A randomised controlled trial to investigate the clinical and cost effectiveness of adding an ablation device-based maze procedure as a routine adjunct to elective cardiac surgery for patients with pre-existing atrial fibrillation (AMAZE)

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Health Technology Assessment

Authors' objectives
Atrial fibrillation (AF) is a fast irregular heart beat caused by abnormal electrical signalling. It is very common (affecting 1 in 20 middle aged people & 1 in 10 aged over 80) & the high risk of clotting leads to stroke in 1 in 25 AF patients if left untreated. AF patients are therefore given blood thinning drugs. These reduce strokes by about two thirds but can cause bleeding so patients need careful monitoring. In short, the complications & treatment of AF all reduce the patient's quality of life & are very costly for the NHS. The 'maze' procedure (major surgery which involves cutting & stitching the atrial wall to re-direct electrical signals down correct paths) can stop AF but is not widely used due to its complexity. However ablation devices, consisting of a probe and energy source, are now available and can be used to make a 'maze' procedure simpler, quicker and safer. The vigorous marketing of these devices claims that they can restore normal heart rhythm when incorporated into a routine heart operation. However this needs rigorous evaluation before the technology creeps into practice. An experienced multidisciplinary team (surgeons, cardiologist, statistician, health economist, hospital & R&D managers) has been assembled to conduct a multicentre randomised controlled trial to answer the questions that matter: is adding this costly technology to routine heart surgery worthwhile for the patients and the NHS? Survival, quality of life & cost effectiveness will be compared between patients who have cardiac surgery alone & those who have a device maze procedure as well. The results will inform patients, clinicians & the NHS about routine adoption of these devices. Patients from 6 NHS hospitals will be recruited & treated by surgeons & clinicians experienced in the technology, the trial coordinated & managed by staff at the nationally recognised R&D Unit at Papworth Hospital and data analysed by a statistician and health economist who have worked on many HTA trials. The devices are licensed and the surgeons experienced in using them, so the main ethical issue will be any risks associated with the 10-15 min extension of the operation. Patient representatives will be consulted and their input incorporated. Research costs are mainly for staff (f/t Trial Coordinator for the 6 sites, p/t Trial Manager to oversee & monitor/audit, 5 local CRAs, p/t statistician, health economist, cardiac technician) & tests (7 day ECG for definitive SR assessment, transthoracic echo for atrial transport). NHS costs cover CI and collaborators' time and theatre time. Treatment costs cover ablation consumables.

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**Address for correspondence**
NETSCC, Health Technology Assessment, Alpha House, University of Southampton Science Park, Southampton, SO16 7NS UK Tel: +44 23 8059 5586 Email: hta@hta.ac.uk

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