# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## **Diagnostics consultation document**

# Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash for cardiac imaging in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners

## **1 Provisional recommendations**

- 1.1 New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash) are recommended for first-line imaging of the coronary arteries in people with suspected stable coronary artery disease (with an estimated likelihood of coronary artery disease of 10–29%, as described in 'Chest pain of recent onset' [NICE clinical guideline 95]) in whom imaging with earlier generation CT scanners is difficult.
- 1.2 New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash) are recommended for first-line evaluation of disease progression, to establish the need for revascularisation, in people with known coronary artery disease in whom imaging with earlier generation CT scanners is difficult. However, CT scanning might not be necessary if immediate revascularisation is being considered.
- 1.3 Service providers, working with commissioners and cardiac networks, should take into account the benefits of access to new generation cardiac CT scanners for use in the circumstances described in 1.1 and 1.2. They should do this when selecting CT scanners as part of medium term asset planning.

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# 2 The technologies

2.1 Aquilion ONE (Toshiba Medical Systems), Brilliance iCT (Philips Healthcare), Discovery CT750 HD (GE Healthcare) and Somatom Definition Flash (Siemens AG Healthcare) are new generation computed tomography (CT) scanners that have a variety of enhancements compared with earlier generation CT scanners. It is claimed that the new generation CT scanners can better detect coronary artery stenosis in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners. New generation CT scanners can image with greater speed and reduced radiation dose.

# 3 Clinical need and practice

## The problem addressed

- 3.1 The primary focus of this evaluation is to assess the diagnostic accuracy, effect on patient outcomes and cost effectiveness of specific new generation cardiac CT scanners in :
  - adults (18 years or older) with suspected coronary artery disease in whom imaging with earlier generation CT is difficult (see section 3.4) and with a 10–29% pre-test likelihood of coronary artery disease
  - adults (18 years or older) with known coronary artery disease in whom imaging with earlier generation CT is difficult (see section 3.4) and in whom revascularisation is being considered.

#### The condition

3.2 Coronary artery disease is characterised by narrowing of the coronary artery. It is most commonly caused by atherosclerotic deposits of fibrous and fatty tissue, leading to a reduction in blood flow to the heart and angina. NICE clinical guideline 95 ('Chest pain Page 2 of 24

National Institute for Health and Clinical Excellence Diagnostic consultation document – Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash for cardiac imaging in people with suspected or known coronary artery disease who are difficult to image with earlier generation CT scanners Issue date: August 2011 of recent onset: assessment and diagnosis of recent onset chest pain or discomfort of suspected cardiac origin') defines significant coronary artery disease as 70% or greater diameter stenosis of at least one major epicardial artery segment or 50% or greater diameter stenosis in the left main coronary artery.

- 3.3 NICE clinical guideline 95 recommends CT coronary angiography and invasive coronary angiography to assess arteries and identify significant stenosis. The guideline recommends using a 64-slice (or above) CT scanner in people with an estimated likelihood of coronary artery disease of 10–29% and a calcium score of 1–400.
- 3.4 Conditions that make CT imaging difficult are:
  - obesity
  - high levels of coronary calcium (calcium score above 400)
  - arrhythmias
  - high heart rates that cannot be lowered pharmacologically (after consultation with clinical experts, the definition of high heart rate was broadened from over 70 beats per minute as stated in the scope, to over 65 beats per minute, in order to avoid loss of potential data)
  - stents
  - previous bypass grafts.

#### Prevalence and risk

3.5 In the UK an estimated 2.6 million people have coronary artery disease, with 2 million having symptoms of angina. In 2007, coronary artery disease was estimated to have caused 91,000 deaths in the UK (approximately 19% of deaths in men and 13% in women).

3.6 It is hard to give an accurate number of people with coronary artery disease in whom imaging is difficult. However, a range of data sources can be used to give an estimate of the population. According to the Health Survey for England (2009), 22% of men and 24% of women are obese. Hospital Episode Statistics show that there were a total of 313,765 unique patients with arrhythmias, stent implantations and bypass grafts in England in the last 3 years. If the estimated number of people with a high heart rate (over 65 beats per minute) and intolerance to beta blockers is included, the number of people in England with coronary artery disease in whom imaging with earlier generation CT scanners is difficult can be estimated to range from 10 million to 18 million.

#### The diagnostic and care pathways

- 3.7 The care pathway for this evaluation was taken from NICE clinical guideline 95. The key elements (for the imaging strategy) from the care pathway are as follows:
  - People with chest pain who have an estimated likelihood of coronary artery disease of 10–29% should be offered calcium scoring, followed by CT coronary angiography if the calcium score is between 1 and 400. A calcium score above 400 indicates that imaging using earlier generation CT scanners would be difficult, and the guideline recommends invasive coronary angiography if this is considered clinically appropriate.
  - People with chest pain who have an estimated likelihood of coronary artery disease of 30–60% should be offered noninvasive functional imaging for myocardial ischemia.
  - People with chest pain who have an estimated likelihood of coronary artery disease of 61–90% should be offered invasive coronary angiography if clinically appropriate and if coronary revascularisation is being considered.

- 3.8 The key options for non-invasive functional imaging are:
  - myocardial perfusion scintigraphy with single photon emission computed tomography or
  - stress echocardiography or
  - first-pass contrast-enhanced magnetic resonance perfusion or
  - magnetic resonance imaging for stress-induced wall motion abnormalities.
- 3.9 People diagnosed as having significant coronary artery disease should be initially managed as having stable angina. Management of these people was assumed to follow the recommendations from 'Management of stable angina' (NICE clinical guideline 126) when modelling patient outcomes and cost effectiveness.

## 4 The diagnostic tests

# The individual tests: Aquilion One, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash

4.1 New generation cardiac CT scanners identified and included in this evaluation have advanced technical features that address drawbacks associated with earlier generation CT scanners. These drawbacks include spatial resolution, low contrast detection, noise artefacts and higher levels of radiation. The scanners included in this evaluation are Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash.

#### **Aquilion ONE**

4.2 The Aquilion ONE is a 640-slice CT scanner with 320 × 0.5 mm detector rows giving z-axis coverage of 160 mm. This specification allows the imaging of whole organs in a single non-helical rotation, for example, an image of the heart can be captured within a single

heartbeat. As well as reducing the examination time, the radiation and the contrast dose are also reduced.

#### **Brilliance iCT**

4.3 The Brilliance iCT is a new generation 256-slice multi-detector CT scanner with 128 × 0.625 mm detector rows providing total z-axis coverage of 80 mm. Each detector row is double sampled to increase spatial resolution. It is claimed that it can capture an image of the heart in two heart beats.

#### **Discovery CT750 HD**

4.4 The Discovery CT750 HD is a 2 × 64-slice dual-energy CT scanner. It has a single X-ray source that switches between two energy levels, allowing two data sets – high energy and low energy – to be acquired simultaneously. It uses a Gemstone detector that contributes to high image quality, and a prospectively gated axial scanning technique called SnapShot Pulse, which allows a complete picture of the heart to be captured in three or four 'snapshots' taken at precise table positions and timed to correspond to a specific phase of the cardiac cycle.

#### **Somatom Definition Flash**

4.5 The Somatom Definition Flash is a second-generation dual-source 128-slice CT scanner designed to provide high resolution images at a fast scanning speed with low-dose radiation. It has two X-ray tubes and two detector arrays mounted at 95° to each other. It has a maximum scan speed of 458 mm/s. Fast acquisition times may be of benefit for use with people who cannot remain still or who have difficulty holding their breath. The scanner also uses different strategies to reduce the radiation dose associated with imaging.

## The comparator: invasive coronary angiography

- 4.6 Because earlier generation CT scanners are not considered viable for imaging some people (see 3.4), the comparator is invasive coronary angiography. Invasive coronary angiography uses a contrast dye and X-rays to provide anatomical information about the degree of stenosis in the coronary arteries. A catheter is generally inserted into an artery in the groin or wrist and is moved up the aorta and into the coronary arteries. Once in place, the dye is injected through the catheter, and a rapid series of X-ray images is taken to show how the dye moves through the branches of the coronary arteries. Any narrowing of the arteries will show up on the X-ray images.
- 4.7 Invasive coronary angiography is considered the reference standard for providing anatomical information and defining the site and severity of coronary artery lesions. Some rare but serious complications include death, myocardial infarction, cerebrovascular accident, arrhythmia, vascular complications, allergic reaction to contrast media, haemodynamic complications and perforation of the heart chamber.

# 5 Outcomes

The Diagnostics Advisory Committee (appendix A) considered evidence from a number of sources (appendix B).

#### How outcomes were assessed

5.1 The assessment consisted of a systematic review of the evidence on clinical effectiveness for new generation cardiac CT scanners in people with known and suspected coronary artery disease in whom imaging is difficult.

- 5.2 All studies included in the systematic review reported test accuracy data for people in whom imaging is difficult. Results were summarised by patient group (obese, high heart rate, high coronary calcium score and so on) and further stratified by unit of analysis (patient, artery, or arterial segment). For all included studies, the absolute numbers of true positive, false negative, false positive and true negative test results, as well as sensitivity and specificity values, with 95% confidence intervals (CIs), were presented.
- 5.3 The systematic review was followed by modelling to assess final patient outcomes and cost effectiveness. Diagnostic strategies themselves do not have direct implications for health-related quality of life. Therefore, a linked evidence approach to modelling was used to link intermediate outcomes (diagnostic accuracy of the tests) to treatment outcomes and hence quality-adjusted life year (QALY) gains.

#### Assessment of test accuracy

5.4 Based on the data from the included studies, the External Assessment Group (EAG) was able to deduce true positive, true negative, false positive and false negative rates for new generation cardiac CT scanners. Sensitivities and specificities were computed from meta-analysis (a bivariate summary receiver operating curve [SROC] model). When the bivariate model could not be fitted because of the small number of relatively homogenous studies involved, the DerSimonian and Laird method for meta-analysis was used. Per-patient summary estimates were also used when possible. A summary of the data on the test performance of the scanners among the patient groups in whom imaging is difficult is given below. In all cases the studies were quite consistent and inter-study heterogeneity was low to moderate.

#### Obese people

5.5 One study involving 125 participants reported 543 per segment data on the performance of new generation cardiac CT scanners in detecting coronary artery disease in obese people. Obesity was defined as having a body mass index (BMI) of 30 kg/m<sup>2</sup> or above. The index test was Somatom Definition (a model predating the Somatom Definition Flash) and the reference test was invasive coronary angiography. The sensitivity was 90.4% (95% CI 83.8 to 94.9) and the specificity was found to be 92.1% ((95% CI 89.1 to 94.5).

#### People with high levels of coronary calcium

5.6 Four studies reported on the performance of new generation cardiac CT scanners in detecting coronary artery disease in people with high levels of coronary calcium. The high calcium score threshold was set to above 400. Data were derived from 1304 segments in 91 participants. The index test was Somatom Definition and the reference test was invasive coronary angiography. The sensitivity was 92.7% (95% CI 88.3 to 95.6) and the specificity was 90.6% (95% CI 80.6 to 95.8%).

#### People with arrhythmia

5.7 Five studies reported on the performance of new generation cardiac CT scanners in detecting coronary artery disease in people with arrhythmia. Data for 126 patients and 1526 segments were obtained from the studies. For the patient data, sensitivity was 97.7% (95% CI 88.0 to 99.9) and specificity was 81.7% (95% CI 71.6 to 89.4). For the segment data, sensitivity was 87.4% (95% CI 68.3 to 95.7) and specificity was 96.0% (95% CI 91.2 to 98.2).

#### People with a high heart rate

- 5.8 Eight studies in total reported 24 data sets on the performance of new generation cardiac CT scanners in detecting coronary artery disease in people with a high heart rate. Five studies with 462 participants reported per-patient data. The pooled estimates of sensitivity and specificity, derived from these data using a bivariate model, were 97.7% (95% CI 93.2 to 99.3) and 86.3% (95% CI 80.2 to 90.7) respectively. Four studies reported data for 664 arteries. The pooled estimates of sensitivity and specificity, derived from these data using a bivariate model, were 93.7% (95% CI 87.8 to 96.9) and 92.4% (95% CI 83.3 to 96.8) respectively. All eight studies reported accuracy data by arterial segment (8133 segments). The pooled estimates of sensitivity and specificity, derived from these data using a bivariate model, were 92.7% (95% CI 89.3 to 95.1) and 95.7% (95% CI 92.8 to 97.4) respectively. All eight studies used a threshold of vessel narrowing of at least 50% to define significant stenosis.
- 5.9 No studies were identified of the accuracy of new generation cardiac CT scanners for the detection of coronary artery disease in people who were intolerant to beta-blockers. It should be noted, however, that beta-blockers are normally prescribed to slow the heart rate for people with heart rates too high for scanning. However, some people with high heart rates are intolerant to beta-blockers, which makes it difficult to image them with earlier generation CT scanners.

#### People with previous stent implants

5.10 Seven studies reported ten data sets describing the accuracy of new generation cardiac CT scanners for the detection of coronary artery disease in people with previous stent implantation. Four studies reported per-patient data for 233 participants. The pooled estimates of sensitivity and specificity were 96.0% (95% CI 88.8 to 99.2) and 81.6% (95% CI 74.7 to 87.3) respectively. Six studies reported accuracy data by stent or stented lesion (n = 582). The pooled estimates of sensitivity and specificity were 93.6% (95% CI 86.1 to 97.2) and 91.0% (95% CI 87.3 to 93.7) respectively.

#### **Clinical outcomes**

5.11 The model comprised five sub-models to estimate the clinical outcomes of new generation cardiac CT scanners. QALYs and costs in all five models were calculated and discounted at a rate of 3.5%. These models are described below.

#### **Diagnostic model**

- 5.12 A diagnostic model was used to estimate the initial outcomes of treatment and initial diagnosis. The primary measures of benefit used in this analysis were:
  - the complication rate for invasive coronary angiography and revascularisation (myocardial infarction and stroke)
  - the benefits associated with reduction in the incidence of cancer as a result of reduction in radiation dose
  - morbidity and mortality from coronary artery disease.
- 5.13 Using invasive coronary angiography as a comparator, three treatment strategies were evaluated in people with suspected or known coronary artery disease in whom CT imaging was difficult. These strategies were:
  - Invasive coronary angiography only: people had invasive coronary angiography only, which was assumed to be perfectly accurate.
  - New generation cardiac CT scanner only: people had a new generation cardiac CT scan only; the accuracy of the scan was

based on invasive coronary angiography as the reference standard.

- New generation cardiac CT scan plus invasive coronary angiography: cardiac CT was performed on everyone, and those with a positive scan then had invasive coronary angiography. No false positives could occur with this strategy because invasive coronary angiography was assumed to have perfect specificity.
- 5.14 The clinical outcomes assessed for people with coronary artery disease were mortality, morbidity and the percentage of correct diagnostic classifications (true positives, false positives, true negatives, false negatives) associated with each of the three strategies.

#### Healthy population model

5.15 Using life tables, a healthy population model that only applied to people without coronary artery disease (true negatives and false positives) was used to predict mortality on the assumption that people with true negative and false positive test results do not differ from the average UK population.

#### EUROPA model

5.16 The EUROPA model modelled the progression of stable coronary artery disease by predicting cardiovascular events and mortality. Health-related quality of life estimates were assigned to each Markov state based on age, gender, baseline Canadian Cardiovascular Society classification and whether the person had undergone treatment.

#### Stroke model

5.17 The costs and outcomes of people who experienced a stroke because of initial invasive coronary angiography or revascularisation were modelled with a relatively simple life–death

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National Institute for Health and Clinical Excellence Diagnostic consultation document – Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash for cardiac imaging in people with suspected or known coronary artery disease who are difficult to image with earlier generation CT scanners Issue date: August 2011 model. Mortality rates were based on UK life tables and a relative risk of 2.5 to reflect the increased risk of mortality after a stroke. York radiation model

#### York radiation model

5.18 The York Radiation Model estimated the impact of imaging in terms of radiation dose on cancer morbidity and mortality. This model was used as there is no direct evidence on radiation dose effects in the populations included in the scope.

#### Cost and cost effectiveness

- 5.19 The models described above were also used to estimate the costs of the diagnostic tests and treatments people received for their initial conditions, and any subsequent related conditions that developed. Although there is some variability in the costs of the new generation cardiac CT scanners, the models assumed that each scanner cost £1 million.
- 5.20 The comparator, invasive coronary angiography, was presumed to be perfectly accurate (a gold standard) and thus yielded more QALY gains than CT. It was also more expensive than imaging with a new generation cardiac CT scanner. The lower cost of the new generation CT scanners offset the additional QALY gains in invasive coronary angiography.
- 5.21 The health economic analysis showed that in people with suspected coronary artery disease, using new generation cardiac CT scanners instead of invasive coronary angiography may be considered more appropriate when a cost-effectiveness threshold of £20,000 per QALY gained is used. For investigating suspected coronary artery disease, 'new generation CT scanner only' was the most cost-effective strategy, when compared with 'new generation CT scan plus invasive coronary angiography' for those with positive

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CT scans (incremental cost-effectiveness ratio [ICER] of £71,000 per QALY gained), and with 'invasive coronary angiography alone' (ICER of £83,429 per QALY gained).

5.22 In people with known coronary artery disease, the most costeffective strategy was 'new generation cardiac CT scan plus invasive coronary angiography' for those with positive CT scans. This strategy dominated the 'invasive coronary angiography only' strategy (that is, it was less costly and more effective). The ICER of the 'new generation cardiac CT scan only' strategy compared with the 'new generation cardiac CT scan plus invasive coronary angiography' strategy was £726,230 per QALY gained.

# 6 Considerations

- 6.1 The scope and the diagnostic assessment report assumed that Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash provided broadly similar benefits for people in whom imaging is difficult. The Committee considered comments on the diagnostics assessment report from stakeholders about the equivalence of the four scanners. The Committee heard that the scanners use different technologies to gain image improvement and dose reduction, and that the different approaches may provide differential benefits depending on the reasons for imaging being difficult. For the purposes of this assessment it was assumed that each of the devices was capable of providing adequate imaging for all groups of people in whom imaging is difficult. Moreover, the Committee concluded that many people have combinations of conditions that lead to imaging difficulties and, therefore, it would not be optimal to specify use of only one particular device.
- 6.2 Of the 24 test accuracy studies included in the diagnostics assessment report, 3 studies did not specify the model of the

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scanner used, 1 study used Somatom Definition Flash, 1 used Aquilion ONE and 19 used similar previous model high definition scanners. The manufacturer of the Discovery CT750 HD confirmed that that scanner had been used in one of the studies with an unspecified scanner. Although test accuracy data exist for all of the systems considered, most studies did not stratify outcome reporting for the difficult-to-image subsets and thus the data could not be used in the assessment. The Committee concluded that, in this case, it could write recommendations with the limited available data. However, the Committee considered it important that manufacturers present test accuracy data on important patient subgroups, and noted that the lack of such data made it difficult to make recommendations.

- 6.3 The Committee discussed the extent to which the usable test accuracy studies, particularly the studies of the older Somatom model, could be generalised across scanners. The Committee heard from the External Assessment Group that statistical tests of the test accuracy results of the different scanners showed the results were not heterogeneous and thus could be combined.
- 6.4 The Committee concluded that even though no usable data were available for Brilliance iCT, and only one study each was available for Aquilion ONE, Discovery CT750 HD and Somatom Definition Flash, recommendations could be developed that applied to all four of the assessed scanners. The Committee considered whether all relevant studies had been included in the assessment. In response to comments from representatives of manufacturers about the inclusion of relevant studies, the External Assessment Group confirmed that the literature search was designed to be very sensitive and to maximise identification of papers containing test accuracy data for the groups of patients included in the scope. In addition, all manufacturers had been asked to provide relevant Page 15 of 24

data. However, most of the data provided by manufacturers were excluded because they did not contain test accuracy results stratified for the relevant populations for the assessment.

- 6.5 The Committee acknowledged that the reference standard, invasive coronary angiography, although not 100% accurate in clinical practice, is an accepted reference standard for assessment of anatomic coronary disease. The high accuracy of CT when compared with angiography, coupled with the known inaccuracies of angiography, imply that CT may be even more effective and cost effective than the assessment indicated because it may be more accurate, and angiography less accurate, than modelled.
- 6.6 The Committee acknowledged that from a patient perspective, a non-invasive cardiac diagnostic test is more appealing than invasive coronary angiography because of the greater morbidity and mortality risks associated with angiography. The External Assessment Group informed the Committee that the modelling had reflected this preference, because it included the increased morbidity and mortality resulting from invasive procedures as well as their associated costs. CT was found to be more cost effective than angiography because of these risks and the reduced costs associated with CT, even though angiography had been assumed to be the more accurate test.
- 6.7 The Committee considered how using new generation cardiac CT scanners for evaluating people with suspected coronary artery disease would fit with NICE clinical guideline 95. The Committee concluded that the evidence presented indicated that new generation cardiac CT was more cost effective for people in whom imaging is difficult than proceeding directly to invasive angiography. By implication, because the earlier generation CT scanners used for people in whom imaging is not difficult are even less expensive

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National Institute for Health and Clinical Excellence Diagnostic consultation document – Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash for cardiac imaging in people with suspected or known coronary artery disease who are difficult to image with earlier generation CT scanners Issue date: August 2011 and have similar risks and benefits than the new generation scanners, CT would also be more cost effective than angiography for all people presenting with chest pain and a pre-test likelihood of 10–29% of coronary artery disease.

- 6.8 NICE clinical guideline 95 recommends calcium scoring to assess patients with an estimated likelihood of coronary artery disease of 10–29%, and varied its further imaging recommendations based on the calcium level. As the assessment carried out by the EAG shows that even those with higher calcium levels can be successfully imaged with new generation cardiac CT (see section 5.6), calcium scoring may not be needed to distinguish which further test people should be offered. The Committee, while recognising that calcium scoring does offer prognostic information, was uncertain about whether it provided enough benefit to justify its use if all people in the group would still be offered CT angiography. The value of calcium scoring was not explored in this assessment because it was outside the scope.
- 6.9 The Committee considered whether angiography after CT was needed for people with positive CT scans. The diagnostics assessment report showed that CT alone was more cost effective than CT with angiography for people with suspected coronary artery disease, but CT alone was not more cost effective for people with known coronary artery disease. For both groups, CT followed by invasive coronary angiography for those with positive CT scans was more cost effective than invasive coronary angiography alone.
- 6.10 The Committee was informed that, in current practice, people would usually have angiography either before, or as a part of, treatment, but that the angiography rate was dropping. The Committee also heard that with time and additional experience, it was likely that follow-up angiography solely for diagnostic purposes

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National Institute for Health and Clinical Excellence Diagnostic consultation document – Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash for cardiac imaging in people with suspected or known coronary artery disease who are difficult to image with earlier generation CT scanners Issue date: August 2011 would decline further. A negative CT scan result would be sufficient to avoid angiography and often low-risk patients with a negative scan could be discharged from specialty care immediately. The Committee heard that if a CT scan result shows moderate stenosis (40–60%), then the patient usually proceeds to functional imaging, whereas for severe stenosis (80%), the patient would be offered invasive coronary angiography. The Committee was advised that having the option to diagnose with CT before proceeding to functional imaging and/or invasive coronary angiography would not affect the throughput of a cardiology department.

- 6.11 The Committee noted that other forms of non-invasive testing for coronary artery disease were significantly less accurate than cardiac CT scanning and were unlikely to cost significantly less.
- 6.12 The Committee considered whether it was appropriate to recommend CT scanning for people with known coronary artery disease in whom imaging was not difficult. However, data for that population had not been examined and no analysis had been undertaken, so no recommendation was produced.
- 6.13 The Committee also considered whether it was appropriate to recommend CT scanning for people with suspected coronary artery disease who had higher prior likelihoods of coronary artery disease. The sensitivity analysis had shown that new generation CT scanning reaches NICE's standard threshold levels of cost effectiveness compared with angiography for people in whom imaging is difficult and who have moderately higher pre-test probabilities of coronary artery disease. The Committee heard that immediate revascularisation was no longer considered the preferred practice in this population. However, because data for this population had not been examined, it was not possible to make a recommendation.

- 6.14 The committee concluded that, based on the results of the assessment carried out by the External Assessment Group, new generation cardiac CT scanners should be recommended for first-line imaging of coronary arteries in people with suspected stable coronary artery disease whose estimated likelihood of coronary artery disease is 10-29% and for first-line evaluation in people with known coronary artery disease in whom imaging is difficult.
- 6.15 The Committee was informed that there are currently as many as 40 new generation cardiac CT scanners being used in the NHS in England. The Committee considered that its recommendations should aim to optimise the use of the scanners that are currently in operation. The Committee considered the speed of development of technology and acknowledged that the impact of its recommendations would support the further introduction of new generation cardiac CT scanners in the NHS in the next few years.
- 6.16 The Committee considered if there were any specific equalities issues that would be relevant to this assessment, but none were raised.

# 7 Proposed recommendations for further research

The Diagnostics Advisory Committee has not made specific recommendations for further research. Although there is uncertainty about a number of issues related to the new generation cardiac CT scanners for the assessed population (for example test accuracy in obese people and people with very high calcium scores) and concern that the angiography was not an accurate gold standard, it was not felt that additional research was likely to change the Committee's recommendations.

# 8 Implementation

NICE intends to develop tools, in association with relevant stakeholders, to help organisations put this guidance into practice.

# 9 Related NICE guidance

#### Published

- Chest pain of recent onset: assessment and diagnosis of recent onset chest pain or discomfort of suspected cardiac origin. NICE clinical guideline 95 (2010). Available from www.nice.org.uk/guidance/CG95.
- Management of stable angina. NICE clinical guideline 126 (2011). Available from www.nice.org.uk/guidance/CG126.

#### Under development

There is currently no related guidance under development.

# 10 Review

NICE has not set a specific time for review, but will monitor improvements in the evidence base for the technologies to determine when a review would be appropriate.

Adrian Newland Chair, Diagnostics Advisory Committee August 2011

# Appendix A: Diagnostics Advisory Committee members and NICE project team

### A Advisory Committee members

The Diagnostics Advisory Committee is an independent Committee consisting of 22 standing members and additional specialist members. A list of the Committee members who participated in this assessment appears below.

#### **Standing Committee members**

#### Dr Trevor Cole

Consultant Clinical Geneticist, Birmingham Women's Hospital Foundation Trust

#### **Dr Paul O Collinson**

Consultant Chemical Pathologist, St George's Hospital

#### **Professor Ian Cree**

Director of Efficacy and Mechanisms Programme, NIHR Evaluation, Trials and Studies Coordinating Centre

#### **Dr Erika Denton**

National Clinical Director for Imaging, Department of Health

#### **Dr Simon Fleming**

Consultant in Clinical Biochemistry and Metabolic Medicine, Royal Cornwall Hospital

#### Professor Elizabeth (Lisa) Hall

Professor of Analytical Biotechnology, Institute of Biotechnology, Department of Chemical Engineering and Biotechnology, University of Cambridge

#### **Professor Chris Hyde**

Professor of Public Health and Clinical Epidemiology, Peninsula College of Medicine and Dentistry

#### **Professor Noor Kalsheker**

Professor of Clinical Chemistry, Molecular Medical Sciences, University of Nottingham

#### Dr Mark Kroese

Consultant in Public Health Medicine, Peterborough Primary Care Trust and UK Genetic Testing Network

#### **Professor Dietrich Mack**

Professor of Medical Microbiology and Infectious Disease, School of Medicine, Swansea University

#### **Professor Adrian Newland (Chair)**

Consultant Haematologist, Barts and the London NHS Trust

#### **Dr Richard Nicholas**

Consultant Neurologist, Heatherwood and Wexham Park Hospital, Imperial Healthcare Trust

#### Ms Margaret Ogden

Lay member

#### Dr Diego Ossa

Global Head, Health Economic and Outcomes Research, Novartis Molecular Diagnostics

#### Mr Stuart Saw

Director of Finance and Procurement, Tower Hamlets PCT

#### **Professor Mark Sculpher**

Professor of Health Economics, Centre for Health Economics, University of York

#### **Dr Steve Thomas**

Senior Lecturer and Consultant Radiologist, University of Sheffield

#### Mr Paul Weinberger

Managing Director, Diasolve Ltd

#### **Mr Christopher Wiltsher**

Lay member

#### **Specialist Committee members**

#### Ms Anne Keatley-Clarke

Lay member

#### Mrs Susan Ruth Clarke

Consultant Radiographer, Mid Yorkshire NHS Trust

#### **Dr Owen Miller**

Consultant in Paediatric and Fetal Cardiology, Evelina Children's Hospital

#### **Dr Simon Padley**

Consultant Radiologist, Chelsea and Westminster Hospital and Royal Brompton Hospital

#### Dr Francesca Puglese

Consultant Radiologist, Barts and the London NHS Trust

#### **Professor Carl Roobottom**

Professor of Radiology, Peninsula College of Medicine and Dentistry

#### Dr Ramesh de Silva

Consultant Cardiologist, Bedford Hospital NHS Trust

#### Mr John Walsh

Lay member

## B NICE project team

Each diagnostics assessment is assigned to a team consisting of one Technical Analyst (who acts as the topic lead), a Technical Adviser and a Project Manager.

#### Farouk Saeed

Topic Lead

#### Hanan Bell

Technical Adviser

#### Jackson Lynn

**Project Manager** 

# Appendix B: Sources of evidence considered by the

# Committee

- A. The diagnostic assessment report was prepared by Kleijnen Systematic Reviews.
  - Westwood M, Al M, Burgers L. Computed tomography (CT) scanners for cardiac imaging – Somatom Definition Flash, Aquilion ONE, Brilliance iCT and Discovery CT750 HD, May 2011.
- B. The following organisations accepted the invitation to participate in this assessment as stakeholders. They were invited to attend the scoping workshop and to comment on the diagnostics assessment report and the diagnostics consultation document.
  - I Manufacturers/sponsors:
    - a. The technologies under consideration
    - Toshiba Medical Systems
    - GE Healthcare
    - Philips Healthcare
    - Siemens AG Healthcare
    - b. Comparator technologies
    - None
  - II Professional/specialist and patient/carer groups:
    - ImPACT, Medical Physics Department, St. George's Healthcare NHS Trust
    - NHS Bradford and Airedale