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Strategic Intelligence Monitor on Personal Health Systems (SIMPHS):
Structure of Available Data and New Measurement Framework with Selected Indicators

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1 Introduction

1.1 Background

Healthcare systems in EU Member States are facing a number of interrelated socio-economic challenges such as the increasing costs of healthcare, the ageing of the population, the rise of chronic diseases and the expected shortage of healthcare professionals. These challenges and the potential benefits that ICT enabled solutions and particularly Personal health Systems (henceforth simply PHS) can deliver are discussed in greater length in Deliverable D3.1. PHS are applications looking particularly interesting for delivering home care and supporting the remote monitoring of patients. In particular PHS are expected to improve quality of care, quality of life and cost efficiency of healthcare processes.

1.2 The SIMPHS project: original aim and empirical limitations

SIMPHS aim was to develop a monitor that would facilitate the understanding of the market and innovation dynamics of Personal Health Systems (PHS) in Europe.

However, the lack of a clearly defined PHS market, with clear boundaries and segments and with a shared definition of what PHS is was identified already at the start of the project as a barrier to creating a monitor. For instance there is a lack of consensus among stakeholders as to how to best define PHS; should a technological or a medical perspective prevail or should only health care and / or social care be treated or should the wider health issues such as healthy lifestyles be included?

Accordingly, a step-by-step approach has been adopted with the objective to construct a strategic intelligence monitor enabling the provision of market intelligence on the (European-based) developments taking place within PHS, with a focus on changes in the roles of the different actors in this domain. This should contribute to an improved understanding of motives, rationales, strategies, expectations and perceptions of actors on the PHS market. The original planning foresaw:

- The first phase of the project (2009-2010) to focus on the set-up of the methodological tools and instruments to provide the market intelligence as part of a Strategic Intelligence Monitor (SIM) using Remote Monitoring and Treatment (RMT), the segment of PHS unanimously considered as the most developed, to test and validate them;
- In the second phase (2010-2011) the operating version of the SIM would be used to update the data and analysis on RMT, and collect and analyse market data on other PHS segments that are of relevance for Europe;
- The third phase (2011-2012) would deal with the update of the data and analysis on all the segments already studied and will provide for a policy analysis on the Strategic Intelligence Monitor to guide policy actions to be undertaken in this domain, taking into account other activities undertaken by the European Commission to promote and support developments within PHS.

When designing the project plan we found estimates of several analysts sizing the PHS market globally at €800 million with a forecast for fast growth. After one year of empirical research on the more consolidated of all PHS segments (i.e. RMT), our understanding of the dimension of this market is radically different. The analysis of the quantitative and qualitative evidence gathered on RMT is fully presented in Deliverable D3.1, whereas the discussion of PHS market typology/segmentation can be found in Deliverable D2.3. Below we synthetically extract a few key findings and elements from these two deliverables:

- **RMT is a tiny fraction of the eHealth market**. In 2008 the RMT market in Europe was worth €127 million, which is 0.9% of the total eHealth market estimated by Rand/Capgemini at about €14 billion;
- **RMT is still mostly about pilots**. The qualitative desk and field research (i.e. country studies), as well as the interviews with stakeholders and consultation workshops, indicate that the cases of sustainable and continuous service provision are rare, and that RMT as a market lives mostly out of pilot projects' funding;
- **Fragmented also in terms of players**. The companies' analysis showed that there are very few pure RMT players mixed with a host of other ICT players of different size that are in a wait and see perspective. Some companies started as pure RMT players but then diversified in other segments of eHealth to survive. Other players make most of their revenues from basic Telecare services (i.e. Tunstall and Tesan) such as tele-assistance and tele-surveillance and alongside also provide RMT services. A corollary of this situation is that for the majority of companies the data available for constructing market indicators (net sales, operating profits, R&D expenditure, etc) cannot be attributed solely to RMT (see more on this in section 3 and in Annex II section 5);
- **PHS segments are difficult to define**. There are no robust and shared empirical and conceptual grounds on the basis of which one could segment the PHS market. Some possible more advanced segments (i.e. Ambient Assistant Living, advance PHS for remote monitoring and actuation, ICT for prevention and early detection) remain the domain of R&D with no empirical evidence of any sizeable markets emerging. The interesting trend is the convergence between social and health care also in terms of ICT supported products and services (convergence between Telecare and RMT).

In sum, Phase 1 of SIMPHS project revealed that RMT is far from being mature and as a result there is little standardised data that could be used as a steady input into the Strategic Intelligent Monitoring (SIM). Evidently in light of this context the final output of the SIM is different from what was originally planned as we explain in next paragraph and as it has been documented in the amendments to the Technical Annex.

1.3 Scope and contents of this report

The conceptual framework and building blocks of the SIM remain valid in principle and could be used in the future, provided that more data become available. They are described in Section 2, where we also explain the large body of evidence collected that is now available in the form of a structured and browsable data repository (this must be considered as part of this deliverable, although it comes as a "non document" output that can be accessed at http://is.jrc.ec.europa.eu/pages/TFS/SIMPHSdata/index.html). The scattered, fragmented, and irregular nature of the data found, makes it hardly feasible to develop the planned dynamic components of the SIM as a true database. The building blocks are excel files, word and pdf documents, the elements of which are not specifically related among themselves and cannot be made functionally linked into a database. For the same reasons we can only provide the conceptual set up of the SIM and we do not provide, as planned earlier, an adapted SIM. In other words, the SIM is a simple data repository rather than the complex database envisaged at the time of writing the Technical Annex. A corollary of this is that there is now difference between the two earlier envisaged separate deliverables:

- D1.1 Draft report on the overall structure of the Strategic Intelligence Monitor;
- D1.2: Report on the overall structure of the Strategic Intelligence Monitor.

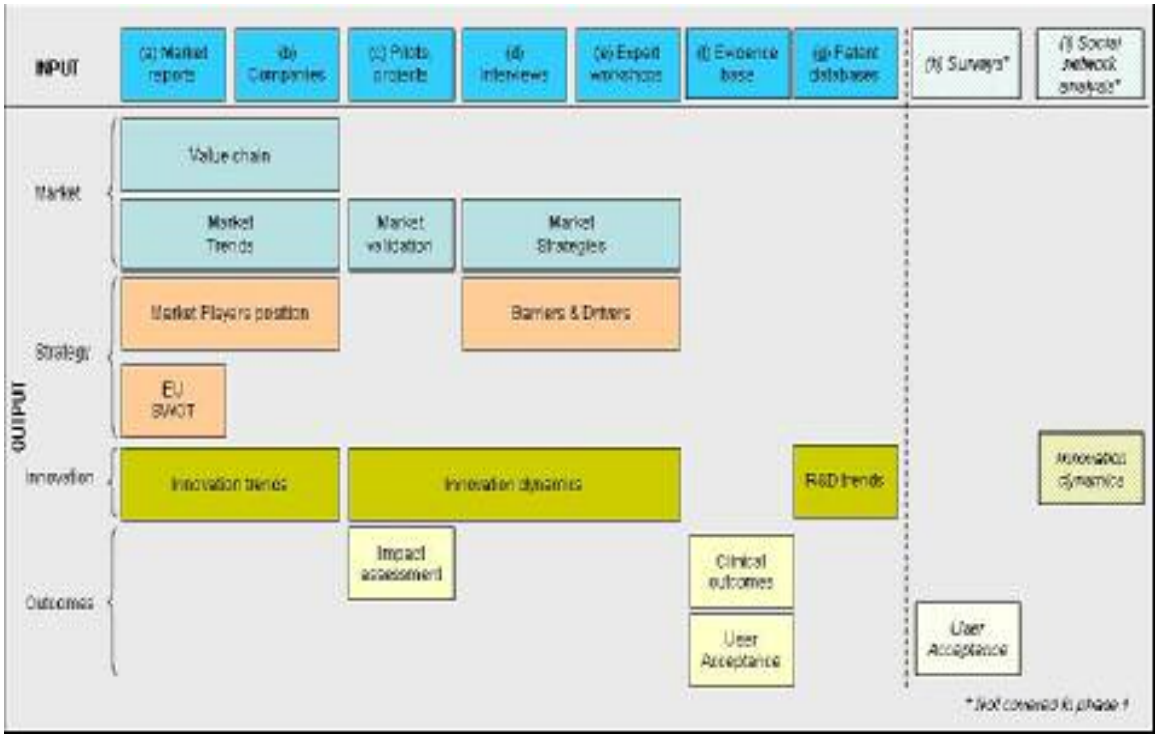
The draft report and final report describe the same elements, since the initial and the actual SIM are the same; hence the two deliverables are redundant. The present Deliverable D1.1 is sufficient to describe the SIM.

The same reasons why the empirical evidence did not support the SIM as a database also prevent the extraction of indicators from the SIM. On the other hand, since this was requested, we present in this deliverable a general proposal for evaluation and measurement indicators, which may be useful and be applied in the future. The indicators are presented contextualised within a discussion of evaluation and measurement (general and specific to RMT) and they are, thus, not related to the evidence in the SIM. Actually, the overall framework proposed could be used to design a new SIM if more empirical evidence becomes available when and if RMT services are eventually taken up and the market matures. This discussion of evaluation and measurement is presented in Section 3 and focuses on the healthcare system perspectives. For reasons that will become clearer later and are also explained in Annex I (included as Section 4), we kept market indicators separately and presented them in Annex II (included as Section 5) together with data we were able to find on some of them for the 50 companies analysed in greater details in Deliverable D3.1.

2 Strategic Intelligence Monitor – SIM – Building Blocks

Figure 1 below represents the types of building blocks originally proposed in the SIMPHS Project Technical Annex, which provided a starting point for setting up the SIM the ultimate goal being to facilitate the analysis of the current state of the PHS/RMT market and its innovation dynamics.

Figure 1: SIM set-up: input and output building blocks



Source: Authors´ elaboration.

As input we refer to all data collected during the SIMPHS project research, which encompasses data of different nature.

2.1 Market reports

Quantitative data on market shares, sales revenues, and market growth projections are the type of data we expected to find in off-the shelves reports provided by analysts. After a thorough review of potential sources worldwide, we could not find any market analysis focusing specifically on the PHS market. This can be explained by the nascent nature of PHS whereby the boundaries of PHS as a market segment are not clear nor are PHS an agreed term among market players.

We reviewed 18 reports content summaries from 13 different providers, covering topics like TeleHealth, wireless health, telemedicine, remote monitoring, vendors etc. In terms of RMT, where e.g. vital signs measurement devices have been available on the market for longer, only a handful of sources out of the above appeared to be of potential relevance for the SIMPHS research and the following reports were acquired for review:

- "European Remote Patient Monitoring Market" (Frost & Sullivan 2008);
- "Global Patient Monitoring Investment Opportunities Analysis and Forecasts to 2015" (GlobalData 2008);
- "Europe Remote Patient Monitoring 2009" (GlobalData 2009);

- "European Global Self Monitoring Blood Glucose Market 2009 (GlobalData 2009);
- "Global Respiratory Devices Market 2009" (GlobalData 2009);
- "mHealth and Home Monitoring" (Berg Insight, Second Edition 2009);

The Frost & Sullivan as well as the GlobalData reports provide analyses of RMT market developments, future trends, and growth potential, and analyse the market position of main actors dealing with different parts of the remote patient monitoring value chain. The reports also provide estimates of current market size and projections until 2012-2015. However the lack of comparability of data and of overlap between the segmentation adopted in each report as opposed to the definition of PHS/RMT in the SIMPHS study make it difficult to draw conclusions for the RMT market based on these reports. Nevertheless some conclusions on the potential size of the market could be extrapolated from the analysis of the data and are presented in Deliverable D3.1.

The "mHealth and Home Monitoring" has a stronger qualitative focus but nevertheless contains relevant market data such as market size and growth rate on home monitoring segments such as cardiac monitoring, air flow monitoring and glucose level monitoring, which are within the scope of the SIM. However the quantitative data mainly focuses on the relative importance of the US versus European market per segment; it also provides indications of revenues for the most important players on each segment. Further the report contains qualitative data on a number of issues including:

- Description and global prevalence of the various types of chronic diseases that can benefit from wireless monitoring devices;
- Short description of main players in the various segments of mHealth and home monitoring;
- Overview of technology trends in health monitoring especially through mobile applications;
- Analysis of Telecom and IT industry initiatives and potential for growth for these players Concluding remarks on market analysis, market drivers and catalysts as well as recommendations for mobile players.

The main findings of all the above reports are presented in more detail in SIMPHS Deliverable D3.1. The reports are currently kept as stand-alone PDF documents in the SIM repository.

While the above reports provide interesting indications and order of magnitudes of current size and expected growth for specific segments, the difficulty to compare data and the lack of data on PHS as such make it difficult to obtain a very accurate picture of the PHS/RMT market size. The only way to obtain data on market shares and growth projections that are suited to RMT and/or PHS as considered in the SIMPHS would be to commission a specific study from one of the analysts, which was not possible within the existing SIMPHS budget. Alternatively, a simulation of market growth based on the collection of data on prevalence and pricing of PHS/RMT could be envisaged for the next phase of the project.

2.2 Desk research on companies

In order to get a better understanding of the type of market players active on the PHS/RMT market, we proceeded to identify companies active in the eHealth or Health IT sector in general so as to narrow down to RMT in a second step, through desk research. Based on the review of specialised conference attendance lists, the above market reports, health IT newsletters and websites as well as further online sources, we set up a list of 200 companies which we checked against the following criteria.

Company name	Locations and subsidiaries	Nr of employees / size in other metrics	Nr of years in business	Geographical focus	Market segments / main focus areas	Products

Value chain focus	Url	Financial and operational review	Partnerships and alliances	Strategy	Comments

Some of the categories ended up being difficult to populate such as financial operational review, partnerships and alliances and strategy. However the overall data collected helped us select a sub-set of 50 companies that seem most relevant for further research and inclusion in the SIM.

Data was then collected on this subset of 50 companies following the template below. The list of companies reviewed and captured in the SIM can be found in Annex II of this report, whereas a more detailed analysis is provided in Deliverable D3.1.

Table 1: Template of company data

Company name					
Country of origin					
Geographical activity	World	USA	Europe	if so: which country/ies	
Market size (Year: EUR)					
Venture Capital (firm/organisation: EUR, year)					
# of YRS in business	0 - 2	2 – 5	5 - …		
# of employees	Small (0-49)	Medium (50-499)	Large (500 - …)		
Disease perspective	Cardiac	Diabetes	COPD	Co-morbidity	Others
Technology perspective					
Devices	Vital sign monitoring	Intervention device	Medical platform	Communication device	
Infrastructure	Networks	Protocols	Standards		
Software	Vital signs DP	Vital signs diagnostic software	Personalised feedback	Educational content	
Systems integration	Value chain integration	Back end integration			
Services perspective					
Monitoring health conditions	Monitoring vital signs	Implants			
Clinical intervention	Call centre	GP	Hospital	Homecare	
	In home/Outsourced	Supporting service	Supporting service	Supporting services	
	Emergency alerts	Emergency alerts	Emergency alerts		
Guidance and education	Provision of direct patient feedback	Provision of educational content			
Clinical Information Services	Connection to EHR	Connection to HIS	Connection to PACS	Connection to billing	…
Alliances/networks/cooperations	Business partnerships	Industry associations	Joint ventures	Spin-offs	Mergers & Acquisitions
Projects					
Contact Person					
Websites					
Comments					

Source: Authors´ elaboration.

2.3 Desk research on pilots and projects

The next building block refers to data collected on the various pilots and projects going on at EU, national, regional and local level as well as other relevant national initiatives. The data has been structured into separate worksheets for projects, pilots, and assessment by national agencies (such as HTA), projects at national level, populating the following criteria:

Projects

Project Name	Partners involved	Type of activity	Start & end date	Geo scope	Condition (e.g. heart, diabetes, COPD…)	Focus incl. type of innovation addressed	Outcomes

Pilots linked to project	Part of the value chain addressed	Industry developments	Contact name	Website

Pilots

Pilot Name	Funding	Type	Start & end date	Geo scope	Condition (e.g. heart, diabetes, COPD…)	Focus incl. type of innovation

Number of patients	Short description of pilot	Technology /solutions used in RMT	Outcomes & Impacts	Contact name	Website

RMT Assessment by agencies

Study Name	Organi-sation	Geo scope	Date	Focus	Condition	Nr. of patients	Outcomes	Link to sources	Website

National RMT policy/strategy:

Study Name	Geo scope	Date	Focus	Link to sources	Website

2.4 Stakeholder interviews

Stakeholder interviews have been carried out directly by IPTS, or as part of the country study which consisted in: (a) characterising the healthcare and social care context in which RMT unfolds so as to (b) identify key stakeholders in various domains (e.g. healthcare professionals, payers, industry players etc.); and (c) unveil the stakeholders' perception of the PHS/RMT market, their expectations for its future development and their strategies to position themselves on this market. The resulting country reports are stored in the SIM and address the following elements:

- The National Healthcare System
- Management of chronic conditions
- PHS and RMT Market: Stakeholder Interviews
- RMT in Social Care Context
- Patient Empowerment – Vision or Reality?
- Conclusion and summary

- A contractor has carried out stakeholders' interviews in France, Germany, Sweden and the UK while IPTS addressed the Netherlands and Italy.
- Country report Germany
- Country report Sweden
- Country report France
- Country report Sweden
- Country report UK
- Country report Netherlands
- Country report Italy

2.5 Expert workshops

In parallel further qualitative information was gathered through stakeholders' workshops and face-to-face or phone interviews. The information is kept in the minutes of the various events. The data collected could be structured along the following main themes, for each of the stakeholders:

- Company size and presence
- Funding
- Targeted health conditions
- Products, services and technical solution
- Market focus, market size
- Revenue streams
- Reimbursement
- Evidence
- Certification
- Research and innovation activities
- Partnerships

2.6 Evidence base

RMT systems have been assessed in scientific literature reviews, clinical trials, randomised controlled clinical trials, but also cost-benefits analyses, system reviews and other types of studies. As the success of PHS/RMT implementation is linked to outcomes in terms of efficiency and clinical benefits in particular, it was deemed necessary to collect data on the various types of assessments that have been carried out so as to gather knowledge on outcomes. The data is structured as follows, with separate worksheets for each condition (CHF, Diabetes, COPD and co-morbidity):

Study Name	Type of study	Partners/ Authors	Start & end date	Focus	Objectives	Outcome

2.7 Patent databases

A patent analysis has been performed in order to analyse R&D activities and trends from a patent perspective. Two databases were tested, by doing searches on a trial and error basis. Only one of the two databases yielded relevant results and was therefore used for final analysis, the World Intellectual Property Organisation database while Patstat was eliminated. The SIM input consists in the outcome from the search via the WIPO interface called Patent@Scope.

2.8 Surveys

When designing the project proposal, it was deemed important to look into user surveys, including patients and healthcare professionals, in order to gather data and knowledge on acceptance of PHS/RMT. While a number of eHealth surveys were identified, they do not address PHS and RMT specifically. Although patient organisations for instance have an interest and get involved in telemedicine and related issues, none of the organisations we talked to have undertaken any specific survey on PHS/RMT. The main reason for this is their need to prioritise resources in the huge field of health and eHealth, and PHS/RMT, although considered important, is not the top priority. In terms of healthcare professional as users of PHS/RMT systems, no survey focusing on PHS/RMT could be identified.

Designing a user survey could be one goal of SIMPHS in the future, however reaching out to a group of patients or users of significant size may be difficult as the market for RMT/PHS is still in early stages of development. Further considerations may be needed before launching such a survey.

2.9 Social network analysis

A social network analysis was suggested in the design phase of the project in order to unveil relations between stakeholders, understand better the strategies they may pursue and contribute to building knowledge on the innovation dynamics on the PHS/RMT market. However because the PHS/RMT market is in an emerging stage it is too premature to analyse relations on a number of stakeholders that is too limited to lead to meaningful results. Such a study should be envisaged in future stages of the SIMPHS research.

2.10 Output from the SIM

Figure 1 shows the types of output that the input building blocks described above contribute to. They can be split in four main themes enabling the analysis of different aspects of market structure and innovation dynamics on the PHS/RMT market:

- **Market:** this building block covers the detailed understanding of the PHS/RMT value chain, the description of market trends, the activities carried out in terms of market validation through projects or pilots, and the strategies stakeholders follow to enter the PHS/RMT market or consolidate their position on this market. The input building blocks contributing to building market knowledge are Market reports, Companies review, Pilots & projects as well as stakeholders' interviews and experts' workshops;
- **Strategy:** covers the understanding of the positioning of market players on the PHS/RMT market, the barriers and drivers influencing their position and development, as well as a EU SWOT analysis. The input building blocks feeding this theme are the Market reports, Companies review, stakeholders' interviews and experts' workshops;
- **Innovation:** covers the understanding of innovation trends and dynamics, as well as R&D trends and focus; this is fed by all input building blocks except the one on Evidence base**;**
- **Outcomes**: cover the cost-benefit assessment of implementing PHS/RMT systems, as well as the impact on clinical outcomes (e.g. reduced hospital stays, better quality of care, of life…) and user acceptance. This dimension is covered mainly by data on pilots and projects, and the evidence base building blocks.

3 Indicators in Context: Evaluation and Measurement

Indicators are the last operational step defined within a system of evaluation and measurement, and before defining them there are a number of pillars upon which such a system of evaluation and measurement should be built that must be addressed:

- The definition of key concepts and of a general model of evaluation
- The unit and level of analysis of the system;
- The purposes for which the system is set up;
- Which stakeholders/beneficiaries the system considers;
- The temporal dimension of evaluation and measurement.

For the reasons illustrated in the introduction, there is no longer a direct and automatic relation between the SIM findings and the indicators for the PHS/RMT context. It was nonetheless requested that some indicators be defined, without however, basing them on a context and purposes for which these indicators were required. Accordingly before providing our proposal in § 3.4, we needed to establish such context in 3.1and 3.2, which address the five pillars above. Additionally we also briefly present a state-of-the-art on evaluation and measurement of eHealth and identify a few challenges preparing the grounds for our proposal (§ 3.3).

In § 3.1 at a very general level we first define the key concepts (3.1.1), next we discuss the differences between the public sector and the private/market sector (3.1.2) justifying treating market indicators separately (see also Annex I), and we provide a very general and generic model of evaluation in the form of the logic framework (3.1.3, see Figure 2, p. 18). Such framework, however, is only a very general model of evaluation, which needs to be fleshed out in relation to each specific domain of evaluation. The model of evaluation establishes the documented (empirically) or hypothesized (on the basis of theory, tacit knowledge, and common sense) causal relations linking the outputs to outcomes and impacts. We discuss this in more detail when dealing with the domain of RMT (see in particular § 3.4.3).

In § 3.2, still moving at a very general level, we discuss the unit and level of analysis (3.2.1), the purpose of evaluation and measurement (3.2.2), the need for a multi-stakeholders perspective (3.2.3), the temporal dimension of evaluation and measurement (3.2.4), and we conclude with a summary snapshot of how an ideal system would look like (3.2.5, see Figure 6, p. 27).

After the brief state-of-the-art review in § 3.3, in § 3.4 we present the proposed framework and related indicators considering all of the pillars established in § 3.2: the unit/level of analysis, purpose and stakeholders, evaluation model and measurement indicators, overall framework and processes.

The contents of this section are based on the consolidated experience and expertise of our experts in the field of evaluation and measurement, which include full command of the relevant literature that has been only selectively reported in § 6 and cited in the text.

Finally, we need to explain what we mean by the two expressions “evaluation and measurement model” and “evaluation and measurement framework”. The model concerns the key causal relations (assumed or already empirically known) existing among all or some of the key variables considered. The model shapes the definition of the indicators to be measured. The model, the indicators, the unit/level of analysis, the stakeholders and beneficiaries addressed, the measurement techniques, the different phases (i.e. *ex ante*, *in itinere*, *ex post*), and the organisational processes and responsibilities, are the components that taken together constitute the Framework.

3.1 Key concepts, public sector versus market, logic model

3.1.1 Key concepts

We will use throughout this section terms such as input, output, outcome, and impact that we illustrate in a general way here using standard definitions adopted in field of evaluation and measurement. This clarification is not simply a terminological matter but has methodological implications, as we explain further on in this paragraph.

Input. It refers generically to what goes into the production of an output by way of the processes and activities carried out to this purpose. It includes both the tangible and direct budget costs as well as indirect and intangible efforts and costs. An extended view of input includes also the higher-level antecedents leading to the decision to invest into the production of a given output such as strategic objectives, policy guidelines but these however, were kept outside the definition of input.

Output. This refers to the direct product resulting from the activities and processes put in place to transform the input. We can reasonably affirm that the production of an output is to a large extent under the direct control of the generic organisational producing unit in charge of it (although it can be influenced by internal arrangements and potential resistances).

Outcome. It generally refers to the direct short and mid term changes (improvements) for well delimited constituencies (beneficiaries/ stakeholders) that can be attributed to an output. One can also distinguish between direct and intermediate outcomes depending on their temporal or logical distance from the output. The occurrence of an outcome is not entirely under the control of the producing unit and is influenced to various degrees by external factors and intervening variables.

Impact. The term is used to indicate broader and aggregate longer term changes for economy and society as a whole (generally resulting from the accumulation of outcomes as defined above). The link between an output and an impact is evidently mediated by the outcomes and very difficult to prove empirically, as the number of external factors and intervening variables increase substantially.

3.1.2 Differences between the market and the public sector domains

The differences between measuring market situations and the public sector and the peculiarities of the latter are illustrated in greater details in Annex I (included as Section 4). Below we briefly summarise them and provide some illustration.

The most basic and straightforward difference is that companies and markets can use for measurement purposes the standard and ready available metric provided by market prices. Prices can be applied to measure the input, the output (value of production in stock) and, naturally, the most direct outcomes (sales and eventually profit). Since consumers in the market have several alternatives among which they can choose, if they elect to buy for a price X the good or service Y to some extent we can assume that the acceptance of the price also reflects an appraisal of the quality of the good or services purchased. If they are dissatisfied, next time they can chose another good or service (so called exit mechanism).

The same does not apply to the public sector domain, where the only ready monetary measure is usually the value of aggregate expenditure and where, most often, there are no exit mechanisms

since the public actor operates in condition of monopsony.[1] Even with respect to the input, we must stress that in the public sector its quantification in monetary terms it is often more challenging that one might think and it has been shown that frequently in the evaluation of public programmes a full quantification of costs is lacking.[2] Public sector outputs, if measured at all, are quantified at best in volume metric. The lack or presence of price shapes also how quickly one can measure the most short-term outcomes. A company operating in the market produces an output and then tries and sell it. The total revenues the output generates can be considered a short-term outcome, for its occurrence is not entirely under the control of the company (despite marketing and commercial efforts the output may not find a demand due to a number of external factors the company cannot entirely control). Yet, at the end of a given time period it will be easy to extract from the accounting system the value of the outcomes "revenues" and "profits" and extract from them all sort of market ratios indicator (in combination with other internally available metrics such as cost of labour, cost of other input, investments in R&D, etc). No matter how many other intervening variables shaped final revenues, from the company perspective this outcome can be attributed to the output (for the sake of simplicity we assume that either the output includes also the supporting commercial and marketing efforts or that the latter are incorporated in the measurement of input). In the case of public sector output this is not possible and the attribution of even the most direct and short-term outcome to an output is methodologically more time consuming (see *infra*). The discussion so far can be well summarised in the following quote from the latest OECD report on the efficiency improvement produced by the introduction of ICT in the healthcare sector:

> *"In the health sector there is often no measure of performance analogous to profits for private sector firms. While a non-healthcare business selecting its investments in ICTs might consider only financial return on investment, health care is a sector that places an unusual emphasis on non-financial goals. In health care, a standardised production process is difficult to identify, and, depending on the care setting, there is considerable variation in how and what outputs are produced, and what type and mix of inputs are used to produce them" (2010: p. 35)*

The considerations on the difference between the perspective of the healthcare system and the perspective of the private/market sector justify our choice to focus mainly on evaluation and on measurement indicators from the perspective of the healthcare systems, and treat market indicators separately in Annex II (included here as Section 5).

3.1.3 The logic model and methodological implications

The logic model depicted in the figure below is how evaluation and measurement are conceptualised at a general level of abstraction in the relevant literature (see among others Algemene Rekenkamer 2006; Boyne and Law 2004; Codagnone 2009a; Codagnone and Undheim 2008; van Dooren et al. 2006; Hatry 1999; Johansen, 2004; Irani et al, 2005, Heeks, Molla, 2009; OECD, 2007a).

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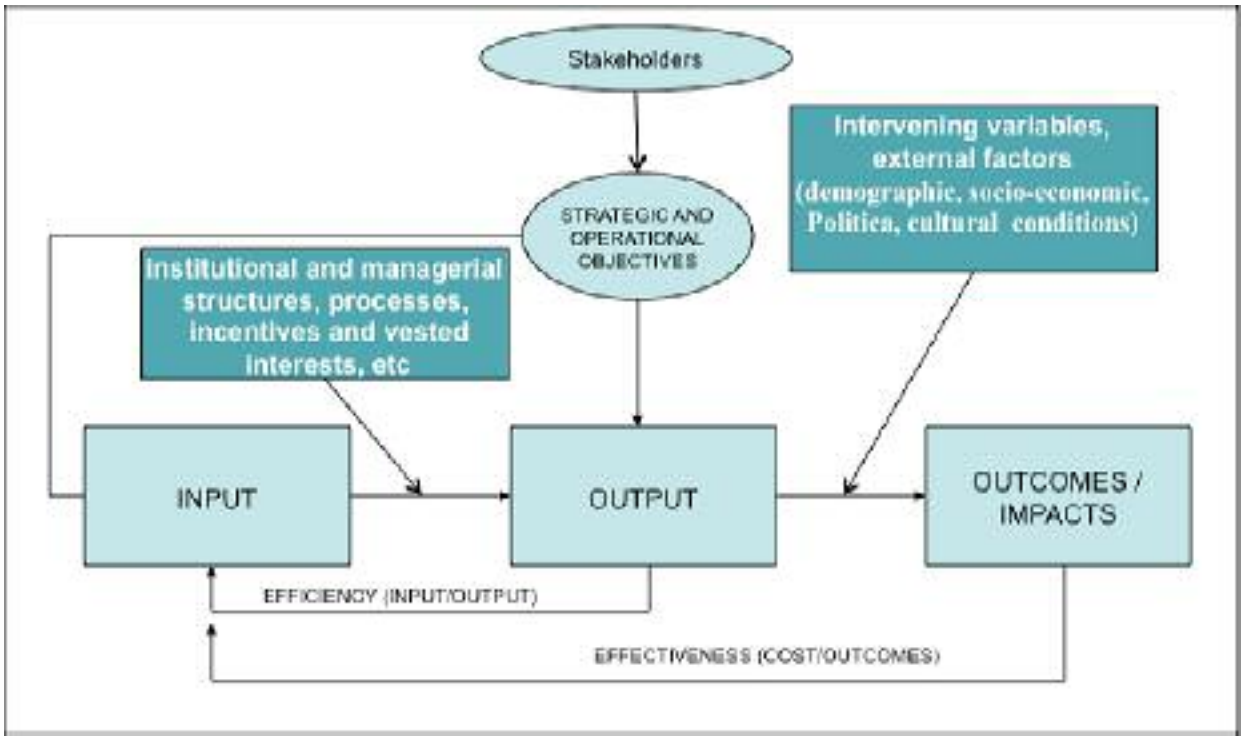
1 Indeed, in the health sector and in the educational sector there are market alternatives to the public offering, but these are limited to the small pool of well-off individuals who can pay out of their pocket for these essentially public services.

2 See, for instance: Johnstone et al. (2005).

Figure 2: The logic framework of measurement



Source: Authors´ elaboration.

This model tells us, among other things, that as we move from input toward impacts, the number of intervening variables one has to control in order to measure increase. The methodological implication of this is that while input and output can be measured in relatively simpler ways, the attribution of an outcome (and more so of an impact) to an output is much more difficult especially in the context of the public sector[3] where we lack the ready available measure of prices and of a market mechanism. As stated in one of the most complete and comprehensive recent comparative study of public sector performances:

> *"It is often more difficult to relate production processes directly to effects (outcomes) than to output. It is, therefore, useful to distinguish between objectives that can be measured objectively via the final product and deeper, underlying social objectives" (SCP 2004: p. 39).*

In the public sector to attribute an outcome to an output in scientifically and empirically robust way one would have to demonstrate that there is a true causal relation and not a spurious correlation. An output and an outcome may be correlated but they could be both caused by a third not observed intervening variable. This is a question concerning the debate as to what extent evaluation done for policy purposes and disseminated to the public are scientifically valid, a classical topic on which relevant contributions date back to the '60s (for instance Campbell 1963 and, especially, 1969).

Methodologically a robust relation between an output and an outcome requires experimental design (the randomised assignment of the beneficiaries to a target group receiving the output and to a control group not receiving it) or the application of statistical and econometric techniques to large longitudinal and cross-sectional datasets.

[3] For instance, in the market, a product is steadily bought at a certain price; we can assume that this reflect the fact that consumers are satisfied with its quality; the same does not apply in the public sector.

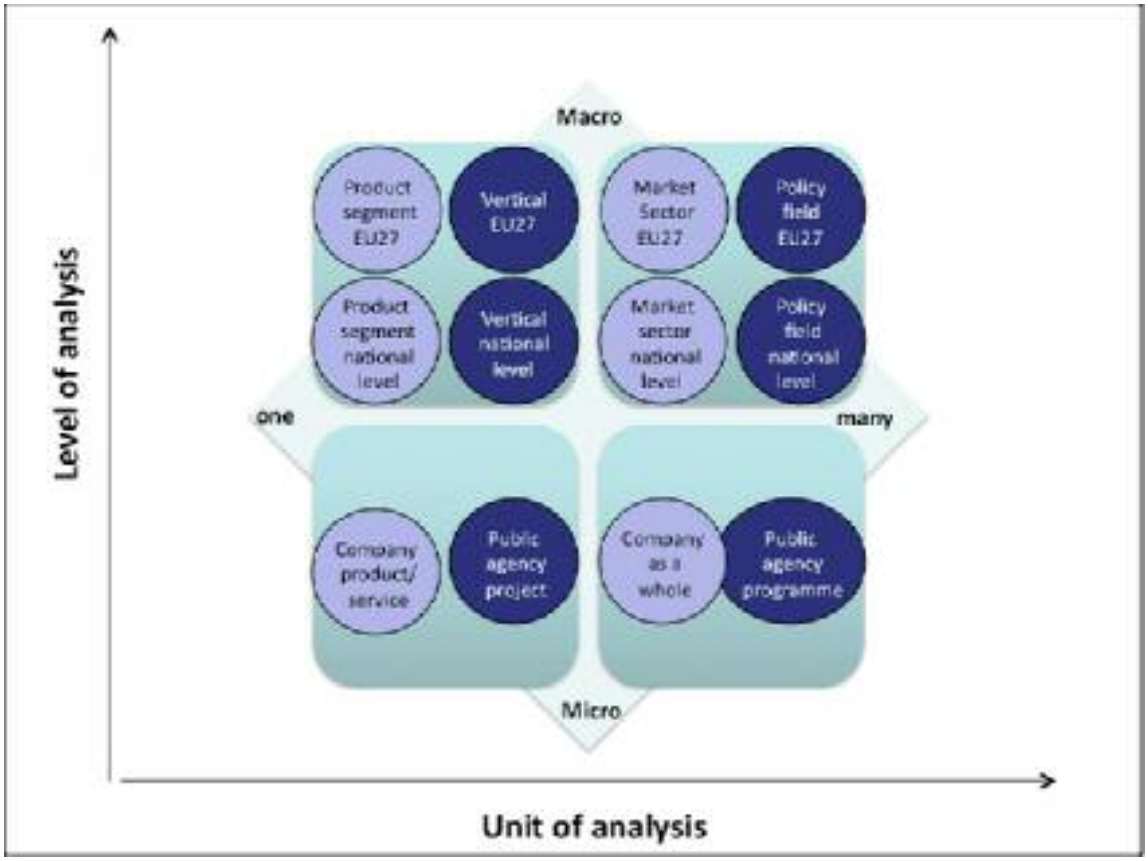
Assuming, but it is a strong assumption, that reliable and robust measures of all the elements in Figure 2 are available, then one could calculate standard efficiency, cost-effectiveness, and effectiveness ratios. As we show later, the question of robust measures of outcomes consensually accepted by all stakeholders is a thorny issue in general and especially in the field of PHS/RMT.

3.2 The pillars of evaluation and measurement

3.2.1 Unit and level of analysis

In Figure 3 below we present a simplified and illustrative typology of both the unit and level of analysis that suffices for our purpose here.[4] The unit of analysis can vary from a single project/service (one) to a bundle of projects/services (many) as for instance those of a public programme or portfolio of projects/services or the entire offering of a company (which can include different lines of products/services).

Figure 3: Exemplificative typology of unit and level of analysis



Source: Authors´ elaboration.

The level of analysis can either be micro (one single public sector producing unit, one single company) or broadly defined macro in the sense that it aggregates the micro level into a regional, national and eventually EU27 levels of analysis.

[4] A fully comprehensive typology, especially for the public sector would require to distinguish not simply from the local to the international level of aggregation, but also in terms of different sectors at the same level. So one could distinguish between different sector within the same tiers of government (i.e. tow ministries at the same national level, or two departments at the same regional level, and so on) and between different tiers of government (local, regional, national, etc).

The unit/level mix one selects has clear implications in terms of the data required for measurement, their comparability, the cooperation needed from different players and, thus, the overall feasibility/difficulty of evaluation and measurement. We discuss these issues below separately for the public sector and for the private/market sector.

The simplest and relatively less complicated unit/level mix is that represented in the bottom left box where the focus is on a single projects/service of one public sector producing units. As we move to the bottom right box the mix gets slightly more complex as data for different projects/services must be aggregated and evaluated jointly. Yet, this level of complexity remains manageable. At these two levels one can probably get the more in depth and precise kind of evaluation and measurement analyses and data. As we move to the upper part of the matrix the difficulties increase exponentially. In a way the upper part of the matrix concerns the much-debated topic of applying the benchmarking approach to the public sector and particularly that of EU27 benchmarking within the framework of the Open Method of Coordination.[5] Only in principle one could expect that the aggregation of data from the lower level mix of unit/level of analysis could smoothly result in aggregate level data for benchmarking. In practice this is not so for various reasons among which we can mention the following two as the most important ones:

- **Cooperation/ compliance.** Ensuring cooperation and compliance from the lower level layers upon which the benchmark is imposed and which must provide data is not that easy. Since evaluation and measurement is time consuming and requires some real commitment and awareness about its merits, it would be naïve to expect to all relevant public sector producing units have a steady and ongoing system of evaluation and measurement in place from which easily extract the required data. They would need to do an ad hoc work, which is unlikely to be performed unless mandatory by law or by the funding mechanisms**;**

- **Comparability of data**. The more sophisticated public sector producing units may have a system of evaluation and measurement in place defined for their own purposes in many cases before the higher level benchmarking is launched. The chances are very high that the objects, definitions, data gathered by these micro level evaluation and measurement systems do not coincide exactly with those of the higher level benchmarking and differ across different producing units. Under these circumstanced making micro level data comparable for a higher level benchmarking is a daunting task.

The difficulties with these two dimensions may still remain manageable at the regional level of aggregation, but they become unmanageable at the national and international level. Not surprisingly most national and EU27 benchmarking exercises are outsourced to consulting and market research companies. The companies produce the benchmarking using a mix of web based search and telephone surveys, responding to simply binary (yes/no) or ordinary scale type of questions. The results of such benchmarking tend to be shallow as width is achieved at the expenses of depth.

In the private/market domain things are simplified by the existence of the ready-made and standardised metrics represented by market prices. If we want to look at aggregate market indicators for a NACE industry or sub-sector we can easily find data[6] for all EU27 countries on items such as R&D expenditure and number of employees (input), volume of production (output), net sales and

[5] Benchmarking of the public sector is not an entirely new trend (i.e. Dorsch & Yasin, 1998), but within the EU policy context it has acquired a new importance within the 'Open Method of Coordination' (OMC), upon which the Lisbon Strategy rests. Within the OMC, benchmarking plays a "quasi-regulatory" role (with its merits and pitfalls, see for instance De la Porte et al 2001; Dolowitz 2003; Dolowitz and Marsh 2000; Kaiser and Prange, 2004; Kastrinos 2001; Lundvall and Tomlinson 2002; Radaelli 2003; Room, 2005).

[6] For instance Eurostat Structural Business Statistics or the innovation scoreboard published by the DG ENTR of the European Commission.

operating profits (outcomes), etc. These can then be used for the calculation of standard market ratios (i.e. R&D/operating profit, and the likes).

A different issue is, however, to get data for specific services/products within the overall offering of companies included in a given industry category. The industry level sources provide aggregated data only and do not collect data broken down by line of offering. Large and medium size companies surely have sophisticated accounting systems providing granular data for all the different products / services they produce, but they usually make public only aggregated data from their accounting system (total revenues), since the more granular ones are considered confidential. As we show later, these considerations are very relevant for RMT for this "market" is not reflected in any NACE classifications. We come back to these issues briefly in Section 5 where we list the market indicators proposed and we illustrate the kind of data we were able to find.

3.2.2 The purposes of evaluation and measurement

The six possible purposes for which a system of evaluation and measurement may be set up are graphically illustrated in Figure 4 below.

Figure 4: The multiple purposes of evaluation and measurement

Source: Authors´ elaboration.

- **Compliance**. This can be seen from two different angles: (a) in the boundaries of national governmental and democratic processes it refers to the classical form of government control namely the procedural correctness in the usage of public funds where data on evaluation and measurement can help government respond to the questions raised by the controlling bodies (i.e. auditing courts in continental Europe and watchdogs responding to the legislative branched in the Anglo-Saxon model such as the National Audit Office in the UK), or vice versa are independently gathered and used by the latter to control the former; (b) in the context of EU level policy making process evaluation and measurement can provide input to benchmarking as the main instrument to ensure compliance with commonly agreed objectives within the WTO (World Trade Organisation);
- **Accountability**. It is of the uttermost importance that those using public funds account to their higher-level institutional stakeholders and to the public as a whole about the efficiency

and effectiveness outcomes they produced for specific constituencies and for economy and society as a whole. Evaluation and measurement clearly support this purpose;
- **Self-legitimating**. It is a quintessential private technique, that of using measurement data into scorecard systems. Lately this has been increasingly adopted in the public sector by executive branches for institutional communication and political campaign purposes;
- **Policy/decision-making**. Prospective evaluations (i.e. business cases) can support the decision making process both at macro (overall national policy or investment decisions) and micro (an agency deciding on a project) level. While often performed as a sort of "shooting in the dark" activities, their accuracy would benefit from consolidated past evidence such as that used for accountability purposes;
- **Management/monitoring**. Data from evaluation and measurement can be an invaluable source of insight for those responsible for the implementation of projects to monitor the status of delivery and take management decision in case of deviations from the work plan;
- **Policy learning**. Partially, this is the result of the use of evaluation and measurement in support of all the previous five reasons. While this is basically correct, true policy learning requires instruments going beyond evaluation metrics and indicators to explain the processes and reasons behind a given level of produced effects. One such instrument is benchlearning, which is no further treated in this document as it is outside of our scope.

A very systemic and comprehensive approach to evaluation and measurement would probably provide support and data/information for all of the above purposes. Needless to say, however, the six purposes may have in common a basic set of data/indicators but would also require ad hoc ones. In the presence of budget constraints, indicators should be defined and calculated in view of which of the purposes above takes priority over others.

3.2.3 The need for a multi-stakeholders perspective in the public sector

Also in the private sector one could think of a complex system of stakeholders (especially from the perspective of Corporate Social Responsibility). Yet, this is an option rather than a necessity in the private context. On the contrary, in the public sector a multi-stakeholders perspective is necessary.

The international literature (see, for instance: Johansen, 2004; Holzer and Kloby, 2005, Estevens and Rhoda, 2007; Sluijs et al., 2008) converges in placing the "beneficiary" of a proposed project and/or of a service already being provided at the centre of evaluation and measurement. The literature also converges in distinguishing the ***beneficiaries*** as those more directly addressed/involved by/in the project/service, from the wider set of ***stakeholders*** who can be also impacted positively or negatively by the project/service without being directly addressed by, or involved in, it.

We define and exemplify the various categories below. In order not to anticipate here the specificities of PHS/RMT, the exemplification are made with respect to the contiguous domain of Ambient Assisted Living (AAL) services of tele-control and tele-surveillance (assuming no medical services entailed).

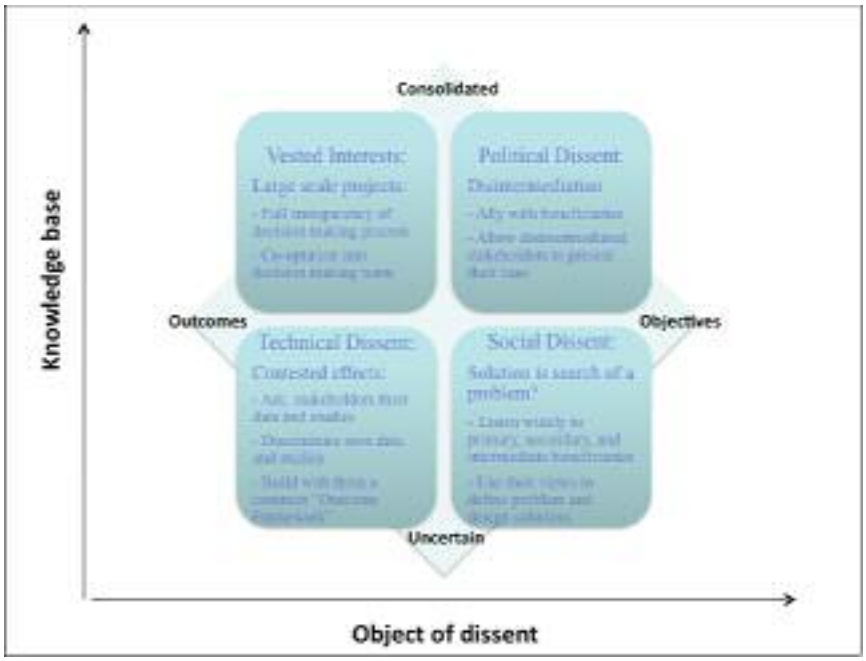
- **Primary beneficiaries**: final users for whose needs, interests and well being a project is launched or a service is provided – example: the elderly addressed by a AAL service;
- **Secondary beneficiaries**: individuals indirectly improving their situation as a result of the benefits produced for the primary beneficiaries – example: the relatives and friends of the elderly receiving the AAL services;
- **Intermediate beneficiaries**: in some cases the service may need the intervention of an intermediate body or of professional intermediaries before it reaches the primary beneficiary – example: the AAL service is set in place by a regional authority and made available for

use by local municipalities, which in turn need for its activation professional carers, so we have:
    - **Institutional intermediate beneficiaries**. The local municipalities are both service providers and beneficiaries of the regional initiative, for they can improve their image and legitimacy among their constituencies by providing such services;
    - **Professional intermediate beneficiaries**. The professional carer is also both a provider and a beneficiary as long as the service improve his/her work (simpler, more efficient, more effective, more gratifying, etc)
- **Institutional stakeholders**: the higher level authorities deciding the provision of a service and the agency funding the project leading to its provision (the two can be part of the same body or can be separate) – example: in the case of the AAL service (assuming national general funding of social care and regional investments decisions) the institutional stakeholder for the region is the national social welfare ministry, the institutional stakeholder for the regional social care department deciding to launch the AAL service is the regional government, and the institutional stakeholder for the municipalities is the regional social care department;
- **Suppliers**. The realisation of a project and, subsequently, the provision of the related public service may require the outsourcing of a large part of activities to external private sector suppliers. Once selected according to public procurement rules, the supplier becomes part and parcel of the system of evaluation and measurement;
- **Other stakeholders**. This category includes organised stakeholders who may be positively or negatively affected by the decision to launch a project and by the eventual service provision resulting from it. They can include industry organisations, associations allegedly representing the interests of the primary beneficiaries, organisations of professionals, or even associations/consortia of local governmental bodies. Following on the example of AAL service we make some illustrative but non exhaustive hypothetical exemplifications:
    - **Industry**. The provision of an AAL service, assuming it is more advanced and sophisticated of existing tele-control and tele-surveillance systems, is an opportunity for some companies and represents a threat to the business of those companies not capable of scaling up their offering to new more sophisticated services;
    - **Professional organisations**. If the new AAL services reduce the need of intervention on the side of professional carers, this would be considered a benefit for some (those retaining their jobs) but a disaster for others (those loosing their jobs) leading to opposition on the side of their professional organisation. This observation highlights how the category of intermediate beneficiaries is ambivalent and may turn into that of negatively affected stakeholders;
    - **Association of local municipalities**. If the new AAL services disintermediates established practices and threatens consolidated vested interests (i.e. relations with suppliers of call centre based simple services) also local municipalities turn from intermediate beneficiaries into negatively affected stakeholders;
- **Community as a whole**. Finally one should consider the higher level and long-term impact on the community as a whole (at the highest level on economy and society).

It is clear that the perspective of the beneficiaries and of all other stakeholders heavily shapes the kind of indicators one may want to define also in relation to the purposes discussed earlier.

Analysing the needs and interests of all broadly defined stakeholders (including beneficiaries) and consulting with them is fundamental for both analytical and political purposes, using the typology of contested domains with respect to ex ante decision making or ex post evaluation (see Figure 5).

Figure 5: Typology of possibly contested domains



Source: Authors´ elaboration.

The two dimensions used in the typology are: (a) the quality of the knowledge base (ranging from consolidated to uncertain) upon which the decision to launch a project is taken (prospective evaluation) or an ongoing services is evaluated; (b) the object of potential dissent with beneficiaries/stakeholders (for simplicity considered as focusing on either the evaluation of effects being produced or on the definition of objectives/ desired outcomes).

The upper part of the typology concerns what we can call "non genuine" dissent in the following sense: under conditions of a consolidated knowledge base (widely empirically documented evidence) dissent may still be phrased technically but it has underlying vested economic and political interests. In the two boxes we made only two illustrative and interpretative examples: (a) in the upper left box the case of very large projects representing a good economic opportunity that some stakeholders may want to define differently (prospective) or change (ongoing) to improve their chances of getting a piece of the cake (this may also be the case where the prospective evaluation of a public agency leads to discard the project, whereas industry may want to push ahead with it); (b) in the upper right box the case of a project disintermediating existing economic and political positions whereby the potentially disintermediated stakeholders may be attempting to oppose it on the grounds that its objectives are not supported by evidence. In both these two cases considering and consulting the stakeholders, while it does not bring much added value in terms of analytical and empirical perspective, it is nonetheless still fundamental to build consensus and win resistances.

In the bottom part of the typology we have what we can call "genuine dissent" since in a context of uncertain and non-consolidated knowledge base all assessments and evaluation can in principle be right or wrong. Under such circumstances consulting beneficiaries and stakeholders, besides representing also a political strategy for consensus building, can bring important analytical and empirical insights. We distinguish between a technical dissent when it focuses on the effects and a social dissent when it focuses on the problems that a project or service addresses and its desired outcomes.

Considering the two cases jointly, full consideration and consultation of beneficiaries and stakeholder can help:

- **Define a common and consensual "Outcome Framework"**. By "outcome framework" we mean a list of outcomes (benefits) that are considered relevant and achievable by intermediate beneficiaries and by representatives of primary beneficiaries. Such framework may also include a quantified range of level of outcomes considered feasible to achieve by all interested parties. This would avoid the inclusion of irrelevant benefits and of unrealistic quantitative target in the prospective estimates generated in the decision making stage. Furthermore, it may provide a basis for commitment on the side of the intermediate institutional beneficiaries to the gathering of the data needed for ex post evaluation.
- **Avoid building solutions in search of a problem**. Buy consulting especially the beneficiaries in the design phase one may avoid to decide for solutions that do not address any real problem or need and could instead gain insights on what issues must be addressed and what outcome might be achieved and should be measured.

It is worth stressing that in the public sector it is not uncommon to face a situation of non-consolidated knowledge base especially for what concerns scientifically and empirically robust attribution of causality links all the way from input to outcomes and impacts. As anticipated earlier, this would require evidence from time consuming sophisticated design and techniques not always available in the public sector.

3.2.4 The temporal dimension and the different phases of evaluation and measurement

The fact that evaluation and measurement entail different temporal phases was already implicit in the logic framework, in the different purposes of evaluation, and in the discussion of the multi-stakeholders perspective (in the consideration of possible contested domains in the decision making process and in the ex post evaluation). The importance of the temporal dimension and its simplification are illustrated in the table below using the concept of a project life cycle. The table is designed on the following hypothetical conditions: (a) in relation to regional administration; (b) assuming funding comes directly from the regional budget; (c) considering that the hypothetical Project I is part of a portfolio consisting of N Projects all in the same policy domain; (d) assuming that part of the implementation of the project is outsourced to private sector suppliers.

Table 2: Life cycle and implications for evaluation and measurement

Column 1 Different stages	Column 2 Main context of reference	Column 3 Phases, types and objects of evaluation and measurement	Column 4 Stakeholders
1. Strategic objectives of policy domain	Political	Definition of desired targets on the basis of previous cycle (outcomes/impacts)	Regional government, relevant regional department, all other stakeholders and especially primary and intermediate beneficiaries consulted
2. Selection of Project I ($\sum_{i-n}$=Portfolio)	Managerial and technical	*Ex ante evaluation* (Allocated input, expected outputs, outcomes, impacts and data requirements for measurement)	Top management of relevant regional department, administrators, professional intermediate beneficiaries, input from consultation above
3. Definition of Tender Specifications and selection of suppliers	Administrative, economic and technical	Relevant parameters *from Ex ante evaluation*	Administrators and technical experts
4. Implementation plan	Technical and administrative	Relevant parameters *from Ex ante evaluation*	Same as above plus supplier
5. Project delivery	Technical and administrative	*In Itinere* evaluation (Actual project costs, expected output versus state of advancement and final output)	Same as above
6. Projects completed and turned into service being provided	Political	*Ex post* evaluation (Realised outcomes/ impacts)	Same as first cell of this column

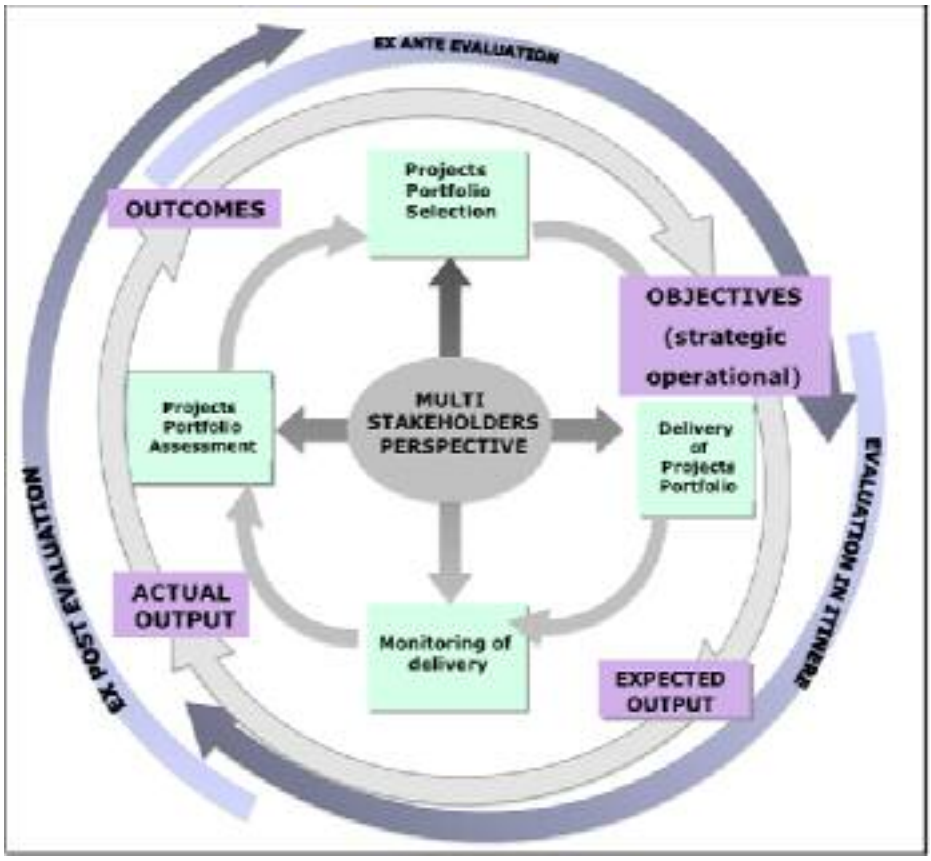
Source: Authors´ elaboration.

The table is self-explanatory and we limit our comment to underline that it presents the distinction between three phases/type of evaluations (*ex ante*, *in itinere*, and *ex post*) and to show how the combined use of these three phases/type would address basically all of the various purposes discussed earlier. The ex ante and in itinere evaluations combined provide the basis to respond to queries on the compliance with procedural rules for the use of public money and to monitor, and take management decisions regarding, the process of implementation and delivery of the output. The ex ante and ex post evaluations combined provide the basis to support both decision making and accountability issues. Results from previous ex post evaluations in relevant domains provide input for new ex ante evaluation upon which decisions to launch a project are taken, which in turn set the target and baseline against which the next ex post evaluation will be carried out for accountability purposes. All three forms of evaluation can provide material for self-legitimating scorecards and for learning purposes.

3.2.5 Summing up: the ideal approach to evaluation and measurement

The figure below sums up in a snapshot fashion the discussion of the previous sub-paragraphs presenting the ideal logic flows of how a comprehensive and ideal system of evaluation and measurement should work.

Figure 6: Snapshot of a comprehensive and ideal system of evaluation and measurement



Source: Authors´ elaboration.

With such a system in place and steadily working in a standardised fashion across all the lower level public sector producing units, the bottom up aggregation of data into a macro level benchmarking is feasible. However, such system is likely to remain textbook material never to be really implemented in the public sector. The reasons are many and include lack of awareness, commitment, capacities, and, last but not least, resources. Thorough and robust evaluation and measurement do not come for free and require money and time efforts.

Precisely because resources may be limited, one would have to set the most important evaluation and measurement priorities and select which components to develop. Once again the implications of this and of all the contents of this entire paragraph is that one cannot start directly from measurement indicators without considering all other more strategic and structuring parameters.

3.3 State of the art and challenges for evaluation and measurement of eHealth

3.3.1 A huge potential for impacts

The importance of the aggregate health status of the population has long been recognised as contributing to economic growth in the economic theory and formally tested and documented empirically. In the 1990s economists started to include health among the factors leading to growth into standard growth models alongside capital deepening and technological growth (the standard Solow model). Health capital measured in various ways entered the growth equations (i.e. Mankiw et al 1992; Barro 1996; Strauss and Thomas 2004; Bloom et al 2004).[7] Healthcare is the most

[7] Stated simply evidence has been produced showing a significant effect of health conditions on economic growth by a number of channels: better health indicators increase the incentives to invest in education and lower the human

information intensive sector of our knowledge based economy and society and is poised to benefit enormously from the introduction of ICT as an instrument optimising the use of information. Better and timelier sharing of information between patients and professionals, among professionals, between healthcare tiers (primary, secondary, tertiary), and across all the involved players (to include third party payers, and other players entering in various ways into the delivery and financing of healthcare) can contribute to improving information flows and the turning of information into knowledge in various ways. This in turn can increase patient safety and clinical outcomes, improve productivity and optimise the uses of resources, reduce administrative burden, and curb optimistic behaviours causing unnecessary costs (we come back to the outcomes later when discussing the evaluation model).

3.3.2 Lack of consolidated and standardised methods and evidence

Certainly there is no dearth of evaluation studies (and related meta-studies) that try and formally test some or all of the potential outcomes mentioned above. Only one meta-analysis article, for instance, identified 612 different studies focussing on the evaluation of telemedicine outcomes (see Whitten et al 2002). If we consider the field of eHealth broadly defined, one can find hundreds of case studies whose focus span from clinical information systems, to decision support systems, to electronic health records, etc (for instance 257 of such studies are reviewed in Chaudhry et al., 2006). Even only for the specific field of remote monitoring it was possible to find several meta-studies analysing a large number of other sources (they are treated in Deliverable D3.1). Yet, there is to date no consolidated consensus on the outcomes of the introduction of ICT into the healthcare sectors, not to mention evidence of their spill over impact onto economy and society at large. There is a lack of widely used and standardise approaches and particularly of institutionally approved and applied systems of evaluation and measurement (by this we mean specifically systems adopted and used by healthcare institutions at national, regional, and local level).

The field of telemedicine, which has been practiced by now for about three decades, is still characterised by 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 2007). 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 on randomised clinical trials and assessment also present shortcomings, in that they are discontinuous and, between one test and the other, clinicians must use data that can be unreliable due to their obsolescence (see for instance Gorin and Stone 2001). More generally the evaluation of eHealth applications shows 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 (Ammenwerth et al, 2004, p. 481).

Not surprisingly, given this situation, the earlier cited 2010 report of the OECD states at its very beginning that:

> *"With consistent cross-country information on these issues largely absent, the OECD has used lessons learned from case studies in six OECD countries (Australia, Canada, the Netherlands, Spain, Sweden, and the United States)" (OECD 2010: 9).*

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capital depreciation rates, and positively affect productivity directly (fewer days of work lost due to health problems) and indirectly (increased educational level). Moreover, improved health conditions and slow down of human capital depreciation can prolong the productive life of workers and curb early retirement (with positive effects on the pension systems) and, needless to say, better health conditions entails less costs for the public budget.

An earlier OECD state of the art report discussing what we know about the socio-economic effects of using ICT in the healthcare sector concluded that: (a) there are a fairly large number of methodologically robust studies relating input to output in the healthcare system in general (so with no specific analysis of the role of ICT;[8] but (b) as of 2007 there were only four studies that tested through formal techniques (through production/efficiency frontiers techniques, see Infra) the efficiency and effectiveness effect of ICT in the healthcare sector (OECD 2007: p. 10).[9]

Most case studies (both those reviewed in Chaudhry et al 2006 and in OECD 2010) show positive outcomes from the introduction of ICT in healthcare delivery. Yet, case studies do not enable to attribute ICT investment to observed effects for it is not possible apply randomisation or case-control design to the evaluative study. Moreover, it is difficult to generalise from the particular study to the broader context since in many instances the cases concerns leaders and best practices and are much less representative of usual practice (Chaudhry et al., 2006). This drawback and a lack of transparency in the evaluation method, for instance, has limited the relevance and reliability of the much publicised *" eHealth is worth it report"* (Stroetmann et al., 2006) and of its sequel on the impacts of Electronic Health Records and ePrescription (both EC funded). Both studies are basically a collection of good practice cases to which a collage of measurement and evaluation tools is applied.

One certain facts that we can extract from the literature is that no single study or framework devoted to evaluate the introduction of ICT in the healthcare sector, considers market indicators as well; this confirms our choice to treat them separately from the issue of measuring outcomes from the healthcare system perspective.

3.3.3 The Challenges

It is worth considering some of the reasons explaining the difficulty of evaluation and measurement in the domain of eHealth, since this prepares the grounds for the following paragraphs. From the literature and from our own research experience we have identified the following 4 challenges for evaluation and measurement:

1. **Distance of outcomes from ICT output per se**. We can appreciate this problem by a contrasting analogy with eGovernment. In the latter case, for instance, once the supplier delivers the ICT application allowing citizens to make their tax return online and the tax agency puts it online, the output can be directly used with actual take up level representing the direct outcome, which in turn can lead to time saved and increased user satisfaction (end outcomes). In the case of eHealth applications (and particularly of telemedicine and PHS) the ICT output per se does not reach automatically the final user, as it must be adopted and utilized first by healthcare producing units and/or professionals. Once this happens and a number of users are served by the ICT enabled application we still do not have an outcome but what we can call a healthcare output delivered via ICT (i.e. number of patients remotely monitored). Next in the shortest term we may register improvement in vital parameters (i.e. blood pressure, glucose, etc). Only on a long enough timeframe we may appreciate outcomes such as reduced re-hospitalisation and/or reduced mortality rates. Moreover, for most clinicians to be convinced, an experimental design

[8] Two examples among many are to be found in Jacob *et al* (2006) and in Smith and Street (2007).

[9] A study on the effect of implementing a decision support system in eight US hospitals found a positive but not immediate contribution to quality and profitability (Devaraj and Kohli, 2000). • A longitudinal study (1976-1994) of 54 general and surgical hospitals in the US state of Washington shows that ICT enabled efficient production and substituted other costs (Menon and Lee, 2000). Re-using the data from the study of Menon and Lee (200), other authors argued that the ICT investments had an impact also on productivity in the healthcare industry (Ko and Osei-Bryson, 2004. Finally, Menon *et al* (2000) re-analyse the data presented in Menon and Lee (2000) using a Stocastic Frontier Analysis technique and support efficiency impacts.

(randomised control trials) would be required. Accordingly, even at the micro level (i.e. without aiming at demonstrating macro level impacts), the causal attribution of a positive effect to a very delimited ICT enabled service/output provided by a single entity is difficult and requires experimental design.

2. **Sample size problems**. Directly related to the above is the difficulty of having large enough samples to meet the requirements of statistical analysis. Sampling for randomised control trials is difficult in general. The current little deployment and adoption of ICT enabled services further limits this possibility when evaluating eHealth services.

3. **Heterogeneity**. This dimension affects evaluation and measurement at three levels:
   a. Production processes: health care activities in general cannot always be conceived as a simple production processes with standard input and output. First, there is considerable variation both in the processes and in the actual output. Second, there are outputs produced through the contribution of institutionally distinct entities. Both these forms of heterogeneity make it difficult to generalise the same evaluation model to different objects. Therefore, the problem of comparability exist also within the same unit/level mix and not only when one tries to move at an higher level of aggregation (see discussion of the matrix in Figure 3 p. 7);
   b. ICT enabled applications/services: the heterogeneity of production processes is enhanced by the heterogeneity of ICT applications chosen to support a given service. As adequately documented in Deliverable D3.1, in the field of RMT there is considerable variations in the level of sophistication of the ICT solutions used and, accordingly, in the degree to which these require professional interventions; yet a further challenge from the perspective of comparability;
   c. Business models and procurement. As illustrated in Annex I of this report (see § 4.3) remote monitoring services can be provided in different ways according to how the money flows (from whom to whom) and to the extent to which the service is provided entirely by suppliers (players institutionally external to the healthcare system proper) or suppliers provide only the ICT components to healthcare players who in turn deliver the final service. So, first, there is a difference between models where the health care policy making authorities are also the third party payers (i.e in the NHS model) and those where the policy-making authorities are distinct from the third party payers (i.e. in the social insurance model). Second, the role of suppliers clearly changes in terms of their accountability if they only provide the ICT component or also the medical component of the services. Third, the policy-making/paying authority can procure the services from the suppliers directly through a centralised tender (i.e. the case of the Veneto region tender assigned to Tesan SpA) or can establish reimbursment rules and leave each health care producing unit to select its supplier (i.e. the case in the Lombardy Region). These three components of heterogeneity do not impact so much on the technical side of comparability, but change the stakeholders landscape and their roles (by determining for example, who is an intermediate beneficiary and who is a stakeholder) thus requiring possibly different focus and different indicators depending on which business model one is evaluating. For instance, under certain models the data about clinical outcomes would have to be gathered and provided by suppliers.

4. **Multi-stakeholders perspective needs multiple data sources**. Last but not least, the evaluation of eHealth services and applications calls for the adoption of a multi-stakeholders perspective considering the potentially converging or conflicting perspectives of:
   a. the users/ patients and their associations/ advocates (possibly including institutional privacy "watchdogs");

b. the healthcare professionals (possibly further distinguishing between nurses and doctors, and among the latter between primary, secondary, and tertiary level professionals);
c. the managers of the healthcare producing units (i.e. an hospital);
d. the health care policy making authorities;
e. the public third party payers (social insurances, national funds);
f. the private insurances;
g. the broadly defined "market" suppliers.

The corollary of this is that evaluation and measurement needs many sources of data producing different type of metrics that are not always commensurable and suitable to be compacted into a few composite indexes supporting clear-cut *ex ante* decision-making or *ex post* assessment. Metrics evaluating the quality and reception of outcomes will be expressed in different way from those related to cost-effectiveness and efficiency and one could still be faced with dilemma where quality metrics have high values whereas monetary measures are not positive (negative ROI), leaving again the decision on whether to continue or discontinue the provision of a service to the judgement and discretion of decision-makers.

It is worth recalling here for what concerns specifically RMT that the question as to whether evidence from Randomised Control Trials is sufficient or not to convince healthcare professionals and decision makers was much debated during the November 2009 expert workshop. This issue remains among the key barriers to full take-up of RMT and is treated as such in Deliverable D3.1.

3.4 RMT evaluation and measurement framework: exemplificative ideal type

The framework and related components finally presented in this paragraph are 'ideal-typical' and difficult to implement for obvious reasons:

1. we fully illustrated that one may set up an evaluation and identify related measurement indicators for several purposes and select a different mix in terms of unit and level of analysis;
2. these two choices heavily shape the set of beneficiaries/stakeholders addressed and in turn also influence the kind of indicators needed;
3. a lot of variability exists in terms of production processes and remote monitoring technological applications used, which make the definition of generally applicable indicators quite difficult;
4. institutional long-standing arrangements make the healthcare systems of EU27 MS quite different from one another and these differences impact on the identification of the different institutional stakeholders;
5. RMT services can be provided according to a variety of business models according to which the roles of stakeholder may change radically;
6. the suppliers, not institutionally belonging to the healthcare system proper can be involved through central procured tenders or on an ad hoc basis, and they can simply provide ICT services or may also be involved into the provision of the final service (including its medical components).

It goes without saying that if we combine together all these possible dimensions of variability we may come up with dozens of different situations, for each of which we would need to define *ad hoc* components with respect to the overall framework, the set of stakeholders, and the indicators. Finally, we did not receive indications facilitating us in making a choice and focussing better on a particular situation. As a result, what follow is an ideal-typical proposal where we made a number

of simplifying choices that are made explicit where relevant as we progress with the illustration of the contents of this paragraph.

3.4.1 Unit/level of analysis and related assumptions

The level of analysis selected is that of a generic regional level healthcare authority (regional health agency, or the health department within a regional government) overseeing a number of remote monitoring services delivered by lower level health care-producing units and fully reimbursed from the health care regional budget. In this respect we simplify the picture of one level (in fact, between the regional authorities and the final producing units there could be other intermediate bodies such as provincial health units). We assume that producing units apply with the regional authority to be eligible and subsequently use the public reimbursement for RMT services and that the regional authority decides on the basis of an *ex ante* evaluation. We also refer generically to healthcare producing units without entering into the variations possible within this category (hospitals, joined up GP practices, etc).

For the sake of simplicity we make the assumption that this regional authority plays also the role of third party payer out of its budget. For instance, such as is the NHS public delivery model, considering neither the split between policy making authorities and financing bodies (i.e. social insurances), nor the case of services paid for by private insurances for specific segments of users. We also simplify the relation between the regional and national level and we assume that the outcomes the former is interested in coincide with those of the latter.

The unit of analysis is represented by the RMT services provided by each individual producing-unit and also assuming that the data from each of the producing units are then aggregated to achieve a complete picture at the regional level. In choosing the provision of service as the unit of analysis we make a very important simplification in relation to the life cycle and temporal dimension discussed in § 3.2.4 and summarised in Table 2 (page 26); we assume a compressed time between the project phase and the moment the service provision is offered. In practice when a producing unit decides to launch a service, after approval from the regional authority, it will have to prepare the internal conditions, write the Tender Specifications and select a supplier (stage 3 in Table 2), set up a plan and implement it in collaboration with the selected supplier (stages 4 and 5 in Table 2), and finally launch the service provision (stage 6 in Table 2). The life cycle from stage 3 up to stage 6 when the service starts can last up to a year, so that if T_0 is the moment of launch, T_1 (beginning of the first year) will probably mark the beginning of the service provision, and at the end of this time unit the first measurement data might be gathered and be available at T_2 (beginning of the second year). But for the sake of simplicity, and since such complication is not entirely useful for our purposes here, we eliminated it. We basically collapse and compress stages 3, 4, and 5 of Table 2 and concentrate on stage 6. So, we assume that service provision starts already during the first year (so T_0 in the following text/pictures marks launching and T_1 marks the end of the first 12 months after launching). It would be, however, only a matter of changing the coding for time units and adding a few layers in some of the following graphs to account better for the full life-cycle from project status to service provision.

We reason mainly on the business models depicted in Figure 18 contained in § 4.3 (see p. 52), whereby suppliers are in charge of providing the ICT components of the service whereas professionals from health care producing units intervene for the medical components. We assume that regional authorities set guidelines and regulations but do not procure the ICT components of the services directly, so that each producing unit can select its ICT supplier. Finally, we generally talk about ICT suppliers without distinguishing between vendors of devices, and provider of services. All of these simplifications (and a few others explained later) are necessary to make our work manageable within the scope of this deliverable. On the other hand, as it will become clear in

the following sub-paragraphs, the models and the indicators can be adapted to situations that differ from the ideal-typical one considered here.

3.4.2 Purpose, beneficiaries, and stakeholders

We consider as the three main purposes for which the evaluation framework and the measured indicators are proposed the following three:

- **Decision-making:** *Ex ante* evaluation before launching a service at T_0. This will establish a baseline of parameters, and then will include estimates of how the provision of the services will improve such parameters. It will focus on input, expected output, and outcomes;
- **Accountability**: *Ex post* evaluation at T_{0+1} (first relevant time unit, it can be a year) to verify empirically to what extent the target outcomes have been achieved. The outcomes will naturally be put in relation with the input needed to produce them;
- **Monitoring/Management:** Evaluation *in itinere*, several times between T_0 and T_{0+1}, to verify the level of actual output as compared to the expected one and, if applicable, identify the causes for lower output levels.

The following are the categories of beneficiaries/stakeholders considered:

- **Primary beneficiaries:** Individuals with chronic conditions (their relatives/friends are secondary beneficiaries);
- **Intermediate beneficiaries 1:** Health care professionals involved for the producing units in the delivery of the medical components of the remote monitoring services;
- **Intermediate beneficiaries 2:** Manager of health care producing units;
- **Institutional stakeholders:** These include, moving from the bottom up, the regional health care authority (to which health care producing units must report), the regional government, the national ministry of health, and eventually the national ministry of finance. As anticipated in our analysis we stop at the level of the regional government (assuming its interest coincides with those of the higher tier of executive power).
- **Other stakeholders:** We will only consider the ICT industry, from the complete list of other stakeholders we made in § 3.2.3, under this category.

Remote monitoring and treatment, as any other ICT enabled services in health care sector, deals with the most precious of all values: life. A mistake in the provision of a remote monitoring service would have incommensurably more negative effect than in the case of a flawed online tax return application (to use the earlier applied analogy with eGovernment). So we can reasonably state that all involved beneficiaries and stakeholders are interest in patient safety. Having clarified this, we can also proceed with some level of conceptual simplification to identify the priority interests/objectives of different beneficiaries/stakeholders. We talk about a conceptual simplification because there can be naturally overlaps among stakeholders objectives, which for the sake of simplicity we do not consider here.

The **primary beneficiaries** are the users/patients and they are naturally interested in improving their health status, as well as their quality of daily life, and possibly their potential of being in charge and self-care for themselves.

The health care professionals as **intermediate beneficiaries** have on the one hand interests which converge with those of the patients – for what we can in general call clinical outcomes – and on the other, clinical outcomes and patient safety for them have also specific implications, they may want to avoid such as: i) inappropriate treatment or delay in care (inaccurate/inappropriate information may confound or complicate treatment decisions and delay care); ii) unintended errors; iii) damage to the 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). All of these to be avoided implications, raise the risk for professionals to be held responsible for malpractice and may change their relationship with the patient. In addition, health care professional may expect to obtain an improvement in their conditions of work and possibly a more effective allocation of workloads, or they may fear the stratification and increase of the workload without corresponding incentives.

Managers of producing units as a second tier of **intermediate beneficiaries** (naturally taking for granted that they also care about patient safety and clinical outcomes) may also be interested in improving the efficiency of production processes and of the allocation of resources as this reflects their ability to increase the quality and quantity of output with the same level of input. On the other hand, they may fear that home caring for an increasing number of chronic patients without an adequate reimbursement scheme or new structure of incentive will lead to a net decrease of the funds provide to them.

Broadly defined **institutional stakeholders** (without distinguishing among the various tier) are interested in containing the cost of caring for chronic patients while at the same time, managing with increasing shortages of professionals, meeting growing demands and increasing the level of satisfaction and trust on the side of the citizen with respect to the health care system. Naturally, though from a different perspective, also institutional stakeholders would like to avoid issues of malpractice, privacy violations, etc. Moreover, when deciding to invest public funds into such services, decision makers would like to ensure that these funds are not wasted and that such services do not drain resources that may be better deployed for other purposes.

Finally, **ICT suppliers** are interested in providing quality services and contribute to achieving and demonstrating outcomes in order to consolidate and expand this market opportunity. Naturally they are interested in generating revenues and profits from such activities.

Having established these general and preliminary objectives for the different stakeholders, we proceed to develop the evaluation model where we eventually identify which can be the effects of remote monitoring and how they can affect the different stakeholders.

3.4.3 Evaluation hierarchical model

As we anticipated in the premise to this section (see page **Error! Bookmark not defined.**), the model is different from the framework. The model is the component of the framework illustrating the key causal relations (assumed or already empirically known) existing among all or some of the key variables at stake.

In this paragraph we do not enter into the discussion of the extent to which the causal relations we have defined have been empirically tested and demonstrated in robust ways. We do not, therefore, discuss the evidence from Randomised Control Trials, which is considered in Deliverable D3.1. Actually, the model we propose is designed for the gathering of measurement data without experimental design but from the perspective of steady longitudinal comparison of data, time period after time period. Below, thus, we provide a synthetic illustration the various possible effects of remote monitoring services, from which we derive a hierarchical model.[10] In the following sub-paragraph some measurement indicators are matched to this model.

[10] The model is derived using the Analytical Hierarchical Process (also known as AHP) approach (see Saaty 2008), which progressively deconstructs the evaluation issue into increasingly simpler sub-issues instrumental to eventually extract measurement indicators.

As long explained by economists, ICTs are general purpose technologies that do not produce any specific results by themselves but that rather can enhance the productivity of other factors of production. Such positive effects may spring from faster and better information flows, exchange, and use, eventually turning such information into knowledge and direct support for more informed action. While this applies in general, it is even more salient in the health care delivery, which is the more information intensive domain of all those characterising the functioning of our societies and where information is more mission critical than in other situations.

Better and timelier uses, flows, and sharing of information between patients and professionals, among professionals, and between different tiers of the health care system can enable improved decisions and actions in all the phases of health care delivery (diagnosis, prognosis, cure, management of disease), potentially positively contributing to both the quality of care and cost containment.

Remote monitoring services can provide the healthcare professionals with the information and instruments to take better decisions and actions and the patients with the opportunity to take a more active and informed role in deciding about their health and in managing their lifestyle to achieve a better health status. In addition to providing timelier and better information, remote monitoring services also bring the advantage of dis-located delivery that, as we see below, has also its own potential positive effects.

Timelier information exchanged between patients and professionals can increase the **quality of care** (i.e. clinical outcomes) in two ways. First, professionals have frequent information upon which they can take decisions about treatment of the patients. Second, patients themselves have more information and can receive automatic feedbacks to fine-tune their daily activities and may feel less anxious and more comfortable with less stress. Such a situation can certainly help cope better with the emergence of acute symptoms/situations. Yet, important effects can be achieved also in the daily routine that can add up and avoid the emergence of such acute situations. Patients can be steered to better adhere with drugs and lifestyle prescription (taking the right drug at the right time, do the required physical activities, follow a dietary regime). Professionals can monitor to what extent vital parameters are within the ranges prescribed by the guidelines of scientific associations, and also to what extent patients' behaviour is within the parameters set within such guidelines and protocols of care. In case of deviations they can intervene directly or provide input to the patients as to how to **improve adherence**. Adherence has been shown to be of great importance to manage the conditions and avoid complications for patients with diseases such as asthma, diabetes and chronic heart failure. Already a decade ago it was pointed out that prompting physicians about deviations in vital parameters and/or in adherence to prescriptions by their patients could greatly improve the quality of care in a preventive mode (Balas et al 2000). Improving quality of care in this direction also automatically generates cost effectiveness. Fro example, in the province of British Columbia an ICT enabled programme of disease management led to an increase in the number of diabetes patients complying with guidelines from the Canadian Diabetes Association (measured by their vital parameters) from 21.8% in 2001 to 48.6% in 2004, leading to a cost reduction per patient from Canadian dollars 4.400 to 3.966 (reported in OECD 2010: p. 36).

Remote monitoring services also provide all patients with the benefit of **convenience** in the form of being able to feel safe and being treated in their home. For some patients this can be seen as an **empowering effect**. For others who are traditionally underserved by institutionalised health care (because they live in remote areas or come from socially disadvantaged groups not at ease to being instituted), remote monitoring, as other telemedicine applications, represents also **access** and **social inclusion** effects. It has been shown, for example, that remote delivery can offset workforce shortage and the often skewed distribution of physicians between rural and urban settings, and also

within the latter for what concerns urban neighbourhoods mostly inhabited by ethnic minorities (Balamurugan et al., 2009; Bashshur et al., 2009; Shea et al., 2006).

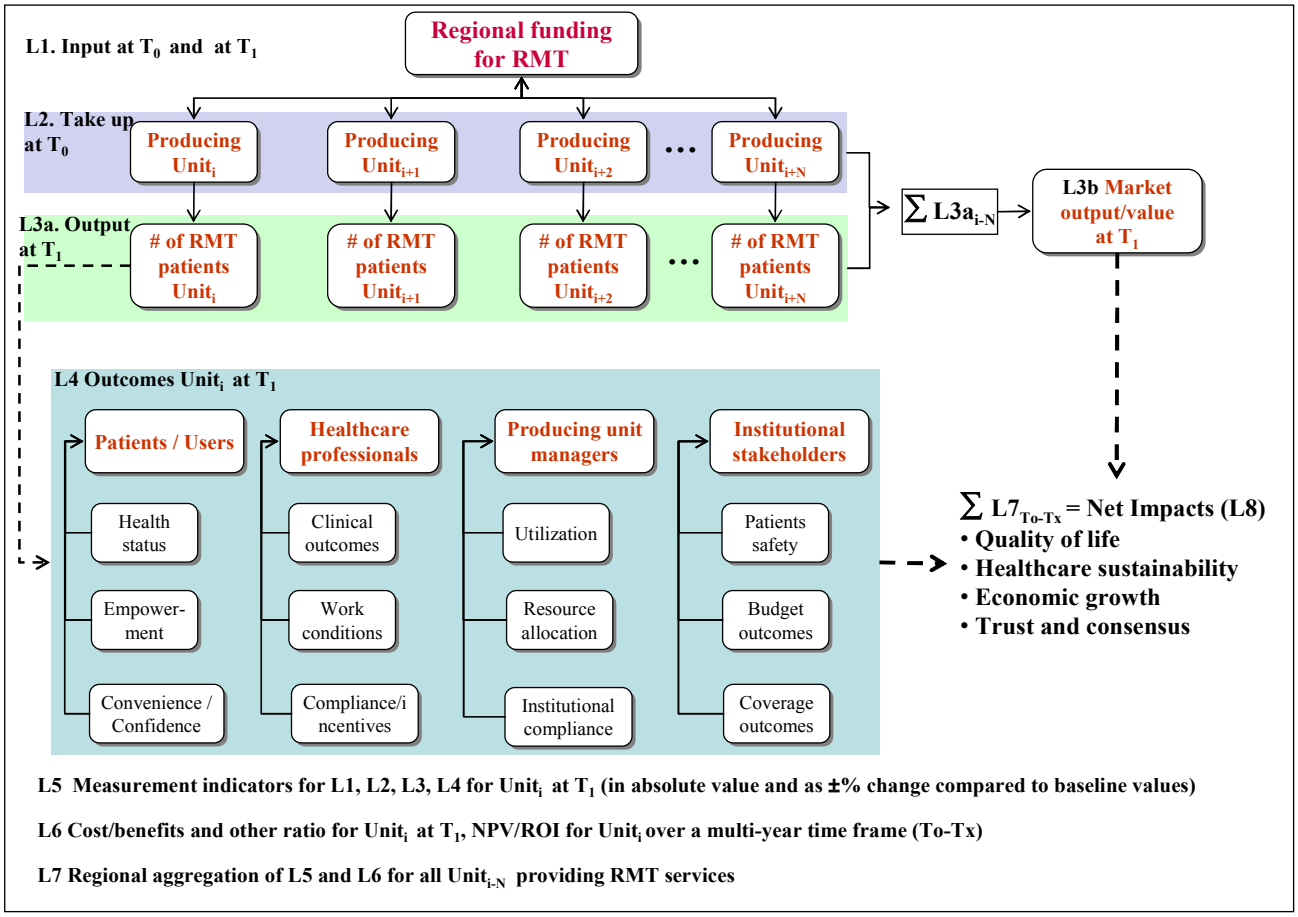
An important positive side effect of increased quality of, and access to, care for chronic patients through remote monitoring services should be **reduced utilisation**. Better management of disease should reduce re-hospitalisation, as well as additional diagnostic and treatment costs (both in terms of in-hospitals intervention and of drugs). This could also be achieved because better informed and less anxious patients may reduce requests of second opinions and use of unnecessary drugs. The positive implications could be manifold increased if remote monitoring and other PHS services would be part of an integrated and inter-operable system including: (a) electronic health records; (b) personal electronic health records; (c) clinical information systems with integrated clinical evidence and clinical pathways and guidelines (combining information from different segments and tiers of the health care system). Under this scenario professionals could have readily available information about a patient clinical history, including reports from earlier hospital discharge, drugs prescribed, etc. When treating their chronic patients they could also consult records and information on how similar patients have been treated/managed by other professionals working in different institutions. Such integrated access to information could help take the right decision earlier and avoid unnecessary diagnostic and treatment costs. It could also positively influence prescribing behaviours avoiding potential opportunistic prescription unnecessarily inflating costs.

Finally, remote monitoring services when matched with organisational innovations and restructuring could produce **more efficient resource allocation**, along the lines proposed by Christensen *et al* application of the theory of disruptive innovation to the healthcare sector (2000).[11] Christensen *et al* argue quite correctly that health care has devoted so much resource to the treatment of the most acute problems as to overshoot the majority of less complex needs many patients have. Additionally, since the system must treat also less demanding needs, much specialised institutions and specialists have been forced "down market". This means that they have to deal with problems that could instead be addressed through a combination of less expensive carers (nurses) and enabling technologies. As specialist physicians continue to concentrate their efforts on the most acute situations and on "the most incurable of illnesses for the sickest of patients", not-so-highly-skilled and expensive practitioners could take on more complex roles and deal with ever larger numbers of chronically ill patients through remote monitoring services integrated into disease management programmes. In other words remote monitoring could release professional resources to be deployed in other tasks as qualified nursing personnel supported by remote monitoring services (requiring the specialist's interventions only in rare and well-delimited cases) treat a large part of the chronic population.

The proposed hierarchical model reflecting to a large extent the outcomes discussed above and also considering inputs, outputs, and impacts is depicted in a fairly clear and exhaustive way in the figure below that we comment only briefly.

[11] This is the contribution specifically devoted to healthcare, which is part of the wider work done by Christensen and colleagues in general on this concept (see for instance Bower and Christensen 1995; Christensen 1997; Christensen and Raynor 2003).

Figure 7: Hierarchical Evaluation and measurement model



Source: Authors´ elaboration.

Let us first clarify the simplifications introduced for reason of graphic space constraints. By "producing units" we mean health care producing units in the generic meaning explained earlier. We convey with only four boxes the idea that producing units can vary from "i" to an unspecified "N" number. After the Level 3 of output (L3), we make the Level 4 (L4) of outcomes follow only for producing unit "i", but it is obvious that the same applies to any of the producing units. We generically indicate RMT, but one such model should be applied separately (possibly with some specificities) for each of the different group chronic disease patients addressed (i.e. diabetes, COPD, CHF). The same simplification applies later for the indicators. We assume T_0 being equal to the moment of launching of the service and T_1 to the end of the first year, then all the following years results will be compared to both the previous year and to T_0. Empirical reality will surely be less simple than that; for example one possible complication could be that different producing units may start at different times and, thus, complete aggregate regional level analysis may not be possible after the first year.

Next, we comment each of the various levels included in the figure. For the various areas of outcomes we will not enter into much detail since they will become fairly clear in the following paragraphs when the corresponding measurement indicators are presented.

1. **L1 Input**: Here we consider only the monetary input provided by the regional authority that can consist of both the funds for reimbursement and those to pay incentives to the producing units (and consequently to managers and professionals) provided performance targets are achieved. A more extended definition of input could include also less tangible elements we at this phase do not consider (i.e. regulations, guidelines, leadership, of which some could be

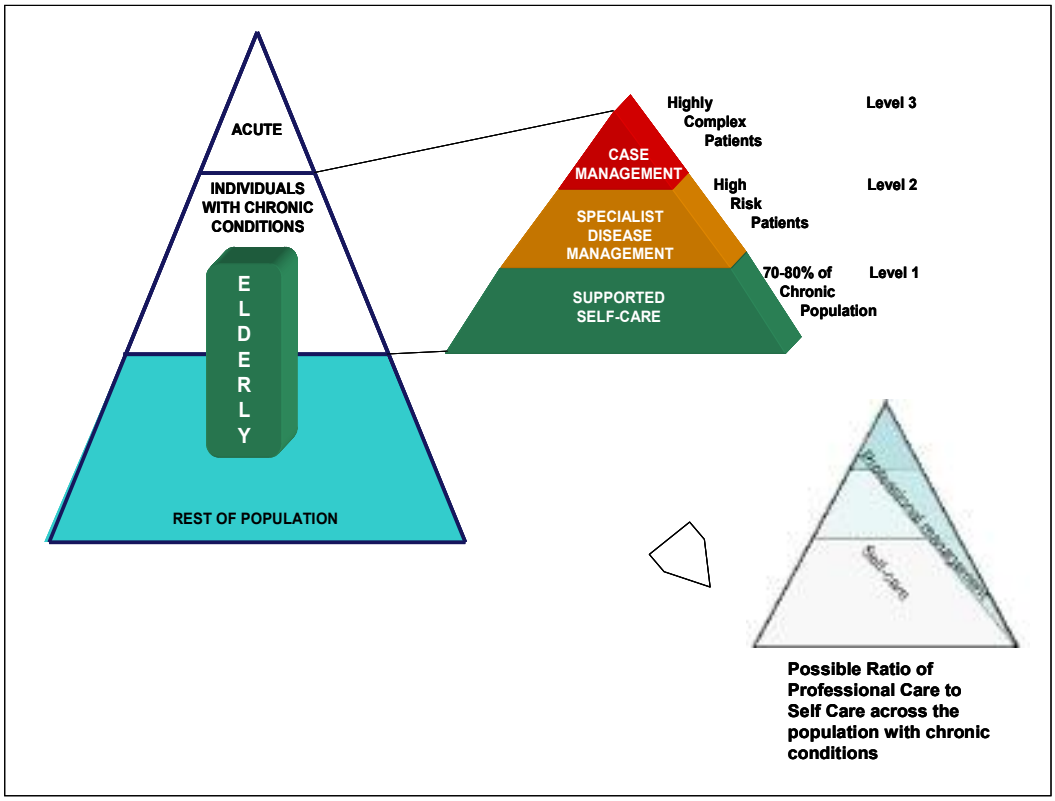
given a monetary value as opportunity cost). The inputs from the producing units are not taken into account because they are reflected in some of the areas of outcomes. The arrow from the regional input to the producing units is bidirectional to reflect that the regional authority: (a) allocates *ex ante* the budget available for RMT; but (b) calculates it *ex post* aggregating the data reported from the producing units;

2. **L2 take up**: We assume that provision of RMT is not mandatory and that it is an option (supported by incentives) made available to the producing units. How many apply and actually implement it represents the level of take up. In this case we can anticipate the indicator, as it is straightforward: "% of producing units in the region providing reimbursed RMT services". It is assumed that the producing units first apply to become eligible for reimbursement by presenting to the regional authority a prospective *ex ante* evaluation (business case), whereby target values of measurement indicators for outcomes are defined with respect to the existing baseline. This provides the basis for the *ex post* evaluation and measurement. Such *ex ante* business case should also set target health care outputs and also target ICT outputs to shape the Service Level Agreement with the external ICT suppliers. The outputs defined *ex ante* are the main benchmark for the evaluation *in itinere*;
3. **L3a output**: Here we refer to the health care output, whose simpler measure is the number of patients treated via RMT (other output indicators are presented later). The figure assumes the total number of patients treated is measured *ex post* at the end of the year (to be compared to the expected level included in the business case). In practice it is realistic to assume that measurement *in itinere* will register this value at least quarterly (i.e. as the basis for requesting reimbursement);
4. **L3b output/market value**: The figure in a simplified way conveys the reasonable assumption that the volume of health care output provided in aggregate by all producing units will shapes the volume of the supporting ICT output and of its market value. If producing units report *ex post* to the regional authorities the payments made to their ICT suppliers we would then get a precise measure of the value of the regional RMT market. As anticipated market related indicators about suppliers are discussed in Annex II (Section 5);
5. **L4 Outcomes:** Three areas of outcomes are identified for each of the four categories of broadly defined stakeholders. The meaning of each area will become clear in the next sub-paragraph when we present the indicators. The outcomes are measured *ex post* although their target value is defined *ex ante*. Having a baseline for outcomes is of strategic importance in order to clearly document the positive results of the RMT services;
6. **L5 Measurement indicators:** These are matched to the various areas and are discussed in the next sub-paragraph (the figure logically refers to Unit i, but they can be replicated for all units). Here we only stress that such indicators should be expressed both in absolute values and as percentage changes with respect to the baseline (or the previous period). Only having percentages indicators one can construct composite indexes from metrics of totally different nature (money, numbers, vital parameters, etc).
7. **L6/L7**: These two levels refer to what we can define as the techniques of evaluation and measurement, including cost/benefit analysis, ratios construction, construction of composite indexes. These are important components of a framework and pertain to the details of technical implementation. No further discussion on this will be attempted;
8. **L8 Net impacts:** If outputs and outcomes are steadily produced over a large enough number of years, provided that take up gradually reaches all or at least the majority of producing units, then one would expect macro level impacts for the economy and society as a whole. These are also only mentioned here and not treated further for they require large cross-sectional and longitudinal datasets in order to allow demonstrating empirically (so different from a forecast modelling approach) using statistic and econometric techniques. Today and for some time to come the data available do not allow to carry out such analysis

3.4.4 Measurement indicators

As anticipated, establishing a baseline or so-called "zero measurement" is of strategic importance for methodological and technical reasons. First, since the proposed evaluation and measurement is not based on any experimental design (with treated and non treated groups as in the practice of RCTs) it needs a point of reference against which the indicators to be calculated and be compared to acquire a meaning. Second, having a baseline comparison allows a normalisation in percentage value indicators expressed in different metrics, so that they could be aggregated into composite indexes providing a high level picture of disease management improvement. For instance, let's assume all health care producing units provide to the regional authority three indicators: mortality rates (number), cost per patient (money), and user satisfaction (index from scale). The absolute values of the three cannot be aggregated. But if they are expressed as percentage changes with respect to the initial baseline (or to the previous time unit in the successive years) they can be weighted and aggregated into a regional composite index of "Disease Management Improvement". So the gathering of baseline data and the calculation of baseline indicators is the first important building block upon which the *ex ante* evaluation is designed and against which the *ex post* evaluation is conducted. Chronic patients risk categories (Figure 8) need to be taken into account.

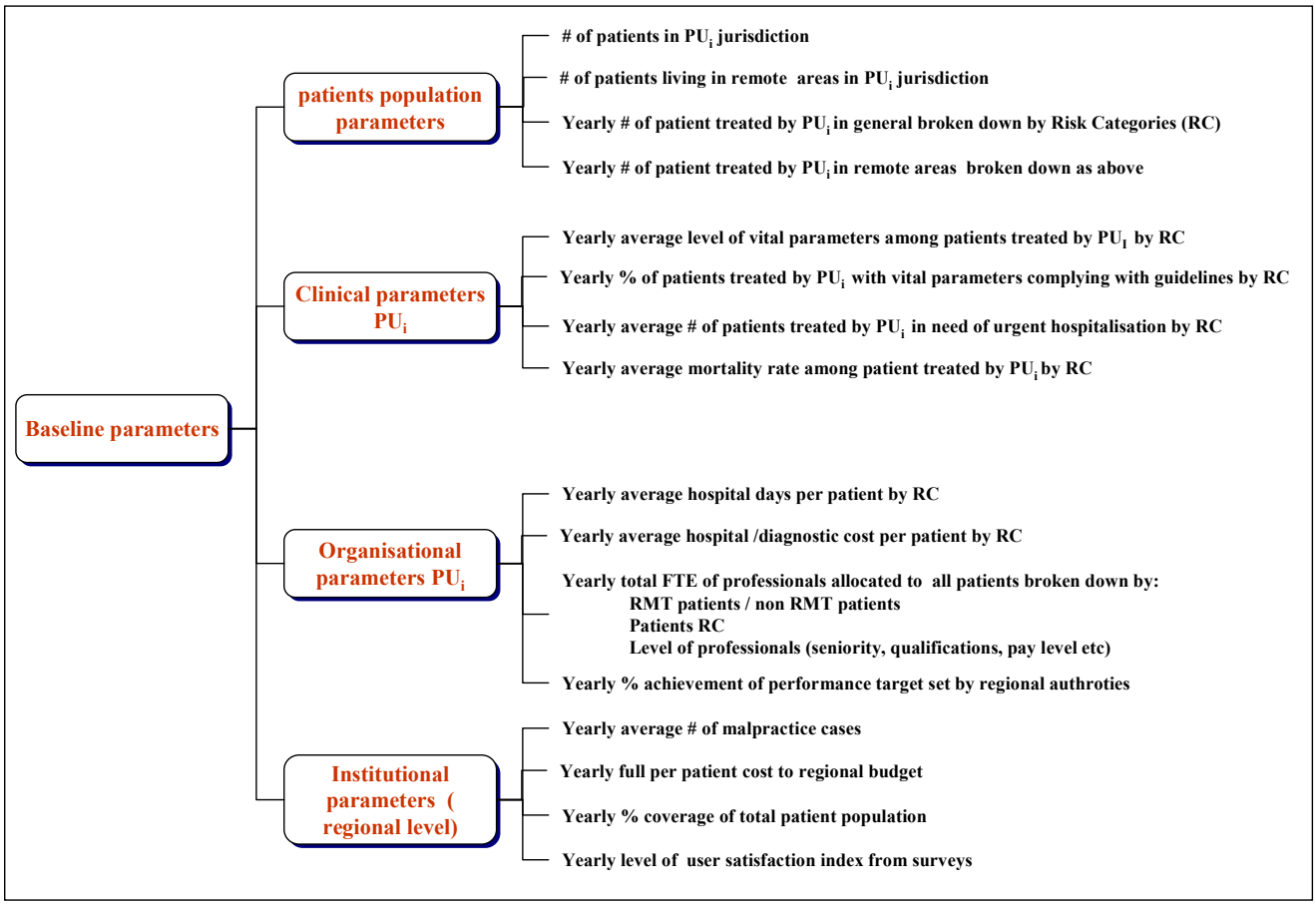
Figure 8: Chronic patients Risk Categories (RC)



Source: see Deliverable D2.3 on PHS segmentation.

The figure above has been taken from the deliverable on PHS segmentation and included here to clarify the three Risk Categories (RC) of chronic patients, to which some of the indicators presented in the following refer. So RC1 are the majority (70-80%) of chronics patients for which various forms of self-care (of which RMT can be considered one) are most appropriate. RC2 patients are those at high risk, and RC3 are highly complex patients. For these categories professional management is required, although also for them some level of self-care is possible. Having clarified this, below we present a number of figures containing different set of measurement indicators. We will add comments to such figures only when needed.

Figure 9: Proposed measurement indicators: baseline



Source: Authors' elaboration.

The first block concerns **patients' population parameters** both in terms of general prevalence in the territory coinciding with the "jurisdiction" health care producing unit i and in terms of the patients actually treated by the same unit. The general prevalence may serve the purpose of a weighted comparison among different PUs. The break down by Risk Categories (RC) is needed to put clinical outcomes in perspective and also to look at resource allocation, that by type of areas of residence provide the basis to measure coverage/access outcomes.

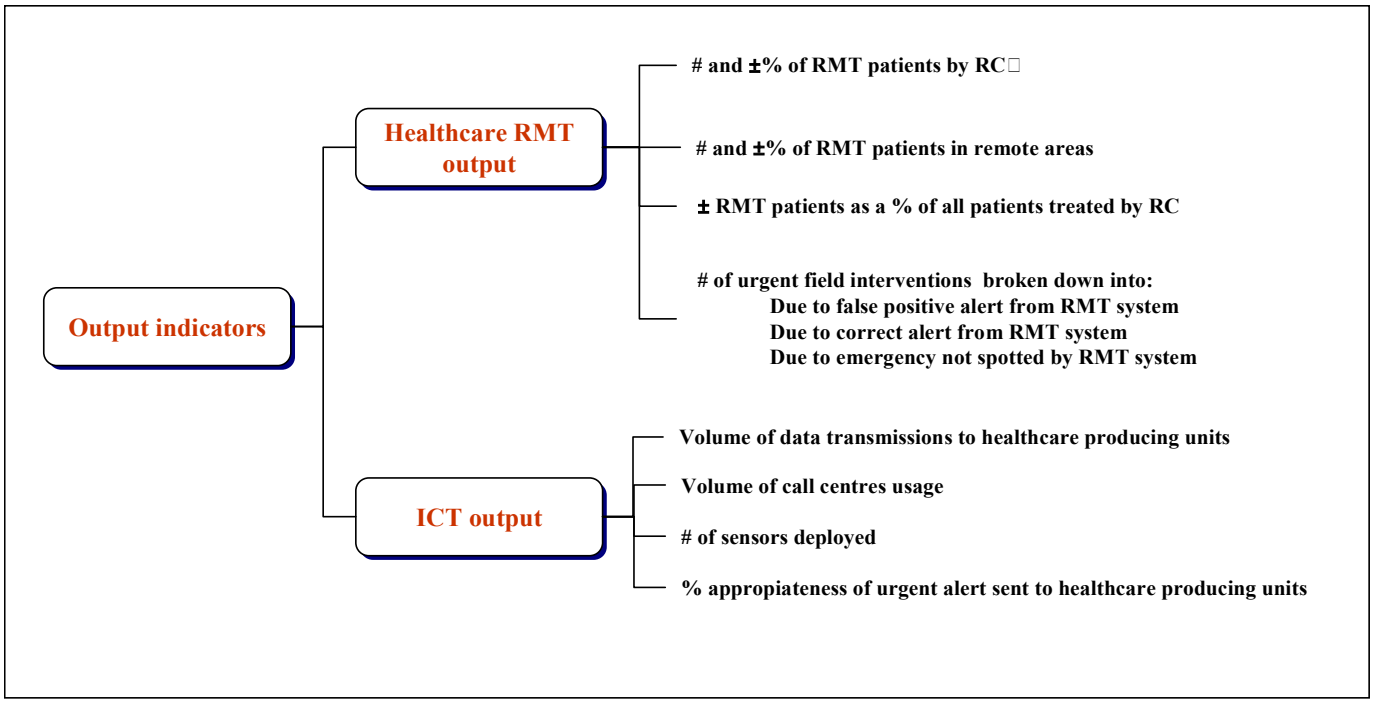
The second block is about **clinical parameters** that are pretty standards and we have selectively chosen from those usually reported in scientific articles about the findings of randomised control trials. The vital parameters naturally change from disease to disease (i.e. for diabetes they could be HbA1c, blood pressure and lipid tests). The other indicators, however, we extracted from the case studies on the British Columbia disease management programme mentioned earlier and reported in OECD (2010). In this case they reported the percentage of patients treated whose vital parameters met the guidelines value provided by the Canadian Diabetes Association.

The third block considers **organisational parameters** from the perspective of the producing unit management. The first two are straightforward and do not require any comment. The third one is a parameter aimed at measuring the resource allocation outcomes and to test to what extent RMT does indeed help release resources for more acute situations or for other value added activities by enabling the majority of the less complex chronic patients to be cared with less (both in terms of quantity and of professional level) resources (toward the ideal 20% of resources to manage 80% of patients). The fourth one assumes regional authorities set performance targets linked to incentives

and measures, and the extent to which these targets were met by the producing unit before the introduction of RMT, so as to measure its contribution toward achieving them.

Finally, the fourth block includes the **institutional baseline parameters**, which are at the aggregate regional level (whereas the former three were at the level of the individual producing units). The first indicator is a proxy of the aggregate level of patient safety. The second one concerns the full cost per patient to the regional budget. The third one is about the coverage/access aggregate outcome. Evidently, if RMT produce an increase in the latter without increasing the former, this is proof of achieving the "doing more with the same" result. The final one reflects the subjective appreciation on the side of regional users of the health care system and more generally of all the regional citizenship (non patients can reply with respect to the experience of their relative and friends). Naturally it pre-supposes that such surveys are periodically carried out. Also in some of the next set of indicators we included measures of subjective perceptions. If data from such surveys are not available there is naturally no baseline, which would be constructed if they were carried out after the hypothetical introduction of a system of evaluation and measurement.

Figure 10: Proposed measurement indicators: outputs



Source: Authors' elaboration.

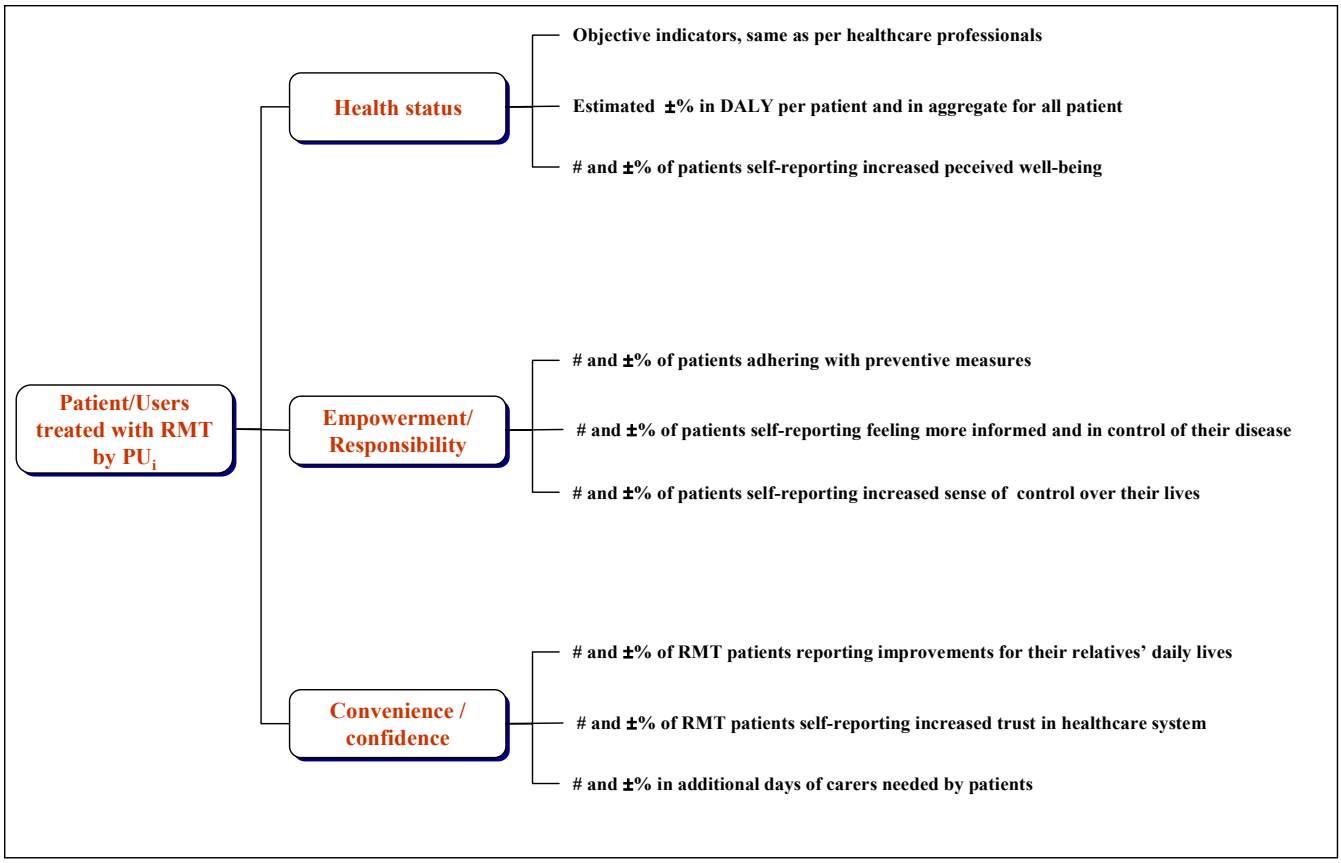
The figure above contains indicators proposed to measure the health care and ICT outputs. The health care outputs concern the number and percentage change in the RMT patients in general, in remote areas, and as a percentage of all chronic patients treated.

The fourth indicator aims to measure traditional health care intervention prompted by the automatic alert which is part of the RMT applications. This would be a very good way to test the reliability of such applications. The ICT output indicators, not to be confused with the market indicators that are proposed in Annex II (see § **Error! Reference source not found.**), are to be used in the *in itinere* evaluation to control that the services provided by the ICT suppliers comply with the contractual Service Level Agreement.

Figure 11 focuses on outcomes for users/patients. The health status is an important area of outcome for users/patients, and can be measured in at least three ways: (a) objectively, using the same

indicators on clinical outcomes presented in Figure 12; (b) economically, estimating the changes in DALY on the basis of such clinical outcome indicators out of international standard parameters and techniques used to calculate such measures; and (c) by subjectively asking RMT patients how they feel in general and compared to before.

Figure 11: Proposed measurement indicators: outcomes for users/patients

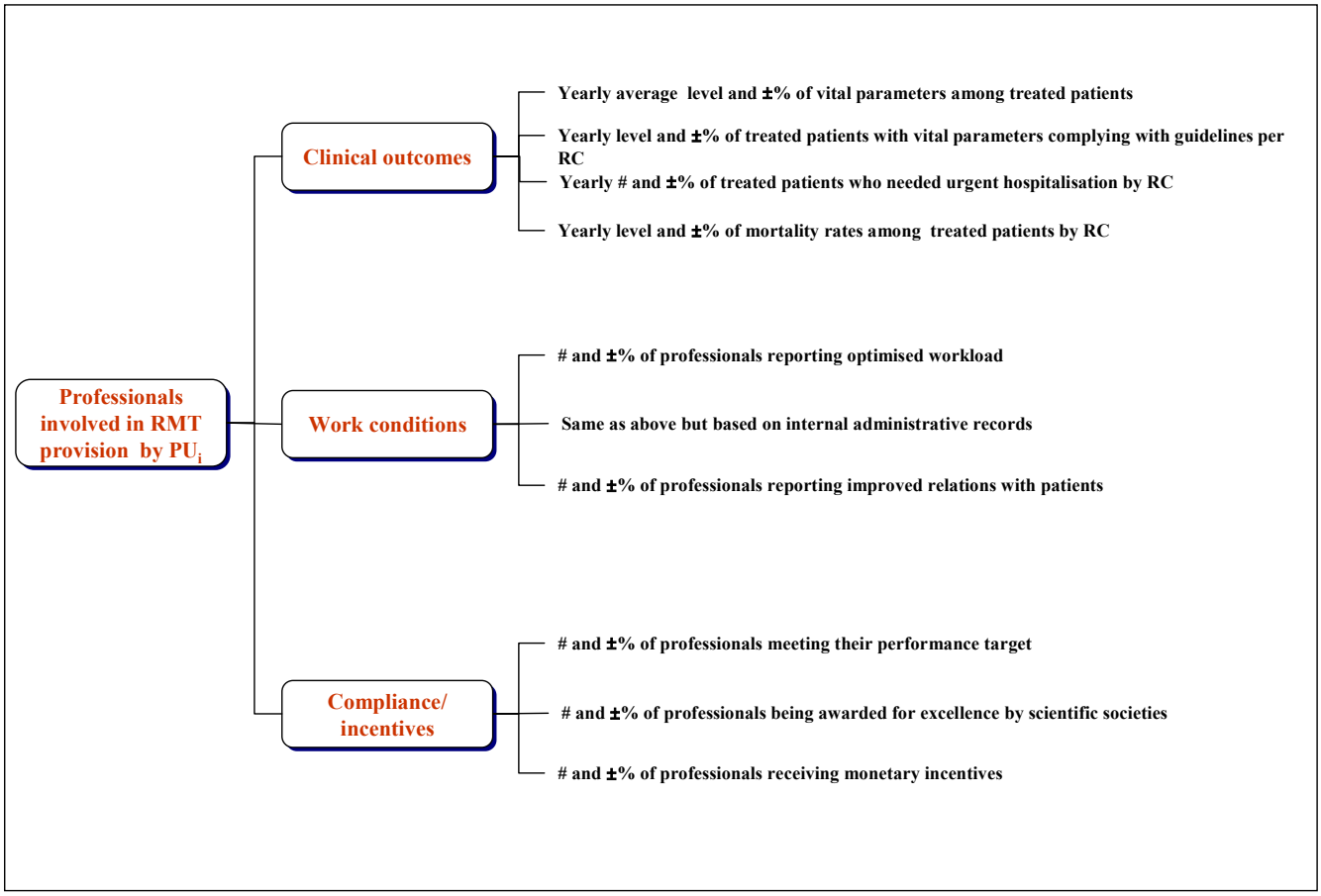


Source: Authors' elaboration.

RMT is also a form of self-care and can generate empowerment and responsibility (or playing with words "response-ability) since it enables patients proactively adopt better lifestyles and adhere to drug prescriptions. The first indicators attempt to objectively measure this. Subjectively, one can ask the patients the extent to which they feel less anxious and more in control of their disease and of their life in general (second and third indicator in this block). Finally, convenience and confidence is about the patients but also about their relatives (who are secondary beneficiaries), about trust in health care system, and also about tangible saving in terms of additional care needed. Evidently a few of these indicators presuppose the availability of data from surveys of patients/users.

Moving to those include in Figure 12 below, the indicators of clinical outcomes are straightforward in light of the illustration provided on the analogous baseline parameters and do not require further comments. The second block of indicators concerns the work conditions for professionals (workload but also professional-patient relation) measured subjectively by asking them (first and third indicators). Internal records on workloads (second indicator) can be used to objectively measure and check the subjective perceptions. Naturally, as anticipated, the first and third indicators need surveys of the professionals involved in RMT service provision. The first and third indicators of the third block are based on the assumption that management has set performance targets and related monetary incentives for professional. The second, instead, is about external recognition of excellence as a result of outstanding clinical outcomes from RMT.

Figure 12: Proposed measurement indicators: outcomes for healthcare professionals

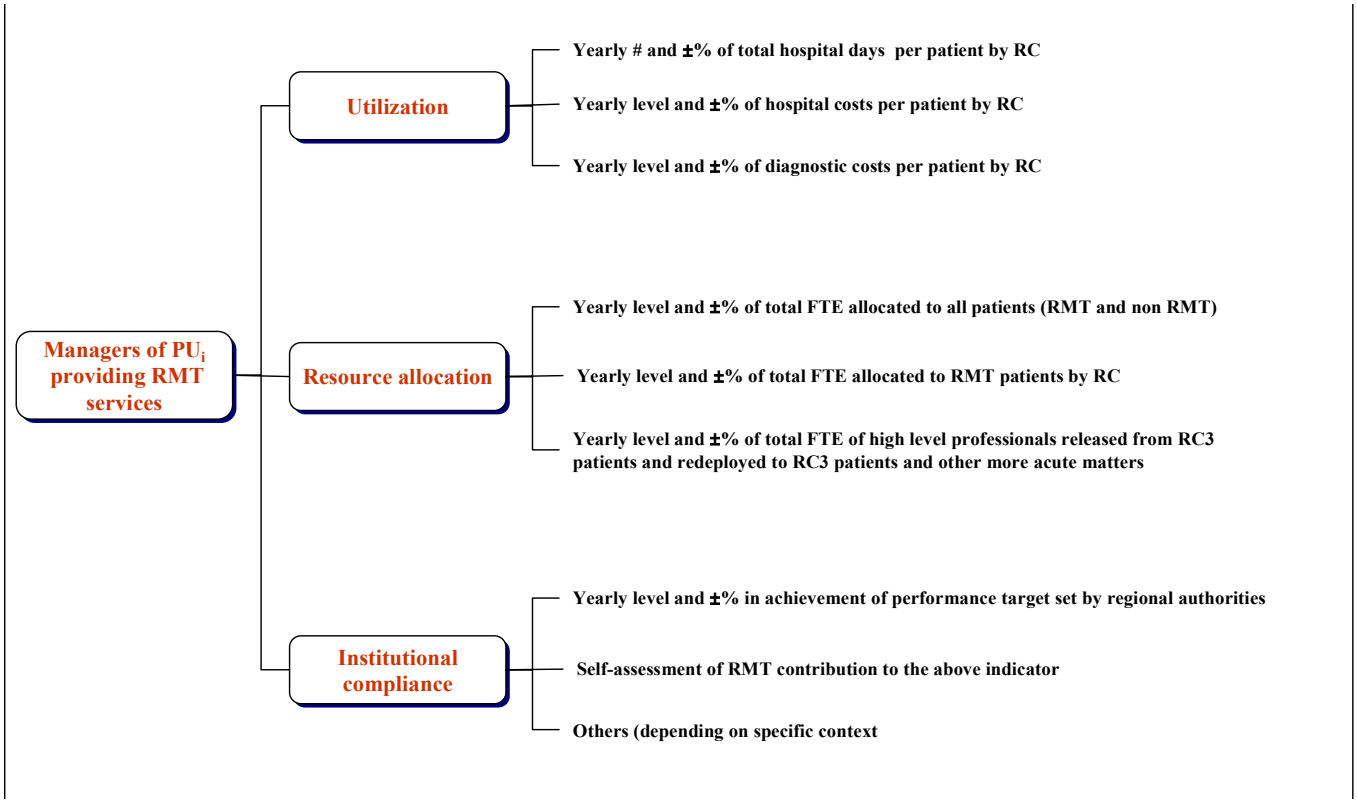


Source: Authors' elaboration.

In Figure 13 the indicators for the three blocks of outcomes are presented, which are relevant to the organisational perspective of PUs management. Utilization is measured both in volume (hospital days) and in monetary terms (total hospital ad diagnostic costs), with all three indicators facilitating breaking down and reporting by patients RC.

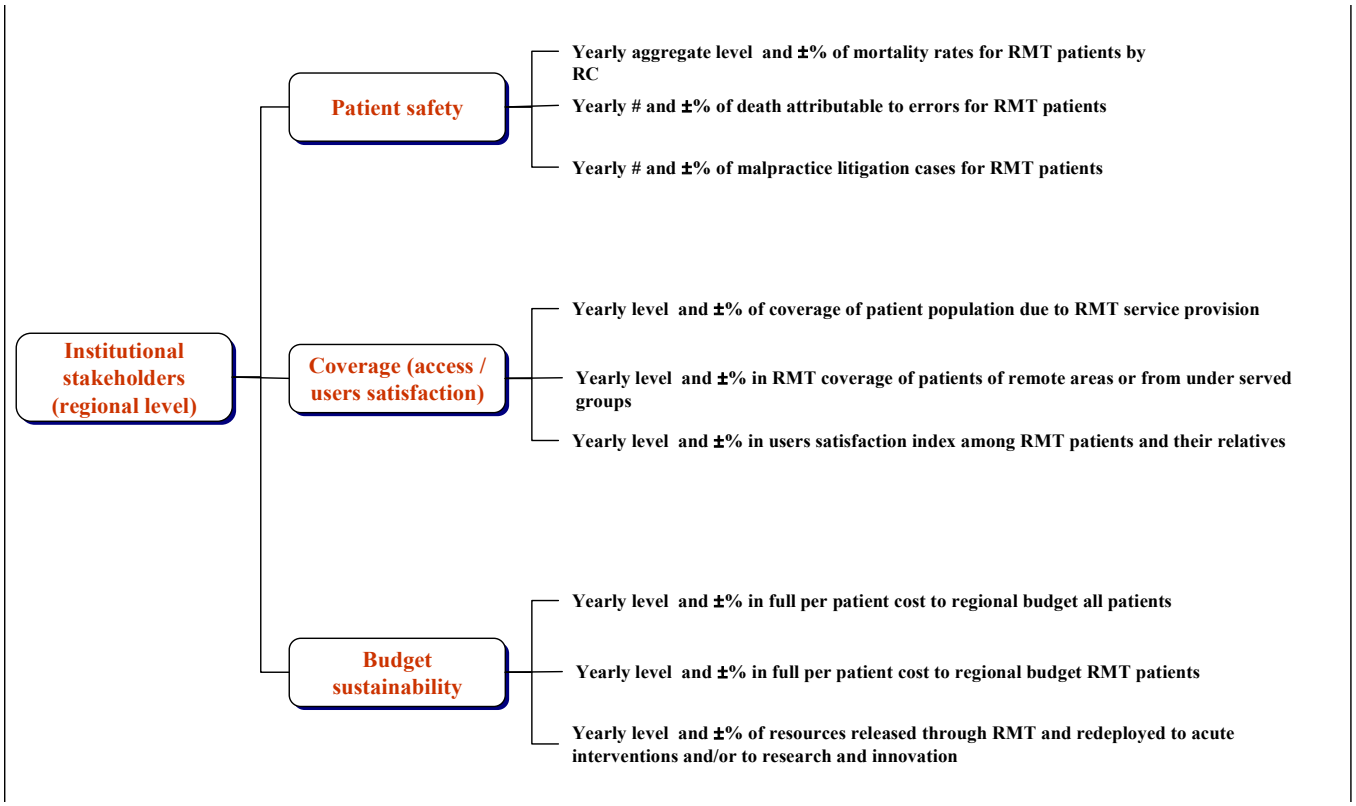
The indicators in the block on resource allocation are probably worth discussing just a bit further, and especially for the third one. The first and the second indicators are to be read and interpreted together to see whether in general RMT has resulted into a better resource allocation, or instead might have caused a stratification of workload, that is more work for RMT without a decrease of work for treatment of patients in traditional ways. The third indicator is, however, the most interesting one since it would tells us to what extent RMT is enabling a move toward a 20/80 allocation (20% of the professional workforce managing 80% of the patient base) and releasing resources for more complex chronic patients or for others acute activities. The first and second indicators of the third block termed "institutional compliance" are based on the assumption that the regional authority has set performance targets and related incentives for all producing units. The second, most likely to be based on self-assessment, measure the specific RMT contribution in meeting the institutional targets.

Figure 13: Proposed measurement indicators: outcomes for healthcare producing units managers



Source: Authors' elaboration.

Figure 14: Proposed measurement indicators: outcomes for institutional stakeholders



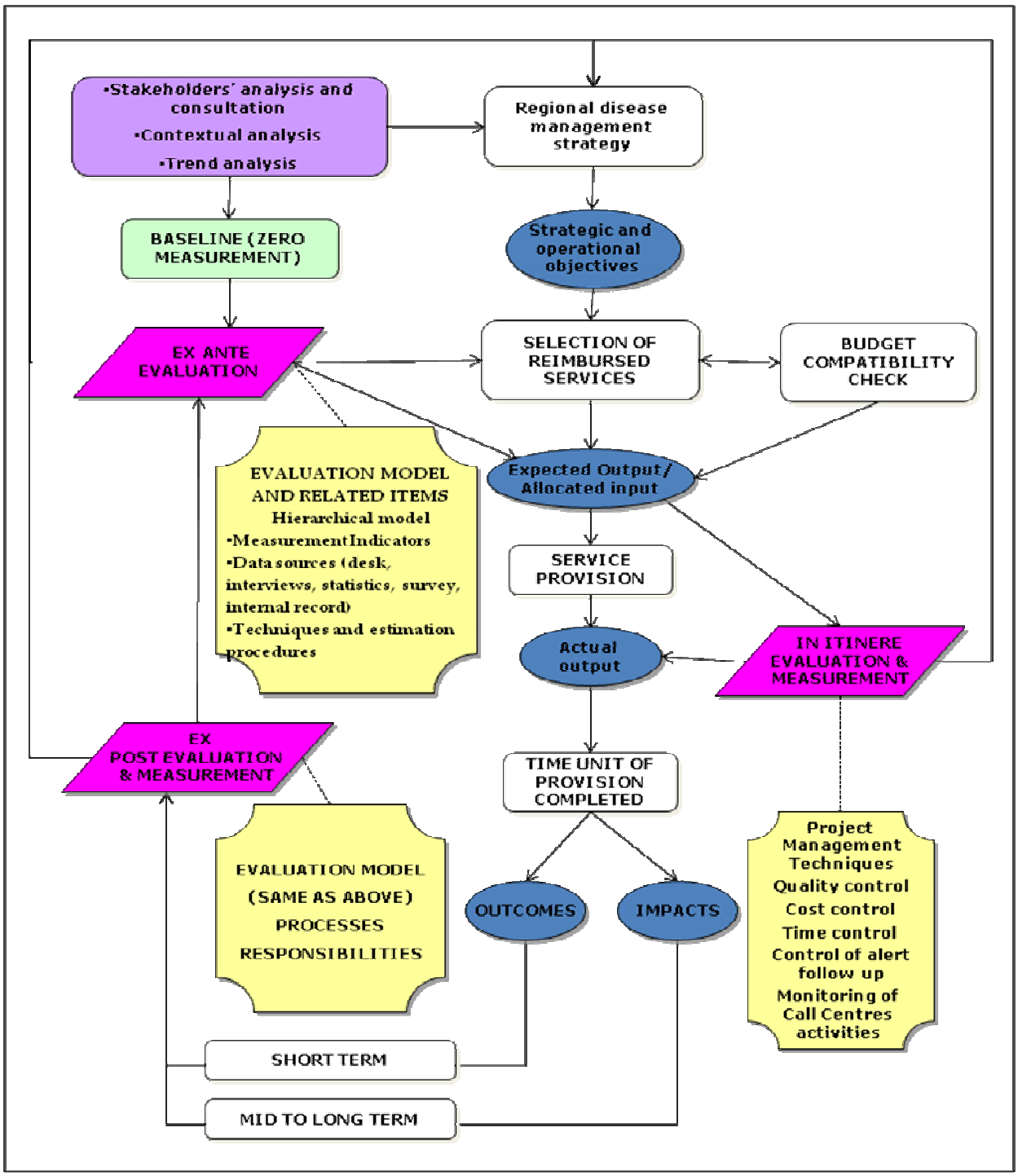
Source: Authors' elaboration.

Finally, above we present the measurement indicators proposed for the institutional stakeholders at the regional level, which are pretty self-explanatory also in view of the illustration of their corresponding baseline parameters and do not require any additional comment.

3.4.5 The overall framework and supporting processes

The next two pictures adapt to the hypothetical and ideal-typical context defined so far the general views illustrated earlier in Figure 6 (page 27) and in Table 2 (page 26). They provide a sketch of the overall framework and supporting processes.

Figure 15: Overall Framework



Source: Authors' elaboration.

Before commenting the figure above, we recall that for the sake of simplicity we basically collapsed and compressed stages 3, 4, and 5 of the earlier mentioned Table 2 and in turn better fleshed out stage 6 (see pp. 31-32 for full illustration of this conceptual simplification). In addition, regarding Figure 15 above, we must specify that:

a) It assumes a consolidated system of evaluation and measurement running steadily so that one can reason along the lines of the closed loop evaluation and measurement circuit depicted in **Figure 6** (page 27)**;**

b) White boxes indicate **stages in the lifecycle** (first column of Table 2), whereas light blue ellipses mark the different objects of measurement occurring at different times (temporal dimension, column 3 in Table 2)**.**

The lifecycle (white boxes) is the thread of the overall framework and results into the different temporal occurrence of the object of evaluation and measurement (blue ellipses) going all the way from objectives-expected output/allocated input to actual output/used input and to outcomes and impacts. The regional strategy, informed by previous evaluation and measurement cycles and supporting analysis (violet box), defines the strategic and operational objectives, from which target output, outcomes and impacts derive and should be incorporated into the *ex ante* evaluation and measured *ex post*. The decision on the selected services to be reimbursed shapes the allocated budget and the expected output, also fixed *ex ante* but measured *in itinere*. Service provision determines the actual output and the actual costs, which are monitored *in itinere* but finally fixed *ex post*. Once a time unit of provision is completed it is possible to identify outcomes, whereas impacts if any would occur after several time units.

The circular nature of the process indicates that the various forms of evaluation and measurement (*ex ante, in itinere, ex post*) continuously feed each other. Depending on the stages the circles provide the emerging insights to:

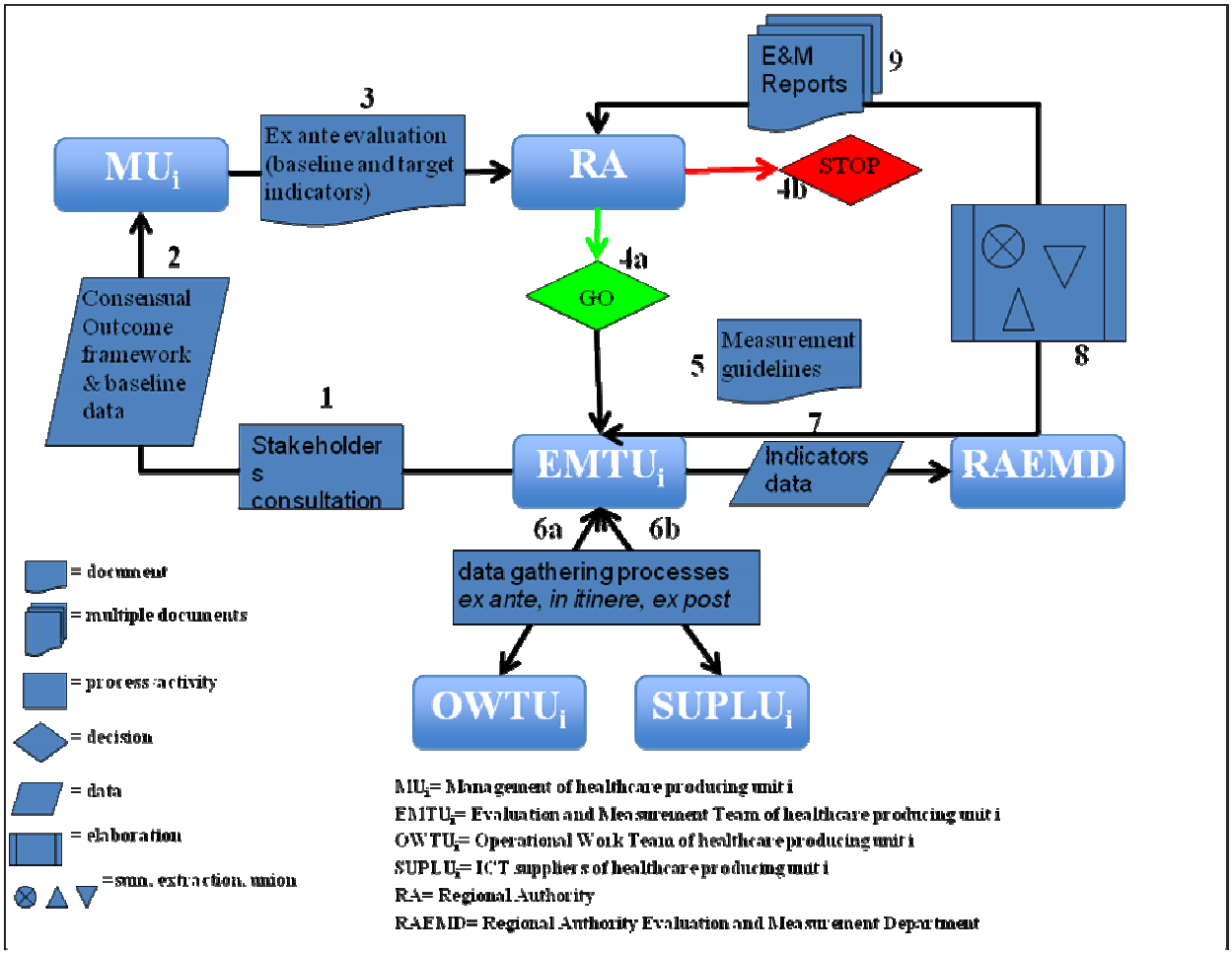
- Improve/ modify service provision using input from the *in itinere* indicators;
- Verify *ex post* the aggregate outcomes of the regional portfolio of services in comparison with objective and targets in order to improve the next version of the strategy and the next selection of services (or adjustment of existing ones);
- Incorporate *ex ante* the changed conditions (violet box: needs, stakeholders' inputs, trends) and insights from the previous *ex post* indicators.

The tight and strategic link between the *ex ante* and *ex post* indicators is underscored by the need of a gap analysis between the expected/estimated and the realised output/outcomes/impacts [ΔOutput (expected-measured)]; [ΔOutcomes(expected-measured)]; [ΔImpacts(expected-measured)].In order to do this, one needs a stable and shared evaluation model, which further underscores the importance of multi-stakeholders consultation and cooperation. Finally, the figure indicates that earlier presented hierarchical model and indicators are part of the building blocks for both *ex ante* and the *ex post*, whereas it additionally specifies that the *in itinere* requires the application of project management, cost and quality control techniques.

For this overall framework to function naturally roles and responsibility must be defined and the needed organisational and inter-institutional supporting processes and cooperation set in motion. This is probably the most challenging and crucial question for the success of a system of evaluation and measurement. Modelling and technical issues are difficult but can always be solved. The Gordian knot is devoting to evaluation and measurement the financial and human resources needed to steadily gather the needed data and information and systematically store and elaborate them. The most beautiful theoretical and technical artefacts will fail and remain in the form of manuals left accumulating dust on bookshelves if there are no operational teams that work on data gathering, storage and elaboration. Whether this occurs or not is a matter of governance and political will,

which we do not intend to discuss here. The Figure below provides a simplified and ideal-typical sketch of how such process and cooperation may work, which we comment below.

Figure 16: Sketch of processes



Source: Authors' elaboration.

All the forms used in the figure are from the flowchart diagram notation (explained in the right bottom side) except for rounded boxes with acronyms in capital letters (explained at the bottom) that indicate the key actors. The figure assumes that each producing unit has its own Evaluation and Measurement Team (EMTU$_i$) and that the Regional Authority (RA) includes an Evaluation and Measurement Department (RAEMD, it could also be a Portfolio Management Unit). The various steps in the overall process are numbered, and we comment them below using such numbering notation.

1) EMTU$_i$ consult with broadly defined stakeholders (beneficiaries and stakeholders proper) to gain context data (violet box of Figure 15) and to preliminarily define a realistic and shared framework of eligible/achievable outcomes (see discussion of this concepts in § 3.2.3).
2) EMTU$_i$ provides its management with data on the above.
3) Management uses the data to present a draft *ex ante* business case to the RA.
4) This is split into:
   4a) RA approves proposal and include service among those entitle to reimbursement;
   4b) RA rejects and the all process stops.
5) Under 4a, then the RAEMD is assigned the responsibility to provide measurement guidelines to the EMTU$_i$ and to oversee and steer its activities. Such guidelines would contain both insights on processes and procedures and requirements for the data to be

gathered and provided. It would also set a time schedule for the gathering and the provision of such data.

6) This step is split in two parts and it a bit more complex than depicted in the figure, but we try to illustrate it in a sketchy way:
   6a) $EMTU_i$ drafts a refined version of the *ex ante* business cases which set the basis for the gathering of data relevant both for the *in itinere* and the *ex post* measurement. It passes this onto the Operation Work Team of the producing unit ($OWTU_i$), assign data gathering responsibility, and periodically requests the data;
   6b) $EMTU_i$ incorporate relevant metrics as requirements of Service Level Agreement with suppliers and periodically request the corresponding data.
7) $EMTU_i$ periodically provides measurement data to the RAEMD.
8) RAEMD, having received the data from producing units from i-N, elaborate them in various ways (using standard techniques and ratios and creating composite regional indexes).
9) RAEMD provides RA with Evaluation and Measurement Reports with key strategic highlights.

Assuming these processes repeat over time at the beginning of a new cycle such reports become an input for decision-making and revisions, if needed.

3.5 Brief conclusive considerations: implications for SIMPHS

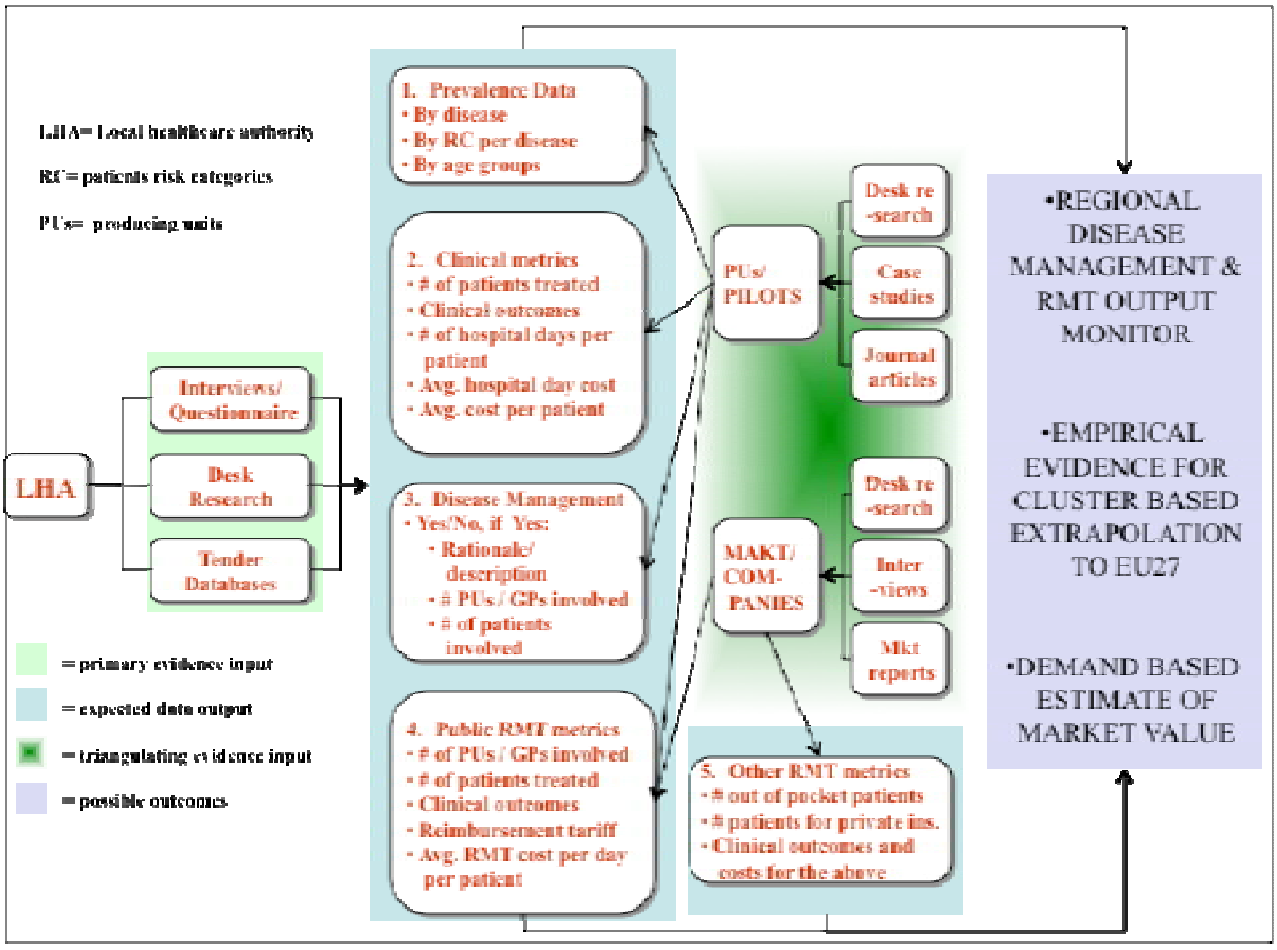
With the benefits of hindsight we could now better design the SIM and structure the data gathering process differently and, we think, more efficiently.

The original building blocks upon which the SIM was designed (illustrated in Figure 1 page 7) aimed at providing a much more comprehensive and ambitious picture and set of indicators than the one implied in the framework and model described in the previous paragraph. Indeed, within the SIM the issues of outcomes and impacts are only one component along several others (and in fact in Deliverable D3.1 these are treated in one of the many annexes) within a framework that is overwhelmingly designed around the market dimension (as a result also of the input received during the design stages of the project). Such a comprehensive framework, however, would be justifiable and feasible to be steadily fed with data and turned into a monitor only if a consolidated market existed, which we discovered at the end of our research is not the case for RMT (by all considered the segment of PHS more widespread in the practice of delivering health care and not confined only in the domain of R&D). The original SIM design was supply driven and top down, in the sense that it assumed that looking at the market, value chain, companies, etc would provide the main avenue to gather all the relevant data. Most market research companies focussing on the ICT industry such as Gartner, IDC, Frost & Sullivan and the likes usually adopt such supply driven approaches since their analysis and estimations are mostly based on information they obtain from vendors. While we remain sceptical on the empirical reliability of such approach in general, it is reasonable to consider it adequate for well-established and consolidated markets where they can draw exhaustive and reliable samples of all the relevant vendors. Yet, in the case of RMT and PHS such approach is patently unfit as demonstrated for example by the fact that the list of vendors Gartner provided to the PHS2020 team was not exhaustive and needed a lot of integration, and that the SIMPHS team found several RMT companies that were not listed in Frost&Sullivan report. Knowing now these conditions, it is clear to us that the design of the SIM has been focussed around the typical "solution in search of a problem", whereas it would have been more fruitful to start from the "problem/need". In other words the design of the SIM should have been demand driven starting from the needs of health care organisations as several of the November 2009 validation workshop experts suggested.

As a result the success of a similar future exercise would fare better if accepting the strong recommendation that the SIM (or its renamed equivalent) be designed not around the market

dimension but rather around the need of regional or other local level healthcare authorities, starting by focussing on the existence of disease management strategies and programmes, then proceeding to verify whether disease management programs are at work and what forms of self-care are adopted, next identifying broadly defined ICT supported forms of self-care[12] and RMT proper. The logic of such approach and its potential outputs are described in **Figure 17** and is based on the triangulation among different sources of data, as a result of which anyone starting from the demand side would eventually be capable to estimate the size of the market.

Figure 17: Blueprints for a Future Demand Driven SIM



Source: Authors´ elaboration.

A second way in which the content of this section can be put to use in the future is extracting from the evaluation and measurement framework presented a number of parameters and requirements both to select and subsequently manage CIP pilots and other possible future EC funded deployment activities (i.e. ELSA). This is very briefly illustrated in the next table, where we adapted the content of Table 2 (page 26) to a hypothetical EC funded deployment project.

[12] ICT can support disease management not only through RMT as defined in our research, but also as a result of a mix of tools. In the British Columbia case studies considerable reduction of the cost per patient for diabetes were achieved through a combined adoption and use by physicians of Electronic Medical Records, a web-based Toolkit for Chronic Disease Management, two-way electronic communication with the patients (e-mail, web, videoconference, call centres).

Table 3: Life cycle and implications for evaluation and measurement of EC deployment projects

Different stages	Main Actors	Phases, types and objects of evaluation and measurement(adapted framework and model from this document to be used as benchmark)	Stakeholders involvement
1. Definition of Call objectives	Commission	Strategic objectives and desired output /outcomes	MS representatives, experts, industry, patients association, healthcare players
2. Definition of call requirements	Commission	Criteria and guidelines for preliminary *ex ante* business case to be included in proposals (worth 40% of technical points)	Experts and list of external evaluators
3. Presentation of proposals	Proposers	• **Draft *ex ante* business case with: expected output, outcomes (with corresponding measurement indicators), baseline;** • **Design measurement plan, processes, responsibility**	Consultation with beneficiaries and stakeholders not required, but if carried out quality of business case improves
4. Selection of Proposalsi-N ($\sum_{i-n}$=Portfolio)	Commission and external evaluators	Assess proposed business case and related processes against benchmark framework and model	Not applicable
5. Negotiation and work plan	Commission and proposers	• Request needed changes /integration to business cases and supporting plan/processes; • **Define measurement time schedule**	Not applicable
6. Project delivery/monitoring	Commission, evaluators, projects consortia	• **Consortia periodically provide Commission with data from *in itinere* measurement (advancements, outputs, etc)** • **As piloting of service provision start Consortia to provide preliminary data on outcomes**	Projects consortia to consult, and obtain data from, all relevant beneficiaries and stakeholders
7. EC funding ended	Project consortia	Comprehensive *ex post* measurement providing data on: Actual total costs, realised output/ outcomes, continuation of service after end of funding, spin off, transfer to other entities	Same as above
8. EC $\sum_{i-n}$=Portfolio assessment	Commission	Aggregate data from all projects and produce relevant measurement indicators	Wide dissemination of results

Source: Authors´ elaboration.

The table is self-explanatory and we only comment the fact that in this document there are all the instruments to build and evaluation and measurement system specifically tailored to the peculiarities of EC funded deployment activities.

4 Annex I: Market versus Public Sector and Implications for RMT

4.1 What is a market

Markets have the following three key characteristics:[13]

1. Consist of transactions for goods and/or services for which a price is paid by the customer and, thus, their value are given by multiplying the volume sold by the price. Accordingly markets are quantified in terms of revenues and not of costs (although the costs are reflected in the price= costs + margins);
2. They presuppose an exit: customers can choose from among several different providers;
3. They transact goods and services that are "private" in the pristine sense of the word where consumption is individualised and "rival".

4.2 Public sector peculiarities

The latter characteristic distinguish markets from the public sector, which often produces public goods with externalities where consumption is "non rival" and nobody can be excluded from it.[14] Such public goods with are traditionally not computed into market values. For instance, a tele-care infrastructure whose costs have been entirely covered with public money should not be computed into the quantification of Telecare market *strictu sensu*, which is in the way defined by the three elements above. The public sector to a large extent provides such collective goods for which a price cannot be charged and where there are no exit mechanisms (public sector monopsony).

Education and health are two cases where the public sector provides individualised services for which, to different degrees in different countries, there are private sector alternatives and exit mechanisms (naturally restricted to those who can afford the out of pocket disbursements). This not withstanding, up to now there is not yet any standardised valorisation in monetary term of such services. Until recently in the all public sector, given lack of price as a key measurement unit, the convention in use was output=input, that is to say the value of the goods and services produced was made equal to public sector expenditure. This is a very unsatisfactory proxy and cannot in anyway be equated to the valorisation of any private market. In recent years progresses have been made and an increasing number of countries have produced volume metrics of output, including in the healthcare sector. Yet, it must be noted that sophisticated accounting and budgeting techniques (i.e. activity based costing) are rarely used within the public healthcare producing units and it is hardly possible to get from most of them accurate and robust data providing a monetary value of the human resources costs of providing a very specific and well defined output. In other word one can get from public accounting some figures of the total cost of personnel in a given healthcare producing unit but very rarely figures on how such costs can be imputed to different activities.

4.3 What is market and what is public in RMT: looking at business models

For our purpose and in light of the discussion in the previous two paragraphs we look at four basic RMT business models to pinpoint the components that can be considered and measured as market and those that are not.

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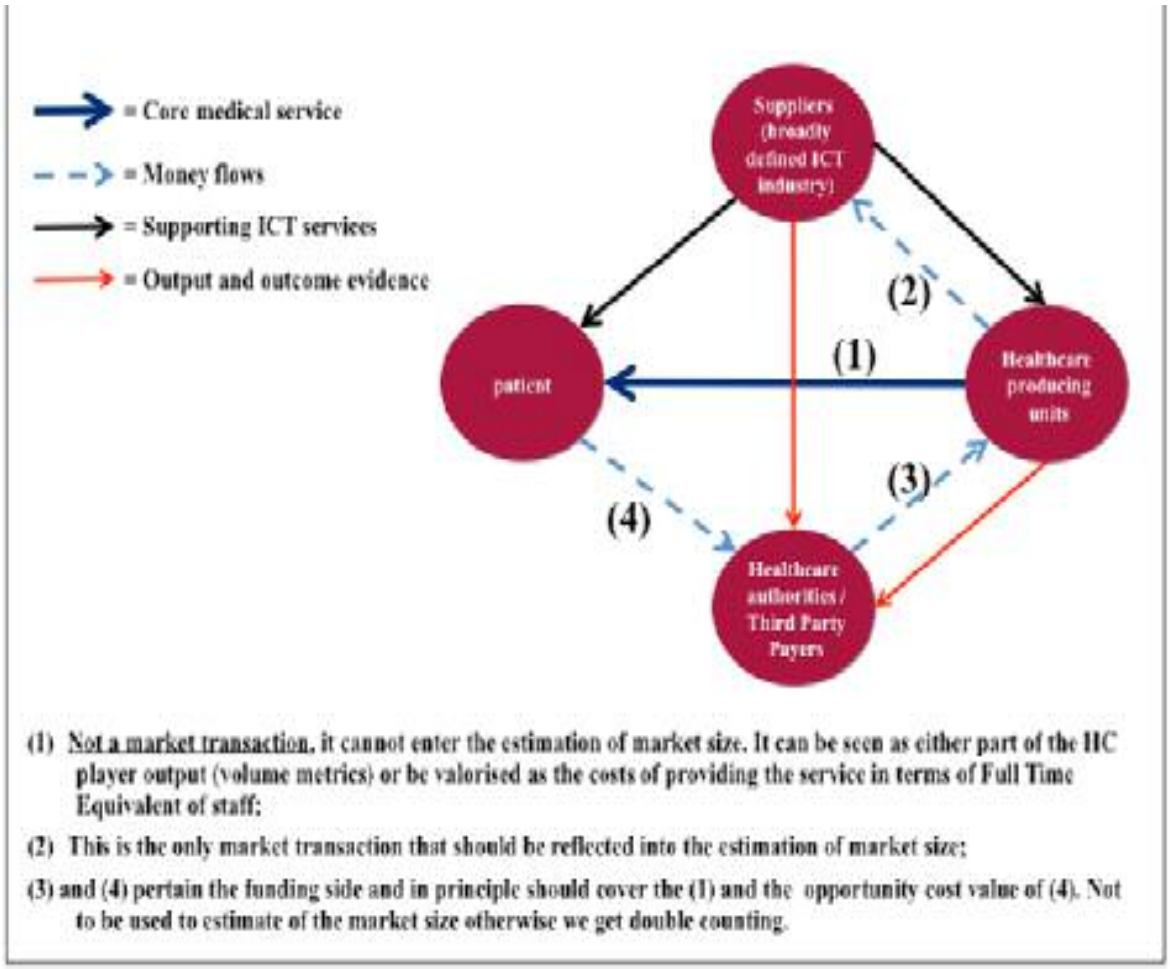
[13] The following is based on various sources, among which, see: a) for definition of market transactions and corresponding market valorisation Eurostat, (1995, 2001) b) For a review of the state of the art in measuring and giving value to public sector output Atkinson (2005); c) On the distinction between private and public goods and on the overall issue of the public sector see the classic public economics work of Musgrave and Musgrave (1984).

[14] A public good it is either available for free to everybody or a basic equal fee can be charged, usually substantially lower than if the same public good was hypothetically provided by the private sector.

Under the business model of Figure 18 the only market transactions concern the provision of ICT devices and services by suppliers to the healthcare producing unit that utilize them and is subsequently reimbursed from the public health budget. The medical part of the remote services remains fully produced by the healthcare producing unit. Since the final customers do no pay for the services and the healthcare producing units are reimbursed, the actual provision of the core medical services is not reflected into any market transaction. Attributing a monetary value to the labour costs entailed in the provision of the medical service amounts to a valorisation of a public sector output, which should not go into the quantification of a market strictu sensu. In the case of Lombardy Region illustrated in Deliverable D3.1, for instance, the reimbursement of 750 € per patient per 6 month of RMT treatment of Chronic Heart Failure is split 50:50 between the suppliers of the ICT services and the hospitals. So 350 € go into the market for RMT services and 350 € pay the work of the hospital professionals engaged in the provision of the service. If this case was not a case but a standard then we could assume that the overall expenditure for RMT could be valorised at double the figure provided by Frost&Sullivan (127 million € in 2008 in Europe), as the latter explicitly exclude the medical part of the services and compute only the payments for devices and ICT services. Unfortunately the situation is much more fragmented and we cannot take the Lombardy case as a benchmark.

Figure 18: Healthcare centred business model (reimbursed)

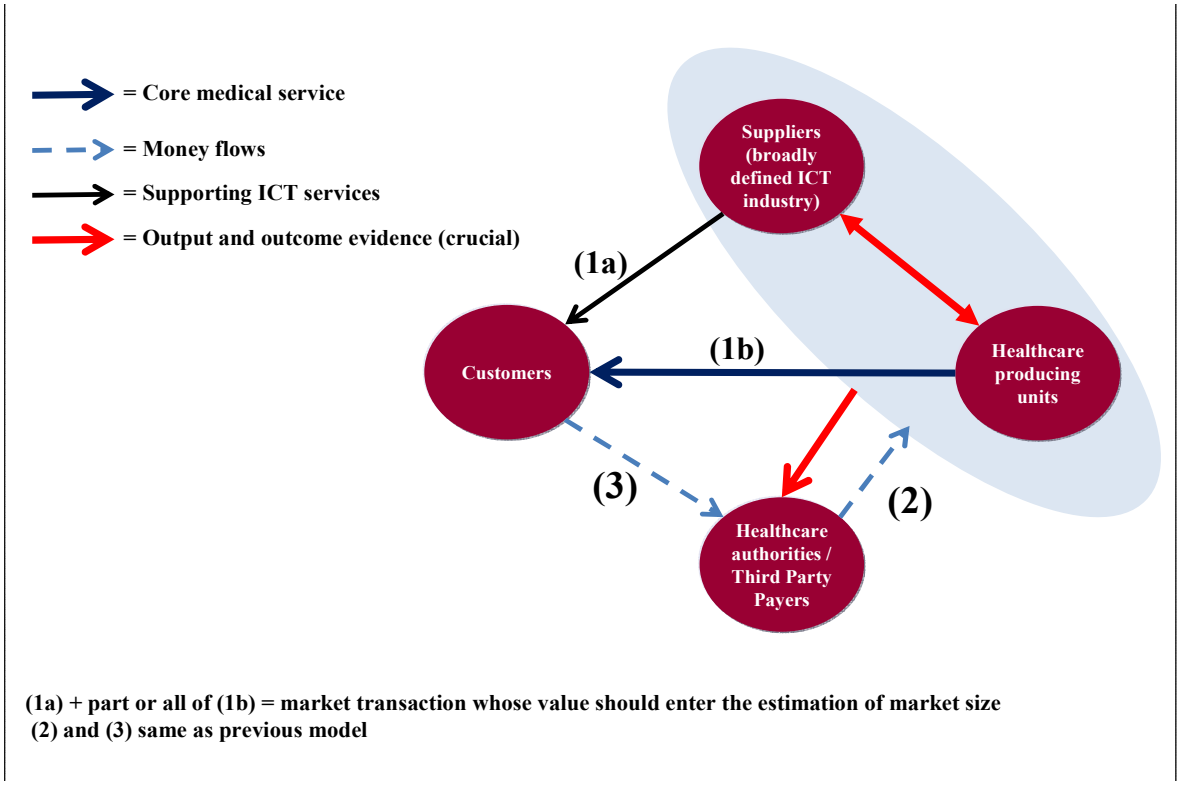


Source: Authors´ application to SIMPHS empirical evidence of data first presented in the article referenced in footnote[15]; also the basis for the elaboration of Figure 19, Figure 20, and Figure 21.

[15] TEN-HMS study: Implementation of TeleCare Services: Benefit Assessment and Organisational Models, in: Integration of Health Telematics into Medical Practice, IOS Press, 2003, pp. 131-141.

Under the model of Figure 19 both the ICT and medical services are provided in full (or to a large extent) by the suppliers. So, the entire value chain is fully reflected in market transactions. If all RMT services were provided according to this model, then the market would comprise devices, ICT services, and the medical part of the RMT activities. Applying just hypothetically the Lombardy benchmark of 50:50 split between ICT devices and service and medical services then the market could be estimated in 2008 at 254 million € (double the Frost&Sullivan figure).

Figure 19: Extended suppliers value chain business model (reimbursed)



Although under different arrangements, also in the managed care approach depicted in Figure 20 both ICT services and medical services are fully part of the market definition. The same naturally apply by definition to the pure private out of pocket model depicted in Figure 21.

Figure 20: Insurance centred business model (managed care)

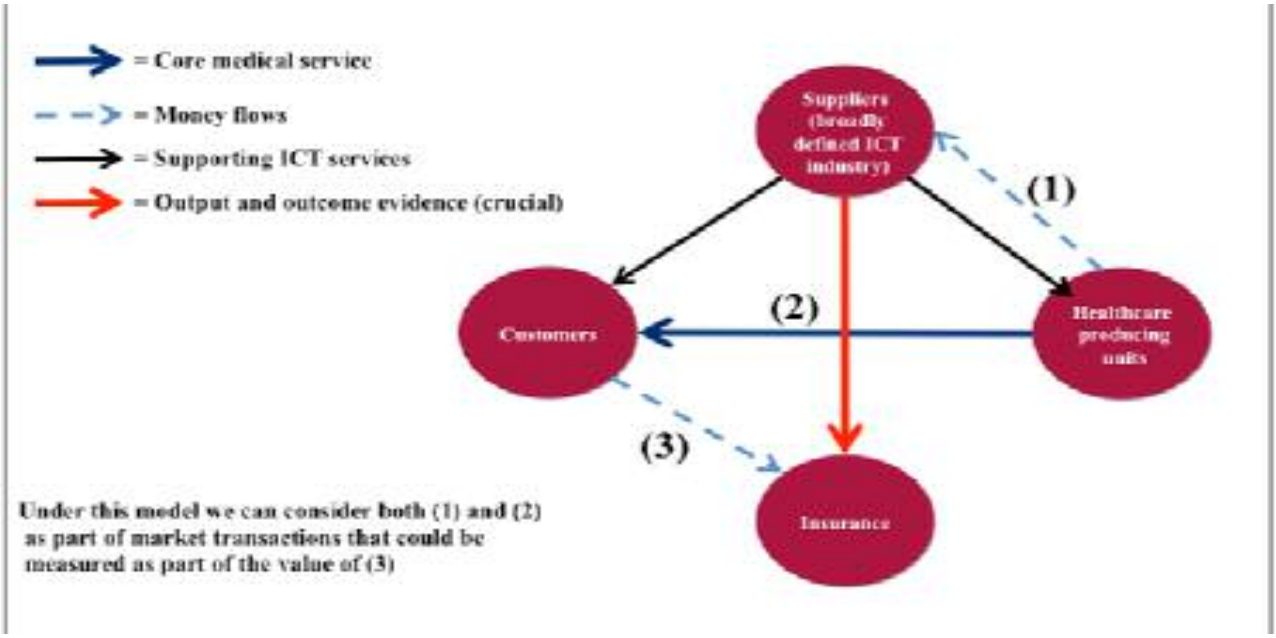
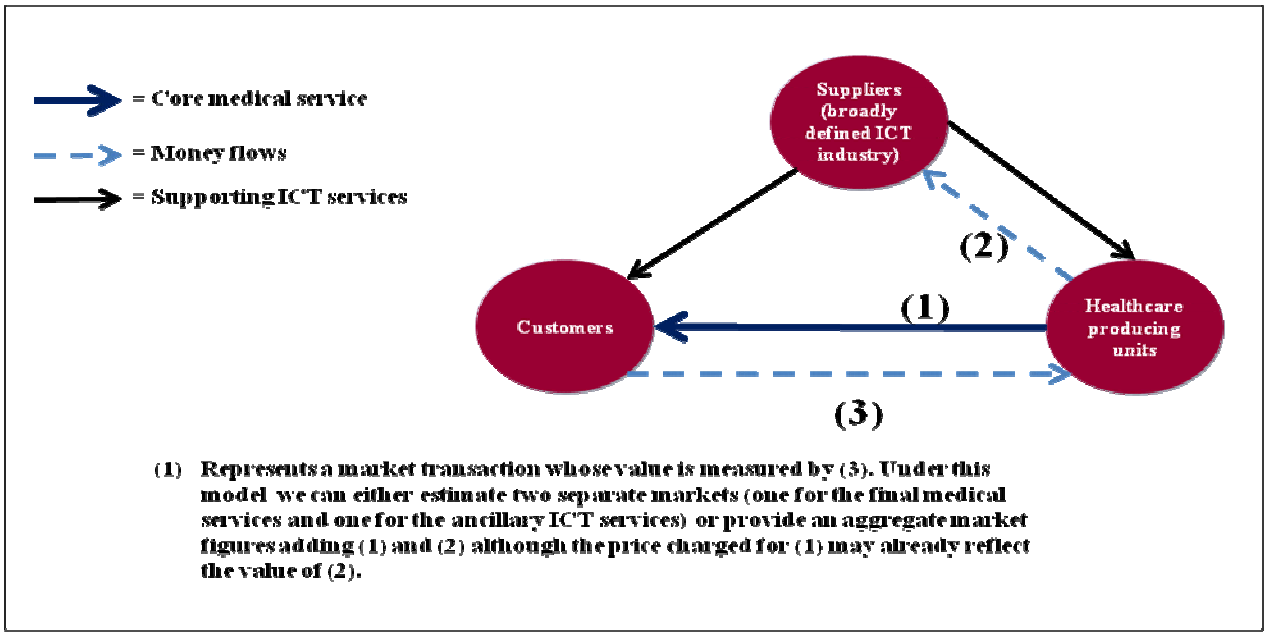


Figure 21: Private out of pocket business model



Source: Authors´ application to SIMPHS empirical evidence of data first presented in the article referenced in footnote 15.

4.4 Implications in light of empirical findings on the RMT domain

The main findings reported in D3.1 and anticipated in the introduction of this deliverable are the following:

- Continuous and self-sustaining RMT service provision is rare and most activities still occur within the framework of pilots and with R&D money;
- We did not find many cases in Europe falling within the second and third business models (Figure 19 and Figure 20: Insurance centred business model (managed care)) with the work of doctors and the call centres entirely provide by suppliers for a price. In the vast majority of cases the costs for doctors, paramedics etc. are costs borne by the public healthcare.

Matching these findings with the definition of the market and with the illustration of the business models we come to the following conclusions:

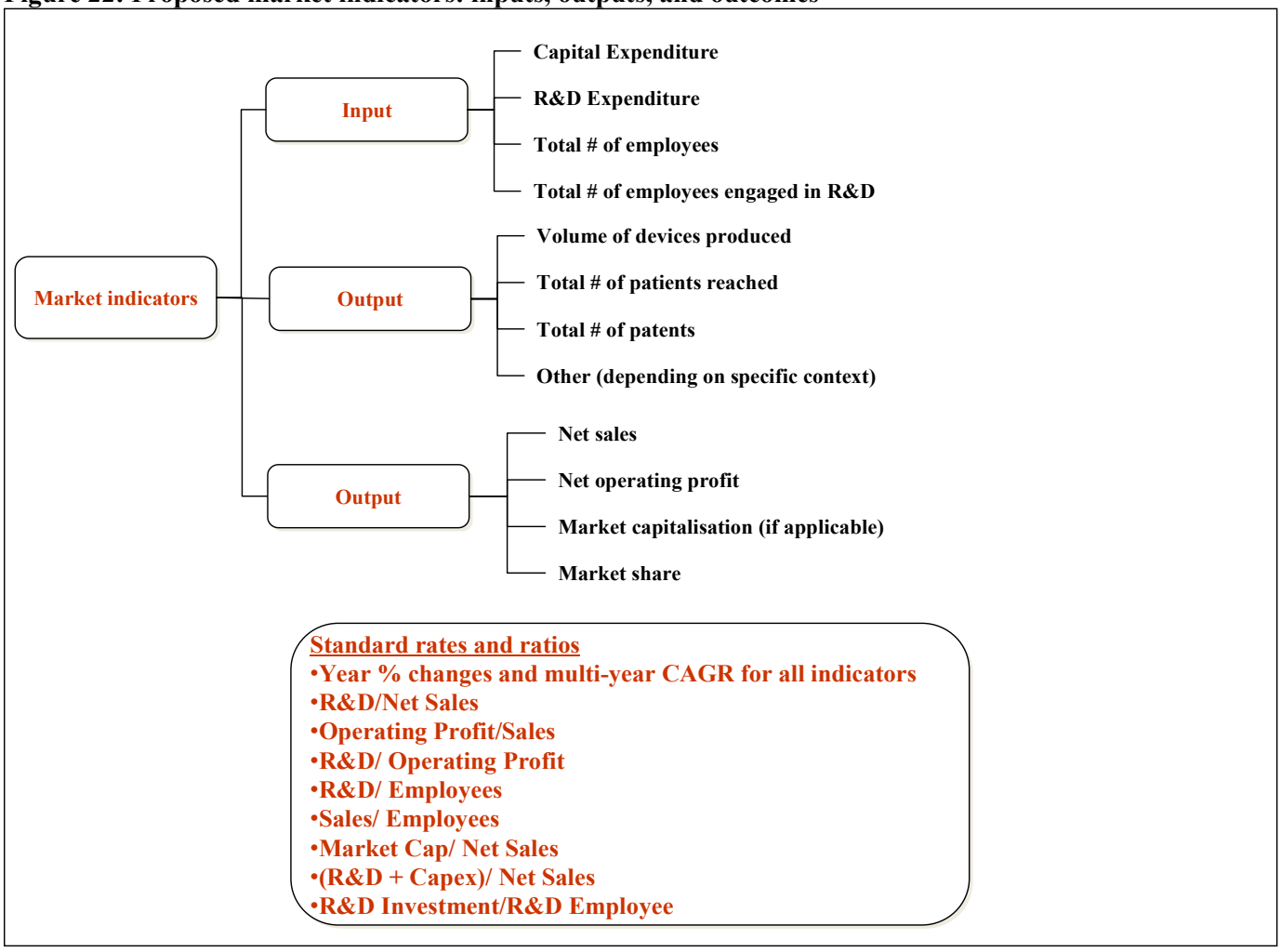
- We know that the 127 million € market value estimated by Frost&Sullivan includes only the devices and the ICT services but not the medical part of RMT services;
- Under the current situation (infancy of the RMT market), this figure reasonably reflects the demand for devices and ICT services generated by few self-sustained services and by various pilots and R&D funded activities that are not sustainable;
- Evidently this figure does not reflect the monetary value of the work produced by the health care professionals in delivering the services. Taking this into account, the figure would certainly increase.
- This additional monetary value cannot be considered by default as part of the market quantification, as in many cases it remains work paid to the health care-producing units out of the public healthcare budget without entailing any market transaction.

In sum, both for what concern the quantification and the measurement indicators we find it appropriate to treat separately what can be included into the concept of the market as defined earlier from the health care system perspective.

5 Annex II: Data for Selected Market Indicators: 50 Companies

The figure below contains the proposed market indicators divided into input indicators, output indicators and outcomes indicators. The box at the bottom includes the standard change rates and ratios that are calculated using the value of the above indicators. An additional indicator not fitting the input-output-outcome frame is the "share of employees located in Europe" to measure the extent to which a company can be considered a European market player proper.

Figure 22: Proposed market indicators: inputs, outputs, and outcomes



Source: Authors' elaboration.

In proposing the above indicators we can transparently state that we simply selected the key ones we found in the ICT sector scoreboard of data used at IPTS. As anticipated, there are many such scoreboards but they are a level of aggregation that does not enable to capture the RMT market.

For the 50+ companies we managed to find some data on some of the above-proposed indicators.

We have looked for financial information, such as their Revenues (in million €), Operating profit or EBITA (in million €), No of employees, Expenditure in R&D (in million €), Market- cap (in million €). We used the data that we found publically available data and in a few cases the companies have been contacted. For listed companies the information was available through the investor relations part of their web sites, their annual report or their U.S. Securities and Exchange Commission (for those listed in the US) fillings. For non-listed companies, in some countries the possibility exists to

access the trade registers or company houses. The laws concerning disclosure for non-publically traded companies demand not such a high degree of transparency as for companies issuing shares to all investors. So even at trade registers and at company houses database the data available are not rich.

As we explained in Deliverable D3.1 there is not yet a RMT market as such, and most of the players are not active only this segment of broadly defined eHealth. So, many of market indicators in the table that follows cannot be attributed solely to RMT activities of the various companies.

Table 4: Selected market indicators for 50+ companies

Company	Country	Revenues (in million €)	Operating profit (in million €)	No of employees	Expenditure in R&D (in million €)	Market- cap (in million €)
Implants						
Biotronik Se & Co KG	DE	341[16]	N.A.	5,100[17]	N.A.	Unlisted
Boston Scientific	US	5,888[18]	(-737)	26,000	579	7767[19]
BOSTON SCIENTIFIC IBERICA SA	ES	122[20]	(-1)	116	N.A.	Unlisted
Medtronic	US	10,446[21]	2,377[22]	41,000[23]	970[24]	36,015[25]
Medtronic Iberica SA	ES	47[26]	3	242		Unlisted

16 Hoover's US$ 499 Million, exchange rate for fiscal year 2008 according to the interbank rate, http://www.hoovers.com/Biotronik-Gmbh-&-Co--Kg/--HD__yrhjtftts,src__global--/free-co-dnb_factsheet.xhtml

17 http://www.biotronik.de/de/de/3518

18 All Data on Boston Scientific's based on SEC 10-k filling for the year 2009 http://phx.corporate-ir.net/phoenix.zhtml?c=62272&p=irol-sec&control_selectgroup=Annual%20Filings, conversion based exchange rates according to the interbank rate.com for the year 2009: US$ to € 0.719

19 Market cap based on NYSE Euronext as of March 2010 conversion based exchange rates according to The interbank rate for: US$ to € 0.729

20 Amadeus Database Fact Sheet.

21 Based on the company website for the fiscal year 2008/2009 ending 24th April 2009 http://investorrelations.medtronic.com/phoenix.zhtml?c=76126&p=irol-fundSnapshot conversion based exchange rates according to the interbank rate for the fiscal year 2009: US$ to € 0.716.

22 Based upon EBITDA Source see above.

23 Source: Medtronic INC SEC 10-K 2009, full time equivalent.

24 Source: Medtronic INC SEC 10-K 2009.

25 Market cap based on NYSE Euronext as of March 2010; conversion based exchange rates according to the interbank rate for: US$ to € 0.729.

26 Source for all Data on Medtronic Iberica: Amadeus Database.

Company	Country	Revenues (in million €)	Operating profit (in million €)	No of employees	Expenditure in R&D (in million €)	Market- cap (in million €)
St Jude Medical	US	3,199[27]	559[28]	14,000[29]	565[30]	9472[31]
Sorin Group	IT	643[32]	(-37.1)	3,400[33]	54	696[34]
Large players						
Philips (Phillips healthcare only)	NL	1,110[35]	645	121,398	1,590[36]	23,542[37]
GE Healthcare	US	11,517[38]	1,740[39]	304,000[40]	683 (PHS 36[41])	101,782[42]

[27] Source: St. Jude Medical INC SEC 10-K 2009.
[28] Based on the company website for the fiscal year 2009; conversion based exchange rates according to the interbank rate for the fiscal year 2009: US$ to € 0.719.
[29] Source: St Jude Medical INC SEC 10-K 2009, full time equivalent.
[30] Source: St Jude Medical INC SEC 10-K 2009; conversion based exchange rates according to the interbank rate for the fiscal year 2009: US$ to € 0.719.
[31] Market cap based on NYSE Euronext as of March 2010; conversion based exchange rates according to the interbank rate for: US$ to € 0.729.
[32] Source: all information based on the annual report 2008 http://www.sorin.com/eng/ir_reports2008.asp
[33] Among them are 450 Researchers.
[34] Source: Milan Stock Exchange, March 2010, http://www.borsaitaliana.it/
[35] Source: Philips Annual Report 2008.
[36] Research expenditure for the total Philips' activities.
[37] Source: NYSE Euronext March 2010 http://www.euronext.com
[38] Source: GE INC SEC 10-K 2009, numbers related to GE Health Care division, if not differently indicated; conversion based exchange rates according to the interbank rate for the: US$ to € 0.719.
[39] Source: GE INC SEC 10-K 2009, numbers related to GE Health Care division, if not differently indicated; conversion based exchange rates according to the interbank rate for the: US$ to € 0.719.
[40] Source: GE INC SEC 10-K 2009, numbers related to the total operations of GE; full-time equivalent.
[41] Source: Health care related research as indicated in the Annual report, news release http://www.ge.com/pdf/investors/events/05072009/ge_healthymagination_factsheet.pdf, conversion based exchange rates according to the interbank rate for the fiscal year 2009: US$ to € 0.719.
[42] Source: NYSE Euronext March 2010 http://www.euronext.com, conversion based exchange rates according to the interbank rate: US$ to € 0.731.

Company	Country	Revenues (in million €)	Operating profit (in million €)	No of employees	Expenditure in R&D (in million €)	Market- cap (in million €)
Agfa Healthcare	BE	861[43]	(-166)	6,229	107[44]	565
Honeywell	US	20,713[45]	2,035	100[46]	1,054	20,530
Bosch	DE	45,127[47]	3,801	281,700[48]	3,889	Ownership by Foundation, unlisted
Intel	US	26,696[49]	3,617	83,900	3,910 PHS: 36[50]	89,823[51]
ICT providers						
Nokia	FI	50,710[52]	4,966	125,829	5,968	38,428
Ericsson	SE	21,513[53]	2563	82,493	3,444	25,880[54]

[43] Source: Agfa Annual report 2008, http://www.agfa.com/en/co/investor_relation/reports_presentations/annual_reports/index.jsp, numbers refer to the Agfa Group(Agfa-Gevaert).

[44] Source Annual report 2008 Agfa Gevaert, spent 175 million in 2008, of which 61% was dedicated to health care.

[45] Source Annual report 2008. http://phx.corporate-ir.net/phoenix.zhtml?c=94774&p=irol-reportsAnnualArch, exchange rate for fiscal year 2008 according to the interbank rate.

[46] PHS related employees, according to expert interview with Adam Wragg, Honeywell HomMed.

[47] All numbers are found on the corporate website of Bosch Group and the http://www.bosch.com/content/language2/html/2226.htm

[48] Source: Annual Report Bosch 2008 http://www.bosch.com/content/language2/downloads/GB2008_En.pdf

[49] Source Annual Report 2008 0.68341.

[50] Source: Annual report 2008, Conversion based on the exchange rate for the fiscal year 2008; news release http://www.ge.com/pdf/investors/events/05072009/ge_healthymagination_factsheet.pdf, conversion based exchange rates according to the interbank rate for the fiscal year 2009: US$ to € 0.719.

[51] Source NASDAQ March 2010, conversion based exchange rates according to the interbank rate: US$ to € 0.731.

[52] Source: Nokia Ovy. All numbers based on the 2008 Annual accounts and SEC Form 20-F.

[53] Source: Ericsson Annual report 2009, conversion based exchange rates according to the interbank rate SEK to € 0.104.

[54] Source: Ericsson webpage, March 2010, conversion based exchange rates according to the interbank rate SEK to € 0.103.

Company	Country	Revenues (in million €)	Operating profit (in million €)	No of employees	Expenditure in R&D (in million €)	Market- cap (in million €)
Vodafone	UK	49,421[55]	14,483	79,097	337[56]	68,737
Orange	FR	38,144[57]	9,644[58]	186,000	900	46,641[59]
Telefonica	ES	69,000[60]	2,797	251,775	668	81,490[61]
Cisco	US	26,405[62]	16,884	66,129	3,707	110,595[63]
DGN Service (hospital information systems)		N.A.	(-0)[64]	N.A.	0[65]	Unlisted
InterComponentWare (electronic personal health records, other data systems)	DE	7[66]	(-0,027)	500[67]	N.A.	Unlisted
ISPro (ICT & telematic solutions for hospitals) part of CompuGroup AG	DE	230[68]	12	N.A.	N.A.	435[69]

[55] Source: Annual Report financial year ended 31/03/2009, conversion based exchange rates according to the interbank rate GBP to € 1.205.
[56] Operating Profit is ebita-capex.
[57] Source: All data based on the Annual Report Financial year 01/10/2008- 31/09/2009.
[58] Operating Profit is ebita-capex.
[59] Source: NYSE Euronext March 2010.
[60] Source: All data based on the Annual Report 2008.
[61] Source Company Website, March 2010.
[62] Source: All data based on the Annual Report fiscal year 07/2008- 31/06/2009, conversion based exchange rates according to the interbank rate SEK to € 0.103.
[63] Source: Onvista.com financial information, March 2010.
[64] Source: Unternehmens register, loss of (- 1) €.
[65] Source: Contacted the company, according to the Investor Relations department, no research is conducted.
[66] Source: Hoover's http://hoovers.com/Intercomponentware-Ag/--HD__ytsxycshr,src__global--/free-co-dnb_factsheet.xhtml
[67] Source Company Website.
[68] Source: Company Website, Revenues refer to CompuGroup.
[69] Own calculation, shares outstanding multiplied with the share price.

Company	Country	Revenues (in million €)	Operating profit (in million €)	No of employees	Expenditure in R&D (in million €)	Market- cap (in million €)
Service providers/Product vendors/SMEs						
Aerotel	Israel	N.A. [70]	N.A.	N.A.	N.A.	Unlisted
Vitalsys	BE	N.A.	N.A.	8[71]	N.A.	Unlisted
Aipermon	DE	N.A.	(-0,002)[72]	20-49[73]	N.A.	Unlisted
Tunstall	UK	64[74]	N.A.	653	N.A.	Unlisted
Docobo	UK	N.A.[75]	N.A.	N.A.	N.A.	Unlisted
Vitaphone	DE	N.A. [76]	(- 1)[77]	>150[78]	N.A.	Unlisted
Saludnova	ES	[16,770][79]	[17]	[92,773]	[>7,1%][80]	Unlisted

[70] No information disclosed.
[71] Company Website.
[72] Source: Unternehmensregister.de.
[73] According to the Medica Medical Trade Fair, the company employs 20-50 employees.
[74] Source: According to HOOVERS, conversion based exchange rates according to the interbank rate for the fiscal year 2009: US$ to € 0.719.
[75] No information disclosed.
[76] No information disclosed.
[77] Source: www.Unternehmensregister.de
[78] According to the Company Website more than 150 people work for the company.
[79] Source: Annual Report of Cooperacion Mondragon a federation of workers Cooperative, the date refers to the federation Cooperative.
[80] Source: Mondragon, website More than 7.1% of the overall revenues of the cooperation have been spent on research and Development.

Company	Country	Revenues (in million €)	Operating profit (in million €)	No of employees	Expenditure in R&D (in million €)	Market- cap (in million €)
HeartLink Online	BE	N.A. [81]	N.A.	N.A.	N.A.	Unlisted
E-HTN (Lombardy)	IT	N.A.[82]	N.A.	104[83]	N.A.	Unlisted
Bmeye (cardiovascular)	NL	1[84]	N.A.	13	-	Unlisted
IEM (blood pressure)	DE	11[85]	N.A.	40	N.A.	Unlisted
Goodit (diabetes, other remote monitoring)	FI	N.A.	N.A.	N.A.	N.A.	Unlisted
Kiwok (ECG)	SE	N.A.[86]	(-0.01)	N.A.	N.A.	Unlisted
T+ Medical (disease management systems)	UK	-[87]	-	-	-	0.059896[88]
Vamstec Croatia (image and data management systems)	Croatia	0,5[89]	N.A.	7	N.A.	Unlisted
eHIT (system integration)	FI	2[90]	(-0,006)	15	N.A.	Unlisted

81 No financial or company information disclosed.
82 No financial or company information disclosed.
83 Source: http://www.registroimprese.it/dama/comc/navcom
84 Source: Hoover's.
85 Source: Company Website.
86 No information disclosed.
87 No information disclosed.
88 Market capitalisation nominal Value on the shares, not publically traded.
89 Source: Hoover's.
90 Source: Company Database Amadeus.

Company	Country	Revenues (in million €)	Operating profit (in million €)	No of employees	Expenditure in R&D (in million €)	Market- cap (in million €)
GEM-MED (measuring and monitoring, patient platforms)	ES	0.3[91]	N.A.[92]	4	N.A.	Unlisted
Schiller Medizintechnik (telemonitoring, medical platforms)	DE	7.7[93]	N.A.[94]	700	N.A.	Unlisted
Vitaltronic (vital data real-time managmnt)	BE	N.A.[95]	N.A.	N.A.	N.A.	0,4 (equity)
SHL Telemedicine (cardiac monitoring, & remote monitoring)	Israel	N.A.[96]	N.A.	N.A.	N.A.	Unlisted
MeTeDa (teleanalysis and outpatient management)	IT	1 - 6[97]	N.A.	1 – 19[98]	N.A.	Unlisted
TMA Medical (mobile care unit: multi-device examination system designed for mobile and stationary operation)	AT	N.A.[99]	N.A.	N.A.	N.A.	Unlisted

[91] Source: Company Website.
[92] No information disclosed.
[93] Source: www.Unternehmensregister.de
[94] No information disclosed.
[95] Vitalsys is the parent company of Vitaltronic, both are not publically listed. Source: Companies website and http://www.telecareaware.com/index.php/vitalsys-vitaltronics.html
[96] No information disclosed.
[97] Source: http://www.wordpublish.org/me-te-da-srl.htm, and Hoover's; conversion based exchange rates according to the interbank rate for the fiscal year 2009: US$ to € 0.719.
[98] Source: http://www.wordpublish.org/me-te-da-srl.htm, and Hoover's ; conversion based exchange rates according to the interbank rate for the fiscal year 2009: US$ to € 0.719.
[99] No information disclosed.

Company	Country	Revenues (in million €)	Operating profit (in million €)	No of employees	Expenditure in R&D (in million €)	Market- cap (in million €)
F&S Report						
Omron	Japan	1, 896[100]	(-193)	35,426[101]	408.9	3,129[102]
Cardguard (LifeWatch AG)	CH	61[103]	3	604	3	18[104]
Viterion (BAYER AG)	US DE	1[105]	N.A.	N.A.	N.A.	N.A.
Healthhero Network (part of Bosch Healthcare USA, Health Buddy,)	US DE	29[106]	N.A.	44	N.A.	N.A.
Bodytel Scientific	DE	(- 2)[107]	N.A.	N.A.	N.A.	N.A.
Roche	CH	32,493[108]	9,944	81,507	6,541	84,[109]620
Bayer Healthcare [Bayer Diabetes] {Bayer}	DE	15,407[110] [970][111] {32,918}[112]	2.362	53,100[113] {108,600}	{2,578}	39100[114]

[100] Source: Reuters corporate information , http://www.reuters.com/article/idUST278O8WS720090427, conversion based exchange rates according to the interbank rate for the fiscal year 2009 ending 31 March: ¥ to € 0.0071.
[101] Source: Company's website.
[102] Source: Reuters http://in.reuters.com/money/quotes/quote?symbol=6645.OS, conversion based exchange rates according the interbank rate for the fiscal year 2009 ending 31 March : ¥ to € 0.0071.
[103] Source: Annual report http://www.wordpublish.org/me-te-da-srl.htm, and Hoover's; conversion based exchange rates according to the interbank rate for the fiscal year 2009: US$ to € 0.719.
[104] Market cap based on Six Swiss echange March 2010, conversion based exchange rates according to the interbank rate CHF to € 0.68.
[105] based on research published by http://www.spoke.com/info/c5g423l/ViterionTelehealthcareLlc
[106] Based on data released by the Federal Business Opportunities Agencies of the U.S. Government, conversion based on the interbank rate.
[107] Based on publicly-available information at Unternehmensregister.de.
[108] Source: Annual report 2008.
[109] Based on Company Website, conversion based on the interbank rate.
[110] Source: Annual report 2008 Data for Bayer the data refers to Bayer Healthcare.
[111] Figures for Bayer Diabetes.
[112] Figures for Bayer Corp.
[113] Bayer Health care.
[114] Source Company website march 2010.

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Abstract

This policy brief provides findings from empirical research on market and innovation dynamics regarding Personal Health Systems (PHS) in Europe. Even the already most consolidated of all PHS segments (i.e. RMT) is found to be radically different than the initial assumptions. The research has revealed that the market is in a state far from being mature and as a result there is little standardised data available. RMT contributes only a tiny fraction of the eHealth market revenues. Pilots are still dominating the form of implemented cases. The market is fragmented also in terms of players without distinct segments. This policy brief recognise a huge potential in a modified approach towards evaluation and measurement of eHealth.

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