



A model for a life-long personalised Continuum of Integrated Care revolutionising healthcare delivery: Description of technological impact.

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Abstract

The goal of this work was to analyse the impact of new emerging technologies on models of care and organisation of the health system to consequently develop a conceptual model for healthcare systems on how smart and emerging technologies can be exploited to increase the benefits for the patients and the sustainability of healthcare systems in the future. Discussions with experts from technological networks, clinics and regulatory agencies were used to identify and structure future development strategies for different healthcare-related key enabling technologies (KETs) and medical products with respect to their impact on healthcare systems. The “Continuum of Integrated Care”, as a conceptual model for healthcare enabled by KETs and an increasing amount of available health data, provides a basis for how smart healthtech can be effectively used in healthcare systems to provide solutions improving the quality of life and clinical outcomes of patients, in addition to reducing costs related to the intensive acute phase, the post-acute and homecare phase. The model offers also the opportunity for more equal access to healthcare even in rural and remote areas. Thus, the presented holistic concept of the new “Continuum of Integrated Care” puts all changes in healthcare into perspective to give guidance for all actors on how to align with the ongoing healthcare revolution.

1 Introduction

Healthcare systems across the world are in transition from reactive to preventive and personalised precision medicine, with the primary objectives to improve clinical outcomes, while ensuring the sustainability of healthcare systems. A major challenge, besides providing a patient-centred healthcare and ensuring sustainability, is to guarantee a broad coverage of access to healthcare even in rural and remote areas, at minimal costs enabled by emerging technologies and rising health and technology literature. Currently, healthcare is facing multiple challenges, which can be solved by technological advances and understanding of complex biological body processes that are helping to bridge gaps in existing healthcare systems and how healthcare is delivered. On the one hand, the understanding of biomolecular processes causing diseases has advanced in recent years, which in turn, can be used as targets for new and emerging therapies or precise patient monitoring to prevent, predict and fight disease.

Currently, a contextual basis is lacking for how emerging smart health technologies will facilitate disruptive transformation in healthcare through the patient care pathway. Most of the literature is only concentrating on one or a few aspects of the changes in healthcare, e.g. how technology is empowering the patient [1] but a question is still unanswered, 'how PE will be effectively achieved?' Beyond psychological implications, empowerment of patients in daily practice relies on technology and the way it is used. Unfortunately, the heterogeneity of approaches and technologies makes difficult to have a global vision of how PE is being performed. Objective: To clarify how technology is being applied for enhancing patient empowerment as well as to identify current (and future, and is therefore not considering

the impact on healthcare providers. Additionally, the literature is typically only focussing on one phase of healthcare, for instance remote patient management in chronic disease [2], and thereby neglecting the other phases. The aim of this work is to develop a conceptual model for healthcare which targets a holistic view on how emerging technologies will revolutionise healthcare. This article describes the "Continuum of Integrated Care" concept which aims to support all kinds of actors in healthcare, e.g. hospital doctors, health managers, policy makers, health insurers, and researchers in development, as well as the implementation and evaluation of new emerging technologies to facilitate informed clinical decisions and improved clinical proficiency leading to better clinical outcomes. In this article "integrated care" is defined based on the WHO definition as coordinated, person-centred and cross-sectorial organisation of care ranging from prevention to palliative care services including multiple providers and stakeholders from different sectors [3]. To establish such a holistic approach a shift in how healthcare is delivered, organised and reimbursed is needed [4]. Primarily, patients will be empowered to manage their own health supported by emerging medical technologies, medical products and data. One of the greatest changes will be the increase in technology-based decision support for diagnosis, monitoring and treatment of clinical conditions with closed-loop therapeutic systems automating therapy in well-understood scenarios. Moreover, this change will also have disruptive effects on many other stakeholders, including professional healthcare providers, and their workflows, the involved industries and their more inter-sectorial business models as well as the regulatory and reimbursement systems.

2. Methods

2.1 Technological expert discussions and design of the conceptual model

Besides analysing the literature, we have addressed these questions by engaging with representatives of different European Technological Organisations (ETO) such as European Technology Platforms (ETPs) and technological networks who provided continuous input and feedback on the developed model. Based on the corresponding Strategic Research and Innovation Agendas (SRIAs) of those organisations and inputs from the assigned experts for the medical application of the respective technology fields, a shared vision of how healthcare will be delivered in the future and how patients will pass through the healthcare system has been elaborated. In particular, we considered the SRIA and expertise from the following ETPs and technological networks:

- ▶ ETPN (European Technology Platform for Nanomedicine),
- ▶ Photonics21 – Working group on Life Science and Health,
- ▶ ESB (European Society of Biomaterials),
- ▶ EuMat (ETP for Advanced Engineering Materials and Technologies) – Working group on Biomaterials,
- ▶ ECSEL Joint Undertaking – Electronic Components and Systems for European Leadership,

- ▶ EPoSS (European Technology Platform for Smart Systems Integration) – Working Group on Healthy Living,
- ▶ ETP Fibers Textile Clothing,
- ▶ BDVA (Big Data Value Association),
- ▶ DIH-HERO – Digital Innovation Hub in healthcare robotics.

The expert opinion leaders of these organisations for healthcare-related applications of the relevant technology provided us with an overview of potential technological developments expected for the next 5-10 years. The results of several discussion rounds with the experts were the basis for the conceptual model of the “Continuum of Integrated Care” described below. This model was enriched with peer-reviewed and grey literature including technological horizon scans and technological trend reports from various (inter)national agencies such as the Organisation for Economic Co-operation and Development (OECD) [5], The Canadian Agency for Drugs and Technologies in Health (CADH) [6],[7], Rijksinstituut voor Volksgezondheid en Milieu, The Netherlands (RIVM) [8].

2.2 Discussions with regulatory expert

As a next step, the first draft of the “Continuum of Integrated Care” was further refined by including results from discussions about the impact of emerging technological products on healthcare systems and stakeholders with regulatory agencies

from different EU countries, including Germany, the Netherlands and Ireland. The methods used to develop the “Continuum of Integrated Care” are of a qualitative nature.

3. Results

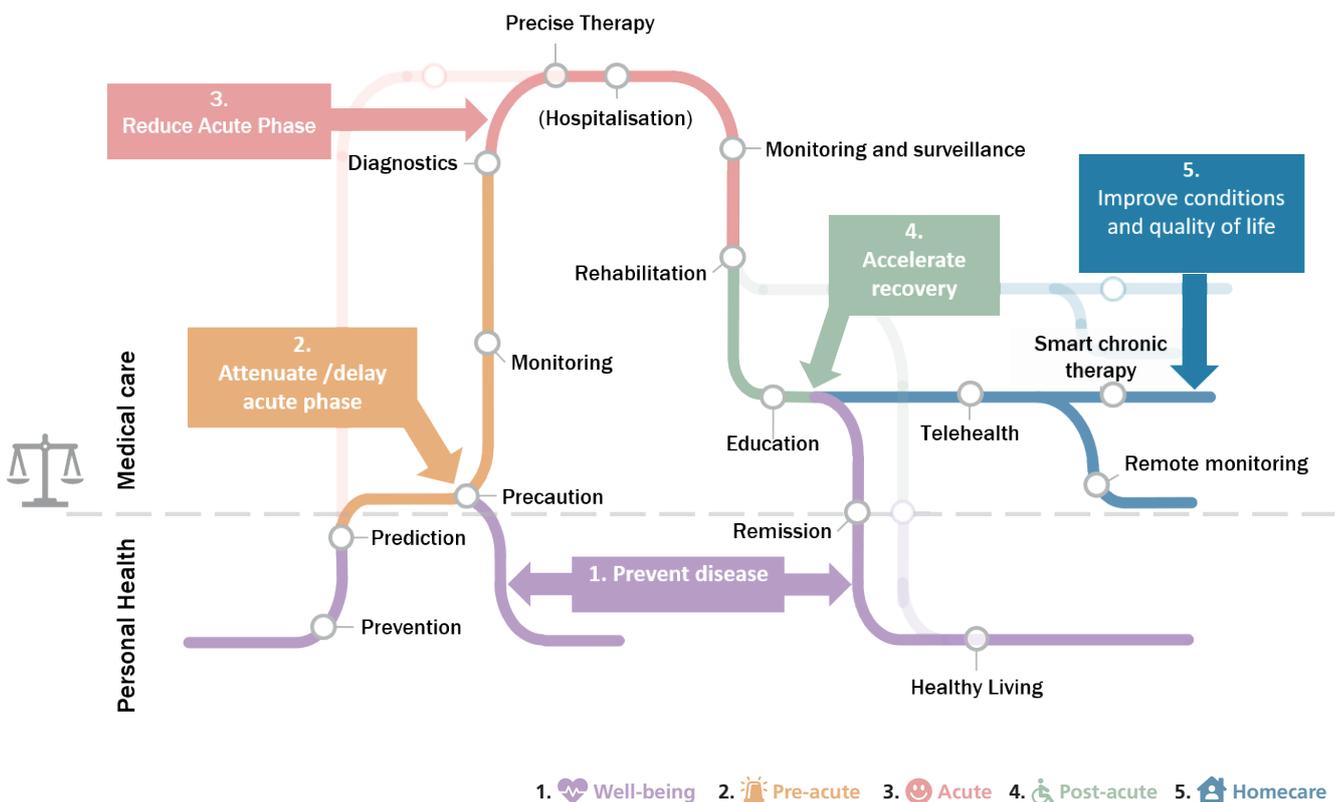
3.1 Holistic model of care – The Continuum of Integrated Care

New approaches in healthcare technologies have the potential to significantly improve the way healthcare is delivered. On the one hand, this paradigm shift will be mainly achieved by exploiting the complementarities and individual contributions of biology-based innovations, i.e. a dramatic increase in scientific knowledge on the detecting, understanding and treatment of diseases based on fundamental biological interventions, including the control of mimicry complex biological mechanisms used for regenerative tissue replacement for organs. Recent technological advances in omics and wearable monitoring enable deep molecular and physiological profiling, and provide important tools for precision health. On the other side, innovation driven by different Key Enabling Technologies (KETs) such as photonics, microelectronics, advanced materials, nanotechnology and robotics joins with ICT-based advances, to create cross-technological and cross-sectorial products entering the healthcare market. They offer more functionalities in healthcare including continuous monitoring [9], tele-medicine [10], augmented reality surgery [11], decision-making support systems [12], assistive care [13] and lead to increased patient engagement [14].

We identified four main changes based on the impact of emerging technologies and innovations entering the healthcare market (Figure 1) [5] influencing the current healthcare system. They will profoundly alter the workflow on how healthcare is delivered, together with the respective roles of patients and healthcare providers.

The well-being phase is the phase where the personal health status is optimal, and no health problem is present (lavender line). A higher focus on prevention and prediction in the well-being phase and the newly added pre-acute phase will reduce or even avoid entering the acute phase (the dotted grey line marks the entering point into the healthcare system). Early diagnosis and personal health data accumulated already in healthy condition and the pre-acute phase allow to deliver a precise and personalised therapy to the patients. Consequently, the acute phase might be shorter and less intensive (red line) allowing a quicker patient transfer into rehabilitation and home-care (green and blue line).

Figure 1: The Continuum of Integrated Care transforms the way healthcare is delivered. Own graphic representation.



3.2 Higher emphasis on prediction and prevention for a patient-centred pre-acute care

The first big change is caused by the increased emphasis on prediction and prevention of diseases. More prediction and prevention measurements aim to reduce the acute phase in medical care with respect to time, burden and costs (Figure 1). To achieve a healthy preventive lifestyle, new products and technologies allow continuous monitoring of body functions and vital parameters in combination with affordable diagnostic tests, which can be performed by patients themselves in a home setting outside professional medical laboratories. Compared to healthcare systems today, the pre-acute phase will be more important for the clinical pathway of patients, because interventions at a much earlier asymptomatic stage prior to the onset of a disease or a health concern, will most likely change the scenario of patients entering the healthcare system. One keystone for this change is the increased awareness that lifestyle and behavioral factors strongly influence health status and well-being. This awareness has been growing for several decades and new mega-trends such as “Well-being” and “Healthy Living” have emerged, opening at the same time multi-million Euro markets at the crossroads between medicine, pharma, sports, food, IT and consumer electronics. One example of cross-technology products shaping the active and healthy living trade market are wearables [15] including consumables such as fitness trackers and smartwatches. In this case, consumables initially being designed to serve the lifestyle market, gain medical device characteristics and enter the regulated healthcare market, thereby empowering patients to manage their health status and to produce valuable medical data that can be used during monitoring, therapy and medical research [16]. Recent studies demonstrated the impact and clinical value of such devices not only in terms of better monitoring, disease prevention and diagnostics of patients, but also in terms of changing the

patient experience, as well as cultural standards of a society [17],[18],[19].

Besides a healthier lifestyle and behavior, new and affordable methods such as next generation sequencing allow predictive and personalised analysis of potential genetic risk factors and the diagnosis of genetic disorders in pediatric medicine [20],[21]. Recent technological developments in omics technologies including genome, immunome, transcriptome, proteome, metabolome, microbiome analyses enable molecular and physiological profiling resulting in more precise and personalised prevention decreasing the risk of disease onset [23]. Moreover, these accumulated health data from different sources including data generated by patients themselves such as activity, social and environmental data will enrich medical records which support medical providers in therapeutic decisions to deliver more precise and personalised medical treatments [23],[24]. One option could even be corrective intervention at the DNA or RNA level through technological advancements such as RNA-based gene therapy or gene editing with the CRISPR/Cas system to treat certain congenital diseases (Table 1) [22].

Thus, the strong emphasis on prevention and prediction resulting in earlier and patient-centred interventions will prevent many patients progressing into the acute phase of the Continuum of Integrated Care compared to the healthcare system of today. However, the above-mentioned changes and new products require a transformation of the healthcare industry and the medical device regulation, in order to deliver solutions for patients in the pre-acute phase of medical care. In particular, the integration of consumables into the regulated healthcare market remains a challenge for regulators.

Table 1: Examples of cross-technology medical concepts and products in preventive care

New concepts of integrated care	Cross-technology products and solutions	Involved KETs
Continuous monitoring	Wearables	Photonics, (Micro)-Electronics, Big Data, Advanced Materials, Smart system integration, Nanotechnology
Affordable diagnostic tests	Lab-on-Chip technology	Photonics, (Micro)-Electronics, Big Data, Smart system integration, Robotic
Prevention	Gene editing, e.g. CRISPR/Cas	Nanotechnology, (Micro)-Electronics, Photonics, Biotechnology
Prevention	Genome sequencing	Biotechnology, Nanotechnology, Advanced materials

3.3 Altered acute phase in medical care

The second major change in healthcare is a shorter and more efficient acute phase. First of all, the continuous collection of personal data generated in the well-being and pre-acute phase combined with high-quality medical data gained with early monitoring of biomarkers [25],[26], [27] enable medication or medical treatment in the acute phase to be more personalised, precise and ultimately more effective [28],[29]. On top of that, AI-based analysis of available general health data allows to correlate personal health data to disease phenotypes previously identified by pattern recognition through big data analysis and machine learning which will support physicians in clinical and therapeutic decisions for different diseases in the future (Table 2) [30],[31].

The second reason for a more efficient acute phase is support systems for surgeons. Connected smart surgical tools and surgical robots allow minimally invasive surgeries. They are complemented by virtual (VR) and augmented reality (AR), tools for simulation and support of surgeons prior and during surgeries to increase precision and personalisation for a patient-centred care and to improve surgical skills and performance by virtual training of complex surgical procedures [34],[35],[36]. The surgical innovation tools will likely lead to reduced patient stays in hospitals and improved cost-effectiveness in some scenarios [8],[32],[33] 1818 OP and 250 LP. Moreover, VR can be used for the therapy of several diseases such as mental health disorders resulting in better clinical outcome [37].

The third cross-technological innovation to allow personalised treatments are generated in the area of regenerative medicine.

Bespoke implants manufactured by 3D printing and equipped with tailored surfaces, reduce host rejection and thus increase biocompatibility (Table 2). Insights from profiling of biomolecular processes and mechanisms can be used for instance for artificial organ growth attenuating current problems of limited availability of donated organs and host-transplant rejection processes. Artificial organs and tissue grafts can be manufactured by e.g. 3D printing in combination with advanced biomaterials to build organ scaffolds which are afterwards colonised with cells [38]. New approaches of engineered tissue, for instance, are based on pluripotent cells generated directly from patient-derived cells and allow more personalised replacement of tissue parts, but also personalised drug development or clinical testing with patient-derived pluripotent cells in a organ-on-chip-technology model [39],[40] there is an urgent need for preclinical drug testing models that are predictive of drug response in human tissues or organs. Despite tremendous advancements and rigorous multistage screening of drug candidates involving computational models, traditional cell culture platforms, animal models and most recently humanized animals, there is still a large deficit in our ability to predict drug response in patient groups and overall attrition rates from phase 1 through phase 4 of clinical studies remain well above 90%. Organ-on-a-chip (OOC. An additional layer of personalised therapeutic treatment is added by gene editing approaches such as CRISPR/Cas9 to potentially cure e.g. congenital diseases via intervention on patients' genetic level. While the potential of gene editing technologies is enormous and it can enable wide-ranging application in personalised medicine, it is still not completely understood regarding safety and administration issues, [41],[42].

Table 2: Examples of cross-technology medical concepts and products in acute medical care

New concepts of integrated care	Cross-technology products and solutions	Involved KETs
Early diagnostics with new biomarkers	Point-of-Care Lab-on-Chip Biosensors	Photonics, (Micro)Electronics, Smart System Integration, Biotechnology, Nanotechnology, Big Data
Automatized hospital and surgery	Smart surgical tools	Photonics, (Micro)Electronics, Robotics, Advanced Materials, Big Data, Smart System Integration
Automatized hospital and surgery	Partially or fully automated surgical robots	Photonics, (Micro)Electronics, Robotics, Advanced Materials, Big Data, Smart System Integration
Highly biocompatible replacement of body parts	Surface tailored implants	3D printing, Nanotechnology, Advanced materials, Biotechnology
Personalised regenerative medicine	Artificial organs and tissue parts	Biotechnology, Nanotechnology, Advanced materials
Personalized and disruptive therapeutic approaches	Gene Editing, e.g. CRISPR/Cas	Biotechnology, Nanotechnology, Advanced materials

All the mentioned technological innovation will give rise to new therapeutic opportunities and will add a layer to personalised integrated care [43]. These new technologies have the potential to treat currently incurable diseases, as well as helping alleviate the burden to reduce pressure on healthcare systems. A higher cost-effectiveness ratio might be achieved by these new con-

cepts of integrated care, enabled through technological innovations. This might have impact on either the expensive acute phase, and /or in the post-acute phase by reducing recovery time of patients from a disease and facilitating a prompter return to well-being.

3.4 Personalised and patient-centred post acute medical care

The third change concerns the post-acute phase after acute medical care. Continuous monitoring of patients remains one of the key challenges, and has the potential to alter how medical care is delivered in the future. Hence, today's care delivery has started to change based on tools for patient monitoring enabled by new technological possibilities and communication infrastructures. Mainly, ICT-supported tools such as telemedicine and remote consultation of physicians and medical professionals, allow continuous monitoring of patients and assistance by medical professionals to lower the risk of relapse after acute situations in some medical conditions such as heart failure [44]. To generate and deliver personal health data, smart connected devices such as wearables (but also smartphones) are indispensable, thus allowing medical professionals to have live data streams of patients' health status. Multi-sensor technology, as used in wearables, for example, could also be used in everyday objects of daily life of patients, such as in smart textiles or directly e.g. as in skin patches already used today for efficient glucose level management, or electronic tattoos especially for EEG

applications [45], [46],[47]. Advantages of these multi-sensor technologies are not only found in the continuous monitoring of patients, but also in the patient's self-management in chronic diseases, as well as rehabilitation for many conditions including stroke and movement disorders [48]. In return, these tools also increase patient participation in therapeutic and rehabilitation programs, including compliance with therapy and medication as shown in many studies [49]. To empower patients to recover faster, assistive robotic systems, gamification and VR technology, respectively or in combination will support the rehabilitation process, potentially also in a home-based setting (Table 3) [50],[51], [52],[53].

Altogether, these technologies allow appropriate rehabilitation therapies to be addressed earlier and can be deployed remotely in a home-based setting with higher precision, resulting in enhanced patient benefits and reduced pressure on healthcare systems.

Table 3: Examples of cross-technology medical concepts and products in post-acute medical care

New concepts of integrated care	Cross-technology products and solutions	Involved KETs
Continuous monitoring	Smart devices (Wearables, Smartphones, Multi-sensors in objects of daily life and textiles)	Photonics, (Micro)Electronics, Smart System Integration, Nanotechnology, Big Data, Robotic, 3D printing, Textile
Telemedical consultation	VR-technology ICT tools	(Micro)Electronics, Robotics, Advanced Materials, Big Data, Smart System Integration, IT infrastructure
Patient self management of rehabilitation and chronic disease	Assistive robotic systems VR-technology Multi-sensors	Photonics, (Micro)Electronics, Robotics, Advanced Materials, Big Data, Smart System Integration, 3D printing, Textile
Gamification	VR-technology Assistive robotic systems	3D printing, Nanotechnology, Advanced materials, Big Data, IT infrastructures, (Micro)-Electronics, Smart System Integration

3.5 Continuous integrated care at home

Similar concepts are also the main driver of the fourth big change in healthcare expected to be effective in the home-care phase (Table 4). One of the major challenges in this phase is to enable a patient to lead a self-determined life in good quality despite impairment(s) caused by age-related or chronic diseases. New generations of smart and highly biocompatible implants and prostheses restoring lost body functionalities will support this. Functionalised surfaces e.g., via nanostructuring/nanotexturing/nanopatterning increase biocompatibility and reduce medication to antagonize host-graft rejection processes, resulting in a higher quality of life for patients [54], [55].

In addition, assistive robots or exoskeletons support patients and compensate for impairments in daily life [56],[52]. Besides assistive technology, delivery of improved patient education about health conditions supported by ICT tools will be a critical success factor for effective homecare management [57],[58],[59]. Education about health conditions and chronic diseases combined with gamification and VR technology increase motivation to properly cope with chronic disease management [60]. In addition, monitoring of elderly patients or patients at risk through wearables and multi-sensor technology together with ICT tools will facilitate identification of patients in need of medical support at any time, even in rural or remote areas, allowing earlier discharge from acute care and rehabilitation centres [61],[62].

Table 4: Examples of cross-technology medical concepts and products in continuous homecare

New concepts of integrated care	Cross-technology products and solutions	Involved KETs
Self-managed life despite chronic disease and/or impairments	Assistive robots Exoskeletons VR-technology Wearables Multi-sensor technology	Photonics, (Micro)Electronics, Smart System Integration, Robotics, Nanotechnology, Big Data, Advanced Materials, Textile, IT infrastructures
Smart replacement of body functions	Smart implants and prosthesis	(Micro)Electronics, Robotics, Advanced Materials, Big Data, Smart System Integration, Biotechnology
Improved patient education	ICT tools VR-technology	Photonics, (Micro)Electronics, Robotics, Advanced Materials, IT infrastructures, 3D printing
Gamification	VR-technology Assistive robotic systems	3D printing, (Micro)Electronics, Robotics, Advanced Materials, Big Data, Smart System Integration, IT infrastructures

4. Discussion

The conceptual “Continuum of Integrated Care” model described here was elaborated by international and cross-sectorial experts coming from different fields in relation to health including academics, industry, clinics and regulation and was additionally enriched by grey- and peer-reviewed literature. The “Continuum of Integrated Care” model shows that the design, development, implementation and exploitation of emerging medical technologies and products span across different sectors including industry, biomedical research, healthcare providers, health insurances and reimbursement agencies and can be further extended to patients and the society as a whole.

Altogether, the described changes towards the Continuum of Integrated Care are driven mainly by the ability to collect, interpret and use data throughout the lifetime of a person to predict or prevent a disease, and to improve precision and personalisation of diagnosis, therapy and rehabilitation. The result is a more patient-centred and outcome-based healthcare system with major impact on all stakeholders. One of the key changes, as mentioned earlier, are the decision support tools and closed-loop medical systems, helping to attenuate or avoid acute medical care. Wearables and ICT tools allow improved and personalised management of health ranging from lifestyle to chronic disease management. Physicians will need to learn to integrate patient health data from smart medical devices into AI-supported therapeutic decisions, and to interact remotely with their

patients. Second, industries such as pharma, MedTech, biotech and ICT, i.e. Apple, Google, Samsung and Huawei will have to adapt their R&D and production processes and business models, to co-develop smart connected healthtech solutions involving novel materials, sensors, ICT systems and software. SMEs, for instance, can evaluate where in the healthcare system their products can make a difference. In line with this idea, industry can assess where cross-sectorial approaches are needed to develop new products for the healthcare sector. Third, health insurances and reimbursement agencies on the other hand, need to adopt outcome/value-based reimbursement strategies, instead of product and device-centric business models. The cross-industry development also requires new technical standards and the adaptation of several regulatory regimes. The concept of the “Continuum of Integrated Care” illustrated in Figure 1 offers guidance for all stakeholders why, where and how they have to adapt to the future healthcare system. Hence, the “Continuum of Integrated Care” is a versatile concept, offering guidance and support in strategic decision making at the technological level for several stakeholders, but also at a systemic level for the workflow and organisation of healthcare systems.

Therefore, a new mind-set for all stakeholders has to be generated to successfully manage the transition to the “Continuum of Integrated Care” for the benefit of patients and healthcare systems.

5. Conclusions

The value of the “Continuum of Integrated Care” model is that it highlights how emerging technological products will impact on the different phases of healthcare and the clinical patient care pathway (well-being, acute, post-acute and homecare).

Additionally, it can be used to illustrate the transition in healthcare from a reactive, to a patient-centred predictive and preventive approach, providing guidance to all kinds of stakeholders in healthcare.

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