

# National Institute for Health and Care Excellence

## IP1073 – Optical Coherence Tomography to guide percutaneous coronary intervention

### Consultation Comments table

IPAC date: 12<sup>th</sup> December 2013

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 NHS Professional	1	We strongly suggest that clinicians undertaking this procedure should be fully trained in percutaneous coronary intervention (PCI) and in line with BCIS guidelines be performing at least 75 PCI procedures per annum. The procedure should not be undertaken as part of a 'diagnostic only' coronary angiographic procedure by cardiologists without such training and regular practice in PCI.	Please respond to all comments  Thank you for your comment. <b>IPAC considered your comment but chose not to amend the guidance.</b>

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2	Consultee 2 Manufacturer	1.1	<p>We propose that ‘normal arrangements’ are more appropriate for OCT, which is not a stand-alone procedure for a specific indication, but an additional imaging modality that in routine clinical practice is largely used for resolving features that are unclear on the angiogram. In PCI, OCT would be used instead of IVUS and correlates well with IVUS. Procedural success rates are not statistically different (Yamaguchi T, Terashima M, Akasaka T, et al. Safety and feasibility of an intravascular optical coherence tomography image wire system in the clinical setting. Am J Cardiol. 2008;101(5):562-7. Bezerra HG, Attizzani GF, Sirbu V, et al. Optical coherence tomography versus intravascular ultrasound to evaluate coronary artery disease and percutaneous coronary intervention. JACC Cardiovasc Interv. 2013;6(3):228-36.). However, IVUS (which has not been the subject of an IPAC review) is used with normal arrangements for governance, consent and audit. It therefore seems perverse to apply ‘special arrangements’ to OCT, when there is no evidence that OCT is less safe or less effective than IVUS.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment. IPAC considered your comment but chose not to amend the guidance. IP Programme adheres to a process for guidance production based on procedures being notified. It will use its usual process to decide whether to produce guidance on IVUS.</p> <p><a href="http://www.nice.org.uk/aboutnice/howwework/developingniceinterventionalprocedures/developing_nice_interventional_procedures.jsp">http://www.nice.org.uk/aboutnice/howwework/developingniceinterventionalprocedures/developing_nice_interventional_procedures.jsp</a></p> <p>The 2 studies referred by the consultee Yamaguchi et al (2008), Bezerra (2013) are already included as evidence in table 2 in the overview.</p>

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3	Consultee 1 NHS Professional	2	OCT is not an alternative to coronary angiography. It provides additional and complementary information but is never performed as an 'alternative' to angiography.	Please respond to all comments  Thank you for your comment. IPAC amended 2.2 as follows: 2.2. Coronary angiography is used to image coronary arteries immediately before angioplasty or Intravascular ultrasound (IVUS) or OCT may be used to provide additional and complementary information to coronary angiography.
4	Consultee 2 Manufacturer	2.1	The uses of OCT given on 2.1 are correct, but incomplete. A more complete statement would be “It may be used to assess stenotic lesions in the coronary arteries, to image the result of stent deployment during percutaneous coronary interventions and to resolve anatomical features that are unclear on the angiogram.”	Thank you for your comment. IPAC considered your comment and chose not to amend the guidance.
5	Consultee 2 Manufacturer	3.3	3-D reconstruction capability is now available for OCT and this allows for a more flexible and complete assessment of coronary anatomy. It may be useful to include reference to this with an addition so that 3.3 reads “The resolution of coronary OCT is reported to be 10 times higher than that of intravascular ultrasound and rapid 3-D reconstruction capability allows cardiologists to better visualise important vessel characteristics.”	Thank you for your comment. IPAC amended 3.3 as follows: The resolution of coronary OCT is reported to be 10 times higher than that of intravascular ultrasound, and has rapid three-dimensional reconstruction capability. The aim of providing more detailed images is to improve clinical outcome.

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6	Consultee 2 Manufacturer	4.3	<p>These additional interventions were periprocedural and designed, on the basis of OCT imaging, to improve procedural outcomes. These data should not be taken as a 35% re-intervention rate. A recent meta-analysis of more than 19,000 patients showed that IVUS-guided coronary drug-eluting stent (DES) implantation was associated with a reduced incidence of death, major adverse cardiac events and stent thrombosis (Zhang Y, Farooq V, Garcia-Garcia HM, et al. Comparison of intravascular ultrasound versus angiography-guided drug-eluting stent implantation: A meta-analysis of one randomised trial and ten observational studies involving 19,619 patients. <i>EuroIntervention</i>. 2012;8(7):855-65). With published clinical evidence demonstrating the clinical utility of coronary OCT in PCI as a medically reasonable alternative to IVUS for intravascular imaging, there should be confidence in the efficacy of OCT in contemporary PCI.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>NICE did not consider evidence relating to IVUS alone. Therefore the paper Zhang et al (2012) falls outside the scope of our literature search and is not considered in the draft of this guidance.</p>
7	Consultee 1 NHS Professional	5	<p>The potential complications of OCT require that all operators using the technique are qualified and competent PCI operators able to use techniques such as stenting to treat complications as they arise. See comments in section 1.</p>	<p>Thank you for your comment.</p> <p><b>See response to comment 1.</b></p>

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8	Consultee 2 Manufacturer	5	OCT has been used for many years as a research tool and accumulated more than 600 publications. This vast body of literature shows an acceptable safety profile with no significant safety issues reported. (Tearney GJ, Regar E, Akasaka T, et al. Consensus standards for acquisition, measurement, and reporting of intravascular optical coherence tomography studies. J Am Coll Cardiol. 2012;59(12):1058-72.)	Please respond to all comments  Thank you for your comment. Tearney et al (2012), a consensus statement for measuring and reporting OCT studies has been added to 'existing assessments of this procedure' section in the overview document.
9	Consultee 1 NHS Professional	<b>NOTES</b>	Comments submitted on behalf of BCIS	Thank you for your comment

*"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."*