CardioQ-ODM oesophageal Doppler monitor for patients undergoing major or high-risk surgery and patients in critical care

1 Technology

1.1 Description of the technology

The CardioQ-ODM oesophageal Doppler monitor assesses the fluid status of a patient to help guide appropriate administration of fluid and drugs during cardiac output monitoring. The monitor is typically used either in peri-operative management of patients undergoing major or high-risk surgery, or in intensive care of critically ill patients who are treated with invasive ventilation. It is intended to be less invasive than some other options for cardiac output monitoring.

Oesophageal Doppler monitoring involves the use of a monitor and a single-use disposable probe. The probe is placed into the patient’s oesophagus through either the mouth or nose. A low frequency ultrasound signal, generated by the monitor, is reflected by red blood cells as they travel down the aorta and the Doppler principle is used to determine the velocity of the travelling blood cells. The monitor uses a validated proprietary nomogram to extrapolate volumetric data (stroke volume, cardiac output, etc.) from the directly measured flow velocity. This means that any
reported relative change in stroke volume is identical to the relative change in the directly measured flow velocity variable.

Intraoperative Doppler guided fluid management involves inserting and focusing of the probe to obtain a baseline reading. Patients are then challenged with 200–250 ml of fluid (colloid) over 5 minutes. Following the challenge the result is monitored using an oesophageal Doppler monitor. If the stroke volume increases by 10% or more, the patient’s left ventricular end diastolic volume is not optimal and a further colloid challenge is required. Fluid challenges are repeated until the change in stroke volume or stroke distance as monitored by the device is less than 10%. Functional hypovolaemia, which is present before most surgical procedures begin, can be addressed by early stroke volume maximisation using the oesophageal Doppler monitor. It is important to recognise that haemodynamic changes must be interpreted within the clinical context for each patient using the judgement of a senior anaesthetist working with the surgical team.

1.2 CardioQ-ODM regulatory status

The CardioQ-ODM oesophageal Doppler monitor was CE marked in 2008 and indicated for use as a cardiac function and fluid status monitoring system. A previous version, CardioQ, was CE marked in 1999.

2 Reasons for developing guidance on the CardioQ-ODM oesophageal Doppler monitor

The Medical Technologies Advisory Committee (MTAC or ‘the Committee’) considered this technology to be advantageous to patients who require haemodynamic monitoring.

There is evidence that the use of the CardioQ-ODM oesophageal Doppler monitor in the peri-operative care of patients undergoing major or high-risk surgery may reduce length of stay
and complications. There is less evidence of its effectiveness in a critical care environment.

The Committee recognised that this technology has been available to the NHS for a number of years and is routinely used in some hospitals. However they felt there is potential for more widespread use.

3 Relevant diseases and conditions

The CardioQ-ODM oesophageal Doppler monitor is a fluid status and cardiac function monitoring system for patient groups in two clinical scenarios:

- Patients undergoing major or high-risk surgery. This includes those likely to be under general or regional anaesthetic for 1 hour or more, those at high risk because of their comorbidity status; those having surgery involving access to a body cavity, expected significant blood loss, or insufflation of the abdomen for laparoscopic surgery. For the CardioQ-ODM monitor to function properly, the type of surgery must allow the oesophagus to be relatively immobile.

- Patients in critical care who require haemodynamic monitoring.

It is difficult to be certain of the number of patients per year either undergoing major or high-risk surgery, or requiring intensive care nursing. However, the following considerations provide an estimate of the populations involved:

- In general a high-risk surgical case has a predicted mortality of more than 5%. A recent published UK study by Pearse and colleagues used two large NHS databases to suggest that approximately 12.5% of all surgical cases fall into this category. If patients with head and neck cancer or having oesophagectomy are excluded, this suggests that approximately 11% of all surgical procedures per annum (approximately
330,000) patients could use the oesophageal Doppler monitor. It is also possible that some lower risk patients (1–5% mortality) could use this type of monitoring as part of an enhanced recovery programme.

- The Hospital Episode Statistics data show that there were approximately 160,000 critical care periods ending in the year 2008/09. Approximately 8% of the 1.1 million total critical care days analysed had advanced cardiovascular support.

3 Patient benefit

3.1 Current management options (comparators)

Monitoring cardiac output and haemodynamic status to optimise intravenous fluid replacement is important for critically ill patients and to ensure adequate organ perfusion for those undergoing major or high-risk surgery.

The traditional method of monitoring cardiac output is pulmonary artery catheter. In recent years this has been used less often because of concerns about its benefits and the increasing availability of less invasive monitoring methods.

Other less invasive cardiac output monitoring methods include trans-oesophageal echocardiography, thoracic electrical bioimpedence measurement and systems based on pulse contour analysis and dye dilution methods.

These methods may be used with conventional clinical assessment and either with or without a central venous pressure monitoring catheter. This catheter does not directly measure cardiac output but it gives information on cardiac pre-load (which in turn can be used to guide decisions on fluid management).
3.2 **Clinical outcomes relevant to the technology**

The clinical outcomes relevant to the CardioQ-ODMCardioQ-ODM-ODM oesophageal Doppler monitor are mortality, complications, length of stay and hospital re-admission.

All adverse events relating to the safety of this device may result from device failures or device-related complications.

4 **Care pathway and system impact outcomes**

4.1 **Care pathway**

The CardioQ-ODM oesophageal Doppler monitor is designed for use in two clinical settings:

- Many patients undergoing major or high-risk surgery are selected for cardiac output monitoring. This decision is usually taken by the anaesthetist at the pre-operative clinical assessment. However, monitoring may begin during surgery if required. Peri-operative monitoring usually stops when the surgery ends.

- For patients in critical care units, the decision to use cardiac output monitoring to help guide fluid replacement is taken on the basis of clinical need, and also on factors such as the patient’s condition and comorbidities. The oesophageal Doppler monitor is best suited to critically ill patients who are invasively ventilated, under anaesthesia. The decision to stop monitoring depends on changes in the patient’s critical care status.

The National Technology Adoption Centre has supported the implementation of Doppler-guided intra-operative fluid management into routine clinical and operational practice in three NHS trusts.

Individualised goal-directed fluid therapy is also described in the Department of Health (2010) guidance ‘Delivering enhanced
recovery: helping patients to get better sooner after surgery’ as follows: ‘New monitors (such as the oesophageal Doppler) allow just enough intravenous fluid to be given to maximise the amount of blood ejected by the heart each heartbeat, without giving excess fluid which can accumulate in the tissues and slow recovery from surgery.’

No other issues relating to the care pathway, such as supporting equipment, additional training and necessary infrastructure were identified.

4.2 **System impact outcomes**

System outcomes associated with the CardioQ-ODM oesophageal Doppler monitor are the resources released as a result of the reduced length of hospital stay, post-operative complications, re-operations and hospital re-admissions.

5 **Health inequalities and equality impact**

5.1 **Health inequalities**

There are no health inequalities issues identified with the CardioQ-ODM oesophageal Doppler monitor.

5.2 **Equality impact**

There is no evidence to demonstrate variation in effectiveness of the CardioQ-ODM oesophageal Doppler monitor according to the age, gender, class or ethnicity of the target audience. There appears to be no differential impact on inequalities in health within and between different population groups. However, patients from lower socio-economic status tend to have a higher degree of comorbidity, and as such tend to be of higher surgical risk (for the same type of surgery) compared with patients from higher socio-economic classes. Therefore, in principle at least, use of the technology could be of particular benefit to more socio-

Scope
economically deprived patients who undergo major or high-risk surgery and so use of this technology may provide an opportunity to promote equality. A medical technology evaluation of the CardioQ-ODM oesophageal Doppler monitor is not likely to have an impact on the current burden of disease.

6 Approach to cost measurement and health economic analysis

The costs of adopting this technology would include capital costs to purchase the monitor (£11,000) and ongoing costs per patient for probes. Peri-operative probes vary in price between £67 and £88 depending on the intended length of use between 6 and 24 hours. Critical care probes are designed for longer use and vary in price from £107 to £117. Other indirect costs which may be necessary include maintenance (approximately £750 per annum) and staff training.

The cost analysis for use of CardioQ-ODM oesophageal Doppler monitor in peri-operative and critical clinical care settings should be presented separately. The cost analysis should describe the cost impact of the introduction of the technology into the care pathway compared with current patient management. Comparators for cost analysis are current standard care in the NHS in each care setting. There is wide variation in care but the most appropriate comparators are conventional clinical assessment and central venous pressure for surgical patients, and pulse pressure waveform analysis for critical care patients.

7 External organisations

7.1 Professional organisations

- British Society of Echocardiography
- Intensive Care Society
Royal College of Anaesthetists.

7.2 Patient organisations

- Action against Medical Accidents (AvMA)
- Action Heart
- Arrhythmia Alliance
- British Cardiac Patients Association
- British Cardiovascular Society
- British Heart Foundation
- 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)
- Patients Association
- Royal College of Surgeons Patient Liaison Group
- Sudden Adult Death Trust (SADS) UK
- Trauma Care
- Vascular Society.

7.3 NHS trusts or other organisations with experience of the technology

CardioQ-ODM The NIHR Health Technology Assessment (2009) on oesophageal Doppler monitoring commented that CardioQ-ODM oesophageal Doppler monitors have been used in approximately two thirds of the 300 NHS hospitals that regularly undertake moderate or major surgery within the UK.
The National Technology Adoption Centre implementation project took place in three hospitals:

- Central Manchester University Hospitals NHS Foundation Trust (Manchester Royal Infirmary)
- Whittington Hospital NHS Trust, (Whittington Hospital, London)
- Derby Hospitals NHS Foundation Trust (Derby Hospital).

8 Other issues

9 Related NICE guidance

9.1 Published

<table>
<thead>
<tr>
<th>Population</th>
<th>Final scope issued by NICE</th>
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| • Patients undergoing major or high-risk surgery and high-risk patients undergoing any surgery.  
• Patients in critical care treated with invasive ventilation who require haemodynamic and guided fluid status monitoring. |

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<tr>
<th>Intervention</th>
<th>CardioQ-ODM oesophageal Doppler monitor</th>
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| Comparator(s) | Conventional clinical assessment with or without central venous pressure, pulmonary artery catheter, trans-oesophageal echocardiography, thoracic electrical bioimpedence, pulse pressure waveform analysis, systems based on pulse contour analysis and dye dilution methods. |

| Outcomes | Efficacy: length of stay, complications, hospital re-admission, mortality.  
Safety: device failures, device-related complications |
|----------|-------------------------------------------------|

| Cost analysis | Comparative cost analysis of the CardioQ-ODM oesophageal Doppler monitor and the following comparator(s) representing standard care:  
• Surgical patients: conventional clinical assessment and central venous pressure.  
• Critical care patients: pulse pressure waveform analysis. |

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<tr>
<th>Subgroups to be considered</th>
<th>No subgroups need to be considered.</th>
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| Special considerations including issues related to equity or equality | No special considerations. |