NCCHTA

09 July 2008

March 2007

1. Title of the project:

What is the clinical and cost effectiveness of oesophageal Doppler monitoring in critically ill and high risk surgical patients?

2. Name of TAR team and project 'lead'

Aberdeen Technology Assessment Group

Vale, Luke
Senior Research Fellow, Team Leader and Health Economist
Health Services Research Unit/Health Economics Research Unit
University of Aberdeen
Polwarth Building, Foresterhill
Aberdeen AB25 2ZD
Tel. 01224 551127
Fax 01224 554580, E-mail: l.vale@abdn.ac.uk

Reserve contact:

Mowatt Graham
Research Fellow, Senior Systematic Reviewer
Health Services Research Unit
University of Aberdeen
Health Sciences Building, Foresterhill
Aberdeen AB25 2ZD
Tel. 01224 552494
Fax 01224 554580, E-mail: g.mowatt@abdn.ac.uk

3. Plain English Summary

It is believed that measuring heart function during critical illness or during surgery can improve patient outcomes. Until recently the main method used to measure heart function has been pulmonary artery catheterisation (PAC), although for people undergoing surgery even this approach is uncommon. Whilst providing useful information, PACs have not been shown to improve mortality. This coupled with concerns over procedural complications associated with the use of these catheters, along with the development of less complex heart monitors, has resulted in a global decline in the usage of PACs over recent years.

This review will assess the effectiveness and cost-effectiveness of oesophageal Doppler monitoring (ODM) when used for monitoring heart function in comparison with (i) standard care (i.e. no cardiac output monitor perioperatively amongst patients undergoing major surgery; and (ii) other methods of monitoring heart function such as pulmonary artery catheterisation or pulse contour monitoring devices in critically ill patients or in patients undergoing major surgery.

The analysis will focus on outcomes of most importance to patients (e.g. mortality, length of hospitalisation, length of stay in critical care, days of organ support in ICU and complications). Cost-effectiveness will be assessed from the perspective of the NHS and personal social services.

Information of the relative effectiveness of the alternative interventions will be derived by systematically reviewing relevant randomised controlled trials (RCTs) comparing ODM with: (i) standard care (i.e. no cardiac output monitor perioperatively amongst patients undergoing major

surgery); and (ii) other methods of monitoring heart function as outlined above. Information on cost-effectiveness will initially be assessed using a systematic review of economic evaluations comparing ODM to the relevant comparators for the two patient groups specified.

4. Decision problem

Optimal management of cardiac output and haemodynamic status have long been considered as key to improving outcome in critically ill patients and in high risk patients undergoing major surgery. Traditionally pulmonary artery catheters (PAC) have been used to monitor cardiac output and haemodynamic status and to guide treatment. A recent HTA Programme funded study demonstrated that PAC insertion and management of critically ill patients using the parameters monitored by PAC fails to infer an outcome benefit. Further studies have also cast doubt on the value of PAC in high risk major surgery.[1] This coupled with concerns related to procedural complications associated with the insertion and use of the PAC, along with the development and assimilation of less invasive cardiac output monitors into clinical practice, has resulted in a global decline in the usage of the PAC in recent years.

Less invasive technologies to monitor cardiac output and other haemodynamic parameters include Oesophageal Doppler Monitoring (ODM) and systems based upon pulse contour analysis and dye dilution methods. The ODM measures blood flow velocity in the descending thoracic aorta using a flexible ultrasonic probe inserted into the patient's oesophagus. This information is combined with an estimate of aortic cross sectional area (derived from the patient's age, height, and weight) allowing haemodynamic variables to be calculated.

Pulse contour analysis devices employ algorithms to perform real-time continuous monitoring of cardiac output through arterial pulse contour analysis. There are several types of devices available, but all require initial calibration which may be either via transpulmonary thermodilution or lithium dilution techniques.

Information on the relative effectiveness of the alternative interventions will be derived by systematically reviewing relevant randomised controlled trials (RCTs). Information on cost-effectiveness will be assessed using a systematic review of economic evaluations of the alternative methods.

5. Report methods for synthesis of evidence of clinical effectiveness

A review of the evidence for clinical effectiveness will be undertaken systematically following the general principles recommended in the QUOROM statement[2].

5.1 Nature of existing evidence base and justification of approach taken

There are at least two existing reviews of ODM. These reviews are not systematic in that they did not use a search strategy likely to identify all relevant studies. These reviews compared ODM primarily with PAC and focused on measures of cardiac output. However, it is recognised that PAC is an inappropriate gold standard for the measurement of cardiac output[3] and the relationship between these surrogate measures and patient outcomes is unclear. Furthermore, as indicated above, the use of PAC is becoming less common and there is increasing use of other less invasive cardiac monitoring methods. For these reasons, we do not propose to update these existing reviews, rather we propose to

[1] Sandham J D, Hull R D, Brant RF et al. A Randomised , Controlled Trial of the Use of Pulmonary-Artery Catheters in High Risk Surgical Patients. New Engl J Med 2003: 348(1); 5-14.
[2] http://www.consort-statement.org/QUOROM.pdf
[3] Harvey S, Stevens K, Harrison D, Young D, Brampton W, McCabe C, Singer M, Rowan K. An evaluation of the clinical and cost-effectiveness of pulmonary artery catheters in patient management in intensive care: a systematic review and a randomised controlled trial. Health Technology Assessment. 2006. 10, 29.

complete a new systematic review of ODM compared with relevant comparators (including other new methods of measuring heart function) which will focus on outcomes of most importance to patients.

5.2 Population

- Inclusion criteria: (i) Adults being managed in critical care requiring cardiac monitoring
(ii) Adults during major surgery.

- Exclusion criteria: Use of ODM in patient groups other than those specified above
Studies in which ODM was used as a measure of study outcome rather than as a monitoring tool leading to a clinical intervention
- Relevant subgroups: Patients with sepsis vs. those without sepsis

5.3 Interventions

- Oesophageal doppler monitoring (ODM)

5.4 Comparator

For both patient groups:

- No cardiac monitoring
- Pulmonary artery catheters
- Pulse contour analysis monitoring
  Lithium dilution cardiac monitors i.e. LidCO® monitor
  Thermodilution cardiac monitors i.e. PICCO® monitor

5.5 Outcomes

There is no generally recognised Gold standard for the measurement of cardiac output and for this reason we are focusing on patient related outcomes rather than diagnostic performance.

If evidence permits the main outcome measures to be assessed will be:
- 30 day mortality
- Hospital mortality
- Longer term mortality
- Overall length of hospital stay
- Overall length of ICU stay
- Overall length of stay in critical care facilities (ICU & HDU)
- Days of organ support in ICU
- Post-operative complications and morbidity such as cardiac events and organ system failures
- Quality of life in year after surgery

5.6 Search strategy

Reviews of ODM exist but these reviews are not systematic. They also focus on diagnostic performance rather than the impact on clinical management and patient centred outcomes. Such comparisons may be misleading as PACs cannot be considered to be a gold standard. It is for this reason that our search strategy will focus on identifying RCTs comparing management based on ODM with management without monitoring or with an alternative method of monitoring (scoping searches indicate that there may be RCTs meeting our inclusion criteria. However, if when conducting the review, no RCTs are found that meet our criteria then consideration will be given to including data from non-randomised designs).

The search strategy will involve searching of electronic databases and relevant professional and manufacturers' websites.

Electronic searches will be conducted to identify reports of published and ongoing studies, including previous systematic reviews, on the effectiveness and cost-effectiveness of oesophageal doppler monitoring. Searching will be carried out, for the time period 1990 to the present, for full papers only. Only English language papers will be considered eligible for inclusion. Studies published in languages other than English will be noted, however. Databases to be searched are listed in Table 1. Preliminary Medline search strategies to be used are given in Appendix 9.1 and will be adapted for use in the other databases.

Current research registers, including the National Research Register, Current Controlled Trials and Clinical Trials will be searched.

Table 1. Databases to be searched

Clinical effectiveness	**Cost effectiveness**
Medline	Medline
Medline Extra	Medline Extra
Embase	Embase
CINAHL	CINAHL
Science Citation Index	Science Citation Index
Biosis	Health Management Information Consortium (HMIC)
UK PubMed Central	UK PubMed Central
Cochrane Central Register of Controlled Trials (CENTRAL)	NHS Economic Evaluation Database (NHS EED)
Health Technology Assessment Database (HTA)	Health Technology Assessment Database (HTA)
Cochrane database of systematic reviews (CDSR)	
Database of Abstracts of Reviews of Effectiveness (DARE)	

5.7 Inclusion criteria

For the review of clinical effectiveness, only RCTs will be included. Data will be systematically assembled and quality assessed using criteria relevant to each type of outcome. Titles and abstracts will be examined for inclusion by one reviewer. Where there is uncertainty this will be discussed with a second reviewer and a consensus reached.

5.8 Exclusion criteria

- Non-randomised studies
- Studies in which ODM is used to measure a study outcome rather than as a clinical monitor
- RCTs comparing ODM with other interventions not specified in 5.4 above
- Studies published in languages other than English
- Animal models
- Preclinical and biological studies
- Narrative reviews, editorials, opinions
- Reports published as meeting abstracts only

5.9 Data extraction strategy

All citations identified by the search strategy will be screened on the basis of the title and - where available – of the abstract. Full-text copies of all potentially relevant reports will be obtained. One reviewer will assess studies for inclusion and extract data using a standard data extraction form (See Appendix 9.2). Any uncertainty will be resolved by discussion with a second reviewer and any disagreements will be resolved by arbitration by a third party. Information will be recorded on: year of publication, source of funding, study design, methods pre-randomisation (e.g. stratification); method of randomisation; concealment of allocation; blinding procedures; number and characteristics of participants; duration of interventions; choice of outcome measures; length of follow-up. Care will be taken to avoid double counting due to multiple reports of the same data set. The reviewer will not be blinded to authors, institutions, or publications. Where there is insufficient information in the published report, no attempt will be made to contact the authors for clarification because of time constraints.

5.10 Quality assessment strategy

Consideration of study quality of RCTs will be assessed using the Delphi criteria list (Appendix 9.3) adapted from Verhagen and colleagues.[4]

5.11 Methods of analysis/synthesis

For trials with multiple publications, only the most up-to-date or complete data for each outcome will be included. Where appropriate, meta-analysis will be employed to estimate a summary measure of effect on relevant outcomes based on intention to treat analyses. Dichotomous outcome data will be combined using the Mantel-Haenszel relative risk (RR) method and continuous outcomes will be combined using the inverse variance weighted mean difference (WMD) method. 95% confidence intervals (CI) and p-values will be calculated for the estimates of RR and WMD. The results will be reported using a fixed effects model. Chi-squared tests and I-squared statistics will be used to explore statistical heterogeneity across studies. Possible reasons for heterogeneity will be explored using sensitivity analysis. Where there is no clear reason for heterogeneity, the implications will be explored using random effects methods. Where a quantitative synthesis is considered to be inappropriate or not feasible, a narrative synthesis of results will be provided. If a lack of uniformity of the data is present in many studies, a qualitative review looking for consistency between studies will be performed. This will be supplemented, where appropriate, by the investigation of the consistency in the direction of the results using the Sign test.[5]

Length of hospital stay will be defined as time from admission to discharge or death, length of ICU will be defined as time from admission to discharge from ICU or death in ICU. Length of stay data will only be interpreted in the light of the mortality data.

5.12 Systematic review of existing economic evaluations

The cost effectiveness of ODM will be addressed by conducting a systematic review of economic evaluations of ODM against potential relevant comparators and for the pertinent patient groups as described above. Searches for this will be adapted to those used for the systematic review of clinical effectiveness but tailored to find relevant economic evaluations studies. Non-English language studies will be excluded except where an NHS EED English language abstract is available. In this situation the NHS EED abstract will be used as the primary reference.

---

[4] Verhagen AP, de Vet HC, de Bie RA, Kessels AG, Boers M, Bouter LM et al. The Delphi list: a criteria list for quality assessment of randomized clinical trials for conducting systematic reviews developed by Delphi consensus. *J Clin Epidemiol* 1998;**51**(12):1235-41

[5] Sutton AJ, Abrams KR, Jones DR, Sheldon TA, Song F. Systematic reviews of trials and other studies. *Health Technol Assess* 1998;**2**(19):1-276

One reviewer will assess all abstracts for relevance and will ask for full papers to be obtained for those that appeared potentially relevant. Studies that compare relevant alternatives in terms of their cost and effects will be included in the analysis. One economist will assess included studies using well known guidelines for economic evaluation assessment.[6,7] These guidelines address all the important issues that should be reported when conducting an economic evaluation in health care. No attempt will be made to synthesise quantitatively the identified primary studies.

The following data will be extracted for each included study:

1. The study characteristics (the research question; the study design; the comparison; the setting; the basis of costing)
2. Characteristics of the study population (numbers receiving or randomised to each intervention; other systematic differences in clinical management; inclusion/exclusion criteria; dates to which data on effectiveness and costs are related)
3. Duration of follow-up for both effectiveness and costs
4. Results (summary of effectiveness and costs [point estimate and if reported range or standard deviation (SD)]; summary of cost-effectiveness/utility [point estimate and if reported range or standard deviation (SD)]; sensitivity analysis)
5. Conclusions as reported by the authors of the study

Data from all included studies will be summarised and appraised in order to identify common results, variations and weaknesses between studies. If a study does not report incremental cost effectiveness ratios (ICERs) but provides sufficient data then, where possible, the data will be reanalysed to provide estimates of ICERs. Particular attention will be given to relevant subgroup analyses within the included studies. These data will then be interpreted alongside the results of the systematic review of effectiveness to aid assessment of the relative efficiency.

Potential additional work

A health economist will explore the possibility of developing a simple health economic model to further address cost effectiveness of ODM. The structure of such a model would be informed by advice from our clinical collaborators and would be parameterised using the best available UK relevant data. However, due to the very short duration of the present TAR, we cannot anticipate that a full new economic evaluation will be conducted.

6. Expertise in this TAR team

The TAR team are experienced in conducting reviews of diagnostic and therapeutic interventions in both the clinical and technical aspects required to address the commissioning brief. The Lead reviewer and almost all the other members of the review team have all been involved in a considerable number of similar studies. Local clinical expertise will be provided by Dr Brian Cuthbertson, Senior Lecturer in critical care and Dr Gordon Houston, Specialist Registrar in anaesthetics. Dr Cuthbertson is also an experienced health services researcher and has previously worked on NCCHTA commissioned Health Technology Assessments.

6.1 TAR Centre

The Aberdeen Assessment Group has a track record of producing these type of focussed reports whilst keeping to tight timescales for various policy customers such as the National Institute for Health and Clinical Excellence, the National Screening Committee and the NHS R&D HTA programme.
In the last 12 months several similar studies have been completed. These include reviews looking at:

- Minimally invasive procedures for benign prostatic enlargement

[6] Improving access to cost-effectiveness information for health care decision making: the NHS Economic Evaluation Database. CRD Report No. 6. York: NHS Centre for Reviews & Dissemination; 2001.
[7] Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. Methods for the economic evaluation of health care programmes. 3rd ed. Oxford: Oxford University Press; 2005.

- Screening for open angle glaucoma
- Detection and treatment of staphylococcus aureus infection for patients on peritoneal dialysis for end stage renal disease.
- Minimally invasive total hip replacement

6.2 Team members' contributions

Luke Vale, Senior Research Fellow, will be technical lead on this project and will be responsible for the day-to-day running of the review as well as supervision of the economic evaluation and review of effectiveness. Graham Mowatt, Research Fellow, will undertake the systematic review of effectiveness and Rodolfo Hernandez, Research Fellow will conduct the systematic review of economic evaluations and investigate the scope for a simple modelling exercise. Adrian Grant (Professor of Health Services Research) will provide additional supervision, methodological advice and comments on drafts of the review. Cynthia Fraser, Information Officer, will develop and run the search strategies and will be responsible for obtaining papers and reference management. Brian Cuthbertson, Clinical Senior Lecturer, and Gordon Houston, Specialist Registrar, will provide clinical support and advice as well as assisting with the review of effectiveness.

Contact details for clinical experts:

Dr Brian Cuthbertson MB ChB FRCA MD
Clinical Senior Lecturer
University of Aberdeen
Honorary Consultant Anaesthetist
NHS Grampian
Health Services Research Unit
Health Sciences Building
Foresterhill,
Aberdeen
AB25 2ZD

Dr Gordon Houston MB ChB FRCA
Specialist Registrar
Department of Anaesthetics
Aberdeen Royal infirmary
Foresterhill
Aberdeen

7. Competing interests of authors

None of the researchers involved in this review have any competing interests. Neither the Health Services Research Unit nor the Health Economics Research Unit receive any funding from any of the manufacturers of the technologies to be assessed.

8. Timetable/milestones

Final protocol: 16th March 2007
Draft final report: To be agreed

9. Appendices

Appendix 9.1. Draft search strategy

Medline Strategy to Identify Randomised Controlled Trials
Assessing Clinical Effectiveness

1 ((oesophageal or esophageal or intra?esophageal or trans?esophageal) adj5 doppler).tw.
2 ((oesophageal or esophageal or intra?esophageal or trans?esophageal) adj5 ultrason$).tw.
3 cardioQ.tw.
4 teco.tw.
5 Echocardiography, Transesophageal/
6 or/1-5
7 exp echocardiography, doppler/
8 ultrasonography, doppler/
9 or/7-8
10 (oesophageal or esophageal or intra?esophageal or trans?esophageal).tw.
11 9 and 10
12 6 or 11
13 exp cardiac output/
14 cardiovascular physiologic processes/
15 blood circulation/
16 hemodynamic processes/
17 fluid therapy/
18 blood flow velocity/
19 hypovol?emia.tw.
20 cardiac output.tw.
21 (hemodynamic or haemodynamic).tw.
22 ((stroke or circulatory or intravascular or fluid or plasma) adj volume).tw.
23 ((blood or flow) adj1 velocity).tw.
24 (fluid adj1 (load or preload or therap$ or management)).tw.
25 or/13-24
26 12 and 25
27 monitoring, physiologic/
28 intraoperative monitoring/
29 preoperative care/
30 perioperative care/
31 critical care/
32 intensive care/
33 ((intensive or critical) adj care).tw.
34 ICU.tw.
35 (surgery or surgical).tw.
36 (optimis$ or optimiz$).tw.
37 (preoptimis$ or preoptimiz$).tw.
38 (super normalis$ or supernormalis$).tw.
39 (super normaliz$ or supernormaliz$).tw.
40 monitor$.tw.
41 or/27-40
42 26 and 41
43 clinical trial.pt.
44 randomi?ed.ab.
45 randomly.ab.
46 trial.ab.
47 groups.ab.
48 or/43-47
49 42 and 48
50 limit 49 to humans
51 limit 50 to yr="1990 - 2007"

Medline Strategy to Identify Studies
Assessing Cost Effectiveness

1 ((oesophageal or esophageal or intra?esophageal or trans?esophageal) adj5 doppler).tw.
2 ((oesophageal or esophageal or intra?esophageal or trans?esophageal) adj5 ultrason$).tw.
3 cardioQ.tw.
4 teco.tw.
5 Echocardiography, Transesophageal/
6 or/1-6
7 exp echocardiography, doppler/
8 ultrasonography, doppler/
9 or/7-9
10 (oesophageal or esophageal or intra?esophageal or trans?esophageal).tw.
11 9 and 10
12 6 or 11
13 exp cardiac output/
14 cardiovascular physiologic processes/
15 blood circulation/
16 hemodynamic processes/
17 fluid therapy/
18 blood flow velocity/
19 hypovol?emia.tw.
20 cardiac output.tw.
21 (hemodynamic or haemodynamic).tw.
22 ((stroke or circulatory or intravascular or fluid or plasma) adj volume).tw.
23 ((blood or flow) adj1 velocity).tw.
24 (fluid adj1 (load or preload or therap$ or management)).tw.
25 or/13-24
26 12 and 25
27 monitoring, physiologic/
28 intraoperative monitoring/
29 preoperative care/
30 perioperative care/
31 critical care/
32 intensive care/
33 ((intensive or critical) adj care).tw.
34 ICU.tw.
35 (surgery or surgical).tw.
36 (optimis$ or optimiz$).tw.
37 (preoptimis$ or preoptimiz$).tw.
38 (super normalis$ or supernormalis$).tw.
39 (super normaliz$ or supernormaliz$).tw.
40 monitor$.tw.
41 or/27-40
42 12 and 41
43 26 or 42
44 exp "costs and cost analysis"/
45 economics/
46 exp economics,hospital/
47 exp economics,medical/
48 exp budgets/
49 exp models, economic/
50 exp decision theory/
51 ec.fs. use mesz
52 monte carlo method/
53 markov chains/
54 exp quality of life/
55 "Value of Life"/
56 cost of illness/
57 exp health status indicators/
58 cost$.ti.
59 (cost$ adj2 (effective$ or utilit$ or benefit$ or minimis$)).ab.
60 economics model$.tw

61 (economics$ or pharmacoeconomic$ or pharmo-economic$).ti.
62 (price$ or pricing$).tw.
63 (financial or finance or finances or financed).tw.
64 (value adj2 (money or monetary)).tw.
65 quality adjusted life.tw.
66 disability adjusted life.tw.
67 (qaly? or qald? or qale? or qtime? or daly?).tw.
68 (euroqol or euro qol or eq5d or eq 5d).tw.
69 (hql or hqol or h qol or hrqol or hr qol).tw.
70 (hye or hyes).tw.
71 (health adj3 (indicator? or status or utilit?)).tw.
72 markov$.tw.
73 monte carlo.tw.
74 (decision$ adj2 (tree? or analy$ or model$)).tw
75 or/44-74
76 43 and 75

Appendix 9.2. Data Extraction Form

Clinical effectiveness of Oesophageal Doppler Monitoring (ODM) in adults being managed in critical care or during major surgery

Reviewer ID: Data extraction date:

Study design	
Study ID:	Country:
Aim of the study:	
Comparison: ☐ ODM versus pulmonary artery catheterisation (PAC) ☐ ODM versus pulse contour analysis monitoring: ☐ Lithium dilution cardiac monitors, i.e. Lid CO® monitor ☐ Thermodilution cardiac monitors, i.e. PICCO® monitor ☐ ODM versus no cardiac monitoring Patient subgroups: ☐ Patients with sepsis	
Setting:	
Patient recruitment date:	
Length of follow up, mean/median (SD), range:	
Funding: government / private / manufacturer / other (specify)	
Additional information of study design:	

Participants				
Inclusion criteria:				
Exclusion criteria:				
Patient Characteristics				
Specify	Intervention 1: ODM	Intervention 2:	Intervention 3:	Overall
Number of patients				
Randomised				
Lost to follow-up Reason:				
Analysed				
Age, y, mean/median (SD), range				
Sex	M F	M F	M F	M F
Co-morbidities				
Additional information on patients:				

Indications for ODM
Intervention
Details of ODM intervention: Practitioner experience: Additional information:
Details of PAC:
Details of pulse contour analysis monitoring:

Details of standard care if no cardiac monitoring used:			
Outcomes			
Specify	Intervention 1 ODM	Intervention 2	Intervention 3
30 day mortality, % (n/N)			
Hospital mortality, % (n/N)			
Longer term mortality Length of follow up: _____ % (n/N)			
Overall length of hospital stay, days, mean/median (SD), range			
Overall length of stay in ICU, days, mean/median (SD), range			
Overall length of stay in critical care facilities (ICU and HDU), days, mean/median (SD), range			
Days of organ support in ICU, mean/median (SD), range			
Post-operative complications and morbidity, %(n/N) Cardiac events: Organ system failures: Other:			

Details of standard care if no cardiac monitoring used:			
Outcomes			
Quality of life in year after intervention Instrument(s):			
Other effectiveness outcomes			

Authors' conclusions
Additional information

Appendix 9.3. Quality Assessment Form – RCTs (Adapted from Verhagen et al 1998)2

Reviewer ID: Date:

Criteria	Yes	No	Unclear	Comments
1. Was the sequence generation really random? Adequate approaches to sequence generation • computer-generated random tables • random number tables Inadequate approaches to sequence generation • use of alternation, case record numbers, birth dates or week days				
2. Was the treatment allocation concealed? Adequate approaches to concealment of randomisation • centralised or pharmacy-controlled randomisation • serially-numbered identical containers • on-site computer based system with a randomisation sequence that is not readable until allocation • other approaches with robust methods to prevent foreknowledge of the allocation sequence to clinicians and patients Inadequate approaches to concealment of randomisation • use of alternation, case record numbers, birth dates or week days • open random numbers lists • serially numbered envelopes (even sealed opaque envelopes can be subject to manipulation)				
3. Were the groups similar at baseline regarding the most important prognostic indicators?				
4. Were the eligibility criteria specified?				
5. Were the groups treated in the same way apart from the monitoring tool used?				
6. Was the outcome assessor blinded?				
7. Was the care provider blinded?				
8. Were the patients blinded?				
9. Were the point estimates and measures of variability presented for the primary outcome measures?				
10. Was the withdrawal/drop-out rate likely to cause bias?				
11. Did the analyses include an intention-to-treat analysis?				
12. Was the monitoring procedure undertaken by somebody experienced in performing the technique?				

Appendix 9.4 Study eligibility screening form

Clinical effectiveness of oesophageal Doppler monitoring (ODM) in adults being managed in critical care or during major surgery

Assessor initials: _____ Date assessed: _____

Study identifier
(surname of first author + year of publication)

Type of study
Q1. Is the study a randomised controlled trial?

Yes → Go to Next question
Unclear → Go to Next question
No → **Exclude**

Participants in the study
Q2. Are the participants in the study adults being managed in critical care or during major surgery?

Yes → Go to Next question
Unclear → Go to Next question
No → **Exclude**

Interventions in the study
Q3. Does the intervention involve ODM to monitor cardiac and other haemodynamic parameters?

(Exclusions: ODM used as a measure of study outcome rather than as a monitoring tool leading to a clinical intervention)

Yes → Go to Next question
Unclear → Go to Next question
No → **Exclude**

Comparator
Q4. Is the comparator (i) pulmonary artery catheterisation, (ii) pulse contour analysis monitoring (lithium dilution cardiac monitors i.e. LidCO® monitor, or thermodilution cardiac monitors i.e. PICCO® monitor), or (iii) no cardiac monitoring?

Yes → Go to Next question
Unclear → Go to Next question
No → **Exclude**

Outcomes in the study
Q5. Does the study report one or more of the following outcomes? Mortality (30 day/hospital/longer-term); length of stay (hospital/ICU/critical care facilities (ICU & HDU)); days of organ support in ICU; post-operative complications and morbidity (cardiac events/organ system failures/other); quality of life in the year after surgery

Yes → **Include**, subject to clarification of 'unclear' points
Unclear → **Include**, subject to clarification of 'unclear' points
No → **Exclude**

Final decision

Include **Unclear** **Exclude**