Reconstructing the Whole: Present and Future of Personal Health Systems

Cristiano Codagnone

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The opinions expressed in this book are those of the author and do not necessarily reflect the views of the European Commission.

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Preface

This book selectively builds upon and integrates the main findings of Framework Programme 7 project ***PHS2020***[1]. It is an important contribution rooted in the context of European Union policies and research funding in the broadly defined field of eHealth.

eHealth has figured among the priorities of the European Commission Information Society policy and research agenda ever since the launch of the two Action Plans ***eEurope 2002*** (European Commission 2000) and ***eEurope 2005*** (European Commission 2002) and is still among the key objective of the current ***i2010*** European Information Society policy platform (European Commission 2005)[2]. The European Commission has encouraged Member States to take actions in eHealth and managed to reach clear commitments in May 2003 during the Ministerial eHealth Conference held in Brussels, when European Ministers signed a Ministerial declaration and committed their countries to work together towards best practices in the use of Information and Communication Technologies (ICT) as tools for enhancing health promotion and health protection, as well as quality, accessibility and efficiency in all aspects of health care delivery[3]. This was followed by the release in 2004 of the ***eHealth Action Plan*** (European Commission 2004a) and of the ***Communication "on patients' mobility and healthcare developments"*** (European Commission 2004b). The eHealth Action Plan underscores how several trends are resulting in rising demands for healthcare services, which can be addressed also through the harnessing of the potential of ICT in combination with organisational changes and the development of new skills (European Commission 2004a: p. 4 and p. 8). As other areas of ICT applications to economy and society, eHealth is seen as potentially contributing to the Lisbon Agenda of achieving both economic growth and social cohesion in a knowledge based society and, thus, it is considered also a market opportunity. Attention to the concrete possibilities offered by eHealth to Europeans also in terms of business development and innovation has been captured solidly in the Lead Market Initiative for Europe (European Commission 2007a)[4]. Most recently the needs

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[1] The project deliverables can be accessed at:
http://ec.europa.eu/information_society/activities/health/research/fp7phs/index_en.htm

[2] It is worth noting that there appears to be an increasing a sense of synergy between the public health and the ICT domains areas of policy and research in the European Commission. On the public health side, there is a growing awareness of the usefulness and appropriateness of eHealth to supporting health systems and services (European Commission 2007b). The new European Health Strategy (European Commission 2007c) aims to provide, an overarching strategic framework in the field of health and lists as strategic themes: Fostering Good Health in an Ageing Europe, Protecting Citizens from Health Threats, and Dynamic Health Systems and New Technologies. The first and the last of these have particular relevance from our perspective.

[3] Ministerial Declaration at Ministerial e-Health 2003 Conference, Brussels, 22 May 2003 (http://ec.europa.eu/information_society/eeurope/ehealth/conference/2003/doc/min_dec_22_may_03.pdf)

[4] Following earlier argumentation provided by an independent expert group chaired by Mr Esko Aho (European Commission, 2006b), the Communication which underpins the Lead Market Initiative identifies an increase in investment in eHealth as pivotal points to telemedicine for chronic disease management as a

and opportunity of harnessing ICT potentialities to improve the delivery of care have been further highlighted in the ***Communication on Telemedicine*** (European Commission 2008a)

Personal Health Systems (henceforth simply ***PHS***), besides being one of the key pillar of the ***eHealth*** policy and research agenda[5], embody the most innovative vision on how ICT can be used in healthcare. It is precisely in this specific field that ever since the launching of Framework Programme 5 the Commission funding to research and technological development has supported the ***paradigm shift from the traditional hospital-centred and reactive healthcare delivery model toward a person-centred and preventive one.***

The first decade of more sustained funding to PHS research is ending, at the time of writing 2010 is only a few months away from us and will mark the end of the current overall policy Information Society policy framework ***i2010***. A new Commission will be start to work soon. We are, thus, at a turning point and it is today a good time to take stock of what has been achieved and to look into possible futures so to provide input to the design of the policy and research agenda for PHS in the next decade.

The overall objective of this book is precisely to provide an extensive review the state of the art in PHS, upon which several roadmaps of needed future research are proposed. These objectives have been achieved following the methodological steps briefly illustrated in § 1.3 and explained in further detail in the methodological annex (§ 7), which in brief led to : a) establish a state of play; b) extract from the state of play trends leading to the elaboration of four different future scenarios; c) systematically compare the state of play with the scenarios to identify gaps in need of being addressed to support the desirable elements of the scenarios and counter the less desirable ones; d) associate to the gaps various themes for Research and Technology Development (RTD) and/or for other kind of actions; and e) develop these themes into five Roadmaps.

PHS2020 established a standing Expert Support Committee (ESC) that met five times over the duration of the project and constantly evaluated, commented and validated the deliverable produced. In addition, it organised four consultation workshops and one final validation conference. It, thus, carried out a total of 10 consultations events, engaging a very large number of experts and stakeholders covering all the relevant expertise and stakeholder areas (healthcare institutions and professionals, ICT industry and technology experts, policy making bodies, experts of broadly defined socio-economic relevant topics; researchers). So this book benefits from the input from such a large pool of very distinguished experts and stakeholders.

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core domain where actions are required and clear development and progress can be achieved. Equally conscious of these multiple benefits arising from the eHealth technology field, but especially – in this case – electronic or personal health records, is the European Commission's recent Recommendation on interoperability (European Commission 2008c).

[5] On the importance of **Personal Health Systems** see, for instance, the reports: *Connected Health: Quality and Safety for European Citizens* (European Commission 2006a: p. 16) and *eHealth for Safety - Impact of ICT on Patient Safety and Risk Management* (Stroetmann *et al* 2007).

Four project deliverables of PHS2020 cover in great details all the methodological steps, from the State of Play, to the construction of future Scenarios, to the Gap Analysis and the final Road Maps. These deliverables, all available for consultation and download at the project website[6], illustrate in great depth all the methodological technicalities, the sources gathered and analysed, and very extensively the findings of the project. They represent the wider background and knowledge base on which this book rests.

This book has as its main objective the high level dissemination of the main findings of the project and as such will only selectively use the vast contents and information to be found in the mentioned project deliverables. For the sake of brevity and of communication effectiveness we will often refer the reader to each specific deliverable for further details and information on various topic that are treated in this book in a more compact and succinct fashion.

[6] See: PHS2020 Deliverable D2.1, *State of Play*; b) PHS2020 Deliverable D3.1, *Consolidated Scenario Report* ; c) PHS2020 Deliverable D4.1, *Gaps Analysis Report*; d) PHS2020 Deliverable D5.1 *Roadmaps Report* . All these deliverables can be accessed online at: http://ec.europa.eu/information_society/activities/health/research/fp7phs/index_en.htm

1 Vision, promises and scope

1.1 Personal Health Systems: definition and vision

The PHS concept envisions a new generation of applications (i.e. wearable and portable systems) and tools in the hands of users and professionals and increasingly resting on the convergence between ICT and other technologies such as: biomedical sensors, micro- and nano- systems, user interfaces, and digital signal processing and intelligent algorithms. As opposed to past activities focused on connecting the points of care (Regional) Health Information Networks, PHS is about connecting individuals with Health Information Networks. While this concept of PHS has been consolidated as one of the research priorities in FP5, FP6 and FP7, providing a consensual definition of what PHS are is difficult. Particularly challenging is to distinguish PHS in a clear cut way from other related concept one can find the relevant literature. Alongside the general and more widely used umbrella concept of Telemedicine, in the inter-disciplinary literature on eHealth one can find a vast array of other terms and concepts such as "Telehealth", "TeleHomeCare", "Home Health Monitoring", and "Personal Health Management"[7]. Technologies and the supported service applications are often termed differently by different authors. In brief the currently available definitions of the various concepts do not allow determining their taxonomic and clear cut relations.

Defining PHS, thus, was challenging and the elaboration of a shared definition of PHS has been a collaborative and iterative process, involving the European Commission, and the vast numbers of experts engaged during over 10 consultation events organised as part of PHS2020 project.

At the end of this process our final re-elaboration of the various input led to the following definition:

Personal Health Systems (PHS) assist in the provision of continuous, quality controlled, and personalised health services to empowered individuals regardless of location. They consist of:

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

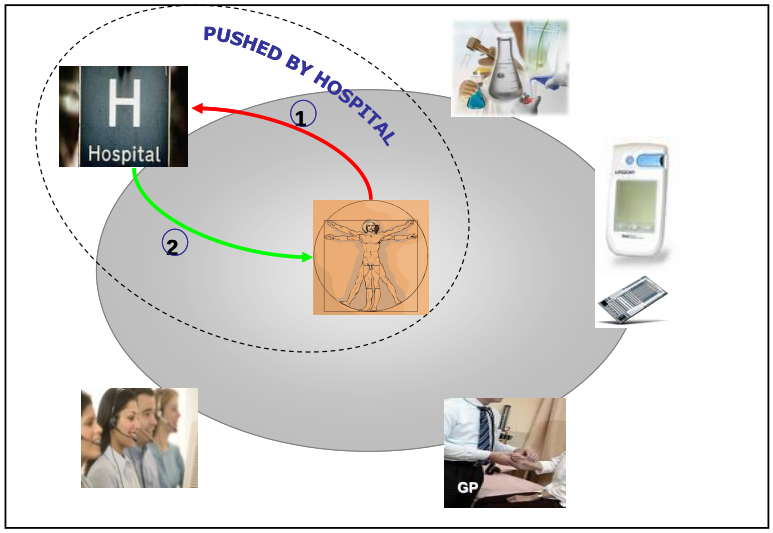
[7] This diversity and overlapping range of concepts and definition can be appreciated in articles providing extensive meta-analysis of the literatures (see for instance: Koch 2006; Koch *et al* 2003; Miller 2007, but also Gartner 2007)

diagnosis, treatment and rehabilitation as well as in disease prevention and lifestyle management.

Evidently the consensus was reached on a pragmatic and "ostensive" definition[8], as it was difficult to come up with a taxonomic one, given the yet not consolidated status of the field. Nonetheless, this definition is widely comprehensive and entails a dynamic element underlying the vision behind the policy efforts in this field.

The definition, in fact, does not 'antagonise' the potential fully empowered self-caring individual on the one hand, and the healthcare system (organisation and professionals) on the other. Both can be the beneficiaries of PHS promises, which can be ripped either directly by the users without mediation or indirectly through the interaction with healthcare professionals and organisations. In doing so it captures both of the two basic service delivery models depicted in the next two figures.

Figure 1 Service delivery model: healthcare pushed



Source: Authors' elaboration

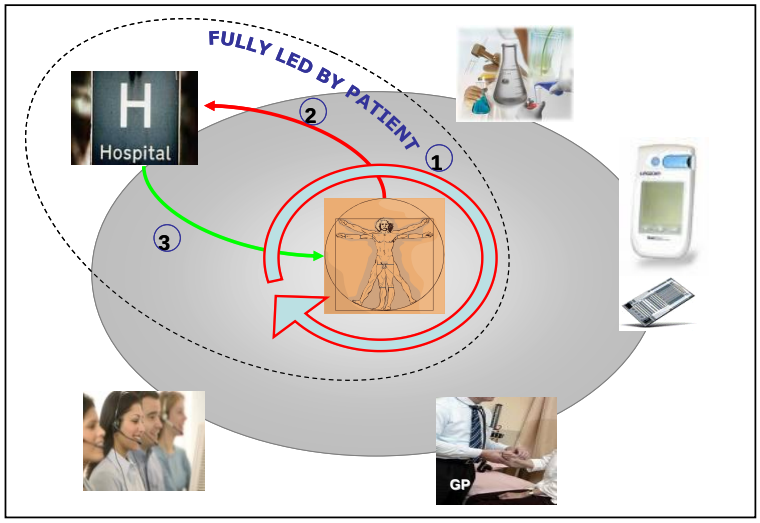
Under the model describe by the figure above the process of delivery of PHS enabled care is initiated and led within healthcare system (in the figure for exemplificative purpose only we indicated the "hospistal" but the initiator could be any other organisation or professional formally part of the healthcare system). The level of technology available

[8] An ostensive definition conveys the meaning of a term by pointing out examples. This type of definition is often used where the term or concept is difficult to define in a clear cut way. It is usually accompanied with a list of objects serving as an example, and for this reason is also often referred to as "definition by pointing." Yet ostensive definitions are useful when the overall meaning of the concept is quite clear. Ludwig Wittgenstein writes: "So one might say: the ostensive definition explains the use--the meaning--of the word when the overall role of the word in language is clear. Thus if I know that someone means to explain a colour-word to me the ostensive definition "That is called 'sepia' " will help me to understand the word.... One has already to know (or be able to do) something in order to be capable of asking a thing's name. But what does one have to know? (Wittgenstein, 1953/2001, §30).

at the user's site helps in providing anytime and anywhere information useful for various purposes, avoiding any unnecessary hospitalization and visits.

In the model depicted below the ownership of the PHS enabled care services is fully taken by the individual and the focus is on empowerment. Technology helps each person to manage certain health matters on his/her own, with reduced or no need of direct intervention on the side of healthcare professionals, naturally under well defined and controlled conditions.

Figure 2 Service delivery model: led by user



Source: Authors elaboration

Moreover, our definition embodies the two dimensions of what we consider the visionary thinking behind PHS, as they developed so far and especially as they may evolve in the future.

First, the definition underlies the vision of increasing the ***Empowerment*** and "***Response-Ability***" for individuals to take as much as possible health matters into their own hand, thus aligning healthcare to other sectors of society where the autonomy and free choice of individuals is increasing and where relation between users and providers of services in any field are becoming more symmetric.

Second, the definition brings a truly holistic vision of both individuals' health and of the various components of PHS. PHS "reconstruct the whole" and in doing so they reflect the new vision of complexity that is behind science in the 21st century.

As it has been forcefully argued by Barabási, scientific research in the 20th century has been driven by the ***reductionist*** assumption, according to which to comprehend nature '***we first must decipher its components…and see the world through its constituents***', and which but ended up running into ' ***the hard wall of complexity'***(2003: p. 6). This complexity where everything is linked to everything else makes it hard to recompose in a mechanistic way the various small components into which we broke done the world and our knowledge of it. This is why in all areas of scientific research, including all the life

sciences supporting medicine and its practice, in the 21st century new innovative and holistic way to cope with this complexity are needed. Medicine and healthcare, due to both the nature of the underlying scientific knowledge and to institutional design, are probably one of the field where this sort of 20th century reductionism has gone the furthest, to the point that the needed specialisation has reached the point of dysfunctional fragmentation drifting often into the dry attitude of ***dealing with diseases rather than treating human beings***. This has now started to change in the direction of re-focussing holistically on the person. This trend is clearly embedded in our definition of PHS, which conveys our vision that such person centric ICT enabled applications and services will play a key role in supporting a new holistic approach to the human body and well being capable to facing the challenges of complexities. The definition entails the idea that PHS must capture a variety of parameters providing a more complete and holistic picture, and ranging from physiological signs, genetic markers, personal characteristics, situation context of various nature. This will emerge even more forcefully in **chapter 5** where current gaps and the needed future research are discussed. Moreover, our definition is holistic also in how it treats the various components of PHS, in the sense that data gathering, data processing and data communication cannot be treated in isolation but must be developed has part of holistic systems. For instance, we will show how in the PHS field more intelligent solutions have not be achieved yet for too much segmented attention has been placed on distributed sensing and too little on tools to manage, analyse, and understand the data gathered.

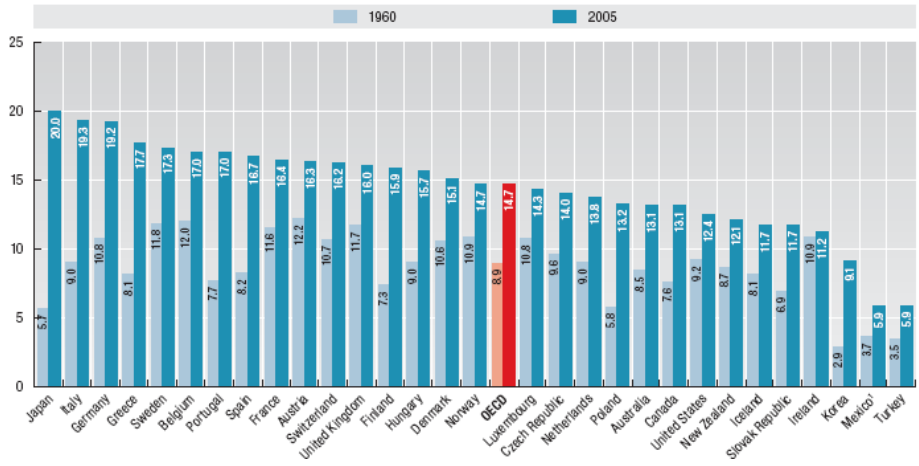
Third, besides these more inspirational elements of PHS vision, the definition also capture more 'prosaic' elements related to the support that PHS can provide to both empowered individuals and to professionals: a) decreased burden on the healthcare systems for less acute matters users can take care of autonomously or for matters will no long arise due to better monitoring and compliance, thus releasing resources for addressing patient with more acute health conditions; b) growing health awareness and preventive attitudes and activities on the side of users, thus leading to healthy life-styles and avoiding or delaying the outset of critical health situations. This is very important in light of the challenges that the healthcare systems are facing today, to which we turn in next paragraph.

1.2 Healthcare challenges and PHS promises

The challenges faced today by healthcare systems can be summarised with the following puzzle: rising costs and ***increasing demands and expectations at a time when various factors are putting public budgets at strain***. These challenges would require a separate treatment in their own right and it is beyond our scope in this book to enter into great details. On the other hand, as a general context and as a way to highlight the potential promises of PHS we briefly recall below some of the trends behind the challenges that are putting the healthcare systems at strain today[9].

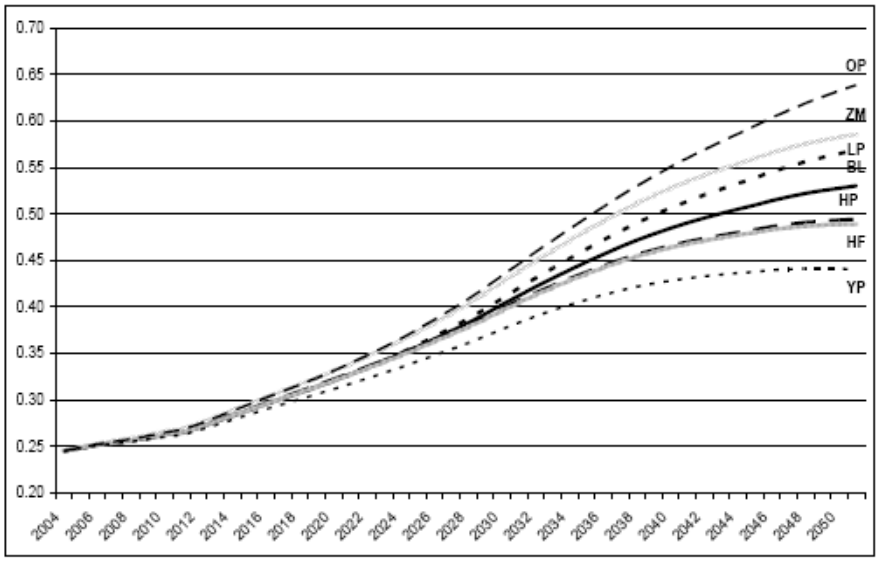
[9] For an analysis of these challenges and the factors behind them see 2001 Communication by the Commission on the future of health care (European Commission 2001).

Figure 3 Share of population aged 65 and over, 1960 and 2005



Source: OECD Health Data 2008, June 2008

Figure 4 Old age dependency ratio, EU-25, 2004-2051



Source: Eurostat (2006: p. 2)

From 1960 until 2008 in OECD countries the percentages of population over 65 has on average doubled. According to all of the Eurostat different projection scenarios plotted in Figure 4, the European population may not decrease but will surely grow older. The ageing of the population and its continuation in the future is, from the perspective of healthcare, **the trend**, the most certain and impactful of all other possible trends one can identify. The ageing of the population, besides reducing the pool of economically active citizens, it is also a main source of rising health care costs in its own right as it creates pressures in various ways such as: a) increasing of ***chronic diseases*** and of their co-

morbidity[10]; b) problems of ***compliance to medication and lifestyle guidance*** among the elderly[11], which is a major challenge facing the healthcare community in industrialized countries (Kausnik *et al* 2008); c) larger number of elderly people in need of long term care and assistance even when no acute chronic disease is present. Other developments related to the changing lifestyle and social fabric of our modern everyday life further pressuring the healthcare system on the demand side include: a) the health care implication of increasing ***obesity***, which the World Health Organisation (WHO) deemed as one of the greatest public health challenges of the 21st century[12]; c) the rising token of ***neuro-psychiatric disorders***, which WHO quantified as being the second cause of disability-adjusted life years (DALYs) lost in the WHO European Region and suffer from a treatment gap (World Health Organisation 2004)[13]; d) the increasing predominance of **nuclear families, work force feminization, and work force mobility** make the care of the chronically ill and of the elderly in general even more difficult increasing demand on healthcare and social services[14]. Finally, structural trends also include the positive

[10] The literature on this topic is vast and it is beyond our scope to review it here. For a very partial but sufficient selection, as it provides all the needed empirical evidence, see Adeyi *et al* (2007) , Nolte and McKee, eds. (2008), Nolte *et al*. (2008), World Health Organisation (2005).

[11] The elderly, in fact, have to take several drugs and/or follow multiple treatments and it has been estimated that patients over 70 take an average of seven prescription medicines and three over-the-counter drugs per day (Fleming et al 1993). Accordingly there is an higher risk of low compliance with the medical prescriptions (e.g., people forget to take their drugs, or take them at different hours, etc.), resulting in adverse events and further need of treatment and hospitalisation

[12] Its prevalence has tripled in many countries in the WHO European Region since the 1980s, and the numbers of those affected continue to rise at an alarming rate, particularly among children. Obesity is already responsible for 2-8% of health costs and 10-13% of deaths in different parts of the Region (http://www.euro.who.int/obesity). WHO latest projections indicate that globally in 2005 approximately 1.6 billion adults (age 15+) were overweight; at least 400 million adults were obese. WHO further projects that by 2015, approximately 2.3 billion adults will be overweight and more than 700 million will be obese (http://www.who.int/mediacentre/factsheets/fs311/en/index.html).

[13] One in four families has at least one member with a mental disorder at any point in time and the spread of such disease will increase from 12% of the total burden of disease to 15% in 2020 (World Health Organisation 2003). Worth noting also that since the 1970s poor mental health has increased in children and young people, particularly among those who are socially disadvantaged and that in general depression appears to be increasing in frequency, particularly amongst young people (World Health Organisation). According to the analysis conducted by Murray and Lopez (1997) worldwide, neuropsychiatric disorders accounted for 10•5% of DALYs, but their contribution was much greater in developed regions, where they accounted for 22% of total DALYs (respiratory accounted for 4,8%, and for cardiovascular 20,4%; malignant neoplasm 13%) as compared to only 9% in developing regions. In particular, when considering individual disorder singularly, the fourth largest disorder appeared to be unipolar major depression (In accordance with ICD-9 conventions, suicides, many of which were due to major depression, were not included in the primary tabulations of unipolar major depression. With the addition of suicide, the burden of unipolar major depression increased by nearly 40%). Other neuropsychiatric conditions in the 30 leading causes of burden included alcohol use, schizophrenia, and bipolar disorder

[14] According to Gartner research on the topic of the "health consumer of the future" (2008b), this situation is giving the rise to the new role of the "consumer care manager"(it can include professionals nurses and social workers, but also friends and relatives), who will be together with the actual patients the

correlation between income and education on the one hand, and the demand for healthcare on the other. As the steady increase in income and educational level is a sought goal of our societies, this will structurally result in higher demand pressures on healthcare. More generally this trend can be seen in light of the rising **consumerism** and demand of **better quality and ubiquitous access** to health care.

While demand side pressures are probably more sizeable, there are also other pressures on healthcare costs inscribed in the functioning of the healthcare system delivery and financing. Healthcare systems have the moral imperative to ***increase the capacity to cure*** even the most difficult cases, which is pursued by introducing new medical treatments and/or prolonging care and inevitably increases costs. Healthcare systems show a tendency at ***overshooting/mismatch in resource allocation***[15] in dealing with the most demanding and complex segment of patients (i.e. elderly persons with multiple acute conditions), and a corresponding incapacity to introduce innovations that would simplify the way they deal with least demanding segments (i.e. prevention of single well-known diseases at an early stage so as to delay the moment when they become a seriously chronic problem or monitoring and management of not yet acute chronic diseases). Excessive ***fragmentation and overspecialisation*** has resulted into a silo approach (the earlier mentioned dealing with diseases rather than treating human beings), which causes: duplications of efforts, lack of integrated information management and use, errors and sub-optimal treatment as, for instance, in cases where the co-morbidity of chronic conditions is not treated holistically. This can also cause adverse events and repeated and potentially unnecessary hospitalisation, both of which contribute to increasing the costs. The presence of a "third party payer" (being it the NHS, social insurances, or private insurances) favour intentionally opportunistic behaviour or simply lack of correct incentives in the prescription and utilisation, which artificially ***inflate costs***[16]**.** Finally, healthcare systems are characterised by ***Fat Administration***: need to process huge amount of information for administrative purposes, which absorbs large amount of resources**.**

customer/consumer of changing healthcare delivery and will demand more time and location efficient and effective services

[15] On this concept see the seminal article by Christensen *et al* (2000).

[16] For an illustration of such dis-functional behaviours see for instance Hsiao (1995).

As shown by the data below, healthcare expenditure as a percentage of GDP has grown substantially in all OECD countries between 1980 and 2005.

Figure 5 Total expenditure on health, percentage of GDP, 1980 to 2005

	1980	1990	2000	2001	2002	2003	2004	2005
Australia	6.8	7.5	8.8	8.9	9.1	9.2	9.5	9.5 *2004-05*
Austria	7.5	7.0	10.0	10.0	10.1	10.2	10.3	10.2
Belgium	6.3	7.2	8.6	8.7	9.0	10.1	10.2e	10.3e
Canada	7.0	8.9	8.8	9.3	9.6	9.8	9.8	9.8
Czech Republic	..	4.7	6.5	6.7	7.1	7.4	7.3	7.2
Denmark	8.9	8.3	8.3	8.6	8.8	9.1	9.2e	9.1e
Finland	6.3	7.7	6.6	6.7	7.0	7.3	7.4	7.5
France	7.0	8.4	9.6	9.7	10.0	10.9	11.0	11.1
Germany	8.4	9.6 *1992*	10.3	10.4	10.6	10.8	10.6	10.7
Greece	5.1	5.8	9.3	9.8	9.7	10.0	9.6	10.1
Hungary	..	7.0 *1991*	6.9	7.2	7.6	8.3e	8.1e	8.1 *2004e*
Iceland	6.3	7.8	9.3	9.2	10.0	10.3	10.0	9.5
Ireland	8.3	6.1	6.3	7.0	7.2	7.3	7.5	7.5
Italy	..	7.7	8.1	8.2	8.3	8.3	8.7	8.9
Japan	6.5	6.0	7.7	7.9	8.0	8.1e	8.0e	8.0 *2004e*
Korea	4.1 *1983*	4.3	4.8	5.4	5.3	5.4	5.5	6.0
Luxembourg	5.2	5.4	5.8	6.4	6.8	7.8	8.3e	8.3 *2004e*
Mexico	..	4.8	5.6	6.0	6.2	6.3	6.5	6.4
Netherlands	7.5	8.0	8.0	8.3	8.9	9.1e	9.2e	9.2 *2004e*
New Zealand	5.9	6.9	7.7	7.8	8.2	8.0	8.6e	9.0e
Norway	7.0	7.6	8.4	8.8	9.8	10.0	9.7	9.1
Poland	..	4.8	5.5	5.9	6.3	6.2	6.2	6.2e
Portugal	5.3	5.9	8.8	8.8	9.0	9.7e	9.8e	10.2e
Slovak Republic	..	..	5.5	5.5	5.6	5.9	7.2	7.1
Spain	5.3	6.5	7.2	7.2	7.3	7.9	8.1e	8.2e
Sweden	9.0	8.3	8.4	8.7	9.1	9.3	9.1	9.1
Switzerland	7.4	8.3	10.4	10.9	11.1	11.5	11.5	11.6
Turkey	3.3	3.6	6.6	7.5	7.4	7.6	7.7	7.6
United Kingdom	5.6	6.0	7.3	7.5	7.7	7.8	8.1	8.3
United States	8.8	11.9	13.2	13.9	14.7	15.2	15.2	15.3
Latest average[a]	..	..	..	..	..	..	..	**9.0**
Consistent average (24)[b]	**6.6**	**7.2**	**8.3**	**8.6**	**8.9**	**9.3**	**9.3**	**9.4**

Source: OECD Health Data 2008, June 2008

Currently the costs of healthcare in the EU is around 9% of GDP but they are projected to reach 16% of GDP by 2020 (European Commission, 2008b: p. 2), representing a much higher rate of growth than that expected for GDP. As can be seen in Figure 6 overleaf, the main European countries members of the OECD have healthcare system overwhelmingly financed directly through general government (so called Beveridge model based on a unitary National Health System, NHS[17]) or through social insurances assimilated to public funding (so called Bismarck model[18]).

[17] Key examples: United Kingdom, Sweden, Italy (though with an emerging regionalization having important impacts)

[18] Key examples: France, Germany, Belgium

Figure 6 Health expenditure by type of financing, 2005

	Total public	of which:		Total private	of which:		
		General government	Social insurance		Private insurance	Out-of-pocket payments	All other funds[d]
Australia (2004-05)	67	67	0	33	7	20	6
Austria	76	30	46	24	5	16	3
Belgium[a]	71	4	66	29	5	22	1
Canada	70	69	1	30	13	15	2
Czech Republic	89	9	80	11	0	11	0
Denmark	84	84	0	16	2	14	0
Finland	78	61	17	22	2	18	2
France	80	5	75	20	13	7	1
Germany	77	10	67	23	9	13	1
Greece[b]	43	43	0	57		57	0
Hungary (2004)	71	11	60	29	1	24	4
Iceland[b]	83	49	34	17		17	0
Ireland	78	77	1	22	7	13	2
Italy	77	76	0	23	1	20	2
Japan (2004)[b]	82	16	66	18		17	1
Korea	53	12	41	47	3	38	6
Luxembourg[c] (2004)	91	17	73	9	1	7	1
Mexico	45	17	28	55	3	51	0
Netherlands[a]	66	3	63	34	20	8	6
New Zealand	78	78	0	22	5	17	1
Norway	84	69	15	16	0	16	1
Poland	69	11	58	31	1	26	4
Portugal	73	72	1	27	4	22	1
Slovak Republic	74	9	65	26	0	23	3
Spain	71	66	5	29	6	22	1
Sweden	85	85	0	15	0	15	0
Switzerland	60	17	43	40	9	31	1
Turkey	71	34	38	29	0	20	9
United Kingdom[b]	87	87	0	13		13	0
United States	45	32	13	55	37	13	5
OECD average	**73**	**41**	**32**	**27**	**6**	**20**	**2**

Source: OECD Health Data 2008, June 2008

On average in the EU countries members of OECD public funding amount to 76% of health expenditure, private insurance to 3.7% and individuals private out of pocket disbursement to 18.3% (the remaining 1.9 goes to other private funds). The historical trend from 1970 till 2005 in terms population coverage by publicly funded healthcare (Figure 7, overleaf), is very telling as it shows that with few exceptions (i.e. especially U.S. but to different degrees also the Netherlands) universal coverage through public funding has increased. The question is, however, given the projections on the unstoppable rising costs of healthcare and increasingly tight budgets, whether public funding can continue to be the main source of coverage of healthcare. To this more structural situation one should also add a more contingent consideration: given the current socioeconomic climate of crisis expected to stay with us for some time is a reduction in universal coverage and/or in the quality of delivered care politically viable?

Figure 7 Total public coverage, percentage of total population, 1970 to 2005

	1970	1980	1990	2000	2005
Australia	85.0	100.0	100.0	100.0	100.0
Austria	91.0	99.0	99.0	99.0	98.0
Belgium	97.8	99.0	97.3	99.0	99.0
Canada	100.0	100.0	100.0	100.0	100.0
Czech Republic	100.0	100.0	100.0	100.0	100.0
Denmark	100.0	100.0	100.0	100.0	100.0
Finland	100.0	100.0	100.0	100.0	100.0
France	95.6	99.1	99.4	99.9	99.9
Germany	89.2	92.3	88.8	90.7	89.6
Greece	55.0	88.0	100.0	100.0	100.0 *2004*
Hungary	..	100.0	100.0	100.0	100.0
Iceland	100.0	100.0	100.0	100.0	100.0
Ireland	85.0	100.0	100.0	100.0	100.0
Italy	93.0	100.0	100.0	100.0	100.0
Japan	100.0	100.0	100.0	100.0	100.0
Korea	..	29.8	100.0	100.0	100.0
Luxembourg	99.6	99.8	98.8 *1993*	98.2	99.7 *2004*
Mexico	..	..	..	51.0 *2002*	50.4
Netherlands	69.0	68.3	61.4	64.5	62.1
New Zealand	100.0	100.0	100.0	100.0	100.0
Norway	100.0	100.0	100.0	100.0	100.0
Poland	..	..	..	..	97.3
Portugal	40.0	100.0	100.0	100.0	100.0
Slovak Republic	..	..	..	98.8	97.6
Spain	61.0	83.0	98.1 *1991*	98.9 *2001*	99.5 *2003*
Sweden	100.0	100.0	100.0	100.0	100.0
Switzerland	89.0	96.5	99.5	100.0	100.0
Turkey	26.9	38.4	55.1	66.0 *1997*	67.2 *2003*
United Kingdom	100.0	100.0	100.0	100.0	100.0
United States	..	..	24.5	24.7	27.3
Latest average[a]	..	..	..	..	**92.9**
Consistent average (27)[b]	..	..	**93.4**	**94.1**	**94.2**

Source: OECD Health Data 2008, June 2008

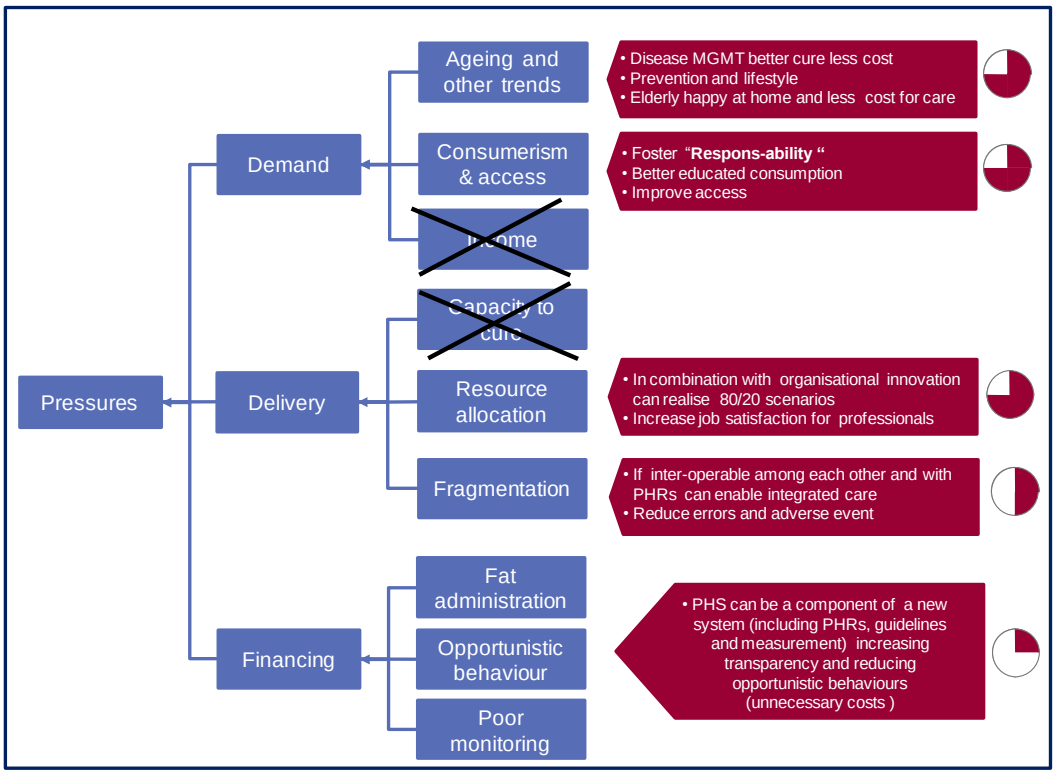
The facts very selectively and briefly reviewed so far unequivocally tell us that we are at a turning point for the sustainability of healthcare in Europe. The systems cannot afford to do "***less"*** and will surely need to do "***more"***, but the resources available are shrinking. The key challenge then is to " ***do more and better with the same or with less***", in other words the formidable task of ***increasing at the same time both effectiveness and efficiency***!

Coping with such challenge require changes and efforts in many directions and fields and it would unrealistic to think that ICT in general and PHS in particular could radically contribute to increase the sustainability of healthcare by themselves. Yet, PHS enabled change can definitely contribute to contain some the pressuring factors. Their potential contribution are summarised in Figure 8 overleaf. It is worth stressing, however, that the content of the figure and the illustrative considerations that follow are hypothetical, under an assumed scenario of the full deployment of PHS enabled delivery of care.

In the figure the two boxes crossed indicate structural trends that cannot be impacted in anyway by PHS (and probably by any other intervention), whereas the Harvey balls at the

right side provide a tentative and qualitative assessment of the potential contribution of PHS.

Figure 8 PHS potential contribution to contain healthcare pressuring trends



Source: Author's elaboration

PHS can contain the effects of ageing (rising in chronic diseases, problems of compliance and long term care, end of extended family) and of other demand related trends (obesity, neuro-psychiatric disorders) in various ways. Personalised monitoring of diseases and related treatment (through the intervention of a professional or directly as automatic actuation), preventive services (lifestyle management, early detection, support to lifestyle and compliance for the chronically ill to prevent worsening conditions), independent living solutions for the elderly, all of this can improve the quality of care and reduce costs. By focusing on preventive lifestyle, PHS can contribute to delaying the time when a disease becomes seriously chronic or avoid its emergence altogether. Thus, it can help reduce the burden on hospitalisation, and facilitate early diagnosis, and thereby improving the chances of healing and decreasing the need for treatment. It can enable remote management and self-management of (chronic) diseases, improving the level of cure and reducing the burden on healthcare providers. PHS includes also applications that could substantially help the elderly comply with prescribed medication and avoid involuntary misuse. PHS can also provide innovative ways to manage and cure neuro-psychiatric disorders.

Through continuous, more personalised care solutions based on better information, dynamic interaction and human friendly interfaces, PHS contribute to empower citizens

and increase access. They provide personalised information at the moment and point of need. PHS applications respond to the increasing demand for self-care and wellness and can improve access, both reducing waiting times and the need for transportation. They also help patients make more appropriate choices with regard to the consumption of healthcare/health products and, thus, increase the quality of their self-care (this can also contribute to avoid cost inflation). There could be impacts also for the health system as a whole and particularly for the public budget and other third party payers (as long as more empowered and better informed citizens avoid unnecessary consumption).

PHS applications, if part of disruptive innovations entailing substantial re-organisation and institutional change, can bring about cost-effective ways of dealing with very large segments of the potential patient population when their needs are less demanding and acute. At the same time, in this way they could reduce the workloads of face-to-face consultation with general practitioners, use of ambulatory services, and hospitalisation. This could also improve the job satisfaction of healthcare professions who, if relieved from more routine tasks to be handled automatically by some PHS applications, could have more quality time for more complex activities and for better face-to-face interaction with patients/citizens in those specific circumstances requiring such form of interaction. The potential impact of PHS in this respect could be high and two-fold, as they could act both as the source of important efficiency gains and cost savings and as a drive of increased job satisfaction.

The holistic vision behind PHS is exactly one to reduce fragmentation and foster integration and exchanges across the tiers of the healthcare systems and across specialisations. Their potential contribution in this respect is high if they are inter-operable among each other across tiers of the healthcare systems (primary, secondary, tertiary, in other words PHS as an instrument of integrated care delivery) and with Personal Health Records (PHRs) system. Under these conditions, they can reduce the problems caused by fragmentation in the delivery of care by: a) placing the individual patient/citizen at the centre of the healthcare delivery process, including a patient-centred approach to data-gathering and data-mining, thus increasing the quality of care and the level of customer satisfaction; b) connecting several stakeholders in the system (patients, primary care providers, ambulatory services, hospitals, etc.) and enabling better and quicker transfer of knowledge from the different layers of care provision, reducing duplication of efforts and, thus, decreasing the costs and improving the productivity of healthcare systems.

An optimised and distributed use of information can indirectly curb the opportunistic or misinformed behaviours that cause costs inflation. On the one hand, information provided through specific PHS applications (such as monitoring systems) can educate patients with regard to appropriate consumption. On the other hand, when PHS are the component of an integrated monitoring system (including prescriptions guidelines, as well as PHRs and ePrescriptions components), by making the same data available to different healthcare providers, it could make it more difficult for them to engage in “moral hazard” through over-prescribing medicines or medical treatments.

Finally in reducing ***Fat Administration*** PHS can have an ancillary role to support an integrated system resting on inter-operable ePrescriptions and PHRs components**.**

In brief PHS could produce benefits for all:

- Health conscious individuals who wish to stay fit
- Healthy individuals at risk who wish to maintain normal health status
- Chronically ill patients
- Elderly persons or people in need, who want to live independently outside care institutions
- Health professionals (support by provision of monitoring and diagnostic data and assistance in making accurate decisions)

And their potential end outcomes include:

- Reduced in-patient costs (i.e. due to delay of the time between when a disease becomes complex and chronic and the end of life or to the elimination altogether of the development of pre-morbid conditions into a full-blown disease);
- Decreased diagnostic and treatment costs as less laboratory tests and visits to hospital will be needed as a result of both preventive monitoring and chronic disease management;
- Increased health practitioners productivity (i.e. reduced patient unit cost for GPs through remote monitoring and self care);

As stated, all of these promises can be realised if full deployment of PHS enabled delivery of care occur. Between the situation today and the full realisation of these promises there are still gaps and barriers of various nature to be filled and overcome, which leads us to discuss the scope of this book, its methodology, and the results delivered.

1.3 Scope and methodology

The scope of the roadmap was defined during the first of the 10 experts and stakeholders consultation meetings, which represent one important component of the empirical basis of this book. In that occasion it was discussed which should be the main focus structuring the state of play and, consequently, the following methodological steps. While the discussion was more nuanced and complex, in simple terms the alternatives considered as structuring the scope were:

- Technology supported applications;
- user needs;
- Adoption/ implementation issues;
- Services/business models;

At the end of the discussion the consensus emerged that the scope was to be ***primarily on the technological dimension*** with the objective of "thinking out of the box" in terms of the kind of possible future technologically supported innovative applications/services in the area of PHS, regardless of the currently existing challenges. It was also agreed that the residual dimensions broadly falling within what can be considered ***environmental conditions*** and concerning issues of implementation and deployment were to serve only as ***context*** and as a ***secondary priority*** of the roadmap. Indeed, this choice reflects the fact that main aim was to produce a roadmap for future research to be funded under the

Framework Programme mechanism, whereas the implementation/deployment issues are the object of other supporting instruments (i.e. pilot under the new Competitiveness and Innovation Programme, or traditional tendered socio-economic studies). Yet, it is probably pleonastic to stress that technological research alone cannot solve some of the existing problems hampering the full deployment of PHS. Just to mention the clearest instance: no technological solution, no matter how revolutionary and sophisticated, can by itself overcome the lack of adequate incentives and of sustainable cost and business models, which are among the most stringent bottlenecks slowing down the deployment of PHS. As a matter of fact, once the consultation process started all the experts regardless of their background (healthcare professionals, ICT industry, and research) brought back the importance of the non technological dimensions. PHS, in fact, are part of a complex socio-technical system[19] and, thus, their successful development is highly interrelated with broader social, economic, and political-institutional dimensions. Accordingly, while maintaining technology as the primary drive of our scope, the broadly defined environmental conditions and the associated implementation/deployment issues have enriched our approach.

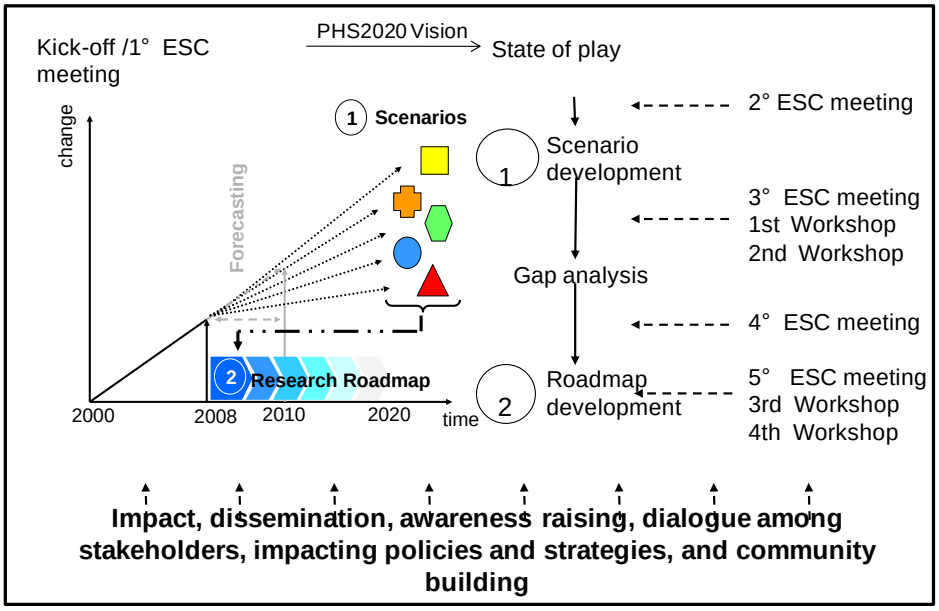
The overall methodology with its articulated set of tools is illustrated in the annex to this book (**§ 7**). Below we very briefly limit the exposition of the methodology to those element that are strictly instrumental for the reading the following chapters, so that the reader can understand the logic without need to read the annex if not interested in it. Before doing this, however, we must clearly acknowledge our debt to another roadmapping project funded by the Commission under FP6. Our overall approach results from the re-elaboration and adaptation to the context of PHS of the methodology developed and successfully applied in the FP6 project eGovRTD2020 in the roadmapping of future research for eGovernment (Codagnone and Wimmer, eds., 2007)[20] and in several other publications resulting from this project (among others see Wimmer, Codagnone and Janssen, 2007; Wimmer, Codagnone and Xiaofeng 2007). On the other hand, we departed from eGovRTD2020 in two ways. First, we developed a different and ad hoc approach to the state of play. Second, our consultation process innovated by establishing the standing ESC cited earlier

[19] On the concept of socio-technical systems see classical analysis such as Forrester (1961), Thompson (1967) and Trist (1981). In brief a socio-technical system in one where: a) to some extent the factors within each dimension affect one another, resulting in different directions for development or different areas of emphasis within the larger idea they represent and b) the non technical (broadly conveyed by the adjective 'social') and the technical elements are continually evolving on their own while continuously interacting with each other in ways that cannot be overtly controlled

[20] See in particular within the final eGovRTD2020 book : a) for the general approach to roadmapping within a foresight perspective in a policy context see par 2.4 by Codagnone, for its operationalisation see par. 2.8 by Ma and Wimmer, and for its application see chapter 6 also by Ma and Wimmer ; b) for the scenario building methodology see par. 2.6 by Janssen *et al* and for its application chapter 4 also by Janssen *et al*; c) for the gap analysis general methodology see par. 2.7 by Pucihar *et al* and for its application chapter 5 also by Pucihar *et al*.

Our methodology rests on a policy oriented and holistic approach to roadmapping including scenarios building and, thus, inscribed within foresight thinking as opposed to more normative and prescriptive roadmapping (see §7.1). Very succinctly the work was carried out following the overall logic and architecture illustrated in Figure 9 and commented below.

Figure 9 Methodology snapshot



Source: Adapted from Codagnone and Wimmer (2007, p. 5)

1. The **state of play** establishing the baseline and providing the basis to extract the trends upon which the scenarios have been developed (see § 7.3 and particularly see § 7.3.2);
2. The **development of scenarios** by extracting possible future trends from the state of play and then selecting the most impactful and uncertain ones to identify the two key dimensions of uncertainty along which alternative and possible contrasting future could be envisaged (see § 7.4 but also § 7.3.3);
3. Comparison of the state of play with the four scenarios and identification of current **gaps** that need to be filled in order to favour the desirable elements of the scenarios and to counter and/or contain the undesirable ones (see § 7.5);
4. Assessment and prioritisation of gaps in terms of relevance and their associations to the actions needed in terms of research themes to be financed in the future representing the **final roadmaps** for PHS from 2011 and up to 2020 (see § 7.5).

One of the key implementation choices within a roadmapping methodology is that of defining the mix between meta-analysis of secondary sources and experts and stakeholders consultation activities, which can range from relying mostly on secondary sources with very limited consultation to limited analysis and a very extensive

consultation process. Our approach is positioned in between these two extremes adopting what we deemed a **multi-tier approach**, which ensured appropriate mix between meta-analysis and consultation of experts and stakeholders.

A standing Expert Support Committee met 5 times throughout the duration of the research work and its members constantly evaluated, commented and validated the findings that are presented in the four core chapters of this book: chapter 2 on the state of play, chapter 3 on future scenarios, chapter four on gaps and proposed roadmaps for future research, and chapter 5 on implementation and socio-economic issues. In addition, these findings went through other 5 open consultation events involving more than 100 between experts and stakeholders from across Europe. So, each chapter is the result a four stage iteration process: a) first draft version submitted to ESC; b) second draft version submitted to experts and stakeholders during open workshops; 3) third draft evaluated by the reviewers; 4) final draft presented in this book.

Finally, two additional conceptual tools are important to briefly illustrate here as they have structured the state of play, scenarios building and gaps analysis and are, thus, instrumental for a correct reading of the next three chapters. ***The State of Play Model"(SoPM)***, based on a multi-attributes approach (Duin, 2006) [21], decomposed the identified market products and research projects into three main building blocks, as illustrated in the figure overleaf (exemplificative and focussing on chronic disease management, but other were used for other applications as it will be shown in chapter 2). The three building blocks are:

1. The areas of applications;
2. The technological sub-systems;
3. The technological components (basically sensors and/or lab on chip)

In applying the SoPM we considered separately[22] and subsequently compared in terms of the frontiers of innovation and sophistication: a) the PHS products/services currently available in the market[23] and to some extent deployed in the delivery of care; and b) the applications developed or being developed by technological research especially within

[21] For a full illustration of this model, besides § 7.3.2 in the methodological annex, see PHS2020 Deliverable D2.1, *State of Play* (*pp*. 18-23, and 79-283 for its application to all the gathered empirical evidence).

[22] On these distinctions and the corresponding sources of the state of play see PHS2020 Deliverable D2.1, *State of Play*, § 1.4 and Annex VI for the application of the SoPM to all products and projects considered.

[23] For the overview and list of the products considered see PHS2020 Deliverable D2.1, *State of Play*, respectively, Annex I and Annex IV.

the Commission FP5, FP6 and FP7[24] but also considering selected national level initiatives[25].

Figure 10 State of Play Model Structure (exemplification)

Chronic Disease Management		Attributes	C1	C2	C3	C4	C5	C6	C7	C8
			Classes							
Application/services	Chronic Disease Management	Clinical focus	cardiovascular diseases	Diabetes	Respiratory diseases	renal insufficiency	neurological diseases	Cancer	Autoimmune diseases: neurodegenerative disorders	Autoimmune diseases: others (specify)
		How is the service provided?	Pushed by: hospital	Pushed by: call centre	Pushed by: other third parties	Pushed by: PoC	Fully led by patient			
		Cost model	out of pocket	third party payer	mixed					
Sub-system	Data Acquisition	Position	stationary	portable	wearable	implantable				
		Scope	single	multiple						
		Embedding other sub-systems?	Non embedding	Partially embedding	Fully embedding					
	Data processing and analysis	Degree of intelligence	low	medium	full	full and self-adaptive				
		Health professional intervention	mandatory	recommended	ad hoc	not needed				
	Data Communication	Type of connectivity	wired	wireless	wireless BAN	wireless BAN+PAN	wireless BAN+PAN+LAN	wireless BAN+PAN+WAN		
		Type of communication flows	mono-directional	bi-directional						
Component	Sensor Device	Position	stationary	portable	wearable	implantable				
		Invasiveness	Low/null	medium	High					
		Level of Comfort	Low/null	medium	High					
		Type of sensor	non organic	organic	biological	molecular				
		Interactivity Level	passive	semi-active	active (SIP)	active (SoC)				
		Signs per Sensor	single	multiple						
		Scope of data gathering	Vital signs	Physical activity	Context awareness	Social parameters	Mental/emotional parameters			
	Lab on chip	Material	Silicon	Plastic	Nano-motor					
		Sample Preparation	non embedded	embedded						
		Target Detection	mono-target	multi-target, low	multi-target, high					

Source: Author's elaboration

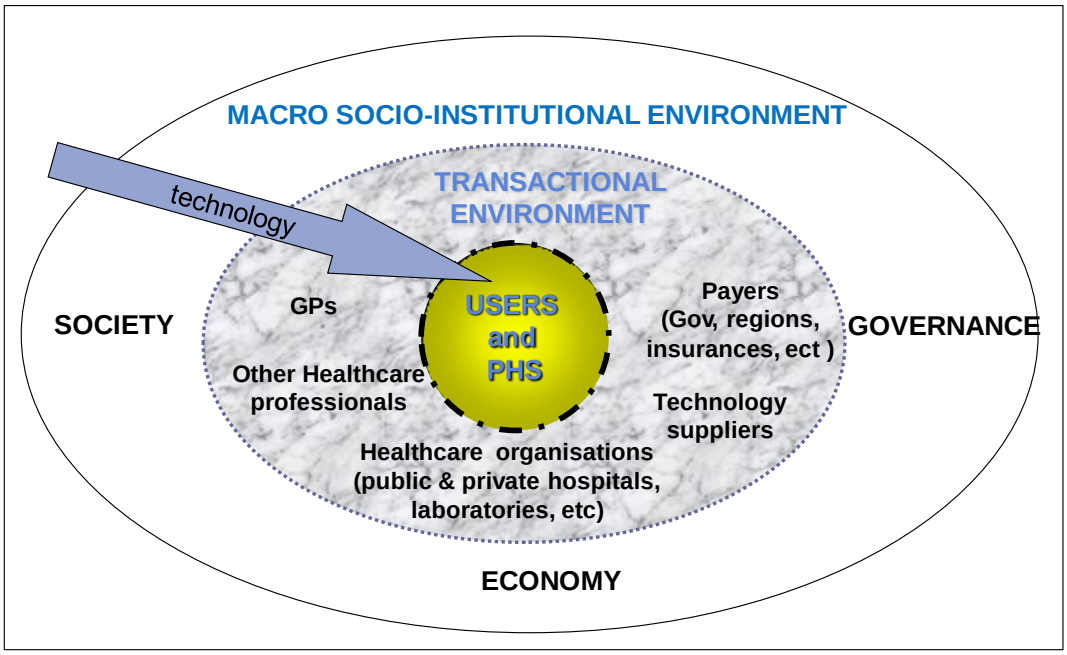
[24] For the overview and list of the research projects considered see PHS2020 Deliverable D2.1, *State of Play*, respectively, Annex III and Annex V

[25] See overview in PHS2020 Deliverable D2.1, *State of Play*, Annex II.

For both market and research we considered three main areas of application: a) chronic disease management; b) lifestyle management; c) independent living[26]. The dimensions and attributes of our **SoPM,** against which current product/services available in the market and research projects have been evaluated, entail a progression from less to more sophisticated/advanced solutions helping defining where we are and where the trends are going and especially the current "frontier" in each of the two domain (market and research) for each of the three areas of application (chronic disease management, lifestyle management, independent living).

Developing the views shaped within the discussion with ESC members we conceived of PHS as a complex socio-technical system, and extracted the General Descriptive Framework (GDF) illustrated in Figure 11 below[27].

Figure 11 PHS2020 general descriptive framework



Source: Author's elaboration

This framework has guided the identification of the non technological trends needed for the scenario building process and structured the also the identification of gaps.

In view of the discussion above it is clear the outcome of PHS2020 has been two-fold:

- The ***primary outcome*** are five ***roadmaps*** proposing research themes for future PHS research in distinct but clearly inter-linked domains, which are presented in ***Chapter 4***;

[26] For the rational and definition of these three areas see 7.3.2.

[27] For a full discussion of this framework, besides § 7.3.3 in the methodological annex, see PHS2020 Deliverable D3.1, *Consolidated Scenario Report*, pp. 16-20.

- The ***secondary outcome*** is a discussion of ***implementation/deployment*** challenges related to broadly defined environmental conditions, which are illustrated in ***Chapter 5***.

These two core chapters are preceded by ***Chapter 2*** on the state of play and by ***Chapter 3*** on the future scenarios. Finally, ***Chapter 6*** contains some conclusive considerations and recommendations.

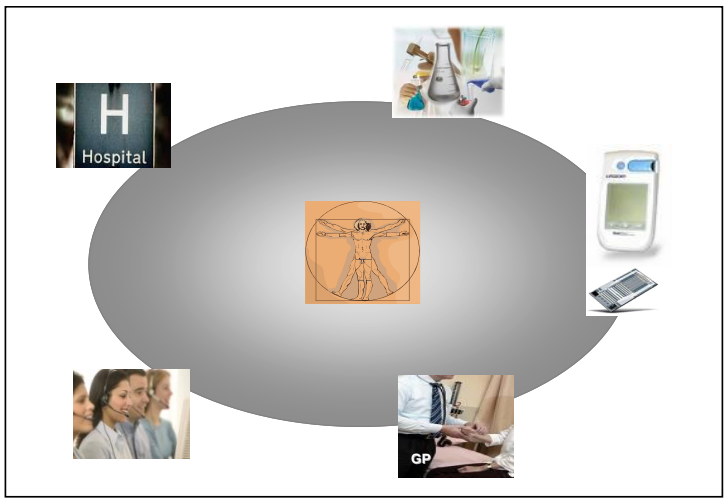
2 State of play: technological developments

In this chapter we first illustrate the different service provision models identified considering both the market and the research domain together (§ 2.1), and we then overview comparatively the key findings of the application of the SoPM to the empirical material gathered and analysed for both the market and research state of the art in § 2.2. Reading this paragraph will suffice to have a general grasp of the state of the art and to proceed further directly to the following chapters. In § 2.3, however, the interested reader will find a still synthetic but more detailed account of the state of development of PHS research[28].

2.1 Service provision models

In Figure 12 the main player relevant for the provision of PHS enabled care are sketched, such as Hospitals, Labs, General Practitioners (GPs); Heath Care Authority, Point of Care, and increasingly call centres run by healthcare organisations or by third parties .

Figure 12: Main actors in health care delivery



Source: Author's elaboration

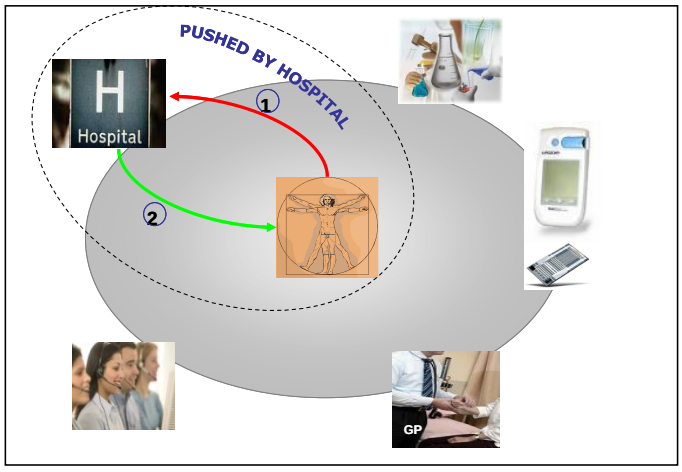
Depending on which of these players takes the ownership of the service delivery process the following possible delivery models were identified:

[28] This still contains only a small fraction of the sheer material presented in the 283 pages of the state of play deliverable, to which we refer the readers desiring to have the full detailed picture In PHS2020 Deliverable D2.1, *State of Play*, the interested reader can find: a) the overall methodological discussion in Chapter 1; b) A longer version of the commented overview in chapter 2; c) a discussion of environmental conditions as barriers in chapter 3; d) The overview and list of the products considered for the market, respectively, in Annex I and Annex IV; e) an overview of national level of research initiatives and projects in Annex II f) The overview and list of the FP5, FP6 and FP7 research projects considered, respectively, in Annex III and Annex V; g) the application of the SoPM and the construction of the innovation frontiers in Annex VI; h) a glossary of terms in Annex VII.

- Model 1: pushed by hospital;
- Model 2: pushed by call centre and/or third parties;
- Model 3: pushed by Point of Care;
- Model 4: led by patient.

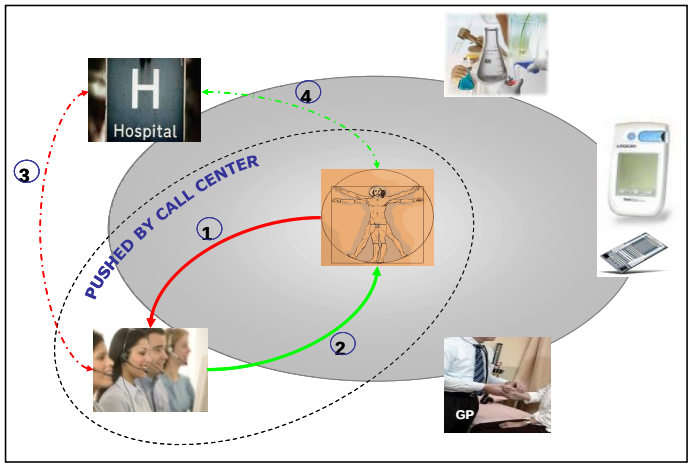
All these models have the dual purpose to reduce hospitalization and related costs, and, at the same time, to increase the quality of care delivery for individual by customizing his/her personal needs. Although, as we anticipated in providing their definition, the vision behind PHS is of increasingly moving toward Model 4. The evidence gathered shows that the more consolidated are Model 1 and Model 2 while those only emerging are Model 3 and Model 4.

Figure 13: Service provision pushed by: Hospital



Source: Author's elaboration

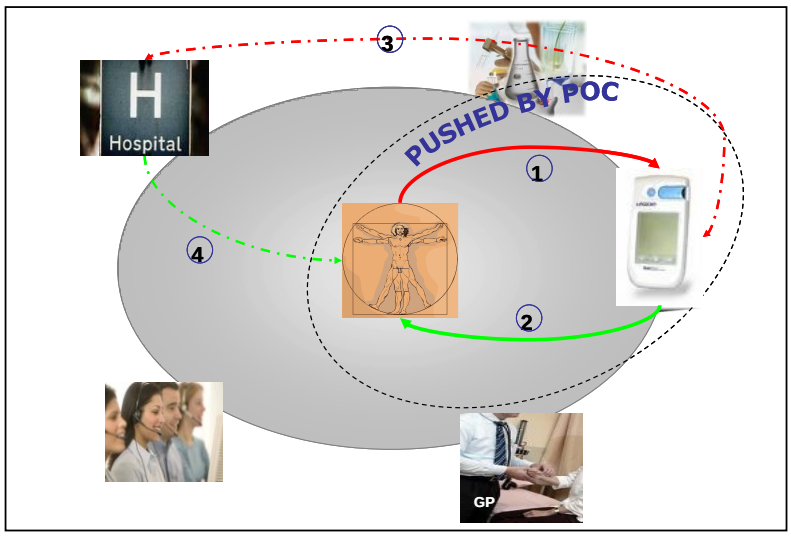
Figure 14: Service provision pushed by: Call Centres[29]



Source: Author's elaboration

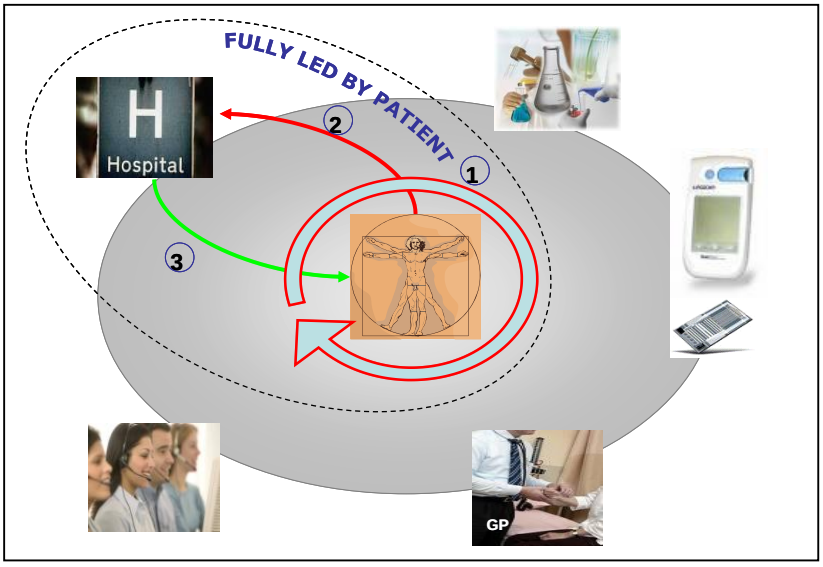
[29] Operated by third parties external to the institutional borders of the healthcare system.

Figure 15: Service provision pushed by: Point of Care



Source: Author's elaboration

Figure 16: Service organization: fully led by patient



Source: Author's elaboration

In Model 1 Hospitals take the lead and the level of technology available at the patient site helps in providing anytime and anywhere information useful for both monitoring, early diagnosis and preventive treatments, avoiding any unnecessary hospitalization and visit. It is a model more suitable for chronic disease management than for lifestyle management or independent living.

In Model 2 call centres act as an intermediary between hospital/heath care professional and patients. However, even if the interaction among each patient and the hospital is intermediated by call centre, in specific relevant situations a direct intervention of

healthcare professionals can be foreseen. Many of the solutions available today on the market follow this model and call centre service are used by the patients as a complement to the regular healthcare services.

Model 3 it is an innovative but just emerging service model. It will become possible only when Point-of-Care (henceforth PoC) is really powered by innovative technological solution (especially for early diagnosis) and fully embedded by services ranging from the usual laboratory exams to traditional GPs delivery ones. In this model PoC has the possibility to deliver early diagnosis by means of evolutionary lab on chip helpful for genetic screening. Evidently this model is relevant only for the early diagnosis and prevention component of the "lifestyle management" area: early diagnosis and preventive screenings are very useful for personalizing any treatments.

Model 4 represents the most evolutionary one. In this service organisation model, the ownership of the care service is fully taken by the individual and the focus is on empowerment. This model is potentially fit for any of the stages of an individual's care cycle, since a healthy person requires preventive and early diagnosis services, while an aging one looks for an independent living, passing through a personalized chronic disease management. Under this model, the technological developments help each person to manage health information by his/her own, minimizing any interaction with other health care actors. Only the hospital personnel can be considered as a source of support in particular in case of chronic disease management, where interaction between patient and doctor is more frequent. Solutions fully led by the patients are the overwhelming majority of those developed by research projects, under all of the three Framework Programmes considered (FP5, FP6 and FP7), and for all the three areas or application identified (chronic disease management, lifestyle management and independent living). In the market, on the contrary, these kinds of solutions have not been implemented. This model, however, can be considered as a target to be reached for it achieves at the same time the goal of empowering users and of reducing workload and costs, provided that the quality and safety of care is preserved.

One of the reasons why this more innovative model still remains only at the level of research potentials is precisely that more need to be done to "infuse medicine into technology" in order to provide 100% safety and win the scepticism of many healthcare professionals. More in general for all of the four models it is not yet clear what can be the reimbursement model, which is another very constraining bottleneck for their full adoption. Research projects, though usually they have a business model work package dealing with the cost model, cannot be taken as indicative of what cost model will make them work (Hoeksma, 2008). We will come back to this topic in **Chapter 5**.

2.2 General overview

Before starting to summarise the findings, it is important to clarify that when we use the expression "market situation" we refer both to the supply and to the demand, namely both to which products are currently sold by technology vendors and to which are used by Healthcare organisations or by other players delivering care services[30].

The overview of the market situation we present below is based on the relevant insights and data obtained from Gartner Research, consultations with Gartner analysts and screening of a list of relevant vendors also provided by Gartner[31]. These sources have been then integrated with input from some of the presentations delivered during the "Personal Health Systems Workshop – Market perspectives & innovation dynamics" organised in Brussels by the EC Join-Research Centre IPTS (Institute for Prospective Technological Studies) on February 6 2009[32].

The taxonomy Gartner uses to quantify ICT spending in the healthcare sector does not allow us to produce exact numbers as to the current market value of PHS in either the USA or Western Europe. On the other hand, on the basis of qualitative insights and research papers Gartner estimates that in the US and Western Europe the products/services falling within our definition of PHS (home monitoring, personal health management tools, patient decision aids) have a market penetration of less of 1% (that is of all the potential healthcare organisations customers) and an estimated time to mainstream adoption of between 10 and 15 years (Gartner 2007 and 2008a). According to Gartner, within the broader telemedicine field only tele-radiology represents today an almost mainstreamed application. The market data presented at the cited IPTS event and mostly originating from another market research company (Frost& Sullivan) estimates the current market value of the all field of telemedicine and mobile health together in Europe at 1.6 billion € (with cardiology taking 70% of the total) and that of Personal Remote Monitoring PRM) only at between 1% and 2% of the total healthcare expenditure (but other figures are even lower estimating a value for PRM in 2008 in Europe at only 200 million €)[33]. Leaving aside the details of these estimates (naturally to be taken for

[30] For what concerns the market, a delimitation of the field was applied in order not to waste time and resources and to get real valuable and useful information: we did not to consider services offered in the market that are based on simple applications and tools (i.e. pedometers or scales), as they are not full blown systems connected to ICT environments (only stand-alone devices). This same delimitation, however, applied also to more sophisticated and complex medical devices (i.e. a pace-maker) as long as they are stand alone and not part of an holistic ICT embedded system (data acquisition, processing and communication).

[31] This premium data and evidence, not publicly available, were provided by Gartner as sub-contractor of MIP in the FP7 Project PHS2020.

[32] The workshop report and the presentations delivered can be accessed at http://is.jrc.ec.europa.eu/pages/TFS/sps.html

[33] See data reported in Jeroen Walls's (Philips Research) presentation "Personal Health Systems: what kind of market is this?(http://is.jrc.ec.europa.eu/pages/TFS/documents/3WalsPhilipsSIMPHS090206.pdf) and in

what they are), ***what is relevant is that the different sources cited (Gartner and Frost & Sullivan) converge in the order of magnitude: PHS penetration is very small and is still a niche market***.

Moving to analyse the positioning of market products with respect to the various attributes and classes of the **SoPM** (Figure 10, p. 24) we can briefly comment the ***enveloped frontiers***[34]reported in the next three pages, which also enable a comparison with the research situation. For a correct reading it is worth stressing here that these frontiers do not reflect the average development but rather up to where considering the products/projects collectively the market or research state of the art have reached. This means, however, that having reached a point on the frontiers does entail that this is representative of the overall situation on average.

The overwhelming focus of products and services available in the market is on monitoring cardiovascular diseases (followed by diabetes and respiratory disease) and on some very basic lifestyle services provided in the same way as other consumer electronics product (by third parties and with little involvement of healthcare players). No proven solution for prevention and early diagnosis has still reached the market.

Rainer Herzog's (Ericsson CEMA) presentation "Personal Health Systems: Towards new business models (http://is.jrc.ec.europa.eu/pages/TFS/documents/4HerzogEricssonSIMPHS090206.pdf).

[34] See explanation of the concept and methodology in methodological annex (p. 209). The full process is illustrated in PHS2020 Deliverable D2.1, State of Play, Annex VI.

Figure 17 PHS Enveloped Frontiers: Chronic Disease Management

		Attributes	C1	C2	C3	C4	C5	C6	C7	C8
Application/services	Chronic Disease Management	*Clinical focus*	cardiovascular diseases	Diabetes	Respiratory diseases	neurological diseases	Renal insufficiency	Cancer	Autoimmune diseases: neurodegenerative disorders	Autoimmune diseases: others (specify)
		How is the service provided?	Pushed by: hospital	Pushed by: call centre	Pushed by: other third parties	Pushed by: PoC	Fully led by patient			
		Cost model	out of pocket	third party payer	mixed					
Sub-system	Data Acquisition	*Position*	stationary	portable	wearable	implantable				
		Scope	single	multiple						
		Embedding other sub-systems?	Non embedding	Partially embedding	Fully embedding					
	Data processing and analysis	*Degree of intelligence*	low	medium	full	full and self-adaptive				
		Health professional Intervention	mandatory	recommended	ad hoc	not needed				
	Data Communication	*Type of connectivity*	wired	wireless	wireless BAN	wireless BAN+PAN	wireless BAN+PAN+LAN	wireless BAN+PAN+WAN		
		Type of communication flows	mono-directional	bi-directional						
Component	Sensor Device	*Position*	stationary	portable	wearable	implantable				
		Invasiveness	Low/null	medium	High					
		Level of Comfort	Low/null	medium	High					
		Type of sensor	non organic	organic	biological	molecular				
		Interactivity Level	passive	semi-active	active (SiP)	active (SoC)				
		Signs per Sensor	single	multiple						
		Scope of data gathering	Vital signs	Physical activity	Context awareness	Social parameters	Mental/emotional parameters			
	Lab on chip	*Material*	Silicon	Plastic	Nano-motor					
		Sample Preparation	non embedded	embedded						
		Target Detection	mono-target	multi-target, low	multi-target, high					

applications/services/products available on the market

applications/services developed by research projects

Source: Author's elaboration of data gathered

Figure 18 PHS Enveloped Frontiers: Lifestyle Management

		Attributes	C1	C2	C3	C4	C5	C6
Application/services	Life style management	*Clinical focus*	Prevention and early diagnosis	Well-being and fitness monitoring and support				
		How is the service provided?	Pushed by: hospital	Pushed by: call centre	Pushed by: other third parties	Pushed by: PoC	Fully led by patient	
		Cost model	out of pocket	third party payer	mixed			
Sub-system	Data Acquisition	*Position*	stationary	portable	wearable	implantable		
		Scope	single	multiple				
		Embedding other sub-systems?	Non embedding	Partially embedding	Fully embedding			
	Data Storage and Processing/analysis	*Degree of intelligence*	low	medium	full	full and self-adaptive		
		Health professional Intervention	mandatory	recommended	ad hoc	not needed		
	Data Communication	*Connectivity Type*	wired	wireless	wireless BAN	wireless BAN+PAN	wireless BAN+PAN+LAN	wireless BAN+PAN+WAN
		Type of Communication	mono-directional	bi-directional				
Component	Sensor Device	*Position*	stationary	portable	wearable	implantable		
		Invasiveness	Low/null	medium	High			
		Level of Comfort	Low/null	medium	High			
		Type of sensor	non organic	organic	biological	molecular		
		Interactivity Level	passive	semi-active	active (SiP)	active (SoC)		
		Signs per Sensor	single	multiple				
		Scope of data gathering	Vital signs	Physical activity	Context awareness	Social parameters	Mental/emotional parameters	
	Lab on chip	*Material*	Silicon	Plastic	Nano-motor			
		Sample Preparation	non embedded	embedded				
		Target Detection	mono-target	multi-target, low	multi-target, high			

applications/services/products available on the market

applications/services developed by research projects

applications/services developed by research projects (Point-of-Care applications)

Source: Author's elaboration of data gathered

Figure 19 PHS Enveloped Frontiers: Independent Living

		Attributes	C1	C2	C3	C4	C5	C6
Application/services	Independent living	*Clinical focus*	Care support	Localisation				
		How is the service provided?	Pushed by: hospital	Pushed by: call centre	Pushed by: other third parties	Pushed by: PoC	Fully led by patient	
		Cost model	out of pocket	third party payer	mixed			
Sub-system	Data Acquisition	*Position*	stationary	portable	wearable	implantable		
		Scope	single	multiple				
		Embedding other sub-systems?	Non embedding	Partially embedding	Fully embedding			
	Data Storage and Processing/analysis	*Degree of intelligence*	low	medium	full	full and self-adaptive		
		Health professional Intervention	mandatory	recommended	ad hoc	not needed		
	Data Communication	*Connectivity Type*	wired	wireless	wireless BAN	wireless BAN+PAN	wireless BAN+PAN+LAN	wireless BAN+PAN+WAN
		Type of Communication	mono-directional	bi-directional				
Component	Sensor Device	*Position*	stationary	portable	wearable	implantable		
		Invasiveness	Low/null	medium	High			
		Level of Comfort	Low/null	medium	High			
		Type of sensor	non organic	organic	biological	molecular		
		Interactivity Level	passive	semi-active	active (SiP)	active (SoC)		
		Signs per Sensor	single	multiple				
		Scope of data gathering	Vital signs	Physical activity	Context awareness	Social parameters	Mental/emotional parameters	
	Lab on chip	*Material*	Silicon	Plastic	Nano-motor			
		Sample Preparation	non embedded	embedded				
		Target Detection	mono-target	multi-target, low	multi-target, high			

applications/services/products available on the market

applications/services developed by research projects

Source: Author's elaboration of data gathered

They overwhelmingly focus on monitoring cardiovascular diseases and on some very basic lifestyle services provided in the same way as other consumer electronics product (by third parties and with little involvement of healthcare players). Compared to chronic disease management (where marketable solutions are clearly present and a consolidated tough small market exists), in the area we termed in general lifestyle management (but reflect more generally all ICT application for preventive health) there seems to be much less viable and proven solutions already reaching the market.

Almost all the **data acquisition sub-systems** available in the market are stationary and portable and the same applies to **sensor devices,** with the only exception of implantable sensors for drug pumps. There are, however, some solutions that combine several stationary instruments and signals to a hub as e.g. Doc@Home, Telestation, and Viterion[35]. There are also some portable solutions, like in the case of GlucoPack for diabetes disease management. Solutions for **independent living** available on the market rely on portable data acquisition sub-system. This is the case of the GeoSkeeper solution, where a wrist-worn device for people localisation has been developed. Moreover, if we look at the **sensor technology** itself we can see how until now all these technology are mainly passive , single use and just for monitoring vital signs, with few exceptions, mostly in the areas of lifestyle management and independent living. Among the execptions we can quote Doc@Home as a multi-disease solution, for cardiovascular diseases and diabetes. Currently these sensors characteristics, as well as the ones of the **data acquisition subsystems,** require more intelligence off line (not embedded in the application) and the intervention of someone to actually provide a services, such as a health care professional of a call centre operator of both. We found only anecdotal evidence of products/services sold in the market that are based on more advanced solutions such as implants and actuators (sensors that gather and process data and lead to an action). Mostly, the signal is processed through a hub like in the case of e.g. Homeclinq. This consideration is valid for **chronic disease management**, as well as for **independent living** services. Among the cases where devices offer individual intelligent feedback and education concerning the patient condition, there are Telestation and Viterion. However, these data are elaborated on an external device, and then sent back to the patient device. This is the situation for both products addressing **chronic disease management,** as well as **independent living.**

The applications currently sold and bought in the market, thus, appear as basic and not very advanced in comparative terms with respect to the frontier of technological sophistication reached by research projects. Evidently the little market penetration of PHS and the sophistication gap existing between the market and the research frontiers strongly suggest the existence of very constraining environmental factors hampering adoption of these services/products. This distance, in fact, can be interpreted as indicative of very high barriers to the full deployment of PHS solutions: if research has reached a

[35] In the following acronym of market products and research projects funded under FP5, FP6, and FP7 are used. Full description of each project can be found in PHS2020 Deliverable D2.1, *State of Play* (in Annex II, Annex III, Annex IV and Annex V).

fairly high level of sophistication that is not transferred onto the market, then there must be very constraining factors at work preventing the enactment in practice of more innovative solutions. Alternatively the explanation would have to be that research funding is going into directions that are too removed from the actual reality of healthcare functioning.

Moving briefly (greater details are provided in next paragraph) to the frontiers of research projects, we can see a clear trend of moving from stationary and portable system toward wearable and implantable resting on sensors that are increasingly efficient and effective: multiple signs data gathering, minimisation of invasiveness (for implantable) and maximisation of comfort (for wearable), embedding some level of data processing and intelligence, and actuation. These are, however, trends at the very frontiers of research and do not represent applications that can be considered representative of the average status of research and that are fully stable and mature.

Projects based on implantable are still rare and have not reached the level of non invasiveness, which is fundamental for users' acceptance (leaving aside the legal issues representing a key bottleneck).

Wearable still have some way to go in the difficult challenge of reducing the area of contact with the body (increasing comfort) while at the same time ensuring reliable data acquisition.

As regard to scope and signs per sensors, within the research projects analysed we can find several solutions with a multi-disease scope, based on many sensors each gathering one sign. Only recently in FP7 we can find example of sensors gathering multiple signs. Moreover, the issue is not only about the number of signs that a sensor can gather but also about the kind of signs. Therefore, much still remain to be done to develop sensors capable not only to capture several signs, but also different kind of signs beyond the vital one (context, emotional/mental state, social state)

Research projects have made noticeable progresses in terms of increasing the level of intelligence embedded into data processing sub-system. Yet, if Personal Health Systems have to develop into Personalised Health Systems more research development is needed to build auto-adaptive and self-calibrating solutions gradually and constantly adapting to each specific individual history, characteristics, mental state and context. This requires the development of sensors reliably gathering environmental and context data, algorithms accurate enough to provide individual targeted services and, last but not least, the steady and continuous infusion of evidence based medicine into PHS: need of integration with clinical evidence and guidelines (which would also help overcome clinicians' scepticism and boost adoption rates).

Though research projects cover more widely the disease spectrum, still the focus is prevalently on the more consolidated diseases (cardiovascular, diabetes, respiratory diseases) and more research is clearly needed to cover new areas and particularly that of neuro-psychiatric disorders.

Finally, much remain to be done to advance research into full actuation and personalised delivery of treatment and drugs.

2.3 More in depth analysis of research state of the art

While for the sake of exposition the three enveloped frontiers have been included in the previous paragraph, they also contain the synthesis of the analysis of the situation at the level of research development and they will be reflected in the analysis that follows in the next sub-paragraphs.

2.3.1 Areas of applications and clinical focus

The importance of better managing chronic disease is evident given the rise in their prevalence (see for instance Adeyi *et al*, 2007; Nolte and McKee 2008; Nolte *et a*l 2008; World Health Organisation, 2005).

There are also many drivers for the saliency of prevention and early diagnosis and of life style management. Prevention and early diagnosis can help reduce the prevalence of, and the costs related to, the development of chronic pathologies (Haskell, 2003; Flemming, 2004; Lindström *et al*, 2008). Support to fitness and well-being helps strengthen citizens' awareness on the importance of maintaining healthy lifestyle in order to avoid the future development of serious diseases and to achieve a status of well-being, which has positive fallouts in their everyday life (Lichtenstein' *et al*, 2006). It also supports citizens' awareness on their primary responsibility for acquiring and maintaining a healthy condition, reducing 'moral hazard' ('they will heal me and the state or insurances will pay') and its impact on health system costs (Mattson-Koggman, *et al*, 2005).

The problems of compliance to medication and lifestyle guidance cut across all the three areas of application and particularly with regard to the elderly. The elderly, in fact, have to take several drugs and/or follow multiple treatments, with a clear risk low compliance with the medical prescriptions (e.g., people forget to take their drugs, or take them at different hours, etc.), resulting in adverse events and further need of treatment and hospitalisation. Poor adherence to medication and lifestyle guidance is a major challenge facing the healthcare community in industrialized countries (Kausnik et al 2008).

On the basis of our analysis we concluded that most widespread applications/services are those focusing on chronic disease management, as compared to lifestyle management and independent living. These applications, in fact, represent about 2/3 of the research projects analysed. Projects focussing on early diagnosis and prevention or on independent living have considerably less covered within EC funded PHS research but are, nonetheless, on the rise.

Within chronic disease management the more recurring focus of FP projects is on cardiovascular diseases, followed by respiratory diseases and diabetes, with other diseases such as, for instance, neuro-psychological disorder receiving far less attention.

Due to the limitations in level of integration of data gathering, processing and communication, but above all to lack of integration between the different tiers of healthcare systems (primary, secondary, tertiary care), the issue of chronic disease co-morbidities is little addressed in either disease management or prevention applications.

Application with a clear and main focus on compliance monitoring and supporting are also rare.

2.3.2 Sub-systems: data acquisition[36]

The characterising attributes of the **SoPM** template for the data acquisition sub-systems are:

- Position;
- Scope;
- Embedding of other subsystems.

2.3.2.1 Position

Position stands for the localisation of the device with respect to the person's body and can take the following values:

- **Stationary**. The data are gathered by static medical devices detached from the person's body that either depend on an external supply of power or are too big to be carried on;
- **Portable**. The data are gathered by devices that are movable and possible to be carried on such as for instance:
  - **Medical devices** (i.e., ECG recorder, transmitter, receiver);
  - **Mobile phones**;
  - **Smart phones** with PC like functionalities.
  - **Devices portable on body parts** (i.e., wrist-worn devices).
  - **Wearable**. The data are gathered through wearable devices in the form of **Smart clothes** (i.e. garments equipped with sensors);
- **Implantable**. The data gathering sub-system is represented by a sensor implanted in the body.

Most solutions developed for **chronic disease management** rely on both portable (e.g. HearthCycle and Adicol, addressing cardiovascular diseases and diabetes respectively) and wearable data acquisition sub-systems (this is the case of Chronius), while stationary solutions are less common and usually older (e.g. Chronic, an FP5 project). In addition, a very few examples of implantable can be found (e.g. SmartPiv). Moving from FP5 to FP7 it is evident the progression from stationary toward small portable and wearable systems.

In the area **lifestyle management** portable solutions are, almost by definition, the most widespread, for they are designed to support citizens in their everyday life. For different reasons also in the case of solutions for early diagnosis designed to be used by the Points of Care, portability can be a relevant factor. Portable devices, in fact, can be easily transported (e.g., among different places of a rural area). This is the characteristic of, for

[36] In the following acronym of research projects funded under FP5, FP6, and FP7 are used. Full description of each project can be found in PHS2020 Deliverable D2.1, *State of Play* (in Annex III and Annex V).

example, Pocemon and SmartHealth, while other solutions (e.g., Microactive) have been designed as stationary.

Finally, solutions for **independent living** are portable, often accompanied and complemented by stationary solutions, as elderly people can have a reduced mobility. Therefore, home-based data acquisition represents a crucial characteristic (see, for example, the K4Care project).

2.3.2.2 Scope

By scope we refer to the number of application/services and/or diseases the data gathering sub-system can address. The value that this attribute can take is either "single" or "multiple".

Research projects addressing **chronic disease management** and relying on the simpler solutions (i.e., single clinical focus, mono-application, mono-vital sign per sensor) are mainly those of FP5, as in the case of Adicol for diabetes. A quite well established solution, especially for treating and monitoring cardiovascular diseases, is the one having a single clinical focus, multiple applications (as several set of data are processed acquired and then processed simultaneously) and one vital sign gathered by each sensor. This is the case, for example, of the HearthCycle and MyHeart projects (FP7 and FP6, respectively).

Finally, the most advanced type of solution is the one addressing two or more diseases, developing multi-applications, and gathering multiple vital signs per sensor, as in the case of the Chronius project (focusing on respiratory diseases and renal insufficiency). This solution is a very recent development, as it has been funded under the Framework Programme 7. In this case, one platform will be developed sharing the same architecture and component (i.e., a smart wearable shirt with embedded sensors), gathering and processing several set of data simultaneously, and gathering many signs per sensor for the two diseases. A graphic illustration is provided by the figure below (the two diseases, and the applications related, are represented with two different colours: orange for respiratory diseases and yellow for renal insufficiency).

Figure 20: Multiple clinical focus, single-applications, and multi-vital sign solution

Clinical focus	cardiovascular diseases	Diabetes	Respiratory diseases	renal insufficiency
Scope	single	multiple		
Signs per Sensor	single	multiple		

Source: Author's elaboration from gathered data

When considering **lifestyle management** and **independent living** projects, mainly single applications have been developed. The main exception is represented by projects developing Point of Care solutions, where a bigger effort is being made to integrate multiple applications into the same solution (i.e., the Pocemon project).

A trend that has been possible to identify is the increasing efforts towards addressing more than one disease and application with the same solution. On the other hand, gathering multiple vital signs through one sensor seems to be a more distant goal.

2.3.2.3 Embedding of other systems

By this attribute we refer to whether a data gathering sub-system also embeds the data processing/analysis and communication sub-systems. In this case, the different sub-systems identified are collapsed into one device, which is an intelligent sensor. This kind of sensor is able to gather the signal from the person's body, transform it into an electrical sign, process it and communicate. The possible values are

- Non embedding, i.e., an external device (e.g., an external hub) is necessary to process data;
- Partially embedding, i.e., the device performs only a partial processing of data (e.g., simple data fusion), that are then transmitted to en external device for full processing;
- Fully embedding, i.e., data acquisition, processing and communication sub-systems are collapsed into a unique intelligent sensor.

Several research projects have developed or are developing solutions where data acquisition and processing are combined in one device, and this has started already within FP5 (e.g., Chronic).

2.3.3 Sub-systems: data processing

The characterising attributes are:

- Degree of intelligence;
- Healthcare professionals' intervention.

2.3.3.1 Degree of intelligence

This attribute refers to the capability of the data processing and analysis sub-system, which can take the following values:

- **Low,** which means that data are simply stored for communication and will have to be analysed elsewhere;
- **Medium**, i.e., the device performs data fusion, that is it collects and combines data gathered from different sources;
- **High**, i.e., the device offers a closed-loop service, including: medical expertise, intelligent analysis, decision support system (including modelling, simulation, intelligent algorithms, alerting, etc.);
- **High-self adaptive,** i.e., the device offers a service by which data processing and analysis can be gradually calibrated to each individual peculiar characteristic.

While in the first three cases the brief definition provided already explains the degree of intelligence in data processing, the fourth requires further explanation. As mentioned, self-adaptivity refers to the degree to which data processing and analysis can be gradually calibrated to each individual's peculiar characteristic and also to the changing context.

This is an attribute requiring some further considerations as it concerns strategic dimension from our perspective of envisioning scenarios, uncover gap, and recommend future research themes.

PHS are called personal as the focus is on the person possibly outside of institutional care but they are not necessarily personalized. They generally do not consider the very specific characteristics of each unique individual. Currently, PHS data analysis focuses on standard measures, commonly accepted in medicine, to detect abnormal physiological conditions or, in the case of ageing, abnormal physical state (i.e., early fall detection), without considering context (location, type of interaction i.e. from voice signalling) and person specific parameters (age, social class, education, life history). This can lead to false positive early warning: that is a vital signs is above the threshold but this may be due to peculiar characteristics of the individual or of the specific context in which he/she is. To avoid this, PHS should be auto-adaptive in the sense that can be gradually calibrated to each individual characteristic (through *ad hoc* algorithms) and also recognize context (in this respect, see the discussion on the type of parameters registered by sensors presented later).

Intelligent data processing has been emphasised since the very beginning of research on the PHS field, so that even during the FP5, projects already performed some level of intelligent data processing. As research progressed, most solutions have been designed with a medium or high level of intelligence embedded in the data processing sub-system in all of the three areas of application. On the other hand, auto-adaptive data processing is rare. This is due to many factors, including the difficulty in gathering and processing environmental and context data, as well as in developing algorithms accurate enough to provide individual targeted services.

2.3.3.2 Need of health care professional intervention

Here we refer to the degree to which the intervention of a healthcare specialist is needed, which takes the following values:

- **Mandatory,** i.e., the health expert has to check the data on a regular basis and make decisions based on the data acquired;
- **Recommended**, i.e., before any change in monitoring, treatment, and/or follow-up, the authorisation by the health expert is necessary;
- ***Ad hoc,*** i.e., no intervention from the health expert is needed, unless an emergency event is detected;
- **Not needed**.

In **chronic disease management** projects, the most common case is the *ad hoc* intervention of healthcare professionals (i.e., after an alerting automatically generated by the system). However, there are few cases where the health professionals intervention is mandatory, in order to take decisions concerning patients' treatment (e.g., in the HearthCycle project). There are also many examples of recommended interventions (as in the case of the Chronic project, for the home-monitoring and treatment of several chronic diseases), in which health professionals, in addition to general supervision and

monitoring, also actively decide about changes in treatment (i.e., drugs intake), on the basis of data gathered.

Even in research projects addressing **lifestyle management** and **independent living** services, health experts' intervention is mainly *ad hoc*.

2.3.4 Subsystems: Data communication

The characterising attributes are:

- Type of connectivity;
- Type of communication.

Recent advances in wireless communications and electronics have enabled the development of low-cost, low-power, multifunctional sensors that are small in size and communicate un-tethered in short distance. Typically these tiny sensors which consist of sensing, data processing, and communicating components, leverage the idea of sensor networks; in this sense, the sensor networks represent a significant improvement over traditional sensors.

A sensor network is composed of a large number of sensor nodes that are densely deployed either inside the phenomenon or very close to it (e.g. Hou *et al*., 2005). The position of sensor nodes needs to be engineered or predetermined. This means that sensor network protocols and algorithms must possess self-organizing capabilities. Another unique feature of sensor networks is the cooperative effort of sensor nodes. Sensor nodes are fitted with on-board processor. Instead of sending the raw data to the nodes responsible for the fusion, they use their processing abilities to locally carry out simple computations and transmit only the required and partially processed data.

In a multi-hop sensor network, communicating nodes are linked by a wireless medium. These links can be formed by radio, infrared, or optical media. To enable global operation of these networks, the chosen transmission medium must be available worldwide. Much of the current hardware for sensor nodes is based on RF circuit design. Another possible mode of inter-node communication in sensor networks is by infrared. Another interesting development is based on the optical medium transmission that typically realizes an autonomous sensing, computing, and communication system.

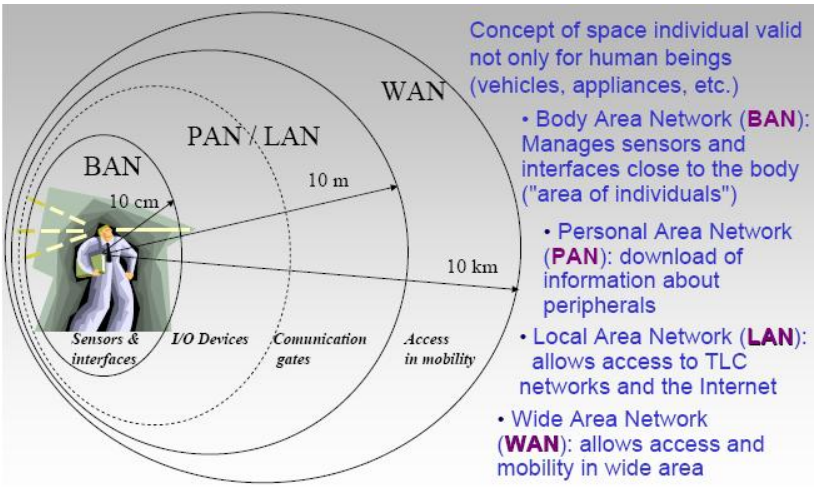
As illustrated before, the main task of a sensor node in a sensor field is to detect events, perform quick local data processing, and then transmit the data (sensing, communication, and data processing). Regarding to the communication, the protocol stack combines power and routing awareness, integrates data with networking protocols, communicates power efficiently through the wireless medium, and promotes cooperative efforts of sensor nodes. Generally, the protocol stack consists of different layers, such as physical layer, data link layer, network layer, transport layer, application layer, and other layers devoted to other tasks and functionalities (typically structured in plane), like power management plane, mobility management plane and tasks management plane.

The physical layer addresses the needs of simple but robust modulation, transmission, and receiving techniques. The data link layer addresses the medium access control. The network layer takes care of routing the data supplied by the transport layer. The transport

layer helps to maintain the flow of data if the sensor networks application requires it. Depending on the sensing tasks, different types of application software can be built and used on the application layer. In addition, the power, mobility, and task management planes monitor the power, movement, and task distribution among the network.

Figure 21 shows the possible "network protocols" that can be used depending on the distance where the sensor (or network of sensors) is positioned.

Figure 21: Examples of "protocol networks"



Source: to be added

As can be seen, near the sensor there is the BAN (Body Area Network), with the sensor/s and the interface/s management around the body (van Halteren *et al*, 2004, Val, 2006). The PAN (Personal Area Network) permits the download of information on peripherals. The LAN (Local Area Network) realizes the possibility of the nomadic access to fixed, mobile networks and to the internet. Finally, the WAN (Wide Area Network) permits the access and routing to fixed and mobile networks with full mobility and QoS (Quality of Service) guarantees (see for instance Istepanian, 2006; Chakravorty, 2006). Regarding to the BAN, also called UWB (Ultra-Wide Band) or IR (Impulse Radio), it recently has been drawn considerable interest for communication applications, especially in proximity and vicinity wireless networks.

2.3.4.1 Type of connectivity

When looking at the type of connectivity, many of the market solutions available today use conventional communication methods as fixed telephone lines and fixed internet connections (i.e., wired connectivity). The wireless applications are connected to mobile phones and smart phones, as in the case of BodyKom, CardiosenC, and GlucoPack, and are in general less common.

At the research level, on the contrary, the overwhelming majority of projects have adopted wireless communications, in all the three areas of service identified. Only very few projects included wired connectivity (i.e., fixed telephone line and fixed internet connections). These projects can be related to old research activities (as in the case of the

Chronic project, founded under the FP5), or to services addressing elderly (like in the HearCom case), who are less likely to adopt new communication devices (including mobile phones and smart phones).

When looking at **chronic disease management** research in more detail, it comes out how recent projects (mainly from FP6 and FP7) have developed solutions based on a network of sensors around the patient, communicating via Bluetooth, and a smart phone (a PDA, in most cases), gathering these signals and communicating with the devices all around the patient. This means that what we defined as the BAN+PAN solution is the most common solution for chronic disease management, especially in the last years. Therefore, also considering the increasing mobility pathways of European citizens in the future, even on a late age, it is possible to consider these as the most likely characteristics of future projects and applications.

2.3.4.2 Type of communication

Normally, the devices currently available on the market only send the information and cannot handle receiving activities. The only cases where receiving is possible, is in the case of "intelligent" devices where the patient is given feedback to according to the results provided, like in e.g. Telestation, and Doc@Home. This situation is common for all the areas of services/applications identified.

When considered the research level, on the contrary, devices already developed or under development all provide bi-directional information: they can send information and data gathered, and receive feedback for the patient/citizen. The bi-directional communication flow can be considered as a consolidated feature in research projects, as it was presented since the beginning of research on this topic.

Therefore, the evolutionary transition that is possible to draw mostly concern market applications, where the increase of bi-directional communication flows in the next years can be envisaged.

2.3.5 Components: Sensors

The characterising attributes are:

- Position;
- Invasiveness;
- Level of comfort;
- Type of sensor;
- Interactivity level;
- Signs per sensor and scope of data gathering.

2.3.5.1 Position

By position, it is intended how the sensor or set of sensors are positioned in respect to the patient's/ citizen's body. Here, the following categories apply:

- Stationary; i.e., the sensor is localised onto a stationary device;
- Portable; i.e., the localisation of the sensor is on a portable device;

- Wearable; i.e., the localisation of the sensor is in a wearable device;
- Implantable; i.e., the sensor localisation is within the person's body (the implantation can be invasive or minimally invasive).

Efforts are being made to integrate the sensor with the data acquisition device as previously explained. Nevertheless, research projects use additional sensors in other positions in order to offer an added value of the service. In the case of the project HearthCycle, for instance, where the main data acquisition device is wearable and equipped with sensors for cardiovascular disease management, stationary sensors are also used in bed sheets and other furniture belonging to the patient, in order to achieve a full-loop circle of monitoring the patient condition at different stages of the day. A trend that, however, was possible to identify is the increasing efforts at developing wearable sensors in the FP research projects as exemplified by HearthCycle, Chronius, and MyHeart. This may be explained by the increasing willingness to detect and follow up on the cause-effect of a certain condition, and the fact that in order to do so, continuous monitoring is crucial. Hence, the best solution and means to conduct such continuous monitoring seems to be through wearable sensors.

Bio- and nano-technologies represent a key factor for the development of new implantable sensors, as explained in the following example. Miniature MEMS sensors are similar to those that trigger airbags in cars might soon be implanted in the hearts of people suffering from a heart disease. The sensors would make it easy to measure blood pressure inside the heart, which at present involves repeated operations. The implant, the size of a grain of rice, is one of a new breed of medical devices that requires no batteries. A radio transmitter and receiver held near the body provide the power and interrogate the implant.

2.3.5.2 Invasiveness

The term "invasiveness" refers to the degree to which the sensor requires invasive interventions to be placed in/on the person's body. Clearly, this attribute mainly refers to implantable sensors[37] and can take the following values:

- Low/null for non invasive sensors
- Medium for minimally invasive sensors (i.e., sensors not requiring invasive surgery for being implanted);
- High for invasive sensors (i.e., sensors that require invasive surgery to be implanted).

Within the research domain invasiveness degree is low/null since almost all projects use stationary, portable and mainly wearable sensors.

In the research FPs, one project exemplifying implantable can be mentioned. It is the Adicol project, in which a glucose meter sensor is implanted in the body for regular monitoring. In attachment to this sensor in an insulin pump placed externally to the body.

[37] The data are gathered by implantable devices that can either require open invasive surgery or avoiding it (surgery usually carried out through the skin or a body cavity).

These two units are fully integrated and automatic in the sense of when the sensor detects a certain glucose level, the pump injects the insulin accordingly. This means, that the insulin level is customised to the real need of the patient. In this case, the invasiveness level was considered to be medium since the actual sensor is positioned just under the skin. Subsequently, no open surgeries are required to place the sensor.

Although the implantable solutions are very practical in terms of the ability to include both monitoring measurements and belonging actions, they are still intrusive. This consequently means that patients may tend to avoid such solutions. The clear trend, especially concerning the FP research projects, is dominated by wearable sensors as exemplified by the projects HearthCycle, Chronius and MyHeart.

2.3.5.3 Level of comfort

The level of comforts refers to the degree of which sensors obtrude a person daily life, for instance, by impeding or reducing possibility of body movements. This attribute can take the following values:

- Low/null, when a small contact area is needed, and/or body movements are not impeded or obstructed;
- Medium, when a moderate body contact area is needed;
- High, when a large body contact area is needed in order to acquire reliable data, and/or body movements are impeded or obstructed (as in the case of some stationary sensors).

This attribute has a particular relevance with respect to wearable solutions, as is key for usability and user acceptance and for thinking future scenarios, uncover gaps and envisions research themes. Smart clothes, for instance, pose a key challenge with respect to how invasive they are. On one hand, the acceptance of the potential users wearing smart clothes everyday demands for a high level of wearing comfort and intuitive handling (many people prefer casual clothes with an as small as possible contact pressure). But most wearable sensors require a close, permanent and, most importantly, **large-area contact to our skin to ensure sufficient signal quality**. Textile design and signal processing are requested to reduce the motion artefacts in the sensor signals. Yet, the signal performance achieved in a standard medical setup cannot be guaranteed in a mobile environment. So methods have to be provided to correlate the clinical and mobile data. Therefore, interaction between the user and the wearable system poses a trade off: unobtrusiveness of the device vs. quality of signals. A trade off for future research to solve.

In most recent projects (FP6 and, mostly, FP7), smart textiles are adopted, either by attaching sensors to the garments or by integrating sensors in the fibre threads of the garments. Consequently, the degree of physical attachment to the body is low. Although, at this stage, the comfort level of the mentioned garments can still be questioned.

2.3.5.4 Type of sensor

This attribute refers to the technical characteristics of the sensor (Lymberis and De Rossi, eds., 2004), which can take the following values:

- Non organic, usually silicon-based or metal-based sensors (e.g., ECG electrodes);

- Organic, sensors that use organic molecules for their active base material;
- Biological, sensors employing biological recognition properties for a selective bio-analysis;
- Molecular, sensors combining the specific interaction between two or more molecules with some form of marker so the presence of the guest can be observed.

Currently the most widespread solutions are non-organic (are usually electrodes intended for ECG recording) and biological sensors. The non-organic are used as complements to the more advanced bio-sensors which are technologically more capable of data acquisition, processing and in some cases also actuation, as previously mentioned. A trend that, however, was possible to identify is the increasing efforts at implementing and using organic sensors, more specifically nano-integrated into textiles and textile fibres, as can be the case for the project Chronius.

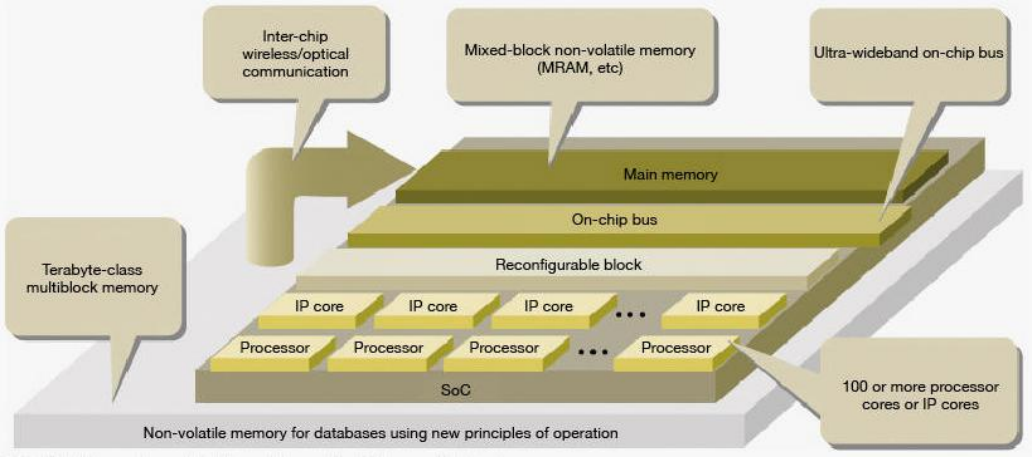
2.3.5.5 Interactivity level

By this we mean the level to which a signal results in an actuation, which can take the following values:

- Passive, no interaction (the signal does not result in an actuation)
- Semi-Active, the signal results only in a limited actuation (e.g., alerting)
- Active (SiP), the signal results in a full actuation. System in Package (SiP) is a number of integrated circuits enclosed in a single package. This means that some or all functionalities (data acquisition, processing, actuation and communication) could be embedded on the sensor
- Active (SoC), the signal results in a full actuation. System on Chip (SoC) is a number of integrated circuits enclosed in a single package. This means that some or all functionalities (data acquisition, processing, actuation and communication) could be embedded on the sensor

The figure below shows the architecture of SoC in 2015-2020, as envisaged by Renesas Technology.

Figure 22: SoC of 2015-2020



Source: Renesas Technology

Renesas Technology predicts that the SoCs will include several processor cores and field-programmable (reconfigurable) circuits, claiming that by 2020 SoCs will mount about 100 times today's logic. Today SoCs are used primarily for multimedia processing, but in the not-so-distant future their image-recognition capabilities will exceed those of human beings. This will demand new applications, such us for example the ones that will include human interfaces and knowledge processing. The former includes such disciplines as voice recognition, translation and biometric identification, while the latter covers information processing activities close to those of people, such as support for inference and brain-storming.

In many research projects the sensors used are active or semi-active. In the case of Adicol, the signal results in insulin dosage. However, in most cases the active and semi-active characteristics are based on historic results and events that may be acted upon accordingly, as exemplified by Chronius and MyHeart. This leads to the clear trend of integrating actuation onto and into the sensors to further reduce external devices and also external assistance.

2.3.5.6 Signs per sensor and scope of data gathering

This attribute tells how many sign a sensor can register, regardless of the type of signs and can evidently take the following two values:

- Single;
- Multiple.

This is another strategic attribute from our perspective of envisioning scenarios, uncover gap, and recommend future research themes. In fact the most common signs detected are physiological (vital signs) and physical activity (body kinematics) ones. The World Health Organisation defines health as a “state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (World Health Organisation, 1946). So we could envision a future scenarios leading from PHS to PHAS, which is Personal Happiness Systems (derived from the fact that the WHO definition of health is close to that of happiness). In order to achieve this also parameters related to the mental and social state of an individual should be detected. Accordingly the values that this attribute could potentially take are

- Physical state:
  - Physiological (vital signs);
  - Physical activity (body-kinematics);
  - Location.
- Context awareness:
  - In-door/ out-door parameters;
  - Environmental conditions (e.g. specific air particles);
  - Etc.
- Mental/emotional state:
  - Stress;
  - Depression;
  - Etc.
- Social state:

- Social interaction;
- Communication styles;
- Etc.

At the research stage, in addition to the vital signs, also the physical activity is addressed as exemplified by HearthCycle, Chronius and MyHeart. Further on, although in very few cases as exemplified by Chronius and HearthCycle, also include context awareness. In the case of Chronius, an integration of monitoring parameters using audio observation methods and selected environmental and social context sensors is used, while at the same time tracking patients' medical condition via vital signs sensors. This approach is increasingly used specifically for the new FP7 projects.

2.3.6 Components: Lab on chip

For the point-of-care solutions, lab-on-chips are used at the component level which is a device that integrates multiple laboratory functions on a single unit capable of handling small fluids volumes. The characteristics attributes are the following:

- Material;
- Sample preparation;
- Target detection.

2.3.6.1 Material

This attribute refers to the base material of which the Lab-on-Chip is made of, which can take the following values:

- Silicon;
- Glass;
- Plastic.

At the research stage, in most cases, silicon-based lab-on-chips are in use as exemplified by the newly launched project Pocemon (FP7) where the technologies involved will deal with both ad hoc Silicon-On-Insulator (SOI) approaches for the realisation of thin suspended Silicon beams with tight thickness control, and the implementation of thin film cantilever.

2.3.6.2 Sample preparation

Sample preparation refers to whether the sample has to be prepared before applying it onto the chip or if it goes directly from patient onto chip. This characteristic is very important due to the time limitations experienced by health care providers. Consequently, if the sample preparation is embedded in the chip, less steps and subsequently effort is required from the healthcare professional. Hence, the attributes can take the following characteristics:

- Non embedded;
- Embedded.

Currently, most research projects address on-board sample preparation, as exemplified by Microactive, SmartHealth, and Theraedge. However, there are also examples where the sample preparation is required to be done off-board as exemplified by Pocemon where an

extraction of the patient DNA from the blood is required. Consequently, the sample put onto the chip is a DNA sequence for the detection of Multiple sclerosis and rheumatoid arthritis.

2.3.6.3 Target detection

This attribute refers to the degree of concentration in target sample sequence, e.g., length of DNA snip necessary for performing a certain analysis. The following attributes values are given:

- Mono-target: the application is designed to detect only one specific target, i.e., only one specific protein;
- Multi-target, low: the application is designed to detect a limited number of target s (2 or 3 targets);
- Multi-target, high: the application is able to detect a large number of targets simultaneously (about 30 to 50).

In most cases at the research level, mono target or multi- target, low detection applications are developed. One example of multi-target application is the Theraedge project, where the lab-on-chip is multi analyte capable using nucleic acid, protein, and metabolite.

3 From the state of play to scenarios

As briefly illustrated earlier (§1.3) and explained in further detail in the methodological annex (see § 7.4), the state of play of PHS applications and technological components was complemented by a selective review of what we broadly termed "environmental" conditions using as a guiding conceptual tools the General Descriptive Framework (**GDF**) illustrate in Figure 11 at page 25 (see also § 7.3.3). This was instrumental to the preliminary identification of trends, later discussed, integrated and assessed during consultation activities leading to the elaboration of the consolidated scenarios presented in this chapter. In the following we first simply report these trends without discussing their rationale[38] and illustrate how we moved from them to the identification of the dimension of uncertainties shaping the scenarios (§ 3.1). Next we present a snapshot of the four scenarios and explain their instrumentality within the overall design of our project (§ 3.2). Finally for each of the scenarios we provide a storyline and a schematic description of how the various dimensions of the **GDF** may change (§ 3.3).

3.1 Trends assessment and organisation

On the basis of the technological state of play and of the selective overview of environmental conditions we extracted a preliminary large list of trends, which became the platform for the scenarios consultation cycle. Experts helped us complete and streamline the list (some trends were added, other merged and or re-phrased) and, most importantly, rated the various trends in terms of their potential impact and of their degree of uncertainty. The final larger list of trends and the final findings on how each of them has been rated can be found in the Consolidated Scenario Report[39]. Below we only report the restricted list including only those trends that, after re-elaborating the scores of the questionnaires filled in by the experts, were rated high both in terms of impact and uncertainty[40].

As it can be seen from Table 1 spreading across the next two pages, only two technological trends have been retained for they were considered, not only very impactful, but also highly uncertain, these are:

- Multiple data integration across all tiers of the healthcare system (including social support and primary care).

[38] For the detailed and commented illustration of the trends and their supporting evidence see PHS2020 Deliverable D3.1, *Consolidated Scenario Report*, chapter 3.

[39] See PHS2020 Deliverable D3.1, *Consolidated Scenario Report*, pp. 47-51.

[40] In the trends assessment exercised we asked all experts to assess the trends on a scale from 1 to 10 (with 10 representing maximum impact or uncertainties). We have deemed high scores of 7 and above, medium score between 5 and 7, and low all those below 4.

- Simulation and modelling tools used from primary care up to policy-making and high level monitoring (Decision Support Systems)

Table 1 Trend assessment: final restricted list

MACRO SOCIO-INSTITUTIONAL ENVIRONMENT	Impact	Uncertainty
Society		
• Homogeneous health aware and consumerist societies;	High	High
• Homogenous health passive and traditionalist societies;	High	High
• Digitally equal and technology confident societies		
Governance and economics		
• Substantial increase in spending for public health and prevention	High	High
• Worsening energy crisis forces energy efficient treatment in healthcare	High	High
• Substantial increase of private financing and expenditure substituting public financing	High	High
• Increasing role of broadly defined private players in the production and/or delivery healthcare services	High	High
• Communitarian/Authoritarian state approach, pushing responsibility onto consumers and enforcing healthy behaviours and compliance;	High	High
• Liberal laissez faire state approach, leaving matters of healthy behaviours and compliance entirely to individuals' free choice.	High	High
TRANSACTIONAL ENVIRONMENT	**Impact**	**Uncertainty**
Healthcare professionals and organisations		
• Increasing acceptance by professionals of preventive and monitoring systems;	High	High
• Healthcare organisations and professionals relinquish control over service provision	High	High
• Centralisation of broadly defined inter-operability decisions (standard, guidelines, procedures, technological) favouring integration	High	High
• healthcare integrated and joined-up across tiers (primary, secondary, etc)/ specialties and functions (diagnosis, treatment, monitoring and prevention	High	High
Payers (financing system)		
• Move to outcome based public reimbursement of PHS and other eHealth applications	High	High
• Over the counter consumer electronics model paid from out of pocket private expenditure consolidates	High	High

MACRO SOCIO-INSTITUTIONAL ENVIRONMENT	Impact	Uncertainty
Technology suppliers and other third party players		
• Industry integration and emergence of few large players leading to increased standardisation and inter-operability	High	High
USERS AND TECHNOLOGY	**Impact**	**Uncertainty**
Users		
• Move toward remote interaction and less healthcare professional intervention;	High	High
• Continuous reliance on healthcare professionals and preference for face2face interactions;	High	High
• Widening social divide between those able and not able to pay healthcare	High	High
• Increased self-diagnosis and potential for non compliance (beyond elderly)	High	High
Technology		
• Multiple data integration across all tiers of the healthcare system (including social support and primary care). This is currently already in place only in fourth tier care (i.e. bio-markers for a certain disease and tailoring of prevention)	High	High
• Simulation and modelling tools used from primary care up to policy-making and high level monitoring (Decision Support Systems);	High	High

Source: Author's elaboration of questionnaire filled in by experts

All other technological trends have been rated as having high impact but in terms of uncertainty they reached only a medium-low average score. The same applies to very important socio-demographics trends. It is worth stressing that this does not amount to a loss of relevant information or that such important trends did not played a role in the subsequent elaboration of the gap analysis and in the final roadmapping. As it is illustrated in the methodological annex (§ 7.4), scenarios should be defined by highly impactful but also uncertain dimensions in order to ensure we envisage contrasting and alternative developments. On the other hand, the trends not defining the scenarios matrix come back in the specific description of each scenario or are considered as cross-cutting all of the four scenarios. In this way they have also been considered in the gap analysis and gave rise to some research themes or to other policy actions.

Starting from the trends in the table above we then proceeded to analyse them in order to extract the two key dimensions of uncertainty defining the 2*2 scenarios matrix, as illustrated in next table.

Table 2 Organising trends along key uncertainties dimensions

Uncertainty variable	Trends shaping uncertainty variable
Governance	• Substantial increase of private financing and expenditure substituting public financing • Substantial increase in spending for public health and prevention • Over the counter consumer electronics model paid from out of pocket private expenditure consolidates • Increasing role of broadly defined private players in the production and/or delivery healthcare services; • Move to outcome based public reimbursement of PHS and other eHealth applications • Communitarian/Authoritarian state approach, pushing responsibility onto consumers and enforcing healthy behaviours and compliance; • Liberal laissez faire state approach, leaving matters of healthy behaviours and compliance entirely to individuals free choice; • Healthcare organisations and professional relinquish control over service provision • Centralisation of broadly defined inter-operability decisions (standard, guidelines, procedures, technological) favouring integration; • healthcare integrated and joined-up across tiers (primary, secondary, etc)/ specialties and functions (diagnosis, treatment, monitoring and prevention) *Continued*
Society and health and technology: degree of differentiation	• Homogeneous health aware and consumerist societies; • Homogenous health passive and traditionalist societies; • Digitally equal and technology confident societies • Move toward remote interaction and less healthcare professional intervention; • Continuous reliance on healthcare professionals and preference for face2face interaction • Widening social divide between those able and not able to pay healthcare • Increased self-diagnosis and potential for

Uncertainty variable	Trends shaping uncertainty variable
	non compliance (beyond elderly);
Not directly contributing to any of the two key uncertainty variables	• Increasing acceptance by professionals of preventive and monitoring systems • Industry integration and emergence of few large players leading to increased standardisation and inter-operability • Multiple data integration across all tiers of the healthcare system (including social support and primary care). This is currently already in place only in fourth tier care (i.e. bio-markers for a certain disease and tailoring of prevention); • Simulation and modelling tools used from primary care up to policy-making and high level monitoring (Decision Support Systems); • Worsening energy crisis forces energy efficient treatment in healthcare

Source: Author's elaboration (validated during 4th ESC meeting and 3rd Workshop)

So we extracted two key dimensions of uncertainty:

- **Governance** : will government opt for a lighter touch and substantially withdraw from both production and financing of services, opening to new players and favouring self-care practices and full consumers/patients empowerment (with the implication that healthcare organisations and professionals will relinquish the full control of service provision)? Or will it retain a strong involvement in many ways (financing, enforcement of healthy behaviours and compliance, retaining full control of both production and delivery of services) and seal the healthcare to new players (with the implication that healthcare organisations and professionals will relinquish the full control of service provision)?
- **Societal differentiation**: will we live in fairly homogeneous society where individuals' attitudes, behaviours and capabilities in relevant domains (attitudes to health, to technology, willingness/capabilities to pay) will tend to converge or will we witness and increasing differentiation even more marked that the one visible today leading to a sharpening of social, cultural and digital divides?

It is evident that moving from the full discussion of trends to the selection of the two key dimensions we have progressively reduced complexity. From the long illustration of the state of play we then moved to the more synthetic discussion of trends. Then the over 50 trends identified were reduced to the 20 deemed at the same time as having high impact and high uncertainties. Finally, from these 20 trends it was clearly possible to extract even four different dimension of uncertainties (about governance, about society, about healthcare organisations and professionals orientation, and about technology), but we extracted only two dimensions.

Financing and reimbursement, for instance, have been subsumed into the **governance** axis, but could reasonably be a separate axis in itself. Yet, its importance will not be lost and will reappear in the characterisation of scenarios. In the same way preference/acceptance of remote versus face2face healthcare delivery could be a dimension distinct from the broader one about societal differentiation in attitudes and behaviours, but will also figure in scenarios description.

A different case is that of trends more strictly related to healthcare organisations and professionals, which have been subsumed into the overall governance dimension. Here the idea is that, when considering governance, we are talking about all the public institutions dealing with healthcare and, thus, the higher level elements permeate also the more micro level ones.

Next we have trends deemed as having high impact and high uncertainties but not contributing to any of the two key dimensions of uncertainties and those very impactful but with low uncertainty that were discarded even before the identification of the scenarios axes. Some of these come back in the scenarios descriptions, others are cross-cutting and horizontal to all the four scenarios and will be discussed at the end of next paragraph and have been considered in the gap analysis and roadmapping. The same applies for technological trends.

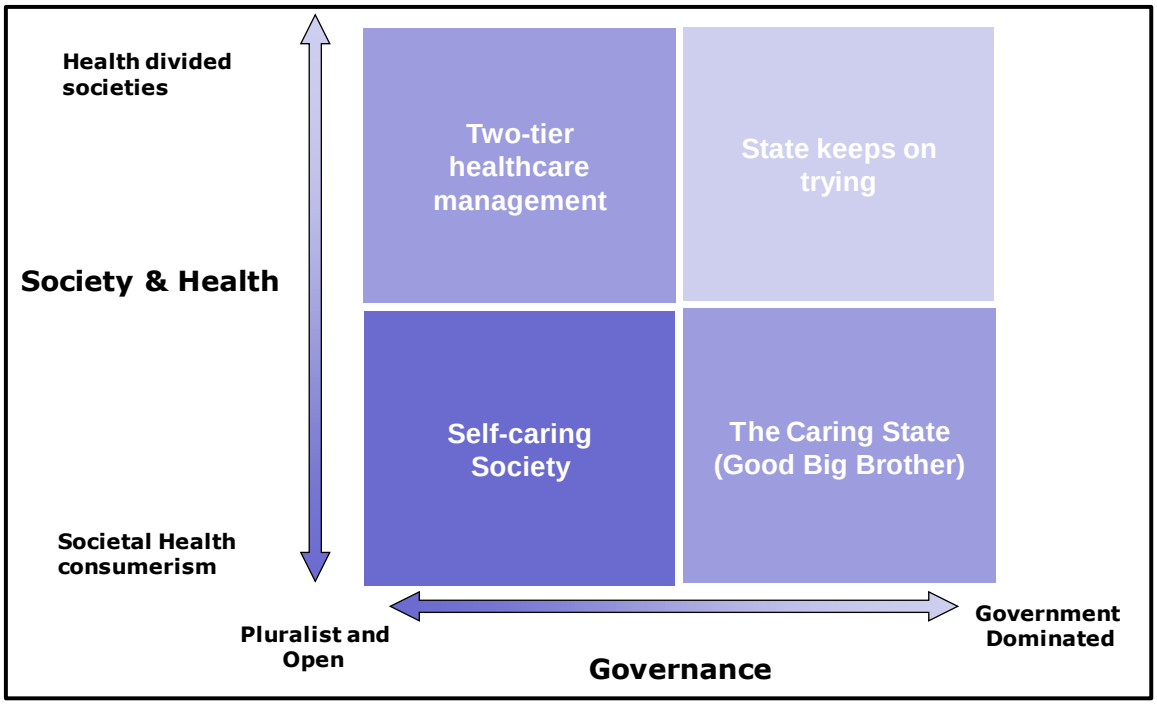
This list of considerations aims to respond to some of the observation received both during the consultation process and during the first project review, suggesting the inclusion of an extra dimension in the scenarios matrix (usually the technological one). We strongly re-affirm that scenarios are a communication tool and as such they must be easy to understand. This is possible using a 2*2 matrix identifying four scenarios, ***whereas adding a third dimensions producing eight scenarios would be cumbersome and not add any value. In fact, the trends not reflected in the matrix axes are not lost information, but come back either in the scenarios description or in the gap analysis.***

Finally, it is worth stressing that in using one dimension related to the institutional domain (government and governance) and one dimension related to societal attitudes and behaviours, our approach is fully in line with other recent scenarios exercise focussed more broadly on the future of government (van der Veer 2005; Di Maio *et* al 2005; Codagnone and Wimmer 2007). Despite differences in some methodological aspects, these three scenarios exercise share the fact that one key dimension concerns society and the other concerns the state. In all three of them for what concerns society the dimension of uncertainty focus on broad socio-cultural attitudes, whereas the other uncertainty related to the state, though in different way, focus on the issue of control/intervention. While following a different and independent methodological and consultation process and focussing on a different topic, we also focussed on society and government and on issues of attitudes, cultures, control and intervention.

3.2 Scenarios snapshot and their role

Figure 23 below reports the four scenarios extracted with some adaptation and liberty from the two key dimensions of uncertainties discussed previously.

Figure 23 Scenarios snapshot



Source: Author's elaboration of input from workshops

For the sake of brevity and simplicity in communication we termed the axis related to the social dimension as "Society & Health"[41] and present two possible extremes: a) societies where health consumerism, confidence in technology and remote treatment with little health professional intervention have permeated 95% of the adult population, thus, much reducing social exclusion potential problems; b) on the contrary, the differentiation existing today has persisted and has possibly been exacerbated thus leading to health divided society and raising serious social exclusion problems.

In the institutional dimension the uncertainty is about the extent to which the government will want to maintain and increase intervention and control continuing to be the main payer and provider (through the public institutions and professionals operating at various levels), or conversely will open to other players and reduce it involvement and direct control. The two extreme are represented by: a) a pluralist and open governance and delivery with new spaces for third party players, where the government will focus mostly on policy making and monitoring of healthcare outcomes, will reduce its direct financing

[41] Although we mean a broader set of issues, including both health as such and the role of technology, and the attitudes and behaviours related to both.

role, will introduce regulations and measures leading to new financing and business models, will stimulate public healthcare organisations and professional to relinquish their full control on service provision; b) a government-dominated governance where the government and its network of healthcare organisations and professional remain the dominant players, where public financing will continue to be the main source of funding along already existing output based models and with closure to third party players confined to very limited niche markets.

In next paragraph we will report the characterising elements of each scenario. It is worth recalling some of the considerations presented in the methodological annex (§ 7.4) and stress that such characterising elements are not mutually exclusive, in the sense that those evidenced for one scenarios could be relevant also for others. They are characterising in the sense that respond to some of the most peculiar extreme situations envisaged in each scenario. The aim is that they are collectively exhaustive of all the potential needs that will emerge in the future configuration eventually taking place for real. This provides the opportunity to briefly recall that scenarios play an instrumental role and avoid misunderstandings. Scenarios are not an end in itself and they have not been constructed so that each one produces a self contained and distinct roadmap. They are an instrument with the aim of collectively producing an exhaustive list of elements, from which gaps and subsequently research themes are derived that will possibly cover all the possible aspect that will characterise the real future. In fact, scenarios are exactly positioned at extremes, yet the underlying assumption is that the real future will be somewhere in the middle and contains elements of each of the four scenarios. The polarisation of scenarios helped more effective communication during the consultation to elicit all the possible divergent and contrasting elements of a future we cannot forecast, so to address all of them in the expectation that they will occur in some combination.

In light of the above, it is evident that gaps and related research can be relevant to more than one scenario and possibly to all of them. In the end, for the list of gaps and research themes, it is irrelevant from which scenarios they are derived.

3.3 Scenarios stories and description

3.3.1 "Self-caring society"

Scenario story

With pervasive health consumerist attitudes and behaviours in a society where digital inclusion is almost complete and confidence in technology high, the government has moved to a steering role (oversees outcomes and stimulate compliances through soft methods), reducing the direct intervention and financing of healthcare except for acute problems. It has, thus, opened up the field to a variety of players, who compete for public but decentralised reimbursements provided through an outcome-based model and/or for consumer out of pocket expenditure. They provide integrated PHS services to consumers/patients taking most health matter in their own hand and at ease with remote technology driven services entailing little intervention from healthcare professionals.

Macro environment

- The implications of ageing society have become fully visible with increase in chronic diseases and in their co-morbidity patterns, with a large pool of elderly requiring assistance, while neuro-psychological disorders are also on the rise. Nevertheless, improvement in prevention and the widely PHS tools available to individuals in their double role of consumer/patients and 'care consumer managers' for friends and relatives, together with full digital inclusion and technology confidence, are maintaining the equilibrium of the system and reducing compliance problems among the elderly;
- The government has moved from 'rowing' to simply 'steering' in a new pluralist and open Networked Governance model where the principle of horizontal subsidiarity is fully implemented. With the exception of acute medicine, other functions are exercised also by private health organisations and by other non health care players especially for the delivery of PHS services, competing with public health care organisations. Government is engaged in strategic policy making, facilitating the processes (privacy, data sharing, standards, inter-operability) monitoring and measuring of outcomes, devising indirect control and soft incentives to compliance, all of which has been largely centralised with lower roles for regional and local governments except for the allocation of outcome based reimbursement. As a result the public funding share of healthcare expenditure has decreased, but affordable coverage for the population is maintained through cooperation and competition between public and private players;
- Government, however, is directly involved in decision, investments and realisation of basic infrastructures favouring the development of innovative technology based PHS and other eHealth applications
- Healthcare costs are still high but the trend is stabilised and being gradually reversed, with new public resources being released for spending on public health and prevention.

Transactional environment

- Public funding has become decentralised and competitive. Regardless of the different institutional model (NHS or social insurance) the higher level bodies provide fixed budget to lower tier bodies that are free to allocate them according to various scheme and particularly using outcome based competitive reimbursement to public and private healthcare organisations and to third parties. Also public healthcare organisations in turns can outsource some of their tasks and enter into various deals with private players. Willingness to pay and actual out of pocket outlay are increasing for most sophisticated services. Outcome based financing is also used by private insurances signing schemes directly with healthcare providers;
- Public healthcare organisations and their professionals, as well as General Practitioners, have embraced PHS services providing full empowerment to consumers/patients directly or through the intervention of third parties. The new

top down standards and inter-operability requirements and the need to open to external private provider and/or compete with them has favoured integration of data systems, which in turn are fostering integrated care solutions at the local level. Benefits are being felt and large public healthcare organisations show a 80/20 patterns, where 80% of less complex matters are taken care by PHS directly entrusted on the citizens/patients or provided by third parties, whereas resources and expertise (naturally with diminished budget) will concentrate on the 20% most critical and difficult cases and on new research;

- Advancement in technological solutions and the new state approach have enabled the emergence of a few large technology suppliers and media companies that, aggregating the services of the many providers populating the value chain, have achieved standardisation, inter-operability and economy of scale. This has mainstreamed earlier niche innovative and very expensive products/services into mass market ones provided at affordable prices.

Users

- They are fully confident in technology, digitally included, and technology-users interaction, if need be, is facilitated bottom up by social intermediaries (family and friends);
- They want to take full part in deciding about their treatment in a symmetric and negotiated relationship with healthcare professionals;
- While increasingly aware and informed, some still represent risks in terms of compliance;
- Are comfortable with remote interaction and willing to proceed with little intervention on the side of healthcare professionals;
- They are reluctant, except that in most acute conditions, to use invasive and uncomfortable data gathering devices;
- Outcome based competitive public reimbursement reduce exclusion from PHS for the socio-economic disadvantaged;
- Recently retired wealthy baby boomers pays for more sophisticated and advanced PHS services

From the more technological perspective of PHS, the implications of this scenario are:

- PHS solutions fully empowering citizens/patients autonomy including patient decision aids to negotiate with healthcare professionals decision about treatment in uncertain situations
- Full ownership by patients of PHR inter-operable with PHS
- Increasingly sophisticated users demanding non invasive and comfortable systems
- Innovative outcome measurement systems combining various sources of data
- Though for different purposes, policy makers, third party payers and healthcare professional all fully use simulation and predictive technology (Decision Support Systems) based on multi-data integration

One key risk under this scenario is that, due to increased autonomy and despite better education about health, some problems of compliance may arise.

3.3.2 "Two-tier Healthcare Management"

Scenario story

While social gaps with respect to health consumerism and access to, and confidence in, technologies persist, nonetheless the government has moved to a steering role (oversees outcomes and stimulate compliances through soft methods) reducing the direct intervention and financing of healthcare except for acute problems, and opened to a variety of players competing for public but decentralised reimbursements provided through an outcome-based model and/or for consumer out of pocket expenditure thus providing integrated PHS services at competitive prices to consumers/patients, who take most health matter in their own hand and are at ease with little intervention from healthcare professionals. The gains and savings derived from the approach to the most advanced health consumers, are used to subsidise the other segment of consumers/patients and provide them traditional treatment and specific PHS services with sophisticated inter-face and with the support of professional intermediaries.

Under this scenario the macro and transactional environment resemble the description provided for the "Self-caring Society" with some variations and additional characterisation. Below for the sake of brevity we only discuss the more peculiar elements.

Macro environment

- With the implications of ageing society fully the two-tiers management of healthcare and the related fairly large use of PHS services by the consumerist segment of society help addressing the traditionalist segment while containing the pressure on healthcare but cannot entirely restore the financial equilibrium of the healthcare system;
- The government has moved from 'rowing' to simply 'steering' but has preserved ad hoc funds and delivery mechanisms for intervention where social inclusion issues persists that cannot be addressed otherwise than through government funded traditional delivery;
- The rise in healthcare costs is contained and partially stabilised but no signs of reversing are visible.

Transactional environment

- Public funding has become decentralised and competitive for the delivery of services to the consumerist segment of users, but central budget allocation are preserved for the treatment of the traditional segment of users;
- Besides full provision of PHS service by public and private and new players, especially public healthcare institutional use ad hoc government funding for delivering services to the traditionalist segment of users;

- The provision of PHS services to the consumerist users by way of new financing mechanisms has helped mainstreaming earlier niche innovative and very expensive products/services but not in such a way to turn all of them into mass market ones provided at affordable prices. Some remain niche services provided for out of pocket payment only by the most affluent among the consumerist users.

Users

Given the split of society between a segment of health consumerist digitally included and technology confident users and one presenting opposite characteristics the characterisation of users under this scenario resemble that of "**Self-caring Society**" scenario with the following additional elements:

- The segment of health consumerist and technology confident users are strongly encouraged to use remote PHS services provided by several players and do use them with ease;
- In society there still is a considerable segment of users who have passive attitudes toward health and/or are digitally excluded, and/or are still not confident with technologies and continue to prefer face2face interaction with healthcare professionals. These users rely on traditional treatment provided by publicly funded public or private healthcare organisations;
- The conscious differential treatment of the two segments of society pursued by government attenuate social divides that, however, persist to some extent in relative terms (the consumerist segment having more opportunities than the traditionalist one and within the consumerist the more wealth having more choices).

From the more technological perspective of PHS the implication of this scenario are:

- More sophisticated inter-face improving human/technology interaction are continuously developed and deployed to help the transition of new users into the more advanced segments;
- Digital TV based PHS services are provided to the elderly.

Despite attempt at containing it, under this scenario the risk that the social divide might increase remains.

3.3.3 "State Keeps on Trying"

Scenario story

Social gaps with respect to key dimensions (health consumerism, access to, and confidence in, technologies) have persisted (constraining take up and mainstreaming of PHS and other eHealth innovations), the role of government related healthcare institutions and basic financing mechanisms have not changed but rising costs are de facto eroding the full public coverage of the population, with PHS services consolidated into a niche consumer electronics market and paid for by out of pocket outlays, thus sharpening social divide between those who can and those who afford them, although acute resources shortages have led to increasing deployment of a few PHS systems especially for long term care of the elderly being financed out of the public budget.

Macro environment

- With the implications of ageing society fully visible and given little innovation and limited take up of PHS healthcare systems are under strong pressure;
- The government directly and through its various healthcare institutions remains the main player and funder of healthcare, although public budget crisis are slowly but gradually *de facto* eroding public coverage of the population, with quality of care varying widely across the system and increasing problems of access and waiting lists, forcing increased out of pocket expenditure and the adoption of private insurances. The government has difficulty to enforce issues of inter-operability, guidelines, and standards for the provision of PHS, though pilot projects and some local specific developments consolidate for some specific applications;
- Fragmentation increases both in verticals terms (across tiers of governments) and within the different tiers of healthcare (GPs, primary, secondary, etc).
- Growth rates in healthcare cost are no longer sustainable and the government is forced to reduce overall amount of funding while still trying to preserve universal coverage, which leads in practice to rationing and high variability in quality of publicly funded/provided care;

Transactional environment

- With public funding *de facto* eroded and affecting average quality and access, besides out of pocket expenditure, regional bodies and/or large healthcare organisation are testing localised agreement with private insurances to cover some

segment of their population of reference. Even public healthcare organisation increasingly provide special services and treatment for out of pocket payments;

- Public healthcare organisations and their professionals, as well as General Practitioners still show resistance to PHS and little signs of integrated care. On the other hand increased workloads and acute shortage especially of nurses and other staff needed to care for patients recovering from sever conditions and for severely impaired elderly in need of steady assistance pushes them to adopt some specific PHS solutions in cooperation and partnership with technology suppliers;
- The consumer electronic model directly paid by consumers/patients consolidate but is not enough for the mainstream of the market still characterised by niche players fragmentation and high prices affordable only by the more affluent segment of society.

Users

Users present the same characteristics described in the "**Two-Tiers Healthcare Management**" scenario with the following additional characterising elements:

- Within the segment of health consumerist and technology confident users the more affluent pay for the limited PHS services available in the consumer electronics market
- Within the segment of non consumerist and more traditionalist users, the wealthy pay for higher quality services provided by private organisation or by public organisation outside of publicly funded schemes, whereas the less affluent must relying only on the traditional services publicly funded, adapting to varying quality and waiting lists;
- The elderly and those in need of long term care are forced to accept technology based solution given lack of carers paid by public financing and of means to pay for private carers;
- Those presenting the characteristics of full health consumerism described in the "free choice self-care" scenarios and capable of paying use the limited services available in the consumer electronics market;
- Social divides are evidently increasing.

From the more technological perspective of PHS the implication of this scenario are:

- Advanced robotics for rehabilitation after severe and acute conditions provided by public healthcare institutions to the less financially capable patients;
- Ambient intelligence for monitoring and independent living provided by public healthcare institutions to the less financially capable impaired elderly.

Under this scenario increasing social divides is more than a remote risk.

3.3.4 "The Caring State (Good Big Brother)"

Scenario story

Although pervasive health consumerist attitudes and behaviours became dominant, the outbreak of acute crisis management have led the government to retain and increase control and direct financing and production of all healthcare services including PHS and reach high level of public financing of healthcare expenditure with little, if any, reliance on private players. Additionally the state enforce through hard incentives as a social responsibility healthy lifestyle and monitoring onto consumers/patients and aims to leverage and shape consumerist attitudes by fully controlling some prioritised PHS, placing high emphasis on compliance with treatment and lifestyles prescribed by healthcare professionals.

Macro environment

- With the implications of ageing society fully visible government controlled and provided PHS services focussing mostly on ensuring compliance and in monitoring acute conditions help containing the pressure on healthcare but cannot entirely restore the financial equilibrium of the healthcare system;
- The government directly and through its various healthcare institutions takes the full responsibility for the health status of its citizens, at all levels. Healthcare is funded for above 80% by public money, gathered through the general tax system. Except for the case of the elderly with ability problems, strict rules sanction non compliance to treatment and lifestyle guidance, excluding the non compliant from public funding of certain treatment and requiring from them cost-sharing for others. Inter-operability, guidelines, and standards for the provision of PHS are strictly dictated from the centre that monopolise the management of PHRs, not inter-operable and open to third parties players such as technology suppliers and media companies;
- Centralised government control and direct intervention in many domains bring about positive outcomes in terms of inter-agency integration and also of integration across social support, primary, secondary, and tertiary care, with healthcare organisations and professionals resistance overcome leveraging against them the expectations and needs of citizens/patients for seamless and technology supported services. Inter-mediate government tiers such as regions and local governments loose power;
- The trend of rising healthcare costs is contained but not reversed, despite efforts to curb non compliance and to enforce healthy lifestyles;

Transactional environment

- Public funding remains centralised, with a limited role for private insurance and the out of pocket outlays remaining of the same level as in the past. The prioritised PHS services provided by public healthcare organisations are directly financed by central government;

- Public healthcare organisations and their professionals, as well as General Practitioners retain full control of government funded PHS services, without any third party intervention and without relinquishing control in favour of consumers/patient empowerment. While some resistance still remain, government enforcement leads to integrated care solutions in limited areas, mostly aiming at early diagnosis compliance and enforcing healthy lifestyles;
- Despite top-down inter-operability and emphasis on some specific PHS applications, the PHS market taken in its entirety is not mainstreamed and remains fragmented into niche each dominated by few preferential providers of public institutions. In parallel a market develops based on PHRs voluntarily provided by consumers to large technology and media companies providing also PHS services, whose scale is such that prices remain high and cater wealthy individuals able to pay for them.

Users

Users present the same characteristics described in the "**Self-caring Society**" scenario with the following additional characterising elements:

- Most citizens/patients tolerate the benevolent but intrusive and limiting approach of government in exchange to the wide and affordable coverage it provides also in terms of PHS services. While reluctant, under certain conditions, they even accept PHS services based on invasive and/or uncomfortable data gathering devices;
- Those most independent an interested in taking health in their hand resort to advanced web tools for information and self-diagnosis provided by non public actors as well as to web 2.0 and community of interests;
- Affluent in the age group 45-55 and recently retired wealthy baby boomers pays for niche PHS services (different from those provide by the government) delivered by private players, while socio-economic disadvantaged individuals are fully excluded from PHS services other than those prioritised and provided by the government;

From the more technological perspective of PHS the implication of this scenario are:

- Sophisticated all encompassing sensors (that are actuators of medication) are used to manage disease and ensure compliance;
- Strict software supported care pathways guide PHS services requiring integration of different health care tiers/specialty (software systems coordinate the activities of all the health professionals responsible for the treatment of a patient and aligning delivery to best practice guidelines)

Under this scenario, the selective public support to only some kind of PHS services on the one hand, and the high cost of other ones to be paid out of pocket on the other, create a new form of social divide.

It is worth noting that a Caring State or Good Big Brother pushing health aware behaviours and sanctioning unhealthy ones is not something totally out of the possibility

and to be expected only in authoritarian state. It is starting to happen even in consolidated liberal democracy such the USA. The State of Alabama, after poor results from educational campaign, has recently imposed on its employees who smokes and/or are overweight a monthly payment of 25 $ for their health insurance, which for all other employees is entirely free[42].

3.3.5 Cross cutting elements

First, there are at least three trends already visible today (captured in the state of play already) and certain to continue in the future that, as such, cut across all of the four scenarios

- Increased chronic disease prevalence;
- Rising co-morbidity among chronic patients;
- Increasing incidence of neuro-psychological disorders calling;
- Increasing need of long term care;
- The increasing need of early diagnosis and prevention

Second, except for the "**State Keeps on Trying**", in all of the other three different scenarios one can identify common elements, though depending on different purposes and characteristics of the system depicted within each envisaged scenario:

- A shift of power from regional and local tiers of government back to the central level. In both "Self-caring Society" and "Two-Tiers Healthcare Management" this is due to the increasing importance of third party players and the need of government to better define policies, set rules and standards, monitor and measure. In "The Caring State" the driver comes from more efficient control through integration;
- Again for evidently different reasons, all of the three scenarios entail more integrated care delivery;
- Data analytics and intelligence and measurement and monitoring of health conditions and how they vary with delivery are crucial in all three scenarios.

Finally, there is one dimension we overlooked both in the state of play and in the draft final version of the scenarios and was brought to our attention during the Pisa Workshop, that is to say the implication for health technologies in general and for PHS in particular of the energy crisis and of the increasing need of environmental sustainability. This calls for attention toward energy efficiency and to reduction of waste also for PHS services.

[42] http://www.corriere.it/esteri/08_settembre_17/obesita_alabama_caretto_710ca5d4-84e0-11dd-be21-00144f02aabc.shtml

4 From scenarios to gaps and roadmaps

We aim here to present a self-standing chapter integrating a brief illustration of the gap analysis with a full treatment of the proposed roadmaps, so that readers interested only in the final results could skip previous chapters and read this one only but still grasp the context and the rationale behind identified gaps and research themes proposed for the future. To this purpose we have structured this chapter in a way that is worth illustrating here to guide the reader.

First, in **§ 4.1** we summarise the gap analysis by: a) very briefly recalling how the gaps were extracted[43] and presenting the first **Full List** of the 54 identified gap (**§ 4.1.1**); b) presenting the results of gaps assessment leading to a **Short List** of the 20 gaps deemed relevant for future technological research (**§ 4.1.2**); and c) reporting boxes synthetically illustrating the rationale and the preliminarily associated research themes for each of the 20 short listed gaps (**§ 4.1.3**).

Second, in **§ 4.2**, as a way of moving from the gap analysis to the proposed research roadmaps, we present and illustrate the reorganization of the 20 gaps into five research domain.

Finally, in the last five paragraphs of this chapter we present the proposed research roadmaps opportunely contextualised and discussed:

- "Bio(medicine) infused PHS" in **§ 4.3**
- "Intelligent PHS data processing" in **§ 4.4**;
- "Third Generation PHS Sensors " in **§ 4.5**;
- "Users Inclusive PHS Interfacing " in **§ 4.6**;
- "Advancing Point-of-Care" in **§ 4.7**;

4.1 Gaps analysis

4.1.1 The Full List of Gaps

A systematic comparison between the state of play and the scenarios, using as a structuring conceptual tool the earlier presented General Descriptive Framework (see Figure 11, p. 25), produced a preliminary list of gaps. After a series of consultation events the full list included 54 gaps, which are illustrated in the three tables reported in the next pages (Table 3, Table 4, Table 5, pp. 71-78).

Evidently the various dimensions of the framework used to structure the gap analysis can be separated only conceptually, for in reality they are closely inter-connected and

[43] The methodological principles and steps leading to the final results of the gaps analysis are illustrated in more details in methodological annex (see § 7.5).

interacting with each other. It goes without saying, thus, that gaps placed under one dimension of our framework could as well be relevant for another one and that there are probably some overlapping among gaps. In some of the cells of the following three tables we added some cross-references and, at any rate, when we moved from the gaps **Full List** to the **Short List** (see **Table 6**) and from this to the aggregation of gaps into research domains (see **Table 7**) overlapping gaps were merged and streamlined.

Each of three following tables deals with one category of the descriptive framework and disaggregates the categories into dimensions and their corresponding issues. Next to each issue there is a brief narrative that qualifies it and illustrates its relation to the current developments (state of play) and the scenarios. Moving right to left the issues are followed by the formulation of gaps.

Table 3 Full List of Gaps: Macro Environment

Dimensions	Issues	Current developments/ scenarios	GAPS
Society: demography and general health situation	Rising Chronic diseases prevalence	Trend already evident and addressed by advanced research applications but only by basic market services. Cross-cutting all four scenarios, a challenge particularly for "State keeps on trying".	1. PHS have yet little market penetration;
			2. PHS sensors still miss calibration, optimised power supply, multiples signs per sensor, actuation, multi-modal analysis and fusion;
	Co-morbidities of chronic disease implication for both management and early detection	Not addressed in currently available market and research applications. It emerged during the consultation process. Cutting across the scenarios but particularly salient in "Self-caring Society" (management) and in "The Caring State" (early detection) "	<u>Integrated care processes and delivery</u> 3. Little integration of care delivery processes 4. Knowledge and information segmented ; 5. Lack of shared platform for data repository and exchange; **N.B**. Not repeated elsewhere but relevant in many other dimensions
			<u>Disease management</u> 6. Inefficient energy and bandwidth use[44] 7. Lack of multi-signs/ multi-disease sensors
			<u>Early detection</u> 8. Encompassing biomarkers per lab-on-chip are limited to 2-3 9. PoC sample handling and preparation still, in most cases, requiring human intervention 10. Time to result is still too long
	Long-term care	The need to assist the elderly will increase even in absence of acute and chronic situation. Independent living research addresses this, but more efforts are needed. Particularly salient for State keeps on trying	11. Need of holistic PHS rehabilitation solutions; 12. Need of holistic PHS monitoring solutions
	Neuro-psychological disorders	These diseases are only staring to be addressed in PHS. Cutting across all four scenarios.	13. Lack of research on how to acquire data on emotional status and social interaction

[44] Insufficient integration of sub-systems resulting in high bandwidth requirement and power consumption (data gathering and processing separated -> large amount of data to be inter-communicated).

Society: Cultural attitudes and inclusion issues	ICT supported health consumerism	Springing from the "Self-caring Society": more personalisation, participation to treatment decisions, ownership of data, etc	14. Need to prepare healthcare professionals for more symmetric relations with citizen/ patients • See also governance and transactional environment and also Users & PHS
	Moral hazard and fatalism	Attitude present today and a challenge for "Caring State" scenario if they persist	15. Need of cogent incentives backed by sanctions
	Low confidence in/access to ICT	Evident today but basically related to "Two-tier healthcare management" and "State keeps on trying" scenarios	16. Need of education campaign and integration between eHealth and eInclusion policies (see more in Table 3 on Users & PHS)
Economy	Energy crisis	Emerged in the consultation process and relevant under a scenario of large scale adoption of PHS such as the "Self Caring Society".	17. Need of energy efficient PHS sub-systems and components
	Environmental sustainability	Emerged in the consultation process and relevant under a scenario of large scale adoption of PHS such as the "Self Caring Society)	18. Need to reduce PHS waste and disposal
Governance	Standard and rule setting (steering)	Fragmentation in legal frameworks (privacy, access to data, responsibility) inter-operability, guidelines, in brief lack of high level steering.	19. Lack of clear legal framework 20. Lack of bodies setting binding standards on inter-operability, protocols, pathways and clinical guidelines and stakeholders fora (including industry) at both national and EU level See more under Industry
	Financing	Current systems not sustainable, from Self-caring scenario springs the idea of outcome based financing	21. Institutional reform (see more in Table 5: 3rd party payers)
	Prevention & Compliance Focus	Little money currently allocated, issues stressed under "Caring State", but relevant to mitigate risk in "Self-caring society)	22. Need to increase investment of public funds

Table 4 Full List of Gaps: Transactional Environment

Dimension	Issues	Current developments/ scenarios	GAPS
Healthcare professionals attitudes/needs	Awareness/skills	State of play evidenced lack of awareness	23. Education, training, PHS embedded eLearning
	Confidence in the scientific reliability of PHS applications	Clinicians in relation to 'Self-caring society' scenarios stressed: • Need of scientific control of PHS; • Need of risk profiling to select target for use of PHS (especially for early detection and prevention)	24. PHS not fully informed by clinical evidence, and by molecular and genetic data
	Patient safety	Concerns about long term effects for human body contact with, ingestion of, sensors voiced by clinicians especially in relation to 'Self-caring society'.	25. Lack of data on long-term effects of contacts between human body and sensors of different materials especially for implantable (e.g., toxic effects)
	Decision support & guidance	Issue raised by clinicians in relation to 'Self-caring society' (decision support to interact with empowered citizens) and for the Caring state (top down pathways and guidelines)	26. Need of innovative DSS based on predictive/simulation/ visualisation 27. Need of PHS systems embedding clinical guidelines and pathways holistically[45]
Healthcare Delivery and PHS	Integration of patients' data	Little achieved in practice, potentially addressed by research but no deployment. Barriers are related to fragmentation of care processes, legal frameworks, interoperability Cross-cutting all scenarios.	28. Lack of shared infrastructures and standards for data exchange 29. Lack PHR inter-operability even at national level, gap relevant also for industry
	Prevention	Market applications are limited to basic fitness focussed services. Lifestyle and prevention research projects have been financed by FP, but they show less advancement compared to chronic disease management. Current reimbursements models provide little incentive. In the Caring state scenario prevention is one of the key characterising elements	30. Lack of business model 31. Lack of consolidated evaluation methods and supporting evidence[46]

[45] Software systems to coordinate the activities of all the health professionals responsible for the treatment of a patient and aligning delivery to best practice guidelines.

[46] Need to build evidence-based PHS prevention services linking PHS data with centrally stored health status indicators, by way of secure communication infrastructure.

Dimension	Issues	Current developments/ scenarios	GAPS
	Early detection, screening and profiling	Detection, screening and profiling are salient for the Caring state scenario	32. Lack of large enough databases for genetic mass screening of population 33. Need of legal framework and consensus
	Compliance	The importance of compliance with prescribe treatment and medication (especially for the elderly) and with life-style guidance (for all) is underscore in the scientific literature, but no products/services are available in the market and the research solutions are still basic (Automatic medication dispensers with certain alarm functions; developments in constant monitoring with wearable solutions) Compliance is key to the Caring State scenarios, but as a risk mitigating factors in light of citizen empowerment also in Self-caring society and Two tier healthcare management	34. Alarm functions and reminders are patently insufficient to ensure compliance 35. Need of closed loop solutions monitoring dispensation/reaction calling for all encompassing sensor 36. Need of more comfortable and less invasive sensors
3rd Party Payers	Outcome-based reimbursement	Large debate on how to increase efficiency and effectiveness of healthcare expenditure and create incentives for PHS. Widely recognised that lack of business model is a main barrier. This innovation is envisioned in "Self-caring society" and "Two-tier healthcare management"	37. Need of innovative measurement systems to support outcome based reimbursement based on integration between PHS generated data and larger public health data bases
Industry Perspective	standards / privacy and legal framework / inter-operability	These issues are clearly documented in the state of play and have already been included in Table 1 (Governance). Industry representatives consulted during workshop sees these creating local rather than Pan-European markets and as the key barriers (relevant for all scenarios). In next cell only the technological gaps are indicated (but it is clear that until these governance issues are not solved, technologies will find difficulties to be deployed)	38. Lack of tailoring of security and encryption techniques for healthcare sector application 39. Need of data management and mining applications integrated into PHS that embed, support and protect privacy (also relevant for Users & PHS, will not be repeated)

Table 5 Full List of Gaps: Users and PHS

Dimension	Issues	Current developments/ scenarios	GAPS
Awareness, trust, access and use	Awareness and trust	All these three sub-issues concerns a situation already evident today but that could become exacerbated in the "State keeps on trying" and "Two tier healthcare management", namely social divide with respect to awareness and trust, access, capacities to effectively use. They have been strongly emphasised by experts during consultation process. Naturally the solutions to these gaps will benefit also more sophisticated users (so are relevant also for the other two scenarios) Currently little has been done in terms of educational campaign, systematic provision of scientific reliable information, more accessible solutions, optimised inter-face, tools (imaging, visualisation) multi-modal interaction (mostly one-way messaging and little two-way interaction with functionalities resembling face2face interaction)	<u>Information campaign</u> 40. Off and online information (on scientific reliability, privacy issue, benefits, etc)
	Access		<u>More widespread and accessible channels</u> 41. Lack of PHS services delivered through Digital TV (way more diffused among the elderly and other less technologically sophisticate segment of the population and more intuitive than other channels)
	Interfaces/interaction		<u>Facilitating use</u> 42. Need of PHS embedded eLearning 43. Need of imaging and visualisation techniques for intuitive and easy to interpret input 44. Need of new technological solutions (possibly 'invisible) enhancing development and implementation of multi-channel interaction systems
Comfort, Acceptance, personalisation	Comfortable devices for acceptance	Efforts toward miniaturisation are visible in research and were considered of strategic importance during consultation process. Cross-cutting all four scenarios	45. Lack of "soft" and "invisible" devices that, however, ensure reliability of data gathered (i.e. wearable)
	Implantable	Implantable are an emerging issue in PHS research and, besides evident legal implications, raise serious issue of users acceptance and safety that were considered of strategic importance during consultation process. Cross-cutting all four scenarios	46. Implanted sensors gather data and actuate but do not communicate and cannot be monitored
Comfort, Acceptance, personalisation	Personalisation	Theme emerging mainly from Self-caring scenarios (see narrative about ICT supported healthcare consumerism). The issue of self-adaptivity and of multi-signs data gathering, however, was already clear from the state of play and is relevant not only more sophisticate consumerist users but also for all other segments of users	47. Need of auto-adaptive algorithms autonomously adjusting clinical parameters to individuals' conditions 48. Need of sensors monitoring different kind of signs ensuring context awareness 49. Development of modelling techniques able to correctly link physiological signs and motions, gestures, environmental data 50. Need of ubiquitous services distributed across

Dimension	Issues	Current developments/ scenarios	GAPS
			territory and of large processing capability into small and easy to carry/wear devices 51. Need of intuitive patient decision aid tool (prediction and simulation) 52. Need of quality controlled web 2.0 tools 53. Need of citizen owned fully inter-operable Personal Health Records (PHR) integrated with PHS 54. Possibility to adapt PHS components (e. g., sensors) according to individuals' characteristics, including, materials (due to allergies, for instance), position on patients' body, etc

4.1.2 Gaps assessment: the short list

The **Full List** was also object of discussion during consultation events and the gaps were assessed by experts in order to produce a restricted and more manageable list containing only those meeting both of the following two criteria: a) high importance of the gap; b) gap clearly linked to technological research[47]. During the cited consultation events experts were also asked to generally discuss the gaps and possibly associate to them actions needed in the future to fill the gaps (either related to technological research or to broadly defined implementation and socio-economic issues). Accordingly, in addition to the assessment and validation of the **Full List**, we also obtained valuables input to: a) rephrase and/or merge overlapping gaps; b) streamline and make the gap storylines more effective (see gaps' boxes 1 through 20 reported in next sub-paragraph)[48]; c) provide a first synthetic grouping of gaps into five domains of research with associated research themes (see **Table 7**).

The collective assessment produced by the experts out of the total 54 gaps singled out 23 of them as being concerning implementation and socio-economic issues and not relevant for future technological research[49]. These were, thus, eliminated and not considered further in the development of the research roadmap. They represent, however, important information that is not lost. In the graphic roadmaps they are visualised and they are then treated further in **chapter 5**.

We were, thus, left with 31 gaps associated to technological research, of which some have been discarded outright because of having low importance while others have been merged to eliminate initial overlapping. This produced the **Short List** of 20 gaps relevant for future technological research illustrated in **Table 6**. The right end column of **Table 6** synthetically provides information of which gaps were merged[50].

It is worth noting that, whereas already at the end of the state of play we signalled how PHS for chronic disease management should expand their reach beyond their current focus (mostly on cardiovascular and respiratory diseases and on diabetes) to include other diseases (of which we particularly mentioned neuro-psychological disorders), this issue does not appear as a self standing gap in the Short List.

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[47] See PHS2020 Deliverable D4.1, *Gap Analysis Report*, chapters 1 and 2 for the overall methodological and process, and Annex I for the illustration of the gap assessment procedure and the quantitative re-elaboration of inputs received from experts.

[48] See also PHS2020 Deliverable D4.1, *Gap Analysis Report*, § 4.2.

[49] These are gaps 1,3,4,5,14,15,16,19,20,21,22,23,28,29,30,31,32,33,37,38,39,40,53 of those in the **Full List**.

[50] See full explanation in PHS2020 Deliverable D4.1, *Gap Analysis Report*, pp. 16-18. The six gaps eliminated are, using their number in the **Full List**, the following: 6, 11, 12, 17, 18, and 50. For illustration of how these gaps are nonetheless reflected by those retained in the **Short List** see PHS2020 Deliverable D4.1, *Gap Analysis Report*, p. 18.

Table 6: Short list of gaps

Gaps	Reference to larger list /comments
1. Lack of integration of clinical evidence, and of bio-medical and genetic information	# 24 of full list
2. Need of auto-adaptive algorithms autonomously adjusting clinical parameters to individuals' conditions	# 47 of full list
3. Need of PHS systems holistically embedding clinical guidelines and pathways	# 26 of full list
4. Lack of monitoring techniques able to correctly link physiological signs and motions, gestures, and environmental data	# 49 of full list
5. Need of innovative and holistic DSS for healthcare professionals based on prediction/simulation/visualisation	# 27 of full list
6. Need of imaging and visualisation techniques for intuitive and easy to interpret input	# 43 of full list
7. Need of sensors monitoring different kinds of signs ensuring context awareness	# 48 but also reflecting # 13 (emotional status) of full list
8. Low possibility to adapt PHS components to individual characteristics	# 54 but also partially reflecting # 36 (implantable) and # 45 (wearable) of full list
9. Lack of data on long-term effects of contact between human body and sensors	# 25 of full list
10. Need of PHS embedded eLearning	# 42 of full list
11. Need of new technological solutions enhancing development and implementation of multi-channel interaction systems	# merge of 41 and 44 of full list
12. Need of quality controlled Web 2.0 tools	# 52 of full list
13. Need of intuitive patient decision aid tools (prediction and simulation)	# 51 of full list
14. Lack of multi-signs/multi-disease sensors	# 7 but also reflecting # 13 (emotional status) of full list
15. Lack of actuators	Derived from # 2 and also reflecting # 46 (implantable and actuation) of full list
16. Personalised drug delivery and compliance	Merging # 34 and 35 of full list
17. Endoscope capsules	New added gap
18. Encompassing biomarkers per Lab-on-Chip are limited to 2-3	# 8 of full list
19. PoC sample handling and preparation still, in most cases, requiring human intervention	# 9 of full list
20. PoC: time to result is still too long	# 10 of full list

Source: Author's elaboration of input from related consultation events

This is so because the gaps related to the expansion of sensors capability in terms of sign captured will make possible to include within the reach of PHS also other disease beyond those currently most commonly addressed. Nonetheless we will come back to this topic and underscore its importance in the conclusive section of the book. Finally, experts

brought up what we can call a meta-gap in the sense that it is not related to the substance of the research funded through EC Framework Programmes but rather to how they are designed. Experts pointed out to the need including clinical validation and clinical expertise in PHS project funded by Framework Programmes. They stressed the importance to include validation of PHS technologies in real environments into research projects. Also on this topic we will come back in the conclusive section of the book.

4.1.3 Gaps summary boxes

In this paragraph we report, for each of the 20 gaps of the **Short List,** summary boxes structured as illustrated below.

Name of the Gap	
Rationale	**Which problem the gap hints at**
Research items	**PHS specific research themes preliminarily associated to the gap**
Overlaps/ complementarities	**Research themes, associated to other gaps, that overlap and/or are in a logic relation of complementarity**
Other	**See explanation in text below**

Under the heading "other" are included themes that are relevant to fill the gap but either point to matters of implementation (i.e. inter-operability) or concern technological and non technological research developments falling outside the traditionally defined scope of PHS or not driven by PHS. An example could be MEMS and NEMS[51] that have been and are being developed in other fields but could enhance also PHS future applications. The two sections of the boxes "Overlaps/complementarities" and "Other" are included only for the gaps for which they apply. We must underline that, whereas all other sections of the summary boxes simply reflect the input obtained from experts during the workshop, that on "Overlaps/complementarities" results from our ex post comprehensive reading of all the 20 short listed gaps. Each box is referenced only with a short version of the name and with reference to its number in the **Full List** of gaps. Detailed gaps' descriptions and storylines can be found in PHS2020 Deliverable D4.1, *Gap Analysis Report* (pp. 19-37).

Box 1 Integration of clinical evidence and genetic information (# 24 of Full List)

Lack of integration of clinical evidence, and of bio-medical and genetic information	
Rationale	**Today PHS are mostly limited to vital and physiological signs and the processing thereof, which results in limited assessment and treatment and in the need of continuous traditional medical interventions.**

[51] Micro-Electro-Mechanical Systems (MEMS) and Nano-Electro-Mechanical Systems (NEMS) based sensors represent technological advancements being developed in other domains but with clear potentiality for PHS. They have been treated briefly in deliverable D2.1 State of Play and will be discussed in more details later (§ 4.5.2) as a result of the further review of the scientific literature conducted in preparation of the roadmap consultation cycle. Here it will suffice to anticipate that they may enable the implementation of micro-level systems interacting with their physical environment, minimally invasive, integrating sensing, computation and actuation, capturing several signs and possibly increasing energy efficiency and decreasing bandwidth requirements.

	In brief: PHS analysis is too general and hence very limited in terms of holistic cause-effect analysis => Need to Include all relevant macro and micro medical information necessary to run a whole and complete assessment of each individual's health status. Filling this gaps also contribute to make Personal Health System more "Personalised".
Research items	• **Integration into PHS of up-to-date medical information from bio-banks, clinical trials;** • **Integration into PHS of genetic and biomedical information;**
Overlaps/ complementarities	• **See Box 2 for the need of integrated interpretation and processing of genetic, biological and contextual data and for the challenge of data gathered under "uncontrolled conditions"**
Other	• **Ongoing investigation on linkage between genotyping and phenotype in pathologies;** • **Insights from chrono-biology (science that examines periodic, cyclic phenomena in living organisms and their adaptation to solar and lunar related rhythms);**

Box 2 Auto-adaptive algorithms (# 47 of Full List)

Need of auto-adaptive algorithms autonomously adjusting clinical parameters to individuals' conditions	
Rationale	**Extended amount of data is collected, however its transformation to valuable knowledge in terms of what the data means, is limited => requiring continuous intervention of healthcare professionals and confining PHS only to monitoring with little actuation and treatment.** **In combination with clinical evidence and bio-medical and genetic information, need of interpretation of body signals in the perspective of "body and mind" and of contextual conditions;** **Overcome current standardisation in clinical parameters => automatically adapt to individuals' conditions and produce real personalisation of PHS**
Research items	• **Improve data fusion and integration of data coming from different sources;** • **Improve self-adaptivity and self-calibration of algorithms to enable personalised data processing, which means recursively taking into account, and learning from, individuals' unique contextual (environmental and emotional) and genetic characteristics together with vital and physiological signs;** • **Devise correction/rectification techniques to normalise data gathered under "uncontrolled conditions"**
Overlaps/ complementarities	• **With box 1 (processing and interpretation of clinical evidence and bio-medical and genetic information)** • **With Boxes 4, 7, 14 on sensors (context awareness and multi-signs/multimodality)** • **With Boxes 3, 5, 13 (instrumental to prediction and modelling)**

Other	• **Controlled studies to correlate and compare data obtained in both "clinical settings" and "uncontrolled conditions" to identify normal and abnormal patterns taking into account personal and contextual factors (to be use for correction/rectification)** • **Full inter-operability among different PHS devices and between them and Personal Health Records (PHRs)**

Box 3 Clinical guidelines and pathways (# 26 of Full List)

Need of PHS systems holistically embedding clinical guidelines and pathways	
Rationale	**There is need for software systems coordinating the activities of all health professionals involved in the treatment of a patient, aligning care delivery around best practice guidelines** **In brief: Guidelines are mono-focused on single health conditions (i.e. one guideline per disease) => Need of guidelines enabling simultaneous assessment of several statuses, and hence their effect on each other.**
Research items	**Integration and modelling into PHS of "holistic" clinical guidelines that:** • **Address co-morbidities;** • **Consider emotional, behavioural personalised factors** • **Capture chrono-biological and environmental aspects**
Overlaps/ complementarities	• **Box 1 and Box 2 (integration and interpretation of clinical evidence and bio-medical and genetic information, including issue related to data gathered under "uncontrolled conditions")** • **Boxes 2,4,7 (On context awareness);** • **Boxes 5 and 13 (on prediction/modelling)**
Other	**Need of more cooperation between different professional profiles in different tiers of healthcare, and between them and research**

Box 4 Monitoring techniques linking various parameters (# 49 of Full List)

Lack of monitoring techniques able to correctly link physiological signs and motions, gestures, and environmental data	
Rationale	**Go beyond vital signs => integration of contextual, emotional posture and gestures data** **Multi dimensional data monitoring and processing => comprehensive representation of patients' status, encompassing all aspects (physical, contextual and psychological)**
Research items	• **Context awareness, multi signs and multi-sensors data integration (see later Boxes 7 and 14)**
Overlaps/ complementarities	• **Box 2 (Advancements in data processing)**
Other	• **Incorporation of developments in human-computer interfaces (in order to "read" emotions though facial expressions and gestures, see later) and ambient intelligence**

Box 5 DSS for healthcare professionals (# 27 of Full List)

Need of innovative and holistic DSS for healthcare professionals based on prediction/simulation/visualisation	
Rationale	Current PHS is limited to monitoring mostly vital and physiological signs. Need to consider the complexity of the human body including also contextual and emotional parameters Go beyond vital signs => comprehensive picture of human body to support decision through prediction/modelling and simulation/visualisation
Research items	• Develop new predictive, modelling and visualisation/simulation capacities for PHS (connected with deeper understanding of links between genotype and phenotype, that is integration and combined processing of several different sources of data)
Overlaps/ complementarities	• Box 1 and Box 2 (integration and interpretation of clinical evidence and bio-medical and genetic information) • Box 2 (data processing) • Box 6 (visualisation) • Box 13 (modelling and prediction)
Other	• Virtual Physiological Human (VPH) developments

Box 6 Imaging and visualisation (# 43 of Full List)

Need of imaging and visualisation techniques for intuitive and easy to interpret input	
Rationale	PHS solutions are limited in interaction and transmission of information in a perceptive manner=> Development of intuitive and easy to understand tools
Research items	Incorporation of self- and environment imaging (integrated with audio and sensing techniques)
Overlaps/ complementarities	• Box 5 and Box 13 (for what concern visualisation)
Enablers	• Ambient Interfacing • Ambient Intelligence and Intelligent Mixed Reality • Immersive Virtual Tele-presence

Box 7 Sensors for context awareness (# 48 of Full List)

Need of sensors monitoring different kinds of signs ensuring context awareness	
Rationale	Go beyond physiological signs => collection of contextual data Achieve real continuous monitoring => data gathering in uncontrolled environment
Research items	• New sensors capturing context (environment, emotional status, punctual location and situation, etc); • Optimisation of on-board processing capability • Integration of data from "external" sensors (i.e., sensors not on patient's body)

Overlaps/ complementarities	• **Box 1 and Box 2 (issue of data from "uncontrolled conditions"** • **Box 2 and Box 14 (multiple signs and multimodality)** • **Box 8 and Box 14 (Optimisation of sensors architecture)**
Other	• **Human-computer interaction / affecting computing**

Box 8 Low adaptability of PHS to individual characteristics (# 54, 36, and 45 of Full List)

Low possibility to adapt PHS components to individual characteristics	
Rationale	**Go beyond current standardised PHS architecture => "plug and play" components, to be combined on the basis of individuals' needs. Overcome fixed design => "modular" architecture, better adapting to individuals' characteristics and changes over time. Addressing also the issue of non invasiveness and of possible allergies to, effects of, sensors depending on individuals' characteristics.**
Research items	• **New sensors' materials (e.g., biological and molecular sensors);** • **Integration of alternative energy supplies, e.g. body energy** • **Optimisation of PHS sensors' networks architecture and components (modularisation, plug & play)** • **Self-calibration of sensors**
Overlaps/ complementarities	• **Box 2 (self-calibration)** • **Box 7 (architecture)** • **Box 14 (architecture and self-calibration)** • **On sensors materials: Boxes 9, 15, 16, 17**
Other	• **Design of innovative and open body area networks;** • **Standardisation of PHS components' inter-communication protocols and advancements in interoperability** • **MEMS and NEMS**

Box 9 Sensors long term effects (# 25 of Full List)

Lack of data on long-term effects of contact between human body and sensors	
Rationale	**Effects of radio waves and long term contact with body of PHS not known => Use of "safe" devices and materials.**
Research items	**Incorporation of alternative organic and/or molecular sensors.**
Overlaps/ complementarities	• **On sensors materials: Boxes 9, 15, 16, 17**
Other	• **Controlled clinical investigation of long term effects of sensors;** • **Development of alternative micro/ nano sensors in organic and/ or molecular material**

Box 10 PHS embedded eLearning (# 42 of Full List)

Need of PHS embedded eLearning	
Rationale	**PHS solutions do not incorporate knowledge transmission and hence, prevention is not sufficiently highlighted => Develop solutions enabling users to be co-producers of health**
Research items	**Incorporation of easy to use training modules into PHS applications**

Box 11 Solutions for multi-channel interaction (# 41 and 44 of Full List)

Need of new technological solutions enhancing development and implementation of multi-channel interaction systems	
Rationale	Lack of diversity in PHS tools => enhance mobility and multi-modal interaction possibilities.
Research items	• PHS applications delivered through many channels at the same time; including: Digital TV; Web (including social networks); Mobile communication devices; • Enhancement of human-computer interaction in PHS
Overlaps/ complementarities	• Human-computer interfaces, affective computing (Boxes 7)
Other	• Human-computer interaction, affective computing • Mobile and broadcasting communications.

Box 12 Quality controlled web 2.0 (# 52 of Full List)

Need of quality controlled web 2.0 tools	
Rationale	Avoid current contradictions and inconsistencies in available health information => scientific control of health information on the Web Better exploit participatory network potential => incorporate such functionalities into PHS
Research items	Integration of Web 2.0 applications into PHS Criteria for scientific control and supervision of participatory Web 2.0 tools
Other	Incorporation of advancements in Web ontologies applications

Box 13 Patient decisions aid tools (# 51 of Full List)

Need of intuitive patient decision aid tools	
Rationale	Provide support to patients' decisions and treatment => integration of users' friendly prediction and simulation tools Provide support to patients' decisions and treatment => incorporation of motivation sustain and psychological support
Research items	• Integration of simulation tools based on prediction and modelling • Integration of user-friendly interfaces and visualisation techniques
Overlaps/ complementarities	• Data processing of several sources of information, prediction, modelling, visualisation/simulation (Boxes 1, 2, 5, • Holistic guidelines (Box 3) • Human-computer interfaces, affective computing (Boxes 7 and 11)

Box 14 Multi-signs/ multi-disease sensors (# 7 and 13 of Full List)

Lack of multi-signs/multi-disease sensors	
Rationale	Avoid current fragmentation => integration of data acquisition in one single unit, thus reducing the number of components (and related data transfer activities) and the corresponding energy consumption (and waste) and bandwidth needs Go beyond vital signs => collection also of contextual and emotional data. Overcome disease-specificity in design=>

	adaptable and standardised plug-and-play systems (common rationale with gap of Box 8)
Research items	**Optimisation of multimodality to ensure multi-disease and multi-signal assessments;**
Overlaps/ complementarities	• **Box 8: optimisation of sensors architecture and self calibration of sensors and self-calibration of sensors**
Other	• **MEMS and NEMS**

Box 15 Actuators (# 2 and 46 of Full List)

Lack of actuators	
Rationale	**Limit professionals' intervention => closed-loop solutions encompassing diagnosis *(endoscope)*, dispensation, reaction and monitoring**
Research items	**All-encompassing sensors/actuators, incorporating several functions (like sensor, actuators and communication) using new materials and reducing invasiveness;**
Overlaps/ complementarities	• **Box 8 and Box 9 (sensors materials and invasiveness)**
Other	• **Development of alternative micro/ nano sensors in organic and/ or molecular material** • **MEMS and NEMS**

Box 16 Personalised drugs delivery (# 34 and 35 of Full List)

Need of sensors for personalised drug delivery and compliance	
Rationale	**Enhance compliance to medical prescriptions => personalised reminders functionalities** **Detection of drug intake/conformity to prescription => patients' continuous monitoring and alarms functionalities** **Reducing care burden => automatic drug delivery**
Research items	• **User adaptive reminders (active both at home and outside)** • **Integration of implantable minimally invasive drug delivery systems**
Overlaps/ complementarities	• **Box 8 and Box 9 (sensors materials and invasiveness)**
Other	• **Development of alternative micro/ nano sensors in organic and/ or molecular material** • **MEMS and NEMS**

Box 17 Endoscope capsules (new gap)

Endoscopy capsules	
Rationale	**Reducing invasiveness of certain medical exams => smart pills for endoscope to be swallowed or injected.** **Enlarge PHS diagnosis capability => integration of endoscope capsules in PHS applications**
Research items	• **Development of automatic orientation and navigation systems;**

	• Integration of medical imaging techniques; • Incorporation of easy to use interfaces.
Overlaps/ complementarities	• Box 8 and Box 9 (sensors materials and invasiveness)
Other	• Advancements in research in very small/alternative energy supply systems; • Development of alternative micro/ nano sensors in organic and/ or molecular material • MEMS and NEMS

Box 18 Biomarkers per Lab-On-Chip (# 8 of Full List)

Encompassing Biomarkers per Lab-On-Chip are limited to 2-3	
Rationale	Avoid fragmentation of testing, i.e. use of traditional lab tests to complete POC testing => encompassing the all biomarkers needed to run a complete assessment into one single biochip
Research items	Investigation on including more than a few biomarkers onto one single lab-on-chip; Further inclusion of genetic info testing
Other	• Research results on "new" biomarkers more adapted to POC • Integration of Micro-Opto-Electro-Mechanical-System (MOEMS)

Box 19 PoC sample preparation (# 9 of Full List)

PoC sample handling and preparation still, in most cases, requiring human intervention	
Rationale	Limitation of human intervention and consequently, adverse errors and long lead time => Human intervention to be limited to only applying sample onto the lab-on-chip.
Research items	Development of automatic and on-board sample preparation; Examination on automatic calibration.
Other	• Further research on micro-fluidic techniques optimising sample course control.

Box 20 PoC time to result too long (# 10 of Full List)

PoC time to result is still too long	
Rationale	Sample analysis results are obtained with drawn out waiting time => optimise time to result
Research items	Optimising of fluidic control and run-time
Other	• Further research on alternative array technologies adapted to POC-solutions

4.2 From Gaps to research domains and roadmaps

The synthetic boxes illustrated in the previous paragraph reflect the discussions and input of the gap cycle consultation events. They clearly needed, however, to be conceptually re-organised and re-elaborated to serve as the platform for the consultation events focussing on the proposed research roadmaps. As matter of fact the boxes already contain hints at overlaps/complementarities between the research themes preliminarily associated to the gaps.

During the 5th meeting of the ESC, leveraging the insights and expertise of the experts who had been supporting our project from its very beginning, the 20 gaps included in the **Short List** were further streamlined, reconceptualised, and finally grouped into five separate research domains.

This grouping of gaps and preliminary research themes has been further re-elaborated and its final version is illustrated in Table 7 presented in next two pages and commented here. This table to some extent selectively and freely re-use and re-phrase the contents of the gap boxes presented in the previous paragraph in light of the considerations that follow. For the sake of clarity, however, the numbers of the related gaps' boxes are also reported at the bottom of each group in the table, in order to reduce the possible confusion generated by the necessary rephrasing.

We used two lenses to read, re-compact and understand in a coherent picture those that at first sight could appear as disparate and disjoint gaps (and related research themes).

First, the gaps of the **Short List** are ***connected by the thread of making Personal Health Systems truly personalised and efficient, which means that they function*****:** a) capturing the very peculiar characteristics of individuals (vital and physiological signs, but also their genetic outlook, as well as their clinical history, and their socio-demographic and socio-economic conditions); b) ensuring awareness of very punctual contextual conditions (location, activity being performed, emotional status, physical and chemical conditions in the environment, etc); c) intelligently processing such information to support traditional action and automatic actuation, thus, enabling new applications and services going beyond monitoring; d) using devices as minimally invasive and comfortable as possible, adaptable to the very personal specificities and needs of each single individuals (i.e. avoiding materials to which one may be allergic, or which may negatively interact with individual specific health and contextual parameters, or which may have negative long term effect regardless in general) ; e) providing 'front-end' fruition modalities that respond to different attitudes and needs of different typology of users;

Table 7: From gaps to research domain and preliminary themes

Research	GAPS	Preliminarily associated research themes
Bio(medicine) Infused PHS ***(boxes: 1, 3, 5)***	• Lack of integration of updated clinical evidence, biomedical and genetic information to ensure scientific control, risk assessment, and personalisation • Validation of data from uncontrolled conditions (enucleated and moved here from Gap of Box 2)	• Integration of up-to-date medical info from bio-banks, trials; • Integration of genetic and biomedical information • Controlled studies to correlate and compare data obtained in both "clinical settings" and "uncontrolled conditions"(from context aware PHS) to identify normal and abnormal patterns of parameters uses for action/actuation taking into account personal and contextual factors (to be used for correction/rectification)
	• Need of holistic clinical guidelines and pathways to align PHS delivered care to best practices and to capture the multi-facet nature of health status	• software systems integrating and modelling guidelines within PHS
	• Need of innovative and holistic DSS for healthcare professionals to provide an holistic picture of human body complexity through prediction/simulation/visualisation	• Integration of PHS and VPH (supported by modelling and prediction); • Development of VPH-inspired interfacing for PHS DSS;
Intelligent PHS Data Processing ***(boxes: 2, 4, 13)***	• Lack of capacity to process data coming from different sources and to address the issue of data generated under "uncontrolled conditions";	• Data fusion and multimodality (data processing, interpretation and modelling capable of simultaneously treating vital and physiological signs, genetic, biomedical, and contextual parameters such as individuals activities, location, emotional status, external environment; • Correction/rectification techniques to normalise data gathered under "uncontrolled conditions"
	• Lack of capacity to recursively learn from individuals specific characteristics and context and automatically adapt data processing to personalise monitoring and enabling actuation reducing the need of healthcare professionals intervention	• Auto-adaptive and data fusional algorithms and related prediction and modelling techniques; • Development of automatic calibration
	• Lack of personalised aid decision tools for users	• Development of simulation tools based on holistic data processing (see above) and easy imaging and visualisation (see VPH related themes)
Users Inclusive PHS Interfaces ***(boxes: 6, 10, 11, 12)***	• Lack of multi-channel delivery and inter-action creating risk of exclusion	• Development of multi-channel delivery and inter-action systems including more commonly used devices (i.e. mobile, Digital TV, etc.)
	• Need of more understandable and easy to interpret input and guidance to users;	• Development optimal and easy-to-use interfacing techniques; • Development of straightforward imaging;
	• Need to better inform and educate PHS users	• Development of PHS related e-Learning and web2.0 tools

Research	GAPS	Preliminarily associated research themes
Third Generation PHS Sensors ***(boxes: 4, 7, 8, 9, 14, 15, 16, 17)***	• Lack of capacity to capture new signs on the environment (both physical and chemical parameters) and on the peculiar situations of individuals (activity, location, emotional status) • Monitoring techniques not able to correctly link physiological signs, with motions, gestures, and environmental data;	• New sensors for context awareness (environment, emotional status, punctual location and situation, etc) and for gathering data in "uncontrolled conditions"; • Investigate out to incorporate data from environmental sensors • Incorporation of advancements in human-computer interfaces and ambient intelligence (in order to "read" emotions though facial expressions and gestures, see later) • Incorporation of on- board processing
	• Need to go beyond the "one sensor- one signal" and "one sensor- one disease" paradigm to optimise energy and bandwidth usage • Need to simplify and reduce the amount of data transfers • Need to increase flexibility and better adapt the sensors to individual characteristics (reduce invasiveness and consider allergies)	• Optimisation of multi-modality to insure multi-disease and multi-signal assessments • Self-calibration of sensors • Optimisation of sensors area networks and modularisation of components (plug & play)

	• Lack of knowledge on the long term effect of sensors contact with, and presence in, the human body;
	• Lack of closed loop systems moving PHS beyond monitoring and into diagnosis and treatment (i.e. dispensation and reaction):
	  ○ Actuators in general
	  ○ Personalised drug delivery
	  ○ Endoscopy capsules
		• Integration of researches on alternative sensors' materials (e.g., biological and molecular sensors)
		• New smart sensors encompassing multimodality, computational power and actuation functionalities (including alternative energy sources: i.e. body energy)
		• Incorporation of controlled drug delivery sensors (implantable and minimally invasive)

Advancing Point-of-Care ***(boxes: 18, 19, 20)***	• Avoid fragmentation of testing and the need of traditional lab tests to complete Point Of Care (POC) testing	• Investigation on including multiple biomarkers on a single chip • Research on "new" biomarkers more adapted to POC; • Integration of Micro-Opto-Electro-Mechanical-System (MOEMS)
	• Reduce human intervention in sample preparation;	• Development of on-board sample preparation; • Further research on micro-fluidic techniques optimising "sample course control";

Research	GAPS	Preliminarily associated research themes
	• Reduce time to result;	• Optimising of fluidic control and run-time; • Further research on alternative array technologies adapted to POC-solutions

Second, many of gaps have been elicited by the two most relevant scenarios from the perspective of PHS: ***the "Self-Caring Society" and the "Caring State" scenarios*** (see chapter 3: pp. 59-62 and pp. 66-68). These two scenarios elicited gaps and research themes that would either support their desirable elements or offset their undesirable ones. Both scenarios, although for different reasons, envisage the large scale deployment and usage of PHS in the future. In the "Self-Caring Society" health consumerist and technology confident individuals will be fully empowered by PHS service to care for their health and engage into symmetric relations with healthcare professionals, whose intervention will be reduced in a context where the healthcare sector will be open to a multitude of players as the public actor will limit its role to that of steering but will reduce its production function. On the contrary the "Caring State" will retain control over the healthcare sector but will heavily rely on PHS solutions, especially for prevention, early detection, lifestyle management with a strong emphasis on compliance to prescriptions and guidelines and sanctions on moral hazard and opportunistic behaviours. Whereas we are not concerned with each of these two scenarios as such, having in view the vision of increasingly functional and used PHS applications and assuming that the actual future will be somehow a mixture of these two scenarios, evidently the gaps and associated research themes elicited by such scenarios are of crucial importance.

As a result of the combined reading through these two lenses an additional important issue emerged that we can call "***Energy Efficient and Environmentally Friendly PHS***". First, if PHS have to be truly personalised and user friendly they must use minimally or non invasive devices and minimise constrains on user normal life, which means wireless and mobile systems. Both of these two requirements raise challenges of optimisation of energy and bandwidth consumption. Second, if we look at this from the perspective of scenarios envisaging large scale deployment and usage of PHS, then the issue of energy efficiency become a must from a macro socio-economic perspective as does the need of reduce waste disposal and pursue the environmental sustainability of PHS.

The gap where the thread of personalisation and the input of the two cited scenarios are most clearly entwined is that stressing how ***current PHS applications lack integration with clinical evidence and with bio-medical and genetic information***. Clearly there is probably nothing more 'personal' than our genes, and ***genomic information*** could greatly enhance the goal of personalised treatment, if combined with other information about phenotypes (i.e. vital and physiological signs) and also about personalised context (emotional and social state, activities and location, external environmental physical and chemical conditions). Yet, this gap also reflects the concern that, if PHS applications reach large scale deployment and usage, they must be scientifically controlled and be constantly fed with updated clinical evidence. This latter aspect is also reflected in the gap about the need for PHS to incorporate holistic (i.e. across specialities and tiers of healthcare) clinical guidelines and pathways to ensure that eventual treatment match the very specific conditions of each unique individual and the multi-faceted nature of diseases (i.e. in particular co-morbidities for chronic patients).

Whereas we initially captured these issues only marginally, as elements among others within the data-processing sub-system, the input received from experts led us to consider them as comprising a research domain in their own right. We termed this domain "Bio(medicine) Infused PHS**" to covey the idea of PHS incorporating input from biomedical biomedical and genomic research and from clinical evidence and practice (main gap of Box 1, p. 79). Under this domain are also included the need of new and innovative Decision Support Systems for healthcare professionals (**

Box 5, p. 82)[52] and of PHS being informed by holistic guidelines (Box 3 , p. 81).

Evidently, the additional clinical and bio-medical /genetic information incorporated into PHS would need to be processed and interpreted. In the same way the innovative DSS tool would need to be based on predictive and monitoring capabilities, and also holistic guidelines are in clear relation with issue related to the processing of data. In this respect, then, it is evident that there are clear overlaps between issues placed under the "**Bio(medicine) Infused PHS**" research domain and those included within the "**Intelligent PHS Data Processing**" one. Moreover, a full and complete personalised picture requires detecting context in its various dimensions, an issue where these two research domain converge with that on "**Third Generation PHS Sensors**". Such intelligent and fully personalised processing, in fact, can be accomplished only inasmuch as the gap stressing the need of sensors monitoring different kinds of signs ensuring context awareness (external environmental factors, situational activities and location, emotional status) is addressed (Box 7, p. 82). Such new sensors would also be fundamental to tackle the issue of data gathering under uncontrolled conditions.

The issues of making PHS more personalised is tackled in most of its dimensions under the ***gap on auto-adaptive and self-calibrating data processing*** (Box 2, p. 80), for it deals with the capacity to process a variety of different data recursively as to learn and adapt to the very peculiar characteristics and punctual situations of each individual. In this respect, although presented separately, the gap about ***PHS currently lacking techniques able to correctly link physiological signs with motions, gestures, and environmental data*** (Box 4 p. 81) can be considered as a sub-issue of the one on auto-adaptive and self-calibrating algorithms (and is also in overlaps with that about context aware sensor of Box 7, p. 82).

Another issue overlapping "**Bio(medicine) Infused PHS**" and "**Intelligent PHS Data Processing**" has to do with the peculiar nature of the data gathered by PHS. In most cases this data, if we compare them to those from traditional clinical settings, will originate within what can be deemed **"uncontrolled conditions"**. This means that the value of the parameters gathered may be influenced by "situation-specific" environmental and/or emotional factors. Data thus produced can be interesting to clinicians but currently cannot

[52] Even in this case the gap partly responds to the need (and possibility offered by advancements in VPH) to provide a more personalised visualisation and simulation/modelling of individuals conditions and partly to better endow professionals with appropriate tools to cope with future more empowered users' demanding the symmetric and possibly negotiating relation depicted in the "Self-Caring Society" scenario.

be used, for instance, to take decision on treatment. Risk thresholds for certain parameters (based on statistically observed patterns in clinical settings) shape decision making about treatment in medicine. The data produced from PHS cannot be currently used against those risk parameters as long as they originate in "uncontrolled conditions" that may cause measurement errors (leading either to unnecessary intervention or to not intervening when needed). This has two implications. First, controlled studies are needed including measurements on a number of parameters for a given sample of individuals in both clinical settings and in "uncontrolled conditions" as to include personal conditions and environmental factors. These should enable to assess normal and abnormal patterns in light of personal patterns and context. Second, with this input PHS powered by innovative self-adaptive algorithms should recursively process data and identify truly abnormal patterns, as well as rectify/correct parameters that may appear as abnormal only due to very peculiar contextual conditions. This topic has implications both from the perspective of clinical research and practice and from that of data processing technicalities. In fact, first input from trials comparing data gathered both in clinical settings and under uncontrolled conditions will be needed, and then solution must be found within data processing technicalities (i.e. data correction and rectification). Accordingly we enucleated the challenge of making the data gathered under "uncontrolled conditions" suitable to support decision making and actuation from the gap on ***auto-adaptive and self-calibrating algorithms*** (Box 2, p. 80) and included it in different ways in the two research domains of "**Bio(medicine) Infused PHS**" and "**Intelligent PHS Data Processing**". On the other hand, once again there is on this issue a convergence between these two research domains and that of sensors, for they are the key sources of data gathered under "uncontrolled conditions".

Following the ***thread of personalisation*** we can see further link (and partial overlaps) between the "**Intelligent PHS Data Processing**" and "**Third Generation PHS Sensors**", in that self-adaptivity and self-calibration of algorithms is a pre-condition for actuation, which is the object of three other gaps related to sensors (see Box 15, p. 85; Box 16, p. 85; Box 17, p. 85). Moreover, self-calibration is an issue associated also to other sensors related gaps (i.e. Box 7, p. 82; Box 8, p. 83; Box 14, p. 84). Finally, all of the six gaps related to sensors (Box 7, Box 8, Box 9, Box 14, Box 15, Box 16, and Box 17) envisage the opportunity and potential of incorporating on-board processing, and in some cases also actuation, within the sensors themselves. If this occurs, the conceptual distinction between data processing and sensors ceases to be relevant and all of the various research themes overlap.

Now considering only the sensors research domain we can identify three sub-groups termed below using the main research direction they suggest:

- Context and emotional awareness:
    - Need of sensors monitoring different kinds of signs ensuring context awareness;
    - Lack of monitoring techniques able to correctly link physiological signs and motions, gestures, and environmental data;

- Sensors multi-modality and networks:
    - Low possibility to adapt PHS components to individual characteristics (architecture, plug and play, on board processing) ;
    - Lack of multi-signs/multi-disease sensors (multi-modalities, self-calibration, architecture, plug and play, on board processing);
- Materials and functionalities (actuation):
    - Lack of data on long-term effects of contact between human body and sensors;
    - Lack of actuators;
    - Personalised drug delivery and compliance;
    - Endoscopy capsules.

Also in this case we are proposing a conceptual simplification of what in practice is a more complex and entwined matter. Sensors for context and emotional awareness may also be integrated into sensors' networks and would benefit from the advancements envisaged there (on board processing, multi-modality, and self-calibration). The same also applies for the third group of gaps, whose main research theme associated is about materials and functionalities. On the other hand, new materials and functionalities are also relevant for the gaps associated to context and emotional awareness and to sensors networks as main research themes.

Next we can group together a number of gaps also related to personalisation but from a slightly different angle. In the context of most of the previous gaps personalisation referred to the capacity of data gathering and data processing to capture the very specific characteristics and contextual conditions of each single individual in order to produce personalised monitoring, diagnosis and treatment, in other words we considered the 'production' or "back-office" side of PHS personalisation. The following gaps, which we grouped under the research domain termed "**Users Inclusive PHS Interfaces**", address personalisation from the perspective of users' experience, in other words users' fruition of, and interaction with, PHS as services, and also from the perspective of the broader matter of health awareness. Also in this case the various future scenarios elaborated have played a role in eliciting these gaps, and in particular the "Self-Caring Society" one. First, a possible negative effect of this scenario is that it would produce further exclusion of those groups in society less digitally connected and less confident with the use of technology and capable of understanding its input. Second, consumerist attitudes toward health and independent self-caring activities can produce negative results if users access uncontrolled source of health information and/or are not adequately educated in health matters in general and on the various aspect of the PHS applications they will use in particular. From these two risks four gaps emerged. First, to counterbalance the risk of PHS being a source of exclusionary processes, the gap ***PHS must address is the harnessing of new technological solutions ensuring multi-channel interaction and including also channels more accessible and easy to use (i.e. mobile and/or digital***

television) for less technology confident individuals (see Box 11, p. 84). Second, assuming individuals use PHS services through their preferred channel, a second ***gap stresses the need for PHS to deliver to users input and indications that are intuitive and easy to use through state of the art imagining and visualisation techniques*** (see box 6, p. 82). Third, in order to at least try to channel health consumerist individuals toward correct information and decisions a third ***gap calls for the production of quality controlled Web 2.0 tools on matters related to PHS (see Box 12, p. 84)***. Finally, a fourth ***gap suggests the opportunity to embed within PHS application eLearning modules for users (see Box 10, p. 83).***

Also for the gaps within the "**Inclusive PHS Interfaces**" domain we can pinpoint some overlaps and links with those of other research domains. First, addressing the two gaps about quality controlled Web 2.0 tools and PHS embedding eLearning modules would require the input and expertise of healthcare professional and, thus, could also be seen as part of the "**Bio(medicine) Infused PHS**" research domain. Second, there is a clear overlap among the following three gaps:

- Need of imaging and visualisation techniques for intuitive and easy to interpret input (Box 6, p. 82)
- Need of innovative and holistic DSS for healthcare professionals based on prediction/simulation/visualisation (Box 5, p. 82);
- Need of intuitive patient decision aid tools (prediction and simulation) (Box 13, p. 84).

The development of new and innovative DSS for healthcare professionals based on the integration between PHS and VPH could have positive overspill for users precisely by producing intuitive imagining and visualisation. If this occurs, then these will become DSS shared between the healthcare professionals and patients/users, making thus redundant the gap reported in the last bullet point about "patient aid decision tools". This latter gap, however, emphasise the modelling and processing of data and could then be retained as part of the "**Intelligent PHS Data Processing**" research domain.

The final research domain identified is that of "**Advancing Point-of-Care**", under which fall the following three gaps:

- Avoid fragmentation of testing and the need of traditional lab tests to complete Point Of Care (POC) testing (Box 18, p. 86);
- Reduce human intervention in sample preparation (Box 19, p. 86);
- Need to reduce time to result (Box 20, p. 86).

The considerations developed so far aimed at reconstructing the common logic behind the final list of 20 gaps. Although it is an *ex post* reconstruction, it clear rests on what we can call the "emergent structure" of the problem, since the perspectives formulated by different experts during different workshops converge toward a common direction we have read ***through the prisms of personalisation***.

These considerations also underscore how there are several complementarities and overlaps between issues currently grouped into distinct research domains and point into the direction of a possible holistic and all-encompassing roadmap. Indeed the five research domains are nothing else but components of the overall PHS research field. Elements within each of these five domains can be combined in various ways to define various configurations of future research projects to be funded. In the next paragraphs, thus, we present five separate roadmaps for each of these five domains as a research portfolio management tool, from which the Commission or any other national or international funding agency can select themes and combine them into a variety of possible configurations. The considerations we developed so far in this paragraph serve the purpose of: a) acknowledging that, as usual, our conceptual organisation of gaps into research domains it is a simplification with respect to entwined complexities of the issue at hand ; and b) pointing out complementarities and overlaps precisely to suggest alternative ways to re-use our work.

Before entering into each of the five proposed roadmaps, a few final illustrative notations are needed to enable the reader smoothly move through the following paragraphs.

First, the reader will not find a perfect "one to one match" between the research themes included in the five roadmaps and those listed in the last column of Table 7 (p. 88). Indeed with respect to the content of Table 7 the five roadmaps: a) have dropped a few of the research themes; c) have added new ones not contained in the table; and c) include some of the themes of the table in slightly modified fashion (either rephrased or grouped together with new themes). These changes are not arbitrary and resulted from the additional consultation steps and data gathering activities (further search and analysis of the relevant scientific literature) we carried out at the end of the gaps analysis.

Second, three gaps presenting clear overlap have been associated to only one research theme to avoid repetition. The three gaps are the following:

- "Need of imaging and visualisation techniques for intuitive and easy to interpret input" grouped in the "**Users inclusive PHS Interfaces"** domain;
- "Need of innovative and holistic DSS for healthcare professionals based on prediction/simulation/visualisation" grouped in the "**Bio(medicine) Infused PHS"**;
- "Need of intuitive patient decision aid tools (prediction and simulation)" grouped in the "**Intelligent PHS Data Processing"** domain (Gap Analysis Report, Box 13, p. 32).

They have all been associated to the research theme termed "**Development of Shared Patient-Doctors Decision Support Systems**". This theme is included in the graphic visualisation of both the "**Bio(medicine) Infused PHS**" roadmap and the "**Intelligent PHS Data Processing**" roadmap, but it is further discussed only in the text accompanying the presentation of the latter.

Each of the following paragraphs is structured in the same manner and includes the following three sub-paragraphs:

1. **Contextualisation**. It briefly recall for the sake of a smooth narrative how the themes included within each research domain relate to the key findings of the state of play;
2. **Further insights.** It provides an overview of the additional insights extracted from the additional review of the scientific literature mentioned above;
3. **Proposed roadmap**. It graphically visualises the proposed roadmap and briefly comment it.

At the very beginning, before the graphic visualisation of the roadmap, a summary table re-compact synthetically and selective the content of Table 7 (pp. 88-93) with the input from the sub-paragraph on ”Further Insights”.

The roadmaps visualisation is presented and includes three layers. The core layer in the middle of the graphic indicates the themes proposed for research. This is preceded at the top by a layer termed “scoping / enablers” requiring a brief explanation. Scoping refers to themes that are proposed for a preliminary assessment (traditionally through Support Actions and/or Tendered Studies) before they can become the object of technological research. They usually concern themes coming from other areas of technological and/or non technological research we term “enablers” in the sense that they are not PHS or in general eHealth specific but can better enable theme. In some cases enablers are include as such and not as an object of scoping activities, which means that they could be already integrated into PHS technological research. The bottom layer contains a few implementation issues that emerged as very strategic both during the consultation process and from the further review of the scientific literature.

The proposed roadmaps are only briefly commented for they are fully substantiated by the contents and analysis produced throughout this chapter.

4.3 Bio(medicine) infused PHS: rationale and roadmap

4.3.1 Contextualisation

The idea of having a separated roadmap on a research domain termed "Bio(medicine) Infused PHS" was not already inscribed in the standard parameters of how the PHS field is defined and was mainly an input from experts (especially clinicians) during the consultation process. This domain could be simply included as a component of the next roadmap on "**Intelligent PHS Data Processing**" or as an external enabler to it. Yet, we considered it worth being treated separately for it points out possible synergies between PHS, Biomedical Informatics (BMI), and Virtual Physiological Human (VPH).

As explained earlier, some of the PHS2020 scenarios lead expert to point out to the need of scientific validation and control of PHS, as well as to the potentialities of integration with emerging trends in bio-medicine and genetics. In brief the inputs from experts have underscored the need to:

- **Integrate clinical evidence and guidelines holistically**. The argument, made especially by clinicians, is that PHS do not sufficiently embed, and are not steadily fed by, the evolving clinical evidence and related guidelines. This results in healthcare professionals scepticism and fear that the use of PHS applications might have unintended consequences and damage the doctor-patient relation. When they do incorporate some level of clinical evidence and guidelines, currently developed PHS applications do so in a mono-dimensional and vertical way (i.e. one disease at the time), whereas in many cases chronic patients present conditions of co-morbidity (2 o 3 more diseases)[53]. Accordingly PHS do not provide a complete picture of the individual health status and may provide inappropriate input, failing to address the needs of patients with co-morbid illnesses. It was added, though, that this lack of multi-dimensional focus characterises also medicine in general, often leading to poor quality of life, physical disability, high healthcare use, multiple medications, and increased risk for adverse drug events and mortality. Accordingly, optimising care for the co-morbid population is a very high priority (Boyd et al, 2005). Patients with multiple co-morbidities put the clinicians under tremendous pressures from different angles (Turner, 2006).
- **Integrate molecular and genetic data**. It was argued, especially by researchers working across the boundaries of medicine and informatics, that the current limitations of PHS is that they are capable of capturing only intermediate phenotypes (biochemical and physiological values) at best, while they have little or no capability to incorporate the assessment of environmental factors and of genetic information. As in the timeframe of 2020 it will probably be possible to have the personal genome in a few hours and at low cost, genetic and

[53] In 1999, 48% of Medicare (USA) beneficiaries aged 65 years or older had at least 3 chronic medical conditions and 21% 5 or more (Boyd et al, 2005).

environmental factors should be included into PHS to increase their capacity of producing personalised and individualised early diagnosis, treatment and prevention. How this fits into the three building blocks, is that the models and the algorithms need to be more complete, and incorporate the mentioned data. Additionally, also the feedback provided can include the crossing of the risk factors of genomic and dynamic information.

4.3.2 Further insights

Knowledge into practice: a challenge for medicine as such. The problem of putting knowledge into practice is more a general and structural challenge of medicine as such rather than a pitfall specific to PHS applications. Medicine is one of the most knowledge intensive empirical sciences, frequently changed, updated, and re-evaluated, with a steady flow of new risk factors identification, new drugs and diagnostic tests, new evidence from clinical studies (Peleg and Tu, 2006). Naturally this creates a formidable challenge in terms of ensuring that such new knowledge and evidence inform even the traditional practice of medicine[54]. Much still remains to be done to ensure that lessons learnt from scientific research and clinical studies and trials inform and improve the quality of health services and the availability of evidence-based medicine (Kerner, 2006). It has been even argued that efforts should go into interpreting existing knowledge more than into producing new one (Choi *et al* 2003)[55]. It is evident the need to constantly inform the practice of medicine with the canonisation of guidelines reflecting the most updated knowledge, carefully adapted on an individual basis (Durso, 2006). This would improve compliance to state of the art knowledge of both physicians and patients (Findley and Baker, 2002; Hayward *et al* 1995; Protheroe *et al* 2003; Shaneyfelt *et al* 1999; Shiffman *et al* 2003). In this respect research on **genomic information** has made a vast progress during the past years and could greatly enhance the goal of personalised treatment (Marcelino and Feingold, 1996). As seen, then, the issue of aligning practice to knowledge it is still a challenge for traditional medicine (Shortell *et al* 2007). Therefore, incorporating the most recent and evidence-based knowledge into Personal Health Systems or, to put it differently, "infusing medicine into technology" is not an easy task. Yet, the potential of information technology to support both clinicians and patients in gathering data, making clinical decisions, and managing medical and lifestyle actions more effectively is high and should be leveraged. It is worth noting that, however, this is not a challenge that science and technology can solve alone. It requires the commitment of policymakers, state planners, managers of service provider agencies (e.g., health departments, managed care organizations), and the purveyors of programs and practices (Rosenthal et al, 2005). Indeed Rosenthal et al (2005) touch upon issues clearly captured

[54] McGlynn (2003), for instance, showed that only 55% of US adults receive care inspired by the most up to date knowledge based recommendations. Actually, it takes approximately five years for new guidelines to be adopted into routine practice (Batel et al, 2003)

[55] Some argue that the best evidence is for what *does not* work (Fixsen et al, 2005).

by three gaps included in our Full List and deemed correctly as being beyond the focus of technological research, which are:

- Little integration of care delivery processes (# 3 in Table 3, p. 71);
- Knowledge and information segmented (# 4 in Table 3, p. 71);
- Lack of shared platform for data repository and exchange (# 5 in Table 3, p. 71)

In different ways they point to the fragmentation and "Turf Wars" that the experts consulted discussed several times in our consultation and events and figure also prominently in several of the presentations delivered during the "Personal Health Systems Workshop – Market perspectives & innovation dynamics" organised in Brussels by the EC Join-Research Centre IPTS (Institute for Prospective Technological Studies) on February 6 2009[56].

The relevance of Biomedical Informatics. The vision behind the emerging field of Biomedical Informatics (BMI) is precisely that of tackling the challenges described above. BMI is emerging from the integration of Medical Informatics and Bioinformatics (see INFOBIOMED 2003 and SYMBIOmatics 2007). Medical informatics (MI), in its original sense before integration with Bioinformatics, can be broadly defined as the *intersection of information science, computer science, and health care, addressing the resources, devices, and methods required to optimize the acquisition, storage, retrieval, and use of information in health*. Health informatics tools include not only computers but also clinical guidelines, formal medical terminologies, and information and communication systems. Bioinformatics (BI), also known as computational biology, can be defined as *the creation and advancement of databases, algorithms, computational and statistical techniques, and theory to solve formal and practical problems arising from the management and analysis of biological data*[57] MI and BI originated in different context and responded to different drivers that have created a gaps between the two for some time. Indeed they differ as much as medicine differs from biology (INFOBIOMED 2003, p. 6 and pp. 13-14). MI emerged to address the practical short term objectives (rather than long term scientific ones) of delivering care and has been fragmented as a result of the the very disparate needs of different specialists and of different administrative and management rules and practices[58]. BI has been much more focussed and oriented to science and basic research as it originated to respond to the need of managing the enormous amount of data that biological research started to produce and particularly to analyse large numbers of protein and nucleic acid sequences. BI focussed on biological sequence analysis, structural biology and molecular information repositories and its development accellerated also in relation to the well known Human Genome Project

[56] The workshop report and the presentation delivered can be accessed at http://is.jrc.ec.europa.eu/pages/TFS/sps.html

[57] See for instance Cristianini and Hahn (2006), Srinivas, ed. (2006), and Baldi and Brunak (2001).

[58] This has resulted for a long time in an application-centred perspective and a wide range of different applications mostly local and with limited level of collaboration across expetise and institutional boundaries.

(HGP). BMI has emerged as the attempt to bridge these two disciplines and finds its rationale in both a more practical and more fundamental reason. First, at the practical level, MI and BI have used similar tools and methodologies such as, for instance, machine learning, natural language processing, image analysis, data mining of large database. Second, more fundamentally the rationale for merging MI and BI is the same that calls for integration of medicine and biology and reside in the well known genotype-phenotype distinction (Johannsen 1911)[59] and the related need of capturing both in order to understand the causes of diseases and improve treatment, medications and drugs development, as well as early detection and prevention. The complete sequencing of the Human Genome and the related genetic and proteomic data have opened new possibilities to grasp the mechanisms of diseases, especially multigenic ones that are more common than monogenic diseases. On the other hand, many diseases, besides the genetic component, have also an environmental component and this calls for knowing also the phenotype of diseases where classical clinincal and epidemilogical evidence comes into the picture. Naturally there are still uncertainties as to the timing when the results for the analysis of the human genome will become fully available for use. Indeed a World Health Organisation (WHO) report suggests the needs of : a) being cautious on the medical benefits of genomics especially for the timescale required; b) pursuing genomics research not to the detriment of clinical practice and of epidemiological research; and c) integrating genomics into clinical research involving patients and into epidemiological studies in the community (2002, p. 6). These are exactly the grounds upon which the BMI vision rests. Results of molecural medicine and biology research can benefit clinical medicine on the one hand, and clinical data will in turn be useful for these research. As a result, many new possibilities could open up in the future. Combining individuals' genotype and behaviour may predict possible emergence (for healthy individuals) or development (for individuals with some initial signs of a disease) of diseases, and accordigly define intermittent diagnostic evaluations plan matched by recommendations regarding changes in lifestyle, a medical regimen or procedures. In order to realise these promises the large amount of data generated in the laboratory by BI must be integrated with the data and techniques of MI, electronic health records, clinical decision systems, image- and signal-processing. So the mission of BMI is *to provide the technical and scientific infrastructure and knowledge to allow evidence-based, **individualised** healthcare using all relevant sources of information*. Indeed in two calls from the FP6, namely Call 1 and Call 4, the objective for Biomedical Informatics was defined as to *"develop and promote knowledge in the areas of medical informatics that enable disease prevention and therapy, and the development of tools enabling the **individualisation** of diagnoses and treatment"*[60].

[59] For an analysis of Johannsen legacy see also Churchil (1974)

[60] European Commission, DG Information Society and Media, (2007), *eHealth portfolio projects – Sixth Research and Development Framework Programme, 2002-2006*, Brussels, available at http://ec.europa.eu/information_society/activities/health/docs/publications/fp6upd2007/fp6ehealth-projects_upd.pdf, (accessed January 2009).

The potential synergies between PHS, BMI and VPH. In the extract from the FP6 Work Programme reported above we added emphasis on the terms '***individualised'*** and '***individualisation'*** as this is the clear link between BMI and the need of making PHS more personalised. In fact, there is probably no other piece of information as unique to each concrete individual as his/her genetic configuration. Accordingly the integration of molecular and genetic data is a way of making PHS more personalised. On the other hand, it must be stressed that BMI is relevant for PHS also for what regards the integration of clinical evidence and clinical guidelines, which responds to the concern expressed by clinicians during our consultation workshop as to ensuring a robust control based on clinical knowledge and evidence. The best way to show how BMI could provide input to, and is in potential synergies with, PHS is to list below the key pillars of current BMI research (INFOBIOMED 2003) and the its future research agenda (SYMBIOmatics, 2007) in BMI.

Key pillars:

- **Patients data as input to Functional Genomics**. Functional Genomics requires patient data coming from clinical information systems (laboratory tests, annotation of biological samples or familial history). Medical Informatics can and should, therefore, play a role in facilitating this data for post-genomic research.
- **Genomic for individualized Healthcare**. Bioinformatics provide input to practicing clinicians and medical informaticians to understand and use molecular level data to provide personalised services. Acquiring, representing, analysing, and integrating this kind of data is the practice of Bioinformatics that help the real integration of genetic data of the patients in clinical information systems;
- **Holistic Genomic Medicine**. BMI integrates information coming from the different levels (molecular, clinical or environmental) and produces the personalization of clinical solutions;
- **Enabling Technologies**. Innovative information and communication platform interfaced with new analytical devices and virtual learning environments to facilitate the implementation of the integration between different sources of information and knowledge.

Research agenda:

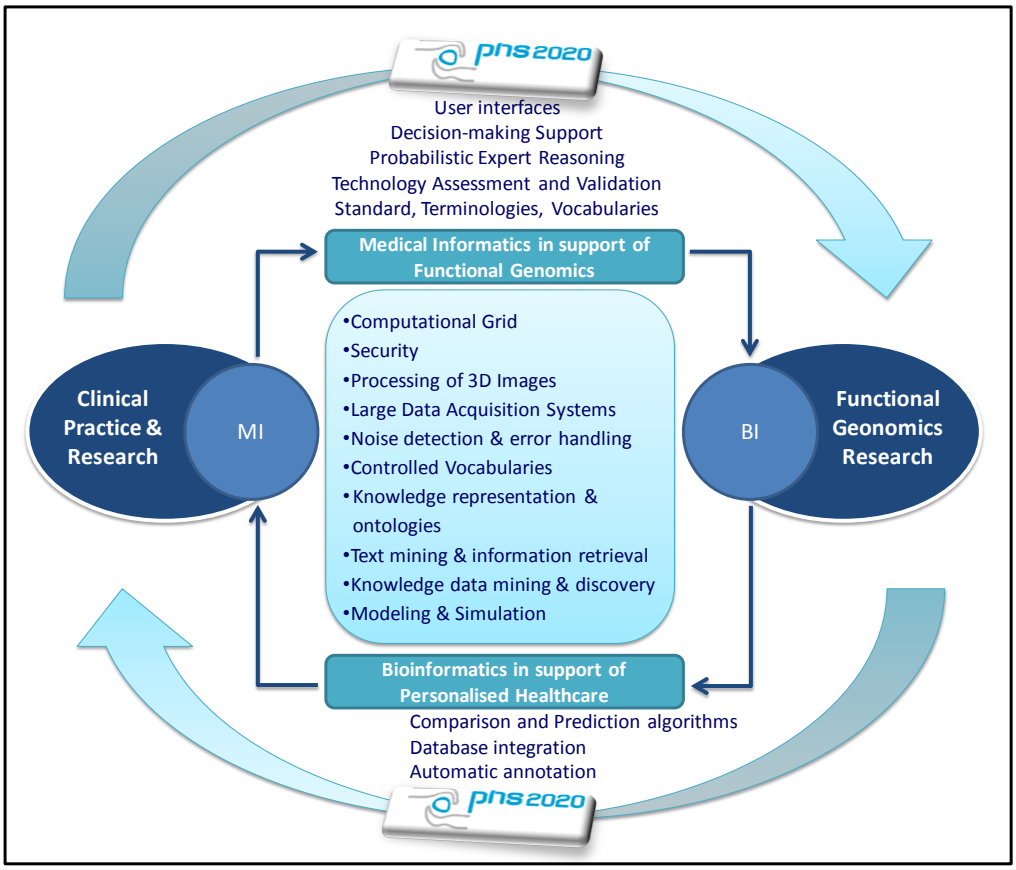
- Integration of data from biosensors and medical devices into clinical information systems;
- Integration of patient molecular data into Electronic Health Records;
- Connecting bio-banks to large scale databases to enable data mining;
- Patient profiling and lifestyle management;
- Modelling and simulation of biological structures and processes/diseases.

It is probably pleonastic to remark how most of the bullet points above resonate many of the issues we have discussed so far in this book with respect to PHS. If we stretch the definition of Medical Informatics to include within it PHS as one of its component, then one could subsume all of our discussion as just one dimension within the emerging BMI domain and related research agenda. It could be argued that PHS are among the various

medical devices contributing to clinical information systems. This, however, would be incorrect for three reasons. First, PHS are not mere medical devices but more complex system including devices. Second, they are still not much connected to clinical information systems. Third and most importantly, PHS if fully deployed would entail a dynamic and personalisation contributions still lacking in clinical information systems. Fourth, the very nature of PHS, which can capture and in the future will better capture different parameters in a mobile fashion, can produce those contextual and environmental data specific to each individual and needed as input to functional genomics currently not contained in clinical information systems and large scale databases. Indeed, as we show with the help of Figure 24 overleaf, we claim that PHS can be an additional and active third pillar in the process of integration between MI and BI. In other word not only PHS would benefit from this integration but they would also contribute to it. PHS would be first strengthened with input from MI and BI, and then once they achieve increased reliability their data would in turn provide additional evidence for both MI and BI applications. Evidently a key challenge to cope with for this scenario to occur is that of ***validating and intelligently processing data gathered under "uncontrolled conditions"***, which cuts across this research domain and that on "**Intelligent PHS Data Processing**". In this respect a clear area of potential synergy between PHS and BMI emerge if we consider the kind of new mobile parameters that context aware next generation sensors may produce. In the traditional medical domain various types of long term databases can be identified - ranging from registries (only few core data elements) up to research data bases (in-depth data about a defined population subset). Integrating these valuable data sources with ongoing mobile data in a data warehouse system would allow correlating objective measures with context related health or subjective well-being. However, current medical databases focus on unhealthy people. Aiming at detecting social and mental status too, additional data bases (e.g. for "stressed" people) are needed. For instance, it has been suggested to create a database of emotional concepts, in order to be able to categorize emotions and to infer emotional trends over time (Lisetti et al 2003). Finally, it is worth noting that in the transitions towards Framework Programme 7, the field of Bioinformatics has been merged into the reasearch priority "Virtual Physiological Human", whose ultimate goal is *to let scientists and medical practitioners know as much as possible about the "real physiological human" by tackling all areas of human anatomy and physiology and integrating data from all levels (molecule, cell, tissue, organ, etc)*[61]. This will enable real "personalised" care, thanks to the use of models, simulation and visualisation techniques for predicting the outcome of interventions (surgical and pharmacological) on the individual.

Figure 24: The bi-directional integration between PHS and BMI

[61] European Commission, DG Information Society and Media, (2007), *eHealth portfolio projects – Sixth Research and Development Framework Programme, 2002-2006*, Brussels, available at http://ec.europa.eu/information_society/activities/health/docs/publications/fp6upd2007/fp6ehealth-projects_upd.pdf, (accessed January 2009).



Source: Adapted from INFOBIOMED (2003, p. 18, Figure 4)

Advancements in the field of Virtual Physiological Human (VPH) will also assist the design of targeted implants and artificial organs for the individual, as well as the discovery of innovative personalised drugs. Also in this case we can point out at the potential synergies that would derive from convergence of PHS and VPH within future research projects. As VPH models are both descriptive, predictive and additionally formed taking into consideration pathological, physiological, and anatomical data, they can become the basis for a PHS new DSS primarily for clinicians but eventually possible to share with users. VPH is further important for developing interfacing technologies that give a just picture of personal aspects, both for clinical use, and for patients to give an illustrative picture of how each individual body is formed and affected by different actions and behaviours. In addition there is also a contribution from PHS to VPH that could derive from this integration. Convergence between PHS and VPH further means that PHS provides better measurement and reliable data so that VPH build better models with in turn produce better design of artificial organs to be implanted ad become also part of PHS. Thinking very futuristically, there could be spin-offs from such integration between PHS and VPH, positively over spilling on the users. It could produce a sort of "tamagochi" of oneself, a device that can tell everyday how one has performed, and whether or not one has behaved well towards his/her health. This could be among those tools that could motivate people to behave in sound and preventive fashion (if they are

healthy), to refrain from certain specific behaviours (if they have been diagnosed with a potential future risk), to adhere to prescriptions and lifestyle guidelines (if they are already chronic patients and/or are following a rehabilitation programme).

4.3.3 Proposed Roadmap

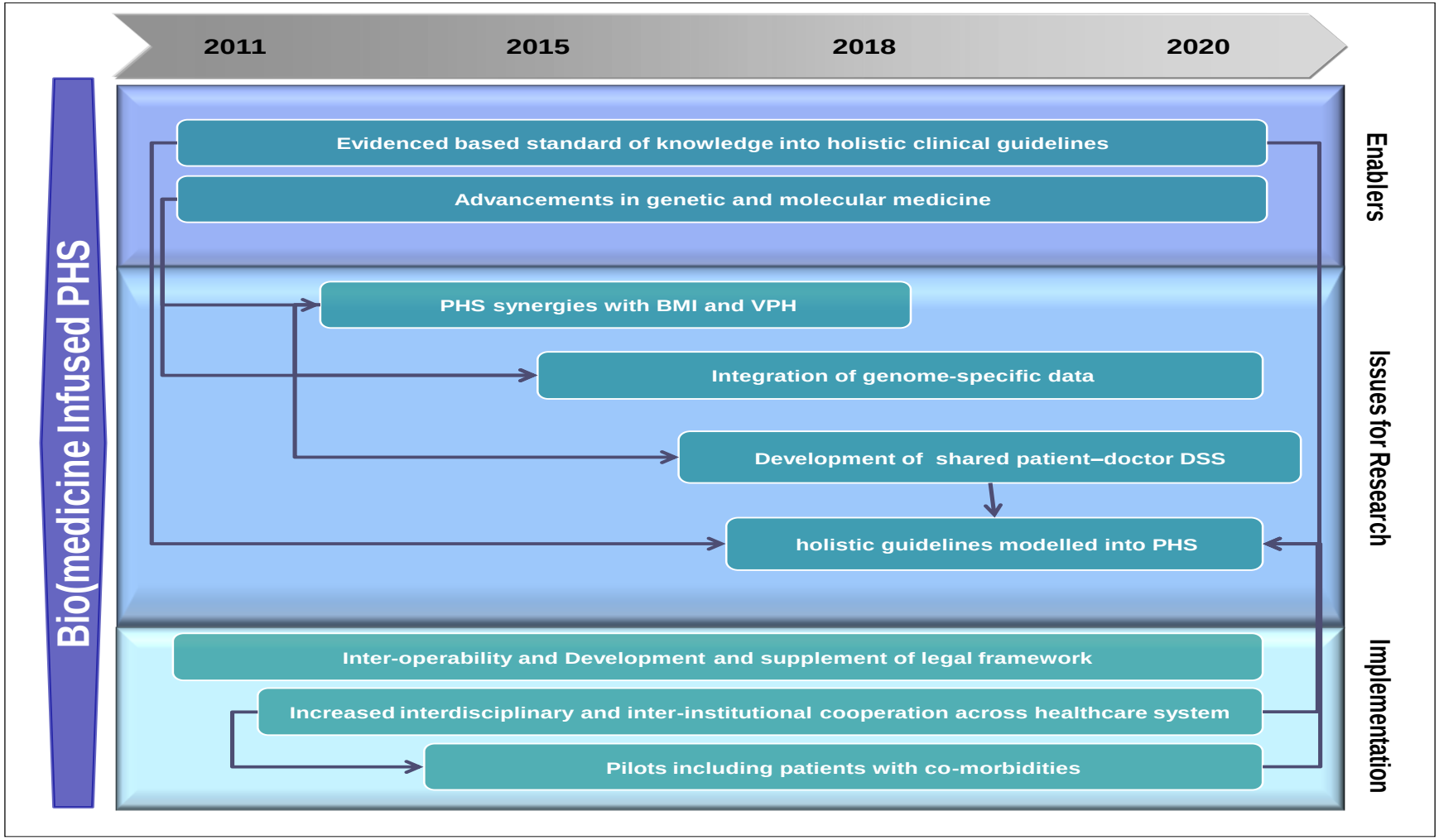
The table below synthetically provides a snapshot of the preliminary research themes associated to the gaps and of the key input from the further review of the literature. In combination with the comments and changes introduced during the two consultation events focussing on the roadmap they shape the final proposal graphically presented in Figure 25 reported in the next landscape page.

Table 8: Re-compacting information: Bio(medicine) Infuse PHS

Gaps (Table 7, p. 88)	Preliminary research themes (Table 7, p 88)	Further insights
• Lack of integration of updated clinical evidence, biomedical and genetic information to ensure scientific control, risk assessment, and personalisation • Validation of data from uncontrolled conditions (enucleated and moved here from Gap of Box 2)	• Integration of up-to-date medical info from bio-banks, trials; • Integration of genetic and biomedical information • Controlled studies to correlate and compare data obtained in both "clinical settings" and "uncontrolled conditions"(from context aware PHS) to identify normal and abnormal patterns of parameters uses for action/actuation taking into account personal and contextual factors	• Knowledge into clinical practice a problem for medicine as such (see also about holistic guidelines) • Relevance of Biomedical informatics (BMI) • Potential synergies between PHS and BMI • Need of new databases storing mobile data to correlate with data in other traditional medical databases
• Need of holistic clinical guidelines and pathways to align PHS delivered care to best practices and to capture the multi-facet nature of health status	• software systems integrating and modelling guidelines within PHS	• Holistic nature of guidelines a matter of institutional / cultural change (recalling implementation gaps 3,4,5)
• Need of innovative and holistic DSS for healthcare professionals to provide an holistic picture of human body complexity through prediction/simulation/visualisation	• Integration of PHS and VPH (supported by modelling and prediction); • Development of VPH-inspired interfacing for PHS DSS;	• Further support to idea of VPH/ PHS synergies

It can be safely stated that the elements already captured at the end of the gap analysis (those summarised in Table 7) have been confirmed and further refined by the consultation and the further review of the scientific literature. The increased ***personalisation of monitoring, preventing and treating*** and more ***robust clinical and scientific control*** through the integration into PHS of clinical evidence and biomedical and genetic data and information is at the core of the proposed convergence with ***Biomedical Informatics (BMI)*** and with ***Virtual Physiological Human (VPH)***.

Figure 25: Visual Roadmap for "Bio(medicine) Infused PHS"



Source: Author's elaboration

To this convergence toward personalisation PHS bring the additional important input of contextual data, which raised the challenge of ***data gathered under "uncontrolled conditions"*** and the need of ***new databases with mobile contextual data***.

Accordingly within the broadly defined theme of PHS convergence with BMI and VPH we can envisage the following topics:

- Controlled studies to ***correlate and compare data obtained in both "clinical settings" and "uncontrolled conditions"*** to identify normal and abnormal patterns of parameters used for action/actuation taking into account personal and contextual factors;
- ***Integrate*** ongoing mobile ***data captured by PHS*** with ***clinical and biomedical and genetics data*** (large scale database, bio-banks, trials, research databases) into ***data warehouse*** system;
- **Data mining** on newly integrated databases to correlate both ***genetics with diseases*** phenotyping and more generally correlate ***objective measures*** (about genotypes and phenotypes) with ***context related parameters***;
- ***Integration*** of data from ***biosensors and medical devices*** into ***clinical information systems***;
- Use of newly combined evidence for ***patient profiling and lifestyle management***;
- Improve ***modelling and simulation*** of biological structures and processes/diseases (***VPH***) with data from ***PHS***

Evidently these research themes present a number of complementarities/overlaps with elements of other roadmaps:

- The integrated interpretation and processing of genetic, biological, and contextual data it is clearly at the cross-road with themes of the roadmap on "**Intelligent PHS Data Processing**";
- Controlled studies to ***correlate and compare data obtained in both "clinical settings" and "uncontrolled conditions"*** need input from new context aware sensing (as do the creation of integrated database mentioned under second bullet above);
- In turn the result of such controlled studies feed into the normalisation of "uncontrolled conditions" data through correction/rectification techniques that are part of the "**Intelligent PHS Data Processing**" roadmap.

With respect to the first dimension very important is the ***inter-operability*** among devices, databases, and with health records (personal and in general all those included in clinical information systems). In addition the ***appropriate legal framework*** will have to be developed if ***patient profiling***, ***early detection*** and ***related secondary prevention*** treatment are to be put in practice.

With respect to the second dimension the enabler is mainly advancement in genetics and molecular medicine. Such advancement would further enable the PHS/BMI/VPH convergence and would eventually lead to the new research theme "**Integration of Genomic-Specific Data**".

Going back more specifically to the **integration between PHS and VPH** we point out that is bi-directional. First, VPH models are both descriptive, predictive and additionally formed taking into consideration pathological, physiological, and anatomical data, they could be merged with new PHS data processing techniques to become the basis for innovative Decision Support Systems initially targeting professionals and eventually also users (see more on the research them "**Development of Share Patients Doctor Decision Support Systems**" in **§ 4.4.3**). Integration of VPH elements into PHS would help developing interfacing technologies (here it is evident the additional complementarity/overlap with the themes treated under the "**Users inclusive PHS interfaces"** roadmap", as we anticipated earlier at p. 95) providing an holistic picture of how each individual body is formed and affected by different actions and behaviours. Second, there is also a contribution from PHS to VPH that could derive from this integration. Convergence between PHS and VPH further means that PHS provides better measurement and reliable data so that VPH build better models, which in turn produce better design of artificial organs to be implanted and that become also part of PHS in the sense that for users with implanted organs PHS will both monitor important health related parameters and the actual function of the implanted organs.

The idea of developing systems that would integrate and model holistic guidelines (addressing ***co-morbidities*** but also many other dimensions to ***personalise*** them) has not been rejected, but both the experts during the consultation and the review of the literature have shown that is a tough challenge technological research alone cannot solve. Turning updated knowledge into standardised and consensual guidelines for clinical practice is a challenge for medicine as such and is not specific to PHS. It depends both on the dynamic of knowledge production itself and on the institutional fragmentation and "turf wars" ridden nature of the Healthcare system. Accordingly the theme of PHS incorporating holistic guidelines is included but further on in the future and it is clearly indicated how it depends on both enabling and implementation issues: further efforts at extract guidelines as a kind of research/analytical activity (enabler) and at putting into practice and improving them through more integration and collaboration between tiers of healthcare and between them and research. In this latter aspect it is worth mentioning that these same two enabling and implementation issue are relevant also for what can be done with new data gathered about context (see later **§ 4.5.2** text on context awareness challenges). Indeed, once sensors will systematically gather mental and social state data we will still need consolidated and standardized measures against which evaluate in a combined way physical, mental and social parameters. Otherwise we would not know what kind of feed-back should PHS capturing emotional and social state, especially those aiming at life-style management, should provide to improve the well-being of users. Accordingly, multi-disciplinary and inter-institutional cooperation is needed especially for lifestyle management to decide: a) what are the signals required to detect context, social interaction and activity; and b) what is the minimum set of signals to achieve a desired performance lifestyle performance.

4.4 Intelligent PHS data processing: rationale and roadmap

4.4.1 Contextualisation

Already at the end of our work on the State of Play and before the all consultation process started we concluded that ***PHS today are called 'personal' as the focus is on the person possibly outside of institutional care but they are not necessarily personalized*.** If Personal Health Systems have to develop into Personalised Health Systems, more research development is needed to build auto-adaptive and self-calibrating solutions gradually and constantly adapting to each specific individual history, characteristics, mental state and context. This requires both the advancement in the development of sensors that we treat later (**§ 4.5**), infusion of clinical evidence and of molecular and genetic data into PHS that we discussed in the previous paragraph, ***and naturally more sophisticated algorithms and data processing solution capable of turning inert data and information into knowledge and knowledge usable for actuation (which knowledge for which action)***.

Currently, PHS data analysis focuses on standard measures commonly accepted in medicine and detect abnormal physiological conditions or, in the case of aging, abnormal physical state (i.e., early fall detection), without considering context (environmental conditions, location, type of interaction i.e. from voice signalling, emotional state) and person specific parameters (age, social class, education, life history, genetic characteristics). PHS applications still concern a limited number of parameters that can vary within a pre-defined range, without capabilities of taking into account peculiar conditions and characteristics of the individual, and to automatically adapt the expected values of medical parameters. This can lead to false positive early warning: a vital sign is above the threshold but this may be due to peculiar characteristics of the individual or of the specific context in which he/she is acting. In this context healthcare professional intervention is still a major part of current PHS solutions. A corollary is that actuation and treatment through PHS is still far away, while monitoring remains the main focus of today's personal health systems. In case of acute episodes, today's PHS are too limited in terms of automatic and in-time intervention. To become truly ***personalised***, requiring less intervention on the side of healthcare professionals and enabling more actuation and treatment, PHS must be powered by ***auto-adaptive and self-calibrating data processing and interpretation/modelling solutions***, on which to build systems that do not only monitor the condition of an individual, but also deliver on-time and evidence-based prediction supporting actuation. In some cases PHS applications may also deliver individual feedback according to patients' status and additionally offer some educational guidance related to the specific condition. However, the value chain of data management and processing is long and fragmented as data are processed with many steps and at several levels (i.e. data elaboration usually involves external devices). Although intelligent systems are being developed (i.e. Decision Support System, DSS), healthcare professionals intervention is still a major part of current PHS solutions, mainly due to the lack of intelligent systems encompassing predictive algorithms enabling self-adaptation and self-calibration, as well as automatic and on-time intervention. A key barrier is also

represented by lack of context awareness and other individualised data beyond vital and physiological signs, which is evidently more an issue of the kind of sensors used than of data processing. Yet, even if other kind of signs and information were available and could be acquired as raw data, it would still be difficult to turn it into knowledge given the status of intelligent processing currently embedded into PHS. For instance, if we talk about self-adaptation and self-calibration, naturally we lack sensors reliably gathering environmental and context data, but also algorithms accurate enough to process the data in such a way that they can provide truly personalised services.

4.4.2 Further insights

Intelligence in support of decision and action. From a general perspective the gaps identified for the data processing capabilities of PHS applications fall into the broad discipline of Decision Support Systems. In a way what PHS applications currently lack is the capability to produce input for decision and action (especially for automatic actuation of action). In this respect we can take from the DSS discipline the idea that the ***intelligence*** needed for decision and action requires first the identification of a problem, then the design of possible alternative solutions, and finally the criteria for analysing the alternatives and choosing one for implementation (Shim *et al* 2002). If we apply this to the field of PHS we see that the problems are clear and that increasing amount of data and information are gathered about an important part of the problems (vital and physiological signs, but we still need to: a) gather and process data ***on other important dimensions of the problems*** (personal context, environment, clinical evidence, biomedical and genetic information); b) improve the design of alternatives (***information into knowledge***); and c) develop criteria and models for choice (***knowledge into action/ actuation***). Without the capability of turning the gathered data into knowledge and action, PHS run the risk of increasing the information overload, a problem already lamented today by healthcare professionals even in their traditional practice. If PHS will generate large amount of data without producing intelligence they will only compound this information overload challenge (Foster *et al* 2005; Kriegel *et al* 2007). It has been argued that, if we did not reach yet more intelligent solutions in the field of PHS and other technology driven applications in the healthcare sector, this is the result of ***too much attention placed on the networking of distributed sensing and too little on tools to manage, analyse, and understand the data*** (Balazinska et al, 2007). In order to proceed into this direction one of the 'grand challenges' is to limit the number of computer-generated recommendations a clinician or a user has to deal with to a manageable number based upon an explicit model, thus ***reducing the ''alert fatigue''*** that is a frequent cause of dissatisfaction both among professionals and users (Sittig *et al* 2007). The goal is to develop decision support systems and automatic actuation in a way that takes into consideration the peculiarities and preferences of users and addresses the concerns of healthcare professionals (Ruland and Bakken 2002). To put these considerations differently, there is a need to move from a fragmented "signal driven design" to a more holistic " personalised and goal-driven design", which would better enable: a) defining what to collect, when, and how to collect it; and also b) processing and visualising its results in view of the sought goal. These broadly defined challenges entail several issues we treat below.

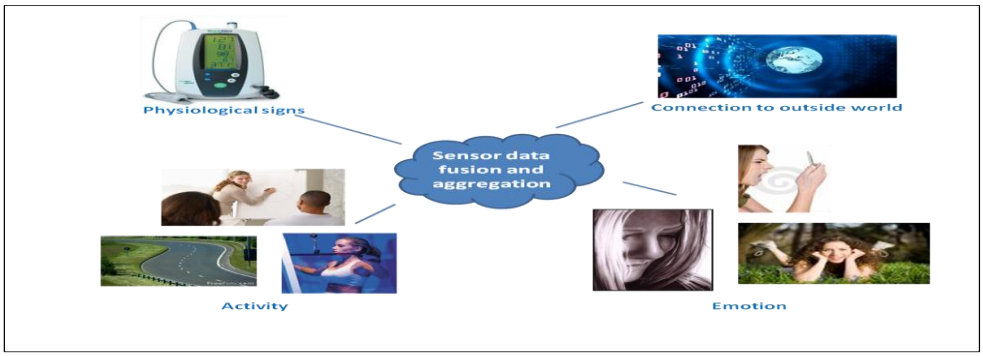
Validation of PHS data. Discussing a broader topic than PHS Foster *et al* (2005) affirm that Decision Support Systems in the healthcare sector must incorporate clinical evidence and knowledge as fundamental parameters for ***data validation*** in terms of both ***quality*** and ***accuracy***. This further reinforces our argument about the need of Bio(medicine) infused PHS. As we anticipated, it is evident here how the two research domains and related roadmaps "**Bio(medicine) Infused PHS**" and "**Intelligent PHS Data Processing**" overlap. The additional clinical and bio-medical /genetic information to be incorporated into PHS would then need to be processed and interpreted. Additionally the issue of treating data gathered under uncontrolled conditions must be addressed. First, controlled studies are needed including measurements on a number of parameters for a given sample of individuals in both clinical settings and in "uncontrolled conditions" as to include personal conditions and environmental factors. These should enable to assess normal and abnormal patterns in light of personal patterns and context. Second, with this input PHS powered by innovative self-adaptive algorithms should recursively process data and identify truly abnormal patterns, as well as rectify/correct parameters that may appear as abnormal only due to very peculiar contextual conditions.

More efficient treatment of data: *multimodal data fusion*[62]. Data is gathered through several sensors distributed over the body and in most cases we still have a situation of "one sensor / one signal", which requires data fusion. Moreover, the more we go in the direction of context aware and personalised PHS the more this data will also present different modalities (for instance strings and graphs) that need to be integrated correctly for a reliable measurement and data processing. Data fusion is particularly important for context aware PHS applications capturing emotional, activity and environmental parameters (Tröster 2005; Lukowic *et al* 2002), at least until multi-signs sensors with on board processing will be developed. The heterogeneity of possible contexts demands for fusion and multi-modal integration of data deriving from various sensors. Whereas vision and speech recognition are established tools to mirror the human's perception, context detection using vision and speech creates a high computing load. The use of different simple sensors capturing these parameters in different ways can reduce the

[62] The literature on data fusion and on multimodal data integration is vast and spans several disciplines and we used selectively to define the two terms (see for instance Mitchell 2007; Qi *et al* 2004; Klein 1993). "Fusion" is a term describing the integration of data from multiple sensors using a combination of mathematical algorithms and data transfer architecture. Fusion Algorithms allow data from various sensors to be combined, painting a more accurate picture of the happenings and allowing taking immediate action if a threat is determined. Two basic architectures are used in theory, Measurement Fusion and Track Fusion. In practice, however, a combination, or hybrid system is often used. In several articles "data fusion" and "multimodal data integration" are used in an alternate manner implying that there is not a substantial distinction among them (see for instance Qi *et al* 2004 or Tripathi *et al* 2008). In this way one may talk about "multimodal data fusion" as a particular case of data fusion, when the data not only come from different sensors but also have different modalities (typically strings and graphs). On the other hand, one could distinguish them as follows: multimodal data integration might be viewed as set combination wherein the larger set is retained, whereas fusion is a set reduction technique with improved confidence. For our purpose here and in the definition of the roadmap we will not distinguish them in a clear cut way and will treat them as one research theme.

communication and computational effort, yet they increase the data fusion efforts. Currently, however, there is still no established framework for exploiting the benefits of data fusion, which hampers the production of consistent actionable intelligence due to invalid incorporation of redundant information and to information corruption (Luo *et al* 2007). Another challenge is the capacity to fuse the gathered data both collectively and on an individual basis, mirroring the situation of users' activities and environmental conditions[63]. The key need is engineering a framework enabling adaptation to "uncontrolled" chaotic environments such as those which would characterise a PHS services embedded into a "smart home" or provided as the users perform normal daily activity at work (Pallapa and Das, 2008). Moreover, we can envisage PHS applications capable to integrate parameters gathered by external environmental sensors (neither in contact with the users' body nor placed in their homes) or available within the health records of hospitals information systems, or even in the information system of organisations not belonging to the healthcare sector. Futuristically, we may picture a situation where PHS applications, after detecting abnormal conditions for a chronic patients, may: a) automatically access and query the patient health profile; b) access databases about patients suffering similar conditions to correlate the parameters; c) obtain data from airport records on his/her latest travel and identify his/her presence in places where some epidemic were recorded. All of this points into the direction of PHS fully context aware and context embedded, going beyond the "Event-Condition-Action approach" (Choi et al, 2006). Yet, for this to happen through automated query-processing task, data should already be in well-defined inter-operable syntax and semantics (Egenhofer, 2002).

Figure 26: Sensor data fusion and aggregation in multiple contexts



Source: Author's elaboration

Such inter-operable syntax and semantics, however, are not currently available even only for vital and physiological signs and, thus, the situation get more complex when we add context awareness. Therefore, efforts are needed for format and semantic integration of data coming from disparate sources (Halevy, 2003). In this respect the issue of

[63] Evidently, it would be more useful to take into account users' behaviour as an entity and deriving work flows from it, rather than considering events as basal units (Shchzad et al, 2005).

multimodal data fusion is crucial. Before data analysis starts, the differences between data from different sources have to be even-handed via fusion and integration. Otherwise one risk identifying patterns as a result of errors due to the different origins of the data rather than reflecting some real health conditions. ***Evidently this points once again to the overlapping between the technicalities of multimodal data fusion and the substantive issue of studies comparing data gathered in clinical settings with those gathered in "uncontrolled conditions" to define normal and abnormal patterns in the observed parameters***. On the side of data processing technicalities we can stress the ***need of well-organized and scalable data pre-processing*** through appropriate statistical examinations and algorithms to integrate data as different as, for instance, strings and graphs[64].

Improve extraction of patterns. Assuming the technicalities of data treatment are solved, intelligent data processing in PHS application should advance the extraction of new understandable patterns and also make previously extracted patterns better understandable. For example, currently many data mining algorithms do not distinguish between causality and co-occurrence. There is a great difference between finding the origin of the disease and finding just an additional symptom. A direction of research that should be leveraged within the PHS field is that of ***machine learning and neural nets***. Since acquiring knowledge from experts is complicated, a major part of decision support systems recently developed machine-learning (ML) techniques, which are able to discover knowledge automatically learning by example (Peleg and Tu, 2006). The most common technique being **neural nets** (network of interconnected simple processing elements). Neural nets recognize patterns in the input data and classify the input. Furthermore, many of the developed decision support systems are based on models that support **probabilistic reasoning**. Examples of such models are **Bayesian networks**. Artificial neural networks, decision trees, support vector machines, Bayesian networks, are all examples of methods that are used today to mine data. The challenge to overcome in this field is represented by the difficulty of transforming attributes of different scales into a mathematically feasible and computationally suitable format. This, however, need to be tackled not only to better extract patterns but also to achieve to achieve predictive modelling and exploration.

Adaptivity and self-calibration. As the complexity increases, there is a need to extract more complex patterns and to recursively process them in order ***to achieve both more personalisation and more modelling and predictive power***. PHS applications that are context aware and dynamically capable of learning and adapting to users very unique characteristics and conditions are a quintessential case of increased complexity. First, currently available algorithms for the most part are dedicated to a limited set of standard patterns and need to be upgraded to treat new parameters such as those capturing context. Second, aiming at providing truly personalized, proactive PHS, adaptivity and personal

[64] Data pre-processing is a useful technique instrumental to improve data fusion. In general, when we obtain a database, it is necessary to select the appropriate variables used as the inputs in order to eliminate the noise contained in the selected variables and to normalize the filtered variable. Achieving this is termed data pre-processing (see for instance Huang *et al* 2002).

calibration of algorithms are very important (Roggen *et al* 2006). Personal calibration is crucial to go beyond standard parameters measuring vital and physiological signs and capture for each single user environmental conditions, emotional and social state, as well as individual demographic and social characteristics (age, social class, past history) and should be integrated with adaptive algorithms for context recognition. These two elements would ensure that PHS data processing system deal with information in an intelligent way, in other words in the same way as a human domain expert would: learning from experience but in an automatic and self-recursive way. A clinician might learn by direct experience (though repeated observation) that vital sign X of patient A goes above a risk threshold due to very specific personal characteristics or under certain situations and does not require any treatment. If this information is not fixed and if patient A change doctor, this information is lost. A PHS intelligent system, embedding personal calibration and adaptive algorithms, would learn and fix such information and many others and dynamically continue to do so a self-modify itself. Under an ideal situation such intelligent system would: a) learn fast from a large amount of data and adapt incrementally in both real time (online), and in an off-line mode (new data is accommodated as it becomes available); b) be open and flexibly incorporate new elements relevant for its task; c) have a memory to keep track of information that has been used in the past and be able to retrieve some of it for the purpose of inner refinement, external visualisation, or for answering queries; d) be self-reflexive and analyse itself in terms of behaviour, global error and success. Currently algorithms learning only in an off-line mode are use to detect physical status only. For full context awareness, however, real time on-line learning is a prerequisite to achieve personal calibration. This new breed of adaptive context recognition algorithms may make use of bio-inspired techniques such as the "Evolving Connectionist Systems" modelled following the brain functioning, which have been shown to provide adaptivity and learning in other fields (Kasabov 2006).

Holistic Modelling and prediction. Adaptivity and personal calibration would reinforce the modelling and predictive capabilities of PHS data processing components. In health science well studied human models are available, which are based mostly on standard objective parameters . Augmenting these models by contextual data, social interactions or activities of daily living, could dramatically increase the predictive power (Roggen *et al* 2006). Thus, PHS could contribute to increase the predictive capabilities of healthcare decision support systems in general. This naturally requires copying with several challenges such as modelling data coming from different sources and different devices (pointing again to the issue of inter-operability). Once these different kinds of data are available, automatic processing need to be developed to track and assess historical, present and future events and related co-dependencies. Recent progress toward unifying the treatment of probabilistic models (for example, through abstractions such as dynamic Bayesian networks) could also pave the way for building a rich toolbox of statistical models (Balazinska et al, 2007).

Patterns management and visualisation. Having addressed all of the previous issues, then the number of potentially applicable patterns will be too large to be assessed by a human user, without a system organizing the results and providing user friendly fruition

through visualisation. Future systems must provide a platform for pattern discovery where it is possible to browse for interesting information, enabling generation of a large variety of well understandable patterns. Combining modelling and visualisation techniques then we could have those patient decision aids that were identified as one of the gap within the data processing research domain.

Privacy algorithms. Finally, advanced data processing could also address ethical issues through the development and application of privacy- preserving algorithms (Agrawal and Srikant, 2000, Samarati and Sweeney, 1998). These advancements aim to control the released data, either through random perturbations or by hiding recognizable attributes, so that individual privacy is not compromised but useful data mining can still be performed. However, these approaches are still very immature and will not become mainstreamed for some time.

By way of concluding the analysis in this paragraph it is worth pointing out two aspects. First, while considered as an issue falling outside strictly defined PHS research and concerning more broadly defined implementation issues, ***inter-operability emerges from the above considerations as a crucial bottleneck today and a key pillar in the future if achieved, as it would lessen the data fusion, multimodal integration and data pre-processing efforts***. Second, it is clear how ***tightly entwined are the "Data Processing" and "Sensor" research domains*** and that the ***two partially merge when smart sensors capable of on board processing and self-calibration are developed***.

4.4.3 Proposed Roadmap

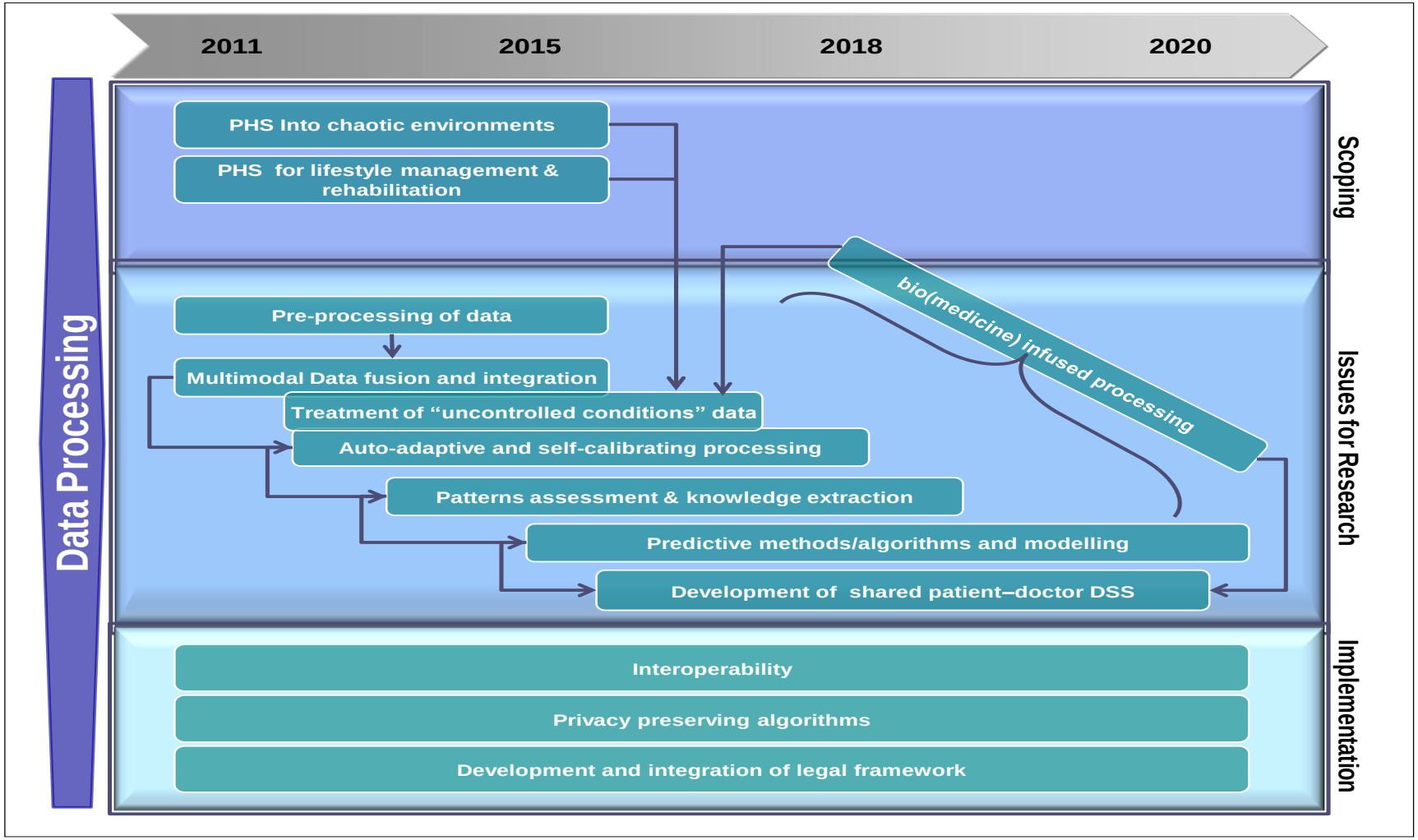
The table below synthetically provides a snapshot of the preliminary research themes associated to the gaps and of the key input from the further review of the literature. In combination with the comments and changes introduced during the two consultation events focussing on roadmapping they shape the final proposal graphically presented in Figure 27 reported in the next landscape page.

Table 9: Re-compacting information: Intelligent PHS Data Processing

Gaps (Table 7, p. 88)	Preliminary research themes (Table 7, p 88)	Further insights
• Lack of capacity to process data coming from different sources and to address the issue of data generated under "uncontrolled conditions";	• Data fusion and multimodality (data processing, interpretation and modelling capable of simultaneously treating vital and physiological signs, genetic, biomedical, and contextual parameters such as individuals activities, location and emotional status, and external environmental data; • Correction/rectification techniques to normalise data gathered under "uncontrolled conditions"	• Main issue becomes multimodal data fusion and integration; • Data pre-processing as instrumental; • Data from chaotic environments interesting test bed for new applications (overlaps with "uncontrolled conditions" data) • Importance of inter-operability (syntax and semantics) • Privacy preserving algorithms
• Lack of capacity to recursively learn from individuals specific characteristics and context and automatically adapt data processing to personalise monitoring and enabling actuation reducing the need of healthcare professionals intervention	• Auto-adaptive and data fusional algorithms and related prediction and modelling techniques; • Development of automatic calibration	• Self-adaptivity and self-calibration one issue, in addition: o Patterns extraction (and related data mining) o Prediction and modelling
• Lack of personalised aid decision tools for users	• Development of simulation tools based on holistic data processing (see above) and easy imaging and visualisation	• Criteria for user friendly visualisation outputs from prediction and modelling (managing/visualising input)

Ever since the end of the state of play review our initial intuition has been that PHS lacked the sophisticated intelligence to be ***truly personalized*** systems, through ***self-adaptation*** and ***self-calibration*** to the peculiar holistic conditions of each single individual, which as result restrains support to decision making, treatment and automatic actuation through ***prediction and modeling***.

Figure 27: Visual Roadmap for "Intelligent PHS Data Processing"



Source: Author's elaboration

This intuition has been corroborated during the gap analysis consultation process and we can safely state that it has been confirmed by the consultation and the further review of the scientific literature. On the other hand, the latter have helped providing a more complete picture where ***self-adaptivity*** and ***self-calibration***, ***prediction*** and ***modelling***, figure prominently alongside other elements that were not given enough visibility in the gap analysis such as: the ***importance*** of advancement in ***data processing*** especially for going beyond monitoring and enabling ***lifestyle management*** and ***rehabilitation*** applications, pre-processing and multimodal data fusion and integration, pattern extraction and related data mining, etc. The roadmapping consultation events and the further review of the literature have also provided more context and importance to the issue of how to treat data originating from **"uncontrolled conditions"**, which have surfaced in the previous paragraph on "**Bio(medicine) Infused PHS**", in this one on data processing, and will be discussed again in the next one on sensors. So, from being a sub-issue it has become a research theme in its own rights, in relation to which it also emerged the importance of ***chaotic environments*** as a test bed for gathering and processing of data raising higher challenges.

The complementarities/overlaps between this roadmap and the one on "**Bio(medicine) Infused PHS**" have been cited several times in previous part of this chapter, so they are simply identified in Figure 27 and not discussed further.

Many of the technologies and the developments later exploited for PHS have sprung from military applications, where users not only under high level of stress but also embedded into chaotic environments. Equally chaotic (though admittedly less stressful) environments in terms of the signs to be gathered would be those characterising a PHS services embedded into a "smart home" or provided as the users perform normal daily activity at work (Pallapa and Das, 2008). As illustrated earlier (see p. 113), these are situations where ICT can monitor and act on medical needs tenuously and promptly but where data challenges are great (fusion and integration of sign with different modality, normalisation of such parameters as they are typically originating in "uncontrolled conditions"). Accordingly we propose here initial **scoping studies** to define how such environments could be integrated as test bed for technological research focussing on advancing PHS level of sophistication in processing and intelligence. ***Scoping activities*** are also proposed on a topic that is clearly correlated to this one on "chaotic environments". Current PHS applications, we have seen, are far too focused on existing medical conditions, mainly entailing monitoring functionalities for cardiovascular diseases and diabetes. However, they have ***major potential for going beyond these boundaries, enlarging to general health management, lifestyle applications and hence, prevention, rehabilitation, and even treatment***. As there is a current increase of focus on prevention, studies should also consider how PHS can optimally be tailored and adopted for the aim of lifestyle management in mobile and/or chaotic situations/environments. Similarly, it has also been suggested several times during the consultation events to assess the potentiality to integrate PHS with users' homes and domotics, to further personalise the services rendered by personal health system applications. A similar investigation should be made for already available service-based information (night/day,

weather, travel, fitness, nutrition etc), giving opportunity to connect health with life-based parameters, and at the same time taking advantage of the "connected society" and the "sensor web".

As long as signs will come from many different sensors (i.e. one sensor/one sign) with little or no on-board processing capabilities and also until ex ante inter-operability with standardise syntax and semantics across many domains (PHS devices, electronic health records of various nature, databases, etc) data processing need to address the challenge of ***treating data with different modalities*** (for instance strings and graphs) that need to be integrated correctly for a reliable measurement and ensuing steps (interpretation, pattern extraction, prediction and modelling). This is a more complicated task than simple ***data fusion.***

The sheer size and diversity of data that truly personalised and bio(medicine) infused PHS will have to processes raise the data handling challenges and calls for new research into efficient "**Pre-Processing of Data**" preferably in order to, amongst other issues, decrease the size of datasets. While visualised separately, this can be considered as an additional instrumental support for the following theme. In case more sensors improve on-board processing, pre-processing could be performed already there at source.

Next and much more important research theme to ensure the high quality of data is what can be broadly defined "**Multimodal Data Fusion and Integration**" of signs with different modalities (for instance strings and graphs). Before data analysis starts, the differences between data from different sources have to be even-handed via fusion and integration. Otherwise one risk identifying patterns as a result of errors due to the different origins of the data rather than reflecting some real health conditions. The goal of this activity should be, first, eliminate data redundancies and distortions and, second, perform ***data fusion at different levels***. In fact, it is possible fuse data at the level of a single network of sensors, at the level of a Lab On Chip, at the level of environmental sensors. Eventually, there is still need of a second level data fusion to merge all that data together. In a similar manner, data fusion can be done for fusion of physiologic data, motion, chemical values, emotional and contextual data, etc, ***finally reaching a real multi-modal data fusion.***

While it could be treated as either part of the previous or of the next research theme, we visualised the separately the "**Treatment of 'Uncontrolled Conditions' Data**", given how prominently has figures as instrumental to achieve true personalisation applying processing, patterns extrapolation, prediction and modelling on a combined set of data also capturing context. In close connection with the results of controlled studies ***correlating and comparing data obtained in both "clinical settings" and "uncontrolled conditions"*** (see previous roadmap), normalisation of such data should be achieved through new and innovative rectification and correction techniques to be developed *ad hoc*.

The theme "**Auto-adaptive and Self-Calibrating Processing**" capture what has been since the beginning the main gaps identified in PHS data-processing sub-system and pursuing this research direction should produce ***auto-adaptive algorithms to be***

integrated into PHS functioning, capable of gathering and recursively processing data from different sources (including from "uncontrolled conditions"/ "chaotic environments", adapting to individuals' peculiarities and modifying/rectifying the information provided to the rest of the system, for it to extract knowledge and take the most appropriate decision in each occasion in relation to action/actuation (treatment in the case of disease monitoring or feedback/assistance in the case of lifestyle management/rehabilitation). Further, under an ideal situation such intelligent system would: a) learn fast from a large amount of data and adapt incrementally in both real time (online), and in an off-line mode (new data is accommodated as it becomes available); b) be open and flexibly incorporate new elements relevant for its task; c) have a memory to keep track of information that has been used in the past and be able to retrieve some of it for the purpose of inner refinement, external visualisation, or for answering queries; d) be self-reflexive and analyse itself in terms of behaviour, global error and success. Achieving such state would bring a key input to enhance ***predictive and modelling power***.

An additional input in this direction would come from research on the theme of "**Pattern Assessment and Knowledge Extraction**", that is systems deriving understandable patterns and making already available patterns understandable, in addition to developing methods to turn discovered trends and patterns into rules. The progress of statistical methods and artificial intelligence discussed earlier in **§ 4.4.2** could offer interpretation of the complex patterns that are created by the collection of data produced by PHS. These patterns are of special interest, not only to extract knowledge for the specific user, but it can also offer knowledge concerning whole populations. Thus, different clinical and lifestyle conditions can be easily linked to cause-and-effect and also to optimal treatments.

The understanding of mentioned patterns together with innovative auto-adaptive and self-calibrating characteristics will support research aiming at advancing and refining "**Predictive Algorithms/Methods and Modelling**". This would give also the ***opportunity for prediction to foresee events and accordingly, act on them on time.*** This is possibly one of the major outcomes of the entire application. ***By using predictive algorithms, establishing patterns or evolution of patterns, it is possible to predict the evolution of a disease, and therefore pave the way for actuation (***e.g., drug delivery, electrical stimulation, etc.). Predictive algorithms are required also to assess and estimate different possible actions and optimal actuation considering a particular situation.

As seen so far, adaptivity and calibration to very person specific characteristics would reinforce the modelling and predictive capabilities of PHS data processing components. Once this advancement is completed with the integration of contextual data, social interactions or activities of daily living, PHS could dramatically increase the predictive power and modelling capabilities of already existing models and predictive applications (Roggen *et al* 2006). The obvious further follow up is to harness these capabilities to develop new and more powerful **Decision Support Systems** that could eventually **be shared** between **healthcare professionals and users**. Such tools should embed automatic processing to track and assess historical, present and future events and related

co-dependencies to help doctors and users jointly decide on the course of actions to take (more futuristically to prompt automatic actuation). Assuming that interoperability among different PHS devices and between them and electronic health records will be in place, if we combine increased data processing capabilities (self-adaptivity and self-calibration), wider scope of data gathered (new sensors for context awareness), recent progress toward unifying the treatment of probabilistic models (for example, through abstractions such as dynamic Bayesian networks), then a rich toolbox of models supporting new **Decision Support Systems** could be developed (Balazinska et al, 2007). Naturally, all of the above would still not be enough. As the complexity and amount of data and related intelligence is bound to increase, another challenge is that of **managing and visualizing input** (Kriegel *et al* 2007). It has been argued, in fact, that an important issue to solve consist in establishing a rank priority order to reduce the **''alert fatigue''**(one of the main cause of users' dissatisfaction), which means limit the number of computer-generated recommendations that a clinician or a patient has to deal through explicit values models (Sittig *et al* 2007). Finally, **DSS** should provide output in the form of imagining and visualisation that are intuitive and easy to interpret for users, but also for healthcare professionals. Indeed such **DSS**, based on strong data modelling/predictive capabilities and infused with the needed clinical and biomedical knowledge and with context related parameters, should enable through innovative visualisation technique a more informed and symmetric dialogue between patients and healthcare professionals, besides naturally helping the latter in more technical activities and improvement of practice and guidelines. It is clear then how the various elements discussed earlier come full circle in the research theme "**Shared Patient-Doctor DSS**". This research theme, in fact, envisages the development of such solutions by incorporating/leveraging:

- Increase in data processing scope and capabilities supporting new sophisticated modelling/predictive techniques;
- Infusion into PHS systems of clinical evidence and biomedical knowledge as part of the recommended synergies of PHS research with and BMI a VPH;
- Advancements in imaging and visualisation techniques.

Concluding the discussion of this theme it is interesting to mention a futuristic vision formulated especially for what concern users by one of the consulted experts as follow: research developments in this area could produce a sort of "tamagochi" of oneself, a device that can tell everyday how one has performed, and whether or not one has behaved well towards his/her health. This could be among those tools that could motivate people to behave in sound and preventive fashion (if they are healthy), to refrain from certain specific behaviours (if they have been diagnosed with a potential future risk), to adhere to prescriptions and lifestyle guidelines (if they are already chronic patients and/or are following a rehabilitation programme).

Obviously, all of the data integration, fusion, and mining activities require the operation of interoperability, why it is strongly recommended to carry on this field of research in the implementation studies. Correspondingly, this has to be further supported by a strong legal framework, where also the privacy and ethical issues are assured.

4.5 Third generation PHS sensors: rationale and roadmap

4.5.1 Contextualisation

In our state of play we considered, among others, the following attributes for sensors in the PHS context:

- Position;
- Invasiveness;
- Level of comfort;
- Type of sensor;
- Interactivity level (lack or presence of actuation);
- Whether it includes on board processing;
- Signs per sensor and disease per sensor;
- Type of data gathering.

At the level of research projects noticeable progress and advancement have been achieved if we look longitudinally at the frontier of innovation of PHS FP5 projects compared to those launched in FP7, although much space remains for substantial improvements. As far as sensors position is concerned, for instance, stationary and portable sensors are being substituted by smart wearable sensors, providing large contact surface with human body (which increases measurement accuracy) and better comfort for users. If we call those developed so far by research projects as "second generation PHS sensors" (distinguishing them from first generation sensors included in product and services currently available in the market), the comparison between the state of play and the scenarios identified various gaps that need to be filled in for the development "third generation PHS sensors". "Second generation PHS sensors" still miss calibration, optimised power supply, capacity of efficient and effective multi-disease and multi-signs context aware data gathering, actuation, on-board processing that already fully perform multimodal data fusion. Sensors still have problems in gathering reliable data under movement. As put it by one expert during consultation, for instance, there are no ECG devices that displays T-wave elevation or sub-elevation under movement and the same applies to respiration. When it comes to wearable sensors, currently there is still the need to calibrate every couple of hours to get them to work properly. There is too rigidity in sensors networks architecture preventing their adaptability to the very peculiar characteristics of each single individual and little space of modularisation and "plug & play" approaches. Capturing signs reflecting the emotional and psychological status of individuals are out of the current possibilities of data gathering by sensors. During the gap identification phase, the main characteristics of sensors were compared to the main features of future PHS applications, as outlined in the scenarios. One of the crucial issues to be solved in order to spread PHS adoption is the comfort of data gathering systems (i.e., the devices where sensors are applied, for gathering patients' data). A key issue is to overcome the trade-off between accuracy of measurement, which requires frequency of measurement, and large contact surfaces, and comfort, as individuals want to have complete freedom of movement (ideally, they should not even feel the contact with sensors).

4.5.2 Further insights

The importance of developments in MEMS and NEMS. Microelectromechanical systems (**MEMS**) are devices with tiny moveable parts that respond to control voltages and are mass produced, for instance, by several manufacturers as airbag sensor in cars (Tröster 2004: 132). We briefly treated these technologies in the state of play[65] and then they have repeatedly surfaced in the gap analysis associated to gaps mainly related to sensors but with implications also for data processing[66]. In very brief and simplified terms the micro- and nano- systems: a) interact with their physical environment; b) are minimally invasive (implanted MEMS can be the size of a grain of rice); c) integrate sensing, computation and actuation, possibly capturing several signs; d) can increase energy efficiency and decrease bandwidth requirements (an implanted MEMS requires no batteries, as radio transmitter and receiver held near the body provides the power and interrogates it). It is quite evident, then, how they can contribute to fill many of the gaps discussed about sensors. Indeed the emergence of MEMS is considered as one of the major technological breakthrough in the last 20 years. They are considered as building blocks for complex micro-robots performing a variety of tasks and are used to construct systems which function very close to biological systems existing in nature (Frenz 2008). MEMS-based sensors have several advantages: can be mass-produced lowering average costs of production, have small size, low power consumption, lightweight and small volume. Fabrication of MEMS involves developing smart structures, which communicate via feed-back in closed-loop systems. This requires merging computation with sensing and actuation into integrated micro-level systems that interact with the physical world. Materials commonly used for fabricating MEMS include traditional microelectronic materials (like, for instance, silicon, silicon nitride, polyamide, gold, aluminium), and non-traditional ones (e.g., ferroelectric ceramics, shape memory alloys –SMA, and chemicals sensing materials). These micro-machines systems are designed by integrating different micro-components into one functional unit comprising sensors, actuators, ICs for data processing, etc. In this development, a variety of micromachining technologies, ranging from the conventional silicon bulk and surface micromachining to LIGA and LASER techniques are employed, each one having specific advantage or merit for a specific product. Another process useful for MEMS application is substrate bonding. Silicon, glass, metal and polymeric substrate can be bonded together through several processes like fusion bonding, anodic bonding, eutectic bonding and adhesive bonding. Substrate bonding helps in achieving a structure that is otherwise difficult to form e.g., hermetically sealed large cavities, a complex system of enclosed channels or simply to add mechanical support and protection (Gupta and Ambad, 2007).

MEMS for wearable sensors. Wearable sensors are indeed a very important development where it is safe to state that PHS application have been a driving force. As

[65] Deliverable D2.1, *State of play*, pp. 36-37 and p. 47.

[66] PHS2020 Deliverable D4.1, *Gap Analysis Report*: Box 8 (p. 29); Box 14 (pp. 33-34); Box 15 (p. 34); Box 16 (pp. 34-35); Box 17 (p. 35).

illustrated by De Rossi and Lymberis (2005) there are three very simple but forceful arguments underscoring the importance of wearable sensors: a) about 90% of the skin surface is into contact with textiles; b) fabrics are flexible and conform well to the human body; c) they are relatively inexpensive and eventually disposable. Yet, there are still a number of challenges and of corresponding innovative solutions emerging (Akita *et al* 2008; Liao *et al* 2008; Roggen *et al* 2006; Bonfiglio *et al* 2005; Tröster 2004)[67]. Not all but many of such challenges can be overcome through the application of MEMS into textile producing **smart wearable sensors** with improved measurement precision and more efficient energy consumption. Tracking of body motions, gestures and positions provide information useful for activity classification, for de-noising of other bio-signals, e.g. ECG, and for interpretation of the physiological status. Miniaturised MEMS based accelerometers, gyroscope, magnetometer, piezoelectric embedded into wearable can improve such tasks. Even before the current rise to prominence of MEMS, micro-systems embedded directly into fabrics, or in clothing components like buttons, were considered a way to improve wearable sensors by decreasing their invasiveness and preserving the quality of the gathered data and by making them energy autonomous through solar cells mechanical (i.e. leg motion) and thermal (i.e. body temperature) energy (Bharatula *et al* 2004; von Büren *et al* 2004; Starner 1996). MEMS greatly enhance these possibilities envisaged earlier for less advance micro-systems. An additional critical issue is that of the material more suitable to be employed and various solutions are being explored(see Liao *et al* 2008; Bonfiglio *et al* 2005)[68]. Even in this case, advancements in MEMS technology embedded into wearable sensor can help improve these aspects.

MEMS, implants, and actuation. MEMS, alongside other bio- and nano-technologies, represent a key factor for the development of new implantable sensors, as explained in the following example. Miniature MEMS sensors, similar to those that trigger airbags in cars, might be implanted in the hearts of people suffering from a heart disease. For instance a very small wireless and battery-less MEMS implant for cardiovascular applications has been developed and tested on animals with promising results (Najafu and

[67] This is only a very selective list of possible references that are sufficient for our purpose here that is mainly illustrative with no claim go into the very details of the various solutions.

[68] The core of the smart wearable is the textile transistors, with respect to which the textile industry has some constraints. For instance, concerning the use of metal yarns, usually the use of a single metal fibre is avoided, because of problems of low flexibility and resistance to stretching and friction. In this respect, some new techniques are being developed: 1) production of a yarn with a core of "normal" textile and with spiralled metal filament; 2) use of pure metal yarns made of several metal fibres, prepared as long filaments or from staples; 3) a yarn made by twisting metal fibres around a filament or a previous spun yarn, thus concealing the core. Applying these techniques, metal yarns can be used with commercial weaving machines, maintaining technical properties comparable with traditional yarns. In addition, more "traditional" material, like optical fibres, can be used to monitor vital signs in a minimally invasive way, having the capability to be modelled like human hair, with similar size and flexibility characteristics. Optical fibres, in fact, are thin, lightweight, chemically stable and generally biocompatible. In addition, fibre communication technology is well established. By the way, in vivo use for monitoring still has some open issues, like the speed and accuracy of measurement over time.

Ludomirsky 2004). It is a devices developed for congestive heart failure[69], which the National Institute of Health in the US has qualified as a new epidemic: with 4.8 million patients and 400.000 new patients per year it is the only cardiovascular disease that is getting worse (reported in Najafu and Ludomirsky 2004: p. 61). Currently the disease is treated with drugs, whose effectiveness need to be monitored. This so far can be done only through a very invasive, costly and very unpleasant way: by temporarily inserting a catheter into the heart, via an artery in the arm or leg (for some patient as often as three times a year). The proposed MEMS implant would require this operation to be done only once to implant the sensor in the left atrium. Thanks to the characteristics of MEMS this device would avoid the problems of other implanted sensors, namely that they get clogged by cells or proteins. This is so because it is micro mechanical system and as such it measures the pressure mechanically by the simple flexing of a membrane. Evidently being battery-less, the monitoring cannot be continuous although it could certainly more frequent check that it is possible with the very invasive traditional method. At any rate, besides the potentiality of MEMS, this example also underscores the need of further research into the issue of power generation.

Moreover, active micro-catheters (see also figure 43) and active guide wires, which incorporate micro-actuators at their tips and are controlled from outside the body, have been developed. These actuators, which incorporate Titanium-Nickel Shape memory alloy (SMA) micro coils, are capable of several motions such as torsional and extending motions, sensibly improving the effectiveness of the catheter for navigating difficult blood vessels branched with highly acute angles, and the selective embolisation of arteries for treatment for treatment of tumours, like myoma of uterus. Modular MEMS-based actuators are being researched to provide **motion systems to capsular endoscope[70],** exploiting the thermal expansion of PDMS (polydimethylsiloxane), and using a bulk micro-machining fabrication technique (Lee et al., 2007). Several other diagnostic and treatment tools for use in the human body are being developed, using the alternatively bonding and micromachining fabrication techniques, as an ultra-miniature fibre-optic pressure sensors, an ultrasonic therapeutic tool for sono-dynamic therapy and sono-poration (Lee et al., 2007). Yet, it must be stressed that the use of metal alloys (including Nickel) in MEMS can limit their potentialities, since it can reduce the adoption of these kind of applications by an increasing part of population due to allergy to nickel, especially when considering that the prevalence of contact dermatitis and atopy is increasing (Dawn et al., 2000).

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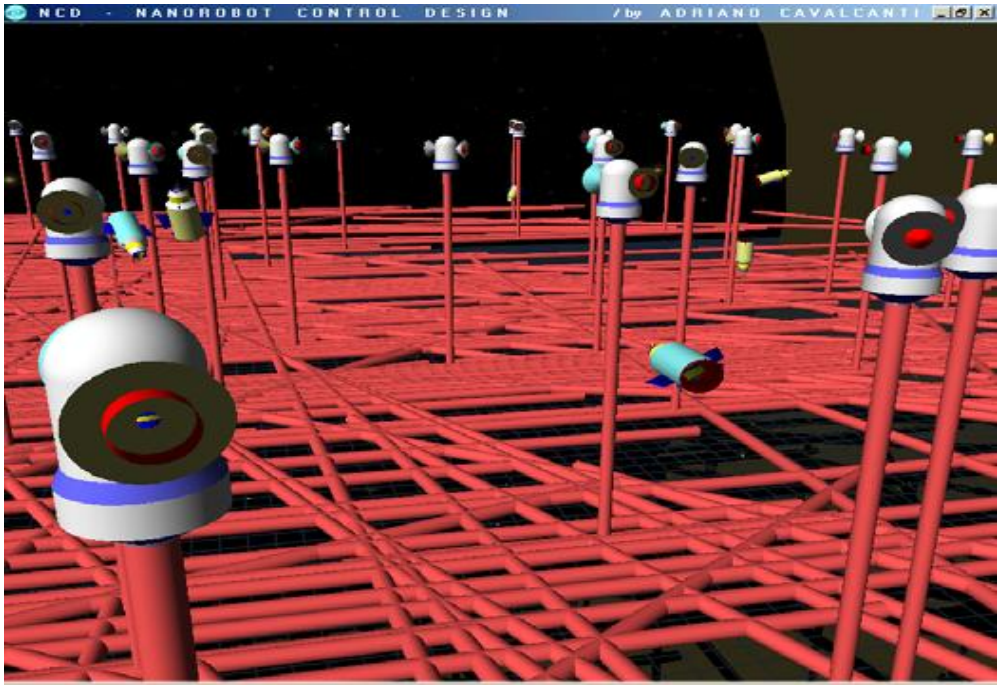
[69] It is a form of cardiovascular disease where fluid builds up in organs and limbs because the heart fails to pump enough blood around the body.

[70] Conventional endoscope is becoming an important medical tool diagnosing human disease, although it has a few drawbacks: a) require sophisticated skills for doctors to use it; b) the endoscope inspection is painful and invasive for the patient; c) it is difficult to inspect the small intestine using the endoscope. New capsular endoscopes, which can move by the motion of the intestine, have been developed to obviate to the three drawback of the conventional endoscope. Yet, this new capsular endoscope still has the limitation of not being able to move by itself. MEMS-based actuators are being developed to produce self-movable capsular endoscope applications.

Molecular Nano Technology and Nanorobotics. Technological developments of relevance for PHS are coming from MNT in general, and from nano-robotics applications in particular. These complex molecular machines, in fact, with embedded nanoscopic features may provide broad advances in the healthcare sector. Current developments in nano-electronics and nano-biotechnology are providing feasible development pathways to enable molecular machine manufacturing, including embedded and integrated devices which can comprise the main sensing, actuation, data transmission, remote control uploading, and coupling power supply subsystems addressing the basics for operation of medical nanorobots. Considering the properties of nanorobots to navigate as blood borne devices, they can help important treatment processes of complex diseases in early diagnosis and smart drug delivery. A nano-robot can provide efficient early diagnosis of cancer and help with smart chemotherapy for drug delivery. Nano-robots as drug carriers for timely dosage regimens allows maintaining the chemical compounds for a longer time as necessary into the bloodstream circulation, providing predicted pharmacokinetic parameters for chemotherapy in anti-cancer treatments, avoiding at least some of the side-effects of chemotherapy (Cavalcanti, et al., 2008a and 2008b). Clearly, this kind of applications is far beyond current solutions for ensuring drug intake and compliance with medical prescription of patients (Barnes and Reeves, 2008, Fook et al. 2007). These, in fact, are mainly based on applications inferring actual drug intake monitoring patient's vital functions and mobility, at occurrence providing reminders and alarm functions for falls detections or common infections (like Urinary Tract Infections). The application of nano-robots with embedded sensor devices for drug delivery and diagnosis is, therefore, undoubtedly an interesting subject, which can enable significant improvements as a high precision device for medical treatments. A nano-robot architecture using embedded CMOS (Complementary Metal Oxide Semiconductor) for sensing, communication and actuation, as the result of many breakthroughs in nanotechnology, with a complete integrated set of nano-bioelectronics, should help in setting directions for the fast development and manufacturing designs of future molecular machines. The nano-robot must be equipped with the necessary devices for monitoring the most important aspects of its operational workspace. For biomedical application the temperature, concentration of chemicals in the blood, and electromagnetic signatures are some of the relevant parameters when monitoring the human body to detect some diseases. The application of new materials has demonstrated a large range of possibilities for use in manufacturing better sensors and actuators with nano-scale sizes. This downscaling will continue, according to the Semiconductor Industry Association's roadmap (International Technology Roadmap for Semiconductors, 2006). By 2016, high performance ICs will contain more than 8.8 billion transistors in a 280 mm2 area—more than 25 times as many as on today's chips built with 130 nm (nano-meters) feature sizes. Those developments allied with 3D simulation should facilitate the manufacturing design of nanorobots with integrated embedded nano-electronics and circuits**.**

Figure 28: Nanorobots search for organ-inlets demanding protein injection



Source: Cavalcanti *et al* (2008a)

Nevertheless, even such a promising field presents some problems when looking at practical adoption of nano-robots. Many of them concern possible toxicity of nano-materials, which can lead to increased production of reactive oxygen species (ROS), including free radicals. So far, there are no conclusive studies on toxicity of all nano-particles, or on long-term effects on human body.

Biosensors and nanobiotechnology. Biosensors and nanobiotechnology, as they are both converging with nanoelectronics, to some extent address the issue of reducing possible undesired effect in that they combine a biological component with a physicochemical detector component for the detection of an analyte. The main potential of these development, however, are not only in the material used, but also in the capacity to identify the target molecule (given the availability of the needed biological recognition element) in a disposable and portable system in alternative to laboratory based techniques. In a biosensor a) the biological component (i.e. tissue, enzymes, nucleic acids, etc) interacts with the target analytes and should produce a signal that b) is transformed into a another signal by a detector element working in various ways (physicochemical way; optical, piezoelectric, electrochemical, etc.), which c) is processed by the associated electronics or signal processors component displaying the results in an intuitive way for the user.

In 2006 in the US an implanted biosensor has been presented in a patent application, for instance, incorporating living components (tissues or cells) that are electrically excitable

or are capable of differentiating into electrically excitable cells to be used to monitor the presence or level of a molecule in a physiological fluid[71]. As the author rightly claim, such solutions compared to traditional laboratory test have the advantage that they enable a high frequency of measurement and avoid the discomfort of associated with periodic blood draws. Moreover, if coupled by user friendly and intuitive visualisation, they could also be used in tertiary prevention: if patients with diabetes were able to continuously see a display of glucose concentration in blood or tissue, they could better avoid extremes of glycaemia and reduce their risk for long term complications. Finally, it is claimed that implanted biosensor (because of the use of biological material) would overcome the problem related to the fact that ***fibrosis of the foreign body capsule typically develops around the implanted sensors 3-4 weeks after implantation and reduce the influx of substrates such as glucose and oxygen***. A further development comes from the convergence between nanoelectronics and nanobiotechnology in the form of ***nanorobots with embedded nanobiosensors and actuators*** (Cavalcanti *et al* 2007; Cavalcanti *et al* 2008b; Liu and Shimoara 2007). This development enables molecular machine manufacturing, including embedded and integrated devices, which can comprise the main sensing, actuation, data transmission, remote control uploading, and coupling power supply subsystems, addressing the basics for operation of medical nanorobots. In 2006 a sensor/actuator with biologically-based components has been patented in the US by Xiong *et al* [72]. This actuator has a mobile member that moves substantially linearly as a result of a biomolecular interaction between biologically-based components within the actuator. Such actuators can be utilized in nanoscale mechanical devices to pump fluids, open and close valves, or to provide translational movement (see Figure 29 in next page).

Contactless sensing and bio-imaging. Whether it applies only to sensing or to both sensing and actuation, the issues of non invasive or minimally invasive sensors/actuators and of the effects that their materials will have on human body have emerged from the consideration so far as of strategic importance, and they apply to both on- (wearable) and in- (implantable) body sensing and actuation, and also to the very new and promising development in MEMS/NEMS and in MNT and nanorobotics. In consideration of this, technologies supporting improvements of non invasive and minimally invasive monitoring and actuation are being given further impetus. Among them, promising technologies supporting development of contactless sensors can be integrated from other areas also in the field of PHS, ***exploiting magnetic field***, for instance, sensors could be developed that integrate also communication capacities through ***nano-antennas***. In the same way, advancements in imaging techniques, exploiting the characteristics of micro- and nano-devices, could lead to interesting applications. Among those, ***bio-photonics*** for non invasive/minimally invasive detection of analytes can be mentioned. This kind of application would allow to measure the analyte in blood without extracting the sample,

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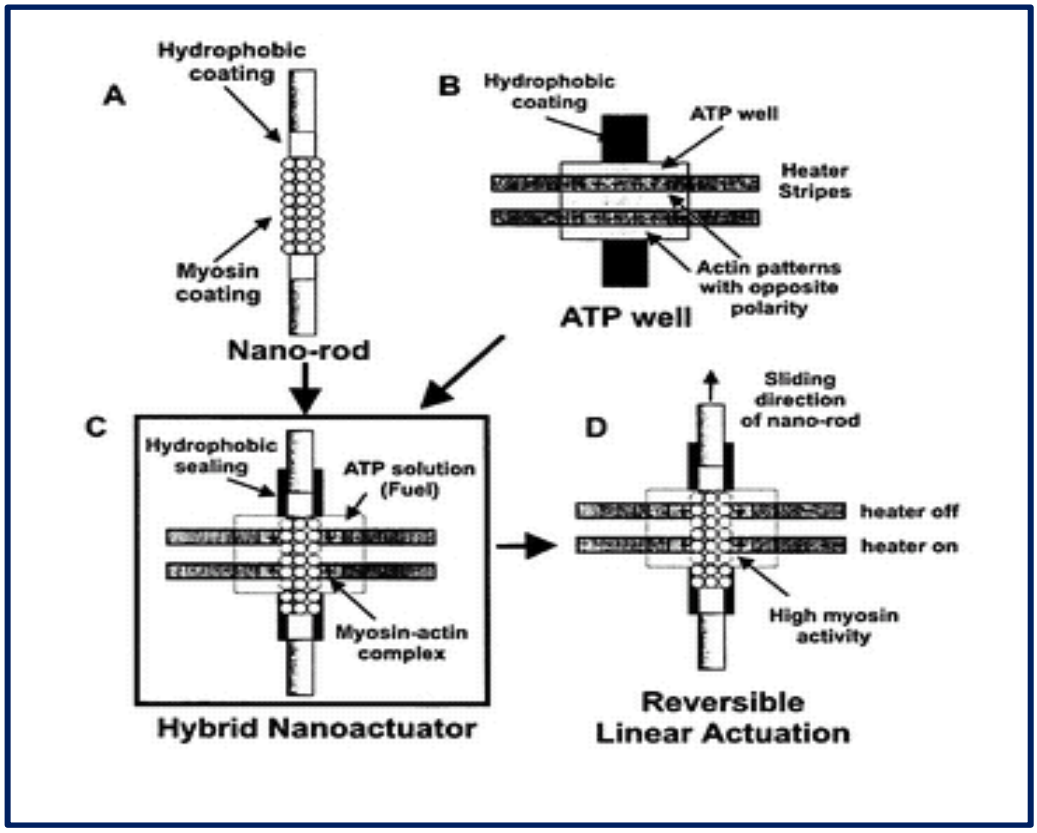
[71] United States Patent Application 20060234369 by Sih, Haris, J. (see details at: http://www.freepatentsonline.com/y2006/0234369.html?query=Implantable+biosensor&stemming=on)

[72] United States Patent 7014823 (see details and name of other inventors at http://www.freepatentsonline.com/7014823.html)

but simply getting almost in contact with it, (e.g., penetrating into the first layer of skin, near blood vessels), and obtaining results in few seconds

Figure 29: Bio-molecular based actuator



Source: Xiong *et al* (2006, see http://www.freepatentsonline.com/7014823.html)

An even more fascinating application of imaging concerns tongue scanning, a developments joining advanced medicine technology with Traditional Chinese Medicine (TCM). Traditional Chinese Medicine has become fascinating because of its holistic approach to health, including physiological but also environmental and emotional aspects, in which modern medicine is gaining interest. Therefore, joining "traditional" knowledge with "scientific" tools and methods is being considered as a very interesting area. Tongue diagnosis in a standard technique of Chinese Traditional Medicine (Liu, *et al* 2007). The relationship between some diseases and abnormalities in the patient's tongue and tongue coating has been substantiated by clinical evidence. The association, for instance, between the various viscera cancers and the changes of colour, coating, degree of wetness and coarseness, shape and dorsum shape of the tongues, has motivated the development of various tongue visualization techniques. There are several issues to be addressed in computerized tongue image analysis. The methods to capture the tongue image, followed by effective segmentations of the tongues and calibrations of their colours need to be considered. Generally, two kinds of quantitative features, chromatic and textural measures, are extracted from tongue images. Selection and representation of

tongue image features are the next issues to be tackled with. In the early studies, charge-coupled device (CCD) cameras were used to capture the tongue images and a red, green, blue (RGB) model was used to represent the colours. The next problem is the fuzzy characteristics of the data itself. Further challenges concern the processing of tongue images: the more recent approaches include fuzzy theory, neural networks, parallel coordinate visualization, Bayesian networks, and integrations of them (Lukman, et al., 2007).

Context awareness: importance and state of the art. The context aware and more holistic data processing going beyond vital and physiological signs discussed earlier must be fed by new sensors capable to capturing the relevant and currently less evident signals. Context awareness is important in two ways. First, the understanding of users' context is fundamental for a full comprehension of physiological parameters ***avoiding false positive or the chance of missing a risk situation***. For instance, it is only matching vital parameters with activity and behaviour information that permits a correct assessment of cardiovascular risk and trigger appropriate action. In this first sense, thus, context awareness is instrumental to monitoring and treatment of users with a chronic disease or with an early detected risk that could develop into a full blown disease. Second, in a much broader sense context awareness is important because ***it has been demonstrated that the mental and social state of individuals have an impact on their health*** (Danner *et al* 2001; Diener *et al* 1997; Diener and Lucas 2000; Giles *et al* 2005)[73] and indeed the World Health Organisation defines health a sense of physical, mental and social well-being and not simply as a the absence of disease or infirmity (WHO 1946)[74]. In this second sense, then, PHS ***context awareness is fundamental also for life style management*** applications helping the health savvy users preserve a good health status along three directions (physical, mental, and social state) and prevent the outset of diseases. The issue of context awareness is certainly not a new one in research and already more than a decade ago it was stressed, for instance, that a truly personalised wearable system should automatically recognize the activity and the behavioural status of a user as well as of the situation around him and to use this information to adjust the systems' configuration and the functionalities (Abowd *et al* 1998). Indeed research has achieved noticeable advancements for the dimensions of context recognition listed in Table 10 overleaf.

Yet these capabilities need to be expanded significantly in order to understand higher level, more complex, and contexts than what is currently state of the art (Roggen *et al* 2006).

[73] Cited in Roggen *et al* (2006).

[74] See comments of this definition as moving from health to happiness in Saracci (1997).

Table 10: Context detecting sensors

Accelerometer	Motion patterns of the body and limbs
Microphone	Speaker recognition, localization by ambient sounds, activity detection, speech features
Visible light sensor	Localization of light sources
Rotation (gyroscope)	Body movements
Compass	Orientation of the body and the head
Air Pressure	Vertical motion in elevator or staircase
IR light sensor	Sunshine, localization of lamps
UV light sensor	Localization of fluorescent light tubes
Environment temperature	Outdoor, indoor
Humidity	Location, weather conditions
WLAN / GSM / CDMA	Location, user environment
Bluetooth, ZigBee	Services and devices nearby

Source: adapted from Roggen et al (2006)

Advancement in this field should lead to have sensors capturing the various dimensions of what we mean by broadly defined context of an individual:

- His/her punctual situation of an individual at any given time:
  - Location (indoor / outdoor);
  - Time of the day
  - Activity (sleeping, walking, performing a particular task)
  - Gesture and position
- His/her environmental surroundings:
  - Weather conditions;
  - Illumination;
  - Noises;
  - Chemical features (i.e. particle in the air)
- His/her emotional state (i.e. stress, depression, etc)
- His/her social state (i.e. degree of interaction, communication style, etc.)

Some of these parameters are detected by the sensors listed in Table 10, although as we will show later even in this case there are challenges for future research. Evidently the area where research is only at an embryonic stage is that concerning emotional and social state. Movements and gait have been analysed deeper than parameters such as facial expressions that could help detect the emotional state, and mainly concern fall detectors and movement patterns in controlled environments using cameras as data gathering devices (Pham *et al.*, 2008), or gyroscopes (Farella *et al*, 2008). In this respect it is worth stressing that out of the large number of EC funded research projects analysed in

PHS2020 state of play[75], only two FP6 project have addressed the behavioural aspect of health: INTREPID[76] and AUBADE[77]. Some of the emerging directions of research are discussed below.

Context awareness: emotional and social state. The notion of 'Affective Computing', introduced more than a decade ago (Picard 1997), is important for achieving context awareness. It designs machines with the skills to recognize their users' affective expressions (including stress, depression and other emotional states), and to respond intelligently. In two recent review of the state of the art in wearable systems it is claimed that social and mental state may be monitored and evaluated using only ***wearable devices*** (Roggen et al 2006; Tröster 2004). This claim is based on the fact that various emotion classes[78] may be detected from brain signals (Davidson *et al* 1990), or physiological signals such as cardiovascular patterns (Schwartz *et al* 1981). Accordingly accelerometers, microphone, galvanic skin response (GSR), temperature and ECG sensors could be sufficient if integrated combination with local communication devices (e.g. WLAN) to detect the basic mental states like stress, fear, depression, as well as basic social states like interactions or communication styles. Several examples are cited to support this view. Four wearable sensors (EMG, SpO2, skin conductance, respiration sensor) have been applied to detect and to classify eight different motions like anger, grief, joy or hate with a classification accuracy between 60 and 70 percent (Picard et al 2001). Acoustical properties of speech, which can easily be recorded by a collar microphone, are suited as indicators of depression and suicidal risk, as described in (France et al 2000). Face-to-face interaction between people within a community can be detected with a wearable 'sociometer' consisting of an IR transceiver and a microphone (Choudhury *et al* 2003). Another direction of research, not necessarily connected to wearable devices, is that of ***Human-Computer Interaction***, where machines that are centred on human needs and react to behavioural stimuli are being developed. In order to understand the role of emotional behaviour in human-computer interaction, and to integrate this knowledge into PHS, however, several aspects still need to be researched in a multi-disciplinary perspective including psychology and anthropology, neurology and, naturally, ICT. Appraisal theory has become one of the most active approaches in the domain of emotional psychology. According to the appraisal theory of emotions, the emotional responses results from a dynamic evaluation (appraisal) of needs, beliefs, goals, concerns, environmental demands that might occur consciously or unconsciously. Several theories have been proposed, but all converge in the view that a specific set of

[75] See PHS2020 Deliverable D2.1, *State of Play*, Annex III (pp. 111-131).

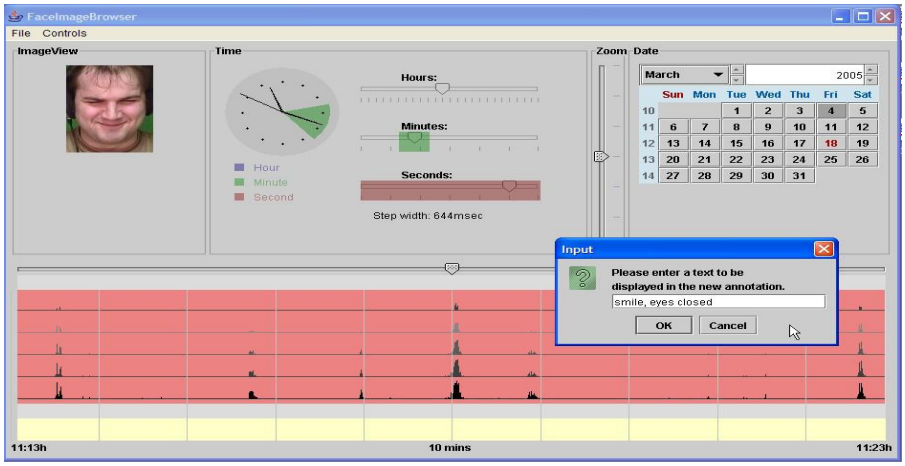
[76] The project developed a multi-sensor context-aware wearable system for the treatment of phobias (see: http://cordis.europa.eu/fetch?CALLER=PROJ_IST&ACTION=D&RCN=71097)

[77] An intelligent, multi-sensorial wearable system that can ubiquitously monitor and classify the emotional state of users in near time using signals mainly obtained from their faces has been developed (see PHS2020 Deliverable D2.1, *State of Play*, p. 118, p. 146, and p. 198).

[78] See Scherer (2005) for a classification of emotions and how they should be measured.

properties of antecedent events defines a particular emotional outcome. Applying dimensions proposed by the theories, and relate them to aspects of the interface or interaction, constitutes an interesting basis to anticipate the user emotional experience towards an interactive system. Also, given the user experienced emotion towards some event triggered by the interaction, it might prove feasible to identify the causes, as a combination of the user evaluation of the event along the different appraisal dimensions (Branco, 2003). Facial expressions constitute the most important but even the most difficult aspects to study, for different reasons. Universal facial expressions, though distinct, are not uniformly produced or perceived. Asymmetry, due to neurobiological constraints and the relative spontaneity of facial movement, is one source of variation, but there are many others. In addition to underlying physical variation in the face and in movement, empirically measured facial behaviour varies according to factors such as sex, age, and cultural background. Also important in facial expression are individual factors, such as sociality of situation and the emotion-eliciting nature of visual or other stimuli. Humans vary in their ability and tendency to produce facial expressions, and this variation is presumably elated to underlying muscular, neurobiological, or social differences, or even different success in nonverbal communication and overall expressiveness (Schmidt and Cohn, 2001). Attempts in automatic analysis and recognitions of facial expressions have so far relied on the use of cameras, and on developing algorithms able to analyse expressions from images of face. Problems related to this methodology relates to three aspects: a) detecting face and its permanent features such as eyebrows, eyes, mouth, in an input image; b) detecting the changes in the shape and location of the permanent facial features by making a comparison with an expressionless face of the observed subject; and c) interpreting these changes in terms of some interpretation categories, like the Action Unit in the Facial Action Coding System (FACS) (Pantic and Rothkrantz, 2003). However, no main achievements in this respect have been attained so far, especially for what concerns visual processing and integration into PHS application (i.e., crossing physiological parameters with facial expressions to extract information about patients' status).

Figure 30: An example of a facial expression automatic analysis



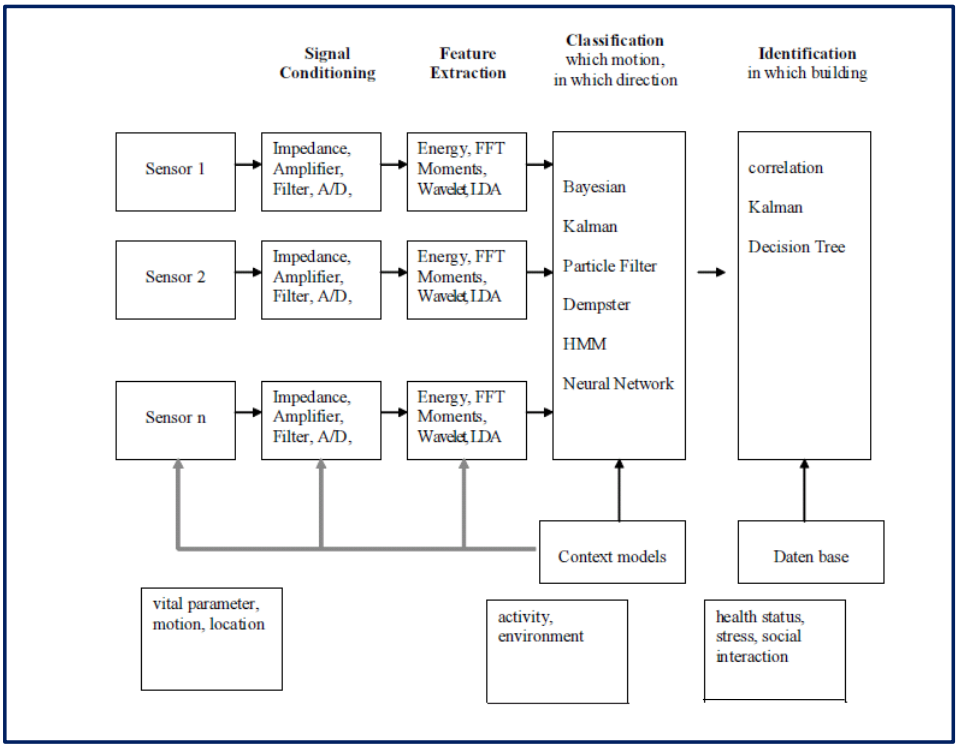
Source: Lyons *et al* (2005)

Before moving to finally list a number of challenges for the achievement of context awareness in PHS, it is worth stressing the potentially many-fold benefits of developing systems capable to intelligently adjusting to users' emotional status. In fact, this has positive effects not only for the mere gathering of data through sensing, but can also improve users' acceptance and adoption of PHS. First, human-computer dialogue can be crucial those groups in society that, for various reasons (i.e. age, education, etc) have reduced capability of interacting with usual PHS devices (like PDAs), and a low attitude towards learning how to use technology in general. Second, advancements in affecting computing and human-computers interaction could produce the appropriate motivations and 'prompts' for individuals adherence to clinical guidelines and lifestyle management, which would apply to both the technology confident and to the technology resistant individuals.

Context awareness: challenges. If we consider the sensors listed in Table 10 capturing some of the context relevant parameters, first they are all based on devices requiring a constant and large area of contact with the skin, which is a barriers for users acceptance, especially by health individuals not suffering from diseases but interested in lifestyle management. Second, they must ensure reliability of measurement in the context of movement. Third, at least for application monitoring life critical situations (so in this case not life style management) in mobile situations , they require ***processing capabilities embedded into on-body sensors, in order to process and transmit all necessary information***. Finally, even in this case we face the issue of "clinical settings" versus "uncontrolled conditions": the signal performance achieved in standard medical conditions cannot be guaranteed in a mobile environment. ***Methods have to be provided to correlate the clinical and mobile data***. Moving to the monitoring of emotional and social state the challenges are in general those of an area of research much less mature. First, such states cannot be easily translated to simple physical outcomes gathered by single sensors. Second, there are not yet consolidated and standardized measures against which evaluate in a combined way physical, mental and social parameters. Third, although affecting computing and human-computer interaction may in the future help, it is not yet clear what kind of feed-back should PHS capturing emotional and social state, especially those aiming at life-style management, provide to improve the well-being of users. Accordingly, to respond to the second and third challenge multi-disciplinary and inter-institutional cooperation is needed especially for lifestyle management to decide: a) what are the signals required to detect context, social interaction and activity; and b) what is the minimum set of signals to achieve a desired performance lifestyle performance. A fourth open issue, which is clearly in overlap with the topics discussed with regard to the "***Bio(medicine) Infused PHS***" and already treated there as one of the object of integration between PHS and BMI, is the question of data collection and correlation of emotional parameters with parameters contained in other clinical databases. Finally, after recognition and sensing of context relevant parameters challenges are still open for their processing. Although we have already treated this topic earlier, it is worth reviewing it again here in light of the more technical discussion developed so far with regard to context parameters. We will do this with the help of Figure 31 overleaf taken from an earlier mentioned contribution (Tröster 2004). The figure illustrates several methods and

tools have been proved for data fusion, feature extraction and classification. The Bayesian decision theory offers a fundamental approach for pattern classification. Nonparametric techniques like the k-nearest neighbour approach enable the design of decision functions only based on sample patterns. The Kalman filter and the recently proposed particle filter are helpful tools for the tracking and monitoring of states, for example, of hand gestures in video sequences. Hidden Markov Models and the Viterbi algorithm are appropriate to estimate a sequence of decisions. The adaptive and learning properties qualify multilayer neural networks for context recognition by the training with repetitive presentations of the target values, e.g. motion patterns. All of these methods, however, are by far not capable of interpreting arbitrary real world situations. ***Progress in multimodal data processing, in cognitive science and artificial intelligence are strongly needed to achieve the vision of context aware, measurement reliable, and intelligent PHS devices***.

Figure 31 Context recognition data path

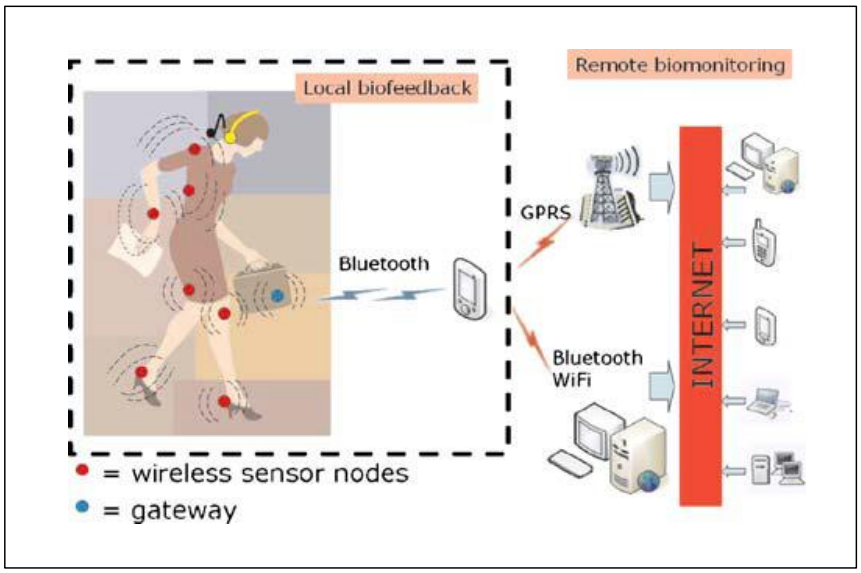


Source: Tröster (2004: p. 131).

Sensors networks. While so far we have focussed on the characteristics of sensors, which are clearly crucial for their application in PHS, the issue of sensors network is also worth discussing. Sensors' networks are essential in order to sense, collect, and disseminate information about the observed individual**.** The issue of sensors' network has two dimensions, one related to ***communication*** and one related to their composition and possibly their ***modularisation*** (or ***componentisation***). Both, however, as many other topics discussed throughout our work have to do with the objective of making PHS more personalised. Sensors' networks constitute the backbone for the construction of really

personalised PHS. It is evident that wired sensors are incompatible with users' everyday life, especially if we aim at lifestyle management or even at monitoring and treatment of users with mild forms of chronic diseases in such a way that they can remain economically and socially active. Therefore, wireless sensors networks represent the only option for ubiquitous health monitoring. Wireless sensor networks share many of the challenges of traditional wireless networks, such as limitation in energy and bandwidth availability at each node, and error-prone channels. Yet, energy limitation is more constraining is in sensors networks than in other wireless networks because of the nature of the sensing activity and of the difficulty in recharging batteries (Tilak *et al.*, 2002). An important peculiar requirement for wireless sensors networks architecture in PHS is openness and reconfigurability of sensors**.** In fact, sensors need to be easily added or removed from the network, since the personalised needs of users may change over time. Adding new sensors in a Body Area Network, then, should be supported by sensors modularisation possibilities, or in other word through a "Plug & Play" mode. Concerning processing capabilities, they are distributed along the network, both in the sensors nodes and in the CPU. Intelligence should also be distributed in all sensor nodes, so as to operate in an overall efficient manner, enabling the nodes to process incoming information and to act accordingly. In this way, the necessary bandwidth required for communication will be sensitively reduced, increasing the overall efficiency of the network. However, the balance of the trade-off between intelligent on-board processing and communication in a condition of limited available energy is influenced by several factors, including the communication technology chosen (Bluetooth, ZigBee, etc), and there are no general rules. On the contrary, the solution is found on a case by case basis. All these issues are not new in the sensor domain, and are being researched on and solved in many fields. However, when considering ubiquitous monitoring for healthcare applications (and PHS in particular), current solutions face the problem of being tightly coupled with the sensor hardware technology involved, resulting in proprietary solutions. Apart from standardisation and interoperability issues, open architecture and standard ways for exchanging information and managing services in the application level are crucial, in order to integrated both sensor platforms and body area networks, towards efficient intra-BAN and extra-BAN communication (Triantafyllidis et al., 2008). These issues assume even greater importance if considering next steps in PHS application, like integration of physiological parameters with contextual and psychological signals, or with Smart Homes.

Figure 32: An example of body sensor network



Source: Farella *et al* (2008)

Sensors self-calibration. Finally, an open issues concerning intelligent sensors with computation capability point to the calibration of sensors, or, even better, self-calibration of sensors (Rivera et al. 2007). This is an issue related to that of reconfigurability of sensors in real time. For instance, the sampling frequency of a physiological parameter monitor may have to change, on the basis of personalised criteria (such as age, for instance). In the same way, personalised thresholds for physiological parameters should also be reconfigurable. Self-calibrating sensors, on the other hand, may obviate these problems. In order to design intelligent sensors for measurement systems with improved features a simple reconfiguration process for the main hardware will be required in order to measure different variables by just replacing the sensor element, building reconfigurable systems. Reconfigurable systems ideally should spend the least possible amount of time in their calibration. An auto-calibration algorithm for intelligent sensors should be able to fix major problems such as offset, variation of gain and lack of linearity, all characteristic of degradation, as accurately as possible. The linearization of output signal sensors and the calibration process are the major items that are involved in defining the features of an intelligent sensor, for example, the capability to be used or applied to different variables, calibration time and accuracy. While these aspects concern better the data processing then the sensor in itself, it clearly affect the performance of the sensor. A sensor extremely sensitive to changes (like movements, for instance, or other conditions) needs continuous calibration, reducing the efficiency of the entire network. While several methods are being researched on to solve this issues (like artificial neural network, piecewise and polynomial linearization methods), none specific solution has been so far envisaged for healthcare applications.

4.5.3 Proposed Roadmap

The table below spreading in the following page synthetically provides a snapshot of the preliminary research themes associated to the gaps and of the key input from the further review of the literature.

Table 11: Re-compacting information: Third Generation PHS Sensors

Gaps (Table 7, p. 88)	Preliminary research themes (Table 7, p 88)	Further insights
• Lack of capacity to capture new signs on the environment (both physical and chemical parameters) and on the peculiar situations of individuals (activity, location, emotional status) • Monitoring techniques not able to correctly link physiological signs, with motions, gestures, and environmental data;	• New sensors for context awareness (environment, emotional status, punctual location and situation, etc) and for gathering data in "uncontrolled conditions"; • Investigate how to incorporate data from environmental sensors • Incorporation of advancements in human-computer interfaces and ambient intelligence (in order to "read" emotions though facial expressions and gestures, see later) • Incorporation of on- board processing	• Context awareness strategic for lifestyle management • Importance of capturing emotional and social state • Lack of databases with data on parameters related to context (already treated within the roadmap on "**Bio(medicine) Infused PHS**") • Non invasive MEMS enabled and energy autonomous smart wearable for context awareness • Need of new/improved on-board processing capabilities • Self-calibration also in relation to the "uncontrolled conditions" of data gathering • Context aware wearable devices • Affective computing • Human-computer interaction/dialogue (also helping motivation for lifestyle management) • Inter-disciplinary and inter-institutional cooperation needed to establish parameters (already treated within the roadmap on "**Bio(medicine) Infused PHS**")
• Need to go beyond the "one sensor- one signal" and "one sensor- one disease" paradigm to optimise energy and bandwidth usage • Need to simplify and reduce the amount of data transfers • Need to increase flexibility and better adapt the sensors to individual characteristics (reduce invasiveness and consider allergies)	• Optimisation of multi-modality to insure multi-disease and multi-signal assessments • Self-calibration of sensors • Optimisation of sensors area networks and modularisation of components (plug & play)	• Sensors networks modularity to improve multimodality, optimise energy and bandwidth efficiency, enhance adaptability to personalised needs and characteristics • On board processing important for overall efficiency of Body Area Network • Advanced in BAN design and communication protocol • Inter-operability strategic • Self-calibration and reconfigurability important for smart sensors with on board processing

Gaps (Table 7, p. 88)	Preliminary research themes (Table 7, p 88)	Further insights

• Lack of knowledge on the long term effect of sensors contact with, and presence in, the human body;
• Lack of closed loop systems moving PHS beyond monitoring and into diagnosis and treatment (i.e. dispensation and reaction):
  ○ Actuators in general
  ○ Personalised drug delivery
  ○ Endoscopy capsules
	• Integration of researches on alternative sensors' materials (e.g., biological and molecular sensors)
	• New smart sensors encompassing multimodality, computational power and actuation functionalities (including alternative energy sources: i.e. body energy)
	• Incorporation of controlled drug delivery sensors (implantable and minimally invasive)
		• Further emphasis on risk of sensors effects on the body and on lack of related evidence
		• Miniaturise MEMS implanted sensors and actuators
		• Personalised diagnosis and drug delivery through nanorobots
		• Bio-imaging (Contactless sensing: bio-photonics for non invasive/minimally invasive detection of analytes)
		• Biosensors and Nanobiotechnology

When we first started the preliminary discussion of gaps at the Pisa Workshop (15 July 2008) one of the leading European experts in the field of PHS sensor formulated the following very general gap: ***"PHS sensors still miss calibration, optimised power supply, multiples signs per sensor, actuation, multi-modal analysis and fusion"*** (included as # 2 in the Full List, see Table 3 p. 71). This key message has been then further elaborated by other experts formulating other gaps related sensors and led to the formulation of gaps and preliminary research themes presented in the first two columns of the table above, which reproduce the simplified sub-grouping illustrated earlier in **§ 4.2** (context awareness, sensors networks, materials and functionalities). In general it can be noticed from the third column of the table that the insights from the additional review of the scientific literature support most of the preliminary identified gaps and provide further context to them and also pointed out new elements. Above all, however, both these further insights and the input obtained during the two roadmapping consultation events underscore how entwined are the various dimensions from which one can look at what is need to produce new third generation PHS sensors filling the identified gaps. It is, thus, a challenging task that of breaking down into separate themes direction of research where there are several complementarities, inter-dependencies and overlaps. For this reason, unlike for other roadmaps, in this case a discussion of these complementarities is in order before presenting the graphic visualisation of the roadmap and commenting it.

Sensing and possibly leading to the activation of an action, accomplished through healthcare professional intervention or direct actuation (an alert, assistance, stimulation, force feedback, neuro feedbacks and treatment and delivery of drug), are in a way the basics of sensors. In practice, however, both sensing and actuation are only two dimensions of a more complex system. To make sense of this complexity in order to present the proposed roadmap it is worth going back to the goal of future PHS as defined earlier in **§ 4.2**.

The overall goal of the research themes proposed in the five roadmaps is to ***make Personal Health Systems truly personalised and efficient, which means that they function*****:** a) capturing the very peculiar characteristics of individuals (vital and physiological signs, but also their genetic outlook, as well as their clinical history, and their socio-demographic and socio-economic conditions); b) ensuring awareness of very punctual contextual conditions (location, activity being performed, emotional and social state, physical and chemical conditions in the environment, etc); c) intelligently processing such information to support traditional action and automatic actuation, thus, bringing new applications and services going beyond monitoring (treatment, drug delivery, feedback of various kinds for lifestyle management, assistance for rehabilitation); d) using devices as minimally invasive and comfortable as possible, and adaptable to the very personal specificities and needs of each single individuals (i.e. avoiding materials to which one may be allergic, or which may negatively interact with individual specific health and contextual parameters, or which may have negative long term effect regardless in general) ; e) providing 'front-end' fruition modalities that respond to different attitudes and needs of different typology of users; f) optimising energy and bandwidth consumption and reducing waste.

We can now try to define what we consider now – so in light of the further evidence gathered and analysed after the completion of the state of play (so in a slightly different fashion from the various parameters of the State of Play Model) – the characteristics of sensors

1) **Scope of data gathering;**
2) **Quality of data;**
3) **Non invasiveness and materials;**
4) **Functionalities;**
5) **Sensing sub-system efficiency.**

Now we show how these five characteristics, whose definition will emerge from the various elements grouped under each of them, respond to the six PHS requirements listed above and how they are closely entwined and inter-related.

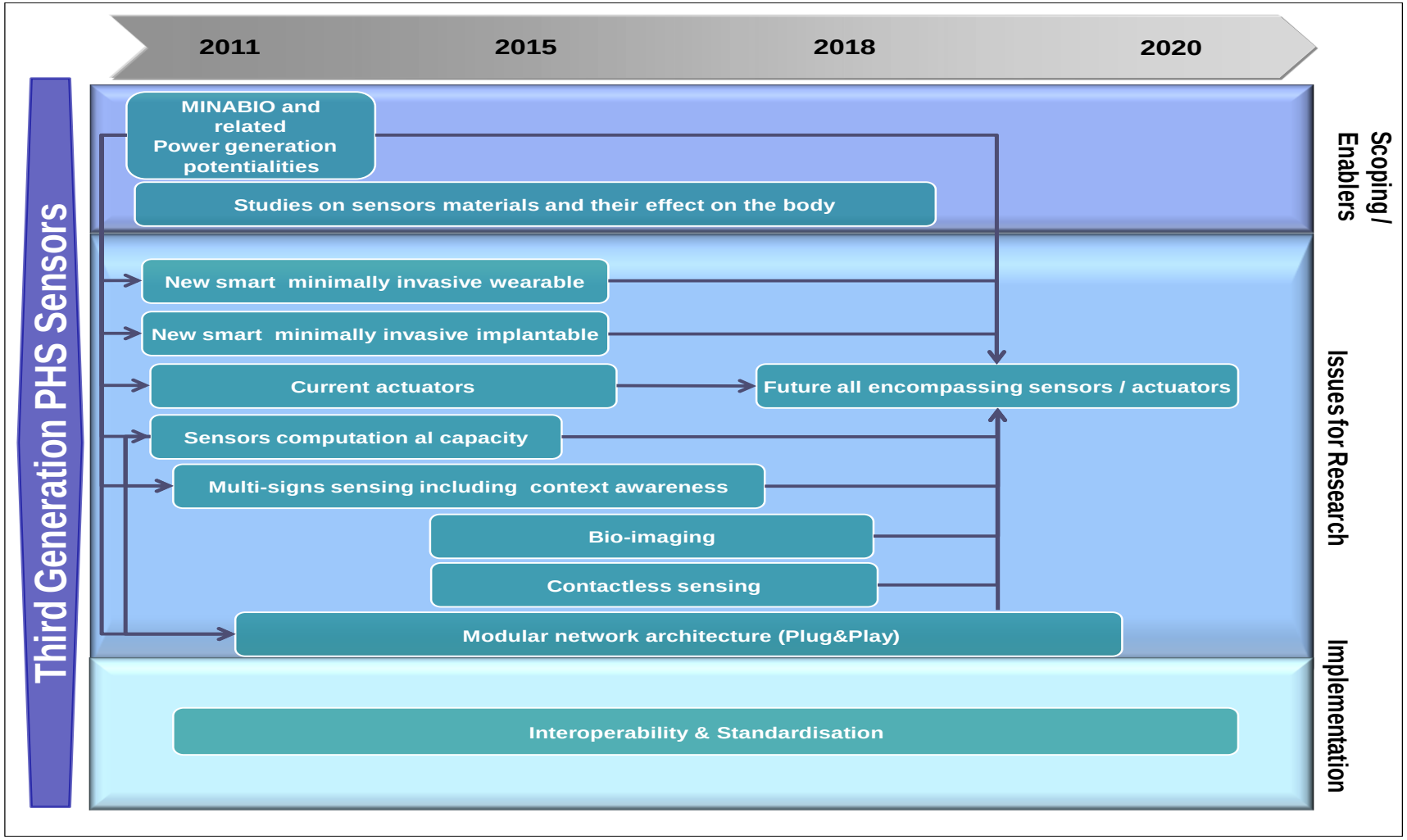
1) **Scope of data gathering**. Addressing requirements a) and b) but also related to **(2)** for treatment of data with different modalities, to **(3)** for non invasiveness and materials, to **(4)** for what concern motivational action, and partially also with **(5)**:
    a. ***New sensors to capture context*** meet requirement b) but need on board processing (for wireless and mobile applications) and raise the issue of correction/rectification of "uncontrolled conditions" data and are, thus, related to, dependent on **(2)**;
        i. ***Affective computing*** as a way of detecting emotional and social state can also help create innovative motivational tool for lifestyle management (thus also related to **(4)**);
        ii. ***MEMS enabled*** miniaturised and energy autonomous ***wearable*** sensors capturing emotional state (requirement b) but also related to **(3)** and **(5)**);

   b. ***Sensors*** capturing ***multiple signs*** addressing a) and also enabling to reach new diseases but naturally related to multimodal treatment and so connected to **(2)** and to **(5)** for reduction of data transfer

2) **Quality of data**. Instrumental to requirement c) and related to sensors ***computational/processing*** capacity but also instrumental to **(4)** and **(5)** below:
   a. ***On board processing*** capabilities for provision of better data to the data processing sub-system or for accomplishing data processing altogether within the sensor (requirement c) , but also in relation with **(4)** for actuation and with **(5)** for optimisation of energy and bandwidth usage by reducing data transfer);
   b. ***Self-calibrating sensors***, same as above plus very important in relation to the challenges raised by new data on context (see **(1)**)
3) **Non invasiveness and materials**. Addressing requirements d) but also converging with **(4)** for what concerns in-body actuation and with **(5)** below (new materials instrumental to alternative power generation):
   a. ***Bio-imaging*** and ***contactless sensors*** fully addressing requirement d) and reducing challenges related to **(5)**;
   b. ***Miniaturised MEMS implantable*** partly address d **(**reduce invasiveness but effect of materials on body still an open issue) and clearly instrumental to (4) (as they embed actuation) plus they may address (5) (MEMS potentiality to harness alternative source of energy);
   c. ***Nanorobots*** same as above;
   d. ***Biosensor, Molecular Nano Technology, Bio Nano Technology***, same as above plus possible improvement due to use of organic / biological components (for effect on body)
4) **Functionalities**. Intended mainly as the capacity of supporting various form of actuation. As seen, this is practically the result of elements already included in the previous three characteristics;
5) **Sensing sub-system efficiency**:
   a. **New sensors networks architecture** optimise energy efficiency and bandwidth usage meeting requirement f) , which is highly related to sensors computational capacities (so **(2)** above);
   b. **Sensors network modularity** also address f) but it is also instrumental to b) and d) in the sense that increase the flexibility to adapt to very personal needs and characteristics and in this sense is related **(1)** (capturing context and flexibly including and correcting sensors) to **(3)** (adapting sensors materials to personal characteristics)

This exhaustive list ensure that the graphic visualisation is contextualised and avoid misleading the readers: the boxes included in the graphic are not and cannot be mutually exclusive given the complex web of complementarities and inter-relation illustrated above. It would probably be possible to present a clearer cut roadmap if we were focussing on sensors for a given specific disease or a given specific task, but not for a general sensors roadmap such as the one we aimed at.

Figure 33: Visual Roadmap for "Third generation PHS sensors"



Source: Authors elaboration

In addition to the long premise above two other considerations are needed before we very briefly review the various elements in the visualised roadmap.

First, precisely as a result of the complex inter-relations discussed above, the time-horizon of this roadmap is very tentative and, we may add, merely illustrative. Indeed the various inter-relations make very difficult defining a time logical sequencing among the various research themes.

Second, many of the new and innovative solutions illustrated in § 4.3.2 (briefly and selectively recalled in the list of the previous page) would result from synergies and fallouts of developments achieved in fields other than those associated to the strictly defined PHS research. These includes: ***MEMS and NEMS, Nanorobots, Biosensors, Bionanorobots and the possibility of alternative power generation (including ways to use energy from the body) that are associated to them***. Sticking to our conceptualisation they would all have to be included as enablers in the "Scoping/Enablers" layer of the roadmap. Instead we propose a scoping study identified in the graphic visualisation with the acronym **MINABIO** on the mentioned **MI**cro-, **NA**no-, **BIO**- technologies. The purpose of the study will be to go deeper than it was possible to do within the scope of PHS2020 in analysing and assessing the applicability of these technologies (including their potentiality to leverage energy from the body) to the field of PHS. We then assume that these technologies will gradually be included into, and further enhance, the various themes included in the layer of the roadmap focussed on research.

Within the "Scoping/Enablers" layer of the roadmap as enablers of most of the research themes we included needed studies on the effects of the sensors materials on human body. Lack of knowledge about this phenomenon is a very crucial gap that is, however, clearly beyond the scope of PHS research. Yet, input from other research field will need to be considered in the design of future PHS research projects addressing the themes proposed here.

We now proceed to list and very briefly comment the various other elements in the roadmap following the order in which they appear

Wearable sensors have been deeply investigated in the medical domain, so that they can be considered as key pillar of PHS research. However, despite the notable advancements, several challenges need to be overcome: improve the quality of measurement increasing users' comfort at the same time, increasing energy efficiency, and improving their embedded processing capacity. New materials can be identified as suitable for building smart wearable sensors, and new fabrication techniques are needed in order to realise the full potential of these sensors. As illustrated earlier, great potentiality may spring by harnessing **MEMS enabled smart and energy autonomous wearable sensors**.

Although a more recent development than in the case of wearable, similar considerations can be made for **implantable sensors**. Future research should both continues along the lines followed so far to ***reduce invasiveness*** and ***increase reliability*** (avoiding problems like ***fibrosis***, see p. 130) and then incorporate the potentialities of ***MEMS/NEMS*** and possibly merge with ***Nanorobots***, ***Biosensors***, ***Bionanorobots*** and practically turn into the **all encompassing sensors/actuators of the future**.

The exact same consideration applies to **current actuators** where research should continue to move from simple ***alert*** to real actuation such as ***personalised drug delivery*** and eventually evolve into the **all encompassing sensors/actuators of the future.** A different issue regards ***actuation*** related to ***lifestyle management*** where input will come from ***context aware sensing of emotional and social state*** through ***affective computing and human-compute interaction and dialogue***. As we explained, these technique would at the same time capture context and devise new way of motivate people which overlap with the topics and research themes treated in the next roadmaps on interfaces and interaction.

The research themes "***Sensors Computational Capacity***" includes under one heading the issues of ***on-board processing***, ***self-calibration***, and ***multimodality***. This is not a new topic in PHS research. However, it acquires a special relevance in light of the evolution process of Personal Health Systems, and their final goal of providing an holistic and really personalised support to users. In order to do this, an increasing amount of data and information has to be gathered and processed, to extract the correct pattern and take the correct decision for each individual. This ambitious goal entails an increase in the number of data to be gathered, in the number of sensors necessary, and in their computational power. In order for sensors to be capable to perform these complex tasks, an increase in their computation power in necessary. In this way, in fact, sensors themselves will be capable of reducing redundancies and errors in measurement, at the same time decreasing the amount of data to be transferred for processing. This represents a fundamental requisite for the final objective of having sensors capable of multi-modal sensing and actuation. "Second generation" sensors (i.e., those developed so far by research project) still miss calibration, in the sense that they have to be periodically calibrated by users, not to mention the impossibility to detect if a value measured in normal for a certain individual because of his/her peculiar characteristics. ***Self-calibrating sensors would represent a fundamental characteristics for intelligent sensors***, being able to detect which are the "real" thresholds of physiological parameters for each individual, at the same time notably increasing the performance of the sensors itself and of the sensors network in general. While this issue is clearly linked to the domain of data processing, research on sensors cannot ignore it, especially if the futuristic vision of sensors able to detect, actuate (and therefore process the relevant information, and take decision) is adopted. So the various elements comprised under this research theme are instrumental and strategic in various ways. They address the challenges of data treatment raised by context aware sensing. They are a key pillar for future all-encompassing and actuation, and as such they will also benefits from new solutions coming from the various technologies summarised under the acronym ***MINABIO***. Finally, they contribute to the goal of energy and bandwidth use optimisation (reduction of data transfer).

Next we have the goal relate to expanding the ***scope of data gathering with sensors capturing multiple and more signs, including those reflecting context***. These advancements should enable to enlarge the number of disease to be treated and improve treatment and especially lifestyle management application through the holistic sensing of context (including emotional and social state), which is also key to personalised and

intelligent data processing. ***Context awareness is a crucial dimensions for PHS***, directly impacting several of the research domains identified as most important for future research: integration of external knowledge, data processing, and sensors. Context awareness is important in order to better comprehend individuals' physiological parameters, thus avoiding false positives or the risk of missing risk situations. In addition to this, context is fundamental to assess the health status of an individual, as social and mental state of an individual have a crucial importance on individuals' health. Therefore, context awareness is important not only for monitoring and treatment of people suffering from chronic diseases or with high risk profiles, but also for lifestyle management applications. While some parameters such as ***movement, and environmental conditions*** (e.g., light, temperature, particles in the air, pressure, etc), ***are easier to monitor***, ***emotional and social state pose major challenges***. First, it is not easy or even possible to translate these states into simple physical outcomes gathered by one single sensor. Second, there are not consolidated methodologies to evaluate physical, mental and social parameters in a combined way. Third, it is not easy to determine which kind of feed-back PHS gathering these information should provide, even though advancements in disciplined such as Affective computing and Human-computer interaction could be of help (it is evident an overlap with the "Interfacing & Interaction" domain).

Bio-imaging and contactless sensors and improve non-invasiveness and comfort of PHS. Integration of bio-sensors would lead to the incorporation of new sensors (made with biological and molecular materials), including to application of ***bio-photonics*** for non invasive/minimally invasive detection of analytes. Contactless sensors, when integrated, would allow including features like radio frequency-based sensors (with nano-antennas). Bio-imaging sensors will lead to develop PHS imaging sensors for non-invasive monitoring, to be applied for endoscope (smart pills probes not requiring robots nor medical direct intervention), or, more futuristically, tongue imaging and retina scanning. In addition, and not less important, this dramatic reduction of invasiveness and obtrusiveness of sensors could represent a key factor for acceptance of Personal Health Systems.

An aspect needing support is the ***integration and testing of modular sensors networks, enhancing a Plug & Play structure*** (i.e., as final goal it would be possible to combine sensors, in terms of numbers and functions, on the basis of needs and requirements of each individuals, without creating an "ad hoc" network each time). This address at the same time efficiency (energy and bandwidth optimised use) and effectiveness (flexibility and adaptability to users' specificities and needs) goal.

As already hinted at, eventually ***all these characteristics of sensors should be merged into "all-encompassing" sensors, able to detect information, not only for physiological parameters, but also for context (including the environment, and the social and mental state of the users), process them, and decide whether to take an action, and which one (actuation)***. In this view, sensors would incorporate many of the functions of data processing, also embedding the analysis of the external knowledge relevant. This would open the way for personalised drug delivery exploiting the characteristics on nano-fabricated intelligent robots, capable of delivering the appropriate dosage directly to the

cells when treatment is needed, notably increasing effectiveness, and reducing side effects, of treatment.

In the field of research support implementation, definition of common standards allowing ***full interoperability*** of sensors emerges as the main issues. It has to be recalled that, also in the case of sensors, full integration with eHRs is a crucial pre-requisite, as it is evidently fundamental that data gathered are needed to feed the profile of each individual, and that, continuous updating is fundamental as well. A further step, allowing for a really comprehensive diagnosis and treatment, would be the link to larger demographic and environmental data (particularly crucial for contextual sensing), in order to have a complete picture of the course of a disease, as well as updated information on health status of the population. As already explained for the "Data processing" domain, this requires interoperability of components and communication protocols, as well as encryption techniques ensuring protection of sensitive data (maybe including also bio-metric security).

4.6 Users inclusive PHS interfaces: rationale and roadmap

4.6.1 Contextualisation

Also for this research domain personalisation is the main drivers, although from a different perspective. Other research domains in a way address the 'production' or "back-office" side of PHS personalisation. The themes of this domain address personalisation from the perspective of users' experience, in other words users' fruition of, and interaction with, PHS as services, and also from the perspective of the broader matter of health awareness. The various future scenarios elaborated have played a role in eliciting these issues and in particular the "Self-Caring Society" one. First, a possible negative effect of this scenario is that it would produce further exclusion of those groups in society less digitally connected and less confident with the use of technology and capable of understanding its input. Second, consumerist attitudes toward health and independent self-caring activities can produce negative results if users access uncontrolled source of health information and/or are not adequately educated in health matters in general and on the various aspect of the PHS applications they will use in particular. From these two risks several gaps emerged directly related to needed actions. First, to counterbalance the risk of PHS being a source of exclusionary processes, PHS need new technological solutions ensuring multi-channel interaction and including also channels more accessible and easy to use (i.e. mobile and/or digital television) for less technology confident individuals. Second, assuming individuals use PHS services through their preferred channel, next PHS must deliver to users input and feed-back that are intuitive and easy to use through state of the art imagining and visualisation techniques. At the end of the gap analysis we also identifies as technological research themes the development of quality controlled Web 2.0 tools on matters related to PHS and of PHS application embedding eLearning modules for users in order educate users and increase correct health awareness and attitudes. During the roadmapping events, however, these two themes were considered more appropriate as object of implementation activities rather than as research themes.

Indeed the issue of ensuring that PHS services are not a new source of exclusionary process and that are users friendly enough to favour acceptance and adoption is very important both from a general policy perspective and from the more practical one of avoiding the risk of PHS remaining a niche market. We pointed out the importance of how the cognitive maps and capabilities of users in interpreting health related information is usually frustrated by the technicality of the information produced by PHS systems. While some of these issues are of broader non technological nature, nonetheless interfacing and interacting aspects were identified as fundamental requirements for the success and take-up of PHS. As a matter of fact, if PHS are to revolutionise in the future the traditional healthcare delivery as we know it, the user perspective has to be put at the centre of research and delivery. This means that PHS personalisation will highly depend on the nature of disease (e.g. chronic care requires different services than preventive one), on the technological level reached by both diagnostic and communication, and last but very importantly on the users' ability to interact with the technology and, on the other

hand, on the technological device's potential to adapt to users' needs and context. The goal is to reduce the patient's mobility limitations to a minimum and particular attention is paid to the design of the interface to the patient (Fischer, 2007). Current PHS applications do not include imaging and visualisation functionalities. Yet patients' awareness about their health conditions and understanding of the ongoing of the therapies are key issues, both for ensuring compliance and for optimising treatment. Consequently, and by taking advantage of the latest developments in enabling technologies, PHS solutions should be designed in a perceptive, adaptive, and most importantly reactive way.

4.6.2 Further insights

It is all very well saying that people could gain incredible benefits from health care services delivered through technological devices, that technology could enable them to live independently, or that ICT would open up the doors of a great many new activities that they have been prevented from carrying out up until today. However, what many might be failing to realise when making such statements is the profile of the average user of PHS and related appliances: a staggering one every ten persons is now 60 years or above; one out of five will be 60 years or older by 2050; and one out of three persons will be 60 years or older by 2150 (Cai and Abascal, 2006). It is unquestionable that with age come reduced functional abilities: from arthritis to decreased learning capabilities, from reduced speech intelligibility to mobility issues; from osteoporosis to reduced organs' sensitivity (may it be vision, hearing, smell, tactile sensation, taste, etc.). Furthermore and as pointed out by Hawthorn in his paper,

> "The effects of age become noticeable from the mid forties onward. So this is not just about design for yet another minority group, the one termed senior citizens. This paper is concerned with design for **the second half of our lives** and for a group that will shortly be nearly half the workforce and over half of the adult population." (Hawthorn, 2000)

The scenario clearly brings in a few levels of complications for the work of PHS-interfacing designers and of engineers who develop interaction and diffusion functions of PHS: they can no longer concentrate exclusively on developing the latest most-advanced highest-resolution flat portable screen, instead they will need to build with our average user's profile in mind and widen usage to the largest universe of user minorities that deserve further attention from medicine-applied technology. And if that was not enough to complicate the work of our designers and engineers, we would like to remind them that on the route to 2020 the "one size fits all" paradigm will no longer apply for no two people are exactly alike, especially when it comes to medicine. New technology will play a very important role in the quality of life of elderly and disabled people who wish to continue to live autonomously and can be assisted by technology in their daily routines (Edwards and Grinter, 2001) and in this process of decision making and science development consultations can play no marginal role. End users are the key to PHS adoption and effectiveness and they will need to voice their needs both during research and implementation.

Choosing as our starting point existing technological devices with high potential in the field of PHS, our attention skews to force feedback devices such as joysticks and steering wheels. These are widely and successfully used in the market of computer games; in fact it is calculated that more than 500 games use force feedback today and more than 100 tactile hardware products are available on the gaming market (Chang, D., 2002). For instance, the application of force feedback devices to the robotic therapy field looks particularly promising for providing assistance to hemiplegic patients; the devices' relative low cost and large availability on the market could also allow further applicability in rehabilitation equipments that can be safely used from home in less severe cases (Feng, X., Winters, J., 2007), such as stroke rehabilitation.

Examples of force feedback devices that could be explored and improved in the near future are **SideWinder Joystick** from Microsoft and **Wheel force-reflecting technology by Logitech**, both of which have been experimented on the UniTherapy project, along with two custom-made therapy platforms, TheraJoy (adapted joystick) and TheraDrive (steering wheel). More specifically, the UniTherapy platform was designed to allow the personalization of the therapy via tasks, devices, and tele-support of the relationships between patient, therapy provider and the rehabilitation technology

As a further development of the technology, personalisation of the therapy should also be a target of research: a signalling device could remind the patient about her daily exercise schedule, a video could show her how to carry out each set of exercises, sensors could be applied to monitor values (such as heart beat) to make sure that the patient is not over-exercising; furthermore, research could make it possible for the rehabilitation machine to detect whether the patient is carrying out her exercises properly (i.e. if she is using the right muscles) and to monitor the patient's improvements (i.e. if ability to raise injured limbs raises over time). Experiments have already proved that different device interfaces (such as wheel and conventional joystick) and device settings (device location in the arm workspace) significantly affect tracking and muscle performance outcomes (Johnson et al., 2007), which is why an effective roadmap cannot but include challenging and promising areas such as this one. Further steps into the enhancement of force feedback devices will entail the use of high-tech sensitive gloves that can capture hands' movements with no need for the user to touch appliances, as well as artificial hands, fingers and a face for impaired users. First, when discussing the great promises of PHS we should never forget that in the large majority of cases the typical user of these services would be over the age of 60. Today one out of ten in advanced societies is 60 years or above and in 2050 this proportion will become one in five (Cai and Abascal, 2006). It is unquestionable that with age come reduced functional abilities: from arthritis to decreased learning capabilities, from reduced speech intelligibility to mobility issues; from osteoporosis to reduced organs' sensitivity (may it be vision, hearing, smell, tactile sensation, taste, etc.). Furthermore and as pointed out by Hawthorn in his paper:

> "The effects of age become noticeable from the mid forties onward. So this is not just about design for yet another minority group, the one termed senior citizens. This paper is concerned with design for the second half of

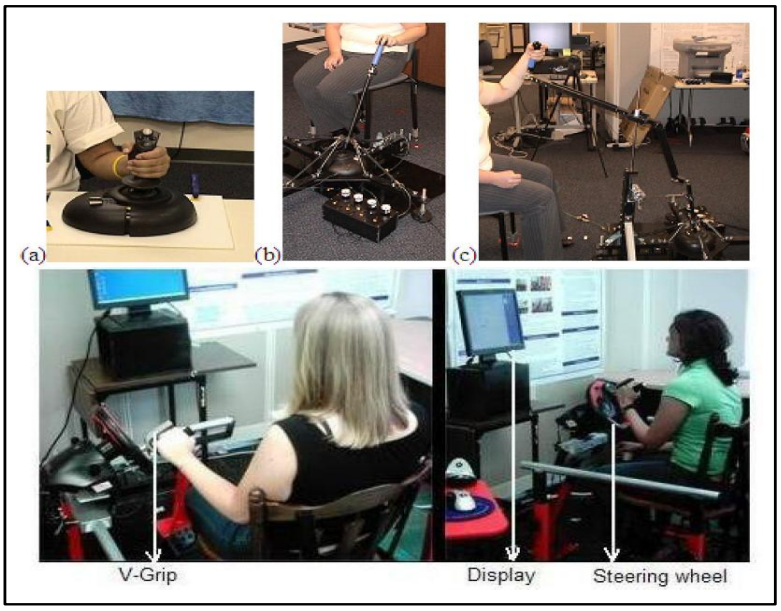
> our lives and for a group that will shortly be nearly half the workforce and over half of the adult population." (Hawthorn, 2000)

This situation brings in a few levels of complications for the work of PHS-interfacing designers and of engineers who develop the interaction and interfacing functions of PHS: they can no longer concentrate exclusively on developing the latest most-advanced highest-resolution flat portable screen, instead they need to design having in mind average users profile in mind and widen usage to the largest universe of user minorities that deserve further attention from medicine-applied technology. Furthermore, on the route to 2020 the "one size fits all" paradigm will no longer apply for no two people are exactly alike, especially when it comes to medicine. New technology will play a very important role in the quality of life of elderly and disabled people who wish to continue to live autonomously and can be assisted by technology in their daily routines (Edwards and Grinter, 2001) and in this process of decision making and science development consultations can play no marginal role. End users are the key to PHS adoption and effectiveness and they will need to voice their needs both during research and implementation.

Force feedback devices and joystick. Force feedback devices such as joysticks and steering wheels can potentially improve the interaction quality of PHS from the perspective of users. These are widely and successfully used in the market of computer games, where it is estimated that more than 500 games use force feedback today and more than 100 tactile hardware products are available on the gaming market (Chang 2002). For instance, the application of force feedback devices to the robotic therapy field looks particularly promising for providing assistance to hemiplegic patients; the devices' relative low cost and large availability on the market could also allow further applicability in rehabilitation equipments that can be safely used from home in less severe cases (Feng and Winters 2007), such as stroke rehabilitation. Examples of force feedback devices that could be explored and improved in the near future are **SideWinder Joystick** from Microsoft and **Wheel force-reflecting technology by Logitech**, both of which have been experimented on the UniTherapy project, along with two custom-made therapy platforms, TheraJoy (adapted joystick) and TheraDrive (steering wheel). More specifically, the UniTherapy platform was designed to allow the personalization of the therapy via tasks, devices, and tele-support of the relationships between patient, therapy provider and the rehabilitation technology. As a further development of the technology, personalisation of the therapy should also be a target of research: a signalling device could remind the patient about his/her daily exercise schedule, a video could show him/her how to carry out each set of exercises, sensors could be applied to monitor values (such as heart beat) to make sure that the patient is not over-exercising; furthermore, research could make it possible for the rehabilitation machine to detect whether the patient is carrying out her exercises properly (i.e. if she is using the right muscles) and to monitor the patient's improvements (i.e. if ability to raise injured limbs raises over time). Experiments have already proved that different device interfaces (such as wheel and conventional joystick) and device settings (device location in the arm workspace) significantly affect tracking and muscle performance outcomes (Johnson et al., 2007),

which is why an effective roadmap cannot but include challenging and promising areas such as this one. Further steps into the enhancement of force feedback devices will entail the use of high-tech sensitive gloves that can capture hands' movements with no need for the user to touch appliances, as well as artificial hands, fingers and a face for impaired users. Needless to say, along with the development of more sophisticated appliances, there is a need to improve the cost-to-benefit ratio of robot-assisted therapy strategies and their effectiveness for rehabilitation therapy in home environments characterised by the low supervision by clinical experts, low extrinsic motivation as well as low cost requirement.

Figure 34: UniTherapy Joystick and Steering Wheel Systems



Source: Johnson *et al* (2007)

Speaking devices and applications for the blind. Another area that has been providing interesting applications and that should, in the near future, produce great utility for users with visual impediments is research on speaking devices. The ageing process leads many people to lose they sight abilities at different levels, sometimes preventing them from reading medicines' prescriptions or any message appearing on technological devices, such as their blood-pressure values on the sphygmomanometer. Similar obstacles are faced by people who have become blind or are blind from birth. It is therefore believed that the use of audio and non-visual interface aspects would allow direct and active interaction with devices that would otherwise be impossible achieve through the visual medium, if not with the help of a third party. Enabling users to interact and improving their level of technology appropriation will free a whole new range of possibilities for technology developments that in the more distant future will be able to have visually-impaired people as their targets. Such advances will provide user empowerment, independence and also alternatives. It is therefore important that these new developments are not perceived as marginalising or stigmatising, but rather as "normalising" tools. It

also hoped that by the year 2020 (and possibly even earlier), **Touch&Braille** technologies will make it possible for visually disabled users to read just about anything, were it on their computer screen, on their mobile phone or on their latest PHS device. These technologies will further enable them to convert anything into Braille, whatever the language of the user, thus facilitating the creation of media content for blind users. The road towards this goal is not far in the distance: some basic technologies have already been created as in the case of **RoboBraille**[79], an email-based translation service capable of translating attached documents to and from contracted Braille and to synthetic speech.

Hand-writing recognition. A further but equally important step in the roadmap of PHS development in the field of interfacing, interaction and diffusion will be the integration of handwriting recognition to computers and other technological appliances: keyboards will be a distant memory, a forgotten hindrance to people's adoption of ICT. Thanks to handwriting recognition typing will no longer be required to interact with machines: if we are not speaking to them or using touch screens, steering wheels or wearing high-tech gloves, you will be sure to catch us handwriting directly into the screen. A much more intuitive, natural way of actively interacting with technology will sure favour many in the use of PHS.

Voice activation devices. Next we come to another theme that has emerged as a potential milestone on our roadmap from the literature review, which is integration of voice activation devices to personal health care devices. The use of technology in the home is on the increase but difficulties in operating household appliances as well as performing other daily activities are part of the effects of, in many cases, growing older and losing sensory and cognitive abilities. Voice activated environment controls and other sophisticated control panels are examples of the effort put into making technology for increasingly comfortable, non-cumbersome and efficient home environments. Ifukube (2007) for instance suggests that intelligent tools that are able to recognise both verbal and non-verbal information should be developed – which leads us to the final potential milestone in the roadmap: imaging and visualisation.

Imaging and visualisation. Nothing could be rendered more personalised in technology than visualisation: users love to customise their computer's desktops, mobile phones or mp3 player' interface by downloading new icons, new wallpapers, changing the font, etc. This is not just because users are increasingly demanding in terms of appearance; rather it has mainly to do with their needs to ease and speed up their use of technology. Personalised imaging and visualisation will help embrace as wide a pool of users as possible in the use of PHS and to make sure they stay connected in the long run. We started off by saying that, whichever the route followed by the roadmap, research will have to focus on the users' profile and on the identified targets of this domain. However, PHS systems do not only aim to support the elderly and people with disabilities; in fact there is an increasingly wide part of the research that focuses on giving people the chance to keep up their healthy living standards, or to improve their eating habits; or to increase

[79] http://www1.robobraille.org/websites/acj/robobraille.nsf

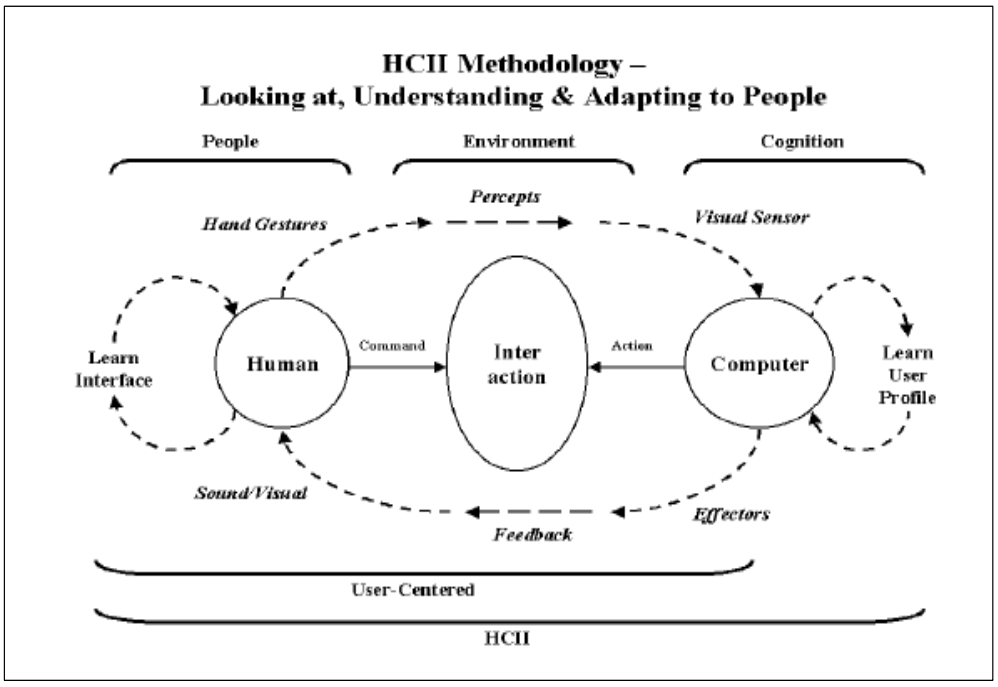
their daily exercise and training, just to name a few. This domain, jointly with the rest, calls for parallel research on improving the imaging and visualisation offered on PHS devices. 3D Holograms have largely been researched in the media and information sector (i.e. hologram anchormen to present the news) and they are a good example of the sort of direction research may steer toward: imagine having your trustworthy caregiver or nurse visit you at home every day to remind you about taking the pills you always forget to take, to encourage you to carry out your daily rehabilitation exercises, to get feedback on the progresses you are making on your diet. Yes, because in the future holograms may actively interact with the patient.

Affective computing. Additional promising fields within the interaction and the interfacing field are brain computer interface and affective computing. The most interesting potential of these technologies is the possibility to finally link physical and emotional signals. According to Chen and Wechsler (2007), affective computing is considered to be a methodology with means to recognize **"**emotional intelligence**"**. The authors present a human-computer intelligent interaction methodology (illustrated below), as a way of improving human activity and creativity. With this methodology, the authors have developed an online educational system which provides an interactive mathematical learning environment that is personalized to each student with **intelligent state feedback** to tailor the appropriate mathematics exam data set for the student in order to evolve his/her mathematical skills. In the case that the student replies correctly he/she will be challenged with a more difficult test question set. On the other hand, if the answer is incorrect, an easier question set will be administered at the next round. After conclusion of test, each student is provided with feedback that shows the correct answers of each question, the difficulty level of the questions, the student's final score to each set, and a predicted score along with probability bands that show satisfactory performance ranges. In the PHS field, this may open up major opportunities not only for providing individuals with a learning platform, but also for adaptation of services to each and every unique case. As the link between mental and emotional states and PHS becomes increasingly inevitable for the pursuit of personalised PHS, complementing the brain-computer interface is the affective computing. This technology has enabled building systems that have several affective abilities, especially: recognizing, expressing, modelling, communicating, and responding to emotion (Picard, 2003). The main goal being; enabling ICT to better serve people's needs by adapting to them and not the other way around

Multi-channel interaction systems. Finally, we come to deal with a theme of this research area that ultimately will enable all aforementioned technologies to yield the highest returns, that is multi-channel interaction systems. Some researchers (see for instance Feng, and Winters 2007) claim that a standardized but flexible abstract user interface description for target devices (e.g. intelligent appliance) or services (e.g. web services, software program) will be required, so that any remote control can connect to discover, access and control a remote device or service on top of network communication protocol (e.g. UPnP, Java/Jini, OSGi). With such an abstract user interface description, a remote control with universal interface capabilities (e.g. speech interface, natural

language interface, tactile interface) should be able to be supported by various computing devices ranging from desktop computer to handheld PCs. Multimodal approach facilitates users' adaptation to the format of information displaying that suits them best, due to external circumstances or personal preferences.

Figure 35: Human-computer intelligent interaction



Source: Chen and Wechsler (2007)

Multimodal interfaces will therefore benefit all users and promote "universal access" (Jacobson, 2002). The richness provided by multimedia and multimodal interactive systems is especially appropriate for older people who often suffer from reduced sensory, motor and intellectual capabilities (Alm *et al* 2001). Particularly important to the group of older people, where cognitive capabilities are diminished, is the fact that the multimodal interface gives people the "feeling of experiencing information instead of acquiring it" (Hoogeveen, M., 1995), due to the increased stimulation of the senses, strong recognition effects and higher emotion arousal. Thus, it is believed that carefully applied multimodality improves user-friendliness, the impact of the message, and the entertaining value of the system and improves learning of the system.

4.6.3 Proposed Roadmap

The table below synthetically provides a snapshot of the preliminary research themes associated to the gaps and of the key input from the further review of the literature. In combination with the comments and changes introduced during the two consultation events focussing on roadmapping they shape the final proposal graphically presented in Figure 36 reported in the next landscape page.

Table 12: Re-compacting information: Users Inclusive PHS Interfaces

Gaps (Table 7, p. 88)	Preliminary research themes (Table 7, p 88)	Further insights
• Lack of multi-channel delivery and inter-action creating risk of exclusion	• Development of multi-channel delivery and inter-action systems including more commonly used devices (i.e. mobile, Digital TV, etc.)	• Force feed-back applications; • Multi-modal interaction; • Alternative sensing; • Affective computing • Motivational support tools • Multi-channel interactions
• Need of more understandable and easy to interpret input and guidance to users;	• Development optimal and easy-to-use interfacing techniques; • Development of straightforward imaging;	• 3D Holograms

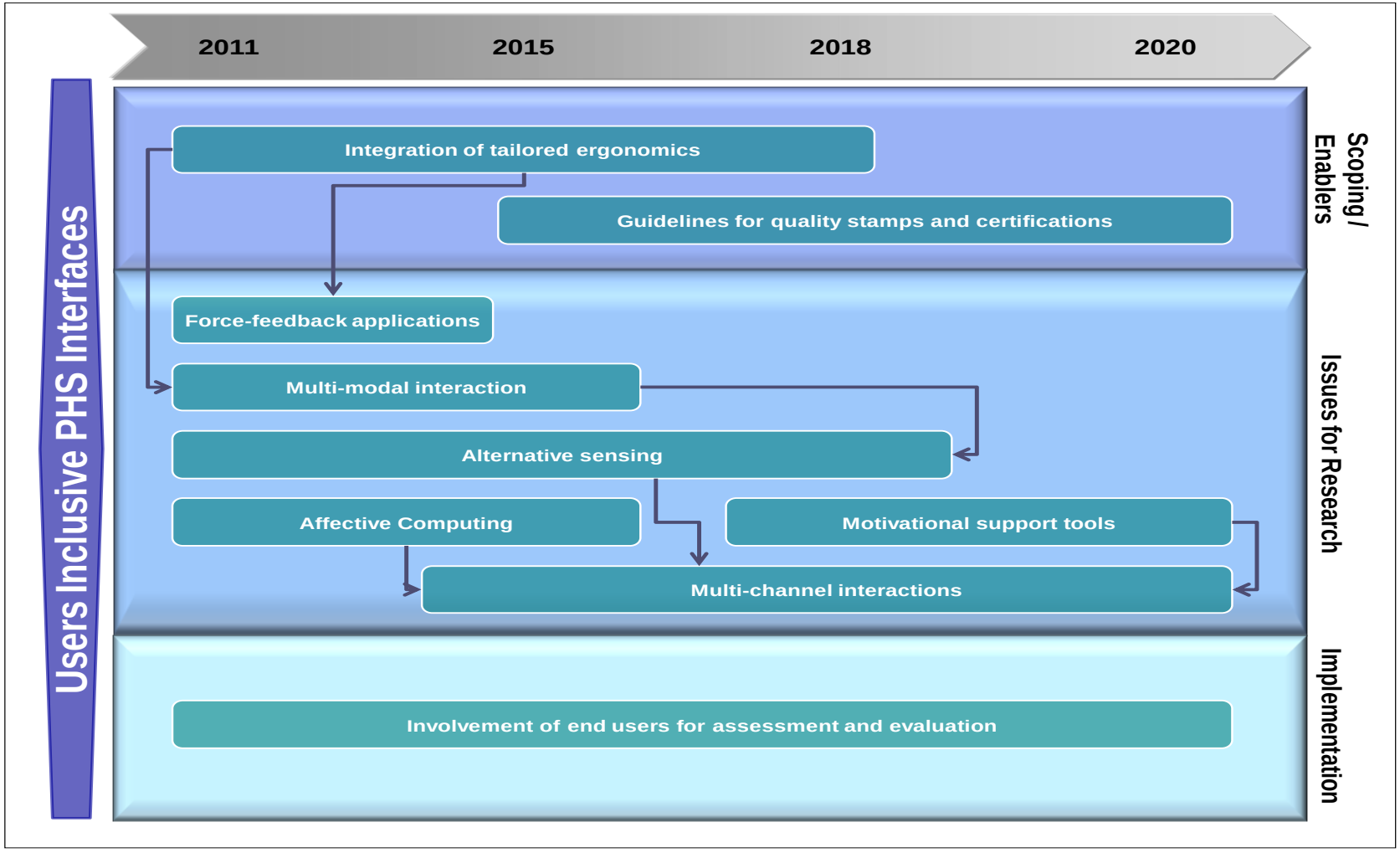
How we interact with our PHS solutions will play a major role in the potential implementation and future take-up. This entails that the main focus of research should be developing user-friendly systems that are adaptable to all individuals and various context of use. This in turn indicates that services are to be offered through several manners and channels, facilitating not only the adoption but also the preferred interaction. In other words, personalisation of Personal Health Systems entails also the users' experience in the fruition of PHS services, and in interaction with them.

Ease of use plays, as mentioned previously, an important role in the adoption of Personal Health Systems. Consequently, it is recommended to look into how to best tailor different PHS to different applications by the use of ergonomics through scoping studies. It would also be favourable to develop guidelines to further ensure that those PHS that are to be developed in the future follow certain quality measures concerning user-friendliness.

As PHS offers special opportunity for disabled individuals, it would be most advantageous to ***implement "natural languages" and alternative sensing***. This entails that current research should continue developing systems using e.g. Braille translations, and methods for "remote reading" by the use of e.g. RFID. This would make it possible for e.g. visually impaired to know e.g. which bus is approaching and which destination it takes by a communicated voice-activation.

Equally, the ***Force Feedback Devices*** currently used by the gaming and entertainment industry and is beginning to be implemented in the PHS field, ***widens significantly the field of treatment and rehabilitation,*** and thus should be further developed with the most

Figure 36: Visual Roadmap for "Users Inclusive PHS Interfaces"



Source: Author's elaboration

recent technological progressions. As also suggested for new research, also affective computing offers many optimistic opportunities in this area.

During the consultation processes, it has also been suggested to carry on in ***enlarging the scope of modes in which PHS is offered, constituting one important step towards multi-channel delivery systems.*** In specific, these are preferred to also be automatic in application transfer i.e. if a user is travelling, the service is offered through the mobile device, when he/she arrives at home the service is automatically transferred and offered through the TV-set. This to enhance mobility and multi-modal interaction possibilities, other than increasing users' comfort in their interaction with machinery

In parallel, new research should focus on implementing ***"natural sensing"*** as far as possible i.e. by developing PHS with voice-activation systems, hand writing recognition systems, speaking functions etc. Static 2D images shall be replaced with 3D visual systems in order to provide more realistic and effective digital information to the user. Creation of dynamic digital content calls for research on more interconnected, highly navigable and intuitively-searchable content.

Furthermore, there is great interest for new research to concentrate efforts on the development of ***avatars and holograms***. These technologies allow for wide opportunities on issues of both interfacing and interaction. In fact, on one hand, representations have incredible potential for creating more-effective and realistic interfaces that will ease the use of technology for many users – both experts and "newbies". On the other hand, provided that humans will be given the possibility to interact among themselves through the graphical interface, impressive opportunities are bound to be created for the healthcare system. It is precisely for these reasons that research will need to pull efforts on this area of technology.

This development area is expected to help overcome the limits of PHS in interaction and transmission of information in a perceptive manner, thus leading to the development of more intuitive and easy to understand tools. It will further allow for the incorporation of self- and environment imaging.

As stated in many ways, both in the literature reviewed and during the consultation process, ***poor adherence to medical prescriptions, and low compliance to treatments are extremely common among patients.*** This can be due to several factors, which often are in combination: complexity of prescriptions (e.g., several medications to be taken at different times during the day), low perception of benefits, mistrust towards the treatment, forgetfulness, etc. In addition, health and lifestyle management often require ***behavioural change*** (e.g., stop smoking, change in diet, start training programmes, etc), which is extremely difficult for patients to pursue for long periods. Therefore, ***it is strongly recommended to develop new systems and tools which meet this challenge, which could help in dramatically increasing effectiveness of medical treatments***. ***This can be done in several ways, depending on treatments' requirements, as well as, and equal important, on individuals' preferences towards the type of interfaces and channels to use.*** Examples can be game/social networks for motivational interaction, applications based on web 2.0 platforms, or as an expert once suggested, simply by

developing a personal traffic light (if one complies with recommendations a green light is provided; if not, a red light is switched on), to be delivered through several channels (e.g., telephone, both mobile and fixed, digital TV, Internet, etc), even combined.

In this roadmap, strong accent has been put of research on ***interfaces,*** including avatars and holograms, and affective computing as well; the immediate outcome of this stream of research being ***powerful tools for providing effective support and feedback to users,*** improving thus their compliance to treatment, and healthy behaviour in general. ***Affective computing*** can go further beyond in this field, as its main potential is to finally link physical and emotional signs. This may lead to PHS not only offering users a learning platform, but also adapting services to each unique case. In other terms, ***Personal Health Systems could become personalised in the sense of recognising, expressing, modelling, communicating and responding to users' emotions, thus adapting their services to peoples' needs and not the other way round.*** This could entail, for instance, finding each time the better way to communicate with the user, depending on his/her contextual and emotional state (e.g., stress conditions, etc.)

Naturally, the ease-of-use is best determine by actual users, why it is of major importance to involve end users as early as possible, both in the development and testing process, as suggested for the implementation assessments

4.7 Advancing Point-of-Care: rationale and roadmap

4.7.1 Contextualisation

Lab on Chip (hereinafter, LoC) is a device used in the field of point-of-care medical solutions and allowing to integrate multiple laboratory functions on a single unit capable of handling small fluids volumes.

In our state of play we identified three main attributes that are generally associated to LoC and that characterise their nature, namely:

- The **material** LoC is mostly made of, which could be either glass, plastic, or silicon;
- The **sample preparation**, more specifically whether the sample has to be prepared before applying it onto the chip (non embedded) or if it goes directly from patient onto chip (embedded), thus requiring less effort and time from the healthcare professional;
- The **target detection**, which is the degree of concentration in target sample sequence (e.g., length of DNA snip necessary for performing a certain analysis). On the basis of target detection, LoC can be defined as:
    - Mono-target: if the application is designed to detect only one specific target (i.e., only one specific protein);
    - Multi-target low: if the application is designed to detect a limited number of targets (2 or 3 targets);
    - Multi-target, high: if the application is able to detect a large number of targets simultaneously (about 30 to 50)

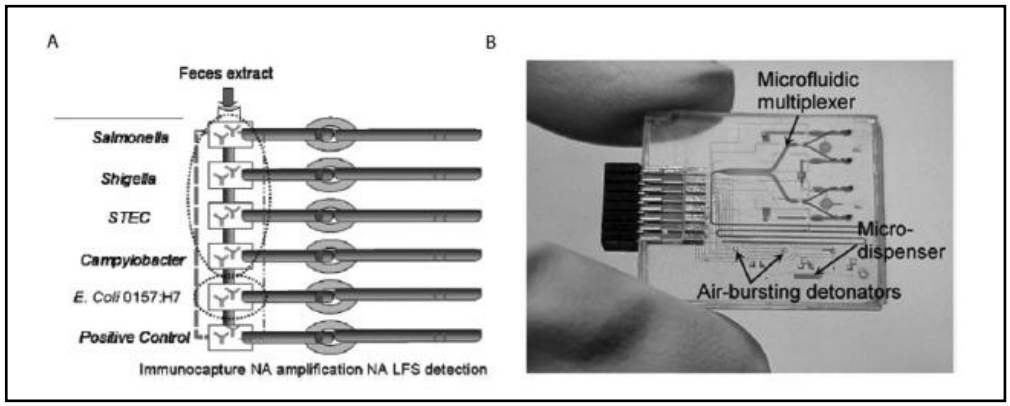
4.7.2 Further insights

General considerations. The rapid development of Lab-on-Chip systems has opened new routes for full integration of sampling, mixing, reaction, separation and detection functions on a single microchip to perform specific analytic tasks. In recent years, online detections of ***DNA, glucose and lactate, oxygen, pH, cells*** in miniaturized analysis systems have been actively pursued with a wide variety of detection schemes, such as electrochemical detection, optical absorbance, fluorescence detection, evanescent-wave coupling and plasmonic resonance, etc (Wu et al, 2006). Despite the impressive achievements that have been made in recent years, ***new devices will undoubtedly be needed*** (see Figure 37) to address future users' needs. The design criteria of these devices are vast, demanding, and context-dependent, and they will need to be considered carefully from the early stages of development (Chin et al, 2006).

What will then be the ***main directions*** for designing and deploying LoC devices? Some argue that the top-ranking overall priority is modified molecular technologies for ***affordable, simple diagnosis of infectious diseases*** (Daar et al, 2002). Others have identified as main priorities the development of technologies for assessment of individuals for multiple conditions or pathogens at point-of-care and enabling quantitative assessment of population health status (Varmus et al, 2003). Also important are ***non-communicable diseases***, such as cardiovascular disease (i.e. ischemic heart

disease and stroke), cancer, ***neuro-psychiatric conditions*** (i.e. unipolar depressive disorder), and respiratory diseases (i.e. chronic obstructive pulmonary disorder and asthma).

Figure 37: Integrated LoC devices



Note: (A) Schematic representation of LOC for detecting enteric diseases.
(B) Picture of a plastic LOC device for point-of-care clinical diagnostics
Source: Chin et al. (2006)

As the standard of living of countries improves and average life span increases, the burden of disease gradually shifts to non-communicable diseases. This shift is exacerbated by changes in diet (towards saturated fats and sugars) and high tobacco use (Beaglehole and Yach 2003). Obesity and diabetes are increasingly becoming a threat to people's wellbeing across the European Union, while asthma, epilepsy, dental caries, diabetes, rheumatic heart disease, and injuries are becoming increasingly prominent contributors to morbidity (Seidell 2002). LoC research holds substantial potential for fulfilling these priorities by ***automating complex diagnostic procedures*** that are normally performed in a centralized laboratory into a hand-held ***micro fluidic chip***. This capability could ***empower*** healthcare professionals and patients with important health-related information in even the most remote settings.

Reducing test fragmentation. Research in this field is expected to fulfil the need to overcome fragmentation of testing, which is usually due to incurring traditional lab tests in order to complete testing procedures. Different classes of diseases usually need to be tested in order to diagnose a patient's health status. In order to do so, several classes of analytes need to be marked, which in turn require different diagnostic technologies to be applied on one single chip. On the other side of the spectrum, multiple classes of assay technologies are needed to produce complete diagnostic information for groups of related diseases, and often even for a single disease - for confirmatory testing, identification of resistant subtypes, and/or staging of a disease. For example, yes/no testing for antibodies, analysis of RNA levels, and counting of CD4+ lymphocytes are all crucial information for diagnosing and staging HIV/AIDS. Chip technologies are being researched that are able to carry out all of the above at the same time in order to provide more sophisticated and reliable information on the patient's health status: detection tests, confirmatory tests,

identification of resistant subtypes, staging of a disease, etc. In some cases different types of detection tests for the same disease may also be useful in order to cross information and obtain more accurate results. As similar classes of analytes (e.g. proteins, nucleic acids) serve as useful markers for very different diseases and conditions, then similar designs of diagnostic technologies will be applicable for disparate classes of diseases. (For example, yes/no protein markers are useful for diagnosis of HIV/AIDS as well as indicators of coronary heart disease. This observation calls for carefully considering the integration of ***multiple modular technologies at the earliest design stages of LOC diagnostic devices***. For complex assays, a ***series of different reagents*** need to be delivered into the micro-fluidic chip. In centralized testing facilities, these procedures can be performed manually by a technician, an external liquid handling robot, or on-chip valves that are controlled by an external instrument. For portable automated devices, passive delivery of a series of reagents is an attractive option (Linder et al, 2005). Some assays will require mixing of samples with different reagents. In such cases, ***active micro mixers*** can be used if a power supply is available. ***Passive mixers***, which rely on the geometry and topography of the micro channels, can also be used to mix and dilute samples (Chin et al, 2006). In general, however, heterogeneous assays (which include many immunoassays) do not require mixing since the analyte is captured on the surface. Bio-degradable materials could, not only be environmentally friendly, but also increase reliability of testing.

Rapid, robust, portable, non invasive, testing and optimised sample preparation. Immediate results of testing are desirable for both professionals and users, but there are still constraints to be overcome. The most prevalent example of diagnostic tests, providing yes/no results in minutes in the form of a visible band (this typically uses gold colloids or latex beads conjugated to antibodies), is the immunochromatographic test (Chin et al, 2006). Moreover, immunochromatographic strips are cheap to produce. These strip tests, however, are not quantitative, and ***are not sufficiently sensitive for the detection of all important markers***. Development to improve strip tests for diseases, such as Chlamydia and trachoma from Lee's group (Lopez et al, 2006) is ongoing because LoC devices are believed to hold great capabilities for high analytical performance and for multiplexed and parallel analysis of many relevant markers at once. This capability, however, is challenged by the fact that different analytes typically call for different LoC designs. For optimisation of time to result nucleic acid amplification methods emerge as promising. Among these methods currently ***Polymerase Chain Reaction*** (***PCR***) has been the most used due to its simplicity. PCR's speed can be improved by ***increasing the heat transfer rate or decreasing the thermal mass***. The dynamic continuous-flow-based PCR amplification can therefore overcome the issue of lack of speed flexibility by utilizing the '***time-space conversion***' concept. The nucleic acid amplification occurs as the sample is continuously pumped through a micro fluidic channel during each temperature cycle. The attractive features of this approach include (Zhang, C. and Xing, D. 2007):

- The analysis processes of nucleic acids can be performed in a dynamic format on an integrated PCR chip;

- The temperature transition times depend only on the sample flow rate and the time needed for the sample to reach a thermal equilibrium;
- The heat inertia of PCR system is decreased to a minimum because only the sample's thermal mass need to be taken into consideration;
- The reaction volume can range from several microliters to several tens of microliters.

Pursuing high-speed PCR, therefore, appears as one of the major motivations in the development of on-chip PCR. With the advent of ***MEMS*** technology, the development of miniaturized PCR chips will become possible (Lee et al, 2007). The miniaturization of PCR devices offers several advantages such as ***short assay time***, ***low reagent consumption*** and ***rapid heating/cooling rates***, as well as great potential of integrating ***multiple processing*** modules to reduce size and power consumption. In order to meet the current demands for a ***fairly rapid lab-on-chip toxicity detector*** the integration of light-emitting whole-cell sensors with solid-state devices for detection of low-emission levels has been proposed (see for instance Elman et al, 2008). ***Optical spectroscopy*** is also signalled as promising. For instance, ***fluorescence-based imaging*** (both single and multiphoton) is perhaps the research direction that has most influenced the development of fast and sensitive optical detectors. Examples of techniques in this class include ***Forster Resonance Energy Transfer (FRET)***, ***Fluorescence Lifetime Imaging Microscopy (FLIM)***, and ***Fluorescence Correlation Spectroscopy (FCS)***. The success of these techniques, particularly FLIM, derives from the ability to characterize an ***environment based on the time-domain behaviour*** of certain fluorophores with high resolution in space domain. The new developments range from multiphoton microscopy, to voltage sensitive dye (VSD) based imaging, particle image velocimetry (PIV), instantaneous gas imaging, etc. Moreover, ***Bio-photonics use for optical spectroscopy could have interesting applications for localisation of molecules***. In some diseases, in fact, like skin cancer, it is extremely important to be able to exactly localise some analytes or also anti-bodies that can be linked to cancer, at the very beginning of cancer appearance (for very early detection and diagnosis, before having symptoms or even chemically detectable sensors in blood). This kind of applications could be used for biopsy (without surgery) or suspect melanoma. Furthermore, advanced processes are also able to ensure in-pixel and on-chip processing of ***ultra-high-speed signals*** that are typical of single-photon detectors. However in such systems, the remaining obstacle appears to be the illumination device that is currently the object of intensive research (Charbon, 2008). Thanks to the use of cutting-edge ***silicon technology***, the final production chip will be likely to be very small, and hence extremely cheap. That in turn should allow it to be integrated into a low cost, disposable, single-use cartridge that plugs into a larger reusable device. For this usage model, bodily fluids will be passed over the chip and the resulting signal or data will be wirelessly sent to a control system. By simply replacing the cartridge, the users (either the patient himself or the healthcare professional) will be able to repeat for each test subject.

Portable, disposable, non invasive, on- in- body chips. The use of LoC devices to advance the capabilities of Point of Care requires the combined optimisation of several

design criteria. For remote point-of-care testing (for instance, in rural areas), the fixed instrument must be ***portable*** and ***cheap***, and the disposable must be extremely cheap. All components of the device (including the instrument and disposable) must be ***robust*** and ***rugged*** under a variety of environmental conditions. Having said that there is a large body of existing research on LoC designs for point-of-care testing for physicians' and home use (Lauks, 1998; Tudos et al, 2001), devices for military applications (Belgrader et al, 2001) and first responders, and extraterrestrial sensors (Akiyama et al, 2001; Cultertson et al, 2005; Skelley et al, 2005) in designing LoC device. In all these settings, ***integration, portability, low power consumption, automation, and ruggedness*** are important qualities. A cheap, disposable Lab On Chip, to be applied directly by the patient on the skin (like patches) could help in having a very wide and low-cost screening, while processing (not low-cost) could be centralised at GPs and/or hospitals. In addition to be small, cheap, and disposable, such chips should also be ***non-invasiveness***. Although whole blood (from venipuncture or finger prick) and its derivatives (plasma and serum) are most common physiological fluids, the use of less invasive samples such as saliva, urine) faeces, sperm, tears and sweat are gaining prominence (Li et al, 2005, Srinivasan et al, 2004). With advancements in markers detection, as well as in miniaturisation, further developments can be envisaged. Such achievements will lead to a progressively easiness of use of Lab On Chip devices, which would progressively become devices suitable for home use, directly by patients. Even more futuristically, on body applications, like disposable "patches" to be applied on moles by patients for early detection of skin cancers (leading to mass screening) could be foreseen. At the same way, in body application, with Lab On Chips applied within the body (with minimally invasive procedures) could be imagined, to be "activated" on demand, or periodically, and providing detailed information when needed.

Optimisation of sample preparation. Future research can also improve sample preparation, currently requiring labelling of the organic sample (e.g., blood), and fluorescence-based detection for imaging and counting. This intermediate labelling step complicates the sample preparation and detection process, the label can alter the molecule's binding properties and therefore decrease the detection reliability. ***Label-free Microfluidic Devices (LFMD)*** are the being researched, and have already had some successful applications in diagnosis of specific diseases as well as on analysis of specific molecules. For instance, a micro fluidic device for whole blood CD4 counting that requires no sample handling or specific labelling for HIV diagnosis (Xuanhong, et al., 2007). Also, detection of proteins linked with certain types of cancer (Wang, 2006), as well as measuring and morphologic analysis of blood components like platelets (Inglis, et al., 2007) have been successfully researched.

Fabrication techniques. Research is also focussing on different fabrication techniques allowing for cheap mass fabrication and integration and easily extendable to a multi-array biosensor with thousands of sensing spots for real Lab On Chip devices, like, among others, Silicon-On-Insulator biosensors based on microring cavities, fabricated with standards Complementary Metal Oxide Semiconductor (CMOS) processing (De Vos et al., 2007).

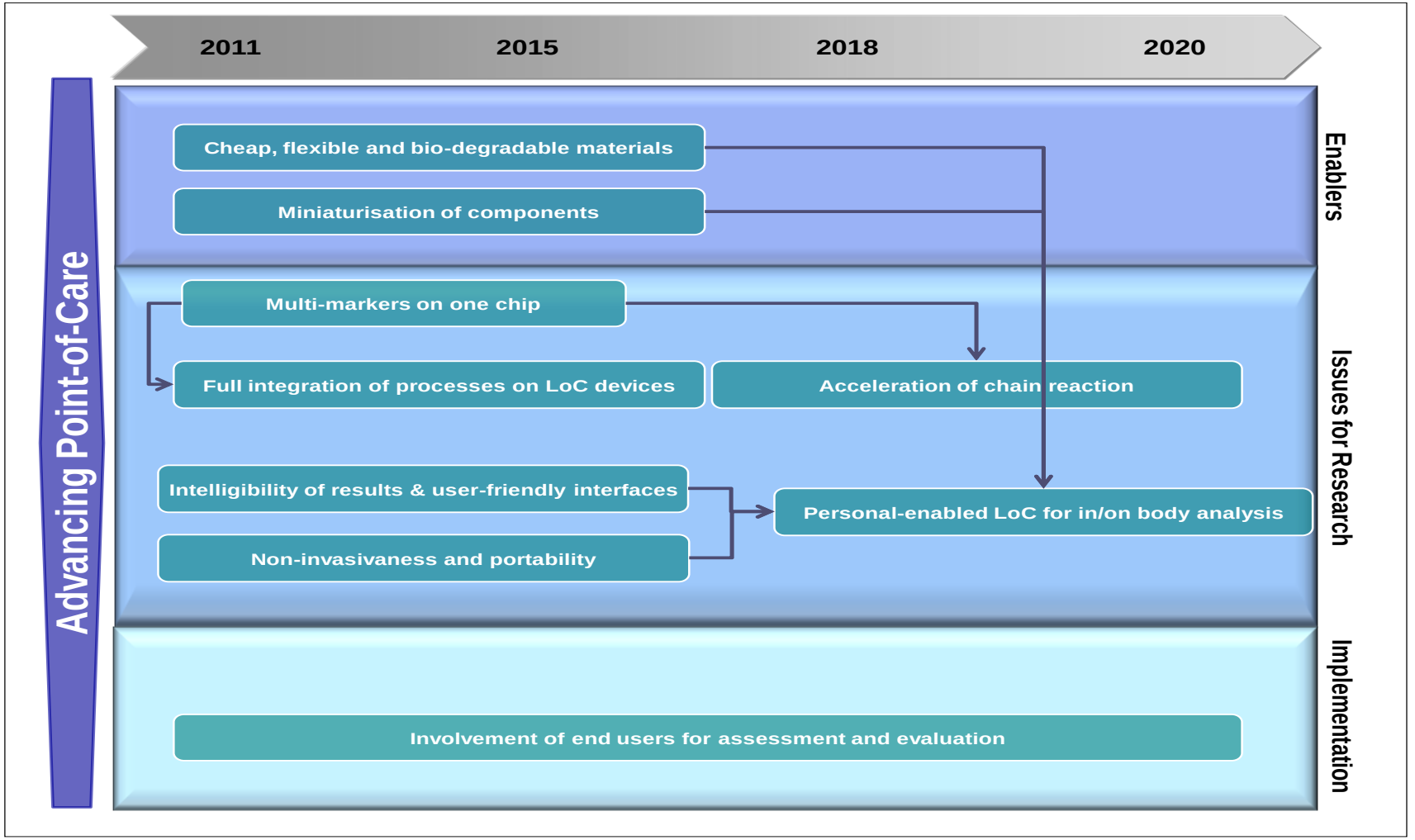
4.7.3 Proposed Roadmap

The table below synthetically provides a snapshot of the preliminary research themes associated to the gaps and of the key input from the further review of the literature. In combination with the comments and changes introduced during the two consultation events focussing on the roadmap they shape the final proposal graphically presented in Figure 38 reported in the next landscape page.

Table 13: Re-compacting information: Advancing Point-of-Care

Gaps (Table 7, p. 88)	Preliminary research themes (Table 7, p 88)	Further insights
• Avoid fragmentation of testing and the need of traditional lab tests to complete Point Of Care (POC) testing	• Investigation on including multiple biomarkers on a single chip; • Research on "new" biomarkers more adapted to POC; • Integration of Micro-Opto-Electro-Mechanical-System (MOEMS)	Further insights • Multiple assays' analysis through multiple chips on the same marker (corollary: multiple modular technologies at the earliest design stages of LOC); • Bio-degradable materials; • Different reagents into Microfluidic chips; • New fabrication techniques for bio-sensor supported Lab on Chip.
• Reduce human intervention in sample preparation;	• Development of on-board sample preparation; • Further research on micro-fluidic techniques optimising "sample course control".	Further insights • Free Label Micro-fluidic Chips; • Widen choice of samples (so to automate sample extraction).
• Reduce time to result (process integration);	• Optimising of fluidic control and run-time; • Further research on alternative array technologies adapted to POC-solutions.	Further insights • Nucleic acid amplification (MEMS-driven miniaturised PCR); • Silicon technology; • Optical spectroscopy and bio-photonics; • Ultra high speed signals.
Not given due importance	Not given due importance	• Improve non-invasiveness at the same time as providing portability • User friendly intuitively readable results • Cost effectiveness

Figure 38: Visual Roadmap for "Advancing Point-of-Care"



Source: Author's elaboration

In looking at Lab On Chip, it seems as ***empowering*** patients and healthcare professionals by way of placing in their hands a fully-functional, automated device that can support the provision of information on their health-status is the very bottom line of the calls for improvements and further developments in the field of Lab On Chips. Many challenges faced by current applications are likely to be overcome before 2020 and those achievements will lead to surmount some of the main issues that are slowing down ***mass adoption***. Naturally such achievement will require a number of research aspects to be fulfilled as prerequisites:

- First of all, ***cheap and flexible materials*** will be key for the marketability of the products and, therefore, for their adoption on behalf of the wider community. Improving the compromise between affordability of devices and rapid analysis may become viable thanks to the use of cutting-edge ***silicon technology***, which will also allow for great improvements in terms of ***miniaturisation of components***;
- Investigations concerning the integration of ***bio-degradable materials*** are also envisaged. These activities would in turn help identify what kind of materials would be more suitable for low-cost, disposable, and easy-to-use Lab On Chips. Studies on alternative materials for sensors and Lab On Chips are mainly carried out outside the development of strictly-defined PHS. However, achievements in this field are extremely relevant for PHS, as they influence factors, like costs, decisive for adoption. ***Contamination*** between fields of studies will therefore be key on these aspects of research;
- Furthermore, it will be vital to widen the spectrum of ***different reagents*** than can be employed on the chip as well as the mixers and to improve the compromise between design and applicability of different analytes.

As these advancements become enablers for the new frontiers of research, breakthrough technologies are required to turn application several ***different classes of analytes*** on the same chip into reality. This would in turn help complete the diagnosis process by informing on for confirmatory testing, identification of resistant subtypes, and/or staging of a disease. Research on biomarkers that can be applied to PoC, as well as investigation on including ***multiple biomarkers on a single*** chip, will therefore require particular attention. However this will only feasible if ***multiple modular technologies*** are developed at the earliest design stages of LoC, thus taking into account all the variables affecting their adaptation on chip. The integration of ***Micro-Opto-Electro-Mechanical Systems*** – nano systems capable of high-precision micromachining - is likely to generate positive results in this respect and will have to be taken into account. Similar arguments will apply to investigation on different reagents into ***microfluidic chips***, which deal with precise control and manipulation of fluids that are geometrically constrained to a sub-millimetre scale; these are considered an especially promising technology for PoC applications, featuring a full process integration, reduced consumption of sample and reagents, as well as short turn-around times and ease of handling.

Next on the roadmap, the full ***integration of all functions into one chip*** (namely, sampling, mixing, reaction, separation, and detection) will ***dramatically reduce the time***

and complexity of the technological devices. Accordingly, this will avoid human interaction in the various phases of detection and will boost their adoption even by the uneducated patients at home. In this respect, ***miniaturisation of components*** is indeed granted even higher significance especially for its contribution to advancements in terms of ***portability and mobility*** of LoC devices. Furthermore, biomarkers should have clearly defined cut-off values with high sensitivity and specificity to allow anyone to ***read the results*** and make healthcare professionals' empowerment possible. Employing low-cost materials to allow lab-on-chips to be integrated into low-cost, disposable devices will be a key aspect in the mass distribution of LoC devices, as well as advancements in terms of invasiveness: biomarkers should be easily attainable from ***non-invasive samples*** such as body fluids (saliva, sweat, etc.) and cells.

In particular, this progress will concern mainly ***the reduction of time to results***, making LoC more compatible with the usual visit time of GPs, and the integration of multi-markers into one chip, widening the range of application. Current systems are still too complex and time-consuming, thus forcing both physician and patient to unnecessary waiting. Consequently, in order to accomplish a closed loop circle of testing and diagnoses, time to result needs to be drastically reduced. In this respect, ***optimisation of control and run-time*** of the aforementioned microfluidic chips need be further investigated by researchers, as well as ***optical spectroscopy and bio-photonics***. In addition, improving ***timing for localisation of molecules*** (i.e. through optical spectroscopy) and exploring ***ultra high-speed signals*** or similar areas of study can improve time effectiveness: these could be the sort of initiatives that should find support in the near future. Finally, the development of ***on-board sample preparation*** and the ***investigation of nucleic acid amplification methods*** (MEMS-driven miniaturised ***Polymerase Chain Reaction***, for instance) represent further promising areas of research and ought to be given appropriate attention.

It has been suggested that ***Lab On Chips could be integrated into on-body or even in-body applications*** by integrating ongoing researches on new materials and techniques for identifying, analysing, measuring and counting cells and molecules. Direct identification of molecules (like components of bloods), but also viruses and bacteria, would speed up the analysis process. On/in the body applications, depending on the type of technology and purpose of the analysis, would allow for the gathering of relevant information on-demand, as well as increase individuals empowerment on their health status, as many steps leading to very early diagnosis of diseases would be in their hands. These kind of applications would include the possible integration of several ***optical and non-optical techniques***, like, among others ***Label-free LoC, bio-photonics applications*** allowing for localisation of single molecules (for instance, for really early diagnosis of cancer, before symptoms appear or chemical substances linked to the tumour are detectable into blood), nano high pressure liquid chromatography (nano hplc).

Finally, several important criteria are essential for the development of biomarkers. Biomarkers should be made easily measurable using standardized and ***cost-efficient*** methods, and their ***effectiveness*** ought to be improved to reduce required quantities of sample. Albeit the strong emphasis placed on Lab On Chips in the last ten years, evidence

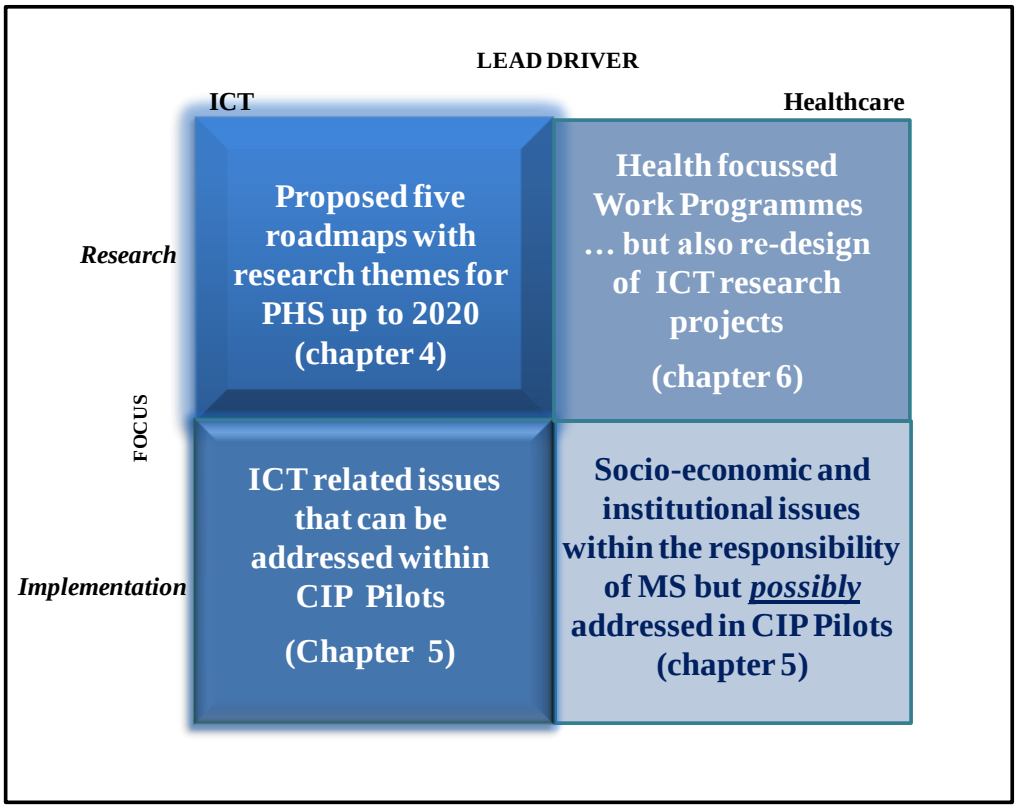
about their benefits (especially in terms of cost-effectiveness) are still questioned by several categories of stakeholders involved in the care process. ***Cost-benefit analysis*** ought to be the main focus of research activities supporting ***implementation***. In order to enhance adoption, as well as to provide evidence supporting efforts in continuing and new research, cost/benefit analysis should therefore receive early support and a strict cooperation between research and ICT industry is required, including at the same time a direct involvement of the healthcare sector (i.e., healthcare research and providing institutions), possibly embracing even a number of GPs.

In conclusion, while not explicitly illustrated in the roadmaps, it is worth recalling that a fundamental pre-requisite for Lab On Chips functioning is their ***direct communication and exchange of data with PHRs.*** A further step, allowing for a comprehensive diagnosis and treatment, would be the link of PHS (and of PHRs) to larger demographic and environmental data, in order to have a complete picture of the course of a disease, as well as updated information on health status of the population. This requires interoperability of components and communication protocols, as well as encryption techniques ensuring ***protection of sensitive data*** (maybe including also bio-metric security).

5 Implementation gaps and possible actions

As explained in the introductory chapter, although our primary focus was on the technological dimension and the related research needs, we also looked beyond technology and considered gaps and barriers of a broadly defined implementation/deployment and socio-economic nature. Indeed, the gap analysis consultation process produced a total of 54 gaps, of which 25 were deemed as concerning implementation (see p. 77) and to which an additional two were added during the roadmapping consultation (see p. 148).

Figure 39 Four areas of actions



Source: Author's elaboration

The matrix of Figure 39 above uses two dimensions to define four areas of policy actions mainly (but not only) from the perspective of the European Commission DG Information Society in the field of PHS:

- **Lead Driver**: a) ICT only to address the specific mandate of DG INFSO; Healthcare as such (where, however ICT can be a component)
- **Focus**: a) research; b) implementation.

First, the top left quadrant is where the core outcome of PHS2020 is positioned as it concerns needed actions in term of future support to technological research. Next, the top

right quadrant is about healthcare driven research funded by other FP work programmes and in this sense is to a large extent outside the scope of our work. Yet, as corollary to the rational and content of the roadmap on "**Bio(medicine) Infused PHS**" (see § 4.3) in the conclusive **Chapter 6** we present what we call a "meta-proposal" for re-designing research projects on PHS funded under Framework Programmes.

Both of the two bottom quadrant concerns implementation and are treated here in light of the earlier mentioned 23 gaps we identified as relevant to this areas of focus, although a premise is in order here. When discussing implementation gaps concerning the very concrete functioning of healthcare we enter into the jurisdiction of Member States (and their possible policy, legislative and reform initiatives), which is outside the direct intervention of the European Commission except for support to deployment pilots or for 'soft' (communications) or 'hard' (directives) legislation (provided that ex ante Impact Assessment demonstrate the need for them). Evidently it is absolutely beyond our scope to propose reform and/or legislative initiatives to either the Commission or the Member States. Accordingly, we will discuss and bring forward the implementation gaps and propose, where possible, how they could be addressed at least partially through deployment pilots to be launched in the next calls of the ICT PSP of CIP. In some cases the nature of the gaps is such that they cannot be addressed at all through such deployment pilots.

The first paragraph of this chapter contains some considerations introducing a table summarising the 25 implementation gaps conceptually organised into six groups, each of which is treated in the following six paragraphs.

5.1 Bringing PHS forward: the main implementation gaps

Discussion of telemedicine dates back almost three decades and of new eHealth applications almost two. Healthcare is the largest service industry and probably the most information intensive one. Yet, healthcare clearly lags behind the adoption of ICT compared to other industry and the full potential of eHealth remains largely untapped (Fonkych and Taylor, 2005; Wickramasinghe and Fadlalla 2005; Westelius and Edenius, 2006). In 2004 the European Commission eHealth Action Plan envisioned the emergence of a new "e-Health industry" with potential of becoming the third largest industry in the health sector with a turnover of €11 billion, which by 2010 could account for 5% of the total health budget (European Commission 2004a, p. 4). In 2006 Commissioner Vivianne Redding in a foreword to a study on the benefits of eHealth affirmed that the eHealth market, while being at the time some 2% of total healthcare expenditure in Europe, had the potential to more than double in size, almost reaching half the size of the pharmaceuticals market (in Stroetmann *et al* 2006, p. 5). These visions to a certain extent strides with the data and considerations we presented in the chapter on the state of play, from which it emerge that PHS is still a niche market (p. 31). We also noticed there how sizeable is the distance between the frontiers of innovation in the market and in research. These facts give rise to the legitimate questions of '***why the obvious is taking so long***' (Shortliffe 2005). The answer resides in the various barriers and bottleneck and it comes

to no surprise that the experts we consulted contributed to identify as many and as important gaps as those summarised in the table below.

Table 14: Six domains of implementation gaps

Gaps (# in the Full List plus comments if need be)	Domain
1. PHS have yet little market penetration (# 1); 2. Institutional reform (# 21 to introduce new financing models); 3. Need of innovative measurement systems to support outcome based reimbursement based on integration between PHS generated data and larger public health data bases (# 37)	***1) Financing, business model and measurement (in general)***
4. Need to increase investment of public funds (# 22); 5. Lack of business model (#30) 6. Lack of consolidated evaluation methods and supporting evidence (#31) 7. Lack of large enough databases for genetic mass screening of population(#32) 8. Need of legal framework and consensus (#33, overlapping with last row); 9. Need of cogent incentives backed by sanctions (# 15, in relation to fatalism and moral hazard, also relevant to the prevention domain);	***2) ICT enabled preventive services***
10. Little integration of care delivery processes (# 3) 11. Knowledge and information segmented (# 4); 12. Lack of shared platform for data repository and exchange (# 5); 13. Need to prepare healthcare professionals for more symmetric relations with citizen/ patients (# 14); 14. Awareness campaigns, education, training (# 23)	***3) System fragmentation, professionals' attitudes and more***
15. Need of education campaign and integration between eHealth and eInclusion policies (# 16) 16. Need of PHS embedded eLearning (# 42) 17. Need of quality controlled Web 2.0 tools (# 52); 18. Off and online information on scientific reliability, privacy issue, benefits, etc (# 40);	***4) The user dimension***
19. Lack of bodies setting binding standards on inter-operability, protocols, pathways and clinical guidelines and stakeholders fora (including industry) at both national and EU level (# 20); 20. Lack of shared infrastructures and standards for data exchange (# 28) 21. Lack PHR inter-operability even at national level, (# 29, strongly stressed by experts from ICT industry) 22. Need of citizen owned fully inter-operable Personal Health Records (PHR) integrated with PHS (# 53, overlapping with gaps in the row above)	***5) Standardisation and inter-operability bottleneck***
23. Lack of clear legal framework (# 19); 24. Lack of tailoring of security and encryption techniques for healthcare sector application (# 38) 25. Need of data management and mining applications integrated into PHS that embed, support and protect privacy (# 39)	***6)"Body Adventures: legal and ethical issues"***

Source: Author's re-elaboration from Table 3, Table 4, Table 5 (pp. 71-78)

In the table each of the 25 implementation gap is included with indication of its number within the Full List of 54 gaps presented earlier in the three tables listed as sources and with some additional explanatory comments when needed. They have been grouped into six separate domains, although naturally there are clear overlaps among them. The rationale of the grouping is to a large extent defined precisely by how the gaps were placed in the Full List and, thus, reflected the various dimension of our General Descriptive Framework. So, for instance, there are clear overlaps on the issue of business model and measurement between domain 1) and domain 2), but the distinction is based on the fact that the gaps included in the latter were specifically mentioned by experts with regard to the field of prevention whereas those included in the formers were framed as general gap concerning the all field of PHS.

It is safe to state, however, that these six domains fully reflect the key barriers that emerged from the state of play[80] and also many of the most impactful and uncertain trends that emerged in the scenario building consultation process[81]. Additionally, they also cover all of the issues that were already hinted at in the five roadmaps. Indeed, with the exception of the more vertical and monographic focus on prevention (which to some extent by default includes elements from most of the other domains), the other five domains are the key sources of barriers and bottlenecks horizontal to the PHS field as a whole and we would say to eHealth in general. They call into question a plurality of areas of intervention and a multitude of different players. To be addressed they require intense inter-institutional and inter-disciplinary cooperation, some potentially radical and innovative institutional re-design, steady consultation efforts to achieve technical standardisation, and sustained ethical exploration and subsequent development of consistent legal regimes as "Pan-European" as possible.

Economic history teaches us that full blown market emerge only when a clear and certain frame of reference is established, when local and national barriers are tore down. It also teaches us that this very seldom happen only as a result of the simple functioning of the market itself. It is clearly inscribed in our history of modernisation that the lead "certainty-provider" player unleashing the emergence of markets has been the centralised nation-state. Evidently, today we live in different context with globalisation, subsidiarity, and the involvement of the private and third sector into the provision of public services, all of which decrease the autonomous role of national authorities. Nonetheless, some of the barriers and bottlenecks standing in the way of the full deployment of PHS and of its evolution into a mainstream market will not be overcome simply as a result of new technological developments and of the spontaneous evolution in its value chain. International, national and local level public authorities and legislators will have to actively contribute to remove such barriers and bottlenecks.

These six domains of implementation gaps, thus, entail a high degree of complexity both from the perspective of analysis and from that of proposing systematic and articulated

[80] See PHS2020 Deliverable D2.1, *State of Play*, chapter 3.

[81] See PHS2020 Deliverable D3.1, *Consolidated Scenario Report*, chapter 3.

solutions. Each of them would require a separate treatment in its own right and could have been the object of a separate book. It is absolutely beyond our scope and ambition to treat them in this chapter in a systematic and exhaustive way. Our goal here is simply to leverage and not lose important hints and inputs received from experts during the consultation process and convey such input as a platform of issues to be considered in future policy initiatives and support in the field of PHS. Accordingly, in the next six paragraphs we will briefly put the gaps into context and, when possible and appropriate, will tentatively and preliminary suggest how they could be addressed within deployment pilots and other actions of support.

5.2 The need of business models and measurement

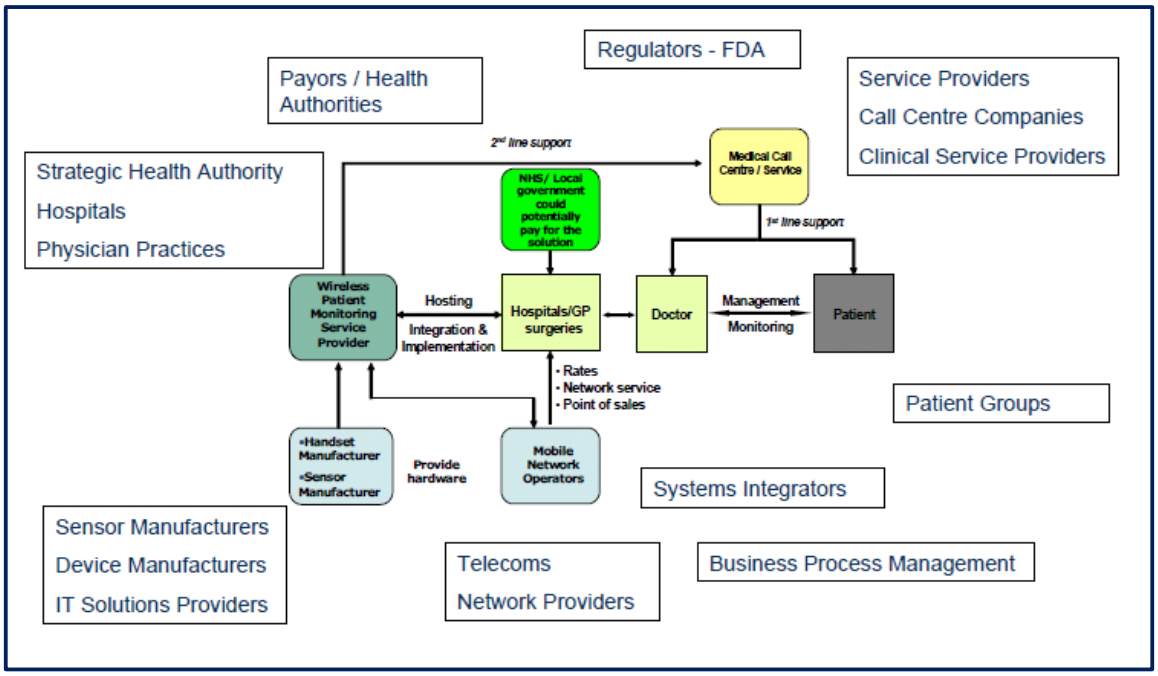
At the very outset of our work when we had brainstorming sessions with Gartner's analysts and read their research briefs it became clear that one key barrier is the a lack of clear **cost and business models** for PHS. The "who, how and for what pays" questions is critical to provide the corrective incentives to reward innovative services that improve health and disease management outside institutional care. The lack of business and cost models is clearly related also to another gap, namely the lack of robust and consolidated evaluation and measurement methodologies documenting the cost-effectiveness, clinical and users' satisfaction outcomes of eHealth application in general and of PHS in particular. Whichever the nature of the player of should decide to invest in PHS, the investment decision should be based on measurement metrics, which are currently lacking. The lack of such metrics further compounds other gaps placed in other domains (i.e. confidence and acceptance of the new delivery methods by both professionals and users).

As we have shown, the financial sustainability of healthcare is at strain given rising costs and shrinking public budgets (§ 1.2). Not surprisingly the possibility of partial withdrawal of the public player from both the production and funding of healthcare and the increasing role possibly taken by private third party players of various nature emerged as one of the key dimension of future variability captured in the scenario matrix (§ 3.2 and § 3.3.1). Alternative business and financing models have been one of the main topics of discussion during the earlier cited IPTS "Personal Health Systems Workshop – Market perspectives & innovation dynamics"[82] and in a recent study funded by the Commission (Dobrev *et al* 2008).

[82] See workshop report and the presentations delivered at http://is.jrc.ec.europa.eu/pages/TFS/sps.html. The issue of business models and funding were discussed particularly in See data reported in: a) Jeroen Walls's (Philips Research) presentation "Personal Health Systems: what kind of market is this?(http://is.jrc.ec.europa.eu/pages/TFS/documents/3WalsPhilipsSIMPHS090206.pdf) ; b) Rainer Herzog's (Ericsson CEMA) presentation "Personal Health Systems: Towards new business models (http://is.jrc.ec.europa.eu/pages/TFS/documents/4HerzogEricssonSIMPHS090206.pdf), and c) in Siddharth Saha's (Frost & Sullivan) presentation "Market Perspectives and Innovation Dynamics: market analysis" (http://is.jrc.ec.europa.eu/pages/TFS/documents/10SahaFrostSullivanSIMPHS090206_000.pdf)

Indeed if we look holistically at the full value chain of PHS (see figure below), that is to say at a more detailed view of what we have called in our General Descriptive Framework the "Transactional Environment", we see a multitude of players who could possibly cooperate in various ways to bring about new business models potentially independent from reimbursement (coming from either NHS funds or from social and private insurance).

Figure 40 The transactional environment: a market analysis perspective



Source: Frost & Sullivan[83]

Using the term "provider" to refer to the healthcare organisations and/or professionals and the term "suppliers" to include a variety of "third party" players (Telco and mobile network operators, IT manufactures, call centres and online media players, new medical service companies established outside of the institutional healthcare system) it is possible to envision two broadly alternative business models to some extent outside of the consolidated institutional healthcare funding:

- **Providers/ suppliers cooperation**. Healthcare organisations and/or professionals (i.e. GPs) join forces and share benefits with the suppliers. Hospitals should achieve cost savings that would gradually pay off the investments and running costs, suppliers are partially paid from such savings and also benefits from spin

[83] Taken from earlier cited presentation delivered at IPTS workshop by Siddharth Saha's (Frost & Sullivan) "Market Perspectives and Innovation Dynamics: market analysis" (http://is.jrc.ec.europa.eu/pages/TFS/documents/10SahaFrostSullivanSIMPHS090206_000.pdf).

off sales (for devices, software, telecommunication services). To some extent this model could also include funding from institutionalised reimbursements models;

- **Suppliers as new service providers**. Players coming from outside of institutional healthcare in various combinations and internalising needed professional expertise provide the services directly to the final users. This is by definition based entirely on out of pocket payment by users or could be included as a premium services in private insurance offering.

The interest of various strands of suppliers into the domain of ICT enabled healthcare in general (and also of PHS in particular) is indeed growing. A telling example is the release of specific health related platforms by such players as Google and Microsoft that we discuss later when addressing the inter-operability gaps. The reality, however, shows that such alternative models have yet to be consolidated and it is illustrative to briefly cite the experience reported at the IPTS workshop by a representative of Health Telematic Network (HTN), a new medical service company operating in Lombardy region: after 10 years of operation the company still rely mostly on funding from pilots and projects, which make it hard to ensure consolidation and especially to continue the need research and developments efforts[84].

There are various reasons why these alternative models find it difficult to consolidate and become viable and sustainable. Providers are afraid and reluctant to join with suppliers and cannot fully see the benefits (also due to lack of clear measurements metrics), unless they have some secure funding from reimbursement schemes. Models based on suppliers provision of services directly to users face the challenge of convincing the latter that is safe and sound to have their health status cared by "untraditional players" (also in relation to privacy and other legally related issues). Finally, they run onto the wall of lack of inter-operability (on which we come back later)

Furthermore, it is our claim, that even if a sort of ***consumer electronics model*** for PHS services paid out of pocket (probably through a subscription based model for more steady services, and pay per use for more punctual interventions) develop, this would not be the most appropriate solutions to ensure a fair and sustainable deployment of PHS services. First, without strong initiatives in public funded schemes, PHS will remain a niche market with no economy of scale and critical mass and as such costs will remain high. Second, remaining a niche market it will be accessible only to affluent consumers and further complicate already existing divides in access to health.

In view of these considerations we are convinced that for PHS to fully develop into sustainable and inclusive services there is a clear need of their integration into consolidated reimbursement schemes and possibly of mixed models between those seen above and the traditional one currently in place. Changes in reimbursements schemes must create the correct structure of incentives especially for healthcare organisational and professionals to fully adopt and deploy the possibilities offered by PHS enabled care. As

[84] Maurizio Nardi's (Health Telematic Network) presentation "The Experience of Lombardy" (http://is.jrc.ec.europa.eu/pages/TFS/documents/7NardiHTNSIMPHS090206_000.pdf).

put it by Gartner (2008a), while the provision of ICT supported prevention and monitoring such services from the perspective of effectiveness and efficiency is the correct course of action, the problem is that health care organisations and professionals do not have the proper financial incentives. The issue of the structure of incentives can be easily seen even in a less complex and, one would think less burdensome matter such as General Practitioners (GPs) tele-consultations. A study, in fact found, that even though GPs generally thought positively about the option of consulting via email, they were concerned about not being compensated for this extra work (2004). An issue that must also be dealt with in order to make the possibility of ICT supported work economically attractive for health professionals as well (Ganesh, 2004; Burke and Weill, 2005). Current reimbursement schemes pay output such as hospital days and provide no incentives for services such as PHS that, if fully deployed and successful, would reduce such output. In this respect one of the most innovative idea arising from the consultation process and framed as a gap is that of **outcome-based reimbursement** (i.e. number of chronically ill patients maintaining good conditions and not require hospitalisation and treatment for acute conditions) rather than **output-based** reimbursement (i.e. instead of number of treatments delivered within institutional care or number of hospital-days). Such radical and possibly disruptive institutional innovation entails, however, as a corollary the need new and robust PHS measurement methodology.

Yet, as anticipated, lack of consolidated measurement is another gap, which compound that of lack of business models and of the appropriate structure of incentives. Even within telemedicine, where evaluation activities have been carried out for at least two decades, the is still a lack of consistency between studies in terms of evaluation frameworks used, the outcome indicators and measures available and adopted, and the tools available and applied (Scott *et al*., eds., 2007)[85]. In absence of robust evidence on outcomes, professionals can reasonably claim that they do not see the benefits for the patients, while healthcare organisations and policy makers are not ready to invest in view of the possible risks that cannot be entirely rule out given lack of evaluation evidence[86].

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[85] Still much debated is the extent to which telemedicine and other eHealth applications are cost effective (Whitten *et al* 2002; Jacklin *et al* 2003; Gustafson and Wyat 2004, 2005). Approaches based clinical trials and assessment also present shortcomings, in that they are discontinuous *and*, between one test and the other, clinicians rely on data that can be unreliable (see for instance Gorin and Stone 2001). Indeed the evaluation of eHealth application in general show a number of shortcomings: a) not based on standard methods, guidelines and toolkit to cope with the complexity of multi-stakeholders and multi-recipients of benefits evaluation; b) fragmentation of evaluation and measurement approaches produced in different disciplines; c) limited resources allocated to evaluation, for it is often seen as a distortion of resources from activities considered more creative and important(Ammenwerth *et al*, 2004, p. 481).

[86] These risks include: a) Inappropriate treatment or delay in care (inaccurate/inappropriate information may confound or complicate treatment decisions and delay care); b) Unintended errors; c) Damage to patient-provider relationship (inappropriate use of applications or information or unintended diffusion of sensitive information may undermine trust and prompt conflicts and motivate consumers to seek care from questionable providers); d) Wasted resources and delayed innovation (in absence of cost-effectiveness data, applications may be implemented which drain resources, preventing development of improved systems).

Changing reimbursement schemes is a matter of high politics and policy that is absolutely beyond our scope here and cannot be addressed merely through deployment pilots. Yet, future PHS pilots within the ICT PSP CIP could be designed in such a way to break new grounds, experiment and raise awareness in this area. For instance pilots should be designed as to include suppliers, providers and local level regulators/policy makers and to experiment mixed public/private alternative business and funding models and with inscribed sustainability and measurement and evaluation mechanisms.

For what concern measurement methodology the eHealth Unit of the European Commission DG Information Society has already sponsored a several studies and activities and we can simply recommend that these are continued and also that they are given more importance and resources in future deployment pilots and FP research projects.

5.3 ICT for prevention: a longer way to go

As we have shown (see chapter 2), PHS enabled preventive services in their various forms lags behind other areas of applications. This is due certainly to a number of technological gaps that research need to fill in, but above all to the simple economics of prevention in general. It will suffice to comment the data reported in the figure overleaf: on average in OECD countries only 3 % of the total health expenditure financed out of the public budget goes into prevention activities.

Health care delivery continues to be mostly designed to reactively treat "life threatening" rather than trying to steadily prevent them and achieve in the medium term increased well being for individuals and costs reduction. Although things are starting to change as illustrated, for instance, by the recent decision of the US administration to include with what is known as the "economic stimulus bill" some funds ad hoc earmarked for preventive medicine[87].

Indeed the three main gaps in this area mirror the earlier discussion about funding and business models:

- Lack of public funds;
- Lack of business model;
- Lack of consolidated methods and data for cost-benefit analysis;

Without increased public funding, business models and cost-benefit methods for prevention in general it is unlikely that ICT for prevention services will further develop.

[87] See https://www.acpm.org/members/030609.htm#1

Figure 41 Current health expenditure by function of health care, 2005

	Personal medical services	of which:			Medical goods	Collective health	of which:	
		Curative-rehabilitative	Long-term care	Ancillary services			Prevention and public health	Health administration and insurance
Australia (2004-05)	77	64	7	5	18	4	2	3
Austria	78	63	13	2	16	6	2	4
Belgium	72	53	15	4	19	8	2	6
Canada[a]	68	47	14	6	21	11	6	4
Czech Republic	65	49	3	12	30	5	2	3
Denmark	82	57	22	3	14	4	2	2
Finland[b]	72	65	6	0	20	6	4	2
France	69	57	9	4	22	9	2	7
Germany	71	54	12	5	20	9	3	6
Greece	..	..	..	..	..	..	..	..
Hungary (2004)	58	50	4	4	35	7	5	1
Iceland	82	65	17	0	16	2	1	2
Ireland	..	..	..	..	..	..	..	..
Italy	78	..	..	..	21	1	1	0
Japan (2004)	75	57	18	1	21	4	2	2
Korea	63	63	1	0	31	6	2	4
Luxembourg (2004)	79	56	17	6	12	10	1	9
Mexico[a]	62	..	..	..	22	14	3	11
Netherlands	73	57	14	2	18	9	5	5
New Zealand	77	55	15	7	13	10	6	4
Norway	83	50	26	7	14	3	2	1
Poland	64	53	7	4	32	4	2	2
Portugal	72	61	1	10	25	3	2	1
Slovak Republic	52	46	1	6	41	6	2	4
Spain	69	58	7	4	26	5	2	3
Sweden	83	..	..	..	15	1		1
Switzerland	80	57	20	3	13	7	2	5
Turkey	..	..	..	..	..	..	..	..
United Kingdom	..	..	..	..	..	..	..	..
United States	75	68	7	0	14	11	4	8
Consistent average (23)[c]	**72**	**57**	**11**	**4**	**21**	**7**	**3**	**4**

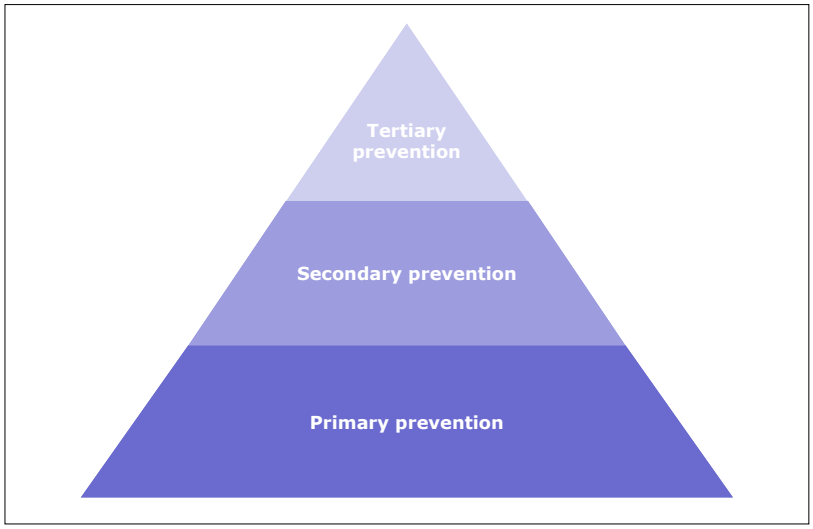
Source: OECD Health Data 2008, June 2008

In the case of prevention the measurement and cost-benefit analysis assumes a peculiar importance.

Prevention services include:

- **Primary prevention.** Lifestyle management avoiding the development of a diseases (i.e. nutrition habits, practicing sports, avoiding smoking, etc may reduce the risk of cardiovascular diseases in the long run);
- **Secondary prevention.** Early detection of risks and/or diseases increasing opportunities for interventions to prevent emergence/progression of a disease and to enable individuals to better cope both practically and psychologically with the situation (being concerned and adapting lifestyle in appropriate ways and reducing unnecessary anxiety);
- **Tertiary prevention** Prescriptions and lifestyle guidance to individuals with already established diseases increasing compliance, reducing the progression and negative impact of the disease, supporting restore function and reduce disease-related complications

Figure 42 The Pyramid of Prevention



Source: Author's elaboration

The challenge is here that potentially the target of prevention services would be the entire population, which is clearly not feasible. As a result, evidence is needed and is still lacking to decide who should be the target of such services and what are the proven costs and benefits of providing them, either in traditional ways or through PHS support. These costs-benefits analysis (especially for secondary prevention) need precisely the kind of biomedical information and genetic risk profiling that we discussed in the research roadmap on "***Bio(medicine) Infused PHS***" and that would have to improve as a result of synergies between PHS and BMI.

Further gaps evidenced by the experts for prevention (again especially for secondary prevention) identify the bottlenecks that hamper the development of evidence based robust costs- benefits metrics:

- Lack of large enough databases for genetic mass screening of population;
- Need of legal framework to carry out such screening (this latter clearly overlapping with the issues discussed later in § 5.7)

Increasing investments on prevention and introducing legislation making it possible the creation of large databases of risk profiling and screening (instrumental for the validating costs and benefits and eventually supporting the investments decisions and new business models) are very important political decisions and, as in the previous case, we do not have the ambition here to affirm that they should be taken and of how it should be done. Furthermore, it is our view that under the current conditions it would be premature to launch in the short run deployment pilots in the field of PHS enabled preventive services. On the other hand, we are confident that advancement in this field could accrue from the future technological research we proposed in the previous chapter and particular from the envisioned synergies between PHS and BMI and also from increase holistic and intelligent data gathering and processing.

Possible scoping support activities we propose are studies to gather and elaborate available empirical evidence on disease prevalence and their suitability for prevention, case studies of application of ICT supported preventive services, emerging costs-benefits methodologies and their application. On the basis of this evidence these studies could better enable policy makers to make future investment decisions in this field.

Finally, a gap that experts mentioned in relation to prevention and is also in clear relation with the issue of users attitudes and information/education (see § 5.5) concerns the persistence of fatalistic ("I will die anyway so I do not care about my lifestyle") or opportunistic ("They will cure me anyway so I do not care about my lifestyle") attitudes having negative externalities and increasing collective costs. The gap here is formulated as a lack of cogent incentives possibly backed by sanctions to curb such attitudes and foster healthy lifestyles. While it seems against the normative principles of liberal democracies, emerging trends in this direction can be found. We do not, however, enter into this issue and simply leave it to the readers for further reflections on it.

5.4 System fragmentation and professionals' attitudes

The issue of fragmentation and overspecialisation of healthcare was signalled as one of the key problems already in the first introductory chapter of this book (see § 1.2). During the consultation process it surface again as one of the gap hampering adequate treatment of co-morbidities in chronic diseases and also in relation to some of the envisaged characteristics of "Self-caring Society" and "The Caring State" scenarios. As a result the following three gaps were identified:

- Little integration of care delivery processes
- Knowledge and information segmented;
- Lack of shared platform for data repository and exchange;

Indeed the fragmentation between the different tiers of healthcare and the segmentation of knowledge and guidelines is cross-cutting to most of the PHS domains addressed and is particularly salient also for the task of integrating PHS with biomedical information and knowledge as we underscored in § 4.3.2.

Personalised and holistic treatment under e new paradigm focused on the user/patient rather than on diseases require increase in the delivery of integrated care (diagnosis, treatment, monitoring and prevention), whose importance can be appreciated from the following *vignette* story:

> *Mr Smith is 50 years old, former smoker and with a family history of COPD and cardiac diseases. He is sedentary and over-weight. After a lung function testing the diagnosis of a moderate COPD is made.*
>
> *The current approach would be: a) initiate pharmaceutical treatment; and b) monitor lung function every 2-3 years.*
>
> *In an integrated care delivery model enabled by PHS, Mr. Smith would start with a health professional in primary care who, through non invasive tools, would assess the levels of bio-markers in exhaled breath and in saliva with prognostic value. If he has high risk of accelerated*

developments in COPD+ cardiac disease + other (proven and evaluated by a simulation modelling tool) he would then go for: a) remote monitoring for compliance with pharmaceutical and non pharmaceutical treatment; b) point of care assessment of biomarkers level at home and likely treatment with appropriate pharmaceutical.

As evident, besides the new technological tools mentioned, the second ideal situation entails for Mr. Smith a seamless and integrate journey across various tiers and speciality within the healthcare systems.

Advancement in PHS research, as well as in inter-operability of devices and databases, would certainly increases the chances of integrated care. Yet, what is needed is inter-institutional and inter-disciplinary cooperation and the end of typical "turf wars", which no technological solution can ensure. The advent of integrated care is above all a matter of institutional and organisational changes backed by new incentives and sanctions to ensure such integration. The way research projects and deployment pilots are design can help spread awareness and exploration of such integrated approach but cannot evidently do what can be achieved only through concrete legislative and reform initiatives.

As regard the attitudes of healthcare professionals toward PHS (applicable in general to eHealth) the following two gaps were identified:

- Need to prepare healthcare professionals for more symmetric relations with citizen/ patients;
- Need of awareness campaigns, education, training;

There is still resistance and little awareness on the side of healthcare professionals about the potential benefits of PHS, and also lack of the appropriate culture and training to engage with users/patients in new symmetric and possibly negotiating ways. This requires awareness and educational campaign and also specialised training. The inclusion of a higher proportion of healthcare professionals within PHS research projects and deployment pilots could certainly help partially fill these gaps. On the other hand, we must also recognise that some of healthcare professionals' resistance and scepticism originate in the lack of consolidated measurement and evaluation.

5.5 The users' dimension

The users dimension has already been treated in some details in the previous chapter (first in § 4.2and then more specifically in § 4.6), where we explained that it entails both issues of inclusion and access and, once these are ensured, of user friendliness, intuitive and correct use, appropriate and reliable information. Some of the gaps related to the users are the object of the research themes proposed in the roadmaps. In addition to them the following gaps considered more of an implementation, and in some cases of policy, nature were identified:

- Need of education campaign and integration between eHealth and eInclusion policies;
- Off and online information on scientific reliability, privacy issue, benefits;

- Need of PHS embedded eLearning;
- Need of quality controlled Web 2.0 tools;

The challenge entailed in these gaps is that of addressing at the same time both those groups who may lag behind and may not be confident enough and trustful, and those with more health consumerist attitudes. First, for the former the goal is to educate and create awareness winning subjective resistance. Second, for the latter, on the contrary, is in a sense a matter of control through support, in other words supporting self-caring practices in such a way to ensure that they do not result into dysfunctional and risky behaviours. Third, for both, there is the overall goal to foster a culture of correct health information and healthy lifestyles. While easy to summarise as we did above, the objectives are difficult to achieve for the situation of the users is very differentiated and fragmented. We further illustrate this point below by addressing first the issue of cultural attitudes to health and then that of digital inclusion and confidence in technology.

Since at least the 1990s many policy documents and reforms have envisaged the need to treat the patient increasingly as a proactive consumer (see for instance Rycroft-Malone *et al* 2000), increasingly health conscious and interested in prevention and lifestyle management demanding a more symmetric relations with doctors (i.e. Neuberger 1999). In this respect many reforms attempted to introduce what can be termed as a "Managed Consumerism" approach as a blend of the patient-centric focus of consumer-driven health care and the provider-centric focus of managed competition (Robinson 2005). One can actually say that rise of health consumerism has been treated as a pressure to which the healthcare system must respond and as positive resource to be stimulated, especially for what concern health awareness, prevention and lifestyle. A health consumer interested and supported in prevention and early diagnosis can help to reduce the prevalence, and the costs related to, the development of chronic pathologies (Haskell, 2003; Flemming, 2004; Lindström *et al*, 2008). Interest and support to fitness and well-being helps strengthen citizens' awareness on the importance of maintaining healthy lifestyle to avoid the future development of serious diseases, and to achieve a status of well-being, which has positive fallouts in their everyday life (Lichtenstein , *et al*, 2006). It also supports citizens' awareness on their primary responsibility for acquiring and maintaining a healthy condition, reducing thus the requirements towards the health system (Mattson-Koggman, *et al*, 2005). This might contribute to shape a new culture of healthy within society. Indeed this is the context behind the vision of Personal Health System entirely focussed on the individual and aiming at boosting his/her "***Empowerment***" and "***Respons-Ability***". The question is, however, how widespread are in society such proactive consumerist attitudes toward health and their realisation through various ICT supported services and applications?

From its research on consumers attitudes toward health Gartner affirms that we are witnessing the rise of a new health consumerism expected to consolidate in the next 5 to 10 years and that a pivotal role is been played by ICT: "*Healthcare consumers — having seen how technology has helped them in communications, retail, banking, entertainment and government — are becoming increasingly dissatisfied with the manner in which*

healthcare is delivered" (2008b). According to Gartner this implies a health consumer of the future demanding healthcare institutions that:

- **Know who I am.** Expectation that the various players within the healthcare system have as much information as possible before he or she shows up for a visit or treatment;
- **Know why I am here.** Savvy consumers expect healthcare to know even more and constantly update data such as for instance family history, recent treatment and tests, biomarkers, etc, and thus anticipate needs and intervene timely;
- **Return me to health quickly.** Recognize that patients' time is valuable — and get them back to daily life as quickly as possible and/or provide alternatives for encounters that do not involve taking an entire day off from work. This entails also, moving away from the paternalistic approach, to provide the patient with alternative scenarios treatment and predictions of different outcomes: For example, the patient with coronary artery disease may have the choice of a coronary artery bypass graft (CABG) or stent placement. The latter allows the patient to return to a normal routine within days; the former involves open-heart surgery, and recovery can take weeks but with less risk of needing a repeat procedure. This will require a careful balancing act between the "desires" of the healthcare system (for example, shorter lengths of stay or even no hospitalization compared to reimbursement) and the desires/needs of the individual. This negotiated evidence based approach was also mentioned by one of the participants to Sheffield workshop as an emerging trend in the UK NHS;
- **Help me to stay healthy.** The most desirable state is to not require any medical care and the savvy health consumer increasingly demands prevention and life-style guidance.

While the above are future predictions extrapolated from emerging trends, empirical research show that in practice the situation is much more complex than this, as can be appreciated from the main findings of the most updated and exhaustive survey of US healthcare consumers attitude published in June 2008 by Deloitte (2008). After examining a vast array of answers on behaviours, attitudes and unmet needs or desires, it concludes that the health consumer market is not homogeneous. While consumerist and innovative attitudes and desires are widespread, when considering actual behaviours, the finding is that two segments are still very traditionalist (i.e. main source of information is the doctor and no use of ICT supported information and services) rooted in the status quo and represent 53% of the population, whereas only other three segments accounting together for 19% of the population can be firmly positioned toward consumerism and innovation (seek information only and/or using remote monitoring services and/or want to co-decide and/or demand new tools for self-care), with the remaining 28% not using the healthcare system and not showing any marked and clear position. If we look at some

of the most recent Eurobarometer survey[88], we can generally conclude that the situation in Europe mirrors that depicted in more granular details by Deloitte for the US[89]. Indeed if we look at the actual practices we can see, for instance, that in 2007 only 3 out of ten Europeans do conduct an healthy life reporting that they do no smoke, do not drinking, do exercise (Eurobarometer 2007, p. 5). Even more telling is that the respondents reporting to have some 'vices' (smoke, drink, etc), when asked "By how much, if at all, do you think that avoiding some of the situations or behaviours you have just described, would prolong your life expectancy?", answered as follows:

- Several years 40% of respondents;
- A year or two 15% of respondents;
- Few months 5% of respondents;
- Not at all 19% of respondents
- Do not know 20% of respondents

One could at least guess that there is still some level of fatalistic or at least indifferent attitudes out there.

Therefore, we can conclude that our societies are still very much differentiated for what concerns cultural attitudes to health.

In general we must consider the issue of digital inclusion in society referring to the use of digital technologies, digital literacy and technology confidence in general. It would take too long to go in great details into this domain and it suffices to take regular Internet usage as a proxy indicator of digital inclusion. Currently in Europe, according to the latest Eurostat statistics, 44% of the adult population does not use the Internet at all, and these 218 million individuals can be considered digitally disengaged. What is more important is to stress that the pool of the digitally 'excluded' to a large extent is made up of social groups already at risk of social exclusion (low educated, unemployed, inactive, living in rural areas, aged 55-64; aged 65-74; women; marginal youth, immigrants and ethnic minorities)[90]. Accordingly at a very general policy level one should consider that the development of PHS and other eHealth applications can be the source of additional divides and exclusionary processes. The findings of the sample based survey conducted by FP6 project eUser in 10 European countries[91] show that only 30% of 30% of the

[88] See the various reports available at the DG SANCO websites (http://ec.europa.eu/health/ph_publication/eurobarometers_en.htm)

[89] In 2003 the majority of Europeans still resorted to healthcare professionals as a source of information and only 3.5% used the Internet (Eurobarometer 2003, p. 5)

[90] See the periodic report produced by the Commission Services and called "Riga Dashboard" (http://ec.europa.eu/information_society/activities/einclusion/docs/i2010_initiative/rigadashboard.pdf)

[91] Denmark, Germany, France, Hungary, Ireland, Italy, United Kingdom, Czech Republic, Poland, Slovenia.

sample used the Internet to find information whereas only 9.1% used tele-consultation services. Moreover, the research warns that further advances in eHealth raises risks of new health divides for "at present those gaining the benefits are mainly better educated and generally more advantaged (eUSER, 2006, p.5)". This is a conclusion concerning simpler eHealth applications. Yet, considering ICT based preventive systems a major risk is seen of widening of technology and health gap as a result of failure to achieve universal information and technology literacy and access to Internet, thus leading to tiered systems (Kopp *et al*, 2002). The second more specific dimension is, assuming access is available and leaving aside the policy dilemma of exclusion/inclusion, what shapes actual use and users' acceptance. A research conducted over time on access to, and use and acceptance of, eHealth applications has shown that, while access is growing, usage and acceptance lags behind (Hsu et al., 2005). An on this issue there is a very large literature illustrating instances of users resistance and extracting various possible explanations[92]. User acceptance is multi-faceted and entails, besides the usability and human/computer interaction dimension, a number of complex socio-psychological and cultural issues and of concerns for privacy and usage of data. A noteworthy one is cognitive dissonance between individuals' holistic, integrated view of health and the constraints of most self-monitoring systems, as well as difficulty relating to traditional clinical health metrics and language. In addition consumers/patients may be reluctant to adopt invasive and/or uncomfortable data gathering devices. Finally, there is the issue of confidence or lack of it with remotely provided services with no direct intervention on the side of healthcare professionals.

5.6 The inter-operability bottleneck

The gaps identified under this domain are:

- Lack of bodies setting binding standards on inter-operability, protocols, pathways and clinical guidelines and stakeholders fora (including industry) at both national and EU level;
- Lack of shared infrastructures and standards for data exchange;
- Lack PHR inter-operability even at national level, (strongly stressed by experts from ICT industry);
- Need of citizen owned fully inter-operable Personal Health Records (PHR) integrated with PHS (overlapping with gaps in previous domain)

As it is conveyed by the first gap in the list above inter-operability in a strict sense, though important and crucial, is one dimension of a wider gap related to lack of technical standardisation in several areas, which further compound the fragmentation of the healthcare systems and negatively affect the full deployment and adoption of PHS. Indeed the field is characterised by the lack of accepted standards and protocols of application, as well as explicit guidelines for seamless integration, communication, and

[92] See discussion in PHS2020 Deliverable D2.1, *State of Play*, chapter 3.

organisational/semantic interoperability (both in term of standard and guidelines[93] and in terms of technology[94]), which have to do also with the higher level institutional dilemma of centralisation versus decentralisation. One of the greatest organisational obstacles to long-term integration has been the piecemeal development of the telecommunications infrastructure in healthcare, which promotes the adoption of health information technologies that cannot "speak" to one another. ***According to insights provided by Gartner analysts, for instance, home health monitoring is the application with the greatest potential for financial and clinical impact, but its market penetration is low because most care delivery organizations do not have an electronic patient record capable of accepting data from home health monitoring applications***. This is a quintessential problem where institutional and organisation issues are closely related to technical ones, such as technological inter-operability and the little integration between PHS and PHR (personal health records). It is evident that standard, procedural and technical inter-operability would be better enhanced by a centralised management and decision system and also by standards shaping procurement decisions as regard purchase of ICT products and services, which is not present in many healthcare systems. As previously discussed, economic historians of capitalism have long established that the key requirement for entrepreneurs is: certainty in the frame of reference and scale of markets. This is fully confirmed since industry stakeholders active in PHS related products/services lamented uncertainty due to lack of legal frameworks, guidelines and inter-operability standards resulting in very fragmented markets with national and even regional entry barriers. While mentioned especially by the ICT industry, the lack of legal frameworks clearly defining issue of privacy and use of the confidential data produced by PHS (who can use them) and spelling out responsibilities is main barriers from all perspectives. If an error occurs causing serious health problems who is responsible? The healthcare organisation or professional prescribing a PHS service, the industry producers of the sub-system and/or component, the user or his/her relative who misuse it?

Inter-operability among PHS devices and between them and electronic health records (including Personal Health Records) in clinical information systems and in large scale databases has been mentioned throughout the previous chapters and included in some the graphic visualisation of the proposed roadmaps as strategic enablers for the advancement PHS. It is also fundamental to make possible the alternative delivery and business models foreseeing the active role of suppliers who are outside the institutional 'borders' of the system. If they are to perform remote monitoring services, for instance, the must be able to exchange data with clinical information systems. Inter-operability is also a pre-

[93] The fact that teleradiology is more advanced, in fact, is also because there are inter-operability standards (Krupinski *et al*, 2002)

[94] . Existing telehealth networks tend to rely on custom built systems made for specific users operating in specific settings. This leads to networks that lack open connectivity with other systems because they do not share the same hardware or software, resulting in higher than necessary infrastructure costs while limiting telehealth's relevance to mainstream health care

condition for the emergence of users owned Personal Electronic Health Records, if these have to be used to facilitate PHS enabled delivery of care.

With respect to the last point it is worth signalling very interesting and recent developments introduced by two big players such as Google and Microsoft (Gartner 2008a and 2008b). ***Google Health*** and ***Microsoft HealthVault*** offer personal health records (PHRs) that are free and a fully controlled by the user, who can decide by whom his/her records, can be accessed[95]. The introduction of such products may herald the advent of new delivery models led by suppliers and fully controlled by the users in the field of PHS enabled care. Yet again, for this to happen inter-operability still remains a barrier to be removed.

All of the above discussion may suggest the need of re-centralisation to standardise the field and eliminate the current fragmentation hampering the emergence of a full blown PHS market. The application of subsidiarity principles and increasing devolution of decision making in healthcare, however, makes such centralisation drive very difficult politically and highly unlikely. It is, thus, evident the strategic steering and integrating role that the European Commission can play to push inter-operability. This has been done and will need to continue through communication and directives and through the deployment pilot of the CIP.

5.7 "Body adventures": present and future ethical issues

The gaps identified under this domain are:

- Lack of clear legal framework;

[95] These systems could achieve several important benefits: a) Lifetime health records that is free to consumers and healthcare payers: both players have very low costs through their cloud computing facilities, today can monetise PHRs by drawing consumers to their other online products, in the future may sell value added health services (see point f); b) They can scale up to cover the expansion in healthcare data driven by increased use of diagnostic imaging, genomics and proteomics; c) Given sheer size and brand , their initiatives could set the pace and lead healthcare organizations to provide PHRs data and in the future support for other third party players; d)They could expedite achieving interoperability among healthcare IT systems by their market presence and vendor-oriented marketing/partnering; e) They offer Internet-savvy approaches to the two most vexing issues in sharing electronic information in many jurisdictions: consumer authorization and consumer identification. Given their trusted brand they could increase users confidence in providing data and overcome concern with privacy and use of their health data; f) Their cloud-computing approach, offering data access as a software service, can help to create a new market of consumer-oriented healthcare applications such as also to some extent PHS, enabling better consumer lifestyle choices and more active consumer participation in choosing a course of treatment for serious health problems. The goals of Microsoft and Google are not simply to provide a repository of data or to provide the single application that consumers use to derive value from their PHR. They are actively recruiting many vendors to provide third-party applications that add specific value to the repository, all operating under consumer control). The cloud-computing approach is synergistic with the underlying philosophy of these products, which is to engage consumers in managing their own data. This consumer engagement is another reason that better consumer choices could stem from their use

- Lack of tailoring of security and encryption techniques for healthcare sector application;
- Need of data management and mining applications integrated into PHS that embed, support and protect privacy;

The last two points to technical and technological solutions and require their testing and further corroboration through deployment pilots.

The first gap is expressed in a generic way but capture various strands of discussions emerged during the consultation process on ethical and legal issues. This is a very technical domain that is clearly beyond our expertise. Therefore, we will not enter in any of such legal technicalities but rather we very generally raise some reflections on how current and future advancement in technologies are producing and will produce a redefinition and re-conceptualisation of the human body and on the ethical implication of it.

The source of inspiration to use the expression "body adventures" in the tile of this is the image of nanorobots navigating across our body as we walk and carry on our normal daily activities.

New electronic micro-, nano- and bio- technologies are seriously reshaping the human body (intended as both body and mind) and provide new potential in such a way that they seem to support the utopianism of the "transhumanity movement"[96] and the vision that the first Western futuristic thinker such as Francis Bacon, also the first in history to talk about what we call today technological and scientific R&D, expressed in 1627 in the *New Atlantis* : the possibility to prolong life, delay ageing, heal incurable diseases, relieve pain, change the temper and psychology of individuals, create new food, etc. (Hottois 2006: p. 69). Apart from this utopianism, the new possibilities in various ways have both a bright and dark side. In the field of PHS the bright side are increased possibilities to monitor and treat diseases and prevent them and to provide ubiquitous access to care anywhere anytime. To appreciate the potential dark side we must further explain what the re-shaping of the human body means.

The full deployment of such new technological devices around and within the human body will turn it into an "***electronic object***", an "***ensemble of data***", in brief ***our body will become and Information System as many others***. If the body becomes a new object and especially an information system then a new reflection on what will be a "personal data" is need to ensure that the current regimes of protection of personal data and of privacy are not made obsolete by technological developments. Developments that more in general put us in front of new ethical challenges and to the need to understand whether these technological developments around and inside our bodies still guarantee the fundamental human rights to physical and psychic integrity, to full decisional autonomy, to the right of

[96] Intellectual and cultural movement affirming the possibility to radically improve the human condition through technology and, for instance, eliminate ageing and maximize intellectual, physical and psychological capacities. On the history of this movement see (Bostrom 2005)

fully governing our body, to the fact that the body cannot be the object of profit making and also whether they ensure full security of their functioning and access to all citizen under condition of equality and without discrimination (Hughes 2004).

Yet, once the body becomes an information system it can be hacked as any other such system and personal data violated. As any information system it will produce redundant data (trash data with respect to its main purposes) that could be nonetheless be of interest to some organisations and the question is what will happen to such data, who guarantees that is not misused? The future will see the emergence of bionetworks to which our body information system can connect to exchange data with environmental biometric sensors and other kind of sensors. This will surely ensure access to ubiquitous health assistance and also the context awareness needed for PHS, but will also multiply the occasion of control on our bodies and of attacks on our information integrity. In general body information systems with localisation feature bear always with them the risk of becoming instruments of excessive and possibly illegitimate control over our lives. In the previous chapter we illustrated how, for instance, affective computing can help gather data on individuals' emotional state thus contributing to full context awareness of PHS. PHS can, thus, expand also to monitor and treat neuro-psychological disorders to improve our well being. On the other hand, the same principle of affective computing can be used to penetrate our most intimate privacy, namely the true feelings and psychological state behind our exterior façade. The "Facial Action Coding System", for instance, use the same principles and techniques of affective computing to derive from our facial expression the deeper elements of our soul to establish whether we are telling the truth.

In brief the other side of the benefits that these technologies offer is always the risk of the rise of new electronic Panopticon leveraging body electronic information. Naturally for PHS one could argue that they will always be used only upon the explicit consent of the user. But the explicit consent will have to be expressed after having listened or read all the possible risks, and we do not yet have a clear and detailed inventory of them. After reading this entire list how many users will consent to use such system? The simple users consent cannot be the solution.

First, a systematic and deep analysis of all ethical dilemmas and risk must be conducted. Next, on the basis of such analysis a robust and systematic legal framework of responsibility and sanctions must be established to rule all possible instances and deter their occurrence. Third, technological development itself will have to invest into increasingly resilient security solutions.

Naturally these issues have not been discussed to propose on theme possible technological research and/or deployment pilots for they reside in deeper philosophical and ethical discussion of technological developments in light of the very basic normative principles and values upon which our liberal democracy rests. They have been presented here simply to recall that such issues exist and that they will have to be addressed and solved if PHS are to become part and parcel of the practice of healthcare delivery.

6 Conclusions

In a nutshell the future evolution of PHS calls for new research infusing clinical evidence and molecular and genetic data, advancing the development of sensors and lab on chips, developing more sophisticated algorithms and data processing solution capable of turning inert data and information into knowledge and knowledge into support for action and actuation, and ensuring that all this rests upon interfaces and channels of interaction maximising inclusiveness and users friendliness.

We highly recommend in particular that future ***PHS*** research position itself at the cross-road of the ***convergence*** between ***micro-, nano- and bio- technologies*** and that ***synergies*** with the contiguous fields of ***Biomedical Informatics*** and ***Virtual Physiological Human*** are pursued.

It is also important to recall that PHS are currently still a very small niche market and that this is due to barriers, bottlenecks and gaps of socio-economic, institutional, cultural and technical nature that technological research will not solve by itself.

Policy initiatives, legislation and institutional re-design, inter-institutional and inter-disciplinary cooperation, as well as support to implementation and deployment efforts are needed to create the correct structure of incentive across the entire value chain, to identify and sustain new business and funding models, to increase efforts in the preventive field, to reduce healthcare fragmentation and increase the delivery of integrated care, to better inform and educate users and overcome resistances on their side and also on the side of professionals, and to increase technical standardisation and inter-operability

Below we briefly recall some of the key points for each of the five proposed roadmap.

Five research directions needed ....

Infuse PHS with (Bio)medicine. PHS will become truly personalised and fully accepted by healthcare professionals only when they will integrate evidence and knowledge from clinical practice and biomedical research. This calls for the need to fund projects aiming at making PHS applications fully embedded into holistic clinical evidence and guidelines and fed by insights from molecular and genetic data. The potentiality for the realisation of this lays in the convergence of PHS with BMI and VPH. Such convergence requires cross-disciplinary efforts and the willingness of policy makers and institutions to collaborate across long established boundaries. In particular for the design of Framework Programmes research projects it calls for more inter-disciplinary teams with a stronger clinical practice and biomedicine research components, as further elaborated under our "Meta Proposal". Finally, it will entail sustained political will and technical efforts to ensure the very complex and wide ranging level of interoperability needed, both across several different applications and between them and Personal Health Records (PHRs).

Make PHS data processing more intelligent. Data processing is a core part of PHS, where all of the fundamental acquired data is to be turned to meaning, a meaning to understand, process and take action on. The understanding of patterns provides the

opportunity to foresee events and, accordingly, act on them on time. This is possibly one of the major outcomes of PHS. By using predictive algorithms, establishing patterns or evolution of patterns, it is possible to predict the evolution of a disease, and therefore pave the way for actuation (e.g., drug delivery, electrical stimulation, etc.). Predictive algorithms are required also to assess and estimate different possible actions and optimal actuation considering a particular situation. If this is achieved, then PHS has also great potential to assist the medical field in medical related discovery by extracting information out of the large amount of data through the use of ICT tools. Evidently advancement in data processing and in the infusion of (bio)medicine, if achieved, would unleash a positive virtuous cycle. To reach this objective much still remain to be done: a) the challenge of handling increasingly large amount of data and turning it into actionable knowledge calls for more work on pre-processing of data; b) advances in the capability of data fusion and integration of different signals, eliminating data redundancies, are needed; c) it is also key to increase the capacity to integrate different kind of data coming from different sources; d) progresses in statistics and artificial intelligence should be leveraged in PHS domain to derive understandable patterns and make already available patterns understandable, in addition to developing methods to turn discovered trends and patterns into rules. This vision entails that PHS will have to be increasingly connected with other systems. Obviously this and all of the data integration, fusion, and mining activities require the underlying pillar of interoperability.

Develop Third Generation PHS sensors. Sensors are the building blocks of PHS and the foundation upon which intelligent data processing rests. If we call those developed so far by research projects in FP5, FP6 and current FP7 as "second generation PHS sensors" (distinguishing them from the very simple first generation sensors included in product and services currently available in the market), then much still remain to be done for "third generation PHS sensors". "Second generation PHS sensors" still miss calibration, optimised power supply, capacity of multi-disease and multi-signs data gathering, actuation, multi-modal analysis and fusion (i.e. on-board processing), as well as a focus on personalised drug delivery and compliance. Sensors still have problems in gathering reliable data under movement. Ongoing research must be continued to improve wearable smart sensors and textiles, implantable sensors, and on-board data processing capacity of sensors. New research, integrating and exploiting several techniques investigated in other fields, need support such as a) bio-sensors, contactless sensors, bio-imaging, all of them improving non-invasiveness and comfort of PHS; b) contextual sensing, reflecting environmental conditions and psychological status of individuals, which has been identified as one of the major gap of current sensors with respect to personalisation and individualisation

Design more inclusive PHS interfaces. Gaps related to inclusion of all users and users' acceptance of PHS were the most numerous among those mentioned by experts. As in all other Information Society policy domains, it is a proven fact that ICT supported services will have an impact and contribute to the prosperity and well being of European societies only inasmuch as the current moderate level of acceptance and take up will increase. This applies to PHS in the same ways as it does to other eHealth applications or to applications

in other domains (i.e. eBusiness, eGovernment, etc.). To some extent increasing acceptance and take up of PHS is a matter beyond the strict technology oriented research perspective (see *infra*). Yet technological research must be advanced in order to make PHS interfaces and channel of interaction more inclusive and users' friendly.

Push advances in Lab on Chip. Lab on chip is the building block of Point-of-Care (PoC), whose aim is to integrate multiple laboratory functions on a single unit capable of handling small fluids volumes. The situation of Lab on Chip is characterised by three main gaps to which clear cut research priorities can be associated. First, PoC can currently run tests (blood, urine etc) limited to 2-3 biomarkers. This often leads physicians to complete tests through traditional means (i.e. laboratories), for they need to base their diagnosis on several inter-dependent factors, thus defeating time savings achievable through PoC. Hence, it is of major importance to encompass all additional biomarkers needed for a complete diagnosis in one single lab-on-chip. Second, after extracting a sample from the patient (normally, body fluids), most of the times healthcare professionals are required to carry out further preliminary steps before the sample can be applied onto the LoC for final analysis. However, body fluids are very sensitive to environmental factors (e.g. temperature and contamination) and this may defeat the use of LoC. Thus, the steps from sample extraction to sample application onto the chip need be decreased to a minimum, in order to assure a valuable quality of results. Third, Current PoC solutions require a minimum of 15 minutes of run-time and time to result. In most cases, this does not even include the time of sample extraction and sample preparation, which often add up to several hours. PoC is designed to be a decision aid tool to professionals in order to take more in-time and accurate decisions. However, current systems are still too complex and time-consuming, thus forcing both physician and patient to unnecessary waiting. Consequently, in order to accomplish a closed loop circle of testing and diagnoses, time to result needs to be drastically reduced.

....To expand the reach and functionalities of PHS

At the end of the state of play we clearly pointed out that a) PHS applications are overwhelmingly focused, on cardiovascular disease (accounting for 50% of the market products and 40% of research projects surveyed), and on diabetes and respiratory diseases (accounting for the remaining 50% of market products and 30% of research projects), with only a few research projects on other diseases (neuro-psychological disorders and renal insufficiency)[97]; b) In the large part of cases the functionalities are limited to remote patient monitoring with little actuation and treatment[98]. Certainly there are nuances between the market and the research state of the art and also a number of more advanced

[97] See full overview of both market products and research projects in PHS2020 Deliverable D2.1, *State of Play* : a) for market products pp. 83-92 (and particularly 87-88); b) for research projects pp. 115-135 (and particularly pp. 119-120).

[98] This can be evinced from the frontier envelopes reported in aggregate fashion in PHS2020 Deliverable D2.1, *State of Play* (pp. 59-66) and product by product and research project by research project in the same deliverable (pp. 173-256).

examples in both, yet it is safe to make the generalisation that so far ***PHS are to a large extent about remote monitoring of patients with cardiovascular risks/chronic conditions***.

It is evident that in the future we need to expand the reach of PHS into new areas of diseases and to increase their functionalities to make actuation, treatment, personalised drug delivery, rehabilitation, and proactive preventive services a reality. The reason why these two issues do not figure as either gaps or research themes in their own right is easy to explain. Our aim has been that of proposing a series of research themes in several domains to support research portfolio management for the European Commission or any other national or international funding agency in need of planning future research investments in the field of PHS. The best way to do this, in our opinion, consisted in addressing the various layers that are needed regardless of the area of application and/or the corresponding desired functionalities. Our roadmaps are exhaustive and can be flexibly used by funding agencies into the various different combinations that could best suit their orientations. Structuring the roadmaps around specific diseases and/or functionalities was equally possible but would have not been as exhaustive and flexible as in the approach we followed. At any rate it is equally easy to quickly show how funding the research themes we proposed can also help: a) expand the reach of PHS into new diseases; and b) go beyond simple remote monitoring, which we do in below.

The research proposed to expand the scope of health related parameters that one single sensor can capture ("multi-signs/multi-diseases" sensors) will make reaching other diseases more feasible. If several detecting capabilities can be concentrated in a fewer number of sensors, then it becomes more feasible and economic to treat more diseases, not only those with the highest prevalence. This would produce a sort of economy of scale effects making more likely that PHS address diseases that have less prevalence. In addition, the proposed new research on sensors capable of capturing context and especially users emotional status, while instrumental in an horizontal way to various different diseases, it will clearly increase the capabilities of monitoring and acting upon neuro-psychological disorders. In the same way as for sensors, support to research for all-encompassing and holistic Lab on Chip would help combine genotype and phenotype parameters and, thus, enable early diagnoses and, eventually, treatments as complete as possible. During the consultation process the experts mentioned several disease area where PHS advancement could help. Rheumatoid arthritis, and more generally neuro-degenerative diseases (such as the various form of sclerosis) with very slow evolution and eventually with negative effects on the patients' abilities, were signalled as an area where early detection, monitoring the course of the disease , and support to rehabilitation (physiotherapy and physical activities) would help delay/contain the most heavy effects of the disease. Since the course of such neuro-degenerative diseases is so slow and gradual and the initial symptoms are too general and difficult to be associated to them, currently the diagnosis arrives too late when the symptoms are full-blown, at a point when it is difficult or impossible to contain the progressive worsening of conditions and the related effects. So new advancements in early detection Lab on Chip would have a tremendous positive effect in better dealing with these diseases. This also applies to

another kind of auto-immune disease that was mentioned by the experts, namely celiac disease where ad hoc Lab on Chip should be further researched. Next also cancer was mentioned, as an area where Lab on chip are being developed but should be further supported also to go beyond the current main focus on the cervix cancer. In the future we can envisage new applications for treatment and/or monitoring of various forms of cancer coming from research on NEMS and on special kind of electromagnetic waves.

As for the need to stretch PHS functionalities beyond simple monitoring, we believe that the discussion contained in the various roadmaps amply documents that many of the research themes are specifically geared to enable broadly defined automatic actuation such as personalised drug delivery, concrete support to rehabilitation, more effective and effects-producing primary prevention. Most of the discussion on the integration of external knowledge and on more sophisticated and intelligent data processing is geared to support action by professionals on the basis of the PHS evidence they access or automatic actuation. The same applies for the emphasis on context aware sensing and data processing as a way to complement data on vital parameters to better interpret them and support action and actuation. Similarly context awareness and various techniques to capture and act upon users' emotional sphere (i.e. affective computing) have been proposed also to enable more impactful lifestyle management application.

In brief, pursuing the five research directions we proposed should be seen not simply as supporting better sensors and data processing, or interaction and interfacing, or the clinical and biomedical evidence base as end in themselves. They are the means by which in the future PHS could reach into new areas of diseases and expand their functionalities beyond simple remote monitoring.

A "Meta-Proposal"

PHS is a dynamic and complex socio-technical system resulting from the interactions of different sub-systems with their respective players, practices, expertises. ICT is only one component of this system, and ICT expertise is only one among a vast range of relevant and needed disciplines, including naturally medicine but also other broadly defined socio-economic issues (business models, users needs and cognitive maps, regulation, organisation and institutional re-design and restructuring, etc). So PHS involve a plurality of different players and a plurality of expertises. While this is rhetorically always acknowledged, the practice of EC funded research is different. Especially large RTD projects formally include involvement of stakeholder players, clinical trial and pilots, as well as "socio-economic" work streams and packages but their actual weight tend to remain marginal, if not 'ritual', in the overall architecture of research activities. This fact seriously compromises the likelihood that research products respond to the actual practice of healthcare and embed the expertise and knowledge needed to convince clinicians, consider the nuances of users needs, organisational and institutional functioning. Surely the Framework Programme is for pre-competitive research that will then have to be adapted for deployment. Yet, when the products of this research are so misaligned with respect to institutional/organisational realities and users needs it is very likely that it will never be used. We have two proposals to address these shortcomings.

First, **a methodological change in the PHS ICT research projects** that might be financed in the last years of FP7 **to increase their multi-stakeholders and multi-disciplinary nature, and particularly to infuse medicine into ICT.** It is not a proposal to change the focus, as this will remain mainly on RTD, but rather a **meta-proposal** in the sense that it concerns the requirements of the calls and the evaluation criteria. We propose the following four criteria:

1. Proposals should include all non ICT relevant stakeholders, clinical and "socio-economic expertise" with respect to the addressed domain;
2. Clinical and socio-economic expertises should be deployed both upstream (i.e. *ex ante*) and downstream (i.e. *ex post*) to the core technological development activities, whereas currently they are mostly downstream and are often carried out residually simply because they are written in the Description of Work (DoW) and not for their real added value;
3. All large scale project should include real life clinical trials of some reasonable dimensions (not 3000 subject but neither 15 as it is too often the case)
4. At least 30% of the requested funding should be allocated between "clinical" trials, "socio-economic" analysis and activities, and at stakeholder involvement activities

These four criteria are self-evident and we simply add a brief consideration on the second one. This criteria aims at ensuring that also single research projects improve the higher level "governance" in terms of the design and modelling of the expected technological product with respect to the targets addressed and the organisational/institutional context of application.

The **second proposal**, in addition to the previous one or in alternative if that prove not feasible, **is the definition and launch of a joint call on PHS between the ICT Work Programme of DG INFSO and the Health Work Programme of DG Research.** This could achieve two objectives:

a) enable a truly multi-disciplinary approach and real synergies between ICT and Health research;

b) Enable cross-fertilisation by groups of applicants that usually do not collaborate: each area of FP create its own silos of organisations presenting proposals that usually do not mix with others, thus foregoing potential important synergies and cross-innovation.

We can conclude by stressing how what we called our "Meta Proposal" is crucial to pursue the goal of infusing (Bio)medicine into PHS and make them develop as to produce that "***Technology Augmented Health***", which will realise the vision of fully empowered and responsible users involved in the co-production of health outcomes

7 Annex: Methodological approach

By Cristiano Codagnone

PHS2020 overall approach, as well as the tools and techniques specifically related to most of various core project deliverables (scenarios, gap analysis, and roadmapping), results from the re-elaboration and adaptation to the context of PHS of the methodology developed and successfully applied in the FP6 project eGovRTD2020 in the roadmapping of future research for eGovernment (Codagnone and Wimmer, eds., 2007)[99] and in several other publications resulting from this project (among others see Wimmer, Codagnone and Janssen, 2007; Wimmer, Codagnone and Xiaofeng 2007). On the other hand, we departed from eGovRTD2020 in two ways. First, we developed a different and ad hoc approach to the state of play. Second, our consultation process innovated by establishing the standing ESC cited earlier.

In the following chapters we start by clarifying how our approach is rooted into a foresight conception of the future and combines (**§ 7.1**) scenarios building and roadmapping and the overall methodological architecture (**§ 7.2**), and then present the methodology, conceptual tools and sources of the state of play (**§ 7.3**), scenario building (**§ 7.4**), gap analysis and roadmapping (**§ 7.5**).

As anticipated in the introduction, all the illustration about methodology and sources are compacted into this chapter, where precise indication as to where further information in the project deliverable can be found is also referenced. Accordingly, starting from chapter 3 we will proceed to illustrate the findings without any further reference to methodological issues.

7.1 Roadmapping high complexity and uncertainty

Technology roadmapping (TRM) is a strategic planning approach to identify future technology research and innovations. It has become a widely used for individual companies, entire industries and governmental policy makers in the past decades (McCarthy, 2003; Kurokawa and Meyer 2001; Probert & Shehabuddeen, 1999; Phaal, Farrukh, & Probert, 2004; Probert et al 2003). The use of the term "roadmap" conveys the main purpose of this approach, namely to chart an overall direction for technology development or usage (MacKenzie et al.2002; Grossman 2004). In the most traditional sense, TRM aims at supporting the development of new products by establishing causal or temporal relations between the technological possibilities and choices and the business

[99] See in particular within the final eGovRTD2020 book : a) for the general approach to roadmapping within a foresight perspective in a policy context see par 2.4 by Codagnone, for its operationalisation see par. 2.8 by Ma and Wimmer, and for its application see chapter 6 also by Ma and Wimmer ; b) for the scenario building methodology see par. 2.6 by Janssen *et al* and for its application chapter 4 also by Janssen *et al*; c) for the gap analysis general methodology see par. 2.7 by Pucihar *et al* and for its application chapter 5 also by Pucihar *et al*.

objectives thereby highlighting the necessary steps to reach the market with the right products at the right time (Groenveld 1997). Indeed roadmapping is gradually developing into a new discipline as numerous studies have been devoted to the theory and methodology of roadmapping (see for instance: Boden 1992; Dierkes et al 1996; Grossman 2004; Kostoff and Schaller 2001; Probert and Radnor 2003; Radnor and Probert 2004; Strauss and Radnor 2004). Yet, in spite of the growing interest in roadmapping and the theoretical and methodological attempts to structure the corresponding process, there is not yet a real systematic roadmapping approach or even visioning methodology defined. In short, it can be said that the practises of TRM are diverse and that such methodologies have yet to reach maturity. TRM is still developing from an art to a discipline, from exploring a spectrum of methodologies for different goals and situations into systematically applying basic principles and methods (Eggermont 2003). A standard definition of technology roadmapping and systematic roadmapping approach does not exist (Albright, 2002), and an examination of roadmaps that have been created indicates that there is considerable diversity among practitioners as to what constitutes a roadmap and the roadmapping techniques employed.

Table 15: Two poles of TRM roadmapping

	Corporate/industry TRM	**Holistic policy oriented R&D TRM**
Diffusion	From mid-1980s	From late 1990s
Scope	One product (**corporate**) or a family of products (**industry**)	Entire R&D landscape seen from an "issue-driven" approach and extended upstream to fundamental scientific research
Objectives	• Optimising strategic planning for development of new products (**corporate**) • Becoming more competitive by sharing R&D investments and results in the pre-competitive domain (**industry**)	Providing the intelligence needed for optimising public R&D investments and ensuring their relevance to society
Approach to the future	Technology-driven and/or market-pull; Forecasting and normative: "what will happen?" and "what are we going to do?"	Future is uncertain and cannot be forecasted. Foresight to envision all possible emerging challenges ad adapt to them decision of public funding to R&D
Time Horizon	Short term: typically 5 years	• Longer term: 12 to 25 years; • connecting long-term socio-economic issues (e.g. demographics, geopolitics, societal concerns and demands, etc.) to shorter-term foreseeable technological developments

Source: adapted from Codagnone and Wimmer (2007, p. 18).

Amidst this plurality of methodologies and lack of a consolidated paradigm a basic distinction can nonetheless be drawn in terms of scope and conceptualisation of future

developments between, on the one hand mono-thematic roadmaps based on a more deterministic and normative view of the future, and more holistic roadmaps focussed on highly complex multi-layered and multi-players domains and resting on a foresight and uncertain perspective on future development (Codagnone 2007).

Basically this distinction to a large extent correspond to one between "Corporate and/ Industry TRM" (henceforth simply **TRM**) [100] and "Holistic Policy Oriented R&D TRM" (henceforth simply **PTRM**) [101]

We can characterize the former as having a very limited scope and timeframe and as resting on the following three steps:

1) The characterisation of the state of play (baseline or '**As Is**');
2) A normative and, to some extent, deterministic view of the future to be achieved ('**To Be**');
3) A structured and limited set of actions to achieve the desired future derived through a simple and straightforward application of the **Gap analysis** technique used in strategic management (comparison between the 'As Is' and the 'To Be').

In addition, but not always, a consultation process with experts and internal (for corporate TRM) and external (for industry TRM) stakeholders integrate the second and third steps after the state of play baseline is established by gathering and analysing secondary sources. It is worth stressing again that the most characterising element of this strand of TRM is a normative view of the future assuming a straight-line projection from the current situation to only one possible future state.

PTRM, by definition, need to focus on wider policy defined issues (i.e. funding R&D to produce outcome for constituencies) and consider the many possible and highly uncertain interactions between different domains, going from the macro down to the micro level and ranging from politics, institutional settings and change, economy, society (demographic, cultures, social position) and technology. In this respect such roadmapping exercises are radically different from a TRM, whose aim is simply to define the strategy

[100] Product or corporate TMR has been developing since the 1980s within R&D and strategic planning teams in high-tech companies (Willyard McClees 1987). It is a forward-looking instrument used to support the development of new products by highlighting the necessary steps to reach the market with the right products at the right time (Groenveld 1997). In the case of corporate roadmapping, the goals are relatively easily defined (Da Costa et al. 2003). They are about optimising R&D decisions and strategic planning for development of new products or more generally delivering the right products on the right market at the right time.

[101] Since the mid-1990s, roadmapping has been increasingly applied to policy relevant and/or funded technological developments and research (Braun et al 2003; Cahill and Scapolo 1999; Codagnone and Wimmer 2007; Da Costa et al 2003; Da Costa et al 2004; Friedewald and Da Costa 2003; Osimo et al 2007). While in different ways, such policy oriented efforts aimed at providing the strategic intelligence needed by policy-makers to identify current and future challenges and, accordingly, optimise policy-making, investments decision, as well as research funding

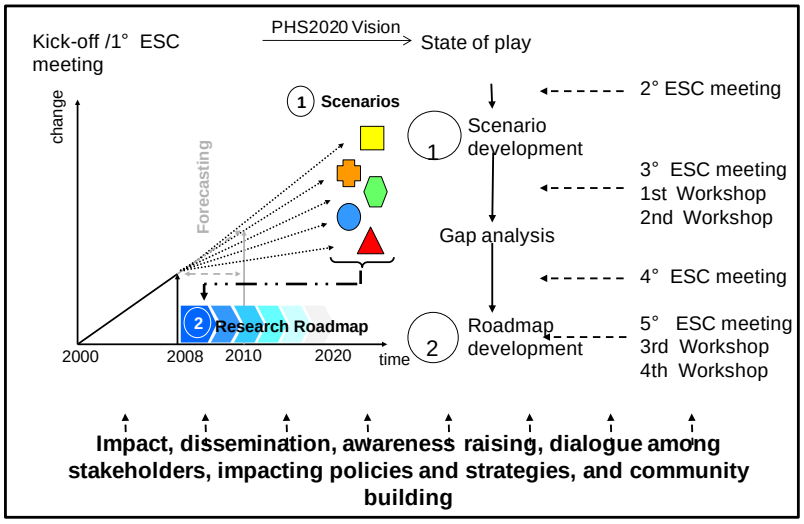
for research in support of one specific product or set of products given a normatively and uniquely depicted desired future.

In sum, the key distinction between TRM and PTRM resides in a different view on the future: a single and normative view in the former, an uncertain view possibly envisaging alternative and contrasting futures in the latter. A corollary of this is that PTRM are more clearly embedded within a foresight (rather than forecasting) approach requiring and integration between roadmapping and scenario building techniques (Lizaso & Reger, 2004)[102]. This is the approach we adopted in PHS2020, which we illustrated in next paragraph.

7.2 Methodological steps

Resting on key elements characterising a policy oriented and holistic approach to roadmapping the work was carried out following the overall logic and architecture is illustrated in Figure 43.

Figure 43 Methodology snapshot



Source: Adapted from Codagnone and Wimmer (2007, p. 5)

The four building blocks of PHS2020, in fact, have been:

1) The **state of play** establishing the baseline and providing the basis to extract the trends upon which the scenarios have been developed;

[102] When taking by necessity a more holistic view at all possible important domains and factors influencing the issue at hand, we cannot pretend to predict and depict exactly one single desired future for the interplay of all these dimensions and related issues. Under these circumstances we can at most imagine various possible combinations of different factors and of their interactions. The solution then is an approach where scenarios development is introduced into an integrated scenario-building and road-mapping methodology.

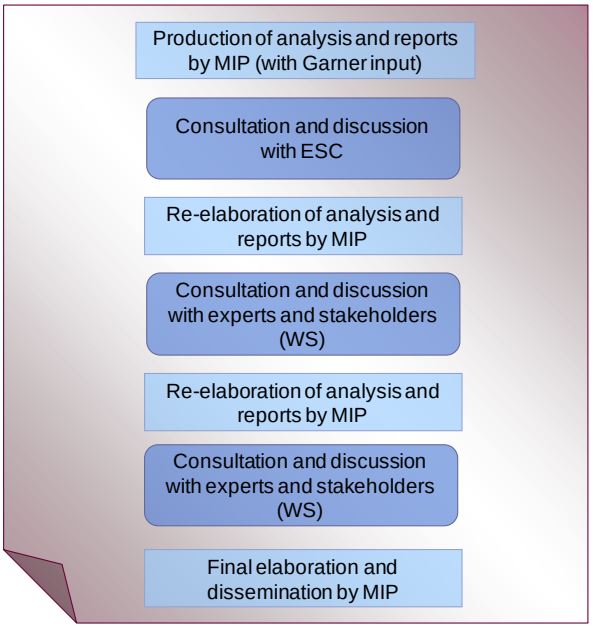
2) The **development of scenarios** by extracting possible future trends from the state of play and then selecting the most impactful and uncertain ones to identify the two key dimensions of uncertainty along which alternative and possible contrasting future could be envisaged;

3) Comparison of the state of play with the four scenarios and identification of current **gaps** that need to be filled in order to favour the desirable elements of the scenarios and to counter and/or contain the undesirable ones;

4) Assessment and prioritisation of gaps in terms of relevance and their associations to the actions needed in terms of research themes to be financed in the future representing the **final roadmaps** for PHS from 2011 and up to 2020.

One of the key implementation choices within a roadmapping methodology is that of defining the mix between meta-analysis of secondary sources and experts and stakeholders consultation activities, which can range from relying mostly on secondary sources with very limited consultation to limited analysis and a very extensive consultation process. PHS2020 positioned in between these two extremes adopting what we deemed a **multi-tier approach**, which ensured appropriate mix between meta-analysis and consultation of experts and stakeholders. As anticipated in the introduction, PHS2020 Expert Support Committee met 5 times throughout the duration of the project and its members constantly evaluated, commented and validated the deliverable produced. This input, together with one to once discussion with Gartner analysts, served as quality control filter before presenting and discussing deliverables in the open consultation events (4 workshops and 1 conference). The multi-tier approach process is graphically represented in the figure below.

Figure 44 PHS2020 Multi-tier approach



Source: Author's elaboration

In general for the production of substantial core deliverables (state of play, scenarios building, gap analysis and roadmapping) between three and five steps[103] have been executed:

1) Analysis and production of first draft deliverable by MIP researchers with the support of Gartner' premium market research and of its analysts;
2) Presentation and discussion of first draft during the corresponding ESC meeting leading to the production of a second draft;
3) Second draft used as background document for consultation and discussion during first interactive workshops with the wider pool of external participants, leading to the production of a third draft;
4) Third draft used as background document for consultation and discussion during second interactive workshops with the wider pool of external participants, leading to the production of a fourth draft;
5) Final elaboration of consensual and consolidated deliverable ready for dissemination and inclusion in the expected PHS2020 book.

As we explain in following paragraph, after the elaboration of the state of play, the input from the ESC members and from the experts and stakeholders engaged in the consultation events has been a key pillar for the production of the consolidated and consensual version of future scenarios, gaps and roadmaps.

7.3 State of Play: approach, scope and tools

7.3.1 Two dimensions

The state of play, while representing only an instrumental step toward the final goal of roadmapping, it is nonetheless very important for it subsequently shapes scenarios building and eventually the gap analysis and the associated roadmapping. It is, thus, of fundamental importance to get it right.

As we explained earlier, the primary focus and scope of our roadmapping exercise was defined as being PHS applications /services and their constitutive technological systems and components. On the other hand, this dimension could not exhaust our analysis that had to consider also broadly defined ***environmental conditions*** (socio-economic, organisational, and institutional factors, and also technological deployment issues such as inter-operability, standards, etc). First, given the complexity of PHS as a socio-technical system and our foresight and holistic approach to roadmapping, we could not overlook trends emerging in domains other and broader than the technological one. Second, since the development of ICT supported PHS applications / services is naturally not an end in

[103] The full five steps have concerned the two key components of the projects, namely Scenario Building and Gap Analysis/ Roadmapping. For the intermediate an instrumental components such as the State of Play (instrumental for the scenario building and Gap Analysis) only three steps have been carried out.

itself but should aim at tackling the challenges and fulfilling the promises discussed in § 1.2 in order to propose future research themes we needed to envisage the future beyond simply technological developments and look at the environmental conditions. Third, a technical but important reason, when building scenarios aimed to defining future technological needs ***neither of the two axes of the scenario matrix can be about technology otherwise one fall into circular reasoning***.

These three reasons for going beyond the technological dimensions were embedded into our methodological approach and, thus, defined *ex ante*. They have been, however, strongly corroborated once the consultation process started, as both Gartner's analysts and the experts and stakeholders engaged underscored the importance of non technological dimensions.

Gartner's analysts argued that in history technology has always shown cycles of convergence and then new fragmentation, despite of which it has always progressed and so could not be the main determining factors shaping future scenarios. Gartner's analysts also affirmed that the most uncertain and differentiating factors are institutional (i.e. financing) and societal (users attitudes to healthcare and technology).

Members of the ESC convened that three layers and their interactions combines to form PHS as ecosystem: a) at the bottom are the technologies (e.g. sensors, devices, systems, repositories, etc) that are being integrated into a; b) the second layer is that of the actual players involved in service provision, that is complex care processes involving various interactions, based on the presence of technologies as enablers of the processes; c) the third topmost layer is that of macro level structures. This view inspires the elaboration of PHS2020 General Descriptive Framework (see *infra).* The usual supply side view is that the push has been and will always be from technology to service provision and from services to structures. Yet, during the 3rd ESC meeting a consensus emerged that: "*90% of failure in PHS application is due to factors other than technology. Most needed technology exist or will soon be developed. The issue is how technology can help the transition to integrated care*".

Finally, when the consultation reached beyond the ESC with the engagement of other experts during workshops, these experts were asked to assess the identified trends in terms of future impact and uncertainties (see more on this in **§ 7.4**). It is quite telling that all the technological trends were scored as having high impact but very low uncertainty. This means that experts overwhelmingly believed that process of technological development will not stop; rather it will consolidate the existing development and go beyond them. On the other hand, societal, institutional and economic elements were the sources of sharp uncertainties according to the experts.

This confirmed the correctness of our approach that focused the state of play both on technology and on the environmental conditions, although given our primary scope the state of play of ICT supported PHS was conducted in greater depth and has an added value in its own right (even beyond the roadmapping for it provides the most up to date and extensive state of the art review available so far), whereas the review of the environmental conditions was more synthetic and strictly instrumental to the scenario

building step. As the environmental dimensions spanned widely, for instance from governance issues to socio-demographic and socio-cultural trends, it was beyond our scope and resources to elaborate a state of play that could be innovative and exhaustive. In this case we limited our work to recalling much consolidated evidence and wisdom.

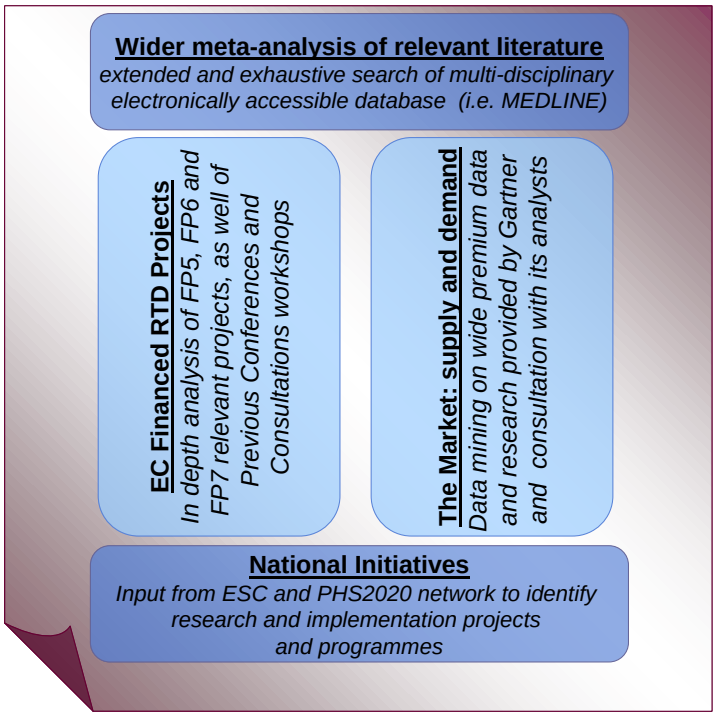
As guiding and structuring conceptual pillars for the technological dimension we used what we called PHS2020 "State of Play Model" (see **§ 7.3.2**) and for the environmental conditions PHS2020 "General Descriptive Framework (see **§ 7.3.3**). In combination they enabled to establish a baseline for both technological and non technological dimensions.

7.3.2 PHS2020 State of Play Model (SoPM)

Before illustrating it, we must briefly introduce the scope and sources of the empirical evidence gathered, to which the model has been applied.

The consensus achieved during the project kick off with the members of the ESC on the scope of PHS2020 also defined the two key domains for the gathering of data and the analysis of technological domain, which are the two vertical tiers in Figure 45[104]

Figure 45 State of Play Sources



Source: Author's elaboration

[104] For a full illustration of the sources used and of the model see project deliverable D2.1 "State of Play" (http://www.phs2020.com/images/stories/deliverables/phs2020_D%202%201_State_of%20_Play_final_.pdf), pp. 13-21, whereas for its application to all the gathered empirical evidence see Annexes I through VI (pp. 72-214), where the empirical evidence is reported in great details.

The first and primary domain has been that of the research stage represented by large RTD projects financed by the EC research Framework Programmes, while the second was that of concrete supply, adoption and usage in the market. In this paragraph and especially in chapter 3 we will always refer to these two domains simply as "Research" and "Market" and will treat them separately.

The analysis of the sources pertaining to the first pillar enabled us to do two things:

- Reconstruct the process and trajectories of PHS relevant projects, both in terms of the way the Commission designed the FP focus and in terms of what areas of PHS the projects have covered or are covering;
- Identify areas of PHS that are still little covered by ongoing projects;

The sources of the second pillar (where the term market is used in a broad sense), on the contrary, have evidenced the current and real situation in terms of penetration and usage of some applications that can be included into the PHS domain. This has been done by looking at the perspective of Care Delivery Organisations (CDO) and of Health Care Professional (HCPs), at available and updated consumer/patients research and, naturally, at the set of products sold by technology vendors.

The two other areas included in the figure above, namely the review of national level initiatives in key EU Member States and a wider review of the relevant literature, are placed horizontally as they provided additional input and context.

Considering both the market and the research domain of PHS amount to a potentially huge amount of information to be gathered and screened, which would have been beyond the time and resource of our project and could also prevent extracting the key trends characterising this field. For what concerns the Market, a delimitation of the field was applied in order not to waste time and resources and to get real valuable and useful information: we did not to consider services offered in the market that are based on simple applications and tools (i.e. pedometers or scales), as they are not full blown systems not connected to ICT environments (only stand-alone devices). This same delimitation, however, applied also to more sophisticated and complex medical devices (i.e. a pace-maker) as long as they are stand alone and not part of an holistic ICT embedded system (data acquisition, processing and communication).

Furthermore, our coverage of the various possible areas of application is evidently not balanced, but this simply reflects the supply both at market and research level. The number of research projects and market products analysed in the field of chronic disease management is far greater than those, for instance, in early diagnosis or prevention and in fitness and well being (where we did not consider simpler application). This, however, is not a limit in our work but rather an empirical finding in its own right: both market products and research projects mostly focus on chronic disease management.

PHS2020 "State of Play Model"(SoPM), based on a multi-attributes approach (Duin, 2006) [105], decomposed the identified market products and research projects into three main building blocks, as illustrated in the figure below focussing on chronic disease management and reported here for exemplificative purposes only. The three building blocks are:

1. The areas of applications;
2. The technological sub-systems (see intuitive snapshot in Figure 47);
3. The technological components (basically sensors and/or lab on chip)

Figure 46 State of Play Model Structure (exemplification)

Chronic Disease Management		Attributes	Classes C1	C2	C3	C4	C5	C6	C7	C8
Application/services	Chronic Disease Management	*Clinical focus*	cardiovascular diseases	Diabetes	Respiratory diseases	renal insufficiency	neurological diseases	Cancer	AutoImmune diseases: neurodegenerative disorders	AutoImmune diseases: others (specify)
		How is the service provided?	Pushed by: hospital	Pushed by: call centre	Pushed by: other third parties	Pushed by: PoC	Fully led by patient			
		Cost model	out of pocket	third party payer	mixed					
Sub-system	Data Acquisition	*Position*	stationary	portable	wearable	Implantable				
		Scope	single	multiple						
		Embedding other sub-systems?	Non embedding	Partially embedding	Fully embedding					
	Data processing and analysis	*Degree of Intelligence*	low	medium	full	full and self-adaptive				
		Health professional Intervention	mandatory	recommended	ad hoc	not needed				
	Data Communication	*Type of connectivity*	wired	wireless	wireless BAN	wireless BAN+PAN	wireless BAN+PAN+LAN	wireless BAN+PAN+WAN		
		Type of communication flows	mono-directional	bi-directional						
Component	Sensor Device	*Position*	stationary	portable	wearable	Implantable				
		Invasiveness	Low/null	medium	High					
		Level of Comfort	Low/null	medium	High					
		Type of sensor	non organic	organic	biological	molecular				
		Interactivity Level	passive	semi-active	active (SIP)	active (SoC)				
		Signs per Sensor	single	multiple						
		Scope of data gathering	Vital signs	Physical activity	Context awareness	Social parameters	Mental/emotional parameters			
	Lab on chip	*Material*	Silicon	Plastic	Nano-motor					
		Sample Preparation	non embedded	embedded						
		Target Detection	mono-target	multi-target, low	multi-target, high					

Source: Author's elaboration

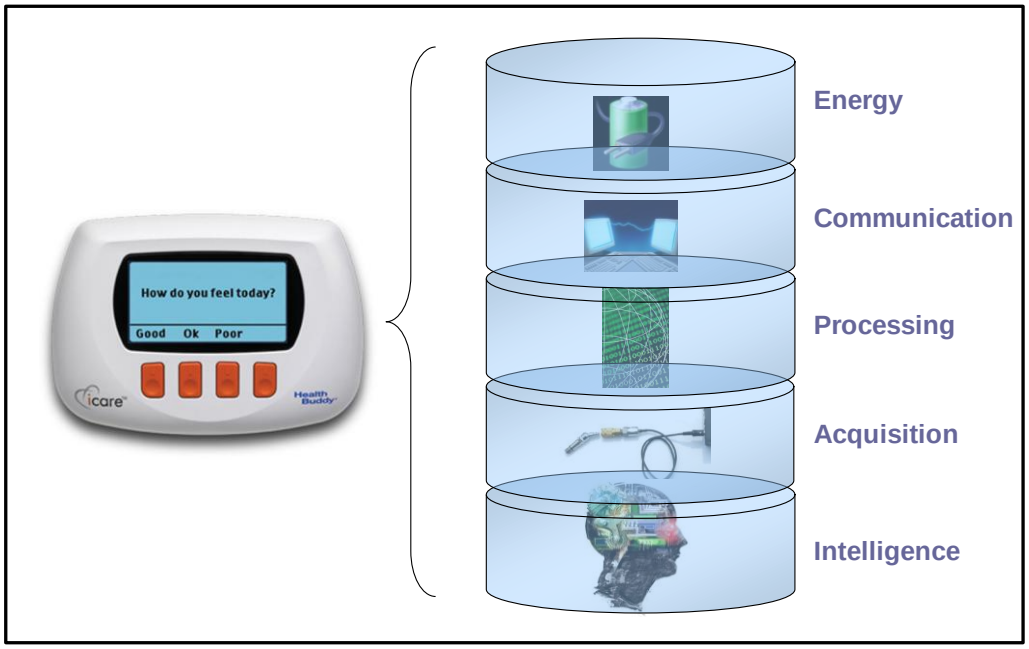
As macro-areas of applications we identify the following:

- Chronic disease management;
- Life-style management;
- Independent living.

[105] For a full illustration of this model see project deliverable D2.1 "State of Play"(http://www.phs2020.com/images/stories/deliverables/phs2020_D%202%201_State_of%20_Play_final_.pdf), pp. 13-21, whereas for its application to all the gathered empirical evidence see Annexes I through VI (pp. 72-214).

This selection is based both on the objective importance of the health issue addressed and on existing and consolidated taxonomies in the field of EC Framework Programme funding (FP5, FP6, FP7).

Figure 47 Technological sub-systems: intuitive snapshot



Source: Author's elaboration

The sheer and growing incidence of chronic diseases as the population grows increasingly older it is a well known fact and make "Chronic Disease Management" one of the primary areas of focus for PHS, where they can be distinguished by their clinical focus (one of the attribute of the model) in terms of the actual disease addressed. We grouped under the general heading of "Lifestyle Management" two different clinical focuses, on the one hand prevention and early diagnosis, and on the other wellbeing and fitness monitoring and support. Indeed we must underline that the former revolving around advanced and sophisticated solutions (i.e. lab on chip) has been analysed in greater depth than the latter, since applications based on advanced and clearly scientific research were more frequent and easy to identify in the field of early diagnosis and prevention than in that of wellbeing and fitness. Independent living applications are important clearly in relation to the ageing of the population and the related challenges of long term care have recently acquired increasing importance as evident, for instance, in the European Initiative on "Ambient Assisted Living" (under article 69), where there are grounds for some joint projects and initiatives aiming to exploit PHS potentialities for enhancing independent living[106].

[106] The Ambient Assisted Living Joint Programme (AAL JP) is a joint research and development funding activity by 23 European Member States and Associated States, with the financial support of the European

Next, conceptually the PHS systems, regardless of the areas of application, can be broken down into the following three sub-systems:

- Data acquisition;
- Data processing and analysis;
- Data communication.

Data and information related to the health status of a patient or healthy individual are acquired generally through the use of sensors and monitoring devices. The data are stored and then processed and analysed to extract the information clinically relevant and useful in the diagnosis, management or treatment of a condition. This can entail different levels of intelligence in the analysis (e.g. through algorithm and modelling). Data processing may occur at both ends: locally at the site of acquisition (e.g., with on-body electronics) and remotely, at medical centres. Processing and analysis must take into account the established medical knowledge and professional expertise where appropriate. The processed and analysed data are then communicated between various actors, in a loop that is from patient/individual to medical centre, from medical centre that analyses the acquired data to doctor/hospital and then and back to the patient/individual from either directly through the data acquisition and/or data processing systems itself or through the doctor or the medical centre (e.g., in the form of personalised feedback and guidance to the patient, adjusted treatment via closed loop therapy, control of therapy devices). For instance, describing a Personal Health Assistant (based on wearable sensor, but the logic could be applied also to other kind of sensors) Tröster explains the functioning logic as follows: *"Several sensors, distributed in clothes, transmit the measured physiological and context data over a body area network (BAN) to a computing unit (e.g. a PDA), which fuses the sensor data out of them, estimates the health status and communicates with the surrounding networks."* (2005: p. 127).

As any conceptualisation, however, the one we used presents some standard limitations with respect to the complexities and nuances of object of analysis to which it is applied. If we envision, for instance, a very sophisticated and advanced sensor embedding data processing and analysis and functioning also as an actuator of treatment, then the three sub-systems are collapsed into one. This would be the case, for instance, of "Molecular Biology" sensor, supported by a highly reliability and innovative technological process and where there are basic factors such as high miniaturization, integration, automation and Bio-Informatics. So all sub-systems are just in one sensor.

The dimensions and attributes of our **SoPM** (see Figure 46, p. 206), against which current product/services available in the market and research projects have been evaluated, entail a progression from less to more sophisticated/advanced solutions helping defining where we are and where the trends are going and especially the current "frontier" in each of the

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Community based on article 169 of the EC treaty. The overall objective of the programme is to enhance the quality of life of older people and strengthen the industrial base in Europe through the use of Information and Communication Technologies (ICT). More information are available on the AAL JP website (http://www.aal-europe.eu/)

two domain (market and research) for each of the three areas of application (chronic disease management, lifestyle management, independent living). Once the SoPM template was filled in for all of the single market products and research projects identified, we then performed an aggregate qualitative Data Envelope Analysis[107] producing the frontiers illustrated in **chapter 2** (see pp. 31-36).

Figure 48 Example of State of Play Model Application

Cronious

		Attributes	C1	C2	C3	C4	C5	C6	C7	C8
Application/services	Chronic Disease Management	*Clinical focus*	cardiovascular diseases	Diabetes	Respiratory diseases	renal insufficiency	neurological diseases	Cancer	Autoimmune diseases: neurodegenerative disorders	Autoimmune diseases: others (specify)
		How is the service provided?	Pushed by: hospital	Pushed by: call centre	Pushed by: other third parties	Pushed by: PCC	Fully led by patient			
		Cost model	out of pocket	third party payer	mixed					
Sub-system	Data Acquisition	*Position*	stationary	portable	wearable	implantable				
		Scope	single	multiple						
		Embedding other sub-systems?	Non embedding	Partially embedding	Fully embedding					
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		Health professional intervention	mandatory	recommended	ad hoc	not needed				
	Data Communication	*Type of connectivity*	wired	wireless	wireless BAN	wireless BAN+PAN	wireless BAN+PAN+LAN	wireless BAN+PAN+WAN		
		Type of communication flows	mono-directional	bi-directional						
Component	Sensor Device	*Position*	stationary	portable	wearable	implantable				
		Invasiveness	Low/null	medium	High					
		Level of Comfort	Low/null	medium	High					
		Type of sensor	non organic	organic	biological	molecular				
		Interactivity Level	passive	semi-active	active (SiP)	active (SoC)				
		Signs per Sensor	single	multiple						
		Scope of data gathering	Vital signs	Physical activity	Context awareness	Social parameters	Mental/emotional parameters			
	Lab on chip	*Material*	Silicon	Plastic	Nano-motor					
		Sample Preparation	non embedded	embedded						
		Target Detection	mono-target	multi-target, low	multi-target, high					

Source: Author's elaboration of data gathered

Figure 48 above, for instance, show for an exemplificative project (Chronius) the result of applying the SoPM model template. For each of the three different areas of application (chronic disease management, lifestyle management and independent living) all of the relevant templates were "enveloped" to produce the "potential" frontiers. This technique allowed us to define where we are so far, yet it must be pointed out that the frontiers do

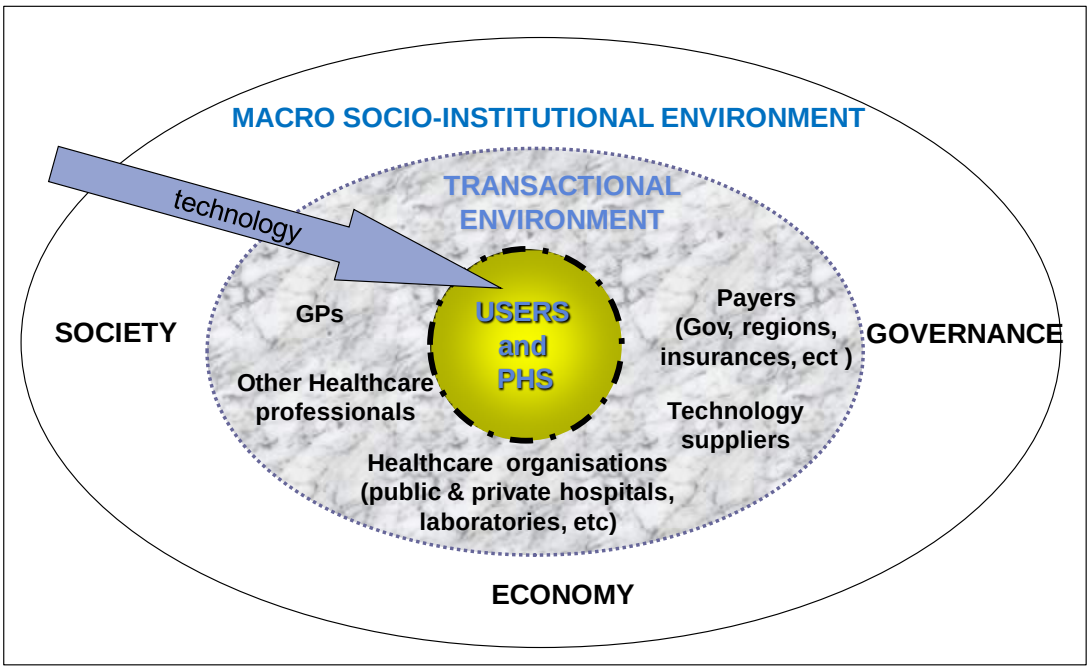
[107] We applied by analogy and only qualitatively, without using any software, the principles behind this well know stochastic technique. Data Envelope Analysis (DEA) is applied to analyse the performance of different production units in various sectors of the economy. While typical statistical approaches focus on the central tendency and, thus, evaluate producers relative to an average producer, on the contrary DEA is an extreme point method and compares each producer with only the "best" producers. The over-arching hypothesis behind such method is that if a given best producer, A, is capable of producing Y (A) units of output with X (A) inputs, then other producers (B, C, D, etc) should also be able to do the same if they were to operate efficiently. Stated in very simplified terms, DEA through sophisticated techniques processes the data from all the producers in a defined sample and, instead of calculating the average efficiency level of the sample, it defines the virtual efficiency frontier that could be reached if the various producer could be combined into a virtual best producers. Such frontier does not represent the current situation but rather it reflects where some of the producers are positioned and what could be potentially achieved if all the producers behaved like the best ones. In our context the frontiers, then, does not reflect the average situation but it has been defined taking collectively, for instance, the market products in chronic disease management and identify up to where they have reached with respect to the classes of the attributes in the SoPM template. This, however, does not mean that all products have reached that level of sophistication.

not reflect the average situation but it has been defined taking collectively, for instance, the market products in chronic disease management and identify up to where they have reached with respect to the classes of the attributes in the SoPM template. This, however, does not mean that all products have reached that level of sophistication.

7.3.3 PHS 2020 "General Descriptive Framework" (GDF)

Developing the views shaped within the discussion with ESC members (see **§ 7.3.1**) we conceived of PHS as a complex socio-technical system[108], and extracted the General Descriptive Framework (GDF) illustrated in Figure 49 below[109].

Figure 49 PHS2020 general descriptive framework



Source: Author's elaboration

The aggregate macro-trends forms the context for the actual transactions between the relevant players, the latter in turn influence the attitudes/behaviours of the final users, which should also reflect the aggregate trends. Yet actual transactions can also take

[108] On the concept of socio-technical systems see classical analysis such as Forrester (1961), Thompson, (1967) and Trist, 1981. In brief a socio-technical system in one where: a) to some extent the factors within each dimension affect one another, resulting in different directions for development or different areas of emphasis within the larger idea they represent and b) the non technical (broadly conveyed by the adjective 'social') and the technical elements are continually evolving on their own while continuously interacting with each other in ways that cannot be overtly controlled.

[109] For a full discussion of this framework see project deliverable D3.1 "Consolidated Scenario Report", pp. 18-19.

different and peculiar paths not perfectly matching the aggregate trends, but they are influenced by them

The **Macro socio-institutional environment** refers to higher level and aggregate trends that apply to **society**, **economy** and **governance** as a whole. Within the broad dimension of society we considered only those elements more directly important for healthcare systems in general and for PHS in particular, that is: a) socio-demographic trends and their implications for healthcare; b) socio-cultural attitudes toward healthcare in general and toward technology. We used "Governance" as a broader umbrella term and concept to refer to both institutional and political developments and policy making occurring at the higher level, which should be distinguished by the meso level of public and private players involvement and transactions that characterise the complex processes of healthcare provision. When considering the economic component we limited our analysis to the overall cost of healthcare and their future sustainability and to the way resources are allocated.

The **Meso transactional environment** concerns the actual players involved in healthcare service provision and financing, that is complex care processes involving various interactions. In this respect we considered the perspective of healthcare organisations / institutions and of healthcare professionals. At this level we also discussed issue which overlap between the actual provision of healthcare and its higher level governance, such as business and cost models (financing) and monitoring and measurement systems. Technological issues of an operational and implementation nature (i.e. inter-operability and standards) are also discussed as part of the transactional environment.

Finally, we have the **micro-level domain of users** (patients / citizens) of the healthcare system and their attitude to technology supported PHS services.

This framework has guided the identification of the non technological trends needed for the scenario building process (see next paragraph), and the supporting analysis is reported in the first paragraph of chapter four on the scenarios. The state of the art review behind this part of our work has not been as extensive as the one conducted on the technological dimension. First, the environmental conditions were a secondary focus of our analysis and served only the purpose of providing the needed context. Second, environmental dimensions span so widely that each of them would require a separate treatment in its own right to produce an exhaustive and innovative state of play. We, therefore, limited our work to recall well known and consolidated evidence and wisdom and extract from it the trends upon which through the consultation process the scenarios were constructed. On the other hand, this analysis also pointed out some bottleneck and barriers that proved very effective in stimulating experts during the consultation on gap analysis, which further enriched.

7.4 Scenarios building

There are many different methods of scenario development (Bouwman & Duin, 2003; Duin, 2006; Glenn, 1999; May, 1996)[110]. Scenario building methodologies received a significant boost when organizations, such as Shell and RAND Corporation, turned the simple 'what if' exercises performed by national armies into fully-fledged future research methods (Duin, 2006). Gibson (1996) found that in the 1960s and 1970s a general sense of certainty existed about where we were going and how to get there. The lesson learned is that the future is inherently unpredictable and may be different than expected. During the twentieth century, more and more orientation on scenarios analysis as part of technology roadmapping (TRM) has emerged (Janssen et al., 2007; Lizaso & Reger, 2004; Wimmer, Codagnone, & Janssen, 2008). Scenarios are an integral description of various information aspects of a context in non-formal, narrative fashion, thus enabling communication and sharing (Carroll, 1995). Scenarios are being used in various situations and have different purposes, form, content and lifecycle (Kurokawa & Meyer, 2003; Phaal, Farrukh, & Probert, 2004). It is important to remark that in our context scenarios is radically different from forecasting. When looking at how future and yet not mature technologies can improve the supply of PHS solutions and their adoptions by healthcare players and by consumers/patients, we depict different - sometimes contradictory or paradoxical - perspectives or images on the future (Handy, 1995). The basic idea is that the real future will be somewhere between those extremes, which are used to sketch an uncharted landscape of the future. Handy (1995) argued that if we understand the contradictory and paradoxical perspectives or images on the future we will eventually be able to find roadmaps to deal with desirable and undesirables outcomes. To develop valuable future scenarios, the implementation process is strategic. So building future scenarios is a radically different exercise from forecasting, scenarios are:

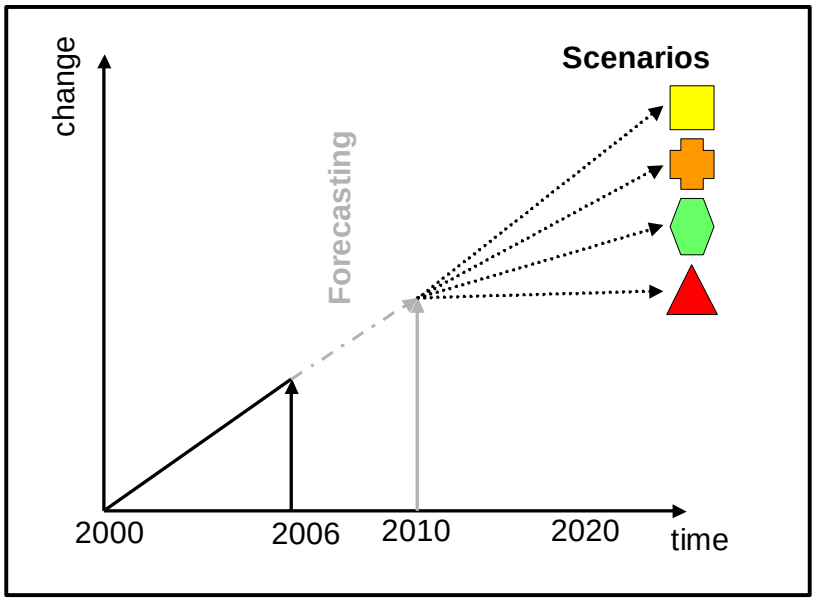
- Archetypal images / pictures of the future;
- Interpretations of the current reality;
- Internally consistent stories about a path from now into the future;
- Plausible, mutually different stories about possible futures.

On the other side, scenarios are not:

- Predictions;
- Mere extrapolations into the future of currently visible developments;
- Good and/or bad futures (in fact they can contain both);
- Strategies.

Figure 50 Scenarios development is not forecasting

[110] For a full and detailed discussion of our approach to scenario building and of the implementation steps undertaken see project deliverable D3.1 “Consolidated Scenario Report”, pp. 5-15.

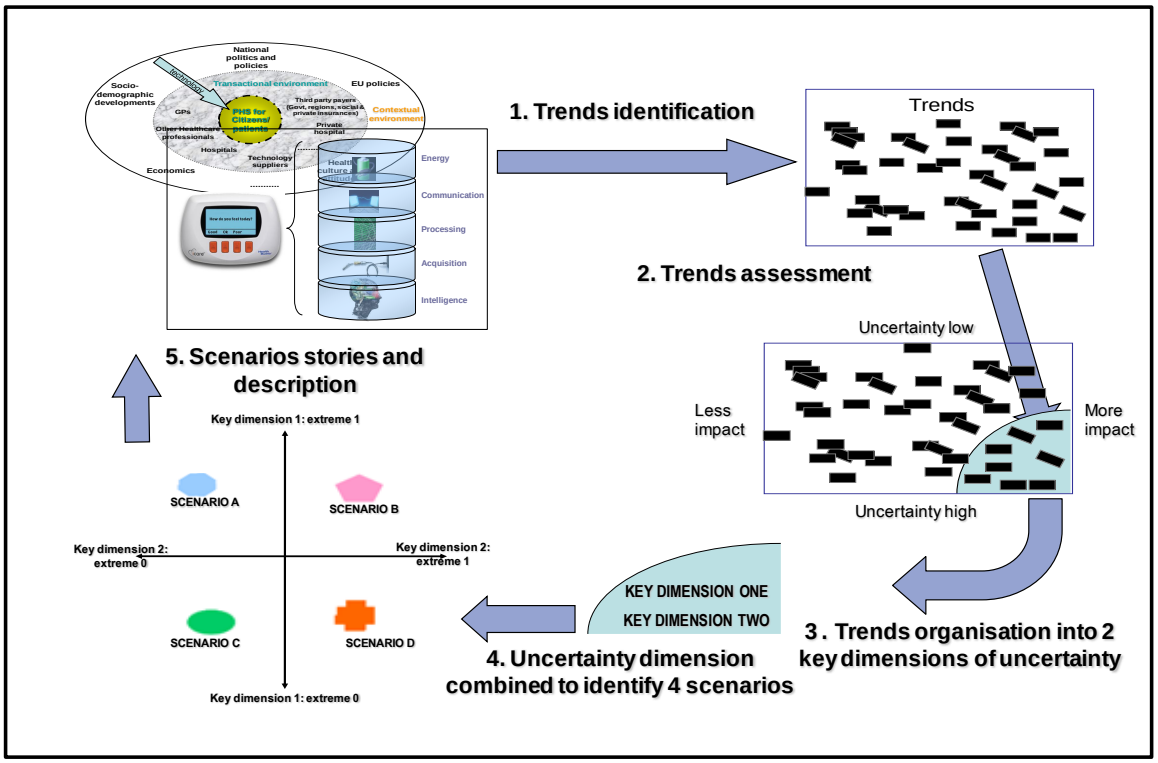


Source: Author's elaboration

Scenarios are not an end in itself, rather they are both a communication and practical tool aimed to elicit divergent and "out of the box thinking" and envision contrasting direction the future might take. They need to simplify a large amount of information into stories that are easy to communicate and share. As they are instrumental to identify gaps and extract topics for future R&D funding roadmap, one should not look at each single scenario separately as a self-contained picture. We assume, in fact, that when the future will actually occur it will not look exactly like any of the envisioned scenario, but will most likely contain elements from each of them. It is, therefore, important to bear in mind that scenarios are useful taken collectively, for having considered all the possible alternative and contrasting 'value' that key variable may take that we ensure to prepare R&D funding decision to any possible future development in a sort of 'portfolio' approach.

Our approach to develop scenarios started, using the General Descriptive Framework and the State of Play Model as basic guiding and structuring tools, by extracting from the state of play developments that have already started and are at work and can, thus, be identified (Bouwman & Duin, 2003). The scenarios, thereby, investigate the type(s) of future(s) to which these trends may lead following the various steps illustrated graphically in Figure 51 overleaf.

Figure 51 Scenarios development framework



Source: Adapted and re-elaborated from Codagnone and Wimmer (2007, p. 23)

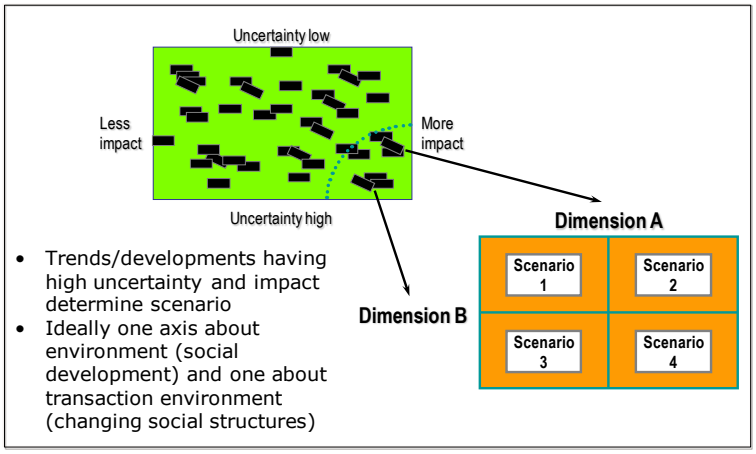
1. ***Trends identification***[111].
    a. The trends were first derived from the State of Play through a clustering and voting process carried out in a brainstorming fashion within PHS2020 project team and with the support Gartner's analysts. This produced a first list of trends and the first version of PHS scenarios for 2020;
    b. The first version of trends and scenarios was then discussed during the 3rd ESC meeting (May 16 2008, Milan). As a result, some trends were discarded, many new added, some merged, others rephrased and clarified, thus producing a second list of trends and scenarios;
    c. This second version was presented and discussed during PHS2020 1st Consultation Workshop (June 19 2008, Sheffield), as a result of which a few but important trends were added. This produced a third version of trends and scenario;
    d. Finally this third version of trends and scenarios was again discussed during the 4th ESC Meeting and during PHS2020 2nd Consultation Workshop (14 and 15 July 2008, Pisa).

[111] See the qualitative description of the trends in deliverable D3.1 "Consolidated Scenario Report", pp. 20-43 and the final summary list of the consolidated trends at p. 44-46.

e. As a result the consolidated PHS 2020 scenarios was produced, which have been described in **Chapter 3** ;

2. ***Trends assessment***. This step went through the same five stages illustrated earlier, and consisted in clustering the identified trends using an uncertainty - impact matrix such as the one below.

Figure 52 From trends to scenarios



Source: Author's elaboration

The rationale is that trends having a high uncertainty and high impact may result in contradictory and alternative futures, shape key uncertainty variables, which in turn will define the different scenarios. ***On the contrary trends having a high impact and low uncertainty should result in one type of future that can be forecasted and will most likely characterise all of four different scenarios*** (i.e. ageing of the population and its consequence in terms of disease prevalence). Trends with expected low impact are irrelevant and should not be considered.

The assessment was carried out using a standard template listing all the trends and providing a space for assessing the impact and uncertainty of each trend on a scale of 0-10 (10= maximum impact and/or uncertainty[112].

3. ***Organization of trends***. The trends classified as having a high uncertainty and high impact were then organized and clustered into a limited number of key uncertainties that defined two key dimensions to produce a 2*2 matrix with four scenarios;

4. ***Extraction of concerted scenarios***. By combining the two key dimensions of uncertainties (each one taking an extreme value) a 2*2 matrix was derived that defines four scenarios.

[112] See the completed assessment template in deliverable D3.1 "Consolidated Scenario Report"(http://www.phs2020.com/images/stories/deliverables/phs2020_d3.1_consolidated_scenarios_report.pdf), pp. 46-51

5. ***Scenario stories and description***. The last step aimed at enabling communication of the scenarios to non-involved and non-experts. An easy to read and understandable story was developed for each scenario. The story is followed by the more detailed description of how the various dimension of the general framework will evolve. Participants to the consultation events were asked to develop scenarios and describe them. This step, however, was mostly fleshed out by the project team using the input from the consultation, but also through a re-reading of the trends and of the actual sentences and specific discussion occurred.

It is worth stressing that for what concerns steps 3 through 5, while they have been elaborated by the research team, organisation of trends and the association of the two key dimension of uncertainties, the extraction and naming of the four scenarios, and the scenarios and description have all also gone through the consultation process. This means that in the course of consultation they have been shaped also by the input received from the engaged experts and validated by them.

7.5 Gap analysis and roadmapping

The application of gap analysis to the context of PHS and the discussion that follows is an adaptation of the approach successfully developed in the FP6 project eGovRTD2020 in the roadmapping of future research for eGovernment (Codagnone and Wimmer 2007)[113].

In its traditional and original application gaps analysis is above all a strategic management tool, and is performed comparing the 'as is' to the normatively defined 'to be' status one aim to shape and reach. Thus a gap is the difference between the 'as is' and 'to be' and, given the clear cut and to some extent deterministic way in which the 'to be' is conceived, can be assessed in a fairly objective and straightforward fashion.

Given our overall approach to foresight, with the indeterminate vision of the future as possible alternatives defined in the scenario-building step and the various complexities and uncertainties that this entails, our understanding of a gap cannot be as simple and straightforward as in the case of traditional strategic management gap analysis.

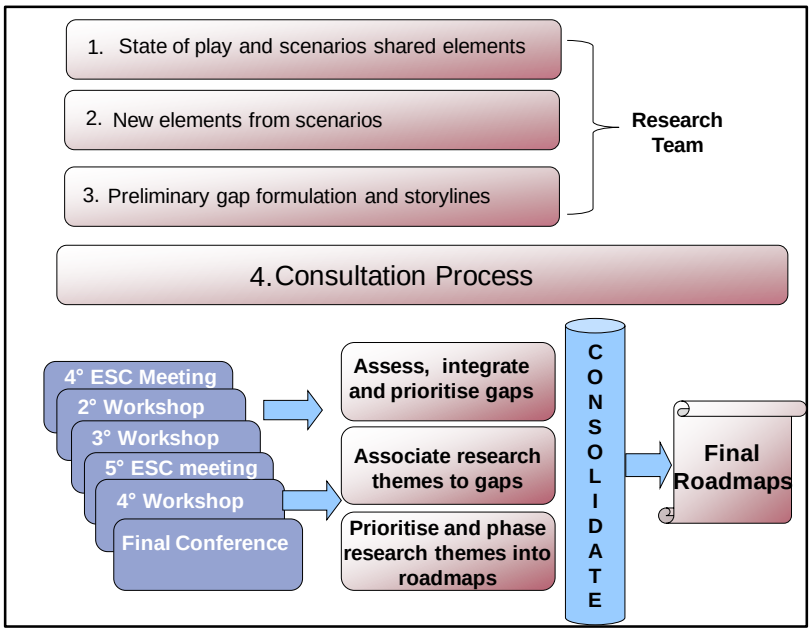
PHS2020 is inscribed in a comprehensive framework that conceives of the PHS domain as a complex and dynamic socio-technical system and as such deals with both broad visions and detailed analyses. The scenarios developed provide a set of internally coherent but alternative visions of the future introducing high uncertainties and the

[113] See in particular within the final eGovRTD2020 book: Pucihar, Bogotaj and Wimmer (2007) and Pucihar, Bogotaj, Wimmer and Janssen (2007). The eGovRTD2020 gap analysis methodology was based on a review of the relevant literature (mostly from the management discipline) from which the elements applicable to the context of policy oriented roadmapping were extracted. In this paragraph we strictly follow this discussion with slight adaptation to the PHS2020 context. Accordingly for the background literature on gap analysis the reader can consult the cited chapters in the eGovRTD2020 book (still available digitally at: http://www.egovrtd2020.org/EGOVRTD2020/FinalBook.pdf) and we do not repeat such review here.

possibility of very radical and complex changes. In this context the simple and automatic operation: SCENARIOS – STATE OF PLAY= GAP is not applicable**.**

Gaps analysis in our context entailed looking at major discontinuities, unknowns, and contrasts between the situation today (examined in the state of play) and the possible futures as envisioned in the scenarios. In our approach *a gap expresses a mismatch that emerge through a systematic comparison between the state of play and the envisioned scenarios clustered around the key dimensions of PHS2020 General Descriptive framework.* A gap may thereby refers to an issue of current research (identified in the state of play), which does not meet the needs identified by one or more of the future scenarios, or by trends that are horizontal and cross-cutting to all of the scenarios. A gap may also refers to an issue, which is not addressed at all by current investigations and not captured in the state of play, but emerged in the scenarios, or more broadly to discontinuities and unknowns not necessarily deriving from contrasting state of play and scenarios. So gaps in our approach are not simply and strictly defined differences between the 'as is' and the 'to be' status; rather they encompass different issues than can emerge by a broad comparison of the state of play with the alternative possible futures elicited by the scenarios.

Figure 53 Gap analysis and roadmapping steps



Source: Author's elaboration

The various steps illustrated in the figure above are briefly explained below. As scenarios were not an end in itself but instrumental to the successive steps of the project, in the same way the identification of gaps was done from the very beginning not as a self-contained task but with the clear goal of uncovering research needs. In a way, though separated conceptually and also in the breakdown of our project activities and consultation events, gaps analysis and roadmapping are tightly entwined.

Step 1 – Identification of common issues between the state of play and the scenarios, where current research will not meet future challenges, or where current research needs to be continued to meet them. Common issues are generally the source of gaps calling for continuation and deepening of research directions that ***have been already*** funded by the Commission in the domain of PHS within FP5, FP6 and FP7.

Step 2 – Identification of lacking issues, which are not mentioned in the state of play but emerged in the visionary scenarios for 2020. These lacking issues are generally the source of gaps calling for research directions that ***have not been so far*** funded by the Commission in the domain of PHS within FP5, FP6 and FP7.

Step 3 – Preliminary gap formulation and storylines, the issues identified in step 1 and 2 were formulated a complemented with a storyline to convey the problem scope of gaps and their implications in terms of needed research themes.

The first three steps illustrated in Figure 53 were carried out by the research team on the basis of the validated and consolidated versions of the state of play and of the scenarios reports and produced a first preliminary list of gaps with their storylines, which became the platform for the subsequent gap analysis consultation cycle.

First, during the 4th ESC Meeting (Pisa 14 July 2008) and the 2nd Consultation Workshop (Pisa, 15 July 2008) this preliminary list was further fleshed out producing a large and comprehensive list of 54 Gaps (see Table 3, Table 4 Table 5, pp. 71-78). A preliminary assessment and prioritisation of the gaps (see *infra*) was also performed during these two events.

Second, during the 3rd Consultation Workshop (Barcelona 26 September 2008) and the 5th ESC meeting experts and stakeholders were asked to assess the gaps list produced as a result of the two earlier cited events.

During these consultation events the experts were asked to assess the gaps with respect to two dimensions:

- **Type of action needed** for filling the gap to be chosen among:
    - Technological R&D themes that can be funded within the Commission FP7 and beyond;
    - Broadly defined implementation / deployment issues clearly of a non technological socio-economic nature, and/or related to technology but falling outside the strictly defined PHS domain of research (i.e. inter-operability)
- **Importance** of the gap for the future development of PHS, on a scale from 1 to 5 (where 1 was the lowest and 5 the highest level of importance). This was done bearing in mind that our primary focus was themes for technological R&D and only secondarily implementation/deployment issues.

During the cited consultation events, beside the assessment of gaps, the experts were also asked to start associating research themes and issues for implementation and deployment and to discuss their view on the gaps and the associated research themes. Accordingly, in addition to the assessment and validation of the list of gaps, we also obtained valuables

input to: a) rephrase and/or merge overlapping gaps; b) streamline and make the gap storylines more effective; c) provide a first synthetic grouping of gaps into five domains of research with associated research themes. All of this provided the platform on the basis of which the last two consultations events devoted exclusively to the production of the roadmaps were run (4th Consultation Workshop Brussels 21 November 2008; Final Conference, Brussels 5 December 2008).

Figure 54 Brown paper and post-it roadmapping building

Source: Picture from 4th Consultation Workshop, Brussels 21 November2008

During these two last events, through interactive discussion using typical post-it and brown-paper techniques, the draft final roadmaps were derived. During December 2008 and up until mid of January 2009 several of the experts consulted throughout the project sent us additional written comments on the roadmaps, which we have incorporated in the final versions presented in **Chapter 4**.

Indeed from the closing and consolidating of the gap analysis during the 5th Meeting of the PHS2020 ESC, we produced a first draft of the roadmaps report that was presented during the PHS2020 4th Consultation Workshop (Brussels 21 November 2008). Input received in that occasion were used to produce a second version of this report that was discussed during PHS2020 Final Conference, (Brussels 5 December 2008). Input from the conference and obtained also through written comments sent by experts who could not attend the conference were incorporated into the final version of the roadmap reports, whose main elements are the core content of chapter 5 of this book. Yet, in between the end of the gap analysis consultation cycle and the beginning of the one on roadmapping we also undertook and additional review of the scientific literature.

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