Exploring New Care Models in Diabetes Management and Therapy with a Wireless Mobile eHealth Platform

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Abstract. Due to demographic changes, European healthcare systems face two serious challenges: healthcare delivery may become inadequate to perceived needs of the citizens or the cost may spiral out of control. With the decrease in the labour force, there is an urgent need to make more health services mobile allowing citizens with chronic diseases stay longer in the labour markets, reduce the number of lost working days and generally support nomadic working. Mobile technologies have the potential to provide better healthcare while at the same time increasing the working population. However, it calls for dramatic changes of healthcare provisioning and of the care models. The REACTION project develops a mobile, cloud-based platform that provides healthcare services to diabetes patients and caregivers. As part of the project, new chronic care models that support separation of care spaces are proposed.

Keywords: Mobile Healthcare, mHealth, New Care Models, Evolution of Care Spaces, Personalized Healthcare, Wireless Sensors and Devices, Electronic Decision Support.

1 Introduction

In recent years, wireless mobile healthcare (or mHealth) has emerged as an important sub-segment of the field of healthcare practice supported by electronic processes and communication (eHealth). While there is no widely agreed-to definition for these fields, the public health community has coalesced around these working definitions [1]:

- eHealth: Using information and communication technology for health services and information.
- mHealth: Using mobile communications for health services and information.

eHealth and mHealth are inextricably linked. Both are used to improve health outcomes and their technologies work in conjunction. While there are many standalone mHealth solutions, it is important to note the opportunity that mHealth presents for strengthening broader eHealth initiatives. For example, a mHealth front-end solution may allow patients to continuously access patient data within a national system, while at the same time being completely mobile. Other mHealth solutions can

serve as access point for collecting vital signs and clinical data online and as remote information tools that provide information to patients, healthcare clinics, home providers, and health workers in the field.

In 2012, the European Commission will publish new activity plans aligned with eHealth and mHealth roadmaps for technological research, implementation practice and policy support with the aim to accelerate the establishment, acceptance and wide use of mHealth solutions that will improve disease management globally and support lifestyle changes among citizens.

In this paper we look at an integrated approach to improve long term management of diabetes developed in the REACTION project, which uses wireless technologies for continuous blood glucose monitoring, clinical monitoring and intervention strategies, monitoring and predicting related disease indicators and, ultimately presenting the perspective of automated closed-loop delivery of insulin. This paper will focus on the clinical decision support system implemented with the platform and discuss the need for new or revised care models as a result of the technological progress in mobile communication technologies.

2 About the REACTION Project

The outcome of the REACTION project will be an intelligent, interoperable, cloud-based platform that will provide integrated, professional management and therapy services to diabetes patients in different healthcare regimes including 1) professional decision support for in-hospital environments, 2) safety monitoring for medication dosage and compliance, 3) long term management of patients in Primary Care clinical schemes, 4) care of acute diabetic conditions, and 5) support for self management and life-style changes for diabetes patients. A range of REACTION applications will be developed, mainly targeting insulin-dependent diabetes patients. The applications aim to improve Continuous blood Glucose Monitoring (CGM) and Safe Glycaemic Control for improved insulin therapy management and basal/bolus dose adjustments.

The REACTION platform connects wirelessly to sensors and monitoring devices in the patients' physical surroundings and provides feed back to the patient as well as to informal carers (relatives, neighbours) and to healthcare professionals and emergency teams in the professional healthcare system. The REACTION platform also connects seamlessly to Health Information Systems for health data, health knowledge and decision support, utilizing medical knowledge repositories (e.g. biomedical models). The platform is visualised in Fig. 1.

Wearable, wireless medical sensors are connected in a Body Area Network (BAN) for multi-parametric recording of vital physiological parameters. The BAN interconnects with other wireless sensors in the environment that can record contextual information about the environment and the patients' activities. Devices are interfaced by standardized web services and data may be formatted and pre-processed in the access layer's active nodes/gateways, which operates on e.g. a mobile Smartphone or iPad platform. The gateway can also execute Apps that handle simple episode monitoring and other services, which are needed during periods of non-connectivity.

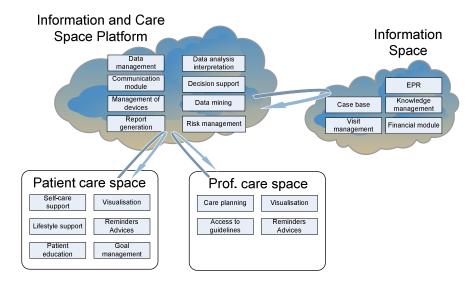


Fig. 1. The REACTION platform integrates information and care spaces

Further, the gateway runs interactive Apps which support self-monitoring and self-management; facilitate access to external Health Information Systems and personalised feedback from health care professionals. For medical devices not capable of operating web services (due to resource constraints or proprietary concerns), the gateway acts as a platform for virtualisation of those devices.

A typical clinical scheme in a mHealth solution will consist of a series of personalised actions, each of which can be described as a service. A typical REACTION clinical care plan will thus be established through orchestration of the relevant cloud based services, executed in a pre-described sequence according to "clinical logistics" modelling traditional clinical workflows. This feature in the REACTION platform introduces higher abstraction mechanisms and thus makes the application developer independent of using a specific programming environment to orchestrate REACTION services.

3 Clinical Practice

The REACTION project implements the service platform in three clinical field trials: Safe Glycaemic Control in the hospital ward; chronic care and lifestyle management in the Primary Care sector and Automatic Glycaemic Control (AGC) with closed-loop feedback. In this paper we will briefly outline the objectives of the in-hospital field trial, which is undertaken by the Endocrinology and Cardiology wards at the Medical University of Graz.

In-hospital hyperglycaemia has been found to be an important marker of poor clinical outcome and mortality among diabetes patients [2] [3]. Other studies have shown that medication errors are common and also associated with poorer outcomes [4]. In a randomized, controlled study conducted in a surgical intensive care unit [5],

strict control of blood glucose levels with insulin reduced morbidity and mortality, significantly reducing in-hospital mortality from 11 to 7 percent in the entire study population. The first application domain of the REACTION platform will thus feature a suite of services aiming at Safe Glycaemic Control (SGC) of diabetes patients in the general hospital ward.

The current workflow related to glycaemic management has been analysed and a REACTION application has been developed that offer decision support for professional caregivers on a mobile iPad platform (Fig. 2.).

The application monitors a range of parameters from various sources including glucose level, nutritional intake, administered drugs and the patient's insulin sensitivity. The data are contextualised and algorithms and physiological models will be used to calculate the required insulin doses for SGC. Results will be delivered to physicians and nurses at the point of care.

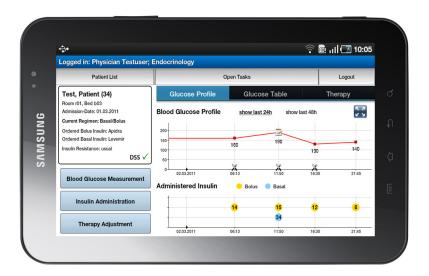


Fig. 2. Decision support application for Safe Glycaemic Control for care givers

The REACTION application will, later in the project, interface to hospital systems and hospital protocols across wards thus supporting integrated care management.

The in-hospital field trial focuses on providing a point-of-care electronic decision support (eDSS) tool for insulin therapy for physicians and nurses not specialised in diabetes. The objective of the first field trial is to compare the efficacy of the eDSS over a published best practice paper-based insulin titration protocol for glycaemic control and evaluate safety and usability of the eDSS. The target group is hospitalised patients with type 2 diabetes for the length of their hospital stay, with a maximum of 21 days.

Technologically, the hospital environment is particularly challenging to mobile communication technologies due to the many sources of electromagnetic disturbances and the potential adverse impact on patient safety caused by possible malfunctioning or black-out.

4 The Need for New Care Models

This first field trial aims to provide insight into the possible enhanced care using the REACTION platform, but do not attempt to establish broad clinical evidence. However, the outlook for enhanced glycaemic control, and thus care management, provoke the entire care model to be reviewed. It is important to remember that mobile health technologies are not objectives, but tools, that should be applied in ways to achieve local, national, and regional health objectives, addressing important public health challenges such as chronic disease management as well as contribute to improving the lives of individuals [6] [7]. Mobile healthcare provides new possibilities for revising central parts of the established care models for chronic diseases.

Planning new care models for the future involving mHealth is highly complex and involves a number of components that play significant roles in the formation of the trends we are looking for, when defining new care models. These factors are several, and include biomedical and clinical R&D, financial incentives, technology development and the socio-economic environment. These factors influence the development and changes in the attitude of the participants of the healthcare system and the ability to carry out changes that are needed to implement a new care model.

Several prediction studies have been published, e.g. by health institutions like the National Health Service (NHS) in the UK, the Australian Centre for Health Research (ACHR) etc. as well as private observers. These studies differ in their approach and in the aspects they consider. Some studies emphasize technological aspects [8] [9]; other focus on healthcare policies [10] [11]. ACHR focus on the aspects of health services [12].

Some common elements can be extracted from these approaches and we have selected those factors which, in our opinion, are significant in the formation of new care models [13] [14] [15]. These factors are (see Fig. 3):

- Systems biomedicine, an important area of the biomedical and clinical R&D
- Care space evolution, integrating many different trends
- The ICT factor, providing information technological support for mHealth
- Personalisation, aiming at the individualisation of the care
- Patient focused organisational re-engineering

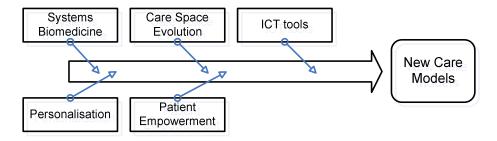


Fig. 3. Significant factors that influence the new care models

Chronic diseases share three important properties: (i) acute and chronic phases alternate during their progress; (ii) their adequate diagnosis and state monitoring require multilevel system biomedical characterization; (iii) their progress may be significantly influenced by the patient's behaviour.

Care for chronic diseases therefore has its own characteristics: (i) it should be continuous, i.e. it should be available between the contact visits and periods of hospitalization and not just during them; (ii) it should be proactive and predictive; (iii) it should consist of professional care provided by medical personnel and self-management provided by the patients themselves; (iv) it should be able to influence the patient's lifestyle; and (v) the care should be dynamic, meaning that all the participants should learn and adapt during the care process. In the medium term this requires re-design and implementation of new care models.

Important aspects of chronic disease management are personalisation, inclusion and patient empowerment. Personalisation and patient empowerment are obvious attributes of mHealth solutions and closely connected to care space evolution, i.e. the changes in physical or virtual spaces where care is provided. In this regard, ICT tools and systems biomedicine act as enabler of mHealth solutions. Care space evolution is thus of particular importance in mHealth care models.

mHealth results in an explicit splitting of the care space into two interrelated spaces, the activity space and the information space. The *care activity space* is the space where the patient is physically located, sometimes coinciding with the professional care space (the hospital or the doctors office) but mostly not (see also Fig. 1.). The *care information space* is a virtual space where patient data and information about the disease are kept and made available through an ICT infrastructure [13] [14] [16].

mHealth solutions makes the patient mobile and thus decouple the actual *activity space* from the traditional physical care space of the professional caregivers. The patient receives care in the home, at work and when travelling, i.e. mostly outside the physical space of the professional healthcare system.

mHealth (and eHealth) solutions also places high emphasis on the sound development of the care *information space*. New healthcare methods generally create a growing volume of data on the one hand, and an ever growing demand for information, on the other hand. The data growth is connected with the development of diagnostic and monitoring methods and tools. The information demand is connected with new decision making methods and with modelling methods required for a better implementation of the necessary actions.

The decoupling of care spaces is thus very important in chronic care, because it allows streamlining the roles of each stakeholder while at the same time providing them with tailored information for each role. mHealth widens and extends the effect of the care space evolution, while at the same time reinforces patient empowerment.

However, a known challenge to be overcome when moving the care activity space out of the doctor's office is the risk of the patient being isolated or alienated. If visits by care givers or family members are substituted with mHealth monitoring tools, patients can become isolated even in the most populated areas, especially senior citizens. It is imperative that a delicate balance is struck between closing the digital

divide and closing patients in a virtual prison. Thus, inclusion enhancing methods must be incorporated in the mHealth solutions and the care models at all levels [17].

Overall, the separation of care spaces in chronic disease management provides, if managed correctly, great opportunities for improved care at the point of need as well as organisational streamlining and thus potential for cost savings. However, new clinically accepted care models, which take advantage of the new opportunities provided by the mHealth solutions, must be developed in order to fully explore the benefits while at the same time conserving and promoting inclusion.

5 Conclusion

The intelligent, interoperable platform developed by REACTION will provide integrated, professional, management and therapy services to diabetes patients in different healthcare regimes across Europe. An in-hospital field trial will focus on providing a point-of-care electronic decision support (eDSS) tool for insulin therapy for physicians and nurses not specialised in diabetes.

The outlook for enhanced glycaemic control supported by mobile healthcare applications provokes the entire care model for diabetes patients to be reviewed and further work needs to be done on this aspect.

The trends in care model evolution are influenced by many factors such as biomedical and clinical R&D, financial incentives, technology development and the socio-economic environment. An important aspect of future chronic disease management is that personalization, inclusion and empowerment of the patient has to be an essential part of the care model.

With insufficient impact data about how mobile technologies are influencing health outcomes, it is difficult to identify and replicate best practices. Good quality randomized controlled trials on mobile technologies in the care of chronic diseases with sufficient power and duration to assess long term and cost effects are required.

Of particular interest is the decomposition of the care space into a *care activity space* and a *care information space* and the further decomposition of the care activity space into a mobile care space (the patient's environment) and a traditional care space (the clinic or hospital).

However, the evolution of care spaces and the potential impact on health outcome must be further investigated and evidenced, before future care models will be adopted. The new care models must be clinically accepted, inclusive and correctly managed in order to fully explore the benefits in terms of improved health outcome and reduction in healthcare costs.

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