

New generation cardiac CT scanners (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

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should [assess and reduce the environmental impact of implementing NICE recommendations](#) wherever possible.

Contents

1 Recommendations	4
2 The technologies.....	5
3 Clinical need and practice	6
The problem addressed	6
The condition.....	6
Prevalence and risk	7
The diagnostic and care pathways	7
4 The diagnostic tests	9
The individual tests: Aquilion One, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash	9
The comparator: invasive coronary angiography	10
5 Outcomes.....	11
How outcomes were assessed	11
Assessment of test accuracy.....	11
Clinical outcomes	14
Cost and cost effectiveness	16
6 Considerations	18
7 Recommendations for further research	23
8 Diagnostics advisory committee members and NICE project team.....	24
Diagnostic advisory committee	24
NICE project team	26
9 Sources of evidence considered by the committee	28
Registered stakeholders.....	28

1 Recommendations

- 1.1 New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash) are recommended as an option 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% to 29%) 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 as an option 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. CT scanning might not be necessary in situations in which 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.

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 CT scanners that have a variety of enhancements compared with earlier generation CT scanners. These enhancements, which vary among the 4 scanners, may include better temporal resolution, better spatial resolution and shorter acquisition times. 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. The scope of the evaluation was limited to these four new generation scanners that, although technically different, were viewed as being broadly comparable for cardiac imaging. The acquisition cost of these scanners varies depending on local discounts but estimates range from £900,000 to £1.1 million.

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% to 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. The [NICE guideline on recent-onset chest pain of cardiac origin](#) defines significant coronary artery disease as 70% or greater diameter stenosis of at least 1 major epicardial artery segment or 50% or greater diameter stenosis in the left main coronary artery.

3.3 The NICE guideline on recent-onset chest pain, before the 2016 update, recommended CT coronary angiography and invasive coronary angiography to assess arteries and identify significant stenosis. The guideline recommended using a 64-slice (or above) CT scanner in people with an estimated likelihood of coronary artery disease of 10% to 29% and a calcium score of 1 to 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 was not possible to estimate the number of people with cardiac disease in whom imaging would be difficult. However, a range of data sources can be used to give an estimate of this population in whom coronary imaging would be difficult. According to the Health Survey for England (2009), 22% of men and 24% of women are obese. Hospital Episode Statistics show that there was 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 heart rate of over 65 beats per minute and intolerance to beta blockers is included, the number of people in England 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 the [NICE guideline on recent-onset chest pain](#), before the 2016 update. The key elements (for the

imaging strategy) from the guideline's care pathway are as follows:

- People with chest pain who have an estimated likelihood of coronary artery disease of 10% to 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% to 60% should be offered non-invasive functional imaging for myocardial ischaemia.
- People with chest pain who have an estimated likelihood of coronary artery disease of 61% to 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 the [NICE guideline on managing stable angina](#) 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 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 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 2 heart beats.

Discovery CT750 HD

- 4.4 The Discovery CT750 HD is a 64×0.625 mm detector dual-energy CT scanner. It has a single X-ray source that switches between 2 energy levels, allowing 2 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 3 or 4 '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 64 × 0.6 mm detector dual-source CT scanner designed to provide high resolution images at a fast scanning speed with low-dose radiation. It has 2 X-ray tubes and 2 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 [section 3.4](#)), and it is this population that is of interest, 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. 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 ([section 8](#)) considered evidence from a number of sources ([section 9](#)).

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 Modelling was undertaken 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 was able to deduce true positive, true negative, false positive and false negative rates for new generation cardiac CT scanners compared with invasive coronary angiography. 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.

People with obesity

- 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 people with obesity. Obesity was defined as having a body mass index (BMI) of 30 kg/m² 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 1,304 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 1,526 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 this 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 8 studies reported accuracy data by arterial segment (8,133 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 8 studies used a threshold of vessel narrowing of at least 50% to define significant stenosis.
- 5.9 Beta-blockers are normally prescribed to slow the heart rate for people with heart rates too high for scanning. Some people with high heart rates are intolerant to beta-blockers, which makes it difficult to image them with earlier generation CT scanners. However, no studies were identified on the accuracy of new generation cardiac CT scanners for the detection of coronary artery disease in people who are intolerant to beta-blockers.

People with previous stent implants

- 5.10 Seven studies reported 10 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 modelling comprised 5 sub-models based on existing models to estimate the clinical outcomes of using new generation cardiac CT scanners. QALYs and costs in all 5 models were calculated and discounted at a rate of 3.5% for benefits and costs. These models are described below.

Diagnostic model

5.12 A diagnostic model was used to estimate the initial outcomes of treatment and initial diagnosis. This model was created through extending and linking the 5 sub-models. 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 diagnostic strategies were evaluated. These strategies were:

- Invasive coronary angiography only: people in whom imaging is difficult had invasive coronary angiography only, which was assumed to be perfectly accurate.
- New generation cardiac CT scanner only: people in whom imaging is difficult 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 in whom imaging is difficult, 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 3 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 mortality 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

- 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 variation 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, despite a known increase in complication rate compared with CT, generated more QALY gains than CT. It was also more expensive than imaging with a new generation cardiac CT scanner. The incremental cost-effectiveness ratio (ICER) of invasive angiography when compared with new generation cardiac CT is significantly greater than the NICE cost-effectiveness threshold.
- 5.21 In people with suspected coronary artery disease in whom imaging is difficult, the health economic analysis showed that, given a threshold of £20,000 per QALY gained, using new generation cardiac CT scanners instead of invasive coronary angiography is cost effective. The 'new generation CT scanner only' strategy was the most cost-effective strategy. The 'new generation CT scan plus invasive coronary angiography for those with positive CT scans' strategy delivered very small additional QALYS per patient (0.002) at a cost of £142. The ICER was £71,000 per QALY gained compared to the 'new generation CT scanner only' strategy. Similarly, relative to the 'new generation CT scanner only' strategy, 'invasive coronary angiography alone' also delivered a very small number of additional QALYS per patient (0.009) at a cost of £726 (ICER of £80,667 per QALY gained).
- 5.22 In people with known coronary artery disease who are difficult to image, the most cost-effective strategy was 'new generation cardiac CT scan plus invasive coronary angiography' for those with positive CT scans. This strategy dominated (more effective and less costly) the 'invasive coronary angiography only' strategy, generating more QALYs per patient (0.022) at reduced cost. The 'new generation cardiac CT scan plus invasive coronary angiography' strategy was the most preferred strategy for this cohort. Although it generated a very small reduction in QALYs per patient (0.001), it yielded a relatively large reduction in cost (£443)

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(ICER £726,230 per QALY) relative to the 'new generation cardiac CT scan only'.

6 Considerations

- 6.1 The scope 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 assessment was carried out on this basis. The committee considered comments on the diagnostics assessment report from stakeholders about the equivalence of the 4 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, the committee considered that it was reasonable to assume 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 any 1 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 scanner used, 1 study used Somatom Definition Flash, 1 used Aquilion ONE and 19 used Somatom Definition (a model predating the Somatom Definition Flash). The manufacturer of the Discovery CT750 HD confirmed the CT750 HD had been used in a study in which the details of the scanner were not provided. 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 assessment was based on the 24 studies with stratified data. The committee concluded that the evidence base for these technologies provided it with sufficient certainty for it to formulate recommendations. However, the committee considered it important that manufacturers make available specific test accuracy data stratified by important patient subgroups and noted that the current lack of such data made it difficult to make recommendations. The committee noted that it would only make recommendations on the scanners included in the scope, although evidence from scanners other than the 4 being evaluated was included in the assessment.
- 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, and the committee accepted this explanation.

- 6.4 The committee concluded that even though no usable data were available for Brilliance iCT, and one study each was available for Aquilion ONE, Discovery CT750 HD and Somatom Definition Flash, nevertheless it was reasonable for the committee to make recommendations that applied to all 4 of the assessed scanners.
- 6.5 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 data. Unfortunately, most of the data provided by manufacturers could not be included because it did not contain test accuracy results stratified for the relevant populations for the assessment.
- 6.6 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.
- 6.7 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 to some extent, 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 the lower risk of these outcomes and the reduced costs associated

with CT (reduced imaging costs and reduced downstream healthcare costs from dealing with complications), even though angiography had been assumed to be the more accurate test.

- 6.8 The committee considered how using new generation cardiac CT scanners for evaluating people with suspected coronary artery disease would fit in the context of the [NICE guideline on recent-onset chest pain](#). 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. The committee noted that earlier generation CT scanners used for people in whom imaging is not difficult are even less expensive and have similar risks and benefits than the new generation scanners. CT could be more cost effective than angiography for all people presenting with chest pain and a pre-test likelihood of 10% to 29% of coronary artery disease.
- 6.9 The NICE guideline on recent-onset chest pain, before the 2016 update, recommended calcium scoring to assess patients with an estimated likelihood of coronary artery disease of 10% to 29%, and varied its further imaging recommendations based on the calcium level. The value of calcium scoring was outside the scope of this evaluation and, thus, not explored further by the committee.
- 6.10 The committee considered whether angiography after CT was needed for people with positive CT scans. The analysis 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.
- 6.11 The committee was informed that, in current practice, people who are expected to have revascularisation would usually have angiography either before or as a part of treatment, but that the rate of elective angiography was dropping. The committee also heard that with time and additional clinician experience with CT angiography, it was likely that follow-up angiography solely for diagnostic purposes would become less frequent. 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% to 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.

6.12 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, evidence for this population had not been examined and no analysis had been undertaken.

6.13 The committee also considered whether it was appropriate to recommend CT scanning for people with suspected coronary artery disease who had prior likelihoods of coronary artery disease higher than 10 to 29%. The sensitivity analysis had shown that the use of new generation CT scanning is within NICE's standard levels of cost effectiveness compared with angiography for people in whom imaging is difficult and who have moderately higher than 29% 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% to 29%, **and**
- first-line evaluation of disease progression in people with known coronary artery disease in whom imaging is difficult.

6.15 The committee was informed that there are currently up to 40 new generation cardiac CT scanners being used in the NHS in England. The committee considered that its recommendations would help optimise the use of the

scanners that are currently in operation. The committee acknowledged that the impact of its recommendations would support the further introduction of new generation cardiac CT scanners in the NHS over 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 Recommendations for further research

The diagnostics advisory committee has not made specific recommendations for further research. Nevertheless, the committee recognised that there is uncertainty about a number of issues relating to the new generation cardiac CT scanners for the assessed population (for example, test accuracy in people with obesity and people with very high calcium scores) and that there is concern that angiography was not an accurate gold standard.

8 Diagnostics advisory committee members and NICE project team

Diagnostic advisory committee

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

New generation cardiac CT scanners (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

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

New generation cardiac CT scanners (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

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

NICE project team

Each diagnostics assessment is assigned to a team consisting of 1 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

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Project Manager

9 Sources of evidence considered by the committee

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.

Registered stakeholders

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.

Manufacturers/sponsors

- Toshiba Medical Systems
- GE Healthcare
- Philips Healthcare
- Siemens AG Healthcare.

Comparator technologies

- None.

Professional/specialist and patient/carer groups

- ImPACT, Medical Physics Department, St. George's Healthcare NHS Trust
- NHS Bradford and Airedale.

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