National Institute for Health and Clinical Excellence

Clinical guideline: Stable Angina

PRE-PUBLICATION CHECK ERROR TABLE

Organisation	Order number	Section number in FULL guideline	Page number	ERROR REPORT	RESPONSES
A. Menarini Pharma UK SRL	1	10.2.5	136	For consistency add 'or' after 'a long acting nitrate' and 'ivabradine' in the two instances on this page.	Change to be made to recommendations as suggested.
A. Menarini Pharma UK SRL	2	10.3.5	153	For consistency add 'or' after 'a long acting nitrate' and 'ivabradine' in the two instances on this page.	Change to be made to recommendations as suggested.
A. Menarini Pharma UK SRL	3	10.4.2	158	Note '(d)' is incorrect in the 'Imprecision' column in the first four rows: See Appendix F, Page 33, 1.1 (please note that the x-axis labels are the wrong way round): The estimate of effect (1.11 – 46.29) crosses the MID (+30) but does not include no effect. Note '(d)' (95% CI includes no effect and the upper and low CI crosses the MID) is therefore incorrect. See Appendix F, Page 33, 1.2: The estimate of effect (4.62 – 54.78) does not include no effect. MID for time to event is not specified in section 3.4.5 so it could be either 'no serious imprecision' or 'serious imprecision'. Either way, note '(d)' is incorrect. See Appendix F, Page 33, 1.3 (please note that the x-axis labels are the wrong way round): The estimate of effect (11.96– 56.04) crosses the MID (+30) but does not include no effect. Note '(d)' is therefore incorrect. See Appendix F, Page 33, 1.4: The estimate of effect (13.91-62.09) does not include no effect so it could be either 'no serious imprecision' or 'serious imprecision'. Either way, note '(d)' is incorrect. Correction of these errors may have an impact on the	Thank you for your comment. We agree that the Imprecision column was incorrect in the first four rows. We have revised the quality of these four outcomes accordingly.

				overall 'Quality' rating for these rows and the overall assessment of 'Quality of evidence' in Section 10.4.5 on Page 165, specifically the statement 'The improvements in exercise time and symptom severity associated with short-term ranolazine treatment are modest and of uncertain clinical significance.'	
A. Menarini Pharma UK SRL	4	10.4.2	160	Rich 2007[60] analysis combined data from both CARISA and ERICA.	Thank you for your comment. We have amended the relevant sentence accordingly.
A. Menarini Pharma UK SRL	5	10.4.4	162	Rich 2007[60] analysis combined data from both CARISA and ERICA.	Thank you for your comment. We have amended the relevant sentence accordingly.
Department of Health	1	General		The Department of Health has no comments to make re: NICE's pre-publication check of factual errors	No action required from NCGC.
Servier Laboratories Ltd	1	10.2.5	137 &138	Servier thank the GDG for it's consideration of the evidence regarding the safety profile of ivabradine, and for altering the sentence on page 138 of the guideline to reflect this. However, for consistency and accuracy, as detailed in our original response, we feel that the sentence "Evidence confirming the long term efficacy and safety of ivabradine is limited" in paragraph 6 of page 137, should also be revised. The safety profile in angina alone is considerable and should be reflected here. As stated in our original comments, the safety data set for ivabradine in angina is one of the largest and most comprehensive of all anti-anginal therapies. In addition, while the GDG has reviewed the majority of studies relating to ivabradine in stable angina, there is one notable omission of a 386 patient randomized, double-blinded, parallel group study published in 2007, looking at long term safety and efficacy of ivabradine: Lopez-Bescos L, Filipova S, Martos R. Long-Term Safety and Efficacy of Ivabradine in Patients with Chronic Stable Angina. Drugs 2007; 108:387-396. This study is not included in Appendix E1 – Included and Excluded Studies.	Thank you for your comment. The study Lopes 2007 compared ivabradine 5 mg to ivabradine 7.5 mg. In the evidence review for ranolazine we considered the following comparisons: ranolazine vs. placebo or ranolazine vs. any other antianginal monotherapy (beta blockers, CCB, long acting nitrates , nicorandil, ivabradine). As this study did not meet our inclusion criteria, we have not included this study in the evidence review.
Servier Laboratories Ltd	2	1.4.6 1.4.7 1.4.11 1.4.12 and 1.4.14	55 & 56	Whilst acknowledging this opportunity to respond to the pre-publication check with regards to accuracy, Servier feels it is essential to reiterate the importance of considering physiological factors such as heart rate and blood pressure when choosing an anginal treatment. The current draft demonstrates the options available for therapy but without guidance on how to tailor therapy for individual patients. Indeed, we have noted that these	No action required from NCGC.

				factors have also been highlighted by other stakeholders during the consultation, namely the BCS and the PCCS.	
Servier Laboratories Ltd	3	4.1	50	Servier thank the GDG for its consideration of suggestions for the algorithm. However, as the algorithm has not been included in the pre-publication document, we are unable to comment at this time. Could the GDG indicate whether this will be available prior to full publication?	No action required from NCGC.
Servier Laboratories Ltd	4	Appendix E2	83 & 90	The GDG have indicated that there was an error in the gradings in the evidence tables where the ASSOCIATE study "Tardif JC, Ponikowski P, Kahan T, et al. Efficacy of the I(f) current inhibitor ivabradine in patients with chronic stable angina receiving beta-blocker therapy: a 4-month, randomized, placebo-controlled trial. Eur Heart J 2009; 30:540-8", was split into two gradings and that this has been amended accordingly. However, there is no evidence of this amendment in appendix E2. Servier would be grateful for clarification.	Thank you for your comment. We have revised the gradings in the evidence tables accordingly.
Society for Cardiothoracic Surgery in Great Britain & Ireland	1	General		SCTS first wish to acknowledge the efforts of NICE to address our earlier concerns and in particular we welcome NICE's support for the role and importance of the multi-disciplinary team.	No action required from NCGC.
Society for Cardiothoracic Surgery in Great Britain & Ireland	2	General		Without testing to detect the presence of ischaemia it is impossible to risk stratify patients or identify those patients who may have a prognostic benefit from revascularization. Without this information, therefore, it is not possible to know if patients are actually receiving the most appropriate therapy.	No action required from NCGC.
Society for Cardiothoracic Surgery in Great Britain & Ireland	3	1.5.5		Section 1.5.5 states that when either procedure would be appropriate offer PCI in preference to CABG. SCTS is uncomfortable with this because if there is true equipoise between treatments then in terms of transparency, patient choice and informed consent patients should be offered both options. This is not only a GMC requirement for informed consent but also consistent with the patient philosophy expounded in the recent White Paper 'Liberating the NHS: Equity and Excellence of "not about me without me". If the NICE proposal is simply on economic grounds then this should	No action required from NCGC.

				be made explicit and caution that it is from highly select trials and without 10 year follow up.	
Society for Cardiothoracic Surgery in Great Britain & Ireland	4	1.5.14		Section 1.5.14 should state that repeat revascularisation is substantially lower after CABG than PCI.	No action required from NCGC.