



## **British Cardiovascular Intervention Society**

### **Statement on the Development and Peer Review of New PCI Services**

#### **Background**

In 2001 an ad hoc Advisory Group of the Coronary Heart Disease Taskforce of the Department of Health, chaired by the National Director for Heart Disease, reported on the development of percutaneous coronary intervention (PCI) services.<sup>1</sup> The Group concluded that:

- the development of new PCI services should be planned within Networks of Cardiac Care and agreed between all relevant parties
- facilities for PCI in tertiary centres should be fully utilized
- all PCI services should adhere to agreed technical, professional and practical standards
- all sites considering setting up a PCI service should undergo BCIS peer review prior to starting such a service.

Since then the number of hospitals carrying out percutaneous coronary intervention procedures has increased rapidly, and there has been a commensurate increase in the total number of PCI procedures done in the United Kingdom. There has, however, been concern that the development of new PCI services has not always been compliant with the 2001 Advisory Group recommendations. At the Angioplasty Consensus Meeting, hosted by the National Heart Improvement Programme in September 2008, the importance of British Cardiovascular Intervention Society (BCIS) Peer Review for new PCI Services was emphasized and there was broad agreement that this process should be re-invigorated.

Technical, professional, and practical standards for PCI services are currently defined in several documents.<sup>1-5</sup> All PCI services in the United Kingdom are expected to comply with these standards, which are intended to support provision of high quality patient-centred care. BCIS will review the full PCI Guidance documents during 2010, but in the interim this document summarizes and updates BCIS recommendations on the development of new PCI services. The guidance in this document is also relevant to all PCI services in the United Kingdom.

## **BCIS Guidance for new PCI services**

### **1. Planning**

- 1.1. A new PCI service should be based on a strategic plan, developed in consultation with all relevant stakeholders. Within the National Health Service (NHS) relevant stakeholders include:
  - 1.1.1. All other local PCI services
  - 1.1.2. The relevant cardiac surgical and ambulance services
  - 1.1.3. The local commissioners of coronary intervention services
  - 1.1.4. The Strategic Health Authority (SHA)
  - 1.1.5. Local patient representatives.
- 1.2. The plan for a new PCI service should ensure that the service will be compliant with BCIS Guidance. It is recognised that a new PCI service may not meet all BCIS Guidance from inception and a development period of defined duration should be explicitly included in the planning process. New PCI services should be fully compliant with BCIS Guidance within three years.
- 1.3. An effective reperfusion service for ST-elevation myocardial infarction requires the strategic coordination of different agencies and services to provide an integrated, sustainable, equitable, and reliable system of care. <sup>6</sup> Primary PCI services should therefore only be developed within the NHS with the support of the relevant commissioners, SHA and Cardiac Network.

### **2. Facilities and Equipment**

- 2.1. Hospitals planning a PCI service must be experienced in the management of haemodynamically unstable patients including the use of echocardiography, inotropic support, intra-aortic balloon counterpulsation, invasive haemodynamic monitoring, and temporary pacing. Hospitals must have ready access to intensive care facilities, transfusion services, renal support and vascular surgery.
- 2.2. A PCI service requires:
  - 2.2.1. At least one dedicated cardiac catheter laboratory with high quality digital imaging, including freeze frame, zoom, road mapping, and immediate playback capability. In hospitals with only one catheter laboratory a high resolution portable fluoroscopy unit should be available to allow safe completion of a PCI procedure if the primary radiographic equipment fails.
  - 2.2.2. Appropriate radiation protection equipment including lead aprons and screens.
  - 2.2.3. High quality physiological measurement equipment.
  - 2.2.4. Oxygen saturation monitoring.
  - 2.2.5. PCI consumables including a range of guide catheters, wires, balloons, stents (bare metal and drug-eluting), covered stents, other equipment (e.g. embolic protection devices), and adjunctive pharmacological agents (e.g. glycoprotein IIb/IIIa receptor antagonists) as appropriate to the intended case-mix.

- 2.2.6. An intra-aortic balloon pump, which should be available for all PCI procedures (a second balloon pump allows the service to continue if the first balloon pump is in use).
- 2.2.7. Facilities for cardiopulmonary resuscitation and management of haemodynamically unstable patients, including access to urgent transthoracic echocardiography, pericardial aspiration, and anaesthetic support.
- 2.2.8. Pre- and post-procedural patient preparation and monitoring areas including facilities for cardiac rhythm, oxygen saturation, and arterial pressure monitoring.
- 2.2.9. Digital archive for storage and retrieval of coronary arteriographic images.
- 2.2.10. IT and audit infrastructure (hardware, software, personnel) to ensure complete data submission on all PCI procedures to the National Congenital Heart Disease Audit (NCHDA), and to support institutional and regional audit of PCI activity.

### **3. Cardiac surgical service support**

- 3.1. The use of coronary artery stents has improved the acute outcome of PCI procedures and has reduced the need for emergency coronary artery bypass surgery. In contemporary PCI practice haemodynamic or ischaemic complications requiring emergency cardiac surgery occur infrequently.<sup>7</sup> Nevertheless, guidance from BCIS and other national societies states that emergency cardiac surgical cover is required for PCI.<sup>3,8</sup>
- 3.2. All new PCI services must agree a written protocol for the provision of emergency cardiac surgical cover with a local cardiac surgical service. This requirement applies to PCI services at hospitals with and without on-site cardiac surgery. The protocol must describe clear lines of communication between the PCI service and the cardiac surgical service, and must ensure that surgical cover is available for all relevant PCI procedures.
- 3.3. Case selection for PCI should take account of the potential need for and access to emergency cardiac surgery. For example, it may not be appropriate to treat high risk patients who are also candidates for emergency surgical revascularization in hospitals without on-site cardiac surgery.
- 3.4. The time between a decision to refer a patient for emergency cardiac surgery and cardiopulmonary bypass being established should be as short as possible and less than 90 minutes.
- 3.5. PCI services without on-site cardiac surgery must agree a written protocol with the local ambulance service that describes arrangements for emergency transfer of patients to the cardiac surgical service. The protocol must include transfer of patients with an intra-aortic balloon pump and should be tested with a trial transfer.
- 3.6. All PCI services must establish a mechanism for interaction with the local cardiac surgical service, including discussion of complex cases within the framework of a regular multi-disciplinary meeting.<sup>9</sup> Where appropriate such multi-disciplinary case discussions should be facilitated by electronic image transfer and video conferencing.

#### 4. Institutional PCI volume

- 4.1. The optimal size of a PCI service has not been determined. Infrequent practice is not likely to promote high quality care and conversely, excessively large services may be unable to sustain consistently high practice standards.
- 4.2. An association between institutional or operator volume of PCI procedures and procedural outcome has been reported. The reasons for this association have not been fully elucidated, but outcomes following PCI relate to a complete system of care, not just to the skill of individual operators. Previous BCIS guidance documents have therefore concluded that clinical staff involved in providing a PCI service (including nurses, physiologists, radiographers, junior doctors, and interventional operators) all need to experience a sufficient number of cases in their centre to ensure institutional competence.<sup>3-5</sup>
- 4.3. Total institutional PCI volume
  - 4.3.1. Several registry studies have demonstrated an inverse relationship between total hospital PCI volume and rates of in-hospital adverse outcomes, but this has not been confirmed in all studies.<sup>10-18</sup> Nevertheless, in 2007 an ACCF/AHA/SCAI report concluded that technological advances have not offset the influence of procedural volume on outcome, and confirmed that there are statistical associations between activity levels and short-term complication rates (emergency coronary bypass surgery and mortality) in contemporary PCI practice.<sup>19</sup>
  - 4.3.2. It has been suggested that the relationship between volume and outcome has been harder to demonstrate since the introduction of coronary stents into routine practice, particularly for elective PCI. The available evidence suggests that the volume-outcome relationship is strongest for patients at highest risk of adverse outcomes, including patients with non-ST and ST-elevation acute coronary syndromes.<sup>20-22</sup>
  - 4.3.3. Total institutional PCI volume is one of many factors contributing to variability in service quality, and other relevant quality indicators (e.g. risk adjusted outcomes, call and door to balloon times) will become increasingly important as local and national audit programmes develop (see section 8). In the interim total institutional procedural volume provides an easily measured but imperfect surrogate for PCI service quality.
  - 4.3.4. As a minimum, total institutional volume should be sufficient to allow all members of the team to maintain proficiency in the care of PCI patients (see section 5.3 for individual operator requirements). It is recognised that some operators work in more than one institution but current evidence suggests that total institutional activity is as important as individual operator activity. All new PCI services should therefore plan to carry out at least 200 therapeutic coronary interventions in the first year and increase activity to at least 400 cases per annum within three years. Instrumentation of a coronary artery for diagnostic purposes (e.g. with a pressure wire or intravascular ultrasound catheter) should not be included in this number of interventions. If the local catchment population is unlikely to require 400 cases per annum there should be other explicit imperatives that justify the development of the new PCI service (e.g. long distance to the nearest alternative PCI service).

- 4.3.5. The number of PCI procedures carried out within each United Kingdom PCI service is published annually.<sup>7</sup> A BCIS peer review visit will be recommended for all PCI services that carry out fewer than 200 procedures per annum for three successive years.

#### 4.4. Primary PCI volume

- 4.4.1. The objective of a primary PCI service is to provide timely reperfusion therapy to unselected patients with ST-elevation myocardial infarction. These patients range from stable patients with limited myocardial injury to haemodynamically unstable patients with cardiogenic shock, pulmonary oedema, or out-of-hospital cardiac arrest who may require ventilation and intensive care.
- 4.4.2. The design of primary PCI services should be negotiated within clinical networks between PCI centres, commissioners and the SHA. The agreed service plan will depend on many factors, including local geography, demographics, ambulance service isochrone maps, access to catheter laboratories, availability of relevant clinical staff, provision of support services, and overall service cost. The service plan may need to balance the need to minimise transport times against the requirement for continuous (24 hour, 7 days per week) access to an effective and sustainable primary PCI service (both for patients who present via ambulance services or via Accident & Emergency departments). Optimal delivery of a primary PCI service will depend on effective communication between all relevant parties, supported by unambiguous protocols between ambulance services, emergency departments, catheter laboratory teams, and critical care facilities.
- 4.4.3. Several studies have reported a relationship between institutional or operator volume and outcome for primary PCI,<sup>20-27</sup> but the minimum number of primary PCI procedures required to maintain institutional or operator competence has not been established.
- 4.4.4. Primary PCI services are unlikely to be sustainable with fewer than five operators and operators carrying out at least 20 primary PCI procedures per annum have been reported to have lower in-hospital mortality than operators doing fewer primary PCI procedures.<sup>20</sup> Hospitals carrying out at least 50 primary PCI procedures for ST-elevation myocardial infarction per annum may achieve better outcomes than services carrying out fewer procedures.<sup>20,23-25</sup> High total institutional PCI volume (more than 400 PCI cases per annum) has been associated with short door to balloon times and lower hospital mortality for patients undergoing primary PCI.<sup>21,22,27</sup>
- 4.4.5. European Society of Cardiology (ESC) and American College of Cardiology (ACC)/American Heart Association (AHA) guidance documents recommend that individual hospitals providing a primary PCI service for patients with ST-elevation myocardial infarction should operate that service continuously (24 hour, 7 days per week).<sup>28, 29</sup> In the United Kingdom there are approximately 500 reperfusion-eligible myocardial infarction patients per million population per annum. If an individual United Kingdom hospital provides an independent and continuous (24 hour, 7 days per week) primary PCI service (with an appropriate number of medical and non-medical staff to cover a rota) the hospital would need to serve a population of at least 200 000 to achieve a minimum number of 100 primary PCI procedures per annum.

- 4.4.6. Notwithstanding ESC and ACC/AHA guidance, in some cardiac care networks in the United Kingdom primary PCI services are provided by a group of hospitals, including some hospitals that offer primary PCI during restricted hours. Individual hospitals participating in a primary PCI service should be able to maintain a level of activity that will ensure institutional competence in dealing with unselected patients with ST-elevation myocardial infarction. If a single hospital provides primary PCI during normal daytime working hours only (for example, Monday to Friday, 9am to 5pm) and wishes to carry out a minimum of 100 on-site primary PCIs per annum it would need to serve a population of approximately 500 000. Operators who carry out primary PCI at hospitals with lower institutional primary PCI volumes would need to participate in a regional primary PCI rota to maintain individual operator volumes of 20 primary PCI procedures per annum.
- 4.4.7. An individual hospital contributing to a primary PCI service must be part of the network-wide primary PCI strategy to ensure that all patients with ST-elevation myocardial infarction have equitable, continuous (24 hour, 7 days per week), and effective access to primary PCI, regardless of the time of presentation.

## **5. Staffing requirements**

- 5.1. The provision of a high quality PCI service requires an experienced multidisciplinary team capable of delivering high quality care throughout the patient pathway, including pre-procedural assessment, consent, intervention, post-procedural care, and rehabilitation.
- 5.2. All PCI services should have at least three independent PCI operators to ensure that an uninterrupted service can be provided. An independent PCI operator is someone who has successfully completed a United Kingdom (or equivalent) training programme in PCI and is on the Specialist Register for cardiology. An independent operator decides that PCI is appropriate management, plans the intervention strategy, and carries out the procedure without supervision. A service with only three independent operators may be difficult to sustain long-term and services should plan to increase the number of operators to four to six, depending on workload.
- 5.3. Independent operators must carry out at least 75 PCI cases as primary operator per annum to maintain competence. The primary operator does the PCI procedure and assumes responsibility for the procedural outcome. New PCI services should be planned to ensure that all operators meet this standard. PCI operators who carry out fewer than 75 primary operator procedures per annum, and operators who work on more than one site but will contribute fewer than 50 cases per annum to the new service, should not form part of the team of three independent operators at the new PCI site.
- 5.4. When new PCI services start, some fully trained PCI operators may wish to resume coronary interventional practice after a period of low volume activity or a period of absence from coronary interventional practice. Operators who have carried out 75 cases per year for the previous two years but are then absent from coronary interventional practice for less than 6 months (for example illness, pregnancy, temporary suspension, etc.) do not require additional training before resuming independent practice. If the period of absence exceeds 6 months but is less than two years the operator is advised to carry out a minimum of 20 cases with the support of an independent operator colleague before resuming fully independent practice. Operators who have been fully trained but have not maintained 75 cases per annum for two years

or more are advised to spend two years performing at least 75 cases per annum under the supervision of an independent operator before resuming independent practice.

- 5.5. Cardiologists who have never been fully trained in PCI and who wish to start PCI must undergo formal PCI training. Where possible the training should be negotiated with and be directed by the local cardiology Training Programme Director. A baseline assessment of knowledge, skills, attitudes, and experience should be carried out so that an individualised training and assessment plan can be formulated. This plan should cover the curriculum for interventional training defined by the cardiology Specialist Advisory Committee and include a logbook of interventional cardiology experience, workplace-based assessments, and records of appraisal with supervisors.<sup>30</sup>
- 5.6. New PCI services must be supported by a range of other clinical staff with relevant nursing, radiography and physiology expertise. Formal training opportunities for non-medical staff are limited, but the non-medical clinical team must have sufficient experience in PCI to ensure safe and effective PCI service delivery. The number of non-medical staff will depend on work load and local practice but should be sufficient to sustain the service, including requirements for out-of-hours rotas.
- 5.7. All PCI operators should have four days per year for participation in interventional educational programmes and for “Continuing Professional Development” (CPD), including attendance at national and/or international interventional cardiology meetings. All non-medical staff also require opportunities for education and this must be explicitly included in the service plan.

## **6. Peri-procedural care**

- 6.1. PCI procedures range from elective procedures that can be carried out at low risk to emergency procedures in haemodynamically unstable patients that involve substantially higher procedural risk, but any PCI patient can develop peri-procedural complications.
- 6.2. All PCI services must ensure that arrangements for peri-procedural care are appropriate for any possible case-mix that may be encountered. All new PCI services must develop written protocols describing the patient care pathway through a PCI procedure. These protocols should include patient education and consent (with involvement of relatives and carers as appropriate), pre-procedural assessment, post-procedural care, discharge and follow-up procedures, and rehabilitation. The protocols must facilitate the recognition and management of procedural complications (such as pericardial tamponade, major haemorrhage, radiographic contrast reactions, and stent thrombosis) by nursing and junior medical staff. The protocols should define clear lines of communication between nursing and junior medical staff and the consultant interventional cardiologist responsible for the patient’s care. Relevant staff should be regularly updated on the patient care protocols.
- 6.3. Provision of optimal patient care requires continuous (24 hour, 7 days per week) local consultant interventional cardiologist cover and continuous access to the local catheter laboratory after all PCI procedures. All PCI services should develop plans to provide this level of service within three years.
- 6.4. Individual PCI operators have a clinical responsibility for a patient throughout the care pathway. Before proceeding with a PCI procedure the individual PCI operator must

ensure that appropriate medical cover and catheter laboratory access will be available following the procedure.

#### 6.5. Elective PCI:

- 6.5.1. Patients undergoing elective PCI for stable symptoms can be scheduled during routine working hours (9am to 5pm), and are generally at low peri-procedural risk.
- 6.5.2. As a minimum, a consultant interventional cardiologist must be available on a formal on-call rota to provide overnight medical cover after all elective PCI procedures, including day-case procedures. The rota should be published and formally agreed between all participating cardiologists. The rota must cover days when elective PCI is carried out at the PCI site, but all services should develop plans for continuous (24 hour, 7 days per week) consultant interventional cardiologist cover.
- 6.5.3. As a minimum, all PCI services must provide access to the local catheter laboratory for six hours after routine working hours (9am to 5pm) and after completion of all elective PCI procedures. The laboratory should be fully operational within 60 minutes of a call. Complications more than six hours after elective PCI are infrequent but may require emergency catheter laboratory access, and continuous (24 hour, 7 days per week) access to the local catheter laboratory therefore provides optimal patient care. If uninterrupted access to the local catheter laboratory cannot be provided, arrangements for emergency transfer of a patient to another PCI service providing continuous catheter laboratory access must be agreed in writing between all relevant parties. All PCI services should develop plans for continuous (24 hour, 7 days per week) access to the local catheter laboratory.

#### 6.6. Urgent PCI (for non-ST-elevation acute coronary syndrome):

- 6.6.1. Patients with non-ST-elevation acute coronary syndrome present at any time, may require urgent or emergency PCI, and are at increased peri-procedural risk. PCI services treating patients with acute coronary syndrome must be able to manage haemodynamically unstable patients who may require intra-aortic balloon counterpulsation, anaesthetic support and ventilation, and intensive care facilities.
- 6.6.2. PCI services managing patients with non-ST elevation acute coronary syndrome should provide continuous (24 hour, 7 days per week) local consultant interventional cardiologist cover and continuous local catheter laboratory access. Plans to establish an uninterrupted service should be apparent at the inception of the new PCI service.
- 6.6.3. If a continuous local service cannot be provided (for instance, during the development phase of a new service), there should be access to the local catheter laboratory for an absolute minimum of six hours after routine working hours (9am to 5pm) and after completion of the last PCI procedure. In addition, a robust written protocol for the management of patients with non-ST elevation acute coronary syndrome outside of local operating hours must be developed and agreed in collaboration with other PCI services. This protocol must ensure that patients with non-ST elevation acute coronary syndrome have continuous consultant interventional cardiologist cover and catheter laboratory access throughout their hospital admission. If a continuous local service is unlikely to

be feasible within three years, the rationale for providing a service for non-ST elevation acute coronary syndrome and the agreed provision of cover from other PCI services should be made explicit in the service plan.

#### 6.7. Primary PCI (for patients with ST-elevation myocardial infarction):

- 6.7.1. Patients with ST-elevation myocardial infarction range from relatively stable patients with side-branch occlusion of an epicardial artery to haemodynamically unstable patients in pulmonary oedema and cardiogenic shock. In the United Kingdom in 2008 primary PCI was associated with a mortality of 4.1%, and mortality for patients in cardiogenic shock was 29.7%.<sup>7</sup>
- 6.7.2. Following primary PCI patients may be haemodynamically unstable and require intra-aortic balloon counterpulsation, and are at increased risk of complications including re-infarction and stent thrombosis.<sup>31,32</sup> Primary PCI patients require specialist cardiology care and may need re-intervention in the catheter laboratory on an urgent or emergency basis. Optimal care of primary PCI patients requires continuous (24 hour, 7 days per week) consultant interventional cardiologist cover and catheter laboratory access at the hospital where the primary PCI is carried out.
- 6.7.3. In some cardiac care networks in the UK some hospitals contributing to primary PCI services may operate a restricted hours service for logistic, geographic, or other reasons. If a continuous local primary PCI service cannot be provided, robust arrangements for management of patients requiring reperfusion therapy outside of local operating hours must be developed in collaboration with all other relevant stakeholders. In addition there must be robust arrangements for the care of primary PCI patients treated at the hospital offering a restricted hours primary PCI service throughout the patients' admission to that hospital. These arrangements must be agreed with relevant stakeholders as part of a network-wide primary PCI service strategy and must include continuous (24 hour, 7 days per week) consultant interventional cardiologist cover and uninterrupted access to a catheter laboratory.

#### 6.8. On-call rotas

- 6.8.1. All independent PCI operators should be involved in the care of, and share responsibility for PCI patients throughout the patient pathway. Arrangements for on-call rotas must be sustainable and agreed locally between all independent PCI operators contributing to the PCI service. On-call rotas may include participation in a primary PCI service. Individual PCI operators who carry out PCI must ensure that arrangements for post-procedural care meet the standards defined in sections 6.1 to 6.7. This can be achieved by local institutional or regional out-of-hours rotas. These arrangements must be explicit, robust, and formally agreed in writing between all participating operators and hospitals.
- 6.8.2. The contribution of medical and non-medical catheter laboratory staff to PCI on-call rotas should be considered in the business plan when a new PCI service is proposed. On-call commitments should be reflected in consultant and non-medical staff job plans.
- 6.8.3. An adequate number of clinical (medical and non-medical) catheter laboratory staff must be available to support the local and/or regional PCI on-call rota.

## **7. Consent**

- 7.1. The patient consent process should comply with relevant Department of Health and General Medical Council guidance, and should include a description of 'significant, unavoidable or frequently occurring risks' of the proposed procedure.<sup>33,34</sup>
- 7.2. The patient consent process for PCI at hospitals without on-site cardiac surgery must inform patients of the potential need for emergency transfer to another hospital for management of complications, which may include emergency cardiac surgery.
- 7.3. The patient consent process for PCI at hospitals without a continuous (24 hour, 7 days per week) local PCI service must inform patients of the potential need for transfer to another hospital for the management of complications.

## **8. Audit**

- 8.1. All new PCI services must submit complete procedural and in-hospital outcome data to NCHA. This includes the recording of all major adverse cardiovascular and cerebrovascular events up to hospital discharge. These data will be used to assess the quality of individual PCI services using a range of metrics, including risk-adjusted outcomes, and call to balloon and door to balloon times for patients undergoing primary PCI.
- 8.2. All PCI services should formally audit local PCI activity at least annually, but more frequent audit may be appropriate, particularly during the development phase of a new PCI service. All services should develop plans for participation in regional audit and peer review with colleagues from other PCI centres and from the local surgical service.
- 8.3. Any patient treated by a local PCI service but subsequently transferred to another PCI service or a cardiac surgical service for the management of a complication of the initial PCI procedure should be the subject of an individual case review involving all relevant clinicians.
- 8.4. All institutions providing a primary PCI service should participate in the national audit programme and provide outcomes of all primary PCI patients to the point of hospital discharge. Analysis of these audit data and further clinical research may influence the future provision of services.

## **The BCIS Peer Review process**

The BCIS peer review process is designed to assess whether a proposed new PCI service complies with BCIS guidance. As agreed with the DoH Heart Team, all hospitals wishing to start a new PCI programme are required to undergo a BCIS peer review visit. To initiate this process, a formal letter from the Trust Chief Executive should be addressed to the BCIS Honorary Secretary, requesting a site visit. This letter should confirm the Chief Executive's intention to create a PCI service that is consistent with the BCIS standards and that the service will not be initiated until a satisfactory site visit has been completed and the confirmatory report received. The peer review visit will be carried out by a member of BCIS Council or a member of the BCIS Clinical Standards Group, together with one other senior interventional cardiologist. If necessary, the peer review team may include non-medical catheter laboratory staff representatives. All members of the peer review team will work in separate PCI services outside the region of the proposed new PCI service.

The following information must be forwarded to the BCIS Peer Review team before the peer review visit:

1. An overview of the Trust (size, location, and facilities) and a description of supporting medical services (including access to intensive care, vascular surgery, cardiac surgery, transfusion services and renal support).
2. A description of local cardiology services, facilities, and staffing levels (including consultant, other medical and non-medical staff).
3. An outline of existing regional arrangements for myocardial revascularization (current providers, case numbers, waiting times for elective and non-elective procedures) and the projected impact of the proposed service on existing providers. Any Network Revascularisation Strategy, including any plans for primary PCI should also be described.
4. The business plan for the new PCI service, including an overview of the catchment population (demographics, disease prevalence), projected demand and capacity for PCI, the proposed case-mix and anticipated volume of PCI activity.
5. Written confirmation that all relevant stakeholders have been consulted about the proposed new PCI service. For a new NHS PCI service stakeholders will generally include the local Cardiac Network, the Strategic Health Authority, the local commissioners of PCI services, local patient representatives invited by the commissioners and/or local Cardiac Network, the relevant cardiac surgical service, the local ambulance service for hospitals without on-site cardiac surgery, and other local PCI service providers.
6. A protocol for emergency cardiac surgical support including the written agreement of the relevant surgical service.
7. If appropriate, a written agreement with the local ambulance service, with evidence that patients with an intra-aortic balloon pump can be transferred to the cardiac surgical service to allow cardiopulmonary bypass to be established within 90 minutes of a call.
8. A description of arrangements for consultant interventional cardiologist cover and catheter laboratory access after all PCI procedures, including confirmation of support from any other PCI service contributing to these arrangements.

9. The proposed schedule of catheter laboratory activity.
10. The records of each independent PCI operators' training and experience in PCI, including recent PCI activity and CPD.
11. The arrangements for audit, including submission of complete PCI procedural and in-hospital outcome data to NCHDA.
12. Description of interactions with other PCI and cardiac surgical services including arrangements for multidisciplinary meetings and case discussion, regional audit and peer review, research, and training.
13. Protocols for patient care, including case-selection and consent, and pre- and post-procedural care.

A mutually convenient time for the peer review site visit will be arranged as soon as possible after receipt of the request and relevant documents and information about the proposed PCI service. BCIS will charge a fee for the peer review site visit and preparation of the report, and will expect all reasonable travel and subsistence expenses of the peer review team to be reimbursed by the institution being reviewed.

The peer review visit should be attended by the local independent PCI operators and other relevant clinical and managerial staff. Representatives of all major stakeholders should be invited to the event. For NHS institutions this will include other local PCI service providers, the local cardiac surgical service, the ambulance service (if appropriate), the local commissioners, the Cardiac Network, and the Strategic Health Authority. Two local patient representatives should also be invited to attend the peer review visit by the commissioners and/or Cardiac Network.

The peer review visit should commence with introductions followed by presentations from the local team describing the plans for the proposed PCI service. During the site visit the BCIS team will expect to see the catheter laboratory and patient care facilities. The BCIS team will also wish to interview individual members of the team and may request access to private office space for this purpose. The visit will usually conclude with preliminary feedback from the BCIS team.

Following the site peer review visit a report will be prepared highlighting any strengths or weaknesses of the proposed PCI service. The report will make recommendations as necessary and will conclude with a statement of compliance with BCIS Guidance. The report will be addressed to the Trust Chief Executive but will also be circulated to the Director and Clinical Lead of the Cardiac Network, the local Commissioners for PCI, the Chief Executive of the Strategic Health Authority, and the National Director for Heart Disease (Department of Health).

In all cases a second service review will be advised to review progress after the service has been operational for at least twelve months. If a PCI service is not compliant with BCIS guidance additional site peer review visits may be recommended.

BCIS Council, February 2015

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