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# Methodological framework for the management of neck and low back pain

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### Abstract

This document describes the approach of Back-UP for neck and back pain, based on end-user case scenarios, considering the present medical, occupational and regulatory conditions. The clinical scenario, return to work, and self-management of pain are considered. For each scenario this document describes the current workflows and bottlenecks, and the targets and features of Back-UP that will help to address them.

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## Executive summary

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Back-UP is conceived as a cloud computing platform oriented to three potential end-user profiles: patients of nonspecific neck and low back pain (NLBP), clinicians, and employers (company and insurance occupational managers). Users will interact with the system via a computer with a web browser or a mobile app, focusing on a different stage of the NLBP course (pain onset, rehabilitation, and return to work) depending on their role. This document describes how Back-UP approaches the management of NLBP, based on the three end-user cases: the clinical scenario, return to work, and self-management of health.

In the clinical end-user case, the main issue is the often arbitrary and inconsistent decision-making about treatment related to the non-specific nature of the disease, the variety of clinical procedures in different contexts, and lack of information about factors that may support appropriate different treatment decisions. Thus, in this context, Back-UP will be a useful stratification tool as it will provide prognostic information for the individual, designed to support treatment decisions based on objective, scientific evidence, as well as facilitating interoperability, coordination and consistency between the multiple clinicians that may participate in a patient's management.

With respect to return to work (RTW) we have considered two intervention sub-scenarios: the preparation for RTW during sickness absence, and health provision at the workplace designed to decrease the risk of recurrence and provide care for the worker's health. Back-UP will give support for a multidisciplinary approach to facilitate an early RTW, and the adoption of tailored interventions at the workplace, based on the individual needs of the worker, and the data that has been gathered during the whole process.

The self-management end-user case will be supported by selfBACK, a technology based support system for patients developed in the homonymous project (<http://www.selfback.eu>), delivered as a smartphone app along with a personal activity monitor, which provides effective advice on physical activity and exercise, and educates the patient on self-management of low back pain. The selfBACK system will also link data back into the Back-UP system, in order to extend and enrich our data models.

Since Back-UP will deal with health data, special care has been put in order to comply with the ethical and legal principles of privacy protection and compliance of the General Data Protection Regulation (GDPR). The patient that provides the data will be its owner, and will have complete control of it. Part of the protection is the access rights that different user profiles will have to patient data. This is a specially sensitive issue in the context of the workplace, since health is improved by personalised interventions that take into account the specific conditions and needs of the employee, but at the same time the employee's health must be kept confidential and undisclosed to protect the fundamental rights of workers.

These three end-user cases are illustrated with the story of "Anita", a worker who suffers low back pain and goes through primary healthcare and rehabilitation with the support of Back-UP, which facilitates an early restoration of her normal daily activity, and a safe return to work.

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## List of abbreviations

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CBR	Case-based reasoning
DSS	Decision support system
EU	European Union
FCE	Functional capacity evaluation
GDPR	General Data Protection Regulation
GP	General practitioner
HTTPS	Hyper Text Transfer Protocol Secure
LBP	Low back pain
NLBP	Neck and low back pain
OHS	Occupational health services
QoL	Quality of life
RTW	Return to work
SSL	Secure Sockets Layer
WP	Work package

## 1. Introduction

---

The aim of the Back-UP project is to develop a technological platform with prognostic models to support more effective and efficient management of neck and low back pain (NLBP), based on the digital representation of multidimensional clinical information, and *in-silico* assessments of possible interventions.

This document describes how Back-UP approaches the management of NLBP, based on the three main end-user cases that have been considered in the project: the clinical treatment of the patient that seeks healthcare (cf. chapter 2), the return to work of a patient who has been off work due to NLBP (ch. 3), and the self-management of health (ch. 4). Finally, chapter 5 shows an integrated case story that illustrates the interactions of users with the platform through the whole process.

The description of those end-user cases is meant to provide the general audience with a general vision of how Back-UP will operate and in what terms it will improve the current workflows of NLBP management. Moreover, for the project partners this document will be the basis of the technical requirements that will guide the development of the platform.

The contents of this document have been obtained by the collaboration of the Back-UP Consortium during the first months of the project, integrating the knowledge of partners with experience in different domains (primary and occupational healthcare, insurance, rehabilitation, psychology, etc.). The three chapters that describe each end-user case follow a common structure, starting with a description of the current work flows in usual practice, and an analysis of the main issues and bottlenecks that may be found. Those issues lead to a list of targets that have been defined for Back-UP, and a description of the main features of the platform that will be developed to meet such targets, in terms of data that will be managed, expected outcomes, interventions that will be considered, and models based on scientific evidence that will be used.

The method that has been used to elaborate the integrated story in the final chapter is the “Personas” method (Randolph, 2004). These *personas* or user models are focused on activities, attitudes, motivations and skills of users, and help to understand their needs. They are integrated within use cases and scenarios, describing the sequence of interactions that take place between external actors and the system.

With the description of end-user cases we have defined a conceptual model of Back-UP: the model that stakeholders and users of the system have of the system itself, and will be used to guide developers in the design process. At this stage, interactions are only described in a high level, which is needed to understand the business logic of the interactions, so that we can focus on satisfying the business goal of the system.

## 2. Clinical end-user case

### 2.1. Description of the work flow

The workflows in NLBP healthcare are very varied, because of diversity in national healthcare provider systems, and diversity of processes even within the same national system. For instance, depending on the starting point of pain (work-related or non-work-related illness, traffic accident, etc.), the patient may go to an emergency department, their family doctor, a physiotherapist, chiropractor, osteopath, manual therapist, company doctor, or an occupational health clinician. In many cases, the patient has different options and the choice is made rather arbitrarily.

Taking into account such diversity of healthcare options, a generalisation of the workflow is the following (Figure 1).

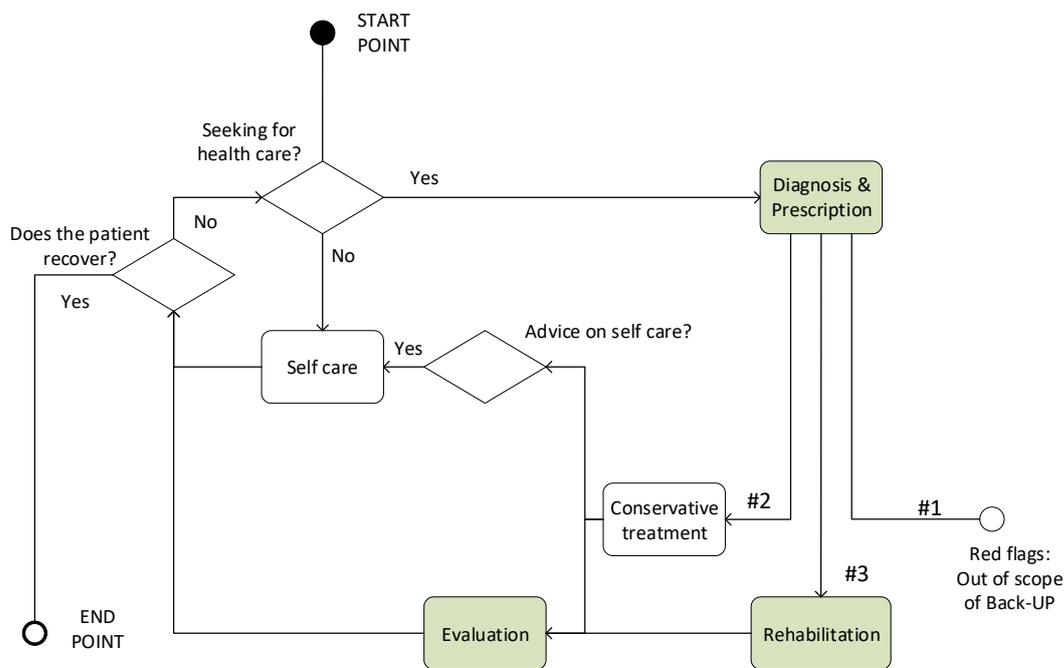


Figure 1. Simplified work flow of NLBP. The stages in coloured boxes may be supported by the technology of Back-UP (see the appendices). Numbered trajectories after diagnosis and prescription are referred to in the text.

At the starting point, patients have a choice whether to self-manage their symptoms or to seek professional healthcare, visiting a first contact clinician such as their family doctor or chiropractor.

Clinicians typically take a subjective history including an assessment of potential serious pathology (red flags) that might require urgent medical attention and further investigation, e.g. medical imaging (trajectory #1 in the figure). However, **cases with red flags are rare and will be out of the scope of Back-UP, which will concentrate on the vast majority of cases with non-specific neck and low back pain.**

For the majority of patients, a conservative care plan is prescribed, consisting of a wide choice of possible treatments such as pain medication or exercise, which can be accompanied by advice and education on self-care (#2). The outcomes of the plan are evaluated, with possible iterations depending on the level of improvement.

And yet another possibility is that the patient is referred to specialised physical therapists, psychologists or social workers to receive a specific rehabilitation plan (#3). The first-line management of NLBP remains a challenge, with suboptimal results common and a wide variation in clinician decision-making. Part of the difficulty is the wide heterogeneity in this group of patients making the personalisation of treatment important, but often difficult in busy clinics.

The decision on what best fits the patient with non-specific NLBP may be guided by the medical history, including questions to risk factors that may influence the recovery process and the patient's prognosis. These risk factors can be assessed through general clinical questioning following the clinicians' intuition or in combination with a structured prognostic risk assessment tool such as the Orebro or STarT Back Tools. In addition, clinicians can use a battery of clinical test to evaluate patient symptoms and its impact such as their pain severity, pain-related disability, quality of life, performance on physical capacity tests, and assessment of yellow flags (e.g. fear of pain or movement, catastrophising, psychological distress, and other vulnerability factors). In some contexts other risk factors are also assessed, like "blue flags" related to workplace factors, or "black flags" related to insurance and economic compensation.

Regardless of whether formal tools are used, clinicians are still responsible for the treatment decisions made, which are typically not only influenced by patient information but also by the clinician's own preferences, experiences and the treatment options available to the patient. It is relevant to note that treatment decisions are frequently revised in some settings following further assessments of whether the patient is progressing as expected. The timing of re-assessments is very dependent on the culture and processes within different national healthcare systems, and the clinical setting (e.g. private insurance vs. public healthcare). There may also be differences according to the payer of the patient's healthcare (e.g. a shift between health providers, for instance the case of a worker that received a medical certificate can be transferred to a company doctor or a mutual insurance company, depending on the national health system). In some cases, that transfer may imply changes in the resources involved for treatment and revision periods, and even among public healthcare the clinical pathways for NLBP differ substantially across the EU. It is therefore not uncommon for these patients to feel confused or to find navigation of the healthcare system difficult.

## 2.2. Main issues and bottlenecks

One of the major challenges in this clinical scenario is the often arbitrary and inconsistent decision-making, related to: (a) the non-specific nature of the problem and inherent diagnostic uncertainty, which leads to decisions often guided by idiosyncratic criteria of the care providers; (b) variety of procedures and priorities of the different care structures, such that small differences in the context of the patient (e.g. whether the starting point is work or non-work related) may yield very different courses; and (c) lack of information about the

factors that may support appropriate treatment decisions, and the time or logistics to acquire and process that information.

When the patients go through different phases of the clinical pathway, there is often a disconnection and weakness in communication across these clinical transition points or a breakdown in information systems that fail to transfer appropriate patient data, which further increases the inconsistency in the care provided, sometimes even for the same patient.

Furthermore, some assessment or treatment procedures are expensive and have restrictions which apply. Waiting times can be long, and these delays can lead to time and resources being unnecessarily wasted both by the patients, their employers and healthcare. All of this impacts on the efficacy of the care and the motivation and participation of the patients.

### 2.3. Targets of Back-UP

- Interoperability between different systems and users, to facilitate coordination and avoid inconsistent processes.
- Facilitate shared decision making when different professionals are involved in the same or different phases of the process.
- Facilitate gathering and processing information to support tailored decisions based on objective, scientific evidence.
- Provide prognostic information for the individual based on data gathered by the system
- Dynamic intervention models, which can be adapted according to the progress of the patient.
- Monitor the patient to obtain data in shorter periods, which may help to make faster decisions.
- Give economic information that encourage cost-effective decision making.

### 2.4. Features

#### 2.4.1. Data portability and privacy protection

There is no single solution that may be used by care providers to share information with patients directly or with each other. Data protection regulations impose restrictions to such information sharing, which may be further increased by national and institutional policies, and by the diversity of technology used by different countries, healthcare systems, company, etc. The variety of stakeholders involved in healthcare across and within countries accentuates this problem.

However, as long as the data are provided by the patients, directly or indirectly (e.g. by monitoring, a physical test, etc.), the GDPR enforces the care providers to facilitate their portability. Back-UP will support such portability. Patients must be registered in Back-UP with personal accounts, and all data that is registered by care providers or patients themselves will be linked to their accounts, such that the data will be owned by the patients, and always

under their control. If a patient is referred to another care provider, the new clinician will have access to the previously collected data upon agreed portability.

#### 2.4.2. Patient data and measures

Back-UP will register patient data necessary to verify the identity of the user, and for which there is evidence that may influence the patient trajectory. The definitive list of data will be defined during by the systematic reviews performed during the course of the project.

Part of those data will be descriptive characteristics of the user like the following, which are risk factors for chronicity or recurrence of NLBP (Hancock et al., 2015; Kim, Wiest, Clark, Cook, & Horn, 2018; McLean, May, Klaber-Moffett, Sharp, & Gardiner, 2010; Nilsen, Holtermann, & Mork, 2011):

- Sex
- Age
- Educational attainment
- Body mass index
- Employment status
- Habits (e.g. smoking)

In addition, the portal may be used to collect and show different measurements belonging to the categories presented in Table 1, including time stamps.

*Table 1. Examples of measurements that can be used by Back-UP in the clinical end-user case.*

Category	Example measures (to be decided)
Case history	Events (e.g. onset of pain, accident, etc.)
Activity	Daily time walking, doing exercise (monitored through sensors). Structured subjective data, e.g. IPAQ. Sleep time
Health/QoL*	SF-36, PSEQ, HRQOL
Pain locations	Body map with graded pain levels (shoulder, neck, upper back, low back, legs, arms)
Pain scales*	VAS, Quebec, Roland-Morris, painDETECT, NRS, McGill (MPQ)
Disability*	Oswestry (ODI), PDI, NDI, NPQ
Cognitive/behavioural scales*	Tampa scale, Fear of Pain, Pain Catastrophising
Physical tests*	ROM, Flex-relax, Ned/IBV
Psychological tests*	alAT
Biomarkers	Glycans (e.g. ICG)

(\*) To be selected after systematic review in WP2, 3 and 4

Given the high dimensionality of the data base, the interface will need different methods to sort and search the available measures. For this the system will define the priority that users can manage. That prioritisation will be defined by the following criteria:

- Professional profile (e.g. general practitioner, rehabilitation physician, chiropractor...). The tools that are usually available for each professional will be

taken into account, such that only the measures that are feasible for them to upload will be shown.

- Selected interventions (see below). Some measures may be associated to specific interventions.
- Sensitivity analysis. New measures are expected to increase the likelihood of estimates, but the level of this increment will be different for each measure at each time. Simulations with different values for each measure may be used to determine what measures are worthier.

In addition, there may be quantitative criteria that the users may use to sort and re-prioritise the measures, like the estimated cost of taking them.

### **2.4.3. Interventions**

There will be a list of available interventions at different phases, which will be populated after the systematic review performed in the WP4 (intervention and prevention measures). The interventions may also receive a personalised level of prioritisation, or be recommended taking into account the measures, thanks to some models implemented in Back-UP.

The users may select and set up those interventions (starting and end points). The active selection is expected to behave as modifiers in the prioritisation criteria for measurements, or in the results of the models (see below).

### **2.4.4. Outcomes**

The models (see below) will give estimates of the following outcomes for the clinicians:

- Level of pain intensity or related disability, in the next 3/6/9/12 weeks, in one or various of the scales defined in section 2.4.2.
- Risk of chronicity and/or recurrence within 12 months.
- Difficulty in performing daily living activities, in relative terms with respect to the normality of people of the same sex and age.

Costs will not be shown as a direct outcome, but estimates of indirect costs due to each of the outcomes may be calculated. A summary of costs, including these and the direct costs of measures and interventions, may be shown in a separate chart (but not aggregated in a single figure, since they may be hardly comparable).

Each outcome will be estimated with a defined degree of uncertainty. Such uncertainty must also be displayed, either as dispersion value, confidence interval, or another appropriate statistic.

### **2.4.5. Models**

According to the current data and studies, the following relations are expected to be computable:

- Relations that map pain locations, disability and cognitive measures to recommended interventions (based on STarT Back).

- Trajectories of pain intensity and disability.
- Risk ratios (chronicity, recurrence) defined from measures associated to psychosocial factors - yellow flags.
- Odd ratios to adjust risk of chronicity from blood samples (obtained from PainOmics studies).
- Risk ratios of sick leave and time of sickness absence defined from patient and work profile, and physical measures/tests.
- Relations between physical tests plus psychosocial factors and functionality/difficulty of performing daily living activities.
- Odd ratios to adjust uncertainty values from psychological tests that determine possible response bias (model defined after study with aIAT).

### 3. Return to work end-user case (RTW)

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#### 3.1. Description of the work flow

In the majority of cases NLBP progresses such that there is a point of improvement in which the patient returns to normal daily activities —including work, in case of sick leave. Such restoration of normal activity is not only a desired endpoint, but also an advocated measure that favours a faster improvement, if the appropriate safeguards are considered. For that reason, RTW should not be considered a scenario that is fully separated from the clinical end-user case, but a process that can partially overlap with the treatment received by healthcare.

Therefore, RTW is presented with two subcases: in the former (“Before return to work”) the overlap is higher, such that the users may be the same profiles as in the clinical case, although with a more specific objective of facilitating RTW; in the latter (“After return to work”) the patient is already in the workplace, and the users of Back-UP are more related to the employee’s context.

##### 3.1.1. Before Return to Work

RTW may be used to hasten the process, and facilitate an early integration in the work place (Brendbekken et al., 2017). In an ideal situation, RTW follows a multidisciplinary approach involving the perspective of physicians, nurses, psychologists, physiotherapists, occupational therapists, and others. The process starts with the assessment of diverse conditions of the worker and working and social context:

- Conditions of the worker: general wellbeing (former and present health, sleep, physical activity, social participation), assessment of musculoskeletal problems and work capacity for the designated duties in the work place, and attitudes and beliefs towards pain and working with pain.
- Conditions of the work place and its context: physical and mental demands, stress, relations, and participation. This includes job role (e.g. sedentary, physical,

repetitive tasks, vibrations, etc.), and social context (collegial relations, challenges, satisfaction, sickness absence policies, etc.).

Then follows an assessment of risks due to issues or conflicts between work place and worker conditions, barriers to work participation, maintaining factors of pain problems (e.g. inactivity, anxiety or low mood) and other issues. This assessment is done first by the multidisciplinary team, and then in a meeting with the patient, in order to make an agreed action plan.

That action plan may be composed of different interventions prior and during reincorporation to the work place, typically including fear avoidance programs and physical activity. There are some situations, specially for settings with high physical and cognitive loads, where functional capacity evaluation (FCE) is used to evaluate the physical capabilities of the workers relative to the demands the work place. This approach is mostly introduced in the USA, Canada, and Australia. Within Europe, it is used in countries such as Switzerland, Germany and the Netherlands (Wind, Goutteborge, Kuijer, Sluiter, & Frings-Dresen, 2006).

### **3.1.2. After Return to Work**

RTW is a milestone, but does not necessarily mean full recovery. In many cases there is still a tolerable degree of pain or problems derived from it, including some loss of capacity or performance in the work place. Depending on insurance provisions, disability claims may be economically compensated to the worker as a fraction of his or her earnings.

Health provision at the work place comes from occupational health services (OHS). We can distinguish between “public” vs. “corporate” OHS, depending on the level of responsibility and control that employers have on their administration. Public OHS are provided by national, regional or municipal health systems, to part of or all workers in countries like Finland, Italy, Luxembourg or the United Kingdom; but they are often complemented by corporate OHS paid by the employers, which are the unique option in many other countries (HOPE, 2000).

In both cases, OHS can provide work-related interventions like adaptation of tasks, equipment, work schedules and training programs. Public OHS are also in the position of providing integrated care interventions which combine such workplace interventions with usual care, and individually graded activity, based on the patient’s functional capacity (Lambeek, Mechelen, Knol, Loisel, & Anema, 2010).

On the other hand, corporate OHS that report to the employers may have restricted access to health data of individual workers to protect their privacy and fundamental rights, and avoid discrimination (De Hert & Lammerant, 2013). That limitation constrains the adoption of measures based on previous illness and trajectories, including personalised interventions, such that the programs implemented in the workplace in those cases are often limited to general actions to reduce risks, where personalisation is reduced to work profiles.

## **3.2. Main issues and bottlenecks**

One of the main issues is the challenge of applying the advocated multidisciplinary approach for favouring early RTW. Mature frameworks for RTW, targeting all workers and valuing early interventions and individualised approaches are limited to the northern countries of the EU

(Figure 2). Some other countries have legal and institutional frameworks, but lack of coordination between actors.

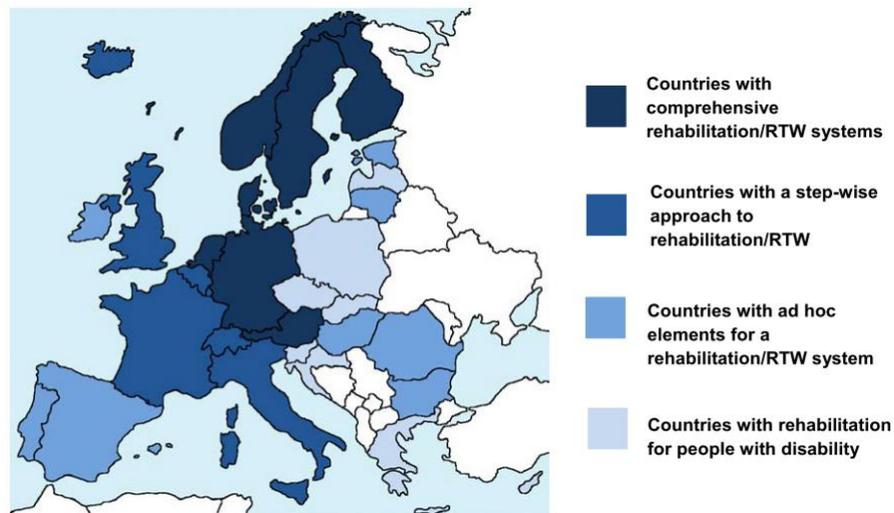


Figure 2. Four types of national profiles based on approaches to rehabilitation and RTW (Belin, Dupont, Oulès, Kuipers, & Fries-Tersch, 2016).

In many cases there is also a disconnection between the information shared by OHS and the stakeholders involved in patient care during sickness absence. This problem is due to their belonging to different institutions, and aggravated by regulatory constraints for sharing information. The privacy protection for this context in the context of the EU has been studied by De Hert and Lammerant (2013): in some countries the employer (and therefore the OHS that report to them) may process medical information linked to legitimate concerns, which are mostly related to recruitment (e.g. evaluate fitness to do the job, risk prevention, etc.), and even in those cases the rights of the employer to survey the applicant’s health conditions are limited to prevent discrimination. During sick leave the employer has the right to be reported on the fitness to work of the employee and the possible duration of inability. During the employment relationship, medical examination is normally only obligatory for the same reasons and under the same circumstances as in recruitment. In general, the processing of medical data has to take place under the supervision of a medical professional, who is under a confidentiality duty, and this physician can only report the conclusions with respect to fitness to work, and not give information that may harm the privacy of the worker or lead to discriminatory actions.

Another issue is the idiosyncrasy of occupational sectors and individual companies within sectors. Employers are obliged to protect their employees’ health and prevent risks, but individualised occupational interventions are not generally compulsory beyond ergonomic adaptations for certain incapacities. So the adoption of the measures described above mainly depends on organisational policies. Many small companies do not have resources or adequate structure to implement them.

Related to both factors, there is often lack of awareness and engagement of employers. Even in the case of companies that might have the possibility to invest in personalised occupational

interventions for RTW, the benefits of such actions are difficult to measure, and that hinders decision-making in that direction.

### 3.3. Targets of Back-UP

- Favour a multidisciplinary approach, taking into account physical, mental, and social aspects related to RTW.
- General scope, which provides utility to diverse occupational sectors, and also to healthcare frameworks with and without integrated RTW policies.
- Facilitate personalised interventions during the full course of RTW, including the actions that may be done by OHS.
- Protect the privacy of workers, providing to employers and corporate OHS only the health-related data that is linked to legitimate interest of the employer, in order to improve the worker's health and safety.
- Improve knowledge and awareness of employers of the interventions that can be done, tools and facilities, and individual and organisational benefits.

### 3.4. Features

#### 3.4.1. Data portability and privacy protection

The general principles defined for the clinical scenario (§2.4.1) are applied, but with a higher privacy bar. Clinicians involved in RTW will have access rights equivalent to those of the clinical case, assuming that they will obey their obligation to keep personal health data undisclosed. There will be also a non-clinical profile that may also participate in OHS tasks, like occupational engineers or technicians that evaluate the workplace of the person that has returned to work. That “technical” profile will not have access to patient health records.

#### 3.4.2. Data and measures

The information used by Back-UP for RTW models can be divided between data of worker- and workplace-related data. Worker data includes the same items of the user profile that were defined in the clinical end-user case (§2.4.2), plus further details that may be used to personalise the interventions:

- **Questionnaires** to evaluate physical and psychosocial aspects that are used in the multidisciplinary approach to RTW, or have predictive capacity to estimate RTW. In addition to the scales mentioned for the clinical case, for this scenario we can include the Örebro Musculoskeletal Pain Screening Questionnaire (Linton & Boersma, 2003), One-item self-rated health (Momsen et al., 2017), or the Work Ability Index (Reeuwijk et al., 2015).
- **Anthropometric data:** stature, weight, and body size measures that influence the physical load and interactions with equipment at work.
- **Measures of functional capacity evaluation (FCE)**, used in some settings to assess the capacity to RTW or as baseline for individually graded activity programs.

In addition, the risks that are calculated as outcomes in the clinical scenario (§2.4.4) can be used as baseline for further adjustment (see below).

On the other hand, workplace-related measures include:

- **Time/calendar of return to work.**
- **Physical and time requirements** (load handling, manipulation, posture, movements, task times and schedules), as assessed by methods like RULA, REBA, or NIOSH (Stanton, Hedge, Brookhuis, Salas, & Hendrick, 2004).
- **Psychosocial factors**, as assessed by the Copenhagen Psychosocial Questionnaire (COPSOQ).

Patients/workers, multidisciplinary team professionals, and OHS will have different permissions to upload and see those measures, according to the data privacy principles mentioned above.

As in the clinical case, the measures that can be added will be prioritised according to the user profile, and the sensitivity of results to new data. Selected interventions

### 3.4.3. Interventions

Interventions considered in RTW will include:

- Physical activity plans
- Back school training materials
- Physical conditioning programs (“work hardening”)
- Ergonomic adjustments of the work place equipment and schedules

As in the clinical end-user case, the interventions may be prioritised for each patient/worker taking into account the results of the models (see below).

### 3.4.4. Outcomes

The main outcome during sickness in this scenario is the RTW time, i.e. estimated time of sick leave. After RTW, performance-related outcomes are:

- Absenteeism (unplanned absence due health conditions).
- Presenteeism (working while sick with associated productivity loss).

The outcomes of the clinical scenario (§2.4.4) may also be used as secondary outcomes in RTW:

- Level of pain intensity or related disability, in the next 3/6/9/12 weeks.
- Risk of chronicity and/or recurrence within 12 months.
- Difficulty in performing work-related tasks.

Those values may be adjusted taking into account the effects of workplace-related interventions and user profiles on those variables (Burdorf & Jansen, 2006; Chen, O’Leary, & Johnston, 2018; Jun, Zoe, Johnston, & O’Leary, 2017; Panken et al., 2016).

There will be two levels of details in the reports of those outcomes. On the one hand there will be the reports addressed to clinicians, which will contain all the information. On the other hand there will be abridged reports that may be used to present results without potentially

discriminatory data; in those abridged reports the outcomes will be reduced to measures of the increase or decrease of risks with respect to baseline values associated to an immediate return to work without RTW interventions, with a categorical representation.

### 3.4.5. Models

Using previous knowledge, and by investigation during the course of the project we expect to generate models to simulate and calculate:

- Musculoskeletal load due to forces, postures and repetitive movements, with respect to worker's capacity.
- Adjusted risk of recurrence, from physical requirements and psychosocial factors of the work place, as assessed by structured tools (RULA, REBA, NIOSH COPSOQ).
- Sick leave times depending on the trajectory of the patient and the implementation of multidisciplinary RTW programs.
- Economic costs due to the implementation of interventions and impact on return to work and performance.

## 4. Self-management end-user case

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### 4.1. Description of the work flow

As mentioned above, at the starting point, patients with NLBP have a choice whether to self-manage their symptoms or to contact a healthcare provider. However, even after contact with a healthcare provider, self-management of NLBP is crucial to reduce pain and disability, maintain or increase physical function and workability, and reduce risk of recurrence and chronicity. In the following, we describe the main content and features related to self-management of low back pain (LBP) as it pertains to the ongoing SELFBACK H2020-project that will be incorporated in Back-UP.<sup>1</sup> Clinical guidelines state that patient education, exercise therapy, multidisciplinary treatments and combined physical and psychological interventions should be recommended for the management of LBP. Digital solutions, such as mobile applications (apps), have been suggested as promising platforms for supporting self-management of chronic conditions.

Within the SELFBACK project, we have developed an evidence-based decision support system (DSS) delivered as a smartphone app along with an activity recognizing wearable (wristband) that is to be used by the patient him- or herself. The core of the SELFBACK system is to 1) provide effective advice on physical activity and strength/stretching exercise according to personal goals, symptom progression, and functional ability, and 2) to educate the patient on self-management of his/her LBP condition. To accomplish this, SELFBACK incorporates existing knowledge to recommend tailored advice based on information from the patient.

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<sup>1</sup> <http://www.selfback.eu/>



#### 4.1. Main issues and bottlenecks

Evidence-based guidelines for the management of non-specific LBP have been adopted by several countries, and although some variation exist, the main components in the management of LBP to prevent recurrence, chronicity and pain-related disability include education and reassurance, physical activity on and off work, and regular strength and/or stretching exercises. Close adherence to self-management advice is essential to obtain desired effects, but without additional support, patients often experience that self-management of their illness is challenging. This could explain the small effects of self-management programs on pain and disability observed in persons with non-specific LBP. Adherence to self-management programs is influenced by a variety of factors, such as degree of individualization of the self-management program and support to persist with self-management. A “one size fits all” approach is less likely to succeed than a tailored decision support approach to individual patients, particularly for non-specific LBP. Each patient will have different characteristics that influence pain prognosis, function, and workability, as well as adherence to treatment and self-management strategies – and the influence of these characteristics may vary with factors such as time since diagnoses and disease progression. Thus, successful self-management plans should be adapted to individual characteristics, symptoms, motivations and goals to facilitate, improve and reinforce self-management of LBP. Mobile technologies may be a promising mode for both delivery of self-management since it allows for tailored support and follow-up to individual patients.

However, selection of patients that may benefit from self-management of LBP could be challenging. It should involve clinical examinations to rule out serious pathology that requires medical attention and exclude patients that otherwise are not suited for self-management (e.g. cognitive impairment, mental illness, mobility problems, etc.). One could also argue that selection into self-management programs could include evaluations related to motivation and readiness to change.

For the particular case of the SELFBACK project, the wide range of data collected both at baseline and during follow up could be a challenge, both in terms of patient’s willingness to participate, and in terms of data security and data transfer (between countries). Other factors that influence the feasibility of SELFBACK as a self-management program are; 1) the use of a separate activity-recognizing device (wristband) with its additional costs and potential for non-wear time; 2) the need for installation of additional apps to each patient’s smartphone to capture data from the wristband; 3) the potential for extra costs related to data transfer between the smartphone and the back-end system (depending on each participant’s mobile data plan and Wi-Fi access); 4) finally, the SELFBACK system is developed for self-management of LBP only, and is not developed for patients with neck pain or pain at other sites.

#### 4.2. Targets of Back-UP

- Evidence based decision support for self-management of LBP, focusing on physical activity, exercise and education
- Deliver personally tailored self-management plans adapted to patient characteristics, symptoms progression, individual capabilities and goal setting
- Reduce pain related disability, and thus increase workability

- Utilise a broad spectrum of patient data to gain new knowledge on self-management, and possibly influence future guidelines
- The dynamic and self-learning features of the CBR system enables improved patient support over time

### 4.3. Features

#### 4.3.1. Data portability and privacy protection

The general principles defined for the clinical scenario (§2.4.1) are applied. Additionally, SELFBACK data will be stored at a secure server at NTNU, Department of Computer Science, Norway. The servers are firewall protected. The entire virtual machine has back-up on a daily basis, and back-ups are kept for a one-year period. Data storage is compliant with existing European law.

Data from the SELFBACK app is protected from unauthorized use, disclosure or modification by following the latest recommended security guidelines from the device manufacturers. A secure data transfer is ensured by an encrypted communication between clients (the patient's web browser and app) and servers by using HTTPS (Hyper Text Transfer Protocol Secure) and SSL (Secure Sockets Layer) certificate and by storing sensitive information in the keychain/keystore. Additionally, a feature in the application will be implemented to completely wipe the stored data from the device when the user signs out or removes the application. Lastly, safety is ensured by digital signing in both Android/iOS before they can be installed.

#### 4.3.2. Interfaces

The self-management plan, educational content and activity monitoring data will be available to users through the smartphone app. Baseline data will be collected through a web-based questionnaire, whereas follow-up data on symptoms progression, function, physical activity, etc. will be obtained via the app. All activity on the app regarding the completion of a self-management-plan together with the provided content is stored in the back-end of the selfBACK system. This allows the selfBACK system to learn from the experience all participants make and improve its self-management-plans. The selfBACK system is mainly targeted to provide information for the app, but also allows creating analytical tools for co-decision making between patients and clinicians. The back-end sends complete self-management plans to the app, where the received information is processed and presented for laymen. This includes explanations on the content as well as creating personalized libraries for content that has been presented in the past. All processing for generating, adapting and personalizing self-management plans, achievement statistics and knowledge libraries is done on the backend. The app only contains those information relevant for the patients at the given time.

#### 4.3.3. Data and measures

Figure 4 gives an overview of the data that will be obtained on a patient case within the SELFBACK system. In this context, a case is defined as the patient description (baseline or

follow-up) along with the matching self-management plan. Patient data is collected with different frequencies in the SELFBACK life cycle and the self-management plan is updated accordingly. A substantial part of the information obtained at baseline is somewhat static (e.g., demographics) while other information is expected to vary over time and hence will be updated at subsequent follow-ups (e.g., pain-related disability and function).

	Case Part	Content	Updates
Problem Description	Subjective Description	- Demographics - Quality of Life - Pain Intensity - Functionality	Initially  Tailoring (weekly)
	Objective Description	- Activity Stream	Continuously
Solution	Advice	- Activity Plan - Exercise Plan - Educational Session	Weekly
Outcome		- Pain Intensity - Functionality	Weekly

Figure 4. Components of a patient case within the CBR system contains a problem description (patient characteristics), a solution (the weekly self-management plan), and an outcome.

Baseline data from the web questionnaire include the following items:

- Demographics (age, sex, family, ethnicity)
- Height and weight
- Employment and work characteristics
- Current LBP and history of LBP
- Pain medication use
- Pain-related disability and function
- Work ability
- Physical activity level and barriers
- Comorbidities
- Quality of life
- Sleep problems
- Fear-avoidance beliefs
- Pain self-efficacy
- Illness perception
- Perceived stress
- Mood

#### 4.3.4. Interventions

The interventions that constitutes the self-management plan within SELFBACK include:

- Increase physical activity (number of steps)
- Reduce inactivity time (i.e. prolonged time sitting/lying down)
- Conduct specific strength/flexibility exercises
- Deliver educational content (grounded on behavioural change technics)

The SELFBACK system aims to deliver all these components as personally tailored advice to each patient. The effectiveness of the overall SELFBACK system will be examined in a randomized controlled trial within the SELFBACK project.

#### 4.3.5. Outcomes

The main outcome in SELFBACK is pain related disability as measured by the Roland Morris Disability Questionnaire. Secondary outcomes include:

- Pain intensity and duration

- Pain medication
- Pain self-efficacy
- Fear avoidance beliefs
- Activity limitations
- Work ability
- Self-reported physical activity
- Patient specific function scale
- Sleep
- Perceived stress
- Quality of life
- Illness perception
- Mental health/depression

#### 4.3.6. Models

Based on the data collected, we aim to

- obtain unbiased effects of the SELFBACK DSS system (as an add-on to usual care) on the primary and secondary outcomes
- examine the possible modifying role that patient characteristics may have on these effects; e.g. differential associations related to baseline pain severity, functional disability, demographic factors (age, sex, employment status), etc.
- utilize repeated data from the app/wearable on physical activity/exercises and relate this to symptoms progression

## 5. Integration of *personas* in the end-user cases

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### 5.1. Introduction

The end-user case approach focuses first on identifying the actors or users, which are presented as *personas*. Actors represent all entities external to the system, either users or other systems, interacting with the system. Primary actors initiating the end-user case always have a particular goal in mind. The end-user case exists to satisfy the goal of the primary actor and shows how the system provides value to them. A complete set of end-user cases specifies all the different ways to use the system, and therefore defines the complete functionality of the system, bounding its scope (Vredenberg, Isensee, & Righi, 2001).

A different scenario is written for each end-user case, in order to illustrate how the product is used. Those scenarios represent a single path through the end-user case from the user's perspective. Thus, one may construct a scenario for the basic flow of a end-user case representing the most important or common course of events. The end-user cases that are presented in this document are based on a persona suffering nonspecific low back pain, related to intense physical loads in the workplace although not caused by a specific injury at

work, which is the most common of the cases of NLBP (Nachemson, Wadell, & Norlund, 2000).

For Back-UP we will define three main actors:

- The patient (described in 5.1.1)
- Clinicians (described in 5.1.2)
- The OHS manager (described in 5.1.3)

The patient will be described with a greater level of detail, since the ultimate purpose of Back-UP is to provide an effective and integrated management of the health issue of this persona. The other actors are described more generically according to their professional profile. In fact, there are various personas that take the role of clinicians in the story that is told here, although the specific profiles are all described within the same section below.

### 5.1.1. The patient (Anita)

The patient that features the story is Anita, a 45 year old woman that lives in a small village 20 km from the city, she is married and has 2 children of primary school age. Anita has been working in a big company for 10 years. Her work in this company has always involved manual tasks; for the last 3 years she has been in the same packaging and assembly line.

She considers that she has a “normal, happy life”, although she lives in a situation that involves some stress.



Her husband is a truck driver, who has been unemployed for two years now. So the family income is chiefly depending on her. She also usually takes care of household duties (cooking, cleaning...), with little support by her husband, who basically takes care of their children off school time. On the other hand, living in a small village also gives her some comfort, with close community contact and support.

She is not used to regular and structured exercise; she goes out for a short walk with friends one or two times per week. But she feels that she does enough exercise at work:

She works from Monday to Friday, from 8:30 AM to 5:00 PM. In that time she has one long break for lunch (12:30–13:30), and two shorter breaks at 10:15 AM and 3:15 PM. During her work day she rotates between tasks like assembling mechanical parts, examining containers (measuring, counting and visual inspection of products), packaging, taping and labelling, and also transportation between different areas of the store, plus some office work related to writing and managing reports. Many of them are manual tasks, with small and repetitive movements of the trunk and upper limbs, but she is also carrying loads in carts (up to 35 kg) or manipulating a forklift.

She likes her job, because it provides stability to her life, and after many years in the company she has made very good relationships with colleagues and managers; her position has changed, such that now she has more responsibilities and less manual work than at the beginning. However, she thinks that such rewards are small and take quite a lot of time, effort

and sacrifice; she has never taken sick leave, even when she did not feel totally in shape, and now she feels that she cannot do as much as when she was younger.

In fact, during the last month she has been suffering with low back pain, although she has been tolerating it with some anti-inflammatory pills (self-administered) in order to continue with her normal activity. This is a big cause of worry, because she is not accustomed to be sick, and fears the consequences. She tries hard to keep things “normal”, but she feels worse each day; things improve in the weekend, although at the expense of neglecting some household duties and the walking with friends, and on Monday the problem starts to grow again.

### **5.1.2. The clinicians**

There are different clinicians involved in the story:

- The general practitioner (GP) is a primary care physician of the municipal health centre in the village where Anita is living.
- Specialists in physiotherapy, psychology and occupational medicine that work in a hospital in the city, managed by the health insurance company that assists the workers of Anita’s company.
- An occupational physician working for the OHS of the company.

All these clinicians are well acquainted with the guidelines for back pain treatment, and the usage of technology.

### **5.1.3. The OHS manager**

Occupational health services (OHS) are administered in the company where Anita works by a private organisation. Its manager is a specialist in occupational safety and prevention, who is in charge of developing and executing health and safety plans according to legal guidelines. Those plans include medical examinations for recruitment, training on ergonomics and injury prevention, assessment of working equipment, definition of work schedules, and investigation of accidents or worker sickness.

Although she works for a big company, the OHS manager is a person committed with her duty, who knows personally most of the workers (including Anita, who has been in the company for a long time), and her main concern is to ensure that the employees are healthy and safe. That is actually also a commitment of the general management of the company, which includes worker wellness as one of the corporate values.

## **5.2. Anita’s story with Back-UP**

### **5.2.1. First contact with Back-UP**

As worker of that company, Anita has private medical insurance for work-related sickness and accidents. Both the OHS and the medical insurance, and the national health services in her town are using Back-UP.

After one month, she feels that her quality of life is worsening too much: at the end of every work day she feels sore, and sleeps badly, so she seeks healthcare. She goes to the municipal health centre, and she reports her problem to her GP, asking for a certificate of sick leave because she feels unable to keep on with her routine.

The GP asks some questions and does a physical examination to determine if there may be a structural injury or a serious pathology that would require urgent medical attention. After ruling out such red flags, the doctor explains to Anita that she is suffering nonspecific low back pain, and to relieve her anxiety associated to her increasing pain, she receives the medical certificate, and some advice: it is a condition that normally improves after some time, and there are general recommendations that she can follow with respect to daily activities, in order to facilitate a faster improvement and return to work.

The doctor also presents Anita brochures of selfBACK and Back-UP, which she can use respectively as a personal tool to manage her low back pain, and to help the clinicians to give her a more personalised and effective treatment. She agrees to use them, so the doctor makes some additional questions to make the initial registration.

### **5.2.2. Interaction of the patient with the platform**

At home Anita receives a personal e-mail from Back-UP, with links to more detailed information about how the platform works and will process her data, and an invitation to confirm whether she wants to sign up and use that service. After reading it, she accepts, and she is directed to the portal for the patient.

In the Back-UP portal, Anita can read the preliminary information that the doctor included about her case in the platform, as well as the general recommendations given to her. Then she fills out some web forms with questionnaires suggested by the platform, which will help the clinician to update her knowledge about the case and provide a more accurate treatment.

In the afternoon of the next day, Anita receives a notification from Back-UP with more specific advice, including an adjustment of the anti-inflammatory pills that she is taking, and an appointment to take a blood sample prior to the visit scheduled for the next week. Through selfBACK she also receives an exercise program and postural recommendations, and reassuring and motivating feedback.

In the next visit, Anita is referred to the physiotherapist. Since she has been sick for more than one week, she receives a call from her work health insurance, and after commenting her case, she is offered to visit the physiotherapist of the insurance company. She agrees, and through the Back-UP platform makes a portability request, so that the insurance company can also manage her case.

Anita receives manual therapy two days every week in the insurance clinic, during five weeks. In Back-UP she always has updated information about her appointments and the prescribed therapy. During that time she keeps on using selfBACK to complement the manual therapy with her own activities. In the first visit and two weeks after, she also goes through a set of specific tests, involving doing some movements and carrying loads while she is instrumented with sensors, and answering questions on a computer.

Anita is reporting how she feels on a weekly basis. After two weeks of rehabilitation she is less disturbed by her pain and sleeps better, and she does not take medication anymore; but

she has experienced occasional bursts of pain with some movements, and has fear about feeling worse in the workplace.

In the first session of the third week, she is interviewed by a team formed by the physiotherapist, an occupational physician and a psychologist. They talk about the conditions of her workplace from different perspectives: the tasks that she performs, the relationships with co-workers and the management, responsibilities, pressures, etc. The day after, she receives a message by Back-UP with information about a more complete rehabilitation program that combines the manual therapy with graded exercises, new tests, and educational sessions to avoid fear of pain. In the following session she meets again the multidisciplinary team, and after discussing the details Anita agrees to follow the program.

In the fifth week Anita feels reassured, and meets the OHS manager of her company to discuss the conditions for return to work. The OHS manager tells Anita that the company can use Back-UP to define workplace interventions that may ensure a safer, personalised return to work — while ensuring that her personal health data remains fully invisible for her employer. She agrees with that usage of her case by Back-UP, and two days after receives a suggestion of temporary changes in the work conditions and schedules, which she accepts to return to work while the rehabilitation is completed.

### 5.2.3. Interaction with the clinicians

The questionnaires that Anita filled out when she signed up in Back-UP contained standard patient-reported outcome scales (PROMs) that are used for patient stratification. Thanks to this, the GP had the results of those questionnaires the day after the first visit, which indicated that there were some yellow flags due to her psychosocial situation. The doctor adjusted her advice accordingly, such that Anita could see it in the next day.

Moreover, the computational engine of Back-UP made simulations to estimate Anita's trajectory in the following weeks. Thus the clinician could look at plots representing projections of:

- Estimated level of pain.
- Normality of body function (e.g. trunk flexion, weight lifting, compared with healthy population of the same age, sex, etc.).
- Risk of recurrence or chronicity.
- Readiness to return to work.
- Risk of absenteeism or presenteeism.

(The interest of each plot depends on the clinician's profile, such that the GP in primary care would be more interested in the first three categories, whereas an occupational physician would be also interested in the two last ones.)

Initially, the level of uncertainty with only the inputs of those questionnaires was still high in most plots. However, the week after, the clinician uploaded the analysis of glycans taken out of the blood sample, and the system was automatically fed with the inputs provided by Anita with selfBACK. Now, the doctor had more precise estimations of the level of pain that Anita could experience in the next weeks.

Unfortunately, the estimations based on self-care and advice indicated that pain improvement would be slow, and the risk of chronicity was high. But when the engine was run simulating two weekly sessions of manual therapy, the prospects improved substantially.

So the doctor made the decision of referring Anita to a specialist in the first week, thus saving some weeks of re-evaluations.

When the insurance company took over Anita's case, they uploaded new information to Back-UP from the biomechanical and psychological tests, uploading output files or linking applications. Those results also improved other estimates, showing good prospects to restore musculoskeletal, but increasing the risk of chronicity due to psychological distress and negative feelings about returning to work, as well as the risk of absenteeism.

The clinician changed the treatment of Back-UP simulations, including a multidisciplinary treatment, and the expected improvement was worth the additional cost for the insurance company, so they scheduled the interview just after the second week. The multidisciplinary team prepared the suggested program right after the interview and uploaded it to the platform on the same day, so that Anita could read it before the next session.

#### **5.2.4. Interaction with the OHS manager**

The OHS of the company where Anita works could use Back-UP to perform an assessment of the musculoskeletal and psychosocial loads of her workplace, using standard methods that do not require information of the worker. With such information the company might redefine the work places and schedules in order to reduce general risks.

But Anita also consented to using Back-UP to personalise the workplace to her needs as worker returning from back pain. Thus, Back-UP scaled the risks according to the individual data obtained from the questionnaires and tests that she had done during her treatment. The OHS received a report with "traffic lights" that indicated that the risk of absenteeism due to new pain episodes would decrease significantly if her work schedules were adapted. The OHS manager took that information into account when she met Anita, and facilitated the decision to adopt those measures.

#### **5.2.5. Contributions of Back-UP to a better management of Anita's case**

Through the example of Anita's story we can see how Back-UP can contribute to improve the management of NLBP, reducing intervention and sickness times and supporting better decisions that facilitate a faster and more stable improvement of the patient.

In this example, Back-UP saved time of the first contact decisions, by facilitating self-filling information that is important for the diagnosis and stratification. The prognostics provided by the system also helped to make better informed decisions. And the number of visits to make such decisions was also reduced, thanks to the frequent update of information through selfBACK.

The combination of data from different domains helped a better understanding of Anita's problem, which seemed to be very associated to the high physical loads that she had been enduring at work, but might have been perpetuated by the psychological distress that her sickness had caused.

Finally, the adoption of personalised interventions that improved the conditions of Anita in the workplace was facilitated by the summary reports that — without disclosing confidential health data — allowed the OHS manager to be aware of the risks, and the benefit of implementing those interventions in terms of absenteeism and performance.

## 6. Ethical assessment

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This deliverable defines how NLBP patients are expected to interact with Back-UP, which implies processing personal health data and communicating them to other users, and advice about stratification and interventions that will be administered to patients.

Such interactions and workflows have been defined with care to ensure that the privacy and fundamental rights of the patients is protected, and that the advice that Back-UP will provide is based on scientific evidence and not harmful to the patients.

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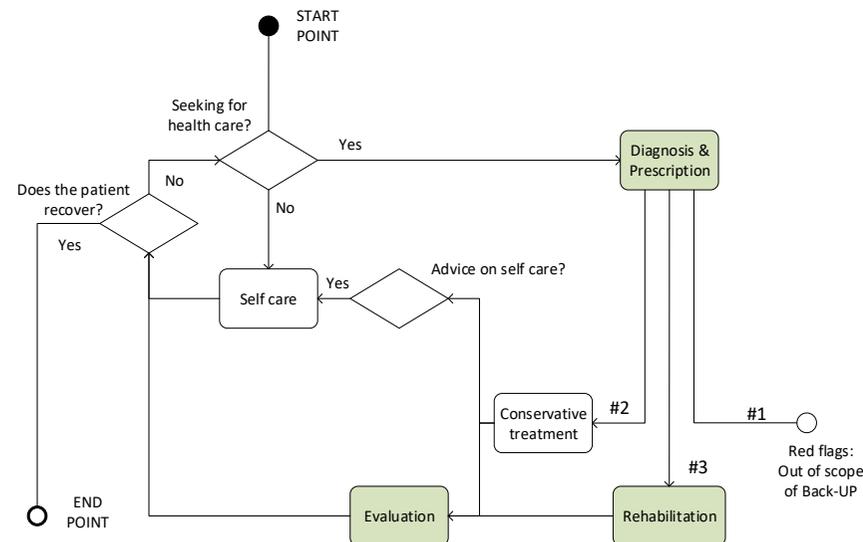
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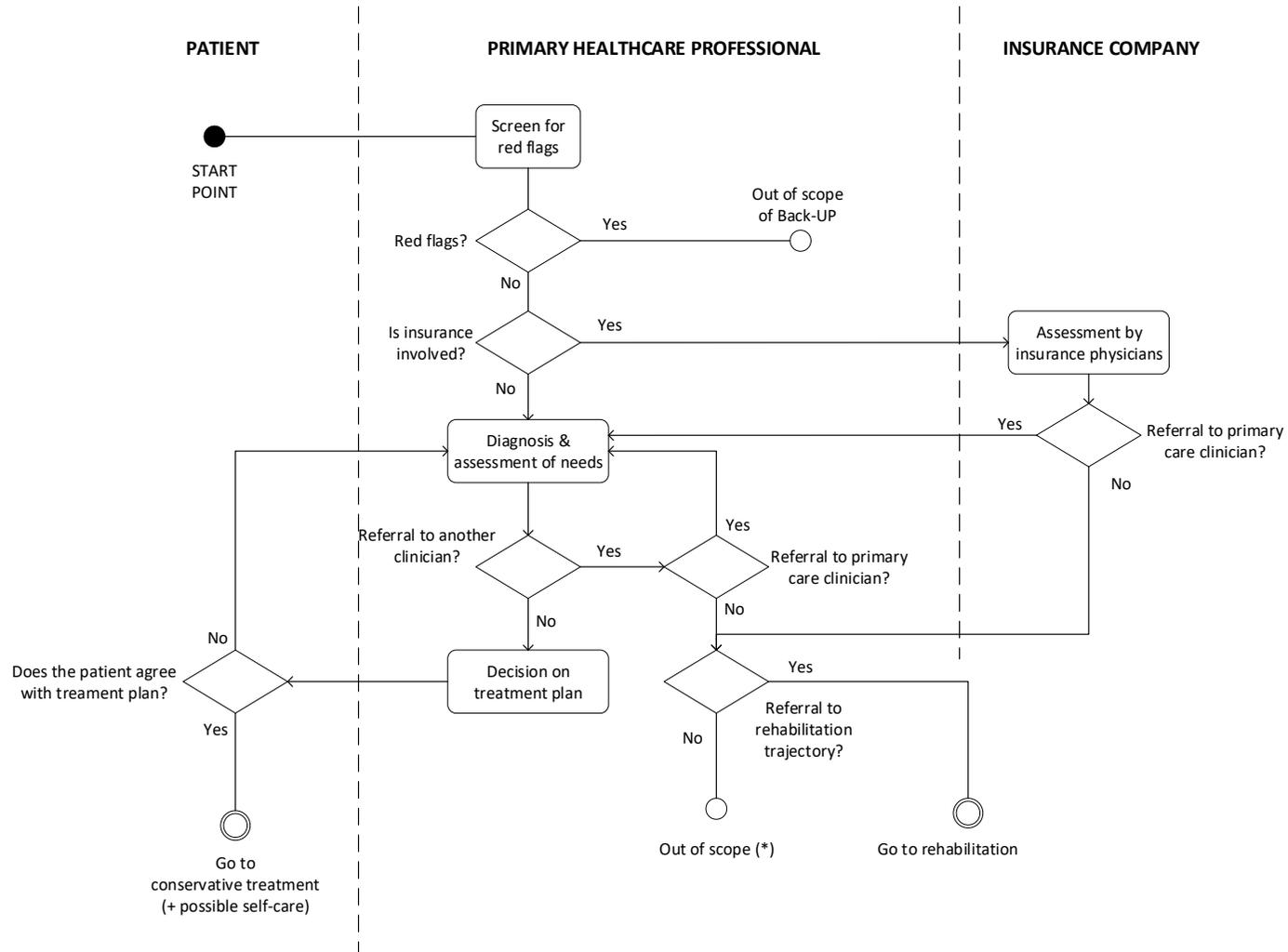
## Annex A. Detailed work flows of the clinical case

The workflow presented in the section 2.1 as Figure 1 (also copied below for ease of reference) includes three coloured blocks that consist of complex sequences of actions and decisions, the technology of Back-UP is meant to give support to. This annex presents the detailed workflow diagrams of those blocks, distinguishing between the current workflows and the potential workflow supported by Back-UP.

The black filled circle of the diagrams (●) always represent the entry point to the block. Two concentric circles (◎) are exit points to the main diagram. The exit points that do not carry to another point of the general workflow are represented with simple empty circles (○), and labelled as “Out of scope”. In some cases it is due to the finding of red flags (see section 2.1), and in other cases because of failure to find a suitable solution. That and other situations are explained after each diagram.



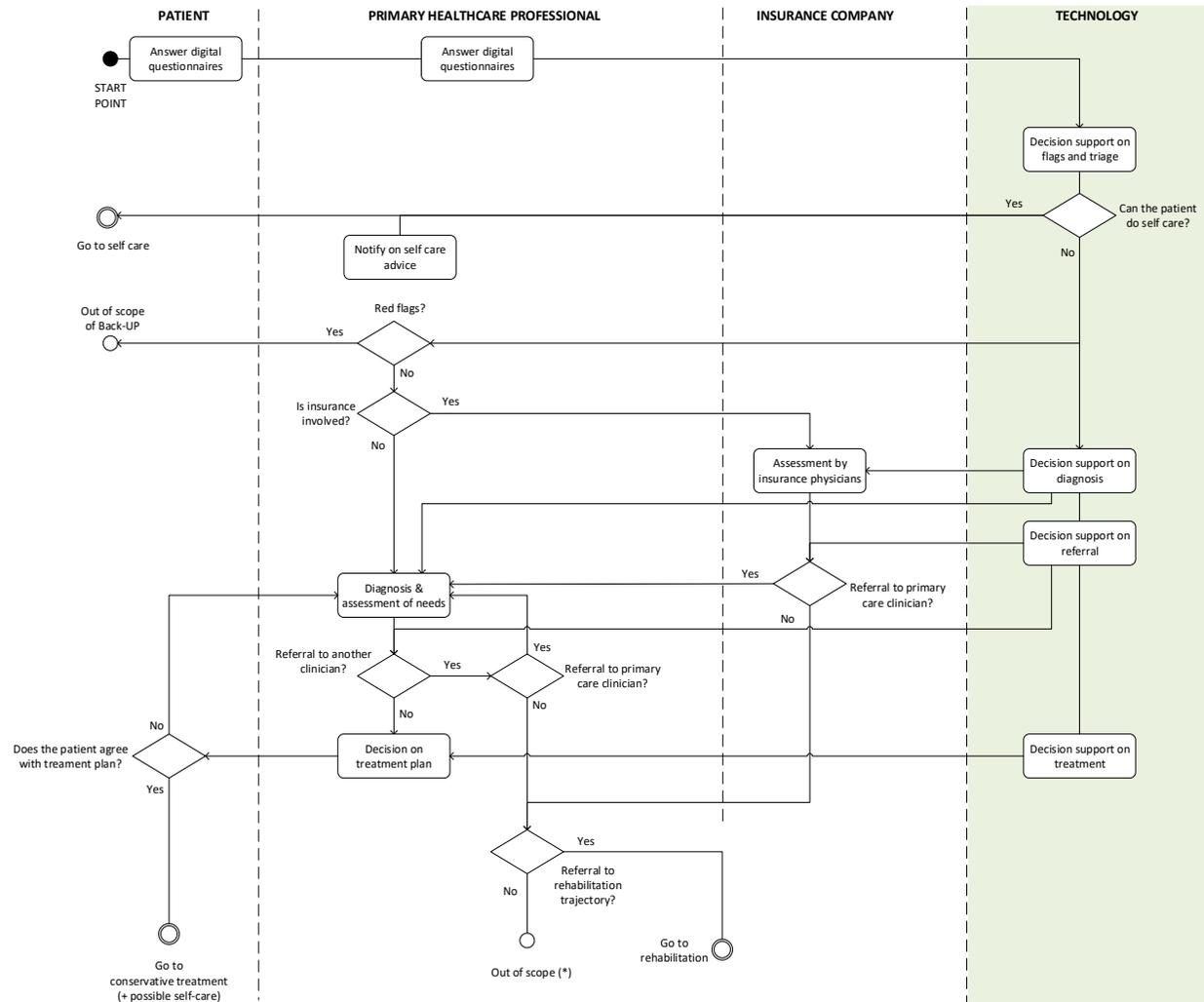
### A.1. Current diagnosis and prescription



The process of diagnosis and prescription is normally done by collaboration between the patient and the clinicians. The screening of possible red flags is the first action. This diagram includes a section of case management by an insurance company that covers work-related injuries or sickness — or depending on the type of contract with the employer, also long term non-occupational disease. An important complexity in this workflow is the possibly intricate sequence of referrals from one clinician to another.

There is a possible exit point that does not involve any treatment or referral to a rehabilitation trajectory, marked with an asterisk. Such decision can be made if the clinician considers that the problem can disappear without any particular treatment (which is often the case in nonspecific NLBP). In other cases it is the patient who does not agree with the prescription, looking for further investigation or advice elsewhere.

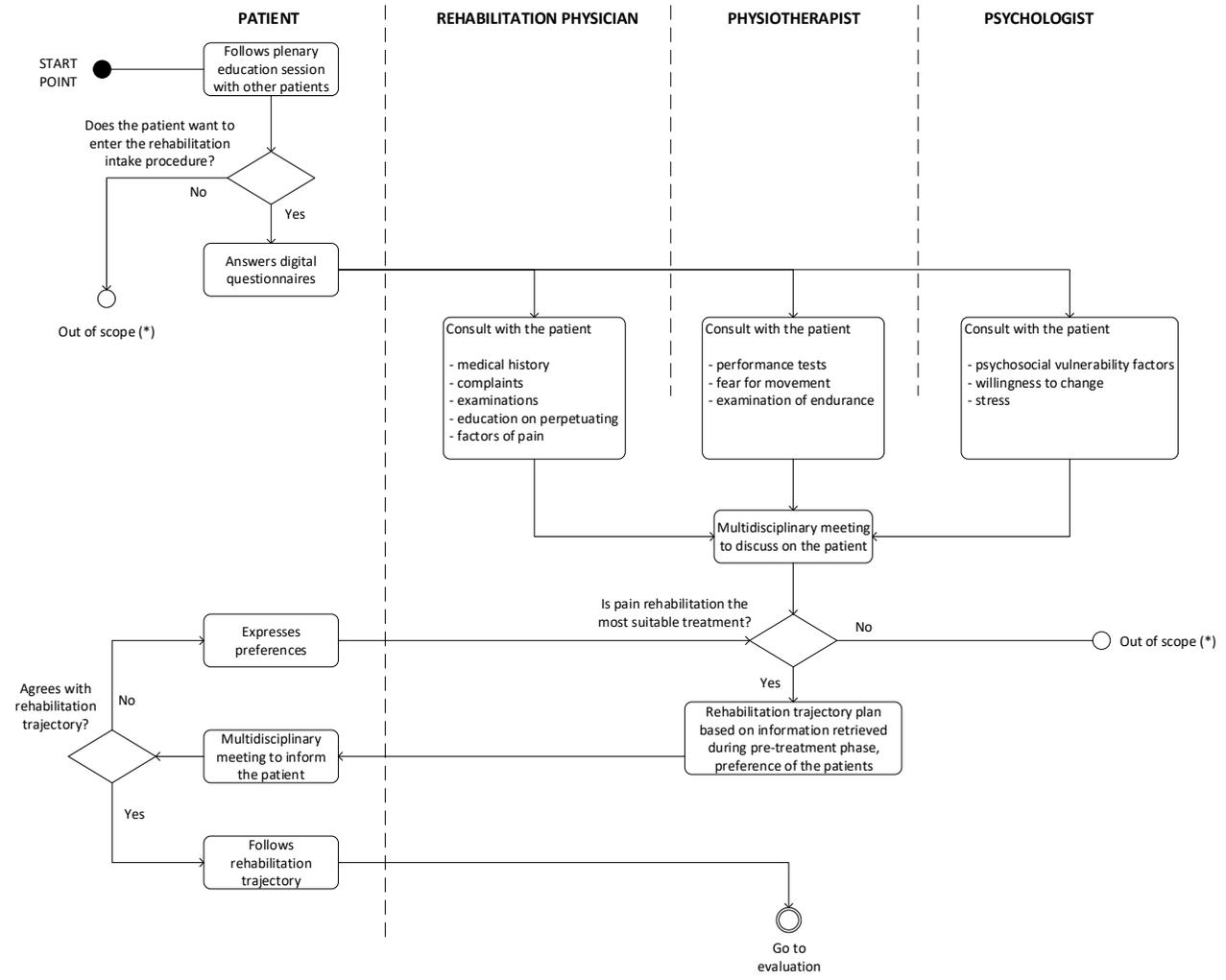
## A.2. Diagnosis and prescription with Back-UP





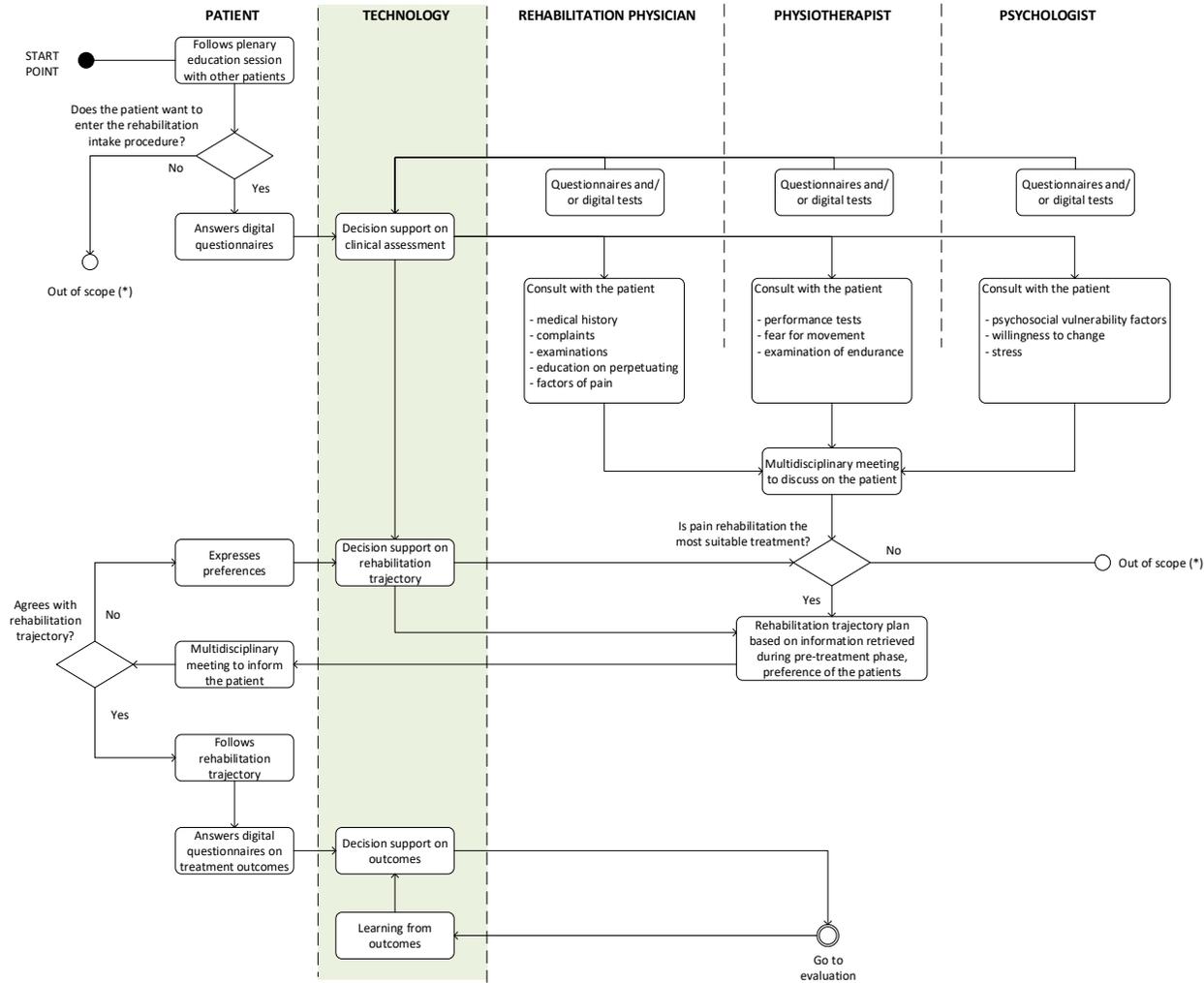
This diagram presents the extension of the previous workflow, with support of Back-UP technology. Back-UP can support the decisions on flags and triage, and about the advice on self-care, as well as in the steps diagnosis, referral and treatment (see the coloured column on the right side). The input that the system needs to provide such support is a set of questionnaires with self-reported measures that can be given by the patient, or signs observed by the clinician.

### A.3. Current rehabilitation trajectory



This diagram presents the workflow of the rehabilitation trajectory, involving a multidisciplinary assessment by rehabilitation physicians, physiotherapists and psychologists. Each specialist considers different types of information related to their specialities, and meet first between them to prepare a rehabilitation trajectory plan, and then with the patient to discuss their preferences and define a mutually agreed plan.

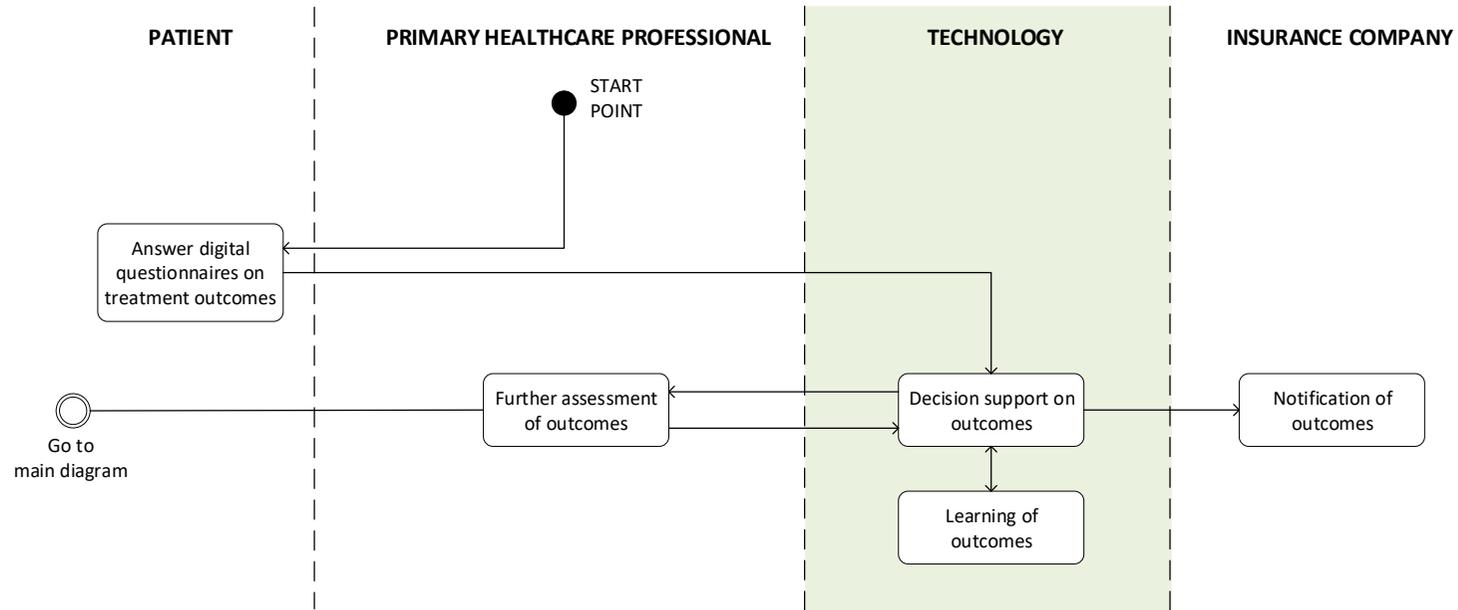
### A.4. Rehabilitation trajectory with Back-UP





This diagram presents the extension of the previous workflow, with support of Back-UP technology. Back-UP can use self-reported measurements answered by the patient in digital questionnaires, as well as measurements taken by the specialists, to support decisions about clinical assessment, the definition of the rehabilitation trajectory, and the outcomes to be evaluated. In addition, the system can learn from the outcomes obtained in the evaluation, in order to build better decisions in the future.

### A.5. Evaluation with Back-UP



The evaluation process is basically the assessment of outcomes, which are used to determine if the patient is improving (in the main diagram). Back-UP will provide information not only of the current outcomes, but of estimates on future outcomes, and will learn from the decisions made in each case to provide better support to such decisions.



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