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- Title:

User-centred design for developing e-Health system for renal patients at home (AppNephro)

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- Declarations of interest: none

➢ Abstract

Background: Despite the promising benefits of the e-Health approaches (including provide technology-based healthcare services to anyone, anytime, and anywhere), few solutions are adopted in daily practice. User acceptance is one of the major obstacles that hinder the success of technology approaches. End-users often stress misalignments among their problems and the solutions that technology systems aim to solve. In other cases, systems developed are unfriendly or unadjusted to the daily practice of clinicians or patient's life. To maximize user acceptance, the relevance of adopting user-centred design and development techniques is well-known. However, users are often assumed to be a homogeneous group with the same set of requirements, what leads to an ineffective identification and addressment of user requirements. Furthermore, usability and accessibility issues must be carefully addressed to guarantee also the right alignment of solutions with user needs.

Objective: to develop an e-Health system for renal patients at home by adopting user-centred design practices, usability and accessibility standards.

Material and methods: users were categorized in four different groups (i.e., digital patients/caregivers, non-digital patients/caregivers, clinicians and nurses) and a sample was included in the design and development team. Questionnaires and interviews were used to identify user requirements and assess prototypes.

Results: Requirements were considered for every kind of user, what resulted on a multi-faceted e-Health system implying different technologies and functionalities regarding to each target user.

Conclusion: Identification and continuous involvement of all kind of users allow their needs to be properly understood and addressed by technology, raising user acceptance of the final product.

➢ Manuscript

1. Introduction

Health systems are facing the increasing demand and cost related to chronic conditions that urges to seek new solutions. The e-Health paradigm (including m-Health solutions) has emerged with potential to address those new requirements meanwhile providing healthcare services to anyone, anytime, and anywhere [1][2]. However, few e-Health solutions are adopted in daily practice. User acceptance is one of the major obstacles that hinder the success of technology approaches [3]. End-users often stress misalignments among their problems and the solutions that technology systems aim to solve. In other cases, systems developed are unfriendly or unadjusted to the daily practice of clinicians or patient's life. [4]

Two features should be carefully considered in any efficient e-Health solution: context and users. On one hand, technology enables the provision of pervasive healthcare services. This may lead to a variety of scenarios and contexts of use (e.g., indoors –home, hospital, third party facility- or outdoors), with a heterogeneous set of requirements regarding technological, privacy/security and organizational issues. On the other hand, a broad spectrum of users (e.g., patients, health professionals, informal caregivers, relatives, etc.), each one with his/her own needs and expectations, may interact with e-Health systems and influence their success. To foster user acceptance of technology, it is important healthcare consumers to have a positive attitude toward using such system [5][6].

Key factors influencing user acceptance are the usability and accessibility [3][5-8]. It is critical for real-world applicability to situate e-Health systems within the context-specific needs of the people benefiting from or otherwise affected by them. Usability and accessibility issues must be carefully addressed in order to guarantee also the right alignment of solutions with user needs. e-Health systems should address every user need to maximize acceptability [9]. But dominant culture in the health industry continues training people to adapt to poorly designed technology, rather than designing technology to fit their characteristics, needs and work requirements.

For e-Health systems to be usable and friendly, there is a need to adopt a human-centred design approach in their development [10]. But most e-Health systems include end-users late in the design cycle, either at the end of the system design or after implementing the system [11]. In recent years, the number of publications involving users in the development process is increasing [4][12-15]. Nevertheless, there is a general lack of studies that both show the design evolution of e-health systems and explain the rationale for the choices made [8].

Chronic kidney disease (CKD) is a chronic condition that affects in Spain to 10% of population and consumes 3% of the total health expenditure [16]. Home peritoneal dialysis is one of the most promising renal replacement therapies to provide efficient healthcare, increasing quality of life and diminishing costs. However, a remote and supervised monitoring is mandatory to effectively act if health risks or emergencies happen.

This paper illustrates the development of an e-Health system for the monitoring of renal patients at home by adopting a user-centred design approach in which target users are involved throughout the product development process [17]. Requirements are considered for every kind of user what results on a multi-faceted e-Health system, implying different technologies and functionalities regarding to each target user. User requirements stressed the potential of mobile technologies for self-monitoring, and a mobile app (AppNephro) was developed accordingly.

2. Materials and methods

2.1. Study case: e-Health system for renal patients at home

The system e-Nefro is the result of a multicentre research project between the University of Sevilla and five Spanish hospitals. Its objective is easing the monitoring of renal patients at home through an e-Health system adaptable to different kind of users and scenarios [18].

One of the first activities was the specification of the target audiences (by adopting the code of practice of ISO/IEC 30071-1 [19]), including disabled and older users alongside non-disabled users. For the analysis of user accessibility needs of the target audiences in appropriate contexts of use, semi-structured interviews with nephrologists were performed. In addition, patients and caregivers were consulted through specific questionnaires to understand their experiences in the hospitals. Several accessibility standards were analysed for extracting design requirements of user interfaces for people with limitations. For example, the standard ISO 29138 [20] on needs of users with disabilities, the Spanish standard UNE 139803 [21] for accessible web content (inspired by the Web Content Accessibility Guidelines, WCAG 2.0 [22]) and the standard ISO 9241 [23][24] for tactile devices.

A methodological approach based on user centred design [25] and agile development process practices was adopted [26]. Involvement of users in all stages of design and development eases the product final to be flexible enough to adapt itself to the needs, uses, and preferences of each user no matter his/her characteristics (i.e., accessibility). A continuous evaluation based on user during design and development stages were also included.

3. Results

3.1. User identification and requirements

Fig. 1 shows target audiences identified. Although patient and clinician are the main end-users of any e-Health system, formal/informal caregiver and nurse may also play relevant roles in remote healthcare, and their requirements must to be considered. Furthermore, technology literacy and access may influence the deployment of solutions and acceptance by patients and caregivers. So, individuals should be divided in digital and non-digital sub-populations.

Semi-structured interviews and questionnaires were performed to health professionals, patients and caregivers with the objective of understanding their real needs and translating them to requirements [18]. Table 1 shows technological specifications and initial requirements extracted from users to design the e-Health system. Besides requirements of each kind of end-user, any user may present impairments and disabilities that hinder the effective usability of non-adapted technology systems. Thus, accessibility requirements must be considered in parallel for any kind of user, and the standards referred above are a good starting point. In addition, standards ease the extension and translation of the final product to other scenarios and countries.

Requirements served for the conception of an initial system design and the development of a low-fidelity prototype (by adopting an iterative process of design and incremental development based on periodic revisions). User validation of this prototype allowed assessing usability and functionality of the system e-Nefro, and several issues raised in this stage.

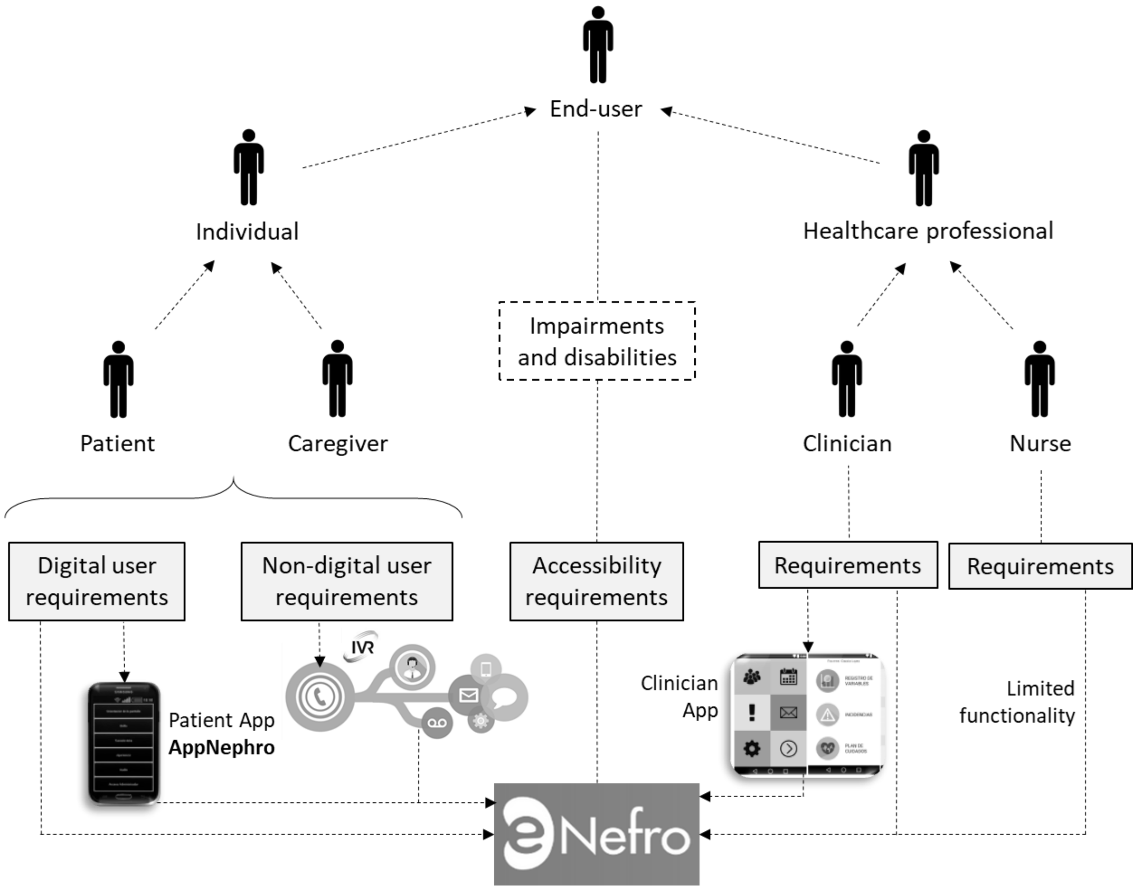

Fig. 1. Target audience of the system e-Nefro and developed modules devoted to each group

Two main usability issues of the low-fidelity prototype made hard the completion of tasks (such as access to monitoring records or introduce measures of physiological variables) and discouraged to any user: an abrupt learning curve and an excessive navigation across different screens to exploit system functionality. Both patients and professionals unanimously emphasized the need of simplifying the navigation through the system and making it as intuitive as possible. Furthermore, most patients and clinicians were interested in being provided with a mobile app devoted to the system e-Nefro as alternative access method.

This identification of requirements led to new development iterations, resulting in a high-level prototype of the e-Nefro system consisting in six modules (Fig. 1): (1) web and (2) mobile app for digital patients/caregivers (i.e., AppNephro), (3) access module based on interactive voice response (IVR) for non-digital patients/caregivers, (4) web and (5) mobile app for clinicians, and (6) web for nurses. All modules work together to provide a shared service. Thus, no matter what module is used to access to the system or to store/retrieve information since data of patients and care plans is stored in a shared database.

Table 1. Initial user requirements and technological specifications

<table>
<tr><th colspan="8">Patients and caregivers</th></tr>
<tr><td colspan="2">Capacity to monitor and transmit automatically health and environment status</td><td colspan="2">Capacity to notify automatically or per-user-demand emergency situations</td><td colspan="2">Straight and simple communication with health professionals and caregivers</td><td colspan="2">Reception of useful information about treatment and access to health information</td></tr>
<tr><th colspan="8">Clinicians</th></tr>
<tr><td colspan="2">Access to complete and reliable health records of patients</td><td colspan="2">Anytime availability of monitoring data updated in real-time</td><td colspan="2">Reception of critical events in real-time</td><td colspan="2">Don’t be overwhelmed with non-critical alarms</td></tr>
<tr><th colspan="8">Nurses</th></tr>
<tr><td colspan="4">Access to complete and reliable health records of patients</td><td colspan="4">Management of patient appointments</td></tr>
<tr><th colspan="8">Technology requirements</th></tr>
<tr><td>Remote access</td><td colspan="2">Transparency of complexity for end-user</td><td>Interoperability</td><td>Asynchrony & concurrency</td><td colspan="2">Reliability on message communication</td><td>Heterogeneity of access systems</td></tr>
</table>

3.2. The system e-Nefro: e-Health system adapted to users and contexts of use

A. e-Nefro for digital patients/caregivers

Digital patients and caregivers can access the system e-Nefro through a web application or an Android-based app (AppNephro). Both channels allow a patient (or his/her caregiver) to check pending activities on his/her treatment plan (i.e., medication intake, vital signs measurement, medical appointments…) and to introduce information about its performance. In addition, he/she can inform about risk events or contact his/her health carer. The web access provides a friendly interface with some elements that ease navigation (Fig. 2). For example, when the patient logs in his/her pending activities are showed at the entrance screen with no need to search for them. Furthermore, the side agenda allows consulting activities to perform in previous and future days, shows next medical encounters, and warns if any monitoring data has not been introduced in previous days.

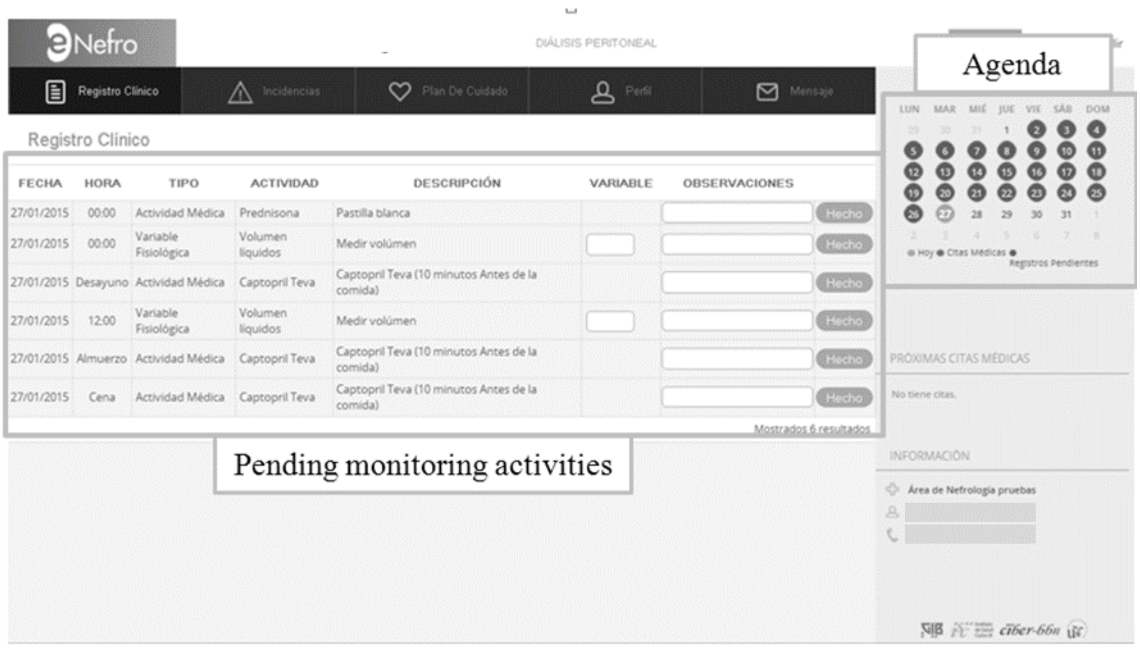

Fig. 2. Screen for the follow-up of patient's care plan

The mobile access is provided by the AppNephro, an Android-based application where accessibility and usability are addressed through the inclusion of the following capabilities: (1) interface customization regarding user needs; (2) remote change of accessibility settings by an administrator, if user needs help; and (3) the possibility of making calls and managing contact list in an accessible environment. Fig. 3 shows various screenshots of the AppNephro. This has several configuration options to customize the interface to user preferences and limitations. Accessibility options chosen are stored in the application and automatically incorporated into the interface during the execution of patient's care plan.

Fig. 3. Screenshots of AppNephro (left to right: setting menu, home screen, and temperature input)

AppNephro validation was carried out iteratively and consisted of two parts: accessibility test and usability test. The former focused on evaluating the customization options, and the latter sought to assess the ease of use and performance of the care plan, once AppNephro was configured according to user preferences. A controlled sample of users was involved in the preliminary assessment, covering different ages, vision and hearing limitations, and technological skills (Table 2). The realization of these tests was repeated during the design and implementation of AppNephro until at least 75% of average rating in both phases, resulting in the first prototype of AppNephro shown in Fig. 3. The most relevant findings obtained during the validation process are described below.

Table 2. Characteristics of participants in assessment tests

Gender	Age	Limitations	Skills on use of smart devices
Man	70	Visual	Low
Woman	66	Visual and Auditory	Null
Man	61	Visual	Medium-Low
Woman	55	Visual, difficulties of understanding	Low-Null

Firstly, a practical presentation was performed for each participant in the test of how to adjust the application to suit his/her personal preferences, and how to access to general functionalities of the phone (e.g. making calls or managing contacts). Then the participant was asked to undertake by itself a number of configuration changes such as changing the orientation of the screen, adjusting text size or selecting colours.

After performing these tasks, participants completed an evaluation questionnaire including questions pondering both simplicity of use as impressions of users in its management. The result of this first test was successful, and the consensus was unanimous in assessing the accessibility of the application (Table 3). These results are consistent with the design methodology adopted that conforms international standards of e-accessibility, actively involved users in the process of design and development, as well as specifying the accessibility requirements the application.

Table 3. Sample of questionnaire of AppNephro customization assessment

Questions	Answers (N=4)

Do you consider it is easy to…			
…modify customizable settings?	Yes (75%)	No (0%)	Only a few (25%)
… make calls?	Yes (100%)	No (0%)	I don't know (0%)
… see, add, edit or delete contacts?	Yes (100%)	No (0%)	I don't know (0%)
… initiate the care plan?	Yes (100%)	No (0%)	I don't know (0%)
In general, do you consider the smart device is easy to use?	Very easy (75%)		Easy (25%)
Would you know use AppNephro without prior help?	Yes: 25%	No: 0%	I don't know: 75%
Do you consider AppNephro is accessible for people with limitations?	Yes:100%	No: 0%	I don't know: 0%

A second validation stage took place on the same sample of users and was based on accessibility settings made in the previous step. However, it is worthy to mention that the configuration may be performed remotely by the administrator, for greater patient comfort. Since the previous survey concluded that the participants showed hesitant to test AppNephro without help, this stage began by performing a practical showing. Thus, it was explained how to enter the physiological parameters requested by the care plan and symptoms. Then the participants were required to perform the following tasks: launching the app, registering a set of physiological variables, introducing symptom "fever", and finally making a video call.

After completion of the tests, participants performed a more extensive questionnaire, addressing the most relevant elements of the application relating to the care plan. The results were positive, with an acceptance rate above 90%, but all participants were opposed to replace face medical consultations by the application. This confirms the suitability of harmonizing m-Health solutions as AppNephro with standard medical practices in order to complement healthcare delivery.

B. e-Nefro for non-digital patients/caregivers

Patients with low technology literacy or access, low economic level, or living in remote geographic areas are often excluded as potential recipient of brand new healthcare approaches based on technology. Non-digital end-users should be considered as a population with specific requirements. Furthermore, chronic kidney disease has a high incidence on older and diabetic populations, what are often technology reluctant audiences.

The system e-Nefro provides an access module for patients based on telephone network. Patients or caregivers introduce monitoring data through the telephone where the only interface is the physical keyboard. A system of Interactive Voice Response (IVR) guides users through the process. The IVR system can receive a call and interacting with the patient through voice recordings and the recognition of simple responses, such as "yes", " no" or other. It is an automated interactive response system, aimed at delivering or capturing information through the telephone, allowing access to information services, purchase, reservations and other operations, including its use in health services [27][28]. Fig. 4 shows the architecture of the IVR module. A calendar submodule allows to recover appointments and reminders for the patient from e-Nefro and transform them into voice to call the patient when the programmed date comes.

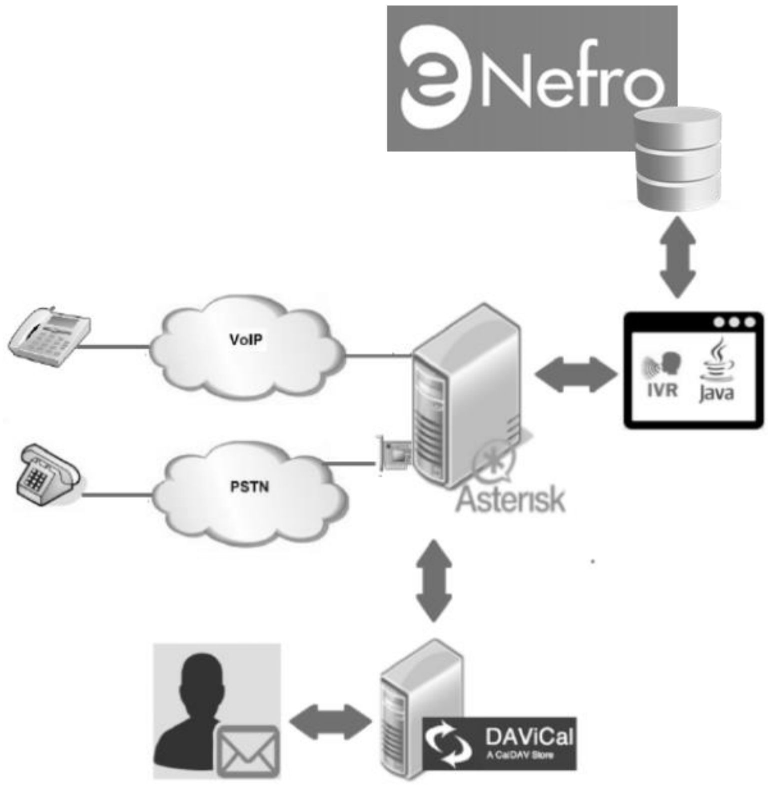

Fig. 4. Architecture of the e-Nefro IVR module for non-digital patients and caregivers

C. e-Nefro for health professionals

Clinicians can access the system e-Nefro through the main web application or an Android-based app. The web application is analogous to patients' but with different functionality. Clinicians can modify the care plan of patients, monitor their evolution and contact them. In the validation stage, health professionals stated out the simplicity of this prototype to create registers into the patient's care plan and to access to planned encounters. The medical encounter screen includes accesses to all the information that can be of interest in the encounter such as the patient's care plan, clinical registries, incidences, and personal message exchanged between the patient and the professional (Fig. 5).

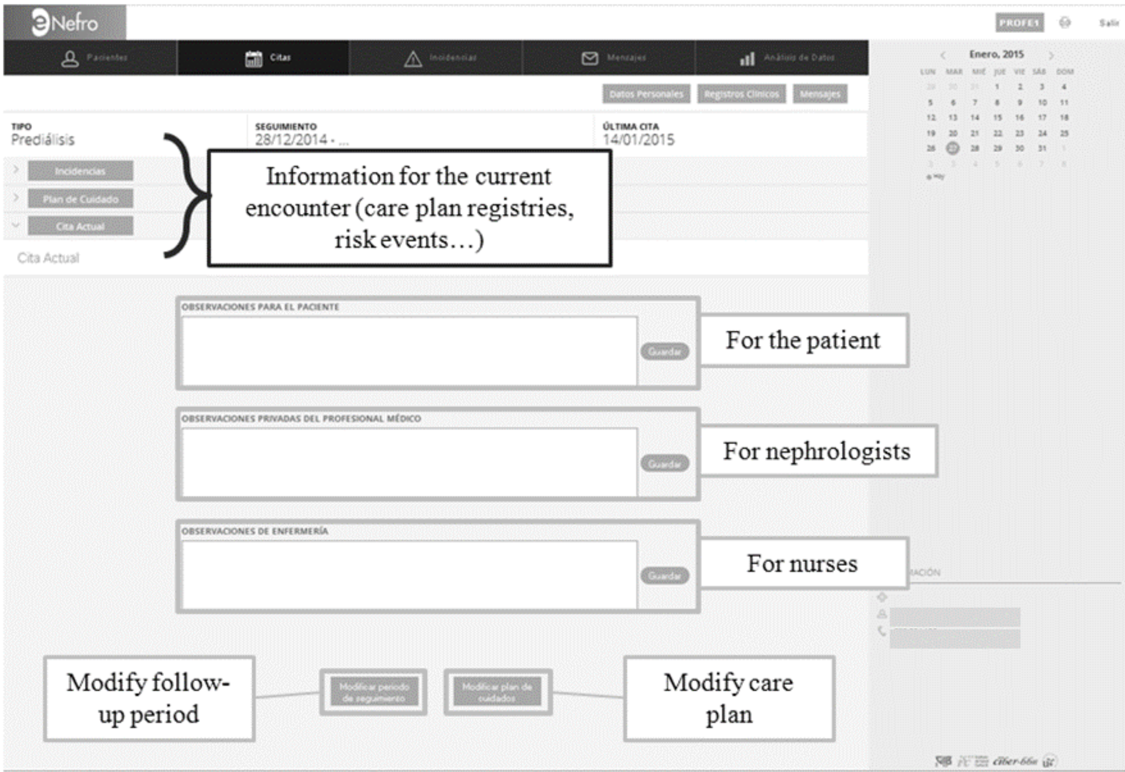

Fig. 5. Medical encounter screen in the e-Nefro web application

Information generated during the medical encounter can be included in three different fields: one shared with the patient (who can consult it afterwards to clear the conclusions of the encounter and indications of his/her clinicians), one for the clinicians' observations (with access limited to medical doctors), and another one for collecting nurses' observations (that can be checked by any health professional). The mobile app for clinicians was developed to serve as complementary access methods for the remote follow-up by professionals (Fig. 6).

Finally, nurses are provided with a web application with limited functionality. They can make appointments, review monitoring data of patients and contact them, meanwhile the modification of the patient care plan and generation of reports are out of their scope.

Fig. 1. Screenshots of e-Nefro app for clinicians (left to right: main menu, patient menu, and patient data)

4. Discussion

User involvement in design and evaluation stages is common in the health domain, but user contributions are often dismissed in the implementation process what results in systems facing user refusal since they are not aligned enough to the healthcare delivery or present a limited usability. Furthermore, most e-Health systems are used by different kind of users with separate needs and/or roles (e.g., nurses and clinicians or patients and caregivers) what leads to the imperative of considering their requirements separately.

As drawback, user involvement in all the development stages of an e-health system increases the complexity of the process. Working with a multidisciplinary team inevitably slows down system development due to the necessity of reaching a common understanding. A further issue is the continuous reconciliation between desires, preferences and needs of different kind of users and technology that imposes limits on the cost-efficiency of the product. Involving users requires to agree on every decision on system development by establishing balances among user needs and desires, technology possibilities and costs. Meanwhile avoiding users in such technological decisions results in increasing the refusal rate of the final product, involving them requires an additional effort to close them to technology reality.

Currently, the system e-Nefro has been deployed in five Spanish hospitals to perform a pilot in real settings. The objective of this pilot is evaluating how an e-health system for remote monitoring of renal patients at home can increase the quality of life and commodity of patients meanwhile reduce costs for displacements and hospital stays.

5. Conclusions

There is an increasing understanding of the relevance of adopting user-centred design and development techniques in the health sector. However, users are often assumed to be a homogeneous group with the same set of requirements. In this work, the study case of an e-Health system for renal patients at home has been presented, where users are categorized in four different groups (i.e., digital patients/caregivers, non-digital patients/caregivers, clinicians and nurse). User requirements of each group have been analysed and different modules have been developed to coping with them, resulting in a multi-faceted e-Health system currently in piloting. Identification and continuous involvement of users allow their needs to be properly understood and addressed by technology, raising user acceptance of the final product.

Acknowledgments

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Summary points

What was already known on the topic

- Numerous e-Health solutions are not adopted in daily practice due to user refusal. User acceptance is one of the major obstacles that hinder the success of e-Health approaches.

- User-centred design and development techniques put the users in the middle of the development team, easing right alignment of solutions with user needs.

- Users are often assumed to be a homogeneous group with the same set of requirements, what leads to an ineffective identification and addressment of user requirements.

What this study added to our knowledge

- Most e-Health systems are used by different kind of users with separate needs and/or roles (e.g., nurses and clinicians or patients and caregivers) what leads to the imperative of considering their requirements separately.

- Involving users requires to agree on every decision on system development by establishing balances among user needs and desires, technology possibilities and costs.

- Requirements from non-digital users must be considered in any kind of e-Health solution in order to include the biggest audience possible. Technology can play a crucial role on the provision of alternative access methods to health services.