PhenX Toolkit

Data Collection Worksheet

Please Note: The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

1. Has a doctor ever told you that you had a myocardial infarction or heart attack?

1 [ ] Yes

0 [ ] No

9 [ ] Dont Know

2. Have you had an outpatient or day surgery procedure to unblock blocked or narrowed blood vessels of the heart (called a PTCA, coronary angioplasty, stent, or atherectomy)?

1 [ ] Yes

0 [ ] No

Remainder of protocol to be abstracted from patients hospital medical records.

3. Was there an acute episode of pain, discomfort or tightness in the chest, left arm or jaw within 72 hours of the hospitalization or within 72 hours of the in-hospital event?

[ ] Yes

[ ] No

[ ] Unknown

4. Was the discomfort or pain diagnosed as having a non-cardiac origin?

[ ] Yes

[ ] No

[ ] Unknown

5. Were electrocardiograms (ECGs or EKGs) recorded?

[ ] Yes

[ ] No

[ ] Unknown

If "No" or "Unknown," skip to 6.

Record dates of ECGs and make two copies of FOUR ECG tracings as described below. Send one copy to the ECG Reading Center and attach one copy to this form:

-- If four or fewer tracings were made, include all tracings.

-- If more than four tracings were made, include:

1. First two codable tracings after admission (ECG#1-First and ECG#2)

2. Last codable tracing prior to discharge or death (discharge tracing) (ECG-Last)

3. Last codable tracing on day 3 (or the first tracing thereafter) following an admission or in-hospital event (ECG#3)

4. The next codable tracing after day 3

-- If the participant is readmitted (transferred) to the ICU/CCU because of a new episode of chest pain, the first codable tracing may be sent.

[img[cardio_008_image002.jpg|]]

Serum Enzymes

6. Were any cardiac enzyme measurements performed during this admission?

[ ] Yes

[ ] No

If "No," skip to end.

7. Did the participant have any active liver disease (cirrhosis, hepatitis, liver cancer, etc.)?

[ ] Yes

[ ] No

If "Yes," specify:

_____

8. Is there any evidence of hemolytic disease during this hospitalization?

[ ] Yes

[ ] No

9. Is there any mention of the participant having either trauma, a _ procedure, or rhabdomyolysis within one week prior to the measurement of the cardiac enzymes?

[ ] Yes

[ ] No

[ ] Unknown

If "Yes," please specify type of trauma or procedure below.

Date m/d/y: __ / __ / __ __

Type of Trauma or procedure:

_____

* Please complete ENZYME CHART. *

[img[cardio_008_image004.jpg|]]

[img[cardio_008_image006.jpg|]]

10. Myocardial infarction

[ ] Definite

[ ] Probable

[ ] No MI (skip to end)

If “Definite” or “Probable” enter date of MI (MM/DD/YYYY): __ __ / __ __ / __ __ __ __

Criteria

11. Chest Pain

[ ] Present

[ ] Absent

12. Cardiac Enzymes

[ ] Abnormal

[ ] Equivocal

[ ] Incomplete

[ ] Normal

13. ECG Serial Reading (pick one)

[ ] Evolution of Major Q-Wave

[ ] Evolution of ST-T Elevation with or without Q-Wave

[ ] New LBBB

[ ] Evolution of ST-Depression/Inversion alone

[ ] Evolution of Minor Q-Wave alone

[ ] Single ECG with Major Q-Wave

[ ] Single ECG with LBBB, described as new

[ ] Absent, Uncodable or Other ECG

14. Procedure-related:

[ ] Yes, cardiovascular

[ ] Yes, non-cardiovascular

[ ] No

Diagnostic Criteria:

Acute, Evolving or Recent MI

Either one of the following criteria satisfies the diagnosis for an acute, evolving or recent MI:

1. Typical rise and gradual fall (troponin) or more rapid rise and fall (CK-MB) of biochemical markers of myocardial necrosis with at least one of the following:

- ischemic symptoms;
- development of pathologic Q waves on the ECG;
- ECG changes indicative of ischemia (ST segment elevation or depression); or
- coronary artery intervention (e.g., coronary angioplasty).

2. Pathologic findings of an acute MI.

Established MI

Any one of the following criteria satisfies the diagnosis for established MI:

1. Development of new pathologic Q waves on serial ECGs. The patient may or may not remember previous symptoms. Biochemical markers of myocardial necrosis may have normalized, depending on the length of time that has passed since the infarct developed.

2. Pathologic findings of a healed or healing MI.

Protocol source: https://www.phenxtoolkit.org/protocols/view/40801