NHS
Musgrove Park Hospital

Proposal for Introduction of a New Clinical Technique

For completion according to the Trust policy for the approval of new clinical techniques to the Trust. It is the proposing clinician's responsibility to ensure completion and that all necessary signatures are obtained.

Date: 15/12/11	**Division:** Acute Care
Proposing clinician(s) name(s): Dr Mark Dayer	**Designation(s):** Consultant Cardiologist

Technique details

Procedure / technique name: Subcutaneous implantable cardioverter-defibrillator (Cameron Health S-ICD System)

Description: Conventional ICDs require a box placed under the skin in the pre-pectoral region and between 1 and 3 leads inserted via the cephalic/axillary/subclavian vein into the heart. There are a number of potential complications related to the placement of leads within the venous system. You can get significant bleeding around the access site, pneumothorax and haemothorax, endocarditis and ventricular perforation leading to tamponade. All of these complications have been recorded at Musgrove and are accepted complications of the technique. In the longer term, in younger patients you can see problems with lead damage occurring where the lead passes between the clavicle and the first rib, requiring replacement of leads and sometimes extraction of the lead (which is associated with a 1-3% mortality).

The new Cameron Health S-ICD is an entirely subcutaneous ICD. The box is placed under the skin in the mid axillary line at the lower end of the rib cage. The lead is tunnelled sub-cutaneously from there medially to the sternum and then along the left border of the sternum cranially to just below the suprasternal notch. It required no intravascular access and thus avoids a number of the complications associated with intracardiac placement of leads. Over 1000 of these devices have been implanted worldwide and there are data to support its use:

http://www.cameronhealth.com/
http://www.nejm.org/doi/full/10.1056/NEJMoa0909545

We have successfully implanted 1 device here without complication (as it was a semi-emergency) and follow-up 3 devices. The implantation process is relatively straightforward, although it requires general anaesthesia and would be easier with diathermy.

Target condition/population: We anticipate that we will implant no more than 5 devices per year at present. They are likely to be appropriate for younger patients at risk of ventricular fibrillation. The most common recipients will be younger patients with inherited cardiac conditions deemed to be at higher risk of sudden cardiac death. Examples of these conditions include hypertrophic cardiomyopathy, arrhythmogenic right ventricular dysplasia and long QT syndrome.

Assessment of criteria for use (see section 3.1 of policy)

1i) Clinical Evidence – Is there clear supportive clinical evidence of efficacy and safety? Yes

Summary: In small, nonrandomized studies, an entirely subcutaneous ICD consistently detected and converted ventricular fibrillation induced during electrophysiological testing. The device also successfully detected and treated all 12 episodes of spontaneous, sustained ventricular tachyarrhythmia (**http://www.nejm.org/doi/full/10.1056/NEJMoa0909545**).

Please attach supportive literature/list of references

1ii) Is the proposed technique an interventional procedure?(see section 1.3 of policy) Yes

If yes, is this procedure listed on the NICE Interventional Procedure Guidance programme? ICDs are recommended by NICE. They do not specify the type. We implant between 80-100 each year at Musgrove.

If Yes: Specify web page address: http://guidance.nice.org.uk/TA95

Current status of guidance: Guidance issued

If NICE Interventional Procedure Guidance is issued please attach and ensure that adherence to the guidance is demonstrated within this proposal.

2 Professional Competence/Training:

2i) Has expertise in the proposed technique already been achieved and demonstrated by all relevant clinicians? Yes.

If Yes: Please attach documented evidence of training and/or experience in non-NHS settings

There is no formal training course. There is a web video (reviewed), advice and mentoring by the company (who support all implants) and we have successfully implanted our first device here without complication. The patient has gone back to rock climbing. The procedure itself is technically more straightforward than a "normal" ICD implant and there are fewer complications associated with its implant.

If No:

Training issues:
2ii) Give details of arrangements including names/designations of mentors where mentoring is proposed and course details where a structured programme of training is proposed. Attach evidence of arrangements.

3 Service Implications

3i) Please summarise any associated practice/ service design implications :

The principal implication is that we will require anaesthetic and ODP support. We have the equipment and the lab space, but there will be the additional staffing costs

3ii) Other Divisions/ Departments/ Teams affected by introduction:

Anaesthetics/ODP

3iii) Have all affected parties been informed about and support this proposal? Y / ~~N~~ / ~~NA~~
Details:

See embedded email trail

Email trail - anaesthetics - S-ICD.

4 Resource / Business Implications (for completion in conjunction with Divisional General Manager/Divisional Accountant)

4i) How does the procedure fit with the Trust's and / or the Division's business development objectives (eg quality improvement / access improvement etc)?

4ii) Will the cost of this technique be contained within the current divisional budget? Y / ~~N~~

If yes, please provide evidence and attach

If no, please attach details of all costing inclusive of: equipment provision / staff training / theatre time / any trade off against changes to existing practice and indicate how it is proposed these costs will be met

5 Patient Information/ consent process

5i) Is it considered that special arrangements for consent would be required for patients undergoing this procedure? ~~Y~~ / N

5ii) Has a specific patient information leaflet been produced? Y / ~~N~~

5iii) Please attach all available documentation associated with consent


Subcutaneous ICD - Consent.doc


S-ICD leaflet.doc

6 Clinical Information/Audit

6i) Can data be collected prospectively for appropriate audit, eg codes changed etc

I have discussed specific coding issues with Sue Eve-Jones.

6ii) Please outline how auditing/ monitoring will be carried out, including lead clinician and measures:

We carry out a prospective audit of all pacing procedures including complications that occur around the time of implant and later. All patients with devices are followed up regularly through the pacing clinic. We submit information to the CCAD audit no more than 3 months in arrears.

Signatures (All mandatory)	**Date**
Lead proposing clinician:	
Clinical Service Lead:	
Signature of Directorate Manager	

Divisional Review and approval