CHIF: A Connected Health Impact Framework

Ioanna Chouvarda, Christos Maramis, Kristina Livitckaia, Vladimir Trajkovik, Serhat Burmaoglu, Hrvoje Belani, Jan Kool, Roman Lewandowski, The ENJECT Working Group 1 Network

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Abstract

Background: Connected Health (CH) as a new paradigm looks after the individual and community health in a connected and holistic manner by leveraging a variety of technologies and has a promising potential for the incorporation of telehealth and integrated care services, covering the whole spectrum of health-related services addressing healthy subjects and chronic patients. The reorganization of services around the person or citizen has been expected to bring high impact in the health domain. A series of concerns (e.g., contextual factors influencing the impact of care models, the cost savings associated with CH solutions, the sustainability of the CH ecosystem, and others are the CH concerns) should be addressed better to reach stakeholders more successfully. Overall, there is a need to synchronize an understanding of the concepts of CH impact better. As services based on Connected Health technologies go beyond standard clinical interventions and assessments of medical devices or medical treatments, the need for standardization and new ways of measurements and assessments emerge when studying CH impact.

Objective: This paper aims to introduce the Connected Health Impart Framework (CHIF) that serves an approach to assess the impact of CH services.

Methods: This work focuses on the subset of CH consisting of services that directly address patients and citizens toward the management of disease or health and wellness. The CHIF is developed through various activities, including literature review, workshop focusing on knowledge elicitation regarding CH concepts, development of the initial version of the framework and framework refining with the experts as the result of the second workshop, and composing and deploying a questionnaire for preliminary feedback from early-stage researchers in the relevant domains.

Results: The developed framework addresses the needs for a better understanding of what is CH impact, support in better designing of CH services from the perspective of how to achieve the impact, and understanding of methods to assess, gather knowledge and compare impact in CH services. The CHIF is based on the four concepts, including CH system and service outline, CH system end users, CH outcomes, and factors towards achieving CH impact. The framework is visualized as an ontological model.

Conclusions: The CHIF is an initial step towards methodologies to objectively measure CH impact while recognizing its

multiple dimensions and scales.

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Original paper

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CHIF: A CONNECTED HEALTH IMPACT FRAMEWORK

Abstract

Background: Connected Health (CH) as a new paradigm looks after the individual and community health in a connected and holistic manner by leveraging a variety of technologies and has a promising potential for the incorporation of telehealth and integrated care services, covering the whole spectrum of health-related services addressing healthy subjects and chronic patients. The reorganization of services around the person or citizen has been expected to bring high impact in the health domain. A series of concerns (e.g., contextual factors influencing the impact of care models, the cost savings associated with CH solutions, the sustainability of the CH ecosystem, and others) should be addressed better to reach stakeholders more successfully. Overall, there is a need to synchronize an understanding of the concepts of CH impact better. As services based on Connected Health technologies go beyond standard clinical interventions and assessments of medical devices or medical treatments, the need for standardization and new ways of measurements and assessments emerge when studying CH impact.

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Methods: This work focuses on the subset of CH consisting of services that directly address patients and citizens toward the management of disease or health and wellness. The CHIF is developed through a multistep procedure and various activities. These included as initial steps a literature review and a workshop focusing on knowledge elicitation around CH concepts. Next followed the development of the initial version of the framework and framework refining with the experts as the result of the second workshop, and. Lastly, composition and deployment of a questionnaire for preliminary feedback from early-stage researchers in the relevant domains.

Results: The developed framework contributes to a better understanding of what is CH impact and analyses the factors towards achieving it. CHIF elaborates on how to assess impact in CH services. These aspects can contribute in an impact-aware design of CH services. It can also contribute to CH services comparison and further knowledge of the domain.

The CHIF is based on the four concepts, including CH system and service outline, CH system end users, CH outcomes, and factors towards achieving CH impact. The framework is visualized as an ontological model.

Conclusions: The CHIF is an initial step towards methodologies to objectively measure CH impact while recognizing its multiple dimensions and scales.

Keywords: connected health; impact; framework; outcomes; enablers and barriers.

Introduction

Nowadays, information and communication technologies, including a growing number of consumer and medical devices as well as patient services, have created new opportunities to improve the health and wellbeing of individuals and populations. Such improvements are expected to be succeeded through behavior change at a personal level, better health care coordination, and multilevel information sharing, gradually building the Connected Health (CH) landscape [1].

CH as a new paradigm looks after the individual and community health in a connected and holistic manner by leveraging a variety of technologies [2,3]. CH is a promising vehicle for the incorporation of telehealth and integrated care- services, covering the whole spectrum of health-related services from the ones directing the *healthy subject* (as a citizen who seeks health services support, or a wellness service consumer) to those addressing the *chronic patient* as an integrated (tele) care service

beneficiary. The evolution of connected health ecosystem and related concepts (e.g., telemedicine) is well discussed from a bibliometric viewpoint in the work of Burmaoglu [4].

The reorganization of services around the person or citizen, withe person-centered care being a promising area[5], is expected to bring an important impact in the health domain. This will require better addressing a series of concerns to more successfully reach stakeholders: contextual factors influencing the impact of care models, the cost savings associated with CH solutions, the sustainability of the CH ecosystem, etc. Overall, there is a need to shed some light regarding the concepts of CH impact.

This paper introduces the Connected Health Impact Framework (CHIF) that serves in the assessment of CH services' impact. CHIF was born from the ENJECT COST ACTION[6] , a network actively involved in the evaluation of Connected Health Technologies. Within the whole spectrum of CH, this work focuses on the subset of CH consisting of **services that directly address patients and citizens** at large, toward the **management of disease or health and wellness**. These CH patient services are heavily dependent on new technologies. Nevertheless, CH services are not considered detached from the established health information technology (either secondary care medical technology, or technology primarily oriented to the healthcare professional, like e-prescription) and the respective healthcare services.

The reason for focusing this work on CH patient services, on the verge of consumer informatics, is because this is a new, highly promising area, yet unmapped and in a grey zone concerning healthcare, in the sense that there are not yet explicit care models incorporating CH services, neither health policies or guidelines, or standard ways of assessing these services.

When considering Health Impact Assessment (HIA) of a policy, program, or project, its potential effects on the health of a population and the distribution of those effects are evaluated [7,8] so as to produce 1) recommendations supporting decision-makers and other stakeholders in making choices about alternatives and 2) improvements to avoid risks, prevent disease or injury, and to actively promote health. The impact of CH technologies and services needs to be well defined [9], providing relevant evidence, linking to and extending the HIA procedures.

On a broader scale, relevant work regarding assessment of integrated care services and scaling up of integrated care in European regions has taken place from European Innovation Partnership on Active and Healthy Ageing (EIPonAHA) B3 [10] group (the Action Group on integrated care) . The topics addressed include the following: (1) assessment of health care system's capacity to adopt integrated approaches to deal with challenges of aging; (2) assessment of the uptake of a particular good

practice by a health and care system; (3) identification of maturity characteristics necessary for adoption and scale-up of good practice; (4) understanding the context and conditions in adopting and transferring practices among regions. The Maturity Model of B3 group was developed [11] as a tool to assess maturity along 12 dimensions reflecting the various aspects that need to be managed to deliver integrated care.

Also, as regards assessment of telemedicine applications and services, the MAST tool (Model for Assessment of Telemedicine) was developed [10] to describe the effectiveness of telemedicine applications and their contribution to the quality of care. MAST summarizes and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine, considering seven assessment domains (i.e., health problem, safety, clinical effectiveness, patient perspectives, financial aspects, organizational aspects and socio-cultural, ethical and legal aspects). A framework for the emerging area of behavioral interventions was recently proposed [13], yet not elaborating on impact. Methodological aspects for connected health evaluation were introduced by O'Leary [14] and Carroll [15], although not uniquelly focusing on impact. Consumer health informatics assessment is discussed in the work of Gibbons et al [16]; this includes users, barriers at the system and individual level, implementation of applications (i.e., function and process) and outcomes at different levels and directions (Intermediate, Health Care Processes, Clinical, Economic and Relationship-centred).

There are not many publications that specifically refer to CH and its impact, or to the use of specific frameworks for that. In the CH review of [17], the theoretical construct of [18] for self-management is adopted. It applies to both chronic conditions and health promotion and considers work, context, process, proximal and distal outcomes. More specifically, according to this framework, self-management takes place in the context of (1) risk and protective factors specific to the condition, (2) a particular physical and social environment (e.g., healthcare access, culture, transportation), and (3) a set of individual and family factors (e.g., literacy and family structure, capacity to self-manage). Self-management is a process involving individuals and families that includes (1) knowledge, facts, and beliefs (e.g., self-efficacy), (2) self-regulation skills and abilities (e.g., goal setting, decision making, emotional control), and (3) social facilitation, including influence, support, and collaboration, to achieve positive health-related outcomes. Interventions to the person and family consider both process and context. The proximal or short-term outcomes lead to the achievement of distal outcomes. Thus, a temporal causal relation is introduced. Proximal outcomes include mainly individual and family self-management behaviors, such as engagement in activities and recommendations of treatment, symptom management, and adherence to recommended

pharmacological therapies. Secondarily, engagement in health-related behaviors may positively impact the cost of healthcare services in the short term. The distal outcomes are threefold: (1) health status as an indicator of the disease trajectory (indicating prevention, attenuation, stabilization, and worsening of the condition), (2) quality of life and perceived well-being, and (3) direct and indirect costs.

In the same vein, as services based on Connected Health technologies go beyond standard clinical interventions and assessments of medical devices or medical treatments, the need for standardization and new ways of measurements emerge when studying CH impact in depth. As mentioned in [17], *“We likely need more sophisticated study designs if we are to adequately assess which element of a comprehensive program is affecting the outcome, asking how exactly do the 'interventions impact the psychosocial aspects of the lives of people with diabetes?'“*. Therefore, this area needs further research and disambiguation, especially as regards outcomes and impact. While the abovementioned efforts are relevant to the concept of CH and offer valuable insights, CH services constitute more complex constructs that are not compartmentalized and assessed in the same manner as pharmacological trials.

The emerging CH technologies impose the definition of a CH impact framework (CHIF). The CHIF was created in the process of exploring concepts around *what CH impact is*, *how it can be described*, *assessed*, and *how it can be achieved*. Specifically, CHIF is based on the inputs from the two workshops conducted in the scope of ENJECT within the last two years. In the following sections, the steps taken for deriving CHIF are presented, and the framework itself is described in detail along with a preliminary assessment tool based on CHIF. The paper also discusses challenges and future steps.

Methods

The formulation of the CHIF framework took place in a multi-step process, as delineated below and it is visually outlined by Figure 1:

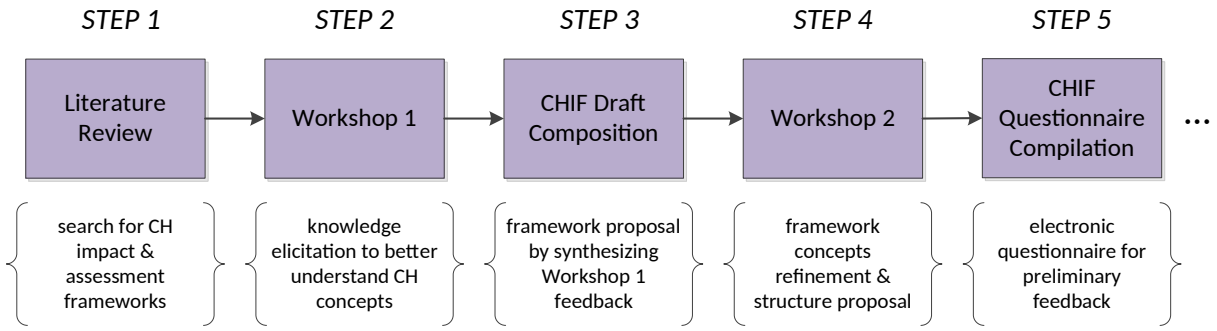

Figure 1. Methodological steps for the derivation of CHIF.

- **Step 1**. A literature review was conducted on the topics of connected health impact and assessment frameworks. This step helped to identify the main concepts and issues discussed in the domain and helped us further shape our research.
- **Step 2**. A workshop for further knowledge and insight elicitation, towards better understanding the concepts around CH impact was conducted (Workshop 1). The methodology employed was based on the structured group feedback approach [19].
- **Step 3.** Following Workshop 1, knowledge elicitation took place which resulted in a proposal for a CH impact framework, based on a synthesis of inputs.
- **Step 4**. In Workshop 2, the first CHIF proposal for CH impact framework was presented and discussed among the participants, and this was the base for the further effort to organize and propose the framework for reporting impact, including discussion and refinement of the previously established concepts and framework structure. The result was the consolidation of the CHIF structure. Also, different visual representations of CHIF were suggested, e.g., the ontological model.
- **Step 5**. CHIF was implemented in an electronic questionnaire for preliminary feedback.

More details about the workshops can be found in the supplementary material (Appendix 1).

Results

Overview of the Connected Health Impact Framework

The CHIF serves in the assessment of CH services impact. It aims to contribute in (1) better understanding of what is CH impact, (2) exploring how to achieve impact and thus support in better designing CH services , and (3) methods to measure/assess impact, which can also help to compare impact of CH services and gather further knowledge d. To meet these aims, four axes are considered:

1. CH system/service outline. Of note, both the concepts of ‘system’ and ‘service’ are mentioned, as the focus is sometimes on the developed application and sometimes on the

provided service, which adds a broader scope.

2. CH system end-users and their profile, including the profile of primary users that the system targets, and secondary users.
3. CH outcomes and measures of impact at different levels.
4. Factors towards achieving CH impact, including barriers and enablers, as well as a clear value proposition.

Below, the framework is visualized as an ontological model (see Figure 2). CHIF is organized as a tree with the concept of CH Service at its root. Nodes beyond the 3rd tree level are not depicted in the figure to reduce the complexity of visualization; however, all the nodes are presented in the following sections.

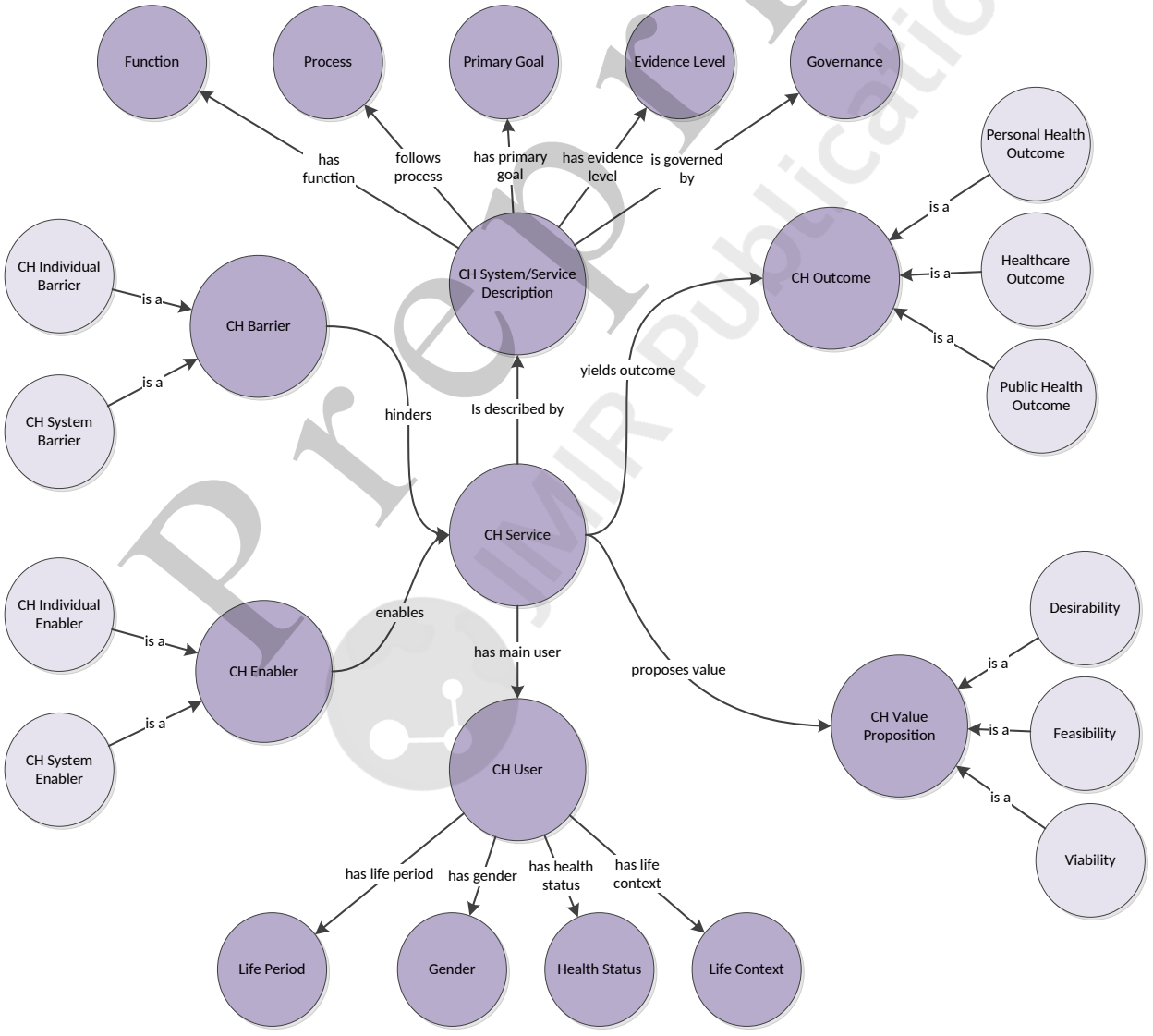

Figure 2. The ontological model of CHIF; the framework is organized as a tree whose root is the concept of CH System/Service. Nodes beyond the 3rd tree level are not depicted here to reduce the complexity of visualization. Note that the arrows tagged as “is a” denote a subsumption relationship (i.e., lighter colored nodes are subclasses of darker colored nodes)..

CHIF axes

The following subsections refer to the description of the CHIF.

CH System/Service Description

As a prerequisite, CH services need a basic level of functionality description.

We propose five elements, helping to describe a CH service through its **function**, **process**, **primary goal**, **evidence level**, and **control**. The *function* element reveals the functionality behind the service, such as assessment or monitoring, knowledge building, disease or condition management, or lifestyle management. The *process* element is responsible for describing how the function is implemented (e.g., receiving a measurement from the user and returning automated feedback to the user). This element can include specific components supporting user personalization, such as social interactions and other. The *primary goal* reflects the health-related intent for optimization (e.g., daily activity through the number of steps a day, night sleep duration). The *evidence level* describes the validation and evaluation of the service, including technical validation, clinical testing, and user experience. The last proposed element, *control*, refers to the governance of the service on a higher level. The control may belong to the patient or consumer, healthcare representative, social services, or payers, depending also on the CH services funding (private or public insurance).

These CH functionality elements can be directly or indirectly linked to impact, and further support a better understanding of the service as well as compare services.

CH Users

When addressing the personal CH outcomes coming from a specific technology or service, one has to specify the offered functionality and aim explicitly, as well as what users it addresses or applies to. Particularly as regards services and interventions, the targeted users should be well described. It is necessary to note that CH has many *contextual factors* influencing its adoption that should be reflected. These include geographical, social, demographics, human factors, educational, regulation, interoperability, and big-data contexts of the specific CH systems within particular deployments. The contextual factors influence the clinical trials concerning the CH. Similarly, CH systems might vary significantly in different geographical regions, due to, for example, different environmental influences (e.g., a training/coaching application should provide a different sports suggestion for the desert region). The same argument is valid for different demographics and socioeconomic contexts. The acceptance of services is often determined by human factors such as the engagement, the education level, and – especially – the digital literacy of the end users. These contextual factors are

essential to understanding that, for example, "*the CH system X is efficient for female elder users with dementia in rural areas*". This fact is crucial when designing the system and reporting outcomes [20], especially if aiming at personalized interventions and avoiding "one size fits all" ones.

We propose an initial approach where the **primary user** (i.e., patient or citizen) is described with four elements: Phase of *Life (Young, Working, Retired,* or *Dependency), gender*, *health status (healthy, chronic patient, comorbid, acute disease, disabled)*, and *life context*. The concept 'young' includes Young includes childhood, adolescence, transition to young adulthood. The last element consists of a list of factors that help to describe the life circumstances of the user, including the location of living (e.g., rural area), social activity, financial status, and others.

When not targeting consumer apps but health services, other involved users have to be identified, in addition to the direct beneficiary (i.e., patient or citizen). The **secondary users** could be healthcare professionals (HCPs), state and policymakers, as well as business. CH may have an impact on all the user groups.

CH Outcomes

The health-related outcome of a CH service can be viewed from three different perspectives: (1) the personal perspective, (2) the healthcare process related perspective, or (3) the wider socioeconomic or public health perspective (see Figure 3). These outcomes belonging to the three different perspectives are potentially intertwined.

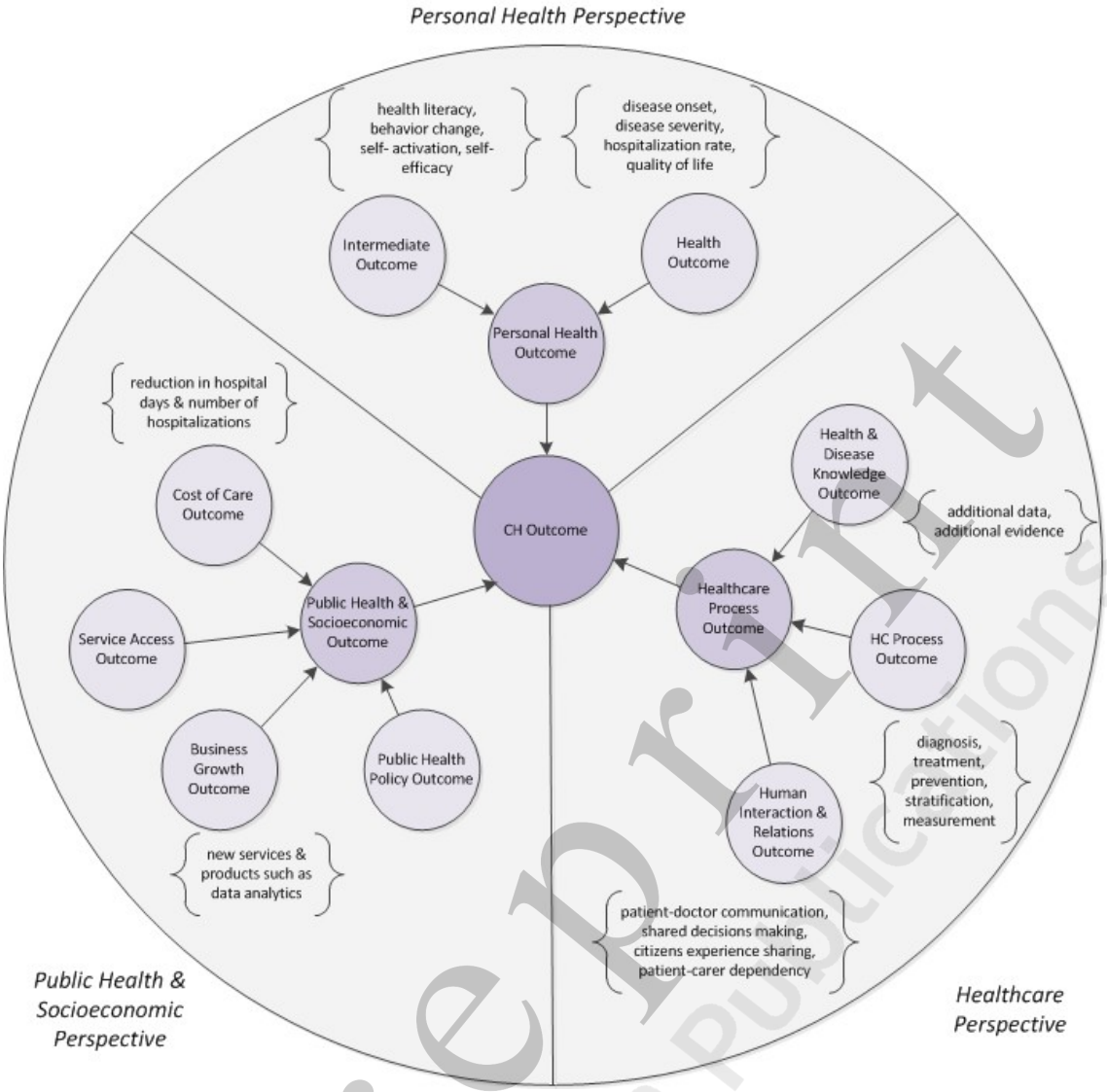

Figure 3. Perspectives on health-related outcomes that are associated with the impact of CH services. All arrows denote “is a” relationships

Personal Outcomes

First of all, CH can affect the patient’s or citizen’s empowerment and engagement, as well as compliance with treatment [21, 22] or other health behavior. These outcomes are expected to lead to the promotion of a healthy lifestyle, with further positive care and social consequences, improved health and a better quality of life. In this respect, personal health outcomes are divided in:

- intermediate outcomes (health literacy, behavior change, self-activation, self-efficacy) [23], and
- health outcomes (disease onset, disease deterioration, hospitalization rate, quality of life),

where the former are considered as potential mediators of the latter.

The introduction of CH tools may bring improved self-efficacy, understood here as a person’s ability to implement situation-specific behaviors towards attaining established goals, expectations, or

designated types of outcomes [24]. Individuals knowing more about their health status may better cope with their health-related problems by themselves. Improved knowledge and understanding about health indicators, achieved through CH while a person suffers from health problems, can also reduce uncertainty in illness.

The timescales are expected to differ depending on the two types of the outcome, and many pilot studies decide to report on either but not both. However, reporting on both effects would help better understand the mechanisms of outcome formation and its further impact on the personal level.

A significant challenge is how to best measure these outcomes in a consistent manner, including both subjective or qualitative parts that are mostly measured with questionnaires, and objective parts that are quantitatively measured through the use of various devices (e.g., number of steps on a pedometer, heart rate on a smartwatch). Another challenge is when to measure the outcomes, and more importantly, how to express their temporal nature. Importantly, personal health outcomes are also linked to the care process outcomes (e.g., improved access/accessibility to healthcare services), especially when combined with health literacy [25].

Healthcare process Outcomes

The utilization of CH relates to better patient's safety, decreased duration of diagnostic processes (e.g., early diagnoses), and better disease management (e.g., identification of the risk of deterioration, primary and secondary prevention of disease) [26, 27]. In the scope of the CH, it is also expected to offer better access to the data, which can be used to improve understanding of the disease (especially in the case of chronic diseases) and provide evidence for health policy makers and other involved stakeholders. CH technologies offer great opportunities for a unified collection of patient-reported outcomes, which can affect the healthcare process [28].

The introduction of CH services impacts the models of care by enabling novel pathways for health monitoring, which include new interaction models supporting the involvement and empowerment of all stakeholders. These perspectives outline the need for novel clinical healthcare and social care guidelines, which can influence long-term health strategy design by promoting the economic efficiency of these services.

Overall, the directions identified as regards the care-related impacts of CH can be organized in three axes:

- healthcare process (diagnosis, treatment, prevention, stratification, measurement of outcome) [29]
- human interaction & relations (patient-doctor communication & shared decisions,

information and experience sharing, patient-carer dependency)

- new health and disease knowledge (more data and evidence)

Public Health and Socioeconomic Outcomes

There are also horizontal aspects in CH outcomes, which affect multiple stakeholders and levels of health, and thus can be considered both as drivers and outcomes of the CH. These include mainly the facilitation of communication and information flow between health stakeholders and the improvement of health data analytics and management.

A characteristic example is the MyData Nordic Model [30]. This is an infrastructure for human-centered personal data management and processing, aiming to provide individuals with the practical means to access, obtain, and use datasets containing their personal information (i.e., medical records, financial information, data derived from various online services). This approach introduces interesting dynamics at the societal and business level. Another example that relates CH data to public health policies is the BigO programme, a European research project that analyzes daily living behavioral patterns of the youth to propose optimal physical activity-, diet- and nutrition-related policies [31].

Cost reduction as an outcome can be expected at different levels, from the personal to the level of public health. There are studies on the cost-effectiveness of various telemedicine services. The main CH horizontal socioeconomic effects include (1) reduction of cost of care (e.g., reduction in hospital days and number of hospitalizations), (2) improved and cost-efficient access to services, (3) improved public health policy, and (4) industrial activity and business growth , related to new services and products (for example, analytics services).

Factors towards achieving CH impact

CH Value Proposition

To achieve scalability and impact, CH value proposition must be clearly articulated. In this respect, it is important to elaborate on what critical information regarding the CH applications is required for understanding the value proposition pertinent to each of the different stakeholders (e.g., consumers and patients, their families, clinicians, developers, and payers). This is a clear statement of how the proposed solution relates to some improvement for the user, what specific benefits it brings, and how it differentiates from others. While the value proposition is a consumer informatics concept, rather than a healthcare one, this concept may help crystallize the virtues of the CH application and its adoption.

As suggested in a McKinsey report [32], the three main properties that generally describe the value

proposition of a CH solution are: (1) *desirability* for all involved users (custom-centred and easy to use), (2) *feasibility* both technical and organizational, and (3) *viability* and sustainability (e.g., via a supporting ecosystem, involving smart elements, involving integration and collaboration of stakeholders, and more.).

To support these properties, the new solutions should be designed following a user-centered approach to (1) *respect the activities* a potential user has to perform, (2) *meet the expectations* (e.g., comfort of use, easy to learn how to use), and (3) *minimize the fears* associated with the solution (e.g., fears related to the new technology, fear of high costs). A CH service or a product should be proposed based on the above- mentioned elements.

Barriers and Enablers of CH impact

Error: Reference source not found provides a visual outline in the CH impact enablers and barriers that have been identified by CHIF.

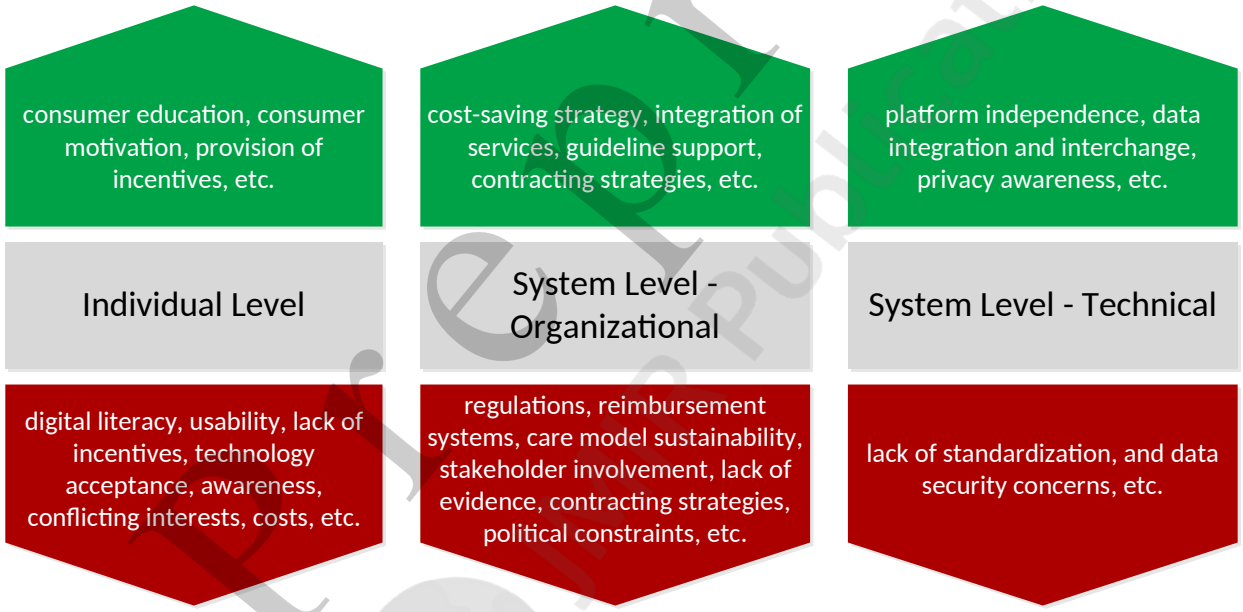

Figure 4 Classification of enablers (upward arrows) and barriers (downward arrows) of CH impact as identified by CHIF; Individual (left) and system (right) level enablers and barriers have been identified.

When designing and later evaluating a CH service/system or an application, it is necessary to recognize and report barriers that users (clinicians, developers, consumers, their families, and caregivers, as well as policy makers) encounter and that can potentially limit the implementation or utilization of the CH solution. Considering **the user-CH system dipole**, we propose to classify the barriers, as **individual level** ones related to internal users features and abilities (e.g., literacy gaps) and barriers external to the user, and attributed at **system level.** The latter might be **technical** (e.g., design problems that limit usability) or **organizational** (e.g., regulations). The individual level

barriers include *digital literacy*, *usability*, *lack of incentives*, *technology acceptance*, *awareness*, *conflicting interests*, and *costs*. A series of system-level barriers related to an organization have been identified, including obstacles in *regulations*, reimbursement systems, care *model sustainability*, *stakeholder involvement*, *lack of evidence*, *contracting strategies*, and *political constraints.* Significant technical barriers at system level include, among others, lack of standardization, and data security concerns.

The enablers that a CH system employs towards achieving impact can be reported at the same levels as the barriers, i.e., **individual** and **system** (categorized as **organizational** or **technical**) level, and span beyond merely overcoming technical challenges, to address the problems identified at these levels and contribute to their solution. At the individual level, it is essential to *educate and motivate* consumers, potentially through incentives, e.g. via offering a clear user-perceived health-related benefit.

At the system level, both organizational and technical issues need to be addressed. From the organizational side, issues within the health care organization (e.g., *cost-saving strategy, integration of services, guideline support*) need to be identified, and facilitating factors should be clearly defined. A vital organizational enabler is *contracting strategies*. In the developed countries, health care is delivered by the state, and most of the medical services are bought by a paying organization (payer) on behalf of patients or consumers as a third party of the transaction. This method shows that end users are not a party in the contract and are not directly interested in cost savings. Therefore, contracting strategies, as a way medicals services are reimbursed, have to incentivize providers to implement innovative CH solutions. Payers already use many types of contracts that promote a different kind of providers' behavior; for example, Capitation, Pay for performance, and Case-mix contracts (Diagnosis-Related Group (DRG), Health Regulation Division (HRD), Shared saving models, and others). On the technical side, best practices like platform independence of applications, data integration and interchange, privacy awareness [33], are straightforward CH enablers.

While proactively working to leverage enablers and overcome barriers, based on previous experience, the barriers and enablers are not in a static relation to the CH system. Besides, their relationship is not readily observable and quantified, i.e., the power of the association, and the extent to which they affect each other and the outcome at a user level and beyond.

CHIF Preliminary Evaluation

To examine how understandable and usable the CH concepts and terms of the proposed framework and CHIF in general are, we developed an **electronic questionnaire assessment**, which follows a

semi-structured form [34]. The questionnaire, which also encourages insights entered in free text, was introduced to early-stage researchers that work in the domain of Connected Health in multiple disciplines (IT, business, health), in the scope of the ENJECT summer school (London, September 2017). The questions included in the questionnaire are provided in Supplementary material 3. The actual questionnaire was eventually completed anonymously by 5 volunteers from this group. The summarized answers are presented in Supplementary material 4.

While a limited number of responses was received, it helped in observing how the CHIF concepts are perceived. Analyzing the answers of the assessment, we noticed a pattern: most of the participants tended to fill-in specific parts of the questionnaire, while other parts were consistently left without an answer. We assume that the answered questions represent the concepts of the CHIF that are understood and accepted, and the questions that remained unanswered suggest the concepts and terms of the framework which were not clear enough to understand. The answered questions were associated with the following concepts: CH User, CH outcomes towards impact, and partially the means to achieve impact. The parts presenting gaps in the answers included the primary goal of the framework, the information on time scales of the different effects, the industrial and business growth dimensions, and the barriers and enablers beyond the patient or consumer user (system, secondary users). Value proposition section was utterly unanswered. Open questions were mostly unanswered.

Although preliminary, this limited assessment indicates the directions for improving framework (especially the fuzzy areas) and shows a need for a better understanding and contemplating around the concept of CH services and their impact, and beyond a solely technological perspective.

Discussion

This paper provides an overview of CH impact concepts and proposes the CHIF for the consistent description and assessment of CH services' impact in its different dimensions. While this framework may benefit from further refinement, it is an attempt for setting the basis for a complete and consistent reporting of this rather vague area, and it is expected to contribute in better evidence building and better designing of CH services.

A series of steps is foreseen that will lead to the CHIF deployment and use. The development of CHIF ontology is necessary for knowledge standardization and interoperability, that lies in the very heart of CH. Following the example of m-health reporting guidelines [35], CHIF has the potential to evolve as a tool for reporting CH impact, either as checklist or as an e-questionnaire. This will be useful also for comparing interventions. In this respect it can be part of a broader CH framework and can form the basis for a digital registry of CH interventions to be further studied and compared.

An important step before that is to proceed with a thorough evaluation of CHIF-based tools in terms of clarity, completeness and redundance. The existing questionnaire will be the basis for that. A future evaluation will include compare between free text and structured entry of CH impact information and a post reporting questionnaire for user experience.

The following subsections discuss different aspects regarding CH impact that present challenges and could benefit from further investigation.

The Multiple Dimensions and Scales of CH Impact

We see CH impact as a multilevel concept, where potentially some CH outcomes at one level can influence those at other levels. The above interaction indicates that outcomes can also include causative relations.. In essence, this requires approaching the concept of impact in a different manner: moving beyond static clinical aggregate key performance indicators (KPIs), towards linking outcomes in a more dynamic way (i.e., personal, healthcare and socioeconomic as well as horizontal aspects of the outcomes). Such approaches can be envisioned within a Big Data framework that can potentially reshape health policies. Among others, it could help to better elaborate on how each type of health outcomes is linked with potential care benefit and cost reduction.

The concepts and directions stated above can set the basis for a CH taxonomy. The taxonomy in its turn can support consistent reporting, evidence building, and systematic reviewing purposes. Similar approaches have been used in Consumer Health [36], Integrated Care, and Behavioral Informatics applications [13].

One of the most crucial and challenging issues is the multi-scale character of the CH impact. The impact can be at different structural scales (e.g., micro-, meso- or macro-scale) and different temporal scales. For example, a CH system can provide more efficient cost-benefit ratio on mid- to long-term due to the initial increase of the cost of the service, and even more increased benefits and savings in the long-term, due to the abundance of information and knowledge produced by CH services.

Connected Health beyond Consumer Health Applications

CH extends beyond primary and secondary healthcare settings to the whole daily life, and therefore, inevitably uses technology that is beyond medical devices as established in clinical care. The *Person-Centered Care* approach is well suited to utilize consumer health technologies [37]. The role of consumer health electronics and systems in daily life has been recently recognized and appreciated. As described in [38], **consumer health informatics applications or tools** were defined as any electronic tool, technology, or system, which is in accordance with the following:

(1) primarily designed to interact with health information users or consumers (i.e., anyone who seeks or uses healthcare information for nonprofessional work),

(2) interacts directly with the consumer who provides personal health information to the system and receives personalized health information from the tool application or system, and

(3) the data, information, recommendations, or other benefits provided to the consumer, may be used in coordination with a healthcare professional but is not dependent on a healthcare professional. In this respect, patients (individuals who have entered in the healthcare process) are distinguished from citizens / consumers.

By repurposing or extending their initial aims, such tools can be used and have already been used (for examples smartwatches and activity trackers) for (1) disease management, to facilitate knowing, tracking, or understanding clinical parameters; (2) monitoring and understanding daily living observations (Quantified-Self perspective); (3) lifestyle management assistance (calendar, reminder); (4) prevention and health promotion; (5) self-care; and (6) assisted care and caregiving. When considering the Quantified Self, Socialization, or patient-health professional relationship domain, few published studies have investigated the determinants of the efficacy of these smart connected devices and their impact on individual behaviors and professional health practices [39].

A valid point for disambiguation is whether "*connected health basically is driven by consumer health electronics and applications*", a point extensively discussed within Enject Workshops. The answers and views seem contradictory. From one side, it is believed that CH impact is mainly driven by consumer electronics in daily life, in other words, CH impact heavily relies on Consumer Health Informatics. The reasoning behind this is that ICT and consumer electronics indeed influence and facilitate different aspects of everyday life and societal needs, including health. The culture of permanent self-monitoring (Quantified Self), is a typical case of this transformational power.

There is also an opinion about consumer electronics as a partial or moderate contributor to the broader impact of CH. The main arguments for the partial contribution are the lack of de-facto integration of consumer electronics data with medical data, and also the lack of actionability at the medical level (professional interpretation of the data).

CH Impact Beyond E-Health and M-Health

E-health has been the generic platform for organizing and delivering digital health content and electronic and remote care services, while m-health contributed to the wealth of mobile services focusing on the patient, the elderly, and the continuity of chronic care. The added value that CH can bring to the previous efforts in the e-health and m-health domain seems to span in three axes: (1) data and service integration and interaction, (2) validation of health-related services, and (3) overall

health.

Data and service integration and interaction: Traditionally, the technological framework for standardization and interoperability has been built within e-health (e.g., the data exchange standard Health Level Seven (HL7)[40]. However, from a functional perspective, the integration and interaction between personal and clinical information in a continuum, instead of overlapping e-health, m-health and telemedicine, is a central point in CH. To a certain extent, this interaction can be regarded as a transfer of evidence from self-management data to the clinical treatment of the patients and vice versa. While this can now be technically leveraged by HL7 Fast Healthcare Interoperability Resources (FHIR) and similar technology and standards [41], neither the organizational capability that is required on the healthcare side nor the scientific evidence on the use of such resources are entirely evident.

Validation of health-related services: This can be regarded as a secondary outcome of data and service integration and interaction, supporting CH evidence formation.

Health: The CH services have the potential to contribute to the improvement in the diagnostic process (e.g., shorter time to diagnosis), wellness, and evidence of self-management. Telemedicine services for the elderly and patients with chronic diseases and those targeting accessibility to healthcare services (e.g., people with disabilities, rural areas residents) have been recognized and adopted to some extent. Other aspects, including patient and consumer empowerment, treatment adherence, prevention of behaviors contributing to health-related risks , and health literacy are candidate future CH targets for achieving impact.

Overall, CH impact beyond e-health and m-health should focus on integration and access to a wealth of information and services. Therefore, there is a need for the explicit descriptions of services and data that will be linked and integrated, from both, technical and organizational perspective.

Which Future Research Activities Can Facilitate CH Impact?

CH is a new promising direction for improved health and wellbeing services [2]. Therefore, further research and investigations should concentrate on how CH can be interwoven into other important initiatives leading to cost containment and improvement of care.

Person-centered care and health promotion are both vital fields where CH tools are potentially able to prove their usefulness. CH in person-centered healthcare systems can support patients or consumers to cope with the health and wellbeing problems using their own resources, and as needed, help to make informed decisions when to invite others, including professionals, to act on their behalf. In this approach, well designed CH tools may be able to prolong the period when patients and

consumers would be capable to successfully manage their health and care according to their lifestyle, preferences, and goals. Patient-centered design and patients' and consumers' data analytics are the essential methods under the theoretical foundations of Health Behavior Informatics.

This direction of the CH development needs studies to investigate what kind of contracting strategies and incentives could facilitate implementations of CH tools that enable cost containment by keeping people longer out of healthcare facilities or providers. The integration of CH services with new promising cost containment and quality improvement policies should be a research priority, and new business models should be designed. Field studies should be promoted to collect evidence and understand needs. Health economics and finance should be revised based on new political guidance.

CH technologies can be employed for adapting public health policies, addressing a broader health-related impact, which also involves transitions to new models of care. The availability of CH data combined with "big data analytics" can be of added value towards supporting the learning health system cycle [42].

Besides the cost and business perspective, it is essential to recognize the role and the rising needs for CH education, entailing for interprofessional aspects. CH education is related to preparing the stakeholders, addressing barriers and concerns, as well as contextual factors. Elaboration of new curricula for healthcare professionals and health researchers, while addressing CH literacy for citizens in an organized and inspiring manner, could have a transformative power towards CH impact.

Limitations

A limitation of the present study is the lack of extensive evaluation of the proposed CHIF framework. In addition, the lack of standard terminology may pose challenges towards extended use of the framework for comparison and new knowledge elicitation. The addition of formal descriptions and semantics and the link to standard terminologies is considered a necessary next step. The adoption of standards and semantics is expected to alleviate some of the possible difficulties and ambiguities related to the current implementation and lead to broader use and evaluation of the framework.

Conclusions

Connected Health Technologies offer new vehicles for implementing "anytime and anywhere" health and care services. Being an emerging and diverse field, CH will benefit from the disambiguation of

concepts. In addition, scaling up of these services is closely related to means for understanding and measuring their impact. In this respect, this work introduces CHIF, a framework for CH impact assessment that contributes to the formalization of the connected health domain, also paving the way towards the introduction of methods for measuring and comparison in multiple scales and dimensions related to CH outcomes. CHIF can evolve towards the creation of a CH impact tool and contribute to the generation of a service registry for further comparison and investigation.

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Conflicts of Interest

The authors declare no conflict of interest.

Multimedia Appendix 1. Workshops description.

Multimedia Appendix 2. Screen captures of the electronic questionnaire based on CHIF framework.

Multimedia Appendix 3. The electronic Questionnaire

Multimedia Appendix 4. Questionnaire summarised answers.

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