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| V 2.9 HL7 Proposal |
| *Change Request ID:* | *To be Defined* |
| *File Name:* | *Supporting Clinical Information*OO\_CR139-771.doc |
| *Description:* | *Clarify the use of Supporting Clinical Information in V2* |
| *Status:* | *New Proposal* |
| *Sponsoring Person* | *Hans Buitendijk* |
| *Sponsoring Business Unit* | *Orders & Observations* |
| *Date Originated:* | *09/27/2013* |
| *Date HL7 approved:* |  |
| *Backward Compatible:* | *Yes* |
| *Forward Compatible:* | *Yes* |
| *HL7 Status & Date* |  |

# Justification Detail:

Currently, both OBR-13, OBX segments under the OBR, and the Prior Results Group in order messages are available to communicate clinically relevant information upon ordering and/or specimen collection and potentially other steps before the order is actually performed. This leads to ambiguous and inconsistent use of these capabilities.

The purpose of this proposal is to remove those ambiguities and inconsistencies and provide one clear, consistent approach to associate clinically relevant information to an order.

It should be clear to all readers that the issue is not whether to communicate certain data, which is a clinical consideration beyond the scope of this proposal, but rather how to consistently communicate such information once it is agreed to that it should be able to be communicated, an information technology consideration between two computer based applications, i.e., no human interpretation and use involved.

The following provides a review of the key areas and the proposed approach to resolve.  **Section 4 Documentation Changes** contains the actual changes necessary in the respective chapters to support the proposed approach.

## OBR-13

OBR-13, Relevant Clinical Information, was defined with an ST data type up to V2.7.1 when it was changed to use a CWE data type. This change was challenged as the first component of a CWE is not a free text string, rather a code, but InM supported the change. Additionally a User Defined table was included using Fasting Status values as initial examples as the intended purpose would specifically include fasting status.

The problems with OBR-13 are:

* It has a wide open definition allowing more than fasting status
* Since it is a CWE without an indication what the actual value represents, the receiving system can only understand what it is if they have full knowledge of the codes in the code set. However that does not work for free text.
* Thus this field can really only be interpreted by humans, therefore not useful to most computer based information systems.
* It represents a subset of an OBX, thus an OBX would be able to capture the information contained in OBR-13 and provide the necessary meaning so a computer based information system can actually do something with it.

Alternative One: deprecate OBR-13 in favor of utilizing the OBX segment under the OBR or SPM as appropriate.

Alternative Two: Keep OBR-13, but allow only one AOE in a question set to utilize OBR-13 so it is clear what it represents. I.e., the repeats of the OBR-13 cannot yield a different meaning.

May 20, 2014 – Motion to adopt Alternative Two – Cindy Johns, Mark Jones – Friendly Mod: update the IG to indicate the use is to be for Fasting only.

Once approved by OO, additional edits to LOI IG are required: change in cardinality, constraining language added in comments, designate table 916 as constrained/closed (pick up in the value set discussion.)

Against: 0 Abstain: 1 In favor: 9

## OBX under the OBR SEGMENT

The OBX under the OBR segment is intended to communicate a variety of clinically relevant information that do not require the full OBR/OBX structure available in the Prior Results Group, or for which such information is not available. Examples include Ask at Order Entry questions AOE (in the Lab setting), or clinical data such as height/weight for Radiology exams.

The concern has been that when such information is sent as part of the order message and either needs to be echoed back with the results, or passed along with the results to another party (e.g., copies to), that it is impossible to distinguish between the information sent along with the order vs. the actual results conveyed in the results message. To remove that issue, V2.8.1 introduces OBX-29, Observation Type, to flag whether the OBX represent supporting clinical information (as these may not just be Lab AOEs) or the actual result.

*eDOS WG Recommendation for V2.9: Add value to HL7 Table for AOE specifically as shown below.*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| OBX-29 Observation Type (ID) nnnnnDefinition: This field indicates the type of observation to enable systems to distinguish between observations sent along with an order, versus observations sent as the result to an order. See HL7 Table nnnn – Observation Type for valid valuesHL7 Table nnnn - Observation Type

| Value | Description | Comment |
| --- | --- | --- |
| AOE | Asked at Order Entry Question | Limited to expected responses to questions by the filler |
| ASC | Asked at Specimen Collection | Limited to expected responses to questions by the filler |
| RSLT | Result |  |
| SCI | Supporting Clinical Information | Placer observations not explicitly requested by the filler to provide context or supporting information  |

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ASC: Discussion in smaller group was to consider adding this level of granularity, because you may need to document that this information was actually obtained at specimen collection as required by the eDOS (expected in future/normative release).

SCI: This could potentially be used as a “flag” to differentiate between what the lab needs to interpret the test (identified as AOE/ASC) vs OBXs identified as SCI.

We believe therefore OBX now has the right fields to manage these distinctions, although additional values to the new HL7 defined table for OBX-29 may be necessary. See further discussion for proposed additions in their context.

However, it is not fully clear in the base standard when to use this OBX vs. the Prior Results Group.

The proposal is to include clarifying text in the LOI IG message structure that the OBX under the OBR is to be used for information specifically observed/measured as part of the ordering process (including specimen collection), while the Prior Results Group is to be used for results obtained prior to and independent of the ordering process for the test(s) at hand, unless the observations being collected as part of the ordering process require the full results structure.

## Prior Results Group

The Prior Results Group is available to provide a place to communicate results that were obtained prior to and independent of the ordering process of the test(s) being ordered.

Add usage Note under Order messages where prior result group is present:

The PRIOR\_RESULT Group is available to provide a place to communicate results that were obtained prior to and independent of the ordering process of the test(s) being ordered. The OBX under the OBR segment in the ORDER Group is intended to communicate a variety of clinically relevant information that do not require the full OBR/OBX structure available in the Prior Results Group and are obtained during the ordering or specimen collection process.

This applies to Chapter 8 – Master Files – and is also used in eDOS

## OM1-31 - Observations Required to Interpret this Observation

OM1-31 – Observations Required to Interpret this Observation is used to define what clinically relevant data is to be sent along with the order to interpret the data. The problem is that it is a single CWE field that repeats. It is therefore not possible to clarify the following:

* Should the data be collected when the order is entered or no later than the specimen is collected?
* Should the data be communicated other than in the OBX under the order OBR? Particularly if the data requires more structure than a simple, single OBX. Or if the data can be accommodated in one of the administrative segments.

While there was a desire to not use this field as it was too restrictive, a choice was made to funnel all data that is clinically relevant for the interpretation of the result through this structure. This would be particularly appropriate if the information is not always needed for every test.

To resolve the inconsistencies in how to indicate what data to collect and how to communicate it, the proposal is to deprecate OM1-31 and create a new segment defined as follows. This segment would be inserted in the appropriate Chapter 8 messages as [{OMC}] under OM1, in M08 as an optional, repeating segment

HL7 Attribute Table - OMC – Supporting Clinical Information

| SEQ | LEN | C.LEN | DT | OPT | RP/# | TBL# | ITEM# | ELEMENT NAME |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 |  | 4= | NM | O |  |  | 00586 | Sequence Number – Test/Observation Master File |
| 2 |  |  | ID | C |  | 0206 | 00763 | Segment Action Code |
| 3 |  |  | EI | C |  |  | nnnnn | Segment Unique Key |
| 4 |  |  | CWE | R |  | 9999 | nnnnn | Clinical Information Request |
| 5 |  |  | CWE | R | Y | nnnn | nnnnn | Collection Event/Process Step  |
| 6 |  |  | CWE | R |  | nnnn | nnnnn | Communication Location |
| 7 |  |  | ID | O |  | 0136 | nnnnn | Answer Required |
| 8 |  |  |  | O | Y |  | nnnnn | Type of Test |
| 9 |  |  | ST | O |  |  | nnnnn | Hint/Help Text |
| 10 |  |  | Varies | O |  |  | nnnnn | Type of Answer |
| 11 |  |  | ID | O |  | 0136 | nnnnn | Multiple Answers Allowed |
| 12 |  |  | CWE | O | Y | 9999 | nnnnn | Answers Choices |
| 13 |  |  |  | O |  |  | nnnnn | Character Limit |
| 14 |  |  |  | O |  |  | nnnnn | Number of Decimals |
| 15 |  |  | HD | O | Y |  | nnnnn | Client Identifier |

#### OMC-1 Sequence Number (NM) 00nnn

Definition:

#### OMC-2 Segment Action Code (ID) 00763

Definition: This field indicates whether this repetition of the segment is being added, changed or deleted. -- The action code adds a validation check to indicate, from the point of view of the sending system, whether this repetition of a segment is being added, changed or deleted. This and the following field are used to implement the "unique key" mode of updating repeating segments. (See Chapter 2, Section 2.23.4.2, "Action code/unique identifier mode update definition.") Refer to *HL7 Table 0206 - Segment action code* for valid values.

If the transaction uses dynamic/action code messaging, the field must be valued, while if using snapshot mode this field is not valued (for action code) is optional (for question identifier).  If there is a better name than question identifier, no problem, the key is that the object can be uniquely identified so the action code can be applied to the right one.  Sequence Number would not work.  An implementation guide can then properly constrain it.

#### OMC-3 Segment Unique Key (EI) nnnnn

Definition: This field contains a unique identifier for one of the multiple repetitions of this segment, to be used in conjunction with the preceding field. Each of the repetitions of the segment will be uniquely identified by this unique key field for the purposes of updates

#### OMC-4 Clinical Information Request (CWE) nnnnn

Definition: This field contains a variable that the diagnostic service needs to interpret the results of an ordered study. The observations specified here should be sent to the diagnostic service as OBX segments along with the order (OBR) segment. Separate multiple items by repeat delimiters.

#### OMC-5 Collection Event/Process Step Limit (CWE) nnnnn

Definition: Indicates by when in the ordering process or workflow this information must be collected. Limit indicates must be done by X point in the workflow.

HL7 Table nnnn - Collection Event/Process Step Limit

| Value | Description | Comment |
| --- | --- | --- |
| ORD | When place order | At time of placing the order |
| DRW | When do the draw | When the specimen is collected (e.g., fasting status) |

#### OMC-6 Communication Location (CWE) nnnnn

Definition: Indicates where in the message this information is expected to be communicated. (e.g. PID, OBR, and SPM).

HL7 defined table

HL7 code system for use in OMC-6 – Communication Location

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| --- |
| Table n-n. HL7 Table nnnn (V2.9) |
| Value | Description | Definition / Comment |
| OBR-OBX | OBX segment following an OBR segment |  |
| SPM-OBX | OBX segment following an SPM segment |  |
| DG1-3 | Diagnosis Code |  |
| NK1-11 | Next of Kin / Associated Parties Job Code/Class | Used to convey patient's or next of kin’s employment job class code |
| NK1-13 | Organization Name - NK1 | Next of kin's organization name |
| NK1-28 | Ethinic Group | Next of kin's ethnicity |
| NK1-35 | Race | Next of kin's race |
| OBR-16 | Ordering Provider |   |
| OBR-13 | Relevant Clinical Information | The purpose varies based on the AOE referencing this field. |
| OBR-49 | Result Handling | This was used for call or fax results back – not sure this is a true AOE, so may remove this one |
| PID-11 | Patient Address |  |
| PID-3 | Patient Identifier List |  |
| PID-5 | Patient Name |  |
| PID-6 | Mother’s Maiden Name |  |
| PID-7 | Date/Time of Birth |  |
| PID-13 | Phone Number – Home | deprecated field as of v2.7 |
| PID-14 | Phone Number – Business | deprecated field as of v2.7 |
| PID-40 | Phone Number | New field in v2.7 |
| PRT-5 | Participation Person |  |
| SPM-4 | Specimen Type |  |
| SPM-8 | Specimen Source Site |  |

If Alternative Two, insert OBR-13 into this table.

#### OMC-7 Answer Required To Complete The Test (ID) nnnnn

Definition: Must the question be answered, or just displayed and can be blank. Refer to [HL7 Table 0136 - Yes/no Indicator](http://wiki.hl7.org/images/Documents%20and%20Settings/K132462/Desktop/V27_CH02C_CodeTables.doc#HL70136) as defined in Chapter 2.

Y Answer must be provided

N Answer not required

#### OMC-8 Type of Test (??) nnnnn

Definition: To identify a test group where a single answer is usable for any test in this group that is in the same order, e.g. AFP, Blood Lead, Pap

#### OMC-9 Hint/Help Text (ST) nnnnn

Definition: To give guidance to the provider on how to answer the question.

#### OMC-10 Type of answers – Value Type (ID) nnnnn

Definition: This field contains the allowed data type for answers, and is drawn from [HL7 Table 0125 – Value Type](http://wiki.hl7.org/images/Documents%20and%20Settings/K132462/Desktop/V27_CH02C_CodeTables.doc%22%20%5Cl%20%22HL70125). Type of answers include: numeric, date, coded, text, etc.

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| *eDOS WG Re: May constrain* [HL7 Table 0125 – Value Type](http://wiki.hl7.org/Documents%20and%20Settings/freida.x.hall/My%20Documents/_HL7%20Ballots/2013JuneOOC/eDOS/Reconciliation%20artifacts/_eDOS%20Master/Documents%20and%20Settings/K132462/Desktop/V27_CH02C_CodeTables.doc%22%20%5Cl%20%22HL70125) *in eDOS IG.* |

#### OMC-11 Multiple Answers Allowed

Defintion: This field indicates if multiple answers are allowed, which may impact EHR system display and selection functionality. Refer to [HL7 Table 0136 - Yes/no Indicator](http://wiki.hl7.org/images/Documents%20and%20Settings/K132462/Desktop/V27_CH02C_CodeTables.doc%22%20%5Cl%20%22HL70136) as defined in Chapter 2.

Y Multiple Answers are allowed

N Single answer only allowed

#### OMC-12 Answer Choices for coded answer set (CWE) nnnnn

Definition: Allowed coded answers to be sent in HL7 file (CWE.1) and/or display Text for Ordering system to present to provider (CWE.2).

The condition is valued only if OMC-10 is valued ‘CWE’ or ‘CNE’.

#### OMC-13 Character Limit (NM) nnnnn

Definition: Total number of characters allowed. Required for numeric and (long) text answers.

The condition is valued only if OMC-10 is valued ‘NM’, ‘SN’, ‘ST’, ‘TX’ or ‘FT’.

#### OMC-14 Number of Decimals (NM) nnnnn

Definition: For numeric answers the number of digits after the decimal.

The condition is valued only if OMC-10 is valued ‘NM’ or ‘SN’.

####  ~~OMC-15 Client Identifier (HD) nnnnn~~

~~Definition: Used to identify the client for client specific test codes.~~

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| *eDOS WG Usage Recommendations for eDOS IG:**OMC-2* Segment Action Code *– X**OMC-3* Segment Unique Key *- O**OMC-7* Answer Required *- R**OMC-8 Type of Test - RE**OMC-9 Hit/Help Text - RE**OMC-10 Type of Answers – R**OMC-11 Multiple Answers Allowed - TBD**OMC-12 Answer Choices for coded answer set - RE**OMC-13 Character Limit - RE**OMC-14 Number of Decimals - RE**~~OMC-15 Client Identifier - RE~~* |

## OBX under the PID

There has been some discussion whether we should accommodate an OBX segment under PID to enable communication of certain observations only once as they do not typically or never change across tests. While that is correct, there is a concern that over time the values still may change and that having sent it along with the PID only may make it difficult in subsequent messages to still maintain the relationship with the specific tests that needed that information. Therefore, this proposal does not include a proposal to add an OBX under PID in the order/result messages, rather to explicitly recommend not doing so.

# Open Issues:

No known issues

# Change Request Impact:

No known impact.

# Documentation Changes: