



CAPABLE

Cancer Patients Better Life Experience

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Coordinator	University of Pavia (UNIPV)
Deliverable Lead Partner	Universidad Politécnica de Madrid (UPM)
Contributing Partners	UPM, UNIPV, AIMAC, ICSM, NKI, BITSSENS
Contact	Prof. Silvana Quaglini
Email	silvana.quaglini@unipv.it
Website	www.capable-project.eu

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DEM	Demonstrator, pilot, prototype	
DEC	Websites, patent fillings, videos etc.	
OTHER		
Dissemination Level		
PU	Public	X
CO	Confidential (Consortium members including the Commission Services)	
CI	Classified Information (Commission Decision 2015/444/EC)	

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Versions History

Version	Date	Author	Comments
1.0	7 th February 2021	UPM	First version with integrated protocols and document structure
2.0	19 th February 2021	UPM	Results of patient interviews
3.0	23 rd February 2021	UPM	Results of health professional interviews
4.0	1 st March 2021	UPM	Final version to be revised
5.0	5 th March 2021	BITSENS	Revised version
6.0	8 th March 2021	UNIPV	Final submitted version

1. Executive Summary

This document presents the results of the first evaluation and validation of the CAPABLE prototypes as defined in previous deliverable D7.1.

In this validation process, the first version of the prototype presented by WP6 (see D6.1 Mock-ups for User Interfaces) has been evaluated applying the three methods presented in D7.1:

- **Heuristic validation of the user experience and usability performed by user Interaction experts.** 10 researchers of UPM expert in digital health and user interaction inspected the developed prototypes and reported the violations of the usability's heuristic principles proposed by Cooper¹. The participants provided feedback on the CAPABLE solutions and how to improve the user experience and the overall usability.
- **Interviews with patients.** These interviews aim to collect feedback from the end users of the Patient App: Melanoma and Kidney cancer patients during the treatment phase. For this validation, other types of cancer patients may be included, cancer survivors (treatment finished since no more than 2 years) or experts in patients' needs, such as a cancer patient association (AIMAC). 8 patients have been interviewed.
- **Interviews with healthcare professionals (HCPs) and experts in digital health.** These interviews aimed to collect overall feedback of the overall solution, understand if the clinical and patients' needs are covered, and revise the core functionalities that have been proposed in the current prototype. A total of 6 health professionals have been interviewed.

The structure of this document follows the presentation of the results of the 3 executed studies. The protocols of each study are attached in the annex. The document also presents the general conclusions from these three validation activities and the next steps to follow in the future developments in order to satisfy the user experience needs found in this process.

The work has been performed using different technological tools that made possible the execution of these studies that normally are face to face, but that at the moment, due to the COVID-19 and recommended social distancing, are not possible. It was used:

- Conference system Zoom and Google Meet.
- Online survey engine based on Limesurvey, used for the interviewer as guide.
- Collaborative functionalities of invisionapp² to inspect the prototype.

¹ <https://www.nngroup.com/articles/ten-usability-heuristics/>

² <https://www.invisionapp.com/>

2. Heuristic validation

Heuristic evaluation (HE) was used with the two prototypes of CAPABLE, the mobile app for patients and the dashboard for health professionals, in order to find out the most remarkable usability errors and inconsistencies, to systematically evaluate each of the prototypes but also to avoid important usability problems that could interfere in the tests with the final users. The HE is carried out with 10 usability experts following the recommendations of the 10 Nielsen Heuristics and ranking each of the issues found:

- H1 - Visibility of system status.
- H2 - Match between system and the real world
- H3 - User control and freedom
- H4 - Consistency and standards
- H5 - Error prevention
- H6 - Recognition rather than recall
- H7 - Flexibility and efficiency of use
- H8 - Aesthetic and minimalist design
- H9 - Help users recognize, diagnose, and recover from errors
- H10 - Help and documentation

In addition, the following 1 to 5 rating scale was suggested to rate the severity of usability problems:

- 1 = I don't agree that this is a usability problem at all
- 2 = Cosmetic problem only: need not be fixed unless extra time is available on project
- 3 = Minor usability problem: fixing this should be given low priority
- 4 = Major usability problem: important to fix, so should be given high priority
- 5 = Usability catastrophe: imperative to fix this before product can be released

In this section, the results of the first round of the Heuristic Evaluation of Capable are reported.

Patient app

The following table summarizes the number of heuristic violations found and the average severity:

HE	Occurrences	Severity avg
H1 - Visibility of system status.	19	3.4
H2 - Match between system and the real world	23	3.176
H3 - User control and freedom	8	3.875
H4 - Consistency and standards	16	3.187
H5 - Error prevention	8	4.142
H6 - Recognition rather than recall	8	3.25
H7 - Flexibility and efficiency of use	6	2.833
H8 - Aesthetic and minimalist design	22	3.142
H9 - Help users recognize, diagnose, and recover from errors	1	4
H10 - Help and documentation	1	4

Table 1: Overview of heuristic violations in the patient app

These results can be also seen graphically in the following two charts:

Occurrences of heuristic violation (Patient app)

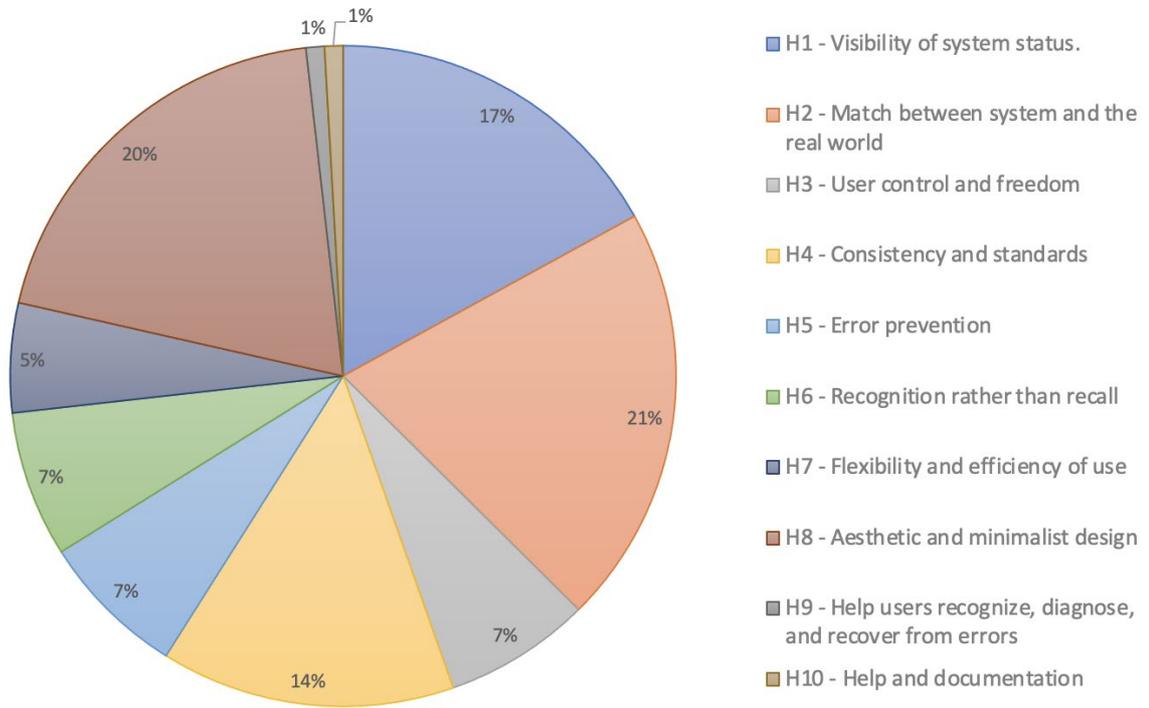


Figure 1: Chart of the distribution of the violations in the patient app

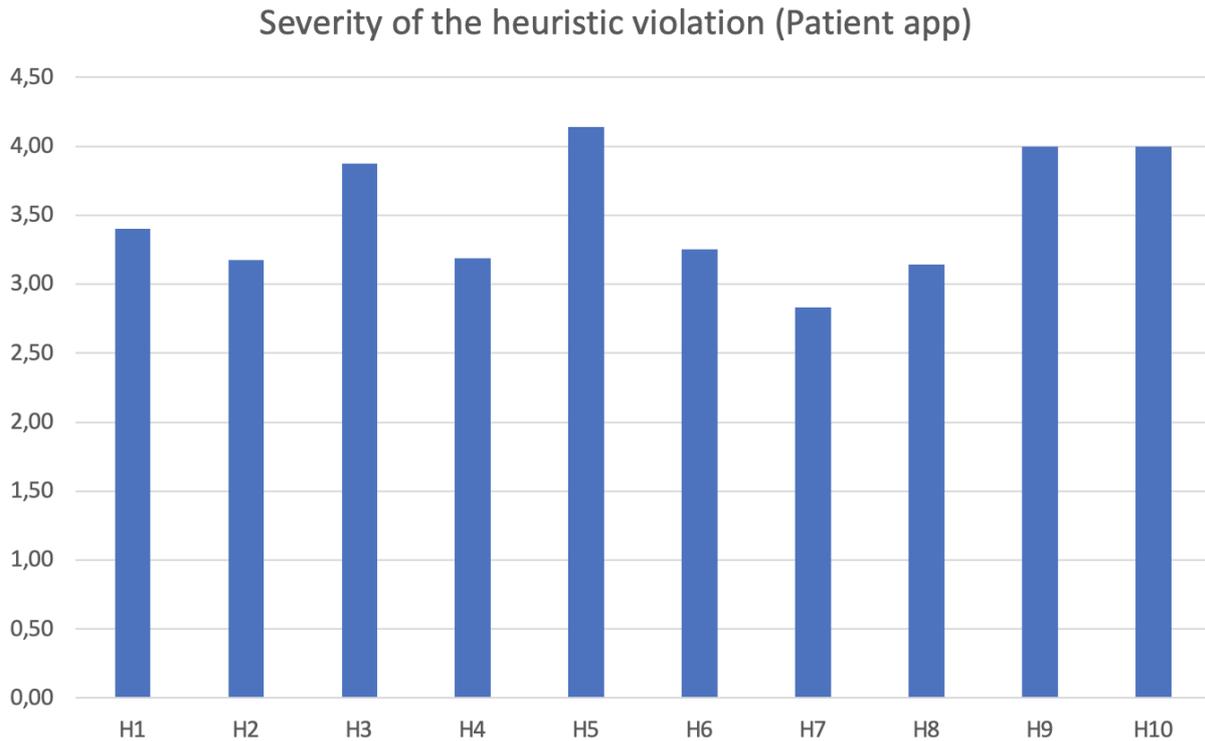


Figure 2: Chart of the severity of the heuristic violations in the patient app

A deeper analysis has been performed to understand the nature of the problem. New categories have been defined according to the reported problem. The following table shares the results.

Error category	Occurrences	Severity avg
Prototype incomplete	5	5
Flow problem	13	4.076
Missing graphics	11	3
Wording	17	3
Consistency	8	3.2
Missing help	5	4
Page structure	11	2.88

Table 2: Overview of the error category of the patient app

Distribution of the errors (Patient app)

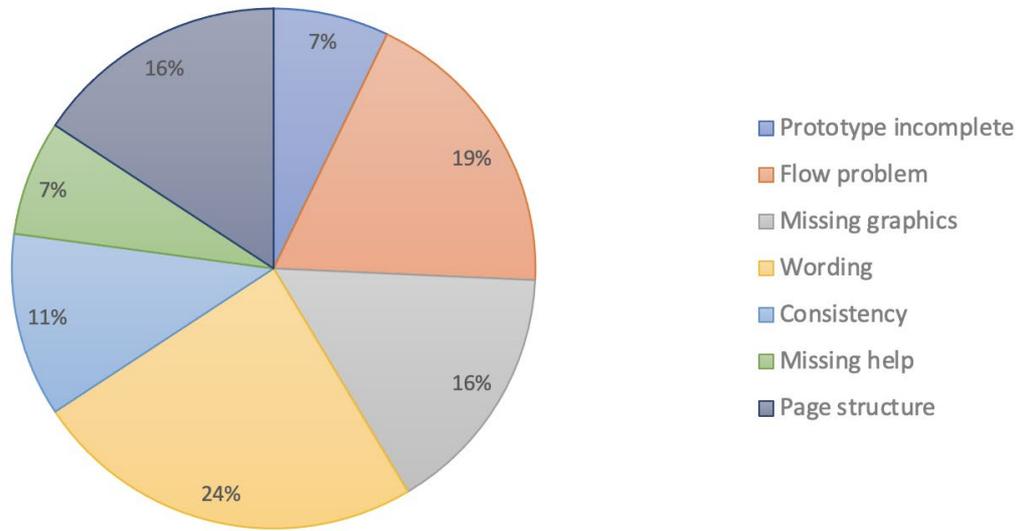


Figure 3: Distribution of the errors in the patient app

Severity of the errors (Patient app)

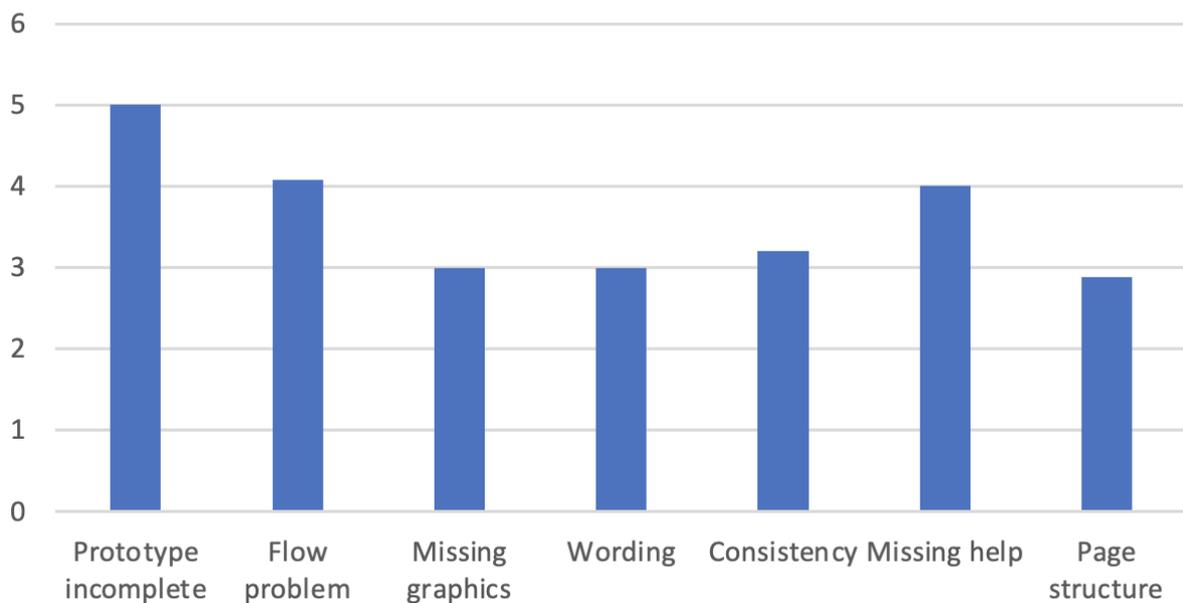


Figure 4: Chart of the severity of the errors in the patient app

Common issues found by the evaluators:

- Back buttons don't work properly (H1, H4, H5)
- Needed more attractive interface (H8)

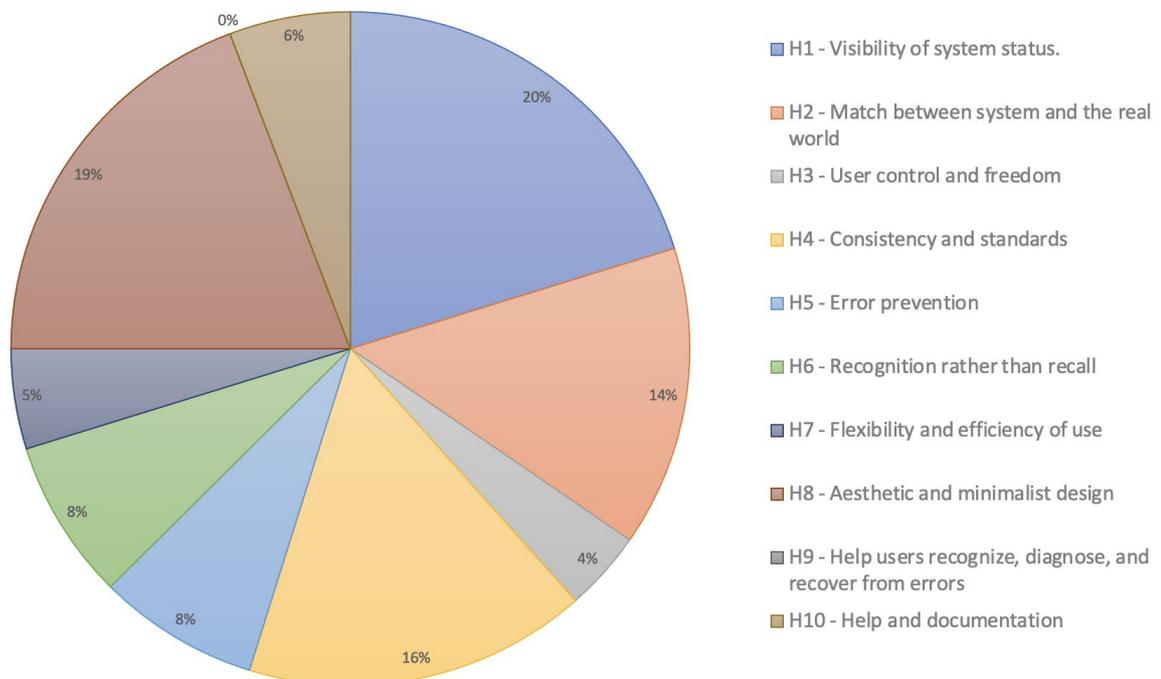
- In questionnaires, when the user presses the X button the progress is lost (H5)
- There is too much text, making the application unattractive to users. (H8)
- When scrolling, the header bar disappears (H1, H3)
- The First Screen shouldn't be the capsules, it is not intuitive (H1, H3, H4, H6, H7)
- The buttons have different styles (H8)

Health professional dashboard

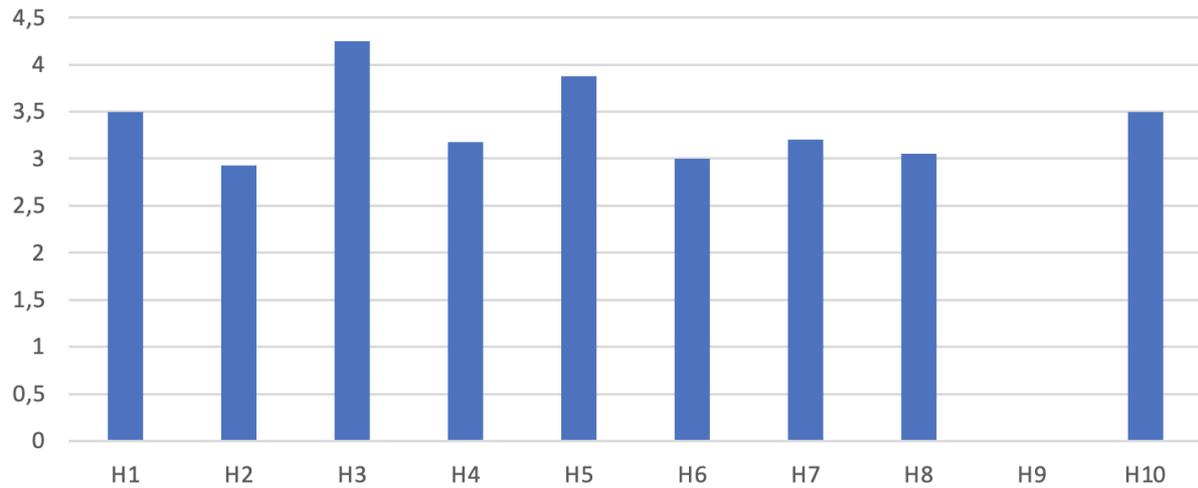
Summary of the number of heuristic evaluations found and the average severity:

HE	Occurrences	Severity avg
H1 - Visibility of system status.	21	3.5
H2 - Match between system and the real world	15	2.933
H3 - User control and freedom	4	4.25
H4 - Consistency and standards	17	3.176
H5 - Error prevention	8	3.875
H6 - Recognition rather than recall	8	3
H7 - Flexibility and efficiency of use	5	3.2
H8 - Aesthetic and minimalist design	20	3.05
H9 - Help users recognize, diagnose, and recover from errors	0	0
H10 - Help and documentation	6	3.5

Occurrences of heuristic violation (HCP Web)

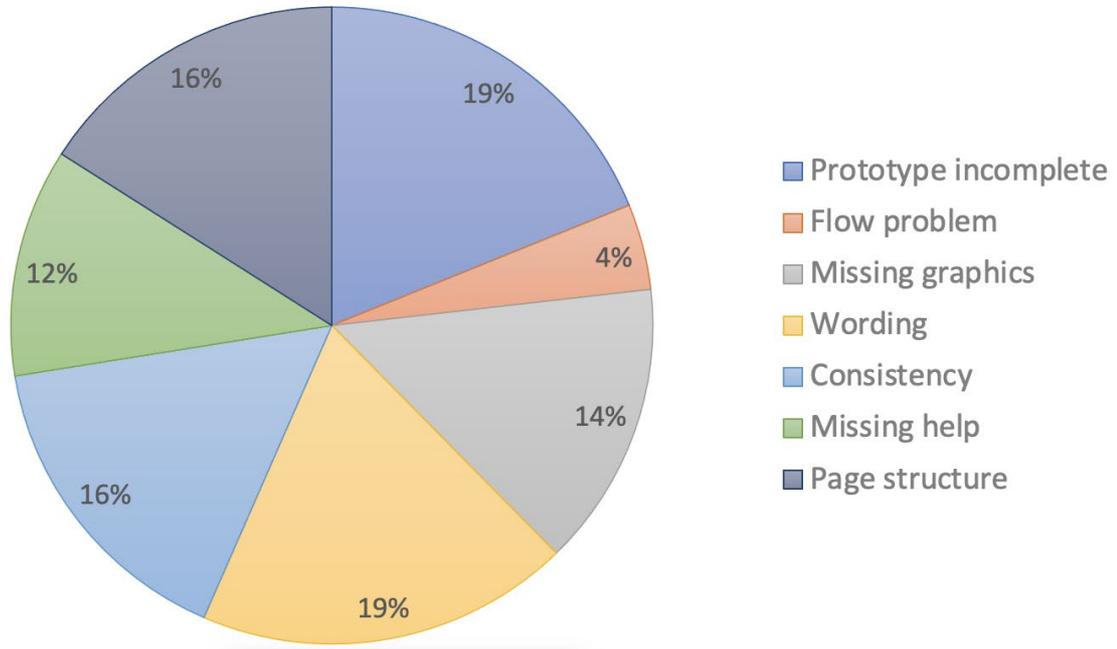


Severity of the heuristic violation (HCP Web)

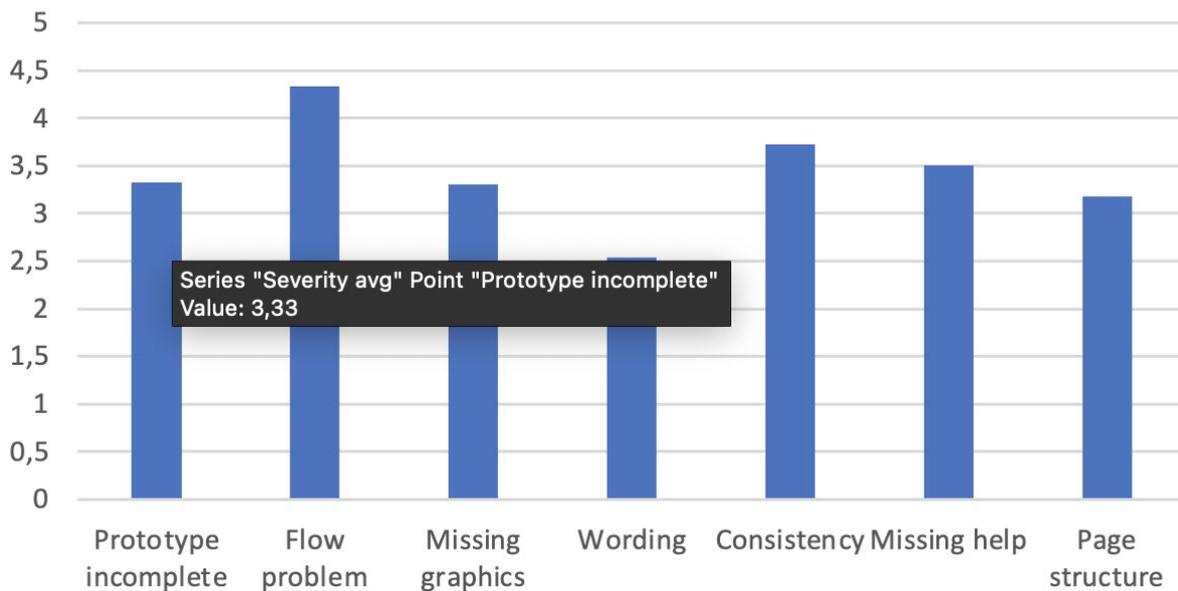


Type of error	Occurrences	Severity avg
Prototype incomplete	13	3.33
Flow problem	3	4.33
Missing graphics	10	3.3
Wording	13	2.538
Consistency	11	3.727
Missing help	8	3.5
Page structure	11	3.181

Distribution of the errors (HCP Web)



Severity of the errors (HCP Web)



Common issues found by the evaluators:

- Needed an improvement of the interfaces making them more attractive visually. (H8)
- Font problems in different sections. For example, too small in summary of the patient. (H4, H5, H8)
- Missing information of the scoring of questionnaires (H6, H10)

- Needed more information in the pop-up for loperamide (H2)
- Needed graphics or tables in order to see better the information (H8)

User experience heuristics

The 10 participants also answered 7 questions related to the user experience. This part of the survey was based on open questions in order to gather suggestions and feedback on the specific proposed topics.

Question 1: Assume we want to minimize the training for clinician and patients. How would you do it ? What needs to be improved?

The following list shares the gathered suggestions:

- Creation of guidelines for each apps
- Tooltips can be provided within the apps.
- Creation of video tutorials
- Inclusion of an information section
- Simplify the actions and screens
- Adopt Tunneling principles in the app

Question 2: Do you think that CAPABLE provides the relevant information to the Graphical User Interface? Feedback and criticisms are welcome.

In general, the evaluators thought that CAPABLE provides relevant information to the end users (health professional and patients). Suggestions:

- Improve the interface with graphics and visual information.
- Add contact tools with physician in the patient app.
- More simplified graphical user interface for the patients.
- Suggestion to an analytical module for the clinician to assess patients ad individual and aggregated level.

Question 3: Do you think that CAPABLE helps patients and health professionals to make the best decision when patients are at home? Feedbacks and criticisms are welcome.

In general, the evaluators agreed that Capable is useful for patients and healthcare professionals. Suggestions:

- The recommendations and instructions should be clear.
- Avoid complexity for the patients.
- In the app, differentiate between suggestion from machine and suggestion from clinicians.

Question 4: Can users (both patients and health professionals) perceive the changes in the service contents or user interface (UI)?

Evaluators agree that Capable UI shows changes in the service but this must be enforced with notifications and a more graphical UI.

Question 5: Can the service adapt to the user's context of use and offers meaningful contextual information?

The context adaptation in the evaluated prototype is not so clear, but it is something that must be implemented in order to achieve a better solution and more users.

Question 6: Is the system supporting trust and privacy of the users? Any recommendations?

All the evaluators agreed that at this stage the trust of the prototype is difficult to evaluate. Suggestions:

1. Section of privacy in settings or configuration of the apps
2. Users should select their preferences
3. Implementation of digital informed consent

Question 7: Any other comments ?

Additional suggestions:

- The representation of the information in both tools is a challenge, due to the large amount of patient information that is managed and presented.
- This evaluation can be more useful if it is performed with a functional prototype, showing all the functionalities of the tools. In its current form is it not possible to assess some things of heuristic evaluation and the usability questions.
- Try to make the interface more dynamic and simpler as possible so as not to overload the user with information or tasks.
- Harmonize the style in all the interface screens so that the operation and behavior of the tools is the same throughout the flow of use and interaction.
- An iOS interface has been shown in the mockup. If we assume all types of users, we must also consider being able to adapt the interface for Android (there are differences in the style guides).
- If sensors or wearables are to be used, information on how they are used and / or synchronized would be interesting (in addition to including notifications of disconnection or lack of battery).

3. Interviews with patients

Participant’s profile

The WP7 team interviewed 8 participants: 7 were patients and 1 was a caregiver. The gender distribution was balanced (50% female, 50% male), the participants were almost adults with an average of 57 year (St. Dev 8,6, Min 52, Max 72). 5 suffered from melanoma cancer, 2 from breast cancer and 1 did not suffer from cancer but was a caregiver very active in the field of patient support of pancreatic cancer. 5 of the 7 cancer patients survived the treatments, 2 were still under treatment. Most of the users lived together with the family (wife/ husband and /or children), just one person reported to live alone. In general, all the participants were opened to new technology. They used the internet on daily a basis, for entertainment and for search on the web. Most of them used the internet also for work and, in the last year, they saw the increment of the usage of teleconference systems due to the pandemic. All the participants have a smartphone, 25% iOS and 75% Android based devices. According to the study protocol the participant also reported their opinion about the importance of specific habits to maintain a good health status. The following chart shows the overall results.

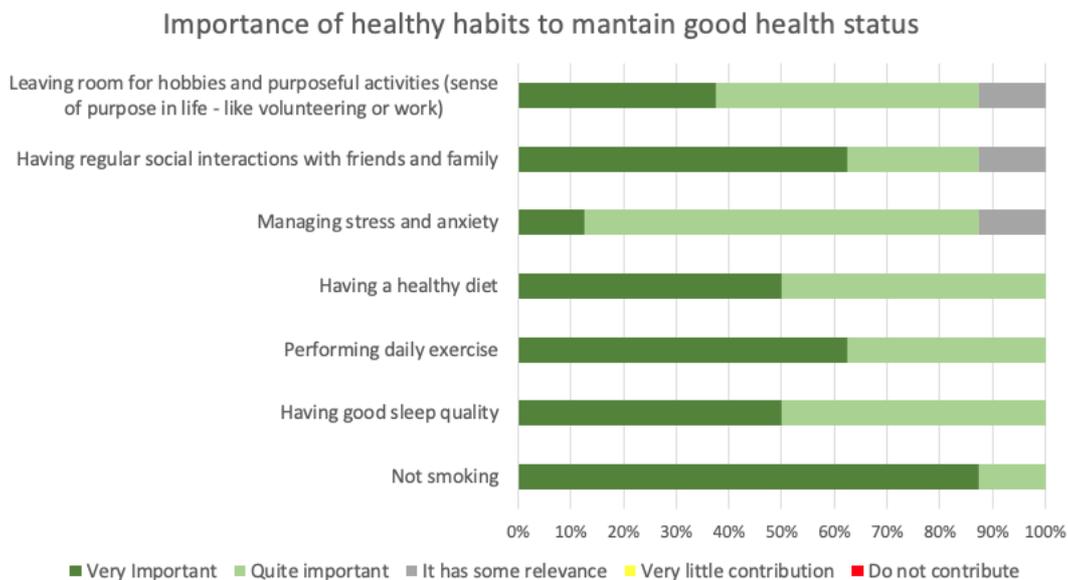


Figure 5: Chart of the importance of healthy habits

In general, the participants consider that health status is not only based on a diagnostic of a disease, and that it is important to adopt healthy habits. The dimensions that received lower score were the management of stress and anxiety because some participants consider not relevant for their own profile, the interaction with the family and friends (one participant self-defined ‘a solitary’) and leaving room for hobby (this is possible when this is compatible with the working and family routine).

Overall feedbacks on the system

According to the scheduled protocol the overall capable concept has been presented and an introduction of the app has been given to the interviewed people. The following sections detail the answer about the two presented topics.

What do you think of the CAPABLE approach? Would it be useful?

All the users thought that is a good approach, even if the real difference is to see how it will be developed and deployed in real settings (2). Capable is perceived as an integrated system for the therapeutic journey of cancer. It can facilitate the communication with the health care team, generate improvement of the health services and save resources. It can generate benefits for the users themselves (having a diary and a set of supportive and educational contents) and also for the overall care process because CAPABLE is supervised by the clinical team. Some users also point out the need to give support to elderly users, but also healthcare professionals will need support on how to remotely manage the patients.

One user also highlighted the importance of studying how to make the system user friendly and of researching proper ways to provide reminders and feedback to the users. One participant suggested avoiding to focus just on treatment but to rather focus on people. Many users also consider that the current pandemic times require technology such as CAPABLE, because of the shift to digital communication in order to minimize the interactions in the hospitals. Most of the users agreed that the connection with the hospital will generate a feeling of safety and control from the health care system.

Do you understand the purpose of the CAPABLE app? What do you think?

One user pointed out that the key must be the simplicity. Regarding the wearable integration one user suggested the integration with the internal smartphone sensors and the available health services (e.g., Google Fit) to get activity data. It can be critical the high demand of collected data and the risk is that CAPABLE could be an invasive tool. A very interesting value found by a patient was that CAPABLE can be a diary to see evolution and help users to have objective ways to evaluate their own condition, because in some moments it is difficult to understand it. CAPABLE is not a system that just sends data to the hospital, it is a tool for self-regulation. Furthermore, in this case some users (3) identify that a system like this can be easily used by younger patients, but elderly patients may have more difficulties. Another important aspect for the patients is the stability, the app should work and not generate unexpected errors.

Unobtrusive tasks

At this stage the interviewer asked the participants to open a specific link³ containing the App prototype, share the screen and perform specific tasks, describing what they are seeing in the interface and commenting on possible problems, improvements. The interviewer took notes of all the feedback and observed also how the prototype was used and if the user was able to complete the specific tasks. The proposed tasks were four:

- Task 1: inspect all the initial page.
- Task 2: report a symptom.
- Task 3: inspect the inbox page.
- Task 4: inspect the Capsule functionality.

Task 1 (Home page)

In general, all the users understand the proposed interface and several comments and suggestions on how to improve the page were provided. Some users had difficulties understanding that the page was scrollable, and 2 users lost the main flow because they started clicking on other buttons. The following table shows the main comments provided by the participants:

Feedback from patients and caregiver of the App's homepage

Missing affordances: that is a situation where an object's sensory characteristics intuitively suggests its functionality and use.
--

³ <https://projects.invisionapp.com/share/TH105SHY2J3V#/screens/444442751>

Missing user onboarding. The home page is not clear if there is not any introduction to the system
Use of appropriate icon in the menu
Not clear way to represent the intake of the pills
Glycemic level could be useful for some patients.
"Treatment as need" section is not clear what is it, not clear also the reason (because of diarrhea symptom)
Sleep capsule perceived as medical treatment for sleep problem
Text of ISI questionnaire not user friendly, it is more for a doctor.
Not clear if must be done or recommend by the app
The home is not clear because the different parts are not well separated.
The daily plan should be more complete
Important to receive reminder
Different greetings to the user
Better check of medication intake and reminders.
The daily plan should contain medicine, nutritional advises, physical activity, sleep.
Missing the evolution and progress of the users
Suggest scrolling (3)
1 User goes to the capsule section and loses the flow.
1 User performed the quiz and lost the flow. (then difficulties to find the menu to come back.)

Table 3: Feedbacks from participants on task 1

Task 2 (Symptoms reporting)

All the users were able to identify the proper button in the menu. Just one user clicked on option, lost the flow and went to the message section to then find symptoms in the menu. 1 User said that menu is too little. All users went directly to the list of symptoms, not searching diarrhea in the search bar (8). One user pressed on stomach ache instead of diarrhea. The following table shows the recommendation from the patients and caregiver:

Feedback from patients and caregiver of the App's symptom reporting
Problem in the label of 4 th grade of diarrhea it cannot be life-threatening, this generates a lot of worries (3)
Not clear the instruction "add symptom", 2 users understand to add another symptom, not to save the current one.
The symptoms list contains terms that are not clear for the users.
A user suggests using AI to interpret the symptoms description
Users criticize the search function because in some cases users do not know what to search. It should be a clear list with simple categories.

Table 4: Feedbacks from participants on task 2

Task 3 (Inbox messages)

All the users were able to find the inbox functionality in the App menu. Two issues were identified: one user gets lost in the flow; the participant pressed on the symptoms reporting. Another user did not understand the message asking a follow up of a symptom. The following table summarizes the issues and suggestions reported by the interviewed people:

Feedback from patients and caregiver of the App's inbox messages
Simplify the management of the messages by creating a filter in which it is possible to select specific categories (e.g., appointment, recommended activities etc.)
Not clear the relationship with the agenda of the day. Why are some questionnaires here and others on the home page?

The inbox page is too much dense page, it should be simplified

Table 5: Feedbacks from participants on task 3

Task 4 (Capsule)

Once the users understand that Capsule was the place to find educational content and suggested activities, this functionality has been reached in the menu of the App. The following table lists the reported issues from the participants:

Feedback from patients and caregiver of the App's Capsule functionality
Missing chart evolution
This module should be revised by a psychologist. It is important to have a uniform way of communicating. Why are "improve your sleep" and other elements called just as "sleep"?
The app should have a more engaging introduction and way to motivate the user.
One user asked if social connection contains topics related to work-life. An important part could be the rights of the workers available online (AIMAC page)
It is important to add more exercises and activities for the users
Activities are more important of educational content because tests are read just one, meanwhile activities should be performed over time.
Good to have contents in the app instead of internet search, this is validated content
It should be simplified , it should also make a follow up of the user and activate reminders.

Table 6: Feedbacks from participants on task 4

Overall easiness of the tasks

The participants scored from 1 (very difficult) to 5 (very easy) the performed tasks. The overall results are positive and above the positive threshold (3). The most critical tasks were the inspection of the homepage of the app and the inbox messages, for the reasons that have been reported previously.

	Average	St Dev	Min	Max
Homepage	3,75	0,89	2	5
Symptom reporting	4,25	0,46	4	5
Inbox messages	4	1,31	2	5
Capsule functionality	4,25	0,71	2	5

Table 7: Easiness scores of the 4 tasks performed by the participants

Final questions

During this last part of the interview four types of information have been gathered:

- Qualitative feedback on missing functionalities and how system can be improved
- Qualitative feedback on the possibility of providing services also for the caregivers.
- Quantitative evaluation of perceived values of the CAPABLE systems
- Quantitative evaluation of the overall system usability

Missing functionalities and how to improve the app.

In general, the participants consider that the proposed system is a complete system. Nevertheless, there is a list of suggestions of functionalities and features to be improved. The following table details these feedbacks. One participant said: "I would re-do because there is a mix between patient and clinical requirement.", referring to the idea that the interface must be designed according to the way of thinking of the user.

Suggestions on new functionalities and system improvements
The current prototype is too textual, the system needs to be more graphical.
Restructure the information and try to follow a mental model of the user.
Missing gamification elements.
Add the possibility to request a visit in the hospital.
Missing the coaching part .
Add a message (feedback) after the report of the symptom
Add tools to communicate with the doctor.
Improve the communication strategy of the overall app.
Add a goal-oriented functionality: propose activities to the users, make a follow-up., reward users and show summary.
Suggestion to give stimulating feedback as in the IWatch in the homepage
Add multimedia video.
Provide a chatbot functionality
Include a community of patients (the participant that suggested this feature also said that this could include problem of privacy)

Table 8: Suggestions on new functionalities and system improvements

Informal caregiver, should be involved?

Most of the participants agree that a good approach is to give the same app to the informal caregiver, but with two different accesses or find a way to track who is using the app. One user suggested that the perception of the caregiver could be different from the patient. All the participants agreed that caregiver is a delegate, and for that reason, should be nominated by the patient. One user also reminds that the principle of PROM is that data are reported by patients and this somehow should be managed if CAPABLE supports the caregivers’ data reporting. Some participants also suggested adding a section specific for the caregiver explaining the type of help he / she can give. The preparedness of the caregiver is considered an important aspect especially when the patient is feeling very well and might not be able to use the app. Other patients proposed two levels of access depending on the type of level of involvement of the caregiver in the health of the patient: the closer one should have full access, meanwhile other caregiver could receive just summaries and alerts in order to be informed. Other patients suggest that younger patients might not need this functionality, but for sure elderly people yes.

Perceived values

The participants responded to a questionnaire aimed to measure the acceptance and the values perceived. In general, all the proposed dimensions were well accepted. Some criticisms have been highlighted by some participants about the idea to install the app in their mobile app and on the idea that CAPABLE can support to cope with all daily life problems. Even that, all the scales have received scores.

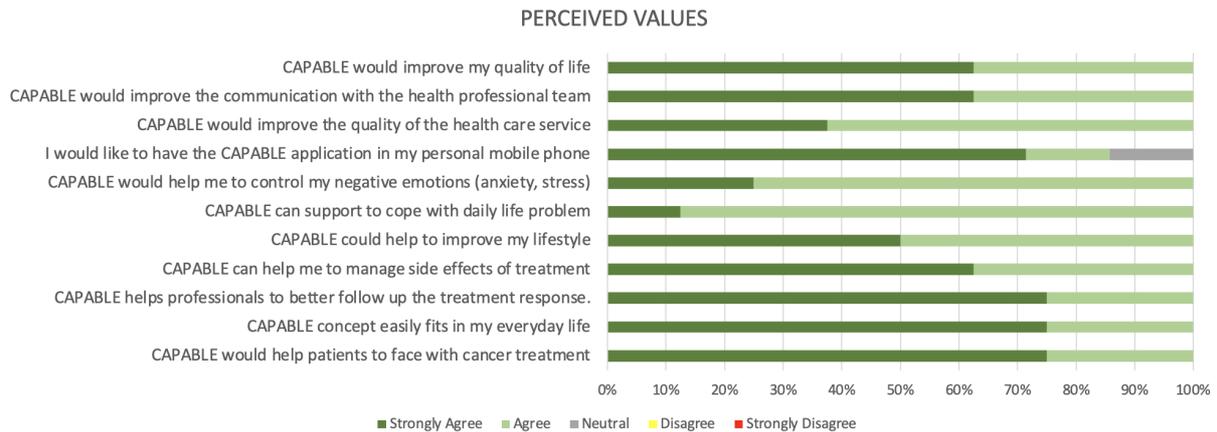


Figure 6: Chart of the perceived values of CAPABLE

Overall system usability

The last questionnaire of the interview was the standard questionnaire about system usability, the System usability Scale⁴. The overall results are good. The system received close to excellent scores (thresholds is 80): the overall mean score of the SUS questionnaire is 79,4 (St.Dev. 24.63, Min 20, Max 97,5) that indicates that CAPABLE has high usability. One participant considered the system unacceptable under the usability point of view and scored the system very low. This can be seen clearly in the following chart. The lowest values have been reported on the fact that users will learn to use it quickly: some participants consider that some users could have difficulties because of their age or digital literacy. All the users (except one user) strongly agree that they feel very confident using the system.

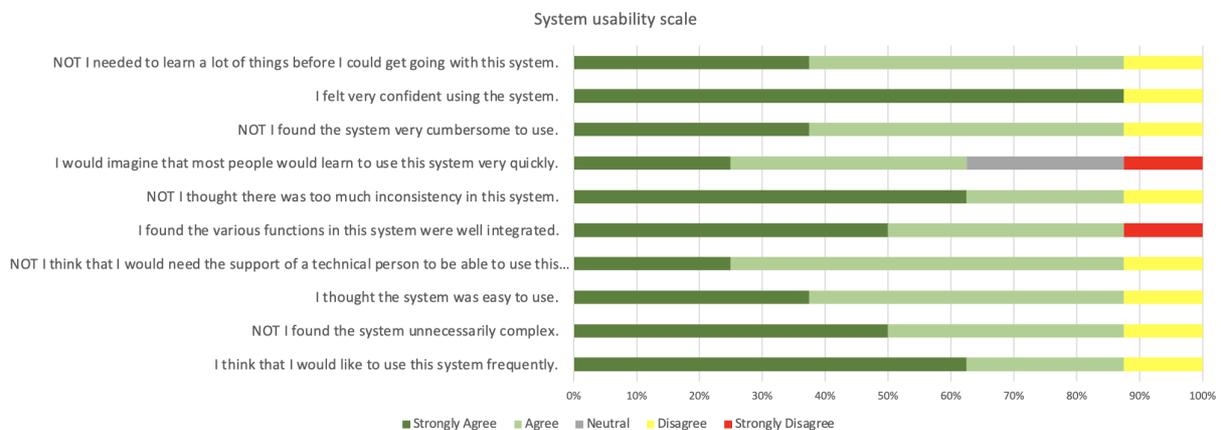


Figure 7: Chart of the System usability questions

⁴ <https://www.usability.gov/how-to-and-tools/methods/system-usability-scale.html>

4. Interviews with health professionals

Participant's profile

WP7 interviewed 6 health professionals: 2 Males and 4 Female. The age average was 39,7 (St. Dev. 11,09, Min 26, Max 55) lower than the patient's one. Out of the 6 interviewed people 3 were oncologists, 1 nurse, 1 radiotherapist and 1 clinical researcher.

Previous experience with health technology

All the users have experience with patients' Electronic Health Record and other tools for the Hospital Information System to track care processes or request extra departmental services such as imaging or biochemical tests or other specialist visits. Some (2) participants also mention using PACS. None of the participants declared to have used a telemedicine system. Just one mention to have some colleagues testing it. Most of the participants also mention the use of conference systems due to the pandemic restrictions, the use of internet, mail, word processors and office software.

Most of the users used technology not only for job but also in their free time, to help children to study, to find information, entertainment, social network and media services. All the participants have a Smartphone, 50% Android and 50% iOS devices.

Overall feedbacks on the system

What do you think of the CAPABLE approach? Would it be useful?

All the participants agreed that nowadays there is a need to foster the technologies like CAPABLE, to provide at home assistance and prevent adverse events. During the pandemic it is also important to minimize the hospital visits. Furthermore, some participants also identified the value of having information between the follow-up visits, from PROm and PREm and physiological data from wearable sensors. One participant was skeptical about the suggestions that could provide the app, he thought that the system requires a high level of personalization and that it can work differently in two similar patients, because *'every patient is a world'*. Furthermore, it is important to find best ways to show the information to the patients and present them a well-balanced quantity of information. One critical issue about the remote follow up is that some patients tend to minimize the worsening of the health conditions and this could be critical.

The amount of new information generated by the CAPABLE system could be critical for the health care professional, it is crucial that a machine is able to digest all the information and generates alerts requiring specific attention and workflow of the healthcare team. Finally, another technical aspect that can be critical is the integration with the Electronic Health Record that in some hospitals can be difficult, not for the technical integration but in getting the approval from the hospital IT department. One participant also commented on a risk on the complexity of the system that can increase the risk of malfunctioning.

Do you understand the purpose of the CAPABLE app? What do you think?

All the participants well accepted the idea to provide an app and a wearable sensor to patients. Some interviewed people pointed out the difficulties of elderly people using the app. One important requested feature is to create an engaging app, to foster compliance on the proposed activities of the system. The health professionals also liked the holistic approach of the intervention, not only focusing on the cancer treatment.

Also in this case some participants pointed out that the coaching would be useful just for part of the patients. We also received recommendations on the importance to correctly craft the contents and activities, in order to be well understood and perceived; CAPABLE must not generate false expectations or worries to patients.

Do you understand the purpose of the CAPABLE health professional dashboard? What do you think?

The most critical part is that health professionals will be not able to be in control of the gathered information from users: the alarms and notification are crucial, and they should be standardized, clear and designed to capture the attention of the health care team. The risk is to receive irrelevant information and not give the opportunity to the care team to put the attention to the right parameter or patient. Another participant appreciated the idea to have a traffic light approach for the patient stratification, but it is important to create a flexible system that gives full control to the healthcare team in order to understand the specificity of every patient’s condition. Another relevant aspect that has been suggested is the personalization of the system because there are different types of patients’ profiles (e.g., users that have some predisposition to side effects as cutaneous toxicity of hypertension). One participant observes that most probably this system will add a certain new overload (the remote management) of the patients, so the support of alerts and notification are crucial to this kind of system. The decision support system has the value to facilitate the patient stratification and for the training of new medical staff; in most of the cases the treating physician will know what to do even if suggested by the system. Knowing early the side effect of a user is the most common perceived value; one participant asked what happened during the weekend, when usually the care team is not available, and the critical cases are managed by the urgency department. Most of the participants also understand that the presented alerts in the prototype must be further elaborated and specified.

Unobtrusive tasks

At this step of the interview the interviewer asked the participant to open a specific link containing the Web Portal for health professionals⁵ and the patient App prototype⁶, to share the screen and perform specific tasks. The user described what they are seeing in the interface and reported possible problems and improvements. The interviewer took notes of all the feedback and observed also how the prototype was used and if the user was able to complete the specific tasks. The proposed tasks were five:

- Task 1: Enrol a new patient through the Web portal for health professional.
- Task 2: Inspect the patient app: homepage and messages.
- Task 3: Report a symptom in the patient app.
- Task 4: inspect the Capsule functionality in the patient app.
- Task 5: Perform a remote follow up of a patient using the Web portal for health professional.

As can be noticed, health professionals were requested to revise the all core use cases of the overall system: their opinion is fundamental also in the design of the patient’s app.

Task 1: Patient enrollment

All the users were able to login into the Web portal, find the button to enroll a new patient and complete the enrollment. One user had difficulties to find the next button to continue the enrollment flow. A couple of users had difficulties understanding the step 3 of the enrollment phase, when the user is asked to tick the operations required to install the devices to the user. The following issues have been reported in the next table.

Feedback from health professionals on the CAPABLE enrollment process
One user did not understand what capsules are. Probably is a problem of naming.
The comorbidity form (step 1) needs to be a longer list of condition.
Not clear who should perform step 3.(installation of patient’s app and wearable). May be another user, different from the oncologist or nurse.

⁵ <https://projects.invisionapp.com/share/GUX2BJUR8C4#/screens>

⁶ <https://projects.invisionapp.com/share/Q6X4P6ATJD3#/screens>

Rename the name of step 1, remove the word 'questionnaire'.
Ethnicity in some cases is not available in the hospitals. In the melanoma users are mostly Caucasian with white skin.
Not all the patients have a caregiver contact.
Emergency contact could also be useful.
The questionnaires of step one should be revised and better detailed (e.g., Physical activity, nutrition).
Alcohol abuse could be quite a critical question, users addicted to alcohol would not be happy to talk about.
The interface needs more colors.
Suggest to add a scale for digital skills of the user.
In the clinical history section why is there only intestinal surgery? There are also others that may be relevant.
It is important to revise the list of comorbidities and separate them from clinical history (a surgery is not a comorbidity).
Step 2: why loperamide in the systemic therapy?
The section historical medical data should be improved and also the treatment section.

Table 9: Feedbacks from health professionals on task 1

Task 2: App home and messages

The health professionals also revised the App prototype. In general, all the participants were able to understand the overall purpose of the home page and of the inbox messages. One user from the home page clicked to the sleep capsule and lost the flow. Other users did not understand that in the homepage there are sections that require the scrolling operation. The following table shares the feedback specific to the home page and messages.

Feedback from health professionals on the patients' app homepage and inbox functionality
The therapeutic plan in the home page is not realistic (see the name of the two main treatments), Nivolumib is an infusion (intravenous) to be performed in the hospital.
Nivolumib should be replaced by appointment reminder.
Capsules are understood as pills to sleep.
The progresses of the user are not clear.
The Italian interface has some texts in English.
The quiz should not go in the messages as a reminder, should be in the plan.
There is a need to distinguish messages and suggested plans on the home page. This should be better detailed.
This GUI will be easy to use by young patients but not elderly ones.
The message to discuss the therapeutic plan is not good. It should not be discussed, eventually revised by the health professional, but there is not a need for a message.
Loperamide (shown after the sleep capsule) is perceived as a treatment for sleep. This happen because is close to the sleep capsule and sleep questionnaire. There is a need to create clear sections in the home page.
Why are other capsules not shown in the homepage as suggested activities? (The participant reminded the step 2 of the enrollment process in which capsules are prescribed / recommended).
All the medical treatments of the user should appear in the homepage.
Important to separate the element in the homepage. At the moment the information is mixed and not clear.
In the inbox page the old messages can be hidden or shown in another page.
The home page can be difficult for the elderly patients.
In general, the home page is perceived more difficult than the inbox functionality.

In the homepage the 'treatment as need' is not clear.
Measurement section should be more visual and show evolution.
Important that the system is not generating too many reminders.

Table 10: Feedbacks from health professionals on task 2

Task 3: Symptom's report

The participants also revised the symptoms reporting functionalities. In general, all the users were able to complete the flow. Similarly, to the patients, during the selection of the symptom All users go directly to the list of the symptoms and do not use the search. The following table details suggestions on how to improve this functionality.

Feedback from health professionals on the report of symptom of the app
Order list of symptoms in alphabetical order.
Move this section before the inbox.
Not clear the abbreviation of the stools in the grade of diarrheal symptom.
Some users did not press in the add symptoms, this button is confusing (people understand that the button is to add another symptom). It should be called save symptoms.
Put more explicit that the drug is specific to manage the symptom effect
The time is not relevant in the start of the symptom.
Leave threatening life out of grade of diarrhoea symptoms.
In the list of drugs to manage side effect one user missed paracetamol
One user suggested that the reported symptom could be edited after the first insert.
One participant suggested revising how every symptom is difficult to report. There are some that are very difficult to quantify (e.g. skin rash, abdominal cramping)

Table 11: Feedbacks from health professionals on task 3

Task 4 Capsule

The participant also revised the Capsule functionality. This module was well accepted, and the participants provided the following feedback.

Feedback from health professionals on the Capsule module
Capsule name not understood. Capsule reminds medical treatment, not a digital intervention.
There is one educational content called 'Questions goes here', not clear for the user
The locked content should be not shown to the patient. It adds an unusual complexity. If a health professional it is not indicating a content is for a specific reason.
Capsule modules need a rewording of the name and of some other texts.
Missing information on side effects.
Change the name 'proposed actions'

Table 12: Feedbacks from health professionals on task 4

Task 5: Follow up in the Web portal

During this last task the participants simulate a remote follow-up of a patient. In general, the users were able to complete the flow. The only difficulty was that in the home page there are three patients with a similar name and surname, and the participants had difficulties to select the right one. The following table reports the feedback related to this functionality.

Feedback from health professionals on the remote follow-up functionalities
Generate alarms when a physiological parameter has critical values (Pulse, BP). Alarm should be on the home page.
Very useful timeline page but it should be more graphical.

The interaction between st. John and loperamide should be an alert for the homepage.
Measurement module needs to have charts.
Questionnaire: important to see in the table the cut off scores and possible the interpretation of that score. Also, in this case an alarm should be generated when values are critical.
Move symptoms after the treatment tab menu.
It would be nice if reported symptoms would be added in the EHR.
Add possibility to add some note related to the patient.
Add possibility to add a visit report.
Add a quick overview page of the patient, in order to show and overview.
In some page the dates are missing the year at this is not clear.
A patient in the header is labelled as 'stable', this is not clear, and it is not consistent with the presented case of Maria that had diarrhea and one interaction between loperamide and st. John.

Table 13: Feedbacks from health professionals on task 5

Overall easiness of the tasks

The participants score from 1 (very difficult) to 5 (very easy) the performed tasks. The overall results are positive and above the positive threshold (3). The most critical tasks was the inspection of the homepage of the app and the inbox messages, for the reasons that have been reported previously. The easiest tasks were the Capsule in the patient app and the remote follow-up of the web portal for health professionals.

	Average	St Dev	Min	Max
Patient enrolment (Web)	4,17	0,41	4	5
App home and inbox	3,50	0,84	2	4
App symptom report	4,50	0,55	4	5
App Capsule	4,67	0,52	4	5
Remote follow-up (Web)	4,67	0,52	4	5

Table 14: Easiness of the performed tasks

Final questions

Similarly to the patients' interview schedule, in last part of the interview four types of information have been gathered:

- Qualitative feedback on missing functionalities and how system can be improved
- Qualitative feedback on the possibility of providing services also for the caregivers.
- Quantitative evaluation of perceived values of the CAPABLE systems
- Quantitative evaluation of the overall system usability

Missing functionalities and how to improve the app.

The overall feedback is that the CAPABLE system has quite a complete set of functionalities. The participant understood that the revised prototype was a first attempt of showing the graphical interface and they understood that some parts were uncompleted. The participant provided the following suggestion on functionalities to be added and features to be considered for the next development

Suggestions on new functionalities and system improvements
Add a form in the web portal to report the periodic patient's visit.

When a patient reports a symptom and the doctor performs an action the system should provide feedback to the user. The action could be "call the physician", "change of dosage", etc.
Add sociodemographic information in the enrolment form.
Add the telephone number of GP it can be useful for the care team of the hospital.
Patient app: must be easy, engaging, stimulating to play with the app.
Web portal: highlight the most important events and situations on the home page. Traffic lights could be too simplistic. Other information should be added.
In the real scenario the problem will be who will perform the remote follow up of the patients, this work is still not recognized in the hospitals.
If the caregiver is the one that is reporting a symptom, the web portal should notify.
Add a form in the app and web portal for technical support and also an help button
Add a contact information of the hospital in the app.
In general, more data visualization and less texts.

Table 15: Suggestions on new functionalities and system improvements

Informal caregiver, should be involved?

All the participants agreed that informal caregivers can use the same app, but it is important that system understands and shows in the web portal who reported the data (e.g., symptom or questionnaire). Another suggestion is to differentiate care givers that assist the user to report and others that need to be informed. In some cases, also the information could generate anxiety to the caregiver. It should be mandatory to ask the consent to the patient to assign a caregiver.

Some participants also suggested creating specific informative content for the caregiver, providing correct instruction of usage of the app and the type of support that can be given to the patient.

Perceived values

The participants responded to a questionnaire aimed to measure the acceptance and the values perceived. In general, not all the proposed dimensions were well accepted. The most criticized sentences were about the fact that CAPABLE can improve the communication between health professionals (usually they have other ways to communicate like board meeting, notes in the Electronic Health record, messages via Smartphone etc), the idea that CAPABLE is a good system to track the treatment response and the idea that a system like CAPABLE fits in the daily work routine (currently there are no remote services in the hospital of the interviewed people , so it is seen as a new process). All the participants agreed that the system will help to manage the side effect of the cancer treatment and that will be a good support for the patients.

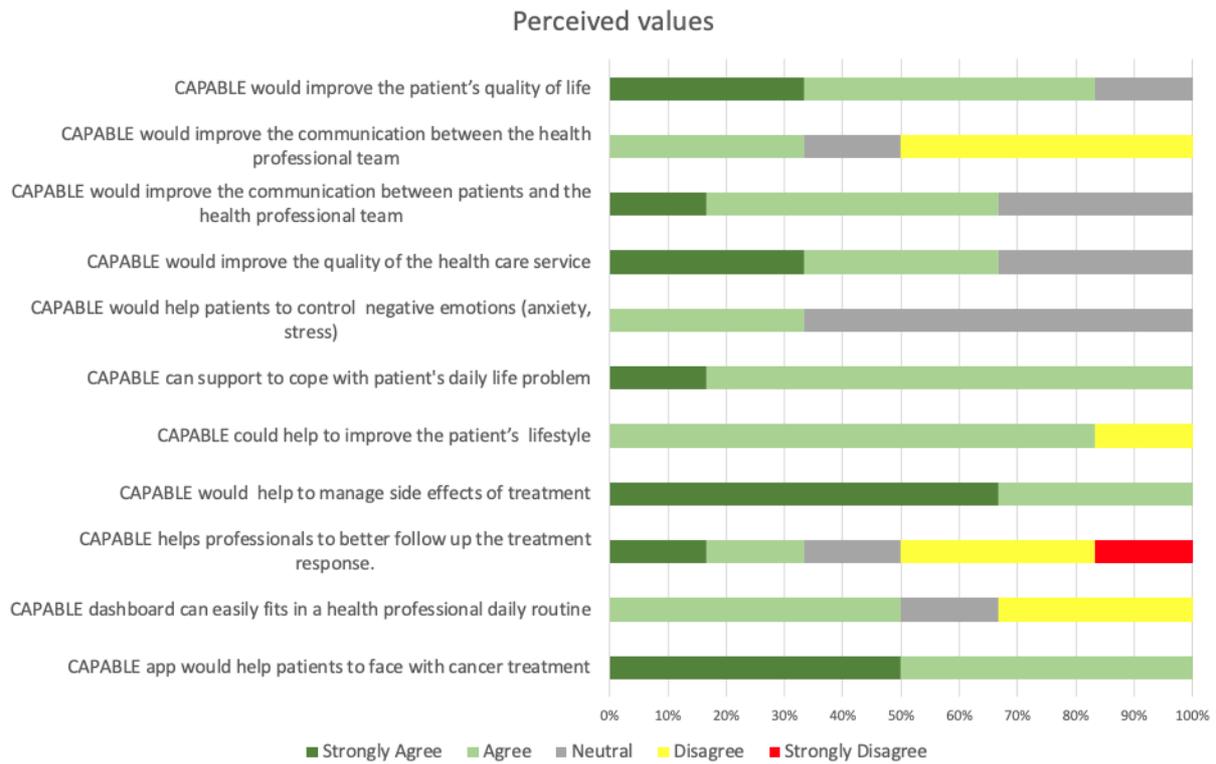


Figure 8: Chart of the perceived values of CAPABLE

Overall system usability

The last questionnaire of the interview was the standard questionnaire about system usability. The overall results are good. The system received good scores (thresholds are between 68 and 80): the overall mean score of the SUS questionnaire is 75,8 (St.Dev. 7.01, Min 67,5, Max 85) that indicates that CAPABLE has high usability. Differently from the patients all the users scored positively the usability of the system and the data has lower variability.

From the analysis of the single metrics of the questionnaire it is possible to notice that the dimensions that received lower scores were about system complexity, the learnability of the system and the need to have a technical support to use the system.

System usability scale

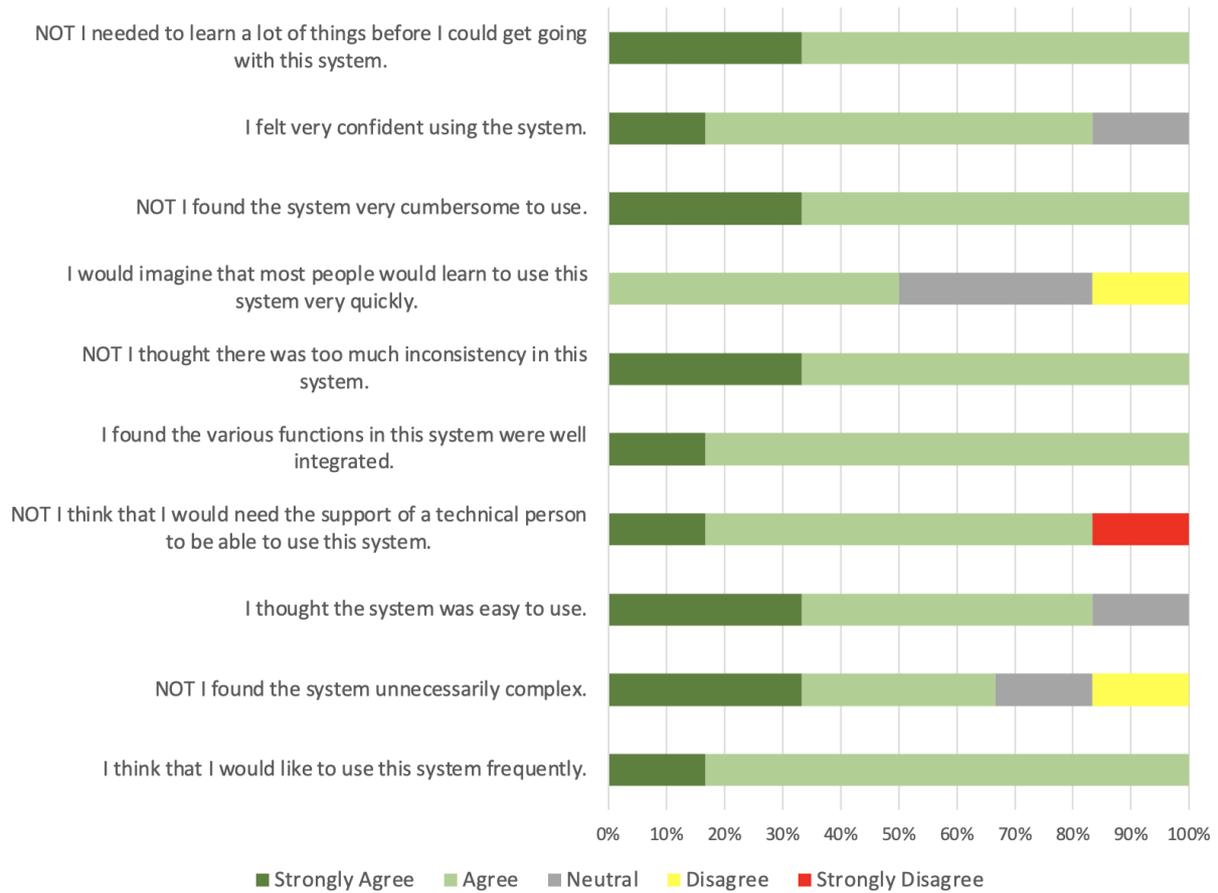


Figure 9: Chart of the System usability questions

4. Conclusions

During this first iteration WP7 set up an exhaustive set of activities that globally involves 24 participants distributed as follow:

- 10 experts of digital health and user interaction from Universidad Politecnica de Madrid
- 7 patients and one informal caregiver selected from the AIMAC networks
- 3 health professionals linked to ICSM hospital
- 3 health professionals linked to NKI hospital

Three different types of protocols have been applied, according to the participant profile (see documents in the annex). Many quantitative and qualitative information has been gathered with different types of perspective, from experts in systems design to end users. All these feedbacks will be used to improve the current version of the prototype and to release other versions to be further developed in the next iteration at month 20 (D7.4 Second interim usability and acceptability report). It is very clear from this first iteration that the CAPABLE concept is well accepted by the end users and it fulfill the unmet needs. Several issues have been identified and this in general is normal in these types of exhaustive revisions of the prototype. The consortium right now planned a new task force to address all the inputs. A preliminary work of systematization of the issues has been done and is presented in the annex, where a list of issues has been organized for the two revised prototypes: the patient app and the web dashboard for the health professional. One more time User Centred Design demonstrate a very good approach to refine the prototypes and to give to the Consortium precious feedback on how to improve the system and what could be the impact on the real end users.

5. Annexes

The following chapter provides links to other documents that are related to the work performed in this deliverable. The Subsections contain the link to the 3 validations that have been performed (heuristic validation interviews with patients and health professionals) and a table that recap all the issues on the prototypes that have been identified thanks to these activities.

Protocol of the heuristic validation

<https://docs.google.com/document/d/1A1yAnJBCw25i228AySGxrWzMaDpNCHzHnbDo0BtYvO0/edit>

Protocol of the patient's interviews

<https://docs.google.com/document/d/1rcon3RpgMab3KpfbcYVTj6yDmKszrrK-yV6SvnaJ0h0/edit#>

Protocol of the health professional's interviews

<https://docs.google.com/document/d/1V5ERT9prv7tFk0qcv5qG3sQHqtd803wf6s-c4w8RDp8/edit>

Analysis of the issues of the prototypes

https://docs.google.com/spreadsheets/d/1XQ3C7O4EM_dDoLbGpB3cRi_UhvtuFcL4loIWN0W2z0/edit?usp=sharing