Chapter 3
Towards Medical Systems to Aid the Detection and Treatment of Chronic Diseases

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ABSTRACT

Early diagnosis and slow progression of chronic diseases are important to improve the quality of life of patients. Physicians and patients can use medical systems to aid the detection and treatment of chronic diseases. In our previous research, a medical system to aid the early diagnosis of the Chronic Kidney Disease (CKD) was developed. However, the current research is concerned with the evaluation and certification of medical system. Regulatory agencies define requirements to approve medical systems to market. The requirements in most of regulatory agencies are defined by prescriptive standards in a process-based approach. This approach alone is not enough to prove systems’ dependability. On the other hand, there is a product-based approach in which one can use techniques such as formal methods to evaluate product properties. This chapter presents medical systems used to aid the detection and treatment of chronic diseases related to the stomach, heart, and kidney. Further, some challenges, solutions, and recommendations in the development and certification of this type of system are discussed.

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INTRODUCTION

The use of technologies in health care has been much researched in the last years. These technologies can include devices embedded on the environment, and personal devices, such as Smart Phones, Tablets, and Personal Digital Assistants (PDA). Physicians can use health care systems to assist the monitoring of patients in the hospital to verify and to analyze health data in order to avoid a risk situation. On the other hand, these systems can also benefit patients from the personal management of diseases. In addition, one can perform the remote monitoring of patients with mobility problems; and can improve the social inclusion of patients with chronic diseases (e.g. Chronic Kidney Disease (CKD)).

Some studies demonstrate the potential of using technologies to aid the health care. For example, Pang and Chen (2009) describe a solution for medications non-compliance. Further, Kulkarni and Ozturk, (2011) presents a software system for monitoring patients using wireless sensors. Nardini et al. (2011) proposes a middleware for coordinating services and security with runtime adaptation, and the application in health care for coordination of Electronic Health Record (EHR). These and other efforts show the need of monitoring and management of clinical information. Monitoring and management provide a better understand of patients about their health situation. Besides, there are health care technologies used to perform the treatment of patients.

In this context, medical systems must be safe and effective because faults can result in health problems. Health problems include physical damage and death. Software and hardware devices compose medical systems. We define “medical systems” as a set of medical applications, and software-controlled medical devices. The number of devices and applications is related to the probability of failure and complexity of the system (Bagade et al., 2013). One must also take into account the interaction of human-device and device-device. The interactions between physical and computational capabilities are related to Cyber-Physical Systems (CPS) (Majikes et al., 2013). CPS combines device with embedded software and computational and communication resources to monitor and to control the physical world (Baheti & Gill, 2011). The integration of devices, human, and environment generates emergent properties, such as security and safety. These properties must be evaluated by the interaction of systems (Systems of Systems - SoS). Thus, it is necessary the evaluation and certification of medical systems before commercialization to avoid risks to the safety of patients (Sokolsky et al., 2011).

In ours previous research, we developed a medical system named MultCare (Sobrinho et al., 2012; Sobrinho, et al., 2013a; Sobrinho et al., 2013b; Pinheiro et al., 2013). Multcare is a system to aid the early diagnosis of the CKD. However, we are currently concerned with the evaluation and certification of medical systems to avoid risks to the safety of patients. Certification of medical systems plays an important role to improve the acceptance, confidence, and safety of patients. This occurs due to the use of devices with different proposes in the diagnosis and treatment of patients, such as insulin infusion pumps and Electrocardiographs (ECG), and the integration of computational and physical aspects in medical systems (Medical Cyber-Physical Systems - MCPS).

Regulatory agencies, such as Food and Drug Administration (FDA)\(^1\) on the USA, Therapeutic Goods Administration (TGA)\(^2\) in Australia, and National Agency for Sanitary Vigilance (ANVISA)\(^3\) in Brazil, define requirements to approve medical systems to market. These regulatory agencies usually define rules and requirements to be met during the lifecycle process in the development of medical systems.

On the one hand, most of the regulatory agencies use requirements of a process-based approach to certify medical systems. International agencies for standardization specify requirements in pre-
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