

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

DIAGNOSTICS ASSESSMENT PROGRAMME

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

Diagnostics Consultation Document - Comments

Diagnostics Advisory Committee date: 11th October 2011

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1, NHS Professional.	1 Provisional recommendations	<p>Most of the data referring to the accuracy of cardiac ct is from 64 slice machines.</p> <p>There is general agreement that cardiac CT should be performed on at least a 64 slice scanner that has the capacity for low dose scanning.</p> <p>This is not the same as saying (as you are) that scanning should be done on the latest most expensive machines. This will make cardiac ct prohibitively expensive as many providers will have to upgrade (often unnecessarily) to a Â£1,000,000 + machine. In addition there is no evidence to show that in patients the scanners listed in 1.2 are clinically more effective than slightly less highly specified scanners.</p>	<p>Thank you for your comments. The committee considered and made recommendations on the four scanners and the population group that were specified in the scope of the evaluation. Other scanners and other patient groups were beyond the scope of this evaluation.</p>

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2	Consultee 2, Manufacturer	1.1, 1.2, 1.3, 2.1	<p>We feel that the recommendation that these 4 scanners only be used to address the scanning requirements in sections 1.1 and 1.2 implies that the Definition AS+ (128 slice acquired, 384 slice reconstructed) would not meet these requirements. This scanner is a 'new generation' high end <i>single source</i> scanner, like the 750HD, iCT and Aquillion One. It is exactly the same technology as the Flash, albeit single source.</p> <p>Suggested supporting text for section 4.5: "The SOMATOM Definition AS+ is a high end single source scanner, achieving high spatial resolution (same as that of the Flash) at very low dose. Like the Flash, double sampling during acquisition in the Z axis provides pitch independent isotropic resolution across the entire scan field. Generator power of 100KW ensures imaging of bariatric patients can be achieved rapidly with no degradation in image quality."</p>	Thank you for your comments. The Somatom Definition AS+ scanner was not included in the scope for this evaluation and therefore the guidance cannot include recommendations on it.

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3	Consultee 1, NHS Professional	2 The technologies	<p>While this is true this statement is low quality evidence and does not justify forcing providers to upgrade their 128 or similar slice machines. Radiation dose is important - providers should use low dose techniques. Indeed the technique is more important than the scanner.</p> <p>Speed is potentially confusing. In radiology we may mean:-</p> <p>1) Throughput in a session - the generation of scanner makes little difference to this as saving 5 seconds on a breath hold makes little impact on the 20-30 minute room time.</p> <p>2) Length of breath hold - for most patients (for whom cardiac ct is indicated) it does not matter whether the breath hold is 20 seconds or 5 seconds.</p> <p>3) Temporal resolution - this defines the crispness of the images. While the Aquilion One is the "fastest" scanner (1 heart beat) it has lower temporal resolution than a lower generation Siemens scanner.</p> <p>In summary - your guidance smacks of the author being blinded by the manufacturers into recommending their most expensive product</p>	<p>Thank you for your comments. The recommendations advise providers to consider the benefits of new generation cardiac CT scanners among people who are difficult to image with prior generation CT scanners. The committee has acknowledged that while all four scanners have different technical specifications, they are broadly comparable and collectively beneficial in imaging the population group in this evaluation.</p> <p>The DAC considers all available evidence on clinical and cost effectiveness before it makes recommendations.</p>

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4	Consultee 3, Manufacturer	2.1	The final sentence of the paragraph states that 'New generation CT scanners can image with greater speed and reduced radiation dose'. We agree with this statement but feel that it neglects to also highlight the improved spatial resolution which is important for these difficult to image patients. We would ask the Committee to consider rephrasing the sentence to more accurately reflect the benefits of NGCCT for example, 'new generation CT scanners can image with great speed, improved spatial resolution and reduced radiation dose.' This would also fit with the description of drawbacks of the prior generation CT scanners as noted on page 5, section 4.1 – These drawbacks include spatial resolution, low contrast detection, noise artefacts and higher levels of radiation.	Thank you for your comments. The sentence has been rephrased to: "These enhancements, which vary among the four scanners, may include better temporal resolution, better spatial resolution and shorter acquisition times."
5	Consultee 1, NHS Professional	3.7	3.7 A normal calcium score does not exclude coronary artery disease. There is much research to support this. Research that suggests a zero calcium score excludes coronary disease is effected by referral bias and is wrong. The population who will be referred for ct will be young and may well have lipid plaque stenosis.	Thank you for your comment. This assessment considered the issue of calcium score based on the recommendations in NICE Clinical Guideline 95 (Chest pain of recent onset) where calcium score was used to differentiate the imaging to be used in different patient groups.
6	Consultee 1, NHS Professional	4 The Diagnostic tests	see my comment above. Listing these few scanners (top of the range for each manufacturer) smacks of appeasing the manufacturers and is not justified by high quality evidence of image quality, diagnostic accuracy or radiation dose when compared to an optimally run lower generation scanner.	Thank you for your comment. The DAC considers all available evidence on clinical and cost effectiveness before it makes recommendations. The scope of the evaluation was based on the use of these four specific scanners to image people with conditions that make them difficult to image with 64-slice CT scanners.

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7	Consultee 3, Manufacturer	4.4	Discovery CT750 HD is more accurately described as a 128-slice dual-energy scanner.	Thank you for your comment. The manufacturers whose scanners are involved in the assessment have confirmed accurate revised descriptions of the scanners and this section has now been modified.
8	Consultee 1, NHS Professional	5 Outcomes	Again do not be blinded by no called new generation ct - see above	Thank you for your comment.
9	Consultee 2, Manufacturer	5.5	<p>There is another study published reporting about coronary CT imaging in obese patients:</p> <p>Moscariello A, Takx RA, Schoepf UJ, Renker M, Zwerner PL, O'Brien TX, Allmendinger T, Vogt S, Schmidt B, Savino G, Fink C, Bonomo L, Henzler T.</p> <p>Coronary CT angiography: image quality, diagnostic accuracy, and potential for radiation dose reduction using a novel iterative image reconstruction technique-comparison with traditional filtered back projection. Eur Radiol. 2011 Oct;21(10):2130-8. Epub 2011 May 25.</p>	Thank you for your comment. The external assessment group has confirmed that this paper was published after the diagnostics assessment report was submitted. In addition the external assessment group advised that the study does not appear to report data stratified for difficult to image people.

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10	Consultee 3, Manufacturer	5.5/5.6	<p>We would question if it is appropriate to state the manufacturer of the CT scanner used in the study noted for obese people (5.5) and people with high levels of coronary calcium (5.6). It is appropriate to note that the evidence is based on a prior generation CT scanner but if all scanners are assumed to offer broadly similar benefits (as noted in section 6.1) there is no need to highlight any one manufacturer.</p> <p>In addition, great clarity would be provided if the model names of the CT systems were used rather than the brand name. As an example: The current Siemens DSCT model name is <i>Flash</i>; the prior model was <i>Dual Source</i>. All Siemens CT are branded Somatom, and all high-end CT is branded Definition. Using these terms meaning to cite a specific model may confuse the reader. There are other Siemens Somatom Definition models currently offered, including single-source CT system GE's premium brand is Discovery; the model name is the <i>CT750 HD</i>.</p>	<p>Thank you for your comment. The committee felt that it is appropriate to state the name of the manufacturer of the CT scanner used in the study for obese people, and people with high levels of coronary calcium was mentioned because it was data from an earlier version of a scanner than those being assessed. The committee felt that section 6.2 should also be modified to mention the name of the scanner.</p> <p>The document will be amended, where appropriate, to reflect the precise scanner names confirmed by the manufacturers.</p>

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11	Consultee 2, Manufacturer	5.9	<p>There is a study published by Renker et al. about evaluation of heavily calcified vessels.</p> <p>Renker M, Nance JW Jr, Schoepf UJ, O'Brien TX, Zwerner PL, Meyer M, Kerl JM, Bauer RW, Fink C, Vogl TJ, Henzler T. Evaluation of heavily calcified vessels with coronary CT angiography: comparison of iterative and filtered back projection image reconstruction. Radiology. 2011 Aug;260(2):390-9. Epub 2011 Jun 21.</p>	Thank you for your comment. The external assessment group (EAG) has confirmed that this paper was published after the diagnostics assessment report was submitted. The EAG has advised that while this paper may have extractable data for per lesion accuracy of Somatom Definition Flash in patients with high calcium, it would be unlikely to change the overall conclusions of the Diagnostics Assessment Report.
12	Consultee 3, Manufacturer	5.17	Typing error at the end of the paragraph (York radiation model)	Thank you for your comment. The error has been noted and corrected.
13	Consultee 3, Manufacturer	6.2	<p>It is noted that 19 of the test accuracy studies in the DAR used similar previous model <u>high definition</u> scanners.</p> <p>It is inaccurate to describe Somatom Definition Dual Source as a high definition scanner, since it was a prior generation model with different characteristics and geometry.</p>	Thank you for your comments. Based on discussions regarding your comment on section 5.5 and 5.6, this section has been amended to name the scanner used.
14	Consultee 3, Manufacturer	6.2	Typing error – 2 full-stops on the 5 th line of text	Thank you for your comment. The typing error has been corrected.

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