

Treatment of Heart Attack National Guidance

*Final Report of the National Infarct
Angioplasty Project (NIAP)*

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Angioplasty Project (NIAP)*

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Foreword



A year ago, Professor Lord Darzi in his Interim Report on the NHS Next Stage Review thought that we were beginning to lag behind other countries in treating heart attack patients with primary angioplasty (a technique for unblocking arteries carrying blood to the heart muscle used as the main or first treatment for patients suffering a heart attack). He commended the approach being taken by the National Infarct Angioplasty Project (NIAP) and highlighted the need to move quickly to put service improvements in place once the way forward had been identified.

The key to successful treatment for heart attack is short times to treatment. This report presents the findings of the NIAP feasibility study, which has considered different service models and geographies and has concluded that it is feasible to provide a primary angioplasty service in a variety of geographical settings within acceptably short treatment times.

In line with Professor Lord Darzi's view that we need a faster pace of change, we suggest a rapid expansion of this service.

Primary angioplasty or primary percutaneous coronary intervention or PPCI, as it is known within the NHS, has been proven to lead to better longer-term outcomes for patients suffering a heart attack, with less risk of having a stroke and less risk of having a further heart attack. It is important that we now roll out this clinically effective treatment for England.

I would like to thank all those involved with the pilots for their contributions to this study, in particular the patients and the staff who gave their views on heart attack treatment, those who collected all the data and those who have given their time to work in the project groups, without all of whom this study would not have been possible.

A handwritten signature in black ink that reads "Ann Keen". The signature is written in a cursive, flowing style.

Ann Keen
Parliamentary Under
Secretary of State for Health

Introduction



The *National Service Framework for Coronary Heart Disease* was published in March 2000. It set out the standards for treatment of heart attack and, over the last eight years, we have made enormous progress.

The NHS has met the target we set nationally to treat 68% of people suffering a heart attack with thrombolysis ('clot-busting' drugs) within 60 minutes of calling for help. In 2007/08, 71% were treated within this time frame. This has been a significant achievement, but it is time to move on if we are to ensure that patients benefit from the latest developments in treatment.

The success of the National Infarct Angioplasty Project in providing national data on which we can plan for the future is a testament to all those who have so freely given of their time and enthusiasm. It has now been demonstrated that it is both feasible and cost-effective to provide primary angioplasty as the main treatment for heart attack across the country. The challenge ahead is to ensure its speedy implementation so that all who can benefit from this treatment for heart attack do so.

A handwritten signature in black ink that reads "Roger Boyle".

Professor Roger Boyle
National Director for
Heart Disease and Stroke

A handwritten signature in black ink that reads "Huon Gray".

Dr Huon Gray
Former President of the British Cardiovascular Society
Consultant Cardiologist
Southampton University Hospital

Co-Chair, National Infarct Angioplasty Project Co-Chair, National Infarct Angioplasty Project

Executive summary

The National Infarct Angioplasty Project (NIAP) is an observational study set up by the Department of Health in collaboration with the British Cardiovascular Society and British Cardiovascular Intervention Society to test the feasibility of developing angioplasty services as the initial treatment for heart attack across England. These are known as primary angioplasty or, in full, primary percutaneous coronary intervention (PPCI) services.

This is the final report on the study. It draws conclusions from data from seven pilots and an independent evaluation of service models, patient experience, workforce and costs, and includes guidance which updates previous guidance on treatment of heart attack in the *National Service Framework for Coronary Heart Disease*.

This report is intended to encourage best practice and to inform commissioners, cardiac networks and service providers in their discussions on the configuration of acute services and to feed into the development of primary care trust (PCT) annual operating plans.

The key to successful outcomes in treating heart attack is short times to treatment. The longer the time to treatment, the more damage occurs to the heart muscle. The *National Service Framework for Coronary Heart Disease*, published in March 2000, set standards for time to treatment of heart attack based on a thrombolysis ('clot-busting' drugs) treatment strategy. Since then, there has been a growing body of evidence suggesting that PPCI delivers reduced mortality and better longer-term outcomes than thrombolysis, when both can be delivered in a similar timeframe. However, PPCI is more logistically challenging to deliver as it requires a cardiac catheter laboratory and highly trained staff to be available 24 hours a day, 7 days a week (24/7). It has therefore been identified as more appropriately provided in specialist centres.

Key findings from NIAP are as follows:

- PPCI can be delivered within acceptable treatment times in a variety of settings.
- The shortest times to treatment are achieved through direct admission to a cardiac catheter laboratory. Longer times to treatment are associated with a higher mortality rate.
- PPCI is more expensive to deliver than thrombolysis but is both clinically and cost-effective when delivered within 120 minutes of patient call for professional help.

- NIAP was not set up to compare PPCI and thrombolysis but it was noted that PPCI was associated with few complications, a low recurrence of heart attack, low incidence of stroke and a low mortality rate, which compared favourably with thrombolysis data published in clinical trials and registries.
- There was a high level of patient satisfaction with PPCI.
- Staff working in PPCI teams preferred starting with a 24/7 service at the outset rather than incremental change. There were some issues about differences in out-of-hours pay and conditions.

Overall conclusions are as follows:

- National roll-out of PPCI is feasible over the next three years but may be logistically challenging in some parts of the country.
- Times to treatment within 120 minutes are achievable but a PPCI service needs to achieve these reliably regardless of the time of day or day of the week.
- Hybrid services offering daytime PPCI and out-of-hours thrombolysis are not satisfactory.
- A PPCI service needs to be 24/7 and carried out in centres with a sufficiently high overall volume of cases to maintain and develop skills.
- If an acceptable PPCI service cannot be established, pre-hospital thrombolysis is preferable to in-hospital thrombolysis. Forthcoming European guidelines are likely to recommend subsequent referral for coronary angiography for anyone having thrombolysis.

Information for commissioners and cardiac networks in this report includes some planning assumptions, the key factors contributing to a high-quality service and examples of learning from some of the pilots.

Purpose and scope

1. This guidance examines the results of the National Infarct Angioplasty Project (NIAP) and, based on these findings and a review of recent clinical trial evidence, advises on best practice for the treatment of heart attack. This advice supersedes that given on the treatment of heart attacks in chapter three of the *National Service Framework for Coronary Heart Disease*,¹ published in March 2000. The National Institute for Health and Clinical Excellence (NICE) is currently preparing a guideline – *Acute coronary syndromes: the management of unstable angina and non-ST segment elevation myocardial infarction* – which will update the remainder of chapter three. This is due for completion in December 2009.

What is a heart attack?

2. A heart attack is said to have occurred when the myocardium (heart muscle) is damaged as a result of impaired blood supply. This is known as a myocardial infarction. The amount of damage is greatest when the blood supply to part of the heart is cut off altogether as a result of a thrombus (blood clot formation) within one of the coronary arteries (blood vessels) supplying that area of the heart. Under these circumstances, the electrocardiogram (ECG) recorded after the onset of occlusion will usually show an abnormality termed 'ST elevation'. Patients suffering from this condition are said to have sustained 'ST elevation myocardial infarction', abbreviated to STEMI. This guidance covers the management of STEMI. Non-ST elevation myocardial infarction or NSTEMI is the subject of the NICE guideline.

The purpose of NIAP

3. NIAP is an observational study set up by the Department of Health in collaboration with the British Cardiovascular Society (BCS) and British Cardiovascular Intervention Society (BCIS) to test the feasibility of developing angioplasty services as the initial treatment for STEMI across England. Data from seven pilots (ten centres) were collected from April 2005 to March 2006. Patients recruited to the study in that year were then followed up for a further year to March 2007. Details of the study design, pilots and findings from the hospital admission data were outlined in the *NIAP Interim Report*, published in February 2008. This guidance focuses more on the follow-up data and draws overall conclusions from the whole study.

¹ Department of Health (2000) *National Service Framework for Coronary Heart Disease*. Available on Department of Health website at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4094275

4. The School of Health and Related Research and the Institute of Work Psychology at the University of Sheffield were commissioned by the National Institute for Health Research NHS Service Delivery and Organisation Programme to undertake an independent evaluation of the pilot sites to determine the feasibility and acceptability to patients and carers of angioplasty for treatment of STEMI, to evaluate the different ways services could be organised, to investigate the organisational barriers to implementing these services and associated workforce issues and, finally, to estimate the cost-effectiveness of these services in practice.
5. Findings from the evaluation report² have been taken into account in the advice given in this guidance. The evaluation report is being published on the National Institute for Health Research's Service and Delivery Organisation programme website (www.sdo.nihr.ac.uk/sdo1202006.html) on 20 October 2008.
6. This guidance is intended to encourage best practice and to inform commissioners, cardiac networks and service providers in their discussions on the configuration of acute services, which will feed into development of PCT annual operating plans.

² Goodacre S, Sampson FC, Carter A, Wailoo AJ, O'Cathain A, Wood S, Capewell S and Campbell S and *Evaluation of the National Infarct Angioplasty Project*. Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation Research and Development (NCCSDO).

Background and context

The clinical context

How is a STEMI treated?

7. Because the mechanism underlying occlusion of the coronary artery is the formation of a thrombus (blood clot), attention was first directed towards various drugs which have the ability to dissolve clots, termed thrombolytic agents. In the late 1980s and through the 1990s these agents became widely prescribed, mainly by hospital staff once the patient had been admitted to hospital. Not surprisingly, these agents increase the risk of bleeding and have also been shown to cause some strokes. However, this risk is outweighed by the benefits of improved survival following the heart attack. Some patients are unsuitable for thrombolysis, for instance because they are at higher risk of bleeding; in those who are suitable for thrombolysis, in approximately 20% to 30% of cases the artery fails to reopen following treatment.

The importance of time to treatment

8. Following the publication of numerous trials, it was shown that the outcome for patients with STEMI was closely related to the length of time that the coronary artery was occluded, and the completeness of restoration of blood flow achieved with treatment; the longer the duration of occlusion, or the more incomplete the restoration of blood flow, the greater the damage to the heart muscle and the worse the patient's outcome. This prompted the investigation of two alternative treatment options. The first involved the use of thrombolytic agents, but given before the patient arrives in hospital, known as pre-hospital thrombolysis (PHT), with the drug usually administered by trained paramedics. This results in earlier administration of the agents and a better outcome for patients. The second involved a more mechanical approach to the problem. By inserting a catheter (tube) into the body, via a peripheral artery in the groin or wrist, a balloon catheter is passed down the coronary artery and the occlusion unblocked, usually with the additional insertion of a stent (a cylindrical metallic mesh) to hold the affected area open. This technique is termed primary angioplasty, or to give it its full name, primary percutaneous coronary intervention or PPCI.

National policy and progress to date

9. At the time of publication of the *National Service Framework for Coronary Heart Disease* in March 2000, the number of patients in whom PPCI had been tried was relatively small and so the clinical and financial consequences were not certain enough to commend it as a routine method for treating STEMI.

- 10.** Chapter three of the National Service Framework therefore concentrated on a thrombolytic treatment strategy for heart attack and, to secure an improvement in patient outcomes, set out a standard that people thought to be suffering from heart attack should be assessed professionally and given thrombolysis within 60 minutes of them calling for professional help. Progress towards this standard was supported by investment in the roll-out of PHT. In 2001, £10 million was made available through the New Opportunities Fund for the purchase of 12-lead ECG machines for ambulances. A further £14 million per annum was invested from 2002/03 to complete the equipping of ambulances with ECG machines and for telemetry, training of paramedics and thrombolytic drugs. Provision of thrombolysis in accident and emergency departments led to significant improvement in times to treatment in the first few years after the National Service Framework. More gradual progress has been achieved since then with the increase in PHT. Progress has been closely monitored by the Department of Health and driven by performance indicators set by the Healthcare Commission. In 2007/08, 71%³ of people who received thrombolysis for heart attack in England did so within 60 minutes compared with 24%⁴ at the time of publication of the National Service Framework. In 2007, 22%³ of patients treated with thrombolysis received it before arriving at hospital.
- 11.** The use of PPCI for treating heart attack has, however, continued to develop in England. The first limited services started to be offered in a small number of cardiac centres by about 2002. In June 2003, the Prime Minister's Delivery Unit conducted a review of national policy for treatment of heart attack. In the light of the experience from these centres and the expanding evidence from clinical trials, the Prime Minister's Delivery Unit recommended that the Department of Health develop a clear policy for expanding PPCI and draw conclusions on the advisability and feasibility of a national roll-out of this service. NIAP was set up to inform this policy with £1 million provided to develop a dataset and to support data collection and analysis at a number of pilot sites. PPCI services have continued to expand during NIAP. In 2007/08, 25% of all STEMI patients had a PPCI.⁵

³ Myocardial Ischaemia National Audit Project (MINAP) (2008) *How the NHS Manages Heart Attacks. Seventh Public Report*. Available at:

www.rcplondon.ac.uk/clinical-standards/organisation/partnership/Documents/Minap%202008.pdf

⁴ Department of Health (2003) *Review of Early Thrombolysis*. Available at:

www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008531

⁵ Data from MINAP 2007 and BCIS.

PHT and PPCI – a summary of conclusions from the evidence to date

- 12.** Broadly speaking, while PHT has the advantage that it can be administered earlier than PPCI, the latter results in more reliable opening of the artery with a lower risk of stroke and of the artery re-blocking over the next few hours or days. Also, as mentioned above, not all patients are suitable for thrombolysis and, for those who are treated in this way, some of the occluded arteries fail to reopen. Some of those whose arteries fail to open following thrombolysis may subsequently be treated by angioplasty, which in this setting (following thrombolysis) is termed rescue PCI. Logistically it is more difficult to undertake PPCI than deliver thrombolysis because it requires in-hospital treatment with the use of technically specialised equipment (a cardiac catheter laboratory) and highly trained staff. It is worth noting however, that it can take between 30 to 90 minutes for a thrombolytic agent to achieve reperfusion.
- 13.** Many international trials have been undertaken comparing thrombolytic agents with PPCI, with the main conclusions being as follows:

 - PPCI reduces mortality and improves longer-term outcome compared with thrombolysis when both treatments can be undertaken within a similar timeframe.
 - The advantage of PPCI over thrombolysis decreases with increasing delay in undertaking the procedure. While much debate still surrounds this issue, it is suggested that the benefit of PPCI may be lost, or considerably reduced, if it takes more than 90 minutes longer to undertake the procedure than it would to administer a thrombolytic drug.
 - More patients are potentially suitable for PPCI than thrombolysis, 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.

The need for specialist centres

14. As evidence of the longer-term benefits of PPCI has been steadily growing, Professor Boyle, National Director for Heart Disease and Stroke, set out the clinical case for developing these services in his paper, *Mending Hearts and Brains*,⁶ published in December 2006. He acknowledged, however, that not every hospital would be able to provide this service as it requires a cardiac catheter laboratory and highly trained staff to be available 24/7. PPCI has therefore been identified as one of those services more appropriately provided in a specialist centre.
15. As part of Lord Darzi's NHS Next Stage Review, each strategic health authority (SHA) published a vision during May and June 2008 for improving health and healthcare in its region over the next ten years. These visions were based on the work of over 2,000 clinicians and stakeholders who looked at the evidence for improving care along eight different pathways including acute care. The visions set out the arguments for creating specialised centres for heart attack in order to deliver better outcomes and a world-class service. PCTs are now taking forward the recommendations in the visions through commissioning and operating plans. Lord Darzi's final report, *High Quality Care for All*,⁷ published in June 2008, refers to the need to improve access to the most clinically and cost-effective treatments as one way of improving service quality. NIAP has examined service delivery in detail in some existing specialised centres and the next section reports on these findings.

⁶ Boyle R and Department of Health (2006) *Mending Hearts and Brains*. Available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063282

⁷ Darzi A (2008) *High Quality Care for All*. Available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085825

Findings from NIAP

16. Following the Prime Minister's Delivery Unit recommendation, the Department of Health sought the support of the BCS and the BCIS to establish a study to test the feasibility of rolling out PPCI as the main treatment for heart attack in England and NIAP was established. Patients were recruited in seven pilots (ten sites) over a one-year period (2005/06) and followed up for one year thereafter.
17. The NIAP Interim Report was published in February 2008 and gave details of the study's design, pilot sites, the in-hospital outcome for patients recruited and initial findings.⁸ These initial findings fed into Lord Darzi's Next Stage Review final report, *High Quality Care for All*. The main conclusions in the NIAP Interim Report were that:
 - the development of primary angioplasty services is feasible in a variety of geographical settings;
 - establishing a primary angioplasty service requires a multidisciplinary approach and good communication between all stakeholders; and
 - acceptable treatment (call-to-balloon) times are achievable by direct or indirect admission to the primary angioplasty centre but the ideal is undoubtedly direct admission to the catheter laboratory at the primary angioplasty centre.
18. This final report updates the NIAP Interim Report and includes new data relating to the one-year follow-up of recruited patients, and the findings of the independent evaluation carried out by the School of Health and Related Research and the Institute of Work Psychology at the University of Sheffield. It should be stressed that this was an observational feasibility study and not a randomised controlled trial. It was therefore not designed to be a direct comparison between the efficacy of thrombolysis and PPCI.

One-year follow-up (a fuller version of findings from one-year follow-up data is provided in Annex B)

19. A total of 2,245 patients were recruited into NIAP during the year April 2005 to March 2006, 65% of whom were admitted directly to a PPCI centre and 35% to a centre not providing PPCI services. Of the one-third of all patients who were

⁸ Department of Health (2008) *National Infarct Angioplasty Project (NIAP) Interim report*. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083061

admitted to a centre not undertaking PPCI, 58% were transferred to a PPCI centre and underwent PPCI.

- 20.** Pilot sites were developing their services during the study period and initially not all provided PPCI 24/7. At times when PPCI could not be undertaken, thrombolysis was used as the alternative treatment, and data were collected on these patients. Data on patients receiving thrombolysis within this study were compared with the large registry of patients recorded in the Myocardial Ischaemia National Audit Project (MINAP)⁹ database and supported the conclusion that the thrombolysis cohort of patients in the study was representative.
- 21.** The time taken for PPCI to be delivered was measured as the time from the patient calling for professional help to the time when PPCI was delivered (known as ‘call-to-balloon’ or CTB time). The length of time from arrival at hospital to the delivery of PPCI (‘door-to-balloon or DTB’ time) was also measured. Where patients were admitted to a non-PPCI centre and then transferred to a PPCI centre, the ‘door’ time was taken as arrival in the first admitting hospital.

Findings for PPCI patients

- 22.** It took longer for the procedure to be undertaken if the patient was initially admitted to a non-PPCI centre and then transferred than if direct admission to the catheter laboratory in the PPCI centre occurred. Those patients admitted directly to a PPCI centre, but assessed first in that hospital’s accident and emergency department, had longer CTB times than those admitted directly to the catheter laboratory (see Table 1).

Table 1	Median CTB time (minutes)
Transfer	159
Direct (via accident and emergency)	140
Direct to catheter laboratory	86

⁹ MINAP (2008) *How the NHS Manages Heart Attacks. Seventh Public Report.*
Available at: www.rcplondon.ac.uk/clinical-standards/organisation/partnership/Documents/Minap%202008.pdf

- 23.** Of those patients admitted directly to the catheter laboratory in a PPCI centre, 98% achieved a DTB time of less than 90 minutes, which is a target time set in some international guidelines.

Lower mortality rate in PPCI patients

- 24.** Overall, in-hospital mortality for all the patients undergoing PPCI was 5.2%. For those given thrombolysis it was 7.1%. While this is not directly comparable, as NIAP was not set up to compare PCI and thrombolysis, this mortality in the thrombolysed patients is the same as the rate recorded nationally for all patients receiving thrombolysis in the MINAP database over the same time period.
- 25.** Patients were tracked by NHS number using the Office for National Statistics, allowing mortality during follow-up to be assessed (see Table 2).

Table 2 – Mortality (%)

Method of treatment	30 days	1 year	18 months
PPCI	5.6	8.7	9.9
Thrombolysis	7.9	12.4	14.8

Effects of time to treatment

- 26.** Analysis of CTB times in relation to patient follow-up data showed that:
- mortality at all time periods (in-hospital, 30 days, one year) was lower when CTB times were shorter;
 - mortality during follow-up was noted for all CTB times except the cohort with CTB times under an hour in whom there was no later mortality (3.3% at one year); and
 - at one year, the mortality for those with longer CTB increased (see Table 3) and most noticeably diverged when the CTB time was greater than 120 minutes.

Table 3 – Mortality (%)

CTB Time	In-hospital	30 days	1 year
60–120 minutes	2.7	2.9	5.1
120–180 minutes	4.5	4.9	8.7
Greater than 180 minutes	11.4	12.2	15.9

The effect of patient delay in calling for help

- 27.** For patients with short delays (time from symptom onset to arrival in hospital of less than 60 minutes), the mortality was 3.0% at hospital discharge and 6.1% at 18 months. For those with long delays (more than six hours), rates were 5.9% and 14.9% respectively. Thus, delay is associated with increased mortality and this association is even more pronounced later, presumably due to the cumulative adverse effects of greater heart damage over time. This highlights the importance of patients seeking help as early as possible if they suspect a heart attack; early defibrillation by ambulance crews can also avoid death from ventricular fibrillation caused by heart attack.

Routes of admission

- 28.** Patients having PPCI who were admitted directly to the catheter laboratory, bypassing accident and emergency departments or wards, had the lowest mortality rates of all the routes of admission (in-hospital mortality was 3.5%; 18-month mortality, 7.0%). Patients assessed first in the accident and emergency department within a PPCI hospital not only had longer times to treatment but this was associated with higher mortality rates (6.0% and 11.8% respectively).

Complications following treatment

- 29.** Complications were low for patients receiving PPCI. The overall in-hospital stroke rate was 0.8% for PPCI patients and 1.3% for those receiving thrombolysis. The overall in-hospital rate of major bleeding was 3.5% in the PPCI group and 6.2% in those receiving thrombolysis.

Length of hospital stay

- 30.** The median length of hospital stay for all groups increased with age but was lower for each age cohort for PPCI patients (three to five days) compared with those

receiving thrombolysis (five to nine days). This effect of age was also found for patients in the MINAP database.

Findings from the independent evaluation undertaken by the University of Sheffield

31. Additional sites from centres historically providing a thrombolysis service (control sites) were recruited by the University of Sheffield in order to increase the number of thrombolysis patients in the evaluation (see report at www.sdo.nihr.ac.uk/sdo1202006.html).

Patients and carers

32. A survey and interviews were conducted with patients and their carers to assess their views of care. It was found that:
 - there was overall a high level of satisfaction with both treatment options (PPCI and thrombolysis);
 - patients rated time waited and the efficiency of treatment with a PPCI service more highly than the thrombolysis sites;
 - carers had concerns when travel to a PPCI centre, distant to their own local hospital, was required because of the distance and problems with parking etc. However, they accepted this requirement in the context of the clinical circumstances and the potential for better treatment; and
 - satisfaction levels were lower than they were for treatment by PPCI or thrombolysis, with respect to discharge planning, aftercare advice and services, and arrangements for cardiac rehabilitation. Some patients felt that the process was so fast that insufficient time was allowed to reflect on events and discuss next steps.

Workforce implications

33. Interviews, focus groups and a questionnaire survey were conducted with staff involved in the delivery of a PPCI service. The observations and conclusions of the researchers included the following:
 - Simple pathways with direct access to a catheter laboratory were recommended, supported by good team working across professional boundaries. The performance of these needs to be regularly audited.

- All stakeholders (ambulance services, hospital departments, managers, commissioners) need to be engaged to optimise service delivery. Clinical leadership and managerial support are essential.
- Staff interviewed expressed a preference for embarking on a 24/7 service from the outset, rather than a process of incremental change through lesser degrees of on-call commitment.
- Differential pay and rest for comparable staff groups working out-of-hours was identified as a source of disharmony. Researchers recommended that pay and conditions were harmonised for staff groups working out-of-hours so that a sense of team responsibility was fostered and grievances avoided.
- Given the complexity of work undertaken by PPCI teams, their need for ongoing training and multi-tasking capabilities was emphasised.
- There was a potential for the emphasis on emergency care to jeopardise other services such as elective work, initiation of rehabilitation etc.

Economic analysis

34. This took account of both in-hospital and follow-up costs incurred by patients undergoing PPCI and those receiving thrombolysis. It was concluded that:

- a PPCI service is more expensive than thrombolysis care but is likely (about a 90% probability) to be a cost-effective use of NHS resources by NICE criteria;
- systems based on direct access to the catheter laboratory are almost certain (95% probability) to be cost-effective, whereas systems based on access via accident and emergency departments, coronary care units or other wards are less certain (about a 75% probability) to be cost-effective; and
- transfer of patients from a non-PPCI hospital to a PPCI hospital with the time delays seen in the NIAP is unlikely to be cost-effective (about a 38% probability).

Overall conclusion and policy direction

- 35.** NIAP was established after randomised controlled trials had confirmed the superiority of PPCI over thrombolysis as a treatment option for STEMI, a conclusion that had already been translated into clinical guidelines from the European Society of Cardiology¹⁰ and from the American College of Cardiology and American Heart Association.¹¹ It was an observational study intended to assess the feasibility of rolling out PPCI services across England. It was not a randomised trial directly comparing the efficacy of PPCI and thrombolysis, although data from both treatment options were used to assess the experiences of patients and their carers, examine NHS workforce implications and make an economic assessment.
- 36.** From the analyses undertaken and consideration of evidence from clinical trials and international guidelines, the following conclusions have been drawn:
- NIAP has clearly demonstrated that acceptably short times to treatment (CTB and DTB times) can be achieved by PPCI delivered in a variety of geographical settings, and supports data from randomised trials and registries that have shown increasing mortality as times to treatment lengthen.
 - If a PPCI strategy is adopted then CTB times within 120 minutes and DTB times within 90 minutes ought to be achievable, and need to be regularly audited to confirm their achievement. The shortest times are achieved by direct admission to the catheter laboratory in a PPCI centre and this is the optimum pathway.
 - Mobilisation of catheter laboratory staff can be accelerated by ambulance crews alerting the PPCI team of the patient's impending arrival at the hospital using a single point of contact and may be assisted by tele-transmission of the ECG.
 - In the absence of the overnight residency of catheter laboratory staff, it is inevitable that times to treatment will be slightly longer if staff have to be called in. The CTB and DTB times above still need to be achieved irrespective of the time of day or day of the week a patient presents. It is important that a chosen treatment strategy for an agreed catchment population can be reliably implemented. Hybrid services which offer PPCI at some times and thrombolysis at other times are unsatisfactory for a number of reasons:

¹⁰ The Task Force on the Management of Acute Myocardial Infarction of the European Society of Cardiology, Van de Werf F, Ardissino D et al. (2003) Management of acute myocardial infarction in patients presenting with ST-segment elevation. *Eur Heart J* 24(1): 28–66.

¹¹ Antman EM, Hand M, Armstrong PW et al. (2008) 2007 focused update of the ACC/AHA 2004 Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction. *J Am Coll Cardiol* 2008; 51: 210–247.

- If PPCI is regarded as a superior treatment and can be offered in a timely manner then it is unsatisfactory to offer a sub-optimal treatment simply based on the time of day or the day of the week. The imminent revised guidelines of the European Society of Cardiology recommend that all centres undertaking PPCI provide this service 24/7,¹² which US guidelines also support.
- Patient pathways work best when they are consistent and when all involved with the delivery of care know what is required of them. Hybrid services (daytime PPCI and out-of-hours thrombolysis) increase the risk of confusion (for instance, between ambulance and hospital teams) and risk greater delays and worse outcomes.
- For PPCI services to work optimally, it is important that all working on their delivery gain as much experience as possible. Patients need to be treated by those regularly undertaking the procedure. Centres undertaking PPCI need to be assured of a sufficient number of cases to maintain and increase their skills.
- The risk of undertaking PPCI in STEMI patients, who may be very sick, is considerably higher than for elective PCI cases. In-hospital mortality for PPCI for STEMI can range from 2% to 40% depending on the severity of the clinical presentation, whereas the average for elective cases is less than 1%. There is evidence from a number of reports that outcome is affected by the number of procedures undertaken by a PCI centre (the greater the experience, the better the outcome). Intuitively this is not unexpected and has underpinned previous recommendations in BCIS/BCS guidelines¹³ regarding the overall number of PCI procedures a centre should be undertaking (between 200 and 400 per annum). More recent registry data have shown that this relationship between volume and outcome is most marked for patients undergoing PCI for myocardial infarction.¹⁴

¹² Professor Frans Van de Werf (Chair of Guideline Committee). Personal communication (September 2008).

¹³ Joint Working Group on Percutaneous Coronary Intervention of the British Cardiovascular Intervention Society and the British Cardiac Society (2005). Percutaneous coronary intervention: recommendations for good practice and training. *Heart* 91: vi1–vi27.

¹⁴ Zahn R et al. (2008) Volume outcome relation for contemporary percutaneous coronary interventions (PCI) in daily clinical practice: is it limited to high-risk patients? Results from the Registry of percutaneous coronary interventions of the Arbeitsgemeinschaft Leitende Kardiologische Krankenhausärzte (ALKK). *Heart* 94: 329–35.

- PPCI centres need appropriate support from other clinical disciplines, particularly anaesthetic and cardiac intensive care services, because patients with STEMI often have other co-morbidities, which requires a multidisciplinary approach to management. BCIS/BCS guidelines have outlined the facilities required for cardiac catheter laboratories undertaking PCI.
- If an acceptable PPCI service cannot be established, for whatever reason (but particularly if geographical factors make transport times too long), pre-hospital thrombolysis as the alternative reperfusion strategy is preferable to in-hospital thrombolysis. Local ambulance services often work in partnership with air ambulance charities, which could help to provide appropriate access to PPCI services. However, patients will not benefit from the substitution of a poor PPCI service as replacement for an existing good pre-hospital thrombolysis programme. When thrombolysis is given, forthcoming guidelines from the European Society of Cardiology recommend subsequent referral for coronary angiography. This is just as important for patients for whom reperfusion is successful as for those for whom it is not.
- In line with the final report of the NHS Next Stage Review *High Quality Care for All*, which refers to the need to improve access to the most clinically and cost-effective treatments and suggests an accelerated pace of change, it is envisaged that a move to a PPCI-dominated treatment strategy for England is feasible over the next three years.

37. In summary:

National roll-out of PPCI services is feasible but may be logistically challenging in some parts of the country.

Acceptable performance measures for a PPCI service are CTB times within 120 minutes **and** DTB times within 90 minutes.

For a variety of reasons, a 24/7 PPCI service is likely to lead to best outcomes.

If an acceptable PPCI service cannot be established because, for example, journey times are too long, pre-hospital thrombolysis is preferable to in-hospital thrombolysis.

Where thrombolysis is given, subsequent referral for coronary angiography is indicated and this will be recommended in forthcoming European guidelines.

It is feasible that a PPCI treatment strategy for the majority of England can be achieved within three years.

Commissioning a PPCI service

- 38.** World-class commissioning is about delivering better health and wellbeing for the population, improving health outcomes and reducing health inequalities. Implementation of this guidance will deliver better outcomes for people suffering a heart attack (STEMI) and reduce inequality of access to quality services. A great deal of work has been undertaken already to plan for the roll-out of PPCI services following on from the publication of the SHA visions for improving health and healthcare in each region as part of the NHS Next Stage Review. The following information is provided to assist in this process. Cardiac networks have an important role in mapping existing services, developing modernisation proposals and advising commissioners on optimum service models. (An example of network facilitation to achieve a PPCI strategy is provided in Annex C.)

Some planning assumptions

- 39.** The incidence of STEMI nationally has fallen by 12% between 2003 and 2007 (MINAP data) possibly linked to reduction in smoking and better treatments preventing recurrence. While it is difficult to predict the future trend, it is reasonable to assume that the number STEMIs will continue to reduce, taking into account the impact of the smoking legislation in 2007 and increasing awareness of obesity and lifestyle factors associated with cardiovascular disease. Implementation of *Healthy Weight, Healthy Lives*, launched earlier in 2008,¹⁵ and the launch of Vascular Checks¹⁶ and the Reduce your Risk campaign in 2009 will also have an impact.
- 40.** In 2007, it is estimated that there were about 25,500 STEMIs, of which 78% had reperfusion (either thrombolysis or PPCI). Assuming that 7.5% will be unsuitable for thrombolysis but could have PPCI, and that about 25% of reperfusion is already PPCI, then just over 16,000 additional people will potentially be eligible for PPCI in future at a national level. This number is likely to reduce over time.
- 41.** The ratio of STEMI to NSTEMI patients is currently about 40/60. There is no definite trend to suggest a reduction in numbers of NSTEMI patients and so a reasonable planning assumption is that these numbers will stay about the same. Patients with NSTEMI are less likely to need a PCI out of hours.

¹⁵ Department of Health (2008) *Healthy Weight, Healthy Lives: A cross-government strategy for England*. Available on Department of Health website at:

www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082378

¹⁶ See: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083822

42. It is important that commissioners and cardiac networks calculate at an early stage of planning the likely volumes of STEMI cases and NSTEMI cases when considering how PPCI services should be configured.
43. The potential for improved outcomes, as well as the optimum use of resources, will prompt identification of centres that are able to sustain adequate volumes of PPCI procedures, taking into account the declining number of STEMIs. The planned 2009 revision of the BCIS/BCS guidelines on PCI will address the evidence related to volumes and outcome in PPCI and recommend a specific minimum if appropriate. As a planning guide, it is worth noting that pilot sites in NIAP which provided a 24/7 service throughout the year of data collection undertook 168 – 241 (mean 196) PPCI procedures in the year of data collection.
44. Different models will be possible provided that within the agreed catchment area there is a joint understanding of the pathway for out-of-hours treatment and that estimates suggest safe volumes will be achieved for each planned centre. Based on findings from the pilots, the split between out-of-hours and daytime work is about 60/40 (daytime is taken as weekdays 8.00 to 18.00 and out of hours 18.00 to 8.00 and weekends).

The time factor

45. The overriding objective in establishing a treatment strategy for STEMI patients should be to achieve coronary reperfusion as quickly as possible. If PPCI services can achieve acceptable reperfusion times (120 minutes CTB, and 90 minutes DTB), then PPCI is the preferred treatment option. An example of improving DTB times is provided in Annex C.
46. In the absence of overnight residency of catheter laboratory staff, it is inevitable that times to treatment will be slightly longer if staff have to be called in. Nevertheless, it is important that the chosen treatment strategy for a catchment population can be reliably implemented at all times.

Arrangements for self-presenters and those already in hospital

47. Around 82% of all patients presenting with a STEMI will activate the emergency services (MINAP data) and can thereafter be managed by the agreed treatment protocol adopted by these services. However, the remaining 18%, which includes those patients self-presenting or those who have a heart attack while already in hospital for some other reason (this applies to both hospitals with a PPCI service and those without), will need clear pathways for rapid activation of ambulance and local PPCI services where appropriate. It is suggested that local protocols are set to include these patients. There may be a need for case-by-case discussion with the PPCI centres. For these patients, the following factors will influence the choice of treatment strategy:

- an assessment of the speed with which PPCI could be delivered if transfer to another hospital were required;
- the speed with which thrombolysis could be administered (assuming no contraindication to its use); and
- the likely duration of existing myocardial ischaemia.

48. The last factor is relevant because rates of reperfusion with thrombolysis decline significantly when an artery has been occluded for more than three hours. Under these circumstances, a slightly longer transfer time for PPCI may be considered the preferred option. Alternatively, there may be merit in considering thrombolysis and immediate transfer to a PPCI centre so that either rescue PCI or early scheduled angiography (and appropriate revascularisation) can be considered. Clear protocols need to be established locally to guide decision-making.

Other factors

49. In planning a PPCI strategy for their patients, cardiac networks need to ensure that all stakeholders are involved in the planning and implementation stages (particularly commissioners, the emergency services and accident and emergency department teams). Stakeholders will need carefully to consider the implications of PPCI with respect to:

- staffing:
 - the need for a reasonable balance between day/night work and weekend working;

- harmonised out-of-hours pay and conditions;
- the potential for staff migration to other hospitals with cardiac catheter laboratories but who have either much less onerous out-of-hours responsibilities, or no on-call requirement at all. Such a migration can jeopardise the viability of PPCI services, but is less likely to occur if staff out-of-hours pay and conditions of service are properly addressed;
- training (initial and continuing);
- clinical and managerial leadership (an example of the importance of clinical leadership is provided in Annex C);
- impact on other services. The greater volume of work undertaken outside normal working hours with larger catchment areas represents a shift from existing practices, and a formalised 24/7 service represents a different level of clinical commitment than is required for historic ‘on-call’ purposes. These changes need to be assessed carefully, and their impact on existing services quantified, as part of the business planning process;
- the impact on staff and their workload in non-PPCI hospitals and whether this involves any new training requirements in hospitals which are bypassed;
- discharge planning, aftercare services and access to cardiac rehabilitation programmes;
- the development and dissemination of clear clinical protocols;
- ensuring regular audit of performance (particularly CTB and DTB times) and taking part in national audit (MINAP and BCIS); and
- the sustainability of safe volumes of PPCI work over time.

50. From April 2008, all acute NHS trusts are required to use the Standard NHS Contract for acute services for their agreements with PCTs. This includes a requirement not to discriminate between patients on the grounds of gender, age, ethnicity, disability, religion, sexual orientation or any other non-medical characteristics and to provide appropriate assistance for patients who do not speak, read or write English or who have communication difficulties. Commissioners and providers will need to take into account the equality impact of a PPCI treatment strategy in planning and delivery, both in terms of patient access to services but also in terms of the impact on staff. For example, introducing PPCI services may increase

out-of-hours working for allied health professionals and, as these professions have proportionately more women, commissioners may need to consider equality issues. Commissioners will require a monthly equality report.

51. Key factors contributing to a high-quality PPCI service include the following.¹⁷

Teamwork

- A consistent, clear and optimum reperfusion pathway exists 24/7 for all STEMI patients, wherever their presentation, including for self-presenters and people already in a hospital.
- Joint understanding between acute and ambulance trusts is needed about any areas in the catchment (using time and/or geographical criteria) where transfer for PPCI may not be the best treatment option.
- Clear communication channels exist between any feeder hospitals and PPCI centres.
- Ambulance crews pre-alert the PPCI centre of patient's impending arrival and the catheter laboratory team is immediately mobilised.

Timing

- Early alert by patients is encouraged.
- There is rapid admission direct to the PPCI catheter laboratory.
- There are CTB times of less than 120 minutes.
- There are DTB times of less than 90 minutes.

PPCI centres

- There is clear clinical and managerial leadership.
- Adequate volumes of procedures are carried out to ensure skills development for the whole team.

¹⁷ These have been based on findings from the independent evaluation undertaken by the University of Sheffield: Goodacre S, Sampson FC, Carter A et al. (2008) *Evaluation of the National Infarct Angioplasty Project*. Report for the National Coordinating Centre for NHS Service Delivery and Organisation Research and Development (NCCSDO).

- There is agreed support from other clinical disciplines (anaesthetics, cardiac intensive care etc).
- Staffing levels take account of the increased out-of-hours workload and likely effect on next day working.
- There is a gatekeeper (daytime and out-of-hours) to activate the process at the PPCI centre.
- There are clearly defined roles for catheter laboratory team members.
- Specialist training for team members undertaking PPCI is provided.
- Regular training opportunities for staff, including training for non-PPCI centre staff in acute care following PPCI, are provided.
- There are agreed arrangements post-procedure for transfer to non-PPCI centres for recovery, where required.
- All patients following PPCI have access to cardiac rehabilitation services.

Review of the heart attack pathway

- All times (symptom to balloon, CTB, DTB) to reperfusion for PPCI are monitored, audited and shared with all stakeholders.
- The accuracy of ambulance diagnosis and appropriateness of PPCI referral are monitored.
- Lengths of stay are reviewed.
- Discharge planning and uptake of rehabilitation are reviewed.
- PPCI centres and ambulance services participate in national audit and clinical trials
- There is active cross boundary working between acute and ambulance service trusts.
- Stakeholder relationships along the heart attack pathway are maintained.

Monitoring – development of audit and indicators

- 52.** During the last 18 months, discussions have been taking place between audit leads for MINAP and the BCIS angioplasty audit to ensure that appropriate data fields are in place to enable analysis of the effectiveness of PPCI services.
- 53.** Discussions have also taken place with the Healthcare Commission to develop a performance indicator for PPCI similar to the ‘call-to-needle’ indicator for treatment with thrombolysis. For 2008/09, there are two indicators relevant to PPCI (time to reperfusion and participation in cardiac audits). These encourage the audit of PPCI and prepare the way for the introduction of a revised performance indicator in 2009/10 on time to reperfusion, which will measure both thrombolysis and PPCI. Further details are available at:
www.healthcarecommission.org.uk/ahcperformanceindicators2008-2009.cfm
- 54.** As part of the implementation of the NHS Next Stage Review final report, *High Quality Care for All*, work is in progress to develop a set of clinical quality indicators that will allow clinicians to benchmark their organisation against other acute trusts. Feeding into this, a number of indicators, including those above and a new measure of the extent of 24/7 PPCI services, are being consulted on this autumn.

National support for implementation

- 55.** The main support for implementation will be through NHS Improvement. This will be in the form of a series of themed national meetings; there will also be web-based resources, publications and bespoke support for cardiac networks and for SHAs. Recent appointments to the NHS Improvement Heart Improvement Team have included a national clinical lead and a national improvement lead focused on reperfusion to support cardiac networks embarking on service changes. Contact details and further information are available on the NHS Improvement website at: <http://www.improvement.nhs.uk/heart/?TabId=66>
- 56.** Work is ongoing to develop web-based data-entry systems for both the MINAP and BCIS audits, which will enable better linking of the audits and avoid the duplication of data recording currently encountered. This is due to be rolled out after piloting from December 2008.
- 57.** Web-based systems to support inter-hospital transfers will be further developed and expanded and will provide an additional tool to support delivery of these datasets for all acute coronary syndromes. NHS Improvement has appointed a national clinical lead to take this work forward. Contact details are available at: <http://www.improvement.nhs.uk/heart/?TabId=63>

Research output from NIAP

- 58.** NIAP involved data collection on 2,245 patients who were followed up for a year. There is therefore a wealth of data available on treatment. In order to make full use of this valuable resource, a time-limited Academic Group has been set up to explore research topics and prepare papers, which will be submitted for publication within the next two years. One of the themes that will be further explored by the Academic Group is the impact of a PPCI strategy on different ethnic groups. Membership is shown in Annex D.

Annex A – Glossary

Acute coronary syndrome (ACS): a clinical condition, usually a combination of chest pain and other features, which occurs as a result of abrupt impairment or cessation of blood flow to the heart. The subtypes of ACS include unstable angina, and two forms of myocardial infarction (heart attack), in which the heart muscle is damaged as a consequence of the impairment of blood flow. Damage is indicated by a rise in cardiac enzymes, as measured on a blood sample. The two types of myocardial infarction are named according to the appearance of the electrocardiogram as ST segment elevation myocardial infarction (STEMI) and non-ST segment elevation myocardial infarction (NSTEMI).

Acute myocardial infarction (AMI): a heart attack – death of some heart muscle (myocardium) which follows a sudden reduction in or cessation of blood flow down a coronary artery due to narrowing or blockage, and confirmed by the presence of elevated cardiac enzymes on a blood sample.

(Coronary) angiogram/angiography: a procedure in which a fine catheter (tube) is inserted via a peripheral artery and manipulated by the operator such that the tip of the catheter engages the origins of the coronary arteries, which run over the surface of the heart. X-ray opaque dye is then injected into the coronary arteries to obtain an X-ray image of their anatomy and to assess the presence of any coronary narrowing (atheroma).

Angioplasty: a procedure in which a small balloon on the end of a catheter is inserted into a coronary artery and inflated to widen a narrowed artery. This is usually associated with the additional insertion of a coronary stent (see below).

British Cardiovascular Intervention Society (BCIS): an affiliated group of the British Cardiovascular Society with specialist interest in interventional cardiology. It has been active in the development of guidelines and making recommendations on various aspects of the practice of interventional cardiology and in supporting research. BCIS has audited interventional activity in the UK each year.

British Cardiovascular Society (BCS): the national body representing healthcare professionals working in cardiovascular medicine, and whose remit includes the promotion of education, training, research and the setting of standards in this field.

Call-to-balloon (CTB) time: the time from the patient calling for medical help to the time when an angioplasty balloon is first inflated, or coronary reperfusion is confirmed on angiography.

Call-to-needle (CTN) time: the time from the patient calling for medical help to the time when intravenous thrombolysis is given.

Cardiac catheter/catheterisation: A long, narrow tube (catheter) which, when passed through the veins or arteries into a heart cavity or associated blood vessels, is used for measuring pressures or injecting X-ray opaque dye for outlining the heart and blood vessels.

Cardiac catheterisation laboratory (cath lab): the X-ray laboratory in which an angiogram/angioplasty is performed.

Central Cardiac Audit Database (CCAD): the repository for all the national cardiac audits, most of which are part of the National Clinical Audit Support Programme (NCASP). The database has been in existence since 1996. The following heart disease audits are being run: adult cardiac interventions, cardiac rhythm management, adult cardiac surgery service, ambulance outcomes, cardiac rehabilitation, congenital heart disease, heart failure, infarct angioplasty and myocardial infarction. Each audit offers reliable information to help health professionals continually measure and improve care by comparing their work to specific standards and national trends.

Coronary heart disease (CHD): narrowing or blockage of the coronary arteries by the fatty material termed atheroma, which may lead to angina, coronary thrombosis or heart attack, heart failure and/or sudden death.

Defibrillation: use of an instrument for delivering an electric shock in an attempt to terminate ventricular fibrillation.

Door-to-balloon (DTB) time: the time from the patient arriving in hospital (whether this be a PPCI centre or a non-PPCI centre) to the time when an angioplasty balloon is first inflated or coronary reperfusion is confirmed on angiography.

Door-to-needle (DTN) time: the time from the patient arriving in hospital to the time when intravenous thrombolysis is given.

Electrocardiogram (ECG): a recording of the heart's electrical activity obtained from electrodes positioned on the chest wall and limbs.

Infarction/reinfarction: death of tissue following interruption of the blood supply. A recurrence of this condition is termed reinfarction. Myocardial infarction is associated with a rise in cardiac enzymes, as measured on a blood sample.

Myocardial Ischaemia Audit Project (MINAP): a project that began in late 1998 when a broadly based steering group developed a dataset for acute myocardial infarction. This

allowed clinicians to examine the management of myocardial infarction within their hospitals against targets specified by the *National Service Framework for Coronary Heart Disease*. Initially the project focused on the hospital management of ST elevation acute myocardial infarction but the dataset has been expanded to cover other acute coronary syndromes, the introduction of pre-hospital thrombolysis and PPCI. MINAP is one of the audits in the CCAD.

Percutaneous coronary intervention (PCI): encompasses a variety of procedures used to treat patients with diseased coronary arteries caused by a build-up of cholesterol, inflammatory material and scar tissue in the walls of arteries (referred to as plaque or atheroma) which can reduce blood flow. When plaque becomes ‘unstable’ and initiates blood clot formation within a coronary artery, the artery can become abruptly occluded, causing a heart attack (myocardial infarction – see above). Typically, PCI is performed by threading a slender balloon-tipped tube – a catheter – from an artery in the groin or wrist to a trouble spot in an artery of the heart (this is referred to as percutaneous transluminal coronary angioplasty – also known as PTCA, coronary artery balloon dilatation or balloon angioplasty).

Pre-hospital thrombolysis (PHT): intravenous thrombolysis treatment given before the patient’s arrival at hospital, usually by paramedics.

Primary PCI (PPCI) or primary angioplasty: refers to PCI being the first treatment to restore coronary blood supply in cases of heart attack.

Reperfusion: the restoration of blood flow to an organ or tissue, for example after a heart attack. An immediate goal is quickly to open a blocked artery and reperfuse the affected heart muscle. Early reperfusion minimises the extent of heart muscle damage and preserves the pumping function of the heart.

Revascularisation: a procedure to improve the blood supply. In the case of coronary heart disease, this includes PCI and coronary artery bypass graft (an open heart operation in which blockages to the coronary arteries are bypassed by grafting on a length of artery or vein to bring a fresh blood supply to the heart muscle).

SDO: the National Institute for Health Research Service Delivery and Organisation (SDO) Programme was established in 1999 to consolidate and develop the evidence base on the organisation, management and delivery of health services, and to promote the uptake and application of that evidence in policy and practice. The philosophy of the SDO Programme is to commission research on six enduring themes running through the organisation and delivery of health services, with the aim of developing coherent ‘bodies of knowledge’

around these themes. NIAP has been evaluated as part of the programme on evaluating models of service delivery and organisation.

ST segment elevation: elevation in the ST segment of an electrocardiogram trace, indicating ischaemic (loss of blood supply) damage to heart muscle, abbreviated to STEMI.

STEMI: a heart attack is said to have occurred when the myocardium (heart muscle) is damaged as a result of impaired blood supply. This is known as a myocardial infarction. The amount of damage is greatest when the blood supply to part of the heart is cut off altogether as a result of a thrombus (blood clot formation) within one of the coronary arteries (blood vessels) supplying that area of the heart. Under these circumstances, the electrocardiogram recorded after the onset of occlusion will usually show an abnormality termed ST elevation, and patients suffering from this condition are said to have sustained ST elevation myocardial infarction, abbreviated to STEMI.

Stent: A metallic (usually stainless steel) tube with a meshwork design that in its compressed state lies on the outside of an angioplasty balloon (see above). Once placed across a coronary narrowing, the balloon is inflated and the stent therefore deployed within the artery. The balloon is then deflated and removed, leaving the stent in place and acting as a 'support' for the wall of the artery, keeping it open and of maximum diameter, thereby improving blood flow. Stents have been shown to improve the results of angioplasty procedures over simple balloon dilatation alone. Many newer stents are also coated with drugs which can improve still further the long-term results of these procedures.

Stroke: a 'brain attack' caused by a sudden disturbance of a blood vessel in the brain. There are two types. **Ischaemic stroke**, the most common form, is caused by narrowing or blocking of blood vessels leading to death of brain cells. An **embolic stroke** is a type of ischaemic stroke which occurs when a blood clot travels from a remote site (for example, the heart, aorta or carotid arteries) to the neck or brain, blocking a blood vessel and causing damage to the dependent area of brain tissue. Embolic strokes may result from heart disease or heart operations and occur rapidly, often without preceding warning signs.

Haemorrhagic strokes are caused by rupture of a blood vessel producing bleeding into the brain and consequent damage.

Thrombolytic drugs/thrombolysis: the dissolving (lysis) of blood clots with thrombolytic drugs.

Ventricular fibrillation: very fast electrical activity of the main chambers (ventricles) of the heart resulting in loss of its pumping action; a variety of 'cardiac arrest'.

Annex B – Results of analysis of NIAP one-year follow-up data

1. A total of 2,245 patients were recruited into the National Infarct Angioplasty Project (NIAP) during the year April 2005 to March 2006, 65% of whom were admitted directly to a primary percutaneous coronary intervention (PPCI) centre and 35% to a centre not providing PPCI services. The study involved all patients admitted with STEMI (ST segment elevation myocardial infarction) over the recruitment period. The average (median) age for males was 61 years (range 25 to 104 years) and for females was 72 years (range 34 to 100 years).
2. Pilot sites were developing their services during the study period and initially not all provided PPCI 24/7. At times when PPCI could not be undertaken, thrombolysis was used as the alternative treatment, and data were collected on these patients, as well as those considered unsuitable for any reperfusion therapy. It should be stressed that this was an observational feasibility study and not a randomised controlled trial. It was therefore not designed to be a direct comparison between thrombolysis and PPCI; the reason for collecting data on all patients, irrespective of their reperfusion strategy, was as an attempt to ensure that the PPCI population was not unduly selected and that therefore the conclusions drawn could reasonably be extrapolated more widely within the NHS (in England). The inclusion of very elderly patients who were excluded from the randomised controlled trials attests to the unselected nature of this study. Also, comparison of patients receiving thrombolysis within this study with the large registry of patients recorded in the Myocardial Ischaemia Audit Project (MINAP) database supported the conclusion that the thrombolysis cohort was also representative.

Patient pathways

3. Of the one-third of all patients who were admitted to a centre not undertaking PPCI (795), 58% were transferred to a PPCI centre and underwent PPCI, 29% were given thrombolysis and 13% received no reperfusion treatment. Of the two-thirds who were admitted directly to a PPCI centre (1,450), 69% underwent PPCI, 16% received thrombolysis and 15% had no reperfusion therapy. Subsequent analyses were undertaken both for the treatment received by patients (PPCI or thrombolysis) and their admission pathway (i.e. whether they were admitted directly to a PPCI centre or to a non-PPCI centre). The time taken for reperfusion treatment (thrombolysis or PPCI) to be delivered was measured as the time from the patient calling for help to the time when thrombolysis (call-to-needle or CTN time) or PPCI (call-to-balloon or CTB time) was delivered. For patients undergoing PPCI, an assessment was also made of the length of time it took from arrival at hospital to the delivery of PPCI (door-to-balloon or DTB time). Where patients were admitted to a non-PPCI centre

and were then transferred to a PPCI centre, the ‘door’ time was taken as arrival in the first admitting hospital.

PPCI patients

- For those patients undergoing PPCI (1,460), it took longer for the procedure to be undertaken if the patient was initially admitted to a non-PPCI centre and then transferred (median CTB time 159 minutes) than if direct admission to the catheter laboratory in the PPCI centre occurred (median CTB time 86 minutes). Those patients admitted directly to a PPCI centre, but assessed first in that hospital’s accident and emergency department before being taken to the catheter laboratory, had longer CTB times (median 140 minutes) than those taken directly to the laboratory (see Table 1).

Table 1	Median CTB time (minutes)
Transfer	159
Direct (via accident and emergency)	140
Direct to catheter laboratory	86

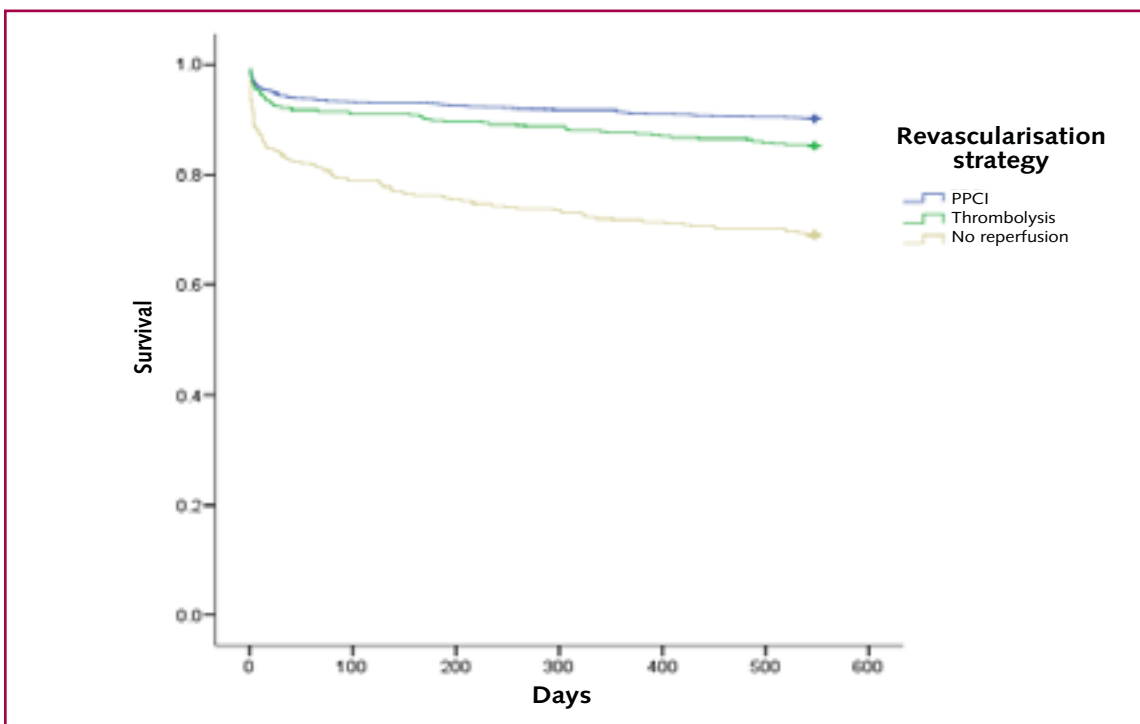
- Of those patients admitted directly to the catheter laboratory in a PPCI centre (who represent those with the fastest access to PPCI), 98% achieved a DTB time of less than 90 minutes (a target time set in some guidelines).

Lower mortality rate in PPCI patients

- Overall in-hospital mortality for the whole cohort of patients undergoing PPCI was 5.2%. For those given thrombolysis it was 7.1%, which is identical to the mortality rate recorded for all patients receiving thrombolysis in the MINAP database over the same time period.
- As noted in all clinical trials, those who had no reperfusion therapy had a much higher mortality (17%). The reasons for no reperfusion therapy being given include, for example, the presence of contraindications and co-morbidities, patient refusal, late presentation etc.
- Patients were tracked by NHS number using the Office for National Statistics, allowing mortality during follow-up to be assessed (Table 2 and Figure 1).

Table 2 – Mortality (%)

Method of treatment	30 days	1 year	18 months
PPCI	5.6	8.7	9.9
Thrombolysis	7.9	12.4	14.8
No reperfusion	16.4	28.3	31.0

Figure 1: NIAP 18-month mortality

Note: 1.0 = 100%

9. As expected, further deaths were encountered during the 18-month follow-up in all groups but were lowest in the PPCI patients.

Effects of time to reperfusion

10. When those patients undergoing PPCI were analysed with respect to the length of time taken for PPCI to be delivered (CTB time), the findings confirmed previous research.

11. Mortality at all time periods (in-hospital, 30 days, one year) was lower when CTB times were shorter.
12. Additional mortality during follow-up was noted for all CTB times except the cohort with very short (less than one hour) CTB times in which there was no later mortality (3.3% mortality). At one year, the mortality for those with longer CTB times was increased (see Table 3) and most noticeably diverged when CTB time was greater than 120 minutes.

Table 3 – Mortality (%)

CTB time	In-hospital	30 days	1 year
60–120 minutes	2.7	2.9	5.1
120–180 minutes	4.5	4.9	8.7
Greater than 180 minutes	11.4	12.2	15.9

13. Two groups of patients were also analysed to assess the association between patient delay in calling for help and mortality. For those with short delays (time from symptom onset to arrival in hospital of less than 60 minutes), the mortality was 3.0% at hospital discharge and 6.1% at 18 months. For those with long delays (over six hours), mortality rates were 5.9% and 14.9% respectively. Thus, the association between delay and mortality is even more pronounced at later time points, presumably due to the cumulative adverse effects of greater heart damage (heart failure, rhythm disturbances) over time.

Routes of admission

14. As noted, mortality was higher in those patients undergoing PPCI who were admitted initially to a non-PPCI hospital. When those patients admitted directly to a PPCI hospital were analysed by route of admission, mortality was found to be lowest in those admitted straight to the catheter laboratory, bypassing emergency departments or wards (in-hospital mortality, 3.5%; 18-month mortality, 7.0%). Patients who were assessed in accident and emergency departments within PPCI centres and then taken to the catheter laboratory had in-hospital and 18-month mortality rates of 6.0% and 11.8% respectively.

Complications

15. The overall in-hospital stroke rate was 0.8% for PPCI patients and 1.3% for those receiving thrombolysis. The overall in-hospital rate of major bleeding was 3.5% in the PPCI group and 6.2% in those receiving thrombolysis.

Length of hospital stay

16. The median length of hospital stay for all groups increased with age but was lower for each age cohort for PPCI patients (three to five days) compared with those receiving thrombolysis (five to nine days). This effect of age was also found for patients in the national MINAP database.

Annex C – Learning from experience – some examples from the pilots

The importance of clinical leadership

Clinical leadership has been key to the success of PPCI at James Cook University Hospital, Middlesbrough. Adopting a holistic approach to the patient journey has meant that all key stakeholders involved with providing services were engaged during the business planning phase thereby ensuring that whole processes of the patient journey were captured. Leadership from both non-medical and medical healthcare professionals has meant that those individuals involved in service development at a practice level have been able to influence the process from the outset. Continued two-way communication between clinical leaders and those clinical staff who actually provide the service remains important since the process of establishing such a service will be evolutionary and change over time. It is useful to feedback data to the team providing the service as this highlights achievements/successes and identifies areas where changes need to be implemented.

Improving 'door-to-balloon' times

At Harefield Hospital, one of the key elements in delivering a sub-30-minute door-to-balloon time for PPCI was to eliminate any delays between the hospital entrance and the cardiac catheter laboratory. Ambulance crews are met at the hospital entrance by the cardiology team, and there is a single 'trolley push' direct to the catheter laboratory table. Critically there are no additional triage steps, no 'holding' periods in other clinical areas and no transfers between trolleys and beds other than from the ambulance trolley to the catheter laboratory table.

The role of the cardiac networks in North East England in facilitating the implementation of PPCI

The James Cook University Hospital in Middlesbrough, a NIAP pilot site, successfully provided PPCI for the local population of Middlesbrough, Redcar and adjacent areas of North Yorkshire. This showed a robust PPCI service was sustainable and could deliver a reduction in 30-day STEMI mortality for local PCTs. Consequently, there was a strong desire to build on the success of the South Tees 24/7 all-comers' programme and roll out to surrounding districts. However, the North East SHA was unhappy to endorse proceeding directly with a roll-out of PPCI to the next adjacent localities because of the perceived injustice that would be suffered by areas further afield not provided with PPCI, i.e. a step-wise roll-out would inevitably exacerbate inequity.

The North East SHA therefore tasked the Coast-to-Coast Cardiac Network and the Northern Network of Cardiac Care to agree a combined approach to scoping and

implementing a delivery plan for PPCI across the whole SHA. This required the development of a plan for two provider sites – the existing service at the James Cook University Hospital, Middlesbrough and a new service at the Freeman Hospital, Newcastle. From the outset, it was clear that the commissioners and the North East Ambulance Service were not able to support any change until a plan for universal provision of PPCI could be launched so that any inequity would only be temporary.

The two directors of the cardiac networks appointed a service improvement manager, to lead the process for the two networks alongside two clinical champions.

The seemingly gargantuan task was boiled down to finding acceptable answers to five key questions.

1. What are the patient pathways associated with implementation of PPCI?
2. What is the appropriate Payment by Results structure for funding these pathways?
3. What are the additional ambulance services required to support these pathways?
4. What is the knock-on impact to non-PPCI units of moving to PPCI?
5. What are the commissioning impacts for all PCTs and acute trusts in the region, including:
 - the one-off consequence of commissioning change; and
 - the sustained revenue consequence and impact on system-wide viability?

The networks arranged many meetings with the key stakeholders to hammer out the details of the answers to these questions. Additionally the networks developed a plan for communication with the local authority overview and scrutiny officers and a plan for a clear and joint patient/public engagement.

Consequently, there emerged an SHA-wide plan for implementation of PPCI.

Roll-out programme

District General Hospital	Commencement date of PPCI
James Cook University Hospital	01/04/03
Friarage Hospital	01/05/07
University Hospital of Hartlepool	02/01/08
University Hospital of North Tees	02/01/08
Newcastle General Hospital	31/03/08
Royal Victoria Infirmary	31/03/08
Bishop Auckland General Hospital	01/05/08
Darlington Memorial Hospital	01/05/08
Queen Elizabeth Hospital	01/05/08
South Tyneside Hospital	01/05/08
Sunderland Royal Hospital	01/05/08
University Hospital of North Durham	01/05/08
Berwick Infirmary	01/07/08
Hexham General Hospital	01/07/08
North Tyneside General Hospital	01/07/08
Wansbeck General Hospital	01/07/08

Annex D – Membership of the NIAP Academic Group

Mark de Belder (Chair)	President of BCIS; Consultant Cardiologist, James Cook University Hospital, Chair of NIAP Data Oversight Group
Huon Gray	Former President of BCS; Consultant Cardiologist, Southampton University Hospital; Co-Chair, NIAP
Roger Boyle	National Director for Heart Disease and Stroke; Co-Chair, NIAP
Tony Gershlick	Consultant Cardiologist, University Hospitals of Leicester NHS Trust; NIAP Steering Group member
Adam Timmis	Professor of Clinical Cardiology at the London Chest Hospital; Chair of the Academic Group of MINAP
Jim McLenachan	Consultant Cardiologist and Clinical Director, Leeds Teaching Hospitals NHS Trust; National Clinical Lead on Reperfusion, NHS Improvement
David Cunningham	Heart Disease Senior Manager, CCAD
John Birkhead	Clinical Director, MINAP
Steve Goodacre	Professor of Emergency Medicine, School of Health and Related Research, University of Sheffield; Chief Investigator for the NIAP evaluation
Sue Dodd	Vascular Programme, Department of Health; NIAP Project Manager



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