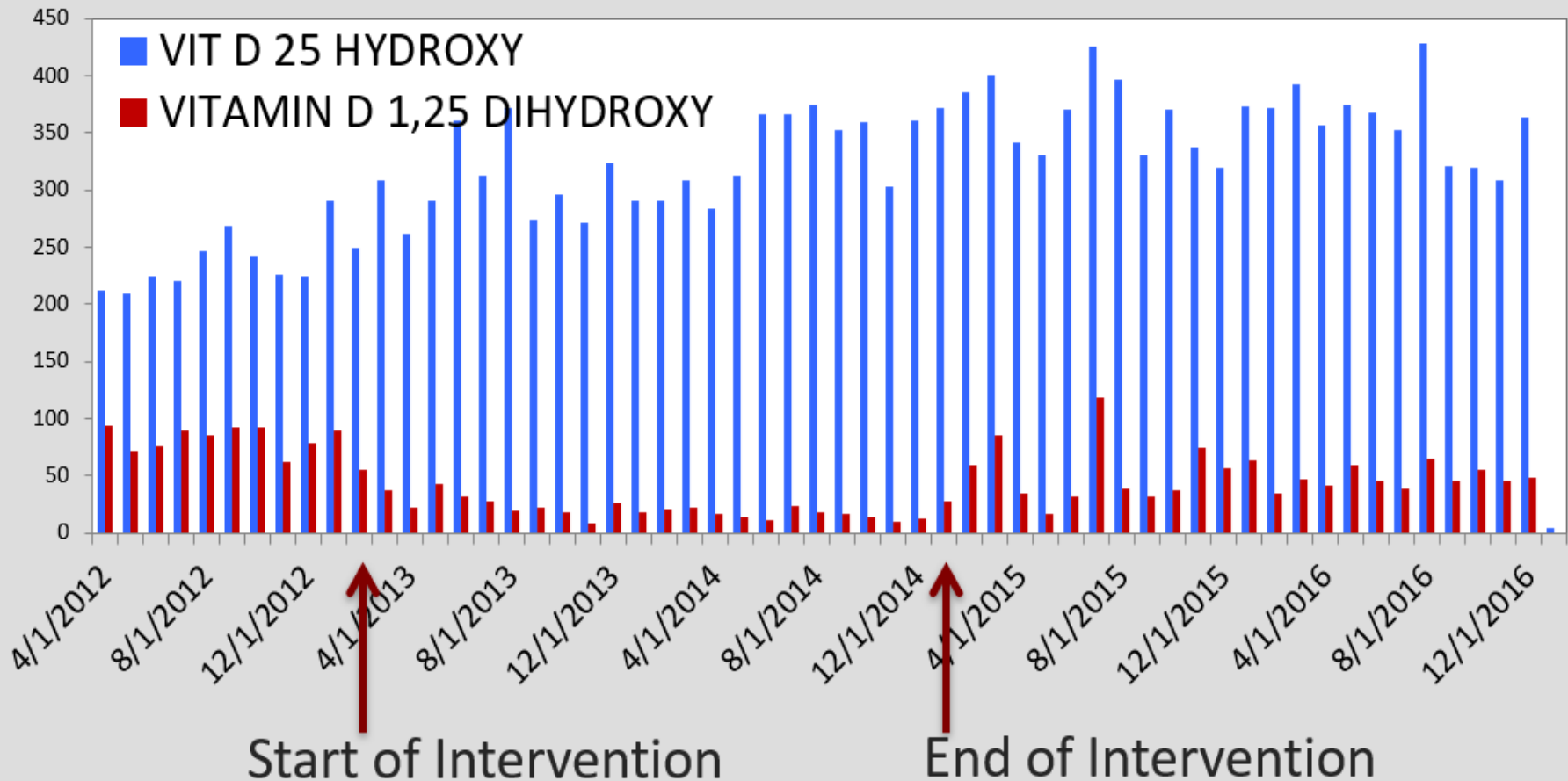
The '**wrong**' Vitamin D test is ordered ~30% of the time

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

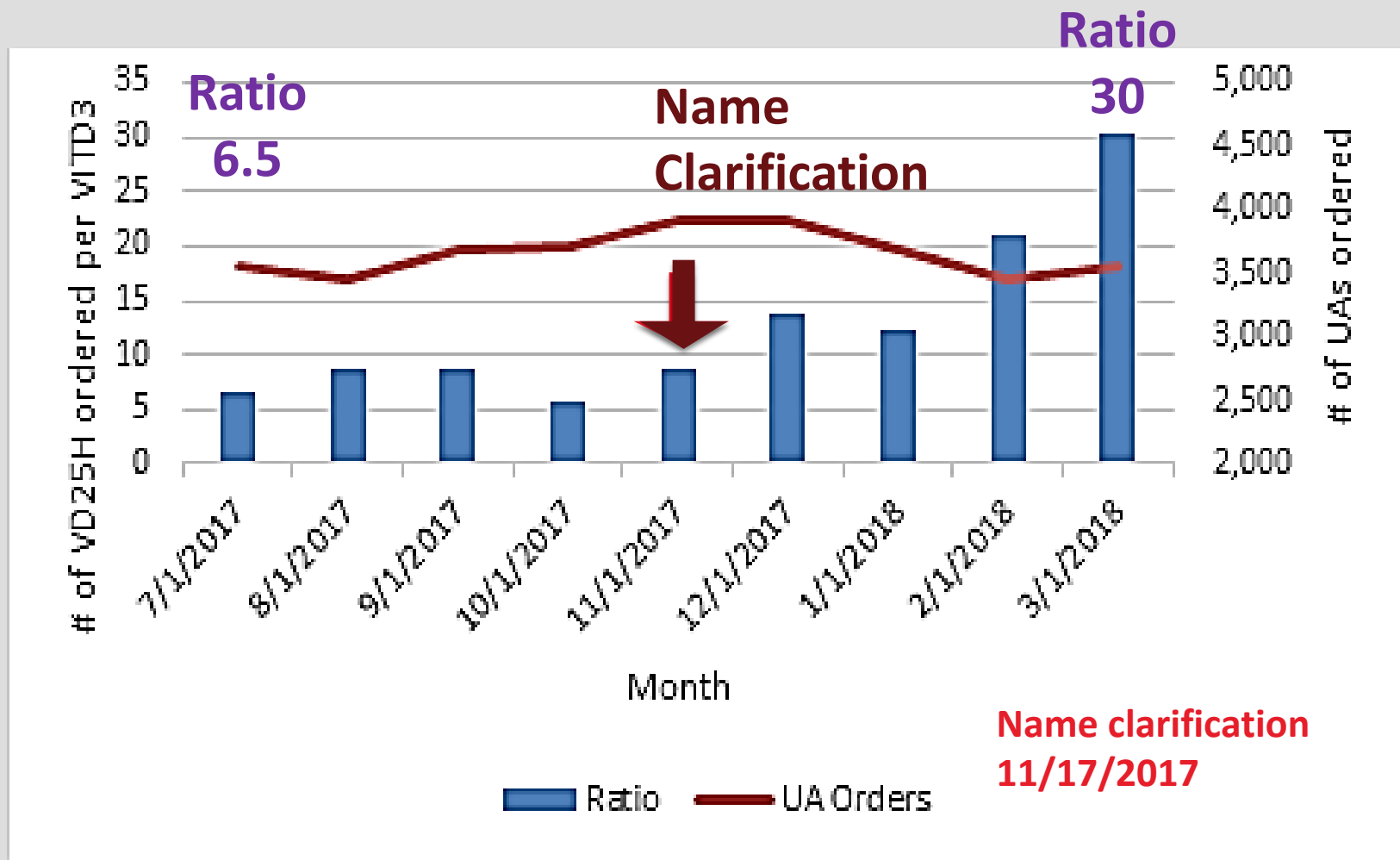
- (for deficiency screening)

1,25 dihydroxy vitamin D

- (NOT for deficiency screening)

Results with Solution 3

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%

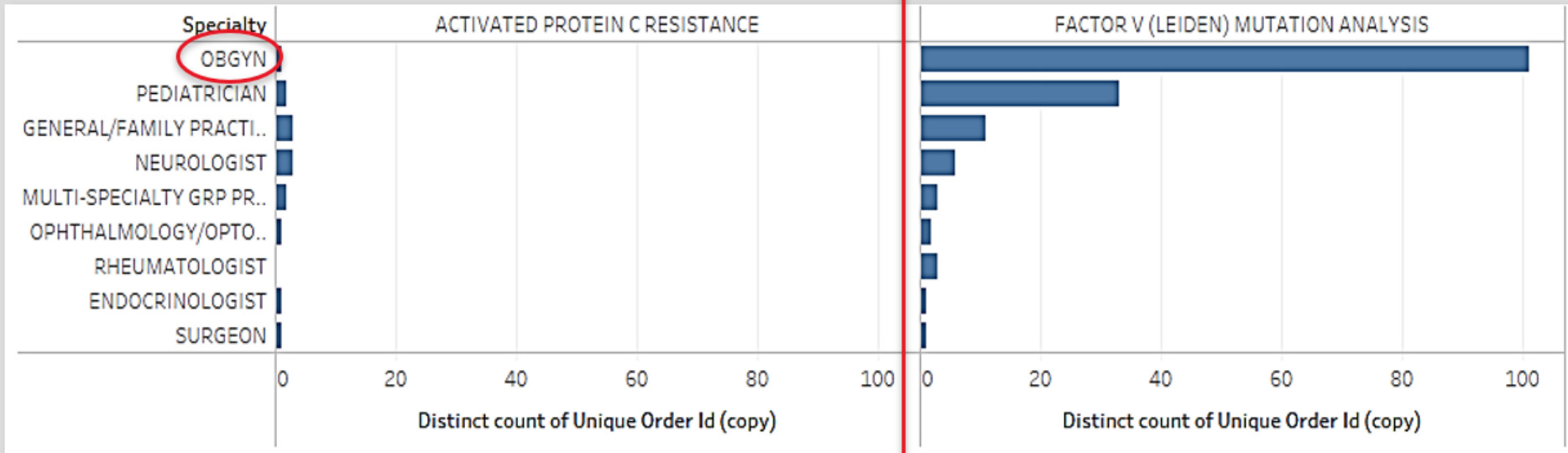
Scenario 3

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 Rubeola
- HSV 1/2
- eGFR vs EGFR Many EMRs convert all names to Uppercase
 - Panels, Celiac Disease/Virus Panels
- ‘Comprehensive’ tests
- Whole Exome Sequencing
- LYMPH LEUK FLW CYT = 18 characters
- Brand Names, Super Quant Hepatitis B Virus DNA Assay
- Free PSA

Considerable Confusion

Even with common, 'easy' to understand test names

Genetic Tests can be even more confusing

Rett syndrome (**MECP2 gene**) vs
Multiple Endocrine Neoplasia type 2- **MEN2**
(**RET gene**)

GLUT1 deficiency syndrome (**SLC2A1 gene**) vs
Congenital Hyperinsulinism (**GLUD1 gene**)

Courtesy Darci Sternan, Seattle Children's

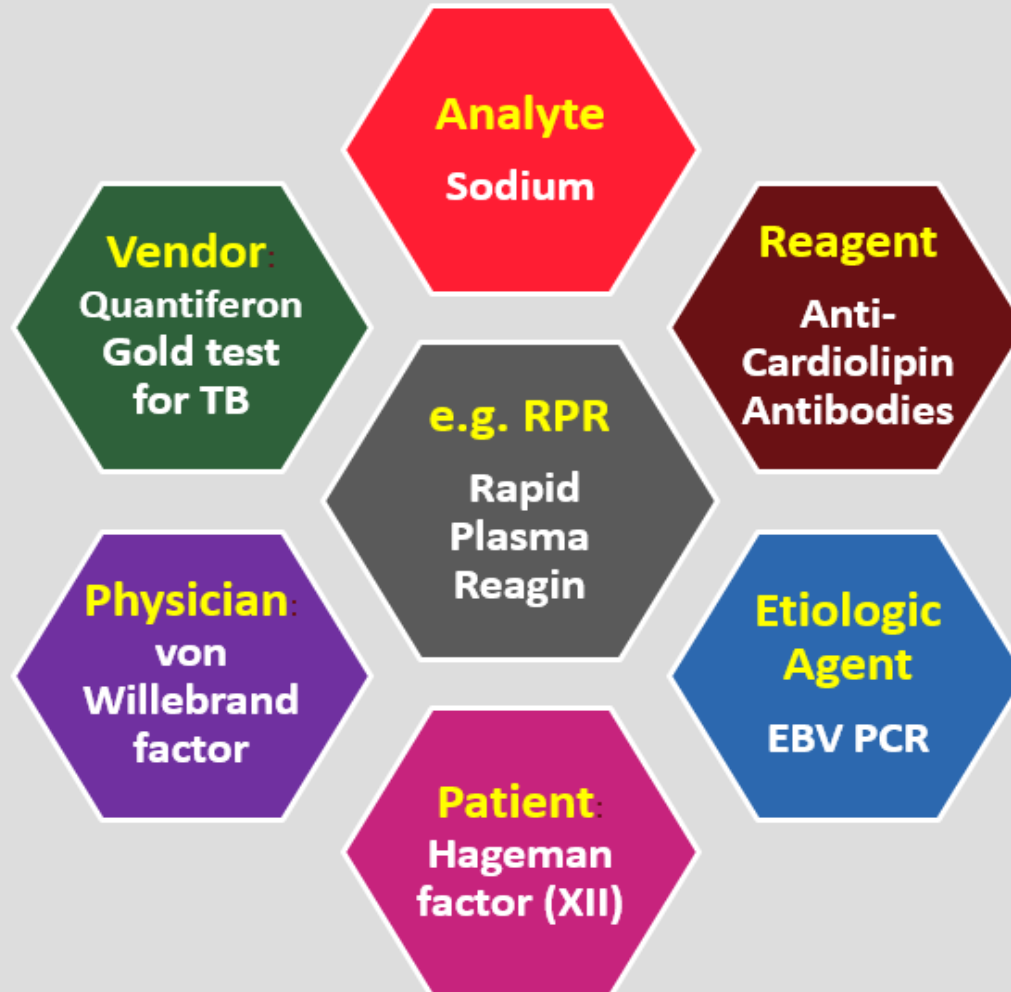
How did we end up here?

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Lab Test names are usually chosen ...

- Without consulting with Pathologists or Clinical Scientists at **Other Institutions**
- Without a **Style Guide**
- Without consulting with **Clinicians**

Test Names have Multiple Sources



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How do we fix this?

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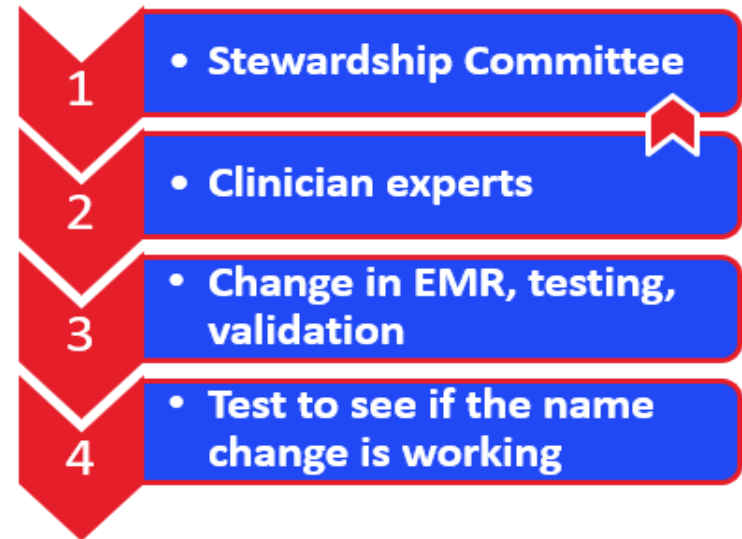


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Hospital/Lab Stewardship Committees



Process for Name Change



Significant safety challenges – Recall Vit D solution

The process can take several months for **ONE** test
Imagine every hospital doing the same process...

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Can this be done at a bigger level?

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Previous Attempts at Renaming Tests

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.

ONC Tiger Team

Standards for Pathology Informatics in Australia

superceding the RCPA-PUTS Royal College of Pathologists of Australasia - Pathology Units and Terminology Standardisation (PUTS) project

Canada: Infoway, the pan-Canadian LOINC[®] Observation Code Database (pCLOCD)

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LOINC

- 1994, Regenstrief Institute
- Designed for interoperability in data sharing
- **LOINC's expectation – neither the short nor long LOINC name should be used as display names**
- Federally required code

Component (Analyte)	Property	Timing	System (Specimen)	Scale	Method
Glucose	Mass/Vol	Point in time	Ser/Plas	Qn	Glucose Oxidase

LOINC

Table 5. Logical Observation Identifiers Names and Codes (LOINC) Codes That Differ Only in the Method Axis/Part^a

LOINC Code	Component	Property	Time Aspect	System	Scale Type	Method
30341-2	Erythrocyte sedimentation rate	Vel	Pt	Bld	Qn	
43402-7	Erythrocyte sedimentation rate	Vel	Pt	Bld	Qn	15-min reading
4537-7	Erythrocyte sedimentation rate	Vel	Pt	Bld	Qn	Westergren
18184-2	Erythrocyte sedimentation rate	Vel	Pt	Bld	Qn	Westergren 2-h reading
4538-5	Erythrocyte sedimentation rate	Vel	Pt	Bld	Qn	Wintrobe
82477-1	Erythrocyte sedimentation rate	Vel	Pt	Bld	Qn	Photometric
3255-7	Fibrinogen	MCnc	Pt	PPP	Qn	Coag
48664-7	Fibrinogen	MCnc	Pt	PPP	Qn	Coag.derived
30902-1	Fibrinogen	MCnc	Pt	PPP	Qn	Heat denaturation
3644-2	Fluoxetine	MCnc	Pt	Ser/Plas	Qn	
35610-5	Fluoxetine	MCnc	Pt	Ser/Plas	Qn	Screen
2571-8	Triglyceride	MCnc	Pt	Ser/Plas	Qn	
12951-0	Triglyceride	MCnc	Pt	Ser/Plas	Qn	Calculated

- **55,000 numeric codes specific for Lab Tests**
- **The process that each lab has to undertake to select codes is *complex, resource-intensive and prone to human inconsistencies***
- **The same test may be assigned different codes by different labs**

Stram et al. Arch Pathol Lab Med, 2019, 10.5858/arpa.2018-0477-RA

Why begin another Test Naming Initiative?

- **Need...**

- Need names that are standardized and easy to understand

- **Timing...**

- Many hospitals have Stewardship committees
 - slow process for each test in each hospital
- Unprecedented numbers of Hospital and Lab M & As
- Greater Mobility of individuals
- Greater awareness that this is a Safety and Quality issue
- EMRs have relaxed character limits for test names
- Machine Learning needs large datasets from many institutions

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Test Renaming for Understanding & Utilization

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TRUULAB.ORG



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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



[Mission statement](#)
[Scope](#)
[Goals](#)
[Members](#)



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.



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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

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 Hilborne, MD
Iman Kundu, Edna Garcia

ASM

Paula Revell, PhD
Dona Wigetunge, PhD

CAP

Peter Perrotta, MD

Federal Liaisons

CDC

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

FDA

- Michael Waters, PhD

EMR/LIS/Terminology Groups

- Nick Trentadue (Epic)
- 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

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/Pharmacogenomics

- Ross Molinaro MD (Siemens)
- Daniel Johnson (Sysmex)
- Jeff Schreier (Diaceutics)

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 Houston)
- Emily Garnett PhD, Chemistry fellow (Baylor)
- Grace Kroner, PhD, Chemistry Fellow (ARUP)



Better health through laboratory medicine.



ASSOCIATION FOR MOLECULAR PATHOLOGY



SIEMENS



AMERICAN SOCIETY FOR MICROBIOLOGY



COLLEGE of AMERICAN PATHOLOGISTS



The Nudge Unit



Quest Diagnostics



CENTERS FOR DISEASE CONTROL AND PREVENTION



PLUGS[®]
Patient-centered Laboratory Utilization Guidance Services



MAYO CLINIC LABORATORIES



TRUU-Lab International Partners

- National Health Service, UK
- Standardization in Pharmacologic/Toxicology testing, Norway
- Royal College of Pathologists of Australasia, Sydney, Australia

Understand previous attempts, failures, successes, cultural differences



Who is under-represented?

- Clinician Professional Organizations
- Instrumentation Makers



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What are TRUU-Lab's Goals?

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

We started with a very simple survey for confusing names

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

ASCP Choosing Wisely/TRUU-Lab Survey

> 250 Responses on > 100 test names, with suggestions for renaming

Vitamin D Assays

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

TRUU-Lab Subcommittee 1

**Use the Surveys to Define and Categorize
Especially Problematic Names**

Lead: Gary Procop, MD, PhD, Cleveland Clinic

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TRUU-Lab Subcommittee 1

Highlights from a very large list

1. **Ambiguous Nomenclature** Thalassemia Screen (does not include genetic testing)
2. **Confusing Abbreviations** SM Ab (Smith vs. smooth muscle)
3. **Similar Sounding Names** Factor V Leiden vs Factor V level
4. **Same Name, but >1 Indication** BRAF, KRAS gene analysis for Noonan spectrum syndromes vs somatic cancers
5. **Brand Names** Quest Assure D for Vitamin D
6. **Synonyms** AVP vs ADH vs vasopressin
7. **Information System Limitations** Panels, Algorithms

Study Existing Guidelines for Naming Develop New Guidelines

Lead: Brian Jackson, MD, ARUP Laboratories

- Few US labs/EMRs follow specific naming guidelines
- ARUP Style Guidelines

Using different Standards to come up with Names *for the same Test*

Original name of test and performing lab	Partners/MGH	ARUP
Brian Jackson MD, MS	Charlene Bierl, MD, PhD Elissa Passiment, PhD	Sridevi Devaraj, PhD
LOINC	ONC Tiger Team	Canadian
Swapna Abhyankar, MD	Maribeth Gagnon, MS	Anand Dighe, MD, PhD

Using different standards ...

Original name of test and performing lab	Partners/MGH	ARUP
Thalassemia Screen [Seattle Children's]	Thalassemia and hemoglobinopathy Reflexive Panel	Hemoglobin Variant Reflexive Panel by HPLC and Electrophoresis, Whole Blood
LOINC	ONC Tiger Team	Canadian
Hemoglobin A2 (Bld) [Mass fraction]		Hemoglobin Electrophoresis Panel

Variation in Names...cont'd

Original name of test and performing lab	Partners/MGH	ARUP
Beta-hCG, Serum Quantitative [ARUP]	HCG, quantitative, pregnancy evaluation	hCG- beta for pregnancy testing by Chemiluminescent Immunoassay , Serum
LOINC	ONC Tiger Team	Canadian
HCG.intact+Beta subunit Qn	Choriogonadotropin beta subunit	bHCG

Variation in Names...cont'd

**Original name of test
and performing lab**

**Vitamin D, 25-
Hydroxy, Total,
Immunoassay [Quest]**

Partners/MGH

**Vitamin D, 25-OH,
(Vitamin D Deficiency)**

ARUP

**Vitamin D, 25-
Hydroxy, Total by
Immunoassay, Serum**

LOINC

**25-hydroxyvitamin D
IA [Mass/Vol]**

ONC Tiger Team

Calcidol

Canadian

**25-Hydroxyvitamin D,
Total**

Variation in Names...cont'd

Original name of test
and performing lab

HIV-1, Quantitative,
Real-Time PCR
[Quest]

Partners/MGH

HIV viral load (PCR)

ARUP

HIV-1 RNA by
Quantitative RT-PCR,
Plasma

LOINC

HIV 1 RNA NAA+probe
[Log #/Vol]
HIV 1 RNA NAA+probe
[#/Vol]

ONC Tiger Team

1) HIV 1 RNA [# /volume]
NAAT w/probe
2) HIV 1 RNA [Log
/volume] NAAT w/probe

Canadian

Variation in Names...cont'd

Original name of test and performing lab	Partners/MGH	ARUP
PhenoSense® Integrase [Monogram]	HIV, drug resistance (integrase inhibitors)	Integrase inhibitors (Anti-viral drug resistance) by RT-PCR, serum
LOINC	ONC Tiger Team	Canadian
HIV integrase inhibitor susceptibility panel Phenotype method (Isol)		HIV Phenotype, Integrase Inhibitors

Variation in Names...cont'd

Original name of test and performing lab	Partners/MGH	ARUP
PD=L1, IHC (Pembrolizumab) Gastric [LabCorp]	PD-L1, IHC (Pembrolizaumab)	PD-L1 by Immunohistochemistry, Gastric tissue
LOINC	ONC Tiger Team	Canadian
PD-L1 by clone 22C3 Immune stain QI (Tiss)	PD-L1 by clone 22C3, IS (Tiss)	PD-L1 by clone 22C3, IS (Tiss)

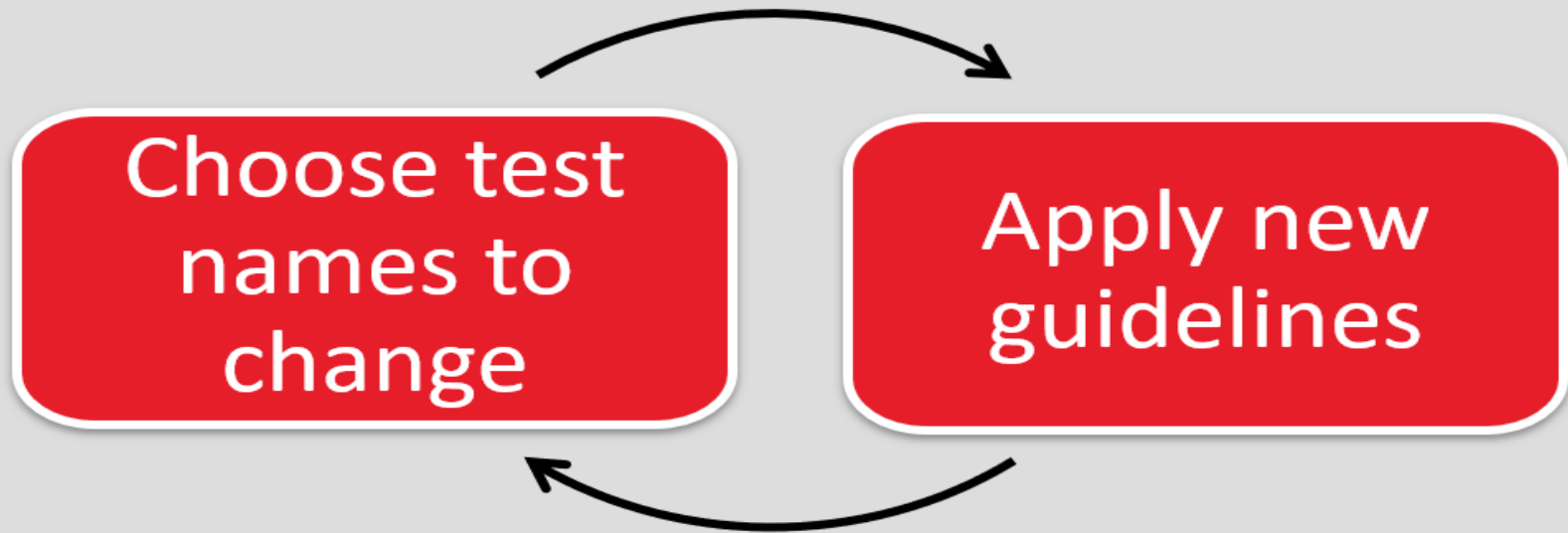
Variation in Names...cont'd

Original name of test and performing lab	Partners/MGH	ARUP
Programmed Death-Ligand 1 (PD-L1) (SP142), Semi-Quantitative Immunohistochemistry, Manual [Mayo]	PD-L1, IHC (atezolizumab, nabpaclitaxel)	programmed cell death 1-ligand 1 by Immunohistochemistry, FFPE sample/Tissue
LOINC	ONC Tiger Team	Canadian
PD-L1 by clone SP142 Immune stain Doc (Tiss)		PD-L1 (SP142); IHC; Tissue

Variation in Names...cont'd

Original name of test and performing lab	Partners/MGH	ARUP
BCR/ABL1 t(9;22) [Neogenomics]	BCR/ABL1 t(9;22), FISH	t(9;22)(q34.1;q11)(ABL1,B CR) fusion transcript by FISH, Blood/Tissue
LOINC	ONC Tiger Team	Canadian
t(9;22)(q34.1;q11)(ABL1,B CR) fusion transcript FISH Doc (Bld/Tiss)		t(9;22) (ABL1,BCR), FISH; Bld/Tiss

Iterative Process



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

TRUU-Lab Subcommittee 3:

Write a Paper

- Describe the problem and our approach
- Secure funding

Lead: **Ila Singh, MD, PhD,**

Texas Children's Hospital Baylor College of Medicine

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TRUU-Lab Subcommittee 4:

Define some guardrails around TRUU-Lab Activity ~NDA

Lead: Nancy van Kleeck, JD, Wolters Kluwer

Once we have all the names,
how do we implement? Safely?

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Testing before Implementation

1. Create a Survey to select names
 2. Create a Mock EMR – with optimal as well as sub-optimal names. See what people choose
- Goal – get these standardized names in the foundation build of all EMRs, LIS

How you can participate in TRUU-Lab



**Learn More about TRUU
Lab**

Help us recruit:
Clinician organizations
Instrumentation makers

Truulab.org

Join Us

Sponsor Us

Participate

Send us an email
truulab@gmail.com

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