NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of Diagnostics Guidance 1: The EOS 2D/3D Imaging System

Final recommendation post consultation
The guidance should be transferred to the 'static guidance list'.

1. Background

This guidance was issued in October 2011.

At the GE meeting of 25th November 2014 it was agreed that we would consult on the recommendations made in the GE proposal paper. A four week consultation was conducted and the responses are presented below. Subsequent to the public consultation, a decision was taken to defer consideration of the review decision until October 2016, to enable the development of further evidence.

In October 2016 stakeholders were contacted and asked to provide any new evidence which was relevant to DG1. 2 stakeholders responded; 1 submitted 2 general comments and 1 submitted a letter which detailed possible clinical and patient benefits, references to new studies on radiation dose and a critique of the original guidance. This was accompanied by a copy of the company's bibliography for the EOS 2D/3D imaging system as supporting evidence. This contained 17 papers and 1 abstract that were published after the evidence submission was made for the review proposal. The new data provided information on radiation dosage which support the conclusions reached by the committee. However there are still insufficient data to allow the clinical benefits of the EOS 2D/3D imaging system to be assessed.

2. Proposal put to stakeholders

The guidance should be transferred to the 'static guidance list'.

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3. Rationale for selecting this proposal

The evidence base and clinical environment have not changed to an extent that is likely to have a material effect on the recommendations in the existing diagnostics guidance. In addition, no ongoing studies have been identified that are likely to fulfil the research recommendations in the guidance. It is therefore proposed that the guidance is placed on the static list.

4. Summary of consultation comments

Comments received during consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The published comments are a record of the comments received, and are not endorsed by NICE, its officers or advisory committees.

Respondent: St Joseph's Hospital, Gwent **Response to proposal:** Disagree I am the [redacted] of St Joseph's Hospital at Newport, Gwent which conducts a significant quantity of orthopaedic procedures. I am also [redacted] of The European Scanning Centre (Harley St) Ltd which has purchased and installed an EOS Imaging System. We have a great deal of interest from many eminent orthopaedic practitioners, who are very interested in developing the use of the EOS scanner. They see very real benefits in the use of the EOS imaging capability. My colleagues and I feel that your review of the EOS System has not fully taken into account many of the benefits of the system, which are now coming to light. You will appreciate that with very few EOS systems installed in the UK, it is difficult for the knowledge and experience of the capabilities and benefits to become widely known. I am writing to see an extension of your review to mid 2015, in order that we and my colleagues may present to the review more convincing evidence of the benefits of the EOS Imaging System.	**Comment from Diagnostics Assessment Programme** Thank you for your comment which has been considered by NICE. New evidence for the EOS 2D/3D Imaging System, which has become available since the guidance was published, was reviewed during the development of the review proposal. The published studies identified were considered unlikely to fully address the uncertainties identified during the assessment regarding the health outcome benefits associated with use of the system. No ongoing studies were identified that are likely to fulfil the research recommendations in the guidance. NICE may review guidance before the expected review date when there is significant new evidence that it considers is likely to change the recommendations. NICE is keen to hear about any new evidence that becomes available before the review date (please send information to diagnostics@nice.org.uk). NICE will assess the likely impact of the new evidence on the

	recommendations and will propose an update to the published guidance if required.

Respondent: Advanced Skeletal Imaging Partners **Response to proposal:** Disagree I am a Consultant Musculoskeletal Radiologist working full time in the independent sector with a primary interest in developing imaging strategies that are more relevant to the assessment of musculoskeletal and spinal disorders that affect standing. This will be of accelerating importance over the next two decades. This interest requires scanners that image the whole body standing up and I work closely with a specialist centre which has installed a Paramed Upright MRI scanner and an EOS Biplane whole body scanner. It has been brought to my attention that NICE is conducting a review of its current guidance for the EOS system and the owners of the EOS system that I work with have forwarded me the Guidance Executive document. This is of significant interest to me and I would appreciate the opportunity to respond in detail to the proposal to review the guidance. However, I note that the timeframe for considered responses is very short and, indeed, expires today. If I understand the document correctly, it is the view of the authors that there is no existing or proposed research that will alter the current Diagnostic Guidance and that this situation will not be revisited for another 5 years. I can appreciate the work that has gone into reaching this conclusion but I fear it may make it impossible for relevant research to evolve or support the statement that "NICE encourages use of the EOS 2D/3D imaging system in specialist research settings to collect evidence about potentially important clinical benefits associated with 3D reconstruction, single image weight-bearing whole-body imaging and simultaneous PA and lateral imaging."	**Comment from Diagnostics Assessment Programme** Thank you for your comment which has been considered by NICE. New evidence for the EOS 2D/3D Imaging System, which has become available since the guidance was published, was reviewed during the development of the review proposal. The published studies identified were considered unlikely to fully address the uncertainties identified during the assessment regarding the health outcome benefits associated with use of the system. No ongoing studies were identified that are likely to fulfil the research recommendations in the guidance. NICE may review guidance before the expected review date when there is significant new evidence that it considers is likely to change the recommendations. NICE is keen to hear about any new evidence that becomes available before the review date (please send information to diagnostics@nice.org.uk). NICE will assess the likely impact of the new evidence on the recommendations and will propose an update to the published guidance if required.

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As with any emerging technology, a broad base of experience is necessary to provide an informed view of the true clinical value of an innovation. The current Diagnostic Guidance strangles any chance of a broader base beyond the current 3 systems in the UK because NHS Orthopaedic Centres of Excellence are prevented from acquiring the system and Independent Sector providers who can, and are more than willing to be involved with research, struggle with the funding stream because insurers use the NICE guidance as a reason not to recognise the procedure. Quite apart from all this, I have professional reservations with the veracity of the original DG document. The primary reason is the comparators which were conventional and digital radiography. There is a fundamental and very important difference between EOS and radiography. Although the end result may look the same (as would a TV image and a photograph of a flower), the process whereby the image was obtained and what it is possible to do with that image are radically different. The closest comparator is a CT scanner; but to go into that is beyond the scope of this brief response. I understand that others have been asking for a deferment of the decision to place DG1: The EOS 2D/3D Imaging System onto the Static Guidance List. I would like to add my name to those asking for this deferment and I would also be pleased to engage with NICE in any process that enhances the understanding of what this system is and what it can do. If nothing else, as an Imaging professional, I cannot ignore the highly significant Dose Reductions that are available with EOS. And, in my view, neither can anyone else.	

Respondent: European Scanning Centre **Response to proposal:** Disagree Thank you for your email and the attached report regarding the draft recommendation that the NICE Guidance on the EOS 2D/3D Imaging System be placed on the Static Guidance List. We would respectfully request that this decision be deferred until 1st May 2015.	**Comment from Diagnostics Assessment Programme** Thank you for your comment, which has been considered by NICE. New evidence for the EOS 2D/3D Imaging System, which has become available since the

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The reason for this request is that we believe there is already a substantial but increasing awareness of the benefits of this technology in the UK. This is supported by the numerous meetings and discussions we have had regarding the use of EOS across a broad spectrum of disciplines including all of those mentioned in your report. This awareness is further demonstrated by the rapid growth of EOS installations across Europe and the rest of the world which now stands at an install base of over 100 scanners and over 400,000 patients have benefitted from this technology. Unfortunately, and one says this with the greatest of respect and in the spirit of open communication, one of the principle reasons EOS has not been taken up more widely in the UK and particularly in the NHS, so as to enable greater experience of it and to generate further prospective clinical data, is the current NICE Guidance. It has been cited on repeated occasions as one of the principle reasons for not being able to get the necessary funding approvals, from whatever source. It is a classic but nonetheless genuine example of a Catch 22 situation. We also feel that the timeline for requesting responses (just 14 working days) was too short to allow proper consideration of all the factors once the report became public and has also coincided with the Christmas period when inevitably people are less available. One fully appreciates the direct nature of the above comments but these are made in the context of a new and innovative technology which we believe has the potential to radically improve the way in which a wide range of orthopaedic conditions are managed. In particular, there are 4 areas which require careful consideration of the available evidence and the views of experienced practitioners. These are: 1. Radiation dose issues 2. Role in minimising leg length discrepancies after surgery 3. Role in management of scoliosis, especially in children but also adults 4. Role in more accurate diagnosis and management (conservative and surgical) of back pain	guidance was published, was reviewed during the development of the review proposal. The published studies identified were considered unlikely to fully address the uncertainties identified during the assessment regarding the health outcome benefits associated with use of the system. No ongoing studies were identified that are likely to fulfil the research recommendations in the guidance. NICE may review guidance before the expected review date when there is significant new evidence that it considers is likely to change the recommendations. NICE is keen to hear about any new evidence that becomes available before the review date (please send information to diagnostics@nice.org.uk). NICE will assess the likely impact of the new evidence on the recommendations and will propose an update to the published guidance if required.

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As mentioned above, we believe there is increasing evidence in support of these different issues, in addition to that referred to in your initial guidance. I attach a list of some of the relevant published literature which requires more detailed evaluation and on which we would like to submit a formal detailed response. Consequently we would request you to consider a deferment of the decision to place the current NICE Guidance on the Static Guidance List to allow more time for all those interested parties to submit comments and evidence to you for consideration. I look forward to hearing from you and thank you for your consideration of this request.	

Respondent: Patient **Response to proposal:** no comment As to the EOS Imaging web site that they introduce some modification. Such as like checking the spinal balance, and it is with low radiation than previous x-ray (50% – 80%) and CT (95%) scan.	**Comment from Diagnostics Assessment Programme** Thank you for your comment which has been considered by NICE.

Paper signed off by: Carla Deakin, Associate Director, 22 December 2016

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