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Towards designing for health outcomes: implications for designers in eHealth design

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Abstract

eHealth development faces the challenge of generating evidence about health effectiveness in real-world settings. Designers can potentially support this challenge but must understand health approaches to evidence generation about health outcomes. This case study investigates how health and care professionals conceptualise health outcomes and their evidence generation in eHealth. Our results identify three key conceptual dimensions: effect, meaning, and collection. We discuss how these inform future design competencies to support evidence generation about health outcomes in eHealth design.

Keywords: evidence-based practice, healthcare design, design practice, design competences, design evaluation

1. Introduction

eHealth systems play an essential role in improving patients' health and well-being, health service delivery, and overall quality of care (WHO, 2016). These systems apply information and communication technologies and leverage the resulting interoperability to continuously collect and display various data types (e.g., biometric, behavioural) at a large scale—from multiple patients at multiple times (Silber, 2003). Examples include electronic health records that store and share patients' medical information or remote patient monitoring systems that collect and transmit health data (e.g., heart rate, active minutes) in and out of the hospital. However, despite their increased application, scientific evidence regarding their effectiveness in the real world is scarce (Bonten et al., 2020). This scarcity derives from the limited joint evaluation of clinical and sociotechnical factors (e.g., acceptance, safety) in eHealth development that influence its adoption and effectiveness in real-world settings (Enam et al., 2018).

Within eHealth development, designers follow a human-centered design approach to explore contextual factors and create eHealth solutions tailored to the intricate dynamics of the patient's sociotechnical system (Melles et al., 2021). In creating such solutions, designers can potentially support the generation of evidence about eHealth effectiveness by embedding data collection mechanisms. They could leverage their competencies to identify aspects of the problem and solution that meaningfully inform the design of data collection mechanisms about eHealth effectiveness in real-world settings. However, designers are hampered by a lack of understanding and clarity about an evaluation of effectiveness that considers health outcomes and their evidence standards in healthcare (Noël, 2017; Lamé, 2018).

Understanding how health and care professionals (HCPs) generate evidence about health outcomes is essential for eHealth development, as this evidence ensures that eHealth systems do not harm their users (Wyatt, 2016). Thus, there is a need to clarify health outcomes and their related evidence generation for eHealth design. Especially with the opportunity these systems bring to collect data continuously at a large scale in the real world. Therefore, we conduct an empirical study to understand how HCPs

conceptualise health outcomes and their evidence generation in eHealth and identify what designers can do to support this evidence generation. Our research questions are: *how do health and care professionals conceptualise evidence generation about health outcomes in eHealth development? And how can designers incorporate this evidence conceptualisation into their competencies?* Accordingly, we explored health outcomes' evidence generation in an eHealth case study via interviews with HCPs and used reflexive thematic analysis to identify their conceptualisation. From our results, we identified how design competencies can be enhanced to support evidence generation in eHealth design.

The paper begins investigating evidence generation about health outcomes. Then, we introduce the case study where we explored the conceptualisation of evidence generation about health outcomes with HCPs. Next, we describe the three conceptual dimensions identified in their conceptualisation of evidence generation: *effect*, *meaning*, and *collection*. Finally, we discuss the implications of these dimensions for design competencies outlined in the literature and highlight design-related frameworks to support their application. We conclude with future research directions to support designers in conceptualising evidence generation about health outcomes with HCPs in eHealth design.

2. Evidence generation about health outcomes

Evidence in healthcare refers to any empirical observation about the apparent association between events, where unsystematic observations constitute one source of evidence and experiments another (Guyatt et al., 2000). Central to evidence generation is the extent to which a credible process (e.g., research study design) produces evidence, where systematic and controlled observations provide more trustworthy evidence (Djulbegovic and Guyatt, 2017). Thus, generating evidence about an association or possible causation between two variables (e.g., intervention and health outcome) concerns systematic experimentation, as this process is one of the strongest to support causation (Hill, 1965). These experiments are called interventional studies—researchers actively interfere in a present situation by introducing an intervention (e.g., drug, device) in some or all participants to establish the effect of the intervention's exposure on the participants (Ranganathan and Aggarwal, 2018). There are various intervention study designs, with randomised controlled trials being one of the most robust studies to generate evidence about the health outcomes of interventions (Aggarwal and Ranganathan, 2019).

As part of the research study design, health outcomes are defined before exposure to the intervention takes place (Ranganathan and Aggarwal, 2018). The WHO defines *health outcomes* as a change in an individual's, group's, or population's health status attributed to one or multiple interventions, regardless of the intervention's intent to change health (Nutbeam, 1998). Here, health status describes or measures an individual's health at a specific time, while health encompasses physical, social, and mental well-being, extending beyond the mere absence of disease. Health outcomes are typically assessed using health indicators—i.e., characteristics of an individual, population, or environment that are subject to measurement and are used to evaluate health in terms of quality, quantity, or time (Nutbeam, 1998). A typical example of health outcomes is survival rate. However, nowadays, defining outcomes that are valuable for patients (e.g., health-related quality of life) is essential to get a holistic view of patients' health and promote value-based healthcare (VBHC) (Porter, 2010).

In defining health outcomes, HCPs developing the intervention define their measurement. In this regard, VBHC champions a patient-centered measurement of health outcomes that includes what is valuable for patients (Porter, 2010). Patient-centered measurement stresses that defining what to measure should be clustered by medical condition, consider the health circumstances most relevant to patients and cover all the stages of care—i.e., consider short and long-term effects on patient health. Once outcomes are defined, one or more measures and indicators are selected to quantify success. Their selection should minimise the ambiguity of the outcome by choosing validated and tailored patient-population metrics. Lastly, contextualising measurement is considered—i.e., when and where to measure in a way that reflects patients' circumstances and allows the health effect to manifest itself.

Accordingly, initiatives to improve patient-centered measurement have been established. For example, international consortia have developed condition-specific standard sets with patients to define patient-centered measures (Kelley, 2015). In addition, patient-reported outcomes (PROs) have been developed to account for the patient's perspective on health outcomes and promote patient-centered measurement (Calvert et al., 2019). PROs are reports about the status of a patient's health condition (e.g., health-

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related quality of life) coming directly from patients without interpretation by someone else (FDA, 2009). PROs are operationalised with patient-reported outcome measures (PROMs); these are instruments and tools, such as self-completed questionnaires, that measure the patient's health status, for example, symptom burden or health-related behaviours like anxiety and depression (Weldring and Smith, 2013). More recently, eHealth has transformed outcome measurement—from collecting biometric health data (Porter, 2010) to enabling online interfaces (e.g., diaries) that capture qualitative accounts of patients' health at various times and outside of hospital settings (Johnston et al., 2023).

As discussed above, HCPs apply their health knowledge to define health outcome measurements and then assess the health effects once exposure to the intervention occurs. However, there is still ambiguity and consequent limited practical insight into how health outcome measurement gets conceptualised towards concrete evidence generation in eHealth development. This conceptualisation is particularly relevant for eHealth design as it can elucidate considerations for designers to embed data collection mechanisms during eHealth design and leverage eHealth's large-scale data collection—i.e., gathering data from multiple users in diverse settings at numerous times. Therefore, in an eHealth empirical study, we will investigate the conceptualisation of evidence generation about health outcomes with HCPs.

3. Methodology

This empirical study aims to explore the conceptualisation of evidence generation about health outcomes from an HCP perspective in eHealth development. Our study is grounded in the qualitative tradition. Accordingly, we employ an inductive case study methodology (Eisenhardt, 1989) via interviews to understand HCPs' conceptualisation and ground it in their practical context. Our empirical research question is: *how do health and care professionals conceptualise evidence generation about health outcomes in eHealth development?*

3.1. Case: Remote patient monitoring to increase physical activity in children with chronic conditions

Following Eisenhardt's (1989) process, we select our case study based on theoretical relevance. Our theoretical construct of interest is the activity of evidence conceptualisation, focused on evidence generation about health outcomes happening in eHealth development. Based on our literature review, we need a case study that allows us to investigate how HCPs define health outcomes' measurement to generate evidence. In addition, the case should exemplify the development of an eHealth system that aims for patient-centered measurement to observe its contextualisation.

To this end, we selected the case study of an eHealth remote patient monitoring (RPM) system currently being developed to increase physical activity (PA) in children with chronic conditions. This case lets us explore our theoretical construct because there are preliminary desired health outcomes, but their measurement needs clarification for a pilot evaluation with patients. Additionally, an RPM system for PA allows the exploration of patient-centered contextualisation of evidence generation given the multiple contexts where it will be deployed to promote and assess PA. Below, we describe the case.

PA is crucial for healthy childhood development. However, children with chronic conditions (e.g., heart disease or asthma) may experience reduced PA levels due to parental anxiety (van Deutekom and Lewandowski, 2021). In response, a collaborative research initiative in The Netherlands involving university hospitals and technical and social science universities aims to improve children's PA levels and reduce parental anxiety through an RPM system. The initiative comprises three projects: one focusing on technology, another on clinical implementation, and the third exploring social implications. The conceptual design of the eHealth system began years ago using a human-centered design approach with these families (see Morales Ornelas, 2020). Currently, the initiative is developing a system prototype for pilot evaluation with the children and their parents.

3.2. Data collection

HCPs are those who study health promotion or diagnose, treat, and prevent illness (WHO, 2013). We invited the HCPs executing the three projects to an exploratory interview. We decided to recruit HCPs because they are responsible for generating evidence about the health effects on the patient group. The

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first author conducted six semi-structured interviews between May and September 2023. Participants had an academic background concerned with health promotion in the medical, social, or human movement science area and had or were pursuing a PhD (see Table 1). All participants had experience with either physical, social, or mental health outcome measurement. Some (P1, P2, P4, P6) had knowledge about eHealth development and application, including the validation of sensors for clinical use and using sensors in and outside hospital settings for clinical research. Others (P3, P5) were less familiar with eHealth development. Nonetheless, their health-related expertise in outcome measurement, academic background, and project involvement enable them to share thoughts on how the RPM system could be used in health outcome measurement.

Table 1. Participants' background details

Participant	**Health-related expertise** (holds PhD)	**Years of experience**	**Project**
P1	Paediatric cardiology and epidemiology (PhD)	6	1, 2, 3
P2	Paediatric cardiology (PhD)	12	1
P3	Human movement science (PhD in-progress)	2	3
P4	Paediatric pulmonologist (PhD)	17	3
P5	Family sociology (PhD)	13	2
P6	Sports medicine (PhD)	11	3

Note. Years of experience are counted from their final academic degree acquisition to the interview date.

The goal of the interviews was to explore with HCPs their conceptualisation of evidence generation in relation to the health outcomes of interest in each project and their measurement. Before the interviews, the first author gathered and read each research proposal to get familiar with the projects. The interview procedure then consisted of three phases. **Phase one** focused on getting to know the participants' expertise to build rapport and understand their health-related perspectives. In **phase two**, the first author asked them to explain their project's overarching aim and health outcomes to have a starting point for reflection. **Phase three** was divided into two steps to explore the conceptualisation of patient-centered health outcome measurement described in section two above. The **first step** focused on exploring the perspective of the child and the parents concerning the defined health outcomes of interest. The first author asked participants to reflect on how their health outcomes related to a child and parent perspective and follow-up questions about how they planned to measure and generate evidence about them. In the **second step**, the focus shifted to the contextualisation of the measurement based on the patient group's needs. The first author started by introducing the three meaningful moments found in previous user research (see Morales Ornelas, 2020) with this patient group: (1) follow-up appointment, (2) Before physical activity, and (3) during physical activity, as well as the related needs from a child and parent perspective per moment. Then, she asked participants to reflect on how the health outcomes and corresponding measures for evidence generation related to these moments and needs.
The interview with P1 lasted two hours because P1 participated in all projects and one hour with participants 2-6. Interviews with participants 1-5 were in-person and with P6 online. All interviews were audio-recorded with consent. Our institution's Human Research Ethics Committee approved this study.

3.3. Data analysis

The first author transcribed all the audio files verbatim with support from MS Office 365, de-identified the transcripts, and proceeded with Reflexive Thematic Analysis (RTA) (Braun and Clarke, 2021b) in ATLAS.ti. Following RTA quality criteria (Braun and Clarke, 2021a), the first author positions herself as a design researcher interested in bridging the design and health disciplines and acknowledges that her positionality informs her reflexive and interpretative activities. She applied RTA to identify patterns of shared meaning in the conceptualisation accounts described by participants and discussed analytic observations with the third author to elucidate assumptions in the analysis (Braun and Clarke, 2021b). She used deductive and inductive approaches and interpreted the data with a latent strategy to explore the underlying meaning of what participants expressed in the transcripts. We describe the analytic process based on the six RTA steps below.

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The **first step** involved familiarising with all the transcriptions by reading them multiple times. In the **second step**, the first author applied deductive coding based on the WHO's definition of health outcomes (see section 2) to create an outcome-related dataset from the transcripts. For instance, she coded the following quote 'Outcome': *"So as a healthcare worker, I hope to see that like the cardiac health is improving."* Once all the transcripts were coded, she applied inductive coding to identify patterns and themes in the dataset. For example, the quote above was coded 'Change-increase'. For the **third step**, she grouped the codes to generate initial sub-themes. For example, the codes 'Change-increase' and 'Change-decrease' created the sub-theme 'Change degree'. Initial sub-themes were discussed with the third author to clarify analytic observations and insights (Braun and Clarke, 2021b). The **fourth step** consisted of reviewing and gathering sub-themes into themes. For instance, the sub-themes 'Change degree', 'Target individual', 'Time frame', 'Environment', 'Desirability', 'Duration' and 'Logical relations' were gathered under the theme 'Effect' due to their fixation with health changes' characteristics and influences. In the **fifth step**, she defined and refined each theme. For example, she returned to the transcripts to observe the dataset in its overall context. This step helped her to sharpen each theme by identifying relationships within them. Finally, in the **sixth step**, she wrote the final themes and related sub-themes, supported by the reflexive journal she wrote throughout the analytic process.

4. Results

The analysis results indicate that HCPs conceptualise evidence generation in three dimensions: *effect*, *meaning*, and *collection* (see Table 2). Each conceptual dimension gathers aspects considered when defining the generation of evidence about health outcomes. Below, we introduce each dimension by providing its description along with associated aspects and illustrate these with participants' quotes.

Table 2. Overview of conceptual dimension themes

Dimension (Participants)	**Description**	**Aspect sub-themes**
Effect (P1, P2, P3, P4, P5, P6)	Describes aspects considered to frame the effect manifestation that the evidence to be generated will support.	Target individual, change degree, time frame, desirability, duration, environment, and logical relations.
Meaning (P1, P2, P3, P4, P5, P6)	Describes levels considered to define observable meaning units as the evidence of effect to be generated.	Outcome definition, measure definition, and data definition.
Collection (P1, P2, P3, P4, P5, P6)	Describes aspects considered to collect data that will serve as evidence.	Contributor, subjectivity, mechanism, temporality, and context.

4.1. Theme one – Effect

A conceptualisation of *effect* involves aspects of the health change manifestation that collectively will be supported by the evidence generated. These aspects are: target individual, change degree, time frame, desirability, duration, environment, and logical connections. All are used to frame the effect's manifestation in the patient's life.

In conceptualising the health effect and its manifestation, a primary aspect is the *'target individual'*, which indicates who will experience the effect and thus the effect of who will be investigated (e.g., child, parents, child's sports coach). Another aspect highlighted was the effect's intended *'degree of change'*, usually expressed as an increase (e.g., increased PA level) or a decrease (e.g., decrease of asthma rescue medication). In addition, a *'time frame'* aspect suggests when the effect is expected to occur in relation to the intervention's exposure, which could be short-term (e.g., two weeks) or long-term (e.g., ten years). For example, in the quote below, P1 describes various degrees of change in psychological health for different individuals expected in a short time frame: *"What I find also very important is that they enjoy sports and that they feel more safe and more secure and more self-efficient, and that parents have less fears and insecurities. So, I guess those are the things that I find most important for the children and the parents in a relatively short term."*

Other aspects in the conceptualisation of effect include the environment, duration, and desirability. *'Environment'* indicates where the effect is expected to manifest. For example, a child's increased PA

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level is expected to happen in their day-to-day life primarily. Another related aspect is *'duration'*, which describes for how long the effect will be evaluated in relation to how long it should last. In addition, the aspect of *'desirability'* differentiates between what effects are desirable and which are not. Here, monitoring desirable and non-desirable effects is crucial, as the latter can potentially jeopardise individuals' health. For instance, below, P5 describes the importance of investigating the non-desired effect of technology reliance within the family and how the expected duration can have implications for removing the intervention: *"I wouldn't want to create an intervention that stimulates reliance on technology for a child to become active. So, it's reassurance, that's what they're hoping for. And then hopefully when the parent is reassured and confident, yes, my child can play outside and look, he's happy. You know it goes well. That that is enough for the parents like, this goes well for a couple of weeks, I think he's doing fine and then you can also remove the device."*

Finally, the aspect of *'logical relations'* describes the kind of a priori hypothesised rationale that can exist between effects, or effects, interventions, and factors. They can be distinguished into three categories. (1) Causal relations describe the cause-and-effect association, usually between an intervention and a desired change or between effects (e.g., PA is associated with better cardiovascular health). (2) Hierarchical relations give insight into the primary and secondary effects as envisaged in the study design. Lastly, (3) influential relations describe factors that can impact the health effect positively or negatively. For example, P4 describes environmental factors as negatively affecting physical health: *"if there's a high pollen count in the air, we have much more asthma cases. If air pollution is high, we have more asthma cases. So, in the ideal situation, you would collect this data as well."*

4.2. Theme two – Meaning

A conceptualisation of *meaning* involves defining the health outcome subject to be assessed for effectiveness and breaking it down into smaller observable concrete units for examination in the real world. This definition happens at three levels that build upon each other: outcome, measure, and data definition. Collectively, these levels represent the evidence of the effect that will be generated.

At the top level, *'outcome definition'* involves defining the overarching health subject(s) that will be assessed for effect. Once these subjects are defined, in the middle level *'measure definition'*, each subject is broken down into more specific meaning units to facilitate the qualification or quantification of the effect. To illustrate both levels, below, P4 explains different outcome subjects related to respiratory health and how, in this case, asthma control is further broken down into more specific meaning units: *"If you look at outcomes that we are measuring it's lung function, which is of course not a patient reported outcome. It's exacerbations of disease, so asthma attacks, but also exacerbation of infections in patients with cystic fibrosis or admissions, it's readmissions to hospital or ER visits because of their disease, that's a really important outcome. It's asthma control, which is sort of a container idea. Asthma control means symptom control. If you do have nocturnal symptoms, if you use your rescue medication a lot, if you are able to do your daily activities."*

Lastly, at the bottom level, *'data definition'* involves defining the kinds of data that will make the unit observable in the real world. For example, in the quote below, P1 describes that physical activity is quantified as the aggregation of minutes per day in a specific data range: *"a common way to express physical activity is the mean minutes per day you are in moderate-to-vigorous physical activity, that's like your physical activity*." Here, it is important to note that the definition of data ranges can sometimes be standardised, as in the quote above. Yet, sometimes, data ranges can be adjusted to the patient's characteristics, as explained by P1: *"Also the medical team also sets the boundaries. So, the doctor can say it is safe for you to exercise with heart rates below 160, but above it's dangerous for you."*

4.3. Theme three – Collection

A conceptualisation of *collection* describes aspects considered in the generation of the data that will act as evidence for the envisioned effect(s). These aspects are: contributor, subjectivity, mechanism, temporality, and context. Together, they inform data collection characteristics accounted for in eHealth.

In conceptualising collection, a primary aspect is the *'contributor'* participating in data collection (e.g., answering a questionnaire or wearing a device). Here, the contributor's characteristics (e.g., age) influence the type of tests or questionnaires available for assessment. Ideally, the aspects of contributor

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and target individual will be the same person. Yet, sometimes, questionnaires assess perceptions of the effect from complementary views (e.g., parental view). Additionally, the aspect of *'subjectivity'* indicates the contributor's involvement with the data it generates. Objective collection describes quantifiable values or perceptions of subjective experiences (e.g., minutes in moderate-to-vigorous PA, questionnaire results), whereas subjective collection captures descriptive qualitative accounts of individual experiences (e.g., online diary). For instance, in P2's quote below, the child is the contributor, and the child's participation in the collection could oscillate between a more objective or subjective involvement: *"It's not like we ask the child to grade their participation or if they think they're normal enough or not in a quantitative way [...] Of course, qualitatively, we do see how they participate. So how often do they do this? Which sports? Which sports are they doing?"*

Other aspects of the conceptualisation of collection include the mechanism, temporality, and context. *'Mechanism'* describes the means (e.g., tools, instruments) used to collect the data. These can range from individual consults, online diaries, or questionnaires to physical tests, medical scans, or (non)wearable devices. Closely related is the *'temporality'* aspect, which refers to the timing and frequency of the collection. Here, timing indicates the moment when the collection happens, and frequency indicates how often the collection happens (e.g., every minute, every day). Lastly, the aspect of *'context'* indicates the conditions where the collection takes place (e.g., play). Ideally, the aspects of context and environment will be the same. Yet, sometimes the collection context will be in a hospital, while the effect's environment will be in the everyday life of patients. To illustrate these aspects, in P5's quote below, we see how the moment of exercise (i.e., timing) can be accessed virtually by a device (i.e., mechanism) in the context of parents' everyday lives: *"if the child is in exercise and the parent is there and the parent has some sort of monitoring this device as well. So, it's not only on the child, but maybe the parent has like a small laptop or iPad or laptop or whatsoever, that as a researcher, we also take time to virtually stand next to the parent and ask them, OK, how are you feeling? How are you interpreting the [monitoring] information?"*

5. Discussion and conclusion

This study identified three conceptual dimensions concerning evidence generation about health outcomes in response to conceptual ambiguity on how one goes from health outcomes to concrete evidence generation in eHealth. The conceptual dimensions are *effect*, *meaning*, and *collection*. Each describes aspects HCPs consider to define health outcomes' evidence generation. However, it remains unclear how designers can incorporate HCPs' evidence conceptualisation into their competencies to support the generation of evidence about effectiveness during eHealth design. Therefore, we elaborate on how the dimensions can enhance the five design competencies outlined by Voûte et al. (2020), as these competencies enable designers to manage the socio-technical complexity in the design process. Additionally, we highlight design-related frameworks accounting for health outcomes from architecture (Hamilton, 2018) and human factors and ergonomics (Carayon et al., 2020) that offer guidance in integrating the dimensions with the competencies into the eHealth design process.

The first competence outlined by Voûte et al. (2020) is *'framing and reframing the design challenge in its emerging future context'*. This competence can benefit from specifying the manifestation of the *effect* during the (re)framing activity to identify what the evidence will support once generated. Designers should clarify with HCPs (1) who the target individual is and (2) what the current health baseline is to measure the degree of change. In addition, designers should specify the environment(s) where the manifestation should be observed within the emerging context and anticipate possible (non)desired health effects with HCPs to include a patient safety perspective. Finally, designers should identify and record the socio-technical factors that (might) influence the challenge to clarify possible logical relations during reframing and understand which factors ultimately influence the effect observed.

The second competence is *'creating and evaluating iteratively to converge towards a desired impact'*. This competence can be enhanced by detailing *effect* and *meaning*. Given the iterative exploration where a creative output (i.e., eHealth system) aims at a desired impact, designers should clarify the logical (causal) thread throughout iterations that explains what was learned. This learning involves a reflection by the designer on the intended cause-and-effect relationship between the eHealth system and its current (health) effect and future exploration directions. This reflection will clarify and systematically build up

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the rationale embedded in the system that regulatory bodies will demand in the certification process (Morales Ornelas et al., 2023). Once iterations converge into a reduced solution space, it would be easier to formulate a precise cause-and-effect relation for evaluation in a controlled setting. Additionally, given the interest in a desired impact (i.e., improve health), it is—fundamental—that designers specify the subject of that impact and deconstruct it into observable meaning units. This means defining with HCPs the measures and data that will indicate the current impact of the implemented eHealth system.

The third competence is *'integrating an increasing amount of relevant perspectives into a working whole'.* This competence can benefit from recognising that 'integrating' the desirability, feasibility, and viability perspectives outlined by the authors should also consider the effectiveness perspective of the 'working whole'. Designers should commit to investigating the *effect* of their output for longer (Jones, 2013) by envisioning an evaluation time frame with HCPs that allows observation of (non)desired health effects. In addition, designers should envision with HCPs a proper effect duration, as it has implications for the eHealth system removal, a limitation already highlighted in eHealth design (van Velsen, Ludden and Grünloh, 2022). Finally, designers can embed data *collection* mechanisms in eHealth systems to support evidence generation about its effectiveness in future evaluation phases. In this way, designers will be able to motivate how (in addition to a desirable, feasible, and viable system) the ultimate effect of the eHealth system is also considered during the creation of the system to track its performance.

The fourth competence is *'meaningfully steering the design and stakeholder process'.* This competence highlights the relevance of considering our conceptual dimensions in the design process because they unravel the evidence that HCPs ultimately need. Designers can benefit from conducting participatory processes where HCPs and other relevant stakeholders like patients and their loved ones are involved in conceptualising the *effect*, *meaning*, and *collection* of evidence. This means involving stakeholders in framing the effect manifestation by considering all its aspects (e.g., target individual, change degree, desirability). It also means facilitating stakeholders' (joint) involvement to identify health subjects, measures, and data that meaningfully inform the qualification or quantification of their health experience. Finally, in terms of collection, it means identifying with stakeholders mechanisms to generate the necessary data and a temporality that accounts for the progression of the effect achieved.

Lastly, the fifth competence is *'working and communicating at varying and multiple levels of abstraction, and across disciplinary perspectives'.* This competence can benefit from bringing together all the conceptual dimensions in designerly ways to elucidate and understand the intricate abstract connections between them. This means visualising, modelling, or prototyping the envisioned manifestation of the *effect*, together with the observable *meaning* units defined in the context where they will be *collected*. Doing so can create boundary knowledge spaces (Carlile, 2002) where HCPs and designers comprehend what effects are aimed for when and where, as well as how these are being observed. These spaces will be useful to identify inconsistencies in measurement (e.g., envisioning an effect manifestation in a specific environment but not defining measures for it) and, thus, improvement opportunities for the design of the eHealth system or the evaluation setting.

Given our suggestions above, we highlight two frameworks that can shed light on (part of) their realisation in the eHealth design process. First, from architecture, evidence-based design (EBD) entails defining goals, using research questions to help gather relevant information, and critically interpreting it to create concepts. Then, it involves defining corresponding hypotheses that can be tested to demonstrate a measurable change in health outcomes (The Center for Health Design, 2023). This process framework can support the second competence and the need for rationale clarification, as it promotes design intent documentation in the form of a design hypothesis before concept evaluation (Hamilton, 2017). This hypothesis acts as a predictive assumption stating the relationship between a design concept and a desired outcome, where outcome clarification allows the selection of measures to evaluate the concept's effect (Hamilton, 2018). Using this framework in the conceptualisation phase of eHealth systems can clarify the causal logical thread throughout iterations.

The second framework, Systems Engineering Initiative for Patient Safety (SEIPS), comes from human factors and ergonomics. This analytical framework offers insight into how systems affect health-related outcomes (Carayon et al., 2020). As such, SEIPS can support the first competence by facilitating a structured way of clarifying the people, environment, tools, and tasks in the problem-solution framing activity of eHealth design. Regarding the second competence, the 'outcome matrix' (Holden and

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Carayon, 2021) can be a helpful tool to document outcomes for eHealth evaluation, considering characteristics such as their desirability, priority, and potential measures. Lastly, we see the complementary approach to SEIPS from Landa-Avila and colleagues (2022) as useful for the fourth competence. This approach can facilitate participatory activities where outcome subjects are defined with stakeholders at eHealth design's research and evaluation phases.

Finally, future research is needed to support designers in improving their third and fifth competencies. Future investigations to support the third competence should facilitate processes to ideate strategies and mechanisms for data collection to be embedded in eHealth systems. These should incorporate different data and various durations to assess effectiveness holistically. Lastly, to support the fifth competence, future research should create design tools that enable shared knowledge spaces between designers and HCPs to incorporate the three dimensions into the eHealth design process.

A limitation of this work concerns the focus on one type of eHealth application (i.e., remote patient monitoring systems). The study of this application enabled us to broadly explore the contextualisation of evidence generation, given the deployment nature of this kind of system in multiple contexts. However, more research is needed to corroborate the usefulness and generalisability of our findings to other eHealth applications. Nevertheless, we encourage the research community to investigate how to support designers in incorporating these conceptual dimensions into their process to advance the impact of designerly ways of knowing on the health and care of individuals.

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