Advancing Lab Data Interoperability with LOINC

An update on current standardization initiatives

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@LOINC

Regenstrief Institute
Better Care. Better Health.

LOINC® from Regenstrief

Disclosures

Many current funders for data standards work (see loinc.org/funding-support/):

U.S. National Library of Medicine
U.S. Food and Drug Administration
U.S. Centers for Medicare and Medicaid Services
National Institute of Diabetes and Digestive and Kidney Diseases
National Center for Advancing Translational Sciences
bioMérieux
Duke University (via NIEHS)
Radiological Society of North America (via NIBIB)

I'm the author of the book *LOINC Essentials* published by Blue Sky Premise, LLC where I serve as President.

Regenstrief Institute

A non-profit research organization driven by a mission to connect and innovate for better health.

Long history of developing, applying, and scaling health information technology solutions

Creator and steward (i.e. Standards development organization for) two key interoperability standards: **LOINC** and **UCUM**

Appreciate CLIAC's consistent recommendations for safe and effective interoperability of lab data

Life without LOINC

CODE	NAME
AGTCE	Angiotensin Converting Enzyme
5523	ACE SerPl Qn
ACE	ACE
22441	AngioTens Conv Enz
99234	ACE (angiotensin)
25284D	Angiotensin-1-Converting Enzyme
2737317	ACE (serum)
6881A	Angiotensin Converting Enzyme, Ser
3800ACE	ANGIOTENSIN CONVERTING ENZYME, S
77934A	Angio Convt Enzym
919109	ACE, SERUM
34ACE	Angiotensin Con. Enz
ANGCE	Angiotensin CE
6621456	Angio. Conv. Enzyme

LOINC

Universal standard for identifying health measurements, observations, and documents

Makes data more portable and understandable to different computer systems

Many tools and resources available for implementers

Community-driven development

It’s free, but invaluable

A global community

61,000+ users from 171 countries

Many kinds of users

federal agencies, reference labs and radiology centers, care organizations, professional societies, insurance companies, health IT vendors, instrument manufacturers, health app developers, etc

Used with many kinds of technologies

Electronic healthcare messages, XML documents, clinical data warehouses, open APIs, mobile apps

Key interoperability puzzle pieces

Structure standards

e.g. **HL7 FHIR** (or v2 messages, C-CDA, etc)

Semantic standards

LOINC for identifying the observation

SNOMED CT for coded observation values *(where needed)*

UCUM for computable units of measure *(where needed)*

```
{
  "resourceType": "Observation",
  "id": ”rbc",
  "text": {
    "status": "generated",
    "div": ""  },
  "status": "final",
  "code": {
    "coding": [
      {
        "system": "http://loinc.org",
        "code": "26453-1",
        "display": "RBC #/vol (Bld)"
      }
    ],
    "text": "RBC #/vol (Bld)"
  },
  "subject": {
    "reference": "Patient/example"
  },
  "effectiveDateTime": "1999-07-02",
  "valueQuantity": {
    "value": 4.82,
    "unit": "10^6/µL ",
    "system": "http://unitsofmeasure.org",
    "code": "10*6/uL"
  }
}
```

User-driven growth

Major releases twice per year (June and December)

Each release contains about 1,400 new terms (average)

160+ organizations requested new terms in last 2 years

Current release contains 86,000+ terms

Advisory body: LOINC Committee

Federal Initiatives using LOINC

ONC

Meaningful Use regulations, 21st Century Cures Act, Interoperability Standards Advisory

FDA

SPL standard has used LOINC for many years. FDA is requiring LOINC for lab test data in studies starting after March 2020. Has broad vision of using real-world evidence in post market surveillance.

CDC

Longtime users of LOINC in many efforts: electronic lab reporting, case reporting, immunization messaging, National EMS Info System, National Trauma Data Standards, etc

CMS

Electronic Clinical Quality Measures use LOINC for much content. Under Impact Act 2014, all CMS-required patient assessment instruments are standardized in LOINC.

NIH/NLM

Longtime funder of LOINC development. LOINC included in UMLS since 1998. Many NIH common data elements and other projects use LOINC.

Other key efforts and users

Collaborations with Standards Developers

Health Level 7 (HL7), IVD Industry Connectivity Consortium (IICC), IEEE, SNOMED International, Radiological Society of North America (RSNA), International Collaboration on Cancer Reporting (ICCR), Clinical Data Interchange Standards Consortium (CDISC), Health Standards Collaborative (HSC).

Observational Research Networks

FDA's Mini-Sentinel project

PCORnet

Observational Health Data Sciences and Informatics (OHDSI)

Key Initiatives

Updates on a few LOINC interoperability efforts

IVD Vendor Collaboration

Fully support efforts to move data standardization further upstream

LOINC Groups

A flexible, computable tool for rolling up groups of LOINC codes that can be considered equivalent for a particular purpose

loinc.org/groups

LOINC PARENT GROUP

LG27-5

Cell differential counts rolled-up by Method

LOINC GROUP

LG32848-0

Basophils|NCnc|Pt|Bld

26444-0	**Basophils [#/volume] in Blood**
704-7	**Basophils [#/volume] in Blood by Automated count**
705-4	**Basophils [#/volume] in Blood by Manual count**

LOINC GROUP

LG32850-6

Erythrocytes|NCnc|Pt|Bld

26453-1	**Erythrocytes [#/volume] in Blood**
789-8	**Erythrocytes [#/volume] in Blood by Automated count**
790-6	**Erythrocytes [#/volume] in Blood by Manual count**

LOINC PARENT GROUP

LG55-6

Mass and molar concentration terms with same Component, Timing, System, Method

LOINC GROUP

LG33250-8

Glucose|Pt|Urine|Test strip|MassMolEquiv|180.156 g/mole

5792-7	**Glucose [Mass/volume] in Urine by Test strip**
22705-8	**Glucose [Moles/volume] in Urine by Test strip**

LOINC GROUP

LG33389-4

Creatinine|Pt|Urine|Test strip|MassMolEquiv|113.12 g/mole

30004-6	**Creatinine [Mass/volume] in Urine by Test strip**
30002-0	**Creatinine [Moles/volume] in Urine by Test strip**

LOINC Groups Community Submissions

Your LOINC Groups Submissions

Submit new Group

Date	Title/Name	Status
2017-09-19	LOINC Codes for Glucose in Serum/Plasma	Pending Review

Pending Review

Date	Title/Name	Submitter
2018-04-03	Test Shaun's input	Tim Briscoe
2017-10-10	ED Initial Set for Chest Pain	JT Finnell
2017-09-19	LOINC Codes for Glucose in Serum/Plasma	Daniel Vreeman

LOINC Groups

loinc.org/groups

Published with twice yearly LOINC releases

Current version (Alpha.2) contains 4,000 groups aggregating 17,000+ LOINC terms

Recent Enhancements

Added attributes such as molecular weights, descriptions clinical information about the concepts within a single group, e.g., the differences in blood and serum/plasma glucose measurements.

Developed community portal where users can share their own groups and nominate others for inclusion in the LOINC published set

Deploy Groups as valuesets using FHIR Terminology Services API

LOINC Display Names

Julius Winfield Erving II

The Doctor

Dr. J

Official LOINC Names

Fully-Specified Name (FSN)

Mapping

Long Common Name (LCN)

Primary display name

Short Name

Column header, old-school systems with character limits

Example LOINC Names

Fully-Specified Name (FSN)

Urea nitrogen:MCnc:Pt:Ser/Plas:Qn:

Long Common Name (LCN)

Urea nitrogen [Mass/volume] in Serum or Plasma

Short Name

BUN SerPl-mCnc

New Display Name

Many years of discussions with users

- Some want shorter
- Some want clearer
- We need names to be unique
- We need to generate them semi-automatically

Created new “Better” Display Names

- Beta release scheduled for June 2018
- Covers all laboratory terms

Naming Rules Summary

System of **Ser/Plas** is default

Timing of **Pt** is default

For quantitative, omit *Scale* but include *Property* with “friendlier” abbreviations

For qualitative, omit *Property* but include *Scale*

Example Display Names

(Beta)

30405-5	WBC #/vol (U)
48345-3	HIV 1+O+2 Ab Ql
2986-8	Testosterone mass conc
30934-4	Natriuretic peptide B mass conc
2019-8	Carbon dioxide ppres (BldA)
5671-3	Lead mass conc (Bld)
3377-9	Barbiturates Ql (U)
8061-4	Nuclear Ab Ql (S)
5196-1	HBV surface Ag IA Ql
35674-1	Creatinine unspecified time mass conc (U)

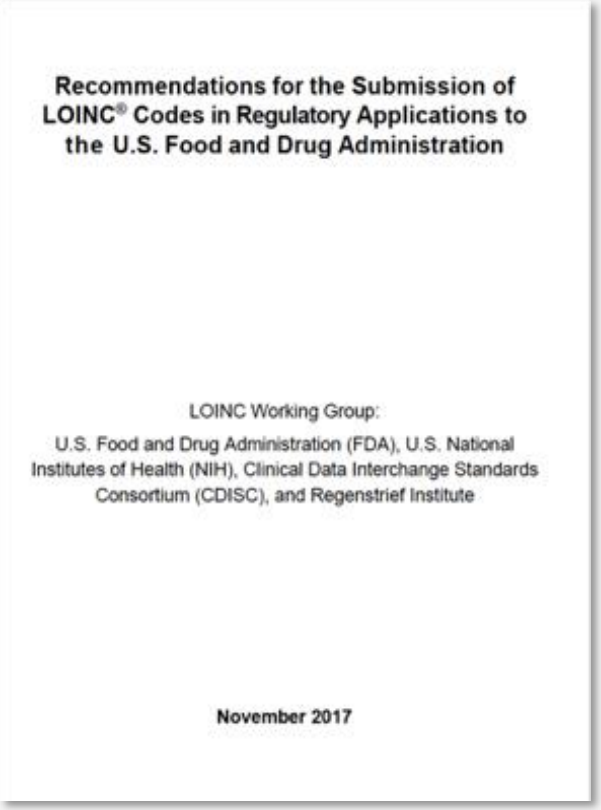
Collaboration with FDA

Broad vision towards using real-world evidence in post market surveillance

LOINC in Regulatory Applications

FDA requiring LOINC for lab test data in studies starting after March 2020

Organized working group (with RI, CDISC, NIH) that created recommendations for [submission of LOINC-coded data (now published)]



Recommendations for the Submission of LOINC® Codes in Regulatory Applications to the U.S. Food and Drug Administration

LOINC Working Group:

U.S. Food and Drug Administration (FDA), U.S. National Institutes of Health (NIH), Clinical Data Interchange Standards Consortium (CDISC), and Regenstrief Institute

November 2017

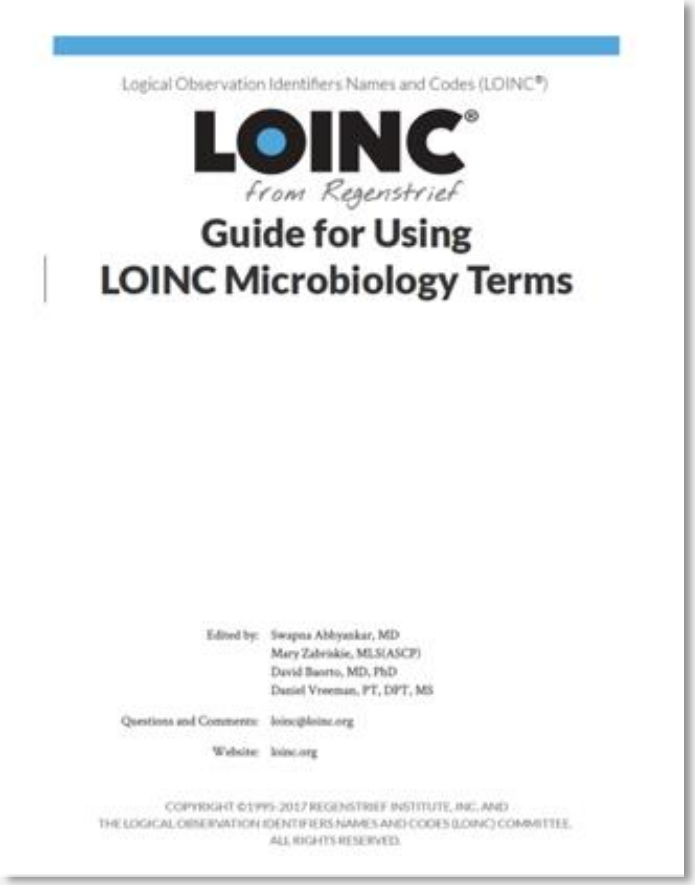
Microbiology Guidance Document

Ongoing FDA-funded Pilot project and final publication of *Guide for Using LOINC Microbiology Terms*

4 sites in pre/post pilot study to evaluate usefulness of guide as mapping aid

Our first (but hopefully not last) “Implementation Guide”

Example of CLIAC recommendation to better understand the nuances, specificity, and compatibility of sharing LOINC or other standard codes


Logical Observation Identifiers Names and Codes (LOINC®)

LOINC®

from Regenstrief

Guide for Using
LOINC Microbiology Terms

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Contract HHSF223201710178P from U.S. Food and Drug Administration

Closing Thoughts

Interoperability is a journey, not a destination

Continue struggling with the variations in conceptualization from labs, IVD vendors

(see CJ McDonald presentation from 2013 03 and SM Huff today)

Still relatively low use of standardized codes for ordering

Variation in units and ordinal/nominal result values are still challenging

Happy LOINCing!

https://loinc.org/

@LOINC