# D2.2 Knowledge Tool 2

## An intervention-specific mHealth programme (Type 2 diabetes)

February 2022

This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Grant Agreement No 737427

mHealth HUB European
A WHO/ITU/Andalusian Regional Ministry of Health initiative

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**Statement of originality**

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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# List of abbreviations

| | |
|---|---|
| AID | Automated insulin delivery |
| BHBM | Be He@lthy, Be Mobile |
| CGM | Continuous glucose monitoring |
| EU | European Union |
| FIC | Family of International Classifications |
| GP | General Practitioners |
| HU | Hungary |
| ICF | International Classification of Functioning, Disability and Health |
| IDF | International Diabetes Federation |
| IT | Information Technology |
| ITU | International Telecommunication Union |
| KT | Knowledge Tool |
| mHealth | Mobile Health |
| NCD | Non-Communicable Disease |
| OAD | Oral anti-diabetic |
| PDA | Personal Digital Assistant |
| SWOT | Strengths, Weaknesses, Opportunities and Threats |
| WP | Work Package |
| WHO | World Health Organization |



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# 1. Revisions

The present deliverable has been revised according to the suggestions of the EC reviewers, specified as follows:

- The benefit that the BHBM project brought to this deliverable has been clarified (chapter 2).
- The long-term impact of KT2 has been developed and included in the D4.4 “lessons learnt” deliverable, with a focus on the indicators.
- In order to test the transferability of this approach to different health care systems, the methodology was shared during a workshop, and the SWOT was administered to participant country experts (Annex 3).
- It has been clarified that the tool does not support a selection of only one regional/national diabetes app, rather the selection of more apps suitable for the specific case (Table 6)

# 2. Background information

Diabetes prevalence is projected to increase worldwide (*Figure 1*) [1] with 60 million people with diabetes in the EU (10.3% of men and 9.6% of women aged 25 years and over).

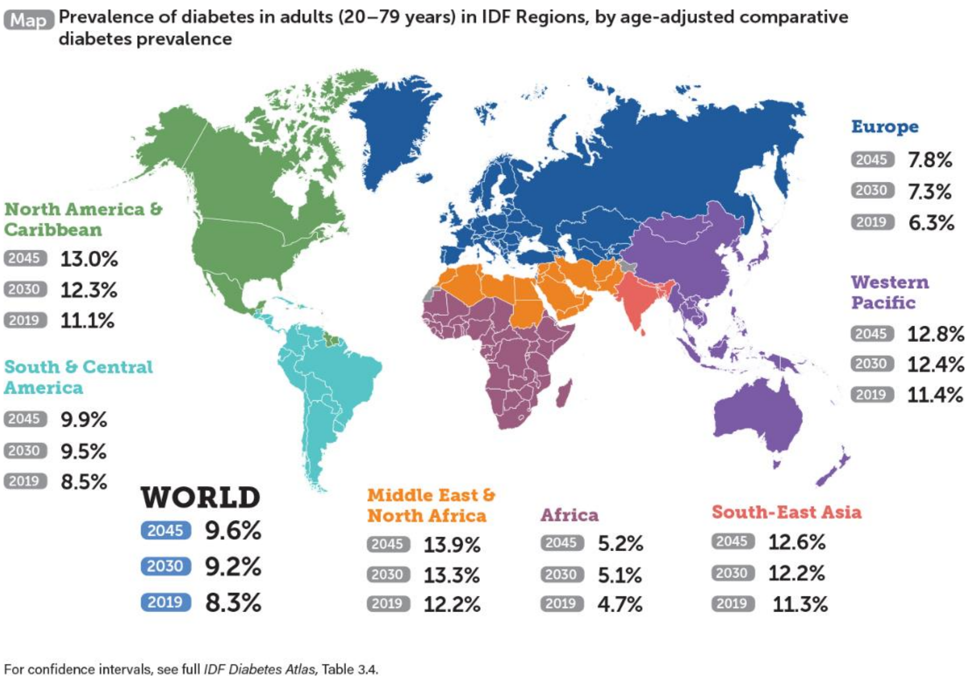


*Figure 1. Reproduction from “IDF Diabetes atlas, 9th edition 2019”.*



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National figures do not capture the heterogeneity of diabetes epidemiology between regions and between the different provinces within the same region. These heterogeneities often reflect inequalities in access to quality healthcare, particularly in low- and middle-income segments of the population that may reside in internal areas or in the peripheries of big cities. Low health and digital literacy often translate into undiagnosed diabetes, or inadequate treatment and management, and people are left unable to access the essential medicines and devices they need, leading to serious health consequences of diabetes-related conditions. In Italy, for example, there are differences in severity and management of diabetes between regions (https://www.epicentro.iss.it/igea/diabete/disePassi), that contribute to the complexity of diabetes epidemiology and care planning at national level.

According to the World Health Organisation (WHO), mobile health (mHealth) is medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs) and other wireless devices [2].

The Be He@lthy, Be Mobile initiative (BHBM) created the mDiabetes handbook for countries that wish to implement national mDiabetes programmes. Its aim is to provide “evidence-based operational guidance and resources to assist countries and governments in drawing up a detailed work plan for the development and deployment of a national mDiabetes programme to prevent or control diabetes by healthy living”. It covers five strategic areas: Operations management, Content development and adaptation, Technology, Promotion and Recruitment, and Monitoring and Evaluation.

D2.2 aims to act in continuity with the BHBM project. According to BHBM initiative, a comprehensive mDiabetes programme in a large geographical area should cover the spectrum of disease, appropriate technologies and the needs and cultural norms of the population that impact on the adoption of solutions. mDiabetes interventions should be embedded in the continuum of prevention and care and treatment, ideally integrated with the health care delivery system to ensure optimal impact. KT2 provides a tool to improve the country/region's capacity to govern innovation because it facilitates the identification of the mHealth solution or combination of solutions that best fit their specific needs, ideally integrated with the healthcare delivery system to ensure optimum impact [3].

However, several limitations arise, related especially to the fact that BHBM refers to solutions designed for text messaging supported, unidirectional interventions, that are not suitable for the exploitation of the validated devices dedicated to self-monitoring, and show limited patient engagement.

The World Health Organization has defined mHealth as the "use of mobile and wireless technologies to support the achievement of health objectives" [4,5]. An mHealth programme impacts the patient’s health outcomes and lifestyle, the quality of the service provision and the professionals’ work, the equal accessibility to care by


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the citizens and data security and would take advantage of a common assessment framework for existing repositories of m-solutions.

The European mHealth Hub, when developing the Knowledge Tool 1 (KT1) about health apps assessment frameworks, has promoted the dialogue and cross-recognition between such frameworks, and highlighted that to this purpose it is pivotal to be aware of real scenarios and needs. Indeed, there is the challenge of addressing assessment elements that are global versus those that are national/regional, with specific regulations.

KT1 results furthermore highlight the relevance of helping organizations to search and find the best product for their targeted needs, rather than just focusing on framework assessment criteria.

In line with KT1 conclusions, and in the framework outlined by the five main areas of intervention highlighted for mDiabetes program by BHBM initiative (prevention, screening, long-term management, secondary prevention of complications and for specific conditions), this Knowledge Tool 2 (KT2) has adopted a user-centred approach for the identification of health needs that could be addressed using mHealth solutions, customised upon the chosen priorities by the pilot country.

The implementation of a mHealth programme on type 2 diabetes can effectively and sustainably reduce inequalities risk factors for diabetes, improving its management. The impact of adoption of mHealth programmes varies among different countries [6]. An implementation strategy for all of the health systems will most likely not succeed. Changing the technology and services or differentiating in the business models is needed, according to differences in epidemiology, cultural and social contexts or IT infrastructure maturity. There is a need for a collaborative approach developed at international level for effective methodology to scale-up innovative, validated good practices and mHealth solutions among countries and regions [7].

The current landscape of digital health solutions that address diabetes concurs to a comprehensive diabetes management, that allows empowered patients to enter a care pathway at any stage of the disease and take advantage of personalised treatment, adding different care loops when required for blood pressure control, glucose management, healthier lifestyle, training and self-help & peer support [8]. This requires supporting measures to be in place, like the integration with medical devices and electronic health records, coordination of professionals, integration in existing healthcare system and continuous quality control and change management. Fleming et al. provide an overview of what diabetes apps currently offer [9].



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| **Category name** | **Description/definition** |
|---|---|
| Nutrition apps | • Offer databases where users can look up carbohydrate, fat, protein, and energy content<br>• Support meal planning and insulin dose adjustment |
| Physical activity apps | • Habilitate users to perform, quantify and track physical activity, count calories and set goals for fitness and weight management, according to the physical capabilities and concurrent medical conditions |
| Glucose monitoring apps | • Log glucose data, typically from an external device that measures glucose (e.g., BGM, CGM)<br>• Graphically display glucose levels to assist the patient and HCPs with management of glucose control |
| Insulin titration apps | • An extension of no. 3 that also integrate bolus calculators with traditional blood glucose meters to help people with diabetes calculate their basal, prandial, and correction insulin doses |
| Insulin delivery apps | • For insulin pumps and smart pens to collect and display data; includes bolus calculators, data downloaders, and firmware update apps<br>• Such apps also provide decision support |
| Automated insulin delivery (AID) systems (also known as closed-loop control systems, artificial pancreas systems, or autonomous system for glycaemic control) | • Consists of a CGM system, insulin infusion pump, and a computer-controlled algorithm (for do-it-yourself AID systems a smartphone app) to allow communication between the CGM system and insulin pump on the patient |

*Source: Fleming et al. (2020)*

*Table 1. Types of digital health apps used for managing diabetes*


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# 3. Introduction to Hub Knowledge Tool 2

The **European Innovation and Knowledge mHealth Hub** (https://mHealth-hub.org/) is a project established by the International Telecommunication Union (ITU), in partnership with the World Health Organization (WHO) and the Regional Ministry of Health of Andalusia (Spain) to support the integration of mHealth programmes and services into the national health systems of European countries. The Hub project is funded by the European Commission under the Horizon 2020 programme and is underpinned by a consortium of 17 public and private partners [10] from 12 European countries led by the Andalusian Public Health System.

KT2 working group involves a diverse number of organizations, who were essential to address the challenge of developing a tool to support the matchmaking between specific needs of a mHealth Hub "client" and available mHealth solutions, balancing the value of their innovative features with the pressure for extensive validation in public health settings.

To this purpose, WHO provided insights into the broader perspective of exploitation for the tool, taking into account sustainability elements. Furthermore, WHO also provided the reference framework for the functionality codes, that we used for the categorization of the solutions, which played a key role in the transcodification effort of the needs for input into the tool. ITU knowledge proved essential in providing the core content required to define the broader process where the KT2 was to be implemented, and supported the development of the links with WP4 and WP5. FPS supported the coordination of the iterative work across the 3 subgroups, contributing to timely overcome emerging bottlenecks and identify key elements to take into account when integrating the results from the 3 subgroups to achieve the intermediate objectives. Osakidetza/Kronikgune provided a contribution in the customization of the "persona", also outlining the foresight towards the second release of the KT2. Ericsson Nicola Tesla and UAS Technikum Wien provided a contribution in the assessment of the solutions. Empirica contributed to build synergies with WP4 for the pilot adoption of the knowledge tool in Czech Republic and Hungary (the selected countries). i-HD provided contribution to the identification of KT2 current limitations and further development. ProMIS, Agder University and PCHA-HIMSS and all KT2 partners reviewed the draft deliverable and approved the final version.



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### 3.1. KT2 and other Hub Knowledge Tools

The European mHealth Hub aims to produce a set of Knowledge Tools (KT), providing advice/guidance on large-scale implementation of mHealth services and interventions. The Hub Knowledge Tools are:

- Knowledge Tool 1: Health apps assessment frameworks;
- Knowledge Tool 2: an intervention-specific mHealth programme (Type 2 Diabetes);
- Knowledge Tool 3: integration of mHealth in health systems.

The ambition of KT2 is to foster the implementation of mHealth initiatives in the planning of countries' primary, secondary, tertiary prevention programmes, including long term care, and related investments. Beyond the testing of the tool Hungary, the long-term impact of KT2 is potentially very high for the development and implementation of mHealth programmes in EU countries with different levels of technological and organisational maturity, through the use of suitable indicators to be taken into account when using the Hub tools, not exclusively KT2. The SWOT analysis provided preliminary information useful to bridge the scale-up of mHealth Hub KTs. Country approaches to diabetes management vary, and looked at diabetes treatment and management guidelines in further details when applying KTs to a specific case study. Future efforts of the Hub might go in this direction, and to this purpose engagement from MS & regions is possible, like shown by the preliminary work of the extended SWOT analysis.

KT2 would undoubtedly benefit from linking to a repository of mHealth solutions (or possibly to more connected repositories) that can be matched to the specific needs of the implementing countries. The aim of the algorithm is to provide a relational match between identified needs and one or more available solutions concurring to address the identified needs. The development of a EU repository of digital health solutions is not part of the ambition of this project, but might become an attractor for organisations that would pay to use mHealth Hub services in the future.



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# 4. History of the document

## 4.1. Abstract

The topic of KT2 is to identify, collect and organize the available knowledge for the iterative development of national or large-scale programs for the prevention and management of type 2 diabetes, supported by mobile solutions, using a person-centred approach. The KT2 set up an approach to guide countries to understand the type 2 diabetes and mHealth landscape in their country starting from a self-assessment, integrated by an interview targeted to diabetes mellitus to allow country specification, and by an adaptation of personas, to represents the health needs of patients with type 2 diabetes mellitus. Through a questionnaire to policy makers, KT2 identifies the specifications of the country/region adopting the program (Setting Specifications) and the "Persona" to whom the mHealth program is addressed.

These unmet needs have been divided into functionalities allowing the alignment with ICF codes for type 2 diabetes, to be addressed through the algorithm by matching solutions available on the market, capable of responding to the identified needs. This version of KT2 allows launching a new mHealth program. It can be expanded by interested actors for further development of results monitoring system and impact.

## 4.2. Purpose of the document

The overall objective of the KT2 is to provide guidance to interested stakeholders (national/regional public health authorities, healthcare organisations, professional or patient organisations) in mHealth programs implementation, which can be tailored according to specific needs on the ground, in order to facilitate the transfer of mHealth solutions that demonstrated an innovative value in terms of benefits and impacts.
The proposed approach makes it possible to suggest mHealth solutions for implementation in the country, providing feedback on adoptability from the design stage and lessons learned from the pilot adoption process, in an iterative manner. The methodology for the identification of available solutions is laid out below.



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# 5. Methodology to develop KT2 tool: the three-stage model

## 5.1. Baseline: Inputs into the tool

The tool has been developed with a collaborative approach by a dedicated working group, in the effort to implement a human-centred design and maintain a human element throughout the process. Such diverse stakeholders were pivotal to identify the essential elements to create the algorithm, and generate guidelines taking into account external factors.

In order to facilitate coordinated development of the elements that contributed to the process, 3 smaller sub-groups were created, focusing on different activities to be integrated at a later development stage:

- Country specification & Personas
- Building blocks & solutions
- Algorithm development

Such approach allowed the set-up of a user-friendly guidance to support the needs assessment, adaptation, adoption and scale-up of mHealth solutions, supporting the piloting country to outline a customised mHealth program, according to the information collected by a complementary strategy shared with KT1 and WP4. A connection with WP5 was also identified, playing a key role in the transfer of the KT2 to current service provision.

The sample of solutions for the KT2 categorization exercise were identified through a survey involving the participants of the KT2 Building blocks & solutions subgroup, and are available in Annex 1.

The following is an overview of KT2 outputs for baseline stage that will feed into an algorithm, to present to countries a menu of relevant and adaptable potential mHealth solutions.

## 5.2. Country specification

In order to identify and specify key digital solutions and high-impact user scenarios for a diabetes solution, an effort was carried out, to define the setting specifications required to define the specific persona use case. We designed an interview focused on country objectives in terms of mHealth agenda, and the local implementation framework for diabetes (Annex 2). It was developed based on the interaction with one of the mHealth Hub collaborating countries, Hungary, the case study for KT2 set up (*Figure 2*).



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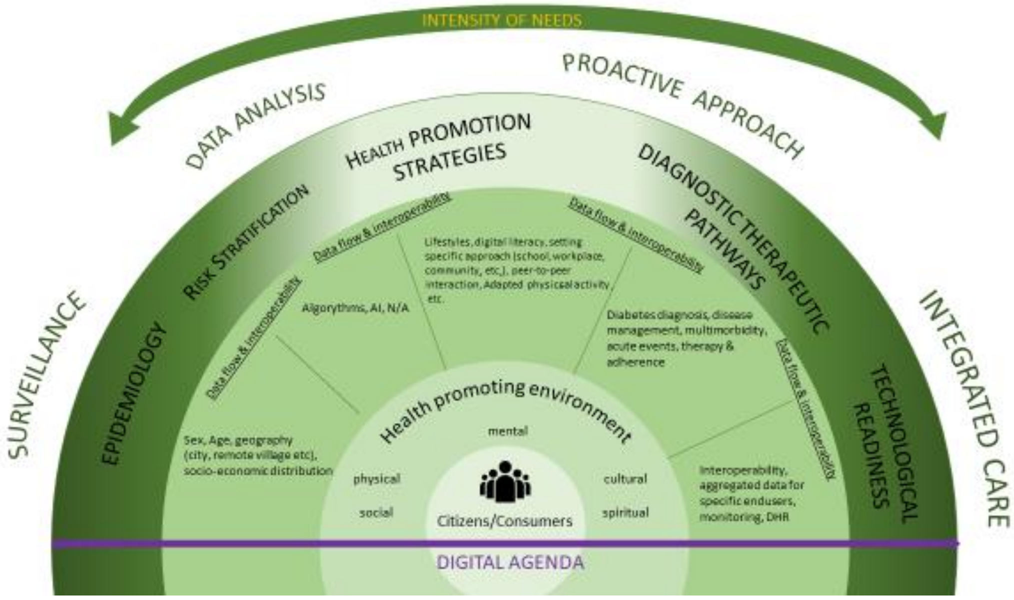


*Figure 2. Country specifications topics [Illario M. et al. manuscript in preparation]*

The country specification consists of the assessment of needs carried out in collaboration with WP4 and aimed at orienting the KT2 customization, taking into account the process of service provision at local level, and has been developed starting from the multi-dimensional country self-assessment (*Table* ***6***). It provided the framework to carry out an interview designed according to the IDF guidelines [11].

| | |
|---|---|
| Country | |
| Country focus for mHealth | ❑ Integrated care for diabetes, including prevention of complications<br>❑ Telemedicine<br>❑ Self-management<br>❑ Other (please, specify)<br>_______________________________________________ |
| Preferred Setting | ❑ Primary care<br>❑ Emergency<br>❑ Specialist care<br>❑ Home care |



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| | |
|---|---|
| | ❑ Hospice<br>❑ Hospital care<br>❑ Risk stratification<br>❑ Other (please, specify)<br>___________________________________________________ |
| Preferred target | ❑ Diabetic complex inpatients<br>❑ Diabetic complex outpatient<br>❑ Diabetic patient without complications or other diseases<br>❑ Diabetic patient newly diagnosed<br>❑ Citizens at risk of diabetes<br>❑ General population<br>❑ Other (Please, specify)<br>___________________________________________________ |
| Possible Challenges | ❑ Service integration between levels of care<br>❑ Adherence to Plan: therapy & lifestyles<br>❑ Other (Please, specify)<br>___________________________________________________ |

*Table 2. Country self-assessment template*

The setting specification data are needed to:

- determine the extent of the diabetes problem;
- determine the prevalence of diabetes/NCD risk factors which can be used to predict the magnitude of future diabetes and related health problems;
- estimate the need for services;
- provide a sound rationale for a national effort to reduce the burden of diabetes;
- set a baseline for future comparisons.

Countries have been guided through their diabetes and mHealth landscape starting from the self-assessment, integrated by an interview targeted to diabetes to allow further specification. The latter covered the elements presented in Figure 2. These inputs led to the identification of a specific persona type, that was used in the development of the process leading to input the algorithm for the identification of suitable solutions for the country. The country specification interview was designed



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to capture country objectives with regards to their mHealth agenda, and implementation framework focusing on diabetes.

Results from the country self-assessment and interview fed a SWOT analysis, to progress in the development of a Plan for specific targets and settings (Annex 3). SWOT analysis is a strategic planning tool used for evaluating phenomena, organisations, systems and services. A matrix is developed and created in order to highlight the strengths and weaknesses of a system, to bring out the opportunities and the threats [12].

The first two, being variables that are integral part of the system and on which it is possible to intervene, are considered endogenous factors. On the contrary, opportunities and threats are considered exogenous factors as being external to the system, that can affect it. The SWOT matrix used is schematically represented in *Table 7*, including guidance questions.

| **Strengths** | **Weaknesses** |
|---|---|
| What are the strengths for the development of mDiabetes programme in country x? | What are the weaknesses for the development of mDiabetes programme in country x? |
| **Opportunities** | **Threats** |
| What are the possible opportunities that could facilitate the development of mDiabetes programme in country x? | What are the main threats that could prevent the development of mDiabetes programme in country x? |

*Table 3. Questions to define Strengths, Weaknesses, Opportunities and Threats of Country x*

### 5.3. SWOT analysis

The results of the interview were used to define a SWOT analysis and develop a service scenario that was targeted to the country targets and settings. In order to test the transferability of this approach to different health care systems, the methodology was shared during a workshop [13], and the SWOT was administered to participant country experts (*Figure 3*).



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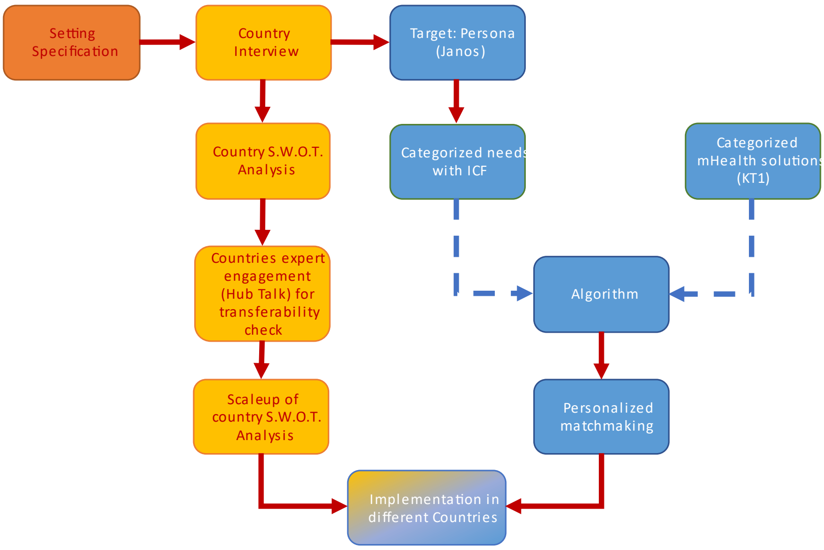


*Figure 3. The methodological process [Illario M. et al. manuscript in preparation]*

In order to outline the different frameworks of implementation for mHealth solutions targeting type 2 diabetes, some of the countries involved in the mHealth Hub community volunteered to carry out a SWOT analysis that was developed on the ground of Hungary interview for country specifications.

The SWOT allowed to identify possible strategies to address weaknesses and bottlenecks exploiting strengths and opportunities.

A schematic overview of the results is provided in the *Figure* ***4***. The Strength-Opportunity box describes how the exploitation of the country/region's strengths generates new opportunities. The Weakness-Opportunity box describes how investing in improving the country/region's weaknesses could generate new opportunities. The Strength-Threats box describes how using strengths to defend against threats. The Weaknesses-Threats box describes how to prevent external threats from exacerbating weaknesses.



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| External analysis / Internal analysis | Strengths | Weaknesses |
| --- | --- | --- |
| Opportunities | **Strength-Opportunity**<br>**AUTONOMOUS PROVINCE OF TRENTO (ITALY):** The mDiabetes programme is implemented by a partnership that includes decision-makers, health service providers, and R&D organizations. Multi-stakeholder approach helps overcome fragmentation of data and IT systems.<br>**MARCHE REGION (ITALY):** Human resources are a key asset for mHealth. New professional figures with soft skills could strengthen patient/caregiver digital health literacy.<br>**NORWAY:** Peer-to-peer training of multi-sector professionals enhances digital health literacy, interoperability and organisational integration of mhealth services<br>**SCOTLAND:** An ambitious strategy recognises the role of digital technology for enhancing health and wellbeing, allowing investments in mHealth implementations.<br>**TURKEY:**Technological alignment allows mHealth solutions to be quickly integrated and scaled up in existing information systems. | **Weakness-Opportunity**<br>**AUTONOMOUS PROVINCE OF TRENTO (ITALY):** Improving digital literacy of patients and strengthening interoperability of mHealth solutions already in place will increase availability of data for secondary use.<br>**MARCHE REGION (ITALY):** The need for integration of new mHealth solutions could result in new funding from the national resilience and recovery plan.<br>**NORWAY:** Strengthening the interoperability of complementary mHealth solutions with each other could improve the capacity for targeted analysis of data clusters.<br>**SCOTLAND:** Training courses, Peer-to-Peer learning opportunities, informal learning networks can contribute to reducing patients' gaps in self-managing their own health.<br>**TURKEY:** Improving Health and social care professionals training can increase the awareness of the importance of mHealth programmes. |
| Threats | **Strength-Threats**<br>**AUTONOMOUS PROVINCE OF TRENTO (ITALY):** A shared vision on new technologies in monitoring and supporting patients with diabetes could overcome the lack of integration in the diagnostic and therapeutic pathway.<br>**MARCHE REGION (ITALY):** Multisectoral professional skills support the integration and avoid fragmentation in continuity of care for type 2 diabetes mellitus.<br>**NORWAY:** Awareness and willingness of professionals clashes with the rigidity of policies and innovative solutions.<br>**SCOTLAND:** Digital health strategy is crucial for the integration of health and social care, and could address digital exclusion.<br>**TURKEY:** Strong IT infrastructure facilitates the wide-scale use of mHealth solutions and the adoption of appropriate legal agreements. | **Weakness-Threats**<br>**AUTONOMOUS PROVINCE OF TRENTO (ITALY):** Lack of interoperability of existing mHealth solutions with medical devices and solutions provided by the private sector prevents secondary use of the data.<br>**MARCHE REGION (ITALY):** Inadequate commitment by policy makers and resistance to change of local environment involve inadequate resources for the development of an integrated pathway.<br>**NORWAY:** Very rigid policies lead to systems obsolescence and resistance to organisational change.<br>**SCOTLAND:** Complex expenditure procedures slow down the process of digital transformation of health and lead to distrust of results.<br>**TURKEY:** The lack of a policy on the repayment of mHealth services means that they are not prescribed by the healthcare system. |

*Figure 4. SWOT Analysis results*

The individual is an essential component in the delivery of trust-based, people-centred care. This focus covers not only patients, families and communities but also the health



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workers who need to be prepared to deploy or use digital health technologies in their work. Planning for capacity building includes workforce assessment, ranging from professionals in information and communication technologies to health workers providing care services. Being intrinsically multidisciplinary and interdisciplinary, capacity-building entails instilling capabilities, attitudes and skills which may range from computer sciences, strategic planning, finance and management to health sciences and care delivery, depending on the digital health application and its context. Assessment of the workforce should also consider the implications for the health labour market of introducing digital technologies and their management.

Attitudes to, practices in and public awareness about of digital health should also be addressed. Possible actions include improving digital health literacy at the population level, engagement of patients, families and communities, and education of patients about health. Better responding to the social and commercial determinants of health to improve digital health-enabled health systems will need the engagement of civil society but also non-health sectors and actors. Increasing awareness of evidence based self-management tools and increasing access to these is a further action to consider.

## 5.4. Development or adaptation of persona use cases

The SWOT was paralleled by the development of a **"personas" approach** [14], adopted to represent several "population segments" with different conditions and needs. This approach enables human centred design and provides a starting point that establishes representative, specific, unmet needs of persons with different diabetes profiles across the life-course.

The "Personas" approach provides more information than health conditions of the target population that are pivotal for successful implementation of a mHealth programme, such as the individual habits and the scenarios where the user lives, the experiences they face in their everyday life and foresee the possible impact that IT can have on health and social care services.

The approach used for the purposes of this Knowledge Tool is often adopted for the design of the user experience in different settings such as in IT industry and in the health and care sectors. Furthermore, the methodology of identification of use cases and user scenarios that have a strong impact on type 2 diabetes is also used by the European Blueprint on Digital Transformation of Health and Care for the Ageing Society [15]. This approach allows a deeper understanding of how a target user will interact with certain technologies [16] by developing "personas", "use cases" and "(service) scenarios" in a shared value chain.

The key elements of KT2 were the personas, the service scenario and the mHealth solutions of the Blueprint methodology [15] and were developed around the priorities identified by the piloting country (Hungary), focusing on a persona affected by



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diabetes and obesity, and on her interaction with current health service provision, and the available IT solutions, to effectively match them to the identified unmet needs.

### Personas

"Personas" [17] are generally defined as hypothetical persons, with realistic name, face and description of their character (objectives, hopes, dreams and attitudes), representing different "population segments" with different health conditions and needs [18]. Personas are used in combination with scenarios to allow a deeper understanding of the different types of people (users) [19] who will interact with a possible product/solution [16] in a human centred design approach.

The personas' descriptions also include behavioural characteristics, which may influence both short and long-term success of mHealth interventions aimed at managing disease or promoting well-being [20-21]. Personas profiles represent different population groups with various personal and behavioural characteristics, preferences, health and social conditions, lifestyles, economic backgrounds and other needs. Examples of relevant characteristics are the persona's trust in the health system, their values and norms around health and health seeking, their disease self-management skills and specific details on their character (e.g., tendency to refuse external support).

The countries choose or develop the personas that represent their target population. The personas will facilitate the identification of specific mHealth solutions to address the personas' needs. Personas and use cases presented in this document are not exhaustive, rather they are starting points and will be iteratively expanded with use of the KT2 in collaboration with the countries applying for the Hub services.

Several personas have been developed in the Blueprint project, representing examples of diabetes use cases, covering different ages and health needs complexity, that were used as a starting point for countries to adapt to their identified priorities and needs. Table 4 provides a simplified overview of the personas available so far, representing examples of diabetes use cases of different age and complexity of health needs, that can be used as a starting point for countries to use as they are, or adapt where appropriate.

| Persona | Lifecourse - Age | Context | Need | Connectivity |
|---|---|---|---|---|
| **Nikos** | Adult 26 | Urban (Greece), High SES | Secondary prevention (at risk) | Broadband Mobile device |
| **Maria** | Aged 80+ | Urban (Spain), Low SES | Chronic conditions and social care | None, but daughter is connected via mobile device and involved in Maria's care |


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| | | | | |
|---|---|---|---|---|
| **Antonio** | Working age adult | Urban (UK) average SES | Complex | Broadband Mobile device |
| **Procolo** | Aged 80+ | Sub-urban (Italy) High SES | Complex | Broadband |
| **Gennaro** | Working age adult (34 years) | Countryside (Italy), Low SES | Chronic conditions and social care | Weak broadband |
| **Anna Luisa** | Child (13 years) | Suburban (Italy) | Chronic condition | Broadband Mobile device |
| **Iria** | 33 | Urban | Chronic type 1 diabetes under control | Broadband Mobile device |

*Source: (own elaboration from the Blueprint [15])*

*Table 4. Personas overview*

### Use cases

Use cases have also often been used in IT development and programming in order to create or refine products designed to successfully meet specific user needs [22,23]. Elements of a use case can include the actor or the main user, other key actors (with whom the main actor interacts), a goal and the actions or interactions between the actors necessary to achieve the goal addressing specific needs. A use case summarises the persona activities to manage their own health, and can help identify corresponding solutions and services as well as designing or customising them.

This framework will help identify gaps and inform other developments in the future (e.g., to scale up the digital transformation of health and care). According to the country specification, a specific use case for potential solution was created to address the personas unmet needs.

Personas will allow countries and/or regions to better understand the needs of their potential users. Creating detailed, but not complex, patients' profile will also allow policy makers to relate to interested people and identify which mHealth solution is important to each individual.

Persona's use cases will hence be identified based upon their representativeness of diabetes epidemiology within the country and likely provided by the needs assessment.



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| Persona | Digital Literacy | Lifestyles | Adherence to treatment players | Monitoring | Peer to peer support |
|---|---|---|---|---|---|
| **Nikos** | Non-profit organizations Information campaigns | Healthy/unhealthy lifestyles adapted to local sociocultural context | Health professionals (GPs, specialists, nurses), patients, caregivers, volunteers etc. (polypharmacy management, medication review, de-prescribing) | Patient-health professional interaction Self-monitoring | Social engagement |

*Table 5. Example of persona-specific essential elements for defining use-cases*

### Service scenario

Service scenario focuses on a specific event or episode taking into account the elements of the socio-economic context, lifestyle issues, data exchange, interoperability, health system that are relevant to inform the setup of service combination. It addresses health needs in a person-centred way that is locally informed and sustainable.

The elements that are taken into account are:

- Triggering factors
- Key actors, roles and interactions
- IT tools and services supporting the scenario elements
- Interoperability
- Other elements such as community services transportation, etc.

Based upon these elements, and on the information collected during the process of development for KT2, a service scenario was developed in WP4 with the selected countries, taking advantage of innovative solutions available in the building blocks, in the framework of local health and social systems.

## 5.5. mHealth solutions: the building blocks

### Building Blocks

The needs assessment, the personas and the use cases might guide the country to focus their current mHealth and diabetes landscape and needs, as well as their target population. Countries might then select the solutions corresponding to the required features [24].



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In order to facilitate the connection of the solutions with personas needs, it was essential to carry out an allocation of the solutions in "functional" building blocks. Building blocks are functional categories of mDiabetes solutions, supporting interventions to be customized according to the country plans/priorities in terms of target and setting (users).

This has been an input for the algorithm leading to a menu of mHealth solutions targeted for a specific country. In this tool, an initial group of solutions have been revised, along with the increase of the maturity of the model. In such categorization, some features have been considered an "added value" for any block, and should be taken into account whenever applicable for all solutions. The proposed categorization is in line with WHO classification of Digital Health Interventions 1.0 [25]:

- Interventions for clients: Clients are members of the public who are potential or current users of health services, including health promotion activities. Caregivers of clients receiving health services are also included in this group.
- Interventions for healthcare providers: Healthcare providers are members of the health workforce who deliver health services.
- Interventions for health system or resource managers: Health system and resource managers are involved in the administration and oversight of public health systems. Interventions within this category reflect managerial functions related to supply chain management, health financing, human resource management.
- Interventions for data services: This consists of crosscutting functionality to support a wide range of activities related to data collection, management, use, and exchange.



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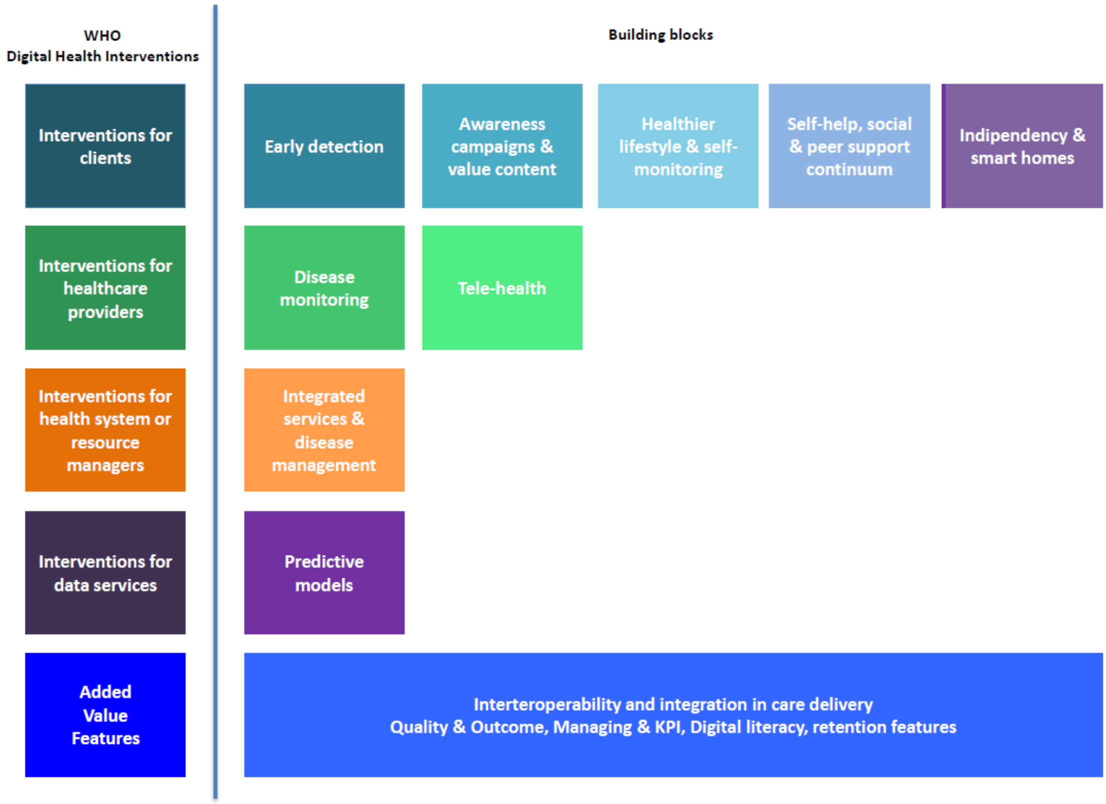


*Figure 5. mHealth Building blocks: initial overview, along the 4 categories of WHO classification of Digital Health Interventions 1.0 [Illario M. et al. manuscript in preparation]*

Early detection: It concerns all tools supporting the detection of a disease at its early stages, when complications did not arise yet and treatment is simple to administer, adhere and manage. Early diagnosis is quite standardised for cancer in the framework of the screenings for breast cancer, cervix, and colon. Early detection may apply to risk factors for example blood pressure in case of cardiovascular disease, or glucose levels in case of risk of diabetes for subgroups at risk. Digital solutions are a key enabler to guide patients along the diagnostic-therapeutic pathways unravelling after positive detection.

Awareness campaigns and value content: Awareness campaigns in public health are a key element to promote health and need to be conceived in a strategic and structured way, addressing a specific target, within a given timeframe and aiming at specific objectives. Innovative communication tools can be identified depending upon a given population target, for example adult, working age women, or children, teenagers etc., and developed around the chosen communication objectives. Sporadic and isolated interventions are not effective. Innovative communication tools make this kind of campaigns more sustainable and pervasive, strengthening their effectiveness as they allow bidirectional flow of information. The final goal is to inform and make the healthy


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choice the easy choice, improving quality of life for individuals and communities. Content should be adapted to specific sociocultural contexts, for example involving testimonials that are appreciated by the chosen target, tailored to local sociocultural preferences.

Healthier lifestyles & self-monitoring: The promotion of healthier lifestyles is usually linked to surveillance platforms that are centralised to allow the deployment of either standardised or personalized interventions, based on the clinical status of the patient. We also need the possibility to follow-up and followed by monitor the target population. Digital solutions can strengthen the campaigns at the same time supporting self-monitoring.

Self-help, social & peer support continuum: Persons affected by specific health conditions may need support to maintain or improve or recover psychological and emotional wellbeing. Peer-to-peer interaction and support groups allow people facing similar challenges to share experiences, feel sense of belonging and find the strength to recover.  Dedicated social platform providing value content may be a precious ally in providing the continuum of support.

Independency & smart homes: Concerns all solutions that can improve quality of life at home and in other types of buildings, also for public service provision, for example improving accessibility, safety and supporting independent living for all special needs. Also, includes solutions improving performances of the electric, thermoregulation (cooling/heating), hydric systems optimizing consumption and integrating functions.

Predictive models: It relates to the systems allowing the analysis of dataflows for the stratification of the population based on:

- risk factors
- diseases
- geo-localization
- age and sex

It allows understanding the complexity of health needs on medium-long term and a more effective and sustainable allocation of resources.

Tele-Health: It concerns communication between health care professional and patients, thus evolving traditional medicine, complementing and integrating it. It facilitates health service provision, from diagnosis to therapy and controls.

Integrated services & disease management: It Includes the progressive reorganization and integration between hospital and community services, clinical and social, to address emerging health needs related to the current demographic and social transition. It requires the integration of different professionals from the clinical and social domains, pivotal to achieve objectives.

Disease monitoring: Referred to integrated systems to monitor health parameters, and are connected with the clinical record, with self-monitoring, polypharmacy management, adherence, interventions for secondary/tertiary prevention.



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## 5.6. Identifying potential mHealth solutions

In order to allocate the solutions to specific "functional" building blocks, it is pivotal to assess the solutions with an approach that transparently ensures the expression of some potentialities of the digital products available, differentiating the solutions and their intended use.

The approach will be iterative, starting from an initial template that may be revised, along with the refinement of the model. The assessment will be carried out of existing mHealth tools previously developed and validated, to be included into the country's programme solutions portfolio.

We identified a tool for the evaluation of adoptability, depending on plan and implementation framework. This is coherent with the value chain for health and care of the Blueprint for the digital transformation of Health and Care (Figure 6).

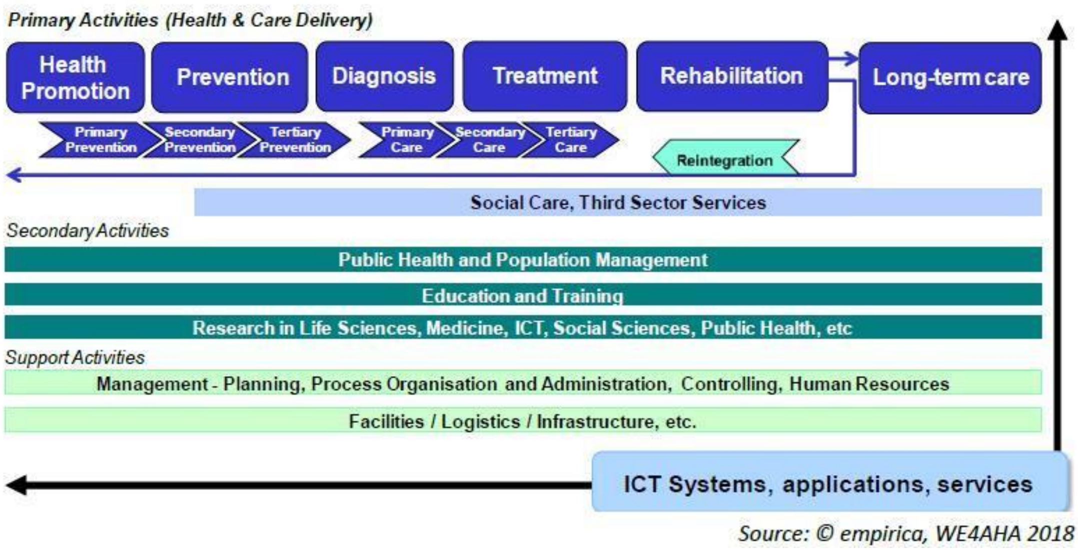


*Figure 6. The value chain for health and care of the Blueprint for the digital transformation of Health and Care*

The proposed approach is iterative, to progressively improve the functional assessment of the mHealth solutions, developed with a user-centred focus. A second release is foreseen, to be integrated with more persona types as described in chapter 7 (Future opportunities for development).

The categorization of the solutions is in line with WHO classification of Digital Health Interventions 1.0 [25].


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Table 6 represents the template of the existing solutions characteristics chart, which will be used to present an overview of the available solutions to countries.

| **Proposed solution name:** | |
|---|---|
| **Solution feature** | **Specific reference** |
| Solution name | |
| Short description | |
| Owner | |
| Owner type | |
| Contact details | |
| Year of creation | |
| Website/Web presence | |
| Update frequency | |
| Last update | |
| Geographical application scope | |
| Target audience(s) | |
| Value propositions | |
| Evidence base (references or links to evaluation reports) | |
| Coding language | |
| Open source | ☐ Yes ☐ No (if no, who is the proprietor: ) |
| Interoperability | |
| Building blocks | ❑ Early detection<br>❑ Self-help and peer support continuum<br>❑ Tele-health<br>❑ Added value features<br>❑ Awareness campaigns<br>❑ Disease monitoring<br>❑ Integrated services and disease management<br>❑ Healthier lifestyle and self-monitoring<br>❑ Predictive models<br>❑ Independency and smart homes |
| Functionalities addressing specific building blocks | |
| Maturity | Pilot/small scale/large scale |

*Table 6. Template of the existing solutions characteristics chart*



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## 5.7. Preparation stage: The KT2 algorithm

In order to allow the transcoding of the information collected in the persona profile into inputs for the algorithm, we compared the latter with the ICF codes for diabetes and obesity courses. This allowed the selection of a specific subset of codes that reflected the country specifications and were used as an input into the algorithm (many-valued relational structure), resulting in a selection of vetted tools for mHealth in diabetes prevention, care and/or management (see Figure 7) that countries can choose to implement and scale up a programme.

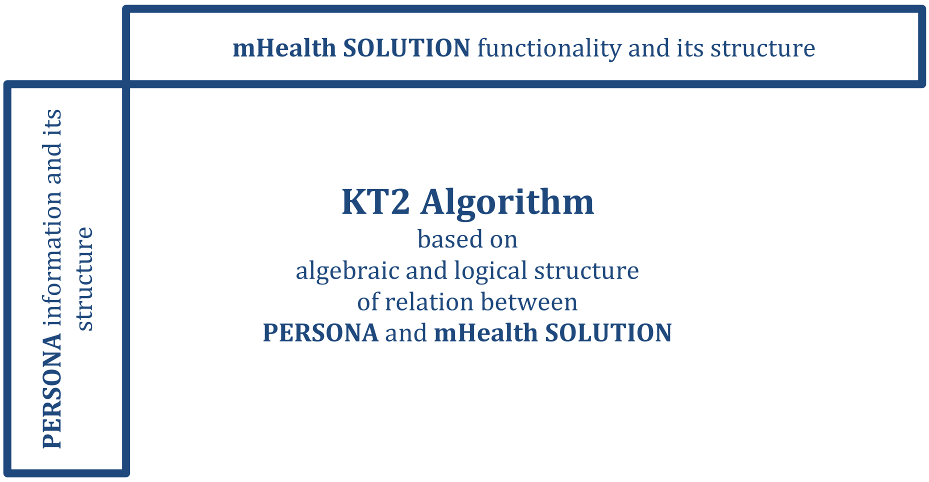


*Figure 7. Visualization of the input and outputs of the baseline stage. [Illario M. et al. manuscript in preparation]*

The aim of the algorithm is to provide a relational match between identified needs and available solutions. The proposed approach is iterative, to design and progressively develop the logical structure of relational link that suggest actions/prevention/intervention/solutions for particular needs, attributes or circumstances of the personas, thus implementing a user-centred approach. Data analysis involving machine learning and reinforcement will be applicable when fine-tuning the rules bases, in particular where data objects in rules are parameterized.

The many-valued features of the data objects in the rule base are constructed logically using *quantales* [26] as algebraic structures for handling the many-valued generic 5-scale in ICF (International Classification of Functioning, Disability and Health). ICF is part of WHO-FIC (World Health Organization - Family of International Classifications) [27], and as maintaining an ICF online browser [28]. There are also translations to a number of languages, and more translations are desired. ICF was officially endorsed by all 191 WHO Member States in the Fifty-fourth World Health Assembly on 22 May 2001 as the international standard to describe and measure health and disability.


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ICF's hierarchical structure contains Components, with components containing Chapters, Chapters containing Sections, Sections containing Items, and Items containing Subitems.

ICF's 5-scale is the following:

| | | |
|---|---|---|
| *xxx.0 NO problem* | *(none, absent, negligible,... )* | *0-4 %* |
| *xxx.1 MILD problem* | *(slight, low,...)* | *5-24 %* |
| *xxx.2 MODERATE problem* | *(medium, fair,...)* | *25-49 %* |
| *xxx.3 SEVERE problem* | *(high, extreme, ...)* | *50-95 %* |
| *xxx.4 COMPLETE problem* | *(total,...)* | *96-100 %* |
| *xxx.8 not specified* | | |
| *xxx.9 not applicable* | | |

It is extended with "not specified" and "not applicable" values, which can be used as "not (yet) known", providing a 6-scale.

From ICF point of view, and looking at the generic 5-scale together with one of xxx.8 and xxx.9 understood as ´not (yet) known' or ´(still) missing', extends ICF 5-scale to a 6-scale, we can see how the missing value can be located in various positions as "sidelined" with the 5-scale. For a set of six points, there are 'ordered structures' with the sideline element positioned in a certain ordered position with respect to the other elements.

It is important to understand that *information*, and its structure, provided to describe "personas", need to be rich enough in order to provide a sufficient foundation for the algorithm that connects persona needs to services and functions provided by various mobile solutions. Similarly, it is important to understand how *processes*, again involving structure, provided to describe "(service) scenarios" need to be detailed enough concerning WHO-WHERE-WHAT-WHY-HOW in order to make the integration of *information & process* a well-founded and sufficiently rich description of the "use cases".

Richness of information and process structure is a key feature and is prerequisite for a successful knowledge tool. Functionalities of mHealth solutions need also to be described using selected nomenclatures so that richness of the persona information structures will be in parity with the richness of the mHealth solutions functionality structure.

Mathematical operations in these ordered structures enable to aggregate data derived from target and setting specifications emerging from country needs/preferences/priorities.

Country specifications will derive from:

- Policy Framework
- Target
- Setting
- Functionalities



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More specifically, pre-qualification requirements fall into six main areas of importance for an mHealth programme:

- mHealth readiness
- Health content
- Technical content
- Promotion
- Monitoring and Evaluation
- Programme Governance

Relevant information will be extrapolated and encoded to allow their entry into the in-flow of the algorithm.

The exemplificative model will be set up starting from the personas that more closely resemble the County needs, that will be adapted, allowing the identification of target and setting. The chosen persona will be related to ICF codes to identify the specific items for the "course" of diabetes.

| Persona | Age | Area | Health need focusing on diabetes |
|---|---|---|---|
| **Millie** | 18 | Urban | Overweight, at risk of diabetes |
| **Antonio** | 33 | Urban | Acquired disability, diabetes, hypertension |
| **Nikos** | 50 | Urban | Metabolic syndrome & COPD |
| **Gennaro** | 65 | Internal area | Unbalanced diabetes, stroke |
| **Procolo** | 79 | Suburban | Multimorbidity, complicated diabetes |
| **Maria** | 84 | Urban | Multimorbidity, complicated diabetes |
| **Irie** | 33 | Urban | Chronic type 1 diabetes under control |

*Table 7. Personas classification per setting and target*

Further KT2 development insights are available in the Annex 2.



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# 6. Synergies towards the guidance for implementation of a mHealth program in Hungary

## 6.1. Synergies with KT1

The European mHealth Hub, when developing the Knowledge Tool 1 (KT1) about health apps assessment frameworks, has promoted the dialogue and cross-recognition between such frameworks, and pointed out to the challenge of balancing it with local-regional and national distinctive elements that may influence their uptake in current service provision.

Providing guidance to interested organization in selecting the solutions that represent the best fit for purpose in their specific case was identified as an important opportunity, captured and developed by KT2 through the implementation of the Blueprint persona approach. The implementation of the KT2 to the Hungarian case allowed the opportunity to pinpoint to a specific persona, to be implemented in a real service scenario.

In synergy with the effort carried out in KT1, KT2 allocated the solutions in "functional" building blocks where some features were considered an "added value". The proposed categorization was in line with WHO classification of Digital Health Interventions 1.0 [25].

## 6.2. Synergies with WP4

WP4 is offering implementation support partly based on KT2 content to Hungary. The objective of the collaboration between the Hungarian Ministry of Health and the European mHealth Hub is to "Co-create a Strategy and Roadmap for the implementation and setup of a large scale mHealth intervention in Hungary in the area of Diabetes management". The collaboration focuses on proposing a possible strategy to strengthen current efforts with an evidence-based and health outcomes-focused digital intervention. The proposed collaboration will:

- Co-create/integrate a new/already existing mHealth application addressed at OAD (oral anti-diabetic) treated Diabetes.
- Facilitate of knowledge exchange on the topic of patient education and for designing an IT communication system between hospital/GP and patient.
- Organise stakeholder engagement workshops and roundtables between Hungary (HU) representatives and mHealth Hub partners.
- Develop offline materials, such as documents developed by the Hub and relevant documents for HU identified through desk research.



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Synergies between KT2 and WP4 Implementation support are evident in the following areas: co-creation of personas and service scenario, process pathways and offering information about relevant existing good practices.

Several meetings have been carried out with Hungarian representatives. At the moment of writing, a persona and service scenario has been co-created and reviewed, and several activities are planned, including defining a process pathway, identifying good practices according to the defined specifications, and co-creation of a twinning concept. All relevant information regarding the implementation support will be captured in D4.6 “Report on performed countries support process”.

# 7. Limits of the proposed approach

One limitation of the proposed approach is that the inputs we have (personas, use cases and solutions outputs) are ‘general-purpose’ in the sense of not taking into account the issue of *transferability*. Namely, country diversity needs to be detailed to appear in an extended functioning (ICF) model of the personas. However, learning algorithms e.g., in form of reinforcement can be added to the algorithm so that when fed back with testing and piloting, country specific key functionalities can be fine-tuned and optimized.

Another limitation resides on the solution side as solutions are mostly not aware of the WHO-FIC classifications of functioning conditions, which means that persona ICF structure tries to “hook” onto a corresponding intervention related ontology respected by the solutions, where that respect for intervention classification does not exist.

However, these limitations, and as they are made explicit for countries and for solution providers, are expected to lead to countries understanding the needs to overcome the transferability issue, and solutions providers to further develop their products and service in light of embracing the appropriate classifications.



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# 8. Future opportunities for further development: insights from a type 1 diabetes patient's journey

## 8.1. Further applications of the KT2

The present version of the KT2 focuses particularly on improving intelligence around the choice of mHealth solutions and Type 2 diabetes programme choices, based on prioritised population profile. The approach developed in KT2 can also be applied to other diseases, especially NCDs. As an example, it might be used to identify mobile solutions to develop a mHealth program for patients with type 1 diabetes. This is the case for Iria's story, that was first developed within the VALUeHEALTH project and has since been exploited in several other contexts. The personas approach also allows us to highlight the additional organizational and interoperability gaps between healthcare organizations and their IT systems, which patients who use apps to manage their condition encounter. In the Annex 5, insights are provided from Iria's journey.

## 8.2. A shared monitoring framework

The proposed stepwise approach supported by KT1, KT2 and KT3 might be exploited for the identification of a shared monitoring framework, useful to monitor a country's journey along the evolution process of adoption and scale-up of a mHealth program.

Indeed, the mHealth KTs allow the development of an indicators subset that can be suitable to be used sustainably to monitor elements for a specific mHealth thread:

- Number of solutions identified and implemented.
- Extent of integration into current service provision.
- Adherence by end-users (citizens/professionals).
- Impact (organizational, technological, on health outcomes, economic).

Indeed, further work might be developed in collaboration with pilot countries in order to outline such indicators clusters, and test their implementation. An example of such indicators is provided in Table 8.



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| Indicator measure | Description |
|---|---|
| Size | Volume of services provided |
| Time continuity | Duration and stability of the mHealth program |
| Complexity | organizational complexity of the mHealth program |
| Quality | Standard and response performance of the mHealth program |
| Efficiency | Cost of the mHealth program |
| Effectiveness | Comparison with the population of users affected by the pathology covered by the mHealth program, but followed in a conventional way, in the area of interest |
| User satisfaction | Patients and caregivers |
| Human resources | Type of professional figures involved and number of operators involved in providing the service (person months) / number of users |
| Standard response time | Response performance No. of performances within standard time |
| Total annual cost of maintaining the service | Personnel, equipment, etc. / number of users followed |
| Reduction of Mortality | % of deaths in the last 12 months among followed users /% of deaths in the last 12 months among users followed by conventional approach |
| Reduction in the incidence of re-hospitalizations among users | % of re-hospitalizations in the last 12 months among users followed in Telemedicine /% of re-hospitalizations in the last 12 months among users followed by conventional approach |
| Reduction in the number of days of hospitalization | Number of days of hospitalization in the last 12 months per user followed in Telemedicine /% of days of hospitalization in the last 12 months per user followed in conventional mode |
| Emergency services use | Reduction of the time spent by users in Emergency Services |
| | Time (hours) spent in the last 12 months in Emergency Services Urgency per user followed by the mHealth program / Time (hours) spent in Emergency Services / Urgency in the last 12 months per user followed by conventional approach |
| | Number of accesses to the Emergency Department |
| Quality of life | Standard measures of quality of life<br>Specific questionnaires administered to users (patients, caregivers) |

*Table 8. Examples of indicators to be identified with countries for assessment of mHealth programs*



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# Annex 1. Solutions' categorization exercise

| | ICF item grouping | MySugar | Medisantè | DiabMemory | DiaWatch | DM4All | Diamonds | Telemenitoring Olomuc | Pepper | C3Cloud | PAL |
|---|---|---|---|---|---|---|---|---|---|---|---|
| A | Ocular | o | o | o | o | o | o | o | o | o | o |
| B | CVD, metabolic/endo, urinary, neuro | *** | *** | *** | *** | *** | *** | *** | *** | *** | *** |
| C | Skin | o | o | o | o | o | o | o | o | o | o |
| D | Stress, attitude | * | * | * | * | * | * | * | ** | * | * |
| E | Mobility and domestic | ** | * | * | ** | ** | * | o | ** | * | ** |
| F | Interpersonal, family, friends, professionals, networks | ** | o | ** | *** | ** | o | o | *** | ** | *** |
| G | Skill, hobby | * | o | ** | * | * | o | o | * | * | * |
| H | Products and personal consumption | *** | * | ** | * | * | ** | * | ** | ** | ** |
| I | Services | *** | ** | *** | ** | ** | ** | *** | ** | ** | ** |
| Like 'suitable' (***), 'partly suitable' (**), 'restricted suitability' (*), 'not applicable' (o) | | | | | | | | | | | |

*Table 9. Summary of the solutions' categorization exercise*



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# Annex 2. Country Specification interview

## Epidemiology

Diabetes is a growing challenge worldwide: which is the prevalence of diabetes in the population 20-79 in your Country?

**Q 1.1** Is there a different distribution of cases across your regions you are aware of?

Do you have a map of the distribution of cases across your Country?

Is it digitally fed?

Would you be interested to be supported and find out, as the availability of data on the epidemiology of diabetes in your region would be useful to improve planning?

## Risk profile & health promotion

Diabetes arises more frequently in specific subsets of population, that are characterised by inadequate lifestyles, food intake, low physical activity, low literacy, comorbidities.

**Q 2.1** Do you have a national strategy for disease prevention?

If yes:

Does it include a health promotion strategy?

Does it identify specific actions targeting the risk of diabetes?

Is it digitally supported? Or would you be interested in digitalising it?

If no:

Would you be interested in setting up one?

**Q 2.2** Do you carry out assessment/monitoring of risk factors for diabetes in your Country, for example in specific subsets (low income/literacy etc) of the population?

If yes:

Which Subsets?

Which risk factors?

Which indicators?

**Q 2.3** Are data self-reported?

**Q 2.4** Do you have IT/health literacy approaches implemented?

If yes:

For which target population (0-6, 7-13, 14-18, 19-25, 26-40, 41-60, 61-75, 76-80, >81)?

In which setting?

Are they digitally supported? Or would you be interested to digitalise it?

If no:

Would you be interested in support to develop and implement such strategy for IT/Health literacy?

## Diagnostic therapeutic pathways

Identifying and implementing operational guidelines to integrate primary and specialist care is essential to ensure continuity and sustainability of service provision, from early diagnosis to management of complications.

**Q 3.1** Do you have a national plan for diabetes?

If yes:

Which are the priorities? (Health promotion, Community empowerment, primary prevention in groups at risk, secondary prevention for early identification of disease, etc.)

If no:



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Would you be interested to be supported in drafting one?

**Q 3.2** Are diagnostic-therapeutic pathways for diabetes implemented in your Country?

If yes:

Are they digitally supported? Or would you be interested in digitalising them?

If no:

Would you be interested to be supported in drafting one?

**Q 3.3** Is the implementation the same in the different regions?

## Technological readiness

Digital solutions are a key enabler to improve effectiveness and sustainability of public health approach to chronic diseases, from prevention and health promotion to integrated care addressing complex needs.

**Q 4.1** Is a national health IT system established in your country?

If yes:

Which dataflows are active?

If no:

Would you be interested in being supported to set up one?

**Q 4.2** Is there an electronic health record implemented (or partially implemented, in progress) in your country?

If yes:

Which features are currently active (Single entry point, Patient history, blood tests, Imaging etc)?

Which interoperability features does it have (ex. with national dataflows, national registries, regional **dataflows etc)?**

**Q 4.3** Is any (self) assessment/monitoring of diabetes available through a surveillance shared database?

If yes:

Is the database interoperable with EHR?

If no:

Would you like to obtain support to set up a self-monitoring fed surveillance system for diabetes?



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# Annex 3. Country Collaboration SWOT analysis

*Aim of this SWOT is to provide an outline of the elements that influence the adoption of mHealth solutions at scale in some of the mHealth Hub participating MS & Regions*

## Strengths and weaknesses

### 1. Strengths

*They are positive internal attributes that we can control. The following questions are intended to facilitate their identification. When going through the questions, you may think of the following, in relation to mobile solutions for type-2 diabetes in your Country/region:*

- *What do we do well?*
- *What relevant resources do we have access to?*
- *What do other people see as our strengths?*
- *What assets do we have, such as knowledge, education, network, skills, equipment, and technology?*

**Question 1.1**: Were financial resources allocated to mobile solutions for type2-diabetes in your country/region? (Drop-down menu)

- Investments (public/private)
- Grants
- Donations
- Other

**Question 1.2**: Are there physical assets dedicated to the deployment of mobile solutions in your country/region? (Drop-down menu)

- buildings
- equipment
- infrastructures
- softwares
- Human resources (employees, volunteers, mentors, researchers etc)
- Other

**Question 1.3**: Who are the key players for mobile solutions for type 2 diabetes in your country/region?

- Medical specialists
- GPs
- IT experts
- Researchers
- Social workers
- Caregivers
- Patients organizations
- Administrative staff
- Policy makers
- Management
- Other

**Question 1.4**: Are there organization workflow including mobile solutions for type 2 diabetes in your country/region? Workflows are to be intended as organized and



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interconnected activities supporting diagnostic/therapeutic pathways including dataflows, exchange of information between patient and professionals, access to specific services etc.

- Yes
- No

If YES: Such workflows are at one or more of those stages of implementation:

- Planning stage
- Training stage
- Partially implemented
- Fully implemented
- Other

If NO: Are you interested in including mobile solutions for type 2 diabetes in the workflow for type 2 diabetes?

- Yes
- No

**Question 1.5**: Does the organization culture of your health/social care systems acknowledges the value of mobile health solutions?

- Yes
- No

**Question 1.6**: Do your health/social care systems foresee life-long-learning opportunities for human resources capacity building in digital skills?

- Yes
- No

If Yes: Which type of activities does your system currently implement:

- Training courses
- Peer-to-peer learning opportunities
- Learning networks
- Mentoring, tutoring, coaching
- Other

## 2. Weaknesses

*They are negative internal attributes that you can control. The following questions are intended to facilitate their identification.*

**Question 2.1**: What could you improve to facilitate adoption of mHealth solutions for type2 diabetes mellitus in your country/region?

- Increase connectivity capacity of health and social facilities
- Reduce obsolescence of available technological assets
- Strengthen interoperability of mHealth solutions with health record



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- Strengthen interoperability of complementary mhealth solutions between themselves
- Strengthen capacity of targeted data clusters analysis
- Improve data usability (pristine data, shared data, secondary use of data)
- Increase digital literacy of patients and caregivers
- Improve training of health and social care professionals
- Other

**Question 2.2**: What should you avoid to facilitate adoption of mHealth solutions for type2 diabetes mellitus in your country/region?

- Data fragmentation between separated/non interoperable databases
- Collection of dirty data
- Siloed approach to the management of type2 diabetes patients
- Lack of clear coordination between services for type 2 diabetes mellitus
- Lack of continuity between services for type 2 diabetes mellitus
- Other

**Question 2.3**: Are there gaps in the teams managing type-2 diabetes mellitus at your organizations hampering the full deployment of mobile solutions?

- Yes
- No

If YES:

- Professional figures with soft skills to strengthen patient/caregiver digital health literacy
- Data analyst
- IT expert to ensure softwares adaptations for interoperability
- Experts for organizational integration
- Ethics expert for data management and sharing
- Other

## Opportunities and threats

*They are external conditions that influence your activity.*
*The categories that have been considered when developing the SWOT analysis for opportunities and threats are the following:*

- *Economic trends: the economy in your area*
- *Market trends: your target market could be driving new trends*
- *Political support: consider changes in political ties*
- *Government regulations: regulations that might influence you*
- *Changing relationships: partners, suppliers*
- *Target audience shift: demographics*

## 3. Opportunities

*Opportunities are positive external conditions that you cannot control.*

**Question 3.1**: Where are the good opportunities in front of you for scaling-up mHealth solutions for type2 diabetes?



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- European funds
- Resilience & recovery funds
- Regional funds
- Regional planning for health service provision
- Regional planning for disease prevention
- Regional planning for health promotion
- Regional planning for social service provision
- Regional planning for digital market
- National planning for health service provision
- National planning for disease prevention
- National planning for health promotion
- National planning for social service provision
- National planning for digital market
- Other

**Question 3.2**: What are the interesting trends you are aware of?

- Trends for the digital single market
- Trends for investments in health services
- Trends for investments in training for new skills to fill in gaps in digital health services
- Trends for digital literacy of the general population
- Other

**Question 3.3**: If your mobile program for type 2 diabetes is up and running:

- do patients think highly of it?
- do health/social professionals think highly of it?
- do companies think highly of it?
- do other regions/countries think highly of it?
- do IT experts think highly of it?
- Other

## 4. Threats

*They are negative external conditions that you cannot control*

**Question 4.1**: What obstacles do you face?

- Inadequate commitment by policy makers
- Weak organizational commitment (external) on mobile solutions for health
- Resistance to change of local environment
- Inadequate support from professional organizations
- Weak engagement of patients/citizens organization
- Other

**Question 4.2**: Whom do you see as competitors in relation to mobile solutions? In public health the concept of competitors may be referred for example to the service offer by neighboring regions/countries, that determine an increase in cost and hinder sustainability.



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- Other regions/countries
- Private health service providers
- Global companies (ex. google, amazon, etc.)
- Others

**Question 4.3**: Is the change of technology a threat to the use of mobile solutions in your country/region?
Health technologies have a high turnover, and play a key role in the competition between centers to provide "high performance" services. Hence a horizon scanning may be pivotal to ensure that organizations and health systems as a whole manage to update their offer, timely.

- Yes
- No

If YES, This is due to:

- Slow purchasing processes
- Fragmented obsolescence
- Weak training processes
- Inadequate interoperability
- Other

**Question 4.4**: Are there funding problems?

- Yes
- No

If YES, they are related to:

- Inadequate resources allocation by central government (regional/national/international levels)
- Inadequate administrative capacity for spending procedures
- Complex spending procedures
- Other


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# Annex 4. KT2 further development insights

## Key elements for the algorithm

The starting point to identify the input to the algorithm tailored to the country needs following the identification of the target population was the persona profile, that was developed as part of the WP4 in our case study, Hungary, was the "Janus" persona (Figure 10).

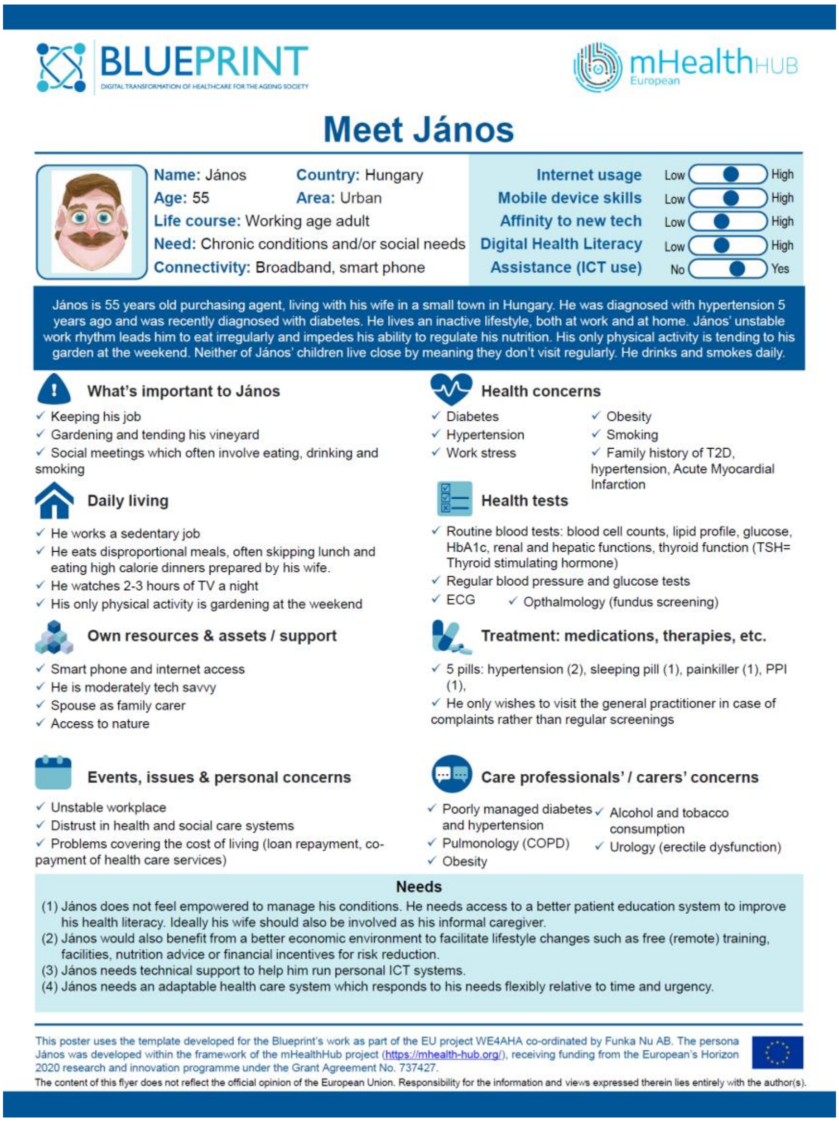


*Figure 8. Poster of Janus Persona. [Illario M. et al. manuscript in preparation]*

Functioning is included in personas description so we caught the opportunity to annotate those functioning according to the ICF codes [29-35] and have a unique way


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to identify them. Indeed, on the ground of the information shared with the country during the customization of the Janus persona, diabetes and obesity were identified as key courses to be taken into account for the ICF codes.

Table 10. provides an overview of the ICF codes selected according to the Janus persona, to feed the algorithm.

## ICF core sets for JANOS Persona

Focusing on ICF core set for diabetes & obesity, a core-set suitable for Janos persona needs was identified (*Table* ***10***).

| ICF Categories | Function (category title) | ICF code | ICF categories for diabetes course applicable for Janus | ICF subcategories | ICF categories for obesity course applicable for Janus |
|---|---|---|---|---|---|
| Body Functions | Consciousness | b110 | | | |
| | Energy | b130 | | | |
| | Sleep | b134 | | | |
| | Attention | b149 | | | |
| | Emotional | b152 | | | |
| | Seeing | b210 | B210 | | |
| | Proprioceptive function | b260 | | | |
| | Touch function | b265 | | | |
| | Sensory functions related to temperature and other stimuli | b270 | B270 | | |
| | Sensation of pain | b280 | B280 | | |
| Body Structures | Heart | b410 | | | |
| | Blood vessel | b415 | | | |
| | Blood pressure | b420 | B420 | B420 | Heart Functions |
| | Haematological system | b430 | | | |
| | Immunological system | b435 | | | |



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| | | | | | |
|---|---|---|---|---|---|
| | Exercise tolerance | b455 | B455 | | Exercise tolerance functions |
| | Digestive | B515 | B515 | | |
| | Weight maintenance | B530 | B530 | | |
| | General metabolic | B540 | B540 | B540 | General metabolic functions |
| | Water, mineral and electrolyte balance | B545 | B545 | | Water, mineral and electrolyte balance functions |
| | Endocrine gland | B555 | | | |
| | Urinary excretory | B610 | B610 | | |
| | Urination | B620 | B620 | | |
| | Sensations associated with urinary | B630 | | | |
| | Sexual | B640 | | | |
| | Procreation | B660 | | | |
| | Mobility of joint | B710 | B710 | | |
| | Muscle power | B730 | | | |
| | Protective functions of the skin | B810 | | | |
| | Repair functions of the skin | B820 | B820 | B820 | Repair functions of the skin |
| | Sensations related to the skin | B840 | B840 | 840 | |
| | | | | S140 | Structure of sympathetic nervous system |
| | | | | S150 | Structure of parasympathetic nervous system |
| | | | | S550 | Structure of pancreas |
| | Reading | D166 | D166 | | |
| | Handling stress and other | D240 | D240 | D240 | Handling stress and other |



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| | | | | | |
|---|---|---|---|---|---|
| Activities & participation | psychological demand | | | | psychological demands |
| | Moving around | D455 | | | |
| | Acquisition of goods and services | D620 | D620 | D620 | Acquisition of goods and services |
| | Preparing meals | D630 | D630 | D630 | Preparing meals |
| | Complex interpersonal interactions | D720 | | Present in the article, not in the course | |
| | Informal social relationships | D750 | | | |
| | Family relationships | D760 | D760 | D760 | Family relationships |
| | Vocational training | D825 | | | |
| | Higher education | D830 | | D830 | Higher education |
| | Recreation & leisure | D920 | D920 | D920 | Recreation & leisure |
| Environmental factors | Products or substances for personal consumption | E110 | E110 | E1100 (food)<br>E1101(drugs) | |
| | Products and technology for personal use in daily living | E115 | E115 | E1150 general tech<br>E1151 (assisted tech) | Products and technology for personal use in daily living |
| | Products and technology for personal indoor and outdoor mobility and transportation | E120 | E120 | E1200 (motorised/non motorised vehicles)<br>E1201 (walking devices, vans etc) | |
| | Products and technology for communication | E125 | E125 | E1250<br>E1251 | Products and technology for communication |
| | Immediate family | E310 | E310 | E310 | Immediate family |
| | Extended family | E315 | E315 | | |
| | Friends | E320 | E320 | | |
| | Acquaintances, peers, colleagues, | E325 | E325 | | |



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| | | | | | |
|---|---|---|---|---|---|
| | neighbours and community members | | | | |
| | Personal care providers and personal assistants | E340 | E340 | | |
| | Health professionals | E355 | E355 | E355 | Health professionals |
| | Other professionals | E360 | E360 | | |
| | Social norms, practices and ideologies | E465 | E465 | E465 | Social norms, practices and ideologies |
| | Services, systems and policies for the production of consumer goods | E510 | | | |
| | Associations and organizational services, systems and policies | E555 | | | |
| | Media services, systems and policies | E560 | | | |
| | Social security services, systems and policies | E570 | 5700 | 5750 | |
| | General social support services, systems and policies | E575 | | | |
| | Health services, systems and policies | E580 | E580 | E580 | Health services, systems and policies |
| | Education and training services, | E585 | E585 | E5850 | Education and training services, |



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| | | | | | |
|---|---|---|---|---|---|
| | systems and policies | | | | systems and policies |

*Table 10. Overview of the ICF codes selected according to the Janus persona*

The solutions to be linked to the Janus persona would be based on the categorization of the solutions based on functionalities (the building blocks). A schematic representation of the service process for KT2 is provided in *Figure **9***.

## Hypothesis of the service process for KT2

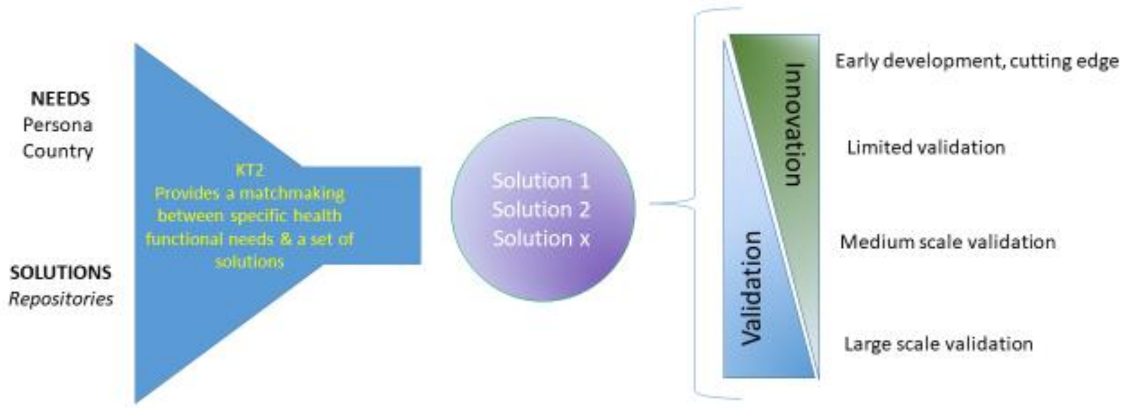


*Figure 9. A schematic representation of the concept for KT2. [Illario M. et al. manuscript in preparation]*

The results would be provided in a graded way by the algorithm, that would blend in selected ICF codes that can be addressed by digital solutions. The suitability degree of the solutions would be based upon the grading of the ICF scale.


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# Annex 5. Type 1 Diabetes management programmes: A patient journey

The approach developed in KT2 can also be applied to other diseases, especially NCDs. The personas approach also allows us to highlight the additional organizational and interoperability gaps between healthcare organizations and their IT systems, which patients who use apps to manage their condition encounter. This is an effort to contextualise national Diabetes Management Programmes through an mHealth enabled patient journey throughout the patient's national health care encounters when at home country and when travelling abroad.

The increased use of mHealth technologies for the management of diabetes has introduced the need for national diabetes management programmes for Member States. The associated challenges have been explored in several areas of work in the mHealth Hub project. Another Knowledge Tool dealing with Assessment Frameworks has exposed the richness but also the diversity of existing Assessment Frameworks for mHealth solutions across Member States, while work in WP5 is exploring mHealth Policy Frameworks.

This Annex also aims to put in context the work achieved so far in KT2, which focuses particularly on improving intelligence around the choice of mHealth solutions and diabetes programme choices, based on prioritised population profiles.

Iria's story is fictional, yet it illustrates what could be achieved with the technologies available today and our current knowledge, both of which are however are not fully integrated in health care systems with considerable variations across Europe.

> Iria Acosta is a financial analyst of 33 years old. Iria has Type 1 diabetes and was diagnosed at the age of 10. She normally takes two injections of insulin per day (she uses Insuman Comb 25, exact units per dose will vary). She has started using a mobile application to help her manage her diabetes. This app was recommended by her physician to empower her to self-manage her chronic condition, and to motivate her in maintaining a healthy life style. She has also learned to eat healthily and is quite motivated, thanks to the self-management apps suite installed on her smartphone. Last year, Iria successfully quit smoking, and started jogging (15 minutes 2-3x/week after work). She typically takes one glucose tablet 15 minutes before jogging.
>
> Iria was promoted to a senior position in the past year and her job is quite stressful. In order to stay fit, Iria enjoys exercising. She is a recreational tennis player, and after finishing work, Iria regularly goes jogging in a beautiful park located near her office.

The preconditions for every step she takes in this journey are laid out in an illustrative way. The objective here is not to be exhaustive but to illustrate the various


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interconnected policies and activities and their articulation in a national diabetes programme. The chosen patient profile is one that can allude to a broad a spectrum of elements of national programs that need be in place as possible. Two situations are explored: the daily management of the patient's condition and the case of an emergency situation when travelling abroad.

Diabetes is a complex care condition that involves many actors and many different stakeholders. It is also a condition in which self-management, including home monitoring, plays an important role. Persons with diabetes, especially elderly persons, are also likely to experience other long-term conditions, co-morbidities, and to be taking other forms of medication. Last but not least, there is already a wealth of useful data available from policy, business, organisational, and motivational perspectives that act as a sound foundation for further development of policies and strategies.

There is growing evidence that technology is changing the way people with diabetes live their lives.  For example, a survey published in April 2019 [36], involving 1052 patients with type 1 and 630 respondents with type 2 diabetes mellitus (DM) showed that using diabetes apps for self-management was positively associated with self-care behaviour. In both respondent groups, the cumulative self-care behaviour score was significantly higher among diabetes app users (compared to non-users) and scores for three individual self-care components, namely "blood glucose monitoring," "general diet," and "physical activity" were significantly higher among diabetes app users than among non-users.

In the following paragraphs we examine the supporting governance and organizational framework that needs be in place at national level and the level of cross border co-ordination that would allow a diabetic patient be truly mobile when at home or traveling abroad in the EU.

The mobile health solutions she uses have empowered Iria to build her own health profile, and to share her self-monitoring health data (glycaemia levels, weight, etc.) with the health professionals involved in her care plan (endocrinologist, GP, pharmacist and nutritionist) through secured access rights.  Iria also uses the personalised e-patient diary on her application which allows her to enter her fitness programme objectives and schedule (for automatic reminders), and to monitor her weight and her adherence to treatment.

Iria monitors her glycaemia and regularly does blood tests thanks to a new "lab on a chip" small device connected to the earphone port of her smartphone. This device allows her to get health assessments in real time to receive personalised alerts regarding potential risks for her health condition in relation to her clinical history, life style and environmental factors (e.g., exercise, diet etc.). This feature includes recommended preventive measures based on European clinical guidelines for the



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management of diabetes. Thanks to her app and to her healthy choices Iria's diabetes condition is now managed well an she has only two injections of insulin per day. She has not experienced any hypo or hyperglycaemia events in the past 7 months.

**Iria's daily management of her condition**

For Iria to enjoy the benefits of mobile health solutions it is necessary that:

### (a) Integration of Solutions into health and reimbursement systems

- There is sufficient integration of these solutions into the national eHealth infrastructures where her health data is captured and recorded electronically -including patient reported data from her mobile app.
- That apps have been developed and validated using usability standards to simplify user interfaces to fit to various socio-economic groups of patients including minorities.
- This data is collected and integrated in a standardised way – and according to national rules and standardisation framework- that makes it possible to share amongst different physicians of different disciplines within her home country. This applies not only to health data but also to social support network.
- The apps she is using may be prescribed by her doctor and reimbursed by her health insurer; for this prescription and reimbursement to be possible these Apps have undergone assessment against a national set of criteria under a national Assessment Framework, such that they can provide assurance including on the quality, safety, security and privacy, usability and effectiveness and reliability of the intervention they support and also that they comply to the national interoperability framework. In all cases, the Apps that are placed on the market, whether prescribed and reimbursable or not, if classified as medical devices will be MDR compliant and CE marked.
- There are supportive polices encouraging and enabling patient-doctor communication and leveraging on the potential of technology to support collection and sharing of patient reported outcomes with their care team.
- The patient has developed the necessary skills that allows her to collect, interpret and share data in a proper and responsible way as a prerequisite



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to establishing and maintaining confidence in her ICT supported care decisions.

- The conditions for integrating patient reported outcomes and patient-physician collaboration into the clinical pathways are in place and all care quality and safety requirements have been properly addressed.

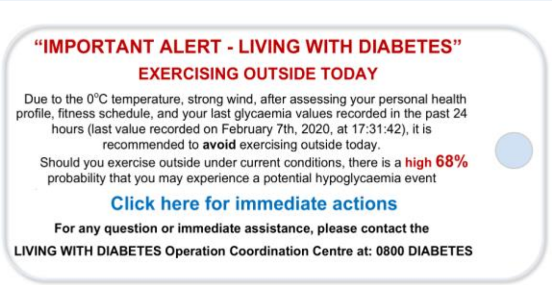
### (b) Wearable medical devices

- Likewise, the wearable devices she is using, even if not classified as medical devices under the MDR, have undergone assessment and certification for their reliability and suitability to use as part of the solution for her disease management.
- That they can transmit and receive data in interoperable formats and that data is transmitted, processed and stored through secure means and in secure environments.
- That collected data can be further used in ways that could return immediate benefit to Iria (e.g., comparisons of her health status within population studies) and for further research and innovation such as decision support systems and for improving clinical guidelines and automated alerts.

**Iria is in an emergency situation when traveling abroad**

Iria lives in Portugal and for the past 3 weeks, she has been working on a short-term assignment for the Portuguese branch of an international bank located in the City of London. Today, Iria is happy to finish a seminar she is attending at 4pm which will give her enough time to go jogging at the FestivalGardens park near her bank's headquarters. As she is walking to the park she receives an alert on her smartphone generated by her diabetes app.

Based on her personal health profile and glycaemia values recorded over the past twenty-four hours Iria receives a recommendation.



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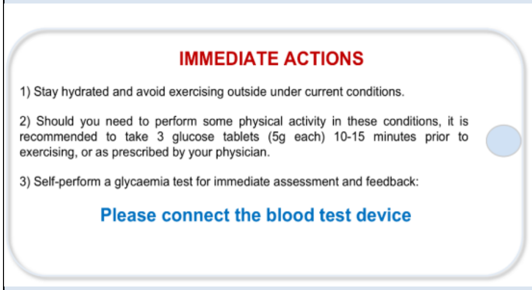
After checking in her pocket Iria realizes that she has forgotten her glucose tablets at the hotel. Iria trusts that she will be fine and sufficiently protected if she jogs for no more than 10 minutes. About seven minutes into her run Iria starts feeling exhausted and has to stop due to serious shortness of breath a rapid heartbeat and hand tremors. She starts to have troubles with her vision and feels lightheaded. She knows that she can do a blood test using an application provided in the app suite installed on her smartphone. After puncturing her finger with the small device connected to her smartphone, the app displays her glycaemia level (0.45 g/l) and immediately sends her current values to the Living with Diabetes European mHealth (mobile health) platform for real time processing.




Seconds later an alarm rings at the Portugal-based operational coordination centre (OCC) which is staffed and open 24 hours a day. The smartphone has immediately and automatically transmitted Iria's glycaemia values to the OCC which also provides real-time access to her patient summary contained in her electronic health record (EHR) based in Portugal. Because the self-management mHealth platform has detected that Iria's glycaemia levels are far below the defined thresholds (hence the risk of her having a severe hypoglycaemia event is considered to be high) a UK-based emergency physician who is on duty at a London clinic near to Iria's location is immediately contacted by the OCC in Portugal. Iria's current glycaemia values are then assessed in relation to her diabetes medical summary prescriptions and recent care/monitoring data that are on file (all of them are based in Portugal) in conjunction with the latest European diabetes treatment guidelines. This enables the UK physician to make quick safe and optimal care decisions in real time.

Iria then receives a short text message recommending her to take three glucose tablets or drink 30cl of a fruit drink, immediately. She should wait a few minutes for a London cab to pick her up at the entrance of the FestivalGardens park thanks to the automatic transmission of her GPS coordinates. As she is unstable and shaky, she asks another jogger to help her to the park entrance and to buy a fruit drink for her at the nearby kiosk. Five minutes later the cab arrives at the park to drive Iria to the nearest emergency unit in London. On arrival a couple of minutes later Iria is examined by the emergency physician on duty. Point of care (POC) diagnostics confirm hypoglycaemia and Iria is then treated for her symptoms.



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For Iria to enjoy the benefits of her national mHealth diabetes programme when travelling abroad, additional conditions must be met:

### (c) Cross border health data exchange

- Patient summaries and e-Prescriptions can be exchanged cross border in the EU, with Iria's home country having met all legal, organisational technical and semantic requirements and successfully onboarded the Cross Border eHealth Information Services community of Member States.
- That there are legal enablers for continuity of care across border, beyond the exchange of patient summaries and ePrescriptions, which will allow a seamless integration between her care providers at home and the ones in the country where she will seek care.
- That there are in addition business models for patient centred cross border chronic care which amongst others include connected clinical communities/networks and commonly adopted clinical guidelines.
- That health records can remain current and be updated with new data generated during an episode abroad.



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