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HEALTH TECHNOLOGIES AND SMART & INTEGRATED CARE – KEY ACTION 2 STAGE OF THE REGIONS4PERMED (H2020) PROJECT

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ABSTRACT

Consumer and system-wide gains remain limited by an outmoded policy regime. With scientific innovation running far ahead of public policy, physicians, researchers and patients are not receiving full advantage of the latest developments. European health systems require a seamless and rapid flow of digital information, including genomic, clinical outcome, and claims data. Research derived from clinical care must feed back into assessment, in order to advance care quality for consumers. National health systems are heterogeneous; the solutions and required fundamental approaches differ between the European member states and are not entirely portable and scalable. To date, this applies not only to general systemic aspects but particularly to cross-border reimbursement issues and the exchange of treatment and patient data.

To answer those needs, an international consortium was established to implement the project "Interregional coordination for a fast and deep uptake of personalised health": Regions4PerMed. A cycle of international events, such as conferences, in situ visits and workshops, has been planned. Interdisciplinary groups of experts will exchange thoughts and experiences to design solutions that could be implemented in the various healthcare systems. Regions4PerMed aims to coordinate regional policies and innovation programmes in personalised medicine and personalised health to accelerate the deployment of personalised health for patients. Key Action 2 is dedicated to health technologies and smart and integrated care.

KEYWORDS: health technology, e-health, m-health, integrated healthcare, personalised medicine, personalized health

Background

With many initiatives launched worldwide for the personal human genome map (Personalised Medicine Initiative in the USA, 100,000 Genomes Initiative in the UK, and the Human Genome Declaration at EU level), it is possible to envision a future where treatments are tailored to individuals' genetic structures [1] – a future where Personalised Medicine is fully integrated into real life setting.

In healthcare, newly emergent scientific and technological innovations are either not yet used or are underused because of slow adoption, data analytics is failing to reach its full potential, and interdisciplinary barriers in medical science need to be overcome.

To accelerate the adoption of personalised medicine approaches and enable early interception of diseases, and deliver new precision and personalised care while balancing and optimising healthcare expenditures based on medical and economic value, health technologies and smart and integrated care must become a key priority for policy makers. Healthcare organisations need to be transformed in order to absorb innovative technologies and deliver more personalised services to patients and citizens. In this respect, worldwide, the

healthcare environment is already changing, and it is becoming increasingly obvious that affordable high-quality healthcare cannot be delivered without harnessing new ways of delivering care [2]. New technology is a promising solution to help cope with current challenges and to improve healthcare and pharmacy practice [3].

Health technology

Health technology is defined WHO as "the application of organised knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem, improve the quality of lives". Health technologies equip healthcare providers with tools that are indispensable for effective and efficient prevention, diagnosis, treatment and rehabilitation [4]. These technologies and, in particular, connected and integrated care solutions, can offer users (citizens/patients and health professionals) enormous benefits and amplify system-wide gains that are currently limited. Connected health or technology-enabled care (TEC) is the collective term for telecare, tele-Health, telemedicine, m-Health, digital health and e-Health services. Within the health industry, TECs are often referred to as smart technologies.

Health technologies can advance diagnosis, prediction and therapies for diseases, and TEC tools, in particular, can provide specific information from autonomous data analysis. This can help both the physician and the patient to predict the patient's future health, and foresee management issues and possible modifications to the therapy regime and/or health management activities, as well as interventions targeted to improving the patient's wellbeing (such as improving relaxation and positive emotions or promoting engagement in self-actualising experiences) [5]. This will also help healthcare systems reduce costs for the management of chronic diseases.

Health technologies hold huge potential for the utilisation of health data in transforming healthcare. The application of analytics, machine learning and artificial intelligence over big data enables identification of patterns and correlations and hence provides actionable insights for improving the delivery of healthcare [6].

Smart solutions

Telecare: a new health service that involves the use of technology within patients' homes, such as home monitoring, safety monitoring, and information service technologies [7].

Tele-health: services allowing patients to access health education and support for self-management through the Internet, via their home computers or wireless devices. Patients can obtain personalized education materials and coaching and may participate in online discussions and support groups as an additional means of managing their health [3].

Telemedicine: delivery of healthcare services where distance is a critical factor. All relevant healthcare professionals will use information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation. This also aids the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities [8].

m-Health: tools providing specific information from autonomous data analysis. These will help both the physician and the patient to foresee the patient's future health, management issues and make modifications to their therapy regime and/or health management activities, as well as interventions targeted to different aspects of the patient's wellbeing (such as improving relaxation and positive emotions or promoting engagement in self-actualising experiences) [5].

Digital health: rapidly expanding medical field premised on the availability of ever-increasing amounts of data about people's lifestyles, habits, clinical histories and pathophysiological characteristics [9]. Digital health includes the following technology: i) all devices that have an effect on health even if they are not designed only for health (e.g. smart watches); ii) digital devices that are designed to provide evidence in terms of better health; iii) digital devices that have a therapeutic effect, such as deprexis in UK and Sleepio in USA, and others that influence behaviour and control rehabilitation activities.

e-Health services: use of digital technology to treat patients, diagnose diseases, conduct research, support health education, inform and communicate with patients or other healthcare providers, and gain an overview of public health in society [10].

Medical decision-support systems (MDSS): computer systems designed to assist physicians or other healthcare professionals in making clinical decisions. MDSS can help physicians to organise, store, and apply the exploding amount of medical knowledge. These are expected to improve the quality of care by providing a more accurate, effective, and reliable diagnoses and treatments, and by avoiding errors due to gaps in physicians' knowledge [11].

Semantic interoperability: the ability of computer systems to exchange data with unambiguous, shared meaning. Semantic interoperability is a requirement to enable machine computable logic, inferencing, knowledge discovery, and data federation between information systems.

Medical communication standards: a set of international standards for the transfer of clinical and administrative data between software applications used by various healthcare providers. These standards focus on the upper layers in the OSI model. The standards are maintained by several international standard organisations and are adopted by other standards issuing bodies.

Healthcare services

Smart health should also have the following characteristics:

– Help patients strengthen their resilience towards health-negative events.
– Strengthen flexibility and adaptation of health delivery organisations when innovation occurs, to generate an impact both for individual and public health.

The exponential rise in TEC requires healthcare providers to redefine staff roles and responsibilities and support them to work differently. Currently, healthcare is largely defined by "place" of work and is based on providing hands-on care to patients. As TEC services are adopted more widely, staff can undertake e-visits, write e-prescriptions and track, diagnose and deliver treatment via remote digital monitoring – delivering benefits for providers and offering savings in direct costs and staff time (Figure 1) [12].

As a repercussion of the implementation of TEC, the organisation of providers, management of services and performance improvement processes has begun adapting and responding to new models of care, such as integrated health services.

The WHO Regional Office for Europe defined integrated health services delivery as follows [13]: an approach to strengthen people-centred health systems through the promotion of the comprehensive delivery of quality services across the life-course, designed according to the multidimensional needs of the population and the individual and delivered by a coordinated multidisciplinary team of providers working across settings and levels of care. It should be effectively managed to ensure optimal outcomes and the appropriate use of resources based on the best available evidence, with feedback loops to continuously improve performance and to tackle upstream causes of ill health and to promote well-being through intersectoral and multisectoral actions.

In order to boost the growth of health innovation for the uptake of personalised medicine innovations, we have identified some initial challenges that can be addressed at regional level.

Challenges

Identified crucial challenges for the sector are the following:

– **Data generation along the whole R&D value chain**: generating high-quality, harmonised, reliable, annotated, interoperable data that can be shared, for example for larger integration, interoperability and/or where economies of scale are needed. For instance, a shift in focus to preven-

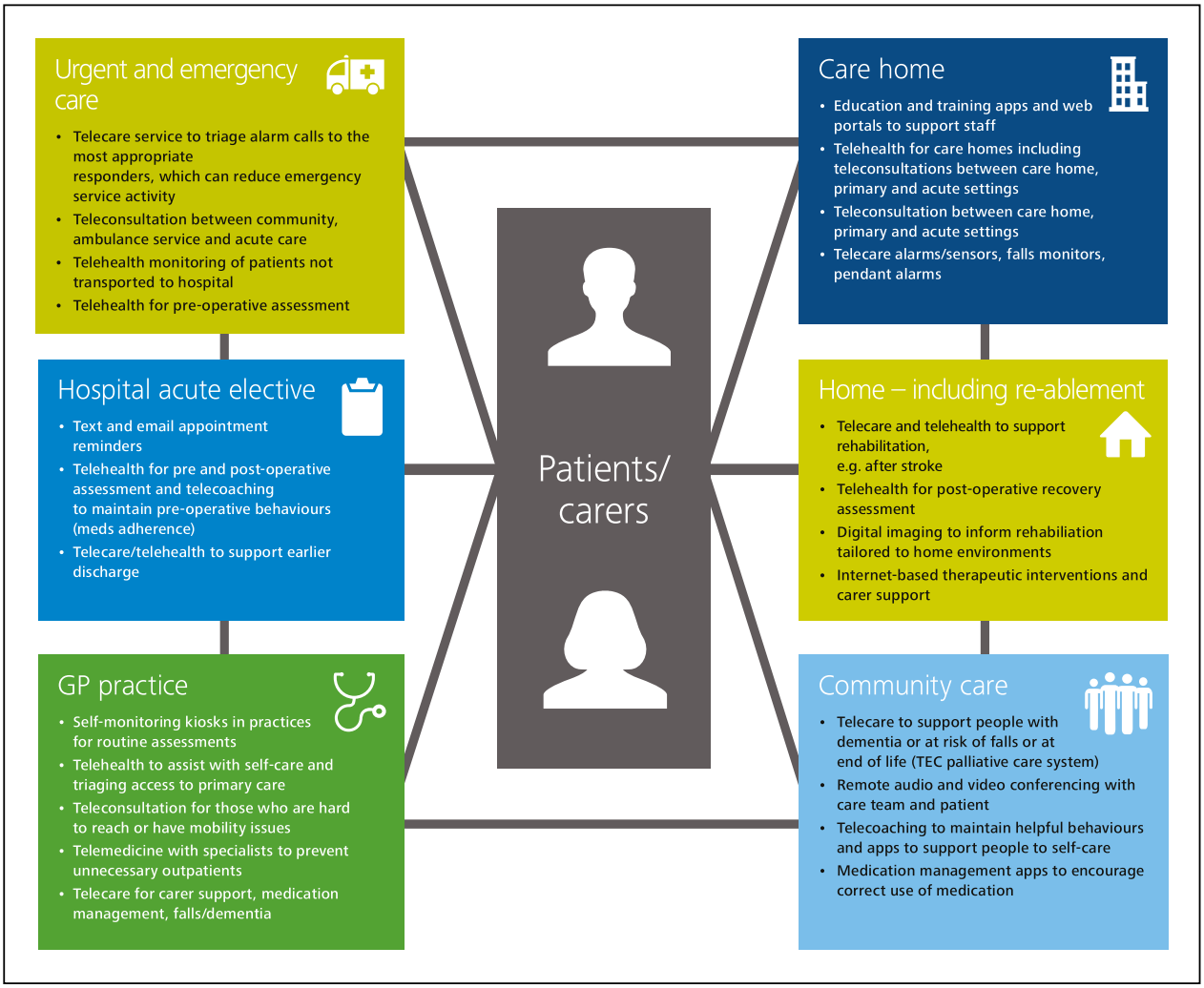

Figure 1: Example of how mobile technology could be used to connect staff with patients and support staff to work differently [12].

tion of disease and diagnosis of pre-disease states will require data on very large cohorts of healthy people that are not identified as high-risk.
- **Integration of technologies for better and safer products and services**: The health industry would leverage new knowledge and technologies, such as artificial intelligence, connected health systems, as well as "omics" and nanotechnologies, for the enhanced understanding of the biology of diseases to develop new products and services for disease prevention, prediction, interception, intervention and management. This integration also includes activities to optimise the innovation pathways both within and across the sectors in terms of common standards, models, platforms, methodologies, etc..
- **Integration of these products and ancillary services to create innovative healthcare solutions**: companies would combine the existing and/or new innovations across the sectors to create solutions and enable their integration within the patient care pathways.
- **Integration of clinical, community, social and informal care workflows**: development of solutions to support improved operational care workflows in clinical or community settings.

Barriers

These ground challenges also present barriers that Key Action 2 (KA2) will address:
- **Quality of data**: accessibility, integrability, relevance, timeliness and rectifiability of data are essential to develop solutions that can be integrated in health systems. In this context, European regions (intended as local and regional authorities), as seen in the context of Key Area 1 (big data, electronic health records and health governance) have a major role to play. Within KA2 we will focus on key enabling investments that regions can promote the wealth of health technology.
- **Regulatory aspects**: health technologies make an essential contribution to healthcare in the EU for the benefit of European citizens. Medical devices, for example, are crucial in diagnosing, preventing, monitoring and treating illness, and overcoming disabilities. They are also important to the economy, providing €110 billion in sales and 675,000 jobs in Europe.

The European Commission has adopted two new regulations which, in order to guarantee a higher degree of safety for the best interests of European citizens, pose a burden on health technologies. This might have consequences, both for the industry and, in general, in slowing the pace of implementation of personalised medicine. These new regulations are as follows:
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Within the conference we would like to examine the potential impacts of the new regulations and the role regions can play in reducing these.
- **Trainings for healthcare professionals:** health technologies are often advantageous for the patient, but health professionals often encounter difficulties in using devices associated with these technologies, which can increase the risk of accidents [14].
- **Patient engagement:** there is increasing evidence that having more-informed patients is starting to improve self-care and adherence to medication, and boost health and wellbeing [12]. Health technologies are essential to enable personalised patient engagement approaches by analysing and providing solutions to the patients' needs. In particular, health technologies can be used to for the following:
  - Increase health literacy, promoting patients' knowledge on their specific health problems through dialogue, guidance on trustworthy sources of information and use of ICT tools.
  - Increase self-awareness (SA): SA level will be assessed using validated tools and improvement will be driven by screening and monitoring variables using ICT tools.
  - Improve risk perception (RP): patients' estimated vs. perceived risk will be assessed by validated tools and RP will be computed by comparing these scores, to enable precision empowerment.
  - More accurate prognosis, which will be estimated by systematic use of updated risk scores.
  - Guaranty of receiving state-of-the-art care. PM programmes will make use of updated algorithms to implement the best individualised diagnostic and therapeutic strategies.
- **Economic impact of health technology:** The key point for health technology to access the market and help implement the personalised medicine promise is health technology assessment, which needs to be discussed to assess market barriers and identify potential solutions.

Conference and Workshop concept – KA2 planning

Within this key action, there are plans for a set of meetings and events aimed at exploring health technologies and integrated care. The conference and workshop will explore, amongst others, the following themes:

- Improve data for better personalised health technologies
- Connecting the regulatory aspect with personalised health technologies
- Patient engagement: Engage citizens and patients with tools to better manage their health
- Training programmes for healthcare professionals
- HTA for health innovations

Main goals of KA2

The main objectives of KA2 are as follows:

1. Set the scene around health technology, identifying potential solutions to the identified barriers.
2. Engage regional authorities and stakeholders to understand how the regions can implement the solutions identified and elaborate key recommendations.

Main events connected to KA2

- **Conference**: The conference will gather experts, with the aim to define and highlight the main technical challenges connected to KA2 (we expect at least 30 participants).
- **In situ visit**: In order to study innovative models and programmes that are having a high impact on implementing personalised health tools, we will organise two field visits per each key thematic area. The in situ visits, as implemented in the framework of Interreg Projects, have demonstrated high value for active learning by regions and regional authorities. In order to stage high-quality technical conferences and interregional workshops, the proactive collaboration of all members of the consortium will be fundamental, also taking advantage of the expertise from the Advisory Board.
- **Interregional workshop**: The workshop will survey the interest of regional authorities and stakeholders to identify appropriate policy instruments and assess the feasibility of actions that can be carried out both at regional level as well as at multiregional level. The workshop will encompass the aspects of e-Health and m-Health.
- **Capacity-building**: In order to improve the skills and knowledge of regional authorities' to exploit the knowledge created within Regions4PerMed, at the end of the interregional workshop we will dedicate half a day to the regional authority for a **capacity-building workshop**. In this context, representatives of more experienced regions will share their expertise with other regions and common knowledge will be created.

Co-Creation and WS 2 programme

The involvement of policy makers, representatives of universities and research hospitals from different regions is fundamental to acquiring an overview of the current state of implementation of health technologies in the smart and integrated healthcare system, as well as identifying areas of improvement and where investments are needed. Thus, the workshop will comprise plenary sessions as well as parallel working sessions.

To this aim, while the first day will be dedicated to the overall introduction of the topic and working sessions, the second day will be focused on collecting all outcomes of the discussions and defining regional path(s) towards personalised health. This will include outstanding "best practice" examples, as well as capacity-building activities and policy co-creation with all the regional authorities and stakeholders involved.

Policy intervention/area 1: m-/e-health technologies for continuous monitoring and self-empowerment

Rationale: The combined intellectual power of the leading European experts in the field of e-health and m-health is required to identify possible future approaches to e-health/m-health that are capable of redefining our future interactions within the healthcare system. Development of m-/e-health technologies allows for continuous patient monitoring and – perhaps even more important – building the patient's self-empowerment.

Policy intervention/area 2: m-/e-health technologies for data integration

Rationale: All connecting systematic approaches and platforms require consented, open and interoperable connections that follow international standards. This does not only apply to existing aspects, e.g. IHE profiling, but also to defining new standards on topics such as cross-platform authentication and data exchange. Standardisation in healthcare services is a major requirement for improving patient treatment by way of modern technology.

Policy intervention/area 3: Artificial intelligence for predictive models

Rationale: European health systems require a seamless and rapid flow of digital information, including genomic, clinical outcome, and claims data. Research derived from clinical care must feed back into assessment in order to advance care quality for consumers. Currently, there is discrete data on diagnosis, treatment, medical claims, and health outcomes in parts of the system, but it is hard to determine what works and how treatments differ across subgroups. As more information on treatment, lab tests, genomics, and financial costs is integrated into healthcare, it is hard to incorporate data from medical history, vital signs, genetic background, and lab testing into diagnosis and treatment. Predictive modelling represents a way for physicians to move towards systematic and evidence-based decision-making. While the first step toward enabling personalised

medicine is to ensure clinicians have access to what is known about patient gene variants, computer models can go beyond this approach and predict which treatments are likely to be most effective given observed symptoms. Public policy should incorporate rapid learning and predictive modelling to gain the full benefits of PM.

With the emergence of artificial intelligence (AI), it is necessary to deal with the effects this will have on the transformation of the market in an appropriate and contemporary way. An environment of trust and accountability, including new legal and ethical questions, is the basis of the full profit from the opportunities of AI.

Policy intervention/area 4: Personal data management

Rationale: Collecting data via e/m technologies involves ethical aspects and policies regarding personal data management. Personal data has an increasingly significant social, economic and practical value. Individuals must be at the heart of their own data control and their digital human rights must be strengthened while companies are able to develop innovative services based on mutual trust.

Policy intervention/area 4: Remote monitoring and tele assistance

Rationale: Personalized medicine is based on personalised medical data. To improve the quality of care for a patient with many chronic diseases, it is important to track their vital signs remotely. Remote cardiological care is also about enabling continuous monitoring of the heart, thanks to a portable ECG signal and breathing movement recorder. The recorder detects the patient's heart rhythm using built-in detection algorithms. The relevant fragments of the ECG signal recording are transmitted to the remote medical care centre and subjected to detailed analysis. Collecting a detailed medical history, in the case of confirmation an anomaly, the paramedic follows the appropriate pattern of personalised action. They can then refer the patient to a remote medical consultation or discuss a specific case with the doctor on duty. In situations that threaten life or health, the paramedic can call an ambulance. Such remote monitoring systems enable tele care and tele assistance and have resulted in a more serious focus on home care. This is also due to the ageing of the population and the increase in the number of chronically ill patients. If the patient feels unwell, they can also initiate the transmission of their data to the monitoring system.

Capacity-building

The capacity-building session aims to increase the awareness, competences and skills of regional authorities and stakeholders about the development and implementation of projects or initiatives on personalised health. Personalised health and medicine, specifically for what concerns the valorisation of patients' and citizens' health data, is characterised by common challenges to be addressed by regional policies and investments.

We believe that the participation of regional stakeholders in the parallel sessions contributes to the development of a shared knowledge of the best practices in the EU in the field of big data in health. The learning outcomes of the sessions could provide input to the S3 strategy of the next programming period.

During the capacity-building session, selected best practices will be showcased and the main aspects of each will be illustrated and discussed. The best practice will be selected from those that emerge from the main projects, initiatives and networks in the field of personalised medicine, for example IC Permed Best Practices. The International Consortium for Personalised Medicine, as part of its work plan, collect, evaluates and provides recognition to the best practices on each topic. We will ask the IC Permed coordinator to get access to these best practices, review and choose the most interesting ones for the Regions4PerMed purposes.

Co-creation meeting

At the proposal stage, a co-creation meeting was planned to fine-tune the overall workshop organisation, by liaising with other European project coordinators (the "PerMed Hub"). However, after the award of the project, the EC requested the coordinator to establish an Advisory Board (AB).

Throughout the duration of the project, the AB is delivering a constant and unique expertise. For this reason, during the planning of KA1, the project partners have agreed to assign the co-creation meeting a new role and responsibilities. This meeting is now designed to gather the members of the Interregional Committee and representatives of the PerMed Hub (we will ask each project listed in the PerMed Hub to send a representative). It is hoped that this will reach consensus on the main points of the Key Strategic Area and to maximise the expected project impact in the following key actions.

Stakeholders and participants

We expect a variety of participants at the workshop. Starting from the partners, we will invite regional authorities, stakeholders and policy makers. In addition, the representatives of the European initiatives on personalised medicine and personalised Health, the PerMed Hub, will be invited and are expected to support the activities of Regions4PerMed, providing input, encouraging networks and exchanges, and maximising the visibility of our activities.

Expected outcomes

The results of the conference and workshop will be summarised in a report that will provide an overview of all the challenges, opportunities and issues

related to the topic of health technologies with smart and integrated care.

The workshop will represent an occasion of exchange of regional experiences and best practices, and most of all an important opportunity for a first meeting of the interregional committee.

The report will also outline a series of recommendations aimed at identifying a "regional way" towards personalised health, with a focus on the implementation of the big data technologies in the healthcare system.

Thanks to the co-creation meeting we will launch a "position paper" that calls upon the responsibility of regional authorities to invest on the valorisation of health-related data. In addition, a commonly agreed definition of personalised health will be sought.

Lastly, with the capacity-building activities, we will share best practices and showcase how common challenges related to the use of health data are being tackled all around the EU.

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