NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Report for Guidance Executive

Review of DG3: 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.

This guidance was issued in January 2012.

The review date for this guidance is January 2015.

NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance. Other factors such as the introduction of new technologies relevant to the guidance topic, or newer versions of technologies included in the guidance, will be considered relevant in the review process, but will not in individual cases always be sufficient cause to update existing guidance.

1. Recommendation

A technical supplement should be produced and the guidance should be transferred to the 'static guidance list'.

We should consult on the proposal.

A list of the options for consideration and the consequences of each option is provided in Appendix 1 at the end of this paper.

2. Original objective of guidance

To assess the clinical and cost-effectiveness of new generation cardiac CT, using CT750 HD (GE Healthcare), Brilliance iCT (Phillips Healthcare), Somatom Definition Flash (Siemens healthcare), or Aquilion ONE (Toshiba Medical Systems) for:

- adults (18 years or older) with suspected coronary artery disease in whom imaging with earlier generation CT is difficult 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 and in whom revascularisation is being considered.

3. Current guidance

Adoption 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 10–29%, 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 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.

Research recommendations

The Diagnostics Advisory Committee did not make specific recommendations for further research.

4. Rationale

Changes in clinical practice, technology costs or evidence that would lead to a change in the recommendations of the original guidance have not been identified. However, all CT scanners included in the original guidance have been upgraded with new features or replaced with newer models. It is therefore proposed that a technical supplement describing these newer versions is produced, and that the guidance is placed on the static list.

5. Implications for other guidance producing programmes

An update of the NICE guideline on Chest pain of recent onset (CG95) has been commissioned to the clinical guidelines updates team. This will include 2 review questions for people with stable chest pain:

- What is the incremental benefit and cost effectiveness of a clinical history, cardiovascular risk factors and a physical examination in evaluation of individuals with stable chest pain of suspected cardiac origin?
- What is the diagnostic utility of non-invasive and invasive tests for the evaluation of patients with stable chest pain of suspected cardiac origin?

It is likely that the second review question will be relevant to diagnostics guidance 3.

6. New evidence

The search strategies from the original diagnostics assessment report were re-run on Medline, Medline in-process, Embase, Cochrane Database of Systematic Reviews and CENTRAL, DARE, NHS EED, HTA Database, and Science Citation Index. References from January 2011 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the diagnostic and care pathways. Companies were asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. Specialist Committee Members for this guidance topic were also consulted and asked to submit any information regarding changes to the technologies, the evidence base and clinical practice. The results of the literature

search are discussed in the ‘New studies’ and ‘Summary of evidence and implications for review’ sections below. See Appendix 2 for further details of ongoing studies.

6.1 Technologies

Since the publication of diagnostics guidance 3 in January 2012, there have been a number of changes in the CT scanner technologies included in the guidance. One CT scanner model is no longer marketed and has been replaced by a newer model. Three CT scanner models have been upgraded with new features. There are also 3 new CT scanners which have become available to the NHS since the guidance was published. These new CT scanners are suitable for cardiac imaging in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners.

The acquisition and maintenance costs of the scanners have [redacted] since diagnostics guidance 3 was published (table 1).

Table 1: Acquisition and maintenance costs for CT scanners (2014)

	Acquisition cost (ex. VAT)	Maintenance cost	Total cost per scan
DAR (2011)	£1,000,000	£137,941	£169.26
Somatom Definition Flash	[redacted]	[redacted] ([redacted]) [redacted] ([redacted])	[redacted]
Aquilion ONE	[redacted]	[redacted] to [redacted] ([redacted]) [redacted] to [redacted] ([redacted]) [redacted] to [redacted] ([redacted])	[redacted]
Aquilion ONE ViSION	[redacted]	[redacted] to [redacted] ([redacted]) [redacted] to [redacted] ([redacted]) [redacted] to [redacted] ([redacted])	[redacted]
Brilliance iCT	[redacted]	[redacted]	[redacted]

Discovery CT750 HD	[redacted] (Revolution HD) [redacted] (Revolution GSI)	[redacted]	[redacted]

6.1.1 Somatom Definition Flash (Siemens)

An upgraded version of the Somatom Definition Flash CT scanner is now available. It is known as the Somatom Definition Flash Stellar, and upgrades include:

- A new Stellar detector which reduces electronic noise, provides sharper slice profiles, and improves spatial resolution.
- New iterative reconstruction software which produces images with improved resolution.
- New software which selects the kilovoltage setting based on patient size and clinical application. This enables optimal image quality at the lowest possible radiation dose.

6.1.2 Aquilion One (Toshiba)

There have been a number of upgrades to the Aquilion One CT scanner, which is now known as the Aquilion One ViSION Edition:

- A new PUREViSION detector which gives improved dose efficiency and reduces electronic noise.
- The gantry rotation time has been reduced which gives improved temporal resolution.
- A larger generator.
- New software which selects the kilovoltage setting based on patient size and clinical application. This enables optimal image quality at the lowest possible radiation dose.

It is possible to upgrade an existing Aquilion One CT scanner to an Aquilion One ViSION Edition.

6.1.3 Brilliance iCT (Philips)

There have been 2 software updates to the Brilliance iCT scanner:

- New iterative reconstruction software which allows increased dose reduction and improved artefact reduction.
- New automatic x-ray tube current modulation software which enables reductions in radiation dose.

6.1.4 Discovery CT750 HD (GE Healthcare)

The GE Discovery CT750 HD scanner model is no longer marketed. It has been replaced by the Revolution GSI and Revolution HD scanner models. The GSI model has dual energy scanning, whereas the HD model double samples the detectors to provide images with higher spatial resolution. The new features of the Revolution GSI and Revolution HD scanners are:

- The Revolution GSI has a touch-screen interface included in the scanner gantry for improved patient workflow.
- New software which corrects for motion and is useful for imaging patients with high heart rates.
- New software for automatic selection of x-ray tube potential for optimisation of image quality at reduced radiation dose.

6.1.5 Additional technologies

Somatom Force (Siemens)

The Somatom Force has a number of enhancements compared to the Somatom Definition Flash Stellar: reduced gantry rotation time, increased longitudinal detector coverage, a larger generator, a new x-ray beam filter, and a ‘turbo flash’ scan mode.

Revolution CT (GE Healthcare)

Compared to the Revolution GSI model, the Revolution CT has a wider gantry aperture and a decrease gantry rotation. However, the Revolution CT model does not have dual energy scanning.

IQon Spectral CT (Philips)

The IQon Spectral has decreased longitudinal detector coverage compared with the Brilliance iCT model. However, it has a new detector array which allows dual energy scanning using a dual layer detector.

6.2 Clinical practice

Searches for guidance produced by relevant professional bodies, and advice received from clinical experts, suggest that the diagnostic and care pathways relevant to diagnostics guidance 3 have not changed since its publication. However, the NICE guideline on Chest pain of recent onset is due to undergo a partial update.

6.3 New studies

Sixteen new studies have been identified which report outcomes relevant to the decision problem. All new studies were diagnostic accuracy studies conducted in patients with known or suspected coronary artery disease. Results from these studies are tabulated below, divided by patient group. Comparisons with results from the original review focus on per patient accuracy (rather than per stent, graft, artery or segment) as these were the data used in the economic modelling.

6.3.1 Patients with stents

Five studies were identified which report the diagnostic accuracy of new generation CT scanners for the detection of coronary artery disease in patients with previous stent implantation. Results from these studies are presented in table 2. In summary:

- Two new studies report per patient sensitivity ranging from 59% to 100%, compared with 4 studies from the original review which report per patient sensitivity ranging from 89.5% to 100%, with a summary estimate of 96.0% (95% CI 88.8% to 99.2%).
- Two new studies report per patient specificity ranging from 53% to 88%, compared with 4 studies from the original review which report per patient specificity ranging from 50.0% to 89.5%, with a summary estimate of 81.6% (95% CI 74.7% to 87.3%).

Table 2: Summary results of studies conducted in patients with stents

Study	Population	CT scanner	Sensitivity	Specificity
Eisentopf et al. (2013)	Patients (n=50) with coronary stents (n=87)	Somatom Definition Flash, Siemens	Patient based: FBP = 97% IR = 100% Stent based: FBP = 85% IR = 100% Vessel based: FBP = 89% IR = 96%	Patient based: FBP = 53% IR = 65% Stent based: FBP = 69% IR = 75% Vessel based: FBP = 79% IR = 84%
Kong et al. (2013)	Patients (n=11) with coronary stents (n=24)	Discovery CT750 HD scanner (GE Healthcare)	Vessel based: 87.5%	Vessel based: 100%
Rief et al. (2013)	Patients (n=91) with coronary stents (n=221)	320-row CT Aquilion ONE, Toshiba Medical Systems	For CTA/CTP: By patient: 82% By stent: 78% For CTA alone: By patient: 59% By stent: 56%	For CTA/CTP: By patient: 88% By stent: 90% For CTA alone: By patient: 74% By stent: 78%
Wuest et al. (2013)	Patients (n=42) with coronary stents (n=73)	128-slice Somatom Definition Flash, Siemens	By stent: FBP = 83% IR = 100%	By stent: FBP = 71% IR = 76%
Yang et al. (2013)	Patients (n=180) with coronary stents (n=256)	128 slice dual-source Somatom Definition Flash, Siemens	By stent: HPS: 90% SEQ: 92.3% LPS: 93.3%	By stent: HPS: 97.1% SEQ: 95.9% LPS: 97.3%
CTA=computed tomography angiography; CTP=computed tomography perfusion; FBP=filtered back projection; HPS=high pitch spiral; IR=iterative reconstruction; LPS=low pitch spiral; SEQ=sequential				

6.3.2 Patients with a coronary artery bypass graft

Three studies were identified which report the diagnostic accuracy of new generation CT scanners for the detection of coronary artery disease in patients with a coronary artery bypass graft. Results from these studies are presented in table 3. In summary:

- One new study reports a per patient sensitivity of 98%, compared with 1 study from the original review which reports a per patient sensitivity of 96.4% (calculated 95% CI 87.5% to 99.6%).
- One new study reports a per patient specificity of 67%, compared with 1 study from the original review which reports a per patient specificity of 87.0% (calculated 95% CI 66.4% to 97.2%).

Table 3: Summary results of studies conducted in patients with a coronary artery bypass graft

Study	Population	CT scanner	Sensitivity	Specificity
Kepka et al. (2012a)	Patients (n=90) with bypass grafts (n=256)	Somatom Definition, Siemens	Per patient: 98%	Per patient: 67%
Sahiner et al. (2012)	Patients (n=284) with bypass grafts (n=684)	64-slice Somatom Definition, Siemens	Per graft: 99.6%	Per graft: 97.3%
Yuceler et al. (2014)	Patients (n=88) with bypass grafts (n=215)	256-slice Somatom Definition Flash, Siemens	Per segment: 97.1%	Per segment: 99.6%

6.3.3 Patients with high heart rates

Six studies were identified which report the diagnostic accuracy of new generation CT scanners for the detection of coronary artery disease in patients with high heart rates. Results from the studies are presented in table 4. In summary:

- Two new studies report per patient sensitivity of 100%, compared with 5 studies from the original review which report per patient sensitivity ranging from 93.5% to 100%, with a summary effect estimate of 97.7% (95% CI 93.2% to 99.3%).
- Three new studies report per patient specificity ranging from 63.6% to 95%, compared with 5 studies from the original review which report per patient specificity ranging from 42.9% to 91.7%, with a summary effect estimate of 86.3% (95% CI 80.2% to 90.7%).

Table 4: Summary results of studies conducted in patients with high heart rate

Study	Population	CT scanner	Sensitivity	Specificity
Kim et al. (2012)	Patients (n=52) with heart rate ≥75 bpm	Somatom Definition Flash, Siemens	By segment: 97.7%	By segment: 95.3%

Study	Population	CT scanner	Sensitivity	Specificity
Neefjes et al. (2013)	Patients (n=228) with heart rate ≥65 bpm	128-slice Somatom Definition Flash, Siemens	By patient: WWS: 100% RS: 100% By segment: WWS: 94% RS: 92% By vessel: WWS: 99% RS: 97%	By patient: WWS: 78% RS: 78% By segment: WWS: 95% RS: 95% By vessel: WWS: 88% RS: 91%
Sun et al. (2011)	Patients (n=33) with heart rate ≥75 bpm	Somatom Definition, Siemens	By segment: 80.3% By vessel: 92.7%	By segment: 98.6% By vessel: 98.7%
Sun et al. (2012)	Patients (n=47) with heart rate >65 and <100 bpm	Somatom Definition Flash, Siemens	By segment: 92.6% By vessel: 90% By patient: 100%	By segment: 97% By vessel: 95.2% By patient: 63.6%
Takaoka et al. (2013)	Patients (n=35) with heart rate ≥65 bpm	Aquilion One, Toshiba Medical	Virtual prospective-ECG-gating without padding: 82% Virtual prospective-ECG-gating with padding: 97% Retrospective-ECG-gating: 97%	Virtual prospective-ECG-gating without padding: 94% Virtual prospective-ECG-gating with padding: 96% Retrospective-ECG-gating: 96%
Zhang et al. (2011)	Patients (n=120) with heart rate >65 bpm	Unspecified 320 slice scanner	Not reported	Per patient: 95%
Bpm=beats per minute; ECG=electrocardiography; RS=retrospective spiral; WWS=wide-window sequential				

6.3.4 Patients with arrhythmias

One study was identified which reports the diagnostic accuracy of new generation CT scanners for the detection of coronary artery disease in patients with atrial fibrillation. Results from this study are presented in table 5. In summary:

- One new study reports a per patient sensitivity of 90%, compared with 4 studies from the original review which report per patient sensitivity ranging from 90.0% to 100%, with a summary effect estimate of 97.7% (95% CI 88.0% to 99.9%).

- One new study reports a per patient specificity of 92.6%, compared with 4 studies from the original review which report per patient specificity ranging from 75.0% to 84.8%, with a summary effect estimate of 81.7% (95% CI 71.6% to 89.4%).

Table 5: Summary results of the study conducted in patients with arrhythmias

Study	Population	CT scanner	Sensitivity	Specificity
Xu et al. (2011)	Patients (n=37) with persistent atrial fibrillation	Aquilion ONE, Toshiba Medical Systems	By patient: 90% By vessel: 93.8% By segment: 90%	By patient: 92.6% By vessel: 96.8% By segment: 99.3%

6.3.5 Patients with high heart rate plus arrhythmias

One study was identified which reports the diagnostic accuracy of new generation CT scanners for the detection of coronary artery disease in patients with a high heart rate and/or atrial fibrillation. Results from this study are presented in table 6. In summary:

- One new study reports a per patient sensitivity of 90%, compared with 1 study from the original review which reports a per patient sensitivity of 91.7% (calculated 95% CI 61.5% to 99.8%).
- One new study reports a per patient specificity of 88%, compared with 1 study from the original review which reports a per patient specificity of 88.2% (calculated 95% CI 72.5% to 96.7%).

Table 6: Summary results of the study conducted in patient with high heart rate and/or arrhythmias

Study	Population	CT scanner	Sensitivity	Specificity
Uehara et al. (2013)	Patients (n=106) with heart rate >64 bpm and/or atrial fibrillation	320-Slice Aquilion One, Toshiba Medical	By patient: 90% By vessel: 76% By segment: 63%	By patient: 88% By vessel: 94% By segment: 98%

7. Summary of new evidence and implications for review

Since the publication of diagnostics guidance 3, all CT scanners included in the original guidance have been upgraded with new features or replaced with newer models. A technical supplement describing these newer versions could be helpful to users of the guidance.

As in the original review, no studies were found that reported evidence on impact of testing on treatment plan or clinical outcomes for patients with known or suspected coronary artery disease in whom cardiac imaging is difficult. All new studies were diagnostic accuracy studies. Of these, the majority reported per patient sensitivity and specificity estimates which are in line with those reported in the studies from the original review. Given that new accuracy data are comparable to those in the original review, they are unlikely to have an effect on the existing guidance recommendations. It is therefore suggested that the guidance is transferred to the static list.

8. Implementation

The national resource impact of the NICE diagnostics guidance on the benefits of access to new generation cardiac CT scanners for cardiac imaging is difficult to quantify, and should be investigated locally. Therefore, NICE developed a costing statement alongside the original guidance explaining the resource impact of this guidance.

9. Equality issues

No potential equality issues were raised in the original guidance.

GE paper sign off: Carla Deakin 25 February 2015

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Appendix 1 – explanation of options

If the published Diagnostics Guidance needs updating NICE must select one of the options in the table below.

Options	**Consequence**	**Selected – 'Yes/No'**
Standard update of the guidance	A standard update of the Diagnostics Guidance will be planned into NICE's work programme.	No
Accelerated update of the guidance	An accelerated update of the Diagnostics Guidance will be planned into NICE's work programme. Accelerated updates are only undertaken in circumstances where the new evidence is likely to result in minimal changes to the decision problem, and the subsequent assessment will require less time to complete than a standard update or assessment.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Diagnostics Guidance does not need updating NICE must select one of the options in the table below.

Options	**Consequences**	**Selected – 'Yes/No'**
Transfer the guidance to the 'static guidance list'	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Diagnostics Guidance on the static list should be flagged for review.	Yes
Produce a technical supplement	A technical supplement describing newer versions of the technologies is planned into NICE's work programme.	Yes
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Diagnostics Guidance is no longer valid and is withdrawn.	No

Appendix 2 – supporting information

Relevant Institute work

Published

Prasugrel with percutaneous coronary intervention for treating acute coronary syndromes NICE technology appraisal guidance 317 (2014)

Myocardial infarction (acute): Early rule out using high-sensitivity troponin tests (Elecsys Troponin T high-sensitive, ARCHITECT STAT High Sensitive Troponin-I and AccuTnI+3 assays) NICE diagnostics guidance 15 (2014)

Myocardial infarction with ST-segment elevation NICE clinical guidance 167 (2013)

Management of stable angina NICE clinical guideline 126 (2011)

Ticagrelor for the treatment of acute coronary syndromes NICE technology appraisal guidance 236 (2011)

The VeriQ system for assessing graft flow during coronary artery bypass graft surgery NICE medical technology guidance 8 (2011)

Chest pain of recent onset NICE clinical guideline 95 (2010)

Unstable angina and NSTEMI NICE clinical guideline 94 (2010)

Clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events NICE technology appraisal guidance 210 (2010)

SeQuent Please balloon catheter for in-stent coronary restenosis NICE medical technology guidance 1 (2010)

Drug-eluting stents for the treatment of coronary artery disease NICE technology appraisal guidance 152 (2008)

Guidance on the use of coronary artery stents NICE technology appraisal guidance 71 (2003)

Guidance on the use of glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes NICE technology appraisal guidance 47 (2002)

In progress

Acute coronary syndrome – rivaroxaban NICE technology appraisal guidance. Publication expected March 2015

HeartFlow FRct for the computation of fractional flow reserve from coronary CT angiography NICE medical technology guidance. Publication expected December 2015

Referred - QSs and CGs

None identified

Suspended/terminated

None identified

Details of new technologies

New technologies are described in section 6.1.5 on page 6.

Registered and unpublished trials

Trial name and registration number	Details
Validation of an Intracycle CT Motion CORrection Algorithm for Diagnostic AccuracY (VICTORY) NCT01856504	An international multicentre cohort study investigating the impact of the intracycle motion compensation algorithm (SnapShot Freeze) in image quality and diagnostic accuracy in patients undergoing CCTA that are not taking heart rate lowering agents. This study is ongoing and it is expected to be completed in May 2015.

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