IMPLEMENTATION OF A MULTI-SPECIALIZED ELECTRONIC HEALTH RECORD FOR MANAGING CARDIOLOGICAL REHABILITATION PATHS

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Cardiac Rehabilitation (CR) is an intervention for managing the post-acute phase of the disease. According to international guidelines, it includes three consecutive phases: the first phase, during the acute period, in the hospital; the second, during a hospitalization or in outpatient, in order to evaluate and modify the patient's risk factors; the third, outside the hospital setting, is carried out to change, support and promote a correct lifestyle. To guarantee that all patients have access to the most appropriate rehabilitation track, it is necessary to create structured paths on the territory and under a multi-professional patient monitoring. The elective tool for patient-centered management is the Integrated Care Pathway (ICP). It is oriented to the communication and integration of all actors involved in patient's management, requires the identification of a case manager and a team of health professionals able to manage complexity and comorbidities, and supports patient involvement. Care pathways as complex as these can be better supported if traditional paper-based approaches are transformed into interactive systems that use Information and Communication Technologies (ICT). The introduction of ICP and ICT implies the reconfiguration of the clinical record that from a repository of the data becomes a multi-accessible tool for the management of visits and the visualization of the results of instrumental examinations. In order to translate this concept in the field of the CR at patient's home, we created a multi-specialist electronic health record accessible to both professionals (cardiologist, nurse, dietician, psychologist, sanitary assistant) that make diagnosis, prescribe therapies and physical exercise, monitor patient's parameters, and patients, to allow them to consult therapies and results of clinical exams. We used Agile Methodology to develop this Medical Device (MD) compliant, by design, with the European laws on MD [2], [4], Privacy [1], [5] and Usability [3]. To avoid malfunctions due to incorrect or incomplete collection of requirements, and to optimize development time, the Agile continuous process of revision and brainstorming were performed by applying simulation technologies [6] that allowed us to accelerate substantially the identification and validation of user interface requirements and to identify and fix potential functional errors. The virtual prototypes reproducing the functionalities and the visual appearance of the system were subjected to the CR's multidisciplinary team of Azienda Provinciale per i Servizi Sanitari di Trento (professionals, engineers, etc.) involved in the project during several "sprint phases" as an alternative tool to the static mock-ups. All this led to the implementation of a MD validated by design.

References

[1] Decreto Legislativo 30 giugno 2003, n. 196
[2] Directive 2007/47/EC of the European Parliament and of the Council
[3] Medical devices – Application of usability engineering to medical devices BS EN 62366-2:2016
[4] Regulation (EU) 2017/745 of the European Parliament and of the Council
[5] Regulation (EU) 2016/679 of the European Parliament and of the Council
[6] http://www.pvsioweb.org/