# **Research**Summary

NHS National Institute for Health Research



# Evaluation of the National Infarct Angioplasty Project

Primary angioplasty is a specialist emergency treatment for patients with a heart attack. The National Infarct Angioplasty Project (NIAP) was undertaken to test the feasibility of providing primary angioplasty in the NHS. This study evaluated the models of service delivery, the workforce and organisational issues, the patient and carer experience and the costeffectiveness of primary angioplasty in the National Infarct Angioplasty Project.

This research summary, based on research led by Professor Steve Goodacre at the University of Sheffield, commissioned by NIHR Service Delivery and Organisation Programme (SDO), reports on the evaluation of the National Infarct Angioplasty Project.

It is for commissioners and managers of acute cardiac services; cardiologists, cardiac nurses and cardiac technicians; managers and clinicians responsible for emergency services; and patients with, or at risk of, coronary heart disease.

#### **Key findings**

- Primary angioplasty was feasible and most likely to be effective when patients were transferred directly to angioplasty facilities.
- Primary angioplasty was more expensive than thrombolysisbased care but appeared to represent a cost-effective use of NHS resources for patients taken directly to an angioplasty centre.
- Patients and carers reported high levels of confidence in treatment with angioplasty and satisfaction with the speed and efficiency of care, although they had concerns about discharge and aftercare.

- Establishing the full primary angioplasty service from the start appeared to work better than incremental expansion.
- Staff pay and conditions need to be harmonised before commencing the service to ensure that team members receive similar rewards and rest after out-of-hours working.



### Background



Acute ST-elevation myocardial infarction is a type of heart attack in which a coronary artery is blocked by a blood clot. Treatment involves removing the blockage to restore blood flow to the heart. Clot-busting drugs (thrombolysis) are a cheap, simple and effective treatment that can be provided in all acute hospitals and most ambulance services. Primary angioplasty, where a balloon catheter is used to restore blood flow, may be a better treatment than thrombolysis.

Trials have shown that primary angioplasty reduces the risk of death, further heart attack, stroke and the need for heart surgery compared to thrombolysis. However, primary angioplasty is a complex procedure delivered by skilled staff using specialist facilities in a catheter laboratory. The effectiveness of primary angioplasty decreases if treatment is delayed. If primary angioplasty is not given within 90 minutes of the time when thrombolysis could have been given then it may be less effective than promptly delivered thrombolysis. Primary angioplasty is also likely to be more expensive than thrombolysis, although a shorter hospital stay may offset some of the additional costs. Even if it is more expensive angioplasty may be worthwhile if enough lives are saved and complications reduced.

The effectiveness and cost-effectiveness of primary angioplasty clearly depend upon the way services are organised, but little is known about how organisational factors affect implementation of primary angioplasty. Providing the service can present substantial demands upon the workforce who are required to provide specialist emergency care, often out of working hours. There has also been little research into what patients and their carers think about treatment options.

To address these issues the Prime Minister's Delivery Unit asked the Department of Health "Heart Team" in 2003 to develop a clear policy for expanding primary angioplasty and to draw conclusions on the advisability of a national rollout of the service. As a result the National Infarct Angioplasty Project (NIAP) was established. Ten hospitals were selected to provide a primary angioplasty service for patients with heart attack and collect data from all patients with ST- elevation heart attack treated at these hospitals between 1st April 2005 and 31st March 2006. These data are reported in the NIAP Final Report (Treatment of Heart Attack, National Guidance: Final Report of the National Infarct Angioplasty Project, Department of Health, 2008.)

We aimed to evaluate the implementation of primary angioplasty in the NIAP project. Our specific aims were:

- To describe the different systems used to deliver primary angioplasty at the NIAP hospitals, such as the referral networks, transfer and access arrangements for patients, the staffing available and facilities used.
- To explore the feasibility of providing primary angioplasty by examining the processes involved in setting up the service, identifying facilitating factors and barriers, and assessing the implications for cardiac and emergency services.
- To assess the effect of providing primary angioplasty upon the specialist team, support staff, and related staff groups.
- To gain an in depth understanding of the patient and carer experience of primary angioplasty, and measure satisfaction in hospitals providing angioplasty and those providing thrombolysis-based care.
- To compare the costs and outcomes of providing angioplasty and thrombolysis-based care, and estimate the cost-effectiveness of angioplasty compared to thrombolysis-based care.



# **Practical** findings

All ten hospitals in the NIAP study implemented a primary angioplasty service, although not all established a 24 hour a day, 7 day per week service. The hospitals varied in size, configuration, infrastructure, referral routes and activity levels. Over the year of the evaluation they treated a total 2072 patients with a heart attack (71% male, aged 24 to 104), of whom 70% were admitted directly to a hospital with angioplasty facilities and 30% were transferred from another hospital. These figures differ slightly from the NIAP Final Report because we excluded patients receiving thrombolysis-based care at Dryburn Hospital, Durham and instead report them in the control group of our economic evaluation.

The average (median) time delay between the patient calling for help and angioplasty successfully restoring blood flow to the heart depended upon the route of access into the service. The shortest average time delay was 87 minutes among patients taken straight to the catheter laboratory at a hospital with angioplasty facilities. Longer average time delays of 132 minutes and 140 minutes respectively were recorded among patients arriving via the coronary care unit and among those arriving via the emergency department. Patients who initially went to a hospital without angioplasty facilities and then had to be transferred to an angioplasty centre had an average time delay of 161 minutes.

These time delays suggest that compared to thrombolysis angioplasty was likely to have benefited patients taken directly to hospitals with angioplasty facilities, but may not have benefited those delayed by being transferred from another hospital.

## Findings from the organisational and workforce evaluation

The evaluation of organisational and workforce factors found that establishing the full 24-hour primary angioplasty service from the start appeared to work better than gradual expansion. This was because gradual expansion led to progressively increasing demands upon the staff responsible for providing the service. On a related issue, failure to harmonise staff pay and conditions before commencing the service meant that different staff groups received different rewards and rest periods after out-of-hours working. This created the potential for conflict among staff providing out-of-hours care.

Primary angioplasty is a complex procedure that has to be delivered quickly and efficiently, often at inconvenient times of the day. The angioplasty team therefore needed to work in a flexible, multi-skilled manner and be prepared to take on tasks that were traditionally undertaken by other professionals. Ongoing training was required to develop their experience and maintain confidence and skills.

Successful delivery of primary angioplasty required simple direct access to the catheter laboratory for patients and good teamworking between staff working across professional boundaries. Appointing a specified "gatekeeper" who was responsible for receiving referrals and ensuring rapid access to the catheter laboratory could assist direct access to the angioplasty service. Regular audit of the efficiency of the pathway helped to find solutions to blockages that reduce the capacity of the system.



Although a relatively small team of specialists working in the catheter laboratory actually delivered primary angioplasty, successful operation required the cooperation of a variety of other professional groups. Building and maintaining relationships with key stakeholders in the acute care system helped to ensure service development and sustainability. In this respect the support of senior management for the service was an important factor, as was having a senior figure as a champion of angioplasty service development. A dedicated manager could help to control resources and balance elective and emergency use of the catheter laboratory. This individual should not have clinical responsibilities and should be proactive to motivate and sustain service development.

Development of primary angioplasty may have been associated with knock-on effects upon elective services and particularly upon rehabilitation. The relatively short length of stay for patients after angioplasty can lead to the role of rehabilitation and follow-up being neglected.

## Findings from the patient and carer satisfaction evaluation

Patients and carers generally reported high levels of satisfaction at both the NIAP hospitals and at "control" hospitals providing standard, thrombolysis-based care. Overall satisfaction with care was higher among patients attending the NIAP hospitals with 78% of patients and 63% of carers rated their care as excellent compared to 71% and 55% respectively at control hospitals.

"The way I was treated by the staff from the cleaner to the doctors was excellent and if private care is better then I would like to see it."

"In these days when too many people are quick to criticise the NHS I have nothing but admiration and praise for the care, professional ability and humanity shown to me and my family by all staff involved."

Patients were particularly impressed by the speed and the efficiency of treatment at NIAP hospitals, with 80% rating the time waited for treatment and 83% rating the efficiency of treatment as excellent, compared to 67% and 74% respectively at control hospitals. These findings were reflected in comments made by patients attending NIAP hospitals:

"This for me was the NHS working at it's very best. From the 999 call to coming out of surgery took 3.5 hours."

# *"I mean the whole beauty about this situation was how it was done. The efficiency was unbelievable. The speed and efficiency was unbelievable."*

Patients reported lower satisfaction with their involvement in decisions about treatment at both NIAP and control sites, with 37% and 32% respectively rating it as excellent and around 1 in 12 patients rating it as fair or poor. Patients often could not recall the consent process fully as they were feeling too ill and anxious at the time. However, they understood the gravity of having a heart attack sufficiently to want to be treated immediately.

#### "Well I mean at this point when you're in agony with pain etc, you're happy to do whatever they say aren't you? If a man said "you've got to have this done or you'll die", you do it, don't you?"

There was some evidence that carers were less satisfied with the convenience of visiting NIAP hospitals, with 28% rating convenience as fair or poor compared with 8% at control hospitals. Carers expressed some concerns about travelling longer distances to visit patients but this was accepted in the context of providing the best patient care.

In general patients at both NIAP and control hospitals were less satisfied about discharge arrangements, aftercare and rehabilitation. One particular aspect of care, the information given on how to manage the condition in future, was rated lower among patients attending NIAP hospitals, with only 38% rating care as excellent compared to 46% at the control hospitals.

"When I was in the CCU the care was excellent, when moved, care went downhill. After care was nonexisting. I was told by the staff that the cardiac nurse would contact me. Never happened. No visit. No advice apart from see your GP."

"There was not enough time to inform me about medication etc as the ambulance was waiting to take me back to (hospital)."

Overall, it therefore appears that primary angioplasty is acceptable to patients and carers and provides a more satisfactory experience than thrombolysis-based care. Patients were impressed by the speed and efficiency of the service and confident in the treatment. Concerns were expressed about shortcomings in discharge arrangements and aftercare however.

#### Findings from the economic evaluation

The economic evaluation compared costs and anticipated outcomes of the patients attending the ten NIAP hospitals providing angioplasty-based care to 919 patients attending control hospitals providing standard thrombolysis-based care over the same time period. Patients at the NIAP sites were more likely to receive primary angioplasty than thrombolysis (67% versus 16%), whereas patients at the control sites were more likely to receive thrombolysis (73% versus 4%). A proportion of patients at both types of hospital received neither angioplasty nor thrombolysis.

Patients receiving primary angioplasty spent less time in hospital on average than those receiving thrombolysis, whether they went to a NIAP hospital or a control hospital. The average length of hospital stay for patients receiving primary angioplasty was 5.7 days at NIAP hospitals and 4.4 at control hospitals, compared to 8.4 and 6.9 days respectively for patients receiving thrombolysis. Since more patients at NIAP hospitals received primary angioplasty the average length of stay for all patients at NIAP hospitals (6.6 days) was shorter than control hospitals (7.3 days).

The average cost of treatment, from first call for help to hospital discharge, was £3,509 for patients receiving thrombolysis at control sites, £4,361 for patients receiving thrombolysis at NIAP sites, and £5,176 for patients receiving primary angioplasty at NIAP sites. There was not sufficient information to calculate the cost of primary angioplasty at control sites so we assumed that this was the same as the cost measured at the NIAP sites. Patients receiving no treatment had a similar average cost at NIAP sites (£3,394) and control sites (£3,353).

The main contribution to the cost of treatment was related to the hospital stay, although staff, catheter laboratory and consumable costs all contributed significantly to the costs of patients receiving primary angioplasty at NIAP hospitals.

Costs after the initial treatment episode were estimated by modelling the expected long-term costs of treating people with heart disease. Taking into account the long-term costs of care the average cost of treating each patient in the NIAP angioplasty based system was £11,500, compared to £10,700 in the control thrombolysis based system. So an angioplasty based system is likely to cost the NHS about £800 per patient more than a thrombolysis based system.

To determine whether this is a worthwhile use of NHS resources we used modelling techniques to estimate the number of lives saved by providing angioplasty-based care instead of thrombolysis-based care, and then estimated the number of qualityadjusted life years (QALYs) that would be gained by providing angioplasty-based care. Because time delays before treatment are crucial in determining the effectiveness of treatment we used time delay data recorded from patients at NIAP and control hospitals to estimate the effect of both systems of care on time delays and thus lives saved.

The model showed that patients treated in an angioplasty-based system could expect an average of 6.58 quality-adjusted life years after treatment, compared to 6.40 among those receiving thrombolysisbased care. On this basis we estimated that it would cost £4,520 to gain each additional guality-adjusted life year by providing angioplasty-based care instead of thrombolysis-based care.



#### **Components of total episode cost**

## Conclusions

The National Institute of Health and Clinical Excellence usually recommend that interventions should be funded if they cost the NHS less than £20,000 for each quality-adjusted life year gained. Our analysis showed that it was very likely (about 90% probable) that angioplasty-based care, as practiced at NIAP hospitals, would be considered a cost-effective use of NHS resources despite costing more than thrombolysisbased care.

The economic analysis also showed that the most important factor in determining cost-effectiveness of angioplasty-based systems for heart attack care was the time delay that occurred before treatment. Time delays were shortest when patients bypassed the Emergency Department and Coronary Care Unit and went straight to the catheter laboratory. In these circumstances angioplasty-based care was almost certain to be costeffective (more than 95% probable). On the other hand, time delays were prolonged when patients initially attended a hospital without angioplasty facilities and were then transferred to an angioplasty centre. As a result this system may have been less effective than providing thrombolysis-based care and would be unlikely to be considered cost-effective.

#### Limitations of this evaluation

Both the economic evaluation and the patient and carer evaluation involved comparing groups of patients that were not randomly allocated to one form of care or another. This means that there could have been differences between the two groups of patients that may have been responsible for the differences we observed in costs and patient or carer satisfaction.

The NIAP hospitals were chosen to participate in the project on the basis of willingness and ability to establish a primary angioplasty service. They may therefore not be typical NHS hospitals. It was apparent that the NIAP hospitals served a more urban, younger and more ethnically diverse population than the United Kingdom average.

The evaluation only lasted one year, so we do not know whether the angioplasty service was sustainable in the long term. We also do not know whether the differences observed in patient and carer satisfaction were related to the novelty of the service, and whether the costs of the service will increase or decrease over time.



Primary angioplasty was feasible in a variety of settings, acceptable to patients and carers, and generally supported by staff. Although it was more expensive than thrombolysis it was very likely to be considered a cost-effective use of NHS resources. Primary angioplasty therefore appears to be the most appropriate treatment for heart attack in most regions of the United Kingdom, and particularly urban areas.

There were substantial differences in the time delays seen in different systems of providing angioplasty. The effectiveness of primary angioplasty depends upon time delay, so it may not be the best system in areas where transporting patients to the nearest angioplasty centre incurs prolonged time delays. The decision to provide angioplasty or thrombolysis-based care should be made on a regional basis, using the data presented in this report and elsewhere.

Primary angioplasty was almost certain to be costeffective if the patient was taken directly to the catheter laboratory of a hospital with angioplasty facilities. It was unlikely to be cost-effective if the patient had to be transferred to an angioplasty centre after initially attending a hospital without angioplasty facilities. Thrombolysis may be more effective and costeffective for patients attending hospitals without angioplasty facilities.

Primary angioplasty can be provided for patients whose nearest acute hospital does not support angioplasty by allowing bypass to the nearest angioplasty centre. Local geography and health service configuration will determine whether this process results in acceptable time delays before treatment.

We make the following recommendations to guide policymakers and practitioners who decide to implement a primary angioplasty service:

 Patients should access the catheter laboratory by the most direct route possible, bypassing the emergency department or coronary care unit if possible. A specified gatekeeper at the angioplasty centre who is available 24 hours a day to accept primary angioplasty referrals may assist this process.

- Primary angioplasty should be implemented by planning the full service from the beginning rather than incrementally building up. Staff pay and conditions should be planned to support the full service from the start, rather than gradually changing working patterns in response to an increasing workload.
- Attempts should be made to harmonise staff pay and conditions for out of hours work so that different staff groups are not all being paid in different ways for the same pattern of work.
- Stakeholders, such as ambulance services and emergency departments, should be engaged in the service. This can be assisted by the involvement of senior management and an appropriate champion for the primary angioplasty service.
- Cardiac service managers should ensure that development of primary angioplasty does not come at the expense of discharge, aftercare and rehabilitation services.
- The source of additional resources required to support primary angioplasty should be identified.
  These resources should be sustainable and adequate to support the changes in staff pay and conditions required to implement the service.
- Carers who have to travel a significant distance from their home to the angioplasty centre should be provided with overnight accommodation or have their travel costs reimbursed.



### Future research

The effectiveness (and therefore cost-effectiveness) of primary angioplasty depends upon local factors, such as the availability of services, distances travelled to access services and transport options. The decision to provide primary angioplasty should therefore be made on a regional basis, particularly in rural areas where the findings from the NIAP evaluation are least likely to be applicable. Our research has highlighted the techniques that can be used to make such decisions rationally. The relationship between time delays and the effectiveness of primary angioplasty is reasonably well understood. Economic modelling can be used to estimate the costeffectiveness of primary angioplasty in a particular setting if we know what sort of time delay before treatment would be expected.

Our economic model provides an overall estimate of the cost-effectiveness of primary angioplasty across the NIAP sites. This approach could be adapted to produce estimates of cost-effectiveness of primary angioplasty in different settings. If we know when and where people with heart attacks present to the health service we can model how long it would take to access treatment with different systems of care. This would then allow modelling of the effectiveness and cost-effectiveness of each potential system. Further research is therefore required to develop a model of heart attack care that can be applied to different regions to determine which system of care is suitable for each region.

One specific issue that needs further evaluation is whether patients whose nearest hospital does not support angioplasty should bypass their local hospital and be transferred directly to an angioplasty centre. This is likely to depend upon local geography and transport options, so the development of a model that can be applied to different systems would again be helpful.

The NIAP evaluation examined the first year of implementation of a primary angioplasty service. Questions still remain about the long-term sustainability of these services. Audit and research are required to determine whether time delays improve or worsen as the service becomes more established. Research is also required to determine how the workforce and their organisations rise to the challenges of providing a 24-hour primary angioplasty service when the novelty has worn off.

Patient, carer and workforce evaluations revealed concerns about the quality of discharge arrangements, aftercare and rehabilitation. Future research should not just focus upon emergency management but should identify ways of improving care at the end of, and after, acute hospital admission.

### About the study

This study evaluated implementation of angioplasty-based care at NIAP hospitals and compared it to thrombolysis-based care at four control hospitals. The following research methods were used:

- The systems used to deliver primary angioplasty were characterised using site visits, data collected by the NIAP hospitals and routinely available health and population data.
- Staff at seven hospitals contributed to the workforce and organisational study by completing a survey and participating in focus groups and interviews.
  Researchers undertook observations in catheter laboratories and collected objective data on procedures conducted during the study.
- Patient and carer perspectives were explored using (a) face-to-face semistructured interviews with ten patients and six carers, (b) postal questionnaires to 679 patients and 486 carers across four NIAP and four control sites, and (c) further interviews with eleven patients at NIAP sites and six at controls.
- Cost-effectiveness was assessed using cost and time delay data from the NIAP hospitals and four hospitals providing thrombolysis based care. Modelling was then used to estimate the long-term costs and effects of providing angioplasty-based as opposed to thrombolysis-based care.

#### Members of the research team

Steve Goodacre, Fiona Sampson, Alicia O'Cathain and Allan Wailoo School of Health and Related Research, University of Sheffield

Angela Carter and Stephen Wood Institute of Work Psychology, University of Sheffield

**Stephen Campbell and James Wardrope** Sheffield Teaching Hospitals Foundation Trust

Mark Jackson and Rod Stables Cardiothoracic Centre, Liverpool

Simon Capewell University of Liverpool

Enid Hirst Independent layperson

#### References

Boersma E and the PCAT-2 Trialists' Collaborative Group. Does time matter? A pooled analysis of randomized clinical trials comparing primary pertcutaneous coronary intervention and in-hospital fibrinolysis in acute myocardial infarction patients. *European Heart Journal*, 2006, 27:779-788.

Bravo Vergel Y, Palmer S, Asseburg C, Fenwick E, de Belder M, Abrams K and Sculpher M. Is primary angioplasty cost effective in the UK? Results of a comprehensive decision analysis. *European Heart Journal*, 2007, 93:1238-43.

Boyle R. *Mending hearts and brains – clinical case for change*. 2006. London, Department of Health.

Goodacre S, Sampson F. Evaluating the National Infarct Angioplasty Project Pilots. www.library.nhs.uk/cardiovascular/Page.aspx? pagename=ED21 2006.

British Cardiovascular Society. National Infarct Angioplasty Project (NIAP). www.bcs.com/pages/full\_news.asp?NewsID =2154 2005.

### Further information

The full report, this research summary and details of current SDO research in the field can be downloaded at: <u>www.sdo.nihr.ac.uk</u>

For further information about anything included in the report, please contact lead researcher Steve Goodacre, <u>s.goodacre@sheffield.ac.uk</u>

#### Feedback

The SDO Programme welcomes your feedback on this research summary. To tell us your views, please complete our online survey, available at: www.sdo.nihr.ac.uk/researchsummaries.html

#### About the SDO Programme

The Service Delivery and Organisation Programme (SDO) is part of the National Institute for Health Research (NIHR). The NIHR SDO Programme is funded by the Department of Health.

The NIHR SDO Programme improves health outcomes for people by:

- commissioning research and producing research evidence that improves practice in relation to the organisation and delivery of health care; and
- building capacity to carry out research amongst those who manage, organise and deliver services and improve their understanding of research literature and how to use research evidence.

This summary presents independent research commissioned by the National Institute for Health Research Service Delivery and Organisation Programme. The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

For further information about the NCCSDO or the NIHR SDO Programme visit our website at <u>www.sdo.nihr.ac.uk</u> or contact:

#### NCCSDO, London School of Hygiene & Tropical Medicine, 99 Gower Street, London WC1E 6AA

Tel: +44 (0)20 7612 7980 Fax: +44 (0)20 7612 7979 Email:sdo@lshtm.ac.uk



#### Disclaimer

This report presents independent research commissioned by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the NIHR SDO programme or the Department of Health. The views and opinions expressed by the interviewees in this publication are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the NIHR SDO programme or the Department of Health

#### Addendum

This document was published by the National Coordinating Centre for the Service Delivery and Organisation (NCCSDO) research programme, managed by the London School of Hygiene & Tropical Medicine.

The management of the Service Delivery and Organisation (SDO) programme has now transferred to the National Institute for Health Research Evaluations, Trials and Studies Coordinating Centre (NETSCC) based at the University of Southampton. Prior to April 2009, NETSCC had no involvement in the commissioning or production of this document and therefore we may not be able to comment on the background or technical detail of this document. Should you have any queries please contact sdo@southampton.ac.uk.