ESP VALIDATION GUIDANCE

Document Version 1.0

Prepared by the Massachusetts Department of Public Health and the Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute on behalf of the Massachusetts Department of Public Health.

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Modification History

Version	Date	Modification	By
1.0	12/22/2017	• Original circulated version	MDPH/DPM

Intent: Provide general guidance for performing a validation of cases identified by ESP, which is an onboarding requirement for MDPH HIRP. This document provides examples of frequently encountered issues and root causes, as identified by past validations. It is emphasized that this document be used only as a guide because it is by nature not exhaustive. Note that table templates for methodically documenting review findings have also been included.

SECTION 1: GUIDANCE FOR PERFORMING VALIDATION

I. **Validation of ESP Detection Algorithm against Site's EMR**

This validation is performed by the implementing clinical site in collaboration with Commonwealth Informatics, Inc. (CII) and the Massachusetts Department of Public Health (MDPH).

A. Were there any cases identified by ESP that were not cases that should be reported to DPH?
    1. Is a lab mapped incorrectly in ESP?
    2. [HIV-specific]: was the case receiving PEP or PrEP? Was this treatment atypical (e.g., receiving PEP several times over a short period)?
    3. Another reason?

B. Were there any cases that should be reported to DPH that ESP did not identify?
    1. Is a lab mapped incorrectly?
    2. Was there information that was not available to ESP?
        a. Was the case diagnosed somewhere else and this documented in their EMR as a note?
        b. Were labs done somewhere else and not accessible to ESP?
        c. Was the case treated somewhere else and prescribed medications not accessible to ESP?

C. Were there cases that were identified by ESP and would be reported to DPH, but did not match predefined classifications (e.g., acute vs. chronic, active vs. latent)?
    1. Was the information required to make this distinction not available to ESP?
        a. Was there information contained in a note within the EMR that was not accessible to ESP?
        b. Were labs done somewhere else and not visible to ESP?

II. **Validation of ESP cases against MAVEN**

This validation is performed by MDPH staff in collaboration with the implementing clinical site.

A. Were there any cases identified by ESP that were not reported to DPH? If so, work with the site to determine if the identified case truly has the condition of interest.
    1. If it is a real case, why wasn't it reported to DPH?
        a. Is a lab mapped incorrectly in ESP or HIRP?
        b. Was there an issue with ELR transmission?
        c. Was the case not reported by clinician?
        d. Another reason?

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2. If it is *not* a real case (i.e., false positive), what caused the case to be identified by ESP?
   a. Is a lab mapped incorrectly?
   b. Can a small adjustment be made to the algorithm to avoid this type of false positive?
   c. If not, can these false positives be identified and triaged in MAVEN?
   d. Is the number of false positives acceptable to DPH?

B. Were there any cases reported to DPH that were not identified by ESP? If so, work with the site to determine why.
   1. Is a lab incorrectly mapped?
   2. Was there information that was not available to ESP?
      a. Was the case diagnosed somewhere else and this documented in their EMR as a note?
      b. Were labs done somewhere else and not visible to ESP?
   3. Can a small adjustment be made to the algorithm to capture these cases that could be considered in future versions of the algorithm?

C. Were there cases that were identified by ESP and reported to DPH, but revoked in MAVEN?
   1. Why was the case revoked?
      a. Was the case out of state?
   2. Could this information have been utilized by ESP to avoid sending the case or to provide information to help determine if the case should be revoked?

D. Were there cases that were identified by ESP and reported to DPH, but did not match MAVEN classifications (e.g., acute vs. chronic, active vs. latent)?
   1. Was there information available to ESP (e.g., prior labs, diagnoses, medications) that were not reported to MAVEN, preventing DPH from making the correct classification?
   2. Was the information required to make this distinction not available to ESP?
      a. Was there information in a note in the EMR that was not accessible to ESP?
      b. Were labs done somewhere else and not visible to ESP?
   3. Is a diagnosis code being used inappropriately/unexpectedlyat a site?
   4. Could there have been an issue with a MAVEN workflow causing it to miss cases?

III. **HL7 Message Validation**

This validation is performed by MDPH staff in collaboration with the implementing clinical site.

A. Can the implementing site successfully send a message via SOAPxmitter to the Staging HIRP?
B. Does the message meet the requirements laid out in the ELR_HL7_231_Implementation_Guide_052104.pdf (supplied by MDPH staff)?
C. Is all mapping in the HIRP complete? This will include
   1. Laboratory tests/results for all relevant organisms
   2. Susceptibility information, with Abnormal flags
   3. Specimen source codes
   4. Race and ethnicity

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5. Message status
6. Report status code
7. All relevant mappings completed under the Organism = Miscellaneous tab (treatment, treatment date, symptoms, symptom date etc)

D. Do HL7 messages create errors in the HIRP staging site?
1. MDPH staff work through syntax errors with the clinical site until messages no longer create errors

E. Were all the expected fields populated in the HL7 messages?
F. Can messages be successfully batched MDPH expects one batch per day)?
G. Can batches be successfully sent even if there are no messages for a particular day i.e. can the system successfully generate empty batches?
H. Initial testing will take place with fake data; has live data been sent to the Staging HIRP?
I. When uploading a case to the MAVEN testing environment:
1. Was the appropriate event created (as opposed to an unknown event)?
2. Are the question packages being updated appropriately? Is the update where you'd expect it to be?
3. Are there variables being reported in the HL7 messages that are not or only partially captured in MAVEN but should be?
4. Are any fields repeating reported information?
5. Are any fields being inappropriately overwritten in MAVEN?
6. Are updates appending to existing cases appropriately?

SECTION 2: GUIDANCE FOR DOCUMENTING VALIDATION FINDINGS

I. Documentation for validation of ESP cases against site's EMR

Documentation is completed by the implementing clinical site.

A. Create a Patient-Level Line List
1. Information that may be helpful to include
   a. Reference IDs
      i. ESP ID
      ii. Patient ID from site's EMR
   b. Date of case identification
   c. Reason case was identified in ESP (which criteria did they meet?), if relevant
   d. Classification as confirmed by EMR (i.e., acute vs. chronic, active vs. latent), if relevant
   e. Notes learned about a case during validation

2. Example of what this table might look like:

Case Status	ESP ID	Pat ID	Date Identified	ESP Criteria	Notes

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Identified by ESP and is a confirmed case	1234	9101	1/1/2017	A	N/A
Identified by ESP, but not a case	1112	1516	1/2/2017	B	Lab was mapped incorrectly in ESP. Mapping was fixed and case would no longer be identified by ESP.
Confirmed case, but not identified by ESP	N/A	2728	1/6/2017	A	Note in EMR states... Confirmatory lab was done prior to being seen at our site, so not in ESP.
Acute in ESP, but confirmed chronic in EMR	2930	3334	1/15/2017	C	Note in EMR states...
Chronic in ESP, but confirmed acute in EMR	3536	3940	1/20/2017	D	Note in EMR states...

B. Create a Validation Summary
1. Using the patient-level line list, put together a summary of findings from the validation to share with MDPH staff.
2. The following information should be included in a summary report for MDPH.
    a. Number of cases identified
    b. Time period in which cases were identified
    c. Number of cases identified by ESP that should be reported to DPH (i.e., "true positives")
    d. Number of cases identified by ESP that should not be reported to DPH (i.e., "false positives")
        i. Include reasons why cases were identified by ESP
    e. Number of cases not identified by ESP that should be reported to DPH (i.e., "false negatives")
        ii. Include reasons why cases were missed by ESP
    f. Number of cases where the ESP classification (e.g., acute vs. chronic, active vs. latent) was incorrect
        iii. Include reasons why ESP misclassified these cases
    g. Any other findings that should be brought to MDPH's attention

II. **Documentation for validation of ESP cases against MAVEN**

Documentation is completed by MDPH staff.

A. Create a Patient-Level Line List
1. Information that may be helpful to include
    a. Reference IDs
        i. ESP ID
        ii. MAVEN ID
        iii. Patient ID from site's EMR
    b. Date of case identification
    c. Reason case was identified in ESP (which criteria did they meet?), if relevant

d. Classification in MAVEN (i.e., acute vs. chronic, active vs. latent), if relevant
e. Notes learned about a case during validation in MAVEN
f. Notes learned about a case during conversations with site or from documented site validation

2. Example of what this table might look like:

Case Status	ESP ID	MAVEN ID	Pat ID	Date Identified	ESP Criteria	Notes from MAVEN validation	Notes from conversation with site
Identified by ESP and in MAVEN	1234	5678	9101	1/1/2017	A	N/A	N/A
In MAVEN, but revoked	1112	1314	1516	1/2/2017	B	Note in MAVEN indicating case was revoked because…	Note in EMR stated…
Not in MAVEN	1718	N/A	2122	1/4/2017	B	Could not find case with name and birth date given	Lab was mismapped, not a case. Mapping has been fixed.
In MAVEN, but not identified by ESP	N/A	2526	2728	1/6/2017	A	Confirmatory lab was done a different site	Confirmatory lab not in EMR, so could not be identified by ESP
Acute in ESP, but Chronic in MAVEN	2930	3132	3334	1/15/2017	C	Teleform/CRF was not returned, so ALT lab identified via ESP was never reported to MAVEN	Site confirmed that this is an acute case
Chronic in ESP, but Acute in MAVEN	3536	3738	3940	1/20/2017	D	Symptoms were reported on CRF, but not identified by ESP	Site confirmed that this is an acute case

B. Create a Validation Summary
1. Using the patient-level line list, put together a summary of finding from the validation to share with appropriate ISIS and program staff at MDPH.
   a. Number of cases identified
   b. Time period in which cases were identified
   c. Number of cases identified by ESP that were also in MAVEN (i.e., "true positives")
   d. Number of cases identified by ESP that were not in MAVEN (i.e., "false positives") or were revoke in MAVEN
      i. Include reasons why cases were identified by ESP
      ii. After discussing with site, should these cases have been reported?
   e. Number of cases not identified by ESP that were in MAVEN (i.e., "false negatives")
      i. Include reasons why cases were missed by ESP
      ii. After discussing with site, should these cases have been reported?
   f. Number of cases where the ESP classification (e.g., acute vs. chronic, active vs. latent) did not match classification in MAVEN
      i. After discussing with site, which classification is correct?
      ii. Include reasons why cases were misclassified by ESP or by MAVEN
   g. Any other findings that should be brought to the attention of ISIS or program staff

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