

A Use Case based requirements specification approach to support the development of a rehabilitation system for CVD patients: The PATHWAY Project

Paolo Zampognaro* Roselien Buys[§] Deirdre Walsh** Catherine Woods[‡] and Fabio Melillo*

*Engineering Ingegneria Informatica, Italy. {paolo.zampognaro, fabio.melillo}@eng.it

[§] Department of Cardiovascular Sciences, KU Leuven, Belgium. roselien.buys@kuleuven.be

** Dublin City University, MedEx Research Group, School of Health and Human Performance and Insight Centre for Data Analytics.

deirdre.walsh@dcu.ie

[‡] University of Limerick, Physical Education and Sport Sciences and MedEx Research Group. catherine.woods@ul.ie

Abstract—Over the last years, due to the emergency of new challenges in the area of the health care domain, particular emphasis was dedicated to the application of ICT in this sector. This, in turn, stimulated the analysis over the software requirements engineering techniques and their applicability in this context. The efficient application of the use-case based technique, within the PATHway project user requirements elicitation and formalisation activities, is here described. Efficiency has been reached by means of (i) a light and progressive introduction of UCs (Use Cases) instrument to the clinical teams by exploiting informal stories (i.e. anecdotes), (ii) a careful evaluation of the best UC description structure and, finally, (iii) an introduction of co-design moments with the final users (i.e. the patients) to speed up the UCs adaptation by the two main involved teams (i.e. technical team and clinical team). The qualitative results demonstrate advantages and limits of such technique applied to the context of cardiovascular home rehabilitation. Additionally the study has highlighted a smooth integration between the distinct phases of the requirements engineering process which can lead, in general, to a return of investment.

Index Terms—Requirements Engineering, Use Case, Cardiovascular Disease, Hospital.

I. INTRODUCTION

This paper summarises on the adoption of the use-case based approach to catch and formalise the user requirements of the PATHway project [1] following an incremental development cycle. Even though UML Use Cases technique is not new and has proved its validity in several contexts, still some points limit, in our opinion, its adoption and performance in several domains even included the health domain.

The *first aspect* relates to a missing, in the scope of this technique, of a clear approach to properly describe the user which in turn often implies requirements are neglected. In this respect the concept of “user role” seems to be too generic and insufficient to catch the context of use and user motivations/expectations [2]; furthermore it must be said that this missing leaves the project teams free to envisage the final future user (and its needs) in a personal (and often wrong) way. Finally not always the needed linkage between the user tasks, user characteristics and context of use (ISO/IEC 9241 part 210

[3]) is properly addressed during the requirements gathering and formalization using UCs technique.

The *second aspect* is that although use cases are part of UML, there is no standard template for writing use cases. In this respect several proposals followed one other introducing improvements from specific points of view [4]; however we are not aware of feedback related to the adoption of such (single or joined) modifications in general and within the health domain in particular.

The *third aspect* is associated to the fact that UCs are often adopted only in the early stage of the projects missing a following update/adaptation by the involved team (technical team and clinical team); this is due mainly, for our experience, to a missing of co-design moments with final users (i.e. patients) from one side and from the other to the feeling, by both the teams, of UCs as an inadequate.

Therefore how the adoption of informal histories (anecdotes) helped us, within the project, to catch that user context natively not supported by the UCs technique (see *first aspect* above) is described in this paper; we also report about the adoption of a tailored UCs description table properly customised in order to facilitate their extraction from the anecdotes and booster the their understanding by the clinical and technical teams (see *second aspect* above). Finally a description of the co-design step with final user and its impact on the UCs update (see *third aspect* above) is summarized. In summary a brief overview of the PATHway project [1] with emphasis on the user requirements specifications is presented in Sec. II. The Sec. III presents an introduction to requirements engineering processes and the utilisation of the requirements workflow (of Rational’s Unified Process [5]) in the elicitation and specification of the user requirements. The PATHway use-case model is presented in Sec. IV and a discussion on the impact of the use-case approach is presented in Sec. V followed by a summary of the main outcomes in Sec. VI.

II. THE PATHWAY PROJECT

The PATHway main objective is to develop an end-to-end modular technology platform that will allow CVD patients to better self-manage their illness through a supportive, holistic, home-based cardiac rehabilitation (CR) programme which has increased uptake and long-term adherence to exercise as its core aim.

In detail 'exercising capabilities' will assure the delivery of an appropriate, patient determined exercise programme (both an exercise class [ExerClass] and an exercise game [ExerGame]) and the monitoring in real-time of the patient's actions and physiological response in order to provide personalised feedback via a virtual 'Avatar' coach. 'Social connectivity capabilities' will enable small groups of remote participants to exercise together mainly enabling communication possibility. An 'all-day assessment' will monitor participants' physiological responses, sedentary behaviour and physical activity levels, and aggregate and abstract this data over time to provide pertinent feedback to the health professionals ('health service data management'). The delivery of timely and relevant information to the patient will be driven by best practice in, and modelling of, behavioural change theories ('behavioural change capabilities').

The PATHway project requirements are owned by its final users landscape (represented by Dublin (Ireland) and Leuven (Belgium) cardiac rehabilitation programs along with clinical experts). A dedicated project activity focused on their elicitation and complete specification; in detail the the early phase of the project carried out an analysis of user requirements ended with formal description of the of the end-user (i.e. clinicians focused on both physical and psychological aspects of cardiac rehabilitation) functional and non-functional requirements. The main results were valuable system design artefacts like: use-case diagrams and descriptions, class diagrams, sequence diagrams and, finally, a logical (and deployment) view of the PATHway application architecture; A detailed description of these results is documented within D2.5 deliverable ("Use-cases and functional requirements definition v2) released by WP2. In figure 1 a snapshot of the project work-packages logical organisation.

The work methodology involved a software engineers team from ENG (Engineering Ingegneria Informatica s.p.a.) in collaboration with the other project partners technical teams. They took care of the requirements specification by interacting with the domain experts and clinical teams. In this respect a requirement engineering process has been applied for the PATHway (i) requirements elicitation and analysis, (ii) the requirements definition and specification extraction and (iii) the final validation.

The requirements specification approach followed the Rational's Unified Process (RUP [5]) model with particular emphasis on the activities involved during the initial phases (i.e. Business Modelling, Requirements, Analysis & Design)

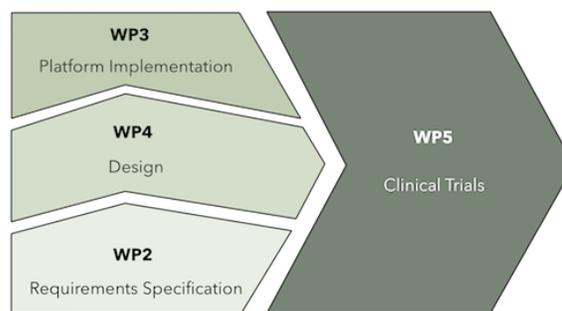


Fig. 1. Work packages dependencies

TABLE I
REQUIREMENTS CATEGORIES

<i>Home Environment</i>	<i>Clinical-Research Environment</i>
Exercising	CRP Management
Usage Reporting	Usage Reporting
Assessment	Patient Management
Behavioural Change	Exercises Management
Useful Resources Access	Clinical Research
Calendar Management	-

and the RM-ODP ISO standard [6].

The requirements engineering process adopted several actions in order to reduce the different background of the involved teams (see III for details) but nevertheless a number of face to face meetings were needed between software engineers and the clinical teams where the remaining unresolved points were analysed and discussed (e.g. general meeting in Leuven - June 2015). Following the process, the domain business entities were identified and described and their relationships made explicit obtaining, such a way, a logical model of the PATHway platform. Almost in parallel design actions produced other useful design artifacts at a very early stage, like UML sequence diagrams (for each identified UC), UML class diagrams (to represent detailed information model) and UML component diagrams (to describe each platform software component).

The requirements analysis took care to cover also non-functional requirements (NFRs) categorised following the common classification suggested by the standards [7]. In detail aspects related to (i) performance (ii) usability (iii) availability (iv) security (v) privacy (vi) scalability and (vii) portability, were captured to assess their fulfilment at implementation time.

The resulting user requirements specification (URS) highlighted the following categories of requirements as those of major interest for the three main actors (i.e. CR Programme Supervisor, Patient, Researcher) that the PATHway project has to support and validate. The Home Environment refers to capabilities offered to the Patient while the Clinical-Research Environment refers to those for CR Programme Supervisor and Researcher (see table I).

A brief resume below about such categories: in the next

section a full report about the extraction process of the UCs within each category.

1) Home Environment

- Exercise: this category covers all the specific requirements (i.e. UCs) in order to support the patient during the exercise activities. For instance the patient can start an [ExerClass] or an [ExerGame] session with the possibility to execute a preliminary health prescreening. During the activity a patient avatar and a coach avatar are displayed along with vital signs and achieved accuracy levels. Real time adaptation and next session adaptation is also performed.
- Usage Reporting: in this category the UCs to support the user in obtaining full feedback about his/her progress against the prescribed physical activity programme (i.e. Frequency, Intensity, Type and Time of exercise; F.I.T.T) and behavioural change goals.
- Assessment: this category contains all the UCs which enable the patient assessment at different moment and for different purposes. For instance an initial and periodic assessment are expected in order to evaluate the patients' exercise progress and to create and renew (respectively) the patient personal goals based on his/her lifestyle. Progress logging of specific behavioural change goals also falls in this category.
- Behavioural Change: UCs allowing the patient to manage his/her behavioural change. Personal goals management and good habits visualisation are examples. Also the possibility to set the notification preferences for receiving progress reports and suggestions is expected.
- Useful Resources Access: UCs related to the possibility for a patient to visualise useful healthy resources (like tips, recommendations, videos etc..) and for an administrator to update such content.
- Calendar Management: set of UCs describing interactions to create an [ExerClass] event and to manage possible actions (e.g. invitation acceptance, reminder notification etc..)

2) Clinical-Research Environment

- CRP Management: UCs describing the way the CR Programme Supervisor can create or edit the exercise programme (F.I.T.T.) of a patient.
- Usage Reporting: same progress can be visualised by both the patient and the CR Programme supervisor.
- Patient Management: this category gathers UCs aimed to support supervisor in managing the enrolment of patients to the CR programme (e.g. add patient, visualise patient, remove patient etc..) but also to acquire lifestyle assessments (e.g. smoking, stress management etc..).
- Exercise Management: UCs describing the administrative tasks to modify the set exercises (to use during a class or game) available in the platform.
- Clinical research: this category refers to those UCs enabling the querying of patient data for research purposes. They relate, for instance, to the query building

activity (by adding/removing filters) or to the download option specification or also to the preliminary patient data anonymization.

III. THE REQUIREMENTS ENGINEERING PROCESS

The requirements specification process is part of the more general software development process and, we initially started investigating the best approach to follow. The Reference Model of Open Distributed Processing (RM-ODP [6]) ISO standard which introduces the concept of *viewpoints* captured our interest. In fact using the five ODP viewpoints to examine system issues, a clear separation of concerns is encouraged. However we found some aspects limiting its adoption. In detail (i) viewpoints are offered as static view of an architecture without any relationship with a development flow/phase and (ii) the standard does not indicate a specific description language/mechanism to adopt. For these reasons the Rational's Unified Process [5] was investigated and finally adopted. It introduces, in fact, the concept of (development) phase (RUP-phase) with indication of the set of activities (RUP-disciplines) to execute in each phase. Furthermore it specifies through UML the modality to deliver the outcomes (i.e. RUP's models) produced by each activity. The figure 2 points out conceptual overlapping between ODP viewpoints and highlights also the UML adoption.

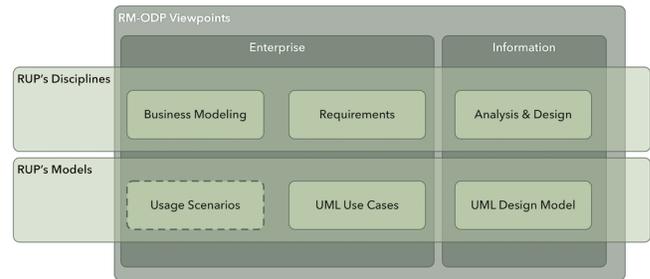


Fig. 2. RUP-ODP

Coherently it was decided to adopt UML Use Cases as the main instrument for the requirements analysis and formalisation. However as the requirements gathering processes started, something was missing: *the context*. For this reason an alternative solution was adopted in PATHway to trigger the interaction and the communication with possible users of the system: the *Usage Scenarios*. They refer to individuals playing a user role and describe a single path of logic. An usage scenario describes a real-world example of how one or more people or organisations interact with a system without any emphasis on formalism or constraints to adopt. Even if they are out of the UML models (dotted box in figure 2) their characteristics make usage scenarios simple for end users to write and read becoming a good working tool to achieve a common understanding and vision between end users and development team on the system behaviour. In conclusion Usage Scenarios were adopted as initial interaction modality with clinicians. After that each portion of textual description revealing an interaction between the user and the system finalised to allow the user to achieve a

specific objective, was highlighted in *italic font*. The analysis of the capabilities that the system should support started exactly from those statements. Each of them led to the definition of one (or more) UML Use Case(s) that have been referred with their identifier in square brackets after the statement (e.g. [H_UC01]).

In order to put in contact clinical and technical teams during the Usage Scenarios definition and UML Use Cases extraction, an on-line collaborative tool (i.e. google drive document) was adopted too see in real time possible conflicts due to the different point of view (see figure 3).

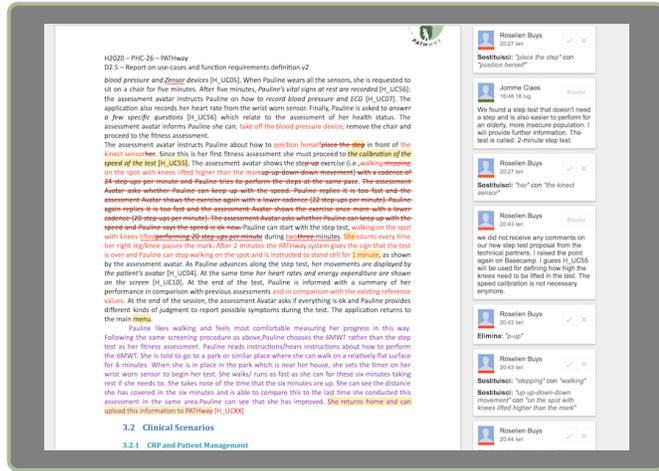


Fig. 3. Collaborative tool

In parallel with the scenarios editing, also the use cases were added. The diagrams use the UML standard [8], and the UC's textual description follows the Cockburn guideline [9]. Those was useful for the non-technical people to better understand the interaction among the actors of the use cases.

IV. THE PATHWAY USE CASES

By adopting the approach and tool described in the previous section the requirements elicitation process was conducted in collaboration with the user community of Dublin and Leuven hospitals and taking into account feedback from an external stakeholder panel. Each identified UC was associated to a specific category (see Table I) and a prefix in the UC label was adopted to catch this association (e.g. H_ = Home Environment).

This section intends to describe some choices during the application of the use-case driven approach by skipping, instead, details about the whole list of the UCs [10]. Currently there is no de-facto standard, universally adopted, about the use case approach neither (i) in terms of UML UCs diagrams organisation nor (ii) in terms of UCs textual description, but exclusively guidelines and recommendations. With regard to the first point in order to simplify the understanding of each *requirements category* (see Table I), an Use Case UML diagram was produced and associated to each main feature

of the system [8], and guidelines [11] [12] were considered to re-factor use case diagram as a whole in order to make it clearer. Furthermore the UML *extension* mechanism has been largely adopted with the main purpose to witness, in a clear and understandable way, the *system behaviours* at a large extent. It's worth mentioning this approach (favouring extend relationship in place of nesting behaviours in the same UCs thought alternative flows) demonstrated a wide approval. In fact it allowed to have a single document where all requirements are clearly reported also promoting the rapid evolution toward the design (hidden behaviours result very limited).

About the second point each use case was unwrapped in a table inspired by the Cockburn's guideline [9] and extended. The first, and useful extension, was the adoption of the Input/Output fields of the table. Reading those informations all the stakeholders, the clinicians and the technicians, were immediately aware of what that UC needed as input and, obviously, what is expected as returned output of the flow (figure 4). Another slightly similar fields used, are the Pre and

Input	Output
<ul style="list-style-type: none"> questionnaire answers Vital Signs sensors data <ul style="list-style-type: none"> heart rate (wrist worn sensor) blood pressure (wrist worn sensor) 	<ul style="list-style-type: none"> Pre-Screening info shown on the screen. The Patient is informed if he/she can (or cannot) start the exercise.

Fig. 4. UC description extension: Input/Output

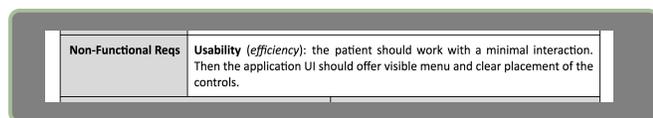
Post conditions; meant as the state of the system before and after the execution of the UC. Those aspects were really useful for retrieving the needed information, earlier in the process, for developing the data model rapidly (figure 5). Bearing that goal in mind, also a typographic emphasis was added to the main concepts present in this section (e.g. *Cardiac Rehabilitation Programme, Exercise Programme, Exercise Sessions*), the same concepts that would be part of the domain model in the following step.

Pre-Conditions	<ul style="list-style-type: none"> PC connected to the Internet, <i>Microsoft Kinect</i> is connected to the PC via USB, <i>WIMU</i> is connected to the PC via Bluetooth, Physiological sensors for heart rate, energy expenditure, blood pressure connected via Bluetooth. The patient has already accessed the platform (see <i>H_UC01 Platform Access</i>). <i>Cardiac Rehabilitation Programme</i> must be available in the system in its parts: <i>Exercise Programme, PreScreening Questionnaire</i> <i>Wearable Sensor Instructions</i> must be available within the system. <i>PATHway</i> application running and ready to receive commands.
Post-Conditions	<ul style="list-style-type: none"> Information gathered along the <i>Exercise Session</i> are recorded and transmitted to the Clinical Environment (HDM - Health Data Management System).

Fig. 5. UC description extension: Pre/Post conditions

Involving the clinicians in that phase, we also inserted the row for maintaining the Non Functional Requirements. Often in those fields were inputted some usability requests to look at

during the following implementation phases (figure 6).



Non-Functional Reqs	Usability (efficiency): the patient should work with a minimal interaction. Then the application UI should offer visible menu and clear placement of the controls.
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Fig. 6. UC description extension: Non Functional Requirements

V. THE USE CASE APPROACH APPLICATION & CO-DESIGN

The adoption of informal anecdotes (i.e. the usage scenarios) and concrete collaboration tool (see III for details) favoured the participation of clinical teams to the requirements formalisation process and their confidence with the UML use cases mechanism too. Nevertheless it was considered appropriate to further improve the requirements and design process by interlinking it with the direct participation of the final users. In that co-design steps the final users and expert stakeholders were directly involved as co-designer of the application from their point of view. This phase of co-design was performed in Dublin and Leuven.

Patients and health professionals were engaged with iterative development work to finalise clinical and user recommendations for the PATHway system and content. A user centred development process is an integral element of any digital health behaviour change intervention. This ensures that the system adheres to both guidelines and recommendations,[13] [14] [15] while maximising the extensive input from patients and stakeholders. In order to extract feedback from the target user group, a user need analysis was performed, aiming at gathering both quantitative and qualitative information.

A first step in the user need analysis, consisted of a questionnaire based cross sectional study investigating technology usage and interest in technology enabled CR in divers cardiac patient population.[16]

Almost 300 patients responded to the questionnaire and a high interest in technology enabled CR was reported. The second step in the user need gathering, consisted of in depth interviews both with cardiac patients and with stakeholders such as cardiologists, physiotherapists, nurses, exercise physiologists... working in the field of CR. The interviews were qualitatively analysed and summarized. Based on the current guidelines for CR, [17] [18] [19] [20] the results from the above mentioned user need analyses and expert opinions, the initial PATHway content was created and formed so that it met the wishes and needs of the patients.

Over a period of three months, three rounds of tryouts using semi-structured scripted focus groups were conducted. These allowed the research team to explore PATHway user friendliness and patient satisfaction while involving the patient in the iterative development of the system. These focus groups showcased an updated version of the PATHway prototype with feedback from each round incorporated by the technology partners prior to the next focus group. Thirty CVD patients (18 male; 12 female; age= 55-75years) from (i) 2 hospital-based

cardiac rehabilitation programmes and (ii) 2 community-based cardiac rehabilitation programmes were invited to participate. In round one interviews, participants were exposed to the PATHway program and system and feedback was elicited. This was repeated on three occasions with an updated PATHway system which incorporated feedback from the previous round insofar as possible. All focus groups were audio-recorded, transcribed and analysed. Key recommendations regarding technical and cardiac rehabilitation content were identified. In round one, the feedback mainly centred on the visuals and aesthetics of PATHway, with suggestions around making the screen clearer and removing distracting graphics. The use of colour (i.e., the traffic light system) was also suggested as an intuitive way to communicate progress to the end-user without requiring several interactive steps that may burden the user. Round two feedback largely focused on the developed risk factor content on the dashboard, as well as peer mentor videos and all information needed for tailoring the system to the patient.

Round three feedback highlighted desired features for the 'Health and Fitness assessment' use-case. Participants also highlighted what they deemed to be necessary components to support patients using PATHway independently (i.e., IT support and the type of content requested for a PATHway training manual).

Additionally, a stakeholder expert panel was hosted to review existing content, the theoretical basis and logic behind the programme. Feedback was also elicited in relation to the key components and functionality of the intervention.

In this Co-Design process, performed by the clinician team, a sub-process of evolutionary prototyping[21] has been put in place for supporting in the best way the clinicians, and for getting more feedback as possible from the participants of the focus groups.

VI. CONCLUSION

The work demonstrated a valuable result associated to the adoption of use case technique and final user co-design, within a more general RUP development process. More in detail we tried to increase the general efficiency of the process by covering implicit weakness/limits of use case approach described in the introduction. For instance the Usage Scenarios technique and appropriate collaboration tool were exploited to support the final user general context elicitation and description in a complementary fashion (see Section III). In fact such instruments simplified and boosted the communication with (and among) the clinical teams appointed to distinct (even if related) health areas - physical (Leuven) and physiological (Dublin) aspects in cardiac rehabilitation programme - which in turn facilitated the arising of the user context.

Similarly tailored choices were implemented to tackle unspecified aspects concerning UML UCs diagram factoring and textual description. They permitted to have from one side a description still quite simple to allow a direct analysis by clinicians and, from the other, to capture aspects useful to technical teams for a rapid evolution toward the design. Last but

not least co-design steps involving final users were interleaved with the design flow with the main result to improve the use case formalisation step and requirements understanding.

Really in the last years the UML UCs approach and the user-involvement principle [22] increased in the health domain and medical solutions. Nevertheless we did not find, at the best of our knowledge, a comprehensive approach covering all the aspects just highlighted.

In [23], for instance, UML use cases have been adopted to model the requirements of a system for (elderly people) falls detection. An UC description table, similar to the one we adopted in PATHway, has been exploited in that context, even if Input/Output fields result missing and there is no reference to the UC diagram factoring criteria. Nevertheless no critical considerations came up about the efficiency of the UC approach and UML expressiveness, demonstrating their soundness in supporting the clinical and technical teams dialogue. In [24], instead the followed approach is different than the presented in the current paper, but aiming at similar results promoting an health care process modelling technique; however the broad adoption of UML UCs instrument within software engineering field and their easy access to not technical teams - thanks to a declarative descriptions (i.e. description tables) - represents and remains an added value.

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