

**SUBMISSION BY THE ELECTROPHYSIOLOGY AND PACING COUNCIL
OF THE
CARDIAC SOCIETY OF AUSTRALIA AND NEW ZEALAND
TO
THE REVIEW OF HEALTH TECHNOLOGY ASSESSMENT IN
AUSTRALIA**

EXECUTIVE SUMMARY

In this submission The Electrophysiology and Pacing Council (EPC) of the Cardiac Society of Australia and New Zealand (CSANZ) has made general comments about the structure and regulations surrounding health technology assessment (HTA) in Australia with particular reference to the Prostheses Regulations. Radio-Frequency Catheter Ablation of Atrial Fibrillation and Other Complex Arrhythmias is used as an example to demonstrate the difficulties of the current system.

The Electrophysiology and Pacing Council of CSANZ is the representative body for cardiologists who specialise in the management of cardiac arrhythmias. This group of physicians implants and follow up pacemakers, defibrillator and cardiac resynchronisation devices and perform catheter ablation procedures to cure cardiac arrhythmias.

Term of Reference 1 is addressed.

Recommendations are then made which address these difficulties.

GENERAL COMMENTS

Introduction

The EPC supports the Government's initiative in commissioning the Review of Health Technology Assessment in Australia. Access to safe, effective and cost effective technology is a pre-requisite for an equitable and efficient health care system. Australia's unique mix of public and private systems in general serves it's citizen's well. However it has become apparent that out-dated regulations and the methodology used in some aspects of HTA in Australia do not provide equitable access to some procedures and technologies.

In this submission we use the example of Radio-Frequency Catheter Ablation of Atrial Fibrillation and other complex arrhythmias as an example of how the current system is not working well in some instances. It is not the purpose of this submission to describe atrial fibrillation and its treatment extensively but some background will be useful in explaining the relevance to this Review.

Radio-Frequency Catheter Ablation (RFA) of Atrial Fibrillation and other complex arrhythmias

Atrial Fibrillation (AF) is a common sustained cardiac arrhythmia. It is estimated that approximately 165,000 Australians have AF.¹ It is an irregular and rapid electrical activity of the atrium and can be associated with dizziness, chest pain and shortness of

¹ Eikelboom, JW, 'The beginning of the end of Warfarin?' MJA 2004; 180 (11): 549-551

breath. It causes disability and decreased quality of life due to decreased cardiac output. Some patients may be unable to work. It is associated with frequent hospitalisations and increased morbidity due to an increased risk of heart failure and stroke. In 2006/2007 there were 45000 admissions into Australian hospitals with a principal diagnosis of AF.

Prior to the development of radiofrequency ablation (RFA) techniques the only available treatment was anti-arrhythmic drugs and anticoagulants to prevent clot formation and possible stroke. This treatment is not curative and is a life long requirement. In up to 50% of patients AF will recur within 2 years despite drug therapy.²

RFA is a curative minimally invasive procedure where catheters are introduced into the heart via the femoral vein. 3D imagery is used to facilitate the ablation. Radio frequency energy is delivered via the catheters to destroy the cardiac tissue that is responsible for the arrhythmia and the catheters are then removed. Studies show that up to 83% of patients are free of AF at one year following ablation³. Once a patient has been free of AF for six months drug therapy is usually no longer necessary.

The Expert Consensus Statement of the Heart Rhythm Society supports the use of ablation as the treatment of choice if anti-arrhythmic drugs are unsatisfactory.⁴

A very recent Australian economic evaluation of AF Ablation compared to medical management determined that the procedure is likely to pay for itself within 4 years due to savings in medical management and decreased risk of other complications.⁵

A significant proportion of patients receiving this procedure are in their fifties, therefore there are likely to be indirect economic benefits of increased work force participation.⁶

RFA and HTA in Australia – a barrier to access

As stated in the *‘Review of Health Technology Assessment in Australia – A Discussion Paper’* the Australian Government is ‘committed to reducing the level of poorly designed regulation.’ It is such poorly designed and outdated regulation that is inequitably restricting access to RFA. The catheters and disposable patient devices that are used during an RFA procedure do not have a place in the current design of the HTA system in Australia. These devices may cost up to \$8000 a procedure. As stated in the Discussion Paper important features of effective HTA systems include:

² Chan et al, *‘Cost effectiveness of AF radio-frequency ablation for atrial fibrillation’* JACC 47, No 12 2006

³ Nadamenec K, et al *‘a new approach for catheter ablation of atrial fibrillation: mapping of the electrophysiologic substrate.’* J Am Coll Cardiol 2004; 43:2004-2053

⁴ Calkins et al *‘HRS/EHRA/ECAS Expert consensus statement on Catheter and Surgical Ablation of Atrial Fibrillation: Recommendations for Personnel, Procedures and Follow-up’* Heart Rhythm Society 2007

⁵ Gross P et al *‘Cost-effectiveness of radio-frequency ablation in paroxysmal atrial fibrillation implications for future reimbursement policies’* DRAFT

⁶ Medicare Australia Statistics: https://www.medicareaustralia.gov.au/statistics/mbs_item.shtml

‘promoting access to cost effective health technologies that positively impact on health outcomes’

‘achieving value for money from investment in health technologies in the context of limited health care resources’

‘keeping pace with international best practice’

‘ensuring the system itself is designed to achieve these outcomes in the most timely, effective, efficient and targeted way.’

RFA procedures receive funding from the Australian Government through the MBS system. The procedures are also performed in major public hospitals throughout Australia. It is the EPC’s experience that RFA procedures are increasingly *not* being performed in *private* hospitals in Australia despite the demonstrated clinical and cost effectiveness of the procedure. This is because the procedure is economically unviable in the majority of cases in private hospitals.

RFA catheters and disposables are considered to be relatively high cost high technology devices. The usual pathway for HTA and then private reimbursement for such items is through the Prostheses List which is administered by the Prostheses and Devices Committee. However, the Prostheses List rules state to be included on the Prostheses List, a product must

‘(a) be surgically implanted in the patient and be purposely designed in order to:

- (i) replace an anatomical body part; or
- (ii) combat a pathological process; or
- (iii) modulate a physiological process;’

The requirement that a device be ‘surgically implanted’ means that RFA catheters do not meet the criteria. This regulation is out-dated and does not acknowledge the current state of device technology. As medical technology continually enables less invasive procedures, this definition will become increasingly anachronistic. Since the cost of the catheters is greater than the benefit most hospitals receive from health funds for the procedure, RFA is economically unviable for many private hospitals.

The arbitrary nature and the inconsistency of the outcomes resulting from this regulation can be seen in the nature and the cost of cardiac devices that do meet the ‘implantable’ criteria. Hospitals performing the procedures receive a benefit for these devices over and above the benefit they receive for the procedure itself.

These include:

| Device | Current Benefit |
|--------|-----------------|
| | |

| | |
|--|-----------------------|
| Pacemakers | Up to \$11,440 |
| Defibrillators | Up to \$45,760 |
| Cardiac Resynchronisation Therapy Defibrillator | Up to \$52,000 |
| | |

It should be noted that treatment of cardiac disorders with the devices listed, unlike RFA, is not curative and these devices must be replaced every 3 – 10 years for the life of the patient.

EQUITY ISSUES

The lack of access of these devices to the Australian HTA system through the Prostheses List results in inequities for both public and private patients alike. It is our experience that many private hospitals are reducing or eliminating these procedures. Every time a procedure is performed without reasonable reimbursement for the cost of catheters and disposables, the procedure will be performed at a substantial loss.

When reimbursement is not available for catheters and other disposables and the hospital is not able to incur the loss, private patients must attempt to access the procedure through the public hospital system and join the often lengthy waiting lists.

Private Health care has been promoted in Australia as a means of reducing pressure in the public sector. It is also promoted by health funds as a means of improving access for those who are willing or have the means to pay for private health insurance. In this case because of the anomalies of our HTA system, neither of these objectives is achieved.

Private patients are denied an effective procedure in the private system despite having contributed to the cost of their care through their insurance premiums - sometimes for many years. Public patients must wait longer for the procedure because of the increased number of private patients joining the public hospital waiting lists. The community at large does not realise the savings that may have been made in reduced use of PBS drugs, reduced hospitalisations, medical consultations, reduction in carer's duties and increased workforce participation.

Recommendation 1: The 'Prostheses List' should be changed to a 'Medical Devices' list that more reasonably reflects the current and future state of medical technology and includes devices such as ablation catheters and other similar disposables.

Term of Reference No. 1

Simplification and better co-ordination between all Commonwealth health technology assessments, including:

- a) consideration of a single entry point and tracking system for applications for market registration and funding and coverage purposes;**
- b) making time to affordable access as short as possible for new technologies while maintaining rigour of evaluation process; and**
- c) examination of the feasibility of conducting concurrent assessments for market registration and funding for coverage purposes, noting current work in this area.**

The three HTA agencies in Australia under consideration in this review are the TGA, MSAC and the PDC. Our comments relate mainly to the PDC with some reference to MSAC.

As noted in the Discussion Paper, MSAC conducts ‘a full HTA including a systematic literature review and modeled economic evaluation’. In contrast no one has been appointed to the PDC, the Clinical Assessment Groups (CAG) or the Prostheses and Devices Negotiating Group (PDNG) for the purpose of assessing health economics evidence within applications for products to be included on the Prostheses List.

In the Department of Health and Ageing’s guide to listing a Prostheses it is stated that ‘CAGs and the PoCE advise the PDC on the relative clinical effectiveness of each product proposed for listing compared with:

- products used for the same or similar purposes listed as prostheses on the Prostheses List; or
- current treatment for the indications the products are designed to treat.’⁷

It would appear that there have not been adequate arrangements made for assessing cost-effectiveness evidence that may be submitted. Any health economics expertise would depend

⁷ Department of Health and Ageing ‘*Prostheses List Guide to listing and setting benefits for prostheses. Part 1 – Understanding the Prostheses Arrangements*

on that available within the membership of the PDC at any one time or that made available via ad hoc arrangements.

In addition the application forms for prostheses specifically seek only the following information:

‘Does the use of your product provide any savings in the cost of hospital treatment compared with the comparator products(s) or treatment/therapy(s) comparators(s) for your product proposed at Sections 2.3a or 2.3b respectively? E.g. theatre time, duration of admission?’⁸

While this information is no doubt useful in assessing possible savings that a device might accrue for a *health fund*, most savings from devices and procedures are likely to accrue in other sectors of the health care system. For example the cost effectiveness of AF ablation procedures is determined primarily by savings in drug therapy paid for by the PBS and medical services paid for by Medicare in addition to any possible reductions in private hospital admissions.

While it is perfectly legitimate for health funds to wish to reduce their costs by supporting technologies that are likely to produce savings in the services they pay for, this only represents one element of cost-effectiveness. Since private health services are supported by the 30% tax rebate and Medicare payments for services performed by doctors in private hospitals, it would seem equitable that savings in other sectors be considered on the same footing as savings made by health funds.

To this end it would seem reasonable that in addition to Recommendation 1 that appropriate resources are made available to assess cost-effectiveness evidence within prostheses or ‘medical device’ applications. Alternatively, in order to streamline the processes, a single cost-effectiveness assessment could be made to serve both MSAC and the PDC.

Additional anomalies in HTA processes may arise. Again RFA will be used as an example:

RFA was listed on the Medical Benefits Schedule in 1995 prior to the establishment of MSAC. At that time the procedure was conducted primarily using 2D fluoroscopic guidance. The devices currently in use with 3D cardiac mapping are, not surprisingly, more sophisticated, offer better outcomes to patients and reduce exposure to radiation for both patients and medical staff. They are also more expensive. The medical resources and staffing required have similarly changed. In 2002 an application was made for an MSAC review of 3D procedures but the application was ‘deemed ineligible’. This was presumably because an item number for ablation procedures already existed. There is therefore no avenue for the evidence supporting this main stream and very promising technology to be evaluated in the current HTA system.

⁸ Department of Health and Ageing ‘*Application to List a Prostheses –Statement in Support*’

Recommendation 2:

Appropriate Health Economics expertise be made available to support the proposed 'Medical Devices List' or alternatively a process adopted whereby such resources can be shared by MSAC and PDC

Recommendation 3

Health economics evidence should always be assessed from a whole of health system perspective or from a societal perspective.

Conclusion

The Electrophysiology and Pacing Council believes that a robust and efficient HTA system can be designed in Australia using the building blocks of the present agencies. It is important that regulations and processes are designed to realistically take into account 21st century technology and promote equitable access to medical technology for all Australians

While no attempt has been made by us to comprehensively address all the issues and concerns that will be considered during the Review of Health Technology Assessment in Australia, we have highlighted the issues that confront us in our work in Australia's hospitals and have made recommendations that we believe will be important elements of an Australian HTA system

List of Recommendations

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Recommendation 2:

Appropriate Health Economics expertise be made available to support the proposed 'Medical Devices List' or alternatively a process adopted whereby such resources can be shared by MSAC and PDC

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References

1. Eikelboom, JW, *'The beginning of the end of Warfarin?'* MJA 2004; 180 (11): 549-551
2. Chan et al, *'Cost effectiveness of AF radio-frequency ablation for atrial fibrillation'* JACC 47, No 12 2006
3. Nadamenec K, et al *'A new approach for catheter ablation of atrial fibrillation: mapping of the electrophysiologic substrate.'* J Am Coll Cardiol 2004; 43:2004-2053
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https://www.medicareaustralia.gov.au/statistics/mbs_item.shtml
7. Department of Health and Ageing *'Prostheses List Guide to listing and setting benefits for prostheses. Part 1 – Understanding the Prostheses Arrangements'*
8. Department of Health and Ageing *'Application to List a Prostheses –Statement in Support'*