A Personalised Integrated Care Platform

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D2.1 Scenarios and Use Cases for Integrated Care

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Agostino Chiaravalloti (UTV)	2016-07-03	Approved with minor comments
Jutta Richter (UDUS)	2016-07-13	Approved with comments and corrections

Index:

1 Executive Summary

This deliverable is based on knowledge gained from the different clinical stakeholders about how they handle patients with Rheumatoid Arthritis (PICASO field trial 1) and Parkinson's disease (PICASO field trial 2). The information was gathered from two separate workshops with the relevant clinicians at the site of the two field trials and from interviews with patients suffering from Rheumatoid Arthritis.

This deliverable draws heavily on the current clinical workflows (As-Is workflows) and on suggestions from clinicians about where practices could be optimised and supported by PICASO. The vision scenarios provide a contextual background by describing end user activities as well as application functionalities, thus bridging the gap to the formulation of technical user requirements. The To-Be use cases describe where and how PICASO can support both clinicians (specialists) and patients and their informal carers. In addition, a number of To-Be use cases describing new ways to handle, collect and share data by using PICASO have been identified in accordance with the suggestions and needs of the clinicians.

In each To-Be use case, the relevant part of the As-Is workflows is briefly described (if it exists) as it provides the contextual background for the proposed To-Be use cases. The As-Is workflows are described in detail in D3.1 Integrated Care Plans across Care Sectors – Analysis and Recommendations.

The To-Be use cases that have been identified are:

Use case ID	Description
Integrated care plans	
UC-1	Presenting symptoms
UC-2	Information sharing during examination and diagnosis of new patients
UC-3	Information sharing during examination and diagnosis of new patients (UTV)
UC-4	Medication plan distribution
UC-5	Browsing for relevant data
UC-6	Authentication by users to share data
Professional Carers	
UC-10	Constructing care plans using narratives
UC-11	Monitoring and handling of events and alerts
UC-12	Intervention strategies, definition and execution
UC-13	Risk assessments during care plan execution
UC-14	Monitoring for co-morbidities and handling of incidental findings[1]
UC-15	Flexible informed consent
Remote Patient Monitoring	
UC-20	Home monitoring for self-management
UC-21	Handling non-connectivity of home monitoring platform
UC-22	Filtering and sorting of data and events
UC-23	Medication reminders and compliance monitoring
UC-24	Joint care – Patients and the informal carers
UC-25	Patient interaction and modalities

[1] UC-14 will be developed for the second iteration of the project.

Table 1: Overview of To-Be use cases

The vision scenarios and the To-Be use cases will be used to elicit the initial user requirements for the PICASO platform which will be documented in D2.2 Initial Requirements Report.

2 Introduction

The PICASO project aims to build a service oriented, ICT based integration platform that will support collaborative sharing of care plans across sectors based on dynamic and personalised orchestration of care services. It will further provide a method for sharing patient information across all relevant formal and informal care providers using a unique, trust federated solution to the problem of data privacy in cloud based health systems.

The PICASO project will conduct two separate but complementary use case driven trials for proof-of-concept demonstrators of integrated care. The trials will be conducted in Germany (Trial 1) and Italy (Trial 2) and involve actual patients. The main purpose of the trials is 1) to demonstrate the concept of the PICASO platform and its components, and 2) to validate the impact on the effectiveness of the care systems and the acceptance of the wider group of stakeholders, patients, relatives and the society at large. Trial 1 "Rheumatoid Arthritis (RA) with Cardiovascular Disease (CVD)" will be carried out by the Policlinic of Rheumatology and Hiller Research Unit Rheumatology at the Heinrich-Heine-University (HHUD) / University Hospital of Düsseldorf (UDUS). Trial 2 "Parkinson's disease (PD) with Cardiovascular Disease" will be conducted by UTV (The University Hospital of Tor Vergata in Rome) in conjunction with the institute of treatment and research Santa Lucia in Rome.

2.1 Purpose, context and scope of this deliverable

To fully understand the challenges and possibilities for improving the ways information and data are generated, stored and shared among the stakeholders, the first step in the project was to identify the current patient pathways, clinical use cases and clinical workflows, including the kind of patient data that is generated, how and when data is shared, and between whom in the two trial sites. Two separate workshops were thus conducted with the clinical stakeholders in the two trials which resulted in a definition of the current As-Is clinical workflows and discussions of PICASO enabled solutions for future To-Be workflows.

The current As-Is clinical workflow describes a typical patient's journey from when symptoms were first presented to a final stage of management (living with the condition). They are illustrated and described in detail in D3.1 Integrated Care Plans across Care Sectors – Analysis and Recommendations. In this current deliverable, the As-Is workflows have been used as the basis on which to propose new To-Be workflows and use cases with PICASO. The To-Be use cases will therefore refer to a particular instance (snap shot) of the As-Is workflow in order to provide the contextual background.

In parallel, a set of scenarios have been defined, and the scenarios and To-Be use cases will be used to elicit the initial user requirements for the PICASO platform and to feed into the iterative requirement engineering process in the project.

2.2 Content and structure of this deliverable

The methodology used to gather the necessary input for this deliverable is described in Chapter Three. Chapter Four and Five briefly presents the trial lay-outs for UDUS (Trial 1) and UTV (Trial 2) respectively, including the identified list of relevant data, either already in play or additional data that the trial would like to collect. The vision scenarios are described in Chapter Six and the To-Be use cases are described in Chapter Seven. Chapter Eight gives some concluding remarks. The agendas for the two clinical workshops can be found in the appendices.

3 Methodology

The scenarios were developed based on As-Is workflows and To-Be use cases, combined with information gathered at the clinical workshops held at UDU and UTV and first results of patient interviews conducted at UDUS.

The To-Be use cases were developed based on the workshops with UDUS and UTV and the resulting definition of the As-Is clinical workflows.

3.1 Vision scenario methodology

The use of vision scenarios is an acknowledged method in human-centred design to provide a vision framework for the subsequent iterative requirement engineering phase. Such scenarios provide a way of communicating the vision of a particular technical system in aid of explaining and documenting requirements. As opposed to To-Be use cases whose methodology is described in detail in chapter 3.2, scenarios explicitly deal with the usage of a technical system, the context of use, and the allocation of functions between the technical system and human users. From an overall perspective they describe how a technical system may be used to fulfil its users' tasks and goals. Therefore vision scenarios describe end user activities as well as application functionalities, thus bridging the gap to the formulation of technical user requirements.

Vision scenarios in PICASO were created to gain better understanding of end user behaviour and interaction with PICASO services, contributing to the identification of key technological, ethical, security, business and societal drivers for definition of end user requirements. They may also serve as input for discussion and finally development of a set of validated technical scenarios by project partners in the course of the project.

For better understanding of the vision scenarios and to make them more vivid, personas have been created that should be understood as representatives of the future PICASO users such as physicians, patients, etc. The tasks serving as the common thread through the vision scenarios were derived from existing workflows, To-Be use cases and information gathered from clinical specialists and patients, as described above. Please refer to chapter 6 for a detailed description of the vision scenarios and the personas involved.

3.2 To-Be use case methodology

In order to identify To-Be use cases for integrated care it was first of all necessary to gain an understanding of the patient pathway and how the clinicians work today (i.e. the clinical workflow), focusing on the hand-over procedures between different clinicians as well as between clinician and patients and/or informal carers.

A focus group workshop with all the relevant clinicians was considered to be the most useful method to get all the information needed. In comparison individual interviews would not only have been very time consuming but a workshop also has the advantage of being more interactive, i.e. allowing for the exchange of knowledge and discussion across the specific clinical domains that are involved in the targeted patient groups.

The workshop format was informal but with a predefined set of themes that needed to be covered (see the agendas in Appendix B and C). The workshops were full day and were followed by extensive communication (conference calls and emails) between the clinical partners and the authors of this deliverable in order to check, clarify and confirm the descriptions and illustrations of the workflows, including the stakeholders and their roles and the chronological order of events in the workflows. The workflows presented here have thus been approved by the two clinical partners, UDUS and UTV.

The main objective was to understand the clinical workflow, identify the clinicians involved and their activities, the handover procedures and the data that is exchanged. The primary objective was thus to understand and define the current clinical workflow and secondly to discuss the challenges and conflicts; in other words to discuss and identify where there was room for improvement by implementing the PICASO system.[2]

The workshops consisted of a combination of presentations, questions and answers and informal discussions. The clinicians involved described their role, responsibilities and activities based a typical patient pathway example. Alternative patient pathways were also described and discussed. The main objective was

[2]" Improvement" refers to the procedures for data exchange; the trials are *not* clinical trials in the sense of testing new medical procedures or treatments.

to generate a complete description of what happens from the first meeting with the patient through to diagnosis, treatment and management in a chronological or subsequent order. Once this was established, it was possible to discuss where in the workflow and which activities PICASO could provide support to optimise the workflow.

A general insight into the German and Italian health care system was also provided which was useful context and background information.

After the workshop, the clinical workflows were mapped in a drawing and presented to clinical partners for verification. The confirmed clinical workflows that resulted from the workshop thus illustrate the current clinical workflow for the selected patient group as a generic group (obviously there are slight differences between different patients). The current clinical workflow is referred to as the As-Is workflow.

Based on this, and based on the suggestions for where PICASO could be implemented, a series of future To-Be use cases have been developed and verified by the clinical partners. Some To-Be use cases have been written referring explicitly to a specific specialist and thus a specific PICASO trial, however, nearly all the To-Be use cases are applicable to both trials just involving other specialists and/or specific type of data. In other words, the To-Be use cases will be based on the same system (PICASO) but adjusted to fit specific trial needs.

3.2.1 UDUS workshop

The clinical workflow workshop on Rheumatoid Arthritis (RA) was held at the Heinrich-Heine University Hospital in Düsseldorf on 3 May, 2016. The trial is presented briefly in chapter 4.

In addition to project partners (FIT, IBM, IN-JET, TUK and UDUS), the forum included rheumatology physicians, epidemiology physicians, a cardiologist, an occupational medicine physician, a physician from the Institute of Medical Sociology, a general practitioner (GP) and a rheumatology nurse, a representative from an insurance company and a representative from the hospital ICT Department.

3.2.2 UTV workshop

The one day clinical workflow workshop on Parkinson's disease (PD) was held at the Faculty of Medicine, University of Rome Tor Vergata in Rome on 19 April, 2016. The trial is presented briefly in chapter 5.

The participants included: a clinical neurologist, a neuropsychologist, a nuclear medicine physician, a psychologist, and a quality pharmacist. Project partners FIT, IBM, IN-JET, INUIT, TUK, and UTV also participated.

4 Trial 1: Rheumatoid Arthritis with Cardiovascular Disease

Rheumatoid Arthritis (RA) is an inflammatory rheumatic disease with a prevalence of 1% of the normal population. RA is an auto-immune systemic disease. Immunosuppressive medication (including steroids, disease modifying antirheumatic drugs, and biologicals) is used to prevent inflammation and damage. However, the medication leaves the patient open to all kinds of infections. The medication may thus be reduced before operations and when the patient suffers from infections. For example, with an infection in the upper airways, the GP prescribes antibiotics and may reduce the RA medication. But then he may forget to increase the RA medication after the infection has been treated. Further, if the patient seeks treatment for other conditions elsewhere, the risk increases because he may not mention that he has RA. Medication may also include pain medication.

The inflammation may cause co-morbidities, but if the inflammation can be contained the risk of co-morbidities may be reduced. The medication for patients with co-morbidities can be very complex. Early treatment is substantial.

The purpose of the treatment is to obtain the highest possible and sustained state of remission, meaning that the patient is functioning as if there were no symptoms at all. The level of remission is increased if the RA is diagnosed early.

4.1 RA treatment

The treatment is primarily pharmacological. The patient may take up to 3 immunosuppressive drugs every day plus infusions every week, month or every 6 months. The drugs basically suppress the immune system, making the patient vulnerable to other diseases. The adherence to medication is important but it is not easy to determine if the patient actually does take the medicine.

In the inpatient clinic the patient is prescribed medicine. In the outpatient clinic, the patient gets renewed prescription for as long they are in the outpatient scheme. Some of the prescriptions are renewed by the GP sometimes depending on the GP and on the costs.

The patient might be seen in the outpatient clinic every week, after 1, 3 or 6 months, and a scoring regarding the disease activity is done at each visit. In the follow-up visits, the physicians are looking for progression on the same points as examined at the time of the diagnosis. It is very important to manage the patient so that they stay on the pathway set out in the beginning of the treatment and / or they are brought back to the pathway or even put onto a new one.

4.2 Trial 1 lay-out

Trial 1 will involve patients with Rheumatoid Arthritis as primary morbidity and a cardiovascular disease as co-morbidity. The patients need to be managed in terms of medication, exercise and health status with the main aim of retaining a permanent good remission status.

Patients will be selected on the basis of the following inclusion/exclusion criteria:

Inclusion criteria:

- Above 18 years of age
- Have at least one known, documented co-morbidity (e.g., CVD and diabetes) at study entry
- Are willing to participate and sign data transfer agreements
- Are willing to interact with the platform
- Have a sufficient understanding of the German language

Exclusion criteria:

- Patients without any co-morbidity are excluded.

4.3 Stakeholders

The following stakeholders have been identified in the clinical workflow at UDUS:

- Cardiologist
- Ergo-/physiotherapist
- GP
- Insurance Company
- Laboratory
- Occupational Physician
- Patient
- Patient's Family
- Pharmacy
- Radiology
- Rheumatologist
- Social Services.

4.4 Data

The following list of data that figure in the workflow will be considered when defining the To-Be use cases and assessing where PICASO can provide support.

- A symptoms description
- Additional patient information (e.g. patient profile/personality, social situation)
- Blood test results
- Clinical conference conclusions
- Clinical notes/suspected diagnosis
- DAS28
- DEXA scan
- Diagnosis
- Education plan
- Ergo-therapy data (what the patient has done of treatment, frequency, and the results)
- Ergo-therapy Report
- Exercise plan
- Existing health related data (x-ray etc.)
- Images and reports / reports
- Level and Activity of RA
- Medication instructions
- Medication list
- Medication plan
- Medication review notes
- Medical history
- Occupational physician report (workability assessment)
- Patient pathway definition
- Patient pathway instructions
- Pension claims.
- Photo of joints
- Prescriptions
- RA progression report
- Reimbursement claim (to Insurance company)
- Report on patient's workability
- Result reports (initial and follow-ups)
- Scheduled appointments (location, date, time, information on what to bring)
- Treatment plan
- Ultra-sound requests and results

5 Trial 2 Parkinson's Disease with Cardiovascular Disease

Parkinson's disease (PD) is a neurodegenerative disorder with an incidence that rises steeply with age. The main histo-pathological feature of this disease is a neurodegenerative process that affects the neurons of the substantia nigra that primarily affect motor symptomatology. If one considers that the diagnosis of PD is usually performed in adult subjects (with the highest peak of incidence being detected in patients over 65 years old), Cardiovascular Disease (CVD), diabetes and kidney failure are among the most frequent co-morbidities in subjects affected by PD. Data show that 80% of PD patients older than 65 have CVD, and 20% as direct cause of PD.

5.1 PD treatment

PD requires a clinical diagnosis (the initial investigative phase takes 2-3 months) and is primarily treated with medications. Levodopa (L-dopa) has been used for years and is the gold standard for treating Parkinson's disease by increasing brain levels of dopamine. It is probably the most effective drug for controlling symptoms and is used in nearly all phases of the disease. The Clinical Neurologist will prescribe the first PD medication to patient but the prescription will then be renewed by the patient's GP, usually combined with a consultation with GP.

If the patient presents symptoms that are of a psychological nature, the Clinical Neurologist will refer the patient to the Neuropsychologist. If the Neuropsychologist judges that medication is necessary for the neuropsychological symptoms, the Psychiatrist will prescribe these. In the UTV case, the Neuropsychologist and Psychiatrist work closely together in the same premises.

Once diagnosed and stable, the Clinical Neurologist will see the patient every 6 months for follow-ups and to check the progress of the disease. It there are signs of co-morbidities, mainly cardiovascular disease, the patient will be referred to the relevant specialist.

5.2 Trial 2 lay-out

Trial 2 lay-out will involve patients with Parkinson's disease as primary morbidity and cardiovascular disease (CVD) as co-morbidity. The patients need to be managed in terms of medication, exercise and health status with the main aim of retaining a permanent good remission status.

Patients will be selected on the basis of the following inclusion/exclusion criteria:

Inclusion criteria:

- Patients above 65 years of age with PD and CVD
- The patients and the patient's family as primary care giver must be willing to use the provided medical devices including the PICASO App targeted at non-professional carers
- Understand the Italian language
- Sign the necessary agreements (informed consent)

Exclusion criteria:

- Patients without co-morbidity of CVD and Parkinson
- Patients with the following co-morbidities: oncological history, history of transplant (i.e. lung or kidney), chronic therapy for immune diseases, psychiatric diseases, chronic infectious diseases (i.e. tuberculosis) and dementia
- Patient's where the family as primary care giver is not willing to participate.

5.3 Stakeholders

The following stakeholders are involved in the As-Is workflow for UTV:

- Cardiologist
- Clinical Neurologist
- Family
- GP
- Laboratory
- Neuropsychologist/Psychiatrist
- Nuclear Medicine Physician
- Patient
- Pharmacologist
- Pharmacy

5.4 Data

The following list of data that figure in the workflow will be considered when defining the To-Be use cases and assessing where PICASO can provide support:

- Blood test results
- Exercise plan.
- Existing images
- Health/medical history & general information
- List of medications used
- Medication withdrawal (necessary for the scan)
- Medicine plan
- Prescription for PD medication
- Referral letter to Cardiologist
- Referral letter to Nuclear Medicine Physician
- Referral to Neuropsychologist
- Report/referral letter from GP
- Scanning images
- Scanning instructions (type of scanning and what to look for)
- Scanning report/results
- Symptoms description
- Treatment plan

6 Vision Scenarios for Usage of PICASO Services

As already mentioned, PICASO vision scenarios were created to give an overall perspective of user interaction with PICASO services for the purpose of supporting them in fulfilling their tasks. The scenarios assist in explaining and documenting requirements for the PICASO system. To make these scenarios more vivid, personas have been created that should be understood as representatives of the future PICASO users such as physicians of various medical specialties, therapists, patients and caring relatives. The vision scenarios describe a mainstream story of a patient being referred from one physician to another for diagnosis, treatment or (physio)-therapy. PICASO's role in support of this process for all stakeholders involved is illustrated, particularly as this pertains to an integrated care approach. The scenarios also show how PICASO services may support patients in keeping track of their daily treatment schedule, e.g., for medication compliance.

6.1 Personas

Patient:
Andrew is a 70-year-old former manager of a grocery store lately noticing tremor in his right hand which has reached a stage where it is influencing his capability read his newspaper and do paperwork.

Informal carer:
Rita is Andrew's daughter who has been helping him out with housework since his wife passed away a year ago. She will take care of him if necessary and may accompany him for instance to see doctors.

Neurologist:
Diane is a neurologist at Smith's Hospital responsible for diagnosis and treatment of patients with Parkinson's disease. For this purpose she depends on examinations conducted by other specialists. Therefore, she has to hand over patients to these specialists. She also writes care plans for patients.

Radiologist:
Peter is a nuclear radiologist organizing and carrying out scans at the department of radiology at Quincy Hospital. Patients with various diseases are referred to him for different types of scans. Prior to scanning, Peter needs to be informed about why the patients are referred to him, the diagnosis of the patients including possible co-morbidities and their medication intake, because this might need to be adjusted beforehand and indication of radiology investigation needs to be proved otherwise the investigation cannot take place. He also needs to know about the physical status of the patient, e.g. whether the patient is physically disabled, for appropriate scheduling of the patient. Peter is also responsible for evaluation of the images and needs to feed back his findings to the referring physicians.

Cardiologist:
Nora works at Smith's Hospital as a cardiologist. She examines patients with a possible risk of heart failure and might detect possible reasons or cares for other heart problems. In accordance with her findings she treats patients, hands over patients and creates care plans.

General Practitioner (GP):
Jacob is Andrew's GP that Andrew visits in case he is suffering from everyday diseases such as the flu or gastrointestinal disorders. Jacob writes care plans and may hand over patients to specialists, if necessary. He might be seen for the neurologic disease as well.

Medical laboratory assistant:
Robert, the medical laboratory assistant at Smith's Hospital receives requests from physicians in the hospital to make certain blood tests and is required to send the results back to the physicians as soon as possible.

Physiotherapist:
Emily is a physiotherapist running a physiotherapeutic practice near Andrew's home. She reports on the physical status of her patients after their completion of the prescribed number of physiotherapy sessions. She also writes exercise plans for her patients.

6.2 Vision scenarios

The following subchapters present the different vision scenarios related to specific activities or events. Together they form a complete vision scenario for the use of PICASO in the case of a patient who is diagnosed with Parkinson Disease.

6.2.1 Documenting initial diagnosis

Lately Andrew has noticed increasing tremor in his right hand that starts to bother him when reading his newspaper and entering the solutions into the grid of the newspaper's crossword puzzle. He therefore decides to make an appointment at the nearby Smith's hospital to seek advice. There, he is sent to the neurological department and meets Diane, one of the neurologist at Smith's. She listens to his description of his symptoms, carries out some physical exams and determines that there is strong evidence that Andrew is in the early stage of Parkinson's disease.

Diane has access rights in PICASO appropriate for the role "neurologist'. This means that she is allowed to see patient data tagged for this role by other users of PICASO and that the PICASO user interface will adapt to provide role-related functionalities and forms, e.g., a form for recording medical diagnosis or the functionality to alter a medication plan of a patient. Diane logs on to the platform, and once authenticated, Diane types in Andrew's patient ID. This brings up Andrew's patient profile that has already been created by the hospital receptionist. The profile contains medical information for Andrew, including his contact details. From a menu Diane selects 'medical diagnosis' and is presented with a template where she can enter the results of her physical exams in the corresponding fields. Upon saving this information she is asked to specify who else should have access to this information and selects from a list 'all physicians', which means physicians from all medical specialties will have access.

6.2.2 Handover neurologist – medical laboratory assistant

Since Diane also needs some blood tests to finalize her assessments, she opens a form with a list where she can indicate the blood tests that are relevant for Andrew's case. Also here she is asked who else should have access to this information, including the results, and selects 'medical laboratory assistant', because in her opinion nobody else needs to see this information. Before sending Andrew on to the hospital lab for blood testing, Diane asks Andrew to see her secretary about making a new appointment two weeks from now.

When Andrew arrives at the hospital lab, Robert logs on to the PICASO platform and enters Andrew's patient ID. In accordance with his role PICASO only shows him that Diane has requested certain blood tests. After completion of the blood tests, Robert accesses PICASO again and is allowed to enter the relevant test results in the form.

6.2.3 Creating a medication plan as part of patient's daily treatment schedule

After having done the blood tests, Andrew returns to Diane who enters the PICASO platform and is shown that there is new information available from the laboratory. She clicks on it, and the blood test results reinforce her initial suspicion that Andrew is suffering from Parkinson's disease. She shares these results with Andrew and explains the need for medication to keep the disease from progressing. Diane selects the option to create a medication plan, and the system shows her that Andrew's existing medication plan is empty at the moment.

Diane explains to Andrew that she will create a medication plan together with him, which he will be able to access from his Smartphone, tablet or whatever device he prefers. Andrew is handed information on the functionalities of PICASO and how to use it for e.g. medication reminders. Diane enters a precise daily schedule for necessary medication intake and selects that this information should be made visible to 'all physicians' and 'patient'. She then explains to Andrew that he can always adapt this medication plan according to his needs by clicking on 'Personal preferences'. For example he can change the time when alerts for medication intake should be sent to him in case his daily schedule changes. She also informs him that when he starts taking his medication, he should enter the package size into the medication plan. This will allow the PICASO system to prompt him in time to request a refill prescription from Diane. He then only needs to approve it and it will be sent to her. In return, Diane will renew his prescription through PICASO, giving him sufficient time to pick up his refill at the pharmacy. Andrew agrees, and Diane initiates a PICASO-generated invitation that includes Andrew's log in details and instructions for use.

6.2.4 Handover neurologist – radiologist

Diane now tells Andrew that he also needs to see a radiologist for a PET scan, which will provide more detailed information about the status of his disease. When recording this treatment requirement in PICASO, an alert comes up telling Diane that the current medication plan needs to be adjusted for this event, since dopamine intake should be reduced prior to scanning. Diane therefore sets up an alternative medication plan and defines that it should be in effect from 2 days before and 2 days after the scan is scheduled. Diane also informs Andrew about these upcoming changes.

Diane tells Andrew that if he agrees, she can put a referral letter for the radiologist in his patient record, giving the radiologist access to his medical diagnosis, medical treatment and personal contact details for planning of the scan, but no other information. To facilitate communication between her and the radiologist and also for Andrew's convenience, the radiologist will then be able to insert the scan results in his patient record. Andrew agrees and signs a corresponding consent letter. After Andrew has left her office, she prepares a referral letter for the radiologist including information about her rationale for requesting the scan. She then scans Andrew's letter of consent and uploads it into PICASO.

Andrew now requests a PET scan appointment in the radiology department, and radiologist Peter is contacted by the department secretary to confirm the suggested date for this scan. Peter logs into the PICASO platform, and after authorisation the information created by the neurologist is visible to him. He opens the referral letter to see what kind of scan is requested and from which brain hemisphere. He looks at the medical diagnosis to check if the patient suffers from co-morbidities relevant for the scan, e.g., diabetes. To be able to organize scheduling of patients more efficiently, he also wants to assess the physical status of the patient, e.g., if the patient is wheelchair-bound. He then checks the medication plan and notes that the patient is receiving dopamine inducing drugs. However, he is also made aware that there is an alternative medication plan available for the patient, once he has confirmed the date of the appointment. Peter confirms the date and updates the patient record. Consequently and automatically, the updated medication plan as defined by the neurologist is presented to the patient.

Andrew arrives on the agreed date and has a short consultation with Peter, who explains the procedures of conducting the scan, including the subsequent upload of all images and Peter's conclusion to his patient record. He tells Andrew to see Diane again to discuss these results. After this introduction he carries out the PET scan.

6.2.5 Treatment supported by PICASO LinkWatch

Back at Diane's office she logs in at the PICASO platform and reads Peter's summary of the scan results. The conclusion is that Andrew's right brain hemisphere is affected by the disease and that he may be at risk of cardiovascular disease. She discusses these findings with Andrew and suggests seeing Smith's cardiologist Nora for further examination. Because of this serious risk, she recommends that Andrew also makes use of the PICASO's gateway LinkWatch to have his blood pressure measured and an ECG recorded once a day via home based devices (see below). PICASO will collect all measurements and analyse them to detect possible deviations from normal patterns as well as values exceeding critical limits. The results of all recordings will be stored at his home, and he will be able to see visualizations of his measurements in his own home on a daily, weekly or monthly basis. In case PICASO detects critical situations, Andrew will be alerted by PICASO and instructed to, e.g., get in contact with Diane or other neurologists at Smith's who will then look at the data and provide specific advice.

6.2.6 Patient diary for recording of well-being

Diane also asks Andrew to keep an e-diary for the next 3 months, recording 3 times a day how he feels, because this will help ensure that his medical treatment is appropriate. In PICASO Diane selects Andrew's daily treatment schedule and adds that Andrew shall be alerted to rate his well-being on a scale from 1-6 two hours after taking his medication. To give Diane permission to access all of the provided information and agreed measurements, Andrew must sign a new letter of consent which he does, but this one limited to Diane exclusively.

In the PICASO platform Diane makes templates for a patient diary accessible to Andrew. She also authorises the LinkWatch technical support to provide Andrew with devices for measuring blood pressure and recording ECG. She furthermore provides critical values for sending alerts to the patient.

6.2.7 Involvement of informal carer

Before exiting the PICASO platform Diane checks Andrew's contact details to see if he has indicated an informal carer. She suspects that involving an informal carer will become necessary at some point, to accompany him to doctor's appointments or to receive alerts in case of exceeding critical values. She discusses these issues with him, and Andrew says that his daughter Rita will be helping him in such cases. Diane adds Rita's name and contact details in PICASO, subscribing Rita to Andrew's daily treatment schedule in PICASO, as for the moment he only needs her support to ensure medication compliance and help picking up refill prescriptions.

6.2.8 Handover neurologist – cardiologist

Next Andrew goes to see Nora, who with his permission accesses results of blood pressure and ECG measurements. She notices that his blood pressure is too high and conducts some further examinations which she records in PICASO's medical diagnosis template. As a result of her examinations she decides that Andrew should take medication for his high blood pressure which she adds in the medication list of Andrew's patient record. Upon entering this medication, an alert pops up informing her that according to the information system for medicinal products, the medication entered by her may be contraindicated for Parkinson's disease patients. Nora looks up in the information system what possible interactions there are and notices that antihypertensive drugs may have negative side effects on Parkinson's disease symptoms and decides to switch to another medication. She then updates Andrew's medication plan, agreeing with him on an appropriate time schedule. Thereafter Nora selects the PICASO template for writing a referral letter and informs Diane about her diagnostic outcomes and the resulting treatment procedure. Once completed, she sends it to Diane through PICASO.

6.2.9 Handover neurologist – physiotherapist

During Andrew's next check-up at Diane's office, she notices that his physical state is deteriorating and decides that he needs physiotherapy. She selects a template for prescriptions and instructs Andrew to search for a physiotherapist that is convenient for him to visit. She tells him that with his consent, she will make Andrew's medical diagnoses and his daily treatment schedule available to this physiotherapist. This will allow the physiotherapist and Andrew to agree on a suitable exercise plan. Andrew agrees, and in PICASO Diane tags that this information in Andrew's patient record is now accessible for the role 'physiotherapist'.

6.2.10 Exercise plan as part of patient schedule

When Andrew comes in for his first appointment with physiotherapist Emily, she logs on to PICASO and sees Diane's prescription. She also looks up Andrew's diagnoses. While treating him, she explains that Andrew should do 2 exercises a day to improve the mobility of his hands. To ensure that Andrew does not forget this, she tells him that she will enter these exercises in his daily treatment schedule. Andrew says that 5 pm will be the most convenient time to do these exercises, and Emily enters this time in his treatment schedule. Since Andrew's schedule now includes both medication and exercises, she also suggests to Andrew to activate PICASO's functionality "end-of-the-day summary". This will be an easy way for him to make sure that he has done everything he was supposed to do. PICASO will then provide feedback in the form of a percentage (e.g., 100% if everything has been done, if less, PICASO will note what Andrew has missed).

To share information about treatment results, primarily with Andrew's neurologist but also other involved physicians, Emily logs on to the PICASO platform. She selects a template for recording physiotherapy results and briefly describes Andrew's current mobility status, particularly regarding his hands, and recommends that further treatment is necessary to counteract loss of functionality. Via PICASO, this information is sent to Diane as prescribing neurologist.

6.2.11 Treatment by GP

Some months later Andrew catches the flu with high fever and therefore visits Jacob, his GP. Jacob enters the PICASO platform and gets the information that treatment information is available from a neurologist, a cardiologist, a radiologist and a physiotherapist. He decides that for his treatment of Andrew's flu, diagnoses and medication lists provided by the neurologist and the cardiologist are the most relevant. After checking those, he does not think that there is contraindication for prescribing fever-reducing medication. He writes a prescription and updates Andrew's PICASO daily treatment schedule to include this medication.

7 To-Be Use Cases

The following 18 use cases have been developed for the PICASO platform. They have been divided into three groups representing three main aspects: i) Integrated care plans, ii) Professional Carers, and iii) Remote Patient Monitoring:

Use case ID	Description
Integrated care plans	
UC-1	Presenting symptoms
UC-2	Information sharing during examination and diagnosis of new patients
UC-3	Information sharing during examination and diagnosis of new patients (UTV)
UC-4	Medication plan distribution
UC-5	Browsing for relevant data
UC-6	Authentication by users to share data
Professional Carers	
UC-10	Constructing care plans using narratives
UC-11	Monitoring and handling of events and alerts
UC-12	Intervention strategies, definition and execution
UC-13	Risk assessments during care plan execution
UC-14	Monitoring for co-morbidities and handling of incidental findings[3]
UC-15	Flexible informed consent
Remote Patient Monitoring	
UC-20	Home monitoring for self-management
UC-21	Handling non-connectivity of home monitoring platform
UC-22	Filtering and sorting of data and events
UC-23	Medication reminders and compliance monitoring
UC-24	Joint care – Patients and the informal carers
UC-25	Patient interaction modalities

Table 2: Overview of To-Be use cases

7.1 Integrated care plans

Six To-Be use cases related to integrated care plans have been identified and are described in detail in the following sub-chapters.

Some of the To-Be use cases are supported by workflow drawings. The meaning of the different symbols used in the workflow drawings is described in Appendix C.

The following colouring of the symbols is used:

- Green: Actor and activities are part of the PICASO trials
- Grey: Actor and activities exists but are not part of the PICASO trials. However, some actions may be simulated

[3] UC-14 will be developed for the second iteration of the project.

- Violet: New actor and activity in the PICASO To-Be process and part of the PICASO trials

7.1.1 UC-1 Presenting symptoms

UC-01	**Presenting symptoms**
Actors	GP, specialists, radiologists, laboratories, patients

Problem(s) to solve
The patient has experienced symptoms such as tender, warm and swollen joints, joint stiffness that is usually worse in the mornings and after inactivity, and/or fatigue, fever and weight loss. The GP has to make a pre-diagnosis and refer the patient to specialist physicians for further examination, either in private practice or in specialist clinics.

The exchange of data between the different professional carers at this stage is often incomplete A study reported in JAMA (Journal of American Medical Association) found that direct communication between hospital physicians and primary care physicians occurred infrequently (3%-20%). Important information may be lost on the way and there is thus a need for more systematic exchange of data between professional carers from the onset.

Description
The referral has to be as easy and efficient as possible with all relevant data being transmitted directly to the receiving physician and with proper feedback to the GP and the patient about the progress.

The patient has a consultation with the GP where he/she presents a series of symptoms. The GP will assess the symptoms and enquire about the patient's general health/medical history and the medications the patient is currently taking. Also laboratory and radiology testing may be done at this stage.

After this preliminary examination, the GP may either rule out a possible diagnosis of RA or PD, may refer the patient to further specialist examinations (radiology, scanning) or, if the symptoms are clear, directly to the specialist clinic.

The GP refers the patient to the RA or PD specialist for examination to confirm the diagnosis.

Existing Flow (As-Is)
The patient is given a referral. The patient will then contact a specialist clinic for an appointment and will be required to bring the documentation and a list of prescribed medications to the consultation.

New PICASO Flow (To-Be)
The GP will refer the patient to a specialist for examination and/or testing and the patient will book the appointment directly with the appropriate specialist or clinic.

The specialists may refer the patient to various other scanning and x-rays, examination by other specialists and laboratory testing, The specialists also perform their own examinations and tests to verify the early diagnosis.

All the professional carers in this phase store data in their local data store, but these data are also accessible through the PICASO platform. At the consultations, the specialists can, through PICASO, retrieve all the relevant data about the patient from other professional carers.

The To-Be workflow is shown in Figure 1 on the following page.

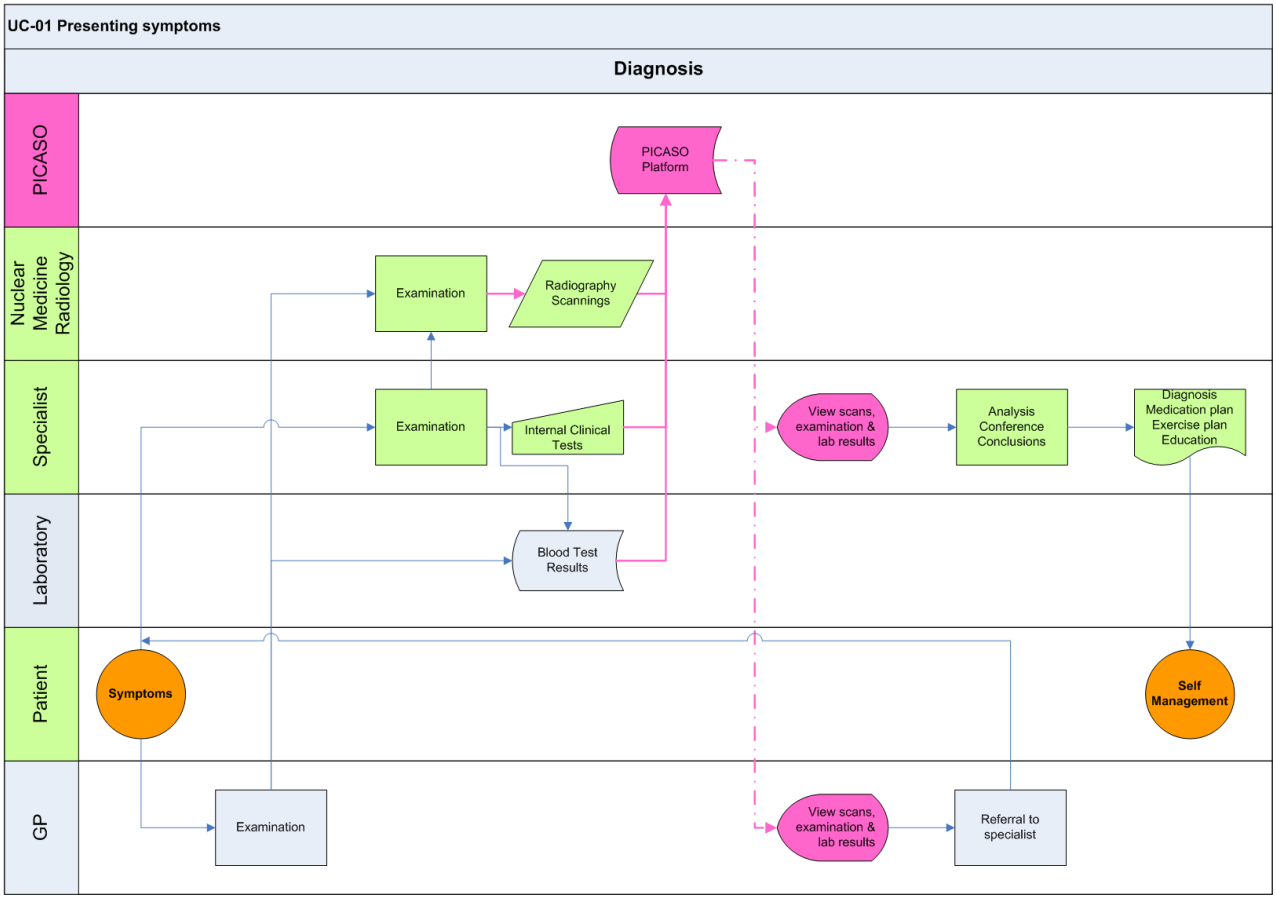

Figure 1 Information sharing among GP, specialists, clinics and laboratories during diagnosing of new patient

Data

- Verbal data
  - Symptoms description, health/medical history, present medication
- Written data on paper
  - Referral letter with pre-diagnosis
- Text data in local datastore
  - Anamnesis (health/medical history)
  - Clinical notes
  - Medication plan
  - Medication instructions
- Quantitative clinical data
  - Lab results
- Image data
  - X-Rays, MRI, DEXA scans, ultrasound images

7.1.2 UC-2 Information sharing during examination and diagnosis of new patients (UDUS)

UC-02	**Information sharing during examination and diagnosis of new patients (UDUS)**
Actors	GP, speciality clinic, specialist, radiology clinic, laboratory, patient

Problem(s) to solve
Patients may consult with several physicians (GP, specialists) before choosing a care provider. This leads to duplication of work in terms of examinations, scanning and laboratory tests and thus increases the cost

of healthcare and the time it takes before the diagnosis and the resulting care plan is established.

The exchange of information (medical history, medications used, test results and other health data) between the involved clinicians is paper based, and the patient is responsible for picking up test results from one specialist and presenting them to other specialists. The patient also needs to repeat his medical history each time he sees a new specialist. A significant amount of time during a consultation may therefore be used to gather the relevant information. Moreover, the information provided to the patient is often not fully understood, and the patient can benefit from more structured information about the progress and the result of the diagnosis phase.

Description
The patient has a consultation with a GP or a medical specialist where he/she presents a series of symptoms. The patient may be referred to a specialist or a rheumatology clinic. The referral has to be as easy and efficient as possible with all relevant data being transmitted directly to the receiving physician and with proper feedback to the GP and the patient about the progress.

The physicians will assess the symptoms and perform a dedicated examination (either by direct measurements or scoring) and order a number of additional tests such as X-Ray, ultrasound, blood tests. All the data from the various tests are automatically tagged and stored in local datastores. From here, PICASO allows other specialists to query and find the relevant examination results and use the information for his/her own assessment. Moreover, the specialists can send instructions and information to the patient through the PICASO platform, including extracts from the local datastore, e.g., care plan overview, medication plan, exercise plan, appointments, etc.

Existing Flow (As-Is)
The As-Is workflow is expressed in the UDUS As-Is workflow presented in D3.1.

If the GP or physician examining the patient suspects that the symptoms are related to RA, he/she refers the patient to a rheumatology specialist or clinic.

The patient will contact the specialist for an appointment. During the consultation, a physician will examine the patient and perform various tests. Other tests will be ordered from a laboratory and radiology clinic.

After all the information has been collected via these time-consuming processes, the specialist physician performs an assessment to confirm or reject the diagnosis hypothesis and documents it in the local datastore. From the diagnosis, he/she will establish a personal care plan including medication plan and exercise plan. Moreover, the patient will be invited to an information and education event to be informed about the disease.

New PICASO Flow (To-Be)
In the To-Be workflow, as presented in Figure 1 below, all data exchange among the professional actors is handled via the PICASO platform, thus saving precious time and efforts. Also the communication with the patient takes place via the PICASO platform.

Once an examination report, a clinical note, a blood test result or a scanning image is stored in the local datastore (residing at the clinic, laboratory or in the GP's office) it is tagged and available to other authorised carers through the PICASO platform.

When a physician or nurse needs further information during the diagnosis phase, they query the PICASO platform in order to find relevant information about other specialists' assessment, images from other clinics or recent blood tests performed by laboratories.

When the specialist physician has established the diagnosis and the care plan for the patient, this information is accessible through the PICASO platform to other rheumatologists inside and outside the clinic, to the GP and to the specialist physician him/herself. The care plan is provided to the patient.

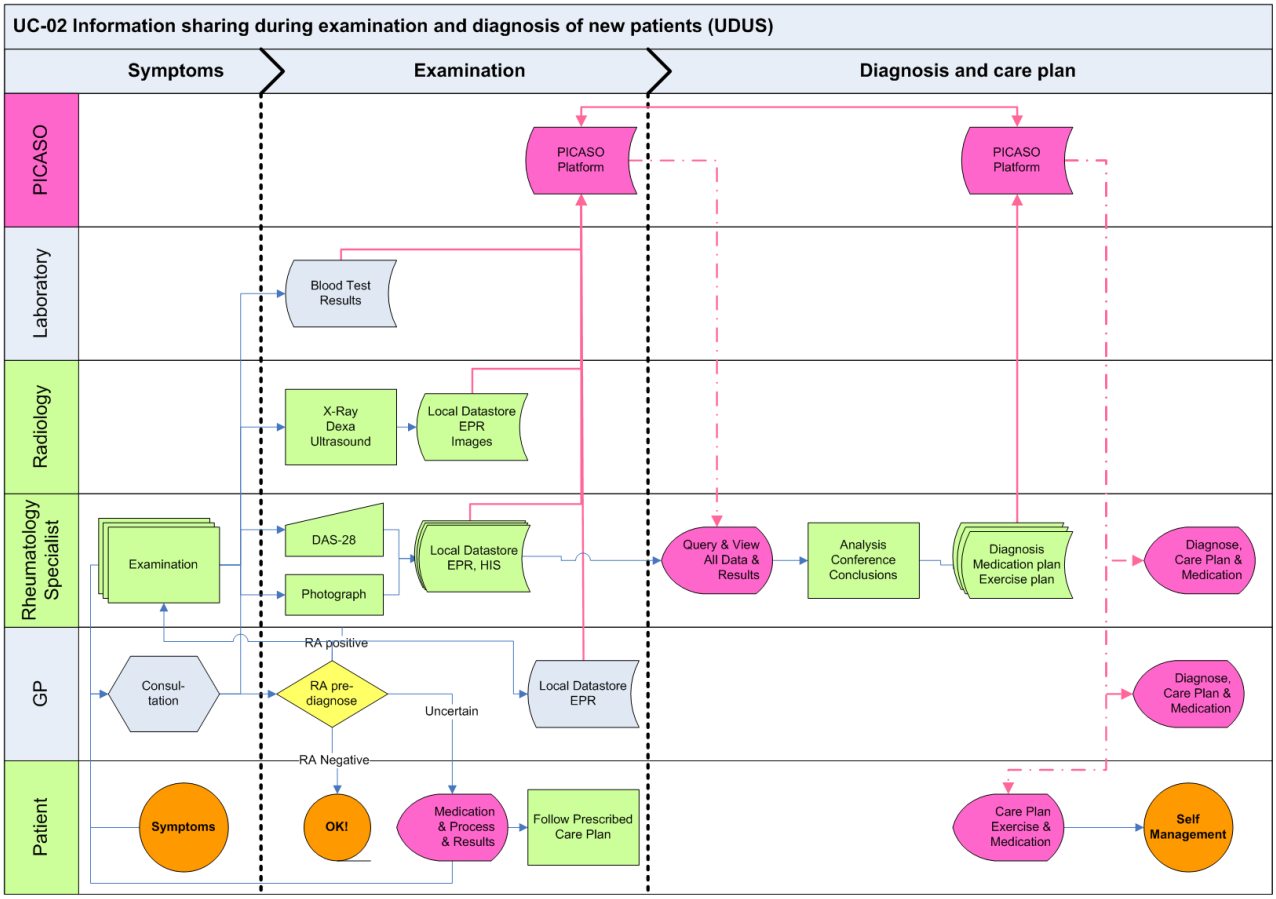

Figure 2 Information sharing among GPs, specialists, clinics and laboratories during diagnosing of new patient (UDUS)

The full care plan with additional information and instructions is also made available to the patient via the PICASO Home Network, where the patient can follow the process, e.g., which physician has stored data, which lab results are available, when is the next appointment for scanning. Moreover, the patient will also be provided with an aggregated medication list (including dose and frequency) and with other relevant instructions and educational material. All the information can be personalised to precisely fit the needs of the patient.

GUI

The professional actors will use a browser to query and view information about the patient from the different actors. Privacy and authorisation use cases will be provided in UC-06 Authentication by users to share data.

PICASO will provide a GUI user interface for the patient (web based or on an app). The patients will use an app on phone, tablet or PC to browse their data and to receive the care and medication plans. The app will provide a diary with daily medication and measurements to be performed and will give alerts when appointments are forthcoming. It will also monitor medication and self-management compliance. All the information can be personalised to precisely fit the needs of the patient.

Data

- Verbal data
  - Symptoms description, present medication
- Written data op paper
  - Anamnesis (health/medical history)
  - Referral
- Text data in local datastore
  - Patient health/medical history
  - Clinical notes
  - Medication plan

- Instructions for exercise, etc.
- Quantitative clinical data
  - Test scores, patient-reported questionnaires and their scores
  - Physiological scalar measurements (weight, blood pressure, heart rate)
  - Time resolved measurements (ECG, exercise)
  - Lab results
- Image data
  - X-Rays, MRI, DEXA scans, ultrasound images

7.1.3 UC-3 Information sharing during examination and diagnosis of new patient (UTV)

UC-03	**Information sharing during examination and diagnosis of new patient (UTV)**
Actors	GP, speciality neurology clinic, cardiologist, nuclear medicine clinic, laboratory, patient

Problem(s) to solve
The diagnosis process for Parkinson's Disease (PD) usually takes 2-3 months during which the patient may see different specialists who perform different types of tests in order to either confirm or rule out PD. The exchange of information (medical history, medications used, test results and other health data) between the involved clinicians is paper based, and the patient is responsible for picking up test results from one specialist and presenting them to other specialists. The patient also needs to repeat his medical history each time he sees a new specialist. A significant amount of time during a consultation is used to gather the relevant information. As a result, the data exchange process itself is slow and often incomplete.

Especially the exchange of information between different specialists treating patients with co-morbidities is often inadequate. The lack of information exchange of medication and diagnoses between the specialists leads to a less than optimal treatment of the patient.

Moreover, the information provided to the patient is often not fully understood, and the patient and the informal carer can benefit from more structured information about the progress and the result of the diagnosis phase.

Description
The patient first has a consultation with the GP where he presents a series of symptoms. If the GP suspects PD, he/she refers the patient directly to a clinical neurologist through the central office for reservation.

The clinical neurologist performs an examination and clinical tests. All data from the GP's initial examination and his referral notes are available to the clinical neurologist from the PICASO platform. Blood tests are ordered and performed either on site or by an external laboratory. The results from the blood test are available to the clinical neurologist through the PICASO platform.

If the clinical neurologist finds that the patient shows symptoms indicating cardiovascular disease, a referral to a cardiologist is issued. The referral letter will contain what the clinical neurologist considers relevant. Data from the examination is made available via the PICASO platform.

To confirm the PD diagnosis, a scanning of the brain is necessary and the patient is thus referred to a nuclear medicine physician. The referral letter includes information on the type of scan requested and what to look for. The clinical neurologist also includes other relevant information in the referral letter, such as the patient's medication list, instructions given, health history and other relevant patient data (e.g., if the patient is wheel chair bound). All this information is available via the PICASO platform.

The clinical neurologist may request further examination by a neuropsychologist. The report will automatically be available to the clinical neurologist via the PICASO platform.

When the responsible clinical neurologist has established the final diagnosis and the care plan for the patient, this information is automatically tagged and placed in PICASO. It is now available to other clinical neurologists, to other physicians, to cardiologists, to neuropsychologist/psychiatrists, and to the GP to use for prescribing the medication. Selected information, the care plan, the medication and therapy plan will be made available to the patient and informal carers in a suitable form via the PICASO Platform and the

PICASO Home Network (see also UC-2x for patient related use cases).

Existing Flow (As-Is)
The existing workflow is expressed in the UTV As-Is workflow with the following highlights.

As per referral from the GP, the patient has a consultation with the clinical neurologist, hand carrying the referral letter from the GP with clinical notes/suspected diagnosis, symptoms description and medication list. The clinical neurologist examines the patient and performs specific clinical test and orders a blood test. The blood test is performed by the on-site UTV Laboratory who sends the results back to the clinical neurologist.

The clinical neurologist refers the patient to a nuclear medicine physician for scanning. The patient is here hand carrying a referral letter with instructions to the nuclear medicine physician (type of scan, what to look for, etc.) and a request to book the scanning.

If the clinical neurologist finds symptoms that could indicate cardiovascular disease, the patient is given a written referral letter to a cardiologist. In this case, a parallel workflow starts with the cardiologist who again examines the patient and performs various tests. The cardiologist also refers the patient to a nuclear medicine physician for scanning. The patient books the scanning through the central office and is also here hand carrying a referral letter with instructions to the nuclear medicine physician.

If there are no cardiovascular symptoms present, the clinical neurologist will prescribe some initial PD medication to the patient and ask the patient to adjust (withdraw) other current medications if these conflict with the scanning results (e.g., give a false negative or positive). The patient is also given a referral letter to the nuclear medicine physician with instruction of which type of scan (PET, DaTscan, etc.) is to be performed and what to look for.

The nuclear medicine physician receives the patient and the written instructions and prepares for the scan. The patient must follow the medication plan given for PD and, if relevant, for withdrawal of other medications in preparation for the scan. The scan produces a set of images and the nuclear medicine physician writes a report. The patient receives the images on a CD and must hand carry the results to the clinical neurologist and the cardiologist.

The clinical neurologist will assess the results from the scan and from his/her own examinations including the effects of the PD medication that was prescribed at the first consultation. If the assessment confirms the PD diagnosis, the patient will be given a written medication plan; either updated or he/she will continue with the existing medication plan.

If there is still some uncertainty about the diagnosis, the clinical neurologist will request a supplementary examination by a neuropsychologist. In this case, the patient will be given a written referral letter. The patient must then book the consultation with the neuropsychologist. The neuropsychologist receives the patient and carries out an examination which consists of various tests. The results will be documented in a report which the patient will bring back to the clinical neurologist for assessment at the next consultation. The clinical neurologist may confer with colleagues and/or the neuropsychologist to discuss the results from the tests before giving the diagnosis of PD.

As a result of the PD diagnosis, the patient is given more information (education) about PD and how to manage it, including an updated medication plan and advice on beneficial exercises. If relevant, family members are present and will be given the same information to enable them to support and assist the patient. Also the patient's GP will be involved in renewing the prescription for the PD medication.

New PICASO Flow (To-Be)
The To-Be use cases are presented below.

All the professional actors are connected to the PICASO platform. Once an examination report, a clinical note, a blood test result or a scanning image is stored in the local datastore (residing at the clinic, laboratory or in the professional carer's office) it is automatically tagged and available via the PICASO Platform. When a physician or nurse needs further information during the diagnosis phase, they query PICASO in order to find relevant information about other specialists' assessment, medication plans, and images from other clinics or recent blood tests performed by laboratories.

When the data are located and the proper authorization obtained, the specialist can use the information as part of the decision support material for establishing the proper diagnosis.

There are three different workflows representing the three major interactions between the formal carers: a)

interactions between clinical neurologist, cardiologist, nuclear medicine physician, and the patient, b) interactions between clinical neurologist, nuclear medicine physician, GP, and the patient, and c) interactions between clinical neurologist, neuropsychologist/ psychiatrist, GP, and the patient. All data exchange among the professional actors as well as the communication with the patient (and thus with informal carers as appropriate) is handled via the PICASO platform, thus saving precious time, preventing duplication of work, and increasing quality in the care process.

a) Interactions between the clinical neurologist, the cardiologist, the nuclear medicine physician, and the patient (see Figure 3).

If there are no cardiovascular abnormalities, the clinical neurologist finalises his/her PD diagnosis and prepares the patient's PD care plan as explained in use case b)

If the clinical neurologist finds symptoms that could indicate cardiovascular diseases, the clinical neurologist refers the patient to a cardiologist. The clinical neurologist issues a referral letter, which will be available via the PICASO Platform, together with relevant data from the clinical neurologist's own examinations. The cardiologist examines the patient and performs various tests.

The cardiologist may refer the patient to a nuclear medicine physician for scanning. The patient receives traditional instructions on how to prepare for the scanning, but the personalised medication instructions will be transferred to the patient via the PICASO Platform. The cardiologist will then issue a referral letter to the nuclear medicine physician, which will also be available via the PICASO Platform.

The nuclear medicine physician receives the patient and retrieves the referral letter with instructions, information about medication, and results of previous examinations via the PICASO platform. The nuclear medicine physician performs the scan and writes a report with the findings. The scan produces a set of images which will be stored in the local datastore. The PICASO Platform will then make the report and selected images available to the cardiologist, the clinical neurologist and other relevant professional carers.

The cardiologist's diagnosis and CVD care plan are finally shared with the clinical neurologist and provided to the patient via the PICASO Platform.

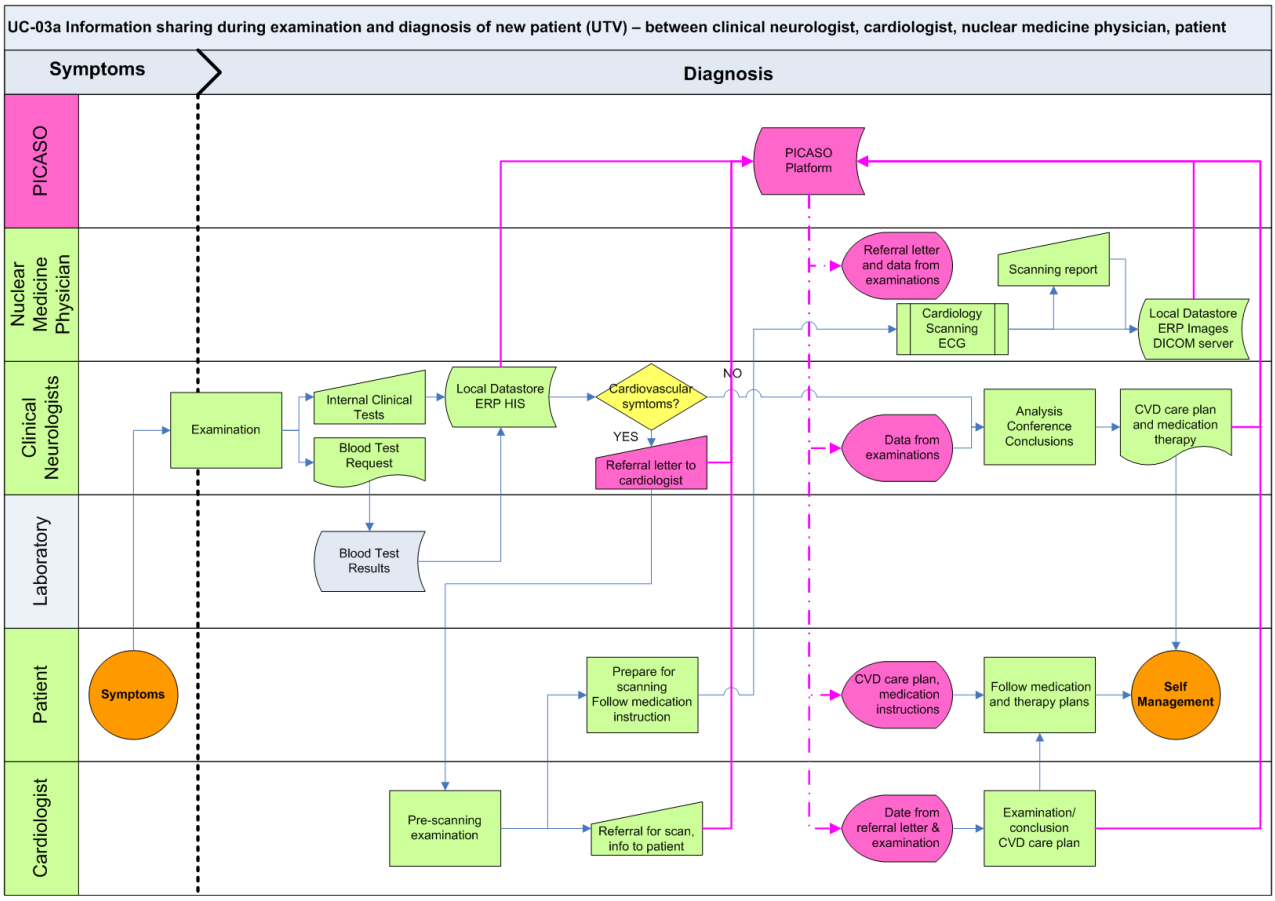

Figure 3 Information sharing during examination and diagnosis of new patient between clinical neurologist,

cardiologist, and nuclear medicine physician

b) Interactions between the clinical neurologist, the nuclear medicine physician, GPs, and the patient (see Figure 4)

The clinical neurologist refers the patient to a nuclear medicine physician for scanning. The patient receives traditional instructions on how to prepare for the scanning, but the personalised medication instructions will be transferred to the patient via the PICASO Platform. The clinical neurologist will then issue a referral letter to the nuclear medicine physician, which will also be available via the PICASO Platform.

The nuclear medicine physician receives the patient and retrieves the referral letter with instructions, information about medication, and results of previous examinations via the PICASO platform. The nuclear medicine physician performs the scan and writes a report with the findings. The scan produces a set of images which will be stored in the local datastore. The PICASO Platform will then make the report and selected images available to the cardiologist, the clinical neurologist and other relevant professional carers.

The clinical neurologist's diagnosis and PD care plan are finally shared with the GP and provided to the patient via the PICASO Platform.

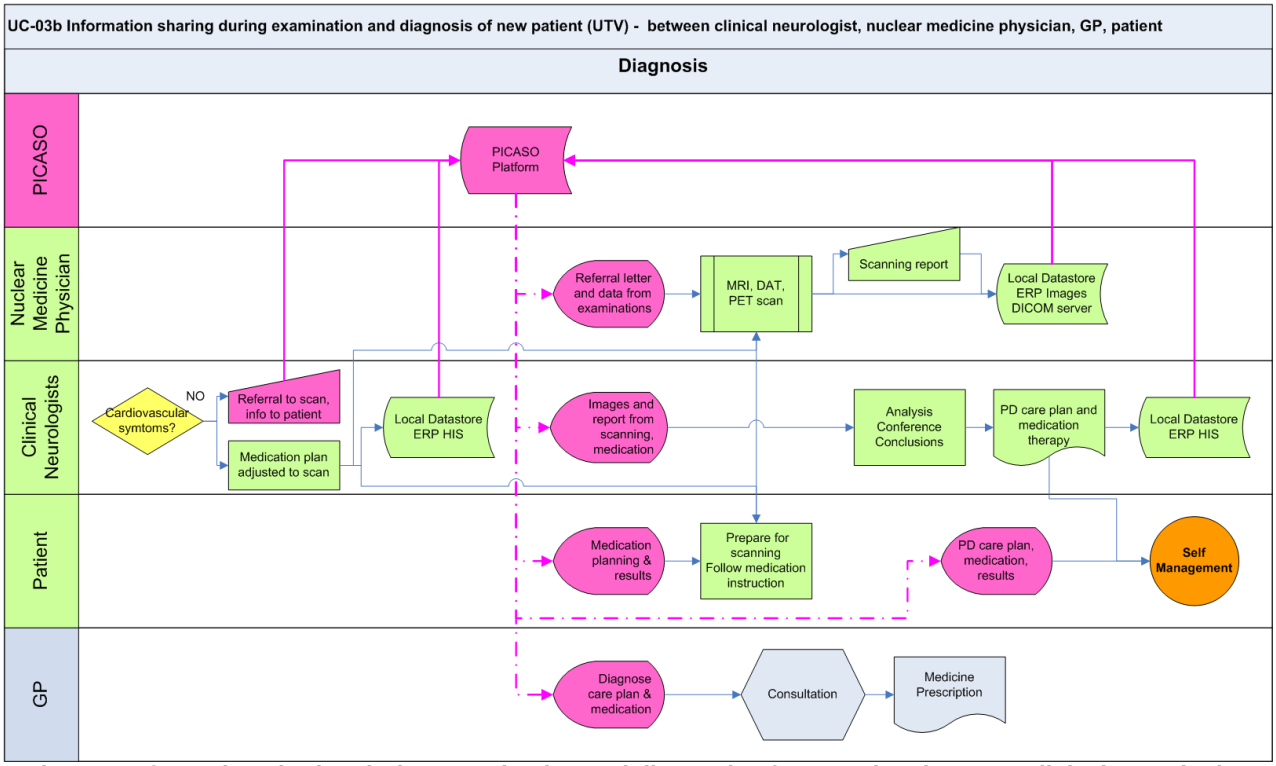

Figure 4 Information sharing during examination and diagnosis of new patient between clinical neurologist, nuclear medicine physician, GP

c) interactions between clinical neurologist, neuropsychologist/ psychiatrist, GP, and the patient (see Figure 5)

The clinical neurologist may request further examination by a neuropsychologist or a neuropsychiatrist.

The clinical neurologist issues a referral letter to the neuropsychologist or neuropsychiatrist, which will be available via the PICASO Platform together with selected information from the neurological examinations and the patient's medication plan. After examination, the neuropsychologist or neuropsychiatrist issues a report of the findings, which is stored in the local datastore and made available to other relevant carers via the PICASO Platform.

The report will be available to the clinical neurologist and can be incorporated in the overall diagnosis, which will then be made available to the GP via the PICASO platform. Also the patient (and informal carers) may be informed about their condition and the care plan for how to manage it.

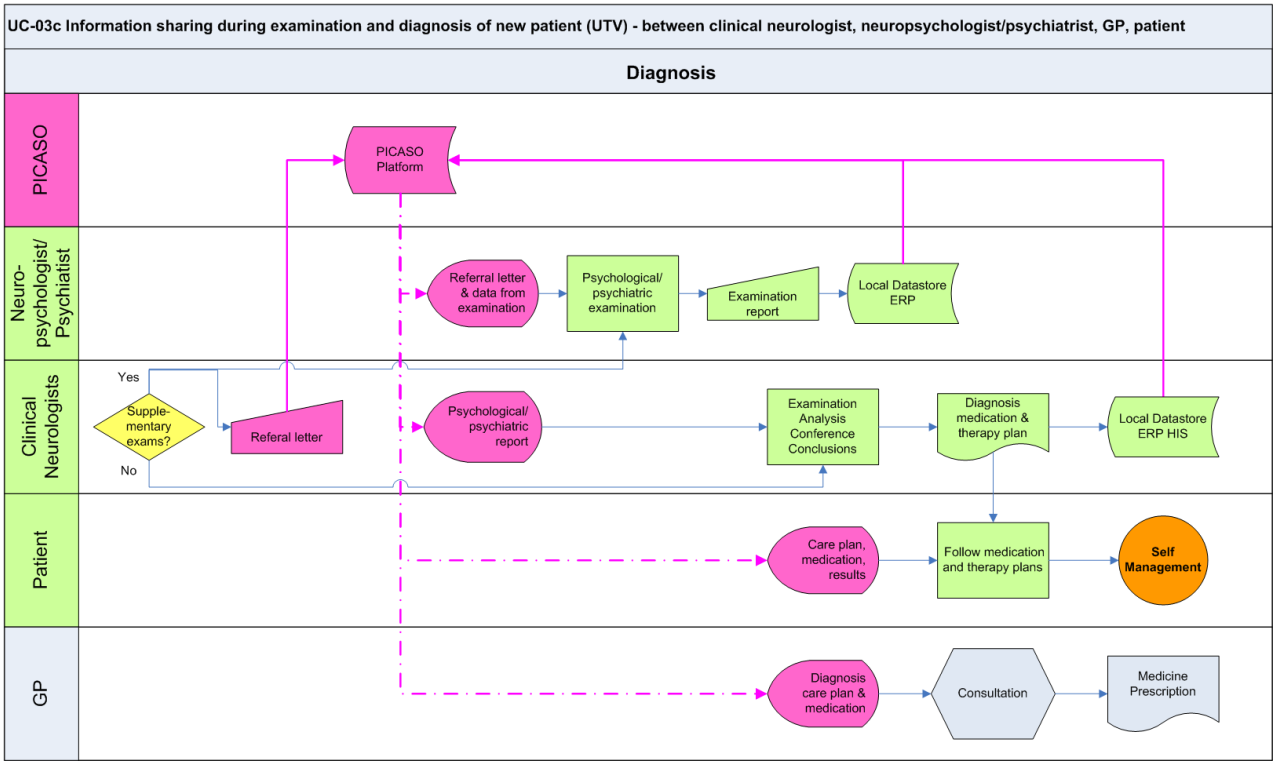

Figure 5 Information sharing during examination and diagnosis of new patient between clinical neurologist, neuropsychologist/psychiatrist, GP, and patient

GUI

The professional actors will use a browser to query and view information about the patient from the different actors. Privacy and authorisation use cases will be provided in UC-06 Authentication by users to share information.

PICASO will provide a GUI user interface for the patient (web based or an app). The patients will use an app on phone, tablet or PC to browse their data and to receive the care and medication plans. The app will provide a diary with daily medication and measurements to be performed and will give alerts when appointments are forthcoming. It will also monitor medication and self-management compliance. All the information can be personalised to precisely fit the needs of the patient.

Clinical neurologist generated data

- Patient health/medical history
- Clinical notes
- Result of the complete neurological examination, type of PD
- Prescription of PD medication and medication plan
- Referral letter to the cardiologist (type of PD, what to look for)
- Medication plan

Cardiologist generated data

- Result and report of the complete CVD examination to the clinical neurologist
- Prescription of CVD medication and medication plan
- Referral letter to the nuclear medicine physician (type of scan, what to look for)

Nuclear medicine physician generated data

- Images and report of the X-Rays, PET or ECG scanning

Neuropsychologist generated data

- Report from the neuropsychologist/psychiatrist

Patient generated data
- Symptoms description
- Anamnesis (health/medical history)
- Present medication list

GP generated data
- Medicine Prescription

Laboratory generated data
- Blood sample analysis results

7.1.4 CU-4 Medication plan distribution

UC-04	Medication plan distribution
Actors	Patient, GP, cardiologist, neurologist, rheumatologist, and other specialists

Problem(s) to solve
Patients are prescribed different drugs depending on the diseases they are being treated for. The medication is often complex with multiple drugs.

When a physician prescribes new medication to the patient, information about the prescribed medication is not always distributed to other carers (physicians, nurses, etc.) treating the patient. The new medication must be considered in the context of medication already prescribed by others physicians in order to avoid medication conflicts.

Description
When a physician prescribes new medication to the patient, the physician enters the information in the patient's medication plan which is then made available to others via the PICASO Platform. Through the user GUI the physician can see which medication has been prescribed for other diseases and a PICASO constraints resolving tool will alert for potential conflicts with existing medication plans. When confirmed by the physicians, the updated medication plan will be visible to all other involved professional carers, and the patient. The patient can share the information with informal carers.

The patient can visit the GP, and the GP can access PICASO, look at the patient's medication plan and prescribe new medication to the patient as needed.

Existing Flow (As-Is)
The existing workflow is expressed in the As-Is workflow. No or limited information exchange of the prescribed medication takes place between the physicians today. It is mostly a written medication plan given to the patient at the end of a consultation or in the summarizing letter to the GP, if the decision is taken when the patient had already left the specialist physician.

New PICASO Flow (To-Be)
When a specialist physician creates a new medication plan for a patient in their local datastore, the plan becomes available to other specialist physicians via the PICASO platform.

When another physician creates a medication plan, it becomes possible for him/her to see other existing medication plans via the PICASO Platform. A PICASO constraints resolving tool will alert for potential conflicts with existing care plans in terms of the following impacts:

- Model constraints – introduced by medical, clinical, pharmacological, actors, patients, etc.
- Care model and pathway constraints – introduced by commonly accepted guidelines, practice, personal, mandated, etc.
- Platform constraints – introduced by data security and privacy regulations, technical availability, and time resolution

- Service endpoints constraints – as represented by ethical, cultural, and personal preferences.

For the medication planning, the model constraints (e.g., what side effects can be expected from a combination of drugs?) and care model constraints (e.g., what are the general rules we follow here at the clinic?) are the relevant constraints covered by this use case.

It is only possible for a physician to change his/her own prescribed medication plan. If a physician wants to make changes to the medication plan prescribed by another physician, he/she must first submit a request for change in the prescription via the PICASO platform. PICASO sends a request to the physician responsible for that particular prescription. Once the other physician sees the message, he/she can investigate and reply to the request. The event handling part of the PICASO Platform handles the messages and alerts the physician when a request has been received. Hereafter, the physicians may engage in a telephone or e-mail consultation in order to find the most optimal solution for both diseases. Each of the physicians will finally modify their own medication plan accordingly.

When the Medication Plan for a patient is updated, it becomes visible to all other involved physicians, the GP the patient, and the informal carer.

PICASO also keeps a complete history of the physicians' activities and the history can be made available to relevant physicians and the GP. The full use case is shown in Figure 6.

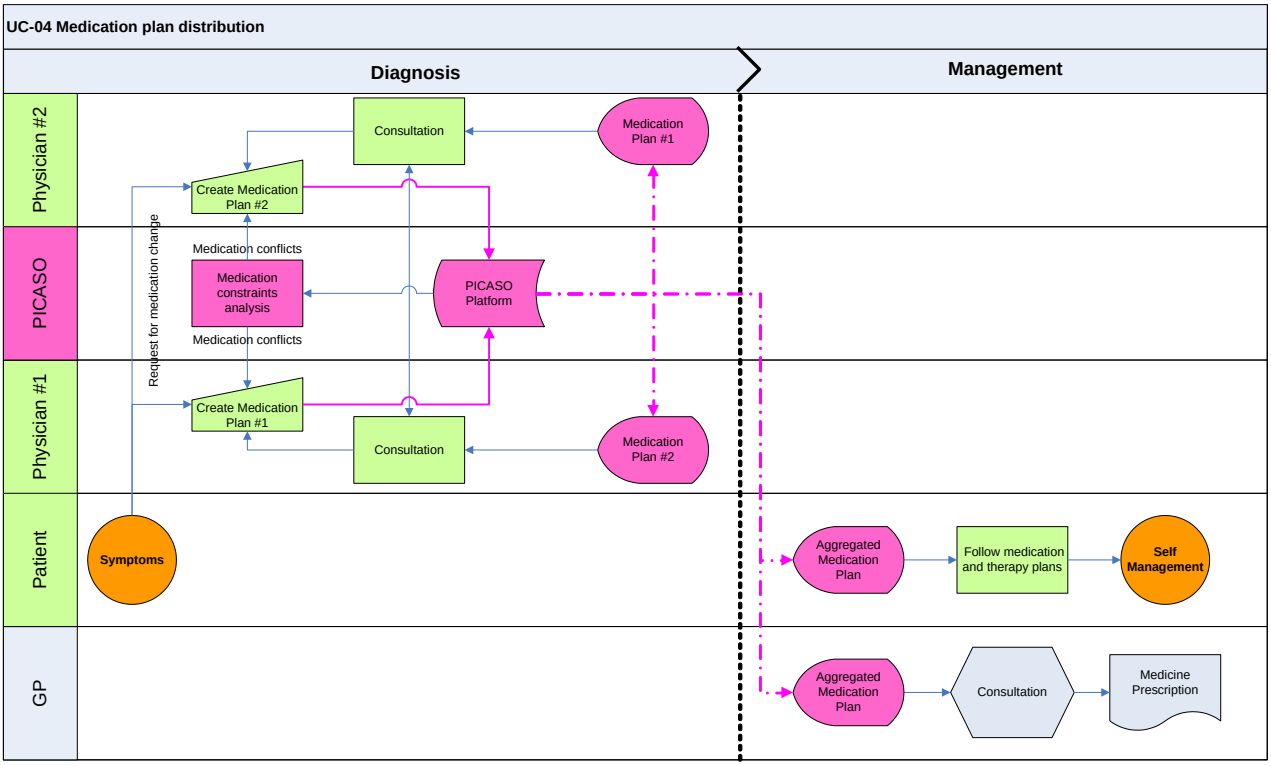

Figure 6 Medication plan distribution:

GUI

The professional actors will use PICASO to query and view the patient's medication plans. Requests between physicians will be handled by PICASO via the browser.

The patients will use an app on phone, tablet or PC to browse the medication plan and obtain guidance for compliance.

Physician #1 generated data

- Medication Plan #1
- Request for change in prescription
- Approval of change in prescription
- Rejection of request for change in prescription

Physician #2 generated data

- Medication Plan #2
- Request for change in prescription
- Approval of change in prescription
- Rejection of request for change in prescription

PICASO generated data

- Alerts for potential conflicts with the existing medication
- Medication Plan history
- Request for change in prescription (Physician → Physician)

GP generated data

- Medicine prescription
- Medication Plan

7.1.5 UC-5 Browsing for relevant data

UC-05	**Browsing for relevant data**
Actors	Specialist physicians, GP, the patient, informal carers

Problem(s) to solve

When all relevant data from a multitude of different professional care providers is to be accessible, the amount of data potentially becomes large. Moreover, when a patient is enrolled in home monitoring schemes, the amount of data to search can be huge. Some physiological measurements will be made once a day, while behavioural monitoring devices (e.g., motion and activity monitors) will continuously generate a huge amount of data.

It can be thus be very time-consuming for the professional carer to manually sort through the data sets and find the relevant data. Even worse, poor data quality can give the wrong impression of the patient status. There is thus a need for data quality enhancing mechanisms combined with intelligent, automated selection of individually different data, based on the physician's need to spend a minimum amount of time sorting and selecting data and the patients' and informal carers' need to be able to easily search and browse for understandable data.

Description

PICASO will provide an intelligent, automated selection of these data, based on the individual actors' need to spend a minimum amount of time searching, sorting and selecting data. The selection of relevant data will be provided by the narratives defined by physicians or nurses, and the user will be able to browse the data in different data stores accessible through the PICASO platform. Also the patient and the informal carers can browse these data or a subset of them. The actors' access is governed by the PICASO privacy and data protection framework represented as a use case in UC-06 Authentication by users to share data.

Existing Flow (As-Is)

In the As-Is workflow few patient data are shared electronically; some sharing takes place in the UDUS workflows, but very little in UTV workflows. Reports and data generated locally by the physician are mostly stored on the physician's local system and not shared with other systems.

The information to the patient is mostly paper based or given orally. Furthermore, no measurements are generated and stored from remote monitoring.

New PICASO Flow (To-Be)

The use case operates with three different types of information with different provenance and different access rights. The three types are:

a) Data generated by professional carers and mainly shared by the same audience. This type includes: Notes, diagnoses, images, and health data from professional carers.

b) Data generated from Remote Monitoring and shared with both formal and informal carers in various forms. This type includes: Health and behavioural data from the patient's home.

c) Data generated and designed to specifically serve the needs of the patient and the informal carers and to be shared with all actors. This type includes: Care plans, Medication plans, Exercise plans, Educational material, and Time schedules

All patient data in local datastores at the professional carers (clinics, specialists, GPs, etc.) will be automatically tagged when created and thus available for other carers to access via the PICASO platform.

Physicians, nurses, and others are able to set up criteria for intelligent selection of data in order to get exactly the data needed. The users can also identify events and subscribe to alerts. This could for example be events generated when data are missing or become available (see UC-11 for types of events and their handling).

Physicians may enrol their patients in Remote Monitoring using the PICASO Home Network, employing a variety of devices to monitor health and behaviour. Some measurements, e.g., blood pressure, will be made once a day, and some measurements, e.g., motion and activity monitoring, will be done continuously, generating a huge amount of data. The data are filtered and stored in the physician's local datastore, where they can be accessed by other professional carers, the patient and informal carers via the PICASO Platform

Finally, physicians, nurses and other professional carers can design specific information intended to help the patient and the informal carers better understand and manage the disease. This information can be tagged and accessed from the local datastores by patients and informal carers as well as other professional carers involved in the care process.

The information can also include educational material about the diseases and risk factors, the meaning of various terms related to the disease, as well as instructions for performing therapy, the use of equipment, etc. This kind of information is stored in local databases accessible via public (or proprietary) URLs and facilitated by the PICASO Platform. The data flow and browsing possibilities are shown in Figure 6.

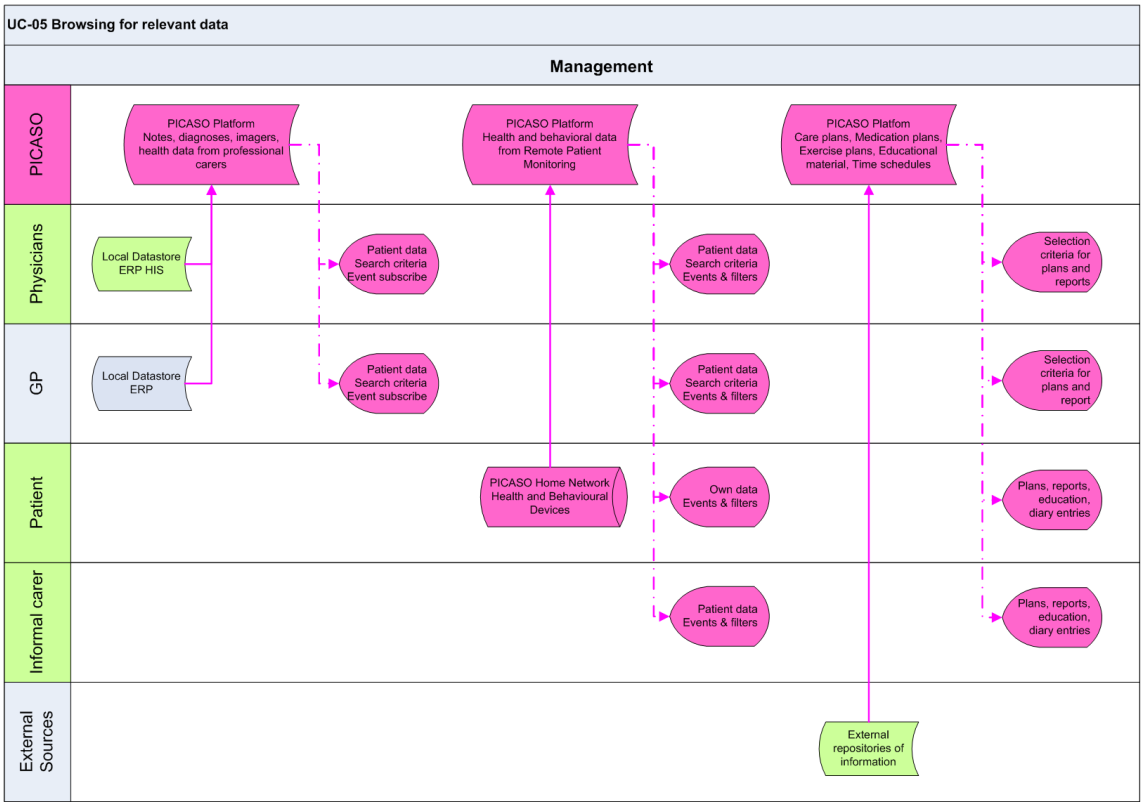

Figure 7 Browsing for relevant data

GUI

The professional actors will use the PICASO Platform to query and view patient data. They can subscribe

to internal events, such as availability of images and documents from other professional actors.

PICASO will provide a GUI user interface for the patient and the informal carers (web based or an app). The patients will use an app on phone, tablet or PC to browse their data and to receive the care and medication plans. The app will provide data, information, actions to be performed, and will give alerts when appointments are forthcoming or events have been registered. The interaction can be personalised to precisely fit the needs of the patient.

PICASO generated data

- Data presentation based upon query and selection criteria defined by Physician/GP/Patient

Physician generated data

- Definition of data selection and search criteria for patient data

GP generated data

- Definition of data selection and search criteria for patient data

Patient generated data

- Definition of data selection and search criteria for patient's own data

7.1.6 UC-6 Authentication by users to share information

UC-06	**Authentication by users to share information**
Actors	Patients, General Practitioners, The Specialist Physician, Professional Carers, Informal Carers

Problem(s) to solve
Much of the data generated in e-health solutions like PICASO are highly sensitive, personal data that must be protected from unauthorised access.

End users, whether patients or professionals, must be able to allow and disallow data access to other actors.

Description of solution
Security and privacy management will be an integral part of the PICASO solution. The solution will use Privacy by Design methodologies and incorporate both ethical, end user and legal requirements, for the latter in particular challenges related to surveillance.

The security and privacy management component will handle data traffic between other components as well as traffic between components and users, undertaking secure transmission of data, privacy compliance and authentication of users based on federated trust models.

Flexible, context and situation aware authentication and access control will be implemented in particular to support patients and non-professional carers.

Finally, the PICASO solution will implement relevant sections of the existing and emerging directives on data privacy protection and handling of health data.

Existing workflow
In the existing workflow the described problems do not exist, as data are not automatically generated or, if generated, typically not digitally shared.

Workflow with PICASO
Sharing of data in PICASO is relevant at different levels and in various contexts.

The Patient: In the framework of informed consent, the patient may opt to share all or selected data, obtained by the patient through home monitoring or otherwise, with professional actors, specifically by authorising medical specialists, the GP and professional carers. The patient also decides whether to share

data with informal carers (family and friends).

The Specialist Physician: The specialist physician may authorise other involved care professionals, e.g., other specialists and the GP, to share the patient's data.

The General Practitioner: The GP may share patient data with medical specialists and with other professionals caring for the patient, and with the patient.

The PICASO authentication process involves Shared Memory Objects, Digital IDs and tokens that must be combined to prevent unauthorised access.

The actor specifies the sender and the receiver of the data object. The sender token identifies the patient, gateway and specific sensor that captured and sent the data. There can only be one token (sender) for each data object. The recipient token is more complex, because several actors may request the same information. The principle is shown in the figure below.

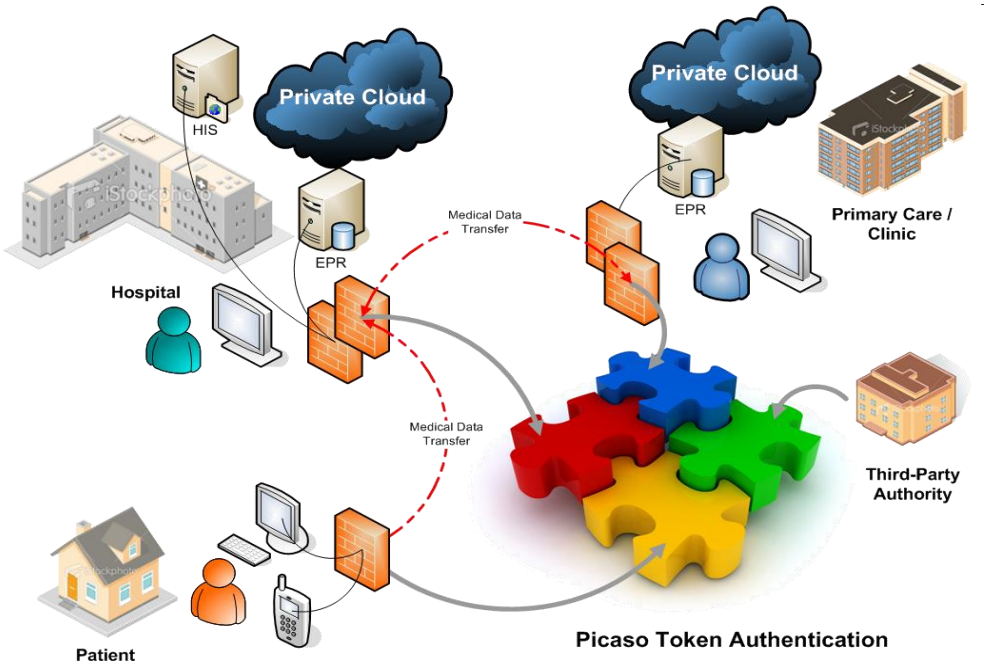

Figure 8 Authentication for data transfer

Protection of user privacy is crucial in establishing and maintaining trust between professionals and patients. It is therefore important that this technically complicated process is made transparent, particularly to the patient, to ensure that he knows when and who with he is sharing his data, and that this does not happen involuntarily or by accident.

7.2 Professional carers

Six To-Be use cases related to the professional carers' perspective have been defined and five of these are described below. The sixth use case, UC-14 Monitoring for co-morbidities and handling of incidental findings, is connected to the planned development work in second iteration and will thus be defined then.

7.2.1 UC-10 Construction care plans using narratives

UC-10	**Constructing care plans using narratives**
Actors	Speciality clinics, specialist physicians and nurses, patients and informal carers
Problem(s) to solve	

Establishing a care plan is a fundamental part of medical and social care. However, communicating the whole or parts of the care plan to other professional actors and to patients and informal carers is highly time consuming and difficult due to geographical diversity, different culture and terminology used in other care organisations, different ICT platforms, and issues of selecting the relevant part of the care plan for sharing.

The problem is therefore that in many cases, the care plan is not properly transmitted to other carers or not transmitted at all. The other professional carers as well as the patients and relatives, may thus miss or misinterpret important aspects of the care plan.

Description
The patient's care plan (care pathway) is established by the specialist clinic based on the examinations performed and with input from the other professional health carers, therapists and other carers. It must provide a clear path to the wanted medical outcomes and lead to a safe and efficient case management. The care plan is foremost created using clinical guidelines from health care authorities, health organisations, and the medical community.

However, the care plan must also adaptable to individual preferences of the involved professional carers and the clinical logistics and organisational setup specific to the carer's organisation. The care plan also needs to be individualised to the specific patient and his/her daily routines, and patients should be involved in the development of the care plan. The patient is involved through interviews and expression of needs of care.

The initial care plan is frequently updated and changed, following the development in the patient status and other conditions. Whenever the care plan is changed, it again needs to be transmitted to the other professional carers and the patient and relatives.

Existing Flow (As-Is)
Normally, the care plan is established based on multiple examinations performed as part of the diagnosis phase. The specialist physician may then determine the care plan based on whether the patient has a severe case or not. The choice of care plan is documented in the local datastore.

If the case is not severe, the patient's GP and the patient himself will be informed of the patient care plan (pathway) in writing. The plan may contain a medication plan, supplementary plans for exercise and training programmes, lifestyle and dietary changes, smoking secession and various information material and activity propositions. The patient's family may be asked to assist the patient in following the care plan.

Follow-up review/consultations with the specialist physician will be planned as part of the care plan. At the follow-up, the specialist physician will review the treatment and the medication plan and carry out an examination using questionnaires, lab tests and scans. External specialist physicians and therapist will write a resulting report and all the test results will be assessed by the specialist physician who will then decide if extra therapy is needed.

If no extra therapy is needed but there are side effects, the patient will go through steps of examination again. If no extra therapy is needed and there are no side effects, the patient will move to the care management phase.

If extra therapy is needed, the patient will be referred to, e.g., an ergo/physiotherapist. The specialist physician will assess if it has had any side effects (e.g., infections). If it has, the patient will go through the examination stages again. If not, the patient will move to the management phase.

The full normal workflows are expressed in the UDUS and UTV As-Is workflows in D3.1.

New PICASO Flow (To-Be)
PICASO provides an ICT support tool for integrating care plans across a multitude of formal and informal carers. It is based on process "narratives" that define the content and sequence of care services to be launched in order to perform clinical logistics in integrated care plans that span across a multi-actor, multi-disciplinary environment.

Integrated care plans (pathways) can be seen as an application of process management thinking to the improvement of patient healthcare. The aim is to focus on the patient's overall journey, rather than the contribution of each specialty or care function independently. Instead, all are emphasised to be working together, in the same way as a cross-functional team.

The PICASO implementation of integrated care plans requires:

- The care plan shall be easy to create, change, store, retrieve and share across different platforms.

- The care plan shall be expressed in machine readable form based on a commonly agreed taxonomy and methodology
- A visualisation tool shall be at hand for creating, viewing and sharing the care plan among the relevant actors.

In the To-Be workflow, the physician establishes the care plan by using a process flow visualisation tool called the PICASO Narratives Manager (a commercial product is shown in Figure 9 below).

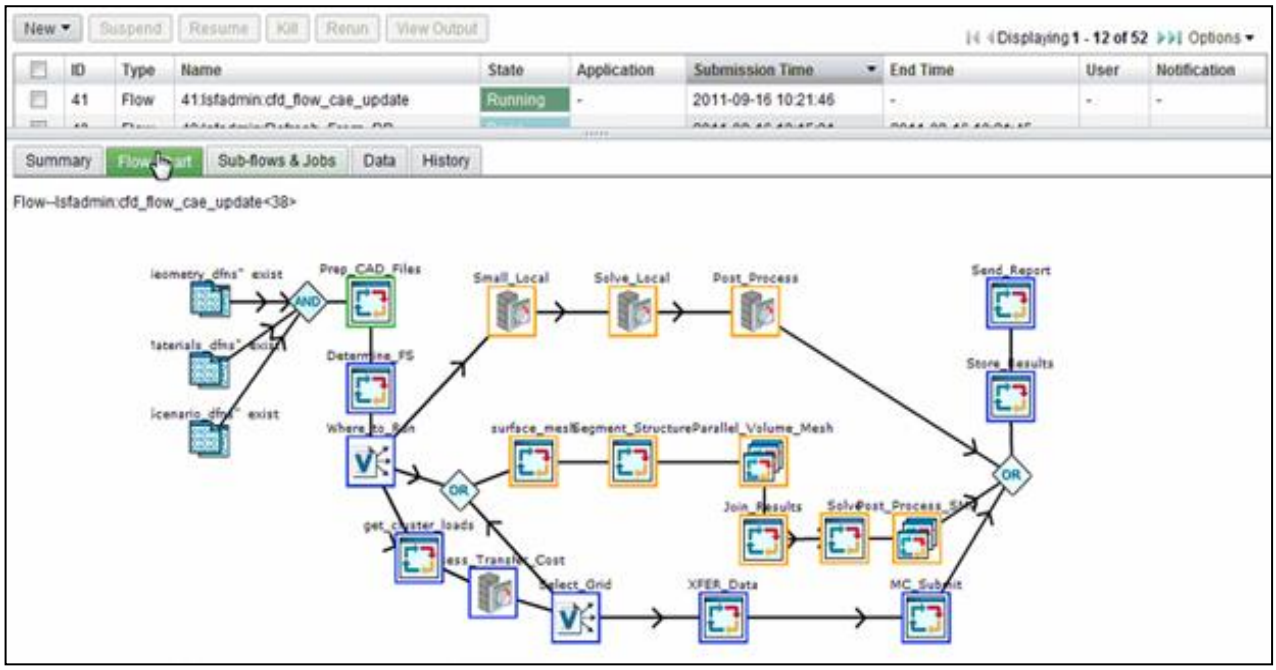

Figure 9 Care plan visualisation tools

The Narratives Manager is used to create a “Narrative” of the care plan almost in “plain language” and with a visual representation that can be easily communicated to other professional carers as well as understood by patients and informal carers. A very simple example of a medication plan is: The patient shall take levodopa/carbidopa pills, 100/25 mg 3 times a day and revisit the clinic in 3 weeks. This “Narrative” translates into a simple string of actions and decisions as shown in Figure 2.

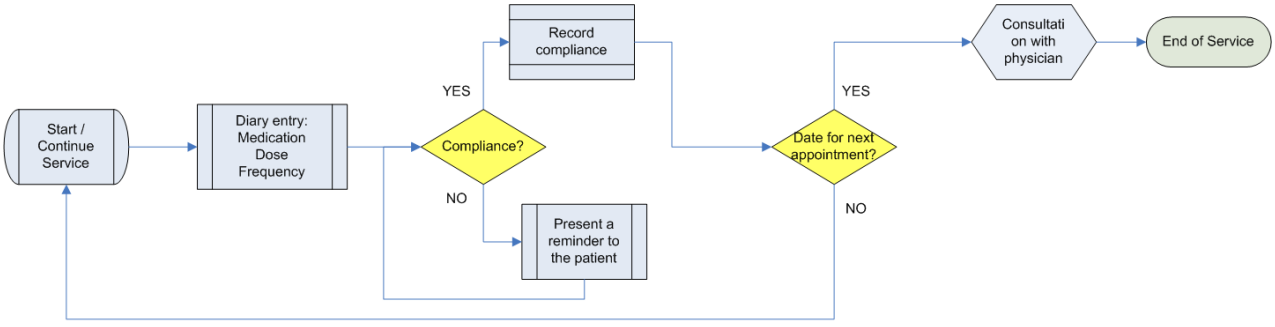

Figure 10 Simple narrative of mediation plan

The narratives are predefined in templates for the most common cases and the physician only has to select a template and adjust the various parameters (e.g., time, frequency, set points for physical values) and select the proper actors (from drop down menus). For more advanced users, the process flow can be changed by dragging and dropping new services.

The narrative may branch out in different processes based on conditions encountered in the person’s health or in the environment. Some processes may run in parallel (AND processes) while some processes may run as alternatives (OR) processes. Different actors may be involved in different processes.

Each activity in the care plan (process), each decision point, each milestone, and each actor is available in

a library and represented with an icon or image that is easily identifiable (a commercial product is shown in Figure 11 below). The physician can double-click on the icon and enter carer/patient specific data and relationships.

A set of user-specific taxonomies can be attached to each element so that the care plan can be expressed in a language that is clearly understood by all involved actors. For example, the history of the patient is called “medical history” or “case history” or “anamnesis” or even abbreviated in different parts of the care system.

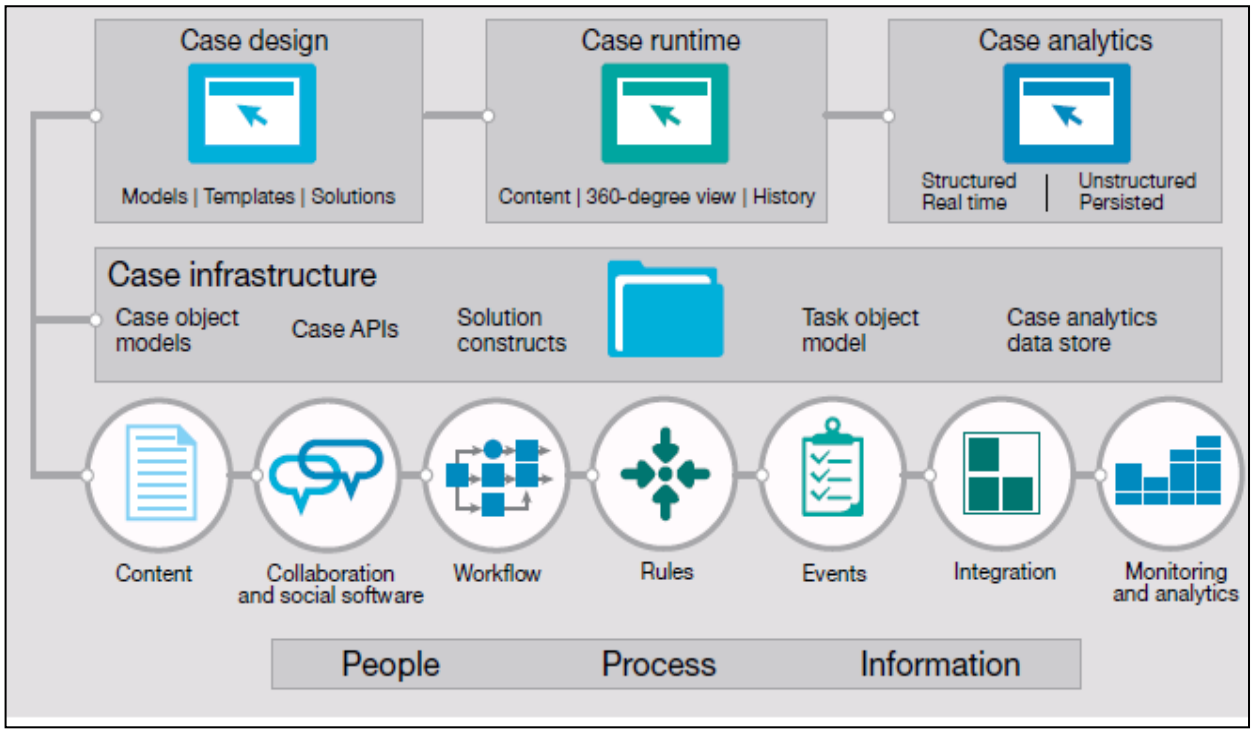

Figure 11 Care plan visualisation tools

After completing the narration of the care plan, the physician saves it in machine readable form so that it is portable to other clinical logistics systems. Further, the physician can choose to save the care plan in PDF format including the visual representation and the content of each of the nodes.

The machine readable representation can now be deployed to the Service Orchestration subset for run-time execution on the PICASO Platform. This will enable real-time execution at the patient level and provide event monitoring and handling for intervention and decision support for the professional carers.

Event handling is one of the driving elements in performing the service orchestration and is able to dynamically change, e.g., the interaction with the patient and informal carers (e.g., reminders, alarms, information and proposals). The purpose is to dynamically adapt certain parts of the care plan to the evolution of the person’s status or changing external factors based on health, behavioural and environmental monitoring and general situational awareness.

7.2.2 UC-11 Monitoring and handling of events and alerts

UC-11	**Monitoring and handling of events and alerts**
Actors	Patient, GP, speciality clinic, physicians, nurses, informal carer

Problem(s) to solve
Unforeseen or unexpected situations are happening in all parts of any healthcare system and at all times. Events need to be detected immediately, properly registered and adequately handled. Some events are critical and life threatening, some events may damage equipment or other assets, some events may cause

inefficiencies, duplication of work and are thus unnecessarily costly. Yet other events are less critical and can just be recorded and handled at an appropriate time in the future.

The problem is that today's complex and stressed healthcare systems do not have an automatic event detection and handling infrastructure in place and are thus not nearly able to detect and handle all the events that happen in the system. Most healthcare organisations have thus chosen to focus on just the critical incidents and adverse events which may be impacting the health outcome of patients.

Description
Event detection, registration and handling (intervention) are crucial elements of a well-functioning healthcare system and should be provided as a key functionality of a personalised and dynamic ICT-based integrated care platform. The ICT platform is able to simultaneously monitor a large number of processes and manage the complex interrelations between processes and events, while at the same time generate the appropriate response and human intervention needed to alleviate the consequences of an adverse event.

This use case will illustrate how PICASO should offer different forms of event processing capabilities, including event detection, registration, retrieving, filtering, transformation and propagation. The interaction with users will be illustrated, in particular in relation to physical interventions, by whom and how; what kind of decision support is needed; and how alerts and alarms shall be handled.

Events are generated throughout the PICASO platform. At every point of interaction, in every processing node and in every component, events can be generated if something does not perform as expected. Events are thus generated online and in real time.

Existing Flow (As-Is)
Most healthcare organisations focus on the critical incidents and adverse events which may be impacting the health outcome of patients. Guidelines are established for detecting and reporting unexpected adverse medical events, manual handling of events, equipment and device events, etc. Reports are often written and entered manually and stored in electronic forms in documents and databases. Intervention is often initiated manually as described in the guidelines. A notable exception from this rule is the handling of emergency response events, where calls to alarm centres are mostly handled and recorded automatically.

New PICASO Flow (To-Be)
Event handling is one of the driving elements in performing the service orchestration. Events are generated in different places in the PICASO platform to signal that some kind of action is needed.

Medical events: A medical event is typically generated as a result of a complex logic algorithm or a query performed by the PICASO platform, but can also be created by a human. For example, if a patient is not performing the required blood pressure measurements, taking the required medication and is still in bed by 10 am for three consecutive days, it can be a sign of increasing depression and an event is raised. A fall sensor activated will also raise an event. And a patient feeling ill and needing help can also activate an event. Since most medical events are critical, there is no automatic processing. Rather, the event will go directly to the responsible professional carer for intervention. (It should be noted that PICASO is NOT handling critical events in this project. All participants in the trials must be explicitly informed about this fact).

Process events: The home gateway will be able to handle event monitoring and alarm handling during periods of non-connectivity. Events are either responded to at the local level, or they are stored and processed when connectivity is re-established. A part of the care plan can be downloaded to the gateway and will be executed there autonomously. The care plan may call for certain actions to be performed by the patient (measuring data, exercise, taking medication, calling the clinic). The event detection will monitor all data flows, including data from specific sensors whose only purpose is to monitor compliance, such as pill dispensers. When the patient or informal carer deviates from the care plan within a certain margin, an event is raised and recorded. A critical event will automatically be aggregated with other data (from devices or stored) and transmitted to the appropriate call centre for intervention or decision. A less critical event may just trigger a closed loop interaction with the patient, e.g., reminders or dialogue about changes and reasons for changes). If possible, such changes will be automatically submitted to the service orchestration engine as requests for changes in care plan/pathway, subject to approval and/or adjustment by a physician. For example the patient is set to measure blood pressure every Monday before 10 am. If the patient for practical reasons changes this to every Tuesday, an event is raised that will automatically change the orchestrated care plan. If the patient changes it from once a week to once a month, the event may first trigger a request to the physician to approve to the request, it the event handling has been set up to require

such approval. Finally, if blood pressure values are over predefined limits for an entire week, an event may be raised to the physician to take control of this patient (see UC-12 Intervention strategies, definition and execution).

Resource events: If a prepared set of services cannot be executed in a planned manner, due to external incidents (e.g., a carer's intervention or inaccessibility of a service), an event is raised and recorded. The event type is then investigated and two possible actions may be performed. If it is possible to re-orchestrate the service, taking into account which services were already executed and which interventions have occurred, the service will be dynamically rescheduled. If this is not possible, the PICASO platform shall have a proper handling system that can transfer the control to the appropriate carer (see UC-12 Intervention strategies, definition and execution). Formal carers and health informatics experts will then be involved and relevant and proper decision support information will be made available for making an informed decision. For example, if a care plan calls for physical rehabilitation in the form of daily swimming exercises and the swimming facility is closed for two weeks, an event is raised. The event will be recorded and will cause the care plan to be automatically re-orchestrated with an alternative rehabilitation exercise in the form of 20 minutes on an exercise bike in a fitness centre. If this is not possible, the physiotherapist is alerted and can then decide to pause until the swimming facility is re-opened, or workflow may be changed to allow the patient to choose a different swimming facility, or change the care plan to other forms of exercises.

The PICASO platform will provide event detection and will be able to process a number of simultaneous events into creating a form of contextual situation awareness, which can be used for decision support for professional and informal carers as well as patients. A fall sensor will generate an urgent, critical event, whereas a missing weight measurement only will generate a routine event. Event control commands are transmitted as any other type of data. However, due to the time dimension (urgency) of events, the platform must be able to handle events with mixed criticality.

In the future, PICASO may be deployed in commercial setting to handle also emergency situations. In cases of critical events, an alarm shall be activated. In these cases, the event is recorded and the alarm is sent to the appropriate carer or care organisation or to an emergency response team. The transmissions recorded and when the recipient attends to the alarm, the receipt is also recorded. The recipient may assign the handling of the alarm to a main responsible person for handling the situation, and this assignment must also be recorded. When the situation is normalised, the responsible person shall report that the situation that caused the alarm has been resolved and the alarm is closed. (Again, it should be noted that PICASO is NOT handling critical event in this project and all participants in the trials shall be explicitly informed about this fact. This part of the use case is only for future commercial implementation).

Data

Events can take different forms. In PICASO the following generic types of events can occur:

- Medical events: physical parameters, well being, pains are not as expected, side effects of medication is seen / detected
- Artefact events: documents, images, reports, etc., are not in place or in a form as expected
- Resource events: persons (carers, patients, relatives, and resources) are not in place or at times as expected. Resource persons shall be easily re-assignable during service execution in case of illness and vacation.
- Process events: cares, patients, relatives are not adhering to processes as expected (compliance, exercise)
- Security events: authentication or certification is not as expected (or required)
- Monetary events: revenues, reimbursements, costs, payments are not as expected (to be a part of a future commercial deployment of PICASO platform).

Events also have a time dimension. Events can be critical (risk of loss of lives, health, money) or non-critical (inconvenient, inefficient, suboptimal) or anything in between.

Notes	N/A

7.2.3 UC-12 Intervention strategies, definition and execution

UC-12	Intervention strategies, definition and execution

Actors	Patient, GP, professional carers

Problem(s) to solve
Unforeseen or unexpected situations are happening in all parts of any healthcare system and at all times. Some events are critical and life threatening, some events may damage equipment or other assets, some events may cause inefficiencies, duplication of work and are thus unnecessarily costly. Yet other events are less critical and can just be recorded and handled at an appropriate time in the future.

However, any event will require some kind of intervention; conceived, described, planned and approved by humans in either the professional care system or in the private care space.

There is thus a need for defining intervention strategies at a much larger scale than is the case today where care plans and interventions are mostly carried out manually.

Description
In eHealth ecosystems the patient is mostly outside the physical care space of the professional healthcare system and observations and interventions must be adapted to this new realm. The carers need a better understanding of the full context of the patient's status in the particular care space in order to make the right decisions.

This use case will illustrate how PICASO users should design their intervention strategies and implement them for execution.

Events are generated throughout the PICASO platform. In every point of interaction, in every processing node and in every component, events can be generated if something does not perform as expected. Events are thus generated online and in real-time.

Interventions mean any action on behalf of a care professional, the patient or an informal carer or event the PICASO system itself, with the aim of responding to the event.

Existing Flow (As-Is)
Most health care organisations focus on the critical incidents and adverse events which may be impacting the health outcome of patients. Guidelines are established of how to detect and react to unexpected adverse medical events. In particular, a multitude of rules exists on how to document the events and the responses and interventions taken to mitigate the effect. Reports are often done and entered manually and stored in electronic forms in documents and databases and submitted to central or national repositories.

New PICASO Flow (To-Be)
Event handling is one of the driving elements in performing the service orchestration. Events are generated different places in the PICASO platform to signal that some kind of action is needed.

When an event is raised, a record of the event is inserted into the PICASO platform meta space. Events are then treated in precisely the same form as other data. With the event, a specified set of all contextual data is related to the event. Later, the examining physician or specialist can see not only the event, but also the related data that caused the event to be raised.

In the Narratives Manager, the physician will lay out the strategy for automatic handling of events and related interventions.

Further, the situation that causes the event, including all the contextual data and their relationships and set points must be included in the model. Templates will be available for the most common form of events so that the physician shall only be concerned with entering the set points that are relevant for him/her and for the patient.

Once the event is defined, a narrative is constructed around the event. First, the criticality of the event is decided and the actions caused by the event are determined. They could be anything from sending an email, sounding a bell, a pop-up on a work station screen to raising a fully blown emergency alarm. Secondly, the narrative describes how the event shall be documented and where. The parameters that trigger the event are selected as part of the event recording. In this way, the narrative expresses the chosen strategy of handling and the intervention needed in responding to events.

Finally, the physician may create further narratives for how the intervention shall be carried out. It can be a series of instructions to different recipients for manual intervention. Or it can be input to the service orchestration subset about changing the orchestration of services.

GUI
An appropriate GUI for alerting healthcare professionals and informal carers with event context and directions for intervention shall be at hand, tailored to the specific target group.

Data
The following data are required in the making of events and intervention strategies:

- Descriptions of events, their cause, context and set points
- Narratives for execution of the event monitor service.
- Narratives for how to handling the event when it is raised
- Narratives for execution interventions, either manually or automatic.

7.2.4 UC-13 Risk assessment during care plan execution

UC-13	Risk assessments during care plan execution
Actors	Physician, patient, informal carer

Problem(s) to solve
- Obtaining up-to-date and situational aware, personalized risk assessment of a patient's status
- Prediction of medium-term to long-term outcomes
- Feeding the result of the assessment to relevant formal and informal carers
- Allow formal carers to "simulate" how changes in care plans or the patient's lifestyle may affect outcomes across a patient's comorbidities

PICASO will provide innovation responding to the following three key challenges:

– Better integration of risk assessment and decision support in integrated workflows
– Inclusion of various patient data towards a personalized assessment: lifestyle, the patient's social environment, care plan and medication changes, genetic risk factors, and clinical events
– Integrated assessment models for comorbidities

Description of solutions
The clinician shall be able to set-up and configure automated risk-assessment on the "dashboard" for each of its patients. The risk assessment should provide an assessment of the patient's current situation and expected future development w.r.t. the PICASO trials (Parkinson disease, Rheumatoid Arthritis and CVD as comorbidity).

Existing Flow (As-Is)
In the UTV As-Is workflows no automated risk assessment is foreseen. There exist no tools for automated data aggregation and risk assessment. Further risk assessment methods integrating clinical, genetic, and lifestyle based risk indicators into account are not available. There are no tools available that would allow clinicians to simulate how a change in treatment plan for one medical condition might affect outcomes with regard to comorbidity.

New PICASO Flow (To-Be)
Assuming the required consent has been given the risk assessment will be updated with the most recent data available for the patient including home monitoring results and lifestyle information each time the clinician accesses the "dashboard" for the patient or upon an explicit update request. This will lead to a significantly better integration of risk assessments into clinical workflows.

The risk assessment should further provide a "simulation" feature for the clinician. This feature should allow the clinician to assess how changes to the care and medication plan, the patient's compliance, and the patient's lifestyle will affect the outcomes for one or more comorbidities. This feature could be extended on an experimental basis to address questions like: "Which parameters should be adjusted to give the best overall outcomes for the patient across several comorbidities?" Some of these more experimental assessments can involve the integration of big data capabilities (IBM Watson) as well as other innovative methods and algorithms.

An important requirement is transparency. It must be clear for the clinicians what results of a risk assessment are based on established methods (e.g. risk tables) and what results are based on methods that are experimental and part of ongoing research. Finally, the clinician should be able to access the original data of the patient on which the patient's risk assessment is based.

As an experimental feature alerts to clinicians and/or patients and informal carers can be integrated in the care plan execution. Alerts could be sent to the patient e.g. if lifestyle changes identified through home monitoring positively or negatively impact predicted outcomes. Alerts could also be sent to clinicians e.g. if changes to a medication plan by a colleague affect expected patient outcomes. It is to be understood that these features are not supposed to trigger emergency interventions of any kind. Furthermore, it should be noted that an implementation of this feature requires careful consideration of legal and ethical requirements. The technical implementation of this feature is straightforward via the Event Manager.

GUI
The professional actors will use the PICASO Data Browser/Dashboard to query and view risk assessments

PICASO Platform generated data
- Patient health data records
- Medication plan
- Exercise plan

PICASO Home Network generated data
- Patient Health data measurement and compliance reporting
- Informal carer health data measurement and compliance reporting

7.2.5 UC-15 Flexible informed consent

UC-15	**Flexible informed consent**
Actors	Patient, PICASO Trial Owner, technicians, specialist physicians, informal carers

Problem(s) to solve
Patients who are invited to participate in the PICASO trials must give their informed consent (on a paper form) before they can be enrolled. The patient must be informed of exactly which data will be monitored, collected and stored in PICASO and who has access. This is an ethical requirement and the informed consent process to be used in the trials is described in detail in D10.3 The PICASO Ethical Guidelines. The problem is that the type of data and who has access to it is not generic for all patients. For example, some patients will consent to informal carers having access to all data, some only to certain sets of data and some will not give informal carers access to any data. Overall privacy and authorisation use cases will be provided in UC-06 Authentication by users to share information.

An additional problem is that as time and the patient's condition progresses, the type of data and the level of data detail may change and additional specialists may become involved in the patient's care plan, thereby changing the content of what the patient initially consented to and in fact rendering the consent non-applicable or in fact violated. Patients may also change their mind later on and wanting to change, retract or extend to whom and what data they allow access to. The problem is thus one of *how* to ensure that the consent given initially by patients can easily be updated so that it always reflects the patients' wishes while at the same time avoiding that the patients constantly changes their mind about their consent.

This use case focus on the specific informed consent to be used in the PICASO trials. However, the requirements have equal importance for the real deployment of PICASO and thus will form part of the PICASO requirements base.

Description of solution
The PICASO system has a specific consent setting which adapts the details and extension of the consent according to a patient's needs and preferences, thus being unique for each patient. The informed consent setting is translated into a set of access rights which are attached to each type of patient data that is stored in PICASO. Specific users thus have access to specific patient data. Patients can request from the Trial Owner that their consent settings in PICASO are changed so that they can either retract or give consent to

new individuals, or they can change the level of data granularity an individual has access to via PICASO.
 	
When entering or changing informed consent information, special data entry procedures will be established that ensures that no errors have been made and that the information is consistently of high quality and reflects the written consents that the patient has given in writing. When information is entered or changed, a notification is send to the patient as receipt. The actual consent information at any time is available in the PICASO Platform where the patient and informal carers (if applicable) can access it.
 	
Existing workflow (As-Is)
No existing workflow. All informed consents today are paper based.
 	
New PICASO workflow (To-Be)
The PICASO Trial Owner will provide selected patients with detailed information about the trial (verbally and written) as described in the Informed Consent Process in D10.3. When patients have signed the paper-based informed consent form, the Trial Owner will create them as users in the PICASO system. The patient will inform the Trial Owner of who is allowed access to data and to what type of data, including the granularity of the data.
 	
Once the settings have been defined, the patient can access the settings in PICASO to verify that they are correct and request the Trial Owner to make any changes if necessary. If any changes are made, the Trial patient will receive a notification.
 	
When the technician sets up the home monitoring system at a patient's home, he can consult the consent details and then configure the authorisation settings accordingly.
 	
If a new professional carer (physician, nurse, therapist, etc.) becomes involved in the trial, the Trial Owner sends a request via PICASO to the patient to provide consent that the new professional carer has access to the patient's data. If the patient accepts the request, the consent settings in PICASO are updated accordingly and a notification of the change is sent to the patient and the new professional carer.
 	
Similarly, if the patient wishes to retract his consent to allow an informal carer access to data, change the granularity of the data an informal carer has access to, and/or add a new informal carer, the patient will request the Trial Owner to do so, and will in turn receive a notification from PICASO.
 	
If a patient withdraws from the trial, the consent settings are nullified by the Trial Owner. With respect to historic patient data, the PICASO platform will adhere to the new data protection regulation draft which foresees exceptions to the 'right to erasure' e.g. article 17(3) that states that the right to erasure will not apply to processing needed for reasons of public interest in the area of public health.
 	
Data
• Verbal data:
  o Trial information, data handling in PICASO, definition of access rights
• Written data:
  o Trial information, data handling in PICASO, trial informed consent form, definition of access rights
• Data input to PICASO:
  o Trial information, data handling in PICASO, definition of access rights.

Notes	This use case is closely related to UC-6 Authentication by users to share information

7.3 Remote patient monitoring

The six To-Be use cases related to remote patient monitoring are described in the following sub-chapters.

7.3.1 UC-20 Home monitoring for self-management

UC-20	**Home monitoring for self-management**
Actors	Patient, informal carer, physician, technician

Problem(s) to solve
Patients can be empowered to take more control of their disease and exercise better self management, if they are provided with knowledge, advice and tools to monitor the progress of their diseases better in the periods when they are out of the direct management of the clinic or GP.

Description
The patient will receive a full care plan including medication plan, exercise plans, educational material and time schedules for future visits to the clinic and the GP.

The patient receives a set of medical devices and a PICASO Home Network gateway with which he/she can measure and control vital health parameters on a daily basis while in the home or on the move.

All the received information and the measured health parameters are available to the patient by using a browser based GUI installed on the gateway.

An Event Manager monitors each measured value and alerts the patient if the values are outside limits. The Event Manager also informs and reminds the patient when it is time to measure health parameters. Also the physician has access to the patient's health parameters and can instigate their own event monitoring and intervention schemes.

Existing Flow (As-Is)
In the As-Is workflow no home monitoring platform exist and no measurements are generated or stored. At UDUS, a self-assessment scoring app has been developed, which should be part of the PICASO remote monitoring scheme.

New PICASO Flow (To-Be)
The use case is based on the monitoring scheme established by the PICASO Home Network. The physician sends the patient home with a variety of devices to monitor health, behaviour and wellbeing.

All information is accessible via the PICASO Platform and can be showed on the patient's display device. The display device can be a phone, tablet or PC. When the patient uses a medical device to measure a health parameter, the measurement is transmitted to the gateway and displayed on the patient's display device. After quality check and approval by the patient, the measured values are sent through the gateway to the local datastore via the PICASO Platform. All the measured health parameters are hence available on the patient's display device by using a browser.

The patient further receives a full care plan including medication plan, exercise plans, educational material and time schedules for future visits to the clinic and the GP. Reminders on future visits to the clinic, time for medicine intake, time for measuring health parameters can be displayed on the patient's display device.

With the PICASO Home Network the patient can display the measured health parameters stored on the PICASO Platform. Different views can be setup in order to bring the patient a complete view of current health parameters, status of health and historical view of health parameters.

An Event Manager monitors each measured value, and alerts the patient if the values are outside limits prescribed by the physician or set up by other professional carers. The Event Manager also informs and reminds the patient when it is time to measure health parameters. If the patient forgets to measure, the Event Manager gently reminds the patient again. However, it is always possible for the patient to turn this feature off.

The professional carers have access to the measured health parameters via the PICASO Platform and can instigate their own event monitoring and intervention schemes. If a measured health parameter is critical for the patient or if the patient forgets to measure, the professional carer (physician or nurse) is alerted and can guide the patient.

A technician sets up the medical devices and the PICASO Home Network in the patient's home, and instructs the patient, how to use the medical devices. The technician is also responsible for the day-to-day technical support to the patient and the professional carers.

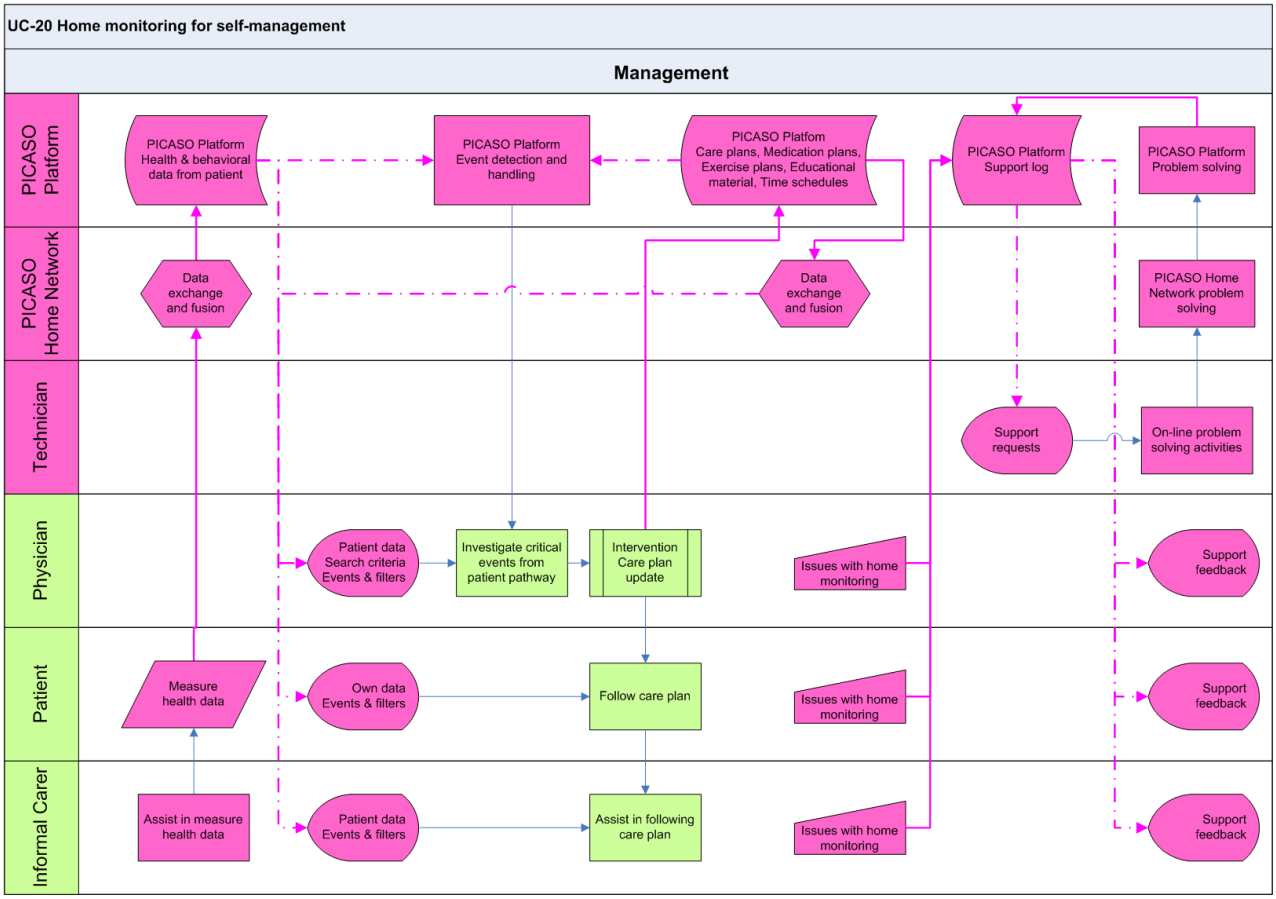

Figure 12 Home monitoring for self-management:

If a user reports a technical or functional problem with the PICASO home monitoring services, an issue ticket is created in the PICASO Support Log. The issues can all be browsed by the technical staff. A new issue raises an event that shows up on the technical teams work stations. The issues are assigned to a technical team, who can access both the general PICASO platform as well as each PICASO Home Network gateways on-line. When the issue has been resolved, the result is automatically reported to the PICASO Support Log, which again creates an event that sends a feedback message to the user that raised the issue.

GUI

The professional actors will use the PICASO Data Browser to query and view the status of the system, receive alerts, and report on how the problem was solved. The patients receive alerts and guidance's on an app, on phone, tablet or PC.

PICASO Platform generated data

- Patient health data records
- Medication plan
- Exercise plans
- Educational material
- Time schedules
- PICASO support log feedback

PICASO Home Network generated data

- Patient health and behavioural data

Physician generated data

- Support to patient regarding measured health parameters
- Verify critical health parameters with patient

- Raise issues with the home monitoring platform

Patient generated data
- Measure health data
- Raise issues with the home monitoring platform

Technician generated data
- PICASO support log
- Support to users e.g. patients, informal cares and professional carers
- Report regarding problem reported by users e.g. patients, informal cares and professional carers

7.3.2 UC-21 Handling non-connectivity of home monitoring platform

UC-21	Handling non-connectivity of home monitoring platform
Actors	Patient, Informal Carer, Physician, Technician

Problem(s) to solve
The patient has been supplied with a PICASO Home Network gateway and devices for home monitoring.

Non-connectivity between the PICASO Platform and the PICASO Home Network will occasionally happen. In this situation, the PICASO Home Network gateway loses its data connection and exchange of data is no longer possible. Non-connectivity can also be caused by a power failure on the PICASO Home Network gateway, resulting in loss of measured data.

Communication between the devices and the PICASO Home Network gateway could also be failing and the measured data could be lost.

If the patient does not follow the intended procedure for home monitoring the professional carer and maybe the informal carer shall be informed so that an issue ticket can be raised.

Description
A PICASO Home Network with gateway and devices for health monitoring and automatic transmission of measured data is installed in the patient's home. The patient also receives the full care plan including medication and exercise plans, educational material and time schedules for future visits to the clinic and the GP.

The PICASO Home Network gateway and the devices are able to communicate with the PICASO Platform 24/7. The exchange of data information between the system components must always be reliable.

However, when non-connectivity between system components occasionally happens, the PICASO Home Network gateway will have sufficient back-up procedures in place that will allow the to continue operations at a sufficient level until the connectivity has been restored.

If the expected data from the home monitoring is not received by the PICASO Platform, the professional carer and the informal carer can be informed using the PICASO Event Handling system.

Existing Flow (As-Is)
In the As-Is workflow no home monitoring platform exist and no measurements are generated or stored.

New PICASO Flow (To-Be)
The patient has received a full care plan including medication and exercise plans, educational material and time schedules for future visits to the clinic and the GP. All information is stored on the PICASO Home Network gateway and the information is accessible to the patient. Any update of the information on the PICASO Platform is automatically transmitted to the PICASO Home Network gateway.

A PICASO Home Network with gateway and devices for home monitoring are also installed in the patient's home. The installation is performed by a technician.

Non-connectivity between system components will occasionally happen, and system procedures must be in place to handle this situation.

Both the PICASO Platform and the PICASO Home Network gateway are constantly monitored by the PICASO Support Log. If a drop-out in connection occurs, an issue is raised and a warning is displayed on to the support team. A message is also displayed at the GUI with Instructions for how to solve or crate a work-around of the problem.

The PICASO Platform and the PICASO Home Network gateway automatically try to re-establish the connection. If this is not possible within a reasonable time, the PICASO gateway will inform the patient and recommend what to do, and an event will be raised to the technical team responsible for solving the problem. As long as the connection is disconnected, both the PICASO Platform and the PICASO Home Network gateway will continuously try to re-establish the connection.

During the disconnected period, the PICASO Home Network gateway will temporarily store the measurements, and when the connection is re-established, it will (re)transmit all the data.

In case of a power failure of the PICASO Home Network gateway, the PICASO Platform and the patient will be informed and an alert will be transmitted to the technician responsible for solving the problem.

If a device cannot communicate with the gateway, the patient is informed and guided what to do. The PICASO Platform will be informed and an alert will be transmitted to the technician responsible for solving the problem.

The PICASO Platform monitor the data received from the PICASO Home Network gateway, and if data is not received as expected from the gateway an alert will be transmitted to the technician responsible for solving the problem.

If it is not a technical problem but the patient not using the home monitoring system as expected, the responsible professional carer will be informed.

In case of an informal carer is involved, he/she will be informed with the same information as the patient.

All instances of exceptions must be handled and reported using the PICASO Event Handling system.

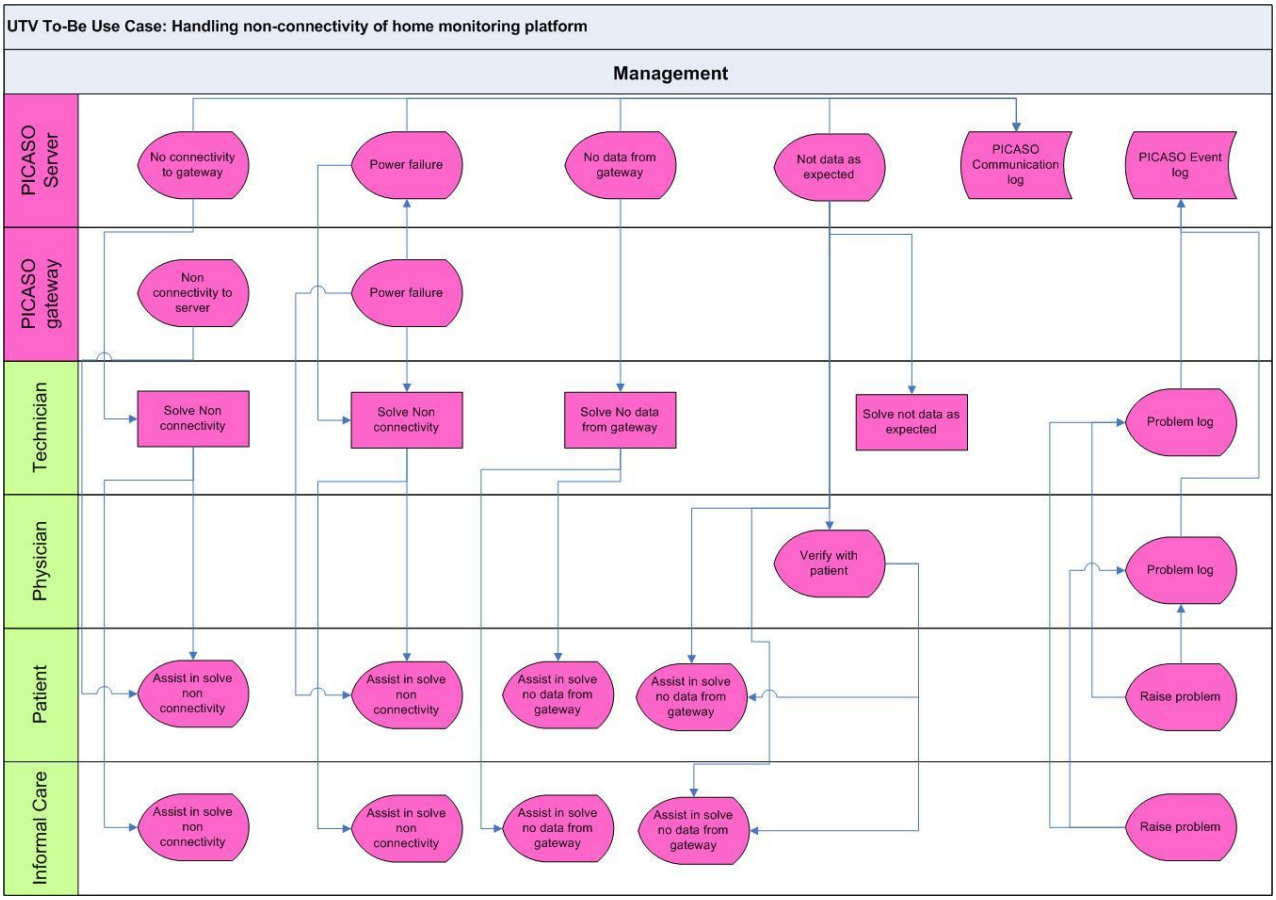

Figure 13 Handling non-connectivity of home monitoring platform:

GUI
The professional actors will use the PICASO Data Browser to query and view the status of the system, receive alerts, and report on how the problem was solved.

The patients receive alerts and guidance's on an app, on phone, tablet or PC.

PICASO Platform generated data
- No connectivity to gateway
- Power failure on gateway
- No data from gateway
- Not data as expected
- PICASO communication log

PICASO Home Network generated Data
- No connectivity to Platform
- Power failure on gateway

Technician generated data
- Report regarding solving non-connectivity
- Report regarding solving no data from gateway
- Report regarding solving data not as expected
- Report regarding problems reported from patient

Physician generated data
- Report regarding data not as expected
- Report regarding problems from patient monitoring part

Patient generated data
- Raise problem with the home monitoring platform

7.3.3 UC-22 Filtering and sorting data and events

UC-22	**Filtering and sorting of data and events**
Actors	Patient, GP, specialist physician

Problem(s) to solve
The amount of patient data and records can be very extensive - especially when the patient uses a home monitoring system - and It can be difficult and very time-consuming to manually sort data and events and find the relevant information.

Data and events needs to be immediately captured, properly registered and adequately handled. Both data and events can be critical and life threatening, some may cause inefficiencies, duplication of work and are thus unnecessarily costly. Other data and events are less critical and can just be recorded and handled at an appropriate time in the future.

The problem is the healthcare systems do not have an automatic event filtering and sorting system in place hence the physician has to manually handle all data and events. Most health care organisations have thus chosen to focus on just the critical data and events and do the filtering and sorting manually.

Description of solution
PICASO will offer different kinds of data and event filtering and sorting processing capabilities. Data from the patient's home monitoring system generate a huge amount of data and events. Also data and events will be automatically generated and captured from every point of interaction, in every processing node and

in every component, and when something does not perform as expected.

In order to ease the complexity of managing many patients while at the same time make sure that important events are properly registered, recorded and handled, the physician shall be able to filter and sort data and events according to a range of different criteria that suites the proper medical care, the established care plan, the patient and the overall care system.

The Data Management subset will thus implement a data fusion component that is responsible for retrieval of relevant patient information according to actual context for the orchestration of care plan services. In particular, steps of narrative execution and the decision support tools need very specific patient information relevant to the patient's actual context. It is the responsibility of the data fusion component to find the relevant information source within the integration platform, retrieve the information, filter, extract, summarize, and visualize context to the carers, based on a common vocabulary.

Existing Flow (As-Is)
Most health care organisations focus on identifying the critical incidents and adverse events which may be impacting the health outcome of patients. Guidelines are established of how to manually identify the most important data and events stored in documents and databases. Reports are often done on paper and entered manually and stored in electronic forms in documents and databases.

New PICASO Flow (To-Be)
Events are generated different places in the Picaso platform to signal that some kind of action is needed.
An event is typically generated as a result of a complex logic algorithm or a query performed by the PICASO platform based upon a combination of data from the patient's home monitoring platform, data record from other physicians and historical data.

A sudden event could be a fall sensor that is activated. A slowly increase in blood pressure over time could also generate an event based upon data analysis performed by PICASO and defined by the physician.

Since most medical events are critical and PICASO might generate many events, based upon data in the system and data from the home monitoring platform, the PICASO platform must filter and sort the events in order to ease the physician's workload. The physician will include in the narrative of the care plan a section on monitoring output parameters and establish the corresponding threshold and filter values that allow him/her to create the proper events. The thresholds are constructed by selecting a relevant measured or recorded value and then inserting a personal threshold value. A threshold value can be a physical value, a time value (e.g. since last event), a non-availability (value not measured, activity not recorded) or a combination of the above.

The filter and sorting of data and events must be able to distinguish between critical, less critical and routine event - all configured by the physician to the patient's individual level.

Data
In PICASO filters and sorting mechanism will be implemented on the following data and event types:

- Medical events: physical parameters, well being, pains, side effects of medication
- Artefact events: documents, images, reports, not in places or in a form not as expected
- Resource events: persons (carers, patients, relatives, resources) are not in places or at the time as expected
- Process events: cares, patients, relatives are not adhering to processes as expected (compliance, exercise)
- Security events: authentication or certification is not as expected (or required)
- Monetary events: revenues, reimbursements, costs, payments are not as expected.
- Home monitoring data from the patient
- Historical data record from other physicians and clinical experts.

7.3.4 UC-23 Medication reminders and compliance monitoring

UC-23	**Medication reminders and compliance monitoring**
Actors	Patient, informal carer, physician, other care specialists

Problem(s) to solve
Patients are prescribed different drugs depending on the diseases they are being treated for. The medication is often complex with multiple drugs to be taken several times a day. The complexity might confuse the patient and often result in the drugs not being taken according to the prescription.

Medication non-compliance can result in a significant number of acute care and nursing home admissions as well as increased number of visits to clinics and physicians.

Description
By using a medication monitoring device the patients can organize and manage their drug intake at home. The system can show reminders to take the prescribed drugs and thus help the patients to adhere to the medication plan. The system is connected through the PICASO Home Network to the PICASO Platform and the physician can thus follow the patients' compliance with the prescribed medication plan.

Existing Flow (As-Is)
The As-Is workflow does not cover medication reminders and compliance monitoring. If the patient is not following the prescribed medication plan, no one and no system will remind the patient.

New PICASO Flow (To-Be)
When a physician prescribes new medication to the patient, he/she enters this information in the patient's medication plan. The patient's medication plan is stored on the carer's local datastore and becomes accessible to others via the PICASO Platform. The PICASO Home Network application can aggregated all medication plans from different physicians into one master medication plan for the patient.

The medication monitoring device receives the medication plan from the PICASO Platform and also sends compliance information to the physicians' local datastore via the PICASO Platform.

In addition to the medication plan, the patient receives a medication monitoring device with which the patient can organize and manage drug intake at home. The medication monitoring device helps the patient to organize and keep track of his medication. When it is time for the patient to take the drug, the medication monitoring device reminds the patient to do so.

Information of the patient's intake is compared to the patient's medication plan. If the patient forgets to take the drug and ignores the reminder, an alert is raised and transmitted to the PICASO Platform. The physician or the informal carer can thus check if the patient complies with the prescribed medication plan and decide what actions should be taken, send a message to the informal carer or neighbour.

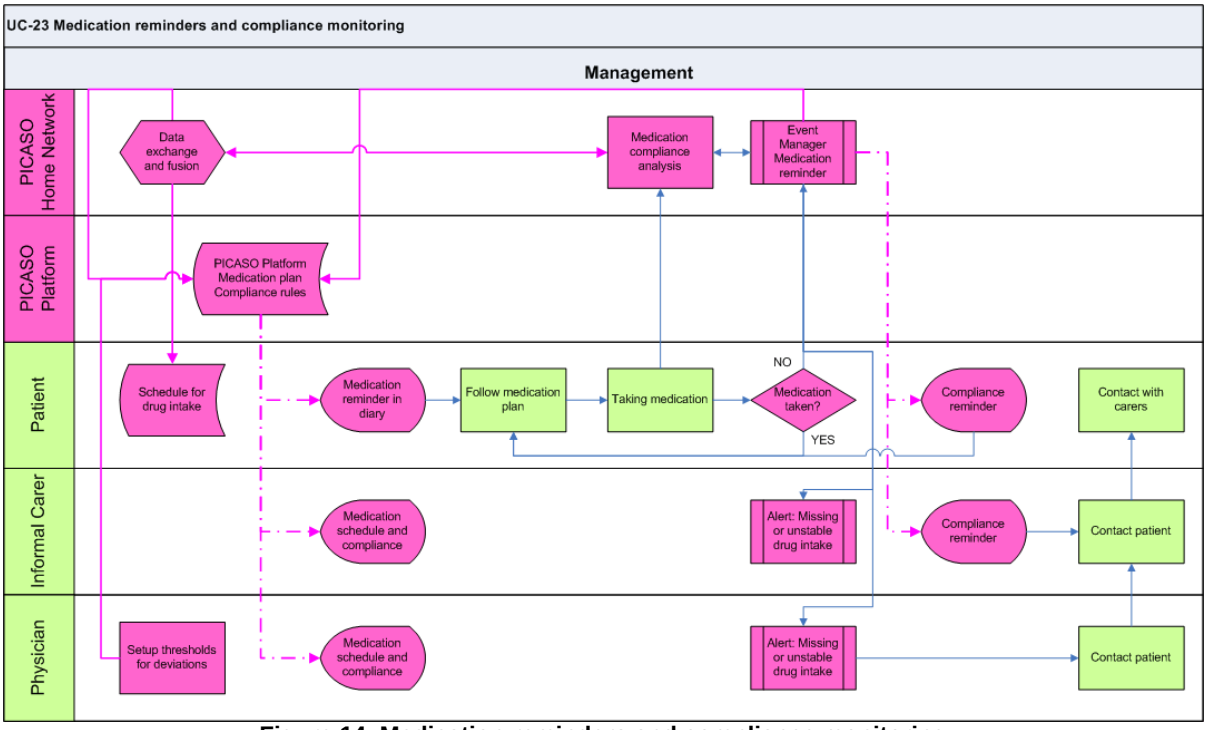

Figure 14 Medication reminders and compliance monitoring

GUI
The professional actors will use a browser to query and view information about the patient from the different actors. Privacy and authorisation use cases will be provided in UC-06 Authentication by users to share data.

PICASO will provide a GUI user interface for the patient (web based or on an app). The patients will use an app on phone, tablet or PC to browse their data and to receive the care and medication plans. The app will provide a diary with daily medication and measurements to be performed and will give alerts when medication is not taken as prescribed. All the information can be personalised to precisely fit the needs of the patient.

PICASO Platform generated data
- Medication plan
- Deliver Medication plan to Medication monitoring device
- Medication compliance analysis
- Drug intake reminder to patient
- Drug intake reminder to Informal Carer
- Drug intake reminder to Physician

PICASO Home Network generated data
- Missing drug intake
- Drug intake reminder
- Drug intake by patient

Physician generated data
- Contact patient regarding missing or unstable drug intake
- Contact informal carer regarding missing or unstable drug intake
- Setup thresholds for drugs intake deviations

Patient generated data
- Perform drug intake
- Setup thresholds for drugs intake deviations

Informal carer generated Data
- Remind patient about drug intake
- Setup thresholds for drugs intake deviations

7.3.5 UC-24 Joint care – Patients and the informal carers

UC-24	**Joint care – patients and the informal carers**
Actors	Patient, informal carers, specialist physician, GP

Problem(s) to solve
Most patients will at some point need support outside the hospital or clinic and in addition to the formal support provided by health and social services. This type of support is provided by their informal carers, usually family members. Informal carers may have a crucial role in supporting the patient in managing and living with their condition(s) and in caring for the patient at home. The level, type and timing of support provided by informal carers will differ and change as the patient's condition progresses.

The main question is how to enable better inclusion of informal carer in the patient's care plan in order to improve patient concordance and patient empowerment. The problem is that informal carers rely on either being present at consultations or on the patient relaying the information. This can often cause inconsistency

or a lack of information (which informal carers obviously will be unaware of by nature) which hinders the optimal support. Secondly, the informal carers can usually not monitor or support a patient 24/7 (be present at the home) which means that the care they can provide is very dependent on their physical presence rather than on the patient's actual real-time needs. Informal carers need a tool to support them in providing joint care in accordance with the care plan the physicians develop for the patient

Description
The GP and specialist physicians use the PICASO Platform to share the care plan and relevant case information with the patient and the informal carers as authorised by the patient. The sharing of data and access to data is always dependent on authorisation by the patient. Informal carers can be created as users of PICASO just as patients, so that they can receive relevant information (e.g. care plans, medication plan, appointment details, health data collected via the home monitoring devices etc.) on their smart phone or email via the PICASO Platform. The informal carer can also choose to receive notifications and reminders, e.g. notifications of any changes to an existing care plan or medications, reminders of consultations/appointments, medications to be taken etc.

Existing workflow (As-Is)
In the current As-Is workflow, the patient receives instructions (e.g. medication plan) in writing from the GP and the specialist physicians. Patients can involve their informal carers when needed by asking them to either accompany them to a consultation or to help them with adhering to the care plan. Informal carers provide support with the medication plan or help them with rehabilitation activities (e.g. driving them to a rehabilitation centre and/or helping to carry out a specific exercise etc.).

New PICASO workflow (To-Be)
In the To-Be workflow, the patient can request that an informal carer is also created as a user in PICASO Platform. This will be done by the GP or the specialist physician e.g. in connection with a consultation. Upon request, an informal carer can be added or deleted at a later stage (i.e. if patient's condition changes thus needing more or less informal care). The patient can authorise that the informal carer has access rights to the data (textual and images) and information the patient receives from the GP/ specialist physician via the PICASO Platform. If plans or any other relevant information are updated, the informal carer and the patient can receive a notification via email and/or text message depending on their preferred setting.

For home monitoring data, the GP/ specialist physician defines a series of thresholds for each parameter and the PICASO Event Handling system activates a notification system if the values are outside the allowed bands. Notifications for non-activity (if no data is collected) can also be set.

The informal carer can access the patient's data that is collected at home via the PICASO system and choose to receive alerts if the data is outside the thresholds defined by the GP/Specialists, or if no data is being collected.

Data

- Verbal data:
  - Contextual, symptoms, examination objectives and conclusions
- Written data:
  - Medical history, journal entering, medications used
  - Care plan, medication plan, exercise plan
  - Instructions, advice, recommendations (e.g. diet, exercise etc.)
  - Referral letters
  - Appointment details
- Image data
  - X-rays, scans, photographs
- Measured monitoring data
  - Physiological data from home monitoring (pulse, weight, ECG)
  - Behavioural data from home monitoring (compliance, exercise, water intake, falls)
  - Environmental data from home monitoring (temperature, light levels)
  - Event data (fall, non-compliance, changes)

7.3.6 Patient interaction modalities

UC-25	Patient interaction modalities
Actors	Patient, informal carer, physician, technician

Problem(s) to solve
Patients and informal carers are reliant on easy and precise interaction with the PICASO platform in the homes. Some patients may have difficulties operating an ICT based system and are not comfortable with using swipe screens or a mouse. Other patients are not technology savvy and have problems understanding how to handle the communication and what it means. Yet other patients have motor difficulties using small items such dropdown menus and other iconic means of navigation, small devices such as smart phones. Some patients have cognitive difficulties using the GUI, problems remembering where the devices are and problems understanding the instructions given to them by the system. Finally, some patients experience technophobia, fear of surveillance, stigmatisation, low threshold of acceptance concerning automation of their homes. Whatever the type of patient that will be subject to the home monitoring, it is inevitable that there will be some kind of antagonism and personal resistance to using the PICASO platform unless the platform can be truly accommodating to the individual wishes of the patients in terms of interaction.

Description of solution
A big challenge lies in the stigmatisation and stereotyping of patients from continuous monitoring, which has to be overcome by careful dialogue with the patient, a personalised setup of the system that truly addresses the fear and anxiety of the patients, and a full and transparent operation that allows the patient or their informal carers to check and understand all aspects of the monitoring. The main point of the dialogue is that monitoring shall be seen as a help for patients with emerging motor and cognitive impairment. It may be too sensitive for healthy people, but patients or informal cares fearing e.g. the severe consequences of a fall or other accident are likely to accept the help they can get to safeguard the patient and his/her active daily life and avoid further complications from their disease.

The PICASO platform should thus be able to handle a personalised mix of all possible modalities of interaction. The basic form of interaction will be based on screen interaction with a suitable GUI. However, the GUI shall respect best practice design guidelines with limited but clear means for navigation to the needed information and with means for adaptive design based on use patterns. Moreover, the GUI shall be easily adapted to language and organisational preferences (e.g. logo and graphical design). Other modalities should include natural language processing for the platform to handle users' instructions for information or actions using speech to text technologies and to convey information or instructions to users using text to speech technologies.

Further, the platform should be able to dynamically adjust the narratives of monitoring based on situational awareness. The adaptation shall be performed locally in the house by an event manager and rule engine residing on the house gateway. For example, it will allow the light to be turned on when there the room is dark or a request for a routine measurement to be postponed if the patient is still lying in the bed.

Finally, the GUI shall preferably be developed as a responsive design browser based interaction platform allowing it to be transported to different platforms such as Android, iOS and Windows. The web server should be accessible from anywhere in the house and also during periods of non-conductivity.

The development of the PICASO front-end shall thus respect the various needs and requirements that can be derived from not only the use cases, but also from usability studies performed with real patients as part of the interaction design process and complemented by the Privacy by Design methodology adopted in the development work. The requirements for user interaction shall be further detailed through interviews and discussions with patients and informal carers possibly supported by simulations.

Existing Flow (As-Is)
In the As-Is workflows no home monitoring platform exist and no measurements are generated or stored. Thus the patients will most likely never have been subject to remote monitoring and the interaction design dialogue has to reflect this status. Moreover, the project can rely on UDUS' data from a feasibility and evaluation trial that evaluated an App with diary function in routine care.

New PICASO Flow (To-Be)
The patient has received a full care plan including medication plan, exercise plans, educational material

and time schedules for future visits to the clinic and the GP. The patient then engage in a comprehensive interaction with the PICASO platform as described in UC-20 Home monitoring for self-management and in UC-23 Medication reminders and compliance monitoring. Also the informal carers' interaction is described in UC-24 Joint care – Patients and the informal carers.

Data capture and verification

Capture of physiological data requires some kind of handling by the patient, e.g. measuring weight, taking blood pressure, etc. All devices used are pre-registered with the gateway and the proper communication interface (Bluetooth, USB, Wi-Fi) is established by a technician or by the patient him/herself

Measuring data and sending them to the data store is very simple. The device is automatically connected to the gateway when used. There is no need to open an app on the gateway, because every device is registered. The app receives the data from the device and sends it directly to the data store.

In order to secure the quality of the physiological data to be sent, the corresponding data type (blood pressure, weight, etc.) can be set up to not send data automatically. Rather, the patient has to verify the values measured and manually send them to the data store. The patient can enter the app and read the newest measurement and then press approve that the data is send to the data store or is deleted.

Some patients will be using a tablet for interaction. In this case, the patient will use the touch/swipe screen for interaction based on the commonly accepted standards for the appropriate OS (Android or iOS).

If the patient has motor challenges, the interaction device may take the form of a large PC touch screen (21+ inches) where the patient has big buttons for the operations.

Figure 15 Different GUI for data capture:

In case the patient is not able to use a GUI, speech processing may be used instead. The patient is instructed to do the measurement with spoken commands generated with text-to-speech technologies on the gateway. When the measurement has been received, the values are read to the patient. The patient then answers by saying e.g. "delete" or "send", where after the gateway performs the desired action.

Text-to-speech modalities can be deployed anywhere in the interaction scheme to accommodate personal preferences of the patient. For example, the patient uses the app to verify and send blood pressure measurements, but uses voice commands and reading of values for the weight measurements, because the weight scale is physically placed in the bathroom.

Data display and analysis

The patient (and informal carers) can access and display the measured data at any time using a browser based platform called MyPICASO Health Platform. For the sake of simplicity when *capturing* data, the data collection platform and the MyPICASO display platform are two different web applications.

When the patient and informal carers wants to see stored data, the MyPICASO application allows them to select one or more data type and show them in tabular or graphical forms. If more than one data series are shown simultaneously, the time axes are synchronised. Various analysis functionalities can be assigned by the physician for the patient's better understanding of his/her values. This could be trend curves, outliers, values bands set out in the care plan, etc.

The MyPICASO application is easy to navigate and has an appealing and trustworthy layout. The different functions can be reached through large embedded widgets so that the user (patient or the informal carer) can personalise the layout as it suites them best. The MyPICASO Health Platform allows the user to see all the measured data and analyse their significance and it shows the results of the exercises that have been

carried out. It also gives access to the full care plan, the medication plan and the prescribed exercise programs. It allows reminders for measurements, medication and exercises to be established and customised Finally, it provides relevant, personalised additional information about the disease, allows the users to participate in video conferences with the professional carers and find contact information for the clinics, physicians, nurses and therapist that are responsible for the fully integrated care plan.

The MyPICASO platform also allows the physician to share the results of risk assessments tailored in a way that is transparent and understandable to the patient and the informal carer in the context of their disease management.

Figure 16 Personalised GUI for data display:

Information, recommendations, compliance monitoring and intervention

The MyPICASO platform allows the user to access educational material for self-studies of diseases, risk factors and recommended treatments. It also provides manuals and instructions for using the various devices that the patient is using.

The relevant information is located in a PICASO data store and selected (tagged) by the physician and nurses as being relevant for the patient during the construction of the care plan. The information can take the form of text documents, images, instruction videos, and hyperlinks. The information can be tagged to specific part of the care pathway. Once the chosen step in the pathway is realised, the information is downloaded and available on the patient's MyPICASO health portal.

Recommendations are extracted from guidelines, health portals or established by physicians. Recommendations are also tagged by the physician during care plan construction and will be available when relevant based on the dynamic evolution of the pathway.

Compliance can be set up by the patient, the informal carers, or the formal carers based on the list of activities or objectives expressed in the personalised care plan. When an activity such as taking medicine, exercising, or performing medication is not performed, the compliance functions can remind the patient of how to comply with the pathway. Compliance can also be reinforced through automatic reminders to the patient in case of non-achievement of objectives, such as a reduced blood pressure where compliance with smoking secession or eating habits can be reinforced.

When the health and medical status is at risk or as a safety precaution, the physician can always introduce physical intervention by a professional carer.

Information, recommendation, compliance monitoring and physical interventions are all build into narrative of the care plan and transferred to the service orchestration subset for final execution in the MyPICASO health portal (e.g. on the home gateway). The actions can be invoked in different combinations depending on the severity of the lack of progress

For example, if the blood pressure is not measured, the first response would be to urge compliance by invoking reminders either by icons on the GUI, by speech in the room, by turning on a reminder lamp or similar thing, or by sending SMS/Text or emails. The exact method of reminders is configured by the patient and the informal cares with the help of a technician. Similarly, reminders can be set for medicine and exercises, for appointments with GP and clinics, and for interaction by an informal carer.

If the measured values are consistently outside the scope of the pathway, the compliance reminders can be intensified and they can be followed by relevant information material as prescribed in the care plan.

Finally, when neither the compliance nor the information material has had the desired effect on the blood pressure, an event is raised with the responsible physician. The physician can then examine the measured data, the medication plan, and the compliance with medication and exercises. All data are residing on the patient's MyPICASO platform. Based on this, a physical intervention is planned or the patient may be called for an unplanned consultation in the clinic.

Behavioural monitoring

In behavioural monitoring (of physical activity, sitting, sleeping, doors and windows opened, air quality, lights on/off etc.) the patient or the user do not interact intentionally with the devices and infrastructure in the home after the system has been set up. The only interaction is through tactile movements and behaviour.

However, the system interact with users through the MyPICASO care platform, where formal and informal carers can monitor instantaneous behaviour as well as longer term trends in behaviour (e.g. sleeping longer, longer periods of inactivity). The behaviour is firstly monitored by logging into the MyPICASO care platform and seeing curves and aggregated data from the sensors. But also events can be generated through establishment of appropriate threshold and event generating algorithms as part of the care plan narrative. During execution of the care plan at the local gateway, the events can be generated and trigger a physical activity (turning on light or heat, staring a ventilator, sounding an alarm or sending out speech or music.

8 Conclusion

The To-Be use cases describe the envisioned PICASO enabled solutions for optimising the existing clinical workflows in the two trials for data handling and sharing between different specialists and between specialist and patients and, if applicable, their informal carers. Most of the To-Be use cases are grounded in current practices thereby indicating suggestion for ways to use PICASO to improve and optimise the current practices. However, some To-Be use cases (e.g. those related to remote patient monitoring) represent new and additional ways to collect patient data – made possible with PICASO – that can support the specialist in providing the most optimal care. The remote patient monitoring use cases are based on input from the PICASO clinical partners who have identified a number of patient health data parameters, that could be interesting and useful for them to have, and that could support their care and ultimately support patient self-management and empowerment.

Vision scenarios were created to gain better understanding of end user behaviour and interaction with PICASO services, contributing to the identification of key technological, ethical, security, business and societal drivers for definition of end user requirements.

The To-Be use cases and the scenarios will be used to elicit the initial user requirements for the PICASO platform, which will be reported in the D2.2 Initial Requirements Report. The To-Be use cases and scenarios will remain active as part of the iterative approach in the PICASO project and therefore continue to feed into the requirement engineering process in the next cycles of the project. It is possible that more To-Be use cases will be developed in the second iteration of the project in which case they will be documented in forthcoming WP2 deliverables.

9 List of Figures and Tables

9.1 Figures

9.2 Tables

10 Appendix A: UTV Workshop Agenda

Meeting Subject: Workshop PICASO Trial 2: Care Models for Management of Multi-Morbidity

Venue: Tor Vergata

Date: 19 April 2016

Chair: In-JeT

Time	Subject	Topics to be covered	Lead participant
9:00-9:30	**Arrival**	Arrival and set-up	IN-JET, FIT, UTV, UNUIT, IBM, TUK
09:30-10:00	**Welcome**	Welcome from the Dean of the Faculty of Medicine Introductions Presentation of the PICACO project & Trial 2 Desired outcomes of the meeting	Prof. Orazio Schillaci (UTV) IN-JET
10:00-10:30	**Use Case Example**	Description of a typical patient and patient pathway • Patient pathway: Management & Strategies • Clinicians involved and their role • Guidelines for care plan management and workflow ○ Multiple care plans and workflow	UTV

10:30-12:30	**Clinical Workflow**	Description of the clinical workflow from professional perspective
		• Description of existing clinical workflows
		  ○ Step by step description: what & who
		• Managing multiple care plans
		• Hand-over procedures between care systems/clinicians
		• Conflicts and constraints
		  ○ Intervention strategies for how to resolve emerging conflicts during the patient pathway
			UTV
			Neurologist
			Psychologist
			Physician
			Nurse (?)
			Cardiologist (?)

12:30-13:30	**Lunch**		
13:30-15:00	**Integrated Clinical Workflows**	Requirements for integrated care and integrated workflows • Integrated clinical workflows • Needs and uncertainties related to the execution of integrated care • Health parameters & Devices	UTV ALL
15:00-15:15	**Coffee Break**		
15:15-15:45	**The Italian Health Care System**	General overview of how the system works • Economic structures	UTV

15:45-16:15	**The Health Information System**	Interaction with the Health Information System	UNUIT
16:15-16:30	**Next steps & Close**	Summary and deciding next steps	IN-JET, ALL

11 Appendix B: UDUS Workshop Agenda

Meeting Subject: Workshop PICASO Trial 1: Cardio Vascular Disease (CVD) with Rheumatoid Arthritis (RA) - Care Models for Management of Multi-Morbidity

Venue: Policlinic of Rheumatology and Hiller Research Unit Rheumatology at the Heinrich-Heine-University.
Building: O.A.S.E (16.61), Room: Raum der Entwicklung

Date: 3 May 2016

Chair: In-JeT

Time	Subject	Topics to be covered	Lead participant
9:45	**Arrival**	Arrival and set-up	IN-JET, FIT, UDUS, IBM, TUK
10:00-10:30	**Welcome**	Welcome and introductions Presentation of the PICACO project & Trial 1 Desired outcomes of the meeting	UDUS Head of the Clinic IN-JET
10:30-11:30	**The German Health Care System**	General overview of how the system works • Policlinic of Rheumatology and Hiller Research Unit Rheumatology at the Heinrich-Heine-University (HHUD) / University Hospital of Düsseldorf (UDUS). • Economic structures • Interaction with the Health Information System & Rheumatology patient documentation system	UDUS Rheumatologists Cardiologist Nurse IT expert UDUS Health care insurance
11:30-12:30	**Use Case Example**	Description of a typical patient and patient care model • Diagnosis • Patient pathway: Management & Strategies • Clinicians involved and their role	UDUS Rheumatologists Nurse Cardiologist IT experts UDUS Health care insurance Others
12:30-13:30	**Lunch**		
13:30-15:00	**Clinical Workflow**	Description of the clinical workflow from professional perspective • Guidelines for care plan management and workflow • Hand-over procedures between care systems/clinicians • Conflicts and constraints ○ Intervention strategies for how to resolve emerging conflicts during the patient pathway	UDUS Rheumatologist Cardiologist Nurse Occupational medicine IT experts UDUS Health care insurance Others
15:00-15:15	**Coffee Break**		
15:15-16:30	**Requirements Discussion**	Requirements for improving integrated care • Needs and uncertainties related to the execution of integrated care • Health parameters and devices	IN-JET, FIT, UDUS, IBM, TUK
16:30	**Close**		

12 Appendix C

A workflow is a model to represent real work. A workflow may thus be seen as any abstraction of real work, segregated in work elements, work split or other types of ordering. Workflows are procedures established with the aim of achieving certain objectives within an application. They can be personalised through parameterisation thus adapting to the needs of any user (patient, healthcare professional, etc.).

Workflows can be recursive, so that one workflow may encompass other (typically more simple and standardised) workflows, each of which can have an independent life in another context.

Workflows may contain complex business logic or include stubs to very complex models and decision support systems used to identify and select appropriate and optimised solutions in highly complex contexts.

Workflow elements

Workflow elements are simple, standardised activities or business processes that typically are used (and reused) to build more comprehensive and complex workflows. Workflow elements are often re-occurring in several forms within a workflow and may be re-used across a wide variety of workflows. Workflow elements may contain business logic to identify and select solutions based on simple business rules involving several objects.

Workflow actions

Workflow activities are construed by a series of Workflow actions. These are very simplified, linear processes acting on a limited number of objects. Workflow actions do not contain business logic because any business logic is handled at the workflow element level. Likewise, workflow actions cannot be recursive. Recursive action is also handled at the workflow element or workflow level.

Workflow symbols

Workflows and workflow elements are described using standardised symbols. Basic symbols to be used to describe various workflows are the following:

Figure 17: Workflow symbols