Clarification of HL7 V2 Conformance Profile Usage Codes and their Relationship to Testing

For improving Meaningful Use HL7 V2 Testing understanding…

UPDATED with comments from I/C Cambridge Meeting

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Purpose

- Clarify the meaning of the HL7 V2 conformance profile usage constructs
- Assess how such constructs are interpreted given a context, i.e., provide data sets to show all permutations
- We are addressing only the sending side requirements in this slide deck; receiving side requirements will also have to be addressed
- Consider proposed changes to the HL7 V2 conformance section
- Develop a common “template” to be included in HL7 V2 implementation guides to describe the meaning of the usage codes and how applications can be tested for conformance to the usage codes

Usage Code Specification (Sending Application)

IG Presence Indicator	Implementation Requirement	Operational Requirement
R – Required	The application shall implement “R” elements.	The application shall populate “R” elements with a non-empty value.
RE – Required but may be empty	The application shall implement “RE” elements.	The application shall populate “RE” elements if there is relevant data. As will be elaborated on the term “relevant” has a confounding interpretation.
C – Conditional[1]	The application shall implement “C” elements.	The application shall populate “C” elements if the condition associated with the element is true. The application shall NOT populate “C” elements if the condition associated with the element is false. (NOTE: Same as “R” if condition is true)
CE – Conditional but may be empty	The application shall implement “CE” elements.	The application shall populate “CE” elements if the condition associated with the element is true and if there is relevant data. The application shall NOT populate “CE” elements if the condition associated with the element is false. (NOTE: Same as “RE” if condition is true)
O – Optional	The implementer may profile an optional element to R, RE, C, CE, or X. The implementation requirements for the specified usage code applies.	The operational requirements for the specified usage code applies.
X – Not Supported	The application shall not implement “X” elements.	The application shall not populate “X” elements.

[1] Proposed to rename “profiled C” to “CR – Conditionally Required” to avoid confusion with the “original C”

Conformity Assessment of Required (R) Usage Code

Test Case	IG Presence Indicator[1]	Test Data	Conformity Assessment Indicator	Test Result ID	Actual Sent Data	Conformity Assessment	Comments
R-1	R	Valued	Present	R-1.1	Present	Conformant	Affirmative test result.
				R-1.2	Not-Present	Non-Conformant	Application does not send the required element when a value is provided.
R-2	R	Not-Valued	None-Expected behavior is that no message is sent.	R-2.1	Present	Non-conformant	Application sends a value even though they do not have a valid value to send.[2]
				R-2.2	Not-Present	Non-conformant	Application sends a message with a required element not populated.
				R-2.3	No message sent	Conformant	Application correctly detects that they don't have data for a required value.

R-1: This is the primary test. Assert that the required (R) element is sent when a value is provided.
R-2: Assert that the application doesn't send a message in this case.

[1] This usage indicator and its interpretation applies to the sending system. Requirements for receiving system may be different.

[2] Such "negative" testing is necessary. For example, application may incorrectly populate the element with a default value.

Conformity Assessment of Required but may be Empty (RE) Usage Code

Test Case	IG Presence Indicator[1]	Test Data	Conformity Assessment Indicator	Test Result ID	Actual Sent Data	Conformity Assessment	Comments
RE-1	RE	Valued	Present	RE-1.1	Present	Conformant	Affirmative test result.
				RE-1.2	Not-Present	Non-Conformant	Application does not send the required element when a value is provided.
RE-2	RE	Not-Valued	Not-Present	RE-2.1	Present	Non-conformant	Application sends a value even though they do not have a valid value to send.
				RE-2.2	Not-Present	Conformant	Application sends a message without the element populated. Affirmative test result.

RE-1: Assert that the required but may be empty (RE) element is sent when a value is provided.
RE-2: Assert that the application doesn't send a message with the element when a value is not provided.

Note: That there are multiple interpretations of "RE" when a value is known. One is "the capability must always be supported and a value is sent if known", the other is "the capability must always be supported and a value may or may not be sent even when known based on a condition external to the profile specification. The condition may be noted in the profile but can not be processed automatically". This is what can be interpreted from the "relevant" part of the definition. Regardless of the interpretation, for the permutations presented here external conditions that may effect a value being sent or not is not considered. Meaningful Use test cases will be developed such that these cases won't exist. For example, a common example of when an element may not be sent is when a patient doesn't authorized it to be sent; in this scenario a pre-condition to the test case is that the patient has authorized consent. Therefore, regardless of the interpretation of the "RE" usage code a set of test circumstances can be developed to test the "RE" element. That is, the external condition can't always prevent an element from being sent, otherwise it is not a condition. Hence, "RE" elements can in fact be fully tested in the manner described.

[1] This usage indicator and its interpretation applies to the sending system. Requirements for receiving system may be different.

Conformity Assessment of Not-Supported (X) Usage Code

Test Case	IG Presence Indicator[1]	Test Data	Conformity Assessment Indicator	Test Result ID	Actual Sent Data	Conformity Assessment	Comments
X-1	X	Valued	Not-Present	X-1.1	Present	Non-Conformant	Non-conformant because value was sent for a not-support element.
				X-1.2	Not-Present	Conformant	Test case results confirms correct usage of X element by providing data and the application did not send value.
X-2	X	Not-Valued	Not-Present	X-2.1	Present	Non-Conformant	Indicates unexpected behavior.
				X-2.2	Not-Present	Conformant	Confirms expected behavior.

X-1: This is the primary test. Assert that the not-supported (X) element is not sent when a value is provided.
X-2: This is the affirmative test. Assert that the not-supported (X) element is not sent when a value is not provided.

[1] This usage indicator and its interpretation applies to the sending system. Requirements for receiving system may be different.

Conformity Assessment of Conditional Usage (C) Code

Test Case	IG Presence Indicator	Test Data	Condition Predicate Result	Conformity Assessment Indicator	Test Result ID	Actual Sent Data	Conformity Assessment	Comments
C-1	C	Valued	True	Present	C-1.1	Present	Conformant	Same as R-1.1
					C-1.2	Not-Present	Non-conformant	Same as R-1.2
C-2	C	Not-Valued	True	None-Expected behavior is that no message is sent.	C-2.1	Present	Non-conformant	Same as R-2.1
					C-2.2	Not-Present	Non-conformant	Same as R-2.2
					C-2.3	No Message Sent	Conformant	Same as R-2.3
C-3	C	Valued	False	Not-Present	C-3.1	Present	Non-conformant	Same as X-1.1
					C-3.2	Not-Present	Conformant	Same as X-1.2
C-4	C	Not-Valued	False	Not-Present	C-4.1	Present	Non-conformant	Same as X-2.1
					C-4.2	Not-Present	Conformant	Same as X-2.2

Conformity Assessment of Conditional but may be Empty Usage (CE) Code

Test Case	IG Presence Indicator	Test Data	Condition Predicate Result	Conformity Assessment Indicator	Test Result ID	Actual Sent Data	Conformity Assessment	Comments
CE-1	CE	Valued	True	Present	CE-1.1	Present	Conformant	Same as RE-1.1
					CE-1.2	Not-Present	Non-conformant	Same as RE-1.2
CE-2	CE	Not-Valued	True	Not-Present	CE-2.1	Present	Non-conformant	Same as RE-2.1
					CE-2.2	Not-Present	Conformant	Same as RE-2.2
CE-3	CE	Valued	False	Not-Present	CE-3.1	Present	Non-conformant	Non-conformant because value was sent when the condition is false.
					CE-3.2	Not-Present	Conformant	Confirms expected behavior.
CE-4	CE	Not-Valued	False	Not-Present	CE-4.1	Present	Non-conformant	Value sent when condition is false and no value provided.
					CE-4.2	Not-Present	Conformant	Confirms expected behavior.

Conditional Usage Conformance Indicator (C) Example Matrix

Test Case	IG Presence Indicator	Element	Test Data	Condition Predicate Indicator	Conformity Assessment Indicator	Test Result ID	Sent Value for RXA.18	Conformity Assessment
1	RE	RXA.20	RE	True	Present	1.1	Present	Conformant
	C	RXA.18	Valued			1.2	Not-Present	Non-conformant
2	RE	RXA.20	RE	True	None-no message expected	2.1	Present	Non-conformant
	C	RXA.18	Not-Valued			2.2	Not-Present	Non-conformant
						2.3	No message	Conformant
3	RE	RXA.20	CP	False	Not-Present	3.1	Present	Non-conformant
	C	RXA.18	Valued			3.2	Not-Present	Conformant
4	RE	RXA.20	CP	False	Not-Present	4.1	Present	Non-conformant
	C	RXA.18	Not-Valued			4.2	Not-Present	Conformant

Condition Predicate: If the Completion Status (RXA.20) element has the value of refused ("RE" code) then the Substance Treatment Refusal Reason (RXA.18) element shall be populated. The usage code for RXA.20 usage code is "RE-Required but may be empty"[1]. For this example it is always valued. In this example RXA.20 is populated with the value of either "CP-Completed" or "RE-Refused"

- The way to interpret the table is for example in test case 1 RXA.20 is valued with test data "RE" therefore the condition is true. RXA.18 is valued therefore a value should be sent in the message. Test Result 1.1 contains a value therefore the SUT is conformant with respect to this test. Test Result 1.2 does not contain a value therefore the SUT is non-conformant.
- Test Data is what is provided by the test harness to system under test for a given test case.
- Conformity Assessment Indicator provides the expected result.
- Sent value for RXA.16 is the result pulled from the message created by the system under test.

[1] Note that "RE" in this example so happens to be the code for refused in HL7 table HL70322 for element RXA.20; not to be confused with "RE" usage.

Conditional but may be Empty (CE) Usage Conformance Indicator Example Matrix

Test Case	IG Presence Indicator	Element	Test Data	Condition Predicate Indicator	Conformity Assessment Indicator	Test Result ID	Sent value for RXA.16	Conformity Assessment
1	RE	RXA.15	Valued	True	Present	1.1	Present	Conformant
	CE	RXA.16	Valued			1.2	Not-Present	Non-conformant
2	RE	RXA.15	Valued	True	Not-Present	2.1	Present	Non-conformant
	CE	RXA.16	Not-Valued			2.2	Not-Present	Conformant
3	RE	RXA.15	Not-Valued	False	Not-Present	3.1	Present	Non-conformant
	CE	RXA.16	Valued			3.2	Not-Present	Conformant
4	RE	RXA.15	Not Valued	False	Not-Present	4.1	Present	Non-conformant
	CE	RXA.16	Not Valued			4.2	Not-Present	Conformant

Condition Predicate[1]: If the Substance Lot Number (RXA.15) is populated then the Substance Expiration Date (RXA.16) should be populated. The usage code for RXA.15 is "RE-Required but may be empty".

- The way to interpret the table is for example in test case 1 RXA.15 is valued therefore the condition is true. RXA.16 is valued therefore a value should be sent in the message. Test Result 1.1 contains a value therefore the SUT is conformant with respect to this test. Test Result 1.2 does not contain a value therefore the SUT is non-conformant.
- Test Data is what is provided by the test harness to system under test for a given test case.
- Conformity Assessment Indicator provides the expected result.
- Sent value for RXA.16 is the result pulled from the message created by the system under test.

[1] Example from HL7 Version 2.5.1 Implementation Guide for Immunization Messaging Release 1.0 03/01/2010 Page 122

Summary

- Users of the standard don't know how to interpret and use the usage codes
  - We need to clarify the text for usage codes and provide a set of examples
  - include the tables given in these slides
  - Relate the usage code interpretation to how they would be tested
- The RE (and also CE) usage code is confounding more than one concept
  - RE does not means "implement and send if known", it means "implement and send if known and my business rules apply" –this is currently being debated
  - Note that this is not a universal interpretation of "RE", many in the community didn't recognize the "and my business rules apply" part
  - An application may choose not to send an item (even if known) based on an external condition that can't currently be specified in the conformance profile (e.g., a user didn't give consent to send certain data).
  - This is a fundamentally broken conformance construct because two interpretations exist; IG authors intended the former interpretation and did not consider the latter
  - For I/C consideration: decouple RE (and CE) as:
    - Shall implement and shall send if known (RK) (an external condition doesn't apply)
    - Shall implement and may send if known (current RE-or latter interpretation)
    - UPDATE: This proposal has not received much support
  - This allows IG writers a more precise conformance constraint in certain circumstances
  - This provides an intermediate conformance construct that would fall between current "R" and "RE" usage codes—what would be the impact of such a change?
  - UPDATE (from discussion on Cambridge): The majority of I/C felt that "RE" meant and should mean "implement and send if known". If external business rules applies that affects a certain element usage then that constitute another version of the profile; that is, it is a different transaction
  - Another profile would exist that would modify the element usage code to reflect the different business rules.
  - The issue then is management of multiple profile
- Overloading the usage code "C" is confusing
  - For I/C consideration: Change profiled "C" to "CR-conditionally required"; un-profiled "C" can remain unchanged
- Harmonize with V3 concepts?
  - Not good to have different terminology and meaning across V2 and V3
  - Can they be harmonized?
  - What will be the impact?