Cost efficiency and reimbursement of remote monitoring: a US perspective

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Demographic and technological changes are driving increased utilization of cardiac implantable electronic devices (CIEDs) remote monitoring. In the USA, fee-for-service model of healthcare delivery, services rendered are valued based upon time, intensity, and technical or practice expense costs. As a consequence of this perspective, and to contain spending, Medicare has grouped physician services into families. Spending within each family of services must, by law, remain budget neutral. Cardiac implantable electronic devices monitoring services, remote and in-person, are grouped into one family. As the volume of services within this family increases, the individual encounters are destined to be discounted into ever decreasing portions. However, if the value of remote monitoring is demonstrated to extend beyond the previous boundaries of in-person interrogations, a rational request can be made to reconsider the relative value of remote monitoring. Outcome data supporting the value-added benefits of remote monitoring are rapidly accumulating, including (i) patient convenience, with reduced use of office services, (ii) equal safety compared with in-person evaluation, (iii) shorter detection time to actionable events (arrhythmias, cardiovascular disease progression, and device malfunction), (iv) reduced length of stay for hospitalizations, (v) reduced inappropriate shocks, (vi) increased battery longevity, and (vii) a relative reduction in the risk of death. Fully automatic wireless technology, only recently widely implemented, will add considerable clinical efficiencies and further increase the value of remote monitoring. The U.S. challenge will be to appropriately define the relative value of CIEDs remote monitoring now that outcome data have demonstrated its value extends beyond in-person interrogation.

**Keywords**
Pacemaker • Defibrillation • Cardiac resynchronization therapy • CIEDs • Remote monitoring • Telemedicine • Pacemaker follow-up • ICD follow-up • Reimbursement • Relative value scale update committee (RUC) • RBRVS • Current procedural terminology (CPT) code set

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Background

Remote monitoring of cardiac implantable electronic devices (CIEDs) provides a new paradigm of healthcare delivery that will extend beyond the sphere of cardiac rhythm management as a diverse array of remote monitors and physiological sensors become clinically available. Demographic and technological changes are driving increased utilization of remote monitoring. This shift in the volume and the way we monitor CIEDs challenges the traditional models of cost and efficiency of care delivery and requires that we reexamine how we allocate manpower, physical space, and financial resources.

The US healthcare system has traditionally rewarded individual services rendered to a patient based upon the time, intensity, and technical or practice expense costs associated with the service. As a consequence of this perspective, and to contain spending, physician services have been grouped into families of services. Overall spending within each family is required to remain budget neutral. Cardiac implantable electronic devices monitoring services, remote and in-person, are grouped into one family. As the volume of services within this family increases, the individual encounters are therefore destined to be discounted into ever decreasing portions.

If the value of remote CIEDs monitoring is demonstrated to extend beyond the previous boundaries of in-person interrogations, a rational request can be made to reconsider the relative value of CIEDs monitoring. In the USA, this will require outcome measures to convincingly demonstrate that any increase in total CIEDs monitoring services is offset by a greater overall reduction in the healthcare resource utilization.

Volume

The volume of remote monitoring services is outpacing patient demographic and CIEDs implant growth alone. This is illustrated by data obtained at the Cleveland Clinic (Figure 1). Several factors
Contribute to this shift including technological innovations, practice guidelines, and updating of the reimbursement coding structure.

Technology: Key technology innovations have made it easier for the medical community to reach patients for whom device follow-up was previously too difficult. Technological improvements have lowered the barrier to implementation of remote monitoring, minimizing the burden on patients to set up, transmit, and schedule remote monitoring encounters. Wireless remote monitoring also increases the value proposition of remote monitoring, providing an early reporting mechanism of arrhythmias, device malfunction, and battery voltage status. Recent device alerts such as the Medtronic Sprint Fidelis recall and the St Jude Riata lead alert have highlighted the advantages of remote monitoring and resulted in increased clinical adoption.

Guidelines: Since the introduction of the first implantable pacemaker in 1958, the morbidity and mortality impact of the implantation of CIEDs among appropriately selected patients has been demonstrated without question. Yet, practice guidelines for appropriate frequency of in-office and remote follow-up evaluations, from the time just after implant until explantation or patient death, has only recently been addressed by professional consensus and review of published literature. Investigations to understand the optimal interval of device evaluation from a quality of care perspective to date have centred on the medical goals of CIED monitoring. These range from monitoring technical function of the hardware, evaluating disease-related data provided by the monitoring and recording functions of the device, to communication with the patient and managing the CIED in the broader context of an individual patient’s medical care. The Consensus document, published in June 2008, clarified for the medical community what the appropriate follow-up interval should be.

The need for such guidance is illustrated by a recent analysis of 38,400 Medicare beneficiaries who underwent implantation of a pacemaker (PM) or implantable cardioverter defibrillator (ICD) between 1 January 2005 and 30 June 2009. In 2005, prior to publication of the consensus document, only 40.3% of patients received follow-up within 12 weeks following implant. By 2009, the number increased to 55.1%. In 2005, 67% of ICD recipients were evaluated within 6 months, and by 1 year 93.9% of PM recipients received appropriate follow-up. These percentages remained relatively constant from 2005 to 2009. Overall, by 2009, 78% of the Medicare population had at least one in-person device evaluation.

Medicare has observed increased utilization of CIEDs follow-up encounter codes, and closer examination of the numbers reveal an important trend. In 2008, 1,324,500 Medicare beneficiaries received on average 3.7 follow-up CIEDs encounters per year. In 2009, the total number of CIEDs encounters for Medicare beneficiaries increased 7%, but the average number of follow-up encounters per beneficiary dropped to 3.0 (data source: Centers for Medicare and Medicaid Services, 2008 and 2009 carrier 5% standard analytic file).

Taken together these data indicate that the timing of publication of the practice guidelines corresponds with improved ratio of care delivery: while most Medicare patients continue to receive too few follow-up visits, overall a greater number are receiving care. Increased utilization of services by a minority is being reduced, as evidenced by a decrease in the average number of encounters per beneficiary between 2008 and 2009.

Reimbursement Coding: In the USA, all medical, surgical, and diagnostic services are identified in the Current Procedural Terminology (CPT) code set which is maintained by the American Medical Association (AMA). The CPT code set, first published in 1966, is updated by the Editorial Panel and is recognized by the Centers for Medicare and Medicaid Services (CMS) as level 1 of the Health Care Procedure Coding Set. As new procedures/services are developed professional societies (typically) will submit an application to revise the code set. The Editorial Panel meets three times per year and revised code sets are published by the AMA annually (October). The development of new procedures, writing of practice guidelines, updating of the CPT code set and assessment of relative work value units for each CPT code is a continuous cycle.
In November, 2008, coinciding with the Heart Rhythm Society (HRS)/European Heart Rhythm Association Expert Consensus document, the CMS approved a revised set of codes developed in conjunction with HRS/American College of Cardiology/AMA that more accurately reflected the services and associated work involved with in-office and remote monitoring of CIEDs. These codes distinguished the work of in-person device interrogation with/without reprogramming as well as transtelephonic vs. remote monitoring capabilities provided by emerging technology. The remote monitoring codes recognize the critical role of the allied professional by assigning a separate CPT code to cover the work of remote data acquisition, receipt and processing of the transmission, technical review and support, as well as distribution of the results. Added to the physician interpretation work value, described by a distinct CPT code, the revised physician fee schedule provides higher reimbursement for remote than in-person evaluation. To prevent overutilization, the codes may be used only once every 90 days.

Updating of the procedure codes, along with educational efforts to inform the physician community of the changes, likely contributed to the increased volume of remote and in-person CIEDs interrogations. The revised codes accurately reflect the added value of remote monitoring and the essential role of the allied professional, and should serve to increase utilization of remote monitoring.

Evidence supporting value of remote monitoring

Technological advances have fundamentally altered the ability of CIEDs to monitor physiological data (arrhythmias, heart rate trends, and heart failure) and to monitor the integrity of the hardware function (intrinsic amplitude sensing, pacing thresholds, impedances, as well as potential non-physiological signals suggesting a lead fracture). Wireless remote monitoring provides the tool to unleash these data. It provides daily if not real-time information to healthcare providers. The intermittent nature of office evaluation (or remote follow-up without interim monitoring) means that important events may go undetected for some time—in contrast to remote monitoring. An accumulating wealth of evidence indicates that remote monitoring of CIEDs is not only equally safe compared with routine in-person evaluations but it also appears to have many advantages.4–8 One study has even suggested that remote monitoring may result in a 50% relative reduction in the risk of death.9 The majority of in-person CIEDs evaluations result in acquisition of CIEDs data that lead to no change in patient management; these data are equally accessible by remote monitoring and the logistical burden to the patient and the healthcare system associated with an in-person evaluation yields no added value. European studies have demonstrated that 78% of scheduled ICD follow-up visits and 71% of PM in-person visits do not result in device reprogramming, medication changes, or other changes in patient management.7,10 These findings are supported by the TRUST study which reported that only 6.6% of scheduled 3-month ICD checks yielded actionable data.5 The advantages of remote vs. in-person CIEDs interrogation include significantly improved adherence to follow-up, earlier detection of actionable events, and reduced in-office visits.5–7 Although sensitivity of this detection technology was limited, the CONNECT study revealed that the median time from a clinical event to a clinical decision decreased from a median of 22 to 4.6 days between the in-person and remote arms of the study (P < 0.001).5 This reduction in time from clinical event to clinical decision in response to an arrhythmia, cardiovascular disease progression, or device malfunction was associated with a significant reduction in healthcare utilization. The length of stay for associated hospitalizations was reduced from a median of 4.0 days in the in-office arm to 3.3 days in the remote monitoring group (P = 0.002). Most recently, the ECOST trial demonstrated that remote monitoring reduced inappropriate shocks and preserved battery longevity.11

Resources utilization of in-person vs. remote monitoring

Remote monitoring provides the opportunity to improve efficiency and quality of CIEDs follow-up but transmissions must still be reviewed by physicians or appropriately trained allied professionals, when necessary office visits must be scheduled, generator replaced, and medications changed. The workflow patterns associated with remote vs. in-person CIEDS monitoring present a different challenge to the healthcare system.

A recent time and activity analysis from the Cleveland Clinic assessed how remote vs. in-person CIEDs monitoring affects the overall cardiovascular device clinic workflow.12 Detailed workflow data were prospectively collected by the registered nurse assigned to remote monitoring for 14 days, accumulating information on 500 transmissions. For comparison of the time taken to complete an evaluation, data were collected on 82 consecutive patients who presented over 2 days for in-person evaluations. Time to process a remote transmission was defined as the time taken by the device nurse from accessing the patient’s transmission on the remote monitoring web site to closing the encounter, including reviewing all received remote monitor data and all data export, comments, billing and rescheduling, and patient and physician phone calls or emails, if applicable. Time to complete an in-person evaluation was defined as the time from when the patient entered the room to the time the patient left the room, with all associated tasks completed.

Remote vs. in-person interrogations were processed faster (11.5 ± 7.7 vs. 27.7 ± 9.9 min, P < 0.01). Clinically relevant events, defined as arrhythmia detection, lead or device problem, ICD therapy, or battery voltage elective replacement indicator status were detected in 27.0% of remote monitor interrogations. As expected, actionable remote monitor transmissions resulted in significantly greater resource utilization than non-actionable transmissions (21.0 ± 7.7 vs. 10.1 ± 2.1 min; P < 0.05). The study included devices from four major remote networks: Medtronic, Boston Scientific, St Jude, and Biotronik. The majority of patient remote monitors tested were manual, requiring scheduled downloads and patient participation, while a minority was wireless and automated. Surprisingly, 49.2% of patients in the remote monitoring arm missed a scheduled transmission (trend was lower for patients with wireless remote transmitters). This resulted in telephone follow-up of an average of 21 patients per day, requiring an average of 55.1 min of nurse time (range 20–98 min). A fully automatic wireless technology overcomes many of these problems, and when used exclusively demonstrated considerable clinic efficiencies.12

One workflow question not addressed in this study (or others) is the change that remote monitoring forces upon communication between the patient and the cardiovascular device clinic. The in-person CIEDs evaluation allows the patient an important
opportunity to ask questions. The patient also is provided with immediate results of their device interrogation. The Cleveland Clinic has instituted an email notification to inform patients of the results from their remote monitor transmission once it has been reviewed, and contact with individual patients is maintained via regular nurse communication. But most cardiovascular centers are not yet able to offer this service. A uniform workflow pattern and technological solution to close the loop and inform the patient of the results of the remote monitor interrogation is needed.

**US model of assigning value and reimbursement for cardiac implantable electronic devices post-implant care**

Since 1992, Medicare, the national social insurance programme administered by the US federal government, has used a resource-based relative value scale (RBRV$S$) to value medical services relative to each other. Every procedure performed and identified by in the CPT code set is reviewed considering resources required: time, technical skill, physical effort, mental effort, and psychological stress.

Also under the leadership of the AMA, a committee of 29 members representing each major medical society meets three times per year, 1–2 weeks following each CPT Editorial Panel meeting. The specialty society(ies) whose members perform a particular procedure are responsible for surveying their physicians to assess the resources required to provide a particular service. Responders are asked to choose from a list of ∼10 procedures, 1 that they believe is closest in work value to the procedure presently being surveyed. This selection is fundamental in achieving relativity across the spectrum of procedures. The results of the survey are then presented to the 29-member committee of AMA. The relative value units ultimately assigned to a procedure is determined by the committee based upon the survey results and the committee’s determination of relative resource utilization across the entire spectrum of procedures.

Often, services that are similar are grouped into families to gain insight of the rank order of work required to perform services relative to each other. Cardiac implantable electronic devices follow-up care consists of one such family. All CIEDs evaluations, in-person, transtelephonic, and remote are included within the family. By US Congressional law, overall spending by Medicare must remain budget neutral. This is enforced within each family of codes.

The requirement by Medicare that overall spending on CIEDs follow-up remain neutral creates a challenge for the cardiovascular device clinic. As the number of CIEDs implanted increases, as patients live longer, and as the modality of follow-up changes, it will result in discounting the value of each encounter. It is incumbent cardiovascular specialists to inform our colleagues that the increasing evidence demonstrates the value of remote monitoring extends beyond the previous scope of device interrogations performed in-person. Outcome data have demonstrated this value to include a dramatic reduction in in-office interrogations and the associated resource utilization of in-person visits (with no change in quality), reduced length of hospital stays for cardiovascular care of arrhythmias, earlier heart failure and device malfunction detected by remote vs. in-person interrogations, and even a potentially dramatic reduction in overall mortality. 4–10 These findings demonstrate that the value proposition of remote monitoring extends far beyond the previous value of in-person CIEDs follow-up. This may stimulate discussion of whether costs of remote monitoring should attract reimbursement from resources allocated, for example, for heart failure management.

A counterbalancing factor that will need to be considered when determining the value and reimbursement of remote monitoring is the improved efficiency that a fully automated wireless technology brings to remote monitoring. If 10 patients may be ‘seen’ remotely within 1 h compared with 2 patients per hour for face-to-face device follow-up, the tremendous efficiencies gained by remote monitoring should be passed along to the patient and payer.

The cost of developing and producing the remote monitoring transceiver software and hardware and the expense of maintaining the wireless transmission network has, to date, been ‘hidden’ by bundling it into the upfront price paid for the pulse generator. As competition drives down the price of each unit, the Cardiac Rhythm Management Device Industry will be forced to try to shift these expenses to the realm of device follow-up where, one could argue, they belong. But the US reimbursement model has no precedent in this arena, and any attempt to increase either the cost to individual physicians/practices or to individual patients could backfire, ultimately slowing adoption of this clearly beneficial technology.

**Conclusion**

The challenge in the USA will be to redefine the boundaries of the value of CIEDs monitoring and convince our colleagues and patients that the increasing value of remote monitoring offsets increasing utilization. The cardiovascular device clinic will need to adapt and re-allocate personnel, space, database and electronic medical record resources, and develop new tools for patient communication. Outcome data have given us powerful tools to support these changes.

**References**


