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# MobiGuide

Guiding Patients Anytime Everywhere

Collaborative projects - Large-scale integrating project (IP)

Start date: 1-Nov-2011 Duration: 48 months

# Deliverable D3.1: Extended CIG format

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# Table of Contents

# List of Tables



# List of Figures

# Executive Summary

Deliverable 3.1 describes the personalization process of computer-interpretable guidelines (CIG).

A personalized CIG takes into account the user's preferences (when clinically possible), and the different possible contexts a patient might be in. Contexts can be induced both by personal (e.g., high physical exercise level) or technological (e.g., no battery in the BP sensor) parameters.

A context-aware DSS might potentially improve effectiveness / efficacy of the medical intervention/disease management whilst preserving its safety. It enhances the main goal of the MobiGuide project (which is the real-time guideline-based monitoring and management of ambulant patients outside the hospital, thus allowing patients to be independent and safe at the same time), by adding a more personal dimension to the guideline-based monitoring and management processes.

The personalization of a CIG is composed of 4 steps: formalization, customization, personalization and execution, as shortly described below:

(1) **CIG formalization** - Models the CIG "as is", creating a "vanilla" version of the existing CIG;

(2) **CIG customization** – Expands the CIG with all possible contexts that can affect the CIG, creating a "customized" CIG - an extension of the "vanilla" version. The customized CIG includes all the different possible *CIG-Customized-Contexts* (CCC), induced by either personal or technological concepts. A CCC defines how the CIG changes for **any** patient that is under this CCC.

In addition, the CIG is prepared for the inclusion of several types of preferences (e.g., the places where a decision model might be used and where the patient's preferences can be taken into account).

(3) **CIG personalization** - Takes place in the patient-physician encounter and includes 2 phases, each creates a *personal* file specific for the patient and for the CIG:

(3.1) Specification of the concepts, that for the specific patient, induce the CCCs (identified in stage 2). The relationship between a patient's event and a CCCs is modelled in a DIRC (Dynamic Induction Relation Context). All the (patient-specific) DIRCs are saved in a *personalized* file specific for the patient and for the CIG. This specification allows the patient to enter different events (e.g., wedding) and have the mapped context (e.g., high-carbohydrate-level) dynamically induced. The induced CCC, reflects the real state of the patient and allows him/her to receive decision-support suited for the context, based on the system's knowledge base that contains recommendations approved by physicians; by entering an event previously linked to a CCC (in his DIRCs), the patient is notifying the MobiGuide system of the change in his/her personal state and receive recommendations based on plans that the care provider has set in the system and has previously discussed with his patient.

(3.2) Acquiring the patient's clinical preferences relating to the (global) preferred treatment (e.g., chemotherapy or radiotherapy) and (local) preferences (such as preferred breakfast time, or injection over intravenous therapy). These preferences, are taken into consideration during the CIG execution, and allow to deliver personalized recommendations at appropriate times. As a result, the patient is able to keep his daily routine by adjusting, when possible, the treatment and its recommendations to changes in his preferences.

(4) **CIG execution**, taking into consideration the customized CIG, as defined in stage 2 and modifying it according to the personalization definitions specified in stage 3.

This deliverable describes how the ontologies defined in D2.2 of 1) personal context; 2) Technological context; and 3) Patient preferences, are modelled using the *Decision Support System* (DSS) schemas: a) The Hybrid-Asbru schema, and b) the *Temporal-Abstraction Knowledge* (TAK) schema to support the CIG's personalization process.

In addition to describing how the different ontologies are modelled in the schemas, we also detail the changes required in the schemas to support the CIG's personalization.

Further details, such as the rationale for developing each ontology model, elicitation of the relevant parameters, methods and instruments, can be found in detail in D2.2.

Regarding the terminology used in D2.2 and the terminology used in D3.1: we denote a "Personal context", as defined in D2.2, a CCC induced by a "personal" concept (e.g., the context "low-patient-adherence" context induced by the personal variable "patient-adherence" with a value=low) and a "technological context", as defined in D2.2, a CCC induced by a "technological" parameter (e.g., the context "no-availability" induced by the technological concept battery-level=none). Note that the CCC as itself is not patient-specific, but CIG-specific.

We define the patient's preferences ("Shared decision" model), as defined in D2.2, as the global preferences of a patient.

In this document, we describe the process supporting the personalization-anytime-anywhere treatment provided by the MobiGuide system, and the required changes to the existent CIG schemas that will enable to take into consideration these contexts while applying the CIG.

This deliverable is organized as follows: Section 2 describes the ontologies that structure the kinds of knowledge that the DSS schemas would need to represent in order to achieve (1) a customized CIG – including the possible contexts induced by either personal (as specified in the "personal context" ontology) or technological (as specified in the "technological context" ontology) and (2) a personalized CIG - the patient's preferences. Section 3 provides a short background of the Hybrid-Asbru and TAK schemas used to specify the MobiGuide DSS language. Having understood the background information about the context and effect ontologies and the DSS schemas, Section 4 describes our vision of how the DSS should provide personalized CIGs, focusing on both the data acquisition and execution phases of the CIGs. Given this vision, we describe in Section 5 how the schemas will be instantiated within the DSS to support the CIG's personalization vision.

# 1. Introduction

One of the goals of MobiGuide (MG) is to enable **personalized** treatment of patients **anytime anywhere** [1].

The personalization of a Computerized Clinical Guideline (CIG) is achieved in 4 steps:

1) *The CIG formalization* – Acquirement of a guideline "as is". The narrative guideline is specified as a formal CIG. The output of this step is a "vanilla" copy of the guideline. This phase already uses a tool such as GESHER and a language such as Asbru, but without any special additions.

2) *The CIG customization* – A process performed per CIG by a knowledge (KL) engineer together with a clinical specialist. The customization process expands the CIG to include all different contexts that could affect the CIG that weren't taken into consideration in the original version. For example, how the CIG should change when the patient is alone, or when the patient is in a high-exercise-level context. We call these contexts CIG-Customized-Contexts (CCCs). Each CCC (e.g., "patient-alone") defines how the CIG changes for **any** patient that enters into this context.

   In addition, the CIG is prepared for the inclusion of several types of preferences (*Global clinical preferences*: adds the appropriate decision model that enables a choice of the right CIG branch according to the patient's utility function; *Local clinical preferences*: making explicit the options of choosing a sub-range of a medication dose, the time to administer a medication, the option of using one of several similar medications, etc.;)

   The output of this step is a customized CIG, generic for every patient.

3) *The CIG personalization* – The personalization stage takes place in one of the first encounters of the patient with her care-provider (no knowledge engineer (KE) is involved at this stage). Together, they define (a) which concepts (specific for the

patient) might induce any pre-defined CCC and (b) the patient's preferences regarding his treatment. Below we describe both:

(a) Mapping the patient's specific events to pre-defined CCCs (defined in stage 2). According to the patient's routine, the care-provider and patient specify the concepts (events, abstractions), specific for the patient, that lead to the pre-defined CCCs. For example, in John's case, the event "training for a marathon" induces the context "high-exercise-level"; In Maria's case the event "wedding" induces the context "high-carbohydrate-level". Note that the same event (e.g., wedding) could induce different contexts for different patients. (e.g. "high-level-of-carbohydrates" for John and "no-availability" for Maria). We call the mapping between events and their induced contexts "*Dynamic Induction Relation Context*" (DIRC). DIRC is part of the TAK schema and of the KBTA methodology. Its computation and details can be seen in [15,16]. These patient-CIG-specific DIRCs, defining the mapping between the inducing-concepts and their induced CCCs are saved in a personalized file in the patient's PHR.

(b) Specification of the patient's preferences regarding his preferences:

i. "Global" preferences" - used to differentiate between different paths leading from each decision point (forking point) in the CIG. Example: Patient X prefers diet (nutritional therapy) to medication; or the results of a formal process of shared decision making, such as the determination that Warfarin is preferred over Aspirin for the patient.

ii. "Local" preferences" - personal customization of an instance of an Asbru action step. Examples: the patient wants to take 2 injections of insulin a day (the CIG recommendation allows a range of 1-4 injections), she prefers to take the bed-time shot around 10pm, she prefers to use the lower recommended dose in the morning, her

breakfast time is around 7:00am so the alert to take the insulin before eating should occur 30 minutes before that time, etc.

The patient's global and local preferences are saved in a personalized file in the patient's PHR.

4) *The CIG execution* – The DSS, during the CIG-execution, loads the customized-CIG (generic for all patients) together with the personalized files for the specific patient, containing his/her global and local preferences and the DIRCs specifications, defined in stage 3. Together, they provide a personalized treatment for each specific patient, in any defined context.

In this document we describe how to integrate the ontologies defined in D2.2 of 1) personal context; 2) Technological context; and 3) Patient preferences into the Hybrid-Asbru and TAK schemas, used by the DSS, to support the CIG's personalization process. We model the personal and technological contexts, as identified in D2.2, as CCCs induced by personal or technological parameters respectively. Note that the personal and technological contexts, as identified in D2.2, are not patient-specific, but general for any patient under these contexts.

By being able to identify and take into consideration different contexts that patients might be in, we allow the treatment of patients in different environments (clinical and non-clinical), in different technological scenarios (e.g., with network connection or without) and according to the patient's preferences – providing a *personalized-anytime-anywhere* treatment.

In the decision-making process, we take into consideration important contexts (e.g., a "high-physical-activity" or "low-battery contexts) and patient preferences (e.g., patient prefers to take drug intravenously instead of orally), that do affect the CIG, in order to provide "tailored", personalized recommendations to the patient. By using the Decision Support System (DSS) we potentially increase the care providers' compliance to clinical practice guidelines, and by tuning the DSS according to the patient's condition, we

increase the appropriateness of treatment and management recommendations, potentially increasing also the adherence of patients to the recommended treatment.

Today, “traditional” CIG language schemas do not include patient-specific support personalization in CIG application. Thus, in order to support the functionality of personalized CIG application, there is a need to extend the existing CIGs and their schemas, which in our case include the Hybrid-Asbru schema for procedural knowledge, and the Temporal-Abstraction Knowledge (TAK) schema for declarative knowledge, with these patient-context ontologies. This process will include (1) extending the existing CIG with possible contexts (induced by either “personal” or “technological” concepts), (2) linking for each patient the events that could induce the different contexts (3) acquiring the patient’s preferences, and (4) enabling the CIG engine to take into consideration the patient’s DIRCs and preferences during the CIG execution by modifying the schemas (TAK and Hybrid-Asbru) accordingly.

# 2. MG Ontologies

Deliverable D2.2 provided a detailed presentation of the patient's "personal contexts", "technological contexts" and "preferences" ontologies. In this section we provide an overview of the ontologies, as defined in D2.2. It is important to note that although we are still using in this section the term "personal context", in the next section we will use a different terminology: we will call the "*patient's personal context*" (defined in D2.2) a "*CIG-customized-context*" (CCC) induced by some personal event. It is important to emphasize that such contexts are not patient-specific, but generic for the specific CIG. It means that **any** patient entering in the CCC will have the CIG changed the same way. The personalization process, as previously described, occurs by linking the events, for a specific patient, that induce the defined CCCs (the DIRCs specification). Similarly, also the "patient's technological-context" is a CCC, but in this case, induced by a technological concept (e.g., no battery).

A CCC, indifferent of the source of the inducing event (technological or personal) is generic for all patients. The personalization (patient-specific) process (step 3) is done, by specifying the (e.g., technological) patient-specific parameters (e.g., in John's case the event "putting the children in bed" and in Maria's case the event "in a meeting") that induce the CCC (e.g., "no availability" context) for each patient.

## 2.1. The patient's personal context

Terminology note: we denote the personal context (as specified in D2.2) a CCC induced by a personal concept. (e.g., the concept "exercise level" with value = "high" induces the CCC of "high-physical-activity"). In the CIG personalization process, the personal context (CCC induced by a personal concept) is defined at the same stage (stage 2 – the CIG's customization process) together with the specification of all the other CCCs for the CIG.

### 2.1.1. Introduction

Improving the patients' adherence to treatments depends on how well these treatments suit the patients' personal needs and considerations (including social and demographic situations). To understand how care providers and patients envision personalized care and how they see the potential role of the MobiGuide system in delivering personalized care, we interviewed 46 clinicians (physicians, nurses, nutritionists) and 15 patients to elicit the main personal categories and their effects on treatment recommendations. We identified 8 context categories and 13 effect categories, which were presented in D2.2. Based on the context categories and effect we created an OWL ontology [2] of context and treatment effects; in the current phase, we would like to integrate its knowledge roles into the DSS schemas of MobiGuide, to enable a personalized decision support.

### 2.1.2. The Personal Context and the Treatment Effect Ontology

The personal context and effect ontology is designed to support the delivery of specific recommendations based on the patient's personal context. It is based on classes that define patient contexts, classes that define effects, and Context_Affects_Object class that defines the effect of the patient's context and the MobiGuide system's context on clinical decision making, as presented in D2.2 pages 21-34. The definitions of the main classes of the ontology, along with examples, are provided in Table 1.

**Table 1. Context and Effect classes**

| Ontology class | Definition | Example |
|---|---|---|
| State Variable Scale | Provides qualitative ranking | mild, moderate, vigorous exercise |
| State Variable (Range) | Provides a domain-specific numerical definition for the scale. The range can also be used to lump together two scale values that for a certain clinical domain should be treated uniformly. | 1-3 MET, 3-6 MET, >6 MET<br>In the AF domain, moderate and vigorous exercise range is lumped together >3 MET |
| State Abstraction | An expression over state variables that forms an abstraction. | During business travel, the patient may have a state abstraction of (diet_routine or semi-diet_routine) and (low_stress or moderate_stress) |
| Patient Context | Combines the clinical-, personal- and preference-state abstractions of the patient over a time frame | Context of patient travelling |
| Technological Context | The technological state abstractions of technological resources of the MobiGuide system | The state of an ECG monitor and AF detection algorithm |
| Patient and MobiGuide System Context | The technological and patient context | Context of patient travelling without internet connectivity |
| Affected Object | The object that is affected by the patient and MobiGuide context. The affected objects could be (clinical) recommendations or technologies | Recommendation changes:<br>The schedule of taking medications, the medication dose, etc.<br>Technology changes:<br>Running a process (e.g., AF detection algorithm, which usually runs on the Smartphone) on a certain component (e.g., BAN) |
| Context Affects Object | This class represents the properties of a relationship that specifies how a patient and MobiGuide system context affects an affected object | In the context of travel, the patient may take fewer doses of insulin |

Note that the defined “personal” context ontology specified in Table 1 is not patient-specific, but CIG-specific (which of course, includes also the domain). Some of the classes are part of TAK state abstractions (state variable scale, state variable range, state abstraction) and others are part of Hybrid-Asbru knowledge roles (such as the affected object). The CIG-dependent contexts (CCCs) could be specified ahead of time for all patients.

In order to define the specific patient context, the physician defined together with the patient the parameters that could induce the different CCCs (DIRCs specification). Adjusting the treatment recommendation, whilst taking into consideration the different

contexts that change during the patient's life routine, can potentially improve the patient's adherence to the treatment.

The ontology structure and its use, based on examples taken from the diabetes domain, are presented in D2.2. As presented in the deliverable, the ontology provides, based on different contexts (induced by personal concepts), changes to routine treatment and helps patients to maintain their quality of life while adhering to the treatment goals and treatment recommendations.

In order to *customize* a CIG, we need to identify all CCCs, relevant for the CIG and define how the CIG will change during the time that the CCC prevails.

For example if different levels of physical activity (e.g., high) could change a CIG recommendation or affect a threshold level, these levels will become CCCs for this CIG (e.g., if a “high-physical-activity-level” context changes the threshold of what is considered a high level of insulin, then the “high-physical-activity” context will be added to the CCCs’ list relevant for this CIG). Any additional CIG change that occurs during the “high-physical-activity” context is also specified for this CCC. Later on, during the patient meeting with his care provider, the personalization will take place by linking for each patient, what are his/her inducing concepts that can induce the “high-physical-activity” CCC.

The *customization* process includes specifying the possible contexts of a CIG and how the CIG’s recommendations are affected in each CCC. This is done by the knowledge engineers together with clinical experts (e.g., changes to the support level of patients may affect the insulin injection – from 4-6 times a day of Basal insulin to 2-3 times a day of long acting insulin). These changes are generic for every patient that goes through a change in the support level.

The next step, the *personalization*, is done together with the physician and the patient and includes defining all possible events that characterize his life’s routine and induce each CCC (the DIRC definition). As mentioned, at this stage, for each CCC the physician has already defined the specific recommendations / CIG modifications that occur. The physician can also define the patient's default context.

An example taken from the GDM domain can be seen in Appendix 6.1, explaining the patient-specific steps.

Note that the patient could also directly indicate the context he is in (instead of entering the event which would induce the context) to indicate that the current context has changed (namely, a different context instance becomes active) and could also define the time interval in which the new context would hold. While the new context holds, the system will deliver recommendations and reminders based on it. After the time interval elapses, the system would go back to deliver recommendations based on his default context.

The changes in the CIG have been categorized in the “personal context” ontology as “Affected Objects”. They include changes in: treatment goals; treatment type; daily routine (work, hobbies etc.); referral to another specialist; drug types; treatment doses; drug variety; physical activities and exercise and diet. Note that alerts could also be defined to notify users when clinical variable values have gone out of their allowed range. The affected objects are specialized into affected recommendations (medication change, measurement change, allowed data thresholds, appointment schedule, diet change, physical activity change and treatment performing and informing agent objects).

In appendix 6.2 we provide an example scenario from the GDM domain of objects affected by contexts induced by “personal” concepts

## 2.2. The patient's preferences

### 2.2.1. Introduction

The importance and impact of patients' preferences on the adherence to treatment in chronic diseases is described in detail in D2.2.

We distinguish between 3 types of preferences:

(a) Clinical *global* preferences - The patient's global preferences relates to the way they perceive the different health states that a decision model takes into account. Thus, the patient might prefer continuing a medication to control AF, instead of installing a pace-maker device or performing an ablation procedure; or vice versa, affecting whether a major [potential] branch of the guideline is to be used at all, or not. Or: within the medication branch, using Aspirin, as opposed to anticoagulants such as Coumadin (Warfarin). These preferences are elicited through an interaction with the care provider, using a specialized tool, as utility coefficients and values, and are used as input to a patient-specific decision tree; this is modeled in the *Shared decision* ontology, described below.

(b) Clinical *local* preferences – The patient's local preferences do not change some aspects of the application of the GL, once the key branches have been determined, possibly using a Global SDM process, but only local "leaves" of the plan, related to his clinical treatment (in cases where personalization can be taken into consideration). For example, preferring to take oral drugs over injections, preferring to take drugs in the morning than in afternoon, and preferences relating to daily routine, such as the preferred meal times, which affect the timing of treatment recommendations. The patient needs to consult the MD ahead of time as to whether she can take the low range of the insulin dose, and she needs to know that there is, in fact, such a range to begin with, all of which should be discussed in the same initial meeting with her care provider. These local (guideline-related) preferences are not modeled in an ontology, but were previously saved in the patient's personal preference file and are taken into

consideration in the CIG during the execution time, as is described in the next section.

(c) Non-guideline-related preferences - Patient's preferences related to the way he wants to interact with the system, e.g., the frequency he wants to be alerted about a specific event, whether he prefers e-mails or SMS, volume of alerts, colors, etc. These preferences, general for every CIG and specific per patient, will be probably set and acquired in a specific user-interface, then saved locally on the mobile device, without needing to access the PHR. The patient may be able to change their preferences as much as he wants, the same way he changes the desktop of his mobile or ringtone.

The patient's non-guideline-related preferences (c) are out of the scope of this deliverable. They do not affect the guideline application per se, only the manner of the interaction of the patient with the DSS.

The patient's clinical local preferences (b) refer mainly to the clinical actions that can be performed in different ways, leading to the same (or almost the same) results (e.g., taking a medicine orally or through injection). In cases where this kind of preferences can be taken into account (this is decided by the physician), we would like to allow the personalization of the treatment according to the patient's individual preferences.

The preferences in this case represent different clinical treatment delivery options. For example, taking an injection in the muscle, under the skin, or in the vein. Other preferences may relate to the daily routine of the patient, e.g., mealtime. For example, the physician may recommend taking medication at about an hour after breakfast, and the personal instantiation will consider the specific Patient Preference stating that his usual breakfast time is 7am. This means that MobiGuide will alert the patient to take his medication at around 8am. These (patient-CIG-specific) preferences are acquired/defined during the patient meeting with his care-provider, and saved in a personalized file, that will be queried by the DSS during the CIG execution for this patient.

The patient's clinical global preferences (a), regarding utility coefficients and costs, are detailed below.

### 2.2.2. Patient's preferences regarding his utility - the shared-decision ontology

The preferences here are related to situations of shared physician-patient decisions that are suggested by the clinical practice guideline. Typically, guidelines suggest to share decisions with patients when there is no scientific evidence to suggest one specific treatment option among the possible alternatives. We refer to such decision points in the guideline, in which one of several branches needs to be chosen but no recommendation is suggested at specification time, as *forking points*. In such cases, MobiGuide will exploit decision trees.

As explained in detail in D2.1, a decision tree is a probabilistic model that represents the consequences of every treatment option. Every path in a decision tree ends with one or more payoffs associated to the path. In our applications, payoffs are (i) life years, (ii) quality adjusted life years (QALYs) and (iii) patient's out-of-pocket costs. Utility coefficients are used to calculate QALYs that are obtained by multiplying the years of life spent in the decision tree-predicted *health state* by the *utility coefficient* associated with that state. Thus, it may happen that, when faced with two options that have the same expected survival, two different patients may prefer different options, because they lead to different time intervals spent in some health states. For example, John may prefer to live with AF, rather than to live with mild stroke consequences, while Maria may prefer the opposite, as shown in Table 2.

We can see that based on John's preferences (utilities for different health states) he would prefer Treatment 2, which provides him with a higher value of QALYs. Now, imagine that living with a post-stroke disability requires the patient to follow a rehabilitation program that is very expensive, and also imagine that Maria lives far from the rehabilitation center, and that this increases the cost, which is unaffordable given her family status. In this case, the patient might prefer to live through a smaller number of QALYs but to save money. Cost can thus be added to the decision model.

**Table 2**. Quality adjusted life years reflecting patients' treatment preferences based on their utilities for different health states

| Option | state | Decision tree-predicted years spent in state | Maria's utility coeff. | John's utility coeff. | Maria's QALY | John's QALYs |
|---|---|---|---|---|---|---|
| Treatment 1 | persistent AF | 8 | 0.7 | 0.8 | **16.4** | 14.8 |
| | Mild stroke consequence | 12 | 0.9 | 0.7 | | |
| Treatment2 | persistent AF | 15 | 0.7 | 0.8 | 15 | **15.5** |
| | Mild stroke consequence | 5 | 0.9 | 0.7 | | |
| | Mild stroke sequelae | 5 | 0.9 | 0.7 | | |

During his life, a patient goes through different health states. A traditional decision tree structure does not allow representing transitions among health states that can occur over time, especially when a long time horizon has to be evaluated. To overcome this problem, MobiGuide exploits the TreeAge tool for decision trees, that enables developers to embed Markov models [3], i.e., mathematical models representing probabilistic transitions among states. Each state of the model may be associated with a utility coefficient and a cost, in such a way that the model can help to determine the treatment recommendations ranking for a specific personal context, as shown in **Table 2** above.

The decision tree application is extensively described in deliverable D2.1 and D5.1. Briefly, the decision tree will use knowledge about the consequences of each treatment option and their probability distribution (knowledge mainly derived from the literature, which can be refined by the medical expert if necessary, given the specific patient), together with patient information about their utilities for different health states (i.e., numbers between 0 and 1, expressing judgment about the states) to compare different treatment options.

Below we present the ontology of shared decisions, followed by a short explanation of its classes.

#### 2.2.2.1. The ontology of Shared decisions

This ontology has been built to represent the general model underlying shared decision problems. In Figure1 below we present the full-shared decision ontology. We denote class names with bold characters and relation names in light blue.

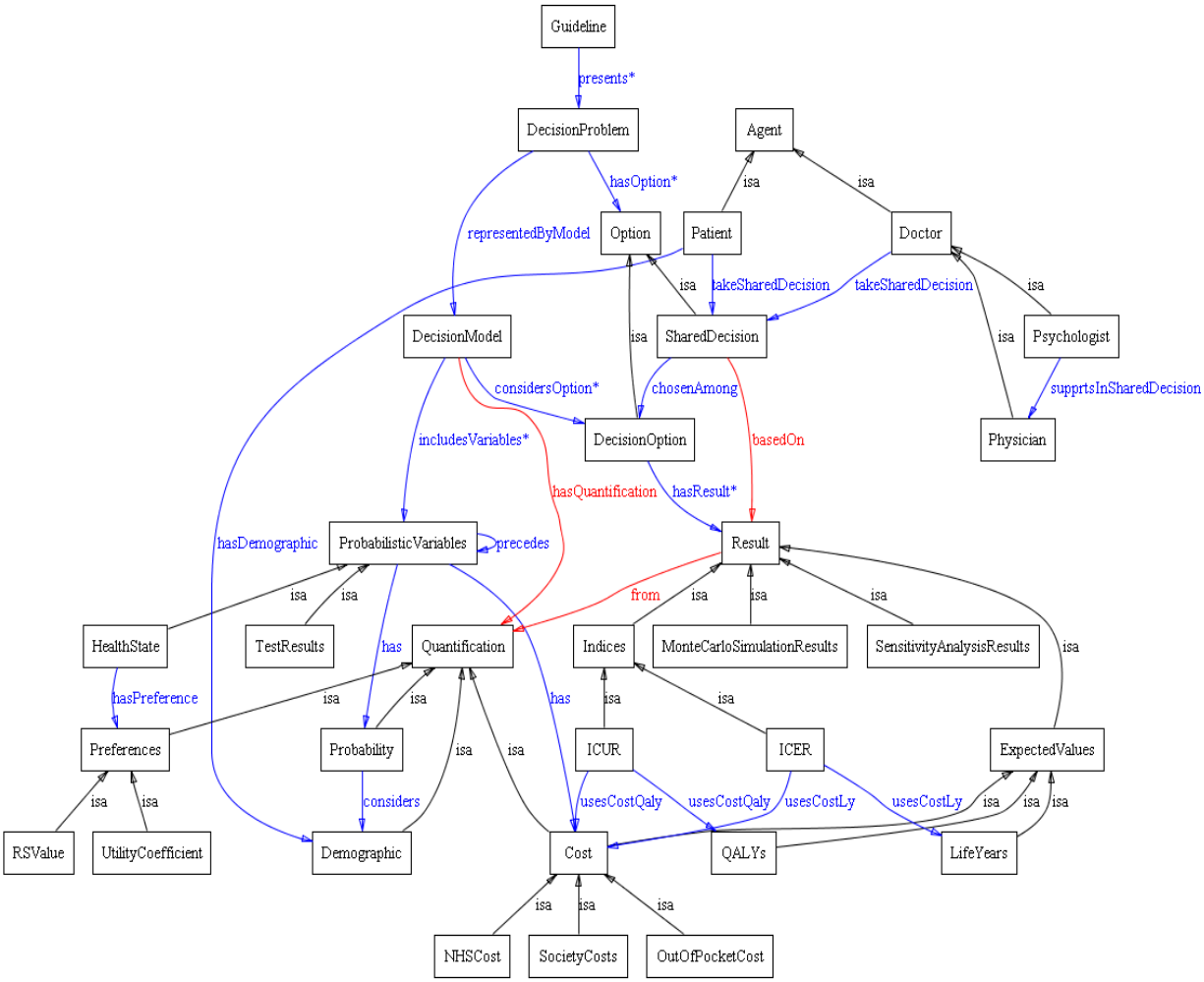


**Figure 1** – the ontology of shared decision

In general, a Guideline presents one or more decision problems (class **DecisionProblem**), which are the clinical problems in which a shared decision is

suggested or needed (i.e., the *forking points*). For example, recommendation II.1 in section 8.1.4 of the Atrial-Fibrillation guideline we use, suggests taking into account patient preferences in the choice of the treatment for thromboembolic risk prevention:

*For primary prevention of thromboembolism in patients with nonvalvular AF who have just one of the following validated risk factors, antithrombotic therapy with either aspirin or a vitamin K antagonist is reasonable, based upon an assessment of the risk of bleeding complications, ability to safely sustain adjusted chronic anticoagulation, and patient preferences: age greater than or equal to 75yrs (especially in female patients), hypertension, HF, impaired LV function, or diabetes mellitus.*

Every decision problem has several decision options (*forking points*), which are the options among which the patient and the care professional will select the final decision. These options are included in the abstract class **Option**, which is connected to the class **DecisionProblem** through the relation hasOption. **Option** has two children: **DecisionOption** and **SharedDecision**. The **SharedDecision** is an **Option** and is chosen among the available decision options (relation chosenAmong between the class **SharedDecision** and the class **DecisionOption**). In the AF example, the available decision options are Acetylsalicylic Acid, Warfarin or No Drug Therapy (for preventing thromboembolism). If, as in the Hello Tallinn scenario, Warfarin is the selected option, that will be the shared decision. The final shared decision is based on the results of the decision model (relation basedOn between class **SharedDecision** and class **Result** discussed in the following of this document).

Every decision problem can be represented by (relation representedByModel) a decision model (class **DecisionModel**). In the case of MobiGuide, we have selected the Decision Tree formalism, but in general also other strategies can be used (e.g., Influence Diagrams). A decision model considers (relation considersOption) several decision options and includes a set of variables (relation includesVariables). These variables are all part of the high-level class **ProbabilisticVariables**. Probabilistic variables can be either health states (class **HealthState**) or test results (class **TestResults**). Both of them have probabilistic values, with the difference that health states can be associated (relation hasPreference) with preferences (class

**Preferences**). The preferences can be either utility coefficients (class **UtilityCoefficient**) or values (class **RSValue**). The difference between these two categories is that utility coefficients can be used to calculate QALYs while values are only used to rank health states according to the patient's perception of such conditions.

The decision model is related to another important class, the **Quantification** class (via the hasQuantification relation). This class represents the step in the modeling that allows assigning values to all the variables that are part of the model. Quantification (which is an abstract class) has four children: **Preferences** (already described in the previous paragraph), **Probability**, **Demographic** and **Cost**. The class **Probability** is used to represent the quantification of the probabilistic values of the variables of the model (relation has between **ProbabilisticVariables** and **Probability**). The class **Demographic** contains some important demographic information on the patient, that are also useful to select the correct value for the probabilities (this concept is expressed by the relation considers between **Probability** and **Demographic**), such as age and gender. The variables of the model can also be associated to a **Cost** (relation has between **ProbabilisticVariables** and **Cost**). Costs can be of different nature according to the subject they are referred to. We can have costs that impact on the national healthcare service (class **NHSCost**), costs that impact on society (class **SocietyCosts**) and costs that directly impact on the patient (class **OutOfPocketCosts**).

After a decision model is run, it produces some results, represented by the class **Result** of the ontology. In particular, results are extracted by running the model based on the quantification settings (relation from between class **Result** and class **Quantification**) and are related to the decision options (relation hasResult between class **DecisionOption** and class **Result**). Results can be of different nature: they can be the expected values for some quantities (class **ExpectedValues**), they can be indices (class **Indices**) or they can be the results coming from some additional analyses, namely Monte Carlo simulations (class **MonteCarloSimulationResults**) and sensitivity analysis (class **SensitivityAnalysisResults**). The expected values that are calculated by our decision models are: the expected values for life years (class **LifeYears**), the expected values for the QALYs (Quality Adjusted Life Years, class **QALYs**) and the

expected values for the costs (class **Cost**, which in this case can be either a quantification step or a result when it represents the expected value of a decision option). Among indices we have selected the two classes **ICUR** (Incremental Cost/Utility Ratio) and **ICER** (Incremental Cost/Effectiveness Ratio). These two indices are computed starting from the analysis results. In particular, ICUR is calculated using QALYs and costs (relation usesCostQaly) and ICER is calculated using costs and life years (relation usesCostLy).

Finally, the class **Agent** represents the actors taking part in the shared decision process. The patient (class **Patient**) and the care professional (class **Doctor**) work together to take the shared decision (relation takeSharedDecision between classes **Patient** and **Doctor** and the class **SharedDecision**). In this schema we have divided the care professionals into physicians (class **Physician**) and psychologists (class **Psychologist**), to allow the presence of a specialist to support the physician in the shared decision process (relation supportsInSharedDecision between **Physician** and **Psychologist**). The **Patient** is also connected to the class **Demographic** through the relation hasDemographic.

## 2.3. The Technological Context

Terminology note: we denote the technological context (as specified in D2.2) a CCC induced by a technological concept (e.g., the concept "battery" with value = "none" induces the CCC of "no availability"). In the CIG personalization process, the technological context (CCC induced by a technological concept) is defined at the same stage (stage 2 – the CIG's customization process) together with the specification of all the other CCCs for the CIG.

### 2.3.1. Introduction

We have identified with health-care providers the potential use of MG to monitor ambulant patients in a safer way, by taking into consideration also the technological context. We defined with cardiologists the potential benefit of physical exercise in AF patients in their daily life routine. The physical exercise training is based on a target heart rate (HR) value. Accordingly, we studied the technological requirements and the effect of the technological context in an ambulant patient especially during physical training therapy, since this scenario requires monitoring the patient with more sensors and devices.

The technological context and its ontology enable the decision-making process when certain resources are not available (temporarily or permanently) or when the quality of them degrades. The ontology's structure for the technological context is presented in detail in D2.2, pages 35-49.

### 2.3.2. Technological Context Affected Objects

The technological context could have an effect on the following classes:

1. Affected_Plan_Activation_States – specify the activations states (e.g., start, stop, delay and continue) at which a plan (e.g,. physical training therapy) could be. For example, when the HR sensor belt doesn't have enough battery and needs to be charged for three hours, the physical training therapy (for those patients who

absolutely need to be monitored during exercise), would be postponed, i.e,. “plan state”=”delay”. Another example could be if the belt is not available or not running properly, the therapy might be cancelled until a replacement of that sensor is provided.

2. Affected_Recommendations – contains all clinical recommendations that could be affected by the context (as explained in Section 2.1.2), such as changing the “Allowed Data Item Threshold” (a subclass of Affected Recommendations). For example, when the Blood Pressure (BP) sensor of the physical training is not available, the training intensity HR of the physical training would be reduced, say by 10%.

3. Affected_Technologies – represents the internal system configuration adaptations required by the MG system to maintain the system support of the therapies when a certain technological resource is unavailable or not functioning optimally. One identified example is a bad quality connection between the server (in particular the server DSS) and the mobile device (in particular LW-DSS) such that the LW-DSS has to operate autonomously. In this case, the functional elements required by the therapy (e.g., AF detection algorithm required by an AF therapy) have to run on the LW-DSS instead of running at the server. Other possible examples are currently being researched.

4. Message_Delivery – Messages sent to the user for advice, feedback or inquiries in cases when the technological resource’s quality (detailed below) changes below a pre-specified threshold. For example, in cases when it is possible to correct or improve the quality level of a resource (e.g., low battery power in the HR sensor belt) or data (e.g., bad skin-sensor contact) by advising the patient to perform some corrective action.

### 2.3.3. Technological Context Resources and their quality dimensions

Technological resources are grouped into four different classes: Physical Components, Functional Components, Data, and Network Connection.

To define a technological context for a CIG, we need first to identify the resources used within the CIG. We defined the *Technological_Resource* class, containing the different resource types that MG could use:

1. Data (from intrinsic data, such as raw ECG, to more general data, such the information of a guideline)

2. Functional elements (e.g., algorithms to compute AF episodes from ECG data)

3. Physical components (e.g., sensors to acquire patient data, processing components like smart phones and a server to accommodate functional elements)

4. Network Connections (e.g., local range Bluetooth or long range public access GPRS connections to facilitate data transfer in a distributed system)

A detailed list of each technological resource and the different categories it includes can be seen in Table 4 in Appendix 6.5.

Each one of the 4 technological resource classes contains different individuals. (e.g., the physical resource class include the “HR sensor” individual). The *final* quality level of each individual (specific resource) is calculated based on five *Quality Dimensions* (described in detail in appendix 6.4.): Accuracy, Reliability, Timeliness, Cost and Quality of Evidence. Each quality dimension might have any of the following values: “none”, “low”, “medium”, “high”, and “optimal”; The combination of the different quality dimensions values (e.g. a low accuracy and an optimal quality of evidence) defines the *final* quality level of each resource. The Quality dimensions’ values are (also) abstracted from the individual’s specific *qualifying characteristics* (e.g., Sensitivity, Specificity,

Noise). A background of the different quality dimensions in the literature and their description can be found in Appendix 6.3 and Appendix 6.4 respectively.

In MobiGuide, a *QoD broker* (as defined in D2.3) is the responsible for 1) retrieving (e.g., from vendor's data sheets (or other sources)) the *qualifying characteristics* and computing the quality dimensions values of each resource in a given time; and 2) abstracting these numerical values into the *final quality level* of the resource (whose values could be: "none", "low", "medium", "high" and "optimal").

In table (Table 5) in appendix 6.6 we specify the possible quality level values for each individual in each one of the resource's class.

The value of each quality dimension can vary on time (V) or be fixed (F). For example, the accuracy of a HR-sensor might vary, while the accuracy of the AF linker algorithm is fixed. In Table 5 in appendix 6.6 we list for each resource's quality dimension its variability on time specification (whether it is variant or fixed).

The different resource's quality abstraction values will induce a CCC (if the CIG changes within this CCC), specifying how the CIG changes (what are the "**Affected_Objects"**) within this CCC.

While all the resources' quality levels are optimal or their quality level values do not affect the CIG (e.g., if a medium quality level of the data don't change the CIG in any way no CCC is induced) the treatment is executed according to the "default" context of the CIG. Once some resource's quality dimension suffers some degradation in terms of its quality dimensions (e.g., low SNR, high delay, too expensive), the quality level, computed by QoD Broker, is recalculated. If the new resource's quality level had a CCC specified beforehand (i.e., there is an impact in the CIG within this quality level value context) a CCC is induced and the CIG changes accordingly to the specifications previously defined in the CCC. For example the quality level of HR belt sensor could be none, low, medium or optimal. For each value, that change the CIG, we will have a different CCC induced. When a quality level of the HR belt is "none" the context "HR-sensor-unavailable" is induced and within this context, the CIG modification (the

"affected-objects") might be to delay or reschedule a physical training. On the other hand, when the quality level of the HR belt is "medium" (quality abstracted from a non-optimal accuracy, together with a noisy data for example) the "HR-sensor-inaccurate" context is induced and within this context, the CIG is modified by changing the thresholds of the max-HR intensity during physical training to ensure the patient stays within safe limits, during the "HR-sensor-inaccurate" context.

In tables (table 7-10) in appendix 6.7 we define possible changes in the CIG (the possible affected objects) by the different resource's quality dimension values of each different resource. These tables are summarized in a single Table (table 11) in appendix 6.7, grouping together all the resource's quality values that affect the same objects.

As described, a technological context is induced by different (technological) resource's quality level. Sometimes though, different resources' quality levels might conflict with each other. For example a low quality of the HR-rate-sensor (inducing a "HR-sensor-inaccurate" context) and an optimal quality of the BP-sensor (inducing a "BP-sensor-accurate" context) might co-exist, and in this case leaving ambiguity of how the CIG should be modified (according to which context's definition – the "HR-sensor-inaccurate" or the "BP-sensor-accurate"). In order to avoid such situations, conflicts between the different resources quality levels will be solved by abstracting the different values into a single value that will induce a single CCC (determining the affected objects for both). For that we are studying algebraic computational models, as used by Widya et al [5].

# 3. DSS Schema: The Hybrid-Asbru and TAK schemas

The process of acquiring the knowledge is called Knowledge Acquisition (KA). Musen defined KA as "transformation of knowledge from the forms in which it is available in the world into forms that can be used by a knowledge system" [9], and make a distinction between tacit knowledge (knowing how) and conscious, explicit knowledge (knowing that).

When experts first solve a task, they have declarative knowledge about the application area of the task (e.g. the definition of "High blood pressure"), but as they become experienced with the application the knowledge becomes to be procedural knowledge (e.g., defining taking a drug plan, or daily work-up plan).

We differentiate between the two types of knowledge into two separate schemas: the Hybrid-Asbru knowledge models the procedural knowledge while the declarative knowledge is modelled through the TAK (Temporal Abstraction Knowledge) schema.

Below we shortly detail each one of them.

## 3.1. The Hybrid Asbru schema - Background

*Asbru* is one of the main languages for CIG representation. It was originally developed as part of the Asgaard project [10]. Asbru includes significant expressivity regarding time-oriented clinical data and procedural actions, as well as the underlying intentions of these actions. Asbru is a state-driven language, i.e., a plan transits from one state to another based on the evaluation of certain conditions (e.g., a filter-precondition). The different states can be grouped into two main phases of the plan's lifecycle: the selection phase and the execution phase. Figure 2 shows the different Asbru states.

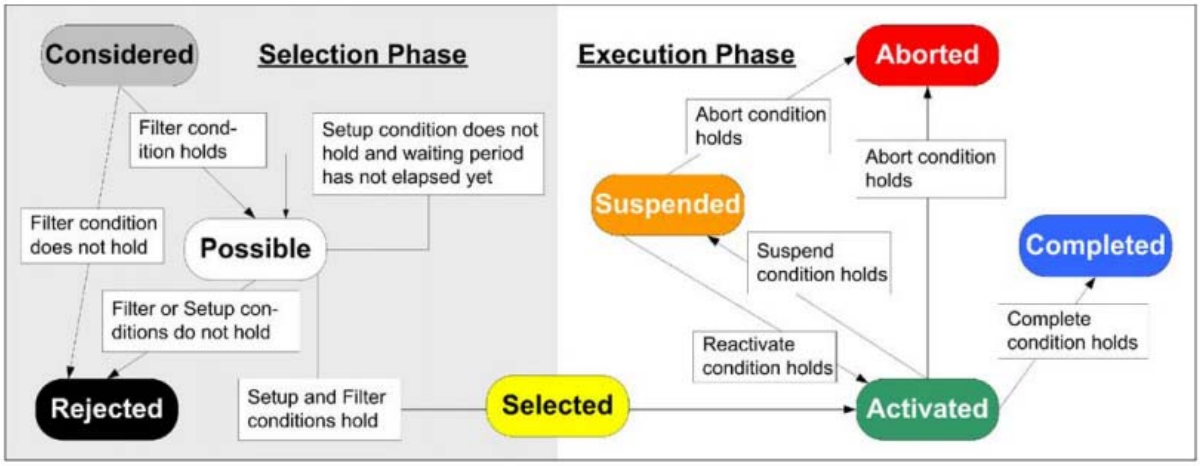


**Figure 2 - The state transition model of an Asbru plan**

The Asbru language was extended into the *Hybrid Asbru* language, which caters for several levels of representation of the knowledge (from the source free text, through semi-structured and semi-formal representations, to a fully formal, executable representation), as part of the DeGeL project [18]. Hybrid Asbru is the default CIG specification language used within the generic PICARD-DSS, the module responsible for the execution of the Guidelines in MG (Asbru interpreter). For simplicity, we will refer to Hybrid Asbru from now on as Asbru.

Currently, Asbru defines several knowledge roles (KRs),some of which which were added gradually to support additional requirements that were missing in its original specification [11]. Below we list a very short and partial list of the knowledge roles of our Asbru guideline specification language, used for specification of all CIGs:

- *Actors* — Specifies who is responsible for taking part in performing the CIG actions, for example: a nurse, a gynecologist, etc.

- *Preferences*—Supports the selection of a plan when more than one option exists. For example: (1) select-method, a matching heuristic to determine the applicability of the entire plan (e.g., exact-fit or roughly-fit); (2) resources, a specification of prohibited or mandatory resources relevant to the current plan

(e.g., in certain cases of a pulmonary infection treatment, surgery is prohibited while antibiotics are mandatory).

- *Conditions*— govern the lifecycle of the plan in perspective of its state transitions. Similar to intentions, conditions are also temporal-patterns at multiple levels of abstraction of patient state (e.g., if the patient has more than two episodes of severe anemia, each episode for a period of at least two weeks, since the start of the plan then abort the guideline) that should be evaluated during plan execution. Some of the condition should be evaluated during the selection phase of a plan:

    - *Filter-precondition*—must be true for the plan to transit from the considered state to the possible state (i.e., the eligibility criteria). If the filter-precondition evaluated to false, the plan transits to the rejected state and cannot be applied for that particular patient.

    - *Setup-precondition*—must be true before the plan transits to the selected state. Unlike the filter-precondition, if the setup-precondition is false when first checked it is possible to define a waiting-period in which it may turn true (e.g., the patient had a glucose-tolerance test taken no later than one month before starting the guideline). If the setup-precondition evaluates to false and the waiting period has elapsed, the plan transits to the rejected state. Thus, the setup-precondition is useful to ensure the existence of optimal circumstances prior to the activation of the guideline for a particular patient.

Other conditions should be continuously monitored during plan execution:

- *Suspend-condition*—if the suspend-condition holds the plan transits to the suspended state, hence its application is suspended and cannot continue for the meantime. Note that the application of the plan's sub plans should be suspended as well. In addition, an optional recommendation, named

onsuspend, can be used to specify an action to do when a plan suspends (e.g., in case of elevated TSH value suspend the plan and refer the patient to endocrinologist specialist).

- *Reactivate(Restart)-condition*—after a plan has been suspended, its reactivate-condition should be monitored to check whether the plan can be reactivated. If the reactivate-condition holds, the plan transits back to its previous activated state. Note that the reactivate-condition cannot be checked as long as the on-suspend recommendation has not finished yet. In addition, when a plan reactivates it should reactivate its sub plans as well.

- *Complete-condition*—while the plan is in the activated state, the complete condition should be monitored continuously. If the condition holds, the plan transits to the completed state and its application is terminated [usually, successfully].

- *Abort-condition*—while the plan is in either the activated state or the suspended state, the abort-condition should be monitored continuously. If the condition holds, the plan transits to the aborted state and its application has terminated [usually, unsuccessfully]. In addition, an optional recommendation, named *on-abort*, can be used to specify an action to do when a plan aborts (e.g., admit patient to the ICU if patient's respiratory rate deteriorates).

- **Plan-body**—contains the recommended actions according to the guideline. As mentioned before, the Asbru language supports the specification of complex controls structures using the plan-body knowledge-role. The types of plan-body elements include for example:

  - *Subplans*—allows grouping of two or more actions to be performed either in sequence, in a restricted order or in any order, or in parallel by setting

the attribute type to one of the following values: sequentially, any-order, parallel and unordered. In addition, the sub plans element contains a special element, also known as the continuation-specification (in Asbru 7.3 it was redefined as two elements: wait-for and abort-if), that enable to specify which of the actions are mandatory (i.e., required to complete successfully in order for the parent plan to complete successfully too).

- *Plan-Activation*—activation of another plan
- *Simple Action*—An atomic plan with simple semantics. Suitable for defining plans with one action such as take drug
- *Switch-Case*—When criteria has some possible values. For each value, a plan should be defined
- *If-Then-Else*—branching statement to reflect various options based on either patient state or plan execution.
- *Cyclical-plan*—allows specifying an action that should be performed repeatedly. In order to control the start time, frequency settings and finish time of the repeated action two main elements are used: (1) The cyclical-step that should be repeated, and its time constraints (2) repeat-specification, which defines the periodicity of the repetition of the plans.
- Monitoring plan – an action or plan activated by a continuously monitored triggering condition. When the triggered condition evaluates to its truth value, the action is activated. Such a plan is purely data driven, applied in an asynchronous manner.
- To-Be-Defined—The plan needs to be defined later.

Above we stated mainly the knowledge-roles in the Asbru ontology that will be affected by the personalization process. A more detailed list can be found in [12].

## 3.2. The TAK schema - Background

The *Temporal-Abstraction Knowledge* (TAK) schema specifies the syntax and semantics of the entities (referred as concepts) in the knowledge base defined according to the principles of the Knowledge-Based Temporal Abstraction (KBTA) method.

### 3.2.1 An overview of the KBTA method

The *knowledge-based temporal abstraction* (*KBTA*) method [Shahar, 1997] is used for derivation of meaningful context-specific, usually interval-based interpretations, called *temporal abstractions* (*TAs*), from raw, usually time-stamped, patient data, using a domain-specific knowledge-base (KB). In general, the KBTA method may be described as follows: the input includes a set of time-stamped measurable concepts (e.g., Platelet count, Red blood cell count) and external events (e.g., bone-marrow transplantation). The events (and, recursively, some of the abstractions derived from the input data) typically create the necessary interpretation contexts (e.g., the therapy protocol used), which could change the interpretations of the raw data. The output includes a set of interval-based, context-specific concepts at the same or a higher level of abstraction and their respective values (e.g., a period of two months of grade II bone-marrow toxicity in the context of particular chemotherapy protocol). Abstractions are only formed within the temporal span of one or more *interpretation-context intervals*, referred to as *contexts*, for brevity.

*Input* concepts for the KBTA method can be one of the following:

- *Raw numeric concept*
- *Raw nominal concept*
- *Raw ordinal concept*
- *Event concept*

And the *output* concepts of the KBTA method can be one of the following:

- *Contexts* represent the state of affairs of patient relevant to the interpretation (e.g., the chemotherapy protocol that is being used)
- *State abstraction* indicates the state of the concept value (e.g., *High* state of the haemoglobin-value concept, in the context of the guideline treatment)
- *Gradient abstraction* indicates the direction of the change of the concept value (e.g. *Decreasing* WBC counts for two weeks, following a BMT transplantation)
- *Rate abstraction* indicates the speed of the change of the concept value (e.g. *Rapid* increasing of the fever)
- *State abstraction of event* indicates the state of the event's attribute(s)' value(s) (e.g., *High* insulin dose)
- *Temporal pattern* represent the fact that certain value and temporal relationship constraints hold among several raw and/or abstract concepts (e.g., two weeks of moderate anemia followed by two to three weeks of low blood pressure).

A full description of the KBTA method can be found in much more detail elsewhere [13].

Below we describe briefly the relevant concepts of the TAK schema that will be affected in order to support the personalization of the guideline. A fully description of the TAK schema including all entities' syntax and semantics is described elsewhere.

**The raw (primitive) concept:**

As stated above, a primitive variable can be of different types: numeric (e.g., quantitative physical observations and medical tests, for example, weight, temperature, White Blood-Cell (WBC) count, Hemoglobin values, etc.), nominal (e.g., gender, in which the values are {male, female}, color, etc.), or ordinal (e.g., set of urine protein values {+, ++, +++}). The raw concept is usually a time-stamped concept. It will have a ValueDefinition expression, which includes the definition of allowed value range (by specifying the minimal and maximal allowed values in the case of a numeric concept, or the definition of allowed symbolic values in the case of a nominal and ordinal concepts). In the case of a raw numeric concept, the units of measure must also be specified.

A raw concept cannot be derived from any other concept.

**The event concept:**

The Event concept refers to external volitional interventions, such as procedures or medications that affect the patient's medical conditions, for example bone-marrow transplantation (BMT), antibiotic drugs, administration of Insulin, Surgery, etc. Note that unlike measurable raw data such as Temperature, over which neither the patient nor her care provider have direct control, events are typically actions that are determined by one of them.

Previous implementations of the KBTA ontology often allowed the Event concept to have only the values {True, False}, depending on whether the event existed or not, making the definition of complex events which include more than one value (e.g., administration of a medication) problematic. To overcome this disadvantage, we have now proposed the full structure of the original KBTA Event concept, to include in the event's definition a list of numeric or symbolic attributes whose name varies per each event (e.g., Dose, Mode, Frequency, in the case of a Medication event); each attribute can have a run-time value in an actual instance of an event. Abstractions of an event are derived from its attribute values.

**The context concept:**

In order to create a Context concept, it is required: (1) the concept and value that generates the context and (2) the definition of the valid time for the context.

Generally, each concept (except the context himself) and specific value (or values) of the concept may generate a context. However, in most cases the generated concept is the *Event* concept. (Another situation, though less common, is the combination of an abstraction and a value, such as Hemoglobin-State and Mild-Anemia). We use the GeneratedBy property notation to denote the inducing concept for each induced context.

The valid time of the context is defined by the pair of time points: *From* and *Until* time point.

To define the each context's boundary point the user specifies the value constraints (i.e., what values of the concept generate the start of the context or finish it) and time constraints (i.e., from what boundary time point of generate interval the context is staring/finishing and, optionally, the time gap).

With respect to the u*ntil* point, optionally, another concept (and concept value) may finish unexpectedly the context. For example, the pregnancy context might be defined as starting from the end of the concept "last menstrual period" and as lasting for nine months relative to that point. However, the resulting context might be clipped by a birth or abortion event. Such concepts are called *clippers* with respect to the context. To define the unexpectedly end point of a context, the clipper concept defines the value and time constraints, similarly to the inducing concept.

It's important to note that the Context concept is required for derivation of all temporal abstractions, i.e., a *State*, *Gradient*, *Rate abstraction* and possibly, for a *Temporal pattern concept*. (We are currently adding a *Trend* abstraction – similarly defined within a context).

**DIRC – Dynamic induction relation of a context interval.**

A DIRC defines the relation between the context interval, inferred dynamically at runtime, and the inducer of the context (event, parameter, or abstraction goal propositions being true over specific time intervals). Certain predefined temporal constraints must hold between the inferred context interval and the time interval over which the inducting proposition is interpreted. (e.g. proposition is interpreted. For instance, the effect of regular insulin with respect to changing the interpretation of blood-glucose values might start at least 30 minutes after the start of the administering and might end up to 8 hours after the end of that administration.

The inference knowledge represented by DIRCs is used at runtime (by the context-forming mechanism) to infer new context intervals.

The full theoretical structure of dynamic temporal contexts, which extends the context-forming mechanism of the basic KBTA ontology is described in [16].

# 4. How MobiGuide's DSS should support personalized CIGs (a vision)

As described in the introduction, the personalization treatment is provided by the DSS by taking into consideration the personalized files of the patient and the customized CIG.

The customized CIG includes all the *CIG-Customized-Contexts* (CCCs). Each CCC defines the CIG's modifications for **any** patient within these contexts. They might include contexts induced by technological (e.g., "no availability" context induced by the *technological* concept mobile-battery="off") and personal (e.g., "high-carbohydrate-level" context induced by the *personal* event "wedding") concepts/abstractions. These modifications (context-specific knowledge) must be represented ahead of time in the DSS schema, by a knowledge engineer together with an expert physician.

The personalized files of the patient include his preferences (global and local) and his DIRCs (mapping the personal events that induce each CCC). The files were specified by the patient together with his care provider before being enrolled to the MG system.

During the CIG customization phase (stage 2) a list of all possible contexts (CCCs) are defined (e.g., specifying what would change in the CIG in case the patient is in an "alone personal-context" (i.e., unassisted by his unofficial care provider), or in a "possible bleeding personal-context" such as dental treatment or operation, or in a "low connectivity" context). For each such CCC we define appropriate plans in the CIG's procedural knowledge (Hybrid-Asbru) and required changes in the declarative knowledge (TAK). Note that whenever we customize a GL by adding new contexts, which lead into new procedural branches, we also need to define in the TAK KB exactly what events, for instance, induce these new contexts, and how the new contexts affect the interpretation of known concepts. As an example for customization, if the narrative clinical guideline recommends a range of 1 to 4 insulin injections a day for the clinical context of diabetes, then a plan of 4 injections a day could be specified for the weekend ("no-routine") context and a plan of 2 injections a day could be specific for the weekday ("routine") context (see [17] for further details).

It is important to note that only contexts defined in this stage can be taken into consideration during the CIG's execution (since it requires both the KL engineer and the clinical expert to define all the knowledge required.)

The next stage (stage 3 – personalization) occurs during one of the first face-to-face encounters between the care provider and patient (and in later encounters, when needed). During the meeting, the care provider defines the personal events (or inducer concepts) that, for the specific patient, induce the different contexts, defining the patient's personal DIRCs, which is saved in a personalized file in his PHR. The DIRC might also define temporal constraints, such as a delay in the start/end of the induced context following the start/end of the inducing concept. The default temporal relationship between inducer concept [interval] and induced context [interval] is that there is no delay in the start of the context relative to the start of the event, and that it ends as soon as the event ends. In addition to the DIRCs specification, the patient's preferences are also discussed and recorded in a personalized file, also saved in his PHR.

Finally, during the CIG execution (stage 4), contexts are dynamically induced by the events previously defined in the DIRCs of the patient. Under the contexts the CIG is changed accordingly (to what was specified in stage 2). In addition, the patient's preferences are also taken into consideration by the DSS, providing a personalized treatment for the patient, accordingly.

An additional way of entering into a different context during the CIG execution stage (in addition to DIRCs) is patient-initiated. The patient could either enter a future event (dental treatment) or directly enter the personal-context that he is in[1]. In some cases, the context can also be automatically detected by the system (e.g., context of "high activity level" can be detected by the activity level algorithm) but not every context can be automatically detected. After the context finishes, the patient will be back to the regular personal-context and the regular plan will resume.

[1] In KBTA, this is defined as an "abstraction goal". De facto "abstraction goal" is an event which only generates the respective context.

# 5. Modeling personalized CIGs in the DSS schemas

In the following three sub-sections we explain how the DSS schemas (Hybrid-Asbru and TAK) support the personalization of the CIG – from the customization (stage 2) to run-time (stage 4). We describe how we the contexts (induced by personal or technological concepts) are modelled into the existing schemas, how the patient's preferences are taken into consideration during the run-time and the adaptations performed in the schemas, where relevant.

As will be seen, the current DSS current schemas support most of the personalization process, and only a few changes were necessary.

## 5.1. Modeling contexts induced by either personal or technological concepts. (CIG's customization)

Modeling inducing concepts

Personal variables, identified in the "personal context ontology" as defined in D2.2, will be mapped either to primitive or to abstraction variables in the TAK schema, according to whether they can be abstracted or not from other concepts.

For example, the "Patient self-ability to Comply with Treatment" will be mapped to a primitive variable while the "living area pollution" will be mapped to an abstracted variable, assuming that it can abstracted from another variable (e.g., the city he lives in).

In the same way, we will map the technological resources' (functional, physical, data) quality level, identified in the "technological context ontology" as defined in D2.2 also to primitive or abstraction variables in the TAK schema. The quality level of each resource is abstracted from the different quality dimensions of the resource. The abstraction process could probably be done by the KBTA mechanism, (instead of the QoD broker) depending on the abstraction function (still undefined).

Note that only concepts that might induce contexts affecting the CIG will be defined in the TAK schema. (e.g., if the communication level of the patient doesn't affect the CIG in any way, it will not be mapped).

This modelling is done during stage 2, in the CIG's customization. Therefore, all the concepts that might induce contexts for **any** patient are specified in the TAK KB at this stage.

Modelling affected objects (CIG's modifications within identified CCCs)

During customization time, the knowledge engineer and clinical editor in addition to defining all potentially induced new contexts (the CCCs) also define how the CIG changes for each identified context (the "affected Objects" as defined in D2.2): (1) defining any TAK instances (e.g., state abstractions within the new context) that are affected by the new context; (the *declarative* effect) and (2) defining all of the procedural actions/plans affected by the existence of the new context (the procedural effect).

The CIG's modifications, defining how the CIG changes within a context, might include changes in the declarative knowledge (e.g., changing of a threshold value), in the procedural knowledge, or both.

Changes in the procedural knowledge are modelled by specifying respective Hybrid-Asbru plans with the specifications for the context. (e.g. if the "high-cholesterol-level" context changes the amount of insulin recommended by the system, a plan with this specification is created, and will run instead of the previous plan while the "high-cholesterol-level" context holds). An additional example could be if within a pre-defined CCC (e.g., "high-intensity-physical-activity" context) a message needs to be sent to the user ("please connect your HR sensor") a new plan is specified for the context, including the action of sending a message to the user, and any other required CIG modification.

Changes in the declarative knowledge (TAK KB) include, in addition to the declarative concepts defined for each (technological or personal) inducing concept, also the

definition of a TAK context which might be created if (and only if) the CIG changes during the CCC (by either declarative (e.g., thresholds) or procedural (e.g., medication dosage) changes.

A concept might have a different impact on the CIG depending on the source that updated it (e.g., updated by the patient or by the physician). Formally, an inducing concept might or might not induce a context depending on the source (i.e., who entered this concept into the system). For this reason, we will expand the primitive/abstraction variable of the declarative knowledge (in the TAK schema) with the attributes “source” - specifying who entered the indicated current personal concept (inducing concept) into the system.

In table 13 in Appendix 6.8 we specify each identified personal concept in regard to the source variable, and in addition specify whether it should be mapped to a primitive or an abstracted variable and their valid time.

Note that the affected object “Run process on component” identified in the “technological context” ontology will be specified after work on DSS distribution in WP5 progresses. Anyhow, we do not anticipate at this point any changes to the Asbru language or to the Picard engine; most changes will be at the level of the TAK ontology and the declarative and procedural knowledge instances, as well as in the patient and care provider interfaces.

### 5.2. The DSS personalized treatment (CIG’s execution time)

The personalized treatment is achieved by (1) running the customized CIG, which is expanded according to the different CCCs dynamically induced by the concepts defined in the patient’s personal DIRCs and (2) taking into account the patient’s defined preferences.

Below we describe how this occurs during the CIG execution (stage 4).

(1) Expanding the CIG with DIRCs

During the CIG execution, every time a context is dynamically induced (by the context-inducing mechanism) the DSS will make the appropriate transition from the "regular" plan application to the new plan application (assuming that the new personal-context was previously defined, (in stage 2), together with the plan specifications)

This transition of plans is supported by the DSS' continuous monitoring to check if there is a new context in the patient's PHR. As with other monitoring, the DSS will be subscribed to the pattern (in this case the context concept itself), as it does for any type of transition condition.

This recursively means that the temporal mediator will need to monitor all of the components that the pattern is derived from, or, in this case, all of the concepts from which the context is induced (induction is really a special case of a derivation relation).

(2) Taking into account patient's preferences

As previously described, we differentiate between global and local clinical preferences. Below we detail how the (a) global preferences (shared-decision) and (b) the local clinical preferences (regarding his medical treatment) which were saved in the personalized file during stage 3 taken into consideration during the CIG execution time.

(a) Modelling global preferences ("Shared decision"):

During the CIG acquisition, we define "decision-points (*forking points*)" - points where a shared-decision between the patient and doctor might take place, shifting control from the DSS engine to the Shared Decision Making module, to elicit the relevant patient preferences and return a pointer to the optimal continuation at the forking point. The decision model which will be used is selected according to what was determined at guideline-specification time for that forking point.

This will be modelled in the Hybrid-Asbru schema by adding two additional attributes to the *subplan* knowledge role:

(1) “isSharedDecision”, which will be set to *true* when a shared decision will take place.
(2) “ModelID” – the id of the selected model.

During execution time, when the DSS Server identifies a forking-point, it will send a notification message to the DecisionModel module, specifying the ID of the model to be used (“*modelID*”) together with the ID of the patient. We will also send to the DecisionModel the possible options of output that the DSS Server expects to receive, thus ensuring that the output returned will be one of the available branches of the CIG. In principle, these outputs should be already known to the DecisionModel specified at CIG-specification time, but it might be the case that we do not desire one of the options mentioned at the forking point at all, only the best of the rest of the potential options.

(b) Modelling local preferences:

As mentioned before, the patient’s local preferences, such as preferred mode or route of administering the medication, were discussed and defined during one of the first physician-patient encounters, and saved in the personalized file (in his PHR) during stage 3 of the personalization process. Note that each preference defined in the personalized file also creates a respective data instance in the TAK ontology and have a specific preferenceGesherID.
During the CIG execution phase, each action in the CIG might require to check whether there are patient’s preferences defined for this action for the specific patient. This will be modelled in the Hybrid-Asbru schema by adding 2 attributes to the “Clinical step” knowledge role:
(1) the “isPersonalized” attribute, which will be set to *true* when the patient’s preference should be taken into consideration for this action in this specific place in the CIG;

(2) the “preferenceGesherID” attribute which will point to the patient’s preference variable – defined as a primitive variable in the declarative TAK schema.

Note that the same action (e.g., taking medication x) could allow personalization in one place of the CIG while not in others by simply specifying *isPersonalized*=true in one place and *isPersonalized*=false in the second place.

During the CIG execution, when the DSS Server identifies an action with the attribute *isPersonalized* set to *true* it checks what has been defined for this specific preference (by sending a query to the mediator for the *preferenceGesherID*) and will act accordingly.

If during execution time the DSS Server identifies an action with “isPersonalized” = true but there is no preferences defined, it could either act according to a default value or, consider asking the user about his preferences.

# 6. Appendix

## **Appendix 6.1 -** A personalized treatment scenario, from the GDM domain

*Maria is a 32 years old patient, married with 1 child, works as an accounting management of a small company and expecting her second child. Maria was diagnosed for GDM and her state requires an insulin therapy and blood pressure measurement, so monitoring needs to be stricter. She is also required to monitor blood glucose levels and to follow diet recommendations.*

*Maria has been enrolled in MG, she has received a Smartphone, a glucose meter and a pulsimeter.*

*The CIG that will be used to monitor Maria (the GDM CIG) is a customized CIG, expanded with the different contexts that any patient could be in, and that would affect the CIG. Each context includes also the time frame for the specific interval for which the context holds. One of the CCCs defined for the GDM CIG is the "Travel routine" context which specifies how the GDM CIG changes for any patient entering into this context.*

*Maria and her physician identified her "Regular routine": (personal state abstraction): Day routine: routine/semi-routine; Diet routine: routine/semi routine; Ability to comply with treatment: full (by patient); support level: full support (by husband); Alcohol use: no use; Smoking habits: none; Exercise level: mild; Physical disability: no disability; Pain level: slight/fair; Stress level: low; Financial capability: medium/high; Distance from medical center: nearby (10-15 min); Living area accessibility: easy access; Communication level: good [Patient wants to know all about prognosis; Education level: medium; Language level: high; Trust level: high and Cooperation level: very good]*

*Based on her routine, the physician and Maria defined the possible events (personal or technological) that could induce any of the previously identified contexts for the GDM CIG. For example, his physician added a DIRC defining the event "meeting-customer-abroad" (since every once in a while Maria has to visit a customer abroad) mapping to the previously defined CCC "travel routine". In addition, the physician filled together with Maria a form regarding her preferences such as preferred times to take medications, between others.*

*Maria receives recommendations to monitor blood glucose levels 4-6 times per day (fasting and 3 postprandial -1 hour- measurements, and possible addition of pre-lunch and pre-dinner measurements). She is instructed to monitor insulin (doses and time), intake deviations from the established diet recommendations (daily), ketonuria (daily), and body weight (weekly). The Smartphone will monitor physical activity according to the defined guidelines and the patient health state (in some cases the physical exercise could have medical or obstetrical contraindications, so the goal will be to monitor the physical activity to guarantee that the patient is resting).*

*After defining the events that, for Maria, induce possible pre-defined contexts (the "DIRCs") and Maria's preferences, she leaves the clinic and starts being monitored by MG.*

*Maria plans to travel in the next month to one of the company's customer abroad, so she enters the event "meeting-customer-abroad", with the appropriate timestamp, which has been defined in her meeting with her physician and linked to the CCC "travel-routing. This event dynamically induces the "travel routine" context and the changes defined for this context will hold for Maria during the time she is in this context.*

*For the "Travel routine" Maria was recommended to monitor blood glucose levels 3-4 times per day (fasting and 2 postprandial -1 hour- measurements, and possible addition of pre-lunch and pre-dinner measurements), the blood glucose threshold level is increased to be below 140 ml/dl. She is instructed to decrease basal insulin and increase long acting insulin to 2 times per day. Keep mild activity 2-3 times per week, with more than half an hour walk. These treatment recommendation are for the traveling period and after Maria's return (when the travel-context context ends) she will continue the "Regular routine" recommendations (back to the default context).*

*Maria uses the system to specify the dates of her travel and during her time abroad she keeps the "Travel context" recommendations. After her return the system automatically returns to her "routine context" recommendations.*

**Appendix 6.2 - objects affected by contexts induced by personal concepts in the GDM treatment:**

Context and Effect classes

| Personal concept | Range | Affected objects | |
|---|---|---|---|
| Daily routine & Diet routine | a – Routine diet or schedule. | Threshold | Decrease threshold of blood glucose: 70-120 ml/dl |
| | | Measurements | Keep measurements: 4-6 times per day |
| | | Physical activity | Keep mild to moderate activity (1-6 MET), 3-4 times a week, 1 hour walk. |
| | b – Semi routine diet or schedule | Threshold | Increase threshold of blood glucose: <140 ml/dl |
| | | Measurements | Decrease measurements: 2-3 times per day |
| | | Physical activity | Decrease to mild exercise (1-3 MET), 3-4 times a week, more than 1/2 an hour walk. |
| Support level | a-b – High to frequent support | Medication change | Decrease threshold of blood glucose: 70-120 ml/dl |
| | | Measurements | Increase measurements: 4-6 times per day (*) |
| | | Physical activity | Keep mild to moderate exercise (1-6 MET), 3-4 times a week, 1 hour walk. |
| | c-d – Some to night support | Medication change | Increase threshold of blood glucose: <140 ml/dl |
| | | | Decrease Basal insulin: 1-2 times a day (*) |
| | | | Increase long acting insulin: 1-2 times per day (*) |
| | | Measurements | Decrease measurements: 3-4 times per day (*) |
| | | Physical activity | Decrease to mild exercise(1-3 MET), 2-3 times a week, more than 1/2 an hour walk. |

(*) measurements refer to event of basal insulin injection

(**) It depends on glucose profile, only in few cases you can delay the start of treatment or prefer basal insulin

## Appendix 6.3 Quality dimensions - Background

In the literature of Quality of Data (QoD) [4] and Quality of Service (QoS) (see e.g. [4] and [5]), we found many different quality dimensions to abstract the quality types or parameters of technological resources. Cysneiros [6], whose study is focused on the health care domain, talks also about the importance of non-functional requirements, which he refers to as quality dimensions. In MobiGuide, we intend to augment messages for patients with a qualifier for the advice. This quality depends on the quality of the resources. Moreover, changes in the quality of the resources may also imply recommendations to adjust the settings of associated therapy plans, e.g. to preserve the safety of the (unsupervised) therapy in a less optimal technological context. In MG, we therefore proposed five main quality dimensions, which were introduced in D2.2. pages 40-43: i.e. Accuracy, Timeliness, Reliability, Cost and Quality of Evidence. These quality dimensions are relevant for the four technological resource types mentioned in Section 2.3.3. However, the interpretations and the representations could be different for these four types. Moreover, qualifiers of the resources of these four types are in general not independent from one another.

For example, an advising message sent to a patient (e.g., “take a rest”) is typically based on many resources. In the physical training therapy, patient's heart rate is monitored by an ECG sensor belt and an HR detection algorithm. If the Zephyr BioHarness 3 sensor belt system is applied, reliability of the computed HR is expressed in terms of the quality parameter “HR confidence” which is based on the ECG sensor noise and ECG signal amplitude. On the other hand, the ECG sensor quality could be expressed by the Signal to Noise Ratio (SNR). Moreover, HR data from the sensor is sent through Bluetooth to the smart phone and for example could be forwarded via a public access network to the server for further processing. At the server, the received HR data experienced a delay (i.e. a quality parameter of timeliness), which could be computed from the sensor belt latency, including the HR detection process delay, and the transmission and propagation times of the network connections. The DSS at the server furthermore is typically more aware of the strength of evidence or the quality of evidence of clinical guidelines than a light-weight DSS which resides on a smart phone. Thus, the server DSS decision has a different quality of evidence, and would accordingly affect quality of evidence of the effectuated advice to a patient.

## Appendix 6.4 Quality Dimensions Description

The proposed quality dimensions Accuracy, Timeliness, Reliability Cost and Quality of Evidence are qualifiers of different abstraction levels in a hierarchical system, for example technological device level or functional level of algorithms of clinical variables or medical events like HR, HR variability, AF episode. Therefore, the precise meaning of these quality dimensions, their respective values and also the types of the values depend on the addressed abstraction level from the type of technological resource.

1. Accuracy is one of the most cited quality dimension in both QoD and QoS literature studies [4]. It represents the correctness or exactness of an event, a set of events, a condition, or data (ISO/IEC 13236). As an example SNR is an accuracy parameter for the data and varies with time, while Sensitivity or Specificity are fixed accuracy parameters for functional elements. The accuracy on a physical component and connectivity could be represented by the resolution that the physical component handles or the error percentage that it causes, which is again varies with time.

2. As shown by Wand et al. [4], there is no generally accepted notion of reliability, but one interpretation is the capability of a system (or function) to perform and maintain the service and its functions within a defined quality. Accordingly, we assume under this quality dimension other parameters as availability, fidelity or integrity. Those would vary on time for the four main resource groups defined.

3. Timeliness not only defines time delay in general terms, but also the state of happening or appearing at the right or an opportune time. There are many temporal dimensions that could be included (ISO/IEC 13236), but in the context of MG, timeliness would be affected by the four resources using for those three sub-classes: freshness for data, latency for DS functional elements and delay for both physical component vs. network connections. The freshness and the delay are variable on time, but the latency, which is the time required by the function (e.g., AF algorithm) to measure or process the data, is a fixed value.

4. Cost is a value of money required to produce something or perform an activity. This is a dimension that might be associated with the four main Technological Resource subclasses. But from now we would consider the cost of physical components and network connection, being a fixed value and variable on time value respectively. As an example for the network connection we can think of a user using a BAN, which data is transmitted to the server. When the patient is at home the data is transmitted via Wi-Fi, for which the user has to pay a minimum fixed price per month. In contrast, when the patient is outdoors and a public Wi-Fi is not available, the data is transmitted via GPRS or 3G network and the cost will depends on the bits transmitted, the country from which he is transmitting etc.

5. Evidence-Based Medicine (EBM) is the integration of best research evidence with clinical expertise and patient values [7]. In line with EBM (i.e., the duality between using best evidence and taking into account the characteristic of the individual

patient), the source used to get the advice sent to the patient in the ambulant monitoring would be related with the Quality of Evidence (QoE). That is, if the patient matches the category defined in the guideline and the advice is generated from this guideline the advice would have high QoE. In some other cases, e.g., for a particular patient, the advice sent to the patient has been generated based on medical expert opinion and would have lower QoE although it matches better with this particular patient. On the other hand the technologies used for guiding the patient also contain QoE dimension based on their proven suitability, limits, qualities, costs, and inherent risks [8].

## Appendix 6.5 – Technological resources table

### Table 3. Technological Resources

| Technological Resources Classes | Technological Resources definition | Individuals | Monitored | |
|---|---|---|---|---|
| | | | AF patient | AF vs. hypertension |
| **Physical components** | A part of a mechanical or electrical system | BP Sensor | Morning (9:00 -12:00) Before Training | Morning (9:00 - 12:00) Before Training **AND** Evening (18:00-24:00) |
| | | HR belt sensor | Training + (30min before/after training) AND (defined by CP[2]) | |
| | | Physical Activity sensor | When HR monitor | |
| | | Smart Phone | Continuously | |
| | | DSS (LW, Server) | Continuously | |
| **Functional Components** | Tasks or functions that the system should measure | AF algorithm | When HR monitor | |
| | | HR algorithm | Training + (30min before/after training) AND (defined by CP) | |
| | | Physical Activity Function | When HR monitor | |
| **Data** | Information (as measurement, signals, or statistics) used as a basis for reasoning, discussion, or calculation Monitored Data (e.g. ECG); Personal Data (e.g. agenda); Environmental Data (e.g. room temperature); Clinical Data (e.g. AF asymptomatic) | BP data | Morning (9:00 -12:00) Before Training | Morning (9:00 - 12:00) Before Training **AND** Evening (18:00-24:00) |
| | | HR data | Training + (30min before/after training) AND (defined by CP) | |
| | | Physical Activity data | When HR monitor | |
| **Network Connection** | Network of data processing nodes that are interconnected for the purpose of data communication. | Wireless Personal Area Network (PWAN) (e.g. Bluetooth) | Continuously | |
| | | Wireless Local Area Network (WLAN) or Public Land Mobile Network (PLAN) (e.g. UMTS) | Continuously (if possible) | |

[2] When the care professional defines the monitoring in a particular timing of the day or more prolonged during the day (e.g. usually the first week patient enrolled more prolonged) apart from during training

## Appendix 6.6 - Resources, Quality Dimension, and variability of time table

### Table 4. Resources, Quality Dimension, and variability of time

| Technological Resources Classes | Individuals | Quality Dimensions and their variability on time | | | | |
|---|---|---|---|---|---|---|
| | | **Accuracy** | **Timeliness (delay, latency, freshness)** | **Reliability** | **Cost** | **QoE** |
| **Physical components** | BP Sensor<br>HR belt sensor<br>Physical Activity sensor<br>Smart Phone | **F**<br>Based on the characteristics of each component | **V**<br>The processor timing varies | **V**<br>Sometimes is not available etc. | **F**<br>Fixed price each sensor and devices | **F**<br>(safety, effectiveness; certificate) |
| | DSS (LW, Server) | - | | | | - |
| **Functional Components** | AF algorithm (Linker, Moody)<br>HR algorithm<br>Physical Activity Function | **F(V)**<br>A priory **Fixed Accuracy**.<br>So defines as fixed and variable Accuracy of Data | **F**<br>Time for function to process the data | **F(V?)**<br>Variability depends on data and components, not in itself | **F**<br>Device on which function run | **F**<br>(safety, effectiveness; certificate) |
| **Data** | HR data<br>Physical Activity data<br>BP data | **V**<br>(e.g. artifacts, SNR etc.) | **V**<br>Freshness. (when data was stored) | **V**<br>(e.g. type of patient that stores value) | - | - - |
| | EBM data(source of decision) | **V**<br>e.g. how patient fits in the inclusion criteria category, | **F**<br>Fixed based on the study, trial date | **V**<br>evidence (statistical certainty) | **F**? | **V**<br>(source used, patient) |
| **Network Connection** | (PWAN) | **V** | **V** | **V** | **F** | - |
| | (WLAN) or (PLAN) | **V** | **V** | **V** | **V** | - - |

## Appendix 6.6 - Quality Level of each Technological Resource table

Table 5. Quality Level of each Technological Resource

| | Technological Resources | Quality level | | | | |
|---|---|---|---|---|---|---|
| | | None | Low | Medium | High | Optimal |
| Physical components | BP sensor | X | | | | X |
| | HR belt sensor | X | X | | X | X |
| | Physical Activity[3] sensor | X | | | | X |
| | Smart Phone | X | X | | | X |
| | DSS (LW, server) | X | | | | X |
| Functional components | Functions | | | | X | |
| Intrinsic data | HR data | X | | | X | X |
| | Physical Activity data | X | | | | X |
| | BP data | X | | | | X |
| | EBM data | X | | X | X | X |
| Network connection | Wireless Personal Area Network (PWAN) (e.g. Bluetooth) | X | | | | X |
| | Wireless Local Area Network (WLAN) or Public Land Mobile Network (PLAN) (e.g. UMTS) | X | | X | | X |

[3] Physical Activity Device and Physical Activity Data: The physical activity during training would be an extra information for the care professional, but would not affect the physical training therapy execution. For the symptoms avoidance scenario it would be required.

## Appendix 6.7 - Impact of the quality levels on the CIG by resource class

### Table 6. Affected Objects by the quality level of Physical Components

| Technological context | | Affected Object | | Case |
|---|---|---|---|---|
| **Technology** | **Quality level** | **AF or AF vs. hypertension well controlled by drugs** | **AF vs. hypertension** | **Case** |
| **BP Sensor** | None | Allowed Data Item Thresholds (Safety factor) | | reduce safety factor by 10%[4]; |
| | | GENERAL (DEFAULT) BEHAVIOUR*[5] | | |
| | | | Affected Therapeutic Plan Activation State | Physical Training Execution STOP |
| | | | Message Delivery | (Physical Training Execution STOP) |
| | Optimal | GENERAL (DEFAULT) BEHAVIOUR* | | |
| **HR belt Sensor** | None | Affected Therapeutic Plan Activation State | | Physical Training Execution, Symptoms Therapy Execution: STOP |
| | | Message Delivery | | (Patient to check: HR Belt)<br>(Physical Training Execution STOP; Be careful, there is not data, you are not monitored) |
| | Low | Affected Therapeutic Plan Activation State | | Physical Training Execution DELAY: 3 hours |
| | | Message Delivery | | (“charge battery”);<br>(Physical Training Execution delay) |
| | High | Allowed Data Item Thresholds (Safety factor) | | Reduce/increase safety factor by 10% |
| | | GENERAL (DEFAULT) BEHAVIOUR* | | |
| | Optimal | GENERAL (DEFAULT) BEHAVIOUR* | | |
| **Physical Activity Sensor** | None | Affected Therapeutic Plan Activation State | | Symptoms Therapy Execution STOP |
| | | Message Delivery | | (Patient to check: Physical Activity Device)<br>(Symptoms Therapy _Execution STOP) |
| | Optimal | GENERAL (DEFAULT) BEHAVIOUR* | | |
| | | | | |
| **Smart Phone** | None | Affected Therapeutic Plan Activation State | | (Therapy Execution: STOP) |
| | | Message Delivery | | (All Plan Execution STOP) |
| | Low | Affected Therapeutic Plan Activation State | | Physical Training Execution DELAY: 3 hours<br>NOTE: IF (training) THEN (STOP AF, Physical Activity monitoring) |
| | | Message Delivery | | (“charge battery”) |

[4] HRmax=HRmax_abs[4]*(%**safety factor**); HRmin=HRmax_abs*(%safety factor)
This values would change for Warming up (HRmax_WU, HRmin_WU), Target Training (HRmax_TT, HRmin_TT) and Cool Down (HRmax_CD, HRmin_CD))
HRmax_abs= Absolute value to HR that the patient should not cross measure by formula (220-age) or Bruce test. Otherwise a clinical event would happen and if that happens more than X times (time, numerical events) the therapy should be cancelled.
[5] GENERAL (DEFAULT) BAHAVIOUR: See Appendix 6.1

| | | | |
|---|---|---|---|
| | | | (Physical Training Execution delay) |
| | Optimal | GENERAL (DEFAULT) BEHAVIOUR* | |
| DSS server | None | Affected Technology (Run Process on Component) | All functions (e.g. AF algorithm) run in LW-DSS |
| | | GENERAL (DEFAULT) BEHAVIOUR* | |
| | Optimal | GENERAL (DEFAULT) BEHAVIOUR* | |

## Table 7. Affected Objects by the quality of Functional Components

| Technological context | | Affected Object |
|---|---|---|
| Technology | Quality level | |
| Functions (Functional components) | High | GENERAL (DEFAULT) BEHAVIOUR* |

## Table 8. Affected Objects by the quality of Data

| Technological context | | Affected Object | | Case |
|---|---|---|---|---|
| Technology | Quality level | AF or AF vs. hypertension well controlled by drugs | AF vs. hypertension | |
| BP data | None | Allowed Data Item Thresholds (Safety factor) | | Reduce safety factor by 10%[6]; |
| | | GENERAL (DEFAULT) BEHAVIOUR* | | |
| | | | Affected Plan Activation State | Physical Training Execution STOP |
| | | | Message Delivery | (Physical Training Execution STOP) |
| | Optimal | GENERAL (DEFAULT) BEHAVIOUR* | | |
| HR data | None | Affected Therapeutic Plan Activation State | | (Physical Training Execution, Symptoms Therapy Execution: STOP) |
| | | Message Delivery | | (Patient to check: HR Belt)<br>(Physical Training Execution STOP) |
| | High | Allowed Data Item Thresholds (Safety factor) | | Reduce/increase safety factor by 10% |
| | | GENERAL (DEFAULT) BEHAVIOUR* | | |

[6] HRmax=HRmax_abs[6]*(%**safety factor**); HRmin=HRmax_abs*(%safety factor)
This values would change for Warming up (HRmax_WU, HRmin_WU), Target Training (HRmax_TT, HRmin_TT) and Cool Down (HRmax_CD, HRmin_CD))
HRmax_abs= Absolute value to HR that the patient should not cross measure by formula (220-age) or Bruce test. Otherwise a clinical event would happen and if that happens more than X times (time, numerical events) the therapy should be cancelled.

| | | | |
|---|---|---|---|
| | Optimal | GENERAL (DEFAULT) BEHAVIOUR* | |
| **Physical Activity data** | None | Affected Therapeutic Plan Activation State | (Symptoms Therapy Execution: STOP) |
| | | Message Delivery | (Patient to check: Physical Activity Device, belt or smart phone??)<br>(Symptoms Therapy _Execution STOP) |
| | Optimal | GENERAL (DEFAULT) BEHAVIOUR* | |
| **EBM data** | None | Affected Therapeutic Plan Activation State | (Therapy Execution: STOP) |
| | | Message Delivery | (All Plan Execution STOP) |
| | Medium | GENERAL (DEFAULT) BEHAVIOUR* (quality grade) | Expert opinion/ Report<br>Not statistically proven |
| | High | GENERAL (DEFAULT) BEHAVIOUR* (quality grade) | Cohort study/ RCT[7]<br>Statistically proven |
| | Optimal | GENERAL (DEFAULT) BEHAVIOUR* (quality grade) | Filtered Information (systematic Reviews) Statistically proven best evidence |

## Table 9. Affected Object for the quality level of each Network Connection

| **Technological context** | | **Affected Object** | **Example** |
|---|---|---|---|
| **Technology** | **Quality level** | | |
| **Wireless Personal Area Network (PWAN) (e.g. Bluetooth)** | None | Affected Therapeutic Plan Activation State | (Physical Training Execution, Symptoms Therapy Execution: STOP) |
| | | Message Delivery | (Patient to check: connection)<br>(Physical Training Execution STOP) |
| | Optimal | GENERAL (DEFAULT) BEHAVIOUR* | |
| **Wireless Local Area Network (WLAN) or Public Land Mobile Network (PLAN) (e.g. UMTS)** | None | Affected Technology (Run Process on Component) | No connection |
| | | GENERAL (DEFAULT) BEHAVIOUR* | |
| | Medium | Affected Technology (Run Process on Component) | Bandwidth reduction, high cost |
| | | GENERAL (DEFAULT) BEHAVIOUR* | |
| | Optimal | GENERAL (DEFAULT) BEHAVIOUR* | Sufficient connection |

[7] RCT: Randomized Control Trials

## Table 10. Affected Object for the Technological Context

| Quality level of Technological Context | Affected Object | Example |
|---|---|---|
| None (BP sensor AND AF vs. *hypertension*) OR<br>None (BP data AND AF vs. *hypertension*) OR<br>None (HR sensor) OR<br>None (smart phone) OR<br>None (HR data) OR<br>None (PA[8] Data) OR<br>None (EBM Data) OR<br>None (PWAN) | Affected Therapeutic Plan Activation State | Physical Training Execution, Symptoms Therapy Execution: STOP |
| | Message Delivery | (Patient to check: HR Belt OR Smart Phone)<br>(Physical Training Execution STOP) |
| Low (HR sensor) OR<br>Low (smart phone) | Affected Therapeutic Plan Activation State | Therapeutic Plan Execution (e.g. Training) DELAY (e.g. 3 hours) |
| | Message Delivery | ("charge battery, %Physical component, ");<br>(Physical Training Execution DELAY) |
| None (BP sensor) OR<br>High (HR sensor) OR<br>None (BP Data) OR<br>High (HR data) | Allowed Data Item Thresholds (Safety factor) | Reduce/increase safety factor by 10%<br>HRmax=HRmax_abs*(%safety factor);<br>HRmin=HRmax_abs*(%safety factor) |
| | GENERAL (DEFAULT) BEHAVIOUR* | |
| None (Server-DSS) OR<br>None/Medium (WLAN OR PLAN) | Affected Technology | Run all functions (e.g. AF algorithm) in LW-DSS |
| | GENERAL (DEFAULT) BEHAVIOUR* | |
| Optimal (BP sensor) AND<br>Optimal (HR sensor) AND<br>Optimal (PA sensor) AND<br>Optimal (SmartPhone) AND<br>Optimal (Server DSS) AND<br>High (functions) AND<br>Optimal (BP Data) AND<br>Optimal (HR Data) AND<br>Optimal (PA Data) AND<br>Medium/High/Optimal (EBM Data) AND<br>Optimal (PWAN) AND<br>Optimal (WLAN OR PLAN ) | GENERAL (DEFAULT) BEHAVIOUR* | |

[8] PA= Physical Activity

## Appendix 6.8 - Patient Personal Variable properties table

### Table 11 - Patient Personal Variable properties

| Personal patient variable name | Source | Primitive / Abstraction | Valid time of variable |
|---|---|---|---|
| Patient self-ability to Comply with Treatment | Physician | Primitive | Valid until new data input |
| Patient ability to Comply with Treatment - with support | Physician | Primitive | Valid until new data input |
| Alcohol use | Physician | Abstraction / Primitive | Valid until new data input |
| Communication level | Physician | Abstraction | Valid until new data input |
| • Cooperation level | Physician | Primitive | Valid until new data input |
| • Desire to know truth about prognosis | Physician | Primitive | Valid until new data input |
| • Education level | Patient | Abstraction[9] | Valid until new data input |
| • Language level | Patient | Primitive | Valid until new data input |
| • Trust level | Physician | Primitive | Valid until new data input |
| Daily routine | Patient | Primitive | Valid until new data input |
| Diet routine | Patient | Primitive | Valid until new data input |
| Distance from medical center (time measure) | System | Abstraction | Valid until new data input |
| Drug addiction level | Physician | Abstraction[10] / Primitive | Valid until new data input |
| Exercise level | Patient | Abstraction[11] | Next meeting |
| Financial capability | Physician | Abstraction | Valid until new data input |
| Living area accessibility | Patient | Primitive | Valid until new data input |
| Living area pollution | System | Abstraction | Valid until new data input |
| Need for Accompanying Person for Visits | Physician | Primitive | Valid until new data input |
| Pain level | Patient | Primitive | Day |
| Physical disability | Patient | Abstraction | Valid until new data input |
| Stress level | Patient | Primitive | Day |
| Support level | Patient | Primitive | Week |

[9] Abstracted from #years of study
[10] From urine test
[11] Via numerical definition relevant to the clinical context

# 7. Glossary

- AF - Atrial Fibrillation
- BMT - bone-marrow transplantation
- BP - Blood Pressure
- CCC - CIG-Customized-Contexts, induced by either personal or technological concepts. A CCC defines how the CIG changes for any patient that is under this CCC.
- CIG - computer-interpretable guidelines
- DIRCs - Dynamic Induction Relation Context. Defines the mapping between events and their induced contexts. DIRC is part of the TAK schema and of the KBTA methodology
- DSS - Decision Support System
- ECG - electrocardiogram
- GDM - gestational diabetes mellitus
- GESHER – graphic user interface tool for knowledge acquisition
- HR - heart rate
- Hybrid-Asbru – schema of procedural knowledge
- KA - knowledge acquisition
- KB - knowledge base
- KBTA - knowledge-based temporal abstraction
- KE - knowledge engineer
- LW-DSS - Light-weight Decision Support System
- PHR - patient Health Record
- QALYs - quality adjusted life years
- QoD - quality of data
- SDM - Shared Decision Model
- TAK - Temporal-Abstraction Knowledge, schema of declarative knowledge
- WBC - White Blood-Cell

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