Instructions for Extracting and Submitting Laboratory Data for the Study *Using Clinically-Enhanced Claims Data to Guide the Selection of Coronary Procedures*

A Summary of the Steps

1. The New York State Department of Health (DOH) will send to the hospital, by secure transmission, a list of patients who received certain cardiac procedures from 2008 to 2010 (a separate list of patients treated in 2011 will be sent in 2012). Patients will be identified by DOH staff from SPARCS data previously supplied by the hospital. The list will include:

- Medical Record Number
- Patient Control Number
- Date of Birth
- Sex
- Street Address and ZIP Code
- Admission Date
- Discharge Date

2. The Laboratory Information System (LIS) staff will search the lab's database for these patients and extract the requested test results (a list of 30 blood tests will be supplied) during a specified period of time (30 days prior to admission through the discharge date). If your system does not allow restricting a data query by comparing the test date with an admission or discharge date, an alternative method would be to select all relevant test results that match the Patient Control Number (sometimes called Visit Number or Encounter Number) *or* to the Medical Record Number from 2008 through 2010.

3. The LIS staff will create a file containing the test results for these patients, along with the patient identifiers as recorded in the LIS. (*Note:* Tests must be identified by LOINC number; a worksheet will be supplied to lab staff for converting local test codes to LOINCs.) There will be no need to merge lab data with any other file. The output files will be sent to the DOH by secure transmission in one of four formats (detailed instructions below):

- Pipe-delimited text file
- Excel file
- Batch of HL7 v2.3 messages of type ORU^R01
- Batch of HL7 v2.5.1 messages of type ORU^R01

Secure Transmission of Data

The data for this study will contain personal identifiers for patients and therefore must be exchanged by a secure method to protect the patients' confidential information. Data sent from the DOH to the hospital/lab need not be sent by the same method as data sent by the hospital/lab to the DOH. *Any of the following methods may be used:*

- SPARCS data exchange tool (the system hospitals currently use to send SPARCS data to the DOH).
- NYSDOH's Secure File Transfer Utility, an online application that is available to anyone with access to the Health Commerce System (HCS) website; users with access would go to https://commerce.health.state.ny.us/hcsportal/hcs_home.portal and, after entering his or her password, click on the Applications tab at the top, select S and then, from the list of applications that appears, select Secure File Transfer Application. The user uploads the file to the application and provides an email address for the person who will receive (download) the file; the file itself is not transported by email – it is uploaded to a secure site on the HCS. The person who receives the file must also have access to the HCS.
- PHINMS (Public Health Information Network Messaging System) is currently used by many hospital labs to send data to ECLRS (Electronic Clinical Laboratory Reporting System); the same tool can be reconfigured (instructions will be available) to send files for the Cardiac study to the correct location at the DOH.
- UPHN Lite is a new DOH tool for exchanging data that operates similarly to PHINMS (which will not be supported by DOH after July 31, 2012); instructions will be available.

Lab Test Identification by LOINC

A LOINC Worksheet (Excel file) and instructions will be sent to the LIS staff containing the list of 30 lab tests requested for the identified patients. The worksheet gives the LOINC ID for each test along with information about the test; LIS staff will indicate which tests are performed by the lab and provide the following information about each test: specimen type, units of measurement, normal range, method, and currently used ID. On the basis of this information, local lab test codes will be mapped to LOINC codes to be used in the results data to be sent to the DOH.

Excel and Simple Delimited Text File Specifications

Test result data, with patient identifiers from the lab's own database, may be sent to the DOH either in HL7 format (see below) *or* as an Excel table *or* as a pipe(|)-delimited text file. In Excel and text files there should be one row or line PER TEST RESULT (even though this means repeating the patient identifiers in each row). Excel and text files should include the following fields, in the order listed:

ITEM SEQ#	DATA ELEMENT	FIELD NAME	VALUE FORMAT	COMMENTS
1	HOSPITAL ID	HOSP	Identify the hospital that treated patient; may be PFI, abbreviation, or National Provider ID	
2	ADMISSION DATE	ADATE	Date in YYYYMMDD format	
3	DISCHARGE DATE	DDATE	Date in YYYYMMDD format	
4	DATE OF BIRTH	DOB	Date in YYYYMMDD format	
5	PATIENT SEX	SEX	Gender M,F,U	
6	MEDICAL RECORD NUMBER	MRN	Patient medical record number	

ITEM SEQ#	DATA ELEMENT	FIELD NAME	VALUE FORMAT	COMMENTS
7	PATIENT CONTROL NUMBER	PCN	Unique ID assigned by hospital to facilitate retrieval of clinical and financial records for patient visit; may also be called Visit Number or Encounter Number	
8	SSN NUMBER	SSN	123456789 format	SSN may be important in linking patients with labs performed anytime 30 days prior to an admission as the PCN or MRN may not yet be assigned; the last 4 digits of the SSN would be acceptable
9	PATIENT FAMILY NAME	LNAME		
10	PATIENT GIVEN NAME	FNAME		
11	PATIENT STREET ADDRESS	ADDR		
12	PATIENT ZIP CODE	ZIP	Up to 10 characters	5-digit ZIP Code *or* ZIP+4
13	LOINC CODE	LOINC	See LOINC WORKSHEET for LOINC formats; include special characters	LOINC code; see LOINC code worksheet for required tests
14	OBSERVATION VALUE	LAB_VALUE	Include special characters if applicable	LAB TEST VALUE, please note that this field is set up as a character field to capture mixed value types; must accommodate decimals
15	OBSERVATION UNITS	UNITS	See LOINC worksheet	e.g., g/dL, %, mEq/L, 10^9 cells/uL

ITEM SEQ#	DATA ELEMENT	FIELD NAME	VALUE FORMAT	COMMENTS
16	NORMAL RANGE	RANGE	Include special characters (e.g., dashes)	Submit normal ranges based on the patient's demographics
17	RESULT STATUS	STATUS	C, F, P	By order of preference: C (Corrected), F (Final), P (Preliminary); other status codes not accepted
18	COLLECTION DATE/TIME	COLL_DATE	Date in YYYYMMDDHHMM (hours in military time 00-23)	Date/time the sample is obtained, hour and minute should be included if known [anytime 30 days prior to admission up to the date of discharge]
19	RESULT DATE/TIME	RES_DATE	Date in YYYYMMDDHHMM (hours in military time 00-23)	Date/time the sample is analyzed, hour and minute of test should be included if known [anytime 30 days prior to admission up to the date of discharge]
20	COMMENT	COMMENT	E.g., 'sample hemolyzed' is always commented when observed; test method may be specified here as well	Additional information that may be useful for understanding submitted lab values

HL7 (v2.3 and v2.5.1) Message Specifications

These specifications are based on *Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm)* (February 2010) but in all but one segment (SFT) they are applicable to messages in v2.3. For several fields, maximum length is not equal in the two versions, but in each case the DOH will be able to read in the longest value.

It may appear that more information is being required for data in the HL7 format than for Excel or the simple pipe-delimited format. The "extra" fields in HL7 are included because of HL7 formatting requirements (e.g., ORU^R01 messages require an ORC segment, which is included in these specifications even though the data elements are not required for the study).

For this study, messages will contain lab result information for one patient visit per message but may contain multiple groups of ORC/OBR/OBX segments for the same patient. If results for the tests of interest were generated during multiple visits for the same patient, please report the results for each visit in a separate message.

For each test, send final or revised (corrected) results if available, preliminary results if necessary; if the same test is repeated on different dates from different samples, send results for each completed test. Information about tests performed for different orders--whether the orders were given during the same or different visits--may be sent in separate messages.

The following tables list the specific data elements and data types required for this study. If other data elements are automatically generated by the lab's IT system, they do not have to be removed; these "extra" data elements will not be inserted into the study database.

Delimiters

Delimiter	Required Value	Encoding Character Position	Description
Segment Terminator	<cr>	-	Terminates a segment record. This value cannot be changed by implementers. Additional Constraints and Explanation: The <cr> denotes the ASCII-013 carriage return character. There is a common misunderstanding that a linefeed character, or carriage return followed by a linefeed character, is allowed also. Neither HL7 nor this profile allows either of these two as part of the segment terminator. Only the ASCII-013 carriage return is allowed.
Field Separator	|	-	Separates two adjacent data fields within a segment. It also separates the segment ID from the first data field in each segment. Additional Constraints and Explanation: It is recommended that senders use ASCII-124, the vertical bar (|) character, as the field separator.
Component Separator	^	1	Separates adjacent components of data fields where allowed. Additional Constraints and Explanation: It is recommended that senders use ASCII-094, the caret (^) character, as the component separator.
Repetition Separator	~	2	Separates multiple occurrences of a field where allowed. Additional Constraints and Explanation: It is recommended that senders use ASCII-126, the tilde character (~), as the repetition separator.
Escape Character	\	3	Use the escape character with any field represented by an ST, TX or FT data type, or for use with the data (fifth) component of the ED data type. If no escape characters are used in a message, this character may be omitted. However, it must be present if subcomponents are used in the message. Best practice is always to include this character. Additional Constraints and Explanation: It is recommended that senders use ASCII-091, the backslash (\) character, as the escape character.
Subcomponent Separator	&	4	Separates adjacent subcomponents of data fields where allowed. If there are no subcomponents, this character may be omitted. Best practice is always to include this character. Additional Constraints and Explanation: It is recommended that senders use ASCII-038, the ampersand (&) character, as the subcomponent separator.

Message Structure

The ORU^R01 message in HL7 v2.5.1 format is required for this study. The specifications listed here are a simplified subset of the complete specifications offered in the hl7.org documentation on Electronic Laboratory Reporting for Public Health.

SEGMENT	NAME	USAGE	DESCRIPTION
MSH	Message Header	Required	The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.
SFT	Software Identification	Required for v2.5.1 *only*	The software identification (SFT) identifies the software used to create the message. It is a new requirement of v2.5 that the Laboratory Result Sender populate the SFT segment.
PID	Patient Identification	Required	The patient identification (PID) segment is used to provide basic demographics regarding the subject of the testing.
PV1	Patient Visit	Required (alternative available)	The patient visit segment provides information about the patient's stay in the hospital, including the dates of hospitalization. For systems that are not set up to include PV1 segments, an alternative is provided below (see OBX segment).
ORC	Common Order Segment	Required if Available	The common order (ORC) segment identifies basic information about the order for testing.
OBR	Observation Request	Required	**The observation request (OBR) segment is used to capture information about one test (or battery of tests) being performed on the specimen. Most importantly, the OBR identifies the type of testing to be performed on the specimen, and ties that information to the order for the testing.** If a single message includes results for multiple requests (with different dates, etc.), there should be one OBR segment for each request, each one followed by the OBX segments reporting the results of that request.
OBX	Observation Related to Request	Required	The observation result (OBX) segment contains information regarding a single observation (analyte) result. It includes identification of the specific type of observation, the result, when the observation was made, etc. If a single message includes results for multiple requests (with different dates, etc.), the OBX segments for each request should be grouped together after the appropriate OBR segment.
NTE	Notes and Comments	Required if Relevant for Observation	The Notes segment (NTE) is for relaying information needed for proper interpretation of an observation; e.g., 'sample hemolyzed' should be noted when observed. NTE segments should immediately follow the OBX segments to which they are related.

Data Elements

MESSAGE HEADER SEGMENT

HL7 position	Field Name	Notes
MSH-1	Main delimiter	Must be '|'
MSH-2	Subcomponent delimiters	Must be '^~\&'
MSH-3	Sending Application	
MSH-4.1	Sending Facility Name/Abbr	
MSH-4.2	Sending Facility ID	Must be CLIA ID
MSH-4.3	ID type	Must be 'CLIA'
MSH-5	Receiving Application	Must be 'CARDIAC'
MSH-6	Receiving Facility	Must be 'NYSDOH'
MSH-7	Message DateTime	YYYYMMDDhhss
MSH-9.1	Message Type	ORU
MSH-9.2	Trigger Event	R01
MSH-10	Message Control ID	Uniquely identifies message
MSH-11	Processing ID	Must be 'P' (Production)
MSH-12	HL7 version	Must be '2.5'

SOFTWARE SEGMENT—v2.5.1 *only*

HL7 position	Field Name	Notes
SFT-1	Software Vendor Name	Identify the vendor of the software that produced message
SFT-2	Version or Release Number	
SFT-3	Software Product Name	
SFT-4	Software Binary ID	"Issued by a vendor for each unique software version instance to distinguish between like versions of the same software e.g., a checksum."

PATIENT IDENTIFICATION SEGMENT

HL7 position	Field Name	Notes
PID-3.1	Patient Medical Record Number	Record number assigned by hospital
PID-3.4	Assigning Authority for ID	Usually, ID of hospital where patient was treated
PID-3.5	ID type	Must be 'MRN'
PID-4.1	Patient's Social Security Number	Format: 123-45-6789
PID-4.4	Assigning Authority for ID	Must be 'SSA'
PID-4.5	ID type	Must be 'SSN'
PID-5.1	Patient's Family Name	
PID-5.2	Patient's Given Name	
PID-7	Patient's DOB	YYYYMMDD
PID-8	Patient's Sex	M or F
PID-11.1	Street Address of Patient's Residence	
PID-11.5	ZIP Code or Postal Code of Patient's Residence	Format: 10-digit text string (ZIP+4 not required but may be submitted if available)
PID-18.1	Patient Control Number	Unique ID assigned by hospital to facilitate retrieval of clinical and financial records for patient visit; may also be called Visit Number
PID-18.4	Assigning Authority for Account Number ID	Usually, ID of hospital where patient was treated
PID-18.5	ID type	PCN

PATIENT VISIT SEGMENT

HL7 position	Field Name	Notes
PV1-39	Treating or Servicing Hospital (if different from lab)	Short Name or ID of hospital; if PV1 segment is not created by lab's IT system, PV1 fields 39, 44, and 45 can be transmitted in OBX segments
PV1-44	Admission datetime	YYYYMMDDhhss
PV1-45	Discharge Datetime	YYYYMMDDhhss

COMMON ORDER SEGMENT

HL7 position	Field Name	Notes
ORC-1	Order Control	Should be 'RE'
ORC-3	Filler Order Number	Number assigned to the ordered tests by the performing lab; must be same number as in OBR-3
ORC-9	Date/time of Transaction	Date when order was placed
ORC-12.1	Ordering Physician NPI	If available, National Provider Identifier for physician who ordered the tests; same as OBR-16 if populated -- *Optional*
ORC-12.2	Ordering MD Family Name	Same as OBR-16 if populated -- *Optional*
ORC-12.3	Ordering MD Given Name	Same as OBR-16 if populated -- *Optional*
ORC-21	Ordering Facility Name	*Optional*

OBSERVATION REQUEST SEGMENT

HL7 position	Field Name	Notes
OBR-1	OBR Set ID	Use '1' for first OBR segment in message, '2' for second, etc.
OBR-3	Filler Order Number	Number assigned to the ordered tests by the performing lab
OBR-4.1	LOINC code for ordered tests	
OBR-4.2	Name of ordered tests	
OBR-4.3	Code type	Must be 'LN'
OBR-16.1	Ordering Physician NPI	If available, National Provider Identifier for physician who ordered the tests -- *Optional*
OBR-16.2	Ordering MD Family Name	*Optional*
OBR-16.3	Ordering MD Given Name	*Optional*

OBSERVATION RESULT SEGMENT

HL7 position	Field Name	Notes
OBX-1	OBX Set ID	Use '1' for first OBX segment related to the OBR, '2' for second, etc.; if message contains a second OBR segment, numbering of OBX segments related to it begins again at '1'
OBX-2	Value Type for Result in OBX-5 >>>>	Format of OBX-2 depends on type of information entered in OBX-5: may be NM (Numeric), SN (Structured Numeric, for numeric ranges, percents, inequalities), or ST (Short Text string)
OBX-3.1	Test LOINC code	
OBX-3.2	Test Name	
OBX-3.3	Code type	Must be 'LN' for LOINC
OBX-5.1	Test Result	See OBX-2
OBX-6	Unit of Measure	Standard abbreviation
OBX-7	Reference Range	
OBX-11	Result Status	By order of preference: C (Corrected), F (Final), P (Preliminary); other status codes not accepted
OBX-14	Collection Date/Time	YYYYMMDDhhmm
OBX-19	Analysis Date/Time	YYYYMMDDhhmm

NOTES SEGMENT

HL7 position	Field Name	Notes
NTE-1	NTE Set ID	NTE segments immediately follow the segments to which they relate (OBR or OBX). Numbering of NTE segments begins at '1' after each related segment.
NTE-3	Comment	Text string containing the comment

SAMPLE v2.3 MESSAGE (with false information in all fields)

MSH|^~\&|PATH|Lab1^33D1234-9^CLIA|CARDIAC|NYSDOH|201108261354||ORU^R01|1018304PQ8|P|2.3
PID|||ACH8303571^^^ACH^MRN|123-45-6789^^^SSA^SSN|MANN^HORACE||19331215|M|||123 MAIN ST^^^^14999|||||||ACH2333971^^^ACH^AN
PV1|||||||||||||||||||||||||||||||||||||||MEGA HOSPITAL CENTER|||||201108190948|201108250408
ORC|RE||956635.9|||||201108191755|||123456789^SMITH^LORRAINE
OBR|1||956635.9|58410-2^Hemogram^LN||||||||||123456789^SMITH^LORRAINE
OBX|1|NM|1751-7^Albumin SerPl-mCnc^LN||5|g/dL|4-12||||F|||201108191821|||||201108211438
NTE|1||Sample from serum
OBX|2|NM|1779-8^S Alkaline Phosphatase^LN||52|U/L|30-120||||F|||201108191821|||||201108211438
NTE|1||RETEST

SAMPLE v2.5 MESSAGE (with false information in all fields)

MSH|^~\&|PATH|Lab1^33D1234-9^CLIA|CARDIAC|NYSDOH|201108261354||ORU^R01|1018304PQ8|P|2.5
SFT|HL7 VENDOR NAME|99.9|LAB REPORTS PLUS|398627
PID|||ACH8303571^^^ACH^MRN|123-45-6789^^^SSA^SSN|MANN^HORACE||19331215|M|||123 MAIN ST^^^^14999|||||||ACH2333971^^^ACH^AN
PV1|||||||||||||||||||||||||||||||||||||||MEGA HOSPITAL CENTER|||||201108190948|201108250408
ORC|RE||956635.9|||||201108191755|||123456789^SMITH^LORRAINE
OBR|1||956635.9|58410-2^Hemogram^LN||||||||||123456789^SMITH^LORRAINE
OBX|1|NM|1751-7^Albumin SerPl-mCnc^LN||5|g/dL|4-12||||F|||201108191821|||||201108211438
NTE|1||Sample from serum
OBX|2|NM|1779-8^S Alkaline Phosphatase^LN||52|U/L|30-120||||F|||201108191821|||||201108211438
NTE|1||RETEST