European Specifications for Value-based Pre-Commercial Procurement of Innovative ICT for Empowerment and Self-management of Diabetes Mellitus Patients

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[7]*UOD Programmazione e Potenziamento Programmi di Health Innovation, Regione Campania,
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Abstract: Current demographic changes require a paradigm shift in the delivery of health and social services. Wide-scale implementation of validated ICT support to clinicians and patients is essential to ensure the quality of services to future generations of citizens. Healthcare providers from four European regions – Turkey, Portugal, Campania and Murcia– have joined forces to procure an innovative ICT solution for patient empowerment and self-management for patients with diabetes mellitus. The procurement is in the form of a joint pre-commercial procurement (PCP) of Research & Development, with participation by EU industry in competitive phases of development. The PCP is part of the EU-funded project ProEmpower, which is currently in the prototype testing phase. The challenge faced by the procurers was to jointly define specifications for the envisioned solution that reflect the needs of all four regions. After an intensive year of consultations with procurers' experts – clinicians, IT staff, procurement specialists – ProEmpower launched a call for tender with the defined specifications, which reflect the unmet needs across the procuring regions with regards to improving management of diabetes mellitus supported by ICT. This paper presents the ProEmpower specifications, which can be easily adapted to the local conditions of any procuring region in Europe and beyond. The specifications thus represent a valuable source for any new development of ICT-supported diabetes management.

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1 INTRODUCTION

In Europe, a strong rise in the prevalence of chronic non-communicable diseases is putting increasing pressure on public expenditure for health services. This can call into question the sustainability of universal coverage models for health, underlining the necessity of innovation in the field of health and care.

Innovative ICT solutions deployed in health and care delivery can certainly help address these challenges, in particular by tackling costs arising from current inefficiencies. According to the European Commission, improving the efficiency of health care over the next 50 years can guarantee provision of the necessary health and care resources throughout Europe, despite the aging population, demographic changes and increased demand for services (European Commission, 2018).

Public procurement represents a huge market to providers, and as such holds strong potential for introducing innovative products and services. Through public procurement, governments can promote innovation at national, regional and local level, resulting in a wide range of improvements including productivity and inclusiveness (OECD, 2017). Public procurement is an important part of the EU market, accounting for around 14% of the EU Gross Domestic Product (GDP) (European Commission, 2017). Horizon 2020, the EU framework program for research and innovation, has introduced two innovative forms of public procurement: Public Procurement for Innovative Solutions (PPI) and Pre-Commercial Procurement (PCP). PPI is a procurement procedure in which contracting authorities act as customers for launching innovative goods and services that are not yet available on a large-scale commercial basis. PCP concerns public procurement of innovation, and accordingly comprises the purchase of Research and Development (R&D) services rather than finished products. PPI and PCP engage industry players as future vendors through all phases of development - from research to the final product - and offer public buyers the opportunity to influence the market, stimulating vendors to develop solutions that respond to well-identified needs.

Diabetes mellitus is a chronic disease with a broad spectrum of severity, accompanied by many concomitant conditions, complications and development stages. Its prevalence is increasing worldwide towards becoming a pandemic, representing an ever greater burden on health care systems (Bommer, et al., 2017). "Procuring innovative ICT for patient empowerment and self-management of type 2 diabetes mellitus" (ProEmpower) is an European funded project under Horizon 2020 programme, with the aim of purchasing R&D services, through a PCP procedure, in order to develop an innovative IT solution for early diagnosis and management of diabetes, facilitating the lives of people with type 2 diabetes, supporting them in their daily lifestyle choices and giving healthcare professionals access to the clinical data needed for the management of the disease and its complications (ProEmpower consortium, 2018). The project involves four public procurers across Europe – Turkey, Portugal, Campania (a region in southern Italy with about 6 million inhabitants) and Murcia (an autonomous community in south-eastern Spain with a population of about 1,5 million). The cooperation has allowed very significant synergies in developing detailed specifications for new diabetes management processes supported by fully integrated ICT solutions. Work started with a thorough investigation of requirements for service provision, followed by specification work. This included an in-depth analysis of opportunities to support end users and care staff as well as of organisational resources and legal/regulatory constraints.

In preparing the project proposal, the ProEmpower consortium already felt that a most important aspect to face was the current fragmentation of solutions for professionals and patients, which do not allow effective interaction between the two. ProEmpower addressed this shortcoming by calling for proposals to supply a unitary continuous diabetes management system for type 2 diabetes patients, centering on comprehensive care pathways.

The joint PCP project addresses a demand for innovation shared by many public procurers across the EU, contributing to the sustainability of private investment in research and development.

At the core of ProEmpower is a competitive R&D process comprising two preparatory steps and three phases:

- Open Market Consultations: dedicated workshops organised by the procurers in their regions to consult with vendors, inform the technical specifications and set realistic, yet innovative procurement objectives;
- Call for Tenders: an international tender launched on the website of the Supplement to the Official Journal of the EU
- PCP Phase I: Concept design, solution architecture and technical specifications
- PCP Phase II: Development of prototype systems

- PCP Phase III: Development and testing of pilot systems

Figure 1: ProEmpower PCP phases.

As the time of writing (November 2018), the ProEmpower PCP is in phase II.

2 APPROACH

The approach to developing uniform technical specifications for a diabetes mellitus management solution involved the following aspects:

- Understanding the specific technical and clinical environment at each health provider
- Engaging an interdisciplinary, international working group with all relevant expertise to draft the technical specification
- Involving end users (patients, informal care-givers, healthcare professionals) in the co-design process
- Jointly defining both functional and non-functional requirements
- Describing appropriate use cases and corresponding process models

2.1 Specific Health Provider Environments

The specific technical and clinical environment in each procurer health provider organisation was analysed both to inform common specifications and to identify any procurer-specific requirements, in particular integration with diverse existing Electronic Health Record systems.

For each procurer, the clinical, organisational, technical and business environment was captured via a series of interviews with key personnel – clinicians and ancillary staff, IT staff, and hospital business managers.

2.2 Co-design with End Users

There is ample evidence that health IT does not of itself achieve better care, and can only contribute if systems and solutions are properly embedded into care processes, working routines and end-users' day-to-day life. Knowledge of the care experience, held only by the patient, is particularly precious. This knowledge is tapped by participatory design, where the client is no longer passive recipient of a new product crafted by experts, but is treated as active contributor, integral to design and to the innovation process as a whole.

The ProEmpower requirements were informed by a selected set of end users (patients, informal caregivers, professionals). 10 patients with diabetes mellitus from each procurer region were first asked a series of questions about possible solutions. Half of them then participated in dedicated local focus groups, fed by the information collected through the questionnaires. User involvement is embedded into the overall innovation process, with the plan to involve users in subsequent phases to test and inform the prototypes.

Example feedback by Turkish end users is captured in the illustration below.

Figure 2: Feedback from ProEmpower professional end users from the Turkish procurer.

2.3 Definition of Requirements

The process of eliciting user requirements in ProEmpower included:

- development, administration and analysis of a questionnaire capturing patients' views on possible system functionalities, and their wishes for future support;
- development, administration and analysis of a questionnaire for professionals in order to capture a professional view of possible improvements to

delivering diabetes care in their respective institutions;

▪ conducting interviews with experts on specific topics, for example to obtain knowledge about regulatory and business conditions.

The collected information was used to inform the elaboration of functional, non-functional, legal and regulatory requirements. Functional requirements are key, as they capture details of the intended behaviour of the system.

Each requirement was described using ID and name, summary, and priority for implementation.

Table 1: An example of ProEmpower functional requirements related to diabetes training.

ID and name	Summary	Priority
R1.2.1 Training - form	The ProEmpower solution shall support training of diabetic patients during physical meetings and as offline follow up (e.g. when the patient is at home).	9,5
R1.2.2 Training - duration	The ProEmpower support training of diabetic patients will be designed in a way as to be able to administer the physical training session in modules, each lasting from 15 to 45 minutes (depending on personalisation and topics covered).	7,7

2.4 Description of Use Cases and Process Models

Based on the collected feedback, a set of use cases and corresponding process models were developed according to previously identified building blocks – key aspects to be taken into account for delivering a comprehensive solution in line with the Chronic Care Model (CCM) (Stellefson, et al., 2013).

While PCP projects must define key requirements and expectations in calling for R&D work, innovative ideas should not be unnecessarily constrained, so as to benefit optimally from expertise among suppliers competing to carry out the necessary R&D.

In ProEmpower, the envisaged functionality is described using use cases and process models. Use cases represent a tabular description of the interaction between a role and a system to achieve a goal. Each use case has an ID, a title, a summary, actors (e.g. patient, professional, system), parents and children (to indicate relationships among use cases), pre-conditions and post-conditions, and key functionalities.

Process models represent a further generalised version of use cases, also providing support and guidance to the R&D work of suppliers. They are developed as BPMN 2.0 process models.
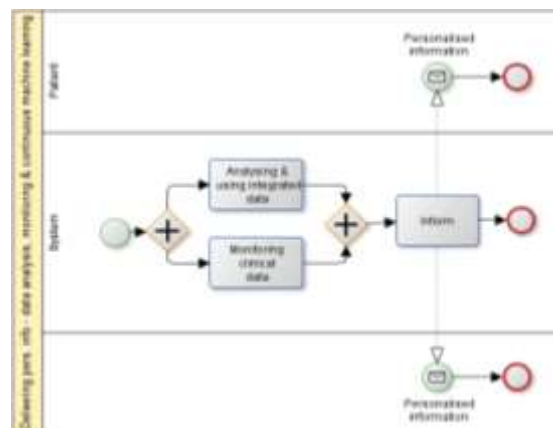
Figure 3: Example process model in ProEmpower.

3 RESULTS

3.1 European Specifications for Development of ICT Solutions for Diabetes Mellitus Management

The ProEmpower procurers have compiled over 165 requirements for new ICT-enabled diabetes mellitus management solutions for their regions, together with a set of twelve use cases and process models. This arguably represents a most comprehensive resource for any European region or nation wishing to procure innovative solutions in the field, as well as enabling IT industry to innovate in line with their clients' requirements.

The requirements are grouped into key topics according to the Chronic Care Model, as shown in the table below.

3.1.1 Functional Requirements

The four procurers requested the development of a Shared Care Plan, accessible by patients and healthcare professionals, to enable them to use a common entity/document that uses relevant information about the patient's diabetes management and allows for scheduling events and reminders, such as follow-up visits and regular tests. The Shared Care Plan is to allow both patients and professionals to enter data such as measurements, while giving each specific rights to do so and integrating data captured directly from devices.

Figure 4: ProEmpower diabetes management building blocks.

The requirements associated with delivering training to diabetic patients in various disease stages include the topics of:

- Physical activity and exercise;
- Tobacco and alcohol consumption;
- Hygiene (mouth, feet);
- Complications from and prevention of diabetes;
- Hyper- and hypoglycaemia and blood glucose self-control;
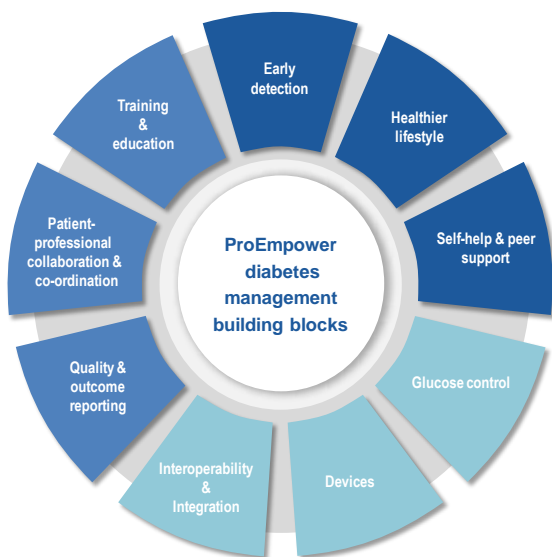- Diet and nutrition;
- Insulin therapy and injectable drugs;
- Drug therapy;
- Life with diabetes;
- Sleep and stress avoidance.

Training to diabetic patients is to adapt to patients, e.g. their age, sex, literacy level, emotional state, working conditions, diagnosis (early stage, advanced, etc), medication, weight trend, etc. Personalisation is expected to motivate the patient to use the ProEmpower solution effectively.

Measurement of parameters used by health professionals and patients to manage the disease are to be transferable to the main ProEmpower solution, including automatic data transfer from sensors complying with standards such as IEEE 11073 PHD. It has been specified that a solution must be compatible with at least two brands of glucometer widely available in the markets of the four procurers.

The solution is furthermore to be able to deliver messages to the patient, including messages formulated by a professional and those automatically generated through data analysis - notifications of deviation from goals, tips for better management, etc. Beyond messages, the solution is to provide guidance/recommendations to the patient and/or physician by using available patient data (e.g. measured values, patient history, nutrition, physical activity, etc) to estimate the short-term trend in blood glucose.

ProEmpower procurers have requested a platform capable of tapping neighbourhood and/or family resources to deliver patients with co-operative diabetes support. This online platform is also for diabetic patients to communicate and be trained on their disease. Professionals may also use it to exchange ideas with colleagues and provide advice to patients.

Requirements for early detection of diabetes include requiring provision of the FINDRISK questionnaire (Schwarz, 2011) in a public portal, prompting the patient to contact a physician in case of high risk. Furthermore, an algorithm is to use specified clinical data to identify those individuals who might have diabetes type 2 and/or other complications.

3.1.2 Non-functional Requirements

A key area of requirements relate to the ease with which a ProEmpower supplier can integrate new processes with the procurers' existing IT systems. Suppliers bidding for R&D work were provided with a comparative analysis of existing systems, and requirements include that any solution must be interoperable with the IT systems of the four procurers. It is further required that at least five languages (Italian, Spanish, Portuguese, Turkish and English) be provided.

Existing electronic health records (EHR), local data standards and existing software packages are central to integration. In Campania, suppliers are to conform with an Italian regulation to ensure interoperability among the different regional IT infrastructures which defines standards for communication, the format of health and social care documents and the encoding of clinical data (Presidente del Consiglio dei Ministri, 2015). Furthermore suppliers are made aware of the use of MyStarConnect® diabetes data management by the Azienda Ospedaliera Universitaria Federico II as pilot site, and of AirDiabete®, a web service supporting reporting on the participation of GPs in the management of diabetic patients.

Murcia has a regional electronic health record which aggregates in a central database medical records from a range of information systems. Sources

include hospital information systems, the Selene GP information system, a patient identity database and information systems for labs, radiology, etc. ETL (Extraction, Transformation, and Loading) procedures extract data from HIS and other systems based, like the regional EHR, on an Oracle database. Data are also obtained through HL7 message parsing.

Portugal's PDS health data platform reduces the gap between health institutions by providing pointers to patient clinical data in many locations. PDS also provides a simple way of visualising the contacts a patient has with the national health system, displayed on a timeline. PDS provides patients with access to their personal health record. A RESTful API® is provided, and data is stored in a central database along with pointers to other systems leaving most clinical data held decentrally in hospitals or a primary care centres.

In Turkey, E-Nabız® allows patients access to their health record and enables them to add information, such as daily exercise or blood sugar measurements. The clinical information can be accessed by a doctor if the patient gives permission, possible through authentication mechanisms. However, E-Nabız® is not intended to be a chronic disease management system and provides no support to doctors to communicate with the patient regarding their condition. Currently, a doctor can only access patient information in the clinical environment and not out of business hours, even if the patient were to consent. However, E-Nabız® is compatible with all mainstream home-use medical devices, whose measurements can be captured wirelessly.

3.1.3 Organisational, Staff and Business Requirements

The four procurers specified that ProEmpower solutions must fit their organisational models and integrate with existing technological infrastructures. The solutions are not to be technology-driven, but clearly meet specific needs of patients and health professionals in effective healthcare service delivery. Common features of organisational models in healthcare serving diabetes patients have been identified. Analysis showed that the set of actors involved in the process depends on the stage of the disease. In early stages of diabetes the General Practitioner and some cases a nurse are the only actors, while in later stages many specialist doctors from different clinics may be engaged. Generally, actors are:

- General Practitioner, responsible for general follow-up and dosage adjustments;

- Nurse, trains the patient in lecture-style sessions and may demonstrate use of blood sugar devices;
- Dietician, advises on nutrition and, when so instructed, on diet plans;
- Specialist doctor (cardiologist, ophthalmologist, nephrologist, neurologist), organise advanced medical tests.

A diabetologist plays a key role in some systems. In Campania, diabetologists have a defined role in the diabetes diagnostic and therapeutic pathway, prescribing diagnostic tests, assessing glycometabolic control and complications risk or development, and making treatment interventions. There, a diabetologist prescribes and reviews medications and delivers tailored education to inform lifestyle choices, including advice on physical activity.

3.2 ProEmpower Use Cases and Process Models

As shown in the diagram below, a set of 12 use cases and corresponding process models was produced. Generally, data-driven use cases are enablers for use cases which deliver functionality.

Figure 5: ProEmpower use cases – key functionalities.
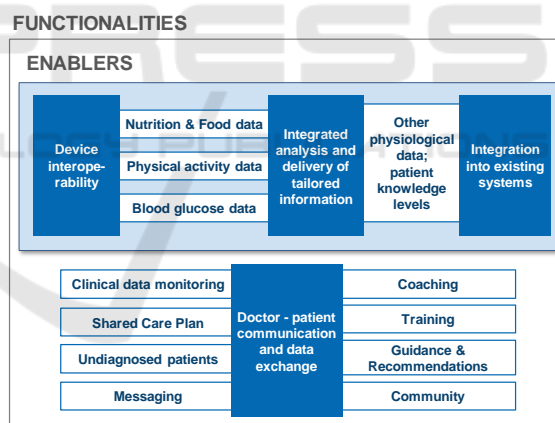
The ProEmpower use cases are:

- UC1: Enrolling users into ProEmpower
- UC2: Integrating data from different sources and ensuring interoperability
- UC3: Capturing patients' level of knowledge and capabilities
- UC4: Delivering personalised information using data analysis, monitoring and continuous machine learning
- UC5: Forecasting Daily blood glucose long-term effects

- UC6: Enabling information exchange through messaging
- UC7: Coaching on physical activity and nutrition & food
- UC8: Providing diabetes training to patients
- UC9: Working with a Diabetes Shared Care Plan (SCP)
  - UC9-1: Setting and tracking targets
  - UC9-2: Managing events
  - UC9-3: Medication and dose management
  - UC9-4: Generating, viewing and exporting reports
- UC10: Participating in self-help and peer support community
- UC11: Peer mentoring
- UC12: Flagging undiagnosed type 2 diabetes patients

Two use cases and process models are described in more detail in the following tables and figures – one for coaching on physical activity (simplified) and one on flagging undiagnosed patients.

Table 2: ProEmpower use case: Coaching on physical activity and nutrition & food for diabetics.

ID	UC6 - Coaching on physical activity and nutrition & food for diabetic patients
Summary	ProEmpower enabled patients will have the opportunity to be coached on nutrition and food choices and ideas which are suitable for type 2 diabetic patients and in line with personal preferences. Harmful effects (such as intolerances and undesired food-drug interactions) can be avoided and the patient can receive comprehensive long-term coaching. Similarly, patients will be coached on activities to prevent and avoid a sedentary lifestyle by receiving helpful and comprehensive long-term coaching.
Actors	Physician, Patient, System, Nurse, Dietician
Key functio-nalities	Coaching relies on data provided by the patient regarding physical activity and is thus closely linked with UC2 and UC4. State-of-the-art techniques shall be used to enable the patient to record such data. Automatic detection (e.g. type of exercise, duration, distance, intensity, steps, floors, sleep, heart rate) and recording are the preferred choice. The system is able to: - check whether the entered physical activity is within recommended levels according to the American Diabetes Association recommended values - propose duration and intensity of selected physical activities appropriate to the patient (e.g. based on latest recorded blood glucose levels).

- give advice related to nutrition in connection with meal intake (e.g. what foods or drinks to take or not, before and after exercise and in what quantity based on the entered training duration and intensity).
- give suggestions, reminders & alerts for exercise routine or walk routine (e.g. based on the levels of sugar and the physical conditions every day)
- provide physical activity lessons / tips for the everyday routine.
- analyse the entries and patient parameters to identify barriers to adherence to the physical activity guidelines and suggests possible actions to overcome them.

Continuously, the system provides positive feedback to the patient and tracks goals. The system gives out warnings to the patient (e.g. poor activity daily, or physical condition alert, excess of sedentary in activities of daily living) in connection with UC4. The physician and/or nurse can monitor entries periodically (weekly or monthly) or view summary reports and provide feedback to the patient during visits. The physician can set and adjust target goals for the different activities and for different periods, which are flagged as such and accompanied by notes and explanations, and are reported by the system to the patient.
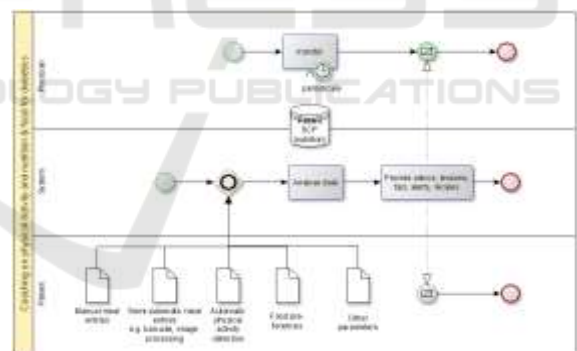

Figure 6: ProEmpower process model: Coaching on physical activity and nutrition & food for diabetic patients.

As can be seen from the descriptions, use cases contain links to further functionalities and aspects that are defined in other use cases.

All ProEmpower use cases and process models can be downloaded from the ProEmpower website.

Table 3: ProEmpower use case: Flagging undiagnosed type 2 diabetes patients.

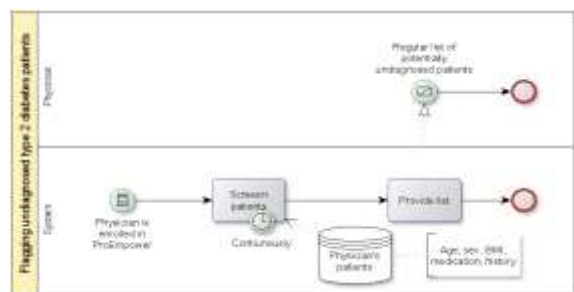| ID	UC12 - Flagging undiagnosed type 2 diabetes patients
Summary	The ProEmpower solution shall provide an algorithmic module that uses available existing patient data to identify those patients which might have type 2 diabetes. Predictors of diabetes could be age, body mass index, prescribed medication, patient history (family), etc. The identified patients will be flagged, and a list/report provided to the physician in charge of their care. Alternatively, the physician may initiate a request to run the module for a specific patient (e.g. during a control visit).
Actors	Physician, Patient, System
Key functionalities	1. Identifying potential undiagnosed type 2 diabetes patients The system reviews patient data continuously using an algorithm to flag patients who might have type 2 diabetes. Example parameters to be used include: - age - body mass index - prescribed medication - patient history The data analysis is possible if the patient has provided consent for their data to be used in such a way, which is the normal case for those patients of physicians (GPs) which are enrolled in ProEmpower. 2. Communicating results to the physician The system provides a list of patients with the results presented in a report format. The list can be printed and provided to the corresponding physicians in charge of the patient's care. Alternatively, physicians may wish to run the algorithm during a patient session, in which case the patient has provided consent for this.

Figure 7: ProEmpower process model: Flagging undiagnosed type 2 diabetes patients.

3.3 Value-based Procurement

The ProEmpower specifications are part of a comprehensive set of award criteria developed for procurement of R&D services in ProEmpower, fully aligned with value-based procurement. Weightings in terms of points and thresholds were assigned to each of the criteria. Depending on the phase, the weightings are adjusted, both in terms of points and thresholds, to reflect the characteristics of the PCP phase. Selection of suppliers in each phase is based on a price-quality formula:

$$
\begin{aligned}
\text{Score for tender X} = & (\text{Cheapest Price} \, / \\
& \text{Price of tender X} * 100 * \\
& \text{Price weighting of 30\%}) \\
& * \\
\text{Total quality score (out of 100) for all} \\
\text{award criteria of tender X} * \\
\text{Quality criteria weighting of 70\%}
\end{aligned}
\tag{1}
$$

A generic evaluation scorecard was configured for ProEmpower and provided to the evaluation committee, as shown in the figure below.

Award criteria	Maximum points	Threshold
Excellence of the proposed solution		
Understanding of the ProEmpower domain	5	
Extent to which the solution matches the ProEmpower vision	10	5
Extent to which the proposed solution meets the requirements documented in the Call	15	8
Evidence of effectiveness	10	
Total for excellence	40	20
Impact of the proposed solution		
Value of benefits for patients	10	5
Value of benefits for procurers	10	5
Total cost of ownership	5	2
Sustainability of supplier business case	5	
Soundness of the approach to integration with procurer systems	10	5
Total for impact	40	20
Implementation of the proposed solution		
Quality and completeness of the work-plan as well as detail of task and result descriptions	5	
Feasibility of plan and resources to meet the objectives specified	10	5
Relevance of the proposed way to involve clinicians and patients in design and development	5	
Total for implementation	20	10
Overall total score for tender	100	60

Figure 8: ProEmpower award criteria scorecard.

3.4 Extendibility

The ProEmpower specifications were designed with extendibility in mind. The specifications are to stimulate vendors to implement innovative solutions

that meet requirements set. These reflect the Global Guidelines for Diabetes type 2 (International Diabetes Federation, 2012) and include the requirement for interoperability with common medical devices. Results are open to be used by procurers worldwide, and can be extended to complications such as kidney disease, and vendors can use them as reference when developing their own diabetes solutions.

The methodology applied in ProEmpower is applicable to other chronic conditions such as hypertension and chronic obstructive pulmonary disease (COPD). ProEmpower procurers have already adapted the approach for a PCP on innovative hypertension management.

ProEmpower procurers have identified useful synergies with other EU-funded projects. These include EU project WE4AHA, further developing the European "Blueprint on Digital Transformation of Health and Care for the Ageing Society" (European Commission, 2018). In work led by empirica GmbH, twelve personas have been developed, intended to represent the EU population. Personas are to inform requirements and specifications and serve to ensure that person-centred approaches are followed. ProEmpower work informed persona development, and personas with diabetes are currently being validated by over 1,000 stakeholders of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA).

3.5 Progress of the ProEmpower Suppliers

Three supplier consortia have been selected for phase II of the ProEmpower PCP:

- DM4ALL – consortium led by Gnomon Informatics SA (Greece)
- CarpeDiab – consortium led by Health Insight Solutions GmbH (Germany)
- DiaWatch – consortium led by Tech4Care srl (Italy)

Detailed information about the suppliers and their approaches can be found on the ProEmpower website.

4 CONCLUSIONS

The ProEmpower procurers have produced a comprehensive set of specifications for value-based pre-commercial procurement of innovative ICT for empowerment and self-management of diabetes

mellitus patients. The requirements, use cases and process models reflect the joint needs of four European regions – Turkey, Portugal, Murcia and Campania. They can be used by any procurer interested in similar solutions, and can be extended and used for other health conditions by procurers and vendors alike.

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