REAL WORLD TESTING PLAN

GENERAL INFORMATION

Plan Report ID Number: EMRDirect.InteropEngine.RWT.2022

Developer Name: EMR Direct

Product Name(s): Interoperability Engine

Version Number(s): 2017

Certified Health IT Product List (CHPL) ID(s): 15.04.04.1397.Inte.17.00.0.161117

Developer Real World Testing Page URL: https://www.interopengine.com/rwt

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

EMR Direct's Application Access and Direct Messaging software product helps our partners meet interoperability-related requirements. In approaching Real World Testing for our own products, we designed measures that will demonstrate the continued capability of certified health IT to exchange applicable payloads as the transport standards and/or payload vocabulary standards advance.

In designing our testing approach, we have leveraged the fact that the functionality of the applicable criteria subject to the RWT requirements for this software product result in discrete transactions (Direct messages, API requests) which can be classified as successful or not successful, allowing for straightforward measurement of functionality as the successful transactions as a percentage of the total transactions. We also considered that our software already collects aggregated data for many of the transaction types of interest, and, that since we operate our software as a service to our customers, we have access to this data across all deployments. Thus, our general approach to RWT is to leverage this actual production data from our deployed software instances, as actual real world data from production use best reflects the intent of RWT in the truest sense. Additionally, to demonstrate ongoing conformance, rather than point-in-time conformance, our plan includes the collection of data for each measure over a period lasting at least 90 consecutive days.

We also recognize that testing interoperability services in this way necessarily underestimates success rates due to confounding effects from other software products involved in each interoperability transaction. For example, in actual production settings, the transmission of a Direct message requires a sending edge system to communicate with the sending HISP software. Messages are then sent to a receiving HISP that is connected to a receiving edge system. Each of these software components is usually provided by a different vendor. This means that a true real-world interaction will usually involve 4 different vendors and at least 4 different software products. Any one of these may introduce an issue that causes a Direct message transmission to fail, e.g. the sending edge system transmits an non-conforming CCDA message. Similarly, for Application Access transactions, our system provides the g.7, g.8, and g.9 functionality but is not a base EHR itself, meaning that the source data used by our software to generate API responses is not stored by our software module, but is retrieved from another health IT module that typically provides the base EHR capabilities. There is also a separate client application that makes the API requests, such that there are typically 3 different vendors using at least 3 different software products involved in an Application Access transaction.

Thus, in general, a successful end-to-end transaction would require all of the involved software products from all of these vendors to work correctly, Our RWT methodology is based on our observations while operating our software as a service, that by aggregating across our deployed customer base, we avoid

potentially negatively skewing of data by any one “other vendor” issue, as these tend to average out such that the overall aggregated success rate of transactions provides a lower bar on the conformity for each of the systems involved. Since our software is common to every transaction, aggregated measures thus also provide a lower bar on the real-world success rate attributed to our own software. We have further refined this by designing measures to exclude transactions where one of the other actors can be readily identified to be the cause of the issue, e.g. expired Direct certificates, unauthorized API clients, etc.

With respect to care settings, we note that the functional requirements for the certification criteria subject to RWT are identical for both the ambulatory and inpatient settings, justifying our decision to aggregate data across all care settings in our measures, as our software is setting-agnostic and operates identically in all settings.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI)) *(projected)*

No applicable required or voluntary standards updates for this test plan cycle.

MEASURES USED IN OVERALL APPROACH

Description of Measurement/Metric

Measurement/Metric	Description
M22.1: Percentage of Direct messages sent that were successfully acknowledged by the receiving system	The % of Direct messages transmitted where the expected MDN acknowledgement was received. These measures will also be partitioned by the edge protocol used by the sending edge system.
M22.2: Percentage of Direct messages received where a non-failure acknowledgement was sent back to the sender.	The % of Direct messages received where the message could be successfully decrypted, the signature validated, and trust confirmed, and, when applicable, where no edge protocol errors were detected during final delivery. These measures will also be partitioned by the edge protocol used by the receiving edge system.
M22.3 Percentage of valid patient selection requests for which data was successfully returned to the client	The % of valid patient selection API requests received where patient identifiers for use in subsequent requests were returned for patients matching the selection criteria, or where the response indicated that no patient matched the selection criteria.
M22.4 Percentage of valid requests for a Data Category for which data was successfully returned to the client	The % of valid data category API requests received where data were returned for data matching the request parameters (patient ID, data category, optional date or date range), or where the response indicated that no matching data was found.
M22.5 Percentage of valid requests for All Data for which data was successfully returned to the client	The % of valid API requests for all data received where data were returned for data matching the request parameters (patient ID, optional date or date range), or where the response indicated that no matching data was found.

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria
M22.1: Percentage of Direct messages sent that were successfully acknowledged by the receiving system	h.2
M22.2: Percentage of Direct messages received where a non-failure acknowledgement was sent back to the sender.	h.2
M22.3 Percentage of valid patient selection requests for which data was successfully returned to the client	g.7
M22.4 Percentage of valid requests for a Data Category for which data was successfully returned to the client	g.8
M22.5 Percentage of valid requests for All Data for which data was successfully returned to the client	g.9

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
M22.1: Percentage of Direct messages sent that were successfully acknowledged by the receiving system	This measure is designed to test end-to-end 'send' functionality covered under this certification criterion in the production setting and requires the proper operation of all component parts. We note that as deployed, the actual content transmitted in outbound Direct messages is always provided by another party (the sending edge system), and that success as defined by this measure also depends on the proper operation of the receiving HISP and edge software which are usually provided by other vendors. As discussed above, this justifies the aggregation of the measurement data across our customer base to average out actions of other HISPs or edge systems that may not conform to the corresponding 'receive' requirements, and also best reflects actual real-world conformance of the system by including all outgoing production traffic.
M22.2: Percentage of Direct messages received where a non-failure acknowledgement was sent back to the sender.	This measure is designed to test end-to-end 'receive' functionality covered under this certification criterion in the production setting and requires the proper operation of all component parts. We note that the actual inbound Direct messages received are typically transmitted by another HISP, and that success as defined by this measure also depends on the proper operation of the sending HISP and edge software which are usually provided by different vendors. As discussed above, this justifies the aggregation of data across our customer base to average out actions of other HISPs or edge systems that may not conform to the complementary 'send' requirements, and also best reflects actual real-world conformance of the system by including all incoming production traffic.

M22.3 Percentage of valid patient selection requests for which data was successfully returned to the client	This measure is designed to test the use of the patient selection API functionality in the production setting. As discussed above, a successful request and response also depends on the client application making the request and the EHR system providing the data to operate correctly. This justifies the aggregation of data across our customer base to average out issues related to client applications or connected health IT modules. Unauthorized or malformed requests received from client applications are also excluded.
M22.4 Percentage of valid requests for a Data Category for which data was successfully returned to the client	This measure is designed to test the use of the request by Data Category API functionality in the production setting. As discussed above, a successful request and response also depends on the client application making the request and the EHR system providing the data to operate correctly. This justifies the aggregation of data across our customer base to average out issues related to client applications or connected health IT modules. Unauthorized or malformed requests received from client applications are also excluded.
M22.5 Percentage of valid requests for All Data for which data was successfully returned to the client	This measure is designed to test the use of the request All Data API functionality in the production setting. As discussed above, a successful request and response also depends on the client application making the request and the EHR system providing the data to operate correctly. This justifies the aggregation of data across our customer base to average out issues related to client applications or connected health IT modules. Unauthorized or malformed requests received from client applications are also excluded.

Care Setting(s)

Care Setting	Justification
Ambulatory and Inpatient	Our software is marketed for integration with both hospital and ambulatory settings. However, as discussed above, we are justifying the aggregation of measurement data across both care settings because the functional requirements for the criteria tested in this plan are identical for all care settings, i.e. our software operates identically regardless of care setting, such that we find no additional value in collecting separate measures for each setting.

Expected Outcomes

Measurement/Metric	Expected Outcomes
M22.1: Percentage of Direct messages sent that were successfully acknowledged by the receiving system	Greater than 80%
M22.2: Percentage of Direct messages received where a non-failure acknowledgement was sent back to the sender.	Greater than 80%
M22.3 Percentage of valid patient selection requests for which data was successfully returned to the client	Greater than 80%

M22.4 Percentage of valid requests for a Data Category for which data was successfully returned to the client	Greater than 80%
M22.5 Percentage of valid requests for All Data for which data was successfully returned to the client	Greater than 80%

SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Begin data collection	All	August 2022
Complete data collection	All	October 2022

ATTESTATION

This Real World Testing plan is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the health IT developer's Real World Testing requirements.

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