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| V 2.8.2 HL7 Proposal |
| *Change Request ID:* | *To be Defined* |
| *File Name:* | *OBX-5 definition expansion* |
| *Description:* | *OBX-5 definition expansion* |
| *Status:* | *New Proposal* |
| *Sponsoring Person* | *Clement J. McDonald & Swapna Abhyankar (NLM)* |
| *Sponsoring Business Unit* | *Orders & Observations* |
| *Date Originated:* | *08/14/2013* |
| *Date HL7 approved:* |  |
| *Backward Compatible:* | *Yes* |
| *Forward Compatible:* | *Yes* |
| *HL7 Status & Date* |  |

# Justification Detail:

We have seen a need in many contexts for OBX-5 to accommodate lists of coded values rather than a single value. Currently, more than one value can only be included if each value by itself is a fragment of a concept, and all of the values taken together reflect the concept as a whole.

The following are examples of contexts in which such expansion of OBX-5 would be useful:

1) Reporting specific mutations that can be detected in a single mutation analysis (can exceed 100's; 1 example study has more than 800);

2) Reporting genes that are being examined in a single study (more than 200 different genes may be explored for oncogenes); and

3) Reporting the list of conditions tested for by a particular newborn screening laboratory (depending on the state, can exceed 40 conditions).

We propose the following updates to the standard to accommodate these lists:

* Update to the OBX-5 definition by loosening the requirement that “one OBX segment should not contain the **result** of more than one logically independent observation“ to also allow lists of like concepts, where all other aspects of the OBX segment apply in the same way, and they should be interpreted together, but are independent concepts. This use of grouping observations is not allowed, when individual observations from this group are needed for linkage to further testing (reflex or other parent-child linkage). Examples of use of the extended defintion of OBX-5, when populated with repeating elements, are conditions tested for in newborn screening, or mutations found during genetic testing.
* Update the LRI implementation guide to allow OBX-5 to repeat.

## Background

As Hans Buitendijk noted when we first inquired about this option, it is true that in principle, one could do something similar with a whole chain of OBX's with distinction in OBX-4, and that is the only way to do it now. But in our experience there is tremendous resistance to this. The HRSA/NLM orchestrated approach to reporting newborn screening results is currently being adopted by 20 some states, and none of them follow the advice of putting the many “conditions tested for” into separate OBX's. Instead, states dump them into an NTE (or other equivalent) field. The same happens in genetic testing, where tens or hundreds of mutations are tested for, but only a few are positive. In this case, they just list the names of the mutations tested for in narrative comments.

We believe that the cause of this resistance is the way a series of OBX results is routinely presented in their display programs -- one per line, which yields a very unreadable report. They get 10’s or 100’s of lines showing only one short string that is relevant per line. And users find it objectionable, because it is not their main point of interest.

## Different Methods for Reporting Cystic Fibrosis Mutations

### Reporting CF Mutations Using Proposed expanded definition of OBX-5 *(276 characters)*

**Here is an example using data type CWE to report a list of coded values for 10 Cystic Fibrosis mutations, where the mutations are highlighted in red font (note that some labs test for as many as 140 mutations):**

OBX|1|CWE|21656-4^CFTR gene mutations tested for in Blood or Tissue by Molecular genetics method Nominal ^LN|1|**c.254**G>A^^HGVS~**c.350G**>A^^HGVS~**c.489+1G**>T^^HGVS~**c.579+1G**>T^^HGVS~**c.1000C**>T^^HGVS~**c.1040G**>C^^HGVS~**c.1364C**>A^^HGVS~**c.1519\_1521**del^^HGVS~**c.1521\_1523**del^^HGVS~**c.1585-1G**>A^^HGVS|||N|||F

This is a much simpler and more digestible format than the current HL7 capacity to send coded lists of answers with one answer per single OBX (shown below), which requires separate OBX segments, incrementally numbered in OBX-4, with a unique code in OBX-5 for each test performed (or mutation found, etc.), and displayed as a simple running list by most EMR programs that digested such a message.

### Reporting CF Mutations Using Current HL7 Guidance *(1,214 characters)*

**Here is an example reporting the same 10 Cystic Fibrosis mutations as one coded value per OBX:**

OBX|1|CWE|21656-4^CFTR gene mutations tested for in Blood or Tissue by Molecular genetics method Nominal ^LN|1|c.254G>A^^HGVS|||N|||F

OBX|2|CWE|21656-4^CFTR gene mutations tested for in Blood or Tissue by Molecular genetics method Nominal ^LN|2|c.350G>A^^HGVS|||N|||F

OBX|3|CWE|21656-4^CFTR gene mutations tested for in Blood or Tissue by Molecular genetics method Nominal ^LN|3|c.489+1G>T^^HGVS|||N|||F

OBX|4|CWE|21656-4^CFTR gene mutations tested for in Blood or Tissue by Molecular genetics method Nominal ^LN|4|c.579+1G>T^^HGVS|||N|||F

OBX|5|CWE|21656-4^CFTR gene mutations tested for in Blood or Tissue by Molecular genetics method Nominal ^LN|5|c.1000C>T^^HGVS|||N|||F

OBX|6|CWE|21656-4^CFTR gene mutations tested for in Blood or Tissue by Molecular genetics method Nominal ^LN|6|c.1040G>C^^HGVS|||N|||F

OBX|7|CWE|21656-4^CFTR gene mutations tested for in Blood or Tissue by Molecular genetics method Nominal ^LN|7|c.1364C>A^^HGVS|||N|||F

OBX|8|CWE|21656-4^CFTR gene mutations tested for in Blood or Tissue by Molecular genetics method Nominal ^LN|8|c.1519\_1521del^^HGVS|||N|||F

OBX|9|CWE|21656-4^CFTR gene mutations tested for in Blood or Tissue by Molecular genetics method Nominal ^LN|9|c.1521\_1523del^^HGVS|||N|||F

OBX|10|CWE|21656-4^CFTR gene mutations tested for in Blood or Tissue by Molecular genetics method Nominal ^LN|10|c.1585-1G>A^^HGVS|||N|||F

## Different Methods for Reporting Newborn Screening Conditions/Disorders Screened

**A more extreme example, comparing the proposed and current method for reporting conditions tested for in a newborn screening study (which can number more than 100 in some states, and for nearly all states at least includes the 31 core conditions from the Recommended Uniform Screening Panel).**

### Reporting Using Proposed expanded definition of OBX-5 *(1,866 characters)*

OBX|1|CWE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|1|15188001^Hearing loss (HEAR)^SCT~ PENDING-LAcodeRequested^Critical congenital heart disease (CCHD)^LN~41013004^Arginosuccinic aciduria (ASA)^SCT~398680004^Citrullinemia type I (CIT-I)^SCT~29914000^Dihydrolipoamide dehydrogenase deficiency (E3)^SCT~11282001^Homocystinuria (HCY)^SCT~27718001^Maple syrup urine disease (MSUD)^SCT~7573000^Phenylketonuria (PKU)^SCT~410056006Tyrosinemia type I (TYR-1)^SCT~21764004^Carnitine uptake defect (CUD)^SCT~307127004^Long-chain L-3-Hydroxy acyl-CoA dehydrogenase deficiency (LCHAD)^SCT~128596003^Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)^SCT~237999008^Trifunctional protein deficiency (TFP)^SCT~237997005^Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD)^SCT~410059004^3-Hydroxy-3-methylglutaric aciduria (HMG)^SCT~13144005^3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC)^SCT~76175005^Glutaric acidemia type I (GA-1)^SCT~87827003^Isovaleric academia (IVA)^SCT~73843004^Methylmalonic acidemia (CBL A)^SCT~82245003^Methylmalonic acidemia (CBL B)^SCT~124680001^Methylmalonic acidemia (MUT)^SCT~360369003^Multiple carboxylase deficiency (MCD)^SCT~360369003^Multiple carboxylase deficiency (MCD)^SCT~69080001^Propionic acidemia^SCT~237953006^beta-Ketothiolase deficiency (BKT)^SCT~190905008^Cystic fibrosis (CF)^SCT~237754008^Congenital Adrenal Hyperplasia (non-classical) (CAH (NC))^SCT~71578002^Congenital Adrenal Hyperplasia (salt-wasting) (CAH (SW))^SCT~52604008^Congenital Adrenal Hyperplasia (simple virilizing) (CAH (SV))^SCT~190268003^Primary Congenital Hypothyroidism (CH)^SCT~127041004^Hb S beta-thalassemia (Hb F,S,A)^SCT~35434009^Hb SC-disease (Hb F,S,C)^SCT~127040003^Hb SS-disease (sickle cell anemia)(Hb F,S)^SCT~8808004^Biotinidase Deficiency (BIO)^SCT~398664009^Classical galactosemia (galactose-1-phosphate uridyltransferase deficiency) (GALT)^SCT~31323000^Severe combined immunodeficiency (SCID)^SCT|||N|||F

### Recommended Guidance from NLM and HRSA for State Newborn Screening Result HL7 Messages Using the Current Standard *(5,404 characters)*

OBX|1|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|1|15188001^Hearing loss (HEAR)^SCT|||N|||F

OBX|2|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|2|PENDING-LAcodeRequested^Critical congenital heart disease (CCHD)^LN|||N|||F

OBX|3|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|3|41013004^Arginosuccinic aciduria (ASA)^SCT|||N|||F

OBX|4|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|4|398680004^Citrullinemia type I (CIT-I)^SCT|||N|||F

OBX|5|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|5|29914000^Dihydrolipoamide dehydrogenase deficiency (E3)^SCT|||N|||F

OBX|6|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|6|11282001^Homocystinuria (HCY)^SCT|||N|||F

OBX|7|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|7|27718001^Maple syrup urine disease (MSUD)^SCT|||N|||F

OBX|8|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|8|7573000^Phenylketonuria (PKU)^SCT|||N|||F

OBX|9|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|9|410056006Tyrosinemia type I (TYR-1)^SCT|||N|||F

OBX|10|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|10|21764004^Carnitine uptake defect (CUD)^SCT|||N|||F

OBX|11|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|11|307127004^Long-chain L-3-Hydroxy acyl-CoA dehydrogenase deficiency (LCHAD)^SCT|||N|||F

OBX|12|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|12|128596003^Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)^SCT|||N|||F

OBX|13|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|13|237999008^Trifunctional protein deficiency (TFP)^SCT|||N|||F

OBX|14|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|14|237997005^Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD)^SCT|||N|||F

OBX|15|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|15|410059004^3-Hydroxy-3-methylglutaric aciduria (HMG)^SCT|||N|||F

OBX|16|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|16|13144005^3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC)^SCT|||N|||F

OBX|17|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|17|76175005^Glutaric acidemia type I (GA-1)^SCT|||N|||F

OBX|18|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|18|87827003^Isovaleric academia (IVA)^SCT|||N|||F

OBX|19|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|19|73843004^Methylmalonic acidemia (CBL A)^SCT|||N|||F

OBX|20|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|20|82245003^Methylmalonic acidemia (CBL B)^SCT|||N|||F

OBX|21|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|21|124680001^Methylmalonic acidemia (MUT)^SCT|||N|||F

OBX|22|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|22|360369003^Multiple carboxylase deficiency (MCD)^SCT|||N|||F

OBX|23|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|23|69080001^Propionic acidemia^SCT|||N|||F

OBX|24|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|24|237953006^beta-Ketothiolase deficiency (BKT)^SCT|||N|||F

OBX|25|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|25|190905008^Cystic fibrosis (CF)^SCT|||N|||F

OBX|26|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|26|237754008^Congenital Adrenal Hyperplasia (non-classical) (CAH (NC))^SCT|||N|||F

OBX|27|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|27|71578002^Congenital Adrenal Hyperplasia (salt-wasting) (CAH (SW))^SCT|||N|||F

OBX|28|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|28|52604008^Congenital Adrenal Hyperplasia (simple virilizing) (CAH (SV))^SCT|||N|||F

OBX|29|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|29|190268003^Primary Congenital Hypothyroidism (CH)^SCT|||N|||F

OBX|30|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|30|127041004^Hb S beta-thalassemia (Hb F,S,A)^SCT|||N|||F

OBX|31|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|31|35434009^Hb SC-disease (Hb F,S,C)^SCT |||N|||F

OBX|32|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|32|127040003^Hb SS-disease (sickle cell anemia)(Hb F,S)^SCT|||N|||F

OBX|33|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|33|8808004^Biotinidase Deficiency (BIO)^SCT|||N|||F

OBX|34|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|34|398664009^Classical galactosemia (galactose-1-phosphate uridyltransferase deficiency) (GALT)^SCT|||N|||F

OBX|35|CE|57719-7^Conditions tested for in this newborn screening study [Identifier] in Dried blood spot^LN|35|31323000^Severe combined immunodeficiency (SCID)^SCT|||N|||F

### Actual Implementation – Example State Newborn Screening Results HL7 Messages

1. **One state is not sending any information about disorders screened for.**
2. **Example of using a ZNB segment to list the disorders screened for:**

ZNB|1|ST||Disorders Screened: FATTY ACID OXIDATION DISORDERS: Med.-chain acyl-CoA dehydrogenase def. (MCAD), Very long chain acyl-CoA dehydrogenase def. (VLCAD), Long chain acyl-CoA dehydrogenase (LCHAD), Trifunctional protein def. (TFP), Carnitine/Acylcarnitine translocase def. (CAT), Short chain acyl-CoA dehydrogenase def. (SCAD), Carnitine membrane transporter def. (CUD), Carnitine palmitoyl transferase def. I (CPT), Glutaric Acidemia Type 2 (GA 2, or Multiple acyl-CoA dehydrogenase def. (MADD)), Carnitine Palmitoyl Transferase Type 1 (CPT 1), Carnitine Uptake Deficiency (CUD). AMINO ACIDEMIAS: Arginosuccinic Acidemia (ASA), Citrullinemia (CIT), Tyrosinemia types I & II (TYR I, II), Hypermethionemia (MET), Maple syrup urine disease (MSUD), Homocystinuria (HCY), Argininemia (ARG). ORGANIC ACIDEMIAS: Isovaleric acidemia (IVA), Glutaric acidemia I (GA-I), 3-OH 3-methyl glutaric aciduria (HMG), Multiple carboxylase def. (MCD), 3Âmethyl crotonyl-CoA carboxylase def. (3-MCCD), 3-methylglutaconic aciduria (3MGA), Methylmalonic acidemia (MMA), Propionic acidemia (PA), Beta-ketothiolase def. (SKAT), Malonic Acidemia (MAL).

1. **Example of using a bunch of NTE segments for disorders screened and other info:**

NTE|1|L|\*Effective January 10, 2011 - Congenital Adrenal Hyperplasia-17OHP normal weight based limits: <1500g < 70 ng/mL; 1500g-2500g < 40 ng/mL; >2500g < 25 ng/mL. NTE|2|L| Normal for repeat specimens is <25 ng/mL. NTE|3|L|\*\*T4- Normal for specimens from infants < 4 weeks of age is 5-27 ug/dL. NTE|4|L| Normal T4 for specimens from infants > or = 4 weeks of age is 5-19 ug/dL. NTE|5|L| Normal TSH is <20uU/mL. NTE|6|L|\*\*\*IRT - Normal for initial specimens from infants < 4 weeks of age is <58 ng/mL. NTE|7|L| IRT - Normal for initial specimens from infants > or = 4 weeks of age is <50 ng/mL. NTE|8|L| IRT - Normal for repeat specimens (regardless of age) is <50 ng/mL. NTE|9NTE|10|L|TESTS CONDUCTED: NTE|11|L|Enzyme Immunoassay: Congenital Adrenal Hyperplasia (CAH), Congenital Hypothyroidism (CH), Cystic Fibrosis (CF) NTE|12|L|Colorimetric Assay: Biotinidase Deficiency NTE|13|L|Fluorometric Assay: Galactosemia NTE|14|L|High Performance Liquid Chromatography (HPLC): Hemoglobinopathies NTE|15NTE|16|L|Tandem Mass Spectrometry (MS/MS): NTE|17|L|Fatty Acid Oxidation Disorders: Medium-chain acyl-CoA dehydrogenase deficiency (MCADD), Very long-chain acyl-CoA dehydrogenase deficiency (VLCADD), NTE|18|L|Long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHADD), Trifunctional protein deficiency (TFP), Carnitine uptake defect (CUD), Carnitine acylcarnitine NTE|19|L|translocase deficiency (CACT), Carnitine palmitoyl transferase I deficiency (CPT-I), Carnitine palmitoyl transferase II deficiency (CPT-II), Glutaric acidemia type II NTE|20|L|(GA-II), Short-chain acyl-CoA dehydrogenase deficiency (SCADD) NTE|21|L|Amino Acid Disorders: Argininosuccinic acidemia (ASA), Citrullinemia Type I (CIT-I), Tyrosinemia Type I (TYR-I), Maple syrup urine disease (MSUD), NTE|22|L|Homocystinuria (HCY), Phenylketonuria (PKU), Argininemia (arginase deficiency) (ARG), Citrullinemia Type II (CIT-II), Hyperphenylalaninemia (H-PHE), NTE|23|L|Hypermethioninemia (MET), Tyrosinemia Type II (TYR-II), Tyrosinemia Type III (TYR-III), Nonketotic Hyperglycinemia (NKHG) NTE|24|L|Organic Acid Disorders: Beta-ketothiolase deficiency (BKT), Isovaleric acidemia (IVA), Glutaric acidemia Type I (GA-I), 3-Hydroxy-3-methylglutaric aciduria (HMG), NTE|25|L|Multiple carboxylase deficiency (MCD), 3-Methylcrotonyl-CoA carboxylase deficiency (3MCC), Methylmalonic acidemia (MMA Cbl A, B, C, D), Methylmalonyl-CoA NTE|26|L|mutase deficiency (MUT), Propionic acidemia (PA), 2-Methyl-3-Hydroxybutyric aciduria (2M3HBA), 3-Methylglutaconic aciduria (3MGA), Isobutyryl-CoA NTE|27|L|dehydrogenase deficiency (IBD), Malonic acidemia (MAL), Ethylmalonic encephalopathy (EE), 2-Methylbutyryl-CoA dehydrogenase deficiency(2MBDH) NTE|28NTE|29|L|The laboratory values in this report represent screening test results and are intended to identify infants at risk for selected NTE|30|L|disorders and in need of more definitive testing. The above results should be correlated clinically with consideration of age at the NTE|31|L|time of collection, nutrition, birth weight, prematurity, health status, and treatments. It is very important for physicians to be NTE|32|L|aware that a negative screening result does not indicate with certainty the absence of the above listed disorders. The physician NTE|33|L|should be alert to the clinical symptoms of these conditions, so that diagnosis and treatment can take place as early as possible in NTE|34|L|infants who are not identified through the newborn screening program.

# Open Issues:

No known issues

# Change Request Impact:

No known impact.

# Documentation Changes:

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#### 7.4.1.5 OBX-5 Observation Value (varies) 00573

Definition: This field contains the value observed by the observation producer. OBX-2-value type contains the data type for this field according to which observation value is formatted. It is not a required field because some systems will report only the Interpretation Codes (OBX-8), especially in product experience reporting. The length of the observation field is variable, depending upon OBX-2-value type. This field may repeat for multipart CWE and CNE single answer results.

Representation

This field contains the value of related to the OBX-3-observation identifier of the same segment. Depending upon the observation, the data type may be a number (e.g., a respiratory rate), a coded answer (e.g., a pathology impression recorded as SNOMED), or a date/time (the date/time that a unit of blood is sent to the ward). An observation value is always represented as the data type specified in OBX-2-value type of the same segment. Whether numeric or short text, the answer shall be recorded in ASCII text.

Reporting logically independent observations

The main sections of dictated reports, such as radiologic studies or history and physicals, are reported as separate OBX segments. In addition, each logically independent observation should be reported in a separate OBX segment, i.e., one OBX segment should not contain the **result** of more than one logically independent observationunless it is part of a, list of like concepts that belong together (e.g., a list of conditions tested for in newborn screening or mutations looked for in genomic testing). This requirement is included to assure that the contents of OBX-6-units, OBX-8-interpretation codes, and OBX-9-probability can be interpreted unambiguously. This means that all other OBX field values apply equally to the whole of OBX-5 noting that OBX-6 does not apply in the case of coded values. The electrolytes and vital signs batteries, for example, would each be reported as four separate OBX segments. Two diagnostic impressions, e.g., congestive heart failure and pneumonia, would also be reported as two separate OBX segments whether reported as part of a discharge summary or chest X-ray report. Similarly, two bacterial organisms isolated in a single bacterial culture would be reported as two separate OBX segments.

Though two independent diagnostic **statements** cannot be reported in one OBX segment, unless they represent elements of a single list to which all other OBX field values apply equally, multiple categorical responses are allowed (usually as CWE data types separated by repeat delimiters), so long as they are fragments (modifiers) that together construct one diagnostic statement. Right upper lobe (recorded as one code) and pneumonia (recorded as another code), for example, could be both reported in one OBX segment. Such multiple "values" would be separated by repeat delimiters. The other example where use of repeat delimiters is allowed for coded values would be a list of conditions or mutations tested for to provide reference for the test results reported in related, but independent OBX segments. Multiple answers to a single question (for example mark all that apply type questions) could also be handled using this approach. It is important to state that ANY independent observation, that may require parent-child linking to additional tests, such as reflex testing, SHALL NOT be included in a single OBX-5 field using repeat delimiters, nor any list elements that require variations in the values of other OBX field values.

Multiple OBX segments with the same observation ID and Sub ID

In some systems, a single observation may include **fragments** of more than one data type. The most common example is a numeric result followed by coded comments (CWE). In this case, the logical observation can be sent in more than one OBX segment. For example, one segment of numeric for the numeric result and another segment of CWE data type for coded comments. If the producer was reporting multiple coded comments they would all be sent in one OBX segment separated by repeat delimiters because they all modified a single logical observation. Multiple OBX segments with the same observation ID and sub ID should always be sent in sequence with the most significant OBX segment (the one that has the normal flag/units and or reference range and status flag) first. The value of OBX-6 through 12 should be null in any following OBX segments with the same OBX-3-observation identifier and OBX-4-observation sub-ID. For the purpose of replacement or deletion, multiple OBX segments with the same observation ID and sub ID are treated as a unit. If any are replaced or deleted, they all are replaced.

Coded values

When an OBX segment contains values of CWE data types, the observations are stored as a combination of codes and/or text. In Section 7.8.3, "CSS - Clinical Study Data Schedule Segment," examples of results that are represented as CWE data types are shown in the first and second OBX segments of OBR 1 and the first and second OBX segments of OBR 2. The observation may be an observation battery ID (for recommended studies), a diagnostic code or finding (for a diagnostic impression), or an anatomic site for a pathology report, or any of the other kinds of coded results.

It is not necessary to always encode the information stored within a coded observation. For example, a chest X-ray impression could be transmitted as pure text even though it has a CWE data type. In this case, the test must be recorded as the second component of the **result code,** e.g.,

OBX|1|CWE|19005^X-Ray Impression^LN|1|^CONGESTIVE HEART FAILURE.|...<cr>

However, separate impressions, recommendations, etc., even if recorded as pure text, should be recorded in separate result segments. That is, congestive heart failure and pneumonia should not be sent as:

OBX|1|CWE|19005^X-Ray Impression^LN|1|^CONGESTIVE HEART FAILURE AND PNEUMONIA|...<cr>

but as:

OBX|1|CWE|19005^X-Ray Impression^LN|1|^CONGESTIVE HEART FAILURE|...<cr>

OBX|2|CWE|19005^X-Ray Impression^LN|2|^PNEUMONIA|....<cr>

Even better would be fully-coded results that include computer understandable codes (component 1) instead of, or in addition to, the text description (component 2). One may include multiple values in a CWE value and these can be mixtures of code and text, but only when they are needed to construct one diagnosis, impression, or concept. When text follows codes as an independent value it would be taken as a modifier or addenda to the codes. E.g.,

OBX|1|CWE|19005-8^X-ray impression^LN~29548-5^DiagnosisImpPatient^LN |1|428.0^CONGESTIVE HEART FAILURE^I9C~^MASSIVE HEART|...<cr>

The text in component 2 should be an accurate description of the code in component 1. Likewise, if used, the text in component 5 should be an accurate description of the code in component 4.