National Institute for Health and Clinical Excellence

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

DIAGNOSTICS ASSESSMENT PROGRAMME

Evidence overview

Computed tomography (CT) scanners for cardiac imaging – Somatom Definition FLASH, Aquilion ONE, Brilliance iCT and Discovery CT750 H

This overview summarises the key issues for the Diagnostics Advisory Committee's (DAC) consideration. It includes a brief description of the topic, a description of the analytical structure and model, a discussion of the analytical difficulties, and a brief summary of the results. It is not a complete summary of the diagnostics assessment report (DAR), and it is assumed that the reader is familiar with that document. This overview contains sections from the original scope and the DAR, as well as referring to specific sections of these documents.

1 Background

1.1 Introduction

The Medical Technologies Advisory Committee referred the Somatom Definition FLASH computed tomography (CT) scanner to the Diagnostic Assessment Programme for recommendations on its use. The Somatom Definition FLASH CT scanner (Siemens AG Healthcare) was expected to be particularly useful for detecting coronary artery stenosis in people with suspected or known coronary artery disease (CAD) in whom imaging is difficult, and for imaging in children and adults with congenital heart disease.

Research by the Programme's technical team at the scoping stage identified three other CT scanners for potential inclusion in the evaluation: Aquilion ONE (Toshiba Medical Systems), Brilliance iCT (Philips Healthcare) and Discovery CT750 (GE Healthcare). Attendees at the scoping workshop supported the inclusion of these technologies in the evaluation. The four scanners are collectively referred to as new generation cardiac CT (NGCCT) scanners.

1.2 The condition(s)

This assessment concerns the use of NGCCT scanners in two populations:

- adults (≥ 18 years) with suspected or known CAD in whom imaging is difficult and who are not candidates for 64-slice CT
- children and adults with congenital heart disease.

Coronary artery disease (for those in whom imaging is currently difficult)

CAD is characterised by narrowing of the coronary artery, usually as a result of atherosclerotic deposits of fibrous and fatty tissue, leading to reduced blood flow to the heart, angina and myocardial infarction. In 2007, CAD was estimated to have caused 91,000 deaths in the UK (approximately 19% of deaths in men and 13% in women).

NICE clinical guideline 95 ('Chest pain of recent onset') defines significant CAD as ≥ 70% diameter stenosis (narrowing) of at least one major epicardial artery segment or ≥ 50% in the left main coronary artery. To assess the state of arteries and identify significant stenosis, NICE clinical guideline 95 recommends CT coronary angiography and invasive coronary angiography ICA). The guideline recommends the use of a 64-slice (or above) CT scanner in people with an estimated probability of CAD of 10–29% and a calcium score of < 400. Recent systematic reviews have estimated the sensitivity and specificity of 64-slice CT for the detection of ≥ 50% coronary artery stenosis among people with CAD to be 92–99% and 89–92%, respectively.

The population for this portion of the evaluation is defined as adults (≥ 18 years) with known CAD who have symptoms that are no longer

controlled by drug treatment and/or who are being considered for revascularisation and adults with suspected CAD in whom CT imaging is currently difficult. These people may have:

- obesity
- high levels of coronary calcium (calcium score > 400)
- arrhythmias
- high heart rates (> 70 beats per minute)
- intolerance of beta-blockers
- stents
- previous bypass grafts

Congenital heart disease

Congenital heart disease is a general term used to describe birth defects that affect the heart and great vessels (aorta, pulmonary arteries and pulmonary veins). There are over 30 different types of congenital heart defects, the most common being ventricular or atrial septal defects, pulmonary or aortic stenosis, patent ductus arteriosus, tetralogy of Fallot and transposition of the great arteries.

The incidence of congenital heart disease in the UK is estimated to be 1 in every 150 babies born and approximately 85% of children born with these conditions respond well to treatment and will survive into adulthood. Adequate imaging of the defect is essential for planning surgery and/or treatment. Imaging methods currently employed in the diagnosis of congenital heart disease include echocardiography, magnetic resonance imaging (MRI) and 64-slice CT.

NGCCT scanners could provide additional information in people with complex congenital heart disease. Expert advice indicates that this would primarily involve lesions with a major extra cardiac component that is not well imaged by echocardiography. Examples of such lesions include pulmonary atresia with major aortopulmonary venous drainage, variants of anomalous pulmonary venous drainage, aortic arch abnormalities, and lesions with both a vascular and an airway component. NGCCT scanners may also be useful for

imaging in people with stents or pacemakers, which make imaging with MRI or 64-slice CT difficult or impossible

NGCCT scanners have a faster acquisition time and reduced radiation dose compared with 64-slice CT. These advantages might allow babies to be scanned without general anaesthesia and might reduce the rates of radiation-induced cancer in later life.

1.3 Diagnostic and care pathways

Coronary artery disease

Diagnosis

The care pathway for this evaluation is taken from 'Chest pain of recent onset' (NICE clinical guideline 95). The guideline recommends anatomical imaging for the diagnosis of significant CAD and functional imaging for the diagnosis of reversible myocardial ischemia. Both significant CAD and reversible myocardial ischemia can be included as a diagnosis of stable angina, which is defined as chest pain or discomfort that typically occurs with activity or stress and disappears at rest.

The key elements (for the imaging strategy) from the care pathway are as follows:

- People with chest pain who have an estimated probability of CAD of 10–29% should be offered calcium scoring followed by CT coronary angiography if the calcium score is between 1 and 400; those with high calcium scores (> 400) are considered difficult or impossible to image using current CT technologies (64-slice CT) and the guideline recommends ICA if this is considered clinically appropriate.
- People with chest pain who have an estimated probability of CAD of 30–60% should be offered non-invasive functional imaging for myocardial ischemia.
- People with chest pain who have an estimated probability of CAD of 61–90% should be offered intravenous coronary angiography if clinically appropriate and coronary revascularisation is being considered.

The types of non-invasive functional imaging are as follows:

- myocardial perfusion scintigraphy with single photon emission computed tomography
- stress echocardiography
- first-pass contrast-enhanced magnetic resonance perfusion
- MRI for stress-induced wall motion abnormalities.

It is important to note that the recommendations from NICE clinical guideline 95 for the diagnosis of chest pain of recent onset have not been implemented in all cardiac centres across the UK. This is most probably because the guideline is comparatively new and technological advances have been very rapid.

Clinical management

People with a diagnosis of significant CAD should initially have their condition managed as stable angina. The key provisional recommendation from NICE draft guidelines for the management of stable angina state:

- Functional tests for myocardial ischemia or anatomical tests for obstructive CAD to stratify risk are not routinely recommended.

- A short-acting nitrate should be offered for preventing and treating episodes of angina.

- Aspirin 75 mg daily should be considered for the secondary prevention of cardiovascular disease.

- Treatment with one or two anti-anginal drugs should be offered for the initial management of stable angina.

- First-line treatment options for stable angina are beta blockers and/or calcium channel blockers.

- For people who cannot tolerate beta-blockers or calcium channel blockers, or these drugs are contraindicated, monotherapy with a long-acting nitrate, ivabradine, nicorandil or ranolazine can be considered.

- For people on beta blocker or calcium channel blocker monotherapy whose symptoms are not controlled and the other option is contraindicated or not tolerated, one of the following can be considered as an additional drug: a long-acting nitrate, ivabradine (only in combination with a dihydropyridine calcium channel blocker), nicorandil or ranolazine.

- A third drug can be considered when symptoms are not controlled with two anti-anginal drugs and the person is waiting for revascularisation or it is not considered appropriate or acceptable.

Revascularisation

'Stable angina' (NICE clinical guideline 126) recommends considering revascularisation for people whose symptoms are not controlled by optimal medical treatment. Results of any functional and/or anatomical tests performed at diagnosis should be reviewed when revascularisation is being considered. Coronary angiography to guide the revascularisation strategy should be offered if not recently completed during diagnosis. Additional non-invasive or invasive functional testing may be required.

Two revascularisation strategies are available: coronary artery bypass graft involves major cardiac surgery; percutaneous coronary intervention involves widening of the artery using a balloon catheter and may be performed with or without stent implantation.

'Stable angina' (NICE clinical guideline 126) recommends that percutaneous coronary intervention should be considered in preference to coronary artery bypass graft for people with single-vessel disease or multi-vessel disease, including left main stem disease, and continuing symptoms despite optimal medical treatment if the anatomy is suitable for PCI. NICE clinical guideline 126 also recommends that the potential survival advantage of coronary artery bypass graft should be considered for people with multi-vessel disease, whose symptoms are not satisfactorily controlled with optimal medical treatment and who are over 65 years or have diabetes or have anatomically complex three-vessel disease, with or without involvement of the left main stem.

Congenital heart disease

No acceptable guidelines on the diagnosis and management of congenital heart disease in newborns, infants and children were identified. Limited information from other sources, such as patient UK and NHS choices, suggested that in cases of suspected congenital heart disease, a full clinical examination of the mother should be undertaken before echocardiography. Other tests such as electrocardiogram, chest X-ray, pulse oximetry , and in some instances CT and MRI, may also be used.

The European Society for Cardiology's (ESC) guideline on the management of adult congenital heart disease recommends:

- Clinical examination should be carried out followed by an electrocardiogram and pulse oximetry.
- Chest X-rays, although not routinely recommended, may be performed when indicated.
- Further investigation of anatomy and physiology by non-invasive protocols involving cardiovascular MRI and CT.
- ICA is reserved for the resolution of specific anatomical and physiological questions, or for intervention.

2 The technologies

2.1 Technologies under assessment

NGCCT scanners included in this evaluation have advanced technical features which address drawbacks such as spatial resolution, low contrast detection, noise, artefacts and high levels of radiation that are associated with 64-slice CT scanners.

Aquilion ONE

The Toshiba Aquilion ONE is a 640-slice CT scanner with 320 x 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 heart beat. In addition to

reducing the examination time, the radiation and the contrast dose are also reduced.

Brilliance iCT

The Philips Brilliance iCT is a new generation 256-slice multi-detector CT scanner with 128 x 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 it can capture an image of the heart in two heart beats.

Discovery CT750

The Discovery CT750 from GE Healthcare is a 2 x 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

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 uncooperative people, such as young children, and people who have difficulty holding their breath. The scanner also utilises a number of strategies to reduce the radiation dose associated with imaging.

2.2 Comparators

Coronary artery disease

ICA 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 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 are 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.

Despite some limitations, ICA is considered the reference standard for providing anatomical information and defining the site and severity of coronary artery lesions. Some serious complications include death, myocardial infarction, cerebrovascular accident, arrhythmia, vascular complications, allergic reaction to contrast media, haemodynamic complications and perforation of the heart chamber.

Congenital heart disease

Cardiac CT is likely to be used in people with congenital heart disease for planning surgery and/or treatment after diagnosis and as an addition to echocardiography and MRI. Therefore, 64-slice CT is the only relevant comparator for assessment of congenital heart disease.

3 The evidence

3.1 Test accuracy

The External Assessment Group (EAG) conducted a systematic review to identify the evidence on the clinical effectiveness of NGCCT scanners for the diagnosis of clinically significant CAD in people in whom imaging is difficult, and for treatment planning in people with complex congenital heart disease.

Coronary artery disease

A total of 24 studies matched the inclusion criteria and were test accuracy studies conducted in people with known or suspected coronary artery disease. 3 studies did not specify the model of scanner used, 1 study used Aquilion ONE, 1 used Somatom Definition FLASH and 19 used Somatom Definition (a previous model of Somatom Definition Flash).

Sensitivities and specificities used in the economic model are shown in table 1 below. These were computed from meta-analysis [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 wherever possible.

Congenital heart disease

No studies of people with congenital heart disease, which met the inclusion criteria of the review, were identified during the assessment. Diagnostic accuracy in this population was not considered a relevant outcome as existing imaging strategies can provide accurate initial diagnoses without the need for radiation exposure.

Table 1 Summary of test accuracy results

Patient group	Unit of analysis	No of studies	n	Sensitivity	I^2	Specificity	I^2
Obesity (BMI ≥30 kg/m2)	Segment	1	543	90.4% (95% CI 83.8 to 94.9)	NA	92.1% (95% CI 89.1 to 94.5)	NA
High calcium score (>400)	Segment	4	1304	92.7% (95% CI 88.3% to 95.6%)	54.2 %	90.6% (95% CI 80.6% to 95.8%)	92.2 %
Arrhythmias	Patient	4	126	97.7% (95% CI 88.0% to 99.9%)	1.4%	81.7% (95% CI 71.6% to 89.4%)	0%
	Segment	4	1526	87.4% (95% CI 68.3% to 95.7%)	79.6 %	96.0% (95% CI 91.2% to 98.2%)	89.5 %
High heart rate (≥65 bpm)	Patient	5	462	97.7% (95% CI 93.2% to 99.3%)	39.0 %	86.3% (95% CI 80.2% to 90.7%)	49.8 %
	Artery	4	664	93.7% (95% CI 87.8% to 96.9%)	0%	92.4% (95% CI 83.3% to 96.8%)	83.7 %
	Segment	8	8133	92.7% (95% CI 89.3% to 95.1%)	67.1 %	95.7% (95% CI 92.8% to 97.4%)	92.8 %
Previous stent implantation	Patient	4	233	96.0 (95% CI 88.8% to 99.2%)	19.0 %	81.6% (95% CI 74.7% to 87.3%)	0%
	Stent/ stented lesion	6	582	93.6% (95% CI 86.1% to 97.2%)	0%	91.0% (95% CI 87.3% to 93.7%)	35.1 %

3.2 Clinical outcomes

Coronary artery disease

Five models were combined to estimate the cost effectiveness of NGCCT scanners. Quality-adjusted life years (QALYs) and costs in all five models were calculated and discounted at a rate of 3.5%. These models are:

- Diagnostic model: a decision tree that models the diagnostic pathway.
- Healthy population Markov model: a life–death Markov model for 'healthy' people without coronary artery disease.
- Stroke model: a simple stroke model to estimate the impact of tests and treatment related to stroke.
- EUROPA model: a model for the prognosis of people with coronary artery disease.
- York Radiation Model: a model that estimates the impact of imaging in terms of radiation dose on cancer morbidity and mortality. The same model was used in the assessment of the EOS 2D/3D X-ray imaging system.

Diagnostic model

The diagnostic model estimates the initial outcomes of treatment and initial diagnosis. Morbidity and mortality associated with diagnostic tests and treatments were modelled. Using ICA as a comparator, three treatment strategies were evaluated in people with suspected or known CAD in whom imaging was difficult or impossible. These strategies are:

- ICA only: people undergo ICA only, which was assumed to be perfectly accurate.
- new generation cardiac CT scanner only: people undergo a new generation cardiac CT scan only; the accuracy of the scan was based on ICA as the reference standard.
- new generation cardiac CT scan plus invasive coronary angiography: cardiac CT is first performed on everyone and those with a positive scan then undergo invasive coronary angiography; no false positives can occur with this strategy because ICA is assumed to have perfect specificity.

The clinical outcomes assessed for people with CAD 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 (see tables 55 and 56 on pages 152–154 of the DAR for more information).

Healthy population model

The healthy population model only applies to those who do not have CAD (true negatives and false positives). Life tables were used to predict mortality for these people on the assumption that they do not differ from the average UK population.

EUROPA model

The EUROPA model models the progression of stable CAD 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

The costs and outcomes of people who experience a stroke because of initial ICA or revascularisation were modelled with a relatively simple life–death model. Mortality rates were based on UK life tables and a relative risk of 2.5 to reflect the increased risk of mortality following a stroke. The model was calibrated to fit with results from earlier studies which indicated an average health utility of 0.37.

The primary measures of benefit used in this analysis are:

- the complication rate for ICA 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.

Congenital heart disease

No studies of people with congenital heart disease met the inclusion criteria and resource constraints precluded seeking expert advice on likely changes in outcomes as a result of better quality images provided by NGCCT scanners.

The only clinical outcome examined for people with congenital heart disease is the impact of radiation dose reduction. NGCCT scanners were assumed to produce 50% less radiation than 64-slice CT scanners. The York Radiation Model was used to model the impact of radiation on future cancer incidence. This modelling was restricted to breast, lung, colorectal and prostate cancers. This is essentially the same model used in the assessment of the EOS 2D/3D X-ray imaging system.

For 64-slice CT, radiation doses were based on expert opinion. The figures ranged from 1.6 mSv for very small children to 6 mSv for adults (see table 69 on page 178 of the DAR). Incremental quality-adjusted life years (QALYs) varied by age from about –0.000071 to –0.000397 (see table 74 on page 180 of the DAR).]

3.3 Costs and cost effectiveness

Coronary artery disease

The models described above were also used to estimate the costs of the diagnostic tests and treatments the people received both for their initial condition and any subsequent related conditions that developed.

Diagnostic model

The model estimated the costs of diagnosis and initial treatment in addition to the mortality and morbidity associated with the two revascularisation procedures. The average cost for the revascularisation procedures and the ICA were calculated based on the NHS reference prices (see table 31 on page 128 of the DAR). Reference costs for each of the different types of scan were unavailable. Consequently, a bottom-up costing was performed (see table 30 on page 127 of the DAR). It should be noted that when this was done, the estimated cost of 64-slice CT was higher than the reference cost. This was attributed to increased staff costs for specialist scans as well as the

fact that much of the capital cost of existing scanners is not included in the reference cost.

Healthy population model

No costs were assigned to this Markov model.

EUROPA model

Healthcare costs were grouped into three categories:

- Background costs. These are the costs applied to the trial entry state and non-fatal event states. They were based on age, the existence of vascular diseases, diabetes mellitus, medication usage, clearance and symptomatic disease (see tables 37 and 38 on page 135 of the DAR).
- Non-fatal event costs; £11,805 was added to the background costs for the year in which a non-fatal event occurs.
- Fatal event costs; £3641 was added for the year in which a fatal cardiovascular event occurs and £12,421 was added when a fatal non-cardiovascular event occurred.

Stroke model

A cost of approximately £6260 in the first year after a stroke was estimated and an average annual cost of £3400 in subsequent years. The costs were discounted at a rate of 3.5%.

York Radiation Model

The costs used in this model were those associated with radiation-induced cancer (see table 46,on page 144 of the DAR).

The health economic analysis showed that in people with suspected coronary artery disease, the use of new generation cardiac scanners only is the more cost effective option. The incremental cost-effectiveness ratios (ICERs) for other options were too high (ICER for CT and ICA compared with CT alone was £71,000 per QALY gained and ICA only was dominated). In people with known coronary artery disease, the most cost effective attractive strategy would be to perform a cardiac CT scan and then ICA (see tables 59 and 60 on pages162–165 of the DAR).

3.3.2 Congenital heart disease

The key parameters of the York Radiation Model were the same for congenital heart disease as for coronary artery disease. The only difference was the radiation doses, which were based on expert opinion (see table 69 on page178 of the DAR). Scenario and sensitivity analyses were carried out in which key parameters for congenital heart disease were varied. A summary statistic of the distribution of the incremental effects, the incremental costs, and the ICER of the probabilistic sensitivity analysis in the base case are given in table 80 on page 183 of the DAR. With an ICER that ranged from £521,000 per QALY gained for the youngest children to £90,000 per QALY gained for adults, the analysis showed that when considering only radiation exposure, the use of NGCCT scanners instead of a 64-slice CT is not cost-effective in this group.

4 Issues for consideration

a. A number of stakeholders have pointed out that there is no clear definition of NGCCT scanners and questioned whether the four technologies assessed should be considered as equivalent. It should be noted that this issue was acknowledged and discussed thoroughly in the scoping workshop and at the assessment sub-group meeting. The manufacturers and clinical experts all agreed that while the scanners used different technologies, the net result was that these scanners could all image the population in the scope where the previous scanners could often not do so. There was also agreement to assessing the four scanners as a group rather than individually because comparative studies were not available.

b. Of the 24 included studies, only 2 used NGCCT scanners (Somatom Definition FLASH and Aquilion ONE). 3 studies did not specify the model of scanner used and the other 19 studies used the Somatom Definition, a product that preceded the Somatom Definition FLASH. The main differentiations (as stated by the manufacturer) between Somatom Definition FLASH and Somatom Definition are reduced scan

time and reduced radiation dose. The 2 studies that used the scanners under assessment were on people who are difficult to image due to stents. All data on other difficult to image groups were obtained from studies using Somatom Definition, the previous version of Somatom Definition FLASH. While the results of diagnostic accuracy between Aquilion ONE, Somatom Definition FLASH and Somatom Definition were not heterogeneous, the inclusion of data on other scanners may be an issue.

c. The reference standard, ICA was assumed to have 100% sensitivity and 100% specificity. In clinical practice, ICA is not a 100% accurate because of inter- and intra- observer variations and vessel overlap and because angiography only shows the vessel lumen. If the assumption of 100% accuracy does not hold and false positives and negatives do occur, it is possible that the true sensitivity and specificity of the index test will be underestimated (see pages 196-197 of DAR). Furthermore, the assumption of perfect diagnostic accuracy of ICA is important because NGCCT itself has high sensitivity and specificity. The additional accuracy assumed for angiography is the key to ICA coming out as the clinically superior approach. It should be noted, however, that despite its limitations, ICA remains an accepted reference standard for assessment of anatomic coronary disease.

d. On page 132 of the DAR, the health-related quality of people without CAD but who have already exhibited symptoms that mimic the disease was assumed to be equal to that of the general population. The difference between the two populations was assumed to be extremely small.

e. No studies of people with congenital heart disease, which met the inclusion criteria of the review, were identified. The analysis of people with congenital heart disease focused only on reduction of radiation dose.

f. The incremental QALYs as a result of reduction in radiation dose varied by age from about –0.000071 to –0.000397 with greater benefit for older people. Table 74 on page 180 appears to suggest that people exposed to radiation at the age of 35 have an increased risk of cancer compared to those exposed at the age of 1. This is counter-intuitive and may have resulted from the assumption in the model that cancers occur at the same age irrespective of the time of radiation exposure. Thus the benefits to younger people are reduced because of discounting.

g. There are at least seven NGCCT scanners currently in use within the NHS in England. Recommendations can focus on the use of existing NGCCT scanners for cardiac imaging or alternatively extend to the purchase of additional scanners for that purpose.

5 Equality considerations

The scanner weight limit and table height limit may have equality related implications for people with a disability.

6 Summary

The objective of the evaluation was to assess the clinical and cost effectiveness of NGCCT scanners in the diagnosis of clinically significant CAD in people in whom accurate imaging with 64-slice CT scanners is difficult or impossible and in planning treatment for people with congenital heart disease. A systematic review was conducted to identify the evidence on the clinical effectiveness of NGCCT scanners. Twenty-four studies (26 publications) that reported data on the accuracy of NGCCT scanners for the diagnosis of clinically significant CAD in people in whom imaging was difficult were included in the systematic review. Estimates of test accuracy were generally high. The pooled estimates of sensitivity were 97.7% (95% CI 88.1% to 99.9%), 97.7% (95% CI 93.2% to 99.3%) and 96.0% (95% CI 88.8% to 99.2%), for people with arrhythmias, people with high heart rates and people with previous stents, respectively. The corresponding pooled estimates of

specificity were 81.7% (95% CI 71.6% to 89.4%), 86.3% (95% CI 80.2% to 90.7%) and 81.6% (95% CI 74.7% to 87.3%), respectively. The high per patient estimates of sensitivity (>95%) indicate that NGCCT scanners could be used to reliably rule out significant stenosis and thus potentially avoid invasive investigations such as coronary angiography in these groups.

In the health economic analysis, the cost effectiveness of NGCCT scanners was assessed against ICA for people with CAD in whom imaging is difficult, and against 64-slice CT in people with congenital heart disease. Five models were combined to estimate the cost effectiveness of the NGCCT scanners in people with CAD and one model was used to assess the cost effectiveness of using the scanners to reduce radiation exposure in people with congenital heart disease. The results of the analysis showed that in people with CAD in whom imaging is difficult, the use of a new generation cardiac CT scanner instead of ICA may be considered cost effective (cardiac CT scan only in suspected CAD and cardiac CT scan followed by ICA in known coronary artery disease).

The health economic analysis of the use of NGCCT scanners in congenital heart disease showed that, when only radiation exposure was considered as an outcome, the use of a new generation scanner instead of 64-slice CT was not cost effective.

The principal uncertainties relate to the assumption of perfect accuracy for the analysis adults in whom imaging is difficult and the lack of information about any imaging benefits in people with congenital heart disease.

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Appendix A: Sources of evidence considered in the preparation of the overview

A The diagnostics assessment report for this assessment was prepared by Kleijnen Systematic Reviews Ltd. Assessment Group:

- 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 Submissions or statements were received from the following organisations

I. Manufacturers/sponsors

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

II. Professional/specialist, patient/carer and other groups:

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