GUIDANCE DOCUMENT

NASTAD

Practical Guidance for Managing Hepatitis B and C Lab Result Notes with HL7 Feeds

Health Level 7 (HL7) feeds are vital for transmitting laboratory data to public health surveillance systems. While results are often successfully transmitted and integrated, important notes or comments associated with lab hepatitis B and C results can provide critical context, yet they can be underutilized or missing. These additional notes can offer essential context for accurate classifying hepatitis cases and public health action.

This document is intended to support hepatitis surveillance staff in working collaboratively with their informatics team to identify, retrieve, and integrate lab result interpretation notes within HL7 messages and incorporate them into the surveillance system. By strengthening the use of hepatitis result interpretative notes, surveillance programs can improve data completeness, enhance case classification accuracy, support the building of the Hepatitis C Continuum of Care (also called a Care Cascade), and better inform public health programing.

Step 1: Identifying Additional Notes in HL7 Feeds

1. Check the Existing Feed:

- Review your current HL7 messages to determine if additional notes or comments are included.
- Look for specific HL7 segments, such as NTE (2), which may contain this information (example provided below).
- If you do not have access to the HL7 messages, ask your informatics team about the NTE segments.

Example:

```
OBR|1||hepctestpt1^fakeMD^1.2.840.114350.1.13.541.2.7.3.798268.1111^ISO|ConnectionTest^
fakeMD^1.2.840.114350.1.13.541.2.7.3.798268.1111^ISO|11011-4^HCV RNA NAA+probe
Qn^LN^551300^HCV RealTime Abbott^L|||20241202103055-0800|||||Unknown pregnancy||
|1234567890^Fake^Doctor^^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|^WPN^PH^^1^123^8144
095|||||20241202103055-0800|||F||||||B19.20^Unspecified viral hepatitis C||
OBX|1|SN|11011-4^HCV RNA NAA+probe Qn^LN^551301^Hepatitis C Quantitation^L||<^12|
[IU]/mL^^L|||||F||||||Abbott RealTime|| 20241202103055-
0800||||TESTLAB^D^^^^CLIA&2.16.840.1.113883.4.7 &ISO^XX^^^05D0123456 |1616 CAPITOL
AVE^^SACRAMENTO^CA^95814|
NTE|1|L|<12
NTE|2|L|      HCV RNA not detected
```

Note: Due to the page width, the OBR and OBX line may wrap onto the next line(s). Please read them as a continuation of the same line.

Step 2: Collaborating with the Informatics Team

1. Requesting a Designated Location:

- If notes are found in the HL7 message but a location to store them does not exist, work with your informatics team to designate a specific location in your surveillance system where these notes should be stored and accessed.
- Ensure the location aligns with system architecture and is easily accessible for downstream analysis.

2. Adding Missing Information:

- If notes are found in the HL7 message but are not yet mapped in the surveillance system, work with informatics team to map and populate this data into the designated location (if available).

3. Reaching Out to Labs:

- When notes are absent from the HL7 message, coordinate with your informatics team to contact the laboratory.
- Request that the lab includes additional notes or comments to interpret the result in the HL7 feed, ideally using standardized segments like NTE.

Step 3: Updating the Surveillance System & Code

1. System Updates:

- Once additional notes are successfully integrated into the HL7 message and mapped to the surveillance system, update the system's code or configuration to:
    - Recognize and process these notes.
    - Display the information in user-friendly formats for analysis.

      Note: This same approach can also be used to identify the reason for testing and the associated pregnancy status in the OBR.

2. Testing and Validation:

- Conduct testing to ensure the additional notes appear as expected.
- Check that the system properly associates the notes with corresponding lab results.

3. Ongoing Maintenance:

- Implement routine checks to ensure continued inclusion of notes in the feed and system functionality.
- If new ambiguous results appear follow up with the laboratory to gain clarification, and, if necessary, work with your informatics team to ensure any new notes or results are mapped and integrated into your surveillance system.

Step 4: Handling Missing Information

1. Interim Measures:

- If the information still does not feed through after contacting the lab, document the gap and what the result means for each laboratory.
- Build code that takes the ambiguous result and laboratory combo to appropriately interpret the result positive or negative.

APPLIED EXAMPLE: Hepatitis – Managing Additional Notes on Interpretation of Lab Results via HL7 Feeds

This section provides practical steps for handling interpretation notes in hepatitis lab results—especially for HCV RNA—when using HL7 feeds. Proper interpretation of low viral load results (e.g., "<15 IU/mL") often depends on additional context that may appear in NTE segments or be inferred from lab-specific reporting patterns.

Step 1: Identifying Additional Notes in HL7 Feeds

1. Check HL7 Messages for Interpretation Fields:

- Review the OBX segment:
  - OBX-5 for HCV RNA results (e.g., "<15")
  - OBX-6 for units (e.g., IU/mL)
  - OBX-7 for reference range (e.g., <11.00)
  - OBX-8 for abnormal flags (e.g., "N" for normal, "A" for abnormal)
  - Additional OBX segments of interest can be identified using the following guide, starting at page 104: HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (May 2014)
- Review the NTE segments:
  - Look for text like "HCV RNA detected" and "HCV RNA not detected" that clarifies result interpretation.

2. If You Do Not See Interpretation Fields:

- Ask your informatics team to check whether these fields are available in the HL7 feed but not currently mapped into your surveillance system.
- If not present, follow up with the lab to request the inclusion of these interpretation notes in the HL7 message, ideally via the NTE segment.

Step 2: Handle Lower Limit of Quantification (LLOQ) Results when Interpretation Notes are Missing

1. Recognize Common Reporting Patterns:

- Some labs report quantitative results like "<15 IU/mL" or "<12 IU/mL" without an accompanying interpretation (e.g., "Detected" or "Not Detected").
    - When interpretation is unclear:
        - Check the notes field for interpretive comments.
        - Refer to the supplemental lab interpretation document for Quest, ARUP, or LabCorp or other lab-specific guidance, if available.
        - Look up the LOINC code on https://loinc.org/ to identify the appropriate reference range for the test reported.

2. Review the Full Panel of Test Results:

- Examine all hepatitis-related results reported in the same panel or timeframe.
- Check if there is a qualitative result (e.g., "Not Detected") that accompanies a quantitative result (e.g., "<15 IU/mL").
- Use the qualitative result to help interpret the quantitative value when the latter lacks clear interpretation.

3. Create a Lookup Table for Consistency:

- Build a reference table to help your surveillance system interpret ambiguous results. Include:
    - Lab Name
    - Reported Format (e.g., "<15 IU/mL")
    - Lab Interpretation (if known)
    - Surveillance Interpretation (e.g., Detected / Not Detected)
- This helps standardize interpretation across jurisdictions and over time, even if formal interpretations are missing from the feed.

Step 3: Collaborate with Informatics and Lab Partners

1. Ensure Interpretation Notes Are Mapped into the Surveillance System:

- Work with your informatics team to map OBX and NTE fields to a designated location in the system.
- Test that notes display correctly and are linked to the correct lab result.

2. If Notes Are Missing:

- Work with the informatics team to contact the lab and request the inclusion of interpretation comments in HL7 feeds.

Step 4: Apply Interim Solutions When Interpretation Is Unavailable

1. Document Known Gaps:

- Keep a record of laboratories and test types where interpretation is missing or ambiguous.

2. Incorporate Logic for Classification:

- Build case classification or care continuum logic using lab-specific rules.
- Example: Treat "<15 IU/mL" as "Not Detected" if lab guidance confirms this interpretation.

3. Flag Records for Review:

- When interpretation cannot be inferred automatically, flag the result for manual review to ensure correct classification.

By following these steps, jurisdictions can more accurately determine hepatitis B and C status, fill gaps in reporting and lab data interpretation, and build reliable care continuum metrics—even when HL7 feeds lack complete information.

Coding Guidance

Steps in the Code:

1. Clean and standardize test type and results fields for clear interpretation.
2. **Check for "not detected":** Use index to find occurrences of "not detected" in the lab_comment field.
3. **Identify Reference Range in Comments:** If "not detected" is associated with "reference range," mark it as part of the reference range (reference_range_flag = 1).
4. **Check for Specific Results:** If "RNA not detected" is found, treat it as the actual result (test_result_flag = 1).
5. **Handle Positive Cases:** If "detected" appears without "not," the result is interpreted as positive.
6. **Handle Ambiguity:** For ambiguous cases where "not detected" is present but not clearly defined as the result or reference range, flag the entry for manual review (final_result = "Needs Review").

To ensure that the first "not detected" in the lab_comment field is not incorrectly scanned as the test result, you can write SAS or R code to distinguish between a reference range comment and the actual test result. Here's an example of how you can structure the code:

SAS Code

```
/* Process the lab data – After coding for the test type and the results that are easy to interpret  */
data clean_lab_results;
   set Lab_data;
  if HCVRNA = 1 and result = ' ' then do;
   /*  Identify whether 'not detected' in the comments field refers to the result or the reference range*/
   if index(lab_comment, "not detected") > 0 then do;
/* If 'not detected' appears with 'reference range', flag it as part of the reference range */
if index(lab_comment, "reference range") > 0 then do;
          reference_range_flag = 1;
          test_result_flag = 0;
          final_RNA_result = "Check Comments";
       end;
 /* "RNA not detected" indicates the actual result */
 else if index(lab_comment, "not detected") > 0 then do;
       reference_range_flag = 0;
       test_result_flag = 1;
       final_RNA_result = "Negative";
end;
/* If 'not detected' is present but without clear context, flag it for review */
else do;
       reference_range_flag = 0;
       test_result_flag = 0;
       final_RNA_result = "Needs Review";
       end;
end;
/* If 'detected' appears without 'not', classify as positive */
else if (final_ RNA_result ne " Negative"  and    reference_range_flag = 0 ) and index (lab_comment,
"detected") > 0 then do;
        Positive_result_flag = 1;
       final_RNA_result = " Positive";
       end;
   end;
run;
```

```
/* Review cleaned results */
proc print data=clean_lab_results;
   var lab_comment reference_range_flag test_result_flag Positive_result_flag final_ RNA_result;
run;
```

R Code

```
# Load required libraries
library(dplyr)
library(stringr)

# Process the lab data – After coding for the test type and the results that are easy to interpret
clean_lab_results <- Lab_data %>%
 mutate(
  # Convert lab_comment to lowercase for consistent pattern matching
   lab_comment = str_to_lower(lab_comment),

   # Initialize all flags and final result
   reference_range_flag = NA_integer_,
   test_result_flag = NA_integer_,
   Positive_result_flag = NA_integer_,
   final_RNA_result = NA_character_
 ) %>%
 rowwise() %>%
 mutate(
#  Identify the words “reference range”, “not detected”, “detected” in the comments fields
   reference_range_present = str_detect(lab_comment, “reference range”),
   not_detected_present = str_detect(lab_comment, “not detected”),
   detected_present = str_detect(lab_comment, “detected”) & !str_detect(lab_comment, “not detected”),
   # Assign final_RNA_result and flags
   final_RNA_result = case_when(
     HCVRNA == 1 & result == “” & not_detected_present & reference_range_present ~ “Check Comments”,
     HCVRNA == 1 & result == “” & not_detected_present & !reference_range_present ~ “Negative”,
     HCVRNA == 1 & result == “” & detected_present ~ “Positive”,
     HCVRNA == 1 & result == “” & not_detected_present ~ “Needs Review”,
     TRUE ~ final_RNA_result
   ),
```

```
  reference_range_flag = case_when(
    final_RNA_result == "Check Comments" ~ 1,
    final_RNA_result %in% c("Negative", "Needs Review") ~ 0,
    TRUE ~ reference_range_flag
  ),

  test_result_flag = case_when(
    final_RNA_result == "Negative" ~ 1,
    final_RNA_result %in% c("Check Comments", "Needs Review") ~ 0,
    TRUE ~ test_result_flag
  ),

  Positive_result_flag = case_when(
    final_RNA_result == "Positive" ~ 1,
    TRUE ~ Positive_result_flag
  )
) %>%
 ungroup() %>%
 select(
   lab_comment, reference_range_flag, test_result_flag,
   Positive_result_flag, final_RNA_result
 )

print(clean_lab_results)
```

Alternatively, you can code the laboratory and result they provide to be interpreted as positive or negative. If you choose this option, ensure regular follow-ups to confirm that the result continues to be interpreted accurately.

Note: Some laboratories report RNA results in tandem. For example, an RNA result may be reported qualitatively as "Not Detected/Negative," while a separate quantitative RNA result is transmitted as "<12" without additional notes. In this case, the interpretation of "<12" should be based on the concurrently reported qualitative result. Ensure that both results are processed and integrated into the surveillance system. The code should prioritize the qualitative result for interpretation over the quantitative result.

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