

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**GUIDANCE EXECUTIVE (GE)**

**Consideration of consultation responses on review proposal**

**Review of TA71; Guidance on the use of coronary artery stents**

This guidance was issued October 2003.

Recommendations 1.2, 1.3 and 1.4 of this guidance have already been updated. This review only covers recommendations 1.1 and 1.5 of the guidance.

**Background**

At the GE meeting of 1 July 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.

<b>Proposal put to consultees:</b>	The guidance should be updated in a forthcoming guideline.
<b>Rationale for selecting this proposal</b>	<p>Because bare metal stents have been considered standard of care for several years, it is not considered useful to carry out an update of the still extant recommendations 1.1 and 1.5 of TA71 as a technology appraisal.</p> <p>However, it would be beneficial for these recommendations to be updated when CG167 (Myocardial infarction with ST-segment elevation) and CG94 (Unstable angina and NSTEMI) are reviewed in July 2015 and September 2015 respectively. It has previously been agreed to update the TA152 (drug eluting stents) in these clinical guidelines.</p> <p>This would lead to all NICE's recommendations on the use of stents to be brought together within the entire context of clinical management of the conditions, which will allow for an analysis of the new technologies and ongoing research which compares drug-eluting stents and bare-metal stents. The clinical guidelines can also contextualise the use of stents with the use of CABG.</p>

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 recommendations in TA71 on the use of stents for treating people with acute coronary syndromes (unstable angina, NSTEMI and STEMI) should be updated in the updates to the NICE clinical guidelines CG167 (Myocardial infarction with ST-segment elevation) and CG94 (Unstable angina and NSTEMI).

The recommendation for treating people with stable angina should remain in TA71, and should be updated in a review of the NICE Clinical Guideline 126 ('Management of stable angina', published July 2011).

Once updates to CGs167 and 94 are complete, and if this occurs before the update of CG126, the box on the webpage for TA71 should be updated with the text (highlighted), and the remaining recommendations amended as follows:

This guidance replaces TA4 'Ischaemic heart disease coronary artery stents' (NICE technology appraisal 4).

Sections 1.2-1.4 of this guidance have been replaced by ['Coronary artery disease – drug-eluting stents'](#) (NICE technology appraisal 152).

Recommendation 1.1 has been updated by [title of new clinical guidelines] and now only recommends stents when PCI is the clinically appropriate procedure for patients with stable angina.

*1.1 Stents should be used routinely where percutaneous coronary intervention (PCI) is the clinically appropriate procedure for patients with stable angina.*

*1.5 This guidance specifically relates to the present clinical indications for PCI and excludes conditions (such as many cases of stable angina) that are adequately managed with standard drug therapy.*

Respondent	Response to proposal	Details <sup>1</sup>	Comment from Technology Appraisals
B Braun		<p>With reference to Point 1.1 in section 3 (of the proposal paper). This may be in contrast to emerging drug coated balloon technology as it reads 'Always use stents' independent of the lesion and patient. Perhaps we could propose to rephrase this:</p> <p><b>Stents can be routinely used whenever vessel scaffolding is necessary in coronary lesions given that a percutaneous coronary intervention (PCI) is the clinically appropriate procedures for patients with either stable or unstable angina or with acute myocardial infarction (MI).</b></p> <p>Perhaps it could further include: <b>PCI without stents in particular drug coated balloons may be indicated in patients with in-stent restenosis.</b></p>	<p>Thank you for your comment. The current recommendations of TA71 cannot be amended at this stage. In addition, the use of drug coated balloon technology is outside of the remit from the Department of Health for this appraisal.</p>

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<sup>1</sup> 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.

<b>Respondent</b>	<b>Response to proposal</b>	<b>Details<sup>1</sup></b>	<b>Comment from Technology Appraisals</b>
British Cardiovascular Intervention Society	Agree, with caveat	BCIS agree with this proposal with one reservation. We would like to point out that stents are also used for the treatment of stable angina so that replacing current guidance with guidance on the use of stents in STEMI, NSTEMI and unstable angina (CG 167 and CG94) will not entirely cover the range of use of coronary stents.	Thank you for your comments. The guidance for treating people with stable angina should remain in TA71, and should be updated when the NICE Clinical Guideline 126 ('Management of stable angina', published July 2011) is reviewed.
Medtronic	Agree	We support this proposal, acknowledging that the CG updates will reflect the current evidence base and the evidence published since TA 71 & TA152.	Comment noted.

**No response received from:**

<u>Manufacturers/sponsors</u>	<u>General</u>
<ul style="list-style-type: none"> <li>• Aachen resonance (ARTAX, Vita, Flex force, Elutax, Multi-Link range, Coronary RX)</li> <li>• Abbott Vascular Devices Ltd (Xience stent ranges, TREK range, Voyager)</li> <li>• Acrostak-uk (Across CTO, Across HP)</li> <li>• Alvimedica (Coracto, Coraxel, Ephesos II, Constant, Commander, Invader range, Turquoise)</li> <li>• AMG International GmbH (Itrix, Pico Elite, Icross, Arthos, MAC4, ISOLV)</li> <li>• Arterial Remodelling Technologies (ART Stent)</li> </ul>	<ul style="list-style-type: none"> <li>• Allied Health Professionals Federation</li> <li>• Association of British Healthcare Industries</li> <li>• Board of Community Health Councils in Wales</li> <li>• British Cardiovascular Industry Association</li> <li>• British National Formulary</li> <li>• Care Quality Commission</li> <li>• Department of Health, Social Services and Public Safety for Northern Ireland</li> <li>• EUCOMED</li> <li>• Healthcare Improvement Scotland</li> </ul>

<ul style="list-style-type: none"> <li>• Balton (LUC-CHOPIN2, CARLOS S, PROLIM, PAXEL, ALEX, Chopin 2, Flexus, Kos, CoFlexus, River, Fryderyk, Bottle)</li> <li>• Blue Medical (Track, Everest, Force NC, Summit)</li> <li>• Biosensors (Chroma, Gazelle, BioMatrix Neoflex, BioMatrix Flex, Axxess, BioStream, BioPath, Powerline)</li> <li>• Biotronik (Orsiro, Pantera, Pantera LEO, AngioSculpt PTCA, PRO-Kinetic, PRO-Kinetic Energy, PK Papyrus)</li> <li>• Boston Scientific (Taxus range, Promus range, ION, Synergy, Premier, VeriFLEX, OMEGA, Apex, Emerge, Maverick, NC Quantum Apex, Quantum Maverick)</li> <li>• Capella (Sideguard)</li> <li>• CID (Cre8, Optima Jet, Janus Flex, Avantegarde, Chrono, Tecnic Plus, Fluydo, Pro HP, Brio, Across CTO OTW, Across CTO RX)</li> <li>• Clearstream Technologies Ltd (Intrepide, SatinFlex, ClearFlex-X, Nimbus Pico, Nimbus Salvo)</li> <li>• Cordis (Dura, Firestar)</li> <li>• DISA vascular (Solarflex, ChromoFlex)</li> <li>• Elixir Medical (DESyne Novolimus, DESyne BD Novolimus, Core)</li> <li>• Endocor Gmbh (Sequence, Prodigy, Constellation, Spirit, Ghost, Cardioglide range)</li> <li>• Eucatech (eucaTAX, eucaLimus, CC Flex, STSflex, Euca VI, euca CTO RX)</li> <li>• EuroCor Gmbh (MAGICAL, Genius MAGIC, Genius TAXCOR I, AMADEUS SUPERCROSS)</li> <li>• Fortimedix (Kaon)</li> <li>• Innovative Health Technologies (Active, Apolo, Bionert, Fairway)</li> </ul>	<ul style="list-style-type: none"> <li>• Medicines and Healthcare Products Regulatory Agency</li> <li>• National Association of Primary Care</li> <li>• National Pharmacy Association</li> <li>• NHS Alliance</li> <li>• NHS Commercial Medicines Unit</li> <li>• NHS Confederation</li> <li>• NHS Supply Chain</li> <li>• Scottish Medicines Consortium</li> </ul> <p><u>Comparator manufacturers</u></p> <ul style="list-style-type: none"> <li>• None</li> </ul> <p><u>Relevant research groups</u></p> <ul style="list-style-type: none"> <li>• Antithrombotic Trialists' (ATT) Collaboration</li> <li>• British Society for Cardiovascular Research</li> <li>• Cardiac and Cardiology Research Dept, Barts</li> <li>• Central Cardiac Audit Database</li> <li>• Cochrane Heart Group</li> <li>• CORDA</li> <li>• European Council for Cardiovascular Research</li> <li>• Health Research Authority</li> <li>• MRC Clinical Trials Unit</li> <li>• National Institute for Health Research</li> <li>• Wellcome Trust</li> </ul> <p><u>Assessment Group</u></p> <ul style="list-style-type: none"> <li>• National Institute for Health Research Health Technology Assessment Programme</li> </ul> <p><u>Associated Guideline Groups</u></p>
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- Insitu Technologies (Siro, Direct-Stent range, Arriva PTCA)
- InspireMD (MGuard, MGuard Prime)
- Kiwimed Ltd (Yukon Choice, Yukon Plus, CURARE Cathy No. 3)
- Meril Life Sciences (Biomime, Nexgen, Mozec)
- Microport (Firebird, Firebird 2, Mustang, Tango, Pioneer, Jive)
- Minvasys (Amazonia Pax, Nile Pax, Amazonia Croco, Nile CroCo, Yangtze range)
- MIV Therapeutics (GenXSync, VestaSync, GenX CrCo, Protea, VestaCor, Genx)
- Orbusneich (Combo, Genous range, Azule, R Stent, Sapphire range, Scoreflex)
- Pyramed (Cristal Balloon, Occlutech Sizing Balloon)
- Rontis (Abrax, Phoenix, Leader Plus, Europa range)
- Sahajanand Medical Technologies (Supralimus, Indolimus, Infinnium, Coronium, Millennium Matrix)
- Stentys (Stentys DES, Stentys BMS)
- Stron Medical (Avior Curvus, Cursa, Pyxis-C, Galaxy)
- Symbiorph (Symelute, Symolus, Symflex CC, Symtrek)
- Terumo (Nobori, Kaname, Tsunami Gold, Tazuna, Ryujin Plus, Hiryu)
- Translumina (Yukon Choice 4 DES, Yukon Chrome DES, Yukon Choice PC, Yukon Choice 4, Yukon CC, Cathy No. 4)
- TriReme Medical (Antares, Chocolate, Glider range)
- Vascular Concepts (ProNOVA, ProTAXX, ProLink, ProZeta, Accura)
- W L Gore (NIRflex and NIRflex Royal)

Patient/carer groups

- National Clinical Guideline Centre

Associated Public Health Groups

- Public Health England
- Public Health Wales NHS Trust

- 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
- Specialised Healthcare Alliance

Professional groups

- 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 Nursing
- Royal College of Pathologists
- Royal College of Physicians
- Royal College of Surgeons
- Royal Society of Medicine

<ul style="list-style-type: none"><li>• Society for Cardiological Science and Technology</li><li>• Society of Cardiothoracic Surgeons</li><li>• UK Health Forum</li><li>• United Kingdom Clinical Pharmacy Association</li><li>• Vascular Society</li></ul> <p><u>Others</u></p> <ul style="list-style-type: none"><li>• Department of Health</li><li>• NHS Blackburn with Darwen CCG</li><li>• NHS East Lancashire CCG</li><li>• NHS England</li><li>• Welsh Government</li></ul>	
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**GE paper sign-off:** Elisabeth George, Associate Director – Technology Appraisals Programme

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