Proposal for LOINC Lab Committee regarding
Gene Targets for Microorganism
Identification in LOINC
June 8, 2017

Special topics workgroup goal

To develop a proposal regarding the level of specificity in the LOINC *Component* for nucleic acid-based detection for microorganism identification.

Background

From Section 3.4.2 - Microorganism identification based on nucleic acid targets in the LOINC Users' Guide:

"PCR-based testing for the presence of microorganisms is becoming more common. Early on, we received requests for and created codes with *Components* such as Acinetobacter baumannii DNA or Influenza virus RNA. More recently, we have received requests for tests that detect bacteria, viruses, and other pathogens based on a specific genetic target. Thus, LOINC now contains terms with more specific *Components* such as Clostridium difficile toxin A+B (tcdA+tcdB) genes and Zika virus envelope (E) gene.

As genetic testing continues to evolve, distinguishing the specific analyte (i.e. the genetic target) will be important for understanding the differences between tests, interpreting the results, and guiding further testing. Therefore, we will continue to create new LOINC codes that specify the gene targets, and ask requesters of new LOINC codes to supply this information. This specificity is important for bacterial identification, but also for other pathogens."

Process

1. Reviewed current approach in LOINC for defining nucleic acid-based tests for microorganism detection and identification.

2. Reviewed recent requests for microorganism nucleic acid-based tests, including Zika virus tests, where the target information was known or the target information was considered propriety and not disclosed.

3. Gathered and reviewed feedback from IVD manufacturers, CDC, FDA, EHR vendors, public health labs and other stakeholders.

4. Discussed IICC guidelines (not published yet) that include reporting the UID with the lab result and how this information (e.g., manufacturer, kit name, lot #) will be helpful in preserving information about the assay and targets.

5. Determined what we (the workgroup) thought was the best way forward in light of the impact on LOINC users and stakeholders.

Summary

The workgroup agreed on three main points:

1. Not specifying the gene target in the LOINC term could result in a loss of information, which may impact future clinical care decisions.

2. Gene target information should not be required to be included in the LOINC term if not currently clinically relevant.

3. There is a practical need for codes now, particularly for emerging diseases.

Two main approaches were discussed:

1. Manufacturers disclose the gene target information to Regenstrief Institute (RI), and RI would create codes such as 'Zika virus target 1 gene', 'Zika virus target 2 gene' based on this knowledge. Only RI and the manufacturers would know which LOINC code is associated with a specific target.

The majority of the workgroup members did not think this was a good option since LOINC, as an open, standardized health vocabulary, should have concepts whose precise meaning is publicly available. Additionally, this approach would likely increase RI's burden to provide ongoing support to users who need assistance in determining which codes to use.

2. When the target information is available (e.g., published in the package insert), Regenstrief should create more specific codes. For others, RI should create more generic LOINC codes and encourage labs to send information about the specific assay used along with the result. In LOINC, associated observation panels containing codes for reporting the manufacturer/assay and gene target information could be attached to the more generic codes. The LOINC Group project could be used to group all the codes together.

Workgroup decision

Workgroup members agreed that the second approach is the best (and most practical) at this time.

Recommendations

1. Create LOINC codes based on the published target information for the assay.

2. Create generic codes for assays where the targeted information is proprietary and not disclosed. If the target information becomes publicly available in the future, more specific LOINC terms may be created based on user requests.

3. Continue requesting target information from manufacturers but be more flexible in creating codes if the target isn't disclosed. Manufacturers may decide to provide target info in some cases and not others.

4. Link associated observation panels to generic terms to help users identify which codes can be used for reporting manufacturer/assay and gene target information.

5. Consider creating LOINC Groups to group together generic and target-specific codes for similar assays.