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***Empowering patients and strengthening
self-management in cancer diseases***

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citizen engagement and mHealth**

***D6.4: Implemented application scenarios in
iManageCancer Platform using psycho-emotional and
health assessment tools***

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² **PU** = Public, fully open, e.g. web, **CO** = Confidential, restricted under conditions set out in Model Grant Agreement

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1. Executive Summary

The present deliverable aims to describe the implementation of the Psycho-emotional Monitoring tool (including the PsychE and the ALGA questionnaires), the Family Resilience (including the FaRe questionnaire) tool, the Parental Distress Questionnaire (for caregivers of children with cancer disease), and their usage through other iManageCancer services and tools. The European Institute of Oncology has leaded the construction and the psychometric validation of the tools, together with the University of Saarland (for the Parental Distress Questionnaire), in order to include in the iManageCancer platform the assessment of patients' psycho-cognitive and family resilience status.

The Psycho-emotional Monitoring tool is designed to assess individual emotional and psycho-cognitive aspects that can affect the patient involvement level in the therapeutic process.

The Family Resilience tool, instead, is an instrument to assess the family system, the family dynamics and resources, and the estimation of the adaptation to the disease.

One hundred and four patients (51 prostate cancer, 53 breast cancer) from the European Institute of Oncology were presented with both the PsychE, ALGA, and FaRe tools, together with an already validated questionnaire, the Resilience Scale for Adults (RSA). One hundred and five caregivers were presented with the FaRe and the RSA. The tools were an online survey version in order to emulate the final version of the instruments that will be part of the iManageCancer platform.

Since ALGA was validated only in breast cancer patients, an additional validation study of the ALGA instrument, in order to assess the psychometric properties of the questionnaires for a different cancer patients' population. More specifically, ALGA was validated also on a prostate cancer group of patients in order to connect these results with the construction of the decision aid for prostate cancer fulfilled in the WP5.

2. Introduction

Patient empowerment is a concept borrowed from social sciences and generally described as a “concept of social process in detection, promotion, and enhancement of individual's ability in confrontation with needs, as well as problem solving and getting equipped with the necessary resources to manage their life.” (Jones & Meleis, 1993). In particular, in medicine empowerment constitutes a mean and, at the same time, an objective of health promotion. The attention to the patient as a *person*, which is strictly associated with her/his empowerment levels, should therefore become pivotal in the care flow. The WHO declared repeatedly that promotion of patient empowerment is a *prerequisite* of health.

Empowerment represents a core component of personalized medicine, an approach that is rapidly spreading in oncology as well, and traditionally intended as the possibility to individuate the best therapeutic strategy based on the profile of the single patient. Until recently, this approach took into account only the biological and genetic characteristics of the patient, while a challenge for the future remains the attempt to tailor personalized care starting also from the psychological aspects of the person/patient. This shall consider her/his needs and values, her/his expectations and the quality of life that results also from the therapeutic regimen he/she is undergoing. From a psychological perspective, a personalized approach to the patient which aims to promote her/his empowerment allows, on the one hand to understand how the person interprets, faces and experiences the diagnosis, the treatments and the associated risks and benefits, thus increasing the possibility for her/him to actively intervene in the therapeutic pathway. On the other hand, it allows to provide the physician with a personalized profile of the patient, which may help her/him to find the most suitable approach to the patient's needs, values and priority, thus ultimately increasing adherence, satisfaction, and wellbeing.

In this perspective, empowerment facilitates oncologic self-management i.e., the “awareness and active participation by the person in their recovery, recuperation, and rehabilitation, to minimise the consequences of treatment, promote survival, health and well-being” (NCSI, 2009). This process can be supported by social and clinical staff, as well as from organization.

3. Aim of the tools

The tools included in WP6 shall constitute ICT based assessment tools which provide information on the psycho-emotional status of the patient seen both as an individual as well as part of a family system.

These tools provide techniques which allow for smart, personalized or tailored information provision, recommendations and self-management support.

More specifically, the WP6 aims to:

1. develop an instrument to assess individual emotional and psycho-cognitive aspects that can affect the patient involvement level in the therapeutic process. Such instrument is used to constantly monitor the evolution of the patient's emotional functioning, and to support the health professional-patient relationship;
2. develop an instrument to assess the family system and, more specifically, the family dynamics and resources, estimating the adaptation flexibility to the disease. Cohesion, communication, coping style, and relational style were considered as critical functional areas in the construction of the instrument.

3.1. *Psycho-emotional Monitoring Tool*

The Psycho-emotional Monitoring tool is composed of two questionnaires: ALGA and Psyche. Prior studies of the Applied Research Division for Cognitive and Psychological Science in IEO validated the ALGA tool for the general population and for patients affected by breast cancer (Gorini, Mazzocco, Gandini, Munzone, McVie et al., 2015).

The ALGA questionnaire is a patient-profiling tool that assesses the cancer patient's physical and mental characteristics in order to provide physicians, prior to the consultation, with a patient's profile that is supposed to facilitate subsequent communication, interaction, and information delivery between the doctor and the patient. The purpose of such instrument is twofold: on the one hand, it allows to optimize information delivery from doctors to patients (i.e., doctors, having a patient profile, can rapidly adjust the content and the level of verbal information to the patient's needs and level of understanding). On the other hand, it allows to inform the patient about his/her own critical psychological areas, providing coherent recommendations.

ALGA allows a global assessment and uses a personalized approach to the care of the person, providing a brief evaluation of the cancer patients' psychological status. As soon as the patient completes the questionnaire, her/his answers are automatically elaborated and put together to create a patient's profile, and sent to the physician's computer. Provided to the physicians at the very beginning of the visit, such information is supposed to be crucial for them to find a tailored way to communicate with the patient. Furthermore, a better interaction between patient and physician can increase the patients' understanding and their ability to retain information, in order to improve the coping with the disease.

However, in proceeding with the implementation of a personalized approach and refining its use, further psycho-cognitive aspects should be considered. In particular, it is fundamental to consider the individual with his thinking style, decision preferences that interact with a specific environment such as the health professionals, but also their own family, that can improve the empowerment process, or can hinder it.

In this perspective some factors have been highlighted as important determinant e.g., the *need for cognition*, the *patient's decision style*, and the *emotional status*.

Despite the importance of a systemic approach in oncology, no validated instruments are available to measure it. For this reason, the PsychE questionnaire adds to ALGA in the Psycho-emotional status monitoring tool.

3.2. Family Resilience Tool

The aim of the Family Resilience tool is to assess patient's and caregivers' beliefs about the resilience of the family in facing cancer disease, defined as the ability to recover from adversity stronger and more resourceful (Walsh, 1998). Scientific literature underlines just few questionnaires aiming to explore the family resilience construct. Nevertheless, most of them are focused on the individual belief of the subject in respect with their family resilience status.

The aim of iMC Family Resilience tool is to assess all the family members' resilience in order to compare them and evaluate the family's beliefs on the disease, the organizational patterns involved in the disease and the communication processes and the problem solving processes acted by the family to face the disease. In this sense, the tool focused on the whole family resilience from a systemic point of view: both the cancer patient and the participant separately completed the tool in order to consider the whole family system resilience.

3.3. Health Assessment Tools

The health assessment tools referenced in the title of this deliverable comprise the so-called health enquiry tool and the monitoring tool for vital signs. Initial prototypes of both tools have been described in previous deliverables of Work Package 6 (D6.2, D6.3). We present here the features of the current versions of these tools as they are used in the clinical pilots of the project as well as their wider application in the iManageCancer Platform. The monitoring and management of the life style is provided by the app MyHealthAvatar for iManageCancer of Work Package 4. It is not part of this deliverable.

The health enquiry tool as such is an embedded feature in the Care Flow Engine in the Central Decision Support System of the iManageCancer Platform. By the help of the Care Flow Designer clinical experts can design short questionnaires for patients and health professionals as part of so-called Care Flows. In such Care Flows experts design also how the answers to the questions are assessed and what information will be fed back to the users. The users can receive and answer such health enquiries with the client apps iManageMyHealth and iSupportMyPatients that interact with the Care Flow Engine. Health enquiries are an essential part of a Care Flow. The main aim with such health enquiry tool is to enable the clinical administrator of an instance of the iManageCancer Platform to dynamically incorporate useful Care Flows in the system to monitor the health of the patients outside healthcare organisations according to the individual needs and the local healthcare delivery model, and to provide automated feedback to patients and doctors.

The monitoring tool for vital signs has the aim to support the patient in tracking certain vital parameters and laboratory parameters of relevance for cancer care by capturing such measurements from devices or by entering them by the patient himself and presenting these values to him/her as trend charts. In addition, requests to carry out a measurement can be incorporated in Care Flows to follow an individual monitoring regime as well as assess the results in the Care Flow Engine and control further interventions.

4. Psycho-emotional Monitoring Tool

4.1. Summary of user scenario and requirements from D2.2 and D2.3

4.1.1. General description and goals

The iManageCancer platform use standardized psycho-behavioural questionnaires in order to monitor psycho-emotional status of cancer patients and their individual resources in coping with cancer. This tool allows to tailor information provision and services in accordance with patients’

preferences and attitudes and to develop individualised self-management action plans. We expect these intermediate goals to ultimately allow a better fitting between the patient and the Avatar, thus increasing self-management abilities and patient empowerment. The corresponding workflow as described in D2.2 is as follows

Case 1: The patient has to visit the clinic for a scheduled consultation with a physician

Patient user

- Prior to consultation (at arrival in the hospital or 24 hours in advance) the system reminds the patient via email or some other system to perform a whole or a partial Psycho-emotional assessment
- Data are computed and scoring is generated. Detection of significant variations from previous assessments
- Patient profile is generated based on scoring, and feedback is provided on his status
- If the consultation includes discussion on therapies, Decision Aids tool is activated
- Depending on scores in ALGA, Family Resilience Tool is activated
- Depending on scores in different areas, suggestions on actions are activated, e.g., suggest psycho-oncologic consultation if depression scores are elevated; provide indications on pain management and/or alert clinicians if pain is increased.

Clinician user

- The doctor receives a notification that a profile is ready for a scheduled patient
- Scoring on different areas is provided along with short feedbacks and suggestions based on the patient's situation

Case 2: Periodic monitoring

Patient user

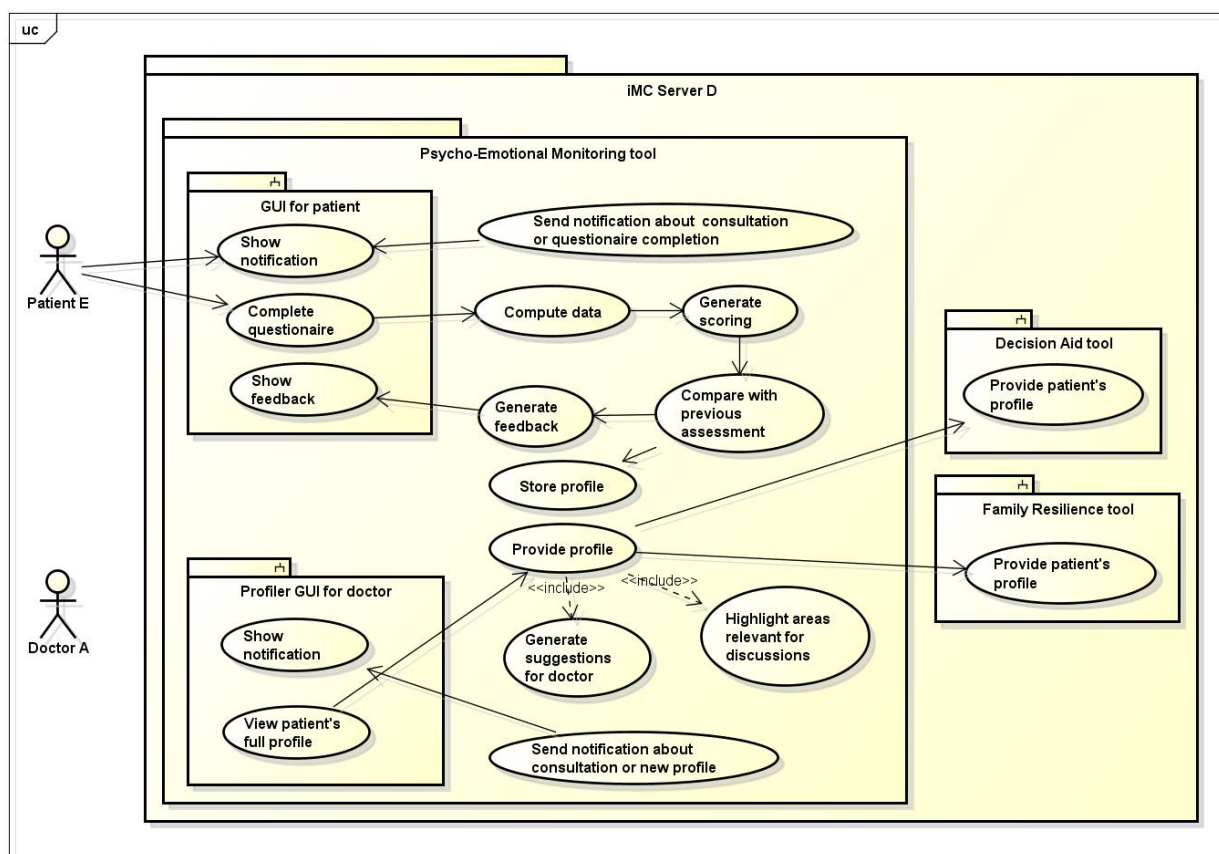
- A periodic reminder inform the patient to perform a whole or a partial Psycho-emotional assessment
- Data are computed and scoring is generated. Detection of significant variations from previous assessments
- Patient profile is generated based on scoring, and feedback is provided on his status

- Depending on scores in different areas, suggestions on actions are activated e.g., suggest psycho-oncologic consultation if depression is scores are elevated; provide indications on pain management and/or alert clinicians if pain is increased.
- Psychological profile activates different patterns of information provision from the Personal Health Information Recommender

Clinician user

- If scores in certain areas are significantly elevated, an alert is sent to clinicians.
- Scoring on different areas is provided along with short feedbacks and suggestions based on the patient's situation

Then in D2.3 the following use-cases were generated:



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Figure 1: Use cases diagram for Psycho-Emotional Status and Management.

Use Case ID	UC.PESM.1	Priority	REQUIRED
Use Case name	Psycho-Emotional Status and Management tool for patients		
Scenarios	SC10		
Actors	Patient		

Brief description	Questionnaires will be filled by patients to monitor their psycho-behavioural status.	
Trigger	A notification will be issued by the Messaging and Notification Centre for a scheduled consultation with a doctor or for a periodic completion of the questionnaire.	
Pre-conditions	<ul style="list-style-type: none"> The patient should be already registered to the system 	
Post-conditions	-	
Successful end condition	The patient successfully completes the questionnaire and proper suggestions are provided him according to the generated profile.	
Fail end condition	The patients profile is incomplete.	
Relationships	Extends: -	Includes: -
Basic flow	Step	Action
	1	The patient completes the questionnaire
	2	Data are computed and scoring is generated.
	3	Variations from previous assessment or from the reference standard are identified and feedback is provided.
Usage frequency	High	
User interfaces	Proper apps installed on actor's smart device/laptop etc.	
Notes and issues	-	

Use Case ID	UC. PESM.2	Priority	REQUIRED
Use Case name	Psycho-Emotional Status and Management tool for doctors (Profiler)		
Scenarios	SC10		
Actors	Doctor		
Brief description	A patient profile is constructed and presented to the doctor for enhancing patient-doctor communication		
Trigger	A notification is issued by the Messaging and Notification Centre that a new profile is available or that a consultation meeting is scheduled.		
Pre-conditions	<ul style="list-style-type: none"> The Decision Aid profile of the patient should be available. The family resilience tool should be already available and completed. Experts (psychologists) have defined the formulas for identifying the relevant areas in information processing, understanding and decision making according to patient answers. Experts (psychologists) have defined the suggestions to doctors according to the aforementioned formulas result. 		
Post-conditions	-		
Successful end condition	A doctor retrieves the full profile for a scheduled patient containing indications on patient's psychological and cognitive situation that can affect the management of his/her situation.		
Fail end condition	The profile presented is incomplete or not salient for the doctor.		
Relationships	Extends: -	Includes: -	
Basic flow	Step	Action	
	1	The doctor receives a notification that a profile is ready for a scheduled patient	
	2	The profile contains indications on psycho-emotional and cognitive areas that are relevant in (and can impair) information processing, understanding and decisions, other than on patient's preferences on decision style and self-management resources. Suggestions are provided to the doctors to avoid negative effects of dysfunctional cognitive and emotional areas.	

Usage frequency	High
User interfaces	Proper apps installed on actor's smart device/laptop etc.
Notes and issues	-

In consequence, D2.3 lists 4 important functional system requirements which were derived from these use cases. They are briefly listed in the following table.

ID	Name	Description
REQ. PESM.1	GUI for completing the psycho-emotional and cognitive questionnaires	The platform should provide a GUI enabling patients to complete the psycho-emotional and cognitive questionnaires.
REQ. PESM.2	Database for storing patient questionnaire choices	The platform should provide a database for the patient choices.
REQ. PESM.3	GUI for presenting the combined Patient profile for Doctors	The platform should provide a GUI for presenting the combined patient profile with indications on psycho-emotional and cognitive areas that are involved in information processing and understanding and in decision-making, including patient's decision style preferences.
REQ. PESM.4	Secured access to the Psycho-Emotional Status and Management Tool	The Psycho-Emotional Status and Management tool should be secured by a user authentication mechanism.

All those functional requirements were implemented and are currently available within the iPHR system.

4.1.2. Data

- Data input on scheduled appointments is received from the calendar and activates the Tool
- Data entry is provided from the patient.
- Data regarding profile:
 - Activate suggestions on self-management actions
 - Are stored in the PHR
 - Modulate information provision from the Personal Health Information Recommender
 - Are fed to the Decision Aid Tool and to the Family Resilience Tool
 - May send alerts to clinicians

4.1.3. Interaction with other user scenarios

Scenario PHR and e-diary, Health Avatar, Personal Health Information Recommender, Decision Aids, Family Resilience Tool, Data Analysis.

4.2. Questionnaires development

4.2.1. ALGA

ALGA is a validated tool for the general population and for patients affected by breast cancer (Gorini, et al., 2015), which was initially developed in the context of the European project p-medicine. ALGA allows a global assessment and uses a personalized approach to the care of the person. The tool individuates possible critical areas and provides useful indications, which may be used by physicians in the clinical consultation or to improve communication between clinical staff and the patient. In fact, an increase in the knowledge of the patient from the physician's side might result in a better and more efficient relationship between the two. Moreover, the psychological profile obtained by the questionnaire can increase the patients' understanding and their ability to retain information, in order to improve the coping with the disease.

The questionnaire is formed by 29 items divided in eight key factors: *global self-rated health*, *perceived physical health*, *anxiety*, *self-efficacy*, *cognitive closure*, *memory*, *body image*, and *sexual life*. From a statistical point of view, the ALGA questionnaire shows significant evidence of validity and reliability, and the item-total correlations for the total scale is high (Gorini et al., 2015; Gorini, Mazzocco, Kondylakis, McVie, & Pravettoni, 2016; Kondylakis et al., 2014) .

ALGA is supposed to improve the patient–physician relationship as well as the patient's compliance, and to increase her participation in the medical decision making. Moreover, this information is also an important predictor of the patient's future quality of life and health, being related to the way in which the patient copes with the disease.

Furthermore, using ALGA oncologists are recommended to put their attention on the psychological effects of the disease or treatment and eventually recommend the patient to refer to other specialists to cope with them.

4.2.2. Psych-E questionnaire

For the construction of the Psych-E questionnaire, quality criteria for the development of health questionnaires (Terwee et al., 2007) were reviewed. As to what concerns content validity: the identified measurement aim is the *evaluation* of patient psycho-emotional status. The designed target population is that of cancer patients (with possible differentiations in sub-categories depending on the specific cancer disease or cancer stage).

Relevant concepts considered in the construction of the questionnaire were: patient engagement, cognitive needs, decisional needs, and emotional profile. For every concept, a list of items was

created. For internal consistency, the hypothesized factorial structure of the questionnaire includes: patient engagement, cognitive needs, decisional needs and emotional profile as shown on *Figure 1*.

In the psycho-cognitive part the patient was asked to evaluate the degree of accordance - on a seven points Likert scale (strongly agree/strongly disagrees) - with sentences regarding her/his general status or attitudes, and regarding her/his experience with the current disease or her/his last consultation. Items are connected to different subscales of the constructs.

In the emotional part, the patient is asked to report how often he experienced a list of emotions relative to different emotional scales (Vitality, depression and anxiety, anger, etc.) similarly to the Profile of Mood States (Curran, Andrykowski, & Studts, 1995).

Through a pilot study the items were rephrased in an iterative process in order to control fluency and comprehension. Items reduction was performed following validation procedures in order to maintain only those items which result necessary for the definition of the constructs (see Section 6.1.).

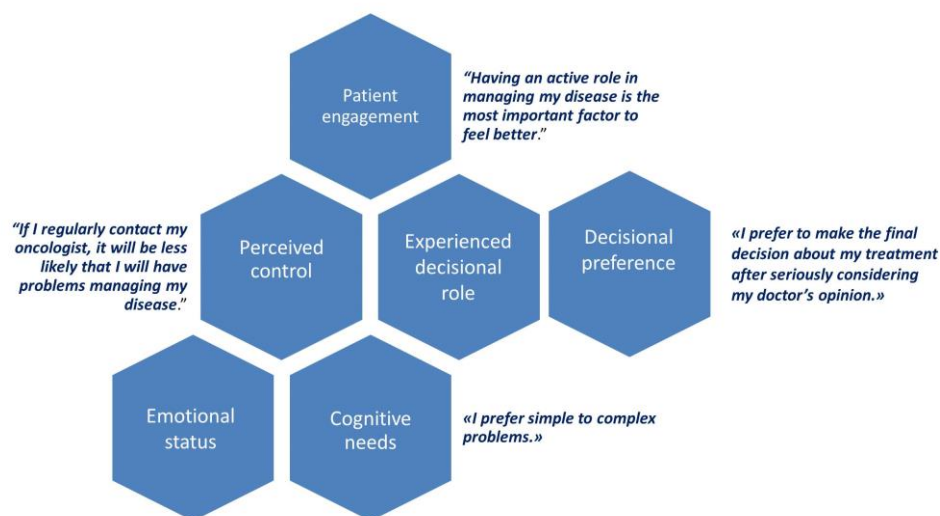


Figure 2: The hypothesised sub-scales of the Psycho-emotional Monitoring tool for cancer patients including patient engagement, decisional preference, perceived control, and experienced decisional role (decisional needs), cognitive needs and emotional profile. Examples of questions are provided next to the factor.

A pilot study with 20 citizens (healthy people between 25 and 80 years of age, with no diagnosis of cognitive or psychological deficits) was performed to assess the first version of the Psych-E (Version A). After explaining the procedures of the study, written informed consent was obtained. Participants were asked to evaluate the degree of clarity of each item. In case they found it not

sufficient, they were asked to point out what they understood of the question and how they would rephrase it.

On the basis of this results, the items were iteratively reviewed (two iterations) by three judges and rephrased. The process was concluded when the last 5 participants found no issues in understanding the questions. This version of the questionnaire was denominated Version B.

4.2.3. Validation study methods

In order to carry out validation studies for these tools, a proposal to the local IEO Ethical Committee was drafted and submitted.

The proposal and approval by the Ethical Committee is included in Deliverable 11.1. The proposal contained the structure of the validation studies, the first version of the questionnaires and the informed consent for the participant.

Ethical approval was obtained on April 11th 2016.

Since the ALGA questionnaire was validated only for breast cancer patients, we implemented an additional validation study of the tool in order to assess the psychometric properties of the questionnaires for prostate cancer patients, which is the target population for the pilot together with breast cancer patients.

Participants

104 patients (53 breast cancer patients and 51 prostate cancer patients) from the European Institute of Oncology were recruited for the study after explaining study aims and procedures. All participants gave their written informed consent. Patients were not receiving psychological support at the time of the assessment. After the evaluation, two patients requested psychological support.

Patients were presented with the version B of the Psych-E questionnaire and the ALGA questionnaire.

Inclusion criteria were the following:

1. age between 25 and 80 years of age;
2. cancer diagnosis of breast or prostate cancer;
3. signed informed consent;

4. no psychiatric, addictive, or cognitive disorder that would prevent compliance with protocol requirements.

4.2.4. Results of the validation study

For **ALGA**, the overall analysis with both disease groups yielded the same factors of the original ALGA validation. Cronbach's alphas for all factors were above 0.60, indicating that the factors are above the conventionally used reliability threshold. Factors were: Global Self-rated Health, Perceived Physical Health, Anxiety, Self-efficacy, Cognitive Closure, Memory, Body Image, Sexual Life.

Further analyses were run to compare the factors across disease groups. In a multivariate analysis, taking age into account, Body Image and Sexual Life resulted to be significantly different between prostate and breast cancer patients.

Complaints in body image were reported more often by breast cancer compared to prostate cancer patients. This result is consistent with the type of surgery performed. In fact, quadrantectomy and mastectomy imply a modification in the physical appearance of the breast, while prostatectomy does not imply radical modifications in the appearance of sexual attributes. Men with prostate cancer also reported being more often sexually active or interested in sex than women with a diagnosis of breast cancer.

Disease specific scoring systems will be implemented for each factor.

For **PsychE**, the factorial structure was analyzed after validation procedures using the factor analysis. We selected 10 factors, namely: Tendency to reflect, Internal Health Locus of Control, External Health Locus of Control, Knowledge of disease, Adherence, Autonomy in decision, Depression and anxiety, Vitality, Anger, Exhaustion. All Cronbach's alphas were above 0.6 except for the Internal and External Locus of Control, which were respectively 0.54 and 0.52. No significant differences were found between different disease populations.

Nevertheless, disease specific scoring systems will be implemented for each factor.

In order to assess construct validity of PsychE, we analyzed whether the subscales of the questionnaire correlate with other measures.

Factor Tendency to reflect correlated negatively with cognitive closure in ALGA ($\rho = -0.25$, $p = 0.01$). Factor Knowledge of disease correlated negatively with Anxiety in ALGA ($\rho = -0.24$, $p = 0.01$). Factor Adherence correlated positively with cognitive closure in ALGA ($\rho = 0.27$, $p = 0.005$) and with factor Perception of Self in RSA ($\rho = 0.28$, $p = 0.003$). Depression and anxiety factor in PsychE correlated positively with trait and state anxiety (factor Anxiety) in ALGA ($\rho = 0.67$, $p < 0.0001$). Factor Vitality of PsychE correlated negatively with perceived problems in health status (factor Perceived physical health) in ALGA ($\rho = -0.39$, $p < 0.0001$) and correlated positively with sexual life in ALGA ($\rho = 0.38$, $p < 0.0001$). Exhaustion factor correlated positively with perceived problems in health status (factor Perceived physical health) in ALGA ($\rho = 0.48$, $p < 0.0001$) and memory problems ($\rho = 0.33$, $p = 0.0006$).

4.2.5. Final questionnaires

For ALGA, the factorial analysis confirmed previous validation, therefore the original questionnaire composed of 29 questions will be maintained as is in the Psycho-Emotional monitoring tool of the platform.

For PsychE, based on the results of the factorial analysis, 10 factors were selected for a total of 42 items. The items with the highest weights were selected. The number of items ranges from 3 to 8 in each factor.

4.2.6. Patient profiles

Different profiles for each factor of the two questionnaires with feedback for patients and clinicians were prepared depending on the score of the patient: score falls 2 standard deviations (SD) above or below the mean population score; between 1 and 2 SD above or below the mean population score; within the range of -1 and 1 SD from the mean.

5. Family Resilience Evaluation Tool

5.1. Summary of user scenario and requirements from D2.2 and D2.3

5.1.1. General description and goals

When a family member is faced with a life-threatening illness, the potential death presents a crisis and a challenge to the entire family as a system. According to the family systems theory (Bateson, 1971) individuals cannot be understood in isolation from one another, but rather as a part of their family, as the family is an emotional unit (Kerr, 1988). Families are systems of interconnected and interdependent individuals: what happens to one family member affects the other members.

The main goal for this scenario was to create a tool able to measure the family resilience in order to individuate the critical areas that can deplete the patient's resources and to foster interventions that empower the whole family system.

5.1.2. End users and workflow

The end users of the tool are both the clinicians, the patients and possibly the family.

Patient (and family) user

- The patient (and the family) periodically will be remind by an alert to perform the family resilience evaluation
- Data are computed and scoring is generated. In the first assessment the scores will be compared with a normative sample, while variations from previous assessments will be analysed
- A feedback on family resilience profile in lay language is provided
- Depending on scores in different areas, suggestions on actions are activated. Whenever recommendations consist on small changes in the family dynamics they will be provided by means of the platform. When severe criticisms appear a suggestion to contact a health care professional will be suggested.
- The Family Resilience Profile activates different patterns of information provision from the Personal Health Information Recommender

Clinician user

- If scores in certain areas are significantly elevated, an alert is sent to clinicians.
- Scoring on different areas is provided along with short feedbacks and suggestions

5.1.3. Data

- Data input on scheduled appointments is received from the calendar and activates the Tool
- Data entry is provided from the patient.
- Data regarding profile:
 - Activate suggestions on self-management actions
 - Are stored in the PHR

- Modulate information provision from the Personal Health Information Recommender
- Are fed to the Decision Aids Tool
- May send alerts to clinicians

5.1.4. Interaction with other user scenarios

Scenario PHR and e-diary, Health Avatar, Personal Health Information Recommender, Decision Aids, Data Analysis.

5.1.5. Questionnaire development

A first version of the Family Resilience tool was constructed by IEO after a deep revision of scientific literature in the field of resilience and cancer. The questionnaire was composed by 60 items referring to the six aspects identified by Walsh (1998) and Sixbey (2005):

1. **family communication and problem solving**
2. **utilizing social and economic resources**
3. **maintaining a positive outlook**
4. **family connectedness**
5. **family spirituality**
6. **ability to make meaning from adversity**

Questions are on a seven points Likert scale (strongly agree/strongly disagrees).

The tool starts with a brief sentence explaining patients and caregivers how to complete the tool: “We kindly ask you to read carefully each of the following statements. For each, please define how well it describes your family. Referring to your family you can mean all the significant people that in your opinion are part of it”.

A pilot with 20 citizens (healthy people between 25 and 80 years of age, with no diagnosis of cognitive or psychological deficits) was performed to assess the first version of the Family Resilience Evaluation tool, and to evaluate the degree of clarity and comprehension of the questionnaire’s items. They read the first version of the Family Resilience tool and indicated those items which resulted unclear, providing suggestions or comments to the researchers. On the basis of the collected results, the items were adapted and a version B was created. Overall, the version B of the tool is similar to the first version, but some items were revised and clarified.

5.1.6. Validation study

In order to carry out validation studies for these tools, a proposal to the local IEO Ethical Committee was drafted and submitted.

The proposal and approval by the Ethical Committee is included in Deliverable 11.1. The proposal contained the structure of the validation studies, the first version of the questionnaires and the informed consent for the participant.

Ethical approval was obtained on April 11th 2016.

104 patients from the European Institute of Oncology and 105 family caregivers (i.e., son/daughter, wife/husband/partner, father/mother, sister/brother) were recruited for the study after explaining study aims and procedures. All participants gave their written informed consent.

Patients were presented with the version B of the FaRe questionnaire.

Inclusion criteria for patients were the following:

1. age between 25 and 80 years of age;
2. cancer diagnosis of breast or prostate cancer;
3. signed informed consent;
4. no psychiatric, addictive, or cognitive disorder that would prevent compliance with protocol requirements.

The inclusion criteria for caregivers the following:

1. age over 18;
2. relative with diagnosis of breast or prostate cancer;
3. signed informed consent;
4. no psychiatric, addictive, or cognitive disorder that would prevent compliance with protocol requirements.

In order to assess the psychometric characteristics of the questionnaire, data collected were compared with another questionnaire measuring the resilience construct in individuals. The Italian version of the RSA scale (Bonfiglio et al., 2016) was selected for this task.

5.1.7. Results of the validation study

After having collected data, a factorial analysis was run in order to select the significant factors and items and to define the validated version of the tool to be included in the whole platform.

The factorial analysis yielded four relevant factors which were named: Communication and cohesion, Perceived social support, Perceived family coping, Religiousness and spirituality.

Cronbach's alphas for all factors were above 0.80.

Further analyses were run to compare the factors across the two populations (patients and caregivers) and disease groups. In a multivariate analysis, taking age into account, perceived social support resulted to be significantly different between breast and prostate cancer patients, the former reporting receiving greater support from family and friends for their disease. Perceived family coping was significantly different between patients and caregivers, the former perceiving the resources of the family being stronger.

Population specific scoring systems will be implemented in the platform.

In order to assess construct validity of FaRe, we analyzed whether the subscales of the questionnaire correlate with the RSA.

Total scores of FaRe and RSA were positively correlated ($\rho = 0.40$, $p < 0.0001$). Factor Communication and cohesion correlated positively with factor Family Cohesion in RSA ($\rho = 0.48$, $p < 0.0001$). Factor Perceived social support correlated positively with factor Social Resources ($\rho = 0.47$, $p < 0.0001$). Factor Perceived family coping correlated positively with factor Structured Style ($\rho = 0.19$, $p = 0.005$) and with factor Perception of Self in RSA ($\rho = 0.38$, $p < 0.0001$).

5.1.8. Final questionnaire

For FaRe, based on the results of the factorial analysis, 4 factors were selected for a total of 24 items. The items with the highest weights were selected. The number of items for factor Communication and cohesion and Perceived social support is 8, while it is 4 for the other two factors (Perceived family coping, Religiousness and spirituality).

5.1.9. Patient profiles

Different profiles for each factor of the questionnaire, with feedback for patients and clinicians were prepared depending on the score of the patient or the caregiver: score falls 2 standard deviations (SD) above or below the mean population score; between 1 and 2 SD above or below the mean population score; within the range of -1 and 1 SD from the mean.

6. Parental Distress Questionnaire

The Parental Distress Questionnaire (PDQ) examines the burdens of parents of children with cancer. In addition, it provides a diagnostic tool that is used to standardize and facilitate the whole patient management. The examination of parental distress was based on five burdens (namely “depression”, “anxiety”, “somatization”, “posttraumatic stress disorder (PTSD)” and “obsessive-compulsive”).

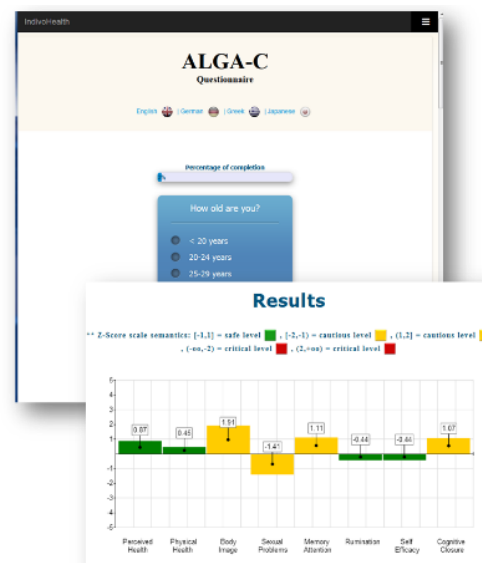
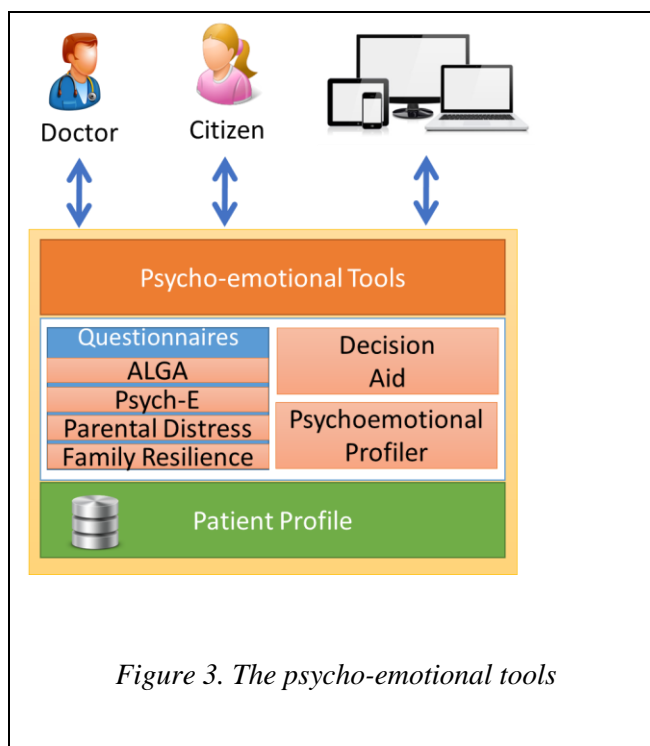
In a doctoral thesis by Kerstin Dietrich³ the Parental Distress Questionnaire was developed for German speaking parents. The questionnaire is divided into four parts addressing different questions to answer the relevance of the above-mentioned 5 selected burdens. All questions are in German language as given below.

The questionnaire is implemented as a tool in iPHR. It will be used in the pilot for children to determine the distress of the parents at the beginning and at the end of the pilot for their child.

³ Dietrich K: Belastungserleben von Eltern krebskranker Kinder. Dissertation. Universität des Saarlandes. 2014

7. Implementation of the tools in the iManageCancer platform

Within iManageCancer, three scenarios are dedicated for creating psycho-emotional tools: a) decision aid to support patients' participation in consultation (which will be described in D5.4), b) psycho-emotional status and management (ALGA-C & PsychE) and c) family resilience evaluation (iManageCancer Consortium, D2.2 Scenarios and use cases including the ethical and legal aspects). According to those scenarios, six individual tools were built, shown in Figure 3 (Kazantzaki et al., 2016). The psycho-emotional evaluation questionnaires are able to construct patient individual profile, the parental distress questionnaire is used to capture the attitude of children's parents, whereas the family resilience tool in addition is used to enhance patient profile with family resilience information. In addition, the decision aid is used to monitor patient health choices, make him organize his questions and propose to him choices to be further discussed with this doctor, as shown in *Figure 3*. Finally, the Profile tool is a tool enabling doctors to quickly visualize patient profiling information providing useful insights and recommendations. The questionnaires are available as an individual app in the iPHR system and collect different types of information in order to create a unique psycho-emotional profile of the patient and his family, to be further explored by other tools. The collected information is then visualized in the profiler tool available for the doctors as an individual app in their iPHR account. In the rest of this chapter we will describe in detail the technical details for the implementation of the psycho-emotional and the family resilience questionnaires and the profiler tool whereas there are already several publications focusing on an initial versions of the questionnaires and the profiler tool (Gorini et al., 2016; Kondylakis et al., 2013, 2014).



7.1. Questionnaires

The questionnaire tools are web-based tools developed to support patient profiling. The questionnaires are multilingual; The ALGA questionnaire is currently translated in English, Italian, Spanish, French, German, and Japanese, whereas the psycho-emotional tool and family resilience tool are already available in Italian and the translations in Greek, German and English are in progress. Finally, the parental distress questionnaire are only available in German and in English since they are going to be used in the German trial only. In both questionnaires the flow of the questions depends on user answers. An example of the answer-based question flow of the first questionnaire is shown in *Figure 6*. In addition, the questionnaires are developed to be compatible with a variety of mobile devices and browsers. They are optimised for the following mobile devices: iPhone, iPad, Nexus 7, Nexus 4, and for the following web browsers: Chrome, Safari, Firefox, Opera, and Internet Explorer. The back-end of the applications is based on the PHP and Spring MVC 3 framework, Apache server, and MySQL database. In addition, the interaction of the application with its database is facilitated by the Java Persistence API (JPA) EclipseLink. The front-end of the applications is based on Java Server Pages, HTML5, and JQuery technologies. In addition, the application guarantees responsiveness by relying on the responsive CSS Framework and Twitter Bootstrap.

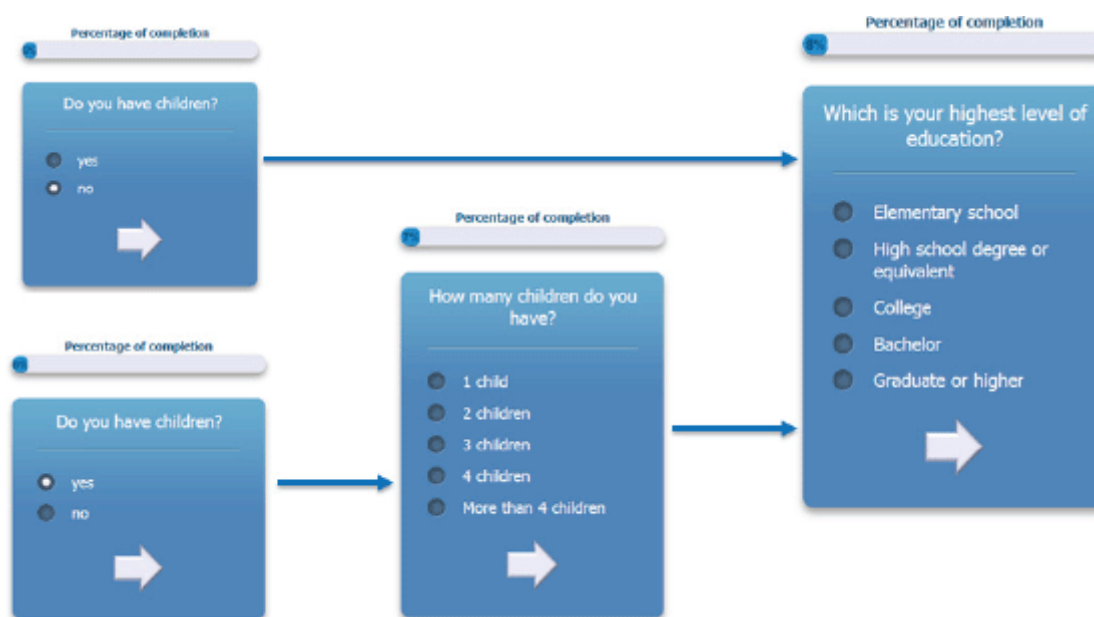


Figure 5. An example of the answer-based question flow

The basic workflow of a patient filling in a questionnaire is shown in Figure 6. A patient logs into the system, and then he is able to view his past completed questionnaires, or he can fill in a new questionnaire. Each time he completes a questionnaire, the results are stored in a local database.

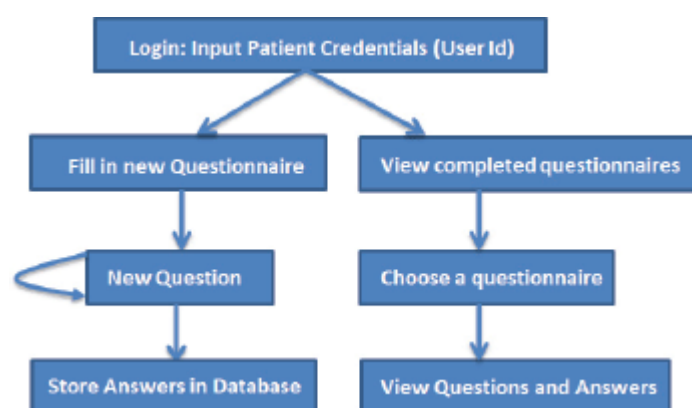


Figure 6. The basic workflow of the ALGA questionnaire

7.2. The profiler tool

The Profiler tool on the other hand, analyses the patients' answers from the questionnaires to extract their psychological profiles. The patients' profiles are then available to patients and to the clinicians in multiple alternative visualisations through the profiler, shown in Figure 7. This knowledge facilitates the patient–clinician relationship in their communications and shared decision making. Currently, the profiling analysis is based on the answers that a patient has given in the ALGA questionnaire. The analysis of the results is conducted in two phases. The first phase contains the calculation of simple average scores. These scores are calculated based on the fact

that each question’s answers have different weights. The second phase of the analysis contains the calculation of Z-scores, which are more complex, as they consider standard deviations of a healthy group of patients that have already completed the questionnaire. The results of the analysis are provided to the clinicians in multiple alternative visualisations for facilitating their interaction in the decision-making process.

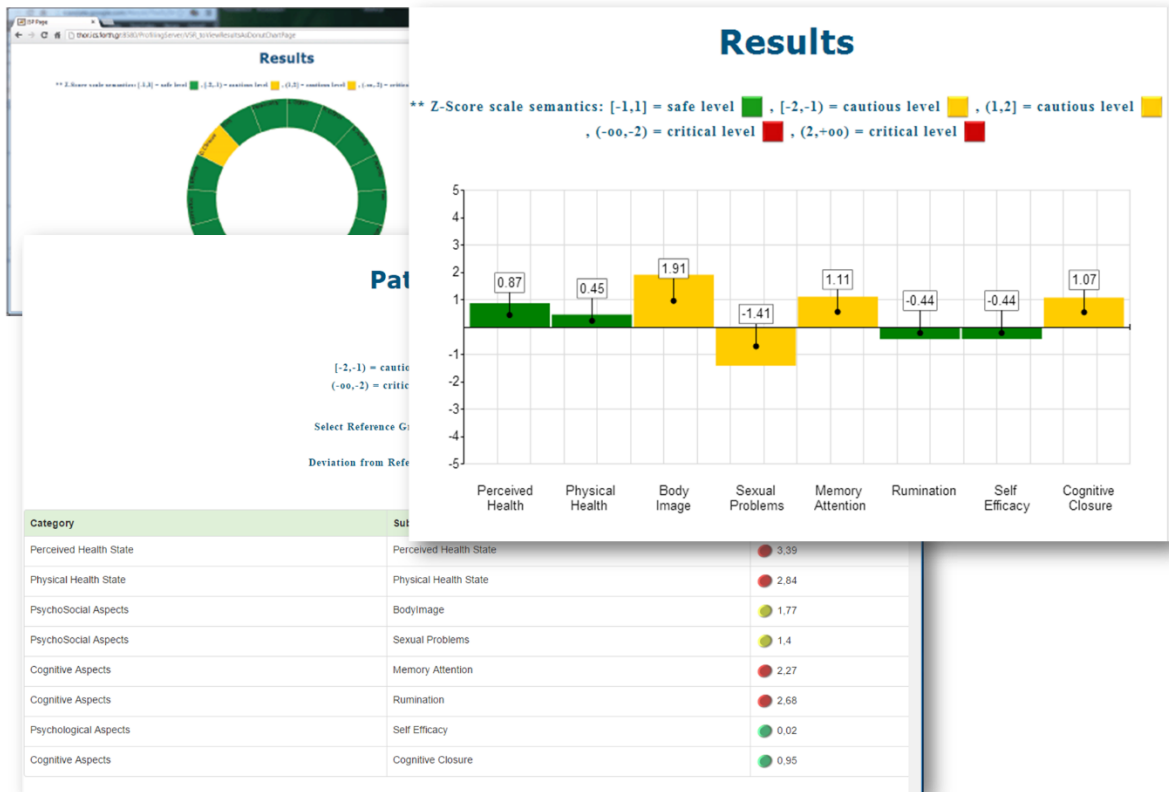


Figure 7. Visualizing the profile of the patient.

In addition, there are psychological explanations of the abnormal values and recommendations provided to the doctors according to the patient’s profiling information shown in Figure 8. Currently the profiles exploit only the answers to the ALGA questionnaire but soon it will exploit in addition the answers from the other questionnaires as well for performing the analysis and the corresponding recommendations.

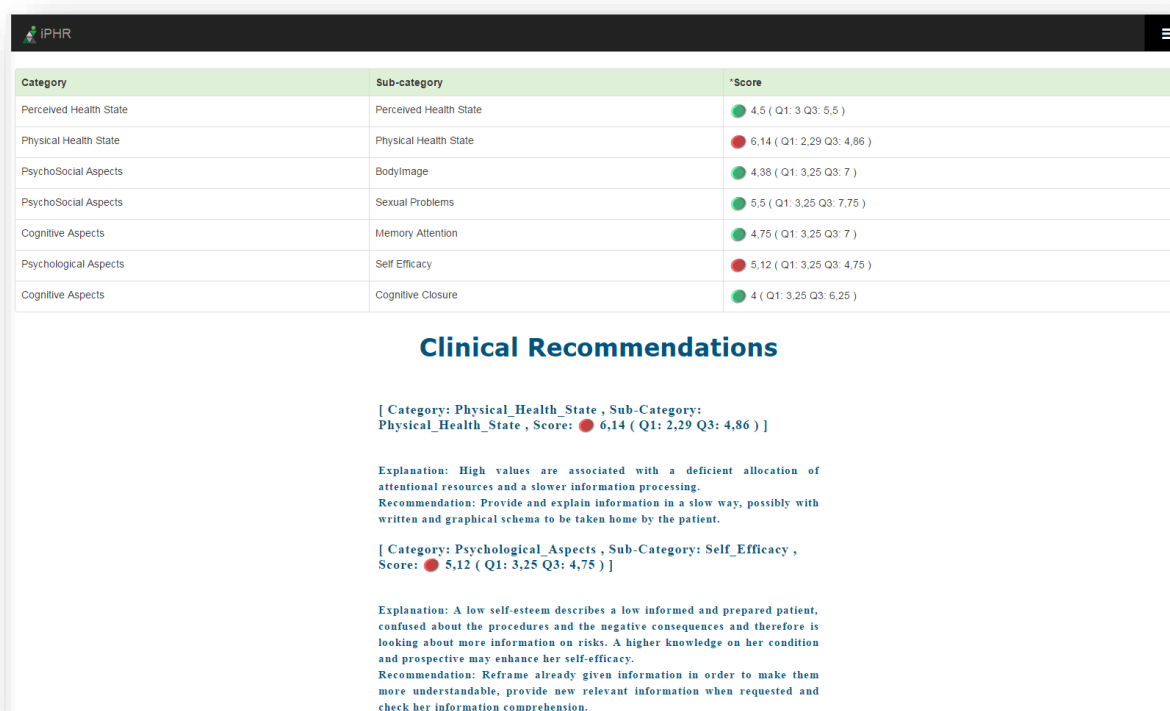


Figure 8. Clinical recommendations to doctors according to patient profiling information

7.3. Links to other tools

As already mentioned the questionnaires are available as an individual app within the iPHR account of the patients whereas the Profiler tool is available as another individual app available to the doctors. The collected information is used by several other tools allowing the further exploitation of the patient psycho-emotional profiling information:

- The decision aid:** Patient's decision aids are tools that translate evidence into a patient-friendly form by providing, at a minimum, information on the options, benefits and risks, and implicit methods to clarify personal values. In addition, many decision aids also include information on the condition, probabilities of the outcomes of options (benefits/harms), exercises to help patients explicitly clarify their values, and guidance in the steps of decision making. A variety of decision aids have been developed and proved successful in increasing knowledge, enhance active involvement in decision making by patients, and decrease patients' decisional anxiety. These tools have the potential to facilitate patient empowerment in the decision-making process. However, there is the need to provide decision aids according the patient personal characteristics, such as the patient's thinking and decision styles. As such the psycho-emotional profile of the patient can be valuable input to be further exploited by this tool. iManageCancer will take these aspects

into account to optimize patients behaviour in gathering the useful information and recognize that a decision needs to be made, understanding the current scientific evidence, clarifying their values associated with outcomes of options, and achieving a quality decision. A consultation planning tool for patients is being currently under development to increase their participation in the consultation process with their physicians and improve their satisfaction with the decision-making process. The tool prompts standardized sets of questions related to the patient's condition, treatment options and potential side effects, from which the patient can choose to create his own list of questions he wishes to discuss with his doctor. The list can be shared with the doctor in advance of the consultation.

- **Personal Health Information Recommender:** Word wide web has become the first choice of patients to inform themselves about their disease, side effects and possible treatments. While patient's knowledge from internet is widely regarded as having a positive influence on the treatment, a lot of criticism exists for the quality and the diversity of the available information. The Personal Health Information Recommender is a semantically-enabled, intelligent platform that empowers patients to search in a high quality set of web documents for relevant medical knowledge. In addition, the platform automatically provides intelligent and personalized recommendations, according to the individual preferences and medical conditions. To this direction the psycho-emotional profile constructed exploiting the aforementioned questionnaires will be used to identify similar users, with similar interests and to provide personalized information.

8. Updates on the implementation of the Health enquiry tool

The health enquiry tool represents an embedded feature in the Care Flow Engine in the Central Decision Support System of the iManageCancer Platform in combination with specific features of the client apps iManageMyHealth and iSupportMyPatients. By the help of the Care Flow Designer clinical experts can design short questionnaires for patients and health professionals as part of so-called Care Flows. In such Care Flows experts design also how the answers to the questions are assessed and what information will be fed back to the users. The users receive and answer such health enquiries with the client apps iManageMyHealth and iSupportMyPatients. Health enquiries are an essential part of a Care Flow. The main aim with such health enquiry tool is to enable the clinical administrator of an instance of the iManageCancer Platform to dynamically incorporate useful Care Flows in the system to monitor the health of the patients

outside healthcare organisations according to the individual needs and the local healthcare delivery model, and to provide automated feedback to patients and doctors. In the following, we summarize the characteristics of this approach as it was implemented in the different components of the iManageCancer platform. More information can be found in the public deliverables D5.3 *Extended decision support and patient guidance services* and D3.4 *Extended integrated prototype of iManageCancer platform*.

The graphical user interface of the designer for care flows is presented in the following figure with an example of a Care Flow Diagram that is composed of different types of tasks. The green task ‘MASCC risk index factors’ represents a so-called health enquiry task.

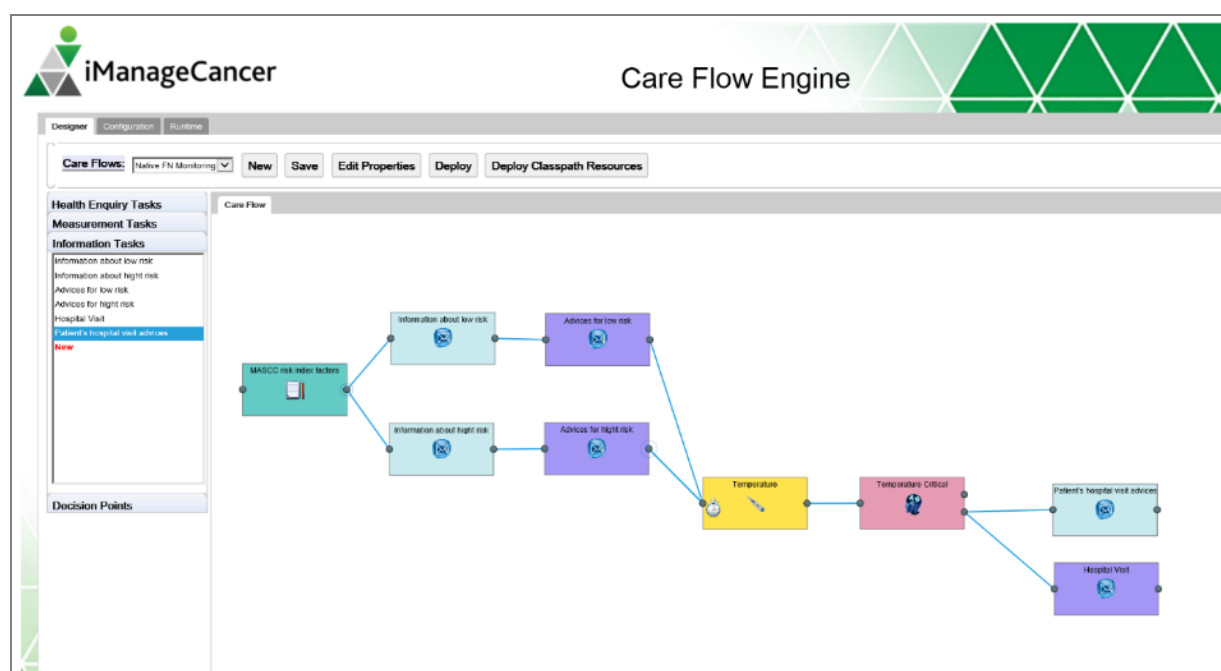


Figure 9: Canvas of the designer with an exemplary Care Flow Diagram.

A specific editor is available for health enquiries that allows the user to design questionnaires with the following type of answers:

- Text
- Date
- Yes/No
- Enumerations
- Numbers, optionally with a unit
- Score

An example of such a health enquiry that contains all 6 types of question items is shown in the following screenshot.

The individual values can be linked with an external service. This mechanism allows, for example, storing the answers in the web application iPHR of the iManageCancer Platform. Questionnaires are stored in JSON format in the database.

Label	Datatype	Unit	Values	Keys	Up	Down	Delete
Diagnosis	Text				up	down	delete
Tumor Localization	Text				up	down	delete
Date of diagnosis	Date				up	down	delete
Participation in study	Text				up	down	delete
Diagnose done by	Enumeration		Symptoms		up	down	delete
Tumor Size	Number	ml3			up	down	delete
Grading	Score		1	Pain	up	down	delete

Figure 10: Designing health enquiries. A cancer enquiry is shown in this screenshot that utilises all supported types of question items.

The services provided by the Care Flow Engine can be used with the apps iManageMyHealth (patients) and iSupportMyPatients (health professionals). Patients and their physicians need to be registered on the iManageCancer platform. Patients using the iManageMyHealth app find the Health Management module in the main menu of the app. It lists the available Care Flows as services to which the user can subscribe. After the subscription the corresponding Care Flow is personalised for the particular patient and executed and the users (patient and health professional) are informed by a notification service whenever new tasks for them have been issued by the Care Flow Engine. In the design phase of a Care Flow Diagram one can specify who is allowed to instantiate a particular Care Flow Diagram for a specific patient, either the patient himself or a health professional or both of them. The users can see in their apps only those Care Flows that they are allowed to subscribe.

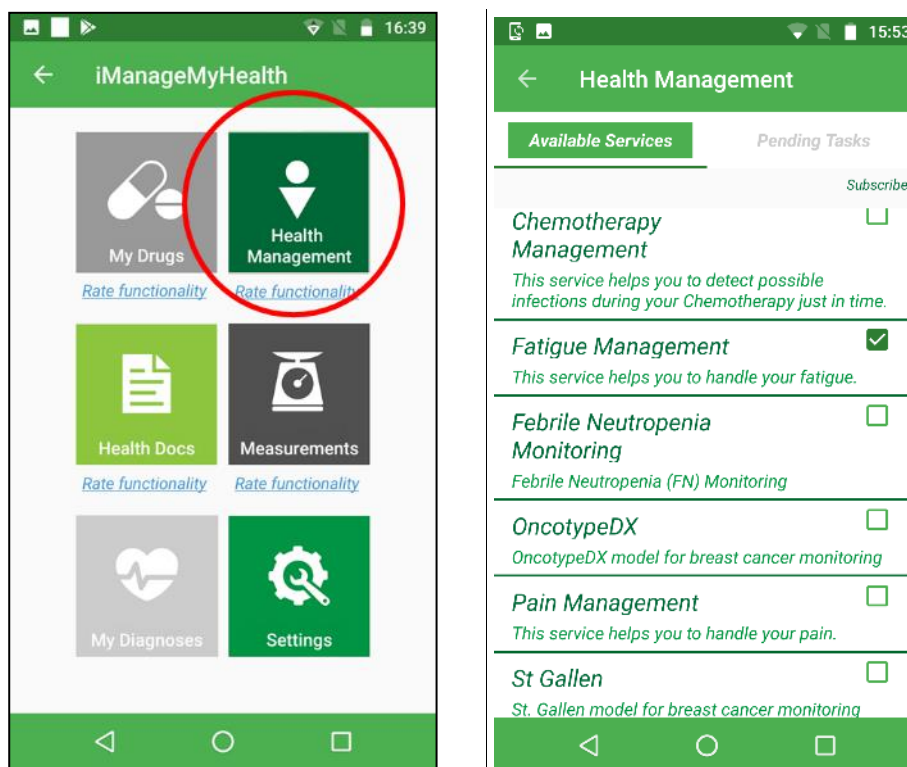


Figure 11: Care Flow Diagrams in the iManageMyHealth app. The patient can subscribe to these services or can unsubscribe from a Care Flow.

The corresponding apps receive tasks from the Care Flow Engine for the specific patients that are associated with the user account entered in the app. In the case of a health professional account in the app iSupportMyPatients the physician can see a list of those patients who have agreed in their iPHR to share data with this physician. The number of the currently pending tasks of the physician is shown in the list behind each patient.

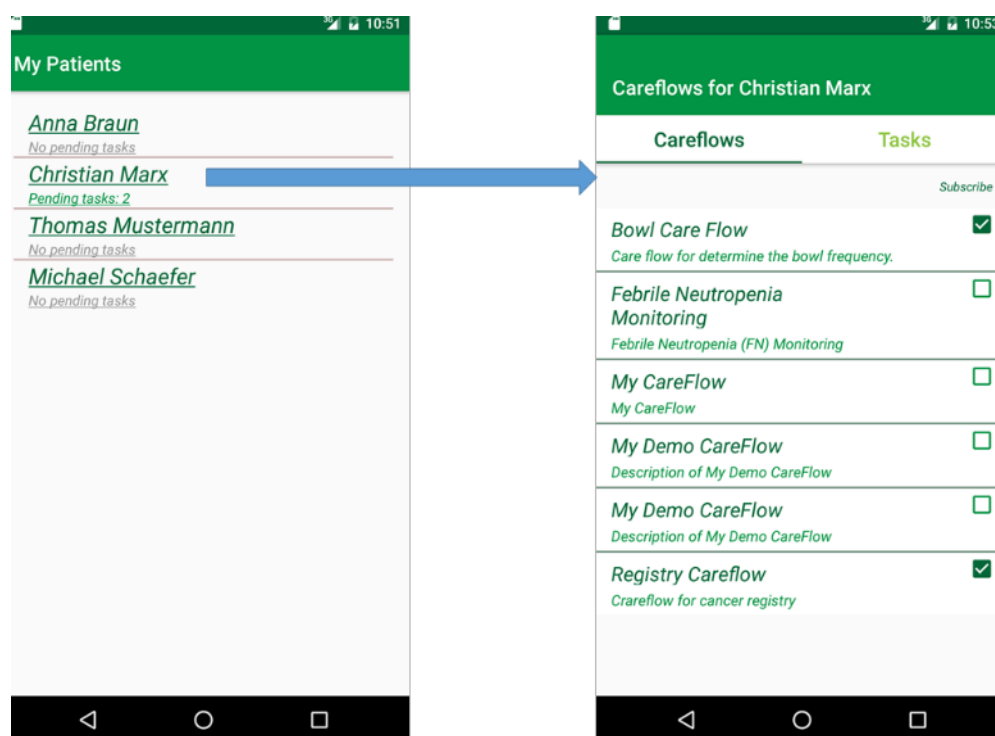


Figure 12: Care Flow Diagrams in the iSupportMyPatients app. The physician can subscribe to these services for a specific patient or he can unsubscribe from a care flow for this patient.

The user can select a pending task for displaying and executing the task. The task is retrieved from the Care Flow Engine and a view with the content of the task is dynamically generated to display it to the user.

Below is an example for a received health enquiry that shows how different types of generic questions are supported and rendered: text, date, number, enumeration (for selecting one or more value(s) from multiple answer possibilities), scores, and yes/no values.

The screenshot shows a mobile application interface for a health enquiry. At the top, a green header bar contains the text 'Health Enquiry for Christian Marx'. Below this, the title 'Cancer Registry' is displayed in green, followed by '(Careflow: Registry Careflow)' in a smaller font. Underneath, the text 'Cancer registry by physician' is shown. The form consists of several sections: 'Diagnosis' with a text input field, 'Tumor Localization' with a text input field, 'Date of Diagnosis' with a text input field, 'Participation in study' with two radio buttons labeled 'Yes' and 'No', 'Diagnosis done by' with five radio buttons labeled 'Symptoms', 'Cytology', 'Hystology', 'Autopsy', and 'Unknown', 'Tumor Size' with a text input field, and 'Grading' with a horizontal slider bar ranging from 1 to 10. A green 'SUBMIT' button is located at the bottom of the form. The entire interface is set against a white background with green accents.

Figure 13: Enquiry task for a user that demonstrates how the different types of questions of the designed enquiry in Figure 10 are presented to the user in his app.

The Care Flow Engine sends notifications to the mobile devices of the users by leveraging Google Cloud Messaging whenever new tasks are available for the users. The screenshot below shows a notification about a new health enquiry task. After clicking on the notification, the task is retrieved from the Care Flow Engine and user is forwarded to the corresponding view in the app that is generated for handling the retrieved task.

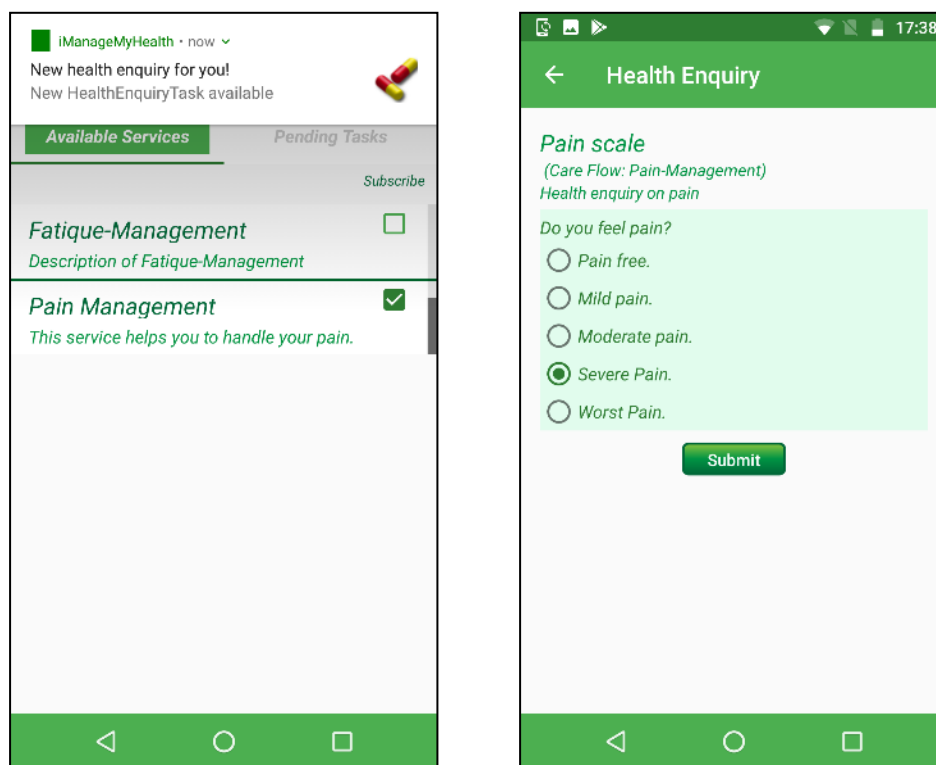
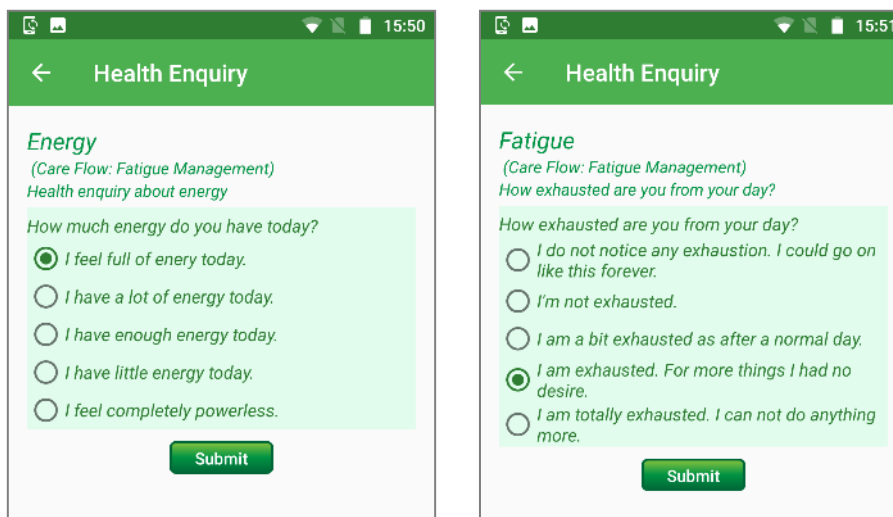


Figure 14: A message about a pending task is received on the smartphone. If the user touches the message he is forwarded to the corresponding page in his app.

Implemented health enquiries for patients in the system belong to two basic Care Flows for the management of pain and fatigue as shown in Figure 14 and Figure 15. They are further explained in the public deliverable D5.3.



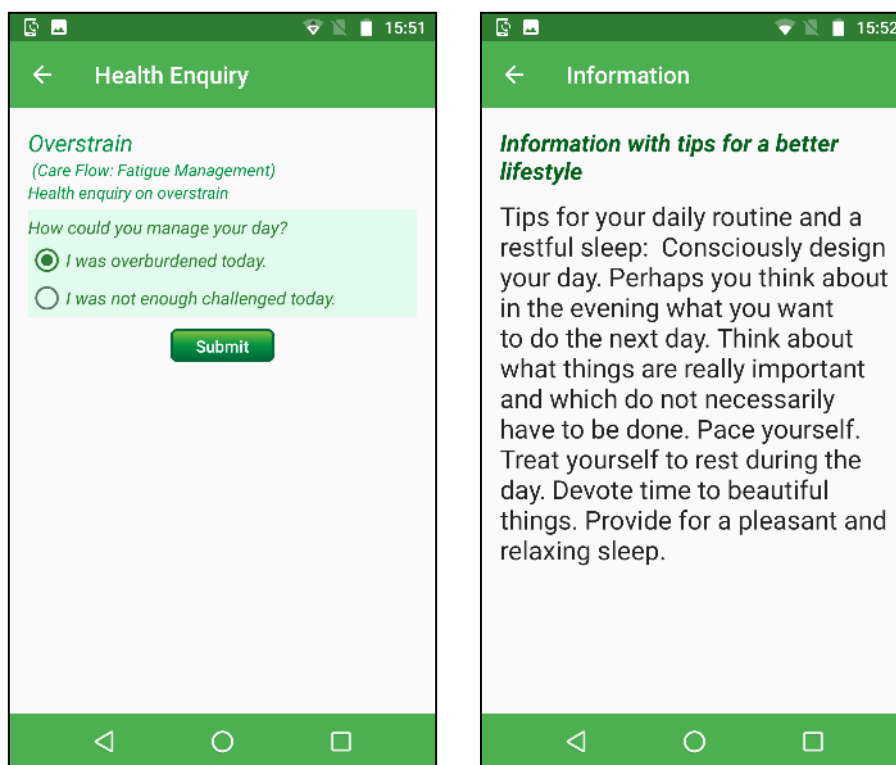


Figure 15: Fatigue Management: Health enquiry about energy in the morning and exhaustion in the evening.

Several services provided by the Care Flow Engine include the Model Repository with some predictive models related to breast cancer, its individualised therapy, and the complication Febrile Neutropenia. They represent exclusive decision support services for health professionals in the context of breast cancer therapy. The following screenshot illustrates a health enquiry task for a health professional for a specific patient when the health professional subscribes to the health service *St Gallen-Oncotype DX* for his patient. More details can be found in deliverable D5.3.

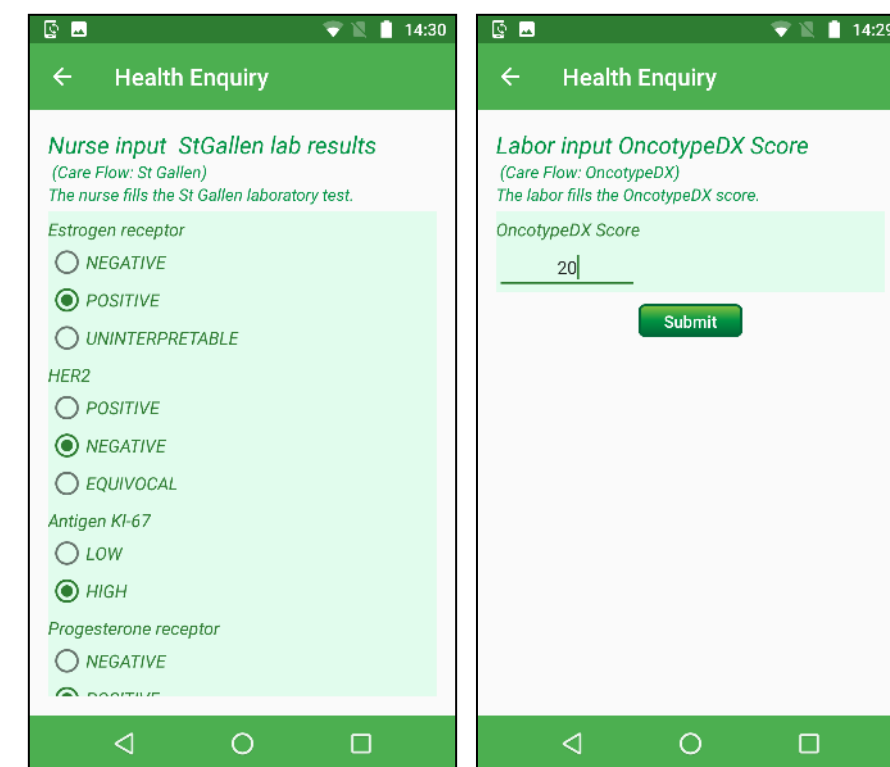


Figure 16: Health enquiries of the Care Flow 'St.Gallen-OncotypeDX' to suggest suitable treatments for breast cancer patients based on the subtype of their tumour following the St Gallen consensus and an Oncotype DX laboratory test.

9. Updates on the implementation of the vital sign monitoring tool

The monitoring tool for vital signs supports the patient in tracking certain vital parameters and laboratory parameters of relevance for cancer care by capturing such measurements from devices or by entering them by the patient himself and presenting these values to him/her as trend charts. In addition, requests to carry out a measurement can be incorporated in Care Flows to follow an individual and auto-adaptive monitoring regime as well as to assess the results in the Care Flow Engine and control further interventions. This was already presented in detail in deliverable D6.3 *Initial versions of psycho-emotional monitoring instrument, family evaluation tool and monitoring tool for life style and vital signs* and in the public deliverable D5.3 *Extended decision support and patient guidance services*. In the following, we summarize the main characteristics of the vital sign monitoring tool in the app iManageMyHealth and its invocation by the Care Flow Engine.

The technical implementation of the tool follows the user scenarios and formal use cases and requirements described in the deliverables D2.2 and D2.3. Life style management based on activity monitoring has been implemented in the context of WP4 and is presented in D4.2.

The diagram below shows the communication of the components that provide the features of the vital sign monitoring tool.

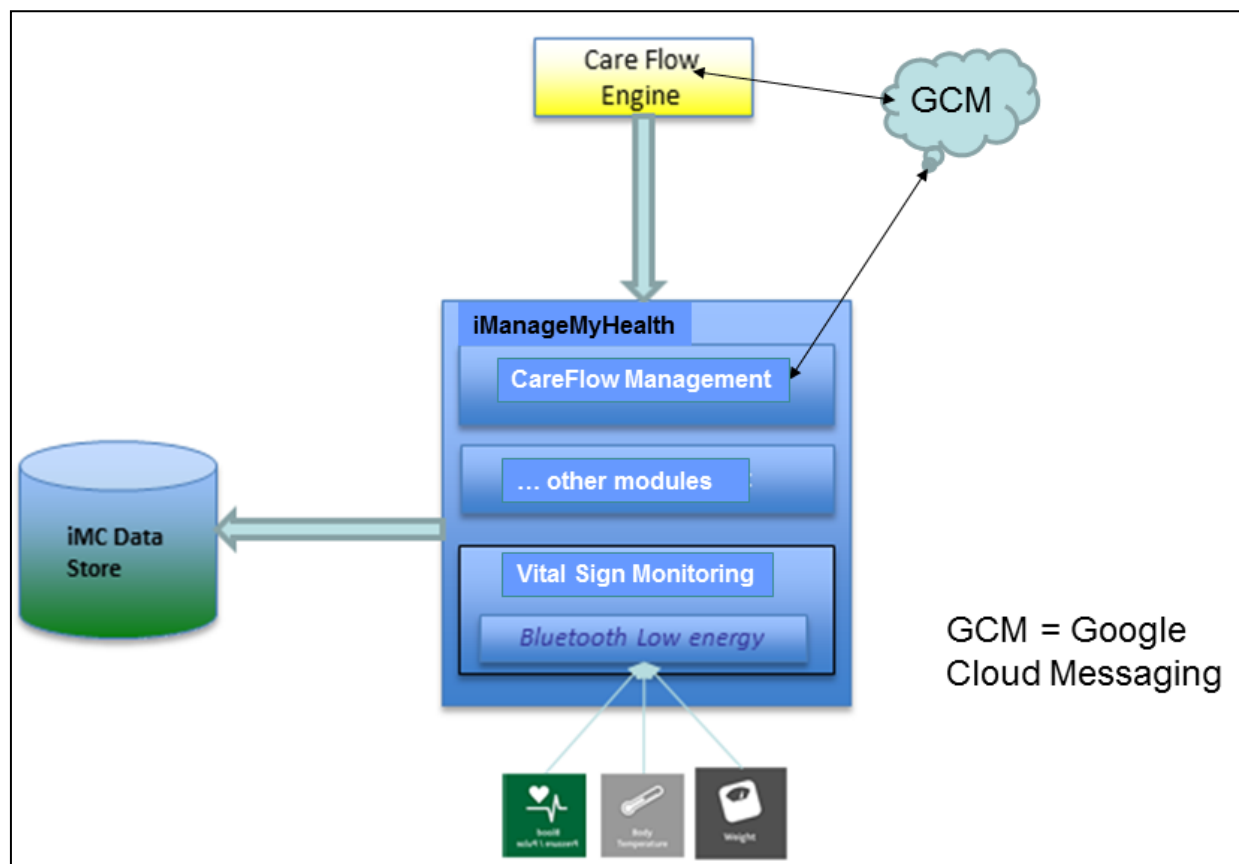


Figure 17: Components of the Life style and vital sign monitoring tool

A patient can perform measurements using devices for the measurement of his weight, his blood pressure and body temperature and record the measurement results. The patient can perform measurements with specific compatible devices upon need or on demand following corresponding notifications received from the Care Flow Engine from executed Care Flows for such patient.

There are two possibilities for entering measurement values in the iManageMyHealth app:

- Entering measurement values automatically: this option is possible if one of the medical devices below is connected to the smartphone via Bluetooth LE protocol.
- Entering measurement values manually: this is an alternative possibility if the patient uses other medical devices than the above mentioned devices.

Measurement results are presented in charts.

The following devices are supported by the app iManageMyHealth under Android 5 devices only:

- Scale A&D Medical UC-352BLE⁴
- Blood pressure device A&D Medical UA-651BLE⁵

The following device is supported by the app iManageMyHealth under Android 5 and Android 6 devices:

- Ear thermometer FORA IR21b⁶

These devices follow the Bluetooth Low Energy (LE) communication protocol. A mobile device, on which the iManageMyHealth app is installed, has to be configured respectively to use one of these devices.

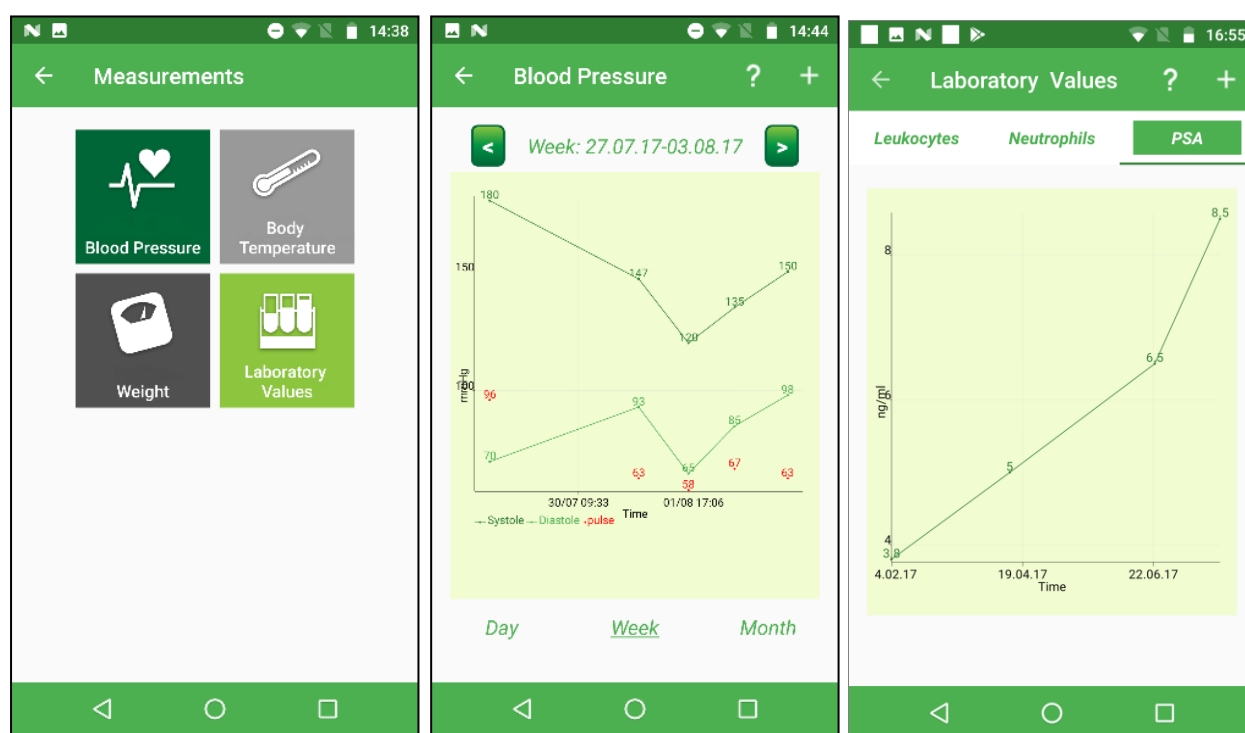


Figure 18: Measurements module of the app iManageMyHealth and views of measurement charts for PSA and blood pressure.

The Care Flow Designer allows to add so-called measurement tasks to Care Flows (Figure 19). In this way, dynamic monitoring schedules for patients can be constructed and personalised as part of a larger Care Flow for a specific application scenario.

In this way, we implemented a Care Flow to monitor chemotherapies with respect to the serious side effect febrile neutropenia (FN). After the onset of FN the patient is classified as low risk or

⁴ https://www.andonline.com/medical/products/details.php?catname=Scales&product_num=UC-352BLE

⁵ https://www.andonline.com/medical/products/details.php?catname=Blood_Pressure&product_num=UA-651BLE

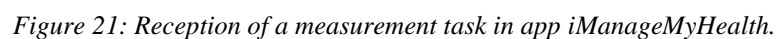
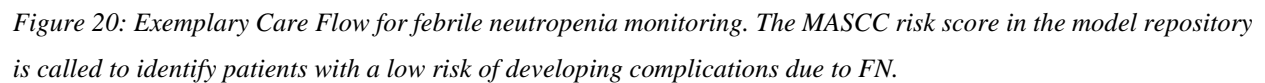
⁶ <http://www.foracare.ch/Meter-IR21.html>

high risk patient regarding complications following the MASCC risk model. The Multinational Association of Supportive Care of Cancer (MASCC) risk index score is one of the most widely clinically accepted neutropenia risk models. The MASCC model is for use by clinicians with patients who have already entered a febrile episode. The assessment for ‘burden of illness’, a feature of this model, requires a professional judgement to be made by a health care professional. Preventative measures and additional resources can then be targeted at those high-risk individuals in an effort to reduce FN emergency admissions. In the corresponding Care Flow Diagram low-risk patients need to measure less frequently their temperature at home. In case of an elevated body temperature they are informed to visit the hospital. The corresponding BPMN diagram of the Care Flow is shown in Figure 20 while the reception of a measurement task in the app is shown in Figure 21. This service has experimental character and is not used in the pilots as the underlying service models do not involve physicians.

For future versions we plan to extend the capabilities of the monitoring tool by allowing the patient to define himself novel parameters for vital sign measurements and laboratory tests that are relevant in his disease case.

The screenshot displays the iManageCancer Care Flow Designer interface. The top header includes the iManageCancer logo and the title 'Care Flow Engine'. Below the header, there are tabs for 'Designer', 'Configuration', and 'Runtime'. The 'Designer' tab is active, showing a 'Care Flows' dropdown set to 'condition'. A toolbar contains buttons for 'New', 'Save', 'Edit Properties', 'Deploy', 'Delete', and 'Deploy Classpath Resources'. On the left, a sidebar lists 'Health Enquiry Tasks' (Measurement Tasks, Information Tasks, Service Task) with a 'New' button. The main workspace is titled 'Care Flow Condition' and contains a table with columns 'Name' and 'Description'. The 'Name' column has a value 'TemperaturesElevated' and the 'Description' column has 'Body temperature is elevated.'. Below this, a 'Condition' section shows a table with columns 'Parameter', 'Operator', 'Value or Key', and 'Combination'. The first row shows 'Body Tempe' with operator '>' and value '37.0'. The second row shows 'Body Tempe' with operator '<=' and value '37.5'. There are 'Save' and 'Cancel' buttons. At the bottom, a 'Properties' section shows 'Name: condition', 'Version:', and 'Description:'.

Figure 19: Care Flow Designer: Definition of a measurement task for body temperature in a Care Flow together with conditions for the control flow based on the result of the measurement.



Conclusions

In the present deliverable the validation and implementation of the tools that allow the personalization of the medical approach that takes into account the patient's physical and psychological aspects were described.

More specifically, we gave an overview of the implementation of *a)* an instrument to assess individual emotional and psycho-cognitive aspects that can affect the patient involvement level in the therapeutic process (containing the ALGA and PsychE questionnaire), and *b)* an instrument to assess the family system, the family dynamics and resources, and the estimation of the adaptation to the disease (containing the FaRe questionnaire and the Parental distress questionnaire).

Furthermore, updates on the health enquiry tool and on life-style and vital sign monitoring tool (which were already described in detail in deliverables D6.2 and D6.3) were provided.

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Appendix A. Psycho-emotional Monitoring Tool

A.1 PsychE questionnaire

The complete questionnaire will be published soon in a scientific publication

A.2 ALGA© questionnaire

The publication containing ALGA questionnaire is available at:
<https://www.dovepress.com/development-and-psychometric-testing-of-a-breast-cancer-patient-profil-peer-reviewed-article-BCTT>

Appendix B. Family Resilience Tool

The complete questionnaire will be published soon in a scientific publication.

Appendix C. Parental Distress Questionnaire

Introduction to the questionnaire:

Liebe Eltern, vielen Dank, dass Sie sich bereit erklärt haben, den Fragebogen auszufüllen. Sie ermöglichen uns zu erkennen, wie wir Sie am besten unterstützen können. Gleichzeitig helfen Sie uns die Versorgung nachfolgender Familien zu verbessern. Bitte beantworten Sie die Fragen ohne viel nachzudenken. Wir versichern, dass die Befragung anonym ist. Ihr Name und Ihre Antworten können zu keinem Zeitpunkt in Verbindung gebracht werden. Zu Beginn werden Ihnen einige Fragen zu Ihrer familiären Situation gestellt. Sollten Sie diese nicht beantworten wollen, können Sie diese überspringen, indem Sie auf „weiter“ klicken.

No.	Question or text to explain next questions	Answer(s)		Action
1	Zu Beginn möchten wir Sie bitten, einige Fragen zu Ihrer familiären Situation und zur Erkrankung Ihres Kindes zu beantworten.			Go to question No. 2
2	Heutiges Datum?	[Date field]		Go to question No. 3
3	Wie ist Ihre gegenwärtige familiäre Situation?	[one selection field]	verheiratet oder zusammenlebend mit dem anderen Elternteil des Kindes	By selection of this answer go to question No. 4
			verheiratet oder zusammenlebend mit einer anderen Person	By selection of this answer go to question No. 4
			alleinerziehend	By selection of this answer go to question No. 4
4	Mit der folgenden Frage möchten wir die wirtschaftliche Situation Ihrer Familie erfassen.			Go to question No. 5
5	Ihr monatliches Nettoeinkommen in Euro?	[one selection field]	Ich möchte diese Frage überspringen	Go to question 6
			Nettoeinkommen [€]:	Open a [Number field] after entering a number go to question 6
6	Alter des erkrankten Kindes? (Angabe in Jahren)	[number field]		Go to question 7
7	Geschlecht des erkrankten Kindes?	[one selection in field]	Männlich	Go to question 8
			Weiblich	Go to question 8
8	Wie viele Geschwister hat das kranke Kind?	0		Go to question 10

		1 oder mehr (bitte Anzahl angeben)		[number field] to enter the number of siblings. After entering the number of sibling go to question 8a
8a	Geben Sie bitte Geschlecht und Alter der Geschwister an			Go to question 8b and repeat 8b as often as the number of siblings is. In that case change the text of the question (8b) according to the number of the sibling. So for the 1 st sibling write: 1. Geschwisterkind, for the 2 nd sibling: 2. Geschwisterkind, etc.
8b	1. Geschwisterkind	[one selection field]	Männlich	Repeat 8b as often as the number of siblings is chosen (see action of 8a). If finished go to question 9
			Weiblich	
		[number field]	Alter:	
9	Wie lautet die Diagnose des erkrankten Kindes?	[Text field]		Go to question 10
10	Wann wurde die Diagnose gestellt?	[date field]		Go to question 11
11	Welche der folgenden Behandlungen hat Ihr Kind bisher erhalten?			Go to question 12
12	Operation?	[one selection field]	nein	Go to question 13
			ja	Go to question 13
13	Chemotherapie?	[one selection field]	nein	Go to question 14
			ja	Go to question 13a
13a	Wie viele Wochen?	[number field]		Go to question 14
14	Bestrahlung?	[one selection field]	nein	Go to question 15
			ja	Go to question 14a
14a	Wie viele Wochen?	[number field]		Go to question 15
15	Stammzelltransplantation?	[one selection field]	nein	Go to question 16
			ja	Go to question 16

16	Hat Ihr Kind einen Rückfall erlitten?	[one selection field]	nein	Go to question 17
			ja	Go to question 16a
16a	Wie viele Rückfälle?	[number field]		Go to question 17
17	Wie viele Tage war Ihr Kind bisher stationär im Krankenhaus?	[number field]		Go to question 18
18	Die folgenden Fragen beziehen sich auf Ihre Person. Wir möchten Sie auch an dieser Stelle noch einmal daran erinnern, dass Ihre Daten zu keinem Zeitpunkt auf Ihren Namen bezogen werden können und Sie somit anonym bleiben.			Go to question 19
19	Ihr Geschlecht	[one selection field]	Männlich	
			Weiblich	
20	Ihr Alter? (Angabe in Jahren)	[number field]		Go to question 21
21	Ihre Nationalität?	[Text field]		Go to question 22
22	Ihre Religion?	[Text field]		Go to question 23
23	Welchen höchsten Schulabschluss haben Sie?	[one selection field]	Ich möchte diese Frage überspringen	Go to question 24
			Schülerin/-in	Go to question 24
			Ohne Schulabschluss	Go to question 24
			Haupt-, (Volks-)schulabschluss	Go to question 24
			Realschulabschluss (Mittlere Reife)	Go to question 24
			Fachhochschul- oder Hochschulreife (Abitur)	Go to question 24
			Einen anderen Schulabschluss und zwar:	Go to question 23a
23a	Welchen Schulabschluss?	[Text field]		Go to question 24
24	Welche höchsten beruflichen Ausbildungsabschlüsse haben Sie? (Mehrfachnennungen sind möglich.)	[multiple selection field]	Ich möchte diese Frage überspringen.	Go to question 25
			Ohne beruflichen Ausbildungsabschluss	Go to question 25
			Noch in beruflicher Ausbildung (Berufsvorbereitungsjahr oder Auszubildende/r oder Praktikant/-in oder Student/-in)	Go to question 25
			Abschluss einer anerkannten Berufsausbildung	Go to question 25

			Meister-/Techniker- oder gleichwertiger Fachschulabschluss	Go to question 25
			Bachelor	Go to question 25
			Diplom/ Magister/ Master/ Staatsexamen	Go to question 25
			Promotion	Go to question 25
			Habilitation	Go to question 25
			Einen anderen beruflichen Abschluss und zwar :	Go to question 24a
24a	Welchen Abschluss?	[Text field]		Go to question 25
25	Welche berufliche Tätigkeit üben Sie derzeit hauptsächlich aus?	[one selection field]	Ich möchte diese Frage überspringen.	Go to question 26
			Aktuelle Tätigkeit:	Go to question 25a
25a	Aktuelle Tätigkeit?	[Text field]		Go to question 26
26	Wenn Sie nicht mehr erwerbstätig sind, welche berufliche Tätigkeit war Ihre frühere hauptsächlich Erwerbstätigkeit?	[one selection field]	Ich möchte diese Frage überspringen.	Go to question 27
			Hauptberuf:	Go to question 26a
26a	Hauptberuf?	[Text field]		Go to question 27
27	Zu welcher Gruppe gehört der Beruf, den Sie derzeit ausüben bzw. ausgeübt haben?	[one selection field]	Ich möchte diese Frage überspringen.	Go to question 28
			Selbstständig	Go to question 28
			Angestellte/r	Go to question 28
			Beamten/er	Go to question 28
			Arbeiter/-in	Go to question 28
			Sonstiges (bitte angeben):	Go to question 27a
27a	Berufsbezeichnung:	[Text field]		Go to question 28
28	Im Folgenden möchten wir Ihre Befindlichkeit während der letzten 14 Tage erfassen. Bitte wählen Sie-ohne lange zu überlegen- die Antwortmöglichkeit, die Ihrer Befindlichkeit innerhalb der letzten 14 Tage am ehesten entspricht.			Go to question 29
29	Traurigkeit	[one selection field]	Ich bin nicht traurig.	Go to question 30
			Ich bin oft traurig.	Go to question 30
			Ich bin ständig traurig.	Go to question 30

			Ich bin so traurig oder unglücklich, dass ich es nicht aushalte.	Go to question 30
30	Interessenverlust	[one selection field]	Ich habe das Interesse an anderen Menschen oder an Tätigkeiten nicht verloren.	Go to question 31
			Ich habe weniger Interesse an anderen Menschen oder an Dingen als sonst.	Go to question 31
			Ich habe das Interesse an anderen Menschen oder Dingen zum größten Teil verloren.	Go to question 31
			Es fällt mir schwer mich überhaupt für irgendetwas zu interessieren	Go to question 31
31	Verlust von Freude	[one selection field]	Ich kann die Dinge genauso gut genießen wie früher.	Go to question 32
			Ich kann die Dinge nicht mehr so genießen wie früher.	Go to question 32
			Dinge, die mir früher Freude gemacht haben, kann ich kaum mehr genießen.	Go to question 32
			Dinge, die mir früher Freude gemacht haben, kann ich überhaupt nicht mehr genießen.	Go to question 32
32	Energieverlust	[one selection field]	Ich habe so viel Energie wie immer.	Go to question 33
			Ich habe weniger Energie als sonst.	Go to question 33
			Ich habe so wenig Energie, dass ich kaum noch etwas schaffe.	Go to question 33
			Ich habe keine Energie mehr, um überhaupt noch etwas zu tun.	Go to question 33
33	Unruhe	[one selection field]	Ich bin nicht unruhiger als sonst.	Go to question 34
			Ich bin unruhiger als sonst.	Go to question 34
			Ich bin so unruhig, dass es mir schwerfällt, still zu sitzen.	Go to question 34

			Ich bin so unruhig, dass ich mich ständig bewegen oder etwas tun muss.	Go to question 34
34	Ermüdung und Erschöpfung	[one selection field]	Ich fühle mich nicht müder oder erschöpfter als sonst.	Go to question 35
			Ich werde schneller müde oder erschöpft als sonst.	Go to question 35
			Für viele Dinge, die ich üblicherweise tue bin ich zu müde oder erschöpft.	Go to question 35
			Ich bin so müde oder erschöpft, dass ich fast nichts mehr tun kann.	Go to question 35
35	Konzentrationsschwierigkeiten	[one selection field]	Ich kann mich so gut konzentrieren wie immer.	Go to question 36
			Ich kann mich nicht mehr so gut konzentrieren wie sonst.	Go to question 36
			Es fällt mir schwer mich längere Zeit auf irgendetwas zu konzentrieren.	Go to question 36
			Ich kann mich überhaupt nicht mehr konzentrieren.	Go to question 36
36	Veränderungen der Schlafgewohnheit	[one selection field]	Meine Schlafgewohnheiten haben sich nicht verändert.	Go to question 37
			Ich schlafe etwas mehr als sonst.	Go to question 37
			Ich schlafe etwas weniger als sonst.	Go to question 37
			Ich schlafe viel mehr als sonst.	Go to question 37
			Ich schlafe viel weniger als sonst.	Go to question 37
			Ich schlafe fast den ganzen Tag.	Go to question 37
37	Entschlussfähigkeit	[one selection field]	Ich bin so entschlossfreudig wie immer.	Go to question 38
			Es fällt mir schwerer als sonst Entscheidungen zu treffen.	Go to question 38
			Es fällt mir sehr viel schwerer als sonst Entscheidungen zu treffen.	Go to question 38
			Ich habe Mühe überhaupt Entscheidungen zu treffen.	Go to question 38

38	Reizbarkeit	[one selection field]	Ich bin nicht reizbarer als sonst.	Go to question 39
			Ich bin reizbarer als sonst.	Go to question 39
			Ich bin viel reizbarer als sonst.	Go to question 39
			Ich fühle mich dauernd gereizt.	Go to question 39
39	Im folgenden Teil werden Sie zu Ihrer momentanen Befindlichkeit befragt. Überlegen Sie bitte nicht lange und wählen Sie die Antwort aus, die Ihren momentanen Gefühlszustand am besten beschreibt.			Go to question 40
40	Ich bin ruhig	[one selection field]	fast nie	Go to question 41
			manchmal	Go to question 41
			oft	Go to question 41
			fast immer	Go to question 41
41	Ich fühle mich geborgen	[one selection field]	fast nie	Go to question 42
			manchmal	Go to question 42
			oft	Go to question 42
			fast immer	Go to question 42
42	Ich fühle mich angespannt	[one selection field]	fast nie	Go to question 43
			manchmal	Go to question 43
			oft	Go to question 43
			fast immer	Go to question 43
43	Ich bin bekümmert	[one selection field]	fast nie	Go to question 44
			manchmal	Go to question 44
			oft	Go to question 44
			fast immer	Go to question 44
44	Ich bin aufgeregt	[one selection field]	fast nie	Go to question 45
			manchmal	Go to question 45
			oft	Go to question 45
			fast immer	Go to question 45
45	Ich bin beunruhigt	[one selection field]	fast nie	Go to question 46
			manchmal	Go to question 46
			oft	Go to question 46
			fast immer	Go to question 46
46		[one selection field]	fast nie	Go to question 47

	Ich fühle mich selbstsicher		manchmal	Go to question 47
			oft	Go to question 47
			fast immer	Go to question 47
47	Ich bin nervös	[one selection field]	fast nie	Go to question 48
			manchmal	Go to question 48
			oft	Go to question 48
			fast immer	Go to question 48
48	Ich bin zappelig	[one selection field]	fast nie	Go to question 49
			manchmal	Go to question 49
			oft	Go to question 49
			fast immer	Go to question 49
49	Ich bin verkrampft	[one selection field]	fast nie	Go to question 50
			manchmal	Go to question 50
			oft	Go to question 50
			fast immer	Go to question 50
50	Im Folgenden werden Sie zu körperlichen Beschwerden befragt. Bitte geben Sie an, ob und wie stark diese bei Ihnen in den vergangenen 7 Tagen bei Ihnen aufgetreten sind.			Go to question 51
51	Kopfschmerzen	[one selection field]	Überhaupt nicht	Go to question 52
			Ein wenig	Go to question 52
			ziemlich	Go to question 52
			Stark	Go to question 52
			Sehr stark	Go to question 52
52	Herz und Brustschmerzen	[one selection field]	Überhaupt nicht	Go to question 53
			Ein wenig	Go to question 53
			ziemlich	Go to question 53
			Stark	Go to question 53
			Sehr stark	Go to question 53
53	Kreuzschmerzen	[one selection field]	Überhaupt nicht	Go to question 54
			Ein wenig	Go to question 54
			ziemlich	Go to question 54
			Stark	Go to question 54

			Sehr stark	Go to question 54
54	Übelkeit oder Magenverstimmung	[one selection field]	Überhaupt nicht	Go to question 55
			Ein wenig	Go to question 55
			ziemlich	Go to question 55
			Stark	Go to question 55
			Sehr stark	Go to question 55
55	Muskelschmerzen (Muskelkater oder Gliederreißen)	[one selection field]	Überhaupt nicht	Go to question 56
			Ein wenig	Go to question 56
			ziemlich	Go to question 56
			Stark	Go to question 56
			Sehr stark	Go to question 56
56	Hitzewallungen oder Kälteschauern	[one selection field]	Überhaupt nicht	Go to question 57
			Ein wenig	Go to question 57
			ziemlich	Go to question 57
			Stark	Go to question 57
			Sehr stark	Go to question 57
57	Taubheit oder Kribbeln in einzelnen Körperteilen	[one selection field]	Überhaupt nicht	Go to question 58
			Ein wenig	Go to question 58
			ziemlich	Go to question 58
			Stark	Go to question 58
			Sehr stark	Go to question 58
58	Gefühl, einen Klumpen (Kloß) im Hals zu haben	[one selection field]	Überhaupt nicht	Go to question 59
			Ein wenig	Go to question 59
			ziemlich	Go to question 59
			Stark	Go to question 59
			Sehr stark	Go to question 59
59	Schwächegefühl in einzelnen Körperteilen	[one selection field]	Überhaupt nicht	Go to question 60
			Ein wenig	Go to question 60
			ziemlich	Go to question 60
			Stark	Go to question 60
			Sehr stark	Go to question 60
60	Schweregefühl in den Armen oder den Beinen	[one selection field]	Überhaupt nicht	Go to question 61

			Ein wenig	Go to question 61
			ziemlich	Go to question 61
			Stark	Go to question 61
			Sehr stark	Go to question 61
61	Traten einige dieser Beschwerden schon vor der Erkrankung Ihres Kindes auf?	[one selection field]	nein	Go to question 61b
			ja	Go to question 61a
61a	Um welche Beschwerden hat es sich gehandelt?	[multiple selection field]	Kopfschmerzen	Go to question 61b
			Herz und Brustschmerzen	
			Kreuzschmerzen	
			Übelkeit oder Magenverstimmung	
			Muskelschmerzen (Muskelkater oder Gliederreißen)	
			Hitzewallungen oder Kälteschauern	
			Taubheit oder Kribbeln in einzelnen Körperteilen	
			Gefühl, einen Klumpen (Kloß) im Hals zu haben	
			Schwächegefühl in einzelnen Körperteilen	
			Schweregefühl in den Armen oder den Beinen	
61b	In den folgenden Aussagen werden Verhaltens- und Erlebensweisen beschrieben, die viele Menschen in ihrem Lebensalltag zeigen. Markieren Sie bitte die Antwortmöglichkeit, die am besten beschreibt, wie stark Sie im vergangenen Monat durch eine Verhaltens- oder Erlebensweise beeinträchtigt waren oder unter ihr gelitten haben.			Go to question 62
62	Ich bewahre so viele Gegenstände auf, dass sie mich behindern.	[one selection field]	gar nicht	Go to question 63
			wenig	Go to question 63
			mittel	Go to question 63
			stark	Go to question 63
			sehr stark	Go to question 63
63	Ich kontrolliere Dinge öfter als notwendig.	[one selection field]	gar nicht	Go to question 64
			wenig	Go to question 64

			mittel	Go to question 64
			stark	Go to question 64
			sehr stark	Go to question 64
64	Ich werde unruhig, wenn Gegenstände nicht korrekt (an)geordnet sind.	[one selection field]	gar nicht	Go to question 65
			wenig	Go to question 65
			mittel	Go to question 65
			stark	Go to question 65
			sehr stark	Go to question 65
65	Es fällt mir schwer, meine eigenen Gedanken zu kontrollieren.	[one selection field]	gar nicht	Go to question 66
			wenig	Go to question 66
			mittel	Go to question 66
			stark	Go to question 66
			sehr stark	Go to question 66
66	Ich werde unruhig, wenn andere etwas daran ändern, wie ich die Dinge (an-)geordnet habe.	[one selection field]	gar nicht	Go to question 67
			wenig	Go to question 67
			mittel	Go to question 67
			stark	Go to question 67
			sehr stark	Go to question 67
67	Ich fühle mich durch unangenehme Gedanken beunruhigt, die mir gegen meinen Willen in den Sinn kommen.	[one selection field]	gar nicht	Go to question 68
			wenig	Go to question 68
			mittel	Go to question 68
			stark	Go to question 68
			sehr stark	Go to question 68
68	Ich vermeide es, Sachen wegzuwerfen, da ich Angst habe, ich könnte sie vielleicht später noch brauchen.	[one selection field]	gar nicht	Go to question 69
			wenig	Go to question 69
			mittel	Go to question 69
			stark	Go to question 69
			sehr stark	Go to question 69
69	Für mich müssen Dinge in einer bestimmten Weise geordnet sein.	[one selection field]	gar nicht	Go to question 70
			wenig	Go to question 70
			mittel	Go to question 70
			stark	Go to question 70

			sehr stark	Go to question 70	
70	Ich wasche meine Hände öfter und länger als nötig.	[one selection field]	gar nicht	Go to question 71	
			wenig	Go to question 71	
			mittel	Go to question 71	
			stark	Go to question 71	
			sehr stark	Go to question 71	
71	Ich bekomme häufig abscheuliche Gedanken und es fällt mir schwer, sie wieder los zu werden	[one selection field]	gar nicht	Go to question 72	
			wenig	Go to question 72	
			mittel	Go to question 72	
			stark	Go to question 72	
			sehr stark	Go to question 72	
72	Im Folgenden werden Sie zu schwerwiegenden Lebensereignissen befragt, wie z.B. die Erkrankung Ihres Kindes aber auch anderen traumatischen Erfahrungen. Geben Sie bitte für jedes Ereignis an, ob es passiert ist, und wenn ja, wie oft es passierte, und Ihr ungefähres Alter, als es passierte. Wenn sie sich nicht sicher sind, geben sie Ihre beste Schätzung an.			Go to question 73	
73	Wie viele traumatische Ereignisse hatten Sie?	[one selection field]	0	Go to question 74	
			1 oder mehr	Go to question 73a	
73a	Geben Sie bitte die genaue Zahl an:	[number field]		Go to question 73b	
73b	Ereignis 1 Welches Ereignis? (Bitte eine Beschreibung eingeben)	[Text field]		Repeat question 73b to 73f as often as the number is given in question 73a, and replace the number after the word 'Ereignis' in question 73b to 73f with the next number, so after 'Ereignis 1' continue with 'Ereignis 2' and so on. After the last repeat go to question 74	
73c	Ereignis 1 Wie oft ist dieses Ereignis passiert (Bitte geben Sie eine Zahl)	[number field]			
73d	Ereignis 1 Wie alt waren Sie, als es das erste Mal passierte	[number field]			
73e	Ereignis 1 Während des Ereignisses fühlten Sie sich hilflos?	[one selection field]	nein		
			ja		
73f	Ereignis 1 Während des Ereignisses hatten Sie starke Angst oder waren voller Entsetzen?	[one selection field]	nein		
			ja		

74	Die letzten 7 Fragen beziehen sich auf den letzten Monat			Go to question 75
75	Haben Sie sich bemüht, Aktivitäten, Menschen oder Orte zu meiden, die Sie an die Erkrankung Ihres Kindes erinnern?	[one selection field]	überhaupt nicht	Go to question 76
			einmal pro Woche oder seltener / manchmal	Go to question 76
			2-4 mal pro Woche / die Hälfte der Zeit	Go to question 76
			5 mal pro Woche / fast immer	Go to question 76
76	Haben Sie deutlich weniger Interesse an Aktivitäten, die vor der Erkrankung Ihres Kindes wichtig für Sie waren, oder haben Sie sie deutlich seltener wahrgenommen?	[one selection field]	überhaupt nicht	Go to question 77
			einmal pro Woche oder seltener / manchmal	Go to question 77
			2-4 mal pro Woche / die Hälfte der Zeit	Go to question 77
			5 mal pro Woche / fast immer	Go to question 77
77	Fühlten Sie sich den Menschen in Ihrer Umgebung deswegen entfremdet oder anders?	[one selection field]	überhaupt nicht	Go to question 78
			einmal pro Woche oder seltener / manchmal	Go to question 78
			2-4 mal pro Woche / die Hälfte der Zeit	Go to question 78
			5 mal pro Woche / fast immer	Go to question 78
78	Fühlten Sie sich abgestumpft oder taub (z.B. nicht weinen können oder sich unfähig fühlen, liebevolle Gefühle zu erleben)?	[one selection field]	überhaupt nicht	Go to question 79
			einmal pro Woche oder seltener / manchmal	Go to question 79
			2-4 mal pro Woche / die Hälfte der Zeit	Go to question 79
			5 mal pro Woche / fast immer	Go to question 79
79	Hatten Sie das Gefühl durch die Erkrankung Ihres Kindes, dass sich Ihre Zukunftspläne und Hoffnungen nicht erfüllen werden (z.B. dass Sie keine Kinder haben oder dass Sie keinen Erfolg im Beruf haben würden)?	[one selection field]	überhaupt nicht	Go to question 80
			einmal pro Woche oder seltener / manchmal	Go to question 80
			2-4 mal pro Woche / die Hälfte der Zeit	Go to question 80
			5 mal pro Woche / fast immer	Go to question 80
80	Hatten Sie Ein- oder Durchschlafstörungen seit der Erkrankung Ihres Kindes (d.h. davor noch nicht)?	[one selection field]	überhaupt nicht	Go to question 81
			einmal pro Woche oder seltener / manchmal	Go to question 81
			2-4 mal pro Woche / die Hälfte der Zeit	Go to question 81
			5 mal pro Woche / fast immer	Go to question 81
81		[one selection field]	überhaupt nicht	Go to question 82

	Waren Sie nervös oder schreckhaft (z.B. wenn jemand hinter Ihnen Geräusche macht)?		einmal pro Woche oder seltener / manchmal	Go to question 82
			2-4 mal pro Woche / die Hälfte der Zeit	Go to question 82
			5 mal pro Woche / fast immer	Go to question 82
82	Vielen Dank für die Teilnahme am Fragebogen!			

The questionnaire is integrated into the IMC platform.