Guide for using LOINC in NDHM FHIR Resources

REVISION HISTORY

Date	Version	Description
30/04/2021	1.0	The document describes the way to use LOINC codes in NDHM FHIR resources for coding of laboratory tests and observations

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INTRODUCTION

Logical Observation Identifiers Names and Codes (LOINC®) is an international standard for identifying health measurements, observations, and documents. It provides a common language to unambiguously identify things you can measure or observe that enables the exchange and aggregation of clinical results for care delivery, outcomes management, and research. LOINC is a rich catalog of measurements, including laboratory tests, clinical measures like vital signs and anthropometric measures, standardized survey instruments, and more. One of the main goals of LOINC is to facilitate the exchange and pooling of results for clinical care, outcomes management, and research.

It is developed and maintained by Regenstrief Institute, Inc., a non-profit medical research organization associated with Indiana University, USA. At present, LOINC is used in more than 170 countries to move data seamlessly between systems.

LOINC standard is one of the medical terminologies for observation, measurement, test-panels, test items, and units specified for adherence in EHR Standard for India (2016) and National Digital Health Blueprint (NDHB).

SCOPE

This document provides brief information on LOINC and its usage as terminology binding in FHIR resources of National Digital Health Mission (NDHM) Health Data Interchange Specifications 1.0. This document is only for reference purposes. The approach for implementation may vary from application to application based on the requirements, resources, and scope.

LOINC CONCEPT

A LOINC term is defined as the combination of the LOINC code, the Fully Specified Name (FSN), and associated names. The LOINC code is a unique, permanent identifier and has no intrinsic structure except that the last character in the code is a mod 10-check digit. LOINC codes are for computers while LOINC names are for humans.

LOINC terms are broadly classified into, Laboratory and Clinical category. Each LOINC term corresponds to a single test, panel or observation. When used as the test result, the LOINC code is referred to as a label and the values may indicate presence/absence or the amount.

LOINC NAMES

LOINC names provide a human-readable text associated with the LOINC Code. Let us take an example of the *Glucose Test* to illustrate –

Fully-Specified Name (FSN)

The FSN (also known as the Formal Name) includes the following five to six fields (the sixth field being optional).

Component/Analyte

- What is measured, evaluated, or observed
  e.g., Potassium, Hemoglobin, hepatitis C antigen

Kind of Property

- Characteristics of what is measured
  e.g., Mass concentration (mg/L), Molar concentration (moles/L), count (5,000)

Time Aspect

- Interval of time over which the observation or measurement was made
  e.g., Point in time(Pt), 24-hour urine

System

- Context or speciman type within which the observation was made
  e.g., blood, urine

Type of Scale

- The scale of measure
  e.g., Quantitative (a number), Ordinal (Positive/Negative, 1+, 2+, Mild, Moderate),
  Nominal (E.coil, Staphylococcus aureus), Narrative (Dictation result from X-rays)

Type of Method

- Procedure used to make the measurement or observation
  e.g., Manual count, Automated count, Spirometry

Figure 1 Main parts of FSN

Based on the above fields, LOINC format for fully specified name code of a test result or a clinical observation is given using:

<component/analyte>:<kind of property>:<time aspect>:<system type>:<scale>:<method>

E.g., Glucose:SCnc:Pt:Urine:Qn:Test strip

The FSN is the combination of the main *Parts* and the colon character, ":", which acts as a separator.

Note
Apart from *Method*, all the parts from FSN should have a value for every active LOINC term. Only *Method* may have a null value. There are few panel terms where one or more parts may have a dash (**-**) as a value.

Long Common Name (LCN)

In LCN, the abbreviations and acronyms that are used in the *FSN* have been fully spelled out in English and human-readable name for a LOINC term.
E.g., Glucose [Moles/volume] in Urine by Test strip

Short Name

The Short Name in LOINC is case significant in contrast with FSN. They can be acronyms, abbreviations, and globally used common names in practice. They are not unique and there might be duplicate short names (where LOINC concept differs only by having a *Scale* of Nar vs Nom). LOINC terms may not always have a Short Name as they are optional.
E.g., Glucose Ur Strip-sCnc

Display Name

The display name is more of a clinician-friendly name compared to the current LOINC Short Name, LCN, and FSN. They are created algorithmically from the manually crafted display text for each Part and are generally shorter than the LCN. Display names are unique for a given concept; however, in the case of truly duplicate concepts, the Display Name will be the same. Some rules used to create the Display Names are mentioned in the LOINC Users' Guide. (Refer 9.1.1.3 Display Name)
E.g., Glucose Test strip (U) [Moles/Vol]

LOINC TERM USAGE AND IMPLEMENTATION ASPECT

For Reporting Pathologists/ Lab Technicians

With the provision of different LOINC Name for each concept, the lab technicians may choose a suitable name for reporting. LCNs are created via an algorithmic process where most abbreviations and acronyms that are used in the LOINC database have been fully spelled out in English. Hence, LCN becomes a more readable format than the fully specified name which can be a preferred choice for pathologists for reporting.

However, amongst these, display names are a more clinician-friendly name for LOINC concepts. Although all LOINC concept does not have display names. In that case, a consumer name/locally crafted name can be used. Most of the implementations around the world using LOINC have a local "interface name" that users see.

For Storage in Healthcare Application

As per the LOINC License, healthcare applications require to store FSN as well as the Short Name along with the LOINC code. Being human-readable and unique, storing LCN is also strongly recommended.

If the application has a table of observation (or any other table) for patient data where LOINC code and names are stored, it is recommended to use LCN. Another way is to have codes in the table, and then look-up information from a separate LOINC repository /terminology server.
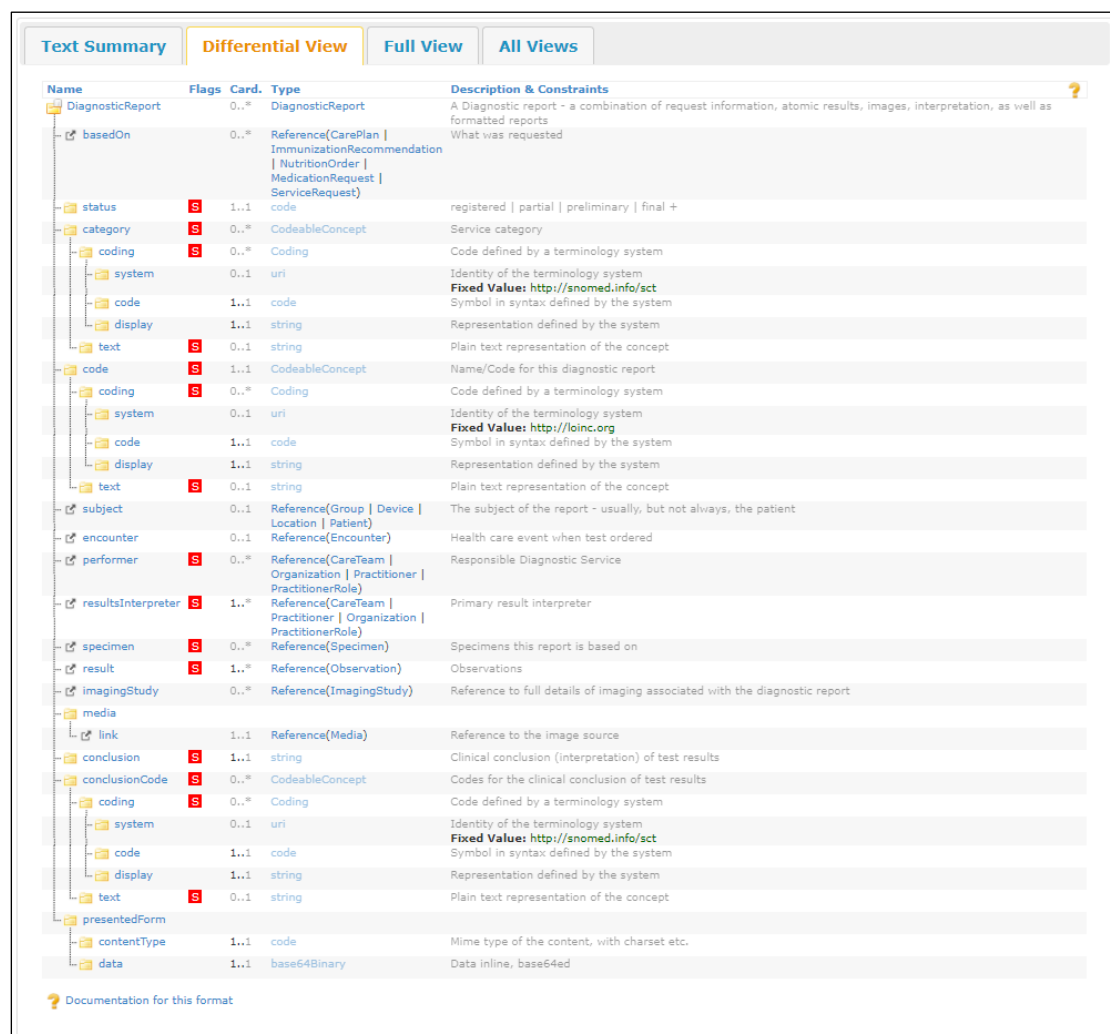
For Exchange

Fast **H**ealthcare **I**nteroperability **R**esources (FHIR) Release 4 is specified as the data exchange standard in the NDHB report. Many elements in the FHIR resources have terminology binding for the existing code systems like SNOMED

CT, LOINC, and ICD-10. The resources carrying measurements, tests, panels, observations, interpretation, and many more can use LOINC codes while exchanging health information amongst systems. The FHIR resources have a special structure called code element, to send standard codes and terms, that identify a concept as defined by the code system.

LOINC concept provides at least 3 names for each term (i.e., the six-part FSN, Short Name, and LCN). Amongst them, LCN and the LOINC code is considered the preferred choice to use in the terminology binding of FHIR resource, as it is complete, unambiguous, and the most understandable LOINC description for human readers.

In the scenario where there are character limits in sending and receiving systems and the use of LCN may not be possible then, the Short Name is an acceptable alternative. Sending the FSN is generally not recommended.

Figure 2 FHIR Resource Structure

USING CODE SYSTEM IN FHIR RESOURCES

In FHIR resource, *code* element is used to represent *coding/terminology* binding like SNOMED CT, LOINC, ICD-10, etc., This has further elements like code, display text, and system (*coding/terminology* system), or just a text to represent a concept (*text* element).

code	S	1..1	CodeableConcept	Name/Code for this diagnostic report
coding	S	0..*	Coding	Code defined by a terminology system
system		0..1	uri	Identity of the terminology system **Fixed Value:** http://loinc.org
code		1..1	code	Symbol in syntax defined by the system
display		1..1	string	Representation defined by the system
text	S	0..1	string	Plain text representation of the concept

Figure 3 Structure of the code element

With upper bound cardinality *, the *code* can have multiple *coding* elements. However, the *text* element has one text representation of a concept as its upper bound cardinality is 1.

The c*oding* data type further refers to –

- *system* is a URI that identifies the code/terminology system
- *code* is an identifier defined by a terminology system
- *display* is one of the description for the code defined in the code/terminology system.

Here, both *code* and *display* element have upper and lower bound cardinality is 1..1, which means, there has to have one representation of the code system in each *coding* element. For the LOINC coding system, LOINC code for *code* element and long common name (or short name) for *display* element is a preferred choice to represent laboratory test panel or observation.

```
"code" : {
    "coding" : [
        {
            "system" : "http://loinc.org",
            "code" : "24331-1",
            "display" : "Lipid 1996 panel - Serum or Plasma"
        }
    ]
},
```

Figure 4 Example of code element without text

The *text* is the representation of the concept as entered or chosen by the user, and which most closely represents the intended meaning of the concept. The *text* element without *coding* should be used, only if there is no appropriate code found to represent the clinical meaning in the bonded code system.

```
"code" : {
   "text" : "Lipid Panel"
},
```

Figure 5 Example of text element when appropriate LOINC code not found

The *text* element can be used along with the *code* element, where a more general representation of the concept defined in code is needed or text processing for display over the web is expected. In the case of LOINC, LCN or Display Name would be the preferred choices. It is generally considered as a best practice when both *coding* and *text* element is specified in the *code* element.

```
"code" : {
   "coding" : [
      {
         "system" : "http://loinc.org",
         "code" : "24331-1",
         "display" : "Lipid 1996 panel - Serum or Plasma"
      }
   ],
   "text" : "Lipid Panel"
},
```

Figure 6 Example of code element

LOINC PANELS

LOINC contains a detailed representation of many panels. LOINC panels are logical collections of LOINC terms that represent specific sets of information, such as a set of laboratory tests, a group of findings from a procedure, and forms or assessments as required for care purposes. LOINC panel contains the tests/observations like primary measurements, derived observations, Ask at Order Entry (AOE) questions, impressions, interpretations, and comments. A LOINC Panel has a specific structure, and depending on the type of panel, attributes such as form coding instructions, skip logic, and nested panels can be included.

LOINC codes have been defined for most individual laboratory and clinical observations and claims attachments. Two or more codes can be used together to represent meaningful and broader laboratory and clinical observations, as well as to report the result. For example, if a physician order blood pressure measurement and expect to get (at least) the diastolic blood pressure and the systolic blood pressure. Though these are separate observations, for practical purposes, one is never measured without the other.

LOINC panel structure is defined with the conditionality attribute for each test/observation of the panel indicates whether it should be present in the panel.

_____

Table 1 - Options for Term Conditionality within Panels

Code	Meaning	Definition
R	Required	The test/observation must be included
R-a	Required with alternatives	The test/observation is required but has alternatives. The alternatives will usually be paired, and both will be marked with the R-a code.
C	Conditional	The required status depends on other factors
O	Optional	The test/observation is optional to record
Rflx	Reflex	The test/observation will be included in the panel only if it satisfies a reflex condition based on other results in the panel (e.g., The absolute count of neutrophils versus the percentage of total white count of neutrophils in a differential blood count – if one is absent the other must be present)
Rflx-a	Reflex with alternatives	The test/observation is a reflex and another test (marked as a reflex) in the panel can serve as an alternate. Either or both reflex tests can be reported, but if the reflex condition is met, at least one of the alternative pairs must be included.

LOINC	Name	R/O/C	Cardinality	Example UCUM Units
24331-1	Lipid 1996 panel - Serum or Plasma			
2093-3	Cholesterol [Mass/volume] in Serum or Plasma	R		mg/dL
2571-8	Triglyceride [Mass/volume] in Serum or Plasma	R		mg/dL
2085-9	Cholesterol in HDL [Mass/volume] in Serum or Plasma	R		mg/dL
13457-7	Cholesterol in LDL [Mass/volume] in Serum or Plasma by calculation	O		mg/dL
13458-5	Cholesterol in VLDL [Mass/volume] in Serum or Plasma by calculation	O		mg/dL
11054-4	Cholesterol in LDL/Cholesterol in HDL [Mass Ratio] in Serum or Plasma	O		{ratio}
9830-1	Cholesterol.total/Cholesterol in HDL [Mass Ratio] in Serum or Plasma	O		{ratio}

Figure 7 LOINC panel example

LOINC also has some panels containing nested child panels. These child panels have collections of LOINC terms.
E.g., Pulmonary function test panel (LOINC Code - 81458-2)

The details about the LOINC panel can be referred to in *Section 7-Panels (Batteries)* of the LOINC Users' Guide.

FINDING PANEL CODE IN LOINC FOR FHIR RESOURCE

For implementers, finding an appropriate LOINC code or mapping to the local test or panel for a given order or observation is vital. The two most important principles to follow:

1. Map to the most specific LOINC term possible based on the available information; and
2. Do not over-specify by assuming information that is not known

LOINC has many equivalent terms for the same analyte that vary by subtle distinctions. These distinctions are important because they reflect the

differences in clinical utility for each test panel. Mapping accurately requires attention to those details and not making assumptions about the test being mapped. This makes the implementer come across the following scenarios for using appropriate LOINC codes -

- **Matching panel found**
  A LOINC panel covering all the desired tests from the local logical package may be considered as a suitable panel code for mapping. It should be noted that minimally all the *Required* and *Conditional* (if apply) tests from the prospective panel should be covered in the local logical package.

  In this case, LOINC panel code, as well as single LOINC code for single test/observation can be represented in *code* elements of respective FHIR resources. In the case of Panel, the panel elements can be coded with LOINC codes in the *result* element.

- **No matching panel code found**
  LOINC has many concepts having required analyte/component, but these concepts may not have specific property or time aspect or method that a doctor has ordered. Also, there might be a local logical package (such as health checkup packages or customized medical condition-specific packages) for which exactly matching LOINC panel codes may not be available. In such a case, it is required to find LOINC codes for all the required individual tests/observations that belong to the local package and form a customized local panel.

  In this case, a customized local test panel name can be represented in the *code.text* element in test name, while the individual tests/observations can be coded with LOINC codes as *result*.

- **The partial matching panel found**
  There can be scenarios when, LOINC panel code is found for the required local package, but:
  - There are some additional observations (non-measured components such as *date of collection*) required to be included apart from the listed tests in the panel
  - The listed tests/observations in the panel are method-less or without any specific analyte and the local package has a specific method or analyte expected in the method

  In such a case, the addition/substitution of the specific tests/observations is possible in the same panel retaining the panel code as an identifier.

  While using FHIR resources in this case, LOINC panel code can be referred to in test name, and panel elements can be coded with individual LOINC codes (including additional element) as *result*.

  The rules for addition and substitution of elements in the panel can be referred to in *Section 12.1 Business rules for users mapping their local panels*

to *LOINC panels* of LOINC Users' Guide. If the addition/substitution rules do not apply, then the case will be classified as 'No matching panel code found'.

USING LOINC CODE IN FHIR RESOURCES

The FHIR resources which carry measurement, observations, instructions, result values can have a terminology binding as LOINC codes.

In NDHM, the following profiles are developed on DiagnosticReport resource, provides a clinical/workflow context for a set of observations made in a report -
- DiagnosticReportLab
- DiagnosticReportImaging

The same LOINC concept can be used to represent both test name as well as an observation and hence, the order and observation concepts resemble the panel and panel children constructs in LOINC. Considering a scenario where a doctor/practitioner orders a set of tests. The diagnostic center generates a report which contains a summary of the outcomes and test results. Here, a test or set of the test are referred and can be represented using LOINC code in two ways, one as a group of panels (test package) and other as individual test/observation. These two common use cases can be illustrated using DiagnosticReport resource as below -

A Laboratory Test Report with a single Observation/Test

For single laboratory observation/test report, DiagnosticReport resource has *DiagnosticReport.code* to represent name of the report from LOINC Diagnostic Report Codes value set and a single Observation resource can be represented under *DiagnosticReport.result*. *Observation.code* element describes this observation/test performed in this type of report scenario.

```
"code": {
  "coding": [
    {
      "system": "http://loinc.org",
      "code": "718-7",
      "display": "Hemoglobin [Mass/volume] in Blood"
    }
  ],
  "text": "Haemoglobin"
},
```

Figure 8 Example of DiagnosticReport.code and Observation.code

Observation resource has *Observation.value* and *Observation.referenceRange* elements to represent actual result and interpretation value respectively.

In *Observation.value, Quantity* data type can be used. It has *Quantity.value* and *Quantity.unit* elements to define value of the measured amount and human-readable form of the unit respectively. The below example represents result values and interpretation of observation.

```
"valueQuantity": {
  "value": 176,
  "unit": "g/L",
  "system": "http://unitsofmeasure.org",
  "code": "g/L"
},
"referenceRange": [
  {
    "low": {
      "value": 135,
      "unit": "g/L",
      "system": "http://unitsofmeasure.org",
      "code": "g/L"
    },
    "high": {
      "value": 180,
      "unit": "g/L",
      "system": "http://unitsofmeasure.org",
      "code": "g/L"
    }
  }
]
```

Figure 9 Example of Observation.value represented in Quantity Data Type

A Laboratory Test Report with a single Panel

In this scenario, a DiagnosticReport resource represents a laboratory test/panel (such as a Lipid and glucose panel - Serum or Plasma) performed and it provides a clinical/workflow context for a set of observations made in a report. The *DiagnosticReport.code* always contains the name of the report itself i.e. LOINC code for a panel from LOINC Diagnostic Report Codes value set.

```
"code" : {
  "coding" : [
    {
      "system" : "http://loinc.org",
      "code" : "24331-1",
      "display" : "Lipid 1996 panel - Serum or Plasma"
    }
  ],
  "text" : "Lipid Panel"
},
```

Figure 10 Example of DiagnosticReport.code

DiagnosticReport.result refers to Observation resource and represents an individual clinical observation/lab test and result (include value, component, and interpretation). Multiple observations can be carried out as a part of the diagnostic test panel. The below example represents multiple observations for *cholesterol, triglyceride* from laboratory test panel i.e. *Lipid 1996 panel – Serum or Plasma.*

```
"result" : [
  {
    "reference" : "Observation/cholesterol"
  },
  {
    "reference" : "Observation/triglyceride"
  }
],
```

Figure 11 Example of DiagnosticReport.result

In an Observation resource, *Observation.code* element describes what was observed, that is, the type of observation and sometimes this is called the observation "name". The element has binding to LOINC codes for observations from the LOINCCodes value set. The below example represents the use of LOINC code for representation of observation taken during the laboratory test i.e. *Cholesterol [Moles/volume] in Serum or Plasma.*

```
"code" : {
  "coding" : [
    {
      "system" : "http://loinc.org",
      "code" : "35200-5",
      "display" : "Cholesterol [Moles/volume] in Serum or Plasma"
    }
  ],
  "text" : "Cholesterol"
},
```

Figure 10 Example of Observation.code

For actual result and interpretation value with comparison to a normal or recommended range, observation resource has *Observation.value* and *Observation.referenceRange* elements respectively. The *Observation.value[x]* element has a choice of more than one data type for their content. Depending on the context one can choose data type from among the list of permitted data types.

To record value for Observation described in LOINC, *Quantity* data type can be used. It has *Quantity.value* and *Quantity.unit* elements to define value of the measured amount and human-readable form of the unit respectively. The below example represents result values and interpretation of observation.

```
    "valueQuantity": {
      "value": 6.3,
      "unit": "mmol/L",
      "system": "http://unitsofmeasure.org",
      "code": "mmol/L"
    },
    "referenceRange": [
      {
        "high": {
          "value": 4.5,
          "unit": "mmol/L",
          "system": "http://unitsofmeasure.org",
          "code": "mmol/L"
        }
      }
    ]
```

Figure 13 Example of Observation.value represented in Quantity Data Type

A related example of this scenario is published in FHIR Implementation Guide for NDHM. (Refer - Examples: Bundle-DiagnosticReport-Lab-example-03)

A Laboratory Test Report with a Group of Panels (Package)

This is a scenario, DiagnosticReport resource represents a set of laboratory test/panel (like Lipid and glucose panel - Serum or Plasma; CBC (hemogram) panel - Blood by Automated count). In such a case, the *DiagnosticReport.code* contains the collective test name from the LOINC Diagnostic Report Codes value set to represent the group of panels (package name). If a relevant name is not found in LOINC code then *text* in the *code* elements can be used.

```
"code" : {
  "text" : "General Health Profile"
},
```

Figure 14 Example of DiagnosticReport.code to represent test package

The *DiagnosticReport.result* element references the individual observation resource which represents the test panels to be performed in the package.

```
"result": [
  {
    "reference": "Observation/p1",
    "display": "Lipid 1996 panel - Serum or Plasma"
  },
  {
    "reference": "Observation/p2",
    "display": "CBC (hemogram) panel - Blood by Automated count"
  },
]
```

Figure 15 Example of DiagnosticReport.result to refer the panel

In observation resource, the *Observation.code* represents the "panel" LOINC code and *Observation.hasMember* element can be used to represent the individual observations belonging to that panel. Here, the *Obesrvarion.value* element will

not be present. For actual result and interpretation value by comparison to a normal or recommended range, observation resource has *Observation.value* and *Observation.referenceRange* elements respectively.

```
"hasMember": [
  {
    "reference" : "Observation/cholesterol"
  },
  {
    "reference" : "Observation/triglyceride"
  }
],
```

Figure 16 Example of Observation.hasMember

A related example of this scenario is published in FHIR Release 4 Specification. (Refer - Examples: Diagnostic report-example-ghp)

REFERENCE

- FHIR Implementation Guide for NDHM - www.nrces.in/ndhm
- Get LOINC - www.loinc.org/downloads
- LOINC Users' Guide - https://loinc.org/kb/users-guide/
- RELMA Users' Manual - https://loinc.org/kb/relma/
- Using LOINC with FHIR - https://www.hl7.org/fhir/loinc.html#4.3.3