The Cardiac Society of Australia and New Zealand

Guidelines on Support Facilities for Coronary Angiography and Percutaneous Coronary Intervention (PCI)

including

Guidelines on the Performance of Procedures in Rural Sites

These Guidelines were originally developed by a Working Group chaired by Dr Nigel Jepson. The Guidelines were reviewed in 2011 by members of the Interventional Council Executive, chaired by Dr Jim Stewart, and in 2016*. None of the reviewers have a Conflict of Interest to disclose.

The guidelines were reviewed by the Quality Standards Committee and ratified at the CSANZ Board meeting held on Friday, 25th November 2016.

The Cardiac Society of Australia and New Zealand in general endorses the ACC/AHA/SCAI Update of Guidelines for Percutaneous Intervention (http://www.acc.org/qualityandscience/clinical/guidelines/percutaneous/update/index.pdf), and the SCAI Expert Consensus Document on the Current Status and Future Directions of Percutaneous Coronary Interventional without on-site surgical backup. (www.scai.org)

The Cardiac Society believes that diagnostic coronary angiography and percutaneous coronary interventions (PCI) should only be performed were there are:

- Proper hospital infrastructure and facilities;
- Critical mass of appropriately trained workforce;
- On site cardiac surgery or formalised links with a cardiac surgical unit.

In addition, the safe performance of these procedures requires:

- Careful patient selection;
- Comprehensive staff training;
- Structured clinical protocols.

DIRECTOR OF LABORATORY

All cardiac catheter laboratories should have a Director who is experienced in interventional procedures as described in "Guidelines for competency in diagnostic cardiac catheterisation and coronary angiography" and "Guidelines for competency in percutaneous coronary interventions (PCIs)".

* *The Guidelines were updated in 2016 to clarify CSANZ's role in providing advice to sites wishing to perform coronary interventional procedures in less than the recommended 12-month period.*

For centres without on site cardiac surgery the laboratory director or his nominee should establish a formal relationship with a cardiac surgical unit. For rural and regional centres without cardiac surgery ideally the Director should be cross accredited at this referral hospital and perform procedures at this hospital on a regular basis.

NURSING AND TECHNICAL STAFF TRAINING

There are no nationally recognized training standards for nursing or technical staff in coronary angiography or angioplasty. It is recognized that such training will need to be individualized in each institution but should include:

- a didactic component;
- on-site observational training;
- hands-on experience as a second operator.

For rural and regional centres it is recommended that the affiliated metropolitan tertiary hospital assume joint responsibility for training nursing and technical staff.

CORONARY ANGIOGRAPHY

Cardiologists performing diagnostic angiography should have completed training as outlined in CSANZ "Guidelines for competency in diagnostic cardiac catheterisation and coronary angiography."

Laboratories performing diagnostic angiography should have access to coronary care or intensive care facilities and they should be capable of inserting intra-aortic balloon pumps, and transvenous pacemakers. Staff capable of managing patients with temporary pacing wires or intra aortic balloon pumps should be available in the coronary or intensive care unit to management patients requiring these devices following a coronary angiogram.

Cardiac catheterization laboratories performing only diagnostic coronary angiography do not require on-site surgical facilities. With careful patient selection it may be appropriate to perform angiography as a day case procedure. Patients selected for day angiography should have a stable clinical profile. Special care should be taken in cases with left main stenosis, critical valvular disease and in patients with significant associated co-morbidities including uncontrolled hypertension, unstable diabetes significant renal impairment or significant left ventricular impairment.

ELECTIVE PERCUTANEOUS CORONARY INTERVENTION

Units with and without on-site surgical back-up

The Society believes that coronary interventional procedures are preferably performed in hospitals with on-site surgical support. However the Society believes that centres without on site surgical backup can provide coronary interventional procedures in accordance with the following standards:

- All operators and centres should meet the minimum requirements set in the Cardiac Society's "Guidelines for Competency in Percutaneous Coronary Intervention (PCI)".
- Hospitals should accredit Cardiologists individually to perform PCIs.
- Ideally there should be a minimum of two appropriately trained interventional cardiologists in centres providing elective PCI.

- Facilities providing only elective PCI should have an on-call team available to deal with post-procedural complications for at least 24 hours after the last procedure is performed.
- It is not ideal that low volume operators (<100 PCIs per year) perform PCIs in low volume centres (centre performing <400 PCIs per year).
- There should be access to Coronary Care facilities for routine post procedure management and an *Intensive Care Unit to facilitate management of mechanically ventilated patients. All units should have the ability to provide support IABP insertion and subsequent care and also the capability to provide a routine and urgent echocardiographic service.*
- Individual hospitals should have a written policy covering these issues. It is recommended that these arrangements be reconfirmed at regular intervals (at least yearly) and updated when necessary.
- The Society believes that under certain circumstances coronary interventions can be safely performed as a day case procedure. Patients selected for day case angioplasty should have stable clinical profile and non-complex anatomy. They should be functionally independent, or have adequate domestic support following discharge, to ensure they are able to promptly access medical attention should early post-procedural complications occur.

Units without on-site surgical backup

The Cardiac Society recognizes that rural patients have lower access to diagnostic angiography and interventional procedures. Furthermore, the Society acknowledges that providing this service as close to the patient's place of residence as possible facilitates equity of access which should result in improved quality of care.

Under certain conditions the Cardiac Society believes that appropriately trained individuals can perform coronary interventional procedures safely in hospitals without on-site surgical backup. These include:

Facilities contemplating performing coronary interventional procedures without on-site surgical back up should first develop a diagnostic coronary angiography service. This should operate for 12 months and demonstrate acceptable morbidity and mortality for performance of these procedures before commencing a coronary interventional program. *Consideration may be given to abbreviating this period particularly in circumstances where a highly experienced operator (performed more than 1000 PCI cases) is developing the new interventional service and is supported by appropriately skilled cardiac catheterization staff. While the Interventional Council of the Cardiac Society of Australia and New Zealand does not have a mandate to credential facilities, or individuals within them, it does have a leadership role in establishing and maintaining standards in the region. As such, a volunteer from the Interventional Council may be available to inspect facilities if the Council is asked for its advice.*

- When consent is obtained from a patient to perform a PCI in a facility without on-site surgical backup, the potential delay in obtaining cardiac surgery for complications should be explained to individual patients.
- Once coronary interventional procedures are performed at a facility, there should be an on call team available for at least 24 hours following the last case to deal with any post-procedural complications.

- The Society believes that careful selection of cases is important and patients with a stable clinical condition but high risk anatomy may be better served by performing the procedure in a facility with on-site surgical back up. On the other hand the Society is aware of the potential benefits of early reperfusion with potential myocardial salvage in individuals with large ST elevation myocardial infarction or in individuals with cardiogenic shock.

- Rural and regional centres without cardiac surgery should establish a formal liaison with a high volume PCI centre which has on site cardiac surgery.
  - There should be a formal written agreement with a cardiac surgery team and a policy for the transport of patients to the surgical centre.
  - There should be a formal agreement to perform high risk elective PCIs at the referral centre (see below).
  - The referral centre should assume joint responsibility for training of medical, nursing and technical staff.
  - The referral centre should participate in regular case discussion and peer review with the regional centre.
- New PCI services, especially those in rural and regional centres more than 1 hour travel time from cardiac surgery, should be initially supervised by an experienced operator (experience of more than 1000 PCI cases), who should be present during cases and mentor less experienced operators. This supervision should continue until the mentor and all operators are satisfied that local policies, facilities, case selection, and outcomes are sufficient to allow the service to operate safely without the presence of the mentor.
- Rural and regional centres more than 1 hour travel time from cardiac surgery, should not perform elective, high risk PCIs defined as:

  Patients with:
  - Left ventricular ejection fraction < 25%.
  - Unprotected left main stenosis.
  - Single or multiple target lesions that in aggregate jeopardise over 50% of the remaining viable myocardium.

  Target lesion with:
  - Excessive proximal tortuosity or lesion angulation.
  - Moderate or greater calcification of the target lesion or proximal segment.
  - Bifurcation lesions (side branch > 2.25mm) where iatrogenic occlusion of a side branch would be an indication for emergency CABG.
  - Degenerative vein grafts.
  - Chronic total occlusion.

PRIMARY PERCUTANEOUS CORONARY INTERVENTION

- The Society believes that a policy of primary PCI should only be performed after an elective PCI program has been established and shown to perform with acceptable morbidity and mortality. Outcomes appear to be optimal when the centre is treating more than 36 STEMIs with primary PCI per year (at least 11 cases per year/operator), however a policy of 24/7 primary PCI should not be offered until in the view of the laboratory director, there is:
    - Sufficient infrastructure (workforce and clinical services) to ensure that procedures can be performed safely outside routine working hours.
    - Appropriately trained interventional cardiologists willing to participate in such a program
    - Clearly defined roster of on-call interventionalists - for 24/7 cover, at least 3 Interventional cardiologists are required to maintain an adequate roster but additional Interventionalists may be required depending on case load.
- Patients transferred to a private facility as part of an in-field STEMI activation program should not denied primary PCI therapy at that facility if they do not have private health insurance coverage. Similarly, these patients should not subsequently be expected to reimburse costs related to treatment.

QUALITY ASSURANCE

The Society believes that careful and complete record keeping and peer-review auditing of individual and procedural results is mandatory and an intrinsic part of quality assurance related to coronary angiography and coronary interventional procedures. The lack of prompt availability of these details would constitute a major breach of this policy.

Reference

SCAI Consensus Statement on PCI w/o Surgical Back-up www.scai.org/asset.axd?id=68c55b15-90df-4e66-a345-4f31a1421fd8&t=634112004575130000