Renaming Lab tests for Better Understanding and Utilization

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Chief of Laboratory Medicine, Texas Children’s Hospital
Professor, Baylor College of Medicine
Objectives

1. Recognize that names of lab tests lead to considerable confusion in ordering

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
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
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
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

15% uncertain about which test to order

8% 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 Sometimes to zero

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

Laboratory Test Utilization Management Stewardship

Dickerson et al, 2017, JALM, 02:02:259-6 (PLUGS)

Ordering fewer tests

It could, in some cases, mean more testing

Ordering the right test at the right time for the right price
Hospitals all over the US are Setting Up Stewardship Programs
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

- Hemoglobin A1C
- Glycosylated Hemoglobin
- Glycated Hemoglobin
- HgbA1C
- HbA1C
- A1C

Makes it hard to find the test
Some Standardization...

Basic Metabolic Profile

BMP

Chem7/8

Because there are CPT codes for these panel, the components are standardized

Hepatic Function Panel
No Standardization

Liver Function Panel

Respiratory Virus Panel

Lactate Dehydrogenase? Gamma Glutamyl transferase?

Panel depends on the manufacturer

There will be a technical fix someday

Hovering over the name ➡️ Explode to components
Scenario 2

Test Names are Difficult
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
The Vitamin D Problem

Total Vitamin D Testing
3,351 Patients
5,105 Tests

Vitamin D, 1,25Dıyordu 1,541 Tests

$80,733*
*based on Medicare allowable

Vitamin D, 25Hy 2,564 Tests

Both tests were ordered for 906 patients (1,962 tests)
Three Hospitals with the Same Problem

Three Different Solutions
Solution 1: Call the Ordering Clinician

March 2013 - Feb 2015
Solution 2: Change Test Names in CPOE

25- hydroxy vit D \rightarrow \text{Vitamin D for Deficiency Screen}

1,25-dihydroxy vit D \rightarrow \text{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 changing names

- 25- hydroxy vitamin D
  - (for deficiency screening)

- 1,25 dihydroxy vitamin D
  - (NOT for deficiency screening)
Results with Solution 3

- **Name Clarification**

![Graph showing results for VD25H (Vit D 25 hydroxy) and VITD3 (Vit D 1, 25 dihydroxy) for deficiency screening vs NOT for deficiency screening.](image)
Results with Solution 3

RATIO between for deficiency screening & NOT for deficiency screening

Name clarification
11/17/2017
Even so-called ‘Simple’ Interventions are not so simple
## Testosterone Test Utilization

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

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

Algorithm - APCR screen followed by factor V Leiden mutational analysis

Prices from NEJM, 2014
Many Test Names are Confusing

- Lupus Anticoagulant
- Measles
- HSV 1/2
- eGFR vs EGFR
- Panels
  - Celiac Disease/Virus Panels
- ‘Comprehensive’ tests
- Whole Exome Sequencing
- LYMPH LEUK FLW CYT = 18 characters
- Free PSA
Considerable Confusion

Even with common, ‘easy’ to understand test names
Genetic tests can be even more confusing

Condition, gene, or protein name overlap:
- Rett syndrome (MECP2 gene) vs Multiple Endocrine Neoplasia type 2 (RET gene)
- GLUT1 deficiency syndrome (SLC2A1 gene) vs Congenital Hyperinsulinism (GLUD1 gene)

Allelic disorder: Which methodology is for somatic vs germline testings?
- BRAF, KRAS, PTPN11 gene analysis for germline Noonan spectrum syndromes vs for somatic cancers/malignancies

Courtesy Darci Sternan, Seattle Children’s Hospital
Genetic tests can be even more confusing

COL2A1 gene
achondrogenesis, chondrodysplasia, early onset familial osteoarthritis, spondyloepiphyseal dysplasia congenita, Langer-Saldino achondrogenesis, Kniest dysplasia, Stickler syndrome type I, and spondyloepimetaepiphyseal dysplasia Strudwick type

Ambiguous Test Names
more than one common method to work up a condition
“Thalassemia Screen” – Genetic test? Biochemical test?

Courtesy Darci Sternan, Seattle Children’s Hospital
How did we end up here?
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**: SuperQuant HBV PCR
7. **??**: RPR, Rapid Plasma Reagin
How do we fix this?
Process for Name Change

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

**Significant safety challenges** – Recall Vit D solution
Can this be done at a National Level?
Previous Attempts at Renaming Tests

Identifying the Naming Problem, CLIHC, CDC


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 - 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

Test Renaming for Understanding and Utilization-Lab
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

AACC Choosing Wisely
• Lee Hilborne, 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
• 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

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 Houston)
• Emily Garnett PhD, Chemistry fellow (Baylor)
• Judy Trieu MD, MPH (UTMB)
How does TRUU-Lab Work?
Steering Committee

AACC
ACLPS
AMP
API
ASCP
Choosing Wisely
ASM
CAP
CDC
EMR/LIS
Terminology Grps
FDA
Nudge Unit
PLUGS Reference Labs Instrumentation Makers Clinical Pathologists and Scientists
Governance

Steering Committee

Work Groups By Specialties

Work Groups by Task

Structure with project lead and project manager
Current TRUU-Lab Subcommittees

1. Developing guidelines
   – Brian Jackson, MD, ARUP Laboratories

2. Selecting perplexing names to pressure test
   – Gary Procop, MD, PhD, Cleveland Clinic

3. Whitepaper
   – Ila Singh, MD, PhD, Texas Children’s Hospital/Baylor

4. Developing guidelines for action (~NDA)
   – Nancy van Kleeck, JD, Wolters Kluwer
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.**

<table>
<thead>
<tr>
<th>#</th>
<th>Current name of test</th>
<th>Suggestion for renaming the test</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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
> 250 Responses on > 100 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
Use the Surveys to choose a small set of especially Problematic Tests to Rename
Develop Rules for Naming – Look at Existing Guidelines

• Most US labs/EMRs do not follow specific naming guidelines
• Examine existing Guidelines or Preferred list of names
  • ONC Tiger Team’s Guidelines
  • ARUP Style Guidelines
**ONC Tiger Team Guidelines**

| **ANALYTE IDENTIFICATION** | 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. | Identification of organisms, use the scientific name |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANIONIC NAME FOR CHEMICALS</strong></td>
<td>Use anionic name</td>
<td>Use the acid name when it is more commonly accepted and space is not an issue</td>
</tr>
</tbody>
</table>
| **ANTIBODY/ANTIGEN** | 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 | Antinuclear Ab and Anti D Quantitative Assay; Use of Anti for inhibitory activity e.g. Anti Xa. |
<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>
<table>
<thead>
<tr>
<th>Substance analyzed by the test (compound, drug)</th>
<th>Always</th>
<th>Form of analyte measured</th>
<th>CARBAMAZEPINE, <strong>Free</strong> and <strong>Total</strong> Carnitine, <strong>Free</strong> Protein, <strong>Total</strong>, Plasma or Serum</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(Free, Fractionation, Total, Quantitative, Qualitative, Quantitation, Level, Functional, Enzymatic)</strong></td>
<td>When it is necessary to clarify the exact nature of the test to assist in ordering the correct test.</td>
<td><strong>Quantitative &amp; qualitative</strong> 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. <strong>Quantitation</strong> is generally reserved for Drugs of Abuse.</td>
<td>Adrenal Steroid <strong>Quantitative</strong> Panel by LC-MS/MS Glutaryl carnitine <strong>Quantitative</strong> Bence Jones Protein, <strong>Quant.</strong> Free Lambda Light Chains BCR-ABL1, T315I Mutation Detection, <strong>Quantitative</strong> Bence Jones Protein, <strong>Qualitative</strong> Free Kappa and Lambda Light Chains Drug Screen (Non forensic), <strong>Qualitative</strong> Malaria Detection &amp; Speciation, <strong>Qualitative</strong> by RT PCR Cryoglobulin, Qual - Reflex to <strong>Quant.</strong> IgA, IgG, IgM Drugs of Abuse Confirmation/Quantitation - Opiates - Meconium Confirmation/Quantitation - Serum or Plasma</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Level</strong> generally reserved for antimicrobial drug level test</td>
<td>Ticarcillin, Antibiotic trough and peak <strong>Level</strong> Vancomycin, Antibiotic Peak <strong>Level</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Functional and Enzymatic Activity</strong> are generally reserved for coagulation-type test (Protein C)</td>
<td><strong>Protein C, Functional Antithrombin, Enzymatic Activity</strong> Galactosemia, (GALT) <strong>Enzyme Activity</strong> and 9 Mutations</td>
</tr>
</tbody>
</table>
Develop Rules for Naming – Look at Existing Guidelines

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

But be creative in generating new consensus guidelines
Iterative Process

Choose test names to change

Apply new guidelines

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 chosen from 10 possibilities)
6. Secured a domain, twitter handle, Gmail address
7. Developing a website and logo - truulab.org
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.
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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 trulab@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 (trulab@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 trulab@gmail.com

Your Name (required)

Your Email (required)

Your Message
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7. Sent out a survey (with ASCP Choosing Wisely)
8. Reviewed existing guidelines worldwide
9. Sub-committees: Guidelines, ‘bad’ test names, whitepaper
10. Ways to work together – Basecamp, Slack, Google doc
How you can participate in TRUU-Lab

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

Truulab.org