Enabling smart integrated care: Recommendations for fostering greater interoperability of personal health systems

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>> About this publication

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Disclaimer

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>> Personal health systems and smart integrated care

The final goal of promoting interoperability in general, and for Personal Health Systems (PHS) in particular, is to contribute to integrated care. This will be supported through comprehensive, easy and collaborative access to and sharing of a patient's health data for all authorised health professionals, family carers and ultimately the patient itself. Thus they will gain managed access to essential health information about patients, subject to the patients' consent.

The overriding goal of the European Commission (EC) co-funded project SmartPersonalHealth is to promote a greater understanding of the value of interoperability among Personal Health Systems and between them and other eHealth systems, in the landscape of continuity of integrated care, and across multi-cultural environments in Europe. This publication explores key concepts in PHS interoperability, summarises related EU policy developments, synthesises discussions with stakeholders, and sets out recommendations to the European Commission, national governments, stakeholder groups, and industry for fostering greater interoperability of PHS. The focus of these recommendations is on raising awareness with different stakeholders about the needs for and benefits from interoperability, the value of building up a body of knowledge and collecting evidence as well as the need for collaboration and exchange of good practice.

These recommendations for fostering greater interoperability of personal health systems are derived from three stakeholder consultation workshops and the final conference of SmartPersonalHealth as well as from various informal discussions with stakeholder groups. The final conference was held as a satellite event to the Continua Health Alliance European Symposium 2011 on 17th January 2011 in Brussels.

Policy developments in European eHealth interoperability

It is widely recognised that the overall benefits of eHealth solutions can only be realised if all stakeholders involved fully understand and support the fundamental importance of interoperability of eHealth infrastructures and applications. Based on the premise that connecting people, systems and services is vital for the provision of good healthcare in Europe, the European Commission passed a Recommendation in 2008 on cross-border interoperability of electronic health record systems with the aim of achieving overall European eHealth interoperability by the end of 2015.

The Recommendation defines actions at political, organisational, technical and semantic level, and addresses issues relevant for monitoring, evaluation and awareness raising. The EC calls for increasing awareness about the benefits of and need for standards in EHR systems and their interoperability, among the ICT industry, healthcare providers, public health institutions, insurers, and other stakeholders. Information and training should be provided for patients in particular. Inviting patients as stakeholders would make for a sustainable and effective use of health information "as patients move between a variety of healthcare providers, along the continuum of care, and receive whenever possible treatment, care and data in their own homes." SmartPersonalHealth explicitly addresses the issue of raising awareness with various stakeholders.

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Later in 2008, the EC Communication on Telemedicine for the benefit of patients, healthcare systems, and society particularly highlighted the potential of telemonitoring which serves as an example for the benefits of the wide range of personal health systems. Interoperability and standardisation issues are recognised as crucial for telehealth services to spread further. Following the Council Conclusions on eHealth in 2009, the European eHealth Governance Initiative (eHGI) was launched, to reinforce European cooperation at a high level and strengthen the common eHealth area. Four areas for joint efforts towards European eHealth interoperability have been identified: legal (including regulatory and ethics), standardisation/technical issues, semantics, identification and authentication. The Digital Agenda for Europe, published in 2010, defines measures to use ICT to address – among many other challenges - rising healthcare costs and to help Member States to cope with their ageing populations. It underlines "the right of individuals to have their personal health information safely stored within a healthcare system accessible online" as an essential condition for successful uptake of eHealth and calls for actions to remove legal and organisational barriers, particularly those to pan-European interoperability.

> *Both the „Digital Agenda for Europe" and the pilot European Innovation Partnership (EIP) for Active and Healthy Ageing commit us to join up our efforts to not only improve technology, but pull down the legal and organisational barriers that are preventing progress among EU Member States."*
>
> *Neelie Kroes, Vice-President of the European Commission responsible for the Digital Agenda*

The goal of SmartPersonalHealth

In the spirit of current policy developments in European eHealth interoperability, the key issues driving the SmartPersonalHealth activities are raising the awareness and understanding of the concept and values of interoperability amongst key players. This is seen as a fundamental initial step towards such players requiring and implementing interoperable PHS when establishing national, regional, or local solutions and applications.

Several European initiatives address the numerous challenges related to interoperability such as policy, legal, organisational, semantic, and technical issues. *SmartPersonalHealth aims, primarily, to promote the value of interoperability in PHS.*

SmartPersonalHealth actively engaged with, and leveraged the experience of a multiplicity of stakeholders (health professionals, device manufacturers, system integrators, eHealth industry at large; procurers of PHS and other eHealth systems; standard development organisations (SDO), insurers, health care providers, and patients). The need for and the numerous benefits of interoperable PHS as well as stakeholder concerns, major barriers and incentives required to accelerate the development and adoption of interoperable PHS systems were examined in detail.

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The technological potential for integrated care

The potential of PHS to improve health and fitness information sharing and thus empower people to play a greater role in managing their own well-being is widely recognised. Improved sharing will also help physicians make better-informed decisions, enable individuals to age at home independently and with dignity, and is expected to alleviate some of the burden on healthcare systems.

In broader terms, the technology – devices and advanced information technology – to collect information about a patient's condition and that can enable people to age independently at home already exists. What we do not have is an interoperable, interactive system that will allow this information to be efficiently shared and transferred to their families and care teams. The Continua Health Alliance issues design guidelines which contain references to the standards and specifications that Continua selects for ensuring the interoperability of devices.

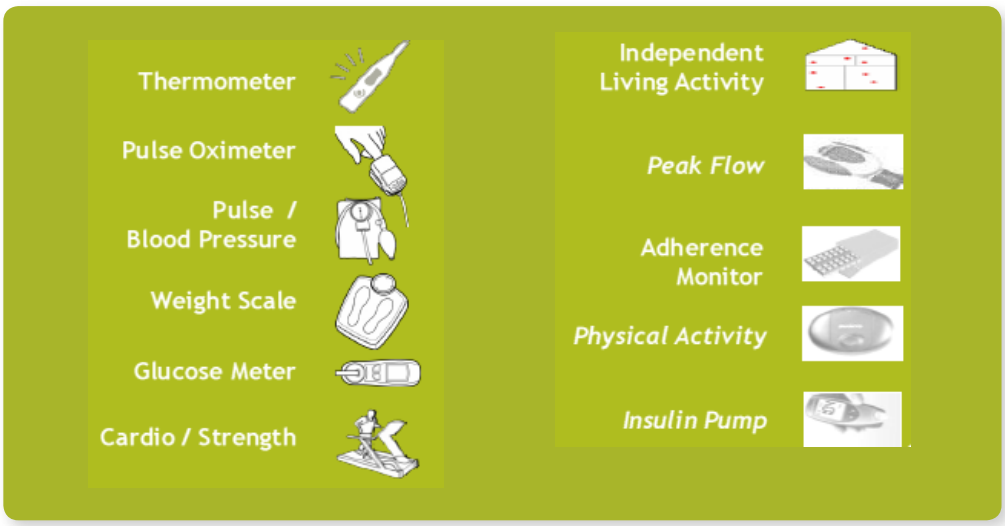
An overview of the type of devices commonly subsumed under the heading of PHS is presented in Figure 1 below.

Personal health systems can play a central role in ICT supported solutions for chronic disease management and integrated care. With the central component health monitoring devices, they form an integral part of telehealth. Telehealth, using ICT-enabled applications to provide services related to health and care at a distance, is an area of eHealth which can be expected to become a major component of future integrated care information systems. Policy makers around the globe have vested high expectations in telehealth for quite some time now. It has been expected that telehealth services will help European health systems to better cope with growing demands arising from an ageing population, increasing consumerism, and limited supply of funding.

However, to date, telehealth services have tended to be differentiated rather than integrated. Telehealth has been implemented in discrete designs to support relationships between

a) a provider, be it a hospital, a GP office, a long-term care organisation, a health or other professional, and their respective client at a distance - at home or elsewhere;
b) one provider and another one, or more recently;
c) a citizen or patient and other citizens.

Figure 1: Examples of personal devices



Source: Continua Health Alliance

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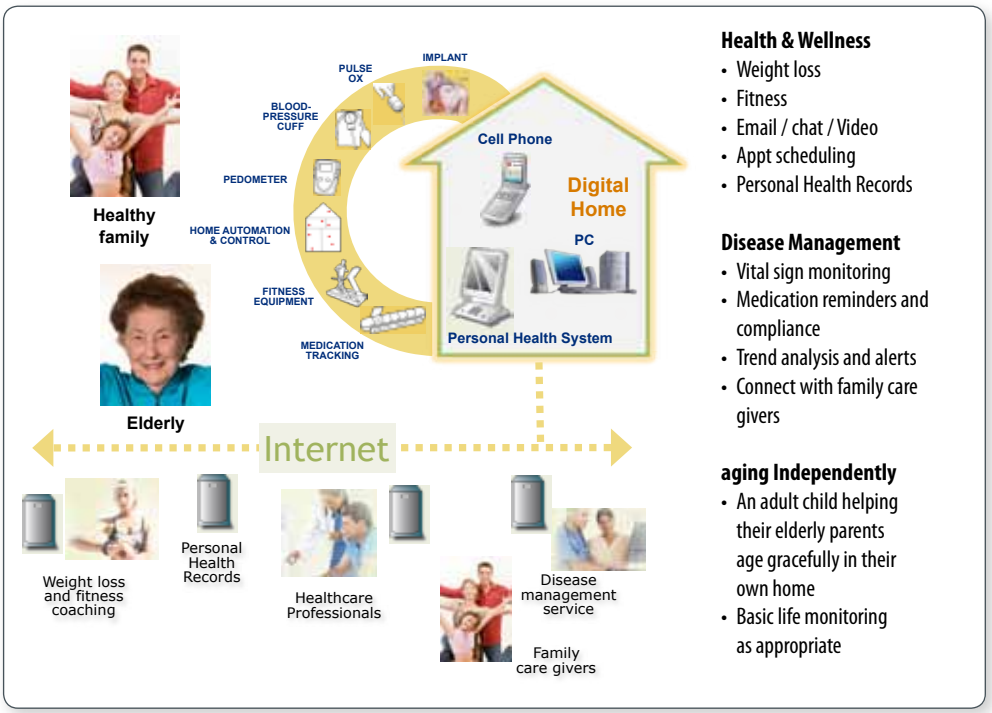
Personal Health Systems, when seen as support to the provision of continuing, quality controlled, and personalised health services to individuals regardless of location, belong to the first category (see Figure 2). Common applications include telephonic services, use of home telemonitoring devices, tele-consultations, or mobile services like text messaging as appointment reminders and medication alerts. Telecare systems, supporting urgent information flows from the home and autonomously detecting intervention requirements, on time or proactively, also fall under this integrated view of telehealth. According to the European Commission co-funded project PHS2020, telemonitoring is defined as a telehealth service aimed at monitoring the health status of patients at a distance. Data can be collected either automatically through personal health monitoring devices or through active patient collaboration (e.g. by entering weight or daily blood sugar level measurements into a web-based tool). The electronic devices are referred to as being portable, wearable or implantable devices to collect data on specific health parameters.

The EC co-funded project PHS2020 and the SIMPHS – Strategic Intelligence Monitor of Personal Health Systems study, conducted by the Institute for Prospective Technological Studies, an EC Joint Research Centre, have come to a consensual vision of future PHS during their work with various stakeholders. This implies a holistic health system view and is guided by a business value chain framework.

Integrated Personal Health/Care Services address the health and/or social care needs of individuals outside of care institutions and support the work of care providers in an integrated fashion: a) they can integrate assistance, remote monitoring of chronic diseases, wellness and fitness; b) they are produced as a result of integration of different institutional and information systems. They are personal and possibly personalised in the way they gather, process and communicate data (for feedback/action) and in terms of technological components they can include all of the items of the PHS2020 definition of Personal Health System.

Figure 2: Personal telehealth: interconnecting devices and eHealth systems



Source: Continua Health Alliance

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The definition of *Integrated Personal Health Systems* is based on the preceding PHS2020 definition:

Personal Health Systems assist in the seamless provision of quality controlled, and personalised health services to individuals regardless of location. They consist of:

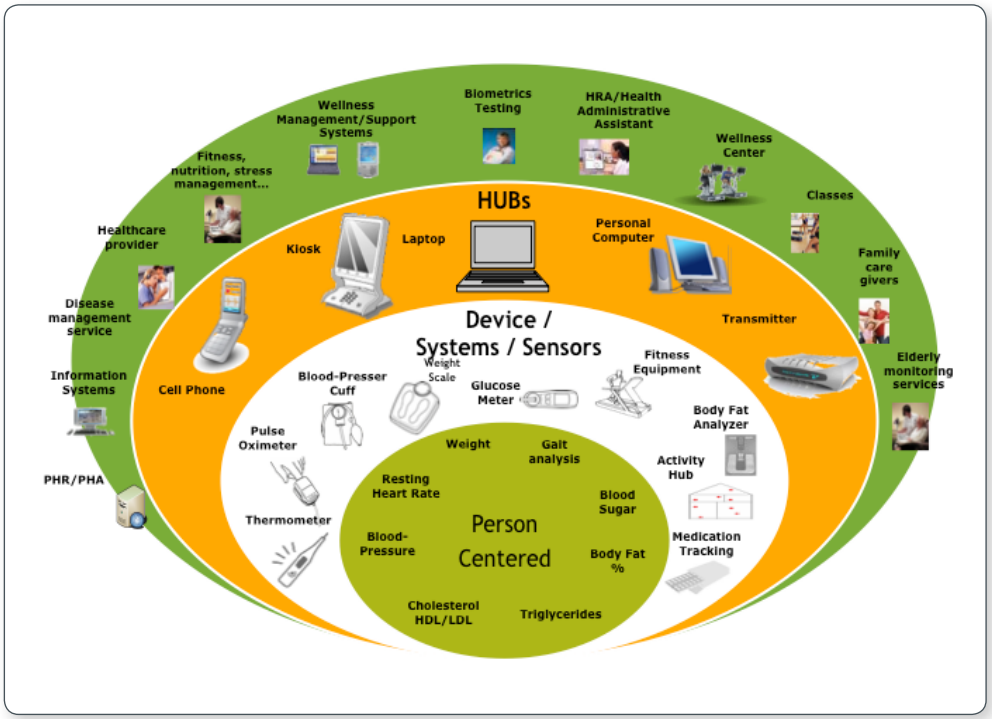
> *Ambient and/or body devices* (wearable, portable or implantable), which acquire, monitor and communicate physiological parameters and other health related context data of an individual (e.g., vital body signs, biochemical markers, activity, emotional and social state, environment);
> *Intelligent processing of the acquired information and coupling of it with expert biomedical knowledge* to derive important new insights about an individual's health status.
> *Active feedback* based on such new insights, either from health professionals or directly from the system to the individuals, assisting in diagnosis, treatment, rehabilitation and social care as well as in disease prevention and lifestyle management.

In a similar vein, the Continua Health Alliance describes PHS as follows:

PHS is a system of interoperable personal telehealth solutions that will foster independence and empower people and organizations to better manage health and wellness. […] [PHS] allow people with heart disease or diabetes to transmit their vital signs – blood pressure, heart rate, glucose levels, temperature, weight, respiration – seamlessly from home to their health professional, and get real-time feedback on their condition.

Continua portrays PHS as an *"ecosystem of connected technologies, devices and services"* that will enable an *"exchange of fitness, health, and wellness information", in order to "build a community of care"*. The ultimate aim is to help healthcare providers and patients to meet "their fitness goals, better manage their chronic diseases, and live independently as they age". Figure 3 illustrates Continua's vision for a person-centred "community of care".

Figure 3: Building a person-centred community of care



Source: Continua Health Alliance

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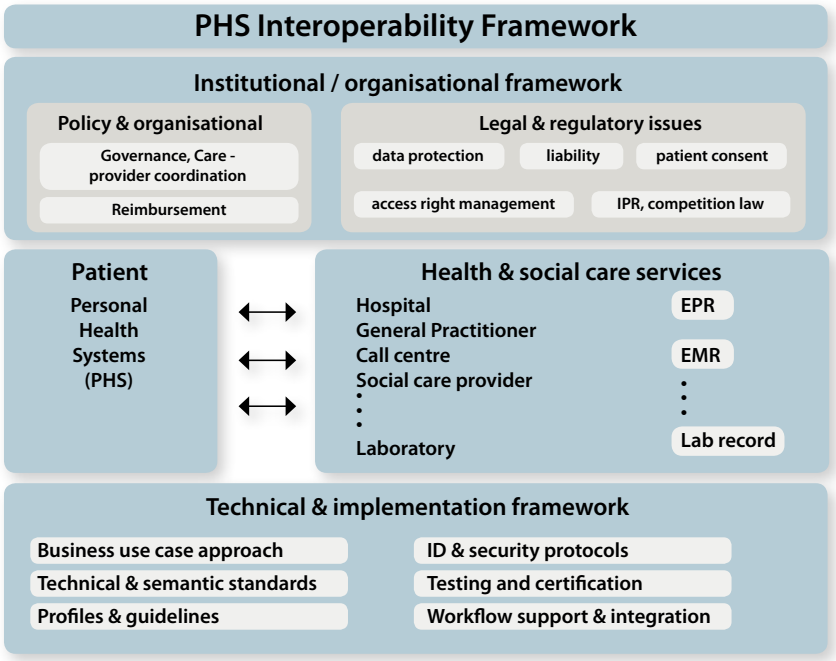
The ecosystem of connected health: seamless exchange of data

In order to enable the seamless flow of information within the community of care as defined above, all parts of the system must be interoperable.

Achieving interoperability of eHealth systems is a complex process involving various actors and challenges far beyond technical and standardisation issues. Interoperability of eHealth systems, defined in the broader context of health system interoperability, is the ability, facilitated by ICT applications and systems, to exchange, understand and act on citizens/patients and other health-related information/knowledge among organisationally, linguistically and/or culturally disparate health professionals, patients and other actors and organisations, within and across health system jurisdictions and administrations in a collaborative manner.

For harnessing the key benefits of PHS, any interoperability scenario needs to account for real business cases and enable seamless and consistent data and information flows by integrating and mixing devices used by patients/consumers at home, for remote monitoring, for home hospitalisation or within the hospital. Such continuous exchange of data can only be realised, once i) an organisational and technical framework has been developed and ii) a process has been initialised to interconnect systems and actors and that allows agreements for adopting common standards. Figure 4 below illustrates the various issues that need to be tackled.

Figure 4: Challenges of PHS interoperability



Source: 2010 empirica

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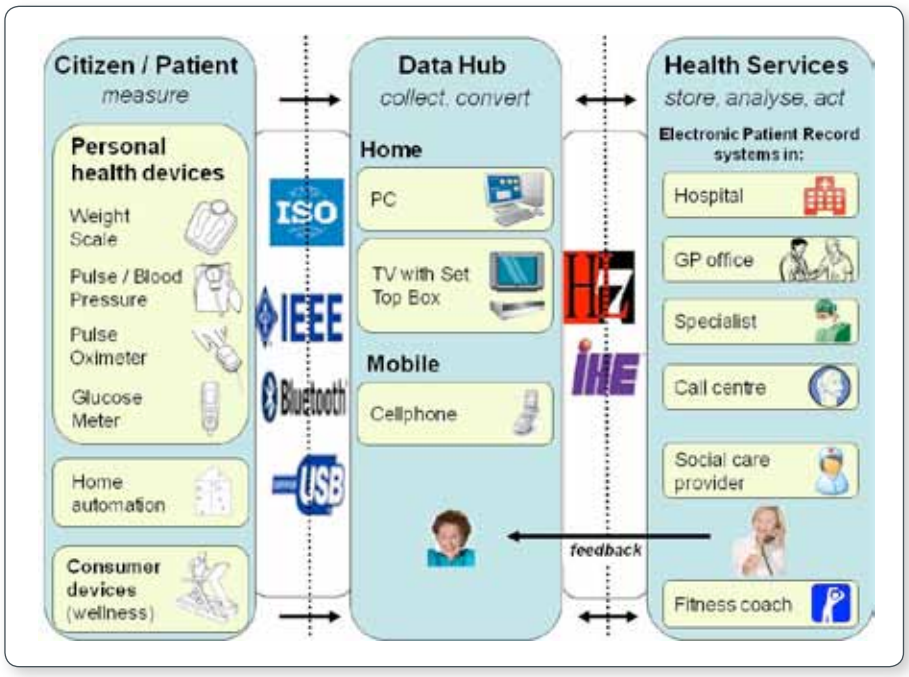
In a generic scenario of PHS based solutions, patient data are transferred from personal devices through a data hub to a health service provider system, e.g. electronic patient record (EPR), electronic medical record (EMR), a hospital information system (HIS) or a General Practitioner patient system. As can be deduced from Figure 4, already this rather simple scenario introduces a vast number of specific interoperability issues which, depending on the maturity of the devices, hubs and provider information systems used, and the local, regional or national eHealth infrastructure components and services available, need an integrated approach by all concerned in order to become solved and maintained in a sustained manner for many years to come. It needs first of all awareness raising but next it needs agreement on the policies to be pursued, the measures to be taken, and funding and organisational structures to become successful in the longer term. The numerous interoperability issues can be subsumed into two broader frameworks: i) technical & implementation framework, including standards, profiles and guidelines for their implementation based on elaborated business use cases, identification & authentication mechanisms, security protocols, testing and certification, etc., and ii) an institutional / organisational framework encompassing policy issues (e.g., governance, reimbursement), legal and regulatory aspects such as data protection, liability, etc.

In order to reduce the overall complexity of technical interoperability issues for discussion with users such as health professionals, SmartPersonalHealth differentiates only among three major areas of data measurement, collection, transfer and analysis (as illustrated by the Figure below):

1. Applying PHS devices for measurement of vital data and personal activities
2. Collecting and converting these data via a data hub which may be in the home or mobile
3. Analysing the data provided and acting upon the results by health service providers

Figure 5: Examples for data exchange in PHS-based health and care services



Source: SmartPersonalHealth

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A wide variety of scenarios and combinations into concrete, more detailed use cases can be imagined. When introducing additional actors like the patient/person himself, informal carers, community nurses, case management, a specialised remote management organisation or a pharmacist, the integration and service process becomes more complex. The respective concrete organisational and process structure will furthermore heavily depend on the peculiarities of the local, regional and national healthcare and social care systems. Therefore, to allow for an initial approach to key interoperability issues, the project team decided to abstract from these further details and focus at the generic level.

As a good example of cooperation, the project considered measurement devices used in telehealth systems. The following considerations were used to introduce key interoperability challenges to the participants in the SmartPersonalHealth workshops:

Interoperability between device and data hub: In order to support a wide range of diseases, it is necessary for such a telehealth system to work with a large variety of measurement devices, such as blood pressure monitors, weighing scales, glucose meters, pulse oximeters, ECG monitors, peak flow meters, etc. For each of these measurement device types there are a number of companies making them, but none of the companies manufactures all of these devices. So a telehealth system vendor will need to work with different suppliers to provide a complete set of measurement devices to its customers.

Today, each of these devices from each of these vendors communicates in a different way. Even if some devices use the same transport mechanism, such as Bluetooth, USB, Infrared or a serial cable, each of them will still use a different way of transmitting the data over that transport mechanism. It becomes clear very quickly that it is a daunting task for a telehealth system vendor to make its system work with all of these different devices from different vendors.

Interoperability between data hub and health service provider ICT application: A complementary need for cooperation emerges at the interface of the hub transferring personal telehealth data into electronic patient or medical records (EPR/EMR). Often the supplier of a telehealth system is not the supplier of the EPR or EMR system that is used to store, integrate, analyse and display health data about the patient. Since there were no proper standards in place yet to transfer health data from a telehealth system into such a health service provider system, the telehealth vendor had to work with all major EPR or EMR system providers to develop custom interfaces for transferring this data. Again a huge amount of work that created a significant barrier for proper integration of telehealth data into other systems and thus limiting the potential health benefits and efficiency improvements that personal telehealth could offer.

In its Design Guidelines Version One, Continua selected various standards for data exchange in PHS-based health and care services aiming to enable continuity and working across health care boundaries. These standards are illustrated in Figure 5 above and in the next section, in Figure 6.

Through its series of workshops and other activities with stakeholders, SmartPersonalHealth promoted the achievements of key players in PHS interoperability. The following section briefly describes efforts and achievements of Continua, IHE and ETSI.

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Interoperability efforts of Continua, IHE and ETSI

The Continua Health Alliance, founded in 2006, now with more than 230 member companies around the world, is dedicated to establishing a system of interoperable personal health solutions. Extending these solutions into the home fosters independence, empowers individuals and provides the opportunity for truly personalised health and wellness management. In 2009, the group issued Version One Design Guidelines, based on proven connectivity standards and including Bluetooth for wireless and USB for wired device connection. In 2010, an extended update of version one Design Guidelines was published (v1.5). The strongest value of Continua is the Continua Certified Logo program, signifying that the product is interoperable with any other Continua-certified products. Certification comes with rigorous independent testing to the selected Continua standards. The main thrust of Continua currently is the personal telehealth arena, which includes chronic condition management, health and wellness, and ageing independently. Products made under Continua Health Alliance guidelines provide consumers with increased assurance of interoperability between devices, enabling them to more easily share information with caregivers and service providers.

IHE - Integrating the Healthcare Enterprise - is a global initiative involving more than 300 stakeholders (healthcare professional associations, industry, health authorities, etc.). It is the worldwide reference organisation for the interoperability of healthcare information systems and devices. IHE promotes the coordinated use of established standards such as DICOM (Digital Imaging and Communications in Medicine) and HL7 (Health Level 7) to address specific clinical needs in support of optimal patient care. With strong involvement from users, IHE has been testing the interoperability of HIT systems for more than a decade. The Connect-a-thon is the healthcare IT industry largest interoperability testing event. More than 250 vendors worldwide have implemented and tested products with IHE capabilities.

Continua's approach is based on thorough use-case collection and refinement. After agreeing upon a limited set of use cases, requirements are extracted from them and appropriate standards selected. Next, profiles are developed over the standards and interoperability guidelines designed which serve as a basis for product certification. The guidelines/profiles address any remaining gaps and constrain options thus facilitating tight interoperability.

Continua's actors in their interoperability paradigm – based on communication needs are: the personal area network devices, PAN (measurement exchange around a person); local area networking (LAN) devices (measurement exchange at a location), application hosting devices (AHD) such as personal computer, cell phone, etc.; wide area networking (WAN) device; and a health record/reporting (HR) device. The interfaces (IF) between these network devices are defined as the PAN, LAN, WAN, and (electronic or personal) health record (reporting) network (HRN) interfaces. These interfaces are key to achieving the interoperability goals and form the basis for most Continua certification targets.

As part of their effort to have interoperable products for Continua's V1.0 (which focused on the PAN and HRN interfaces; the updated V1.5 includes WAN IF), several standards in the PAN and device data exchange have been selected and/or developed and then constrained to meet Continua guidelines for product certification. The following Figure presents an overview of the selected IF standards.

The IHE Patient Care Device domain (PCD), formed in 2005, addresses the integration of medical devices into the healthcare enterprise, potentially resulting in significant improvements in patient safety and quality of care. IHE aligns well with Continua's vision of profiling existing standards and constraining them for interoperability.

IHE-PCD is "concerned with use cases in which at least one actor is a regulated patient care device," which distinctly separates IHE-PCD's goals from Continua's goals. The PCD domain has built a technical framework of use cases which have

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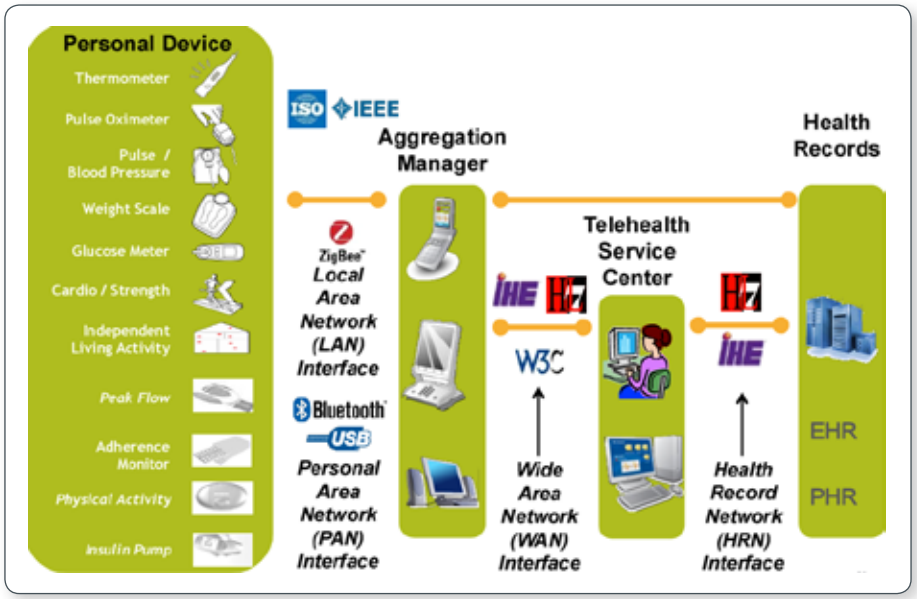
defined profiles describing transactions (with interfaces) and actors. Each of the profiles represents an interface in which the actors are defined and a standard or standards identified for that specific interface and/or transaction.

Relevant profiles include the PCD-01, the Alarm Communication Management (ACM) profile, and the RTM profile with the development of a "Rosetta Stone" that correlates each vendors' internal terms and units of measure for each of the IEEE 11073 defined reference identifications.

Telecommunications System, 3rd generation mobile) and DECT (Digital Enhanced Cordless Telecommunications). The key factor in their success was a very high level of interoperability. To achieve that, the conformance test specifications were standardised in ETSI with a high level of rigor and precision as well as high level of transparency and commitment of technology stakeholders. This effort was as a rule supported in many different ways by policy makers (regulation, co-funding etc.) which was an important additional catalyst.

Figure 6: Overview of Continua interface standards



Source: Continua Health Alliance

IHE-PCD holds Connect-a-thons to determine vendor conformance to the profiles. Conformance is not as strict as certification (as done by Continua). With a successful Connect-a-thon performance, vendors can then state in their literature that they conform to a particular profile.

Another partner in these efforts is ETSI, the European Telecommunications Standards Institute. The most outstanding examples of globally successful communication technologies that have been standardized in ETSI (or ETSI partnership projects) are GSM (mobile telephony), UMTS (Universal Mobile

For numerous other smaller but important technologies an ecosystem based on conformance testing may not be viable. In such cases various levels of interoperability testing may be more suitable. However, even in such cases the quality of the specification of the interoperability testing plays a key role.
This background information served as a basis for discussion with stakeholders. The next chapter briefly reviews main outcomes of the workshops with stakeholders.

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Stakeholder consultations

Health Professionals Workshop Barcelona

This first workshop *entitled Enabling integrated care: harnessing personal health systems (PHS) for better outcomes across the care continuum*, hosted by the Fundació TicSalut, the Continua Health Alliance, IHE Europe, and ETSI, focussed on challenges and benefits for the community of healthcare professionals and providers. Taking place on the 18th March 2010 during the "eHealth week 2010" at the CCIB in Barcelona, the workshop attracted a number of clinical experts, healthcare providing organisations, and practitioners from the broader area of telehealth.

Focussing on the hands-on experience of clinicians, the workshop discussed key issues and challenges for physicians and all other care professionals and staff in making better informed decisions with the help of interoperable PHS and other eHealth systems. The key questions asked were, divided into organisational and technical challenges: which of their healthcare provision needs – in order of priority –could PHS devices and associated interoperability and integration into other health information systems support, in order to improve patient care and reduce resource consumption? Which interoperability issues need to be tackled in which order of priority to indeed achieve these objectives?

The Barcelona Workshop explored the key challenges for integrating personal health applications into routine healthcare services. It underlined a need for further policy actions, community building and awareness-raising, if interoperability among personal health systems and with EHRs is to become reality in daily clinical routine.

Policy makers at regional and national levels lack awareness about the positive impact of PHS on healthcare delivery, and are often only superficially informed about the challenges of integrating PHS into wider healthcare systems. Policy makers need more evidence of the effectiveness of PHS system and the role of interoperability in realising health benefits. A collection and publication of good practice cases would facilitate strategic planning in the direction of integrated care.

Participants of the workshop voiced the need for more, and explicit, "community building" – for the promotion of interoperability, in general, and, in particular, for a project such as the SmartPersonalHealth support action. Many of the experts and practitioners face similar questions like "who is working on similar issues in other countries, what are their problems, and how can we join forces? Is there an international forum for my concerns? Where are decisions happening? Who is influencing them and can I join forces with those efforts?" Having a better overview about who, on a European scale, actually forms and represents the community that might assist in assembling critical masses for moving the agenda of interoperable eHealth technologies, both nationally in the member states and at the EU level.

Procurers Workshop Belfast

Hosted by the Continua Health Alliance, IHE Europe, ETSI and the European Connected Health Campus, this workshop entitled *Enabling Integrated Care: Procuring Personal Health Systems* focussed on procurement and took place Thursday, 17 June 2010, at the ECH Campus Leadership Summit in Belfast, Northern Ireland. The workshop gathered a number of representatives from public authorities and practitioners from the areas of personal health systems, eHealth and procurement.
Attendees of the workshop were introduced to the challenges of interoperability and market development, and discussed key aspects of buying decisions and their potential market impact. The Belfast workshop on procurement provided

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interactive training for buyers of personal health systems and addressed key questions such as: what does interoperability of personal health systems mean? Why should I care? What can I do?

The Belfast Workshop underlined a need for further policy actions, in order to foster more effective interoperability among personal health systems and with EHRs through procurement processes and strategies. The main conclusions on eHealth procurement needs can be summarised as follows:

> Clear guidance is needed on the relevance and impact of standards and profiles of procurement specifications and procedure. This calls for EU level action to provide detailed guidelines and concrete recommendations to procurers.

> Similarly, a collection and publication of good practice cases would facilitate strategic planning in the direction of integrated care and, consequently, facilitate procurement planning.

> Further research on issues of interoperability and pre-commercial procurement, and eventually the juxtaposition of both areas, is necessary.

> Closely related, consultations with the wider community, and guided exchange and networking are a central tool to extract and promote expertise and success factors. In particular, interviews with both private and public procurers can deliver background knowledge for inferring more concrete recommendations and adjust policy measures.

Vendors Workshop Berlin

Hosted by the Continua Health Alliance, IHE Europe, ETSI, and the VDE - German Association for Electrical, Electronic & Information Technologies, a workshop entitled *Enabling Integrated Care: Marketing and Delivering Personal Health Solutions* focussed on a vendor perspective. It took place Tuesday, 21 September 2010, at the Charité Klinik in Berlin, Germany. The workshop gathered a number of experts and vendors of personal health systems.

The workshop addressed key questions such as what does interoperability of personal health systems mean (the workshop walked through some simple interfaces and technical issues). Why should vendors care (producers can lock some customers into their product families and solidify their niche, or contribute to an interoperable ecosystem of personal health solutions that enlarge their market but also expose their products to competition)? What can I do (analyse strength and weaknesses of own product portfolio and pipeline, and make strategic choices)? The workshop dealt with issues such as technical standards in the field, buyers' needs and requirements, market developments, etc. Various speakers shared their experience and discussed what users and national and European regulators can and should do to help advance integrated and personal patient care.

Concerning standards development and adoption, the EC should lead the way in facilitating cooperation between standards organisations, especially de facto and de jure. SMEs and academic partners should play a bigger role in promoting standards. Standards organisations should be more in tune with what customers want. Standards implementation is a key challenge, Continua and IHE are regarded as "the way to go" in terms of enabling optimal use of existing standards and making standards work.

Interoperability should be considered a good selling argument. It must be demonstrated to be useful. It should be made clear that without interoperability each developer has higher individual costs. Furthermore, risk management and future proofing should be part of interoperability enforcement.

2.0 Recommendations

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Validation Workshop Brussels

The final SmartPersonalHealth workshop was held as a satellite event at the Continua European Symposium 2011. This two-day Continua symposium starting on 17th January 2011 in Brussels explored the options of personal connected health systems in areas such as chronic condition and health management, independent ageing and wellness.

Against this background, the SmartPersonalHealth project convened a multitude of stakeholders on the afternoon of 18th January 2011 for a workshop to

> Discuss challenges and opportunities related to the introduction of personal health systems in routine healthcare, and to

> Review and refine policy recommendations for European, national and regional level policy makers to promote the adoption of interoperable personal health systems.

The participants analysed the current state of the PHS market, identified complications and issues from the view of selected professionals, and presented recommended actions for regulators, national and regional decision-makers, professionals, industrial stakeholders, and patients.

From an engineering standpoint interoperability is not so difficult; it depends on the intention of the vendor to be interoperable. The technical requirements for devices are simple. What really matters is a service concept - case management based on an electronic patient record and supported by a Telemedicine Service Centre."

Prof Harald Korb, Vitaphone

It was noted that the PHS market has started to grow more rapidly. Its three currently separate sectors: chronic disease management, ambient assisted living and health & fitness, are on a convergence course with the chronic disease segment defining the pace of PHS adoption and the speed of convergence. Furthermore, the recent shift towards direct engagement with customers requires standardisation.

The PHS market is not isolated; there is some dependency on personal health records and with wider eHealth infrastructure. Technology and infrastructure remain significant barriers to wider adoption, as does reimbursement, and these factors will determine the pace at which services move beyond the initial early adopters."

George MacGinnis, Member EU Policy WG, Continua Health Alliance

Ultimately, this workshop re-convened the stakeholders to review and refine the pre-drafted recommendations which were derived from the previous SmartPersonalHealth events and consultations, networking activities, and research. The central aim was to identify ways to:

> Improve exchange and cooperation among key stakeholders, and

> Create a supportive environment (the structures and organisations, measures and processes to support standards development, certification and uptake.

In a moderated roundtable discussion – with the active participation of stakeholders attending –, voices from the field were invited to present their views on PHS working in practice. Discussants included renowned representatives of patients, health professionals, insurers and industry. The main findings from the SmartPersonalHealth project were discussed and validated.

>> Recommendations for future promotion, outreach and support activities

Whereas Personal Health Systems (PHS) are still emerging offerings, and the European, mainly public funded, market is not yet ready to seize all the opportunities, the following recommendations for the promotion of interoperable PHS, outreach and support activities were identified:

1. Awareness raising with patients, health and care workers
2. Building up of a body of knowledge and collecting evidence
3. Creating a supportive environment – structures and organisations, measures and processes to
   - support the development of interoperability profiles and guidelines
   - support the further uptake of PHS implementation and use
4. Facilitating exchange and cooperation between key stakeholders, driving use and collaboration

> *We have the potential to open up a world of opportunities not only for healthcare, but also for social interaction, physical exercise, mobility, life-long learning according to each individual's needs.*
>
> *Neelie Kroes, Vice-President of the European Commission responsible for the Digital Agenda*

The guiding theme and ultimate objective of the recommendations is a shift from awareness raising and readiness towards coalition building for a sustainable deployment and further development of interoperable Personal Health Systems.

Awareness raising with different stakeholders

A number of stakeholder groups are relevant for further promoting and raising awareness of interoperable PHS. However, among these stakeholders, there is currently a lack of information, a fragmentation of efforts, and a lack of transparency about ongoing activities in the domain. As a consequence, information about the benefits of PHS interoperability for continuity and quality of care is not understood equally across groups, nor is such understanding, in its current form, spread widely enough among different stakeholder groups.

Key stakeholder groups include:

> eHealth industry / vendors including device manufacturers and systems integrators, both individually and in their European and national associations;
> Health and social care professionals such as, for example, physicians, nurses, social care staff, etc. as well as executives, such as hospital and care service provider CEOs and CIOs;
> Professional medical and care associations, especially related to chronic diseases (e.g., International Diabetes Federation - IDF, European Society of Cardiology - ESC);
> Patient associations and self-help groups as well as informal carers;
> Standards development organisations (SDOs);
> Policy makers, including governments, the EC, public and private procurers or similar entities endowed with strategic political decision-making power, operational and administrative teams in national and regional health authorities, third party payers/insurance companies;
> Researchers.

2. Recommendations

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Patients, health and care workers need to be made more aware of PHS and must demand to be able to use them. While both clinical associations and patient groups should act as mediators of knowledge for PHS, patient education can be decisive in creating the demand necessary for a market to grow – with regard to both insurance and healthcare professionals. More outreach to and with patients is instrumental if we are to realise continuity of care. Intensified public relations with patients and citizens, also via the wellness sector (e.g. fitness clubs), can add the power of the consumer to increasingly demanding PHS in their daily lives.

> *Informed decision-making with the use of PHS can only be achieved via the inclusion of patients: no one is a better expert on a chronic condition than the patient him/herself. The aim must be to develop de-medicalised, de-institutionalised devices and tools, and mainstream them into consumer models.*
>
> *Robert Johnstone, International Alliance of Patients' Organisations*

A concrete example for empowering patients to demand more personalised services and, at the same time, control their funding is the introduction of so called "personal health budgets" in England. Thereby patients could also become part of the policy planning process.

Example 1: Personal health budgets NHS England

Personal health budgets can be seen as part of a wider drive to personalise public services, which dates back to the 1970s and the campaign by disability groups for people to be allowed to control their own funding. A pilot involving around half the primary care trusts in England is currently underway, testing out personal health budgets in the NHS. A personal health budget allows people to have more choice, flexibility and control over the health services and care they receive. At the heart of a personal health budget is a care plan, the agreement between the primary care trust and the individual that sets out the person's health needs, the amount of money available to meet those needs and how this money will be spent. The concrete impact of personal health budgets on telehealth and telecare will certainly be worthwhile observing.

In view of a truly sustainable awareness mechanism, other stakeholders, including multiplier platforms, need to be addressed such as:

- EU ICT associations such as DIGITALEUROPE, EucoMed, COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry), etc.;
- National trade associations – 40 of them members of DIGITALEUROPE, e.g., Intellect, UK, VDE (Verband der Elektrotechnik, Elektronik, Informationstechnik e.V.), Germany, etc.;
- National and regional level organisations such as Diagnostic Alliance, platforms like eVIA - the Spanish Technological Platform for eHealth, eWellness and Social Cohesion;
- International stakeholders like OECD (Organisation for Economic Co-operation and Development), WHO (World Health Organization).

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A key recommendation for future EC action is to set up a Support Action to create a sustainable link between all these actors. In the framework of such a Support Action, key organisations could also be supported in developing their communication strategies in favour of interoperable PHS.

Alongside associations of specific eHealth focus like the European Health Telematics Association (EHTEL), the EUROREC Institute, the Health Information Network Europe (HINE), the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), Integrating the Healthcare Enterprise (IHE), the European Connected Health Campus (ECHCampus) and the European Federation of Medical Informatics (EFMI), other European associations addressing the healthcare community such as the European Hospital and Healthcare Federation (HOPE), the European Health Management Association (EHMA), the Standing Permanent Committee of European Doctors (CPME) should be informed and engaged in PHS focused initiatives

National associations such as the Association française d'Informatique Médicale (AIM) in France; the Italian Association for Medical Informatics (AIIM); the Verband der Hersteller von IT-Lösungen für das Gesundheitswesen e.V (VHitG) in Germany; the Association of British Healthcare Industries (ABHI) in the UK, the European Centre for Medical Informatics, Statistics and Epidemiology (EuroMISE Centre) in the Czech Republic; the Greek Health Informatics Association (GHIA); the Healthcare Informatics Society of Ireland (HISI); the Belgian Medical Informatics Association (MIM) in Belgium and the Spanish Society of Health Informatics (SEIS) may also be relevant addressees.

Telemonitoring relates to the telecare domain, thus equivalent stakeholders include the Ambient Assisted Living (AAL) Association, the European Design for All e-Accessibility Network (EDeAN), the Coordination Group on Access to Location Information by Emergency Services (CGALIES), the European Federation of Older People (EURAG), the European Disability Forum (EDF), the European Association of Service Providers for Persons with Disabilities (EASPD), the European Network on Independent Living (ENIL), the European Older People's Platform (AGE), HomeCare Europe, Caring for Carers, Alzheimer Europe and others.

National organisations such as Age Concern or Telecare Services Association (TSA) in the UK, the Bundesarbeitsgemeinschaft der Senioren-Organisationen e.V. (BAGSO) in Germany and the Bundesinteressenvertretung der Nutzerinnen und Nutzer von Wohn- und Betreuungsangeboten im Alter und bei Behinderung e.V. (BIVA) in Austria may furthermore be relevant addressees.

In addition to promoting the overall benefits of telehealth and PHS, the numerous benefits from interoperability should explicitly be emphasized, such as:

> Easy connection with vital services – now and in the future;

> Choice of suppliers;

> Scalability;

> Fast implementation of new features and innovation;

> Consistent semantics for aggregated analysis leading to better medicine;

> Trusted brand: faster adoption, protected investments;

> Future safe integration with other standards including IHE.

2. Recommendations

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Building up a body of knowledge and collecting evidence

Next to a general awareness raising campaign (and as a natural outgrowth of it), more tangibly, an EC action should facilitate the collection, analysis and presentation of empirical evidence on successful routine implementations of PHS in clinical, social care and wellness contexts. Such empirical evidence should cover the clinical and social outcomes achieved, as well as detailed discussion of how organisational and cultural challenges were overcome. The evidence should support the dissemination of knowledge about which solutions are available and where, who the players in the domain are, and which type of policy measures were most instrumental.

More robust evidence of the benefits of PHS must be generated and publicised, while evidence and knowledge should be more easily accessible at the point of need. Greater and more co-ordinated leadership and standards in knowledge management and knowledge authorship will be needed.

For sustaining the knowledge base, its construct should be both simple and attractive for stakeholder groups to input relevant information. This requires not only simple templates for data collection, but, moreover, incentives to submit data.
The database itself needs to be easily accessible and a regular update, maintenance and ownership of the database must be assured. This could be assumed by actors like Intellect (UK) or VDE (Germany), which have already been gathering information at the national level. Professional (healthcare) associations could service and maintain the database for specific disease areas such as diabetes, heart failure or chronic obstructive pulmonary disease (COPD), for example. At the EU level, the database could be hosted by the ePractice portal created by the European Commission which offers a new service / interactive platform for the professional community of eGovernment, eInclusion and eHealth practitioners.

More general information on the telehealth landscape in Europe has been collected by the EC funded study eHealth Strategies, which assessed national eHealth policies, strategies and implementation measures. Furthermore, concrete cases of implementation can be found at the Good eHealth web site, also EC funded. The use of standards has not been surveyed in detail. The analysis of the country reports of the eHealth Strategies study, however, has revealed that all countries surveyed report at least small local telehealth or telemedicine pilots, a small increase (+4) from the already high level of such experimental implementation reported by the predecessor study in 2007. Yet, the widespread use of such services at the national level remains the exception and has been reported for the Nordic countries only. In Poland, a move from local pilots to large scale regional pilots is planned for 2011. The federal/regional organisation of some healthcare systems (e.g. Spain, Italy) makes it difficult to judge the extent to which telehealth services have been implemented across the country. Apart from the Scandinavian countries, a number of countries have explicit national strategy documents for telehealth implementation. Examples can be found in Slovakia, Romania and Spain.
Further to building up a knowledge base, evidence could be collected more systematically by addressing interoperability as a requirement in all relevant EU-funded projects such as those supported by the Competitiveness and Innovation Framework Programme's Policy Support Programme (CIP-PSP) and others. Already at the proposal evaluation stage it should be assessed to what extent a project application addresses the European Recommendation on Interoperability of EHR systems and – where relevant – how interoperability of PHS with other eHealth systems will be addressed. A feedback mechanism to check for ex-post achievements of such projects should also be implemented.

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Such a body of knowledge could take the form of repositories for each country and an integrating EU level knowledge base entitled: *"Who is Who in PHS in Europe".* The recently launched European Innovation Partnership (EIP) pilot on Active and Healthy Ageing could be taken as a starting point to develop such a strategy.

These measures are likely to create a more supportive environment for the promotion of interoperable PHS, because funding would become directly linked to interoperability efforts.

Creating a supportive environment – structures & organisations, measures & processes

A further step towards a supportive environment with appropriate organisational structures, implementation measures and processes should strive to:

Make the use of interoperability specifications and profiles a mandatory element of local, regional and national eHealth infrastructures, and part of defined functionalities for IT systems used by healthcare providers. As a starting point, member states should launch transparent and participatory processes – consistent and coherent with European and global dimensions – leading to the selection of interoperability specifications and the incentivisation of their use.

This should be done by identifying promising initiatives for interoperability take-up such as Continua and IHE. They underline that simple standardisation will not be sufficient because standards are usually too imprecise and flexible to assure the reliable and uncompromised transfer of data and information across actor networks and health systems which PHS demands.

This must be followed by setting up, funding and/or expanding of virtual or real organisations such as Continua and IHE, in order to develop voluntary –or mandatory – test specifications and the creation of test suits/testing environments. The work commenced under the EC Communication on Telemedicine should be leveraged to ensure that PHS is included in funding tools which can, in turn, foster the grass roots involvement of providers and users in nurturing the PHS concept.

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At the same time, support should be given to SMEs to access the processes. As part of the update of the European eHealth Action Plan, further effort should be foreseen for the development and certification for interoperability educational sessions across the EU. Once an ecosystem development has taken place and early test specifications ensuring interoperability become available, the system should become self-supporting and sustainable (similar to the experience with GSM development). Policy makers have a crucial role to play to make this development happen.

Example 2: CNR-Santé, France - example for organisational/ institutional support

CNR-Santé, Centre National de Référence Santé à Domicile et Autonomie, was launched by the French Ministry of Industry in 2009. CNR- Santé has established a national innovation network linking users, providers, and buyers of ICT technologies and services for care and cure at home. CNRS-Santé provides information and training, and offers support to all relevant stakeholders. It helps i) users (citizens, associations, communities) - to better understand the value of ICT in their daily lives or their business processes, and express their development needs; ii) technology providers - to directly work with users and funders to innovate and demonstrate the performance and relevance of their products, and to develop new business models; iii) professional groups and associations of technology providers – to help their members better understand the market and to initiate collective action and collaborative projects; iv) researchers – to share their technological know-how. CNR-Santé works on standardisation, product evaluation and certification, label development, in partnership with national agencies (AFNOR, Association française de normalisation) and international organisations (Continua, IHE) as well as on legal and regulatory issues. It provides opportunities to showcase technology in order to inform and educate users.

Example 3: "Concept Viability Service": an example for pre-procurement support - Intellect, UK

Intellect, the leading representative body for the technology industry in UK with approximately 800 member companies, provides a so called "Concept Viability" service to customers who wish to test the viability of a concept of a complex, demanding or large scale technology (including IT) solution they are seeking to procure. The process starts with a short description of customer's business needs. Intellect circulates this to selected companies and invites comments on the feasibility of the proposal. The purpose is to inform and contribute to rather than to replace wider consultation with the supplier community. Intellect facilitates the exchange between clients and suppliers, e.g., through workshops, collects responses and prepares a Concept Viability assessment report highlighting risks, flaws, opportunities, and providing guidance on the provisions needed to achieve a successful solution. The report is made available to all suppliers interested in bidding for the contract to ensure a level playing field. This approach allows procurers to tap into the expertise of technology suppliers at an early stage in project development and before any formal tender exercise begins. Over 40 major UK government projects have benefited from using this service.

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Interoperability in all policies

PHS and wider eHealth interoperability must become part of all relevant policy fields impacting on its development and anchoring into eHealth activities across Europe. Future policy efforts could be modelled along the lines of the EU "health in all policies" approach. Interoperability needs to be mainstreamed into health policy fields. This follows the insight that the need for and promotion of PHS interoperability is not primarily an ICT phenomenon as such, but rather relates to the facilitating potential of ICT-based solutions for developing new, sustainable approaches towards better health and social care systems.

> *Interoperability will be crucial to achieve the full potential of connected health systems to increase health care access, enhance patient outcomes, improve population health and control costs.*
>
> *Charles Parker, executive director, Continua Health Alliance*

As a first step, PHS interoperability should be put on the agenda and roadmap of eHGI, the European Member States' High Level eHealth Governance Initiative.

The eHealth Governance Initiative should promote PHS interoperability and encourage Member States to include it in their national eHealth strategies and roadmaps. Member States should ensure that well-being and health services collaboration through interoperable network mediated devices is a key pillar of national eHealth roadmaps/action plans.

Furthermore, as political decision-making in healthcare generally resides within the national arenas, the EC should increasingly, and in a more coordinated way, utilise the role of stakeholders and participants in European meetings as messengers who report back to the member states and regions.

Accompanied by periodic meetings with policy makers and industry on PHS interoperability, the progress made in achieving PHS interoperability goals could be measured in an *interoperability barometer,* published by the EC services. This could be undertaken in the context of the European Institute for Prospective Technological Studies (IPTS) efforts.

Integrated wellbeing and health services

In the longer run, member state governments should strive to *"impose" integrated health service provision* (rather than interoperability) across the continuum of well-being up to long-term care provision, in both the public and private sectors, including prevention, chronic disease (chronic condition) management and ageing independently. This will 'naturally' create incentives and demand for interoperability. Based on the European Innovation Partnership, a coalition for integrated well-being and health services could be stimulated.

To deliver early results for incentive creation, such a coalition for integrated well-being and health services could focus initially on a particular citizen risk group where PHS can considerably and in a proven manner reduce their health risk.

In addition, a complementary initiative should be adopted to ensure that the learning and experiences of PHS adoption outside the EU are made more visible and can be integrated at early stages into EU and Member State policy and practice development.

Policy measures: regulatory framework

While the agenda setting function falls to the eHealth Governance Initiative, urgent action needs to be taken at the regulatory level of PHS interoperability. Regulators must respond with new regulations which address the need for legal certainty of both providers and users. Vendors and healthcare

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providers – as well as other health system actors – must understand where their liability begins and ends. Anecdotal evidence suggests that a fear of potential litigation is holding back uptake of PHS enabled collaboration. New privacy and data sharing regulations to support shared services delivery and use across public/private, and formal or informal divides should be considered. More clarity and certainty for all involved when using PHS cross-border is a key issue to address.

A closely related aspect in this context is incentives and reimbursement rules. Whereas it is to be expected that well-structured and calibrated capitation or salary based remuneration systems provide built-in incentives to optimise services, which would imply making use of telehealth solutions where they help achieve this goal, fee-for-service approaches may lead to higher costs when telehealth applications require a specific, additional reimbursement payment which is not compensated by a reduction in other fees. Nevertheless, during an initial diffusion phase, it may be politically justified to provide an "extra" monetary incentive to speed up innovations and reach a critical implementation mass speedily. Moreover, reimbursement and payment systems must be adjusted to ensure that PHS is accessible to patients outside traditional healthcare settings (i.e. at home/on the move).

Regulators must urgently address the need for a reliable regulatory environment including clear liability rules, as well as clear reimbursement structures and incentives for early adopters.

Here, lessons should be learnt from regulators in member states.

Example 4: The recent adoption of the Décret Télémédicine in France

This decree defines the kind of telemedicine services to be made available and how they are reimbursed. The decree lists various possibilities such as integration of telemedicine services in multiannual service contracts ("contrat pluriannuel d'objectifs et de moyens") which the regional health agencies in France sign with healthcare providers and organisations. Alternatively, telemedicine services can receive funding through a fund specially set-up by the social health insurance in order to improve quality and coordination of healthcare, the so called "fonds d'intervention pour la qualité et la coordination des soins." The funds are disbursed through the regional health agencies.

Example 5: Medical Network law adopted in the Swiss Canton of Geneva

The legislation passed in Geneva in 2008 establishes a legal base for setting up an electronic network for collecting and sharing patient data for the purposes of providing care to a patient. It regulates the conditions in which data may be collected and for what purpose, who may access it and how the interests of patients are to be protected and balanced with the interest of public health. It contains, in essence, most of the requirements of data protection as provided at EU level in Directive 95/46/EC, but is unusual in setting it up specifically as an eHealth law.

While the content of the Geneva legislation can be found in many other national legislations, it is usually found buried with data protection laws, or medical regulations and thus does not give political prominence to the importance of electronic health records and their proper maintenance and use in the same way. Other legislations would do well to follow the impact of the law (which came into force in November 2009) and establish if such specific focus in privacy of EHR has an impact on the uptake of EHRs and indeed PHRs by citizens. It would also be advisable that at EU level the Geneva legislation and its impact are studied in the context of the upcoming review of Directive 95/46/EC.

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Example 6: Integrated care reimbursement in the Netherlands

In the Netherlands, the reimbursement rules of integrated care for chronically ill patients allow for eHealth services to become an element in such care plans. Here, instead of reimbursement by fee for service, a fixed budget is allocated for the complete treatment cycle, based on performance standards and output quality criteria. The Ministry of Health, Welfare and Sport has already introduced integrated care reimbursement for patients suffering from diabetes, cardiovascular diseases, and COPD. The impact will be evaluated after three years.

Learning from experiences outside the EU

Europe should closely observe the impact of the USA "meaningful use" requirement for the disbursement of stimulus plan funding from the resources provided by the American Recovery and Reinvestment Act of 2009 (ARRA) on the faster adoption of HIT (health information technology) by healthcare providers. It is expected to also impact on the adoption and diffusion of PHS.

The need for a joint EU-US vision on internationally recognised and utilised interoperability standards – in particular for electronic health record systems - has been underlined by the recently signed "Memorandum of Understanding between the European Commission and the United States Department of Health and Human Services on Cooperation Surrounding Health Related Information and Communication Technologies". Such "common standards are important to achieve widespread interoperable eHealth services so that eHealth can reach its full global market potential," a statement particularly relevant for PHS.

An observatory should be initiated so that experience and lessons learned from non-EU activities like the USA stimulus funding and PHS adoption schemas are analysed and disseminated.

The partnership between the EU and the US, the two world leaders in eHealth, sends a strong signal to all stakeholders that common standards and interoperability bring opportunities for a global approach for the benefit of patients, health systems and the market.

Supporting guidelines and profiles development and uptake

At the technical level, the gap between the activities and output of standard development organisations (SDOs) and standards/profiles and guidelines developed by user and industry consortia and fora (like IHE, Continua) needs to be narrowed. The way forward post Mandate 403 (Mandate to the European Standardisation Organisations CEN, CENELEC and ETSI in the field of Information and Communication Technologies) (recast upcoming) should align with the proposals from the EC White Paper: "Modernising ICT Standardisation in the EU: The Way Forward". The White Paper supports the principle of referencing ICT related standards and/or guidelines from specific fora and consortia in relevant European legislation, policies and public procurement.

Enabling official referencing in public procurement to the latest established standards and guidelines stemming from qualified consortia and fora can be an important means of fostering innovation while providing public authorities with the tools needed to fulfil their tasks (as suggested by the White Paper). These fora and consortia invest time and resources to evaluate specific standards and develop guidelines for their implementation and often can react more quickly than formal SDOs to market demands on issues such as interoperability. Their strong and close cooperation with ESOs will allow for faster implementation of best practice.

2. Recommendations

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The guidelines and standards developed by consortia and fora should be given equal standing as those developed by recognised standards organisations so that procurers may demand effective compliance with them in public calls for tenders/requests for proposals.

Potential implications related to competition law – standards or proprietary systems restricting market competition – should be clarified in collaboration with DG Competition to discuss and study barriers and implications. Procurement can play a massive part in bringing the PHS market forward, and should be key stimulus for greater competition through mandating standards.

> *We need to overcome the pure health economic efficiency debate. Insurers should put quality of life and patient safety high on their agenda.*
>
> *Prof Harald Korb, Vitaphone*

National and regional agencies should ensure that guidelines and profiles developed by consortia and fora are widely disseminated in an understandable format, their benefits understood and their implementations supported. There is a particular need for technical education especially amongst smaller procurers. Simultaneously, regulation is a mixed blessing: it can also encourage closed systems. For example, the scope of mHealth regulation encompasses multiple touch points. Many of those require an end-to-end understanding, including safety and confidentiality, which can act as inhibitor of growth. In the same vein, a market perspective would postulate that issues of interoperability will be solved most efficiently through payment mechanisms and through the incentives that payers would create once the right reimbursement scheme is be in place. Ultimately, interoperability cannot be achieved through regulation; it predominantly depends on the intention of the vendor to be interoperable. In addition, history has shown that proprietary systems rarely survive – a point which should be clearly communicated to PHS manufacturers and other eHealth vendors.

An interesting example for procurement is the UK National framework agreement for telecare, which defines a list of telemedicine items cleared for purchase within the NHS. NHS England, some four years ago, which embarked on establishing a national framework agreement on suppliers of devices and services for telecare, telehealth and home automation. The long and complicated process, after many rounds of negotiations, led to framework agreements with 13 prime suppliers being able to deliver 2,800+ products in the defined field of telehealth and care.

After implementation of the National Framework a number of challenges and constraints surfaced, including issues such as most suppliers not showing a drive for conforming to national or international standards, rather preferring their own proprietary technology and erecting unintended and unforeseen barriers to innovation and interoperability. Such a process and the framework agreements also led to a severe lack of flexibility to accommodate new offerings, and implied only a limited scope for enhancements and new added value services. One of many lessons learned for good procurement is the need for commercial clarity on the use of standards.

As a means of communication, education and training of relevant actor groups, public/private partnerships should be established to create information channels and training courses which promote good understanding and implementation of PHS and related guidelines for procurement.

This is particularly important where procurement is devolved to local level and is undertaken by non-technical partners such as GPs who have neither the time nor inclination to learn 'standards speak'.

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Uptake for guidelines and profiles could certainly benefit from meaningful financial incentives. The guiding idea behind financial incentives should be the establishment of a critical mass in standards uptake. This could be more easily achieved if mechanisms were established through which the procurement of an interoperable solution is rewarded. Here, the impact of the "meaningful use" requirement in the USA should be closely observed.

National regulatory agencies should recognise the achievements of consortia and fora to provide a presumptive adherence to formally required standards – this would mean clear regulatory guidance to procurers. This, in turn, requires that the consortia and fora demonstrate clearly how they bring certainty in the effective interoperability achieved by compliance with their profiles/guidelines. On the other hand, caution needs to be exercised as strictly imposed standards will unlikely find acceptance in industry.

Procurers must become legally empowered to include the following interoperability requirements in tenders:

- **Reference in the procurement documents "robust, complete and standards-based specifications" for interoperability**
- **Ask for "proof" that proposed IT systems comply**
- **Add a project specific "validation" for interoperability**

At the European level, the RENEWING HEALTH (REgioNs of Europe WorkINg toGether for HEALTH) Large Scale Pilot partially supported from the European Community's Competitiveness and Innovation Framework Programme provides a basis for cooperation in implementation of interoperable PHS. RENEWING HEALTH has reviewed the industry status regarding available products which are Continua certified to conform to IHE-PCD DEC (IHE - Patient Care Device Domain, Device Enterprise Communication) and IHE-PCD IDCO (Implantable Device Cardiac Observation). A technical specification for use in procurement is also provided.

Closely related to interoperability requirements, usability remains a key challenge requiring a better dialogue between users and suppliers.

> *The ones who will use the technology are - quite often - the nurses. Engage them right from the start. They have the power to ignore what they do not like – 'if it does not fit in the daily practice, it will not be used'.*
>
> *Paul de Raeve, European Federation of Nurses*

Often neglected, gender issues should find inclusion in any debate about usability of medical technology: women, which constitute by far the majority of nurses, approach technical "tools" in a different fashion than the predominantly male world of device engineering and development.

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Facilitating use through training & education, exchange, and collaboration

Develop strategies and programmes for training and education of different stakeholder groups.

Citizens and providers need to be educated to better understand their role and power, and procurers need education in technical standards. Furthermore, health service providers have to better understand through training and education the value of being able to communicate with one another, and become incentivised to cooperate across organisational and jurisdictional boundaries.

> *The real challenge is to redesign care; to change the hearts and minds of professionals, and empower patients through education, not delivering boxes and devices.*
>
> *Dr George Crooks, Clinical Director/ Chief Operating Officer for NHS 24*

To further expand the market, it would be necessary to go beyond established healthcare system concepts and popularise the concept of the well-being and health services consumer – which is underdeveloped in Europe.

Learning from good practice should go beyond cases described in a knowledge base. More co-ordinated exchange of results between PHS implementations is needed to foster learning.

Examples for good practice in integrated service provision are particularly rare and deserve special attention.

Example 7: an integrated approach to telehealth service provision – the Hull (UK) model

The Hull telehealth service model is an exemplar of integrated care for chronically ill patients, delivered by a variety of health service providers working collaboratively. One of the key priorities in Hull is to extend the telehealth offer from one focused only on monitoring to one that encourages self-care. To support self-management, a closed-loop disease management solution feeds back the short- and long-term effects of users' treatment, based on the physiological and statistical modelling of medication and lifestyle effects.

The telehealth services use technology as the enabler for better services, providing practitioners with the information necessary to deliver evidence-based, individualised care. For example, the heart failure (HF) telehealth service is delivered by secondary care nurses. Patients are predominantly referred to the service from secondary care, following an acute admission. As discharge from hospital nears, a liaison nurse makes the referral to the telehealth team, who arrange for equipment to be installed by the industry supplier. Patients give consent, and receive a home visit by a charity worker and nurse to assess the environment and explain how the equipment is operated.

The patient records their weight, blood pressure and pulse on a daily basis. These data are sent via a secure server to a telehealth nurse, who is automatically alerted of any unexpected findings. In response to these alerts, the telehealth nurse may contact the patient directly via the telephone to offer advice, or may refer the patient onto a community practitioner for a face-to-face visit.

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A good example for integrating health and social services is the Newham Whole System Demonstrator (WSD) trial funded by The Department of Health, UK. It aims to find out how technology can help people manage their own health while maintaining their independence. Around 2,000 people are taking part in the pilot (1,500 of which are telehealth users). The remote health monitoring system recently won a national award (Health Business Award in Telehealth).

Close collaboration between standard development organisations (SDOs) and user and industry consortia and fora such as IHE and Continua, is key to fostering interoperability. Within the SmartPersonalHealth project, this cooperation has resulted not only in common concepts and deliverables but also in a joint demonstration as shown below.

Example 8 : SmartPersonalHealth demo

During the World of Health IT conference in Barcelona 15-17 March 2010, the Continua Health Alliance, together with IHE, presented the benefits of creating an eco-system of technologies working together for patient care. Demonstrations of systems using the IHE profiles as well as Continua certified solutions were shown. The Continua Alliance is working with IHE to establish a system of integrated personal health solutions.

Continua showcased its first end-to-end connected health solution, based on Continua architecture standards, in which data from a Bluetooth enabled wireless pulse oximeter from Nonin was sent to a PC manager running the Vignet connected health services platform.

From there, it was uploaded to an IBM server using the Continua wireless area network interface standard, from which it could be sent to other service providers, including healthcare facilities and personal health record services. All Continua components fit the IHE PCD 01 model and plug and play with IHE tested applications.

EU should consider effective means to support the work of fora and consortia in the area of personal health systems as well as their collaboration with SDOs, in order to speed-up the development of guidelines and increase dissemination and uptake.

Continue to support the close cooperation between the Continua Health Alliance and IHE (Integrating the Healthcare Enterprise) as well as with ESOs (European Standard Development Organisations).

The close cooperation between the Continua Health Alliance and IHE has resulted in the development of consistent and compatible profiles that ensure the smooth and secured flow of health data from home devices to care coordination services and to healthcare organisations: IHE and Continua have also ensured that the same profiles are used within the hospital and the home to move device data into the patient health records.

2. Recommendations

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Outlook and further research needs

SmartPersonalHealth focused on activities and recommendations to promote interoperability of PHS with different stakeholders. Further input and research through, e.g., future support actions and other activities is required to approach the organisational challenges of interoperability and, in particular, *the challenges of seamless integration of PHS into clinical workflows* as well as the care provider coordination in the context of integrated care. The term integrated care reflects more aptly the political challenge behind making PHS work. Human resource issues and co-operation with informal care providers are part of these challenges.

> *A significant theme in chronic disease management is the need for more integrated care. The use of personal health systems forms part of a wider strategy which needs to include provision for other capabilities such as the sharing of care plans across different care settings.*
>
> *George MacGinnis, Member EU Policy Group, Continua Health Alliance*

While technology is global, care pathways are local. For the integration of PHS into clinical and care workflows, many changes at the site are required in parallel. This change management of parallel processes is certainly one of the major challenges.

Besides health and care professionals, key stakeholders to discuss these challenges with are the patients themselves. As patients often know best about their condition and how it affects them in their social situation and quality of life, they can fulfil advisory roles in how PHS could be better integrated into care processes. The patients could even drive the care coordination instead of the care providers. Interoperability, moreover, enables access to patient's own data and should therefore (as suggested by stakeholders) form part of patients' rights.

The real challenge is to redesign care delivery, to change the hearts and minds of professionals, and to empower patients through education – the challenge is not "to deliver boxes and devices".

Shared and interoperable care pathways and plans agreed with all PHS related professions: shared care plans are relevant for both routine and unscheduled care encounters. The care plan should be agreed on by both citizen and professionals. Agreeing on the data which need to be shared and actors and devices implicit in accepting the plan, solves the problem of complex privacy negotiations. The data to be shared is inherent to the plan and defined by clinical excellence – evidence based published guidelines. Withholding data from the care plan would cause it to be driven sub-optimally from an evidence point of view.

Consultation with patient representatives has indicated that "patient-centred and *patient-driven care coordination*", instead of "care provider" coordination around the patient, could be key to really empower the patient. Thereby, the patient could help design the care pathway according to his/her needs and be part of the care planning process.

Furthermore, the EC should *intensify outreach to patients* and their associations in addition to strengthening the liaison with clinical associations. As a patient representative pointed out, "only if we challenge the doctor paradigm we can truly achieve shared health and care".

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An important aspect is also that at the moment part of the knowledge about health and wellness is fragmented and proprietary (BMJ, Map of Medicine, DuoDecim, etc.). Given that 'the interoperable health and wellness proposition' will only work when citizen and professionals' expectations are aligned and governmental provision also matches these aspirations, then the knowledge and evidence driving the systems should also be identical. Taking such an approach to unify knowledge would establish the EU as the industry and professional lead.

User centred design and usability: in addition to technical interoperability, close attention should be paid to user centred design and usability, and how all applications fit together. In real-life many patients are on multiple pathways. For example a 'simple' diabetic can be on a travel vaccination pathway, an exercise regime, a diabetes regime, kidney monitoring, feet monitoring, eye monitoring, drug repeat monitoring, etc. If each of these looks different, has different alerts, and different ways of contacting both carer and patient, this is going to be not only user unfriendly but it may also pose patient safety issues. The work performed by NHS England in the Common User Interface Programme with standards on medication, terminology, alerts and identification, although done with the clinician primarily in mind, could be leveraged and serve as a basis for harmonisation. This may prove a key issue in ensuring uptake and use of the systems and therefore in eventually changing the model of delivery of care.

Enabling scale – a large scale programme for active and healthy ageing under the EIP: Finally, Continua has recommended - through the open consultation process set up by the EC - to develop under the EIP on Healthy and Active Ageing a programme of initiatives which should involve all stakeholders, should have support from (or at least the involvement of) public authorities, and should explicitly stress the interoperability of the solutions to be provided. To help change at European level, one should align objectives and resources of multiple Member States (or regions) on a scale never tried before.

The proposed large-scale programme under the EIP would deploy technologies for active and healthy ageing across Europe, on a very large scale (cohort of 30,000+ individuals) allowing for a comprehensive study (more than three years) of their health status and chronic condition(s).

The study should focus on:

> Capturing the benefits of such solutions;

> Studying interoperability requirements and implementing interoperable systems;

> Capturing live data from the programme (behavioural, medical, social) to identify novel markers of cognitive and health decline so as to drive breakthrough research on predictive knowledge;

> Finding financial and organisational sustainable usages;

> Exploring the societal impact of the programme;

> While providing real, professional support to the cohort.

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