NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Medical technology guidance

SCOPE

The VeriQ system for assessing graft flow during coronary artery bypass graft surgery

1 Technology

1.1 *Description of the technology and claimed benefits*

The VeriQ system is used for the intra-operative non-invasive assessment of graft flow during coronary artery bypass surgery. The technology uses transit time flow measurements (TTFM) and this information can be used for graft patency quality assurance.

The VeriQ system consists of a 19" touch screen and a 160 GB hard drive mounted on a moveable trolley. Blood flow is measured by a sterile TTFM probe. The VeriQ system has a range of probes available for vessels of different diameters (1.5-35 mm) and to suit different surgical procedures. Probes can be sterilized and re-used for up to 30 or 50 procedures depending on the type of probe. All probes deliver a bidirectional ultrasound beam across a target graft vessel and the system analyses the return signal to calculate the amount of blood flow through the vessel. Direction of flow is also indicated and this can be correlated with ECG and arterial pressure traces obtained from connections to the existing physiological monitor. A real time flow curve is displayed together with Mean Flow in ml/min, Pulsatility Index (PI) and Diastolic Filling percentage (DF%) and this information can be used to determine whether flow in the target graft vessel is adequate. If these figures and the flow curve are considered inappropriate, the graft can be revised before the completion of the procedure to ensure optimum flow in all grafted vessels. It is proposed that this will result in a reduction in the incidence of early graft failure and therefore a reduction in peri- and post-operative complications.

VeriQ can also be used to detect coronary arteries that need to be revascularised using a doppler probe. The doppler probe may be used for locating arteries deep in the myocardium and for precise location of stenoses. This may facilitate correct graft placement ensuring adequate revascularisation is achieved. It can also be used to

help distinguish coronary vessel anatomy in coronary artery bypass graft reoperations.

Every measurement is saved in a database and can be exported to the hospital electronic patient records. Hardcopy reports are available via the on-board colour printer.

The VeriQ system can also be used for the assessment of graft flow in transplant and vascular surgery however these applications are not considered here.

1.1.1 The claimed benefits by the manufacturer for patients are:

- The VeriQ system enables a real-time assessment of graft flow which can be used to verify graft function. Use of the VeriQ system to measure the flow in grafts may improve the outcomes of revascularisation procedures by reducing the risk of early graft failure and reducing adverse patient events.

1.1.2 The claimed benefits by the manufacturer for the health system are:

- The VeriQ system enables surgeons to ensure optimal graft flows for the procedure concerned before the patient leaves theatre. If a reduction in early graft failure and peri- and post-operative complications is realized, there is the potential for a reduction in ITU and in-hospital length of stay as well as a reduction in cost associated with fewer post-operative clinical events.

- The additional cost of producing graft flow data using the VeriQ system is likely to be more than offset by the potential savings made with reduced reinterventions and treating other post-operative complications.

- Accurate documentation of graft flow provides a useful tool for clinical goverance and audit. All data produced by the VeriQ system is stored and can be exported into the patient electronic notes.

1.2 *Relevant diseases and conditions*

Coronary artery disease (CAD or atherosclerotic heart disease)
Coronary heart disease (CHD) is the UK's biggest killer, around one in five men and one in seven women die from the disease. CHD causes around 94,000 deaths in the UK each year. In the UK, there are an estimated 2.6 million people living with the condition.

Source: Coronary Heart Disease (2010) NHS Choices

Coronary artery bypass graft (CABG)

Approximately 28,000 CABG operations are performed in the UK each year. There is considerable geographical variation in terms of numbers of operations and referral rates between primary care centres

Source: Coronary Artery Bypass Grafting (2009) Patient UK

1.3 *Regulatory status*

VeriQ is CE-marked and was launched in 2004. The VeriQ system is described as a 'medical ultrasonic non-imaging flow-meter system' in the Certificate of Conformity with European Directive received on 28th October 2010.

2 Reasons for developing guidance on the VeriQ system

- The Committee recognised the importance of quality assurance for all vascular reconstructions. The VeriQ system measures transit time flow and the flow curve and pulsatility index may be used to identify grafts which have reduced flow that may be potentially reversible.

- The Committee considered that the VeriQ system may offer additional patient and system benefits compared to current practice for patients undergoing coronary artery bypass grafts (CABG) and transplant surgery. This scope focuses on CABG applications.

- The Committee recognised that recent guidelines on myocardial revascularization issued by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) have recommended graft evaluation before leaving the operating theatre after coronary artery bypass grafting. These guidelines refer to flow < 20mL/min and pulsatility index > 5 as predicting technically inadequate grafts which require revision before leaving the operating theatre. The Committee considered that developing medical technologies guidance on the VeriQ system may help the uptake of these recommendations in the NHS.

- The Committee considered that to realize maximum patient benefit from this device all grafts would need to be assessed.

- The Committee considered that there may be barriers to uptake associated with ease of use and lack of familiarity by surgeons.

- The main comparators for the VeriQ system are clinical assessment of graft flow, SPY indocyanine green fluorescence imaging and electromagnetic flow meters.

- Clinical outcomes include incidence of graft failure, time to graft failure, peri-operative clinical events associated with graft failure (including mortality), frequency of the need for graft revision and changes in VeriQ measurements afterwards as well as the requirement for repeat coronary revascularisation procedures and long term morbidity and mortality. VeriQ may also be helpful in targeting interventions at the end of the surgical procedure if the surgeon is concerned about the immediate results of revascularisation on cardiac function.

- Procedural outcomes associated with the use of the VeriQ system include accuracy of the measurements, additional operating time, number of probes used per procedure and number of times each probe can be used as well as changes in the flow parameters after graft revision.

- The VeriQ system is an intra-operative device and therefore, current care pathways are unlikely to be impacted by its use.

3 Statement of the decision problem

	Final scope issued by NICE
Population	Individuals undergoing coronary artery bypass surgery.
Intervention	Use of VeriQ system during surgery to assess graft flow
Comparator(s)	Comparators include: clinical assessment of graft flow SPY indocyanine green fluorescence imaging Electromagnetic flow meters Intraoperative or completion Doppler (auscultation) Intraoperative or completion Duplex imaging Intraoperative or completion angiogram
Outcomes	Clinical outcome measures include incidence of graft failure, time to graft failure, peri- and post-operative clinical events associated with graft failure (including mortality), frequency of the need for graft revision and changes in VeriQ measurements afterwards as well as the requirement for repeat coronary revascularisation procedures and long term morbidity and mortality. VeriQ may also be helpful in targeting interventions at the end of the surgical procedure if the surgeon is concerned about the immediate results of revascularisation on cardiac function. System-related outcome measures include accuracy of the measurement, time taken to generate and record data during the operation, number of probes used per procedure and number of times each probe can be used.
Cost analysis	The cost analysis should compare the use of the VeriQ system in CABG against the most relevant UK comparator which is considered to be clinical assessment of graft flow. The cost analysis should be based on the UK NHS setting. It should comprise NHS costs and personal social services costs (where relevant). Costs should include costs relating to the direct use of the technology such as treatment costs, acquisition cost, running costs and any other health system impact costs. Costs should also include indirect costs, such as infrastructural, maintenance and training costs. The costs associated with complications, adverse events and misdiagnosis relating to the use of the device and the comparator should be considered. Include the time horizon for the accrual of costs and describe the lifetime costs of the technology, where applicable. Sensitivity analysis should be used to address all parameter and model uncertainties associated with the cost analysis.
Subgroups to be considered	None defined
Special considerations,	None defined

including issues related to equity or equality	

4 External organisations

4.1 *Professional organisations*

4.1.1 Specialist societies contacted for expert advice

Society for Cardiothoracic Surgery, Great Britain and Ireland

4.1.2 Societies or organisations for consultation

Society for Cardiothoracic Surgery, Great Britain and Ireland

4.2 *Patient organisations*

NICE's Patient and Public Involvement Programme contacted the following organisations for patient commentary:

Arrhythmia Alliance
Action against Medical Accidents (AvMA)
Action Heart
Atrial Fibrillation Association
British Cardiac Patients Association
British Heart Foundation
British Liver Trust
British Lung Foundation
Cardiomyopathy Association
Counsel and Care
CritPaL - Patient Liaison Committee of the Intensive Care Society
Grown up congenital heart patients association
Heartcare Partnership UK
ICU Steps
National Heart Forum (UK)
Royal College of Surgeons Patient Liaison Group
The British Kidney Patient Association
The Kidney Alliance
Trauma Care
The Vascular Society