National Institute for Health and Clinical Excellence

Medical Technologies Evaluation Programme

The VeriQ system for assessing graft flow during coronary artery bypass graft surgery: Consultation comments table

Consultation comments table

There were 26 consultation comments from five consultees (one manufacturer, one distributor and three others). The comments are reproduced in full, arranged in sections with general comments at the end.

No.	Consultee	Section number	Comments	Responses
1.	Consultee 1, Other - Independent Evaluation Group	2.3	Change sentence to 'For assessment of blood flow during CABG procedures, the VeriQ system uses two types of probe (the PS and PQ) which differ in the number of recommended reuses and the method of sterilisation.'	Thank you for your comment. The Committee considered this comment and decided to change section 2.3 of the guidance.
2.	Consultee 1, Other - Independent Evaluation Group	2.3	Change 'optimum blood flow' to 'acceptable blood flow'.	Thank you for your comment. The Committee considered this comment and decided to change section 2.3 of the guidance.
3.	Consultee 2, Other- Patient Representative	2.3	It is not conceivable that either cost-pressures or lack of knowledge amongst staff, may lead to incorrect over-usage or incorrect sterilisation, and the guidelines need to be clear on this? According to the manufacturers guidelines, PS probes may be used up to 50 times, PQ probes up to 30 times, making PS probes more cost-effective (see cost models in appendices) . However, PQ probes are necessary for certain grafts.	Thank you for your comment. The VeriQ system user manual specifies the sterilisation guideline and is provided with consumables. According to the VeriQ user manual, PS and PQ probes can be used in up to 30 and 50 procedures respectively if the recommended sterilisation methods are followed. Both probes are intended to be used for all types of grafts and differ only in the sterilisation method used. The Committee considered this comment and decided not to change section 2.3 of guidance.

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4.	Consultee 1, Other - Independent Evaluation Group	2.4	Change 'for each PS probe' to 'for each PS or PQ probe'.	Thank you for your comment. Only the PS probe is considered in the guidance as the PQ probes require an ethylene oxide based sterilisation method which the Committee were advised is not widely available in the NHS and this has been explained in section 2.3 of the guidance. Therefore the Committee decided not to change the guidance.
5.	Consultee 2, Other- Patient Representative	2.5	The clinical evidence base suggests a more complicated picture than suggested by the claim that use of Veri-Q leads to 'reduced number of repeat procedures and treatments for post-operative complications' (see section 3, particularly 3.6).	Thank you for your comment. This section refers to the Manufacturer's claimed benefits and as such does not represent the Committee's recommendations. The Committee's recommendations are based on the assessment of the submitted clinical and cost evidence and expert advice. The Committee considered this comment and decided to change section 3.7 (section 3.6 of the consultation document) of the guidance to include more description of the evidence from the VeriQ system predecessor devices.
6.	Consultee 2, Other- Patient Representative	3.5	In addition, according to Tokuda et al (Appendix, study 15) TTFM cut-off values for curve analysis for grafts for early graft failure are established, but ' surgeons should exercise caution when interpreting abnormal results, to avoid unnecessary graft revision' (see section 3.11).	Thank you for your comment. The Committee considered this comment and decided to change section 3.13 of the guidance to state that the VeriQ system should be used as an adjunct to other methods of assessment.

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7.	Consultee 2, Other- Patient Representative	3.5	According to ESC/EACTS Guidelines on myocardial revasclarisation (see study 15 in appendices - the VeriQ systen assessment report overview and section 3.6 below) a pulsatility > 5 and graft flow < 20 ml/min is indicative of graft problems. However, as shown by Nordgaard et al (2010), this depends on the type of flowmeter being used. Whilst this point has been made clear in the EAC report, it is not highlighted in the guidance document. To prevent misunderstanding we would like guidelines to be very clear, that, 'as different filter settings show different pulsatility indexes, care must be taken when flow values and flowmeters are compared. Ideally, the type of flowmeter should be clearly indicated whenever graft flow measurements and derived indexes are provided to ensure consistency' (ECA report, p22, under Nordgaard et al (2010)).	Thank you for your comment. The Committee considered this comment and decided to specify the VeriQ system default filter setting in section 2.3 of the guidance. A section on the Committee's consideration of the evidence from Nordgaard et al (2010) has been added to section 3.12 of the guidance to clarify that transit time flow measurements by the VeriQ system differ from other flowmeters and these differences are systematic and consistent.
8.	Consultee 1, Other - Independent Evaluation Group	3.6	Change 'may be easier to carry out' to may be easier and safer to carry out'	Thank you for your comment. The Committee considered this comment and decided not to change the guidance as there was no direct evidence to support this statement.

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9.	Consultee 2, Other- Patient Representative	3.6	Overall, we agree with the conclusion of the EAC that the clinical evidence that the EAC considered valid, does support the routine clinical use of TTFM to pick up on early graft failure. However, as made clear by the EAC in their summary of comparative studies (EAC report p90, Appendices pp64-67) the Veri-Q system will have drawbacks, that need consideration: • Intra-operative fluorescence imaging (IFI) may provide greater diagnostic accuracy than TTFM (Desai et al, 2006) • TTFM may indicate unnecessary graft revision (Balacumaraswami et al, 2005) • TTFM may be more sensitive to other factors (compared to IFI) leading to over/under estimates of need (Mack, 2008) Therefore, we would conclude that Veri-Q is a useful tool, but, as with other TTFM measures, it needs to be used with caution and assessment requires other measures. Furthermore the evidence for long-term morbidity and mortality is not suggested by the evidence. For example Beran et al (2010) (Appendix, p66) found pre-operative left ventricular ejection fraction a better prediction of long-term survival than TTFM, whilst Jokinen et al (Appendix, p67) found it could predict outcome at 6 months, but not into the longer term. We make this comment as long-term prediction is in the criteria (section 3.1) for this discussion document.	Thank you for your comment. The Committee considered this comment and decided to change section 3.7 (section 3.6 of the consultation document) of the guidance to include more description of the evidence on the VeriQ predecessor devices.

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10.	Consultee 2, Other- Patient Representative	3.6	We do not consider the lack of long-term predictive ability to be an issue as to whether Veri-Q should be used. The evidence for saving of life, and avoiding complications in the shorter term, is of benefit to patients.	Thank you for your comment.
11.	Consultee 2, Other- Patient Representative	3.9	We agree with the statement that the Veri-Q system may identify graft failure – so long as it is routinely used, as Kieser et al's study showed that TTFM highlighted problems that were not identified by clinical assessment alone. However, according to the Assessment Report overview, section 3, expert advisers suggest that surgeons would only use TTFM if their clinical assessment is ambiguous. Therefore surgeons will need to be made aware of the value of TTFM, not only when their own clinical assessment is ambiguous. For this reason, we support the EAC statement on p22 of their report, that the use of TTFM should be routine.	Thank you for your comment.
12.	Consultee 2, Other- Patient Representative	3.11	We support the routine use of TTFM (Veri-Q) in addition to clinical assessment alone, but re-iterate the point made in section 3.5, that surgeons need to be made aware of the different cut-off measurements, if they have been used to using other TTFM meters, and also that they need to be aware of the limitations of Veri-Q, in terms of the possibility of over or under-estimates of graft failure, that IFI measures may be more appropriate, and that both IFI and Veri-Q may miss graft failure which angiography may detect (see section 3.6)	Thank you for your comment. The Committee considered this comment and decided to change section 3.13 of the guidance to state that the VeriQ system should be used as an adjunct to other methods of assessment.

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13.	Consultee 2, Other- Patient Representative	3.12	See comment for section 3.5: 'this depends on the type of flowmeter being used.' Nordgaard et al found the different types of flowmeter calibrate differently, so the figures outlined here may be not be generic to all meters.	Thank you for your comment. The Committee considered this comment and decided to specify the VeriQ system default filter setting in section 2.3 of the guidance. A section on the Committee's consideration of the evidence from Nordgaard et al (2010) has been added to section 3.12 of the guidance to clarify that transit time flow measurements by the VeriQ system differ from other flowmeters and these differences in systematic and consistent.
14.	Consultee 1, Other - Independent Evaluation Group	5.5	Change 'between the arms' to 'between the arms of the model'	Thank you for your comment. The Committee considered this comment and decided to change section 5.5 of the guidance.
15.	Consultee 1, Other - Independent Evaluation Group	5.7	Change 'in either arm' to 'in either arm of the model'	Thank you for your comment. The Committee considered this comment and decided to change section 5.7 of the guidance.

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16.	Consultee 2, Other- Patient Representative	6.1	We agree fully with the conclusion from the EAC that, 'Transit time flowmetry is considered to be valuable tool for predicting early graft failure in CABG patients with the ability of improving surgical results. Criteria for predicting abnormal grafts in terms of limiting values of parameters such as pulsatility index (PI) are proposed. However, the measured values can depend on the type and manufacturer of the system and on the system settings. Therefore it is important that both the type of flowmeter and system settings are clearly indicated for graft flow measurements to ensure consistency' (EAC report, p22), and would like the NICE recommendations to more clearly highlight the need for care in interpretation of measurements from different meters.	Thank you for your comment. The Committee considered this comment and decided to specify the VeriQ system default filter setting in section 2.3 of the guidance. A section on the Committee's consideration of the evidence from Nordgaard et al (2010) has been added to section 3.12 of the guidance to clarify that transit time flow measurements by the VeriQ system differ from other flowmeters and these differences in systematic and consistent.
17.	Consultee 2, Other- Patient Representative	6.1	As highlighted by in the Scope document, there may be 'barriers to uptake associated with ease of use and lack of familiarity by surgeons'. The EAC report states that the manufacturer will provide one half day training for proficient use of Veri-Q. Given the potential confusion available between use of different TTFM systems, it would be appropriate that this training indicated that other systems are calibrated differently, and therefore may provide different readings, otherwise surgeons trained on Veri-Q may come across another system in their work and assume the flowgraphs are interpreted in the same way.	Thank you for your comment. The Committee recognises that training issues are very important in contributing to the clinical utility of medical technologies. Although they are beyond the scope of the decision problem, information that is relevant to the implementation of this technology in the NHS, including this comment, is considered in the development of the NICE implementation tools. Therefore the Committee decided not to change section 6.1 of the guidance.

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18.	Consultee 2, Other- Patient Representative	6.1	Additionally, the training needs to highlight the limitations of the Veri-Q system, in terms of potential oversensitivity to other factors, which may lead to an incorrect interpretation. Therefore the training needs to place the Veri-Q system in the context of the range of measures needed to ensure early indication of graft failure.	Thank you for your comment. The Committee recognises that training issues are very important in contributing to the clinical utility of medical technologies. Although they are beyond the scope of the decision problem, information that is relevant to the implementation of this technology in the NHS, including this comment, is considered in the development of the NICE implementation tools. Therefore the Committee decided not to change section 6.1 of the guidance
19.	Consultee 2, Other- Patient Representative	6.1	We agree with the overall conclusion of the Committee that the case is supported for adopting in the NHS 'the routine intraoperative graft flow assessment in patients having CABG surgery'.	Thank you for your comment.
20.	Consultee 2, Other- Patient Representative	6.1	We agree with the comments in the Scope document that, 'to realise maximum patient benefit … all grafts would need to be assessed'.	Thank you for your comment.
21.	Consultee 2, Other- Patient Representative	General	Summary response to Advisory Committee's questions: • Consideration of relevant evidence appears thorough • Summaries of clinical effectiveness and resource savings appear reasonable • Broadly, the provisional recommendations appear sound, however, guidelines need to make limitations clear (see comments below) • Equality issues – none.	Thank you for your comment.

No.	Consultee	Section number	Comments	Responses
22.	Consultee 3, Department of Health Representative	General	Thank you for the opportunity to comment on the Veri Q system for assessing graft flow during coronary artery bypass graft surgeryl. I wish to confirm that the Department of Health has no substantive comments to make, regarding the above consultation.	Thank you for your comment.
23.	Consultee 4, Manufacturer	General	On behalf of the manufacturer we would like to comment that we are happy with the draft as it stands at present, ant that we have no further comments to add.	Thank you for your comment.
24.	Consultee 4, Manufacturer	General	We of course welcome any medical and scientific input from specialists and surgeons in the field. We would like to express our thanks for the opportunity to participate in the process.	Thank you for your comment.

25.	Consultee 5, Distributor	General	The whole document appears to be extremely thorough.	Thank you for your comment.
26.	Consultee 5, Distributor	General	The fact that money can be saved by using the device routinely is important, as of course is outcome improvement for those undergoing CABG.	Thank you for your comment.

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