

A09/S/d

**2013/14 NHS STANDARD CONTRACT
FOR CARDIOLOGY: PRIMARY PERCUTANEOUS CORONARY INTERVENTION
(PPCI) (ADULT)**

PARTICULARS, SCHEDULE 2- THE SERVICES, A- SERVICE SPECIFICATIONS

Service Specification No.	A09/S/d
Service	Cardiology: Primary percutaneous coronary intervention (PPCI) (Adult)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Percutaneous coronary intervention (PCI), or coronary angioplasty, is a procedure carried out under local anaesthetic in which narrowings (stenoses) of the coronary arteries are dilated with a balloon catheter and are then treated with a stent (a tubular metal alloy device) which is implanted into the artery. The stent provides a permanent internal scaffold to maintain patency of the artery. In patients with a specific form of heart attack known as ST segment elevation myocardial infarction (or STEMI); the artery supplying the relevant area of heart muscle is usually completely blocked by a combination of atheroma and blood clot. Primary angioplasty (PPCI) is the use of the PCI technique to relieve the blockage as the main or first treatment for patients suffering a heart attack. The alternative treatment for patients experiencing an ST Segment Elevation Myocardial Infarction (STEMI) is fibrinolysis: this involves the intravenous administration a clot busting drug which is injected as soon as possible after a heart attack to dissolve the blockage in the artery. Fibrinolysis, however has a number of disadvantages; around 30% of STEMI patients will have a contra- indication to fibrinolytic drugs and the drugs are successful in re-opening the blocked vessel in only around 60-70% of cases. Even if the vessel is successfully re-opened, the rate of re-occlusion, causing a further heart attack, is high.

For all of the above reasons, primary percutaneous coronary intervention (PPCI) is the preferred reperfusion treatment for patients presenting with ST segment

elevation myocardial infarction (STEMI). During the third quarter of 2008, just 46% of those STEMI patients in England who received reperfusion treatment were being treated by PPCI while the remaining 54% were treated with thrombolysis. Following the publication of the NIAP report in 2008 (see below), there was a coordinated roll-out of PPCI services in England. The use of primary angioplasty continued to increase between 2008 and 2011. By the second quarter of 2011, 94% of STEMI patients in England were being treated with PPCI. The rate of primary PCI reached 287 pmp in 2010. This treatment option was provided 24/7 by 52 of the 97 NHS PCI centres (National Audit of Percutaneous Coronary Intervention 2011 Annual Report).

Evidence Base for PPCI

Percutaneous coronary intervention (PCI) had been used by individual centres for the treatment of acute ST-elevation myocardial infarction (STEMI) for many years, but it was not until the DANAMI-2 and PRAGUE-1 & 2 trials (and the ensuing meta-analysis by Keeley et al) that primary PCI (PPCI) became more widely acknowledged as the preferred method of reperfusion (1-4). Trial evidence had demonstrated the benefits of PPCI over fibrinolysis, but in the UK the infrastructural and organisational changes required for implementation were unclear, and the cost-effectiveness and sustainability of a 24/7 PPCI reperfusion strategy had not been tested. In addition, any proposed change was to be made against the background of a previously successful in-hospital fibrinolysis strategy.

In December 2006, the Department of Health published the report "*Mending Hearts and Brains – clinical cases for change.*" The report advocated a PPCI service, running 24 hours a day, 7 days a week basis as a first treatment for heart attacks. It also stated that by bypassing local hospitals to deliver PPCI in centres of excellence for heart attack victims could save an estimated 500 lives, and may prevent around 1,00 further heart attacks and around 250 strokes.

Treatment of a Heart Attack National Guidance – Final Report of the National Infarct Angioplasty Project (NIAP)

In 2008 the Department of Health guidance '*Treatment of Heart Attack*' reported the outcomes of the National Infarct Angioplasty Project (NIAP) were reported. Analysis of the evidence showed that:

- PPCI reduces mortality and improves longer-term outcome compared with fibrinolysis when delivered within a similar timeframe.
- In-hospital mortality for patients undergoing PPCI was 5.2% and 7.1% for those given fibrinolysis. At 18 months mortality rates were 9.9% for patients who had received PPCI and 14.8% for those who had been given fibrinolysis.
- Patients who were admitted directly to the catheter laboratory bypassing accident and emergency departments had the lowest mortality.
- More patients are potentially suitable for PPCI than fibrinolysis and PPCI is associated with fewer strokes and recurrent heart attacks during the hospital admission.
- The greatest delay in providing effective treatment is often the time taken for patients to recognise that they have a problem and call for help.

Volume and Outcome Relationships for PCI and PPCI

For PCI in general, there is evidence suggesting improved outcomes for patients being treated in higher volume PCI centres, particularly those that perform at least 400 procedures per annum (pa). This forms part of the recommendations of the Joint Working Group on PCI of BCIS and the British Cardiovascular Society (5). In 2010, 25% of PCI units were performing 400 or less cases pa, although some of these were new units undertaking a gradually increasing volume of work

Primary PCI for STEMI is a much higher risk procedure than PCI for stable patients or for non-STEMI acute patients. PPCI patients have a much higher rate than stable PCI patients of requiring a second visit to the cath lab for repeat procedure (after stent thrombosis), intra-aortic balloon pump insertion etc. Primary PCI is a service, therefore, which must be provided 24 hours a day, 7 days a week, 365 days a year with contingencies to deal with broken cath lab, staff illness etc. When PPCI services were being developed across England, most cardiac networks designed their service in such a way that all STEMI patients were taken to a 24/7 PPCI centre. A minority of services were set up with smaller local hospitals providing a limited hours service (typically Mon - Fri 9 – 5 or 8 - 8) with the out of hours presenters being taken to the nearest 24/7 centre. The issue was whether the *possibly* better outcomes of the larger PPCI centre are offset by the possibility of shorter call-to-balloon times had the patients been taken to a local hospital that involved a shorter travelling time. This issue is unresolved although the European Society of Cardiology (ESC) guidelines are specific on this point...

“.....only hospitals with an established interventional cardiology programme (24 h/7 days) should use primary PCI as a routine treatment option for patients presenting with the symptoms and signs of STEMI.....” (5).

The European Society of Cardiology has advocated one 24/7 PPCI centre for every 600,000 to 1 million of the population based on a PPCI rate of 600 per million. In the UK, the rate of PPCI is lower than in east European countries and is currently around 300-350 per million.

The clear consensus view of the Clinical Reference Group was that PPCI patients should only be treated in 24/7 centres only in keeping with ESC guidelines and that high volume centres, where all members of the cath lab and ward teams were familiar with the presentations and complications associated with STEMI patients, were likely to achieve better outcomes. For a 24/7 centre to treat 300 PPCI patients would require a catchment population of around 1 million. Some centres (London, Manchester, Liverpool, Newcastle, and Leeds) will have much larger catchment populations.

The views of the CRG could be summarised as follows:

- PPCI patients should be treated in 24/7 PCI centres.
- PPCI centres are likely to be treating 300 or more PPCI patients per annum, with an absolute minimum of 100 PPCI patients per annum as per BCIS guidance.

- A PPCI centre should have 2 or more cardiac catheter laboratories.

It is recognised that there may be exceptions to the guidance on both choice of reperfusion strategy (PPCI vs fibrinolysis) and numbers in the more remote areas of England where the commissioners will have to balance the arguments in favour of transfer to a large volume PPCI centre against the inherent delay in receiving treatment. Most people now believe that outcomes with PPCI are better than with lysis for most patients with a Call-to-balloon time of 150 minutes or less. Allowing 20-30 minutes for initial assessment of the patient, and a door-to-balloon time of 30-40 minutes for an expected patient, this allows a travel time to the PPCI centre of 80 - 100 minutes. A travel time to a PPCI centre exceeding 80-100 minutes probably applies to no more than 5% of the population of England.

References

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4. Keeley EC, Boura JA, Grines CL. Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infarction: a quantitative review of 23 randomised trials. *Lancet*. 2003;361:13-20.
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2. Scope

2.1 Aims and objectives of service

Aims

The aim of the service is to ensure, where possible, whole population coverage to allow patients experiencing ST Segment Elevation Myocardial Infarction (STEMI) to be treated by timely PPCI in a Heart Attack Centre (HAC). Access to Primary PCI services will be provided 24 hours per day, and 7 days per week. HACs will oversee effective discharge planning including ensuring that appropriate rehabilitation arrangements are in place.

Objectives

The service will deliver the aim of providing timely Primary PCI services, 24 hours per day, and 7 days per week by:

- Working closely with Ambulance services and non-PPCI hospital A&E departments to ensure timely and accurate diagnosis.
- Providing high quality proactive treatment and care.
- Providing high quality audit data to ensure that excellent clinical outcomes are maintained.
- Ensuring that systems are in place to monitor the timeliness of the whole patient pathway (call to balloon time etc).

2.2 Service description/care pathway

National and international guidelines recommend that in the emergency treatment of patients with STEMI, angioplasty treatment should be performed within 90 minutes of arrival of the patient at the angioplasty site, termed door to balloon (DTB) time, and within 150 minutes of a patient's call for help, termed call to balloon (CTB) time.

The pathway includes those patients who self-present to hospital, those who are taken by ambulance to hospital for assessment, and those who are already in hospital at the time of their heart attack whether the first hospital is the PPCI centre or a non-PPCI hospital.

Inclusion criteria

Symptoms compatible with an acute myocardial infarction (MI) within the last 12 hours AND with the following electrocardiogram (ECG) criteria:

- ST segment elevation >1mm or more in contiguous limb leads or >2mm in contiguous chest leads
- Left Bundle Branch Block (LBBB) believed to be new in the context of acute cardiac sounding chest pain
- Patients resuscitated from cardiac arrest with ECG criteria as above.

Note:

Patients with LBBB believed to be pre-existing and appropriate history for MI should be discussed with the PPCI service.

The inclusion criteria are evidence based to maximise patient benefit; in exceptional circumstances, if the senior on-site clinician considers a patient does not meet the standard inclusion criteria, but might still benefit from PPCI, they should discuss the case with the on-call interventionist via the HAC.

Patient Assessment**Ambulance Assessment – In line with local ambulance service protocol**

Upon arrival at scene the paramedic will establish the clinical history whilst ensuring airway, breathing and circulation (ABCs).

Once it is established that the patient is suspected of having cardiac related chest pain, the patient will be placed on oxygen if required to maintain the SpO₂ > 94%, then will receive 300 mg of aspirin and glyceryl trinitrate (GTN) and will be transferred to the ambulance at the earliest opportunity.

Once on board the ambulance the paramedic should acquire a 12 lead ECG and determine if a STEMI is evident (**defined as elevation of 1 mm or more in at least 2 standard limb leads or 2mm or more in at least 2 adjacent chest leads, not including V1**).

If no STEMI is evident, the patient must be transported to their nearest hospital immediately with appropriate treatment being provided en-route.

If a STEMI is evident and if PPCI is available at the present time, then the paramedic must proceed to complete the PPCI assessment checklist to establish if the patient meets the inclusion criteria.

NOTE: Different PPCI centres and different PPCI centres have different protocols for patient referral. Some ambulance centres send the patient's ECG by telemetry to the PPCI centre; the PPCI centre then reviews the ECG and decides whether or not to accept the patient for PPCI. In other services, there is no ECG telemetry and the patient is accepted on the basis of the interpretation of the ECG by the paramedic who has assessed the patient. Both systems are acceptable.

If the patient does not meet the inclusion criteria then they must be transported to their nearest hospital immediately for further assessment.

If the patient fully meets the inclusion criteria and has given consent in principle to being transported to a HAC for the procedure then the paramedic should inform the HAC that a patient requiring 'Primary PCI' is being transported to the HAC, giving the patient's name, sex, age and brief of the patient's condition and an estimated time of

arrival. The patient must then be transported to the HAC immediately using visual and auditory warning devices.

Attempt at cannulation can be made whilst en-route and when it is safe to do so, preferably avoiding the right wrist and forearm.

Whilst en-route to the HAC the paramedic must complete observations and administer pain relief.

In-hospital Assessment

STEMI patients presenting at any of local hospitals will have access to the 24/7 PPCI based at the HAC. In addition, patients who have not fully met the ambulance inclusion criteria and have subsequently been taken to their local hospital may then be considered as suitable candidates following further clinical assessment and/or discussion of their individual case with a specialist clinician at the local HAC. If the referring hospital identifies the need to discuss the clinical or ECG evidence with the on-call cardiology consultant at the HAC then this will be carried out with a minimum of delay. Should discussion be required regarding an individual case with the on call cardiologist, then the patient's ECG can be faxed to the coronary care unit (CCU). Once the patient has been assessed as being a suitable candidate to receive PPCI they will then be rapidly transferred to the HAC via ambulance.

Patient Preference

When a patient is considered suitable for PPCI the final determination in the selection of this treatment strategy must always be that of patient preference. In obtaining the agreement to transfer, it is important that the patient understands the benefits and risks associated with the treatment they are likely to be offered at the HAC. This agreement should be sought before transfer to the HAC. If a patient meets the clinical inclusion criteria but does not consent to transfer, then the patient should be transported to their nearest hospital A&E immediately for further assessment/treatment. They may require fibrinolysis or may consent to the procedure once they arrive at their local hospital.

Arranging Ambulance Transfer from Local Hospital to HAC

The local hospital clinician must arrange an emergency ambulance transfer to the HAC by telephoning the control centre. The local hospital clinician must then activate the local HAC Primary PCI Policy by telephoning the dedicated number. This should be done after requesting an emergency ambulance, to ensure the transfer is as quick as possible. This process will ensure the HAC are informed of the patient's imminent arrival, thus activating the internal protocols that will ensure the PPCI team and the catheter lab are ready to receive the patient. This will include 'calling in' the PPCI team if out of hours. The local hospital clinician must then ensure that a 'Hospital PPCI Transfer Checklist' is completed and placed within the patient's notes, ready for transferring with the patient to the HAC.

Patient/Family Information

It is important that the patient and their family/carer/next of kin are kept fully informed of their condition, the treatment options available to them and the risks and benefits associated with those treatment options. Once consent to transfer to the HAC has been obtained, the patient and/or their family member/carer/next of kin may be handed a 'Primary PCI Information Sheet'. This information sheet briefly describes the procedure they are likely to have at the HAC and gives details of how to get to the HAC, where they should park and what to do/expect when they arrive.

Handover

Upon arrival at the HAC the ambulance will be met at the cath lab entrance by the Cardiac Specialist Nurse/or a CCU nurse; the paramedic crew and patient will then be escorted to the area of Catheter Lab, where handover will take place. If the crew have a relative accompanying the patient the relative should be directed to the designated waiting area on CCU. Paramedics will then complete all relevant documentation including the Patient Report Form (PRF). Copies of all documents and original ECGs should be handed to the nursing team at the HAC.

Consent to Procedure

Consent for the procedure is usually taken, ensuring the clinician who delivers the explanation of treatment also explains the risks/benefits and possible complications, and any alternative treatment available. They must be either medically qualified or trained in obtaining consent and deemed competent by the cardiology consultants. If the patient is unable to comprehend the procedure (unconscious patient etc.), then the clinician can complete a "Form 4" consent stating that he/she believes the procedure is in the patient's best interests.

False Positive Activations

Some patients will be referred as "possible or probable STEMI" but will then be considered by the cardiology team not to be a STEMI presentation and not to require diagnostic angiography or PPCI. If the diagnosis is clear-cut (e.g. pericarditis, NSTEMI), then the patient should be managed in the usual way. This may involve admission to the cardiology ward, admission to a medical ward or transfer to the patient's local hospital. If the diagnosis is not clear and an A&E assessment is required to determine diagnosis, then the Cath Lab Team (CSN or Cardiology Registrar) must speak to the Nurse – in – Charge of A&E to refer the patient. This may be a referral to the A and E of the PPCI centre if the patient is local or a transfer, usually in the ambulance which has brought the patient, to the A and E of the hospital closest to the patient's home. The registrar and CSN must stay with the patient until safe transfer has been organised and delivered. False positive referrals will be audited and fed back to the relevant management teams and personnel.

False Negatives

If patients are taken to their local A&E by ambulance, and are then considered to have a first ECG fulfilling the criteria for PPCI, the patient will be referred for PPCI and the information fed back to the relevant management teams and personnel.

In-Patient Stay

Following the procedure all patients will be transferred from the catheter laboratory to the Coronary Care Unit for a period of monitoring. Different PPCI centres will have different arrangements with the non-PPCI hospitals within their network. In some networks, the patient will remain in the PPCI centre until discharge 48-72 hours after the procedure. In other networks, patients who are stable may be transferred to their local hospital 6-24 hours after the procedure. Discharge planning will take place from the time of arrival, utilising the PPCI inpatient pathway.

Discharge

The majority of patients will be discharged home 48-72 hrs after PPCI. The extent of CK or Troponin rise will not determine length of stay. Some units may routinely repatriate patients at 6-24 hours to their local hospital.

A Medical Discharge Pack will be completed. Patients with the following complications may require a longer inpatient stay. This will be guided by the duty Consultant or the Consultant responsible for the patient's care.

- Cardiogenic shock
- Hypotension.
- Poor left ventricular function.
- Persistent or recurrent post reperfusion rhythm disturbance.
- Prolonged slow flow or no reflow.
- Awaiting further angioplasty or surgical opinion.
- Concomitant significant cardiac disease such as severe aortic stenosis.
- Access site complications.
- Sepsis.
- Adverse drug reaction or drug intolerance.
- Renal impairment for observation of contrast induced nephropathy.
- Newly diagnosed diabetes mellitus.
- Other significant co-morbidity.
- Inadequate social circumstances.

Patients suitable for transfer to their local hospital will be identified as soon as possible, and notice given to the local hospital of the anticipated date of discharge. Local hospitals should commit to complete transfer as early as possible in order to free up beds in the PPCI centre for subsequent referrals.

Referral of patients to the local hospital will be made by the PPCI centre to the relevant personnel as per local hospital arrangement.

The patient will be provided with a discharge pack indicating diagnosis, pre-procedure ECG, the procedure undertaken (cath lab report), management plan, rehab information, out-patient follow up, medications and contact numbers for discussion in case of problems or concerns directly related to the admission.

The GP will receive a discharge summary, including medicines and medicine information sheet for drug titration.

The discharge summary will clearly indicate whether or not the patient has had a confirmed myocardial infarction (MI) and whether or not a pre-discharge echocardiogram (ECHO) was undertaken, as this will impact on the follow up care provided.

The nurse responsible for the patient's discharge home will fax a discharge summary to the local cardiac rehabilitation team and cardiology unit requesting appropriate follow-up from rehabilitation services and the cardiology department, according to local protocol.

The responsible nurse will go through the discharge pack with the patient pre-discharge.

Medication & Discharge Advice

Patients will receive therapy in accordance with NICE guidelines (May 2007) prior to discharge unless contraindicated.

- Aspirin (indefinite)
 - Aspirin 75mg daily for life
 - For patients with a history of dyspepsia or aspirin induced peptic ulceration consider using an H2 antagonist (Ranitidine) or a PPI (omeprazole)
- Second anti-platelet drug for 12 months. Local protocols should determine whether this is:
 - Clopidogrel 75 mg once daily
 - Prasugrel 10 mg once daily (5 mg if age > 75)
 - Ticagrelor 90 mg bd
- Beta blocker
 - Bisoprolol 2.5 – 5 mg daily or atenolol 25 – 100 mg daily
 - If prescribed for LV dysfunction, bisoprolol 1.25mg titrated up to 10mg if tolerated.
- ACE inhibitor or angiotensin II receptor blocker
 - Ramipril; dose 2.5mg once daily, up titrating as tolerated to 10mg once daily,
 - Do not routinely give angiotensin II receptor blockers unless the patient is intolerant or allergic to ACE-Inhibitors (ACEI).
 - Patients will need to have their renal function and potassium checked 1-2 weeks following commencement and at each dose increment.
- Statins and lipid lowering drugs
 - Simvastatin 40mg once daily, reduce to 20mg if not tolerated.

- LFT at baseline will be noted in discharge letter and should be checked at 6 weeks with repeat cholesterol
- Check serum creatine kinase in patients who develop muscle symptoms. This should not be checked routinely in asymptomatic patients.
- Antihypertensives
 - Target blood pressure should be 140/90mmHg or lower
 - For diabetic patients target blood pressure should be 130/80mmHg.
 - Only after titrating the dose of ACEI and beta blocker to the maximum tolerated should an additional anti-hypertensive be considered. Amlodipine may be a suitable agent in this situation.
- Sublingual nitrates
 - All patients on discharge will be issued with sublingual glyceryl trinitrate.
 - All patients will be instructed as to the appropriate use.

Cardiac Rehabilitation

Phase 1 Cardiac Rehabilitation

- Rehabilitation arrangements will be initiated prior to discharge.
- Phase 1 rehabilitation will be carried out during the HAC inpatient stay. This will be undertaken by the high dependency unit (HDU) ward nurse/cardiac rehab nurse.
- All patients will receive heart manual/leaflet covering basic information i.e. glyceryl trinitrate/chest pain guidance, driving, sexual guidance, risk factor modification etc.
- A patient held record will be started at this point. This will include the risk factor analysis, cardiac diagnosis, procedures undertaken, cholesterol results, blood pressure records, drugs etc. This will facilitate transition to their local DGH rehabilitation programme
- The patients may receive an educational DVD or video to take home and return by post. British Heart Foundation booklets will be given as necessary.
- The patient will be made aware of contact numbers for advice as needed.
- The nurse responsible for discharge will fax the rehabilitation referral and supporting patient information to the designated number for local rehab follow up to ensure that the patient has ongoing arrangements for rehabilitation.

Phase 1 Continued, Phase II and III Cardiac Rehabilitation

- This will occur in the patients' locality.
- For continuity the patient held record should be passed onto the next rehabilitation team by the patient. This will be completed as rehabilitation progresses and will remain in the patient's possession.

Follow-Up

All patients will have a clear follow-up plan at the time of discharge.

Upon discharge patients will be referred to the local district general hospital for medical review **and** to the local cardiac rehabilitation service for cardiac rehabilitation. An introduction to phase 1 rehabilitation will take place at the HAC pre-discharge.

A discharge pack will be provided to the patient and the referring hospital.

Data will be collected and exported to NICOR (National Institute for Cardiovascular Outcomes Research) via the British Cardiovascular Intervention Society (BCIS) and Myocardial Ischaemia National Audit Project (MINAP) databases on the last day of each month, no more than one month in arrears. This dataset is linked to the Office of National Statistics which will provide mortality information.

2.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in *Who Pays?: Establishing the responsible commissioner* and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges). *Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

The intention is to ensure close to 100% population coverage across England for adult patients experiencing an ST Segment Elevation Myocardial Infarction (STEMI) to receive access to primary PCI.

2.4 Any acceptance and exclusion criteria

Acceptance criteria

The service will accept referrals for patients who will meet one of the following criteria:

Symptoms compatible with a STEMI <12hrs duration from maximum chest pain **and** any of the following ECG criteria:

- ST segment elevation >1mm in 2 contiguous limb leads or >2mm in 2 contiguous chest leads.
- LBBB or paced rhythm if the clinical picture is acute myocardial infarction.
- Patients resuscitated from cardiac arrest with ECG criteria as above.

Excluded patients:

- Evidence of significant, active bleeding
- Paced ECG or Left Bundle Branch Block (LBBB) on ECG in a clinical picture not

- suggestive of acute myocardial infarction
- Cardiac arrest patients whose ECG does not show criteria for STEMI.

2.5 Interdependencies with other services

The majority of PPCI patients will arrive at PPCI Centres following assessment by paramedics. It is therefore essential that robust communication is in place with the Ambulance Service and that regular joint service review is undertaken. Since follow-up care will generally be provided within the patient's local area, it is also essential that robust discharge protocols are in place and that regular dialogue is had with district hospitals via existing clinical and managerial Cardiac Network facilitated groups.

Co-located services

Access to cardiac ITU or general ITU shall be available for those patients who are unconscious or who require ventilator support.

Interdependent services

Access to cardiac surgery, not necessarily on-site, shall be available for the small number of patients who have severe and diffuse coronary disease and who are stable enough to be considered for cardiac surgical referral. This will also apply to patients who have a mechanical complication of STEMI (acute ventricular septal defect, acute mitral regurgitation, partial left ventricular rupture).

Related services

Rehabilitation services (see above).

Expected numbers

This is an emergency service in which the providers have no ability to control the number of referrals. The expected number of referrals is 300 - 400 patients per million per annum.

3. Applicable Service Standards

CORE STANDARDS

Institutional facilities

- PPCI centres should operate 24 hours a day, 7 days a week, 365 days a year as per ESC guidance.
- A centre performing PPCI requires at least two cardiac catheterisation laboratories.

- PPCI centres should have contingencies (or Business Continuity Plans) to deal with rare occasions when the service has to be temporarily withdrawn (adverse weather, major power failure etc.)
- Full resuscitation facilities including a defibrillator, intra-aortic balloon counterpulsation, and an anaesthetic backup must be readily available in any catheterisation laboratory undertaking PPCI. Biochemistry, haematological, and blood transfusion laboratories should be immediately accessible.
- A dedicated multidisciplinary team comprising catheterization laboratory and recovery nurses, radiographers, and technicians will be in place.
- PPCI centres need appropriate support from other clinical disciplines, particularly anaesthetic and intensive care services.

Institutional volumes

PPCI centres should perform an absolute minimum of 100 PPCI patients per annum as per BCIS guidance.

Individual operator volumes

Current guidelines suggest that a minimum of 75 PCI procedures per operator per year is required to maintain competence as an independent operator—that is, one who can decide on PCI as appropriate management, plan the strategy, and perform the PCI.

RECOMMENDED STANDARDS

Institutional Volumes

In practice, most PPCI centre will treat 300 or more patients per annum.

3.1 Applicable national standards e.g. NICE, Royal College

- Department of Health (2008) Treatment of Heart Attack Final report of the National Infarct Angioplasty Report (NIAP)
- Department of Health (2000) National Service Framework for Coronary Heart Disease
- Department of Health (2006) Mending Hearts and Brains - Clinical case for change: Report by Professor Roger Boyle, National Director for Heart Disease and Stroke
- Royal College of Physicians (2009) Myocardial Ischaemia National Audit Programme (MINAP) How the NHS Manages Heart Attacks: Eighth Public Report 2009, Prepared on behalf of the MINAP Steering Group June 2009
- National Institute for Health and Clinical Excellence. MI: Secondary Prevention; secondary prevention in primary and secondary care for patients following a myocardial infarction. Quick Reference Guide (May 2007) 2007
- National roll-out of Primary PCI for patients with ST segment elevation

myocardial infarction:

- An interim report Gateway Reference: 14878
- How the NHS Cares for Patients with Heart Attack (MINAP 10TH Public Report)

4. Key Service Outcomes

Key outcomes

- The service is based on an accepted international and national evidence base
- The service will be sustainable and value for money
- Equity of access to the service across c England
- Delivers on the recommendations of “Evidence to Excellence”

Key service outcomes for a PPCI service are:

All patients experiencing a STEMI who fulfil the clinical inclusion criteria will be transported straight to a Heart Attack Centre (HAC) to receive a PPCI, (even if it is not their local /closest hospital) for treatment once the diagnosis of STEMI is confirmed/suspected.

The percentage of patients achieving a Call-to-balloon time of 150 minutes or less should be audited and will be 75% or greater.

To maximise the proportion of patients who achieve the “call to balloon time” target of 150 minutes, it is essential that patients are diagnosed correctly by Ambulance services and taken straight to a HAC, avoiding A&E and non-PPCI hospitals. The % of direct referrals from the ambulance service will be audited.

Door-to-balloon times will be audited. These will vary depending on the route of admission but will be less than 45 minutes for daytime presenters and for those patients about whom there has been advance warning (direct ambulance referrals and inter-hospital transfers).

Fibrinolysis will be available for the small number of patients who decline PPCI or who cannot have PPCI within an appropriate time-frame for whatever reason. If these patients fail to reperfuse with thrombolysis, then they will be referred for rescue PCI. Even if thrombolysis is successful, patients will still be considered for angiography and possible PCI, preferably within 24 hours.

All PPCI centres will submit their procedural and outcome data on-line to the BCIS database. The data will then be analysed at NICOR (National Institute for Clinical Outcomes Research). Analysis of submitted data will give PPCI centres information on their processes (Call-to-balloon time, door-to-balloon time etc.), their outcomes (mortality etc.) and whether any patient groups are under- represented in their

treated population (e.g. patients over the age of 80).

The Clinical Reference Group (CRG) strongly recommends that NHS England should establish formal contract arrangements with NICOR to provide procedural and outcome data, by named centre, for all centres performing PPCI

Interim for Adoption from 01/10/13