Appendix 1

Structured review for the UK National Screening Committee appraising the viability, effectiveness and appropriateness of an abdominal aortic aneurysm screening programme

ABDOMINAL AORTIC ANEURYSM

Criteria	Supporting evidence
The condition	
1. The condition should be an important health problem	Rupture of an aneurysm in the abdominal aorta caused about 6,800 deaths in England and Wales in the year 2000, the great majority in men because the age-specific prevalence of the condition is six times greater in men than in women. In men older than 65 years rupture of an abdominal aneurysm is responsible for 2.1% of all deaths and the overall mortality from rupture is between 65% and 85%.
2. The epidemiology and natural history of the condition, including development from latent to declared disease, should be adequately understood and there should be a detectable risk factor, disease marker, latent period or early symptomatic stage	The Medical Research Council and the British Heart Foundation supported a major study called the "UK Small Aneurysm Trial" whose main results were reported in 1998. In this study 1,090 patients aged 60-76 years were randomly assigned either to receive elective surgery or ultrasonographic surveillance. The diameter of these aneurysms was between 4cm and 5.5cm. The trial found that the "overall hazard ratio for all cause mortality" in the group receiving elective surgery compared with the group receiving surveillance was 0.94 with 95% confidence intervals ranging from 0.75 to 1.17. On the basis of this trial the safety of managing aneurysms less than 5.5cm diameter was established. Aneurysms of the abdominal aorta do not regress and are without symptom until they rupture. The mortality rate from aneurysm rupture is due not only to the severity of the injury but also to the speed of its evolution. Of all the deaths attributed to ruptured aneurysms, about half take place before the patient reaches hospital, and of those who reach hospital the mortality rate for emergency treatment is between 30% and 75%.
3. All cost effective primary prevention interventions should have been implemented as far as practicable	The cause of abdominal aortic aneurysm is not understood and primary prevention is not possible. As with other vascular diseases efforts to prevent people smoking or to help them stop smoking will influence risk but there are many other reasons to advocate smoking cessation, and at present abdominal aortic aneurysm can be regarded as a disease that cannot be prevented.

4. Does screening identify carriers of a mutation?	There is a family history associated with this disease but no single mutation or group of mutations has yet been identified. The possibility of using family history to identify people at higher risk of aneurysm has been discussed but is not practicable at present.
The test	
5. There should be a simple, safe, precise and validated screening test	The screening test is an ultrasound scan of the abdominal aorta using a portable ultrasound machine. The two diameters of the aorta, transverse and anterior-posterior, are measured and the image recorded. The larger of the two readings is recorded as the maximum aortic diameter.
6. The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed	The work done during the course of the UK Small Aneurysm Trial has allowed a cut-off point of 5.5cm to be set, based on evidence.
7. The test should be acceptable to the population	The test is not painful and in the trial which took place in four centres – the Multicentre Aneurysm Screening Study – 80% of men accepted the invitation to be screened. In addition there was no evidence that participation had any adverse psychological effects. Ultrasound is perceived as "safe" by the public because of its routine use in monitoring pregnant women.
8. There should be an agreed policy on the further diagnostic investigation of individuals with a positive test and on the choices available to those individuals.	For most people the screening test is also the diagnostic test. The hospital carries out a repeat ultrasound scan to identify the extent of the aneurysm, for example whether or not the renal arteries are involved, but no more sophisticated imaging is required in many cases. In the trial 67,800 out of 70,495 men were randomised. The remainder were excluded from the process of randomisation because their family doctors considered them to be unfit for operation even if screening were positive. Of the men invited 80% accepted the invitation, a high level of acceptability. The overall 30 day mortality after elective surgery was 6%.
The treatment	
10. There should be an effective treatment or intervention for patients identified through early detection, with evidence of early treatment leading to better outcomes than late treatment	Elective surgery is the standard treatment for abdominal aortic aneurysm. There is a 6% 30 day mortality after elective surgery for aneurysm, with the same life expectancy as an age-matched population after recovering from the operation which, when weighing up options, needs to be set against a 30% 30 day mortality after emergency surgery and the failure of half those suffering aortic rupture even to reach hospital.

	The use of endovascular stents is currently being investigated through the R&D Programme and would have a lower mortality if these were to be used instead of elective surgery. Hitherto there have been problems with the stents which can be introduced under local anaesthetic but there is significant investment in the development of stents and the Endovascular Aortic Aneurysm Repair Trial will assess the safety and effectiveness of these prostheses.
11. There should be agreed evidence based policies covering which individuals should be offered treatment and appropriate treatment to be offered	The UK small aneurysm trial and MASS have demonstrated that observation up to 5.5 cm aortic diameter using ultrasound incurs less risk than operative treatment. There is clear consensus that people with an aneurysm greater than 5.5cm diameter should be offered the operation. The operative risk of men identified as having an aneurysm is assessed before elective surgery is undertaken but even in this population, namely men over 65 with known vascular disease, the anaesthetic risk is relatively low. A study in America showed a significant variation in mortality between vascular services but this was attributed principally to the intensive care variations between the different hospitals rather than to differences in surgical technique or anaesthesia.
12. Clinical management of the condition and patient outcomes should be optimized in all health care providers prior to participation in a screening programme	It is important to point out that if stents were shown to be effective in the current trials, then the threshold for intervention would change because stents could be inserted under local anaesthetic. This would probably mean that more people would be invited with fewer being excluded by their general practitioner for health reasons.
<u>The screening programme</u>	
13. There should be evidence from high quality Randomised Controlled Trials that the screening programme is effective at reducing mortality or morbidity	The MASS trial was published in both The Lancet and the British Medical Journal and is a high quality trial.
14. There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/intervention is clinically, socially, and ethically acceptable to health professionals and the public	No direct evidence exists of complete acceptability to health professionals and the public but acceptance is high and the introduction of screening would be supported by the majority of vascular surgeons, provided that sufficient resources were made available to carry out screening effectively and efficiently. In the MASS trial no significant changes in quality of life were detected throughout the screening process. In addition questionnaires asking about acceptability were sent to participants and GPs. The majority of responses were positive.

15. The benefit from the screening programme should outweigh any potential physical and psychological harm	The psychological harms associated with screening are not significant. The main physical harm is death after elective surgery and preliminary work has been commissioned to look at ways in which this could be expressed most clearly to men invited for screening.
16. The opportunity cost of the screening programme should be economically balanced in relation to other medical care	Within the vascular surgery service the surgeons regard this as a high value initiative. Discussions are taking place with health economists to consider the feasibility of assessing the value of screening compared with the value that could be calculated for other common problems managed by a vascular surgical service, for example varicose veins or arterial reconstruction.
17. There should be a plan for managing and monitoring the screening programme	Because the trial was carried out in four centres and because there are at least two screening programmes currently running, there is a significant amount of information that can be used in planning and managing a service.
18. Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be available	Screening teams would vary according to local situations. The team would consist of an ultrasonographer and a facilitator. The ultrasonographers could come (1) from the hospital department or (2) from those taking a break for a family, requiring flexible hours and free time during school holidays (possible when screening for AAA). The facilitators require patient handling skills only, or both can be obtained by training non-medical staff to become screening technicians (a successful training course has been run at Chichester). Operating time could be made available by adequate funding combined with adjustment to guidelines on management of vascular case load.
19. All other options for managing the condition should have been considered	Surgical treatment is the only available treatment.
20. Evidence-based information, explaining the consequences of testing, investigation and treatment should be made available.	Evidence-based information documents made available for patients in the MASS trial are being modified for use in a national screening programme, and work has been commissioned to look at ways in which the risks of surgical treatment could be expressed most clearly to men invited for screening.
21. Public pressure for widening the eligibility criteria, etc, should be anticipated	Screening women is less common. The Chichester study demonstrated no benefit in a randomised trial of 9342 women (published in BJS 2002). Evidence is available on the low prevalence of AAA in younger men and its effect on cost and benefit.