

Risk Assessment And Patient Stratification Using Implantable Medical Devices. The Funding For Personal Health Programs

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Abstract- Chronic diseases are currently recognized as one of the leading causes of mortality and morbidity worldwide. On top of this, these diseases represent a major burden for the healthcare systems in terms of costs and resources, which is driving them to define and adopt novel programs for prevention and chronic disease management. Still, many aspects of the processes of care and follow up of these patients remain unsolved and there is yet uncertainty on how technology can provide an added value to the current processes of care. This paper addresses the importance of the adoption of strategies for the anticipation to acute events within the disease management programs and suggests a holistic approach to embrace the healthcare organizations in the design development and implementation of the new personal health systems.

I. INTRODUCTION

Disease management is a concept that is often understood as a process of care that starts at the moment of diagnosis, sometimes coinciding with a critical episode that determines the onset of a disease or its identification. If this concept is enriched and broadened to the idea of **health management**, it is easy to see that the process of care should start in an earlier stage of the life of the individual, in a moment when the person is still healthy, and should comprehend the complete collection of stages of the progression of a certain disease, as shown in Figure 1.

Most of the aspects of this chain of care have been addressed by the different competent authorities in most European countries. Education and disease awareness campaigns are promoted by the public health administrations among the general population and diverse prevention programs are also starting to be put in place in different regions to address those cases in which the individuals are at risk of suffering a disease that could be prevented if certain actions were taken in time. Likewise, primary and specialized care are provided by the different public and private healthcare systems to attend the population suffering from any disease or condition.

Health and disease management are of special interest and relevance in the context of chronic diseases, which are diseases of long duration and generally slow progression. Chronic diseases, such as

heart disease, stroke, cancer, chronic respiratory diseases and diabetes are, by far, the leading cause of mortality in the world [1] and represent the main burden in terms of cost and resources for most of the health care systems worldwide [2]. Recurrent hospitalizations in these patients are not only an index of the progression of the disease, causing sometimes irrevocable damage, but are also an indicator of healthcare use and cost. Early intervention is key to handle the adverse events happening to the patients but, in this context, anticipation to the critical events for the avoidance of hospitalization becomes of great importance and interest for the development of strategies meant to improve clinical outcomes in these patients and the sustainability of the healthcare systems thanks to the reduction of costs incurred long stay in hospitals.

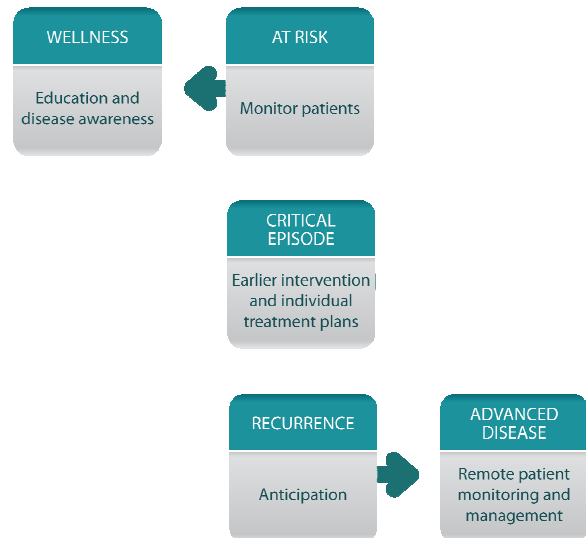


Figure 1 – The chain of Health Management

Anticipation requires an evaluation of the risk of patients to suffer a hospitalization due to worsening of their condition. Moreover, there is the need to assess the general health status of the patients and the specific conditions of their disease to be able to make such predictions of worsening and to prevent the hospitalizations. This type of analysis calls for the usage of systems of intelligent analysis of multiparametric data to transform data into medically meaningful information that can drive medical action

in this direction. On top of this, besides medical interpretation of single patient indicators, the availability of data sets coming from different patients would allow to develop the adequate tools to stratify the sick population into clearly distinguished classes for the segmentation of the population depending on specific clinical criteria, such as progression of their disease and/or need for different levels of medical care and attention or intensity of the follow up. Such a classification of the population would allow the assignment of specific care plans to each cluster and would enable a more efficient delivery of care by the health care systems.

II. THE ROLE OF IMPLANTABLE DEVICES

Telemedicine makes possible frequent or continuous monitoring of physiological variables, opening the door to anticipation of adverse events and taking into account the evolutionary condition of the clinical profile of the patient. It also has the potential to create a new paradigm in clinical research when the possibility to efficiently and dynamically monitor thousands of patients will bring solid evidence about the association between clinical changes and outcomes and whether altering the management of such changes breaks the relationship with subsequent outcome versus the rigidity of the traditional randomized approach.

Special attention has been paid to the cardiac pathologies for the deployment of projects and pilots that have tested the potential of the remote monitoring as a strategy for the treatment and follow up of chronic patients. Difficulties have always been found in these cases in relation to the use of external monitoring devices and the so called wearable monitoring devices, meant to acquire vital signs from patients and other relevant environmental data. The main cause of problems related to the usage of this type of systems lies in the fact that both technologies require the patient to follow correctly certain routines for the placing of the devices and the acquisition of data, jeopardizing the quality of the data gathered if the process is not completed according to the specifications, which is more likely to happen among aged or impaired users.

Implantable devices have been traditionally used as therapeutical devices in many areas of the body susceptible to be treated with electrical stimulation, this is, heart, brain, spine, digestive circuit, etc. but they have lately shown a great potential for the

monitoring of vital signs, as they have the capability to acquire information directly in-body in the most reliable way and independently from the actions performed by their carriers. This opens a great opportunity as in the past years tools have been developed to extract wirelessly this information from the devices with very little or no intervention from the patients, so that it can be transmitted to secure servers where it can be processed, analyzed and presented to the adequate final users (mostly health professionals). An example of this is the Medtronic monitoring platform CareLink®, that is available for all cardiac and diabetes devices to extract, transmit and present data in an optimal way to the users. This technology enables the use of implantable devices for their application in telemedicine, ensuring the quality of data and a continuous monitoring 24/7/365.

Moreover, the technological convergence in synergic fields that has taken place in the past decade is allowing the development of new advances in implantable and subcutaneous devices minimally invasive that have proven to be very reliable and effective in, for instance, the diagnosis of syncope and fibrillation, with continuous and long term monitoring capabilities (Reveal DX/XT®, a product of Medtronic Inc.). In addition, in the close future these devices will be injectable and will allow the detection of far more variables than only electrocardiographic and physical activity data. Advances in genetic analysis, miniaturization and biologics are meant to shape the features of the new generation of implantable technology, not only in the area of cardiology, but also for glycaemic levels assessment, movement disorders, neurological diseases, etc.

III. NEW PERSONAL HEALTH PROGRAMS AND SYSTEMS

Technology is the foundation of the personal health systems that can allow a better and more efficient care of patients suffering from chronic diseases. Still, technology is only an enabler for the set up of new processes of care, while the main challenges remain in the redefinition of the organizational processes that support the aforementioned strategies of health and disease management.

While there exist clear clinical guidelines of care for the treatment of the most prevalent chronic diseases and for the mitigation of critical episodes, there is little knowledge or literature related to the interpretation of

information and to the appropriate protocols of intervention to be applied in the cases previously described, in which patients are still stable but at risk of worsening of their condition, not having entered yet in a critical process that can be treated according to the current clinical practice. This is mainly due to the fact that this status of risk could not be recognized until now, when the new technologies are permitting much more powerful analysis over much larger pools of data. For this reason, it is of paramount importance that new care guidelines are developed for these cases in accordance with the new features and capabilities that technology can provide.

Furthermore, information management can become a burden with the increased amounts of data available and, therefore, it must be handled by these Information and Communication Technologies (ICT) personal health systems. These systems must also facilitate the re-design of the current processes of care and follow up through the provision of services that enable, in the one hand, the correct management of the patients within the healthcare organizations in the different levels of care provision (mainly primary and specialized care) and, in the other hand, the adequate management of information by the medical professionals in each case, providing more information, more reliable, automatically analyzed and together with smart clinical decision support systems that leverage the health professionals from the task of analyzing all the data so they can focus in the relevant aspects that will allow them recognize and treat their patients more efficiently.

IV. CONCLUSIONS. TOWARDS A PROCESS CENTERED DESIGN

The implementation of a risk stratification model of care based on the use of implantable monitoring devices that may guide the management of chronic patients has the potential to represent a new paradigm for chronic care and to set the bases for the new standards of provision of services by the healthcare systems. Since chronic diseases are a major cause of morbidity and mortality, and considering the increase of an ageing population, the impact is likely to be high if the improvements are significant, not only in a clinical dimension, but also at an organizational level.

While the concepts of continuous health and disease management and of anticipation to avoid hospitalizations are revolutionary and are recognized as necessary to guarantee the sustainability and quality

of the public healthcare systems, an innovative approach is fundamental to address the difficulties that the introduction of these technologies represent to the current healthcare organizations.

Regardless of the initial investment that may be required to put in place these services, the key to success in the pursue of efficiency and quality of care is in the adaptation of the processes of care across the different levels of attention that will make possible to extract full potential of these technological tools to maintain patients far from the hospitals, where costs of care are higher, and to implement remote follow up services managed from primary care in connection to specialized care.

This requires a tighter collaboration between the service providers and the healthcare organizations (not only care centers but also administrative organizations that coordinate the activity and interaction between primary and specialized care) involving them from the beginning in the design and development of these tools following a “**process centered approach**”, in opposition to the latest trends of personal health systems design, more focused in fulfilling clinical needs of the final users but leaving aside the administrative and organizational aspects that surround the use of the technology.

Products are not anymore the technological tools that can be provided to the health professionals, but have become the sum of the technology, the processes and the organization that uses them. The future personal health programs must contemplate all these aspects and must address the needs of all the stakeholders involved to achieve the expected impact and standardize the proposed health and disease management programs.

ACKNOWLEDGMENT

We wish to acknowledge to the MEDTRONIC Data Management and CRDM teams and to all our partners and collaborators in the activities for innovation in eHealth Solutions for a more efficient health care delivery.

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