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## User-Centered Design of the C3-Cloud Platform for Elderly with Multiple Diseases – Functional Requirements and Application Testing

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### Abstract

The number of patients with multimorbidity has been steadily increasing in the modern aging societies. The European C3-Cloud project provides a multidisciplinary and patient-centered “Collaborative Care and Cure-system” for the management of elderly with multimorbidity, enabling continuous coordination of care activities between multidisciplinary care teams (MDTs), patients and informal caregivers (ICG). In this study various components of the infrastructure were tested to fulfill the functional requirements and the entire system was subjected to an early application testing involving different groups of end-users. MDTs from participating European regions were involved in requirement elicitation and test formulation, resulting in 57 questions, distributed via an internet platform to 48 test participants (22 MDTs, 26 patients) from three pilot sites. The results indicate a high level of satisfaction with all components. Early testing also provided feedback for technical improvement of the entire system, and the paper points out useful evaluation methods.

### Keywords:

Multimorbidity; Evaluation Studies; User-computer Interface.

### Introduction

The World Health Organization estimates that 63% of all annual deaths (~36 million people) is attributable to non-communicable, chronic diseases [1] and the number of people with multiple comorbidities has increased considerably for some years, mainly due to the ageing of the population [2]. Elderly patients with multimorbidity (i.e., having at least two chronic diseases) [3] are at higher risk of safety incidents [2]. These could include incidents such as delayed diagnosis, no recommended treatment, drug side effects, drug interactions, over/under dosage of drugs, complications, infections, etc [2,4]. Increased risks in patient safety, in this context, may be explained by many reasons. Firstly, patients with multimorbidity are often polymedicated, with a potential

decrease in treatment adherence and a possible increase of drug side effects. Secondly, patients may receive contradictory advice or treatments, due to the application of different guidelines that are designed to manage only single disease pathways. Thirdly, patients with multimorbidity are often cared for by several health and social care (HSC) professionals, who are not always coordinating and communicating throughout the patients' journey. For example, there is often a lack of communication between general practitioners (GPs) and secondary care specialist centres. Finally, these patients are often more vulnerable than others, due to their multiple diseases and their advanced age, which makes the care process even more complex.

C3-Cloud<sup>1</sup> is a European Commission supported Horizon 2020 research and innovation project, which aims at improving the provision of integrated care to patients with multimorbidity via enhanced ICT solutions. The research aims at resolving guidelines' conflicts (by reconciliation of varying recommendations from individual disease guidelines), supporting clinical decision making through clinical decision support services, and facilitating communication among multidisciplinary care team (MDT) members through an interoperable platform, which integrates patients' health records from existing Electronic Health Record (EHR) systems [5]. The project mainly focuses on elderly patients (65+) with diabetes, heart failure, renal failure and depression in different comorbidity combinations. Three European pilot sites are involved in the study: Osakidetza (Basque Country, Spain), RJH (Region Jämtland Härjedalen, Sweden) and SWFT (South Warwickshire NHS Foundation Trust, UK).

The C3-Cloud system consists of a variety of components:

- Coordinated Care and Cure Delivery Platform (C3DP),
- Patient Empowerment Platform (PEP),
- Clinical Decision Support Modules (CDSM),

<sup>1</sup> <http://C3-Cloud.eu>, Federated Collaborative Care Cure Cloud architecture for the needs of multi-morbidity and managing poly-pharmacy.

- Interoperability Middleware, which includes modules of technical and semantic interoperability, as well as privacy and security.

All these components constitute the solution that will be used for the technological trial of the C3-Cloud application. Following a user-centered development (UCD) approach [6], the solution has to be evaluated iteratively during its life cycle; during development and implementation with a restricted number of participants, during deployment with a larger number of users as well as during the routine phase for prospective cost-benefit analyses and real impacts.

The objective of this study is three-fold: the report of the user-centered functionality testing, the conclusions to further improve the C3-Cloud system and, for the community, to present useful methods among the UCD evaluation methods often used in health informatics.

## Methods

This evaluation consisted of a number of questionnaires to collect user feedback regarding system functionality. The questionnaires were created based on a Delphi approach [7]. In the context of the project, a total of 51 pilot application requirements (PARs) and 72 use cases were defined covering the scope of all high level C3-Cloud components to depict expected functionality. Three different types of users interact with the system: multidisciplinary team members (MDTs) also known as health and social care professionals; patients; and informal care givers (ICGs), and are accordingly studied. This is in line with previous informatics research, e.g. OLD@HOME[8–10] and more recent research regarding patient access to health information [11–13]

This qualitative inductive study directly separated the demands or requirements with the use cases needed. For example, “as a patient, I need to access drug interaction information” is a PAR for the pilot sites and “Enabling patients to access self-management material” is a use case of the PEP component. A full list of user scenario descriptions and PARs is presented in deliverable D8.1 [14].

### Evaluation Procedure

Following the Delphi approach [7], the evaluation framework was developed:

#### *Brainstorming: Formulation and Evaluation of an Initial List of Relevant Questions*

Based on an analysis of 51 PARs and 72 use cases, the first step was to formulate a list of questions, starting by a simple mapping (1 PAR to 1 use case) to identify possible links between the PARs. Secondly, the questions were grouped by profiles identified during the PARs’ analysis process, in order to define one questionnaire per user profile. The workflow was based on a C3-Cloud key scenario linked to a use case and defined by application testing criteria.

#### *Refining and Prioritization: Internal Review Based on a Cognitive Walkthrough by Experts*

The initial questions were reviewed by the three pilot sites as well as by the technical partners of the C3-Cloud project. The results of the cognitive walkthrough [11] by five IT and clinical reviewers, allowed us to validate, modify, delete or add questions based on the updated PAR list and covered system functionality. Based on the review from the aforementioned experts, although addressing different professionals and individuals, the questionnaires could be appropriated to, two

user profiles: 1) MDTs and 2) Patients & ICGs, as grouped respondents of the questions.

### Think Aloud

During the test sessions, the think aloud method [11] was encouraged and the pilot site managers, who moderated the sessions, noted all comments of the participants. Feedback from the different pilot sites could be complementary. If feedback was raised more than once, it was reported only once. Examples, issued from the feedback, and how they were handled by technical partners to improve the C3-Cloud components, are reported in the Result section.

### Evaluation Set-Up

We implemented an online application that allowed participants to answer questionnaires. The application site is available at <https://c3cloud.irsan.eu>. In the questionnaire, participants responded with [Yes], [No] and [NA] (for functionality, which was Not Available). When the response was [No], both MDTs and Patients/ICGs had the opportunity to specify and explain the problem faced by writing free text comments.

### Participants

Overall, 26 elderly patients (> 65 years) and 22 MDTs from the three pilot sites: Osakidetza, RJH, and SWFT; participated in the testing. At the time of testing, only an English-language demonstrator and materials were available, and local sites considered this when recruiting test participants.

### Test Sessions

The participants received login credentials for the online demonstrators of the C3DP (for MDTs) and the PEP (for Patients/ICGs) as well as training materials including a walkthrough that guided them through certain activities on the demonstrators. For the Osakidetza and RJH pilot sites, a language facilitator moderated each session, and was available for translation of the material and any other question raised by the participants. Think aloud notes taken during the test sessions generated a summary report.

## Results

Overall 57 questions were formulated; 33 for MDTs and 24 for Patients & ICGs. Below, detailed results of the application testing for MDTs and Patients/ICGs, respectively, are reported, as well as examples of the questions in the questionnaires.

### Evaluation by MDTs

Questions were categorized by the following main topics: Care Plan; Decision Support Module; Patient Data; Communication; and Notifications. The MDT responses [Yes], [No] or [NA] are reported, in percentages, in Table 1.

Table 1– Summary of MDTs average response rates to C3-Cloud application testing

MDTs’ Response rates C3DP Categories	[Yes]	[No]	[NA]
Care plan	94 %	4%	2%
Decision Support Module	72%	0%	28%
Patient Data	75%	6%	19%
Communication	79%	3%	18%
Notification	89%	5%	6%

Questions related to Care Plan received the highest amount of [Yes] responses, 94%. The following questions received positive responses by all (N=22) participants:

- “Are you able to create a new specialized care plan for the patient?”
- “Are you able to define new or update the planned intervention?”
- “Are you able to define new or update self-care activities (like exercise recommendations)?”

The question “Are you able to update an existing care plan?” scored: [Yes] 82%, [No] 9% and [NA] 9%. The [No] responses were complemented with MDT comments, revealing that some update functionalities were missing. For example:

- “I can update some elements of the plan as goals and activities and training material, but I cannot update the health conditions of the patient.”

From the free text feedback, further details about “health conditions,” in a new care plan creation, were considered, together with improvement proposals from MDTs and responses from the technical partners. For example:

- MDT proposal: “When creating a new care plan ‘Addressed Conditions’ may need rephrasing. It is also unclear how it is decided what conditions the list here suggests. The list can be very long if many conditions apply or are possible.”
- Technical partner improvement feedback: “Addressed conditions will be removed, the SNOMED-CT codes of the 4 main diseases will be added.” Regarding the Decision Support Module, an average of 72% of the participants provided [Yes] answers to questions such as:
- “Does the Clinical Decision Support Module give you advice about treatment options such as i) new safety, treatment or lifestyle? ii) starting/stopping of medication, based on the most recent context of the patient including changes in recent remote monitoring results?”

There were zero [No] answers and [NA] responses were rated at 28% on average, meaning that all accessible functionalities were approved by the participants.

For Patient Data, average responses were [Yes] 75%, [No] 6% and 19% for [NA]. There were highly rated [Yes] responses >90% for questions such as:

- “Are you able to access patient data after the Care Plan Manager approved your membership to the Multidisciplinary Care Team?”
- “Are you able to review the patient’s Health Records?”

A lower percentage of [Yes] responses were received, for example, regarding questions like:

- “Are you able to access the readings, that have been uploaded by patients manually or via remote monitoring systems such as wireless medical sensor devices?” with [Yes] 55% respective [NA] 36%.
- “Are you able to follow-up patients’ activities, such as complications, side effects via questionnaires?” 68% responded [Yes] and 18% [No] which were completed with MDT comments like “Not recorded” and “Did not find them...”
- “Are you able to access information completed by the patient such as files uploaded via the PEP?” 64% responded [Yes] and 32% responded [NA].

**Communication** questions were related to message exchange between the MDT members or invitations to another specialist to join the care team. On average, 79% responded [Yes], 3% [No] and 18% responded [NA]. Questions regarded, e.g.:

- “Messaging - Are you able to send messages to other members of the MDT via asynchronous messaging?”
- “Invitation - Are you able to invite another specialist to join the patient’s Care Team?”

Finally, responses related to **Notification** functionalities received an average of 89% [Yes], with questions such as

- “Are you able to notify the existence of the updated care plan to Care Team Members and to the patient?”
- All participants (100%) answered positively on
- “Can you see the upcoming activities in your calendar and in the Activities section of your dashboard?”

**Evaluation by Patients and ICGs**

For the Patient Empowerment Platform (PEP), Patient and ICG responses were categorized in the following main topics: Care Plan; Patient Empowerment; Patient Data; Notifications and Communication. The responses [Yes], [No] or [NA] are reported, in percentages, in Table 2.

Table 2 – Summary of Patients & ICGs average response rates to C3-Cloud application testing

Patients and ICGs Response rates			
PEP Categories	[Yes]	[No]	[NA]
Care plan	87%	4%	10%
Patient Empowerment	68%	8%	24%
Patient Data	48%	4%	48%
Communication and Notification	32%	5%	63%

Questions related to the Care Plan received average responses of 87% [Yes], 4% [No] and 10% [NA]. Examples of questions:

- “As a Patient or Informal Care Giver, are you able to access the care plan?” 96% of participants responded positively, and 4% responded [NA]
- “Do you receive enough advice and support about how to follow the care plan?”

[No] responses were provided, with comments such as:

- Not clear how to work through the system.
- Not obvious what needs to be done, when and how. Some guidance notes would be helpful.
- More time is needed.
- Needs to be more simple with clear single click pathways trough each of the components for the patient. A lot of the technical material in each patient activity is not needed by the patient and therefore confusing.

**Patient Empowerment** average responses were 68% of [Yes], 8% of [No] and 24% of [NA]. Example of questions:

- “Do you think that the information given could help you to improve your health and wellbeing?”
- 85% responded [Yes], 15% responded [NA].
- “Are you able to learn about treatment options through the PEP?” 61% [Yes], 8% [No], 31 % [NA].

- “Are you able to learn about drug benefits through the PEP?” 58% [Yes], 11% [No], 31 % [NA].
- [No] responses were completed, with patients’ comments as: - *Not recorded*, - *Depends on which materials are presented*, - *I have not stopped/answered*.

**Patient Data** gathered average response rates of 48% for [Yes], 4% for [No] and 48% responded [NA]. Some examples

- “Are you able to access the readings uploaded to the system from remote monitoring systems (e.g., wireless medical sensor devices) from the PEP?”
- 42% responded [Yes], 8% responded [No], 42% lacked the functionality with [NA] responses.
- “Are you able to upload documents, such as a picture, to your PEP?” 54% responded [Yes] and 46% [NA].
- [No] responses were completed, with patients’ comments such as: “*Not available*”, “*I have not tried it*”.

**Communication and Notification** average responses were 32% [Yes], 5% [No] and 63% [NA]. Example of questions:

- “Messaging - Are you able to contact MDT members via messaging from the C3-Cloud Platform?” 58% [Yes], 0% [No], 42% [NA]
- “Video calls - Are you able to join a video conferencing session with MDT members?” 8% [Yes], 92% [NA]
- “Notifications - Are you able to schedule an appointment with your Primary Care Provider?” 16% [Yes], 15% “No and 69% [NA]

### Proposed Actions Based on the Evaluation

Based on the technical partners’ feedback regarding the overall responses from participants, below is a summary of issues to be handled to improve the first version of the C3-Cloud system. These issues are currently being followed up in the project in relevant work tasks.

- Bugs – errors related to the expected functionality should be fixed.
- Training needs to be improved – related to the uncertainty of users regarding the functionality of the system, next steps, scope.
- Local configuration – local customizations need to be implemented during deployment.
- Evaluation questionnaires – More time to complete the tests and a way to report issues repeatedly..
- Language – issues related to native language usage on the platform, both for local configuration and content.
- Feature improvement – issues related to aspects such as unclear labels, layout, etc. Some comments for features could be out of scope but noted for future recommendations.
  - Incomplete/unclear specification – insufficient information to implement the improvement, for example: Care plan content, and concept issues – specific issues relating to care plan clarifications are required.
  - New feature – a new feature requested.

- Visual guideline – information missing regarding visual guidelines or available accessibility settings.
- Test data unrealistic – value ranges incorrect: can be improved with realistic test samples as provided by pilot sites.
- Scope clarification – the scope of the project needs to be clarified [to whom?/technicians/developers/?] in order to implement improvements.

### Discussion

Our findings indicate that with the help of a user-centered design methodology [6] it was possible to define the functional ICT requirements for the C3-Cloud project and further refine them through an early application testing by end-users. A combination of different techniques that complement one another should preferably be used as their collective application will be more powerful than applied in isolation [11]. Therefore we used different evaluation methods.

The first approach used, inspired by the Delphi method, permitted “to obtain the most reliable opinion consensus from the group of experts by subjecting them to a series of questionnaires in-depth and interspersed with controlled opinion feedback”[7]. The development of the questionnaires for application testing was therefore preceded by and based upon the creation of pilot application requirements which were matched with the use case scenarios, and later reviewed by both IT and clinical experts. However, we are aware that a second review round by the experts may have improved the formulation of the questions.

During the test sessions, we observed some limitations regarding the contextual coupling and synchrony between the test environments that were based on PARs and case scenarios and the perceived relevance of some items of the questionnaires. This was highlighted by some of the responses from the participants such as: “not finding the option”; “not knowing”; “not been informed about it”; “not clear how to work through the system”; “not obvious what needs to be done”; “more time needed”. Although we encouraged the think aloud method during the application testing, in some cases feedback was too vague to be interpreted. For example, such feedback included statements such as “Depends on which materials are presented” and “I have not stopped/answered”. In such cases, participants need to be more specific about the problem they face, and the observers need to make sure they fully understand what the user means at that specific moment.

The analysis of feedback also highlighted that it would have been advantageous to apply a shorter questionnaire that addressed some site-specific smaller discrepancies of the C3-Cloud platform and the language-related barriers. Most notably, the prerequisite of a good command of English caused both limitations regarding the recruitment of participants and an accurate understanding of nuances in the non-English speaking countries. Additionally, some participants felt that the questionnaire was not sufficiently detailed to allow them to express all their concerns with the C3-Cloud platform. Specifically, some suggested that it would have been more efficient to answer questions directly in the evaluation walkthrough document, which in turn would have enhanced their understanding of the entire test module in advance. Further, two participants did not feel that they wanted to use the patient empowerment platform in its current format at all.

Notably, as the majority of the participants were elderly, early testing in the development is crucial, as one could expect that such users would experience difficulties with the comprehension and adaptation of the novel C3-Cloud platform, but it could be hard to know in advance where in the system the unintended effects arise. This finding is in line with current research on evaluation methods in health IT, used for early detection and addressing of the unintended consequences of IT usage [12]. However, the overall response of the participants was that the system has great potential to simplify and enhance their engagement in and understanding of the care process. This was reflected by the high overall rate of positive [Yes] responses.

This study also demonstrated that with a multi-faceted user-centered design methodology it was possible to perform an early evaluation of a complex ICT infrastructure, involving different groups of end-users from three different pilot sites (in Spain, Sweden, and the United Kingdom), which in turn further consolidated the European-wide collaboration within the C3-Cloud project. This constructive evaluation was performed at an early stage of the development to achieve a fast improvement of the C3-cloud system. The results summarized in the section “Proposed Actions Based on the Evaluation” were communicated as user feedback to the technical partners, who have reconfigured and updated the C3-Cloud components accordingly. Incorporating the end-user’s requests for change and modification has been completed before the pilot application deployment. The C3-Cloud platform, which has been developed by the results of this evaluation, will be subjected to further and more rigorous testing based on real life experience, with actual MDT members and patients/ICGs in the three pilot sites during the planned pilot study starting in April 2019.

## Conclusions

This study demonstrates how an integrated application can be tested against the requirements, as elicited through an extensive European collaboration, to improve care for the elderly with multiple diseases. Mainly, application testing was performed without any adverse incident. The online platform worked well throughout the application testing sessions. The aim of this evaluation was not only to appraise the system’s functionality, but also to investigate how to improve the C3-Cloud application and its implementation further. The results obtained reflect insights from MDTs, patients and informal care givers for both user-facing components: C3DP and PEP. Overall, this application testing is an early evaluation exercise in order to adapt the system, where needed, and to get the first users’ feedback for further development. Integrating the questions into the evaluation walkthrough document, so that participants can answer the questions as they are testing the relevant sections, would make it simpler for the participants.

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