
1197

Final Decision
Analytic Protocol
(DAP) to guide the
assessment of remote
monitoring of patients
with implanted
cardiac devices

April 2013

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MSAC and PASC

The Medical Services Advisory Committee (MSAC) is an independent expert committee appointed by the Minister for Health and Ageing (the Minister) to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Minister on the evidence relating to the safety, effectiveness, and cost-effectiveness of new and existing medical technologies and procedures and under what circumstances public funding should be supported.

The Protocol Advisory Sub-Committee (PASC) is a standing sub-committee of MSAC. Its primary objective is the determination of protocols to guide clinical and economic assessments of medical interventions proposed for public funding.

Purpose of this document

This document is intended to provide a decision analytic protocol that will be used to guide the assessment of an intervention for a particular population of patients. The protocol has been finalised after inviting relevant stakeholders to provide input.

The protocol guiding the assessment of the health intervention has been developed using the widely accepted “PICO” approach. The PICO approach involves a clear articulation of the following aspects of the question for public funding that the assessment is intended to answer:

- P**atients – specification of the characteristics of the patients in whom the intervention is to be considered for use
- I**ntervention – specification of the proposed intervention and how it is delivered
- C**omparator – specification of the therapy most likely to be replaced by the proposed intervention
- O**utcomes – specification of the health outcomes and the healthcare resources likely to be affected by the introduction of the proposed intervention

Summary of matters for consideration by the applicant

- In addition to BIOTRONIK's cardiac implantable electronic devices (CIEDs) there are another three manufacturers of CIEDs in Australia who could all potentially facilitate remote monitoring of patients with implanted CIEDs. The systems available from other manufacturers can provide remote monitoring via landline, GSM/3G and/or potentially a composite system. PASC has indicated that a generic application for listing onto the Medical Benefits Scheme (MBS) of remote monitoring of patients with cardiac devices, and not a manufacturer specific application, would be the most appropriate application to MSAC for this medical technology.
- For the purpose of this assessment, CIEDs will include pacemakers, defibrillators, and resynchronisation devices which have both therapeutic and remote monitoring capability. As a result this will not include implantable loop recorders.
- The devices also need to be those for which the patient does not have to activate the transmission of data i.e. the data transmission is patient independent.
- In order to correctly profile the clinical advantages of each CIED the analysis should clearly identify from which type of device the evidence has been derived. All aspects of the remote monitoring system will need to be described and considered. For example, details will be required in regards to how cardiologists are alerted to the availability data by the service centre, what systems would be established at the cardiologist's office to ensure that the data are reviewed at appropriate intervals and whether the practice will be for patients to routinely be followed up upon review of data to advise whether the patient is required to attend an in-office visit?
- If the MBS item is paid as an annual fee (paid in regular instalments) for the regular review of the data transmitted from the CIED and provided to the cardiologist via a website, in the absence of the patient, what should be the trigger for these payments?
- PASC noted that the proposed MBS items and fees may need to reflect the different services and not preclude remotely monitored patients from attending unscheduled in-office consultations.
- The range of outcomes proposed for determination of comparative effectiveness of remote versus in-office monitoring of patients with CIED will need to adequately capture any potential adverse impacts of reducing the number of in-office consultations with a cardiologist (e.g., if other assessments are conducted at the time of attendance and these assessments are not carried out in the remote monitoring scenario then is there a potential for certain events to be missed).
- A description of the intervention will need to include the frequency of transmission (e.g. daily, weekly, irregular or on demand), the level of automation of the transmission procedure (e.g. automatic or event initiated) and frequency of subsequent follow-up, as these will influence patient outcomes such as the earlier detection of adverse events.
- The source used to guide the estimate of number of in-office consultations required for patients with remote monitoring will need to be included. Evidence for the process included in the intervention to address failure of data transmission, failure to respond to alerts should be included.
- The proposed intervention requires that patient's data be stored overseas. Information will need to be included in the application about how patients consent to this requirement.

- At the moment the applicant reports they absorb the cost of the transmitter (which includes the once-off fee for ongoing costs) for private patients and for public patients they typically sell the transmitter to the hospital as part of a tender arrangement together with the CIEDs. The application will need to include any changes the applicant proposes to this arrangement
- If it is likely patients will be charged for the on-going costs for the provision of remote monitoring, i.e., data transmission, monitoring of the database, maintenance of the database and device will the charge be incorporated as a once-off fee into the cost of the transmitter or is it likely that patients will be required to sign up to a plan with their cardiologist?

CONFIDENTIAL

Purpose of application

A proposal for an application requesting listing of remote monitoring of patients with implanted cardiac devices with remote monitoring functionality was received from BIOTRONIK Australia Pty Ltd by the Department of Health and Ageing in March 2012.

The Deakin Health Economics Unit at Deakin University, under its contract with the Department of Health and Ageing, has developed this decision analytical protocol to guide the preparation of an assessment of the safety, effectiveness and cost-effectiveness of remote monitoring of patients with implanted cardiac devices to inform MSAC's decision-making regarding public funding of the intervention.

Background

Currently, monitoring of patients with implanted cardiac devices (such as pacemakers, defibrillators) is conducted with attendances with cardiologists. Objectives of these attendances include monitoring and optimising device function and troubleshooting of patient- or device-related problems. Such monitoring of patients is funded by the MBS under MBS Items 11718, 11721 and 11727 (in addition to the MBS item relating to specialist consultation [e.g., MBS Item 116]). Details of these items are provided in Table 1.

Table 1: Current MBS item descriptors (as at 1 November 2012) for diagnostic procedures and investigations available for the monitoring of patients with implanted cardiac devices

Category 2 – Diagnostic procedures and investigations		
<u>MBS Item 11718</u>	IMPLANTED PACEMAKER TESTING involving electrocardiography, measurement of rate, width and amplitude of stimulus, including reprogramming when required, not being a service associated with a service to which item 11700 or 11721 applies	
Fee: \$34.75	Benefit: 75% = 26.10	85% = \$29.55
<u>MBS Item 11721</u>	IMPLANTED PACEMAKER TESTING of atrioventricular (AV) sequential, rate responsive, or antitachycardia pacemakers, including reprogramming when required, not being a service associated with a service to which Item 11700 or 11718 applies	
Fee: \$69.75	Benefit: 75% = \$52.35	85% = \$59.30
<u>MBS Item 11727</u>	IMPLANTED DEFIBRILLATOR TESTING involving electrocardiography, assessment of pacing and sensing thresholds for pacing and defibrillation electrodes, download and interpretation of stored events and electrograms, including programming when required, not being a service to which item 11700, 11718 or 11721 applies	
Fee: \$94.75	Benefit: 75% = \$71.10	85% = \$80.55

Utilisation and expenditure on the MBS items listed in Table 1 in the 2010 and 2011 calendar years are summarised in Table 2.

Table 2: Utilisation and expenditure on MBS items

2011 calendar year

Item	Number of services	Total benefit
11718	9,244	\$264,780
11721	101,977	\$5,847,080
11727	33,500	\$2,606,951
Total expenditure	-	\$8,718,811

2010 calendar year

Item	Number of services	Total benefit
11718	8,295	\$233,343
11721	96,782	\$5,447,818
11727	30,801	\$2,351,210
Total expenditure	-	\$8,032,371

The proposed service of remote monitoring of patients with implanted cardiac devices involves the routine transmission of data by a transmitter (kept by the patient) from the patient's cardiac implantable electronic device (CIED) to a database at a service centre operated by the manufacturer of the CIED. Although some remote monitoring systems can send alerts to the medical specialists when the patient is experiencing life-threatening cardiac events, it is not proposed that the system be intended to detect such emergencies. It is anticipated that medical specialists will routinely download a patient's data from the database (available through a protected website) held at the service centre.

Reimbursement of remote monitoring for implantable cardiac devices was the subject of a previous application (Application 1111) considered by MSAC at its meeting in June 2008. The aim of Application 1111 was to present evidence of the safety, effectiveness and cost-effectiveness of remote monitoring systems for patients with pacemakers, implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy (CRT) devices. The public summary document relating to MSAC's consideration of Application 1111 reports the following:

- *Safety* — There appear to be no direct safety issues
- *Effectiveness* — Use of remote monitoring systems for CRT and an ICD was assessed by a study of TGA-listed devices: inadequate follow-up and outcomes reporting limited evidence that remote monitoring may be useful in predicting cardiac events requiring hospital

admission. Evidence that remote monitoring of a TGA-listed pacemaker changed patient management through detection of silent atrial events ¹was also limited: patient follow-up was unclear and outcomes were poorly defined. Studies that investigated non-TGA listed devices also lacked sufficient reporting of their design and outcomes to enable sufficient high-quality clinical evidence to be elicited from the literature. Common limitations among reported outcomes in this body of literature included lack of an appropriate comparison with standard clinic visits, low applicability to Australian clinical settings, non-consecutive patient enrolment, evidence of incomplete blinding, and inadequate duration of clinical follow-up.

- *Cost-effectiveness* — An economic evaluation could not be performed because of the lack of appropriate comparative clinical evidence.

The MSAC recommendation was that the procedure was safe, but that clinical effectiveness is not demonstrated and a formal economic assessment could not therefore be performed. MSAC did not support public funding for the use of remote monitoring systems for patients with implanted cardiac devices at that time.

Current arrangements for public reimbursement

Remote monitoring is currently not reimbursed under the MBS. The proposal for an application did not specify whether the intervention is reimbursed through public or private hospitals. Further details provided by the sponsor to PASC in response to the draft DAP indicate that remote monitoring is reimbursed by some public hospitals. For public patients, the manufacturer typically sells the transmitter to the hospital as part of a tender arrangement together with the CIEDs. Costs are generally not passed on the patient. The sponsor estimates that, as of 1 August 2012, about 20% of public patients with a BIOTRONIK CIED in Australia are already in possession of a transmitter.

Intervention

Description

A proposal for an application that would seek funding for the remote monitoring of implantable cardiac devices has also been submitted to MSAC. Consultation feedback requested including implantable loop recorders (ILRs) into this application. ILRs are electrocardiographic (ECG) monitoring devices used for diagnostic purposes. PASC did not agree and had concerns with regard to the inclusion of ILRs as these devices are used for diagnosis and should not be included with therapeutic cardiac devices. As such the inclusion of ILRs in this application with other therapeutic cardiac devices was not considered appropriate.

A variety of CIEDs may be implanted in patients for a variety of indications. Examples of CIEDs include pacemakers, defibrillators and resynchronisation devices. Patients receive these implants for a number of medical conditions including ischaemic and non-ischaemic cardiomyopathies resulting in conduction blocks, high and established risk for sudden cardiac death, and heart failure. Implantation of these

¹ As described in MSAC Application 1111

devices occurs in both public and private hospitals and the devices are listed on the Prosthesis List Part A. Patients with such devices require routine monitoring to ensure the correct functioning of the device (and associated leads) and to monitor for cardiac events of significance.

CIEDs with the capability for remote monitoring have been available in Australia since about 2005. The transmission devices which facilitate the data transfer between the implanted cardiac device and the telecommunication network are also available in Australia. Patients implanted with a device capable of being monitored remotely may be provided with a transmitter that enables transmission of device data to a remote service centre. Transmission of data from the cardiac implanted electronic device to the transmitter may be initiated automatically or manually at fixed time intervals. This application is particularly concerned with those remote monitoring CIEDs where the transmission of data is patient independent. However the data transmission intervals may be scheduled to meet patient needs and may also include unscheduled transmissions triggered by abnormal or irregular events.

The proposal provided ARTG certificates for four BIOTRONIK transmitter devices that can be used to transmit data from a CIED to the manufacturer's service centre. Although these devices are TGA-approved, they are not eligible for inclusion on the Prosthesis List as they are not implanted.

The proposed service of remote monitoring of patients with implanted cardiac devices involves several aspects, the examples given below all relate to BIOTRONIK CIEDs:

- (i) Transmission of data by a transmitter (kept by the patient) from the patient's CIED to a database at a service centre operated by the manufacturer of the CIED. At a specified time (typically at night when the patient is in bed), the CIED initiates transmission to the transmitter which confirms delivery of the transmission. As soon as the transmission of data from the CIED to the transmitter is complete, the data are sent to the service centre. The service centre receives the data via the cellular network and stores it in a secure database.

Each manufacturer of CIED remote monitoring technology has its own service centre, i.e., the service centre of one manufacturer cannot receive and process data from a different manufacturer's system. Once a patient has been implanted with a CIED and is issued with a transmitter, the treating physician registers this patient with the service centre. The patient is identified by the unique serial number of the CIED. As an example the BIOTRONIK service centre is located in Berlin, Germany and the patient details are protected under German privacy laws. The treating physician accesses the patient information via a secure website. The service is fully automated and does not require any patient involvement (expert advice indicates that this is true of the landline system as well). All the patient has to do once after receiving the transmitter is to place the transmitter within 3 meters from their chest when in bed (e.g., on their nightstand) and plug the transmitter into an electrical outlet (if the patient travels they are advised to take the mobile transmitter with them). The transmitter automatically switches on once it is plugged in. The transmission of patient data is initiated by the CIED at a time programmed by the physician (during an in-office check); the default setting is 2am. The transmission is repeated every 24 hours at the specified time. The proposal for an application suggests that data transmission may occur via the cellular network or via landline. The CardioMessenger II-S 3G now has TGA approval and transmits via the 3G network as well.

(ii) PASC noted expert advice that some systems available from other manufacturers may provide remote monitoring via landline, GSM or 3G networks and some manufacturers may be moving to a composite system. *The Department of Health and Ageing (DoHA) has ascertained that the private sector provisions in the Privacy Act 1988 apply to large organisations and that the Privacy Act includes provisions governing all international data flows. The Applicant will need to be aware of these provisions. Uploading the patient's data from the Service Centre to a protected website for viewing by the cardiologist.* As an example the BIOTRONIK system, when a registered treating physician logs into the service centre website, they are presented with a list of all their patients for which events have been recorded. The presentation is colour-coded, i.e., red for events that need urgent attention, yellow for events that need attention but are not urgent. The colour-coding system has been developed to visually separate events in need of attention from other information confirming the absence of events, which is also routinely transmitted. The physician needs to confirm reading of each of the events.

There are a numbers of alerts that cannot be deactivated, e.g. low battery warning, which will always trigger alerts being sent to the treating cardiologist. In addition, medical specialists can customise reporting of what other events they want to be alerted to. Those events are usually defined based on the patient's history and specific conditions. Such events could be re-defined as needed, or deactivated.

(iii) Reading, interpreting and, if necessary, acting on downloaded data. As well as providing continuous remote monitoring, the implanted CIED can be configured to transmit an extended dataset on a regular basis (between monthly and every six months; typically every three months in Australia). The report contains an ECG recording as well as information stored in the CIED that is similar to what the cardiologist currently reviews during an in-office check.

The application will need to provide information not just about how the service may be configured but factual information on how the service will be configured in practice in Australia. Although it is reported that some remote monitoring systems can be configured to send alerts to the medical specialists when pre-specified events are experienced (e.g., when the patient is experiencing life-threatening cardiac events), it is not proposed that the system be intended to detect such emergencies. Expert advice was received by PASC that patients are made aware (and sign a disclaimer indicating this awareness) that remote monitoring is not replacement for attending an emergency department in case of symptoms.

The applicant clarified that with respect to the BIOTRONIK device there are two triggers that prompt review of downloaded data by the medical specialist. The first is a calendar based trigger: every three months (configurable between one and six) an extended report is generated by the service centre and the treating physician alerted to it. This prompts a review of every remotely monitored patient at regular intervals by the medical practitioner, whether the patient had events or not. The second trigger is an event in connection with the patient's arrhythmia, the device function or lead parameters. Event triggers are designed to alert the treating physician to critical events that may require reprogramming, a change in medication or other intervention. Such an event will be highlighted in the service centre website and also trigger an event message via a channel selected by the treating physician for those alerts (SMS, email, fax). The way in which this process happens with other devices would need to identify if there are resultant changes in downstream health costs and outcomes.

PASC noted expert advice indicating that they were not aware of any system currently in place where the doctor is alerted by pager or SMS alert to the available data. The systems currently in place involve a periodic review of the data by someone employed by the cardiologist and the patients are made aware that this is not a replacement for attending an emergency department in case of symptoms. Patients are made aware of the frequency of review of their data. Most clinics using such systems have a system of informing the patient that their data have been reviewed and that no issues were identified or are requested to attend a consultation with the cardiologist. Review of data is not on the basis of an alarm.

PASC noted expert advice indicating that, currently in the absence of remote monitoring, patients have alarm systems (auditory and vibratory) which can go off prompting unscheduled clinic visits. On occasion, the alarm relates to a minor issue which, with remote monitoring, could be managed by a phone call and would not require the patient to attend a consultation with the specialist.

The proposal suggests that the intervention will be particularly useful for rural or remote populations as 'mobile phone services currently reach 99 per cent of the Australian population'. Clarification was sought about whether the patient is required to have an account with a provider of cellular network services and to clarify who pays for the transmission of data on the cellular network and who is responsible for the cost of the transmitter. The applicant indicated that the patient is not required to have an account with a provider of cellular network services as the transmitter comes with a SIM card preinstalled. The applicant has entered into a global contract with a German telecommunications network service provider which also covers data transmission in Australia. The average costs for this service have been incorporated into the price of the transmitter. At the moment the applicant reports they absorb the cost of the transmitter for private patients and for public patients, the manufacturer reports they typically sell the transmitter to the hospital as part of a tender arrangement together with the CIEDs.

Although some information relating to the functioning of the device (and associated leads) and to cardiac events of significance is available from the CIED's memory, it needs to be clear in the application whether, currently, other investigations and monitoring are routinely conducted in patients with CIEDs at the time of an attendance with a cardiologist (e.g., clinical assessment, laboratory assessments, etc). This is an important consideration if remote monitoring results in a reduced number of consultations with cardiologists particularly if the cardiologist does more than read the output from the CIED at the time of the consultation.

The application will need to include potential issues with transmission of data or what systems or processes will be implemented to address or prevent such issues e.g., the frequency of failure to transmit or download data, how security of the data are maintained, whether the data are deleted from the device upon transmission, what systems are in place to deal with unsuccessful transmissions of data (how are unsuccessful transmissions identified, is the patient notified and requested to re-transmit). Issues in relation to medico-legal issues that may arise in the case of failures of data transmission to the cardiologist should be discussed.

PASC was interested to know how much data the device can hold if the patient has extended periods away from the transmitter, whether the data are lost once transmitted and what type of data are stored. PASC noted expert advice that some of the critical data are never deleted from the device.

Some less important but memory-intensive data may be deleted from the device if there are long periods between download. It was understood that existing technology devices are able to hold long periods of data. PASC requested that the applicant provide further details in the application.

The proposal derived estimates of the incidence and prevalence of patients requiring monitoring of CIEDs from statistics relating to insertion of pacemakers and ICDs. In 2009, there were 12,523 new pacemakers implanted in Australia (Mond, 2009). Additionally, 3,742 pacemakers were implanted as replacements for existing pacemakers. There were 3,555 new ICDs implanted as well as 1,111 replacements. Of these ICDs, 1,519 had the capability for cardiac resynchronisation therapy. Thus, the incidence of patients with new devices implanted is estimated at 16,078 in 2009.

In order to estimate prevalence, the proposal assumed that device longevity of 9 years for a pacemaker and 6 years for an ICD (taking into consideration that the devices that were replaced in 2009 were older generations with shorter battery lifespans). To estimate prevalence of patients with CIEDs in any application, patient mortality rather than device longevity will need to be used.

The proposal estimated that utilisation in the first years of listing will be driven by uptake of remote monitoring in patients already implanted with a device with remote monitoring capabilities (i.e., utilisation in the prevalent population) plus uptake by patients newly implanted with a device with remote monitoring capabilities (i.e., utilisation by the incident population). Uptake of remote monitoring is expected in 10% of the eligible patient population in Year 1, 20% in Year 2 and 30% in Year 3 following a MBS listing. Once uptake in the prevalent population is complete, then ongoing utilisation will be the net result of uptake in the incident population versus cessation of use in the prevalent population (i.e., due to death or replacement with a device without remote monitoring capabilities). If the majority of CIEDs inserted have the capability for remote monitoring, cessation of use is unlikely to be due to the replacement of a device with another device that does not have remote monitoring capabilities.

The proposal reported that MBS data, covering the period January 2008 through to December 2010, indicate that patients implanted with a pacemaker receive on average 2.4 in-office checks over 12 months (MBS items 11718, 11721), whilst patients with an ICD receive on average 3.0 in-office checks over 12 months (MBS items 11727). Each of the in-office checks for patients with a pacemaker or ICD is accompanied by a consultation.

The initial post-operative check is expected to continue to occur in the medical specialist's office (i.e., using the existing MBS items), and that some, but not all, of the subsequent checks would occur remotely. The proposal anticipates that the anticipated number of in-patient office checks will decrease to an average of 1.56 per patient over 12 months for patients with pacemakers and to 1.78 per patient over 12 months for patients with an ICD. The claimed reduction in utilisation of face-to-face consultations would need to be supported in any application with evidence demonstrating that this reduction would apply in Australian practice. Furthermore, in order to claim no reduction in effectiveness as a result of a shift from in-office to remote monitoring, it would need to be demonstrated that a decrease in attendances does not have negative implications for a patient's health (e.g., demonstration that the main purpose of the attendance was only the reading and interpreting of the output from the CIED).

Prerequisites

The proposed application suggests that the proposed service of remote monitoring will be provided by cardiologists. Expert advice is that the system currently in place involves a periodic review of data by a person employed by the cardiologist. Any application will need to clarify how the system is likely to be configured if the service is listed on the MBS.

Co-administered and associated interventions

No interventions are required to be co-administered with remote monitoring. However, as a consequence of monitoring, there may be use of interventions to manage device or patient issues identified by monitoring.

Listing proposed and options for MSAC consideration

Proposed MBS listing

The proposed MBS item descriptors are provided in Table 3. The latter two items proposed in Table 3 are for office-based items that are based on the current MBS items 11718, 11721 and 11727 but are intended for use only by patients having remote monitoring conducted. The items are proposed to facilitate tracking and data linkage of patients managed by remote monitoring.

Table 3: Proposed MBS item descriptor for proposed remote monitoring of patients with implanted cardiac devices

Category 2 – Diagnostic procedures and investigations	
<u>MBS Item XXX</u>	
IMPLANTED PACEMAKER (including Cardiac Resynchronisation Pacemaker) REMOTE MONITORING involving at least two documented reviews in a period of 12 consecutive months (without patient attendance) of arrhythmias, lead and device parameters being transmitted..	
Fee: \$TBA	Benefit: 75% = \$TBA 85% = \$TBA
<u>MBS Item XXX</u>	
IMPLANTED DEFIBRILLATOR (including Cardiac Resynchronisation Defibrillator) REMOTE MONITORING involving at least two documented reviews in a period of 12 consecutive months (without patient attendance) of arrhythmias, lead and device parameters being transmitted.	
Fee: \$TBA	Benefit: 75% = \$TBA 85% = \$TBA
<u>MBS Item XXX</u>	
IMPLANTED PACEMAKER TESTING indicated by remote monitoring involving electrocardiography, measurement of rate, width and amplitude of stimulus including reprogramming when required, not being a service associated with a service to which item 11718 or 11721 applies	
Fee: \$TBA	Benefit: 75% = \$TBA 85% = \$TBA
<u>MBS Item XXX</u>	
IMPLANTED DEFIBRILLATOR TESTING indicated by remote monitoring involving electrocardiography, measurement of rate, width and amplitude of stimulus, not being a service associated with a service to which item 11727 applies.	
Fee: \$TBA	Benefit: 75% = \$TBA 85% = \$TBA

TBA = to be advised.

The MBS item descriptor does not need to be specific to how the service is delivered (via GSM or landline) as services can be appropriately tailored prior to provision to the patient. PASC recommended that the MBS item descriptor will need to specify the requirement for a minimum of two documented reviews of transmitted reports per year rather than specifying a review every 3 or 6 months.

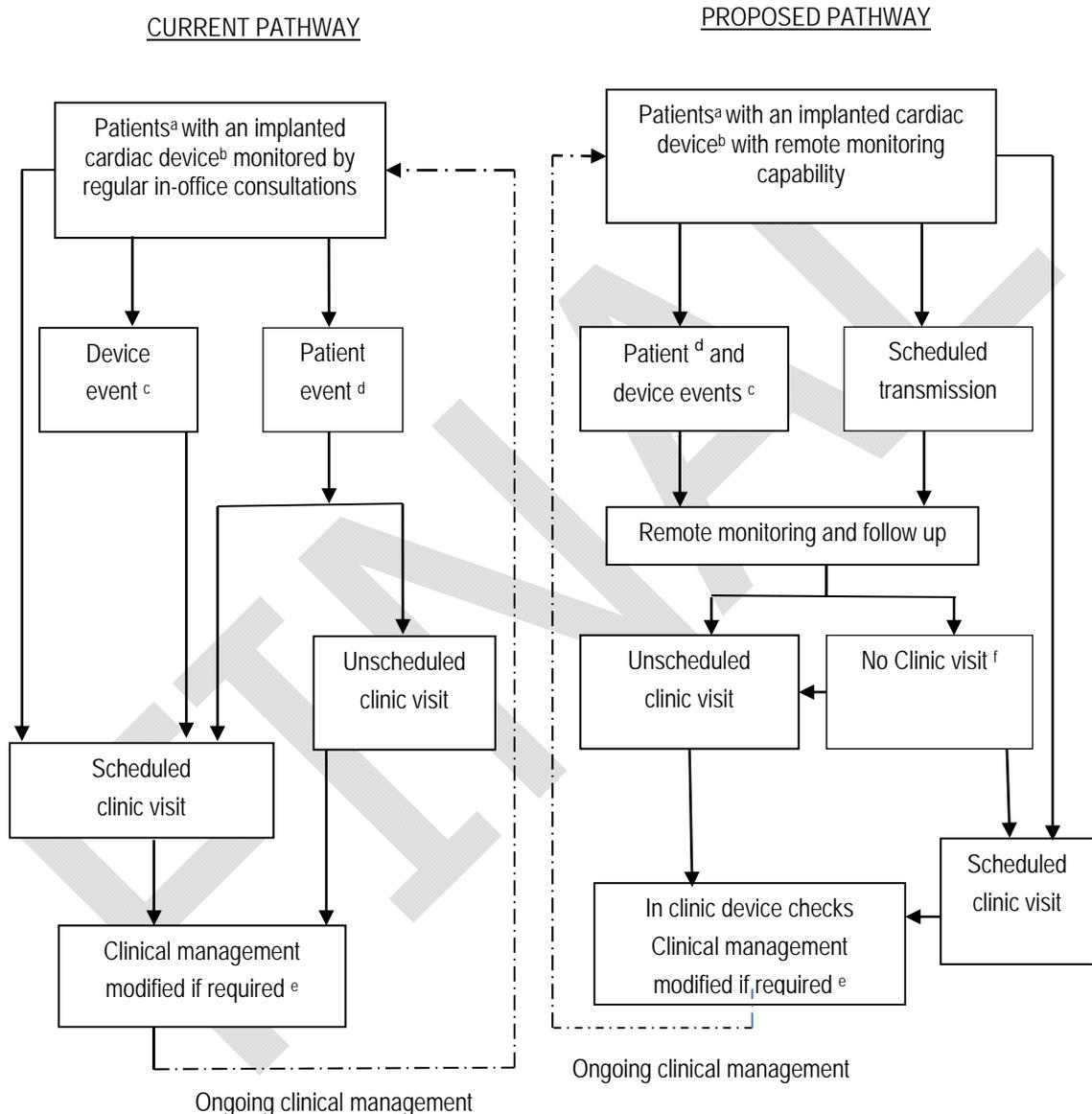
The proposal is that this intervention is reimbursed via a fixed fee per annum (flat fee), in line with a suggestion in the previous MSAC assessment report. The claim is that this would avoid any incentive for over servicing while maintaining physicians choice of treatment. The fixed annual fee could be paid in instalments (e.g. quarterly) so that the timing of benefit payment is aligned with the expected timing of the delivery of the service (i.e. typically a quarterly review of transmitted data). The payment of an annual fee paid in instalments may present some policy issues for DoHA. The trigger for these payments will need to be clarified in any application. At present the definition of telehealth has been restricted to videoconference consultations and there must be both a visual and audio link between the patient and the doctor in order to bill the new items. So this is different from the proposed remote monitoring and thus it would not be considered a telehealth item.

Although the proposal intends that patients should be monitored remotely or in-office, and the two modes of follow-up should be mutually exclusive, the proposal notes that patients who will be monitored remotely will still require unscheduled in-office consultations and thus wishes to ensure that the provision of remote monitoring should not preclude access to such care.

Clinical place for proposed intervention

The suggested management algorithms, that apply currently (when remote monitoring is not reimbursed) and that would apply should remote monitoring be included on the MBS, are summarised in Figure 1.

Figure 1: Proposed management algorithms that apply currently and that would apply should the remote monitoring of patients with implanted cardiac devices be reimbursed under the MBS



^a Patients with implanted devices require routine clinic visits. Patients with pacemakers currently visit clinics approximately every 6 months; patients with ICDs visit every 3 months and patients with CRT devices visit clinics every 3 months

^b Pacemaker; ICD; CRT

^c Patients may be unaware of device events. Device events can be related to device functioning and/or the patient's cardiovascular system

^d Symptoms are present in patient events. Patient events can be related to device functioning and/or the patient's cardiovascular system.

^e Clinical management modifications may include; change in antiarrhythmic drugs, reprogramming of the device for better arrhythmia treatment; anticoagulation therapy for documented atrial fibrillation; device reprogramming to reduce right ventricular pacing and possible left ventricular dysfunction

^f For example, doing nothing, phone call for minor issues or hospital contact for critical events

The current treatment pathway involves patients who have CIEDs being scheduled for regular in-office follow-up at cardiology clinics. Recommendations for follow-up frequencies are issued by Expert Consensus groups or local monitoring guidelines, and vary by CIED. Patients with pacemakers currently recommended to be reviewed every 6 months and ICD/CRT patients are reviewed every 3 months. These calendar-based appointments are complemented with unscheduled in-office follow-up visits as needed, for example, if patients become symptomatic or have acute events.

At each scheduled follow-up visit, the data collected by the implanted device since the last follow-up visit are read out by a programming device and stored locally. Based on these data, the physician adjusts the programming of the device as required, and can also implement changes to the treatment of the underlying cardiac condition (e.g., initiate or adjust drug treatment). The proposal claims that no adjustments to either the device or to disease management are needed in the majority (approximately 90%) of scheduled visits.

An elective replacement indicator (ERI), issued by the device, would be noted during in-office follow-up, signalling the recommendation for device replacement (due to battery exhaustion) within a pre-specified period. In ERI status, follow-ups are usually scheduled more frequently – until elective replacement surgery finally takes place. Other findings warranting system revision or removal can be technical malfunctions or infections. This cycle of scheduled follow-up visits is repeated for as long as the patient has an implanted cardiac device.

In the proposed intervention pathway, patients will be scheduled for in-office follow-up at much longer intervals. It is proposed that only annual in-office visits, complemented with remote monitoring, will be required. The implication is that the only reason that the patient visits the cardiologist is for reading and interpretation of data from the CIED.

The proposal is that, with remote monitoring, the physician “will be alerted automatically to deviations from pre-defined technical and clinical parameters (lead impedance changes, arrhythmic episodes, worsening heart failure etc., even if currently asymptomatic)”. There are a numbers of alerts dependent on the type of remote monitoring capable CIED that cannot be deactivated, e.g. low battery warning, which will always trigger alerts being sent to the treating cardiologist. In addition, medical specialists can choose to set up other events they want to be alerted to. Those events are usually defined based on the patient’s history and specific conditions. Such events could be re-defined as needed, or deactivated. Patients are made aware that this is not replacement for attending an emergency department in case of symptoms. The cardiologist could also be contacted directly by the patient in case of symptoms. In such situations, the physician would access the information that is available from secured web systems. The data available remotely are the same as would be retrieved during an in-office follow-up visit. Based on this remote assessment, the physician can either decide to do nothing, to follow up the patient remotely (by calling him or her although the MBS does not currently provide for reimbursement of telephone consultations) to advise on medication changes, to direct hospital contact (in case of acute episode requiring immediate attention) or schedule an extra in-office visit for this patient (changes to device settings would still have to be done in-office). Based on clinical data, the proposed intervention is likely to lead to an increase in unscheduled visits as remote monitoring will result in detection of a number of silent events. As noted in the section titled “**Error! Reference source not found.**”, the net impact on visits is claimed to be negative as the increase in unscheduled visits is offset by a decrease in scheduled visits. However, expert advice is

that currently, in the absence of remote monitoring, patients have alarm systems (auditory or vibratory) which can go off prompting unscheduled clinic visits. On occasion, the alarm relates to a minor issue which, with remote monitoring could be managed by a phone call and would not require the patient to attend a consultation with the specialist.

It is claimed that remote monitoring eliminates the need for an increased frequency of in-office visits for patients in ERI status as the remaining battery capacity can be monitored continuously, with elective replacement surgery scheduled when eventually indicated. This cycle of remote follow-up visits complemented by a once-yearly in-office visit plus unscheduled visits as needed would be maintained for as long as the patient has an implanted cardiac device.

Comparator

The comparator that is being proposed is monitoring of patients with an implanted cardiac device by regular in-office consultations of patients with a CIED. This comparator appears to be appropriate. However, it will be important that the monitoring strategy is similar to the monitoring strategy currently used in Australia for patients with a CIED (i.e., regular attendances with a cardiologist) and that the monitoring strategy that accompanies the CIED when switched on will be the strategy that is used in practice should remote monitoring be reimbursed on the MBS.

The proposed intervention recommends that the initial consultation remain in-office but some future in-office consultations will be replaced by remote monitoring. The application will require careful description of the provision of the service, what is entailed in an in-office visit in terms of data downloading, other tests and clinical examination versus remote monitoring. The system currently in place for remote monitoring involves a periodic review of data by, or on behalf of, a cardiologist.

Clinical claim

It is anticipated that an assessment report considering the comparative effectiveness and safety of the proposed remote monitoring compared to in-office follow-up of patients with CIEDs will claim that:

- remote monitoring of patients with CIEDs will be at least as safe as in-office monitoring of patients with ICDs.
- Remote monitoring of patients with CIEDs will be at least as effective as in-office monitoring of patients with CIEDs.
- The substitution of remote monitoring services for in-office services will incur no additional costs.

The proposal stated that a budget impact analysis rather than a cost-effectiveness analysis is appropriate. Given the anticipated claims, it seems appropriate that in an application a cost-minimisation analysis should be presented if the available evidence unequivocally supports the anticipated claims. The proposal stated that remote monitoring (including some scheduled visits) may be cost saving compared with only scheduled visits for monitoring of patients with CIEDs. It is claimed that it is possible that remote monitoring may be associated with: reduction in ambulance transport; reduced expenditure on travel subsidy schemes; reduced hospital expenditure due to avoided device replacements; and a reduced need for building of specialist capacities to meet the future demand for mandatory CIED device follow-ups due to growing patient numbers.

The proposal anticipates that the evidence will demonstrate that remote monitoring (which includes annual in-office attendances) is non-inferior to conventional in-office follow-up with respect to comparative safety and effectiveness. It is proposed that the application will provide evidence that remote monitoring:

- Reduces the number of scheduled follow-up visits
- Reduces the time to detection of clinically relevant events
- Reduces the average number of inappropriate shocks per patient
- Extends battery longevity by reducing the number of charged and delivered shocks (aborted, appropriate, inappropriate shocks) per patient
- Provides an overall safety that is at least non-inferior to conventional in-office follow up.

The proposal anticipates a cost-consequences analysis will be presented to evaluate the differential health outcomes of replacing in-office follow-up visits by remote monitoring services. It will be important for the application to demonstrate that the monitoring strategy that is used in the remote monitoring arm of the comparative studies will be the strategy that will be used in practice should remote monitoring be reimbursed on the MBS.

Outcomes and health care resources affected by introduction of proposed intervention

Clinical outcomes

It is proposed that the effectiveness of performing continuous remote monitoring can be assessed by considering:

- Changes in the overall number of detected clinically and technically relevant events, including adverse events (AE)
- Changes in time to detection of clinically and technically relevant events, including AEs
- Changes in the proportion of in-office follow-up visits that result in further action (e.g. adjustment of device settings or medical treatment), and resulting in better targeting of patients in actual need for in-office follow-up
- Changes in replacement surgery of CIEDs due to extended battery longevity
- Changes in patient survival due to reduced mortality

PASC considered that patient satisfaction and quality of life were also relevant outcomes to consider.

Clinical safety issues that it might be relevant to include in the assessment of the comparative safety and effectiveness of remote monitoring include:

- Successful transmission of the data
- Failure of the device to download stored information
- Failure to respond to alerts

Health care resources

In terms of health care resources, the proposal indicates that an application would include an assessment of likely change in use of MBS items relating to in-office follow-up visits (scheduled or unscheduled), and remote monitoring services (routine or alert driven). Other health care resources to be included include elective replacement surgery and hospitalisation for acute events. Transportation costs are also highlighted as being included. If the sponsor wishes to incorporate indirect costs in the economic analysis, two alternative analyses should be presented – one including and one excluding the indirect costs. As discussed in the section titled “Clinical place for proposed intervention”, the proposal for an application (in response to Q.C32) claims that evidence exists that once a year in-office visits complemented with remote monitoring is as safe as the current approach of monitoring by in-office visits exclusively. PASC noted there will need to be consideration of what source should guide the estimate of number of in-office consultations required for patients with remote monitoring (e.g., if there is a discrepancy between the numbers recommended in clinical guidelines and the number of consultations observed in a study).

Costs for in-office consultations with a cardiologist in the arm representing the current scenario appear to be overestimated. The selection of MBS Item 133 as the fee for the consultation with the cardiologist may not be appropriate. This item relates to a professional attendance by a consultant of at least 20 minutes duration for a thorough review of a patient with at least two morbidities.

Table 4: List of resources to be considered in the economic analysis

	Provider of resource	Setting in which resource is provided	Proportion of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS	Safety nets ^a	Other govt budget	Private health insurer	Patient	Total cost
<u>Resources provided to identify eligible population</u>										
- None required	n/a	n/a		n/a						
<u>Resources provided to deliver comparator - patients with pacemaker</u>										
- In-office testing of pacemaker	cardiologist	In-office		2.4 per year	34.75				29.55	
- Consultation fees	cardiologist	In-office		2.4 per year	\$129.65					\$129.65-
<u>Resources provided to deliver comparator - patients with an ICD</u>										
- In-office testing of ICD/CRT	cardiologist	In-office		3.0 per year	94.75				59.30	n/p
- Consultation fees	cardiologist	In-office		3.0 per year						n/p
<u>Resources provided to deliver proposed intervention- patients with a pacemaker</u>										
- In-office evaluation	cardiologist	In-office		1 per year (+initial post-op)						
- Remote monitoring	Cardiologist	remote		2 per year						
- Unscheduled in-office evaluations	cardiologist	In-office		0.5 per year						n/p
-										
<u>Resources provided in association with proposed intervention – patients with an ICD</u>										
- In-office evaluation	cardiologist	In-office		1 per year + (initial post-op)						n/p
- Remote monitoring	Cardiologist	remote		4 per year						
- Unscheduled in-office evaluations	cardiologist	In-office		0.78 per year						n/p

n/p = not provided in proposal

PASC discussed whether patients incur costs for the transmitter, the transmission of data or the remote monitoring. Expert advice is that usually the purchase of the transmitter buys the service of transmitting the data (SIM card is in the transmitter and there is an arrangement by the manufacturer with an overseas telecommunications companies). There are currently no rules or guidelines. Public hospitals purchase the transmitters with the devices, the public hospital pays staff costs to monitor the database and the company provide the maintenance of the database and the monitors. In the private sector, the transmitters are generally provided free of charge at time of implant and the costs of monitoring born by the patients. Charges of \$200 per year are part of a written contract which explains what service is provided for that sum of money. The technology is being covered out of the cost of the device (the company is incurring the cost). PASC requested that the funding for covering the on-going costs of the service, whether it is charged as an annual cost to patients or incorporated as a once off fee when the patient receives the transmitter would need to be clarified in any application.

Healthcare resources relating to downstream events such as elective replacement surgery and hospitalisation for acute events are proposed to be excluded from the economic analysis. This would be appropriate if there is no difference in the incidence of such events across the two scenarios however, as the applicant is claiming that there is likely difference in outcomes these should be included.

Proposed structure of economic evaluation (decision-analytic)

Table 5 summarises the extended PICO that it is proposed MSAC would consider.

The proposal for an assessment does not include a suggested structure for an economic evaluation. It states that the economic evaluation that will be undertaken will be cost consequence analysis or a budget impact analysis reflecting that the proposed fee model would be cost neutral for the MBS budget. Savings to health care resources such as ambulance transports, and to other budgets such as travel subsidy scheme(s) or to hospital budgets for (avoided) device replacement, and investments avoided to build specialist capacities for meeting the future demand for mandatory CIED device follow-ups (due to growing patient numbers), would not be claimed in such budget impact analysis, although their existence should be considered in the decision making. Furthermore, it is claimed there are intangible outcomes such as improvements in rural health care and in easier access to health care that are worth considering.

PASC noted that given claims in the proposal of non-inferiority in respect to clinical effectiveness and safety and that there may be substantial savings that a cost minimisation or cost-effectiveness analysis would be more appropriate economic evaluation in an assessment than the proposed cost consequence analysis.

Table 5: Summary of extended PICO to define the question for public funding that assessment will investigate

Patients	Intervention	Comparator	Outcomes to be assessed	Healthcare resources to be considered
Patients with implanted therapeutic cardiac device with remote monitoring capability	Remote monitoring (by a mixture of remote services and in-office consultations) of patients with a cardiac device with remote monitoring capability where data transmission is independent of the patient	<i>Regular in-office consultations of patients with a CIED</i>	<ul style="list-style-type: none"> • Changes in the number of events, including adverse events (AE) • Earlier detection of arrhythmias, AEs and technical issues • Reduction of in-office visits • Reduction of inappropriate shocks • Reduced need for device replacement • Reduced overall mortality • Safety including network coverage, data transmission and storage 	<p>MBS items relating to scheduled or unscheduled in-office consultations</p> <p>Transportation costs (ambulance costs)</p> <p>Battery replacement surgery</p> <p>Hospitalisation for cardiac events <i>Despite claims of reduced time in hospital, the proposal for an application does not propose that such hospital resources would be included in an economic evaluation.</i></p>

Primary question for public funding

What is the safety and effectiveness of remote monitoring of CIED patients compared with conventional in-office follow-up of CIED patients?

Attachment A

The following information was included in the proposal to estimate a likely price for remote monitoring of CIEDs.

Remote monitoring of patients with a pacemaker

The proposal suggests that the likely market price for remote monitoring of a patient with a pacemaker is between \$193 and \$232.

The price of \$193 is derived as follows. The proposal suggests that the evidence indicates that there will be two event messages per year per pacemaker patients (Lazarus, 2007) requiring an effort estimated to be equivalent to reading a 12 lead ECG (MBS item 11702; \$15.25). Additionally, remote monitoring is assumed to take about 10 minutes per 100 patients per day of clinical time (Elsner, 2006) (i.e., 20 minutes per patient per year) (200 working days) equating to one 20 minute specialist consultation (MBS 133: \$129.65). The selection of MBS Item 133 as a guide to estimate the appropriate reimbursement for the cardiologist's time may not be appropriate. This item relates to a professional attendance by a consultant of at least 20 minutes duration for a thorough review of a patient with at least two morbidities. Thus, the total market price per annum would amount to \$193 (0.5 in-office services p.a. = \$65 plus 2 alert analyses p.a. @ \$15.25 each plus \$129.65 for routine data analyses).

The price of \$232 is derived including:

- One in-office evaluation of the patient every second year, as part of the remote monitoring, at a market price of \$65 (based on the weighted average of the fee for MBS items 11718 [\$33.45] and 11721 [\$67.10]). As discussed, the proposal for an application claims that evidence exists that once a year in-office visits complemented with remote monitoring is as safe as the current approach of monitoring by in-office visits exclusively therefore the inclusion of a cost for only one in-office evaluation every second year may therefore not be appropriate.
- Routine analysis (estimated at 10 minutes every 3 months) of data transmitted from the pacemaker, including electrocardiography, rate and amplitude of stimulus, and correspondence with the patient.

Hence the total per annum would be \$232 (0.5 x in-office services p.a. = \$65 plus 4 routine analyses p.a. of 10 minutes each @ \$300/hr)

Remote monitoring of patients with an ICD

The likely market price for remote monitoring of a patient with an ICD is estimated to be between \$282 and \$391.

The price of \$282 is derived as follows. The proposal estimates the evidence suggests that there will be 4 event messages per year per ICD patient (Lazarus, 2007) requiring an effort estimated to be equivalent to reading a 12 lead ECG (MBS item 11702; \$15.25). In addition, remote monitoring takes about 10 minutes per 100 patients per day of clinician time (Elsner, 2006), i.e. 20 minutes per patient

per year (200 working days), equalling to one 20 minute specialist consultation (one in-office service p.a.*\$91.20 plus 4 alert analyses p.a.*\$15.25 plus \$129.65 for routine analyses.)

The price of \$391 is derived including:

- one annual in-office evaluation of the patient as part of the remote monitoring
- an ICD in-office check is currently reimbursed under MBS item 11727 at \$91.20. The proposed fee for proposed MBS item includes the routine analyses of data transmitted from the remote implanted defibrillator, involving electrocardiography, assessment of pacing and sensing thresholds, and correspondence with patient. The market price for this service can be estimated at 15 minutes of specialist's time every 3 months. Hence the total per annum would be \$391 (one in-office service p.a.*\$91.20 plus 4 routine analyses p.a.*10 minutes each*\$300/hr)

In-office pacemaker testing indicated by remote monitoring

The proposed fee for in-office pacemaker testing, indicated by remote monitoring is \$65 (based on the weighted average of MBS items 11718 (\$33.45) and 11721 (67.10)).

In-office ICD testing indicated by remote monitoring

The proposed fee for the in-office ICD testing indicated by remote monitoring is \$91.20 (in accordance with MBS item 11727).