V29\_R1\_2019NOV

# . Observation Reporting

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## PURPOSE

This chapter describes the transaction set required for sending structured patient-oriented clinical data from one computer system to another. A common use of these transaction sets will be to transmit observations and results of diagnostic studies from the producing system (e.g., clinical laboratory system, EKG system) (the filler), to the ordering system (e.g., HIS order entry, physician's office system) (the placer). Observations can be sent from producing systems to clinical information systems (not necessarily the order placer) and from such systems to other systems that were not part of the ordering loop, e.g., an office practice system of the referring physician for inpatient test results ordered by an inpatient surgeon. This chapter also provides mechanisms for registering clinical trials and methods for linking orders and results to clinical trials and for reporting experiences with drugs and devices.

These transaction sets permit the transmission of clinical observations including (but not limited to) clinical laboratory results, measures of patient status and condition, vital signs, intake and output, severity and/or frequency of symptoms.

If the observation being reported meets one or more of the following criteria, then the content would qualify as a medical document management message (MDM) rather than an observation message (ORU). The reader is referred to the MDM message type in Chapter 9.

* Documents/reports that require succession management to reflect the evolution of both document addenda and replacement documents. Succession management is described in Chapter 9.
* Documents/reports where the Sender wants to indicate the availability of the report for use in patient care using the availability status present in the TXA segment, as described in Chapter 9.

Additional considerations that may affect the appropriateness of using an MDM message:

* Documents/reports where the whole requires a signature as part of the message. While the ORU message does not support the inclusion of signature or authentication, some document content forms support these requirements. Of particular note, CDA documents provide for the inclusion of originator/signature. Thus, if a CDA document requires a signature but does not require succession management or report availability (as described above), then an ORU message may be appropriate. However, if the CDA document requires succession management or report availability, then an MDM message is required.
* Documents/reports where the whole requires authentication as part of the message. As described for signatures, authentication may exist within the document content form. Again, CDA documents provide for the identification of an authenticator. Thus if a CDA document does not require succession management or report availability, then an ORU message may be appropriate. If succession management or report availability are necessary, then an MDM message is required.
* Documents/reports where the content as a whole requires special confidentiality protection using the confidentiality status present in the TXA segment, as described in Chapter 9.
* Documents/reports where document storage status is useful for archival and purging purposes using the storage status present in the TXA segment, as described in Chapter 9.

Using these criteria, the following examples of documents/reports would typically qualify as medical document management (MDM) messages. Note that as clinical content, the following documents/reports typically require succession management and/or report availability thus would require an MDM message even if the payload utilizes CSA.

* History and Physical
* Consultation reports
* Discharge summaries
* Surgical/anatomic pathology reports
* Diagnostic imaging reports
* Cardio-diagnostic reports
* Operative reports
* As an international example, microbiology reports may include clinical interpretation and require authentication. This may not be the case in all jurisdictions, but is an example that the use or requirement of MDM messages may be influenced by local considerations.

Usage Notes:

Transcription is not a defining quality for the selection of an MDM or ORU message. In an MDM message, the document/report is typically dictated or transcribed, but not always. Machine-generated or automated output is an example of a document/report that is appropriate to the MDM but is not transcribed.

Observations may be transmitted in a solicited (in response to a query) or unsolicited mode. In the solicited mode, a user requests a set of observations according to criteria transmitted by the user. The sending system responds with existing data to satisfy the query (subject to access controls). Queries do not elicit new observations by the target system, they simply retrieve old observations. (See Chapter 5 for full discussion of the query transmission.)

The unsolicited mode is used primarily to transmit the values of new observations. It is the mode used by producing services to return the values of observations requested by an ordering system. A laboratory system, for example, would usually send the results of an AM electrolytes to the ordering HIS via the unsolicited mode. An intensive care system would send the blood pressures to the same HIS by the same mode. Calling such transactions unsolicited may sound like a misnomer, but is not. The placing service solicits the producing service to make the observation. It could also (through a query) solicit the value of that observation after it has been made. However, such an approach would demand continuous polling of the producing system until the result was produced. Using the unsolicited mode, the producing service returns the value of an observation as soon as it is available. The unsolicited mode can also be used to transmit new results to a system (e.g., an archival medical record system) that did not order the observation. The transactions that define these modes are more fully described in Section 7.3, "General Trigger Events & Message Definitions."

Observations are usually ordered and reported as sets (batteries) of many separate observations. Physicians order electrolytes (consisting of sodium, potassium, chloride, bicarbonate) or vitals (consisting of diastolic blood pressure, systolic blood pressure, pulse, and temperature). Moreover, tests that we may think of as single entity, e.g., cardiac echo, usually yield multiple separate measurements, e.g., left ventricular diameter, left atrial diameter, etc. Moreover, observations that are usually reported as text (e.g., the review of systems from the history and physical) can also be considered a set of separately analyzable units (e.g., cardiac history, pulmonary history, genito-urinary history, etc.). We strongly suggest that all text clinical reports be broken down into such separate analyzable entities and that these individual entities be transmitted as separate OBX segments. Because many attributes of a set of observations taken at one time will be identical, one OBR segment serves as a header for the report and carries the information that applies to all of the individual observations in the set. In the case of ordered observations, the OBR segment is a "turn-around document" like the manual request forms it replaces. It carries information about the order to the producing service; a copy of the OBR with additional fields completed is returned with the observations to the requesting service. Alternately, text documents can be encoded as a CDA document and sent within a single OBX.

Not all observations are preceded by an order. However, all observations whether explicitly ordered or initiated without an order are reported with an OBR segment as the report header.

The major segments (OBR, OBX) defined in this chapter, their fields, and the code tables have been defined in collaboration with ASTM E31.11 with the goal of keeping HL7 observation transmission the same as ASTM E1238 in pursuit of the goals of ANSI HISPP and the Message Standards Developers Subcommittee. (Some sections of this chapter have been taken with permission directly from the E1238‑91 document and vice versa in pursuit of those goals).

The OBR segment provides information that applies to all of the observations that follow. It includes a field that identifies a particular battery (or panel or set) of observations (e.g., electrolytes, vital signs or Admission H&P). For simplicity we will refer to the observation set as the battery. The battery usually corresponds to the entity that is ordered or performed as a unit. (In the case of a query, observation sets may be a more arbitrary collection of observations.) The OBX segment provides information about a single observation, and it includes a field that identifies that single observation (e.g., potassium, diastolic blood pressure or admission diagnosis). Both of these fields assume master tables that define coding systems (the universe of valid identifying codes) for batteries and observations, respectively. These tables will usually be part of the producing and sending services application and (usually) include many other useful pieces of information about the observation or battery. Segments for transmitting such master file information between systems that produce and systems that use clinical information are described in Chapter 8.

This Standard does not require the use of a particular coding system to identify either batteries or single observations In the past, local institutions tended to invent their own unique code systems for identifying test and other clinical observations because standard codes were not available. Such local code systems sufficed for transmitting information within the institutions but presented high barriers to pooling data from many sources for research or for building medical record systems. However, standard code systems such as LOINC® for observation IDs (OBX-3) and SNOMED for coding categorical observations now exist for many of these purposes, and we strongly encourage their use in observation reporting. These codes can be sent either as the only code or they can be sent along with the local historic code as the second code system in a CWE or CNE coded field.

LOINC® codes exist for most laboratory tests and many common clinical variables and codes for reporting observations from the laboratory, 12-lead EKG, cardiac echoes, obstetrical ultrasounds, radiology reports, history and physical findings, tumor registries, vital signs, intake and outputs, UCUM units of measure references and/or answer lists depending on the data type, and descriptions for most variables. Translations of LOINC® descriptions are provided for more than 14 languages. The most recent version of the LOINC® database, which includes records for more than 70,000 observations and includes codes, names, synonyms and other attributes (such as the molecular weights of chemical moieties) for each observation, the LOINC database and a downloadable browser and mapping tool are available at no cost from the Regenstrief Institute at http://loinc.org/. A web browser for LOINC is available at https://search.loinc.org. Codes for Neurophysiologic variables (EEG, EMG, Evoked potentials) are provided in Appendix X2 of ASTM E1467. Some parts of this document (the discussion and tables defining units, the discussion of the rules of mapping observations to OBX segments, and some of the examples at the end of the chapter) have been copied (with permission) from ASTM E1238.

As is true throughout this Standard, the emphasis should be on the abstract messages, defined without regard to the encoding rules. The example messages, however, are based upon the HL7 encoding rules.

### Snapshot Mode

Chapter 2, Section 2.10.4 defines the meaning of snapshot mode updates and indicates that each chapter or related implementation guides may further refine this definition. The following guidance applies to results messages:

* In some instances there are tests that have a precise relationship between the parent and child to assist the clinician in understanding to which OBX in the parent OBR the child is connected. In those instances the ORDER\_OBSERVATION segment groups of the parent and other children should be included in the snapshot rather than sending the child's ORDER\_OBSERVATION segment group (including the OBR/OBX set) by itself. Example: OBRs of the parent OBR (example would be microbiology with culture and Sensitivity Panels (Sensi-Panels)), unless advised otherwise by trading partners, would be included in the snapshot reporting.

### Preface (organization of this chapter)

Following this Purpose and general information section, the remainder of this chapter is organized into four main subject areas; General, Clinical Trials, Product Experience and Waveform. Sections 7.1 to 7.5 document the trigger events, message definitions, segment definitions and examples for general observation reporting. Sections 7.6 to 7.9 include all information related to Clinical Trials. Sections 7.10 to 7.13 include all information related to Product Experience messaging, and sections 7.14 to 7.17 include Waveform messaging information. Large tables can be found in section 7.18 and outstanding issues are listed in section 7.19.

### Glossary

#### hiddentext

#### Placer:

Person or service that requests (places order for) an observation battery, e.g., the physician, the practice, clinic, or ward service, that orders a lab test, X-ray, vital signs, etc. The meaning is synonymous with, and used interchangeably with, requestor. See ORC-2-placer order number, Chapter 4, section 4.5.1.2, "Placer order number."

#### Filler:

Person, or service, who produces the observations (fills the order) requested by the requestor. The word is synonymous with "producer" and includes diagnostic services and clinical services and care providers who report observations about their patients. The clinical laboratory is a producer of lab test results (filler of a lab order), the nursing service is the producer of vital signs observations (the filler of orders to measure vital signs), and so on. See ORC-3-filler order number, Chapter 2, section 4.5.1.3, "Filler order number."

#### Battery:

A set of one or more observations identified as by a single name and code number, and treated as a shorthand unit for ordering or retrieving results of the constituent observations. In keeping with the mathematical conventions about set, a battery can be a single observation. Vital signs, electrolytes, routine admission tests, and obstetrical ultrasound are all examples. Vital signs (conventionally) consist of diastolic and systolic blood pressure, pulse, and respiratory rate. Electrolytes usually consist of Na+, K+, Cl‑, and HCO3‑. Routine admission tests might contain CBC, Electrolytes, SMA12, and Urinalysis. (Note that the elements of a battery for our purposes may also be batteries.) Obstetrical ultrasound is a battery made up of traditional component measurements and the impression, all of which would be returned as separate results when returned to the requestor. A test involving waveform recording (such as an EKG) can be represented as a battery comprised of results of many categories, including digital waveform data, labels and annotations to the data, measurements, and the impression

The word battery is used in this specification synonymously with the word profile or panel. The individual observation elements within a battery may be characteristic of a physiologic system (e.g., liver function tests), or many different physiologic systems.

#### Observation:

A measurement of a single variable or a single value derived logically and/or algebraically from other measured or derived values. A test result, a diastolic blood pressure, and a single chest X-ray impression are examples of observations. In certain circumstances, tracings and images may be treated by HL7 as individual observations and sent as a single OBX. These include waveform data described in section 7.15, "Waveform – Trigger Events & Message Definitions," and encapsulated data aggregates using the ED data type described in Chapter 2A, section 2.A.24, "ED - encapsulated data," (which can represent actual images, audio data, etc.).

#### Clinical Document Architecture (CDA):

The Health Level 7 Specification (ANSI/HL7 CDA R1.0-2000) for encoding and encapsulating clinical documents.

### Narrative Reports as Batteries with Many OBX

Narrative reports from services such as Radiology usually consist of a number of subcomponents (e.g., a chest X-ray report may consist of a description, an impression, and a recommendation). Other studies, such as echocardiograms, contain analogous components, as well as numeric observations (e.g., left ventricular and diastolic diameter). Surgical pathology reports may contain information about multiple specimens and reports: the anatomic source, the gross description, the microscopic description, and a diagnostic impression for each specimen.

The current Standard treats each component of a narrative report as a separate "test" or observation. Just as a CHEM12 is transmitted as an order segment (OBR) plus 12 OBX segments, a chest X-ray would be transmitted as an order (OBR) segment plus three OBX segments, one for the description, one for the impression, and one for the recommendations. Similarly, an EKG report would be transmitted as an order segment (OBR), two OBX segments for the impression and recommendation, and additional OBX segments for each EKG measurement, e.g., the PR interval, QR interval, QRS axis, and so on.

### Suffixes for Defining Observation IDs for Common Components of Narrative Reports

**Retained for backwards compatability only as of V2.7 and withdrawn as of v2.9, in favor of using LOINC codes that pre-coordinate the appropriate identifiers with the suffices. See Chapter 2.8.4.c.**

## General Trigger Events & Message Definitions

The triggering events that follow are all served by the ORU (Unsolicited Observation Message, Unsolicited Point-of-Care Observation Message, Unsolicited Alert Observation Message), the OUL (Observational Report – Automated Lab), or the OPU (Observational Report - Population) messages in combination with ACK and ORA (Observational Report - Application Acknowledgement). Each triggering event is listed below, along with the messages exchanged, and the segments that comprise the messages. The notation used to describe the sequence, optionality, and repeating of segments is described in Chapter 2, "Format for defining abstract messages."

### ORU – Unsolicited Observation Message (Event R01)

The ORU message is for transmitting observational results, including lab, clinical or other observations, to other systems.. The OUL message is designed to accommodate the laboratory processes of laboratory automation systems.

With the segment (OBX) defined in this chapter, and the OBR defined in Chapter 4, one can construct almost any clinical report as a multi-level hierarchy, with the PID segment defined in Chapter 3 at the upper level, an order record (OBR) at the next level with one or more observation records (OBX), followed by the specimen information (SPM) and one or more observations (OBX) directly associated with the specimen.

One result segment (OBX) is transmitted for each component of a diagnostic report, such as an EKG or obstetrical ultrasound or electrolyte battery.

The CTD segment in this trigger is used to transmit temporary patient contact details specific to this order.

The Device segment (DEV) provides additional device information for a device referenced in one or more of the PRT segments in the message (using PRT-10 Participation Device to match DEV-2 Unique Device Identifier or PRT-22 Participation Device Type using DEV-3 Device Type).

ORU^R01^ORU\_R01: Observation Message

| Segments | Description | Status | Chapter |
| --- | --- | --- | --- |
| MSH | Message Header |  | 2 |
| [{ ARV}] | Access Restrictions |  | 3 |
| [{ SFT }] | Software Segment |  | 2 |
| [UAC] | User Authentication Credential |  | 2 |
| { | --- PATIENT\_RESULT begin |  |  |
| [ | --- PATIENT begin |  |  |
| PID | Patient Identification |  | 3 |
| [PD1] | Additional Demographics |  | 3 |
| [{[PRT](#_PRT_–_Participation)}] | Participation (for Patient) |  | 7 |
| [{[OH1](#OH1)}] | Employment Status |  | 3 |
| [{[OH2](#OH2)}] | Past or Present Job |  | 3 |
| [[OH3](#OH3)] | Usual Work |  | 3 |
| [{[OH4](#OH4)}] | Combat Zone Work |  | 3 |
| [{NTE}] | Notes and Comments |  | 2 |
| [{ | --- NEXT\_OF\_KIN begin |  |  |
| NK1 | Next of Kin/Associated Parties |  | 3 |
| [{[OH2](#OH2)}] | Past or Present Job |  | 3 |
| [[OH3](#OH3)] | Usual Work |  | 3 |
| }] | --- NEXT\_OF\_KIN end |  |  |
| [{ARV}] | For backwards compatibility only as of V2.9 | B | 3 |
| [{ | --- PATIENT\_OBSERVATION begin |  |  |
| [OBX](#_OBX_-_Observation/Result) | Observation (for Patient ID) |  | 7 |
| [{[PRT](#_PRT_–_Participation)}] | Participation (Observation Participation) |  | 7 |
| }] | --- PATIENT\_OBSERVATION end |  |  |
| [ | --- VISIT begin |  |  |
| PV1 | Patient Visit |  | 3 |
| [PV2] | Patient Visit - Additional Info |  | 3 |
| [{[PRT](#_PRT_–_Participation)}] | Participation (for Patient Visit) |  | 7 |
| ] | --- VISIT end |  |  |
| [{ | --- INSURANCE begin |  |  |
| IN1 | Insurance |  | 6 |
| [IN2] | Insurance Additional Information |  | 6 |
| [IN3] | Insurance Additional Information, Certification |  | 6 |
| }] | --- INSURANCE end |  |  |
| ] | --- PATIENT end |  |  |
| { | --- ORDER\_OBSERVATION begin |  |  |
| [ | --- COMMON\_ORDER begin |  |  |
| ORC | Order common |  | 4 |
| [{[PRT](#_PRT_–_Participation)}] | Participation (for Observation) |  | 7 |
| [ | --- ORDER\_DOCUMENT begin |  |  |
| OBX | Observation containing Document |  | 7 |
| [{PRT}] | Participation |  | 7 |
| TXA | Transcription Document Header |  | 9 |
| ] | --- ORDER\_DOCUMENT end |  |  |
| ] | --- COMMON\_ORDER end |  |  |
| [OBR](#OBR) | Observations Request |  | 7 |
| [{NTE}] | Notes and comments |  | 2 |
| [{ | --- OBSERVATION\_PARTICIPATION begin |  |  |
| [PRT](#_PRT_–_Participation) | Participation (for Observation) |  | 7 |
| [{DEV}] | Device |  | 17 |
| }] | --- OBSERVATION\_PARTICIPATION end |  |  |
| [{ | --- TIMING\_QTY begin |  |  |
| TQ1 | Timing/Quantity |  | 4 |
| [{TQ2}] | Timing/Quantity Order Sequence |  | 4 |
| }] | --- TIMING\_QTY end |  |  |
| [CTD] | Contact Data |  | 11 |
| [{ | --- OBSERVATION begin |  |  |
| [OBX](#OBX) | Observation related to OBR |  | 7 |
| [{[PRT](#_PRT_–_Participation)}] | Participation (Observation Participation) |  | 7 |
| {[NTE]} | Notes and comments |  | 2 |
| }] | --- OBSERVATION end |  |  |
| [{FT1}] | Financial Transaction |  | 6 |
| {[[CTI](#CTI)]} | Clinical Trial Identification |  | 7 |
| [{ | --- SPECIMEN begin |  |  |
| [SPM](#SPM) | Specimen |  |  |
| [{ | --- SPECIMEN\_OBSERVATION begin |  |  |
| [OBX](#OBX) | Observation (for Patient ID) |  | 7 |
| [{[PRT](#_PRT_–_Participation)}] | Participation (Observation Participation) |  | 7 |
| }] | --- SPECIMEN\_OBSERVATION end |  |  |
| }] | --- SPECIMEN end |  |  |
| } | --- ORDER\_OBSERVATION end |  |  |
| [{ | --- DEVICE begin |  |  |
| DEV | Device (for Participation) |  | 17 |
| [{OBX}] | Observation/Result |  | 7 |
| }] | --- DEVICE end |  |  |
| } | --- PATIENT\_RESULT end |  |  |
| [DSC] | Continuation Pointer |  | 2 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Acknowledgement Choreography | | | | |
| ORU^R01^ORU\_R01 | | | | |
| Field name | Field Value: Original mode | Field value: Enhanced mode | | |
| MSH-15 | Blank | NE | NE | AL, SU, ER |
| MSH-16 | Blank | NE | AL, SU, ER | AL, SU, ER |
| Immediate Ack | - | - | - | ACK^R01^ACK |
| Application Ack | ACK^R01^ACK | - | ACK^R01^ACK | ACK^R01^ACK |