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The Use of Remote Monitoring for Internal Cardioverter Defibrillators (ICDS): The Infusion of Information Technology and Medicine

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ABSTRACT

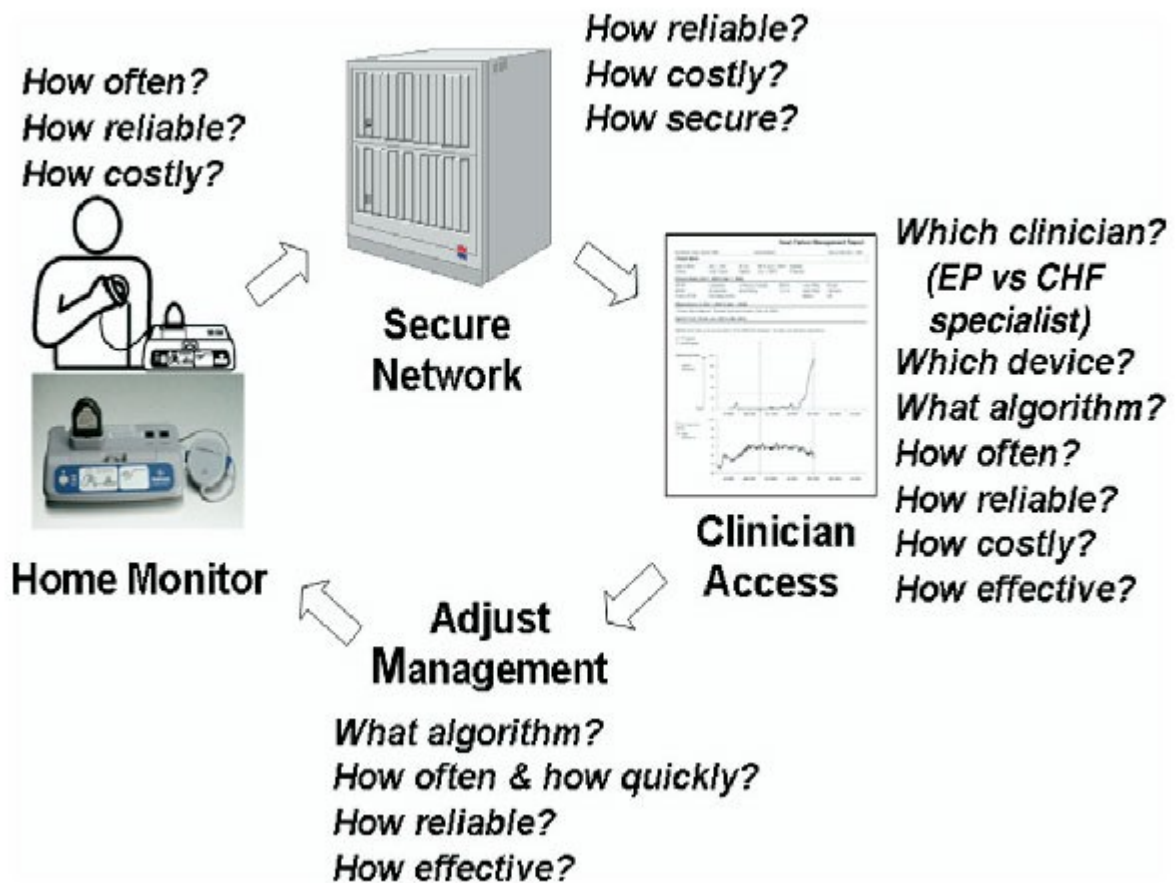
The clinical use of automated implantable cardioverter defibrillators (AICDs) has been rapidly increasing since the results of several randomized trials confirmed the efficacy of AICDs in the secondary and primary prevention of sudden cardiac death. Patients with AICDs require high-quality care and intense follow-up to ensure safe and effective device performance. According to international guidelines these patients should be followed at 1- to 4 month intervals, depending on the device model and the patient's clinical status (Schoenfeld, 2004). Given the expanding indications for use and the complexity of these devices, there is an urgent need to develop new means of ICD follow-up, so as to optimize patient safety and the use of healthcare resources. An internet-based remote-monitoring system could provide a practical substitute to time-consuming and expensive in-office visits. Although the initial experience with these systems has been favorable, many practical issues remain. In particular, more information is required on the usability and safety of remote monitoring for patient-initiated transmissions and cost-effectiveness of the system as a substitute for routine in-office visits during long-term follow-up.





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Lazarus, A. (2007)





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Introduction and Problem Identification

According to Vollmann (2006), the rate of implantable cardioverter-defibrillator (ICD) implantation has increased, as the ICD has become part of the standard therapy in patients who are at risk for life-threatening ventricular arrhythmias. The majority of ICD recipients are followed routinely at intervals ranging from 3 to 6 months. In addition, a substantial number of patients require additional non-scheduled visits due to arrhythmic events or system-related complications. With the growing number of device implants, the demand for ICD follow-up is pushing device clinics to their maximum capacity. The added cardiac resynchronization therapy (CRT) feature in some devices implies that clinicians are dealing with more complexity, rendering follow-up a multidisciplinary task.

The challenge is to be able to avoid routine ICD follow-up visits, such as the system integrity check and/or the confirmation that no arrhythmic events or CRT (Cardiac Resynchronization Therapy) related issues have occurred. A possibility to meet this challenge would be the use of remote monitoring. This new technology will cause an imminent change in the clinical practice of cardiac rhythm management. For the purpose of this paper, I hope to present the role of remote patient monitoring in ICD follow-up, its potential benefits and its barriers to widespread diffusion (Senges-Becker, 2005).



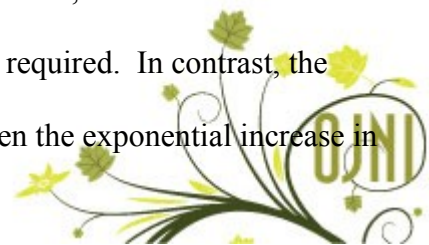


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Routine technical follow-up visits are usually scheduled at three-monthly intervals due to safety concerns. These three-monthly intervals were initially intended for manual capacitor reformation. With the feature of automatic capacitor reformation it becomes notionally possible to increase the follow-up interval. The disadvantage of long intervals is the lack of information on system integrity and the clinical status of the patient. The clustering of system-related complications in the early postoperative period makes a close follow-up schedule mandatory in the first 3 months after implantation (Al-Khatib, 2005). However, more than half of all complications may occur at any time during long-term follow-up. Therefore, any extension of the follow-up interval carries a small but definite risk of delayed detection of late system-related complications. From a clinical point of view, a disadvantage of long intervals can be a delay in the physician's or patient's awareness of changes in the clinical status. As a result, prevention of disease progression and the inherent optimization of therapy can face a setback, for example in patients who are at high risk of developing heart failure. In spite of a regular follow-up scheme, unscheduled visits will occur to investigate symptoms that may or may not relate to their cardiac disease or device.

Another point is the level of ICD follow-up, which can range from routine to complex follow-up visits. During a routine follow-up visit, the system integrity is checked, the confirmation that no arrhythmic events have occurred and that no medical intervention is required. In contrast, the complex follow-up requires active support by the Cardiologist. Given the exponential increase in





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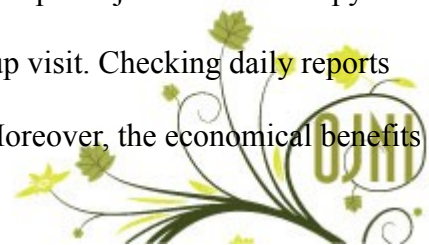
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device implantations and follow-up visits, a possibility to reduce the routine follow-up visits would be to institute the use of remote monitoring for ICDs.

Review of the Literature

Joseph and Wilkoff (2004) found that remote monitoring of ICD function can potentially diagnose >99.5% of arrhythmia or device-related issues, provided that the technology works seamlessly and transfers the same information as during in-office device interrogation. Alter (2005), suggested performing the first visit as an out-patient when current remote monitoring systems are used. The potential to reduce in-office follow-ups is clearly the highest for routinely planned visits. A study by Deharo (2006), showed that for about one-half of the ICD patients not any preset event is automatically transmitted during an average follow-up of 1 year. This study also showed that only in 6% of the planned visits, reprogramming or hospitalization was considered necessary. Although a consecutive in-office visit after the remote evaluation would add to the costs and time-investment for these patients, their small proportion certainly does not counterbalance the important time-savings for patients and physicians that could be achieved for the group as a whole.

According to a study by Res (2006), the remote system automatically transmits diagnostics after fixed time intervals or specifically alerts after detection of a relevant event (like an asymptomatic intervention or device problem) this can allow a more rapid adjustment of therapy which would otherwise be delayed until the next scheduled follow-up visit. Checking daily reports will require investments in infrastructure, personnel, and training. Moreover, the economical benefits





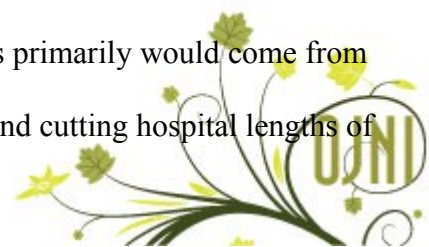
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will be highly dependent on the national health-care system. The data shows that the medical and economic benefit is clearly less in patients who consult for an unforeseen event and that the medical and economic benefit is clearly less in patients who consult for an unforeseen event.

Although remote monitoring significantly more often detected an arrhythmia- or device-related problem in these visits, a clinical evaluation may be necessary to rule out any medically relevant triggering circumstance (ischemia, heart failure, etc.) or the cause of complaints and in about half of the patient-initiated ICD evaluations ensuing reprogramming (during a consecutive in-office visit) or hospitalization is required. Remote monitoring therefore may not be very much time- or cost-saving in this situation. It may however serve as a triage system (e.g. for patients to whom can be confirmed that they received appropriate therapy) and as a rapid response system that is of major psychological importance for the patient (through self-check via a personalized website and/or by telephonic contact with the follow-up center).

Lazarus (2007), found that since patient-initiated visits only constituted 10% of all ICD evaluations, the overall economic and workload impact of remote monitoring may still be considerable, and that remote programming of the ICD could be of help to prevent inappropriate therapy when a relevant cause is detected. Lastly, Deharo and Djiane (2006), found that the use of remote monitoring technology on patients with chronic diseases could reduce the country's health care costs by nearly \$200 billion over the next 25 years. The savings primarily would come from reducing emergency department visits, preventing hospitalizations and cutting hospital lengths of





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stay. In addition, remote monitoring could boost health outcomes and quality of life, which would require an increase in broadband deployment nationwide and policy changes, including reimbursement for remote monitoring.

Alter (2005), recommends education for technology users and the development of workable privacy and liability rules and standards for interoperable systems. Although the technical issues for remote programming can easily be overcome, it will require a legal framework and thorough clinical evaluation before such bi-directional remote interaction becomes reality.

Problem Resolution

Remote monitoring of ICDs would offer patients the convenient and timesaving option to have a device check from home instead of scheduling an office visit. The remote monitor consists of a small battery-powered box with a detachable wand. At scheduled intervals, the patient connects the monitor to the home telephone line and places the wand on the skin overlying the defibrillator. The wand interrogates the defibrillator system and the monitor downloads and transmits the data to a secure web server. The entire process takes between 5 and 10 minutes. The monitor signals the patient when the download is finished, and the system powers down when transmission is complete. Within minutes, physicians can log onto the secure web server and download a full device report.

According to Fauchier (2005), Cardiologists are using home monitoring for routine device





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checks, as well as for arrhythmic event monitoring. Patients appreciate the convenience of the remote monitoring system. It not only replaces one or two annual office visits for routine device check-ups, but also allows patients to be in immediate contact with physicians in case of an arrhythmic event. Referring physicians are also able to continue to receive device reports from the attending Cardiologist.

The newer monitors will allow physicians to gather additional metrics, including weight and blood pressure, critical to managing heart failure patients as well as implantable devices. A future possibility may include being able to program some ICD features remotely and to reset system integrity alerts without an office visit. As indications for ICD use expand, remote monitoring will continue to provide safety and convenience for patients and referring physicians.

Advantages and Disadvantages to Implementation

Remote monitoring for patients with ICDs would provide a solution to problems such as access to care for large segments in the population, continuing healthcare cost inflation, and uneven geographic distribution of quality. Distribution of quality is improved by enhancing accessibility to care for underserved populations, containing cost inflation, and improving quality through the continuous care of patients (Joseph, 2004).

There are requirements for remote monitoring such as periodic transmission of routine vital





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signs and transmission of alerting signals when vital signs cross a threshold, patients cross a certain boundary, or device battery drops below a level, addressing many usability issues including user comfort and trust by monitoring wireless and mobile networks including the use of wearable, portable, or mobile devices.

Diversity of patients including those suffering from mental illness is likely to make patient monitoring by wireless networks a challenge because of possible paranoia related to handheld or wearable wireless devices, comprehensive and high-speed access to wireless networks, reliable and scalable wireless infrastructure, secure and fast databases, and utilization of network intelligence and information. The amount and the frequency of information that needs to be transmitted is another challenge. Remote monitoring of ICD patients includes but is not limited to, maintaining periodic transmissions of routine heart-beating signs and real-time transmission of alert/alarm, creating wearable portable or mobile devices that provide a user with comfort, accommodating the diversity amongst patients, providing comprehensive and high-speed access to wireless networks, reliable and scalable wireless infrastructure, secure and fast databases, utilizing network intelligence and information for calculations, and varying the amount and the frequency of information that needs to be transmitted is another challenge. For example, some patients require that certain vital signs be transmitted every few minutes, while for others continuous monitoring every few seconds is necessary (Fauchier, 2005).

Continuous cardiac monitoring, through wireless technology, can be used to follow up with





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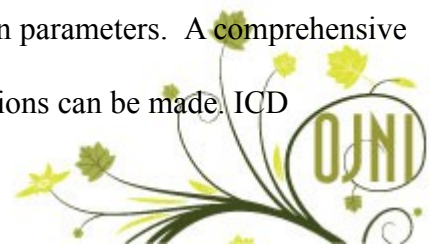
patients that have survived cardiac arrest, ventricular tachycardia, or cardiac syncope as well as for diagnostic purposes in patients with diffuse arrhythmia. As PDA (personal digital assistant) devices are reasonably priced and are becoming increasingly powerful, telemedicine systems using PDAs are a cost-effective solution in a range of medical applications and suitable for home care usage. Some currently used patient operated ambulatory ECG recording equipments, such as holter monitors and transtelephonic devices, are time consuming to setup and suffer from poor patient compliance.

Patients undergoing acute myocardial infarction and subsequent arrhythmia ending in ventricular fibrillation and sudden cardiac arrest will not be able to operate such equipment (Small, 2007).

For reliable monitoring, it is necessary to develop a completely automatic recording and analyzing unit, which can detect cardiac abnormalities and automatically send data and alarms to a health provider or central alarm system. Although development of dedicated guidelines could constitute a key step to improve the consistency and efficiency of telemedicine, this topic remains largely unaddressed. Barriers to guideline development include emphasis on technology rather than the principles and targets of telemedicine, coupled with medical organization's tendency to feel they lack necessary technical expertise (Small, 2007).

Potential Team Members

The physician will order the service and specifies notification parameters. A comprehensive report summary is prepared promptly so that patient treatment decisions can be made. ICD





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monitoring service will be available 24-hours, 7 days a week, and the support staff will consist of the primary care physician, Cardiologist, CRNP/Registered Nurse, CCT certified and/or Certified Cardiac Device Specialists-Allied Professionals, who will be available to speak with patients if questions arise and to review test transmissions, along with technical staff and a dedicated customer service team for physicians, staff and patients.

The remote monitoring company would be required to provide a multi-level quality assurance program for the review of each test to ensure the highest levels of accuracy. Reports would then be triaged, summarized and posted onto a secure online report system, which would be available from any Internet accessible location.

Cost and Limitations to Implementation of Remote ICD Monitoring

Defining medical costs is a complicated process, because medical prices are typically based upon a patient's needs and/or the relationship with a particular insurance company or healthcare provider. It is likely that remote monitoring would save a substantial amount of time and money, regardless of the economic system. The major indirect cost driver in the ICD follow-up is travelling to the hospital. Therefore, the greatest cost benefit is expected among patients who live far away from the device clinic and are still actively working (not retired). In addition, remote monitoring will allow





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physicians extra time to counsel patients with critical conditions, ensuring medical efficiency, and better overall patient management, which is expected to reduce the cost of the treatment even further.

Remote Monitoring and Evaluation

Telemedicine is particularly vulnerable to ethical and legal conflict, mainly because the law-making process tends to lag behind the high pace of technological evolution, and also because of national/federal differences. New sets of medicolegal regulations will be required to define professional responsibilities for decisions guided by transmitted data, especially with regard to suspected equipment malfunction. Response strategies will be required for out-of-hours calls, including emergencies.

Widespread implementation of telemedicine will entail management of huge amounts of data, with important privacy implications. It will be essential to define responsibilities for data management/access (by hospital personnel, providers, public/private institutions, etc.), and formulate regulations to protect the rights of both patients and health care professionals. Patients' provision of consent to medical treatment could be a particularly delicate ethical issue. Questions regarding protection of intellectual property rights will also have to be addressed. From a societal perspective, implementation of remote monitoring using ICDs will obviously depend on evidence that this option improves efficiency and is cost effective. Moreover, research will presumably be needed to identify subgroups of patients for whom use of specific remote monitoring devices is both feasible and cost-





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effective (Brebner, 2006).

Conclusion

The introduction of remote monitoring is an important milestone in the management of patients who require ICD monitoring. It provides a tremendous convenience for patients and clinicians and reduces the cost of follow-up. Although the technology is not intended to replace direct patient contacts completely, it can indeed release resources for other activities and help to maintain proactive patient care. In the context of the rapid ongoing evolution of electronic technology, telemedicine has the potential to enhance and rationalize clinical monitoring of patients implanted with pacemakers, ICDs, and CRT devices (Stanberry, 2006).

It is likely that this prospect will be encouraged by further technological advances in the development of useful novel sensors. A consequent shift from device-centered to patient-oriented telemonitoring could in turn favor a transition to a broader multidisciplinary approach to disease management based on a system of coordinated health care interventions, not only in the field of cardiovascular medicine. However, a series of economic, regulatory, and organizational issues will have to be faced before such an approach can take root in real-world clinical practice, where institutional, cultural, and financial forces interact in complex ways. The ability to overcome these obstacles so as to take full advantage of the potential benefits offered by telemedicine technology may be relevant for the evolution of our financially challenged health care systems (Yellowlees, 2005).





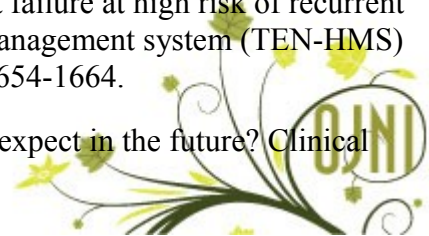
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Finally, if remote monitoring of implanted devices becomes the standard of care, this will have important implications on how implantable device clinics need to be organized in the future. Nevertheless, remote monitoring of ICDs will certainly become increasingly important in the years to come (Maisel, 2006).

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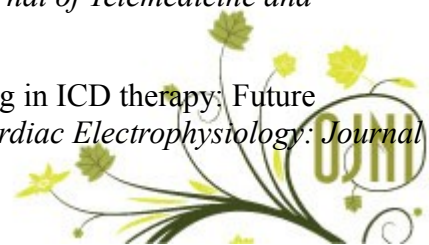
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Ms. Shirato earned an Associate Degree of Science from Community College of Philadelphia, a Bachelors Degree of Science in Nursing from MCP/Hahnemann University, and a Master's Degree of Science in Nursing from Drexel University. She is currently a doctoral student in the Doctorate of Nursing Practice Program (DNP) at the Jefferson School of Nursing, Thomas Jefferson University with a projected completion in May 2010. Susan had been a Board Certified Critical Care Nurse since 1995.

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