

MELBOURNE INTERVENTIONAL GROUP



DATA DEFINITIONS MANUAL

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ACKNOWLEDGMENTS

THIS DOCUMENT WAS CREATED BY ANGELA BRENNAN, DAVID J. CLARK AND STEPHEN J. DUFFY, WHO TAKE RESPONSIBILITY FOR THE ACCURACY OF THE INFORMATION. SOURCE DOCUMENTS ARE ACKNOWLEDGED ON PAGES 9 & 10. THE AUTHORS ACKNOWLEDGE THE SECRETARIAL SUPPORT OF MARDI MALONE & EDITORIAL ASSISTANCE OF A/PROF CHRIS REID. THE DOCUMENT WAS REVIEWED AND UPDATED MAY 2009 BY ANGELA BRENNAN, CAROLINE STEER , DAVID J. CLARK AND STEPHEN J. DUFFY, WITH THE ASSISTANCE OF A/PROF CHRIS REID, A/PROF ANDREW AJANI, DR NICK ANDRIANOPOULOS, DR WILLIAM CHAN AND PHILIPPA LOANE.

FOREWORD

In 2003 a group of Interventional Cardiologists formed the Melbourne Interventional Group (MIG). This group is currently comprised of several public hospitals (Alfred, Austin, Box Hill, Frankston, Geelong, Northern, Royal Melbourne and Western) and associated private hospitals. Clinical trials, data collection and coordination are run from the Department of Epidemiology and Preventive Medicine, Monash University (Centre of Cardiovascular Research & Education in Therapeutics). This venture crosses two universities (Melbourne and Monash) and involves a wide array of experience in Interventional Cardiology.

The aims of the group are:

- To participate in collaborative research activities
- To act as a 'sounding board' for individual research ideas and projects
- Access and utilization of an interventional database (complete with data managerial and statistical support) which will be maintained at a 'neutral' site (Department of Epidemiology and Preventive Medicine, Monash University, Melbourne)
- The potential for multi-centre angioplasty registries which will ultimately have long-term follow-up
- Opportunities in education and training (e.g. attracting interventional cardiology trainees) with plans for a regular annual meeting around the time of major cardiovascular meetings, e.g. Cardiac Society of Australia & New Zealand or ultimately stand-alone meetings
- To demonstrate the collaborative nature of industry in Australia in multi-company sponsorship of altruistic medical activities
- Involvement in international based clinical trials
- To lobby government regarding the importance of coronary artery disease and interventional cardiology as a health priority
- Interaction with other collaborative groups and educational bodies e.g. Cardiac Society of Australia and New Zealand

1.1 Description of MIG PCI Data Standards

These are the data standards (elements) for use in cardiac catheter laboratories to record information about patients undergoing PCI

1.2 Source documents used to develop the MIG PCI Data Standards

National and international registers and internationally recognized guidelines were used to compile the Percutaneous Coronary Intervention matrix from which the data standards were derived.

- National Health Data Committee 2004. Other Data Set Specification, Acute coronary syndrome (clinical), National Health Data Dictionary. Version 12 Supplement. AIHW Catalogue No. HWI 70 Canberra: Australian Institute of Health and Welfare.
- The Acute Coronary Syndromes Data Set Working Group (ACSDWG). The Core Acute Coronary Syndromes Data Set. Sept 2003
- American College of Cardiology (ACC) Clinical Data Standards: Cannon CP, Battler A, Brindis RG, Cox JL, Ellis SG, Every NR, Flaherty JT, Harrington RA, Krumholz HM, Simoons ML, Van de Werf FJJ, Weintraub WS. ACC Key Elements and Data Definitions for Measuring the Clinical Management and Outcomes of Patients with Acute Coronary Syndromes: a report of the American College of Cardiology Task Force on Clinical Data Standards (Acute Coronary Syndromes Writing Committee). *J Am Coll Cardiol* 2001;38:2114–30
- Australasian Society of Cardiothoracic Surgeons (ASCTS) Version 3 2008
- Acute Coronary Syndrome Data Standards *JACC* 2001 Vol 38:2114-30
- NCDR® CathPCI Registry® v3.0 & v3.04, v4.2 (2008). American College of Cardiology Foundation
- European Society of Cardiology, Guidelines for Percutaneous Coronary Interventions. *European Heart Journal* (2005) **26**, 804-847
- Cardiology Audit and Registration Data Standards (CARDS) for Percutaneous Coronary Interventions: PCI Data Standards, Nov 2004.
- Swedish Coronary Angiography and Angioplasty Registry (SCAAR)

NEJM Vol 359:1009-19

- A Polymer-Based, Paclitaxel-Eluting Stent in Patients with Coronary Artery Disease
NEJM Vol 350:221-231 Stone et al
- Joint ESC-ACC-AHA-WHF 2007 Task Force consensus statement "Universal Definition of Myocardial Infarction"
- Emergency CABG In the Contemporary PCI Era. *Circulation. 2002;106:2346-2350*

1.3 Baseline Case Report Form (CRF) format

The Baseline CRF is subdivided into the following sections:

- Section 1 – Demographics: the demographic section contains data fields such as date of birth, and sex.
- Section 2 – Admission: the admission section contains data such as the source and date of the patient's admission.
- Section 3 – History and Risk Factors: includes data on the patient's previous medical history such as, previous myocardial infarction (MI)
- Section 4 – Previous Interventions: data fields for previous interventions and procedures such as, percutaneous coronary interventions (PCI), and coronary artery bypass graft surgery (CABG).
- Section 5 – Cardiac Status at PCI Procedure: includes data on the patient's condition in the period just prior to the PCI, acute coronary syndrome (ACS) type and ST-elevation MI (STEMI) event timings.
- Section 6 – Cath Lab Visit: includes data date of PCI procedure, medications given and extent of coronary disease.
- Section 7 – PCI Procedure / Lesion Information: includes data on ACC/AHA lesion type, stent details and lesion characteristics
- Section 8 – Outcomes / Discharge: includes data on discharge status, date and complications while in hospital.

Please refer to Attachment 1: MIG Baseline Instructions and Attachment 2: MIG Baseline CRF Data Queries

1.4 Follow up CRF format

The follow up CRF captures the following information:

- Procedure ID (unique procedure ID from the baseline MIG CRF), UR number, date of birth and hospital code.
- Type of follow up (30 day or 12 month), date of follow up, vital status, cause & date of death if relevant, smoking status and whether the patient has been readmitted to hospital in the follow up period
- Current medications, answered as yes, no or unknown
- Information about readmission to hospital including date, location, reason, and treatment.

Please refer to Attachment 3: MIG Follow Up Instructions

1.5 Opt-off consent & Patient Information Sheet (PIS)

- MIG sites generally have Human Research and Ethics Committee (HREC) approval for opt-off consent whereby consent is presumed unless the patient "opts off" by calling a 1800 telephone number. Opt-off sites must give each patient a "Patient Information Sheet". If a patient informs a staff member at a site that they do not wish to participate it is appropriate for that patient's data to not be collected. One site requires the patient to sign the PIS (i.e. written, informed consent) and this is retained in the medical record, however a waiver is approved in cases where mortality occurred. One site has a general cardiology procedural consent form that encompasses approval for data collection and follow up.

Please refer to Attachment 4: Patient Information Sheet (PIS)

1.6 Audit process

- Auditing of baseline CRF's commenced in 2007 and is undertaken on an annual basis. Procedures are randomly selected and the audit is undertaken by a researcher not affiliated with the institution being audited. Fifteen verifiable fields from 5% of patients enrolled at each site are randomly selected and audited on an annual basis.

BASELINE CRF DEFINITIONS Version 5

Section 1. Demographics

1.1 UR

Hospital UR Number. A letter or first zero's can be included

1.2 Patient's first name

Indicate patient's first name (hyphenated names should be recorded with a hyphen). Do not use any shortened versions of the name or 'nick names' the patient may have. If the patient has multiple first names enter all sequentially and if necessary print these clearly next to the field on the CRF.

1.3 Patient's middle name

Indicate patient's middle name (hyphenated names should be recorded with a hyphen). If the patient has no middle name leave blank. If the patient has multiple middle names enter all sequentially and if necessary print these clearly next to the field on the CRF.

1.4 Patient's last name

Indicate patients last name (hyphenated names should be recorded with a hyphen).

1.5 Date of birth

Patient's date of birth in DD / MM / YYYY format

1.6 Sex

Patient's gender. Choose from:

- Male
- Female

1.7 Postcode

The postcode of the patient's residence

1.8 Race

Caucasian / Asian / Aboriginal / Torres Strait Islander / Indian / Sri Lankan / Pakistan / Bangladesh / Other (specify)

1.9 Insurance status

Select the category which most accurately describes the patient's insurance status. Choose from:

- Medicare - Patient is funded by Medicare
- Department of Veterans Affairs - Patient is funded by Department of Veteran Affairs
- Private health insurance - Patient has private health insurance
- Overseas visitor - Patient is an overseas visitor
- Self-funded funded - Patient is self-funded (private patient without private health insurance)

1.10 Medicare number

The full Medicare number of the patient (i.e. family number plus person number) if the patient is registered with Medicare

1.11 DVA number

Where applicable, the patient's DVA number

Section 2. Admission

2.1 Admission status

Admission source of patient on admission to PCI hospital. Choose from:

- Referral: patient admitted via referral for procedure by another MD and/or clinic
- Elective: patient admitted electively for PCI
- Emergency Department: patient admitted via the Emergency Department
- Transfer from other facility: patient admitted by transfer from another acute care facility. Code: even if patient transferred due to a referral
- Other: patient admitted for anything other than a planned cardiac catheterization or cardiac diagnosis (i.e. MI) that led to a cardiac catheterization; e.g., admitted electively for angiography and proceeded to infarct on the table, requiring urgent PCI. Specify in free text.

2.2 Date of admission

Date on which the patient was admitted to hospital. (This date is not necessarily the scheduled date for care to be provided or the date on which commencement of care actually occurs.)

In DD / MM /YYYY format

2.3 Number of catheter laboratory visits this admission

The number of catheter laboratory visits the patient has undergone on this admission to hospital. A visit for initial angiography & subsequent PCI in the same admission is counted as 2. (Where a patient undergoes 2 or more PCI's within the same admission, these should be documented on separate baseline CRF's.)

Section 3. History & Risk Factors

3.1 Height

Patient's height in centimetre (cm). (Measured, estimated or self reported)

3.2 Weight

Patient's weight in kilogram (kg). (Measured, estimated or self reported)

3.3 Smoking status

History confirming any form of tobacco use in the past. This includes cigarettes, cigar and/or pipe. Choose from:

- Currently smoking (within 1 month of this admission)
- Previously smoked (more than 1 month prior to this admission)
- Never smoked

3.4a Chronic lung disease

Documented history of chronic lung disease i.e., chronic obstructive pulmonary disease (COPD) or is currently being treated with pharmacological therapy (e.g. inhalers, theophylline, aminophylline or steroids) and/or has a forced expiratory volume in 1 second (FEV1) less than 75%, room air pO₂ less than 60mmHg or room pCO₂ greater than 50mmHg. If yes, answer 3.4b

Yes / No

3.4b Type of chronic lung disease

Given that the patient has a chronic lung disease, indicate if it is either COPD or asthma.

Chronic Obstructive Pulmonary Disease (COPD): is a slowly progressive disease that is characterized by a gradual loss of lung function. Includes chronic bronchitis, chronic obstructive bronchitis, or emphysema, or combinations of these conditions.

Diagnosis of COPD is confirmed by the presence of airway obstruction on testing with spirometry.

Asthma: A chronic lung condition characterized by episodes or attacks of inflammation and narrowing of the small airways in response to asthma triggers.

Note: Both can be selected if appropriate for the patient

3.5a Diabetes

Indicate if the patient has a history of diabetes regardless of duration of disease or need for anti-diabetic agents. If yes, answer 3.5b

Yes / No

3.5b Diabetes treatment

Where the patient is a diabetic indicate the treatment type. Choose from:

- Diet: Patient has received dietary advice appropriate to their condition but is not taking medication
- Oral: Patient uses oral medication to control their condition
- Insulin: Patient uses insulin to control their condition with or without oral therapy

3.6 Baseline serum creatinine

The baseline serum creatinine level in umol/L

Record the absolute result of the most recent serum creatinine measurement in umol/L.

Section 3. History & Risk Factors

3.7 Dialysis requiring

Indicate if the patient is currently undergoing either haemodialysis or peritoneal dialysis on an ongoing basis as a result of renal failure. Dialysis Includes peritoneal dialysis, haemodialysis and hemofiltration.

Yes / No

3.8 Functioning renal transplant

Indicate if the patient has a functioning renal transplant.

Yes / No

3.9 Hypertension

Indicate if the patient has hypertension as documented by one of the following:

- History of hypertension diagnosed and treated with medication, diet and/or exercise.
- Blood pressure >140 systolic or >90 diastolic on at least 2 occasions.
- Currently on antihypertensive medication.

Yes / No

3.10 Dyslipidaemia

Indicate if the patient has a history of dyslipidaemia diagnosed and/or treated by a physician, and/or Cholesterol > 5.0 mmol/L, HDL <1.0mmol/L or Triglycerides > 2.0mmol/L

Yes / No

Section 3. History & Risk Factors

3.11 Previous MI

Indicate if the patient has had at least one documented MI **greater than 7 days prior** to this admission. An MI is evidenced by any of the following.

1. A rise and fall of cardiac biomarkers (Troponin, CK or CK-MB) with at least one value in an abnormal range for that laboratory above the upper reference limit (URL) of normal (i.e. above the 99th percentile of the URL measured with a coefficient of variation $\leq 10\%$).

In partnership with at least one of the following manifestations of myocardial ischemia.

- a. Ischemic symptoms.
 - b. ECG changes indicative of new ischemia (new ST-T changes, new left bundle branch block (LBBB) or loss of R wave voltage.
 - c. Development of pathological Q waves in two or more contiguous leads on the ECG (or equivalent findings for true posterior MI)
 - d. Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.
 - e. Documentation in the medical record of the diagnosis of acute myocardial infarction based on the cardiac biomarker pattern in the absence of any items enumerated in a-d due to conditions that may mask their appearance (e.g. peri-operative infarct when the patient cannot report ischemic symptoms, baseline LBBB or ventricular pacing).
2. ECG changes associated with prior MI can include the following (with or without prior symptoms):
 - a. Any Q wave in leads V2-V3 ≥ 0.02 sec or QS complex in leads V2 & V3.
 - b. Q wave ≥ 0.03 sec & ≥ 0.1 mV deep or QS complex in leads I, II, aVL, aVF, or V4-V6 in any two leads of a contiguous lead grouping (I, aVL, V6; V4-V6; II, III, and aVF).
 - c. R-wave ≥ 0.04 sec in V1-V2 and R/S ≥ 1 with a concordant positive T wave in the absence of a conduction defect.
 3. Imaging evidence of a region with new loss of viable myocardium at rest in the absence of non-ischemic cause. This can be manifested as:
 - a. Echocardiographic, computed tomography (CT), magnetic resonance (MR), ventriculographic or nuclear imaging evidence of left ventricular (LV) thinning or scarring and failure to contract (i.e., hypokinesis, akinesis, or dyskinesis)
 - b. Fixed (non-reversible) perfusion defects on nuclear radioisotope imaging (e.g. MIBI, Thallium)
 4. Medical records documentation of prior MI.

Defining Reference Control Values (MI Diagnostic Limit and Upper Limit of Normal):

Reference values must be determined in each laboratory by studies using specific assays with appropriate quality control, as reported in peer-reviewed journals. Acceptable imprecision (coefficient of variation) at the 99th percentile for each assay should be defined as $< \text{ or } = 10\%$. Each individual laboratory should confirm the range of reference values in their specific setting.

Yes/No

3.12 Family history of CAD

Indicate if the patient has had any first degree relatives (parents, siblings, children) who have any of the following at age < 60 years:

- Coronary artery disease (angina, previous CABG or PCI)
- MI

- sudden cardiac death without an obvious cause

If the patient is adopted or the family history is unavailable, annotate "unknown" on the CRF

Yes / No

Section 3. History & Risk Factors

3.13 Congestive Heart Failure (CHF)

Indicate if the patient has a history of heart failure (HF) documented in the medical record. History is defined as any time **prior to two weeks** before the current date of admission.

HF can also be defined by one of the following:

- Paroxysmal nocturnal dyspnoea (PND)
- Dyspnoea on exertion (DOE) due to heart failure
- Chest X-ray (CXR) showing pulmonary congestion
- Pedal oedema or dyspnoea treated with medical therapy for heart failure

Yes / No

3.14 Peripheral Vascular Disease (PVD)

PVD is defined by either chronic or acute occlusion or aneurysmal narrowing of the arterial lumen of the aorta or extremities and includes the following:

- claudication with exertion
- extremity ischaemic rest pain
- amputation for arterial insufficiency
- vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities
- documented aortic aneurysm
- documented renal artery stenosis
- positive non-invasive testing (e.g., ankle brachial index less than 0.8)

Yes / No

3.15 Cerebrovascular disease (CVD)

Indicate if patient has a history of CVD, documented by any one of the following:

- Unresponsive coma for >24hours: Patient experienced complete mental unresponsiveness and no evidence of psychological or physiologically appropriate responses to stimulation.
- Patient has a history of stroke, i.e. loss of neurological function with residual symptoms at least 72 hours after onset.
- Reversible Ischemic Neurological Deficit (RIND): Patient has a history of loss of neurological function with symptoms at least 24 hours after onset but with complete return of function within 72 hours.
- Transient Ischemic Attack (TIA): patient has a history of loss of neurological function that was abrupt in onset but with complete return of function within 24 hours.
- Non-invasive /invasive carotid test with greater than 75% occlusion.
- Previous carotid artery surgery
- History of stroke resulting from an ischemic event where the patient suffered a loss of neurological function with residual symptoms remaining for at least 24 hrs after onset and which occurred before the current presentation / admission. This does not include neurological disease processes such as metabolic and/or anoxic ischemic encephalopathy.

Yes / No

3.16 Obstructive Sleep Apnoea (OSA)

The patient reports knowledge of, or has previously been diagnosed with obstructive sleep apnoea (OSA).

OSA is the most common type of sleep apnoea and occurs when the upper airway occludes (either partially or fully) but efforts to breath continue. The primary causes of upper airway obstruction are lack of muscle tone during sleep, excess tissue in the upper airway and anatomic abnormalities in the upper airway and jaw.

Yes / No

3.17 Rheumatoid Arthritis

Patient has previously been diagnosed with rheumatoid arthritis.

Yes / No

Section 4. Previous Interventions

4.1a Previous PCI

Indicate if patient has had a prior percutaneous transluminal coronary angioplasty, coronary atherectomy, and/or coronary stent performed at any time prior to this PCI procedure (which may include during the current admission)
If yes, answer 4.1b

Yes / No

4.1b Date of most recent PCI

The date on which patient had their most recent PCI (if only the year is known, this will suffice)

In DD / MM / YYYY format

4.2a Previous CABG

Previous CABG (coronary artery bypass grafting) surgery by any approach prior to the current PCI procedure
If yes, answer 4.2b

Yes / No

4.2b Date of most recent CABG

The date on which patient had their most recent CABG (if only the year is known, this will suffice)

In DD / MM / YYYY format

4.3a Previous valvular surgery

Previous surgical replacement and/or repair of a cardiac valve, by any approach prior to the current PCI procedure
If yes, answer 4.3b

Yes / No

4.3b Date of most recent valvular surgery

The date on which patient had their most recent valvular surgery (if only the year is known, this will suffice)

In DD / MM / YYYY format

Section 5. Cardiac Status at PCI

5.1 Congestive Heart Failure

Indicate whether, **within 2 weeks** prior to this procedure, a physician has diagnosed that the patient is currently in heart failure(HF), or the diagnosis of HF was made on this admission, OR

HF can be diagnosed based on careful history and physical exam, or by one of the following criteria:

- Paroxysmal nocturnal dyspnoea (PND) and/or fatigue
- Dyspnoea on exertion (DOE) due to heart failure
- Chest X-ray (CXR) showing pulmonary congestion
- Pedal oedema or dyspnoea treated with medical therapy for heart failure

Yes / No

5.2 Rhythm

Indicate the patient's heart rhythm (at the commencement of the procedure). Choose from:

- Atrial Fibrillation
- Sinus Rhythm
- Other

5.3 New York Heart Association (NYHA) class

Indicate the patients NYHA classification. Choose from:

- Class I: patient has cardiac disease but without resulting limitations of ordinary physical activity. Ordinary physical activity (e.g., walking several blocks or climbing stairs) does not cause undue fatigue or dyspnoea. Limiting symptoms may occur with marked exertion.
- Class II: patient has cardiac disease resulting in slight limitation of ordinary physical activity. Patient is comfortable at rest. Ordinary physical activity such as walking more than 2 blocks or climbing more than one flight of stairs results in limiting symptoms (e.g., fatigue or dyspnoea).
- Class III: patient has cardiac disease resulting in marked limitation of physical activity. Patient is comfortable at rest. Less than ordinary physical activity (e.g., walking one to two level blocks or climbing one flight of stairs) causes fatigue or dyspnoea.
- Class IV: patient has dyspnoea at rest that increases with any physical activity. Patient has cardiac disease resulting in inability to perform any physical activity without discomfort. Symptoms may be present even at rest. If any physical activity is undertaken, discomfort is increased.

5.4 Killip class

For AMI patients only, indicate the Killip class. Choose from:

- Class 1: Absence of crackles/rales over the lung fields and absence of S3
- Class 2: Crackles/rales over 50% or less of the lung fields or the presence of an S3
- Class 3: Crackles/rales over more than 50% of the lung fields
- Class 4: Cardiogenic shock. Clinical criteria for cardiogenic shock are:
 - Hypotension (a systolic blood pressure of less than 90 mmHg for at least 30 minutes or the need for supportive measures to maintain a systolic blood pressure of greater than or equal to 90mmHg)
 - End-organ hypoperfusion (cool extremities or a urine output of less than 30 ml/h, and a heart rate of greater than or equal to 60 beats per minute)
 - The haemodynamic criteria are a cardiac index of no more than 2.2 l/min per square meter of body-surface area and a pulmonary-capillary wedge pressure of at least 15 mmHg.

5.5 Functional ischemia

Indicate if the patient has functional ischemia. Where a non-invasive test such as exercise or pharmacologic stress test, radionuclide, echo, CT scan was done to rule out ischemia. The test could be performed at this admission (prior to the PCI), or it could be a test that resulted in the admission. Choose from:

- Not Applicable
- Positive
- Negative
- Equivocal

Section 5. Cardiac Status at PCI

5.6 Cardiogenic shock

Clinical criteria for cardiogenic shock are:

- Hypotension (a systolic blood pressure of less than 90 mmHg for at least 30 minutes or the need for supportive measures to maintain a systolic blood pressure of greater than or equal to 90mmHg)
- End-organ hypoperfusion (cool extremities or a urine output of less than 30 ml/hour, and a heart rate of greater than or equal to 60 beats per minute).
- The haemodynamic criteria are a cardiac index of no more than 2.2 l/min per square meter of body-surface area and a pulmonary-capillary wedge pressure of at least 15 mmHg.

Yes / No

5.7 Intra-aortic Balloon Pump (IABP)

Indicate if an IABP was used **during** the procedure

Yes / No

5.8 Out of hospital cardiac arrest

Indicate if the patient was admitted following an out of hospital cardiac arrest

Yes / No

5.9 Acute Coronary Syndrome

Indicate if the patient is suffering from an Acute Coronary Syndrome event. ACS encompasses clinical features comprising chest pain or overwhelming shortness of breath, defined by accompanying ECG and biochemical features. ACS encompasses unstable angina pectoris (UAP), Non-ST-elevation MI (NSTEMI) and ST-elevation MI (STEMI).

Choose from:

- UAP
- NSTEMI
- STEMI

See detailed definitions in (5.10a)

Yes / No

Section 5. Cardiac Status at PCI

5.10a Angina type

Indicate the patient's symptom presentation or angina type on presentation. Choose from:

- **None:** No angina, no symptoms
- **Atypical:** Chest pain: pain, pressure or discomfort in the chest, neck or arms not clearly exertional or not otherwise consistent with pain or discomfort of myocardial ischemic origin. This includes patients with non-cardiac pain (e.g. pulmonary embolism, musculoskeletal, or oesophageal discomfort), or cardiac pain not caused by myocardial ischemia (e.g., acute pericarditis).
- **Chronic Stable Angina** (Stable Angina): Angina without a change in frequency or pattern for the 6 weeks prior to presentation / procedure. Angina is controlled by rest and / or sublingual/ oral/ transcutaneous medications.
- **Unstable Angina:** One of the following is necessary:
 - Angina that occurred at rest and was prolonged, usually lasting more than 20 minutes.
 - New-onset angina of at least Canadian Cardiovascular Society (CCS) angina class III severity
 - Recent acceleration of angina reflected by an increase in severity of at least 1 CCS class to at least CCS class III
- **NSTEMI:** is defined by both of the following criteria:
 - Cardiac biomarkers (creatinine kinase-myocardial band, Troponin T or I) exceed the upper limit of normal according to the individual hospital's laboratory parameters with a clinical presentation which is consistent or suggestive of ischemia. ECG changes and/or ischemic symptoms may or may not be present.
 - Absence of ECG changes diagnostic of a STEMI (see STEMI).

The patient was hospitalized for a non-ST elevation myocardial infarction (NSTEMI) as documented in the medical record.

- **STEMI:** or equivalent is defined by the presence of both of the following criteria:
 - ECG evidence of ST elevation or new LBBB: New or presumed new ST-segment elevation or new LBBB not documented to be resolved within 20 minutes. ST-segment elevation is defined by new or presumed new sustained ST-segment elevation at the J-point in two contiguous ECG leads with the cut-off points: ≥ 0.2 mV in men or ≥ 0.15 mV in women in leads V2-V3 and/or ≥ 0.1 mV in other leads and lasting greater than or equal to 20 minutes. If no exact ST-elevation measurement is recorded in the medical chart, the physician's written documentation of ST-elevation or Q-waves is acceptable. If only one ECG is performed, then the assumption that the ST elevation persisted at least the required 20 minutes is acceptable. LBBB refers to new or presumed new LBBB on the initial ECG.
 - Cardiac biomarkers (creatinine kinase-myocardial band, Troponin T or I) exceed the upper limit of normal according to the individual hospital's laboratory parameters a clinical presentation which is consistent or suggestive of ischemia which is consistent or suggestive of ischemia.

Note: ST elevation in the posterior chest leads (V7 through V9), or ST depression that is maximal in V1-3, without ST-segment elevation in other leads, demonstrating posterobasal myocardial infarction, is considered a STEMI equivalent.

The patient presented with a STEMI or its equivalent as documented in the medical record.

Defining Reference Control Values (MI Diagnostic Limit and Upper Limit of Normal):

Reference values must be determined in each laboratory by studies using specific assays with appropriate quality control, as reported in peer-reviewed journals. Acceptable imprecision (coefficient of variation) at the 99th percentile for each assay should be defined as $< \text{or} = 10\%$. Each individual laboratory should confirm the range of reference values in their specific setting.

Section 5. Cardiac Status at PCI

5.10b ACS time period

Where UAP, NSTEMI or STEMI selected as Angina Type. Indicate the time period since symptom onset. Choose from:

- < 6 hours
- 6 – 24 hours
- > 24 hours – 7 days

If time period is unknown or the patient presented with a silent MI- annotate “unknown” on the CRF

5.11a STEMI onset time & date

STEMI time & date of ONSET

Where less than 24 hours have elapsed since the onset of the STEMI, please indicate the time of onset of symptoms.

In HH – MM and DD / MM / YYYY format

5.11b Time & date of arrival at first hospital

Applicable **ONLY** if patient is transferred from another hospital.

In HH – MM and DD / MM / YYYY format

5.11c Time of arrival at PCI hospital

Time of arrival of patient at PCI hospital.

In HH – MM format

Note: Date of arrival will be ascertained from question 2.2 - Date of admission

5.11d Time of first balloon inflation

Indicate the date and time of the intracoronary treatment device deployment. If the exact time of first treatment device deployment is not known, indicate the date and time of the start of the procedure.

In HH - MM format

Note: Date of first balloon inflation will be ascertained from question 6.1 – Date of procedure

Section 6. Catheterisation Laboratory Visit

6.1 Date of procedure

The date on which the patient underwent the PCI procedure

In DD / MM / YYYY format

6.2a PCI status

Indicate the status of the PCI. Choose from :

- **Elective:**
The patient's cardiac function has been stable in the days or weeks prior to the procedure. The procedure could be deferred without increased risk of compromised cardiac outcome. **If elective PCI - complete question 6.2b**
- **Urgent:**
ALL of the following conditions are met:
 - Not elective status
 - Not rescue status
 - Procedure required during same hospitalization in order to minimize chance of further clinical deterioration
 - Worsening, sudden chest pain, CHF, acute MI, IABP, UAP with intravenous (IV) nitro-glycerine (GTN) or rest angina (but stabilised patient) may be included.
- **Rescue:**
 - Rescue PCI is defined as PCI after failed fibrinolysis for patients with continuing or recurrent myocardial ischemia.

6.2b Staged PCI

For an elective PCI ONLY. Indicate if this PCI being performed as part of a multi-vessel revascularization strategy. If this is the **initial** PCI of the multi-vessel strategy, then the answer is **No**

Yes / No

6.3 Cath / PCI same lab visit

Indicate if the patient had a PCI at the same time as the diagnostic coronary angiogram.

Elective patients may have the diagnostic and therapeutic procedures separated. Emergency or acute patients often have their diagnostic and therapeutic procedures concurrently (*ad hoc*).

Yes / No

6.4 Blood pressure

The individual's measured systolic and diastolic blood pressures in mmHg. (At the commencement of PCI procedure)

6.5 Intravenous inotropes

Indicate whether the patient is on intravenous inotropic support i.e., dopamine, dobutamine, adrenaline, noradrenaline.

Yes / No

Section 6. Catheterisation Laboratory Visit

6.6 Heart rate

Record the individual's monitored heart rate recorded in beats per minute (at the commencement of PCI procedure)

6.7 Thrombolytics

Indicate if thrombolytic medication was given to the patient prior to the procedure. If given, choose from:

- No
- <3 hours prior to the procedure
- 3-6 hours prior to the procedure
- 6-12 hours prior to the procedure
- <7 days prior to the procedure

6.8 Glycoprotein IIb / IIIa Blockade

Indicate if IIb/IIIa medication was given to the patient. Choose only ONE from:

- No
- Prior to the procedure
- During the procedure
- After the procedure

Note: Choose the earliest timeframe applicable.

6.9 Heparin

Indicate if heparin medication was given to the patient and if so, when. If given, can choose more than one from:

- No
- Prior
- During
- After

6.10 LMWH

Indicate if LMWH medication was given to the patient and if so, when. If given, can choose more than one from.

- No
- Prior
- During
- After

6.11 Bivalirudin

Indicate if bivalirudin medication was given to the patient during the PCI procedure.

Yes / No

6.12 Aspirin

Indicate if aspirin medication was given to the patient during this admission.

Yes / No

Section 6. Catheterisation Laboratory Visit

6.13a Clopidogrel

Indicate if clopidogrel medication was given to the patient. Choose only ONE from:
If given answer question 6.13c

- No
- Prior
- During
- After

Note: Choose the earliest timeframe applicable.

6.13b Prasugrel

Indicate if prasugrel medication was given to the patient. Choose only ONE from:
If given answer question 6.13c

- No
- Prior
- During
- After

Note: Choose the earliest timeframe applicable.

6.13c Planned duration of Thienopyridine (Clopidogrel / Prasugrel) Therapy

Where Clopidogrel or Prasugrel is given to the patient, specify the planned duration for treatment. Choose the time frame closest from:

- 1 month
- 3 months
- 6 months
- 12 months
- >12 months

If thienopyridine therapy given (i.e. prior, during or after PCI) and subsequently discontinued during the hospitalisation (due to failed PCI or bleeding for example), annotate this on the CRF.

6.14 Percutaneous entry location

The percutaneous entry location used to provide arterial vascular access for the procedure. Choose ONE from:

- Brachial
- Radial
- Femoral

6.15 French size (guiding catheter)

The French size of the guiding catheter used to cannulate the ostium of the coronary artery. The largest size used should be indicated. Choose from:

- 5F
 - 6F
 - 7F
 - 8F
 - Other (specify in free text in space provided)
-

Section 6. Catheterisation Laboratory Visit

6.16 Closure device

Indicate if a vascular arterial closure device was used. Choose only ONE:

- No
- Seal
- Suture
- Other (specify in free text in space provided)

6.17 Ejection Fraction (EF) test modality

Where the EF was measured, indicate the test used to derive this information. Choose from:

- Cath (for cardiac catheter)
- Nuclear (for a radionuclide scan)
- Echo (for echocardiogram)
- MRI (for a Magnetic Resonance Image scan)

6.18a EF %

The percentage of the blood emptied from the left ventricle at the end of the contraction. NOTE: The most recent test within the last six months, including the current procedure and up to discharge following the procedure. Enter a percentage between 5 – 75%. (Do not use greater than or less than symbols). If EF is greater than 75%, record as 75%. If nuclear scan, echo or angiogram did not yield a digital EF %, provide an estimate from reviewing the study. If only a range is estimated for the EF, i.e. in ECHO the midpoint of the range should be the value noted.

Where EF estimated: NORMAL: LVEF is greater than 50%
 MILDLY REDUCED: LVEF is > or equal to 45% but less than or equal to 50%
 MODERATELY REDUCED: LVEF is > or equal to 35% but less than 45%
 SEVERELY REDUCED: LVEF is less than 35%

6.18b EF value

Indicate whether the EF value given was **Estimated** or **Derived**.

Derived: Where a nuclear scan, echo or angiogram has yielded a digital EF %

6.19a Disease extent: Single or Multi Vessel

Indicate if the patient has single or multi-vessel coronary disease:

Single Vessel Disease: Lesion of $\geq 50\%$ stenosis in 1 coronary system

Multi Vessel Disease: Lesion of $\geq 50\%$ stenosis in 2 coronary systems (Answer 6.19b & 6.19c)

Coronary systems are defined as: left anterior descending (LAD)-Diagonal / left circumflex-marginal (Cx-OM) / right coronary artery (RCA).

(Left main coronary artery (LMCA) is 2 coronary systems as it gives rise to the LAD & Cx systems- therefore is multi-vessel disease. LAD-Diagonal is one coronary system as is Cx-OM and the RCA.)

6.19b Disease Extent: 2 Vessel or 3 Vessel

Where the patient has multi vessel disease, indicate if this is 2 or 3 vessel disease (Answer 6.19c)

6.19c Left Main Disease

Where the patient has multi vessel disease indicate if the patient has left main disease (defined as a lesion of $\geq 50\%$)

Yes / No

Section 7. PCI Procedure / Lesion Information

Complete 7a – 7z for each coronary lesion treated at this PCI

7a Coronary lesion

Indicate the status of the coronary lesion. Choose only **ONE** from:

- De novo: (*De novo* is defined as a lesion that is diagnosed with stenosis and treated for the first time i.e. no prior intervention at that site).
- Restenosis: (Restenosis is defined as a lesion that has had a prior intervention e.g., rotational atherectomy, laser, POBA, brachytherapy, but **NO** prior stent). If yes, answer 7b
- In-stent Restenosis (ISR): ISR is defined as a lesion that has had a prior stent to that site (or within 5mm of the proximal and distal prior stent edges).
If yes, answer question 7e

7b Date of previous balloon treatment (POBA)

The date this lesion was treated with POBA (if only the year is known, this will suffice)

In DD / MM / YYYY format

7c Prior stent type

For ISR lesions ONLY Indicate type of prior stent used. Choose from:

- DES (Prior stent was a drug-eluting stent)
- BMS (Prior stent was a bare-metal stent)
- MIXED (Prior stents both DES & BMS)

Additionally, answer 7d

7d Date prior stent implanted

The date this lesion was previously stented (if only the year is known, this will suffice)

In DD / MM / YYYY format

7e Stent thrombosis

Indicate if the previously treated & stented lesion is being treated because of the presence of a thrombus in the stent (or within 5mm of the prior stent edge). A thrombus is suggested by certain angiograph features, haziness, reduced contrast, density or contrast persistence, irregular lesion contours, or globular filling defects.

Yes / No

7f Lesion code

The Lesion Code: choose from 1-25

1. RCA prox - Right Coronary Artery proximal segment
2. RCA mid - Right Coronary Artery mid segment
3. RCA distal - Right Coronary Artery distal segment
4. PDA - Posterior Descending Artery
5. PLV - Posterior Left Ventricular Branch
6. LMCA left MAIN - Left Main Coronary artery
7. LAD prox - Left Anterior Descending artery proximal segment prior to 1st septal branch
8. LAD mid - Left Anterior Descending artery mid segment
9. LAD distal - Left Anterior Descending artery distal segment
10. D1 - First Diagonal Branch
11. D2 - Second or subsequent Diagonal Branch
12. D3 - Third or subsequent Diagonal Branch
13. LCX prox - Left Circumflex Artery proximal segment
14. LCX distal - Left Circumflex Artery distal segment
15. OM1 - First Obtuse Marginal Branch
16. OM2 - Second Obtuse Marginal Branch
17. OM3 - Third or subsequent Obtuse Marginal Branch
18. LIMA - Left Internal Mammary Artery Graft
19. RIMA - Right Internal Mammary Artery Graft
20. SVG1 - First Saphenous Vein Graft
21. SVG2 - Second Saphenous Vein Graft
22. SVG3 - Third Saphenous Vein Graft
23. RAD1 - First Radial Artery Graft
24. RAD2 - Second Radial Artery Graft
25. RAD3 - Third Radial Artery Graft

Note: Document lesions in the Intermediate vessel as lesion code 15

Note: Document lesions in the Septal branches as lesion code 10, 11 or 12

Section 7. PCI Procedure / Lesion Information

7g Location in graft

Where a graft PCI is being undertaken. Indicate the location of the lesion. Choose only ONE from:

- Ostial: Within 3mm of the origin of the graft
- Proximal: In the proximal 1/3rd of the graft
- Mid: Mid 1/3rd of the graft
- Distal: Distal 1/3rd of the graft.
- Anastomosis: Within 3mm of the anastomosis
- Native: In the native vessel.

7h Lesion type

The lesion type according to ACC/AHA guidelines. Choose ONE from:

- **A**: Minimally complex, discrete (<10mm), concentric, readily accessible, lesion in non-angulated segment (<45 degrees), smooth contour, little or no calcification, less than totally occlusive, not ostial in location, no major side branch involvement, absence of thrombus.
- **B1**: One type B characteristic: lesion moderately complex, tubular (10-20mm), eccentric, moderate tortuosity of proximal segments, lesion in moderately angulated segment (>45 degrees but < 90 degrees), irregular contour, moderate to heavy calcification, total occlusions less than 3 months old, ostial in location, bifurcation lesions requiring double guide wires, some thrombus present.
- **B2**: more than one type B characteristic.
- **C**: severely complex diffuse (>20mm), excessive tortuosity of proximal segment, lesion in extremely angulated segment > 90 degrees, total occlusion greater than 3 months old or bridging collaterals, inability to protect major side branches, degenerated vein graft with friable lesions.

7i Chronic total occlusion (CTO)

Indicate if the lesion treated was presumed to be a CTO defined as being >3 months old and/or bridging collaterals. CTO lesions have 100% pre-procedure stenosis and should not relate to a clinical event leading to this procedure.

Yes / No

7j Ostial lesion

Indicate if the lesion is within 3mm of the origin of the vessel.

Yes / No

7k Bifurcation

Indicate if the lesion is at a bifurcation / trifurcation. A bifurcation / trifurcation is a division of a vessel into at least two branches, each of which is >2 mm or greater in diameter. In a bifurcation / trifurcation the plaque extends on both sides of the bifurcation point. It need not progress down both branches.

Yes / No

7l Pre-stenosis %

Indicate the % of most severe pre-procedure stenosis assessed. If no stenosis then enter 0%.

STENOSIS: Stenosis represents the percentage diameter reduction, from 0 to 100, associated with the identified vessel systems. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diameter of the "normal" reference vessel proximal to the lesion. In instances where multiple lesions are present, enter the single highest percentage stenosis noted.

Section 7. PCI Procedure / Lesion Information

7m Thrombolysis In Myocardial Infarction (TIMI) flow (pre)

Indicate the pre-procedure TIMI flow for the segment identified. Choose only ONE

- **TIMI-0:** No perfusion. There is no antegrade flow beyond the obstruction in an occluded artery.
- **TIMI-1:** Partial, but incomplete filling of the coronary artery. Contrast material passes beyond the area of obstruction but fails to opacify the entire coronary bed distal to the obstruction for the duration of the angiographic panning.
- **TIMI-2:** Partial perfusion. Contrast material passes across the obstruction and opacifies the coronary artery distal to the obstruction. However, the rate of entry of contrast material into the vessel distal to the obstruction or its rate of clearance from the distal bed, or both, is perceptibly slower than the flow into or rate of clearance from comparable areas not perfused by the previously occluded or infarct-related vessel (e.g., opposite coronary artery or the coronary bed proximal to the obstruction).
- **TIMI-3:** Complete and brisk flow/complete perfusion. Ante-grade flow into the bed distal to the obstruction, and clearance of contrast material from the involved bed as rapid as clearance from an uninvolved bed in the same vessel or the opposite artery.

7n Post-stenosis%

Indicate the % of most severe post-procedure stenosis assessed. If no stenosis then enter 0%.

STENOSIS: Stenosis represents the percentage diameter reduction, from 0-100, associated with the identified vessel systems. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diameter of the "normal" reference vessel proximal to the lesion. In instances where multiple lesions are present, entre the single highest percentage stenosis noted.

7o TIMI flow (post)

Indicate for the segment identified the post-procedure TIMI flow. Choose only ONE:

- **TIMI-0:** No perfusion. There is no antegrade flow beyond the obstruction in an occluded artery.
- **TIMI-1:** Partial, but incomplete filling of the coronary artery. Contrast material passes beyond the area of obstruction but fails to opacify the entire coronary bed distal to the obstruction for the duration of the angiographic panning.
- **TIMI-2:** Partial perfusion. Contrast material passes across the obstruction and opacifies the coronary artery distal to the obstruction. However, the rate of entry of contrast material into the vessel distal to the obstruction or its rate of clearance from the distal bed, or both, is perceptibly slower than the flow into or rate of clearance from comparable areas not perfused by the previously occluded or infarct-related vessel (e.g., opposite coronary artery or the coronary bed proximal to the obstruction)
- **TIMI-3:** Complete and brisk flow/complete perfusion. Ante-grade flow into the bed distal to the obstruction, and clearance of contrast material from the involved bed is a s rapid as clearance from an uninvolved bed in the same vessel or the opposite artery

7p Estimated lesion length

For the treated lesion estimate the lesion length in millimetre (mm)

7q Acute closure

Indicate for the treated segment if an acute closure was observed during the PCI procedure. Complete occlusion of treated vessel is usually indicated by TIMI flow of 0 or 1.

Note: If there is an acute closure of a distal segment that is >2mm beyond the treated lesion, note the acute closure and reopening on the newly identified lesion, not this lesion. If an acute closure of a distal segment does not require further treatment, note the acute closure on the original segment.

Yes / No

7r Dissection

Indicate for the treated segment (or for a significant side branch) if a dissection > 5 mm was observed during the PCI procedure. Dissection is defined as the appearance of contrast materials outside of the expected luminal dimensions of the target vessel and extending longitudinally beyond the length of the lesion.

Yes / No

Section 7. PCI Procedure / Lesion Information

7s Perforation

Indicate for the treated segment if a coronary perforation occurred during the procedure. A coronary artery perforation occurs when there is angiographic or clinical evidence of a dissection or intimal tear that extends through the full thickness of the arterial wall. This does not include pre-existing AV fistula and other coronary anomalies.

Yes / No

7t No reflow

Indicate for the treated segment if there was a period where the no-reflow phenomenon was noted during the PCI procedure. Choose from:

- No
- Transient: (Pertains to temporary lack of flow distal to the treated segment)
- Persistent: (Where persistent no reflow has occurred)

7u Lesion result

Indicate for the treated lesion whether the treatment was successful or unsuccessful.

Successful defined as: <50% residual stenosis for POBA lesion OR <20% residual stenosis for stented lesion

7v Stent details for the lesion

Stent Code (**See Instruction Sheet**)

Choose from the list on the instruction sheet. If device not listed call CCRE 1800 022 730

7w Stent Length

For each stent implanted, record the length in mm

7x Stent Diameter

For each stent implanted, record the diameter in mm

7y Maximum balloon size used

For the treated lesion, indicate the **maximum balloon diameter size used during the PCI**. (Record in mm).

Note: The maximum balloon size cannot be smaller than the largest stent diameter for a lesion

7z Intra-coronary devices used

Choose from the list on the CRF:

- No devices deployed (unable to deploy any devices)
- Balloon only
- Bare-metal stent
- Drug-eluting stent
- Rotablator
- Cutting Balloon
- IVUS
- Pressure Wire
- FloWire
- Other
- Distal embolic protection (if yes, select filter or balloon)
- Proximal embolic protection (if yes, select Proxis™ or other)
- Thrombectomy device (if yes, select Export™ or other)
- Brachytherapy

Section 8. Outcomes

8.1 Periprocedural MI

Indicate the NEW occurrence of a biomarker positive MI after PCI. At least one determination of biomarkers obtained no sooner than 6 hours after PCI, and preferably within the interval of 6-24 hours post-PCI, should be used to make this diagnosis.

Q waves with absent, incomplete or inconclusive biomarkers should be considered evidence of MI and should be coded as **yes**.

In rare situations, biomarkers may not be obtained in the setting of a post-PCI acute MI (e.g., sudden unexpected cardiac death without symptoms or ECG changes suggestive of ischemia, patient is transferred or biomarkers were just not ordered). In these situations, the site may choose to report a clinically-diagnosed post-PCI myocardial infarction even in the absence of the usually required biomarker elevations.

Myocardial infarction within 24 hours post-PCI:

a. Pts with normal baseline (pre-procedure) cardiac biomarker values:

Elevations of cardiac biomarkers above 3 times the upper limit of normal for your laboratory (i.e., above 3 times the 99th percentile upper reference limit for a "normal" population) are indicative of peri-procedural MI. ECG changes or symptoms are not required to qualify.

Note: Some patients presenting with ACS will not have biomarker elevations prior to the PCI. Elevated biomarkers after PCI in these cases may indicate the evolution of their ACS, rather than an MI caused by the PCI.

b. Pts with elevated baseline (pre-procedure) cardiac biomarkers have three possible scenarios:

i. Patients with monotonically rising and elevated biomarker levels prior to PCI are assumed to be in the midst of an acute MI. In these patients, it is not possible to distinguish necrosis that resulted from the PCI vs. necrosis arising from the presenting acute MI, so code **no** for MI after PCI.

ii. Patients with elevated biomarkers pre-procedure who do NOT have a characteristic rise and fall in biomarker levels are unlikely to be experiencing an acute MI prior to the PCI (e.g., "flat" chronic elevations of troponin-T in patients with renal failure, chronic stable elevations of CK in patients with myositis or hypothyroidism). In this scenario, code **no** for MI after PCI.

iii. Patients whose biomarkers exhibited a pre-procedure rise and fall most likely have completed their presenting infarct. In these patients, a post-procedural increase in biomarkers that is greater than three times the upper limit of normal for your laboratory is indicative of a post-PCI reinfarction and should be coded as **yes** for this event. 'Greater than three times the upper limit of normal for your laboratory' means an additional rise in biomarkers that is three times the 99th percentile upper reference limit for a 'normal' population. ECG changes or symptoms are not required to qualify.

Myocardial Infarction >24 hours post PCI but prior to discharge is evidenced by any of the following:

a. A rise and fall in cardiac biomarkers (preferably troponin) with at least one of the values in the abnormal range for that laboratory, together with at least one of the developments listed below, is a manifestation of MI. The abnormal range for your laboratory means levels above the 99th percentile of the upper reference limit (URL) for normal subjects.

i. Ischemic symptoms;

ii. ECG changes indicative of new ischemia (new ST-T changes, new left bundle branch block, or loss of R wave voltage),

iii. Development of pathological Q waves in 2 or more contiguous leads in the ECG (or equivalent findings for true posterior MI);

iv. Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality;

v. Documentation in the medical record of the diagnosis of acute MI based on the cardiac biomarker pattern in the absence of any items enumerated in 1-4 due to conditions that may mask their appearance (e.g., peri-operative infarct when the patient cannot report ischemic symptoms; baseline left bundle branch block or ventricular pacing)

b. Imaging evidence of a region with new loss of viable myocardium at rest in the absence of a non-ischemic cause. This can be manifest as:

i. Echocardiographic, CT, MR, ventriculographic or nuclear imaging evidence of left ventricular thinning or scarring and failure to contract appropriately (i.e., hypokinesis, akinesis, or dyskinesis)

ii. Fixed (non-reversible) perfusion defects on nuclear radioisotope imaging (e.g., MIBI, thallium).

Yes / No

Section 8. Outcomes

8.2 Emergency PCI

Indicate if the patient required an UNPLANNED PCI during hospitalization and prior to discharge. Only include ischemia-driven in-hospital PCI (PCI that occurs as a complication related to the index PCI e.g., stent thrombosis, dissection with target vessel occlusion)

Note: subsequent in-hospital PCI's performed as part of a multi-vessel revascularisation strategy are not to be included and should be documented on a separate baseline CRF

Yes / No

8.3 Stent thrombosis

Indicate if since the index PCI was completed and prior to any subsequent in-hospital PCI's, whether the patient suffered a Stent Thrombosis.

Stent thrombosis is defined as an acute coronary syndrome with angiographic documentation of either vessel occlusion or thrombus within or adjacent to a previously stented vessel or autopsy evidence of stent thrombosis.

Yes / No

8.4 Unplanned CABG

Indicate if the patient underwent or was transferred for an UNPLANNED CABG surgery during the hospitalization and prior to discharge. Unplanned CABG is defined as need for surgery after PCI for the following reasons: extensive dissection causing ischemia or threatened ischemia, recurrent acute closure, perforation or tamponade, hemodynamic instability, and other indications warranting CABG that cannot be electively scheduled.

Yes / No

8.5 Cardiogenic shock

Indicate if the patient suffered a new episode or acute recurrence of cardiogenic shock following the PCI procedure. Clinical criteria for cardiogenic shock are:

- hypotension (a systolic blood pressure of less than 90 mmHg for at least 30 minutes or the need for supportive measures to maintain a systolic blood pressure of greater than or equal to 90mmHg)
- end-organ hypoperfusion (cool extremities or a urine output of less than 30 ml/h, and a heart rate of greater than or equal to 60 beats per minute).
- The haemodynamic criteria are a cardiac index of no more than 2.2 l/min per square meter of body-surface area and a pulmonary-capillary wedge pressure of at least 15 mmHg.

Yes / No

8.6 Arrhythmia

Indicate if the patient suffered a new episode or acute recurrence of an atrial or ventricular arrhythmia requiring treatment or a new episode of high-level atrioventricular (A-V) block. (Defined as third-degree A-V block or second-degree A-V block with bradycardia requiring pacing.)

Yes / No

8.7a CVA/Stroke

Indicate if the patient experienced a stroke noted during the cath lab visit or after lab visit until discharge (or before any subsequent lab visits), as evidenced by persistent loss of neurological function (lasting at least 24 hours) caused by an ischemic or haemorrhagic event. If yes, answer 8.7b

Yes / No

Section 8. Outcomes

8.7b CVA/Stroke determination

Where Stroke occurred indicate the type. Choose from:

- Haemorrhagic
- Ischemic

MRI/CT evidence of haemorrhage in the cerebral parenchyma, or a subdural or subarachnoid haemorrhage. Evidence of haemorrhagic stroke obtained from lumbar puncture, neurosurgery, or autopsy can also conform the diagnosis.

8.8 Tamponade

Indicate if there was fluid in the pericardial space compromising cardiac filling, and requiring intervention during the cath lab visit or after lab visit until discharge (or before any subsequent lab visits). This should be documented by either:

- Echo showing pericardial fluid and signs of tamponade such as right heart compromise, or
- Systemic hypotension due to pericardial fluid compromising cardiac function.

Yes / No

8.9 Contrast reaction

Indicate if the patient experienced a contrast reaction during the cath lab visit or after lab visit until discharge (or before any subsequent lab visits). Contrast reaction is defined as at least one of the following:

- Anaphylaxis-including bronchospasm and/or vascular collapse,
- Urticaria,
- Hypotension-prolonged depression of blood pressure below 70mm Hg.

Yes / No

8.10 Congestive Heart Failure

Indicate if the patient experienced documented new onset HF or an acute reoccurrence of HF which necessitated new or increased pharmacologic therapy during the cath. lab visit or after lab visit until discharge (or before any subsequent lab visits). HF can be diagnosed based on careful history and physical exam, or by one of the following criteria:

- Paroxysmal nocturnal dyspnea (PND) and/or fatigue
- Dyspnea on exertion (DOE) due to heart failure
- Chest X-Ray (CXR) showing pulmonary congestion
- Pedal edema or dyspnea treated with medical therapy for heart failure

Yes / No

8.11 New renal impairment

Indicate if the patient experienced acute or worsening renal failure during the cath lab visit or after lab visit until discharge (or before any subsequent lab visits) resulting in one or more of the following:

- Increase of serum creatinine to $>200\mu\text{mol/L}$ and two times the baseline creatinine level.
- A new requirement for dialysis.

Yes / No

8.12a Post procedural rise in creatinine

Indicate if the patient experienced an increase of serum creatinine to $>200\mu\text{mol/L}$ or two times the baseline creatinine level. If yes, complete 8.12b

Yes / No

8.12b Post procedural rise in creatinine value

Where a post procedural rise in creatinine occurred, indicate the creatinine level in $\mu\text{mol/L}$

Section 8. Outcomes

8.13a Bleeding complication

Indicate if bleeding occurred during or after the cath. lab visit until discharge. The bleeding should require a transfusion and/or prolong the hospital stay and/or cause a drop in haemoglobin > 3.0 gm/dl.

If yes, complete 8.13b & 8.13c

Yes / No

8.13b Transfusion of blood products required after lab visit.

Indicate if the patient required a transfusion of blood products at any time after the lab visit & prior to discharge.

Yes / No

8.13c Bleeding Site

Where bleeding occurred, indicate the site. Choose ONE from:

- **Retroperitoneal:** Indicate whether retroperitoneal bleeding occurred during or after the cath lab visit and until discharge. The bleeding should require a transfusion and/or prolong the hospital stay, and/or cause a drop in haemoglobin >3.0gm/dl.
- **Percutaneous entry site:** Indicate whether bleeding occurred at the percutaneous entry site during or after the cath lab visit and until discharge. The bleeding should require a transfusion and/or prolong the hospital stay, and/or cause a drop in haemoglobin >3.0gm/dl. Bleeding at the percutaneous entry site can be external or a hemaotoma >10cm for femoral access or >2cm for radial access or >5cm for brachial access.
- **Other:** Specify: e.g. Genital/Urinary, Gastrointestinal, Unknown. The bleeding should require a transfusion and/or prolong the hospital stay, and/or cause a drop in haemoglobin >3.0gm/dl.

8.14 Access site occlusion

Indicate whether an access site occlusion occurred at the site of percutaneous entry during the procedure or after the lab visit but before any subsequent lab visits. This is defined as total obstruction of the artery usually by thrombus (but may have other causes) usually at the site of access requiring surgical repair. Occlusions may be accompanied by absence of palpable pulse or Doppler.

Yes / No

8.15 Loss of distal pulse

Indicate whether a loss of the pulse distal to the arterial access site occurred (peripheral embolization). Peripheral embolization is defined as a loss of distal pulse, pain and/or discolouration (especially the toes). This can include cholesterol emboli.

Yes / No

8.16 Dissection

Indicate whether a dissection occurred at the site of percutaneous entry during the procedure or after lab visit but before any subsequent lab visits. A dissection is defined as a disruption of an arterial wall resulting in splitting and separation of the intimal (subintimal) layers.

Yes / No

8.17 Arteriovenous (AV) fistula

Indicate whether an AV fistula occurred at the site of percutaneous entry during the procedure or after lab visit but before any subsequent lab visits. AV fistula is defined as a connection between the access artery and the accompanying vein that is demonstrated by arteriography or ultrasound and most often characterized by a continuous bruit.

Yes / No

Section 8. Outcomes

8.18a Pseudoaneurysm

Indicate whether a pseudoaneurysm occurred at the site of percutaneous entry during the procedure or after lab visit but before any subsequent lab visits. Do not code for pseudoaneurysms noted after discharge. Pseudoaneurysm is defined as the occurrence of a disruption and dilation of the arterial wall without identification of the arterial wall layers at the site of the catheter entry demonstrated by arteriography or ultrasound. If yes, complete 8.18b

Yes / No

8.18b Treatment of pseudoaneurysm

Indicate the treatment used for a patient complicated with a pseudoaneurysm. Choose ONE from:

- Ultrasound compression
- Surgery
- Other

8.19-8.21 CK / CK-MB / Troponin measurements post procedure

Record the ULN for each field according to departmental guidelines. Record the date & time of the result in DD / MM / YYYY & HH-MM format.

If not assessed, check "Unavailable" on the CRF

8.22 Date of discharge

The date on which the patient was discharged from hospital following the index PCI. Where relevant, patients who are transferred to another hospital for ongoing care following the index event should have the date of discharge from that hospital recorded as the discharge date and the outcomes documented should include events that occurred in this period. Record in DD / MM / YYYY format

8.23 Discharge status

Specify whether the patient was alive or dead at discharge from the hospitalization in which the procedure occurred. Choose one of the following:

- Alive
- Deceased

8.24 Date of death

The date on which the patient died.

Record in DD / MM / YYYY format

Section 8. Outcomes

8.25 Primary cause of death

The PRIMARY cause of death of the patient. Select the PRIMARY cause of death, i.e. the first significant abnormal event which ultimately led to death. Choose from:

- **Cardiac:** Indicates that the cause of death was sudden death, MI, unstable angina or other CAD, heart failure or arrhythmia.
- **Neurologic:** Indicates a neurologic cause of death e.g., stroke, following cerebral hypoxia
- **Renal:** Indicates a renal cause of death
- **Vascular:** Indicates a vascular cause of death e.g, arterial embolism, pulmonary embolism, ruptured aortic aneurysm or dissection.
- **Infection:** Indicates an infective cause of death
- **Pulmonary:** Indicates a pulmonary cause of death e.g., respiratory failure, pneumonia
- **Other:** (specify in free text) All other causes e.g., liver failure, trauma, cancer

8.26 Location of death

The location at which the patient died. Choose from:

- In Lab – death on catheter laboratory table
 - Out of Lab
-

FOLLOW UP CRF DEFINITIONS

<p>1.1 Procedure Number The procedure number on the follow up form must correspond with the baseline CRF unique procedure ID</p>
<p>1.2 UR Number Hospital UR Number. A letter or first zero's can be included</p>
<p>1.3 Patient DOB Patient's Date Of Birth - in DD/MM/YYYY format</p>
<p>1.4 Hospital Code Choose the hospital code from the list. It must correspond with the hospital where the PCI was performed</p>
<p>2.1 Type of follow up Select from 30 day or 12 months (extended follow is done using a dedicated CRF)</p>
<p>2.2 Date of follow up Record the date of the follow up. For a 30 day follow up, this should be approximately 30 days from the date of discharge from hospital following the index event. For a 12 month follow up this should be approximately 12 months from the date of discharge from hospital following the index event</p>
<p>2.3a Vital Status Specify whether the patient was alive or deceased at the follow up. Choose one of the following:</p> <ul style="list-style-type: none"> • <u>Alive</u> • <u>Deceased</u>: If deceased, indicate the <u>primary</u> cause of death
<p>2.3b Primary Cause of Death Indicate the primary cause of death, i.e. the first significant abnormal event which ultimately led to death. Choose one of the following:</p> <ul style="list-style-type: none"> • <u>Cardiac</u> - indicates that the cause of death was sudden death, MI, unstable angina or other CAD, heart failure or arrhythmia. • <u>Non cardiac</u> – includes vascular death (e.g. stroke, arterial embolism, ruptured aortic aneurysm, aortic dissection, PE) and non-cardiac causes such as respiratory failure, pneumonia, cancer, trauma, suicide or any other already defined cause (e.g., liver disease or renal failure) • <u>Unknown</u> – the cause of the death is unable to be ascertained
<p>2.3c Date of Death The date on which the patient died in DD / MM / YYYY format</p>
<p>2.4 Smoking Status Patient's self reported history confirming any form of tobacco use in the past. This includes cigarettes, cigar and/or pipe. Choose ONE from:</p> <ul style="list-style-type: none"> • Currently smoking (within 1 month of this follow up contact) • Previously smoked (more than 1 month prior to this follow up contact) • Never smoked
<p>2.5 Height Please attempt to collect height where it was omitted at baseline. Refer to the follow-up schedule to determine if this question needs to be asked at follow up (is based on weight collected = yes and missing height). If patient unsure or unable to answer, annotate "N/A".</p>
<p>2.6 Has the patient been readmitted to hospital? Indicate if the patient has had a readmission to any hospital since discharged from the index event. A readmission is classified as an overnight stay in hospital. ED admits do not need to be captured Any day case admit for coronary angiography should be captured</p> <p><u>Yes</u>: If yes, record medications and admissions in Readmission Details section of the CRF <u>No</u>: If no, record medications, then follow up is complete.</p>

Current Medications:

For all the following medications (3.1 - 3.15) record the following:

- Yes: patient is currently taking, or has taken this medication within the last seven days
- No: patient is not currently taking or has not taken this medication within the last seven days
- Unknown: the patient is unable to advise of the medications they are currently taking

Note: 3.11 - 3.15 have additional questions related to agent type, dose and frequency, these will also need to be completed where relevant

3.1 Aspirin

Agents include: Aspirin, Aspro®, Assasantin®, Astrix®, Cardiprin®, Cartia®, Disprin® and Solprin®

3.2 Clopidogrel

Agents include: Iscover®, Plavix®

3.3 Prasugrel

Agents include: Effient®

3.4 Warfarin

Agents include: Coumadin® and Marevan®

3.5 Nitrate

Agents include:

Isosorbide dinitrate - Isordil®, Sorbidin®

Isosorbide mononitrate - Duride®, Imdur®, ImtrateSR®, Isomonit®, Monodur durules®

3.6 Spironolactone

Agents include: Aldactone® and Spiractin®

3.7 Eplerenone

Agents include: Inspra®

3.8 Fibrate

Agents include:

Gemfibrozil - Ausgem®, Gemhexal®, GenRx gemfibrozil®, Jezil®, Lipazil®, Lopid®, Pharmocor gemfibrozil®

Fenofibrate - Lipidil®

Clofibrate – Atromid S®

3.9 Ezetimibe

Agents include: Ezetrol® and Vytorin® (combination with simvastatin)

3.10 Ivabradine

Agents include: Coralan®

3.11a Beta Blocker

Agents include:

Metoprolol - Betaloc®, Metohexal®, Minax®, Toprol®, Lopresor®

Atenolol - Anselol®, Atethexal®, Noten®, Tenormin® ®Tensig

Carvedilol - Dilasig®, Dilatrend®, Kredex®

Propranolol - Deralin®, Inderal®

Bisoprolol - Bicor®

Sotalol - Solavert®, Sotahexal®, Sotacor®

Labetolol - Trandate®

Oxprenolol - Corbeton®

Nebivolol - Lobivon®, Nebilet®

3.11b Beta Blocker Agent

If the answer is **Yes** for patient is taking a beta blocker, identify the agent in free text. Answer 3.11c

3.11c Beta Blocker Dose

State the dosage in milligrams and the dose frequency using the codes below

- 1= Once daily
- 2=Twice daily
- 3=Three times daily
- 4=Other,(Includes all other frequencies for example QID / weekly / Fortnightly etc

Note: Only complete **Unknown** field if both dosage **and** frequency are unknown.

3.12a ACE Inhibitor

Agents include:

Perindopril arginine - Coversyl®, Coversyl Plus® (combination with indapamide)

Perindopril erbumine - Indopril®, Perindo®, Perindo Combi® (combination with indapamide),

Gen Rx Perindopril®,

Gen Rx Perindopril/indapamide® (combination with indapamide),

Lisinopril dihydrate - Fibsol®, GenRx Lisinopril®, Liprace®, Lisinobell®, Lisinopril Pharmacor®,

Lisinopril generihealth®, Lisinopril Hexal®, Lisinopril Winthrop®, Liosdur®,

Prinivil®, Zestril®

Ramipril – GenRx Ramipril®, Pharmacor Ramipril®, Prilace®, Ramace®, Ramipril genrihealth®,

Ramipril Sandoz®, Ramipril Winthrop®, Triasyn® (combination with felodipine), Tritace®,

Tryzan®

Enalapril maleate - Alphapril®, Amprace®, Auspril®, Enahexal® Enalabell®, Enalapril Winthrop®,

Enalapril/HCT Sandoz® (combination with hydrochlorothiazide), GenRx Enalapril®,

Renitec®, Renitec Plus® (combination with hydrochlorothiazide),

Zan-Extra® (combination with lercanidipine hydrochloride)

Fosinopril sodium – Fosinopril Sandoz®,

Fosinopril/HCT Sandoz® (combination with hydrochlorothiazide),

Fosinopril Winthrop®,

Fosinopril/HCT Winthrop® (combination with hydrochlorothiazide),

Fosipril®, GenRx Fosinopril®, Hyforil®, Monace®,

Monoplus® (combination with hydrochlorothiazide), Monopril®

Captopril - Acenorm®, Capoten®, Captophexal®, Captopril Genepharm®, GenRx Captopril®

Quinapril hydrochloride - Accupril®, Accuretic® (combination with hydrochlorothiazide),

Acquin, Apo-Quinapril, Filpril®, Pharmacor Quinapril®,

Quinapril generihealth®, Quinapril Sandoz®

Trandolopril - Apo-Trandolapril®, Dolapril®, Gopten®, Odrik®, Tarka® (combination with verapamil),

Tranalpha®

3.12b ACE Inhibitor Agent

If the answer is **Yes** for patient is taking an ACE Inhibitor, identify the agent in free text. Answer

3.12c

3.12c ACE Inhibitor Dose

State the dosage in milligrams and the dose frequency using the codes below

- 1= Once daily
- 2=Twice daily
- 3=Three times daily
- 4=Other,(Includes all other frequencies for example QID / weekly / Fortnightly etc

Note: Only complete **Unknown** field if both dosage **and** frequency are unknown.

3.13a All Blocker

Agents include:

Candesartan cilexetil - Atacand®, Atacand Plus® (combination with hydrochlorothiazide)

Eprosartan mesylate – Teveten®, Teveten Plus® (combination with hydrochlorothiazide)

Irbesartan - Avapro®, Avapro HCT® (combination with hydrochlorothiazide),
Karvea®, Karvezide® (combination with hydrochlorothiazide)

Losartan potassium - Cozaar®

Olmesartan medoxomil - Olmetec®, Olmetec Plus® (combination with hydrochlorothiazide)

Telmisartan - Micardis®, Micardis Plus® (combination with hydrochlorothiazide)

Valsartan – Co-Diovan® (combination with hydrochlorothiazide), Diovan®,
Exforge® (combination with amlodipine besylate)

3.13b All Blocker Agent

If the answer is **Yes** for patient is taking an All Blocker, identify the agent in free text. Answer 3.13c

3.13c All Blocker Dose

State the dosage in milligrams and the dose frequency using the codes below

- 1= Once daily
- 2=Twice daily
- 3=Three times daily
- 4=Other,(Includes all other frequencies for example QID / weekly / Fortnightly etc

Note: Only complete **Unknown** field if both dosage **and** frequency are unknown.

3.14a Ca Channel Blocker

Agents include:

Amlodipine besylate: Amlodipine generihealth®, Amlodipine Sandoz®, Amlodipine GA®, Amlotrust®,
APO- Amlodipine®, Caduet® (combination with atorvastatin),
Exforge® (combination with valsartan), Norvasc®, Ozlodip®, Perivasc®

Diltiazem hydrochloride - Cardizem®, Cardizem CD®, Coras®, Diltahexal®, Diltahexal CD®, Dilzem®,
GenRx Diltiazem®, GenRx Diltiazem CD®, Vasocardol CD®, Vasocardol ®

Felodipine – Felodil XR®, Felodur ER®, Plendil ER®, Triasyn® (combination with ramipril)

Lercandipine hydrochloride – Zan-Extra® (combination with enalapril), Zanidip®

Nifedipine - Adalat®, Adalat Oros ®, Addos XR®, Adefin®, Adefin XL®, GenRx Nifedipine®,
Nifehexal®, Nyefax®

Verapamil hydrochloride - Anpec®, Anpec SR®, Cordilox SR®, Isoptin®, Isoptin SR®,
Tarka® (combination withtrandolopril), Veracaps SR®

3.14b Ca Channel Blocker Agent

If the answer is **Yes** for patient is taking a Ca Chanel Blocker, identify the agent in free text. Answer 3.14c

3.14c Ca Channel Blocker Dose

State the dosage in milligrams and the dose frequency using the codes below

- 1= Once daily
- 2=Twice daily
- 3=Three times daily
- 4=Other,(Includes all other frequencies for example QID / weekly / Fortnightly etc

Note: Only complete **Unknown** field if both dosage **and** frequency are unknown.

3.15a Statin

Agents include:

Atorvastatin calcium - Caduet® (combination with amlodipine), Lipitor®

Fluvastatin sodium - Lescol®, Vastin®

Pravastatin sodium - Cholstat®, GenRx Pravastatin®, Lipostat®, Liprachol®, Pravachol®,
Pravastatin Pharmacor®, Pravastatin generihealth®, Pravastatin Winthrop®,
Vastoran®

Rosuvastatin calcium - Crestor®

Simvastatin – Geneparm Simvastatin®, GenRx Simvastatin®, Lipex®, Ransim®, Simvabell®,
Simvahexal®, Simvar®, Simvastatin generihealth®, Simvastatin Winthrop®, Simvasyn®,
Vytorin® (combination with ezetimibe), Zocor®

3.15b Statin Agent

If the answer is **Yes** for patient is taking a statin, identify the agent in free text. Answer 3.15c

3.15c Statin Dose

State the dosage in milligrams and the dose frequency using the codes below

- 1= Once daily
- 2=Twice daily
- 3=Three times daily
- 4=Other,(Includes all other frequencies for example QID / weekly / Fortnightly etc

Note: Only complete **Unknown** field if both dosage **and** frequency are unknown.

FOLLOW UP CRF DEFINITIONS

Readmission Details

For each readmission record the following information (up to eight readmissions can be recorded):

4.1 Readmission date

The date the patient was readmitted to hospital in DD / MM / YYYY format

4.2 Readmission location

Choose a location code for the readmission hospital, if other location, specify in free text

4.3 Readmission reason

Choose a readmission reason code, if other reason, specify in free text. Where a patient has a readmission for more than one reason, document the primary or most life threatening reason.

4.4 Coronary angiogram

Indicate if coronary angiography was performed during the readmission. Choose from:
Yes / No

4.5 AMI

Indicate if the patient had an acute myocardial infarction as the reason for, or at any time during the admission. It must be distinct from the index event. Choose from:

No / STEMI / NSTEMI (STEMI / NSTEMI: see baseline definitions)

4.6 PCI

Indicate if PCI was performed during the readmission. Choose from:

No: no PCI was performed

TLR: where a PCI was performed, indicate if it was a Target Lesion Revascularization. A TLR is a repeat revascularization in the follow up period due to restenosis / occlusion either within the stent or either edge (within 5mm).

TVR: where a PCI was performed, indicate if it was a Target Vessel Revascularization. A TVR is a repeat revascularization in the follow up period due to restenosis / occlusion either within the target lesion or anywhere within the same epicardial coronary artery (includes proximal & distal lesions, branches and the left main)

Non TVR: where a PCI was performed to a vessel other than the index vessel (or its branches)

4.7 CABG

Indicate if a Coronary Artery Bypass Grafting operation was performed during the readmission. Choose from:

No: no CABG operation was performed during the readmission

Yes: a CABG operation was performed during the admission. If Yes, choose from:

TVR Yes: where a CABG was performed, indicate if it was a Target Vessel Revascularization. A TVR is a repeat revascularization in the follow up period due to restenosis / occlusion either within the target lesion or anywhere within the same epicardial coronary artery (includes proximal & distal lesions, branches and the left main)

TVR No: where a CABG was performed but not to the Target Vessel (or its branches)

Notes:

Please recapture admissions that occurred in the 30 day period at the 12 month follow up.

If it is known at the time of follow up that the patient deceased after 30 days and prior to 12 months, generate a 30 day CRF with vital status- "Alive" and a 12 month CRF which specifies the date & cause of death.

Refer to Attachment 3: Follow Up Instructions

ATTACHMENT 1: MIG BASELINE INSTRUCTIONS

MIG HREC approved sites aim to collect ALL consecutive PCI's, including in-hours, urgent after hours and failed procedures.

GENERAL RULES

1. Only MIG approved sites can use the MIG CRF. Sites are identified by a unique hospital code which is recorded on the CRF at the top of page 1.
2. Each MIG form is pre-printed and has a unique Procedure ID. Do not change or in any way alter this unique identifier. MIG forms should never be photocopied and re-used. For supplies of MIG forms call CCRE 9903 0517.
3. All fields should be filled in. If information is unknown, unavailable or not measured then "unknown", "unk", "N/A" can be written, otherwise a data query (DQ) will be generated for the missing information.
(see: MIG Data Queries Overview: Attachment 2)
4. It is important to capture information as accurately as possible, by utilising the medical record, the catheterization laboratory database available and the hospital admissions database.
5. The baseline CRF covers the period of hospitalization from the admission where the index event occurred until discharge. Patients who are discharged directly to a rehab facility are considered to have been discharged from the acute setting. The discharge date from the acute setting should be captured on the baseline CRF.
6. Patients who have more than one PCI during the hospital stay should have each PCI captured on a separate CRF. The dates reflecting admission and discharge will match on these forms.
7. Refer to the data definitions manual for detailed explanations of the fields collected on the MIG baseline form.
8. In general, for most questions asked on the baseline form only one response should be selected. Exceptions to this are (3.4b), (3.5b), (6.9), (6.10) & (7.1z).
9. STEMI event timings (5.11): to be completed for patients presenting with STEMI <24 hours since symptom onset (i.e. <6 hours and 6-24 hours). Only transferred patients required 5.11b. Where STEMI occurs after hospital admission, the hospital arrival time and STEMI time will be the same.
10. Additional Lesion Pages should be filled in and attached where more than three lesions are treated in the one PCI. The procedure ID from the baseline form should be entered at the top of the additional lesion form and the forms should be attached together.

Any questions, please call Angela on 9903 0517 or Philippa on 9903 0139
e-mail: angela.brennan@med.monash.edu.au philippa.loane@med.monash.edu.au

ATTACHMENT 2: MIG BASELINE CRF DATA QUERIES (DQ's)

1. The DQ report for a MIG baseline CRF is generated from missing or incongruous data supplied. Therefore the answer supplied needs to be in the same format as on the baseline form.

2. Use the baseline CRF to ensure your “answer” will match. The DQ report will tell you the section to refer to on the baseline form. This is important because the same questions are asked in different sections eg a question about CHF is in sections 3, 5 and 8 BUT the answer would depend upon which section the information was missing from. Section 3 is the patient’s history and risk factors; section 5 is the patient’s cardiac status prior to the procedure while section 8 is post procedure. The patient may have had no previous history of HF, but presented with a STEMI and APO and recovered with or without residual cardiac failure.

3. The above point is especially relevant where patients had more than one lesion treated. Please ensure you are answering for the lesion referred to on the report (it will say lesion 1 / lesion 2 etc). If you are unsure, refer back to the baseline CRF filled out for the procedure to work out which lesion is which (i.e. which is the LAD /D1- given this is documented as a number in the database).

4. Where you cannot find the information write “UNKNOWN” in the space provided.

5. Some data queries will question the information provided. For example if the patient had a hospital stay >10 days it will generate query. If the dates are correct, write “CONFIRMED” in the space provided.

6. Where the admission / procedure & discharge dates are incongruous you will need to check all three and supply the correct information. The start and end of each year requires careful checking and is where many date errors occur. Please write ALL the CHECKED relevant dates (admit / procedure / discharge)

7. Where a patient has had a previous PCI or CABG, at least the year should be obtained, otherwise write “unknown”.

8. When using the DQ report, please tick the resolved box when you have an answer. If you cannot find the info at all and are writing “unknown”, please tick the ignore box. This way the DQ will be removed from the system. There are certain fields DQ’s however that cannot be ignored - discharge status for example we need to know if the patient was alive at discharge otherwise a follow up request will not be generated.

10. Eventually we plan to send the DQ reports via e-mail, but initially they will be posted or delivered. Once attended to either fax back the report on the usual number or secure post it and the database can then be updated. Alternatively arrangements can be made for these to be collected from the site.

Any questions, please call Angela on 9903 0517 or Philippa on 9903 0139
e-mail: angela.brennan@med.monash.edu.au philippa.loane@med.monash.edu.au

ATTACHMENT 3: MIG FOLLOW UP INSTRUCTIONS

Post index PCI and following discharge from the acute care setting MIG additionally follows patients up at 30 days & 12 months. Patients who are discharged directly to a rehabilitation facility are considered to have been discharged from the acute setting. For patients with multiple procedures captured in the database, each procedure needs to be followed up.

RULES

1. The date of follow up is the actual date the patient was contacted or the information was able to be verified by a reliable source (NOK / GP / medical record).
2. The information on the follow up form **MUST reflect the information at the time period being followed up.** This relates to events (including death) / admissions / medications. Up to 8 admissions can be captured at follow up. Do not capture events or admissions that occur AFTER the time period being followed up. These events or admissions would be potentially be captured at a subsequent (i.e. 3 year / 5 year) follow up.
3. If a follow up is done late and a patient cannot accurately recall the ACTUAL medications at the 30 day or 12 month time period or the medications cannot be ascertained from the medical record or pharmacy review, then that medication data should not be collected and “unknown” should be selected.
4. Events and admissions need to be verified and if patient is unsure a record review will be required or information will need to be obtained from the GP or the hospital where the patient was admitted.
5. Where a patient has been readmitted **ALL** data (date / location / reason / coronary angiography /AMI / PCI / CABG) needs to be collected for each admission – if the patient is unsure then record review will be required. If this is impractical or difficult then write “unknown” in the space. Do not leave any sections blank. These become a data query (DQ).
6. With deaths, where possible, try to ascertain the cause of death by history review / discussion with GP. If this is unsuccessful, then select “unknown”. Do not distress patient relatives unnecessarily when a previously unknown death is reported. **The relatives of patients who are known to have died are not to be contacted.** This could cause distress.
7. Events that were captured at 30days are re-captured at 12months. This is because follow up is **from the discharge to 30 days** then **discharge to 12 months**. If it is known at the time of follow up that the patient deceased after 30 days and prior to 12 months, generate a 30 day CRF with vital status - “Alive” and a 12 month CRF which specifies the date & cause of death.
8. Day case admissions (e.g. gastroscopy / colonoscopy / chemotherapy / dialysis) need not be captured UNLESS the admission was for coronary angiography.
9. Up to 8 admissions can be captured at a follow up. Patients who have more than 8 admissions with the same diagnosis (e.g. UAP or chest pain for investigation) in

whom no MI / angiography / revascularisation / complication occurred can have admissions omitted, capturing a selection over the time period & ending with the most recent within the time period.

10. Where there are multiple reasons listed for an admission, capture the **PRIMARY** reason for the admission (MI>HF>UA).

11. Renal & chemotherapy patients should only have long stay admissions captured or if cardiac events / complications or major surgery occurred. If unsure ask.

12. Major non-cardiac surgery should be captured & the patient should specifically be questioned as to whether any cardiac events occurred at that time – if the patient is unsure, then a record review will be required or information will need to be obtained if possible. If it is impossible to obtain this information then write “unknown” over the missing field.

Any questions, please call Angela on 9903 0517 or Philippa on 9903 0139
e-mail: angela.brennan@med.monash.edu.au philippa.loane@med.monash.edu.au

ATTACHEMENT 4: Patient Information Sheet

Melbourne Interventional Group Database

Background

You are about to have (or have recently had) a coronary artery procedure (“intervention”) that aims to improve the blood supply to your heart and improve your symptoms. Most procedures involve the use of a balloon (“angioplasty”) and a metal scaffold (“stent”) to open up any blockages in your coronary arteries. Generally, these procedures are successful and improve the quality of the patient’s life, with a small risk of death or major complications. Your doctor will have explained these risks to you. Some people, however, can have a recurrence of their original symptoms, usually due to re-narrowing of the vessel (“restenosis”). There are continuous improvements in techniques and equipment that reduce the risk of complications and restenosis in clinical trials, but whether these improve outcomes in “real life” is often unknown.

In order to improve the immediate success and long-term outcomes of these coronary procedures we need to know what factors increase a patient’s risk of complications and restenosis. By knowing this we hope to improve procedural success and long-term outcomes of patients undergoing these procedures. Many hospitals already have databases on the in-hospital outcome of coronary artery interventions, but there is no statewide or national data available about long-term outcomes in Australia. To obtain this important information a group of cardiologists (heart specialists) have formed a group called the Melbourne Interventional Group. There are representatives from most Melbourne hospitals in this group. **Our aim is to set up a statewide database that will record information on every adult coronary artery interventional procedure.** The success of the database depends on the amount of information we get, and to be truly representative we want to include all patients.

We are asking you to participate in the Melbourne Interventional Group Database by allowing us to document information about your cardiac condition and procedure. Importantly, we also want to see how you progress over time by collecting follow-up information about your cardiac health.

What Information Do We Need?

The information we require includes your name, date of birth, Medicare number, hospital identification number, the name of your hospital, the reason you are having a coronary intervention, technical details of the procedure, any complications that you have in hospital, and your follow-up cardiac health information. All of your information will be freely available to you.

We Will Keep Your Information Confidential

Your personal information is confidential and cannot be used outside the database. Procedures are in place to protect your information and keep it confidential. The data is accessible by authorised staff of the Melbourne Interventional Group Database project. Only group data will be made available publicly to groups such as participating hospitals, the Department of Health and the National Heart Foundation. You cannot be identified in any reports produced by the database project.

How Will We Collect the Information?

The hospital staff will complete the forms that contain the relevant details during your hospital stay. You will be called 30 days, 1 year and 2 years after your procedure to briefly obtain information about your cardiac health. We will ask you about any new heart symptoms, any further procedures that you have had, and what medications you are taking. The information will be entered into a secure database computer.

Risks and Benefits to You

Your information is protected and we are not allowed to identify you by law. The database will produce general reports on the short- and long-term success of coronary procedures, which we anticipate will improve the quality of procedures in the future.

You Can Choose Not to be In the Database

We understand that not everyone is comfortable about having details related to their heart procedures entered into a database. If you feel this way, and do not want your information added to the database or to be contacted for follow-up, please contact the Project Coordinator (Angela Brennan) on 1800 285 382 at any time).

A decision on whether or not you wish to be involved in the database does not affect your treatment in any way. If you have any questions, concerns or require further information about the database, please do not hesitate to contact the Project Coordinator (Angela Brennan) on 1800 285 382.