NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Review decision

Review of MTG8: The VeriQ system for assessing graft flow during coronary artery bypass graft surgery

This guidance was issued in November 2011.

NICE proposes an amendment of published guidance if there are no changes to the technology, clinical environment or evidence base which are likely to result in a change to the recommendations. However the recommendations may need revision to correct any inaccuracies, usually in relation to providing a more accurate estimate of the results of the cost modelling. The decision to consult on an amendment of published guidance depends on the impact of the proposed amendments and on NICE's perception of their likely acceptance with stakeholders. NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance.

1. Review decision

Amend the guidance to reflect the new name of the technology and to update the estimated cost savings, and do not consult on the proposed amendments.

NICE should publish a summary of the updated cost model.

2. Original objective of guidance

To evaluate the case for adoption of the VeriQ system for assessing graft flow during coronary artery bypass graft surgery.

3. Current guidance

1.1 *The case for adopting the VeriQ system in the NHS for assessing graft flow during coronary artery bypass graft (CABG) surgery is supported by the evidence. The evidence suggests that intra-operative transit time flow measurement is effective in detecting imperfections that may be corrected by graft revision. This may reduce the incidence of graft occlusion and may reduce perioperative morbidity and mortality.*

1.2 The VeriQ system is associated with an estimated cost saving of £115 per patient compared with clinical assessment, when it is used routinely for assessing coronary artery bypass grafts during surgery.

4. Rationale

There are minor changes to the technology but no significant changes to the care pathway or evidence base since MTG8 was published. New evidence (see section 6) provides further support for the technology's claimed benefits. The cost model has been updated and the technology remains cost saving. It is therefore proposed to amend the guidance without consultation on the review proposal.

5. New evidence

The search strategy from the original assessment report was re-run, references from May 2011 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology.

5.1 Technology availability and changes

The VeriQ system is not available to new customers, and has been replaced by the MiraQ which was launched in October 2014. An internal assessment compared the technical specifications of the two systems and concluded that the two systems are equivalent in their capability to perform transit time flow measurements and that the measurement probes are unchanged (see technical comparison for more information). Since the production of the guidance, the cost of the new system has increased from £32,000 to £34,000 while the cost of individual probes has reduced from £1582 to £1481.

5.2 Clinical practice

There has been no significant change to the pathway described in The management of stable angina, NICE guideline (CG126). A review of this guideline in 2016 decided not to update the guideline.

5.3 NICE facilitated research

No research has been commissioned by NICE on this technology.

5.4 New studies

Literature searches conducted by NICE identified 3 relevant published papers and 1 conference abstract on VeriQ or successor systems not considered during guidance development. Further details of the studies and their outcomes are in Appendix 4.

Succi (2012) is a Brazilian study involving 44 patients who underwent CABG and graft flow assessment using TTFM. The study conducts a statistical comparison between different flow measurements used to assess graft patency.

Romasko (2015) is a conference abstract which reports on a study which evaluated the flow precision measurement of the VeriQ Flowmeter System (Medistim, Norway) focusing on the easy accessible T-graft anastomosis (free right into the left internal mammary artery). Only measurements with an acoustical coupling index (ACI) > 50% were included. The measurements in the LIMA trunk were compared with the sum of the LIMA and RIMA flow behind the anastomosis.

Walker (2013) involved 160 patients receiving robotic assisted CABG at Emory University (Atlanta, Georgia, USA). The purposes of this study was to compare TTFM parameters in patients who underwent minimally invasive left internal mammary artery (LIMA)-left anterior descending artery (LAD) grafting; and to determine whether any differences were present between the patent and nonpatent grafts as defined by subsequent conventional diagnostic angiography. All patients had both transit time flow measurement (TTFM, VeriQ) and either intraoperative or postoperative angiography.

Lehnert (2015) sought to investigate a possible correlation between TTFM (MediStim, device not specified) and graft failure at one year angiographic follow-up and if possible determine a numerical flow value for predicting graft failure in the clinical setting. The study population was selected retrospectively from two large randomised controlled trials, both of which enrolled patients between 2002 and 2006. A total of 345 patients from those trials had TTFM and one year postoperative angiography. Graft failure on angiography was defined as more than 50% stenosis or a ‘‘string sign.’’ Univariate and multivariate logistic regression analysis was used to associate the risk of graft failure after one year with the TTFM.

6.5 Updates to cost modelling

The EAC model from the original guidance was updated by the External Assessment Centre which prepared the original assessment report (KiTEC).

The original cost model was revised to incorporate:

- the revised technology prices;
- updated NHS resource costs to current values

Revisions to the cost model suggest the savings should be corrected to £141 per patient. For details on the updated costs please refer to Appendix 2.

7. Summary of new information and implications for review

The findings from the 4 new studies are consistent with the evidence assessed during the development of MTG8 and have no material implications for the recommendations in the current guidance.

Revisions to the base case of the cost model suggest the savings in section 1.2 should be corrected to £141 per patient. The proposed amendments to the guidance are presented in appendix 3.

8. Implementation

The company has stated that the technology is being used in 10 NHS hospitals. No information was received from the adoption and impact team. The company noted that NICE guidance has significantly raised awareness of its technology, and helped with adoption, but that awareness heavily trails adoption. The company attributes this to financial constraints within NHS Trusts and their long and overly bureaucratic procurement processes.

9. Equality issues

No equality issues were raised in the original guidance

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Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	**Consequence**	**Selected – 'Yes/No'**
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	Yes
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Transfer the guidance to the 'static guidance list'	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	No
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

Options	Consequence	Selected – 'Yes/No'
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

Appendix 2 – EAC updated unit costs

Table 1: Updated unit costs

Category	Previous costs (£)	Updated costs (£)	Source of updated costs
Actual or Suspected Myocardial Infarction	£1,415.20	£1,773.29	NHS reference costs 2016 (average of EB10A, EB10B, EB10C, EB10D, EB10E)
Rehab for acute MI and other cardiac disorders	£251.76	£257.78	NHS reference costs 2016 (VC38Z)
Deep sternal infection, intermed wo CC	£860.55	£1119.98	NHS reference costs 2016 (WH07G)
Proxy for IABP	£2,657.37	£2,574.38	NHS reference costs 2016 (average of EC20A, EC20B)
Category	**Previous costs (per hour, £)**	**Updated costs (per hour, £)**	**Source of updated costs**
Cardiac surgeon	£68.54	£138	PSSRU 2016 (hospital based surgical consultant)
Anaesthetist	£41.90	£128	PSSRU 2016 (Associate specialist)

Cardiac nurse	£23.37	£51	PSSRU 2016 (hospital based band 6 nurse including qualifications)
Cardiac perfusionist	£24.17	£60	PSSRU 2016 (hospital based band 7 nurse including qualifications)

Appendix 3 – Proposed amendments to original guidance

Table 2: proposed amendments to original guidance

Section of MTG	Original MTG	Proposed amendment
Throughout the document except where reporting studies	VeriQ	MiraQ
1.2	The VeriQ system is associated with an estimated cost saving of £115 per patient compared with clinical assessment, when it is used routinely for assessing coronary artery bypass grafts during surgery	The MiraQ system is associated with an estimated cost saving of £141 per patient compared with clinical assessment, when it is used routinely for assessing coronary artery bypass grafts during surgery. The cost saving associated with adopting MiraQ have been updated. For further details see 5.12 [2018].
5.12		For the guidance review, the external assessment centre revised the model to reflect 2017 costs (original guidance values given in brackets). The main parameter changes were the cost of the MiraQ console £34,000 (£32,000) and probes £1,481 (£1,582) 50 uses (30 uses) which resulted in a MiraQ system cost of about £141 (£111) per procedure. The cost of the time taken to perform a minor revision was

		estimated to be £24 (£11), and for major revisions, £396 (£180). Treatment costs of postoperative myocardial infarction and associated rehabilitation costs were estimated to be £2031(£1667) per patient and treatment cost by intra-aortic balloon pumping was estimated to be £2574(£2657) per episode. Base case results for the 2017 revised model shows the cost saving associated with the MiraQ system was £141 (£115) per patient. Further details of the 2017 revised model are in the revised model summary [2018]

Appendix 4. Relevant studies published since publication of MTG8

Succi (2012)

Population	44 Brazilian patients who underwent CABG
Intervention	Transient time flowmeter (VeriQ)
Comparator	N/A
Outcome	There was a statistically significant ($p<0.0001$) in mean flow in venous (31.14 +/- 18.31 ml/min) and arterial grafts (50.42 +/- 28.42 ml/min). However a non-statistically significant difference in mean flux for the diagonal (49.38 +/- 23.11ml/ min); posterior interventricular branch (46.11+/-12ml/min) and left marginal arteries (51.84+/-28.21 ml/min), $p=0.789$
Design	Observational
Comments	The authors conclude that the technology was safer for the surgeon and for the patient, ensuring that the operation was technically well done

Romasko (2015 abstract)

Population	370 coronary artery bypass grafts in 280 patients (setting unknown)
Intervention	VeriQ
Comparator	N/A
Outcome	No significant differences were found between the pulsatility indices and ACI values between the mammary segments and probe sizes, respectively. The authors conclude that at the T-Graft anastomosis, bypass flow significantly varies with probe

	(mammary) size. Behind the T-anastomosis, bypass flow is significantly higher in the LIMA compared with the RIMA despite a lower number of distal anastomoses. Flow sum of LIMA and RIMA behind the T is significantly higher than in the LIMA trunk and increases with the probe size and the absolute flow
Design	Conference abstract
Comments	Study focused on the easily accessible T-graft anastomosis [free right into the left internal mammary artery (LIMA)]. Only measurements with an acoustical coupling index>50% were included

Walker (2013)

Population	160 patients receiving robotic assisted CABG in a US centre
Intervention	VeriQ
Comparator	Intra or post-operative angiography
Outcome	TTFM found a significant difference in mean flow (+/- SD) between patent and nonpatent grafts (34.3 +/- 16.8 mL/min vs 23.9 +/- 12.5 mL/min, p = 0.033) but not in PI (1.98 +/- 0.76 vs 1.65 +/- 0.48, p = 0.16) or DF (73.5% +/- 8.45% vs 70.9% +/- 6.15, p=0.13)
Design	Observational study
Comments	The authors conclude that TTFM is a useful tool due to its ease of use and ability to assess various flow characteristics. However it is not as sensitive as angiography in detecting graft defects that can lead to graft failure

Lehnert (2014)

Population	340 patients who had both TTFM and 1 year post angiography
Intervention	Transit time flow measurement (TTFM, Medistim)
Comparator	1 year post-operative angiography
Outcome	In the 23 single internal mammary arteries (IMA) grafts, logistic regression analysis showed that flow measured with TTFM had a significant influence on the risk of graft failure at one year in IMA grafts, with a 4% decrease in graft failure odds for every 1mL/min increase in TTFM (OR=0.96, CI [0.93 to 0.99], p= 0.005). In the 37 vein grafts a non-significant decrease in graft failure odds of 2% for every 1 mL/min increase in TTFM (OR=0.98; CI [0.97 to 1.00], p=0.059) was shown; in the 8 radial artery grafts the result was also non-significant (OR=1, p=0.67). In the LIMA part of the Y-anastomoses there was a significant relationship between flow measured with TTFM and the risk of graft failure, (O.96; CI [0.93 to 0.99], p=0.02)
Design	Retrospective analysis of 2 RCTs
Comments	The authors conclude that TTFM appears to have a close relationship to the risk of graft failure after 1 year in most of analysed graft configurations

References

Lehnert, M., Moller, C., Damgard, S, et al. (2014) Transit-Time Flow Measurement as a Predictor of Coronary Bypass Graft Failure at One Year Angiographic Follow-Up. Journal of Cardiac Surgery 30 (1) 46-52

Romasko, D., Graff, J., Reitmeier, F, et al. (2015) Intraoperative transit time flow measurement evaluation of the mammary T-graft anastomosis during coronary artery bypass surgery. Thoracic and Cardiovascular Surgeon Conference: 44th Annual Meeting of the German Society for Thoracic and Cardiovascular Surgery Freiburg Germany.

Succi, J. E., Gerola, L. R., Succi, M, et al. (2012) Intraoperative coronary grafts flow measurement using the TTFM flowmeter: results from a domestic sample. Revista Brasileira de Cirurgia Cardiovascular: Orgao Oficial da Sociedade Brasileira de Cirurgia Cardiovascular 27 (3) 401-404

Walker P, Daniel W, Moss E, et al. (2013) The accuracy of transit time flow measurement in predicting graft patency after coronary artery bypass grafting. Innovations 8 (6) 416-419