Chapter 11
Remote Follow-Up of Implantable Cardioverter Defibrillators: Technology, Patient Management, Integration with Electronic Records, and ICD Product Surveillance

David L. Scher
Pinnacle Health System, USA

Franco Naccarella
Euro China Society for Health Research, Italy

Zhang Feng
First People Hospital of Jiao Tong University, People's Republic of China

Giovanni Rinaldi
Italian Society of Telemedicine, Italy

ABSTRACT

In this chapter, the authors introduce some concepts about the remote follow-up of Implantable Cardioverter Defibrillators (ICD). Even if this type of remote monitoring system is relatively new, literature has demonstrated the utilization in clinical practice and during the last few years, the medical industry has provided different devices. Starting from the background, some models of utilizations are presented, focusing on the description of the main functions provided by some devices offered on the market. Next the motivations for which remote follow-up is needed are explored; a better management of the patient is described in several studies, and the integration of clinical information from monitoring devices in Electronic Medical Records is presented as the important step in order to provide comprehensive clinical information about the patient. Also, economic issues are shown. Then, some experiences realized in U.S. are explored, and at last, a number of questions are proposed to the discussion as contribution to the next research. Some Italian recent experiences in the field of remote monitoring and home care of patients with heart failure with and without implantable devices are reported.

DOI: 10.4018/978-1-4666-2979-0.ch011

INTRODUCTION

The remote monitoring systems (hereafter referred to as RMS) for follow-up of ICDs is a relatively new technology (Schoenfeld & Reynolds, 2005). It has been utilized in clinical practice for approximately three years.

The first large feasibility study, using Medtronic's Carelink System, was published in 2004 (Schoenfeld et al., 2004). This study demonstrated clinical usefulness as well as physician and patient satisfaction.

Recent large scale ICD generator and lead advisories and recalls have significantly increased the requirement to monitor devices more closely.

The Heart Rhythm Society has recommended the use of wireless and remote monitoring technologies for improved detection of device or system malfunctions (Carlson et al., 2006). Financial and ethical constraints by device manufacturers will likely soon result in significant decrease in industry participation in surveillance of devices in clinics and offices.

Wider use of electronic medical records begs the integration of device follow-up data with them in a seamless manor. All of these factors have accelerated the need and use of Internet-based monitoring systems. These systems are now offered without charge to the physicians and patients. Reimbursement policies for remote monitoring have been established by Medicare and most other insurance carriers. Remote monitoring is therefore needed and feasible as routine follow-up of ICDs.

It is logical to think that this type of follow-up will eventually be extended to pacemakers as well. The focus thus far has been on ICDs for a variety of reasons, but the advantages and rational for the extension of this technology to pacemaker follow-up are the same.

This article will address the technology of RMS, its potential impact on patient and device management, the integration of RMS with EMR, and the potential need to exploit RMS as a means of post market surveillance from a quality control standpoint, of ICDs. There remain unanswered questions about this technology which will be discussed as well.

It is clear that remote follow-up of cardiac rhythm devices in the USA is both accepted, welcomed, and growing, as it should be the home care and remote monitoring and data base assisted follow up of patients with heart failure without implantable devices.

REMOTE MONITORING SYSTEMS (RMS): BACKGROUND

Internet-based follow-up of ICDs was first commercially available in 2002. The appeal of the technology is to decrease time per follow-up, improve patient convenience by decreasing routine office visits, and to improve patient care by utilizing it to rapidly transmit data from patients with symptoms or arrhythmic events. It has significantly increased in usage over the past two years.

Clinics or physician practices were initially charged on a subscription basis by the first device company to market the technology (Medtronic) for utilizing the service.

Physicians and clinics operating within an environment of decreasing reimbursement were against this unprecedented model of having the physician subscribe for a service like this. Once comparable competition appeared with the LATITUDE system, which did not involve a subscription fee, adoption increased significantly, eventually becoming the economic model of the technology.

The advent of wireless devices which makes transmission logistically easier for patients also contributed significantly to increased acceptance. The utilization of the Carelink system in identifying trends of failure of the Sprint Fidelis leads has brought to the forefront the potentially most important role of remote follow-up: a source of early detection of failure of devices and leads (Groves & Medtronic, 2007).