NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of 152; Drug-eluting stents for the treatment of coronary artery disease

This guidance was issued July 2008 with a review date of June 2012. The consideration of a review was deferred at this time to allow for further information gathering.

Background

At the GE meeting of 1 April 2014 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees:	The guidance should be updated in a forthcoming guideline.
Rationale for selecting this proposal	The systematic literature review indicates that treatment of coronary heart disease with stents remains a highly active area of research, and a substantial volume of new evidence and numerous new technologies have emerged since the publication of TA152; in particular, a number of comparisons between different DESs, and comparisons between DESs and bare-metal stents (BMSs), in part with consistent results. However, there is no strong evidence that the key factors on which the current recommendations and the economic models depend would change if a technology appraisal review was carried out. Furthermore, differentiation between all available stents would not be possible based on the currently available evidence. Because of the locally negotiated prices, a recommendation based on local costs remains appropriate and is unlikely to be phrased substantially differently. It is acknowledged that further assessment of these technologies, and in particular the stents that have become available since publication of the original guidance, might potentially be helpful for clinicians. However, a technology appraisal is not an appropriate tool for such an assessment. It is therefore proposed that the guidance should be updated in a forthcoming clinical guideline.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation post consultation:	The guidance should be updated in a forthcoming guideline.

Respondent	**Response to proposal**	**Details**[1]	**Comment from Technology Appraisals**
Abbott Vascular Devices Ltd	Request factual change	In the accompanying proposal paper may I advise that on page 4 there is a reference to biodegradable stents taken from the Bangalore article referenced. It is actually biodegradable polymer stents that are being referred to as it is the polymer that degrades and not the stent. Please could you amend this moving forward in the documentation to avoid confusion, I have inserted the relevant passage below. This is the only comment on behalf of Abbott Vascular in response to this review document	Thank you for your comments. Any future documents will reflect the correct terminology, as requested. No changes to the current proposal are required.

[1] Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Respondent	Response to proposal	Details[1]	Comment from Technology Appraisals
British Cardiovascular Intervention Society	Agree (with caveat)	We agree that the current TA guidance is outdated, particularly the price difference guidance as the market price for drug eluting stents (DES) is now in the region of the 300 pounds price difference threshold. We also agree that a further TA on this topic would not be the most appropriate method of revising guidance in part because of the sheer number of currently available drug eluting stents with differing mechanical properties, polymers and drugs. New generation DES are released frequently and prices are changing rapidly and differ according to unit and to volume used. Any specific clinical or cost efficacy guidance on individual stents in this dynamic area would be likely to be out of date at the time of publication. It is worth noting that as DES are used for elective PCI as well as PCI for acute STEMI and NSTEMI cases, any guidance should cover all of these areas. We therefore agree that DES use should be incorporated in to guidelines for NSTEMI, STEMI but also suggest in to the guidelines for stable angina. When constructing guidance, it may be useful to consider the use and safety of short and long durations of dual anti-platelet therapy and bleeding risk. We suggest that guidance should acknowledge the	Thank you for your comments. We note that clinical guideline 126, 'Management of stable angina', is due to be considered for updating in July 2014, we will forward your comments to the clinical guideline team. No changes to the current proposal are required.

Respondent	Response to proposal	Details[1]	Comment from Technology Appraisals
		utility, clinical benefit and cost efficacy of DES and the remarkable reduction in target lesion revascularization that has resulted from their use. We would suggest avoiding any attempt to provide detailed guidance on the use of individual stents for specific indications.	
Boston Scientific	Agree	We have no comments to make and agree with the proposal.	Noted. No action required.
Cochrane Heart Group		Thank you very much for letting us know about your plans to update the guidance on drug eluting stents. My Co-ordinating Editor would like to make you aware that our review: *Drug-eluting stents versus bare metal stents for angina or ACS.* Greenhalgh J, Hockenhull J, Rao N, Dundar Y, Dickson RC, Bagust A. Iss 1, 2011 10.1002/14651858.CD004587.pub2 Is currently being updated. It is now in the editorial process and has been peer reviewed. We are anticipating that this update will be ready for publication on the Cochrane library soon. Please do let me know if you have any questions regarding this update. We believe it should present a significant contribution to the guideline update.	Thank you for your comments. If appropriate, this review may be considered during the updates to the clinical guidelines. No changes to the current proposal are required.

Respondent	Response to proposal	Details[1]	Comment from Technology Appraisals
Endocor Gmbh	No comment	We don't have any comments to the draft of your guidance.	Noted. No action required.
Medtronic	Agree	Medtronic supports the change to review TA152 during the update of Clinical Guidelines CG167 and CG94 which will begin in 2015.	Thank you for your comment. No action required.
Royal College of Nursing	No comment	We have no comments to submit to inform on the review proposal of the above technology appraisal.	Noted. No action required.

No response received from:

Manufacturers/sponsors	General
• Aachen resonance (ARTAX, Vita, Flex force, Elutax) • Alvi Medica (Coracto, Coraxel) • AMG International Gmbh (Itrix, Pico Elite) • Balton (LUC-CHOPIN2, CARLOS S, PROLIM, PAXEL, ALEX) • B Braun (Coroflex Please) • Biosensors (BioMatrix Neoflex, BioMatrix Flex, Axxess) • Biotronik (Orsiro) • CID SpA (Cre8) • Clearstream Technologies Ltd (Intrepide) • Elixir Medical (DeSyne) • Eucatech (eucaTAX, eucaLIMUS) • EuroCor GmbH (MAGICAL DES system)	• Allied Health Professionals Federation • Association of British Healthcare Industries • Board of Community Health Councils in Wales • British Cardiovascular Industry Association • British National Formulary • Care Quality Commission • Commissioning Support Appraisals Service • Department of Health, Social Services and Public Safety for Northern Ireland • EUCOMED • Healthcare Improvement Scotland • Medicines and Healthcare Products Regulatory Agency • National Association of Primary Care

- Innovative Health Technologies (Active)
- Insitu Technologies (Siro, Monarch)
- Kiwimed Ltd (Yukon Choice)
- Meril Life Sciences (Biomime)
- Microport (Firebird)
- Minvasys (Amazonia Pax, Nile Pax)
- MIV Therapeutics (GenXSync, VestaSync, GenX CrCo)
- Orbusneich (Combo)
- Rontis (Abrax, Phoenix)
- Sahajanand Medical Technologies (Supralimus, Indolimus, Infinnium)
- Stentys (Stentys DES)
- Stron Medical (Avior)
- Symbiorph (Symelute, Symolus)
- Terumo (Nobori)
- Translumina (Yukon Choice DES, Yukon Chrome DES)
- Vascular Concepts (ProNOVA, ProTAXX)

<u>Patient/carer groups</u>

- Afiya Trust
- Black Health Agency
- British Cardiac Patients Association
- Cardiovascular Care Partnership
- Coronary Prevention Group
- Equalities National Council
- HEART UK
- Muslim Council of Britain
- Muslim Health Network
- Network of Sikh Organisations
- South Asian Health Foundation
- National Pharmacy Association
- NHS Alliance
- NHS Commercial Medicines Unit
- NHS Confederation
- NHS Supply Chain
- Scottish Medicines Consortium

<u>Comparator manufacturers</u>

- AMG International (Icros, Arthos, MAC4)
- Arterial Remodelling Technologies (ART Stent)
- Atrium Europe (Cinatra)
- B Braun (Coroflex Blue)
- Balton (Chopin, Flexus, Kos, CoFlexus)
- Blue Medical (Pioneer, Track)
- Biosensors (Chroma, Gazelle)
- Biotronik (PRO-Kinetic)
- Boston Scientific (VeriFLEX)
- Capella (Sideguard)
- CID SpA (Avantegarde, Chrono, Tecnic Plus)
- Clearstream Technologies Ltd (SatinFlex, ClearFlex-X)
- DISA vascular (Solarflex, ChromoFlex)
- Elixir Medical (Core)
- Endocor Gmbh (Constellation, Spirit)
- Eucatech (CC Flex, STSflex)
- Eurocor Gmbh (Genius MAGIC, Genius TAXCOR)
- Fortimedix (Kaon)
- Innovative Health Technologies (Apolo, Bionert)
- Insitu Technologies (Direct-Stent)
- InspireMD (MGuard)
- Kiwimed Ltd (Yukon Plus)

• Specialised Healthcare Alliance <u>Professional groups</u> • Association of Anaesthetists • Association of Surgeons of Great Britain and Ireland • British Association for Nursing in Cardiovascular Care • British Atherosclerosis Society • British Cardiovascular Society • British Geriatrics Society • British Heart Foundation • British Society of Cardiovascular Imaging • College of Emergency Medicine • Royal College of Anaesthetists • Royal College of General Practitioners • Royal College of Pathologists • Royal College of Physicians • Royal College of Surgeons • Royal Society of Medicine • Society for Cardiological Science and Technology • Society of Cardiothoracic Surgeons • UK Health Forum • United Kingdom Clinical Pharmacy Association • Vascular Society <u>Others</u> • Department of Health • NHS City and Hackney CCG • NHS England • NHS Solihull CCG • Welsh Government	• Meril Life Sciences (Nexgen) • Microport (Mustang, Tango) • Minvasys (Amazonia Croco) • MIV Therapeutics (Protea, VestaCor, Genx) • OrbusNeich (Genous, Azule, R Stent) • Rontis (Leader Plus) • Sahajanand Medical Technologies (Coronnium, Millennium Matrix) • Stentys (Stentys BMS) • Stron medical (Curvus, Cursa) • Symbiorph (Symflex) • Terumo (Kaname, Tsunami Gold) • Translumina (Yukon Choice BMS, Yukon CC) • TriReme Medical (Antares) • Vascular Concepts (ProLink, ProZeta) • W L Gore (NIRflex and NIRflex Royal) <u>Relevant research groups</u> • Antithrombotic Trialists' (ATT) Collaboration • British Society for Cardiovascular Research • Cardiac and Cardiology Research Dept, Barts • Central Cardiac Audit Database • CORDA • European Council for Cardiovascular Research • Health Research Authority • MRC Clinical Trials Unit • National Institute for Health Research • Research Institute for the Care of Older People • Wellcome Trust

	Assessment Group • Assessment Group tbc • National Institute for Health Research Health Technology Assessment Programme Associated Guideline Groups • National Clinical Guidelines Centre Associated Public Health Groups • Public Health England • Public Health Wales NHS Trust

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