

Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction

Technology Appraisal Guidance 73

Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction

Issue date: November 2003

Review date: November 2006

This document, which contains the Institute's full guidance for this appraisal, is available from the NICE website (www.nice.org.uk/TA073guidance).

An abridged version of this guidance (a 'quick reference guide') is also available from the NICE website (www.nice.org.uk/TA073quickrefguide). Printed copies of the quick reference guide can be obtained from the NHS Response Line: telephone 0870 1555 455 and quote reference number N0372.

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The quick reference guide has been distributed to the following:

- Primary care trust (PCT) chief executives
- Local health board (LHB) chief executives
- NHS trust chief executives in England and Wales
- Strategic health authority chief executives in England and Wales
- Medical and nursing directors in England and Wales
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- NHS Director Wales
- Chief Executive of the NHS in England
- Chief Medical, Nursing and Pharmaceutical Officers in England and Wales
- Medical Director & Head of NHS Quality – Welsh Assembly Government
- Commission for Health Improvement
- NHS Clinical Governance Support Team
- Patient advocacy groups
- Representative bodies for health services, professional organisations and statutory bodies, and the Royal Colleges

This guidance is written in the following context:

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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ISBN: 1-84257-450-7

Published by the National Institute for Clinical Excellence
November 2003

Typeset by Icon Design, Eton

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1 Guidance

This appraisal covers the use of myocardial perfusion scintigraphy (MPS) using single photon emission computed tomography (SPECT) in the diagnosis and management of angina and myocardial infarction. It does not cover planar MPS or the use of MPS in the management of heart failure or in the assessment of myocardial viability. In this guidance the term coronary artery disease (CAD) is used to refer to angina and myocardial infarction.

- 1.1 MPS using SPECT is recommended for the diagnosis of suspected coronary artery disease (CAD) in the following circumstances.
- As the initial diagnostic tool for people with suspected CAD for whom stress electrocardiography poses particular problems of poor sensitivity or difficulties in interpretation, including women, patients with cardiac conduction defects (for example, left bundle branch block), and people with diabetes, and for people for whom treadmill exercise is difficult or impossible.
 - As part of an investigational strategy for the diagnosis of suspected CAD in people with lower likelihood of CAD and of future cardiac events. The likelihood of CAD will be based on the assessment of a number of risk factors including age, gender, ethnic group, family history, associated comorbidities, clinical presentation, physical examination, and results from other investigations (for example, blood cholesterol levels or resting electrocardiogram).
- 1.2 MPS using SPECT is recommended as part of the investigational strategy in the management of established CAD in people who remain symptomatic following myocardial infarction or reperfusion interventions.

2 Clinical need and practice

- 2.1 Coronary artery disease (CAD) is the commonest cause of death in England and Wales. It is characterised by the development of lipid-laden coronary arterial plaques, which reduce the blood supply to the heart muscle. Significant CAD is defined as a stenosis (narrowing) of more than 70% of the diameter of at least one major epicardial artery segment or more than 50% of the diameter of the left main coronary artery.

- 2.2 Angina (chest pain) is the most common symptom of CAD. It is usually provoked by exercise and relieved by rest. Angina of rapidly increasing frequency, or experienced at rest, is called unstable angina. CAD can also lead to heart attack (myocardial infarction, MI) and sudden cardiac death. MI is characterised by severe chest pain persisting for at least 20 minutes, a rise in cardiac enzymes in the serum, and/or an abnormal electrocardiogram (ECG).
- 2.3 About 2.65 million people in the UK have CAD, and of these 1.2 million have had an MI. There were an estimated 275,000 heart attacks in the UK in 2001, and 335,000 new cases of angina are diagnosed each year. CAD is more prevalent in men than in women. The prevalence of CAD increases with age, and varies across geographic regions and socioeconomic groups.
- 2.4 Preventative strategies for reducing the frequency of CAD include smoking cessation, diet modification, exercise, and treating conditions that exacerbate progression of the disease, such as hyperlipidaemia, hyperglycaemia, hypertension and blood hypercoagulability. Medical treatment of angina symptoms includes the use of nitrates, beta-adrenergic blockers and/or calcium channel blockers. In severe CAD, revascularisation may be required, using surgical procedures such as coronary artery bypass grafting (CABG) or via the use of percutaneous coronary intervention (PCI), commonly with the insertion of an intraluminal coronary stent.
- 2.5 The cost of CAD to the UK healthcare system in 1999 was estimated in the Assessment Report (see Appendix B) at £1.7 billion; the total annual cost was around £7 billion when informal care and productivity losses were included. More than 378,000 inpatients were treated for CAD in NHS hospitals in 2000/2001. Approximately 28,500 CABG and 39,000 PCI procedures are performed each year in the UK.
- 2.6 The individual likelihood for CAD can be estimated from age, gender, ethnic group, family history, existence of symptoms, associated comorbidities and the results of tests such as resting electrocardiography (rECG). rECG is a commonly used test because it is readily available in primary care and is inexpensive, but because it does not exclude CAD, it is of limited diagnostic value. Stress ECG (sECG) and coronary angiography (CA) are commonly used in clinical practice for the diagnosis of CAD.

- 2.7 sECG is normally recorded during progressive exercise on a treadmill, and so is not suitable for people for whom treadmill exercise is difficult or impossible.
- 2.8 CA involves manipulating a cardiac catheter into the heart from a vein or artery in a limb. A contrast medium is injected through the catheter, and its progress monitored by a rapid series of X-rays. CA provides mainly anatomical information and is used to measure the degree of stenosis. It is considered the 'gold standard' for defining the site and severity of coronary artery lesions. However, CA findings are not always a reliable indicator of the functional significance of a coronary stenosis. Routine use of CA without prior non-invasive testing is not advisable, because of its high cost and associated mortality and morbidity. Potential complications include non-fatal MI (0.1%), stroke (0.1%) and death (0.1–0.2%).
- 2.9 Other frequently used non-invasive techniques include myocardial perfusion scintigraphy (MPS) and echocardiography. Imaging techniques such as magnetic resonance imaging and positron emission tomography are used less frequently.

3 The technology

- 3.1 MPS involves the intravenous injection of small amounts of a radioactive tracer to evaluate perfusion of living cardiac muscle via the coronary arteries after stress and at rest. After injection, the tracer is taken up by cardiac muscle cells, and its distribution within the myocardium is imaged using a gamma camera. Three tracers are commercially available in the UK: thallium-201 thallos chloride, technetium-99m 2-methoxy-isobutyl-isonitrile, and technetium-99m 1,2-bis(bis[2-ethoxyethyl]phosphino)ethane. MPS is a non-invasive procedure which provides more detailed information about coronary function than sECG and CA. Cardiovascular stress can be induced by exercise as in sECG, but is most commonly induced by pharmacological agents.
- 3.2 MPS was originally developed as a planar imaging technique, but SPECT is the clinical standard in current practice. In SPECT, the camera rotates around the patient for 10–20 minutes and the raw data are processed to obtain tomographic images of the myocardium. The stress and rest images are normally separated by 3–4 hours. The total patient contact time for stress induction, injection and image acquisition is approximately 60 minutes.

- 3.3 Homogeneous uptake of tracer throughout the myocardium indicates the absence of clinically significant infarction or coronary stenosis. A defect in the stress images that normalises in the rest images usually corresponds to a significant coronary stenosis. A defect in both stress and rest images indicates an area with loss of viable myocardium, such as after MI.
- 3.4 Two technical improvements to SPECT were also considered in this appraisal. Attenuation-corrected SPECT compensates for the fact that many emitted photons never reach the detector as a result of interactions with body tissues. ECG-gated SPECT is synchronised with the patient's ECG, thereby minimising artefacts caused by cardiac motion. Also, left ventricular ejection fraction can be measured at rest with ECG-gated SPECT.
- 3.5 The complication rates for SPECT are no different from those of sECG, and are usually related to exercise or pharmacological stimulation given as part of the stress component in the procedure, with an associated mortality of around 0.01% and a morbidity of around 0.02%. The radiation exposure from SPECT is similar to the exposure from uncomplicated CA.
- 3.6 The cost of a SPECT scan is estimated to be around £265, whereas the costs for sECG and CA are £104 and £1103, respectively (2002 NHS reference costs).

4 Evidence and interpretation

The Appraisal Committee (Appendix A) considered evidence from a number of sources (Appendix B).

4.1 Clinical effectiveness

- 4.1.1 The Assessment Report and the submissions reviewed the literature and focused on two aspects separately: the diagnostic performance of SPECT, and its long-term prognostic value. Much of the evidence consisted of non-randomised open observational (both prospective and retrospective) studies, with several studies using a comparative design.

Diagnostic performance

- 4.1.2 The diagnostic performance of SPECT was expressed as sensitivity and specificity. Sensitivity is the proportion of true-positives that are correctly identified by the test. Specificity is the proportion of true-negatives that are correctly identified by the test.
- 4.1.3 The Assessment Report reviewed 21 studies with 100 or more patients that evaluated the sensitivity and specificity of both SPECT and sECG in the diagnosis of CAD compared with CA. Median sensitivity values for SPECT were higher than those for sECG in all studies (SPECT: 81% for the largest subcategory of studies, with a range of 63–93%; sECG: 65% for the largest subcategory of studies, with a range of 42–92%). However, the results were not pooled because of the heterogeneity across the different studies. Median specificity values were similar for SPECT (65%, range 10–90%) and sECG (67%, range 41–88%).
- 4.1.4 The submission from the professional groups reviewed the diagnostic performance of SPECT only (compared with CA) from 62 studies. Because of differences in inclusion criteria, only two of these studies were also included in the Assessment Report analysis. There was considerable variation in study size, quality and design, but weighted means for sensitivity and specificity were reported to be 86% and 74%, respectively. The manufacturer's submission quoted one publication with sensitivity and specificity for SPECT reported as 91% and 89%, respectively, and the American College of Cardiologists/American Heart Association Task Force guideline, with average sensitivity and specificity reported as 89–90% and 70–76%, respectively.

Long-term prognostic value

- 4.1.5 For the long-term prognostic value of SPECT, the Assessment Report included a systematic review of 46 observational studies.
- 4.1.6 In the 20 studies that provided general prognostic information, cardiac event rates (defined as cardiac mortality or non-fatal MI) were significantly higher for patients with abnormal SPECT scans than for those with normal scans. An abnormal SPECT result was associated with an annual cardiac event rate of 6.7%, whereas a normal scan was associated with an annual cardiac event rate of 0.7% (data from meta-analyses of 15,000 and 20,963 patients, respectively). Furthermore, the extent and size of a perfusion defect can predict the likelihood of future cardiac events.

- 4.1.7 The proportion of normal angiograms was lower in patients who were referred to CA after a positive SPECT than in patients referred directly for CA (two studies: 33% versus 43% [4688 patients], and 18% versus 33% [6800 patients], respectively).
- 4.1.8 However, the rate of subsequent revascularisations was lower for the SPECT-CA strategy (13–27%) than for the direct CA strategy (16–44%) (data from three studies with a combined total of approximately 11,000 patients).
- 4.1.9 In studies where it was possible to analyse the contribution of different clinical parameters to the prediction of clinical outcomes, it was found that SPECT provided independent prognostic information for predicting MI, and had an additional value over clinical and sECG data that was maintained at long-term follow-up.
- 4.1.10 In several studies that investigated whether an abnormal SPECT scan was a predictor of cardiac death, the relative risk or odds ratios were calculated depending on study design. In all studies an abnormal SPECT scan was described as an independent, main or statistically significant predictor of cardiac death. In four studies, with patient numbers ranging from 176 to 947, the relative risk ranged between 1.1 and 17.6. In two studies, with patient numbers of 248 and 1182, the odds ratios were reported to be 2.8 and 4.8, respectively.
- 4.1.11 SPECT also provided independent prognostic information in the following subgroups: women (five studies), patients post-MI (four studies), patients who had undergone PCI or CABG (three studies), medically treated patients with left main and/or three-vessel CAD (one study), patients hospitalised with angina who had a normal or non-diagnostic sECG (one study), and patients with diabetes (two studies).
- 4.1.12 Two studies found ECG-gated SPECT to be more sensitive than non-ECG-gated SPECT, but with slightly lower specificity. Also, ECG-gated SPECT provided incremental prognostic information in patients with known or suspected CAD that was better than perfusion data alone. One study compared SPECT with attenuation-corrected SPECT and reported that attenuation correction had a significant impact on the assessment of the severity and extent of MI.

- 4.1.13 The search strategy used in the Assessment Report did not identify any studies evaluating the role of SPECT in the context of rapid access chest pain clinics or in pre-operative risk assessment of patients undergoing major surgery who were potentially at risk of coronary events. However, the submission from the professional groups lists 20 studies on SPECT in pre-operative risk assessment, and emphasises the acknowledged role of SPECT for this indication.
- 4.1.14 In summary, as studies reviewed in the Assessment Report were carried out under a number of different clinical settings investigating different outcomes, it was not possible to summarise the effectiveness of SPECT in simple quantitative estimates. However, the evidence from the reviewed studies consistently suggested that SPECT provided valuable independent and incremental information predictive of outcome that helped to risk-stratify patients and influence the way in which their condition was managed.
- 4.1.15 The submissions from the professional groups and the manufacturer included reviews of a larger number of papers and, because of differences in the inclusion criteria, there was little overlap between the studies included in each of the three reviews. Despite the differences in the evidence base of the three reviews, similar conclusions were drawn.

4.2 Cost effectiveness

- 4.2.1 The Assessment Group, the manufacturer and the professional group reviewed published cost-effectiveness studies. The Assessment Group and the manufacturer also provided new economic models.
- 4.2.2 The systematic review in the Assessment Report included studies that compared both costs and outcomes of SPECT with alternative diagnostic strategies. The comparison of different publications was complicated by the multitude of strategies considered, differences in study designs and populations, in treatment comparisons, in costing methods and different ways in which outcomes were measured. Overall, it was concluded that direct CA (without any prior tests) was cost effective when the prevalence of disease was high. At low levels of prevalence, strategies involving SPECT and/or sECG were considered to be a better use of resources than a strategy of direct CA. Furthermore, strategies involving SPECT were often found to be dominant or provided additional benefits that might be considered worth the additional cost compared with the sECG-CA strategy.

- 4.2.3 The new economic models provided by the Assessment Group and the manufacturer used similar designs; decision tree models were constructed for the diagnostic performance of different strategies and Markov models were used to estimate the long-term costs and benefits. They both used a hypothetical cohort of 1000 patients (to start at the age of 60), with the assumption that effectiveness of therapy (CABG, PCI, medical management) lasts for 10 years. The time horizon was 25 years with an annual cycle time.
- 4.2.4 The diagnostic strategies considered in both models were:
- sECG, followed by SPECT if sECG was positive or indeterminate, followed by CA if SPECT was positive or non-diagnostic (sECG-SPECT-CA)
 - sECG, followed by CA if sECG was positive or non-diagnostic (sECG-CA)
 - SPECT, followed by CA if SPECT was positive or non-diagnostic (SPECT-CA)
 - direct CA (CA).
- 4.2.5 The results were presented as incremental cost per true-positive diagnosed, per accurate diagnosis, per life year gained and per quality-adjusted life year (QALY) gained, and – importantly – were calculated for different levels of prevalence of CAD.
- 4.2.6 The key results were as follows:
- As prevalence of CAD increased, total cost increased and total number of QALYs gained decreased for each diagnostic strategy.
 - At all prevalence levels of CAD the ordering of diagnostic strategies was the same, with sECG-SPECT-CA being least costly and least effective, and having the lowest average cost per QALY. This implies that an incremental cost is paid for some incremental benefit when SPECT is not included.
 - CA was the most costly strategy in both models and for all prevalence levels of CAD, and (as the reference standard) was defined as the most effective strategy.

- Most incremental cost-effectiveness ratios (ICERs) were less favourable in the manufacturer's model than in the Assessment Report model. However, all ICERs calculated were less than £24,000, apart from the ICER for direct CA compared with SPECT-CA at low and 30% prevalence of CAD.
- 4.2.7 When compared with sECG-CA at low prevalence of CAD, the ICER for SPECT-CA (£8723) was more favourable than the ICER for direct CA (£21,538). Conversely, at high prevalence of CAD, the more favourable strategy was direct CA with an ICER of £1962, whilst SPECT-CA had an ICER of £3242.
- 4.2.8 When direct CA was compared with the SPECT-CA strategy, a high ICER was seen at low prevalence (£42,225). However, as prevalence increased, direct CA became increasingly more cost-effective. At 80% prevalence of CAD, the move to the direct CA from SPECT-CA involved a modest extra cost per additional QALY gained (£942 in the Assessment Report and £4482 in the manufacturer's submission).
- 4.2.9 Several sensitivity analyses showed that the results varied considerably depending on the sensitivity or specificity values entered for SPECT and sECG. When the impact of the additional independent information provided by SPECT was explored by increasing the proportion of SPECT positives whose condition could be satisfactorily managed medically, ICERs generally improved. When the time horizon was less than 15 years, all ICERs became less favourable. In the subgroup analysis for women, the SPECT-CA strategy dominated both the sECG-CA and CA strategies.
- 4.2.10 In summary, when compared with sECG-CA, SPECT-CA has more favourable ICERs than direct CA at low levels of prevalence of CAD. At higher prevalence levels, the sECG-CA and CA strategies lead to more favourable ICERs than SPECT-CA.

4.3 Consideration of the evidence

- 4.3.1 The Committee reviewed the evidence available on the clinical and cost effectiveness of MPS for the diagnosis and management of CAD, having considered evidence on the value placed by users on the benefits of MPS for the diagnosis and management of CAD, from people with CAD, those who represent them, and clinical experts. It was also mindful of the need to ensure that its advice took account of the effective use of NHS resources.

- 4.3.2 The Committee considered the evidence submitted on the diagnostic performance of SPECT indicating that, overall, it is more sensitive than sECG. However, the Committee appreciated that considerable uncertainty remains over the true values for sensitivity and specificity of SPECT. In particular, trials that assessed these values were subject to referral bias, in that only SPECT-positive cases were referred for CA, which was assumed to be the 'gold standard'. Additionally the Committee was aware that, contrary to SPECT, CA does not always provide the fullest evaluation of the patient with CAD, particularly where information relating to myocardial perfusion and function are considered important for the establishment of prognosis and management.
- 4.3.3 The Committee heard from the clinical experts that SPECT is of value at all levels of likelihood for CAD, because it provides highly accurate diagnostic and prognostic information. The experts indicated that, if SPECT and sECG were equally accessible in the NHS, there would be a case for the preferential use of SPECT in certain groups of patients. However, because of the currently limited availability of SPECT in the UK, the committee believed that its use should be particularly directed to patient groups for whom it provides the greatest additional benefit in terms of initial diagnosis of suspected CAD and in the management and prediction of prognosis in those with established CAD.
- 4.3.4 The Committee also recognised that there are circumstances where the information from sECG is important, as in the evaluation of the overall exercise performance of patients with CAD. sECG is therefore likely to remain a commonly used investigation in most circumstances.
- 4.3.5 The Committee reviewed the cost-effectiveness modelling. They noted that because the difference in QALYs derived between the different investigational strategies was small, and the disutility of CA was not included in the models, the conclusions of cost-utility differences between diagnostic strategies (see Section 4.2.4) should be interpreted with caution. However, the Committee considered that, overall, SPECT was cost effective across a wide range of clinical situations.
- 4.3.6 The Committee further considered that, in terms of both clinical effectiveness and cost effectiveness, the absolute 'value' of SPECT as an appropriate diagnostic tool depends on the likelihood of the presence of CAD in the target population under investigation. Thus the diagnostic strategy SPECT-CA is clearly preferred on cost-effectiveness grounds in

individuals with a lower likelihood of CAD and consequently lower risk of future coronary events. However, as the likelihood of CAD increases, differences in the incremental cost effectiveness for the different testing strategies decrease. Thus, at higher likelihood of CAD and of possible intervention (CABG or PCI), a strategy where direct CA is preferred over SPECT-CA could be considered more appropriate.

- 4.3.7 The Committee heard from the experts that SPECT enables the redirection of patients into medical rather than surgical management. SPECT may therefore postpone or completely avert the need for CA in some clinical situations. The Committee also recognised the significance of the disutility associated with CA, which would favour SPECT and had been omitted from the economic models reviewed. It concluded that full consideration of these aspects is likely to improve the cost effectiveness of SPECT.
- 4.3.8 The Committee was advised by the experts that SPECT scanning may be particularly useful as an initial diagnostic tool in people for whom sECG poses particular problems of poor sensitivity or difficulties with interpretation. This includes women, patients with cardiac conduction defects (such as left bundle branch block) and people with diabetes. SPECT also has an important role in assessing the presence of CAD in patients for whom treadmill exercise is difficult or impossible, and in the full evaluation of patients following MI or reperfusion interventions.
- 4.3.9 The Committee considered that increased provision of SPECT within the NHS over that currently available was desirable on the basis of this evidence. However, it recognised that more widespread use of SPECT would require an implementation strategy that may take several years to fulfil and would need a significant increase in the availability of both equipment and trained staff. The Committee therefore concluded that the increased use of SPECT should initially be targeted at those groups for whom it provides the greatest benefit in terms of cost effectiveness, as expressed in Section 1.

5 Recommendations for further research

- 5.1 Further research is recommended in patients with established CAD regarding the value of SPECT relative to other tests of cardiac function such as echocardiography, magnetic resonance imaging and positron emission tomography in order to inform future assessment of the needs of the NHS.

6 Implications for the NHS

- 6.1 According to the British Nuclear Cardiology Society survey, there were about 1200 SPECT scans per million population in the UK in 2000. The average waiting time for a scan was 20 weeks. The submission prepared jointly by the professional groups estimated the optimal level of SPECT provision to be around 4000 SPECT scans per million population per year, calculated on the basis of current revascularisation and CA rates. Furthermore, it suggested that suitable waiting times would be 6 weeks for routine scans and 1 week for urgent tests.
- 6.2 In order to achieve these levels of both adequacy of provision and speed of accessibility, it is estimated that 73 additional gamma cameras would be needed in England and Wales, at a capital cost of around £18 million. This is based on providing 2000 scans per annum per gamma camera, and a unit cost of £250,000 per camera.
- 6.3 Because of the current lack of trained personnel, these levels of provision could take some years to achieve, so the total cost to the NHS is likely to be phased over several years. Once a steady state is achieved, based on the provision of 4000 SPECT tests per million population per year, the estimated annual revenue cost would be in the order of £27 million.

7 Implementation and audit

- 7.1 NHS hospitals and all clinicians who care for people with CAD should review current diagnostic options available to take account of the guidance set out in Section 1.
- 7.2 Local guidelines or care pathways for people with CAD should incorporate the guidance.
- 7.3 To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix C.
- 7.3.1 MPS using SPECT is carried out for the diagnosis of individuals with suspected CAD in the following circumstances.
- As the initial diagnostic tool for an individual with suspected CAD for whom sECG poses problems of poor sensitivity or difficulties in interpretation, and for an individual for whom treadmill exercise is difficult or impossible.

- As part of an investigational strategy for the diagnosis of suspected CAD in an individual who has a lower likelihood of CAD and of future cardiac events.
- 7.3.2 MPS using SPECT is carried out as part of an investigational strategy in the management of established CAD in an individual who remains symptomatic following myocardial infarction or reperfusion interventions (CABG or PCI).
- 7.4 Local clinical audits on the care of patients with CAD could also include criteria for the management of CAD based on the national standards, including standards in the National Service Framework.

8 Related guidance

- 8.1 The Institute issued guidance on the use of glycoprotein IIb/IIIa inhibitors in September 2002:

National Institute for Clinical Excellence (2002) Guidance on the use of glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes. *NICE Technology Appraisal Guidance No. 47*. London: National Institute for Clinical Excellence.

All documents and further details available from:
www.nice.org.uk

- 8.2 The Institute issued guidance on the use of drugs for early thrombolysis in October 2002:

National Institute for Clinical Excellence (2002) Guidance on the use of drugs for early thrombolysis in the treatment of acute myocardial infarction. *NICE Technology Appraisal Guidance No. 52*. London: National Institute for Clinical Excellence.

All documents and further details available from:
www.nice.org.uk

- 8.3 The Institute issued guidance on the use of coronary artery stents in October 2003:

National Institute for Clinical Excellence (2003) Guidance on the use of coronary artery stents. *NICE Technology Appraisal Guidance No. 71*. London: National Institute for Clinical Excellence.

All documents and further details available from:
www.nice.org.uk

- 8.4 The Institute issued a clinical guideline on prophylaxis for patients who have experienced an MI in April 2001:

National Institute for Clinical Excellence (2001) Prophylaxis for patients who have experienced a myocardial infarction. *NICE Inherited Clinical Guideline A*. London: National Institute for Clinical Excellence.

All documents and further details available from:
www.nice.org.uk

- 8.5 The Institute issued a clinical guideline on heart failure in July 2003:

National Institute for Clinical Excellence (2003) Clinical Guideline on management of chronic heart failure in adults in primary and secondary care. *NICE Clinical Guideline 5*. London: National Institute for Clinical Excellence.

All documents and further details available from:
www.nice.org.uk

9 Review of guidance

- 9.1 The review date for a technology appraisal refers to the month and year in which the Guidance Executive will consider any new evidence on the technology, in the form of an updated Assessment Report, and decide whether the technology should be referred to the Appraisal Committee for review.
- 9.2 The guidance on this technology will be reviewed in November 2006.

Andrew Dillon
Chief Executive
November 2003

A version of this guidance written for people with angina or myocardial infarction (coronary artery disease), their families and carers, and for the public is available from the the Institute's website (www.nice.org.uk) and from the NHS Response Line (telephone 0870 1555 455 and quote reference number N0373 for a version in English only and N0374 for a version in English and Welsh).

Appendix A

Appraisal Committee members and NICE project team

A. Appraisal Committee members

NOTE The Appraisal Committee is a standing advisory committee of the Institute. Its members are appointed for a 3-year term. A list of the Committee members who took part in the discussions for this appraisal appears below. The Appraisal Committee meets twice a month except in December, when there are no meetings. The Committee membership is split into two branches, with the chair, vice-chair and a number of other members attending meetings of both branches. Each branch considers its own list of technologies and ongoing topics are not moved between the branches.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each Appraisal Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Dr A E Ades

MRC Senior Scientist, MRC Health Services Research Collaboration, Department of Social Medicine, University of Bristol

Professor Ron Akehurst

Dean, School of Health Related Research, University of Sheffield

Dr Tom Aslan

General Practitioner, Stockwell, London

Professor David Barnett (Chair)

Professor of Clinical Pharmacology, University of Leicester

Dr Sheila Bird

MRC Biostatistics Unit, Cambridge

Professor Rosamund Bryar

Professor of Community and Primary Care Nursing, St Bartholomew's School of Nursing and Midwifery, London

Dr Karl Claxton

Health Economist, University of York

Professor Terry Feest

Clinical Director & Consultant Nephrologist, Richard Bright Renal Unit, & Chair of UK Renal Registry, Bristol

Professor Gary A Ford
Professor of Pharmacology of
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Newcastle-upon-Tyne Hospitals
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Consultant Psychiatrist,
University Department of
Psychiatrists, Oxford

Ms Bethan George
Interface Liaison Pharmacist,
Tower Hamlets PCT and Royal
London Hospital, Whitechapel

Dr Trevor Gibbs
Head, Global Clinical Safety and
Pharmacovigilance,
GlaxoSmithKline, Greenford

Mr John Goulston
Director of Finance, Barts and
The London NHS Trust

Professor Philip Home
Professor of Diabetes Medicine,
University of Newcastle-upon-
Tyne

Dr Terry John
General Practitioner, The Firs,
London

Mr Muntzer Mughal
Consultant Surgeon, Lancashire
Teaching Hospitals NHS Trust,
Chorley

Judith Paget
Chief Executive, Caerphilly Local
Health Board, Torfaen

Mrs Kathryn Roberts
Nurse Practitioner, Hyde,
Cheshire

Ms Anne Smith
Lay Representative; Trustee,
Long-Term Medical Conditions
Alliance

Dr Cathryn Thomas
General Practitioner, & Senior
Lecturer, Department of Primary
Care & General Practice,
University of Birmingham

Dr Norman Vetter
Reader, Department of
Epidemiology, Statistics and
Public Health, College of
Medicine, University of Wales,
Cardiff

Dr David Winfield
Consultant Haematologist, Royal
Hallamshire Hospital, Sheffield

B. NICE Project Team

Each appraisal of a technology is assigned to a Health Technology Analyst and a Technology Appraisal Project Manager within the Institute.

Dr Elisabeth George
Technical Lead,
NICE project team

Dr Dogan Fidan
Technical Lead,
NICE project team

Kathleen Dalby
Project Manager,
NICE project team

Appendix B

Sources of evidence considered by the Committee

The following documentation and opinions were made available to the Committee:

- A** The Assessment Report for this appraisal was prepared by the Health Services Research Unit in collaboration with the Health Economics Research Unit, the Department of Public Health, Institute of Applied Health Sciences, and the Cardiology Research Group, University of Aberdeen, and the Department of Bio-Medical Physics and Bio-Engineering, Grampian University Hospitals NHS Trust.

Systematic review of the effectiveness and cost-effectiveness, and economic evaluation, of myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction

Graham Mowatt, Luke Vale, Miriam Brazzelli, Rodolfo Hernandez, Alison Murray, Neil Scott, Cynthia Fraser, Lynda McKenzie, Howard Gemmell, Graham Hillis, and Malcolm Metcalfe, May 2003.

- B** The following organisations accepted the invitation to participate in this appraisal. They were invited to make submissions and comment on the draft scope, assessment report and the Appraisal Consultation Document (ACD). Consultee organisations are provided with the opportunity to appeal against the Final Appraisal Determination.

I Manufacturer/sponsors:

- Amersham Health
- Ashby GB Ltd
- Bartec Medical Systems (UK) Ltd
- Bristol-Myers Squibb
- GE Medical Systems
- Philips Medical Systems
- Siemens
- Tyco Healthcare UK Ltd

II Professional/specialist and patient/carer groups:

- Action Heart
- Association of British Health-Care Industries
- British Cardiac Patients Association
- British Cardiac Society
- British Cardiovascular Interventional Society

- British Heart Foundation
- British Nuclear Cardiology Society
- British Nuclear Medicine Society
- Department of Health
- Fareham and Gosport Primary Care Trust
- Maidstone Weald Primary Care Trust
- Royal College of Physicians
- Royal College of Radiologists
- Society for Cardiological Science and Technology
- Welsh Assembly Government

III Commentator organisations (without the right of appeal):

- Cochrane Heart Group
- Institute of Nuclear Medicine
- Institute of Physics and Engineering in Medicine
- NHS Confederation
- NHS Information Authority
- NHS Purchasing and Supply Agency
- NHS Quality Improvement Scotland

C The following individuals were selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups. They participated in the Appraisal Committee discussions and provided evidence to inform the Appraisal Committee's deliberations. They gave their expert personal view on myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction by attending the initial Committee discussion and/or providing written evidence to the Committee. They were also invited to comment on the ACD.

- Dr Constantinos Anagnostopoulos, President, British Nuclear Cardiology Society and Consultant & Honorary Senior Lecturer of Nuclear Medicine, Department of Nuclear Medicine, Royal Brompton Hospital, London
- Professor SR Underwood, Professor of Cardiac Imaging, Royal Brompton Hospital, London

Appendix C

Detail on criteria for audit of the use of myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction

Possible objectives for an audit

An audit on MPS using SPECT could be carried out to ensure that the technique is used appropriately.

Possible patients to be included in the audit

An audit could be carried out on people referred for investigation of coronary artery disease (CAD) and people who have CAD and who remain symptomatic following myocardial infarction, CABG or PCI, for a reasonable period for audit, for example, 3 or 6 months.

Measures that could be used as a basis for audit

The measure that could be used in an audit of MPS using SPECT for people referred for investigation of CAD is as follows.

Criterion	Standard	Exception	Definition of terms
1. MPS using SPECT is carried out in the following circumstances:	100% of people who have suspected CAD and who meet 1 a or 1b	None	Clinicians will need to agree locally on how patients are identified as having suspected CAD, for audit purposes.
a. as the initial diagnostic tool for an individual with suspected CAD			For 1 a, people for whom there may be problems of sensitivity or interpretation include women, people with cardiac conduction defects (for example, left bundle branch block), and people with diabetes. Clinicians will need to agree locally on how a patient for whom treadmill exercise is difficult or impossible is identified, for audit purposes.
b. as part of an investigational strategy for the diagnosis of suspected CAD in an individual with a lower likelihood of CAD and of future cardiac events			For 1b, clinicians will need to agree locally on how the likelihood of CAD and the likelihood of future cardiac events is determined to be low, for audit purposes. Risk factors include age, gender, ethnic group, family history, associated co-morbidities, clinical presentation, physical examination, and results from other investigations (for example, blood cholesterol levels or a resting electrocardiogram).

The measure that could be used in an audit of MPS using SPECT for people with established CAD who remain symptomatic following myocardial infarction, CABG or PCI is as follows.

Criterion	Standard	Exception	Definition of terms
1. MPS using SPECT is carried out as part of an investigational strategy for an individual with established CAD who remains symptomatic following myocardial infarction, CABG or PCI	100% of people with established CAD who remain symptomatic following myocardial infarction, CABG or PCI	None	Clinicians will need to agree locally on the definition of symptomatic for an individual patient that is documented, for audit purposes.

Calculation of compliance

Compliance (%) with each measure described in the tables above is calculated as follows.

$$\frac{\text{Number of patients whose care is consistent with the criterion *plus* number of patients who meet any exception listed}}{\text{Number of patients to whom the measure applies}} \times 100$$

Clinicians should review the findings of measurement, identify whether practice can be improved, agree on a plan to achieve any desired improvement and repeat the measurement of actual practice to confirm that the desired improvement is being achieved.



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