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TERRITORY GOVERNMENTS OF AUSTRALIA
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Horizon Scanning Technology Prioritising Summary Update

Remote monitoring systems for implantable cardiac devices

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PRIORITISING SUMMARY UPDATE 2008

REGISTER ID:	000061
NAME OF TECHNOLOGY:	REMOTE MONITORING SYSTEMS FOR IMPLANTABLE CARDIAC DEVICES
PURPOSE AND TARGET GROUP:	REMOTE MONITORING OF PATIENTS WITH PACEMAKERS AND IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

Since undertaking this Prioritising Summary update, it has come to the evaluator's attention that an MSAC assessment is currently underway (Application 1111) and was submitted to the MSAC in June 2008.

2008 SAFETY AND EFFECTIVENESS ISSUES

The retrospective study reported by Lazarus (2007) describes the results of a world-wide (23 countries) database of patients implanted with implantable cardioverter defibrillators (ICD), pacemakers and cardiac resynchronisation therapy (CRT) systems. Patients were also embedded with an antenna which enables the wireless transmission of data stored on the cardiac device. The Biotronik Home Monitoring™ device transmits data daily at a fixed time via the CardioMessenger™, a cell phone-like device.

A total of 11,624 patients were implanted with a device, of which 4,631 were pacemakers, 6,548 were ICDs and 445 had a combination of ICD and CRT. A total of 3,004,763 transmissions were made from all devices and the mean duration of monitoring was 10.5 ± 9.4 months (range 1 to 49 months). Transmitted events included medical event monitoring (eg atrial arrhythmias, ventricular arrhythmias), configuration monitoring (eg sensing/pacing functions, ineffective high voltage shock delivery) and system related events (eg battery status, high voltage lead impedance). Although over 60 per cent of patients implanted with a pacemaker had a medical event transmitted (the majority of these were episodes of atrial fibrillation), the mean number of events per month was 1.1. This low rate is reflected in the mean interval between follow-up visits which was 5.9 ± 2.1 months. Patients implanted with the combined CRT-D had the highest mean number of events per month (2.1) with a mean interval between follow-up visits of 1.9 ± 2.9 months. This reflects the severity of the illness of patients implanted with CRT-D and the complexity of the implanted device. The mean number of events per month for single and double chamber ICDs was low at 0.3 and 0.4, respectively, with the majority of events being associated with ventricular tachyarrhythmias. The mean interval between follow-up visits for patients implanted with single and double chamber ICDs was similar (3.6 ± 3.3 and 3.3 ± 3.5 months, respectively). The most important events reported for both types of ICDs was 66 alerts from 40 devices (1.3%) of abnormal function indicating the inactivation of the device and 271 devices (4.1%) delivering an ineffective shock. The rates of false

positive events could not be ascertained in this study. The authors conclude that the use of home monitoring may allow the detection of adverse events earlier than patients in standard care, who would undergo either quarterly or biannual clinical assessment (level IV intervention evidence).

The small study conducted by Ricci et al (2008) reported on the impact of home monitoring on the medical management of patients and health care resource utilisation. Patients were implanted with either a pacemaker (n=88), dual chamber ICD (n=18) or the combined CRT-D (n=11). In addition, implanted devices were equipped with the Biotronik CardioMessenger™ transmitter device which was programmed to transmit data on a daily basis as well as to transmit events such as those described in the previous study. Three pacemaker patients were excluded from the study due to inadequate network coverage in the home, which made report transmission impossible. Patients were followed-up for a mean of 227 ± 128 days (range 3-426 days). Three patients died from events unconnected to the implantation of the device (stroke, kidney failure and refractory heart failure) and one patient had the device removed due to infection. In addition, three patients needed to have the CardioMessenger™ device replaced due to malfunction.

A total of 167 in-hospital visits were required by the remaining 114 patients, of which 53 were unscheduled follow-ups due to alerts transmitted by home monitoring. Of these 48/53 (90.6%) were due to medical reasons and five (9.4%) were due to device transmission interruptions. A change in drug therapy was recommended in 29 of these cases, a reprogramming of the device in 12 cases, further diagnostic tests in six cases and one case of hospitalisation for impending heart failure. The authors estimated that approximately 200 in-hospital visits would be expected for the equivalent patient group without home monitoring. In 32 patients there were 55 temporary interruptions of message transmission (≥ 5 consecutive days) due to technical problems including the inadvertent switching off of the device or inadequate network coverage (37/55, 67%). During the follow-up period a total of 25,210 reports were received, of which 1,665 (6.6%) were alert events. A dedicated nurse and a physician spent an average of 59 and 12 minutes per week analysing home monitoring data. The nurse referred 133 critical cases in 56 patients to the physician for assessment. The diagnosis in these cases was atrial fibrillation (47%), impending heart failure (10%), ventricular tachyarrhythmia (9%), unsustained ventricular tachycardia (7%), inappropriate ICD intervention (4%) and suboptimal device programming (23%). The average connection time per patient was 115 ± 60 seconds. In summary, the authors conclude that home monitoring of cardiac devices may impact positively on the clinical management of patients by the early detection of device failure or life threatening cardiac events. In addition, home monitoring may also reduce the number of clinic visits per patient, however cost-savings in this regard would need to be offset by the costs of implanting and maintaining the home monitoring device (level IV intervention evidence).

The study by Heidbüchel et al (2008) reported on the results of 169 patients implanted with an ICD. A total of 1,739 clinical visits were required, of which 1,530 (88%) were scheduled. The proportion of clinical or device related events requiring action was significantly higher during unscheduled visits (earlier than planned) than during scheduled visits (80.6 vs 21.8%, $p < 0.0001$). Reprogramming of the device and the hospitalisation rate was also higher during unscheduled visits compared to scheduled visits (33.1 vs 4.0%, $p < 0.0001$ and 18.3 vs 2.0%, $p < 0.0001$, respectively). Remote monitoring was found to correctly *exclude* device function abnormalities or arrhythmic problems in 82.2 per cent of evaluations, but could correctly identify an arrhythmic or a device related problem in 15.3 and 2.1 per cent of evaluations, respectively. Home monitoring missed problems with pacing in 0.46 per cent of evaluations (level IV intervention evidence).

Similar findings were reported by ¹⁻⁷.

2008 DIFFUSION

Several centres around Australia are implanting and monitoring these devices in the absence of an MBS item number. Approximately 100 patients have been implanted in Perth and at least 20 patients in the Eastern states. Although network coverage may still be an issue for some patients in rural and remote Australia, patients from these areas are not precluded from implantation as the devices can store information for up to one month. Therefore, as long as patients in remote areas can access a larger, regional centre every 30 days, the device may still provide important information to the cardiac specialist without the need for the patient to travel to a city centre (personal communication Biotronik).

2008 OTHER ISSUES

Two large clinical trials are currently underway assessing the use of remote monitoring for ICDs and pacemakers.

The TRUST study is a multicentre, randomised study of 1,000 patients implanted with the Biotronik Lumos or Lumax ICD. The study commenced in late 2005 and should have been completed by July 2007, with results expected to be published in 2009. It is expected that 1,000 patients will be randomised in a 2:1 ratio to receive standard care post ICD implantation, or home monitoring. Patients are to be followed up for 15 months \pm 30 days. Standard care or control patients will have the home monitoring function of the device switched off and will undergo office/ clinic based interrogations of the device every three months. Notifications from the home monitoring patients would include events such as ventricular tachycardia, ventricular fibrillation and supraventricular tachycardia. The TRUST study aims to reduce the number of office-based device interrogations and to detect significant cardiac events which would otherwise go undetected (Varma 2007).

The PREFER trial is a multicentre, randomised trial of patients implanted with a Medtronic Kappa[®], EnPulse[®], Adapta[™] or Versa[™] pacemaker device. This study enrolled 980 patients between May 2004 and March 2007 and hopes to follow-up all patients for 12-months. Patients were randomised in a 2:1 ratio into remote monitoring and control groups. Control patients do undergo transtelephonic monitoring (TTM) of the pacemaker device, however this is used primarily to monitor the life of the battery. Cardiac event data (ventricular tachycardia, silent atrial fibrillation, early volume overload and lead fractures causing inappropriate shocks) are not downloadable during TTM and require an “interrogation” of the device. The aim of the trial is to assess whether clinically actionable events can be identified early resulting in positive health outcomes for patients. Patients are required to transmit information from the pacemaker device every 3, 6 and 9-months followed up by a 12-month office/ clinic visit. The control patients are required to transmit TTM data at 2, 4, 6, 8 and 10-months followed up by an office/ clinic visit at 12-months (Chen et al 2008).

2008 SUMMARY OF FINDINGS

Three case series were included for assessment in this Prioritising Summary update, with an additional two case series reporting similar results. All reported the potential of home monitoring to reduce the number of clinical visits required by patients implanted with cardiac devices, which may impact on the health care costs. The study by Fauchier et al (2005) included in the original Prioritising Summary reported that remote monitoring would become cost-saving if two follow-up visits per year were avoided during an average follow-up period of 34 months. A full cost-effectiveness analysis is still required to fully ascertain the cost of running a large-scale home monitoring programme. Remote monitoring was successful in detecting device malfunction and cardiac events which otherwise may have gone unreported. Patient selection issues were also raised as patients living outside of a functioning network were implanted with the device.

2008 HEALTHPACT ACTION:

The MSAC recently completed a systematic review on the use of remote monitoring systems for ICDs therefore HealthPACT has recommended that no further assessment

2008 NUMBER OF INCLUDED STUDIES

Total number of studies	
Level IV intervention evidence	3

2008 REFERENCES:

Chen, J., Wilkoff, B. L. et al (2008). 'Design of the Pacemaker REmote Follow-up Evaluation and Review (PREFER) trial to assess the clinical value of the remote pacemaker interrogation in the management of pacemaker patients', *Trials*, 9, 18.

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- Ricci, R. P., Morichelli, L. & Santini, M. (2008). 'Home monitoring remote control of pacemaker and implantable cardioverter defibrillator patients in clinical practice: impact on medical management and health-care resource utilization', *Europace*, 10 (2), 164-170.
- Varma, N. (2007). 'Rationale and design of a prospective study of the efficacy of a remote monitoring system used in implantable cardioverter defibrillator follow-up: the Lumos-T Reduces Routine Office Device Follow-Up Study (TRUST) study', *Am Heart J*, 154 (6), 1029-1034.

PRIORITISING SUMMARY 2006

REGISTER ID: 000061

NAME OF TECHNOLOGY: REMOTE MONITORING SYSTEMS FOR
IMPLANTABLE CARDIAC DEVICES

PURPOSE AND TARGET GROUP: REMOTE MONITORING OF PATIENTS WITH
PACEMAKERS AND IMPLANTABLE
CARDIOVERTER DEFIBRILLATORS

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed
indication or
modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|---|-------------|--------|
| <input checked="" type="checkbox"/> Yes | ARTG number | 122545 |
| <input type="checkbox"/> No | | |
| <input type="checkbox"/> Not applicable | | |

The Home Monitoring[®] System by Biotronik is the only remote monitoring system currently available in Australia. The system received TGA approval in early February 2006.

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States		✓	
Europe		✓	

IMPACT SUMMARY:

This prioritising summary examines the use of remote monitoring systems for patients with pacemakers and implantable cardioverter defibrillators. Three of the more prominent systems are examined; the Carelink[®] Network by Medtronic, the Home Monitoring[®] System by Biotronik and the Housecall Plus[™] Remote Patient Monitoring System by St. Jude Medical.

BACKGROUND

The management of cardiovascular disease has become increasingly reliant on the use of implantable cardiac devices. Pacemakers, bi-ventricular pacemakers and implantable cardioverter defibrillators (ICDs) have become common options for the

treatment of heart failure and irregular heart activity. At present, patients with implantable cardiac devices require regular visits to outpatient clinics so that practitioners can check on device performance and monitor for instances of cardiac arrhythmia. Unscheduled visits may also be necessary to investigate device dysfunction, or symptoms that may or may not be related to the implanted device. The main disadvantage of intermittent visits to an outpatient clinic is that device dysfunctions are often identified slowly, which can lead to possible emergency situations. Changes in the frequency of arrhythmic events may only be discovered weeks or months after they occurred, resulting in delayed changes of medication for the patient or delayed adjustments to their implanted device.

The problems associated with the intermittent monitoring of implantable cardiac devices have prompted a number of companies to develop remote monitoring systems. Remote monitoring systems are designed to provide practitioners with important data from the implantable device with little or no time delay. Potential advantages of these systems include the timely reporting of arrhythmic events and closer monitoring of device status which may improve longevity. In terms of efficiency, remote monitoring systems have the potential to reduce total follow-up time in clinics and lower patient transport costs. They may also be important in the discovery of new disease processes (Schoenfeld et al, 2004).

Of the remote monitoring systems that have been developed, three of the more prominent systems are the Carelink[®] Network by Medtronic, the Home Monitoring[®] System by Biotronik and the Housecall Plus[™] Remote Patient Monitoring System by St. Jude Medical.

Carelink[®] Network by Medtronic

The system allows patients to gather and transmit information about their implantable cardiac devices using the portable Carelink[®] Monitor. Data read in by the monitor are transmitted to the Medtronic Carelink[®] Network using a standard telephone line, where practitioners can view the data on a secure Internet Web site. The information, which is comparable to the information gathered in a typical follow-up visit, provides the clinician with a detailed summary of how the device and patient's heart are working. The Carelink[®] Network also provides a secure Internet Web site for patients to access personalised information about their device and condition.

The Carelink[®] Network is FDA approved to support a wide range of Medtronic implantable devices, and is widely used within the United States.

Home Monitoring[®] System by Biotronik

The system involves a new type of implantable device which transmits data via radio waves to a mobile-phone like device known as a CardioMessenger[®]. In turn, the CardioMessenger[®] relays this information to a service centre via a digital mobile network. The information can then be forwarded to practitioners for review via fax (referred to as a Cardio report) or the Internet. Transmissions from an implant are initiated automatically once daily when no unusual events are taking place, but may also be transmitted at other times such as immediately after a relevant device-related or physiological event takes place (such as a silent arrhythmias or an asymptomatic device change). In the case of a potential emergency situation, the practitioner is notified immediately. The Home Monitoring[®] System is the only remote monitoring

system in which the transmission of data requires no action by either the patient or practitioner.

The FDA, TGA and CE approved Home Monitoring[®] System is compatible with a number of Biotronik implantable devices, and is commercially available in Australia, Europe and the United States.

Housecall Plus[™] Remote Patient Monitoring System by St. Jude Medical

The Housecall Plus[™] system consists of a small transmitter, about the size of an answering machine, which connects to a standard telephone line and electrical outlet. Information is transmitted to a receiver, which may be located in the office of a practitioner or at a specialised monitoring centre. Information available to medical professionals includes real-time and stored electrograms, surface ECGs, delivered therapies and a variety of device related settings. Medical professionals can communicate this information to patients, or guide them through the transmission process, using a speakerphone built in to the transmitter. The transmission of data is not automated however, and must be initiated by either the patient or the medical professional.

The FDA approved Housecall Plus[™] is currently compatible with St. Jude Medical Atlas[®], Epic[™] and Epic[™]+ families of ICDs, and will be enabled to function with all future St. Jude Medical implantable devices.

CLINICAL NEED AND BURDEN OF DISEASE

The primary candidates for implantable cardiac devices are people who have experienced or are at a high risk of experiencing heart failure (pacemakers), and people at risk of sudden cardiac death due to ventricular fibrillation (ICDs). In 2003-2004, 9346 pacemakers were implanted in patients in Australian public hospitals, the procedure associated with an average length of stay of 4.3 days (AIHW, 2005). A further 3222 separations that year involved the replacement or revision of pacemakers. Finally, 1101 ICDs were implanted in 2003-2004, with an average length of stay for patients of 8.5 days (AIHW, 2005).

DIFFUSION

Biotronik has only recently received TGA approval to market the Home Monitoring[®] System in Australia. While the Carelink[®] Network and the Housecall Plus[™] Remote Patient Monitoring System are both commercially available in Europe and the United States, it is unclear at this stage whether or not the respective companies will seek TGA approval to market in Australia.

COMPARATORS

In the absence of remote monitoring systems, patients with implanted cardiac devices typically undergo periodic evaluations at specialist outpatient clinics to ensure their implanted device is working optimally. In the event of device dysfunction, or symptoms that appear to be related to the implanted device, a patient may also need to make an extra unscheduled visit to the outpatient clinic. Evaluations often involve device interrogation by radio telemetry, which requires the expertise of an experienced programmer.

The main disadvantage of periodic evaluations is the overall lack of efficiency in the follow-up of patients. Device dysfunction may be identified weeks or months after the event, changes to medication schedules may be delayed, and patients may schedule unnecessary appointments for symptoms completely unrelated to their condition or device. While remote monitoring systems do not completely eliminate the need for visits to an outpatient clinic (patients still need to visit the clinic to have their device adjusted), they do offer important insight into when and how often a particular patient should be seen.

EFFECTIVENESS AND SAFETY ISSUES

A recent multi-centre study by Schoenfeld et al (2004) assessed the effectiveness and ease of use of the Carelink[®] Network in 59 patients with ICDs (level IV intervention evidence). In the study, patients were required to transmit data on two occasions, at least seven days apart, as scheduled by their clinic. Questionnaires were used to evaluate the functionality and ease of use of the monitoring system after each data transmission, and were completed by both patients and practitioners. Review of patient data during the study revealed a number of clinically significant findings, including the discovery of silent atrial fibrillation, atrial undersensing and ventricular tachycardia. Overall, more than 98% of the pooled patient responses indicated that the Carelink[®] Monitor was very easy or somewhat easy to setup and use. The majority of practitioner responses (96.5%) indicated satisfaction with the Internet site. Practitioners also indicated that on 96.5% of occasions the monitoring service allowed them to provide care comparable to a normal in-office visit.

The effectiveness of the Home Monitoring[®] System was investigated by Stellbrink et al (2003) in a multi-centre study involving 122 patients (level IV intervention evidence). In the study, device-related and physiological data were transmitted once daily for a period of three months. The primary outcome in the study was the percentage of successful transmissions amongst patients who were successfully monitored. Patients were considered to be successfully monitored when no more than three contacts were necessary to maintain monitoring, or if the longest interval without a message did not exceed 6 days. Six patients were considered failures because monitoring was unable to be established (believed to be due to non-compliance), and a further 21 were classified as failures during the course of the study. Of the remaining 95 patients who were successfully monitored, a successful transmission rate of 97% was reported.

A recent study by Joseph et al (2004) (level IV intervention evidence) investigated the effectiveness of the Housecall Plus[™] Remote Patient Monitoring System in a sample of 124 patients with single chamber ICDs. In the study, both patients and practitioners were able to adjust the frequency of data transmission depending on symptoms and device-related information. Data transmission continued for a period of six months. A total of 570 transmissions were received, data confirming the delivery of therapy for 54 ventricular tachyarrhythmia episodes, aborted therapy for 22 nonsustained ventricular arrhythmias and a further 30 episodes of nonsustained ventricular tachycardia. Patients indicated high levels of satisfaction with the remote monitoring system throughout the six month study period (93 – 99% satisfied), particularly in its ease of use and convenience. Interestingly, patients reported no changes in their quality of life during the study period.

COST IMPACT

Carelink[®] Network

During July 2004, Medtronic began charging \$30 (US dollars) for each transmission delivered to practitioners. If on average patients are sending three to four transmissions per year, the average cost to the practitioner would be \$90 to \$120 (US dollars) annually. The Carelink[®] Monitor adds to the overall cost of the service, but its specific price is currently unknown.

Home Monitoring[®] System

Specific costs for this system are not currently known, however another health technology assessment agency has reported that the mobile phone unit costs approximately £1,000, and that overall the system adds 10-15 per cent to the cost of the basic implanted device (NHSC, 2006).

Housecall Plus[™] Remote Patient Monitoring System

Specific costs for this system are not currently known.

Fauchier et al (2005) examined the potential cost savings associated with remote monitoring in the long-term management of patients with ICDs. Follow-up costs for 502 patients from six university hospitals within France were compared to expected follow-up costs after the addition of remote monitoring systems. For each visit to a clinic, a mean overall cost of \$215 was calculated, which included \$121 for transportation and \$94 for medical services (including practitioner's fees, electrocardiograms and ICD surveillance). The authors estimated that if remote monitoring reduced the number of visits by two per year, then over the five year expected life of the device follow-up costs would be reduced by a total of \$2148. After factoring in the cost of the remote monitoring system, estimated to be \$1200, a \$948 net saving was estimated. On average, these cost savings began after a follow-up time of 33.5 months.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

The Home Monitoring[®] System by Biotronik requires digital mobile coverage to be functional. As a result, the system may not be viable for patients who live in areas where mobile coverage is weak or unavailable.

OTHER ISSUES

At present, monitoring systems are only compatible with implantable cardiac devices of the same brand. To maintain cost effectiveness, it is likely that individual practitioners would need to adopt a preferred monitoring system rather than purchasing all the available systems.

RECOMMENDATION:

While the remote monitoring of implantable cardiac devices offers a number of potential benefits for patients and medical practitioners, a number of questions remain unanswered. At present, it is not clear whether these systems will be financially viable in Australia, to what extent they will reduce practitioner workload and whether or not problems in the transmission of data will result in serious negative health outcomes. Large scale randomised trials involving control groups are required to further assess the financial and clinical effectiveness of remote monitoring systems.

Based on the lack of high quality data regarding the effectiveness of remote monitoring systems, HealthPACT recommended that this technology be monitored.

SOURCES OF FURTHER INFORMATION:

AIHW (2005). *National Hospital Morbidity Database* [Internet]. Australian Institute of Health and Welfare. Available from: <http://www.aihw.gov.au/cognos/cgi-bin/ppdscgi.exe?DC=Q&E=/AHS/drg59899-0304> [Accessed 3rd January 2006].

Fauchier, L., Sadoul, N. et al (2005). 'Potential cost savings by telemedicine-assisted long-term care of implantable cardioverter defibrillator recipients', *PACE*, 28, S255-259.

Joseph, G. K., Wilkoff, L. et al (2004). 'Remote interrogation and monitoring of implantable cardioverter defibrillators', *Journal of Interventional Cardiac Electrophysiology*, 11, 161-166.

NHSC (2003). *Remote Monitoring of Implantable Cardiac Devices*, University of Birmingham.

Schoenfeld, M. H., Compton, S. J. et al (2004). 'Remote monitoring of implantable cardioverter defibrillators', *PACE*, 27, 757-763.

Stellbrink, C., Gill, J. S. et al (2003). 'Feasibility of remote monitoring of pacemakers with the help of home monitoring', Conference Proceeding: North American Society of Pacing and Electrophysiology, In: *Feasibility of remote monitoring of pacemakers with the help of home monitoring*.

LIST OF STUDIES INCLUDED

Total number of studies	
Level IV evidence	4

SEARCH CRITERIA TO BE USED:

*Defibrillators, Implantable
Telemetry/*instrumentation
Defibrillators, Implantable/*economics
Telemedicine/*economics