Working paper - Industry Working Group (IWG) on Cardiac Technical Support Services
December 2020

Executive Summary

In 2017 an Agreement was established between the Medical Technology Association of Australia (MTAA) and the Australian Government to:

- Promote the sustainability of privately insured health care through rebalancing the costs of medical devices to privately insured patients, to help keep private health insurance affordable for all Australians;
- Support a viable, innovative and diverse medical technology sector in Australia and local jobs; and
- Improve the value of private health insurance for consumers by reducing benefits for prostheses on the Prostheses List.

As part of that Agreement there has been a staged reduction of Prostheses List benefits for implantable cardiac devices. Device suppliers expressed concern that in this environment of reduced benefit reimbursement industry may be unable to sustain the existing level of support for device implantation and follow-up technical services.

In response to these concerns the Industry Working Group on Cardiac Technical Support Services was established. The IWG was tasked with detailing the clinical need and extent for the technical support services provided to Australian patients with Cardiac Implantable Electronic Devices (CIEDs). The technical services provided to CIED recipients were divided by the IWG into three broad categories – scheduled services, unscheduled services and remote monitoring.

The Terms of Reference for the IWG are:

1. To provide strategic advice on the technical support services provided in association with active implantable cardiac devices in the private sector
2. To consider how these technical support services are funded (in the private sector, in the public sector, by Medicare)
3. To consider the clinical need for these technical support services
4. To consider the impact of these technical support services for patients and the Australian healthcare system
5. To develop a report to the Prostheses Reform Governance Group

The Medicare statistical database was used to generate estimates for the volume of scheduled services and remote monitoring services. As these services attract a Medicare Benefit Schedule (MBS) payment to the physician supervising the services, the IWG felt that these statistics would provide a reasonable estimate for the total number of services provided. Although the exact proportion of these services that were supported by industry is unknown, it is thought that the majority have some industry involvement.

The number of unscheduled CIED services that occur annually was more difficult to establish. In all cases, these services do not attract a Medicare payment and the vast majority of these services are supplied by industry employees. The IWG requested that the MTAA liaise with its members to provide details about the volume and nature of unscheduled CIED services provided to patients by their members. As such, this paper includes data aggregated by MTAA collected by companies over a six-week period in the first quarter of 2019 (Annex 1).

The IWG acknowledges the importance of the technical support services provided by the suppliers of cardiac devices and notes that the provision of these services has been and will continue to be an important part of ongoing patient care. The aggregate data provided by the MTAA had not been collected before and provides an important baseline from which any future change in service levels can be measured in the future.

The IWG was also tasked with assessing the clinical need and impact of technical services in association with CIEDs. There are a number of practice guidelines that make recommendations concerning follow up of CIEDs. These recommendations are largely based on expert opinion rather than randomised controlled trials (RCTs).

There is some RCT evidence that remote cardiac monitoring may improve patient outcomes and reduce mortality particularly in patients with implantable defibrillators. Given the complexity of modern CIEDs regular interrogation and, where necessary, programming adjustments are likely to optimise device performance and enhance longevity.

There are instances where CIED intervention is required to obtain information from the memory of the device or programming changes are required to facilitate surgical procedures or MRI scanning. In these circumstances access to technical services can have a major influence on other cardiac or medical issues. The degree to which individual patients require access to technical services and the impact on their clinical status varies markedly from patient to patient.

CIED checks have historically been performed by the patient attending a dedicated clinic in the physician's room or hospital. Current and future technologies are changing the nature of CIED services. Increasingly CIED interrogation and data retrieval is performed utilising devices carried by the patient or installed in the patient's home or other locations.

In addition to the routine checks of CIED function, there arise a number of instances where unscheduled or 'ad-hoc' device interrogation and programming may be required. The most common of these occur when patient symptoms or events prompt a check and where patients requiring surgery, or an MRI scan require device interrogation and possibly reprogramming.

Remote monitoring has the potential to reduce service burden of industry employed allied professionals (IEAPs) if the technologies are used in such a way that prevent dual servicing of cardiac device follow-up (for example, patients being followed both remotely and in-person with industry support).

It is evident that there is a need for technical services in association with CIED therapy. It is difficult to establish the impact of the reduction in device reimbursement on the provision of these services in Australia given the absence of coordinated data on the volume of services undertaken by physicians and company representatives.

The device use is predominantly based on the patient's clinical need and preferences. The company's involvement in delivering technical services relating to the device allows relationship building with the implanting Cardiologists, and the MTAA company support can assist in the safe and effective use of the device. The provision of high quality follow-up services may be a differentiating factor in influencing a physician's use of one company's device over another.

A factor that should be considered is to what extent other parties may provide the services, when thinking about the impact of withdrawal of technical services supplied by device companies. The physician caring for the patient or third parties may be able to substitute for the industry employed representatives.

All individuals involved with providing the technical services associated with the implantation and follow up of CIED's should have appropriate training and experience. Currently the Cardiac Society of Australia and New Zealand (CSANZ) provide guidelines for the training and competency of physicians involved with CIED implantation and follow up. These are recommendations and there is no formal accreditation process to ensure practitioners claiming MBS rebates for CIED follow up satisfy the CSANZ training/competency guidelines. There is no standardised training and accreditation process for industry employed technicians involved in CIED follow up. Many choose to undertake the Heart Rhythm Society technical course and examinations. The working group has not specifically addressed the issue about the need for accreditation of IEAP's and the appropriate training program. As it is the physician that ultimately takes responsibility for patient care, it may be appropriate for the individual physician to determine the appropriateness of each IEAP ability to be involved in the care of their patients.

The IWG considered the current funding models for provision of technical services for CIEDs, and alternative funding models in a limited fashion. The MBS provides funding for the physician involvement in CIED follow-up services including their involvement in remote cardiac monitoring. At present, reimbursement to the device companies for their involvement for the full life of the patient or CIED is only via the payment for the provision of the device, and if appropriate, a remote monitor, at the time of implant.

This is the model that exists in most countries and to the knowledge of the IWG separate funding to industry for individual CIED services does not exist in other international jurisdictions, excepting the United States where there is a funding model for cardiac event recorders that is split into a technical and clinical fee. There are limitations to the current funding arrangements but while alternative funding models are considered out of scope of the IWG, the working group's terms of reference state that "the role of the Cardiac IWG is to make recommendations and provide advice to the Prostheses Reform Governance Group on how technical support services for active implantable cardiac devices should be funded to ensure the Australian healthcare system and privately insured patients receive maximum benefit from this technology". Accordingly, industry has provided recommendations for action focusing on improving the environment for remote monitoring of CIEDs.

A number of issues have complicated the discussions about the sustainability of the existing funding arrangements for CIED technical services. Industry representatives were unable to identify which services, if any, would not be continued to be supported by industry following the series of rebate reductions. The industry representatives have suggested one model may be a separate funding stream that is independent of the payments received via the Prostheses List. The Department notes there is often a commercial benefit for cardiac device companies attached to the provision of services. If cardiac device companies are operating efficiently and are unable to provide services to the patients that receive their devices then a solution is required. In a future environment in which prostheses benefits for active implantable cardiac devices declined further, industry would not be able to sustain the enumerated (and growing) service burden, leading to an adverse impact on quality of patient care. Should further device price reductions be implemented, a solution for industry-supported services will need to be found.

The Cardiac Technical Support Services IWG has run in parallel to the Revised Benefit Setting and Review Framework Industry Working Group, which is considering the mechanisms for benefit setting. It is the MTAA's view that consideration of funding should be made on the basis of all aspects relevant to service provision. These aspects can be broadly listed as: hardware, software, quality systems, security, ongoing updates and maintenance, research and development, and customer education and training. Any changes to the benefit setting landscape may impact significantly on the medical device industry's ability to continue to provide CIED technical services. Further meetings of the Cardiac Technical Support Services IWG will be scheduled as the need arises.

Recommendations

1. That the Chair of the Cardiac Technical Support Services Industry Working Group write to the Cardiac Society of Australia and New Zealand Industry seeking advice on matters covered in this report, including its view on the clinically necessary services to be supported by IEAPs.

2. That consideration be given to revising the reimbursement arrangements for remote monitoring so that uptake is optimised.

Introduction

Cardiac Implantable Electronic Devices (CIEDs) include pacemakers, implantable defibrillators, cardiac resynchronisation devices and implantable loop monitors. These devices are used to assist in the diagnosis of cardiac electrical disorders or to treat disturbance of cardiac rhythm. The first pacemaker was implanted in 1958 and was a simple device able to pace at a fixed rate in only one chamber of the heart.

Since that time CIEDs have become progressively more complex and sophisticated. CIEDs have also become smaller and longer lasting due to innovations in battery technology and programming algorithms. Appropriate programming (setting of the various parameters) of devices is an important aspect of optimising the outcomes from device therapy. The programming often needs individualisation to a patient's circumstance and may need adjustment over time.

In an attempt to obtain optimal device performance and longevity, CIEDs are checked on a periodic basis. The need for regular evaluation of device function and the adjustment of the programmed settings is relatively unique to CIEDs as compared to other prostheses such as joint replacements and ocular lenses.

CIED checks have historically been performed by the patient attending a dedicated clinic in the physician's room or hospital. More recently the introduction of remote device monitoring has changed the paradigm of device follow up and this will be discussed in more detail later in this paper. At present, the bulk of device checks are still done by direct contact with the patient. There are a number of factors that determine the frequency of follow up visits. These include physician preference, the type of the device implanted, patient factors and other issues such as alerts pertaining to potential device malfunction or change in patient clinical condition.

There is substantial variation in physician practice as to how frequently routine device checks are performed. There are also regional and international differences. Much of this variation may be a consequence of very limited data as to the optimal frequency for these services. What is evident is that with traditional in office scheduled visits only a very small proportion of patients have a device problem identified or require any adjustment to their device parameters[1]. There are published guidelines that recommend minimum intervals between routine device checks. These recommendations are based on expert opinion rather than data from randomised trials.[2] In Australia pacemakers and defibrillator checks have usually occurred one to two times per annum.

In addition to the routine checks of CIED function, there arise a number of instances where unscheduled or 'ad-hoc' device interrogation and programming may be required. The most common of these occur when patient symptoms or events prompt a check and where patients requiring surgery or an MRI scan require device interrogation and possibly reprogramming.

Personnel involved in CIED follow-up

There is consensus that the physician caring for the individual with a CIED (defined as the cardiologist following that patient or the local hospital cardiology department) is ultimately responsible for the initiation of any device check, interpretation of the resultant data and for any decision concerning device reprogramming. The physical performance of the device interrogation may be performed by the physician; however, this task is often delegated to other individuals. This includes staff employed by the physician, hospital-employed Cardiac Technologists or nurses and industry employed allied professionals (IEAPs). The focus of this IWG is on the involvement of IEAPs in the provision of CIED technical services.

An IEAP may be involved in a number of tasks relating to CIED therapy. These include assistance at the time of device implantation, technical advice about device features/functions, troubleshooting of potential device malfunction, algorithm optimisation, the performance of scheduled or unscheduled CIED checks and involvement in remote cardiac monitoring.

These tasks are performed in a broad range of settings including physicians' offices, in-

[1] http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp.

theatre, intensive care units, hospital wards, emergency departments, nursing homes, morgues, imaging centres (e.g. MRI), radiation oncology, and even in a patient's home. IEAPs attend these tasks in cities, and in rural and remote areas.

The extent to which IEAPs are used to perform CIED technical services depends upon a number of factors, these include:

a. Some physicians relying more on industry assistance/support than others. This may be by personal preference or based on their access to non-industry affiliated and appropriately trained technicians.
b. The circumstances prompting the CIED check may also influence the involvement of IEAPs. 'Ad-hoc' (unscheduled and "out-of-hours") device checks at locations away from the physicians' rooms are in the vast majority of cases performed by IEAPs as in-person service or via remote monitoring systems.
c. Despite a portion of these "ad-hoc" checks being completed via remote monitoring, there is still involvement of the IEAP in regard to maintenance and potential troubleshooting of remote monitor equipment, technical review of data and quite often communication of data.

A number of international guidelines have considered to what degree IEAPs should participate in the provision of the technical services pertaining to CIED therapy. The IWG considered the guidelines published by the Heart Rhythm Society in 2008[3].

While these guidelines are now over 10 years old the IWG agreed both with the general principles and that they are relevant to the Australian environment. A number of principles espoused in the Heart Rhythm Society guidelines are particularly relevant to consider in the context of the terms of this IWG's terms of reference. These include the following principles:

1. The IEAP's role in the clinical environment is to provide technical expertise on the implant, use, and operation of their proprietary equipment specific to their company.
2. IEAPs should perform technical support tasks in the office only under direct supervision by the physician.
3. If an IEAP is requested to evaluate a pacemaker or Implantable Cardioverter Defibrillator (ICD) in the hospital, the physician who made the request should be immediately available by phone if he or she cannot provide direct supervision. It is the physician's responsibility to interpret the recordings and make any related clinical decisions, *including programming changes. *[* Note: as specified above, physician is defined as the cardiologist who follows the patient or the local hospital cardiology department]*
4. Although IEAPs provide expertise and may train and answer questions on their systems and equipment, they should not be used as unpaid employees of a physician's practice or routinely assume administrative functions, such as routine retrieval of patient information or enrolling patients in remote monitoring systems.
5. IEAPs should not provide clinical assistance in the clinical environment when they are alone and/or unsupervised by an appropriately trained or experienced physician* (defined as a physician adequately trained in the management of patients with CIEDs (per CSANZ guidelines)). IEAPs should not provide technical assistance in a patient's home in the absence of a responsible physician.

[Note: IEAPs should not provide in-person technical assistance in any environment other than a follow-up physician's rooms or hospital setting, with the appropriate supervision as defined above]*

** Notes provided in addition to excerpts from HRS guidelines.*

In Australia, the extent to which IEAPs have been involved in the provision of CIED technical services has been unregulated. The overarching principle of physician responsibility for patient care and decision about programming of CIEDs is well accepted in the Australian environment. The degree to which IEAPs are involved in individual patient care is variable. Within the broad principles outlined above, it remains at the discretion of the treating physician to what extent they may involve IEAPs in individual patient care.

Prescriptive guidelines about how IEAPs are involved are unlikely to be acceptable to the broader medical community involved in care of patients with CIEDs. The training requirements and qualifications required to act as an IEAP are not well defined. Industry identified the need for clarity from the Cardiac Society of Australia and New Zealand (CSANZ) on what services are clinically necessary to be supported by IEAPs. This will assist Industry in the development of training and development requirements.

Each device company has its own training program and requirements for an individual to be considered competent to work as a device specialist. Many field specialist staff go through the established accreditation through International Board of Heart Rhythm Examiners (IBHRE).

However, the specifics surrounding the training and competency requirements for IEAPs were considered out of scope of this IWG.

Summary of Industry Comments

1. Industry Employed Allied Professionals (IEAPs) perform relevant services to maintain the performance of CIEDs under supervision of physicians. These services are performed across all segments of primary and allied care and in rural and remote areas.
2. Industry seeks clarity from CSANZ on what services are clinically necessary and need to be supported by IEAPs.
3. Training/education requirements can also be more clearly established. International accreditation pathways are relevant benchmarks for developing an accepted set of standards for IEAPs.

Recommendation

1. That the Chair of the Cardiac Technical Support Services Industry Working Group write to the Cardiac Society of Australia and New Zealand Industry seeking advice on matters covered in this report, including its view on the clinically necessary services to be supported by IEAPs.

Categorisation of CIED technical services

The IWG chose to divide CIED services into three main categories:

a. Scheduled services
b. Unscheduled services
c. And remote monitoring services

Scheduled services are prescribed or recommended intervals by the clinician. As such, the frequency is predictable, and the service is often simply related to checking of the device function (e.g. the battery status) and is independent of the clinical condition of the patient.

The unscheduled services are often unplanned and relate to a change in the clinical condition of the patient. This can include assessment of device function when a patient attends an emergency department, during unscheduled in-clinic visits, when device programming for surgical procedures or MRI scans, or where it may be difficult for the patient to attend the site of routine device follow up (e.g. due to poor mobility). The frequency of scheduled and unscheduled services relating to CIEDs can be due to many factors including the nature of the device and the presence of other patient conditions/co-morbidities.

Remote Monitoring is a more recent development in the provision of CIED technical services. The evolution of remote monitoring and the future impact of this technology is discussed later in this report.

Response to the questions raised by the IWG terms of reference and the MTAA Queries

Current status of Industry involvement in CIED services

There has been considerable discussion concerning the current level of service provision by IEAPs. Some of the issues include the current volume of services provided and future projections, how the provision of device services impacts on the device company resources, how these services are funded and the appropriateness of industry involvement in providing these services.

The IWG had asked the MTAA to provide some information and discussion concerning these services. A number of specific issues have been raised. A work plan had been proposed by the MTAA. This plan is listed below:

1. Identify the cardiac technical services provided in association with implantable cardiac devices by cardiac companies
    a. List technical support services currently provided by IEAP's.
    b. List technical support services currently provided by others
2. Consider the impact of these technical support services for patients and the Australian healthcare system
3. Consider the need for these services to be provided by IEAP's
    a. Estimate volume of cardiac services (specific details of data will be provided by the Department of Health and Device Companies)
    b. Consider treatment guidelines for:
        i. Technical service of cardiac implants in general
        ii. Technical service to be provided by IEAP's.

4. Identify how these cardiac technical services are currently funded.
    a. Document how each of the technical support services identified in Item 1 are funded
    b. List possible other funding pathways
    c. Evaluate accessibility of other funding pathways to cardiac technical service providers
5. Recommend how technical support services for active implantable cardiac devices should be funded
    a. Develop principles that a funding model needs to meet
    b. For items 4.b and 4.c: What would need to happen to open funding pathways other than upfront payment via the Prostheses List benefit?
    c. Provide recommendations to the Prostheses Reform Governance Group on how technical support services for CIED

The terms of reference stated for the IWG on cardiac technical support services are:

1. To provide strategic advice on the technical support services provided in association with active implantable cardiac devices in the private sector
2. To consider how these technical support services are funded (in the private sector, in the public sector, by Medicare)
3. To consider the clinical need for these technical support services
4. To consider the impact of these technical support services for patients and the Australian healthcare system
5. To develop a report to the Prostheses Reform Governance Group

The recommendations from the Cardiac IWG should inform the work of the Benefit Setting and Benefit Review IWG.

There is considerable overlap between the terms of reference and the MTAA workplan. This workplan includes some elements outside of the terms of reference of the IWG as well as issues or questions that can only be addressed in theoretical terms.

To date there has been no systematic recording of the volume of the various CIED services performed within the Australian healthcare system and currently available data can only provide best estimates. In addition, until recently, there has been no direct fees charged to the hospitals, doctors or patients for the provision of the various CIED services supplied by industry.

Following the recent reimbursement reductions to CIEDs on the Prostheses List, there has been an unintended move from some industry players to begin charging for some unscheduled services such as reprogramming for MRI scans, although this is not a universal practice nor is it widespread.

The device companies have held the opinion that a significant component of the fee/rebate they receive for sale of the CIED was intended to cover the cost of providing these services for the full life of the patient or device - which now exceeds 10 years of service life.

The physician members of the IWG were not aware that this assumption had even been formalised. No documentation has been presented to the IWG to indicate whether a portion of the device cost should be considered as payment for the provision of CIED services, and if so, what indicative percentage or sum was allocated to cover these services.

The current model has the potential effect of undervaluing the true cost associated with the services as there is lack of recognition of direct relationship between the provision of a service and a cost recovery.

One of the principal reasons for the establishment of the IWG on the provision of Cardiac Technical Support Services was the fact that the MTAA and its members identified difficulty in continuing to provide the current level of technical services in the environment of reduced Prostheses List benefits.

Historically, gaining clarity around specific services, if any, that the industry will no longer be able to support and detail surrounding the extent to which services may be withdrawn or reduced, was difficult. This has previously hampered progress on this issue at the IWG, as it was difficult to know the true extent of any problem and the need for alternative solutions and funding models.

It is difficult to know to what extent other providers would fill any void in services if industry was to be unable to continue to provide various elements of the CIED technical services. In many instances the services could (are) provided by physicians caring for the individual patient. It is apparent that the provision of technical services allows industry to have contact with the physicians who implant CIEDs and this is seen as an opportunity to create relationships that foster further collaboration.

The provision of high quality technical services is also seen as a mechanism that device companies may differentiate themselves from their competitors and thereby obtain greater market share.

Industry provided data which will assist the IWG in evaluating the current level of technical support services. The data are presented in Annex 1.

Within the limits of current data, the questions raised within the MTAA workplan and questions arising from the IWG terms of reference are addressed below. The document reflects the discussions at the two IWG meetings and a teleconference with the MTAA and representatives of the various device companies.

Summary of Industry Comments

High quality technical services are provided by all device companies in Australia. Industry supports clinical decision making based on patient clinical need and preferences, including in respect of how cardiac device checks are performed.

Industry supports progress towards reducing the services burden under the following principles:

- That patient safety is not compromised
- Physicians maintain choice to provide the best clinical solutions for their patients

- Patient costs are not increased, thereby supporting the value proposition of private health insurance

As discussed above, CIED technical support services can be divided into three main categories. These are implant support and scheduled follow up, unscheduled services and remote monitoring services. These categories are discussed below with reference to the MTAA workplan and the IWG TOR.

Scheduled CIED Services

There are a number of scheduled/predictable technical services associated with the implantation/follow up of CIEDs. These services occur at the time of implant, pre- hospital discharge and then on a regular basis post-implant.

At the time of device implant it is routine for a technician or nurse to provide assistance in the performing of intra-operative testing of lead parameters and programming of the implanted device. In some instances, the technician assisting may provide advice on specific tools or techniques that may assist the physician in successfully implanting the device.

The extent and need for this assistance depends on the nature of the procedure, the experience of the operator and the technical difficulty of the particular case. For a routine pacemaker implant little assistance is generally necessary but for a cardiac resynchronisation procedure advice on the use of the various tools available for implant is more often sought. The number of CIED devices implanted in the private sector over a specified period can be estimated from the MBS statistics available on line (http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp).[1]

While this has some limitations in the assessment of the total number of devices implanted in the private sector it is likely to be a reasonable estimate of the implant volume. In financial year 2017/18 there were approximately 10,000 pacemaker procedures, 2000 ICD procedures and 1500 cardiac resynchronisation procedures. Technical assistance would have occurred at the vast majority of these procedures. Technical support is generally provided at the time of the implant and then immediately prior to the patient discharge.

The actual proportion of the services provided (in the private sector) by industry personnel is not known but is likely to be in excess of 90 per cent (personal opinion by chair of the IWG) (*Note: industry data of 299 post-implant checks per week is consistent with this estimate – 15548 annualised procedures inferred by the service data in 2019 is consistent with 15% growth on the 2017/18 implantation numbers).*

In the instances where these services are not provided by industry personnel, they are provided by staff employed by the hospital or by the physician performing the procedure.

Implant and pre-discharge testing are a critical and integral part of the device implant procedure. Currently, there is no direct funding for the performance of these services. Implant support is not unique to cardiac devices. In many orthopaedic procedures industry staff attend the procedure and provide technical support. In these circumstances any external remuneration to the industry personnel attending is noticeably rare.

In the initial IWG face-to-face meetings, the industry representatives had been of the opinion

that the provision of technical services around the time of implantation was not one of the areas that was creating concern or difficulty for the device suppliers.

For most CIEDs a regular interrogation of device function and status is required at variable intervals. International guidelines suggest that for pacemakers this check should occur every six to 12 months and for ICDs it is recommended to occur at least every six months. The clinical need for these services and the impact of not providing them has not been formally studied. However, these services have the potential to reduce the need for the patient to have frequent clinical visit and may improve safety outcomes relating to device.

A minimum frequency of device checks is mandated in local and international guidelines and is part of best practice. Intuitively, given the complexity of current devices it seems likely that best device performance and enhanced longevity is likely to occur if the CIED is checked and adjusted periodically. Data on the extent to which regular device surveillance improves patient outcomes is lacking.

Most routine follow up device checks have been performed by the patient attending a clinic supervised by a medical practitioner. The physical performance of the device check may be performed by the physician or by a technician authorised by the physician. In many instances the technician performing the check is an individual employed by the device company that has supplied the device. In all instances; the physician takes responsibility for all aspects of the service including the interpretation of the results and any changes made to the programming of the device.

Medicare statistics suggest that the frequency of these device checks in Australia conform to international guidelines. These services are funded by Medicare in the form of a payment for the device interrogation and interpretation of the results. In the vast majority of cases these routine device checks do not identify any problem with device function and no intervention is required. Only a registered medical practitioner can claim these services.

Presently, there are differences in the manner in which the services around routine device interrogation are delivered. In some instances, the entire service (physical performance of the test and interpretation of the results) is performed by the physician claiming the MBS item number. Alternatively, the doctor may employ their own technical staff to perform the device interrogation. In other cases, industry employees perform the technical aspects of the device check at the request of the doctor claiming the MBS item. Precise data on the relative mix of how these routine device checks are performed is not available. Data on the extent to which industry is involved in these device checks has been requested from the MTAA/device companies.

While it is common for the industry representative performing the technical aspect of the device follow up, it does raise some potential issues. It contravenes the Heart Rhythm Society position statement that states that “IEAP should not be used as unpaid employees of a physician’s practice or routinely assume administrative functions, such as routine retrieval of patient information or enrolling patients in remote monitoring systems[3]”. This situation discourages efficient use of services.

The MTAA suggests that there is little incentive to encourage the medical practitioner to plan and use the industry resources in an efficient fashion when there is no direct cost of the service to the doctor. Cardiac device representative members of the IWG are aware of many instances where industry has been requested to perform a single device check at geographically remote locations or where a series of checks during a single day are widely spaced over the day reducing the time efficiency of the IEAP providing the service.

Finally, the MTAA suggests that the provision of technical services by industry has allowed doctors not proficient in device follow up to undertake these services and claim the MBS item number. The CSANZ have guidelines on its website that outline minimum training and ongoing case load for individuals performing device follow up services.

It is the medical devices industry's view that the current situation of industry support has possibly unintentionally enabled individuals without expertise in cardiac technical services to perform device follow up. The MTAA industry highlights that it is not industry's responsibility to know or enforce physician competency in relation to specific training or ongoing continued professional development.

The MTAA has proposed that options for monitoring and ensuring adherence to CSANZ guidelines should be considered. This is out of scope of this Industry Working Group.

Another issue affecting routine device interrogation is the emergence of remote (home) device monitoring. This is discussed at length further in this paper below. With remote monitoring (RM) the information from the cardiac device can be transmitted automatically to a central server via wireless communication with the implanted device. While this service initially used an industry supplied dedicated electronic device/monitor, the technology is rapidly moving towards an app-based system where the patient's own smartphone or tablet transmits the information.

Currently, around 10 per cent of pacemakers have used the remote monitoring (RM) MBS item for billing (Medicare Statistics, 2016/17) but it is anticipated that this percentage will increase. The use of RM can reduce or eliminate the need for scheduled in-clinic/ hospital visits.

Industry identified that the provision of assistance at scheduled device follow-up visits was a significant issue for the company representatives. This was particularly so when the requests were made at short notice, where there was significant travel time for the technicians and where the organisation by the requesting doctor was haphazard.

Industry also identified the fact that it was difficult to refuse doctors' requests for service particularly in a commercially competitive environment and where the ability or not to provide these services may be seen as a factor in the doctor's choice of device brand.

It is apparent that industry has already instituted change in its approach to provision of these services. The use of universal/automated monitors that can perform a device check (similar to a remote monitor) is one mechanism that has been instituted in higher volume clinics. This allows a device check without the need for a technician to attend in person.

Any proposed solution to the manner in which routine device follow up is performed and funded needs to take into consideration:

1. To what extent the current MBS funding is sufficient to cover the cost of providing the services.
2. The current workload of the industry in this service. Industry data appears at Annex 1.
3. Any solution should encourage efficient use of resources.
4. That, at all times, the relevant doctor (as defined above) is responsible for direct supervision of the service, for interpretation of the results and deciding upon any treatment or device programming changes required.
5. That future (and current) technology will have a significant impact on the way in which these services are delivered.

Summary of Industry Comments

Minimum frequency of device checks is an established element of best practice. The extent to which such services can be performed competently by physicians varies and depends upon their individual training.

No agreed method exists for ensuring that cardiac physicians meet CSANZ guidelines for training in cardiac device management. Aligning service provision and funding with competence will assist in addressing the service burden.

To ensure that only individuals meeting the CSANZ guidelines on minimum training and ongoing case load perform device follow up services, the MBS item/s for follow up services could be linked to some patient eligibility criteria, professional training requirements, ongoing case load for individual doctors and facility requirements – this may be through an 'explanatory note' to the MBS item that gives guidance to the doctor on their use of the MBS item.

Unscheduled CIED services

There are a number of instances where a device check or reprogramming may be requested outside of the framework of routine follow-up. The circumstances where this may occur include:

1. CIED interrogation when a patient attends an emergency service with symptoms suggesting device malfunction or significant arrhythmia.
2. Device programming for the performance of MRI scanning.
3. Device programming to allow the use of specialised surgical or procedural equipment such as electrocautery at the time of surgery/medical interventions.
4. Inactivation of ICD therapies prior to autopsy/device removal in a deceased patient.
5. A list of services provided by industry professionals over a representative period is included at Annex 1.
6. The device companies identified that continuing to provide these services has become particularly problematic in the environment of reduced Prostheses List benefits for a number of reasons:
7. Industry is expected to and does provide the vast majority of these services in the private sector.
8. The request for these services is unpredictable and/or with little forewarning.
9. The device companies are expected to provide a 24-hour roster of appropriately

trained individuals.

Information as to the volume of these services and therefore the magnitude of the workload to the device companies has been provided by MTAA. As there is no MBS item number for these services, the Medicare statistics do not provide this information.

The volume of the unscheduled CIED services that required the attendance of an IEAP should intuitively be falling. This should be due to a number of changes to practice and changes in technology. However, it is the MTAA's view that if new technology is not encouraged to be used and changes in practice are not uniform, there is significant potential for this type of unscheduled service to increase due to the increasing patient population with cardiac devices. An example of a common change in practice would be that, in the past the majority of anaesthetists/surgeons would request that a patient with an ICD in place have the device formally inactivated prior to operative procedures that required the use of electrocautery.

This would require a technician attending prior to surgery and then again postoperatively to reactivate the therapy functions of the ICD. In the majority of cases deactivation of an ICD at the time of surgery is now performed by the anaesthetist applying a magnet to the ICD. This temporarily inactivates the high energy therapy function of the ICD until the magnet is removed. In a small proportion of cases a technician's involvement is still requested and/or required.

In the situation of a patient attending the emergency department and requiring an interrogation of their CIED new technology is reducing the requirement for an industry representative (or other technician) to attend. All new CIED's (and many of the older models) have the facility for remote interrogation of the device via a monitor situated in the emergency room or via a hand-held monitor/smartphone in the patient's possession. In the case of CIEDs with this facility the emergency room staff or patient can initiate an interrogation of the CIED with the subsequent information being transmitted to the doctor managing the patient via email, SMS or facsimile.

MTAA notes that while the IEAP may no longer be required to attend the hospital for such cardiac device interrogations, there are still costs and time involved in maintaining these services. Often there still needs to be a 24hr call centre for potential troubleshooting or assistance with interpretation of interrogated data and some companies provide technical assistance with all emergency department remote transmissions. The cost of the remote monitoring systems, IT infrastructure, data storage and management should also be considered as discussed earlier.

Patients with an MRI compatible device generally require their CIED to be programmed to an 'MRI safe' mode prior to the performance of the MRI scan. To date the radiology firms have requested the attendance of the technician to perform this service on an ad- hoc basis and with little warning to the individual performing the service. A number of changes are occurring in this area.

Some CIEDs can be programmed into the safe mode by the patient or MRI staff using a specialised hand-held device. Some companies are developing technology that allows the CIED to automatically detect the MRI environment and perform the reprogramming automatically.

In addition to these technological changes many radiology firms and the device companies are collaborating to establish specific sessions/times that individuals with CIED requiring an MRI attend. By dedicating specific session times for individuals with CIEDs the IEAPs workflow can be optimised and better planned. There have been cases where industry have charged the MRI centre for service of unscheduled scans that cannot be allocated to an agreed scheduled service window.

It is clear that there are many changes occurring in CIED technology/medical practice that are affecting the need for industry representatives to be involved in the provision of unscheduled CIED device interrogation/reprogramming. This aside, currently and in the near future industry will still be expected to provide the bulk of these services.

At present there is no direct reimbursement linked to the provision of these services. Many of the services are of a purely technical basis and do not necessarily require a high level of training (as compared to troubleshooting device malfunction or programming changes to individualise devices for each patient's clinical circumstance). As with other CIED services, the current presumption by most clinicians is that these services are provided by industry as part of their routine support of their products and the funding incorporated into the price the device company receives at the time of supplying the CIED.

The MTAA/industry representatives on the working group had identified the ongoing provision of these unscheduled services as one of the major issues facing them in the environment of reduced benefits to cardiac devices. A number of issues would be relevant to consider in proposing a funding model for these services. These include:

1. The extent to which the new levels of reimbursement should suffice to cover the ongoing provision of CIED services by industry. Although the new rebates for CIEDs represent a significant reduction they remain comparable in many other jurisdictions.
2. Whether there is precedent for reimbursement of these services on a case-by- case basis. There is no evidence that such reimbursement exists in other markets with comparable CIED implant rates.
3. Any reimbursement would need to reward the individual/company providing the service.
4. There would need to be a system in place to ensure the appropriate training and credentialing of individuals if public funding was to be considered for these services.
5. A system that does not incentivise inappropriate use of these services would be an important element.

At present it is difficult for the IWG to advance any further discussions about the funding and provision of unscheduled CIED services for a number of reasons, including a lack of clarity around which services industry would be unable to support in the environment of reduced reimbursement of its products.

In addition, data presented in Table 1 (in Annex 1) about the need and volume of the various unscheduled CIED services is informative to assess the magnitude of the current problem and any potential solutions.

Summary of Industry Comments

The increasing installed base of Australians living with CIEDs will increase the need for ad hoc cardiac services in a variety of conditions.

Industry continues to provide these services which facilitate other healthcare services, including diagnostic imaging, surgery, and palliative care. In particular, industry provides these services in regional areas where hospital services may not choose to invest in their own technical professionals.

On-call services will remain necessary. Changes in technology and healthcare practice (e.g., MRI tolerance) may reduce the requirement but will not eliminate it. Accredited technical professionals are needed throughout the healthcare system to ensure Australians with CIEDs can undergo other healthcare procedures without risk to their CIED. At present industry provides this service over the country without compensation.

CSANZ in collaboration with MTAA should provide guidelines to its members on the range and definition of unscheduled services, and the role of IEAPs supporting these services. The guidelines should outline services that are not the responsibility of IEAPs and the extent these services may be provided by cardiologists, facility employees or a third-party

Remote Cardiac Monitoring

Over the last 15-20 years evolution of device and communication technology has allowed device checks that were done manually in-office to be performed automatically by a monitor installed in the patient's home. The data is then sent to the physician via the cellular network. This is all done without any specific action by the patient. This technology has been labelled remote cardiac monitoring.

While not all legacy (older) devices can access this technology that all newly implanted devices and many devices implanted over the last decade or more can, there is data to suggest that not only does this technology reduce the requirement of patients with CIED to present for in-office device checks, but it may result in improved patient outcomes and improved survival. Patients enrolled in remote monitoring require fewer in-clinic visits which therefore provides potential to reduce the burden of in-person follow up to clinic personnel and industry. However, consideration still needs to be made for the support of the remote services that industry provides, as previously discussed. Many physicians would consider that remote monitoring is the gold standard for device follow up.

Remote monitoring enables real-time insight into device performance and clinical signals from the patient, which can improve a patient's response to an implanted device. However, remote monitoring can add to the aggregate service burden. To ensure this outcome for patients, remote monitoring can require more frequent intervention than devices without the capability. While the specific remote interventions by companies are done more efficiently – by telephone or electronically – the initial burden of screening signals, alerting physicians and addressing alarms requires uncompensated time and labour by industry representatives.

While remote monitoring may reduce the burden of in-clinic/ hospitals CIED checks it requires its own infrastructure and resources. Remote monitoring was subjected to a MSAC review in 2008 and then in 2012. Public funding was recommended in 2014. At that time MBS item numbers for the provision of remote monitoring were created. These item numbers provide reimbursement to the physician responsible for providing the service to the patient. At the same time the physical monitoring device was added to the Prostheses List and a benefit created. The benefit was designed to cover the cost of the monitor itself and the other infrastructure required for home monitoring.

At present, patients are given the opportunity to participate in remote monitoring by the physician implanting and/or following up their CIED. Despite the advantages to remote monitoring the uptake has been slow. Currently around 10 percent of pacemakers and 20 percent of ICDs have used the remote monitoring MBS item for billing (Medicare statistics, 2016/17). It is anticipated that the proportion of patients participating in remote monitoring will increase over time.

While there are funding sources for remote monitoring, there are limitations to the current arrangements. The MBS fees for remote monitoring can only be claimed by a physician. In some instances, the triaging of the information received from home monitoring is performed by technicians employed by the doctor claiming the Medicare rebate. In other instances, industry employees perform much of the processing of the information and the relevant information is then passed on to the treating doctor. MBS statistics for RM are at Annex 2.

The MTAA notes that another limitation and a current issue for doctors impacting their ability to reduce unnecessary clinic visits and adopt remote monitoring for their entire patient population is patient access to a remote patient monitor as part of the Remote Monitoring System on the Prostheses List. The current funding model means the only reimbursed access to a patient monitor is at the time of device implant, meaning patients implanted prior to November 2015 have not had access remote monitoring. To provide all appropriate patients with access to the remote monitoring system, reimbursement options should be considered without the need for hospital admission for those people who received a CIED before November 2015 or were not provided with the option to commence using remote monitoring at time of CIED implant.

To date, industry has performed remote monitoring assistance without cost to the doctor. This may have induced an incentive for physicians to rely on industry support rather than training and employing their own staff. Industry involvement in the remote monitoring process allows the device companies access to a large amount of data that may be useful in assessing the performance and reliability of their products which assists in quality assurance and product development opportunities.

As discussed above there are other incentives for industry to support remote monitoring – it may obviate the need for industry employees to physically attend patients that require interrogation of their device such as when they attend an emergency room. Industry was not clear as to whether the current arrangements for remote monitoring were acceptable. There has been a request to the Department of Health for the benefit on the remote monitor itself to be excluded from the benefit reductions.

The current arrangements for the funding of industry's role in remote monitoring include a number of issues. At present the device supplier receives a sum of money on provision of the monitoring device. The fee established was designed to cover some of the cost of providing the remote monitoring infrastructure such as the computer resources required to store the data received from patients and staff processing the data.

This cost is amortised over many thousands of patients. There is data to suggest that only a small proportion of patients who receive a remote monitor establish and maintain a connection to the monitoring network. Industry receives the benefit whether the monitor is connected or not. As technology advances industry is moving away from supplying a dedicated monitoring device to a system where the patient utilises their own smartphone/tablet and a dedicated app downloaded to their own device.

Currently, patient monitors used in the home are included on the Prostheses List, but as technology evolves, the physical monitor will be replaced with 'app-based remote monitoring' that enables the transmission of CIED data to the remote monitoring network using a smart phone or tablet (for patients that prefer this method for connecting to the remote monitoring network) .

MTAA notes that reimbursement for this technology should be available given it provides the same function and outcome for patients, along with the potential for improved user experience, and enhanced and more efficient patient engagement with their doctors. In addition, the backend systems and infrastructure (databases, servers, websites, etc.) which are necessary to connect the patient and doctor to the network are all ongoing costs being borne by industry, as is the significant cost of developing and maintaining app-based solutions.

MTAA suggests that an option to address this issue, as well as access to the remote monitoring system for people receiving a CIED before November 2015 could be for industry reimbursement for the Remote Monitoring System to be provided when a patient is enrolled and connected to the home monitoring system, instead of linking reimbursement to when a patient is provided with a physical monitor following hospital admission for the CIED implant.

It would seem that moving forward, funding of remote monitoring should be linked more closely to the provision of the monitoring service rather than the provision of a physical device. There is a specific item number claimed by the physician who provides the remote monitoring service. This requires a minimum number of data downloads and assessment by the physician. Linking the reimbursement to the physician item number claims may overcome some of the current and future issues.

Recommendation

2. That consideration be given to revising the reimbursement arrangements for remote monitoring to optimise uptake.

Summary of Industry Comments

Remote cardiac device monitoring offers the potential to reduce the need for in-person device checks. However, with the growth in the number of CIEDs the volume of remote monitoring services will increase. Remote monitoring constitutes close to 40% of total industry provided services.

The current MBS 'fee for service' funding model financially incentivises dual reimbursement for both remote monitoring as well as in-person follow-up, rather than encouraging a model which balances remote and in-person patient management to maximise quality of patient care in the most efficient manner. **The Department notes that MBS does not allow claiming of remote monitoring and in-person follow-up*.

To date, some physicians have relied on industry as the first point of contact for addressing issues identified through remote monitoring.

To provide all appropriate patients with access to the remote monitoring system, reimbursement should be considered without the need for a hospital admission for those people who received a CIED before November 2015 or were not provided with the option to commence using remote monitoring at time of CIED implant.

As technology evolves to include 'app-based remote monitoring' that enable the transmission of CIED data to the remote monitoring network using a smart phone or tablet, equivalent reimbursement for this technology should be available.

Industry have to date managed to minimise the effects of reduced prostheses rebates on the provision of CIED technical services. It is likely that any further reduction in reimbursement may have more profound effects on the ability to provide these technical services.

References

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Industry Data on Cardiac Services

The impact that industry has on remote monitoring services varies from company to company. Most companies assist with remote follow-up from an administration perspective at least, others also provide technical review of data that is obtained. The process by which each company provides this service is varied. Again, the majority of remote follow-up, for CIED patients, has industry involvement.

Aggregated industry data (Table 1) collected over a six-week period in 2019 demonstrates the significant service burden for clinically necessary support services provided by IEAPs:
Table 1: Count of services provided by IEAPs in a six-week period

Aggregated Cardiac Services Data covering a six-week period			
	Type of Follow-Up Service Request	**Total (Six Weeks)**	**Weekly Average**
1	Day 1 Post-Implant Check	1,794	299
2	Doctor Room Clinic/Check	19,419	3,236
3	Hospital Device Follow-up Clinic	5,857	976
4	Ward Check	892	149
5	Emergency Department Check	426	71
6	MRI Check	365	61
7	Radiation Oncology Check	145	24
8	Pre Op/Theatre Check	169	28
9	ICU Reprogramming	43	8
10	EP Procedure Reprogramming	95	16
11	Nursing Home Check	28	5
12	Palliative Reprogramming	26	4
13	Morgue/Funeral Check	4	1
14	Remote Monitoring Transmission Review	19,579	3,263
	Total	**48,842**	**8,140**

The aggregated industry data collected over the six week period in 2019 suggest that approximately 49,000 services are provided to patients over a 12 month period. Of these services around 95 per cent (46,000) are scheduled or planned services. The majority of the scheduled checks are either remote monitoring services (19000) or in office/hospital routine device follow up services (25,000). Under the current arrangements there is some funding for these services.

For remote monitoring the device company receives a payment for the provision of a remote monitor system at the time of device implant. The reimbursement amount for provision of the remote monitoring system is designed to cover the monitor as well as the infrastructure that supports remote cardiac monitoring. Physicians receive a fee from Medicare for the provision of remote monitoring services paid on an annual basis. One of the recommendations of the working group is that the mechanisms for ongoing funding of remote monitoring be considered to continue to encourage uptake of this service and to maintain its financial viability.

For the in-office/hospital checks there is a Medicare item number paid to the physician who supervises these services. The fee is for the interrogation of the device and the interpretation of the data. The physician claiming the Medicare fee takes responsibility for all aspects of this service. Any assistance by an IEAP is of a technical nature. Increasingly the device interrogation can be performed by on demand device monitoring systems (provided by the cardiac companies) placed in the office/hospital and the results electronically transmitted to the physician without the need for an IEAP to be present. A separate fee for the IEAP to provide these services seems unlikely to be introduced. If this was to occur there would be a perverse disincentive for physicians to provide this service themselves or to train and employ staff to undertake this service for them. Device companies are permitted to charge physicians for providing the technical aspects of device follow up.

The remainder of the CIED services (five per cent) fall largely into the category of unscheduled or unpredicted services. These are more problematic for the device companies in terms of planning/scheduling. These do however represent a small proportion of total services. Industry has been proactive in introducing measures provide these services efficiently and without the need for direct involvement of an IEAP. For example, most post radiotherapy checks can now be performed at the radiotherapy centre utilising a universal monitor. This is also possible for device checks performed in emergency departments. While technological advances are unlikely to eliminate completely the need for an IEAP to attend on short notice to perform a device interrogation it would seem likely that this demand will continue to fall. The industry data collected in 2019 could form a basis for future evaluation of the demand for these services.

Annex 2

Medicare Benefit Schedule Remote Monitoring – MBS Items

There are four remote monitoring items on the MBS:

Item No	Description	Fee	Benefit
11719	IMPLANTED PACEMAKER (including cardiac resynchronisation pacemaker) REMOTE MONITORING involving reviews (without patient attendance) or arrhythmias, lead and device parameters, if at least one remote review is provided in a 12 month period. Payable only once in any 12 month period	$67.90	75% = $50.95 85% = $57.75
11720	IMPLANTED PACEMAKER TESTING, with patient attendance, following detection of abnormality 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.	$67.90	75% = $50.95 85% = $57.75
11725	IMPLANTED DEFIBRILLATOR (including cardiac resynchronisation defibrillator) REMOTE MONITORING involving reviews (without patient attendance) of arrhythmias, lead and device parameters, if at least 2 remote reviews are provided in a 12 month period. Payable only once in any 12 month period.	$192.55	75% = $144.45 85% = $163.70
11726	IMPLANTED DEFIBRILLATOR TESTING with patient attendance following detection of abnormality 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.	$96.25	75% = $72.20 85% = $81.85

Remote Monitoring MBS: claims processed from July 2015 to June 2020

	Total Services Per Item No			
	11719	**11720**	**11725**	**11726**
2015-16	3,939	252	2,844	242
2016-17	7,987	717	5,647	575
2017-18	11,178	868	6,939	582
2018-19	15,972	675	8,767	461
2019-20	22,700	964	11,347	574
5 year total	**61,776**	**3,476**	**35,544**	**2,434**

Annex 3

Prostheses List – Remote Monitoring Benefit Amount

Remote Monitoring – Listing Categories				2016[1] Benefit Amount	2020[2] Benefit Amount
Part C	08 - Cardiac	08.16 - Remote Monitoring System	08.16.01 - Remote Monitoring System	$1,960	$1,450

1 Based on the September 2016 Prostheses List.

2 Based on the November 2020 Prostheses List.