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EXPLORING HEALTH AND DESIGN EVIDENCE PRACTICES IN EHEALTH SYSTEMS' DEVELOPMENT

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ABSTRACT

Evidence-based practices play an essential role in the development of eHealth systems. Prior research has investigated the challenge of shared understanding between professionals from the fields of health sciences and design and has highlighted the need for effective alignment of development and research practices in eHealth. However, there is a limited understanding of epistemological differences between these fields and how professionals conceptualise evidence. In this paper, we investigate how healthcare and design professionals think about evidence and how they implement evidence practices in their work. We interviewed eight professionals and used reflexive thematic analysis to identify the challenges and strategies associated with their evidence practices. Our results identify five shared evidence practices between healthcare and design professionals: stakeholder-driven, process-driven, problem-driven, effect-driven, and solution-driven. These five evidence practices indicate opportunities for closer alignment of development and research practices among healthcare and design professionals and offer a basis to create a shared understanding of evidence between both fields.

Keywords: Evidence-based practice, Design practice, Collaborative design, Design methodology, Design theory

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1 INTRODUCTION

eHealth systems are increasingly being developed to reduce healthcare professionals' administrative tasks or to supervise patients' health conditions in and out of hospital settings using information and communication technologies (WHO, 2016). Within their development, evidence-based practices play a vital role in ensuring healthcare quality. However, the current evidence-based health paradigm fails to meet the needs and values of users during eHealth development (Smits et al., 2022).

Design offers an approach to include users' needs and values in eHealth development, yet health sciences and design face the challenge of a shared understanding of their development practices. Pagliari (2007) and Blandford et al. (2018) have investigated differences in development lifecycles and research methodologies between these fields to foster a shared understanding. Now, the challenge lies in creating a shared understanding of evidence between both fields (Komashie and Clarkson, 2022).

Evidence in system development processes is described as 'objective evidence' and defined as *"data supporting the existence or verity of something"* generated through observations, measurements, or tests (ISO, 2015). Thus, a challenge in shared understanding of evidence suggests a misalignment of evidence practices among fields. By evidence practices, we mean the activities (e.g., tests) that professionals from each field employ to generate and use evidence as part of their development process. However, the literature does not explain the underlying epistemological differences in evidence practices among health sciences and design and how evidence is conceptualised despite these differences in eHealth.

The absence of a clear understanding of evidence practices hampers eHealth systems development, as this brings uncertainty about *what* evidence is needed and *how* to generate it through the process (Lamé, 2018). Hence, it is essential to understand evidence practices in both fields since it could shed light on unexplored perspectives for evidence generation and ultimately lead to an evidence-based well-being paradigm in eHealth (Smits et al., 2022). This paper aims to dive deep into the epistemology behind health and design evidence practices and their implementation. The research question of this paper is: *how do healthcare and design professionals conduct evidence practices in eHealth development?* Accordingly, we interviewed healthcare and design professionals experienced in eHealth development to understand their practices and used reflexive thematic analysis to identify their implementation.

The paper is structured as follows. First, we explore epistemologies about evidence generation and use in both fields. Next, we explain our study's qualitative methodological approach. Then, we describe the resulting five evidence practices: stakeholder-driven, process-driven, problem-driven, effect-driven, and solution-driven, as well as the challenges and strategies associated with each practice. Finally, we discuss the relationship of the practices with existing theory and its implications for fostering a shared understanding of evidence between health sciences and design in eHealth development.

2 EVIDENCE IN HEALTH AND DESIGN

2.1 Evidence generation in health

One of the earliest areas of health sciences in giving 'evidence' an established role in practice was medicine with the surge of evidence-based medicine to improve decision-making using scientific evidence in clinical practice (Sackett et al., 1996). Since then, evidence-based practice has been prominent in other areas, including eHealth. Evidence-based eHealth requires that, in addition to expert knowledge, the people responsible for developing and implementing eHealth systems use evidence from rigorous studies on what makes these clinically acceptable, safe, and effective (Wyatt, 2016).

Epistemology in health evidence-based practices has foundations in a logical-positivism view of knowledge (Djulbegovic et al., 2009). Paramount to this epistemology is that what is reasonable or justifiable to believe depends on the trustworthiness of the evidence and the degree to which one believes that a credible process determines this evidence (Djulbegovic and Guyatt, 2017). Accordingly, in eHealth, 'evidence' is regarded as results from scientific research and evaluation, existing scientific literature, and professional experience (Jurkeviciute and Eriksson, 2020). This 'evidence' can refer to multiple aspects of the eHealth system, such as technical, human, societal, clinical, economical, organisational, transferability, ethical, and legal (Enam et al., 2018).

In addition, evidence generation processes follow scientific standards and are ranked according to a hierarchy evaluating the quality of the evidence produced–i.e., evidence with the lowest probability of bias and the capability to predict and establish the effect of interventions (Wyatt, 2016). Thus, this hierarchy rates systematic reviews and randomised controlled trials at the highest level and expert

opinions and untested theories at the lowest. Finally, evidence is used in decision-making during eHealth development, scientific publishing, funding proposals, and teaching (Jurkeviciute and Eriksson, 2020).

2.2 Evidence generation in design

Conversely, the role of 'evidence' is not explicit in design literature when describing design practice. It is only described in the built environment literature as evidence-based healthcare design following health evidence-based practice. Nonetheless, designers do generate and use evidence as part of their knowledge-generation process in product development. Knowledge generation follows a 'designerly' approach guided by the epistemic interest in reaching appropriateness and is concerned with inventing things of value that do not exist yet (Cross, 1982). Accordingly, design literature describes two paradigms for design activity: as an analytical problem-solving process and as a reflective practice.

On the one hand, the view of *design as an analytical problem-solving process* based on technical rationality is characterised by being goal-directed and following rational logic to go from a present to a desired situation (Simon, 1988). Here, the design process is seen from a logical-positivism stance as an *information-processing search process* where the problem space is stable (Dorst and Dijkhuis, 1995). Simon (1988) proposes an afferent and efferent world while designing. In the afferent world related to the senses, the designer needs to represent a (problematic) present situation, the desired situation, and the differences between both. In the efferent world related to actions, the designer needs to *search* for and represent actions that modify the present situation and remove the differences between both situations. To know if the actions taken are achieving the removal of differences, the designer needs to *produce* information about the initial state of the afferent world and its changes and *record* this information to enable comparison between situations. In this way, the designer tries to reach a sufficient set of actions–i.e., satisfactory design outcome, that achieves the desired situation–i.e., design goal.

On the other hand, the view of *design as a process of reflection-in-action* based on constructivism states that designers have a *reflective learning process* through 'seeing-moving-seeing' to reveal and construct meaning (Schön, 1992). Schön (1992) proposes reflection-in-action, where designers understand and make normative judgements of quality about the design situation: the designer *observes* what is wrong and needs to be fixed or what is good and needs to be maintained or developed. Then the designer forms an intention, leading to a *move* that generates a change, and *observes* again to detect the intended and unintended consequences of the move, thereby informing future moves. In this way, designers construct the problem, evaluate their actions to structure and solve it (Dorst and Dijkhuis, 1995), and form design intentions that evolve iteratively. Such iterations enable designers to manage complexity by recognising more in the move's consequences than in their prediction (Schön, 1992).

Based on both paradigms of design activity, 'evidence' is regarded as results from user research and evaluation activities with end-users, relevant literature, and official reports (Muratovski, 2021). In addition, this 'evidence' can refer to user needs and requirements, qualities of the product such as usability or the value perceived by the user (Melles et al., 2021), and the overall product's desirability, business viability, and technical feasibility (Brown, 2008). Finally, evidence is used in decision-making to evaluate design quality based on requirements and objectives (Dong et al., 2016).

Nowadays, healthcare and design professionals work together in eHealth. The complexity arising from the interrelation of the multiple aspects to generate evidence about eHealth systems (e.g., clinical outcomes, usability) calls for a constructivist approach to their development. However, due to its exploratory nature, this approach presents shortcomings for required procedures (e.g., medical ethical approval) in clinical development (Noortman et al., 2022); hence, this approach needs adjustment. Yet, an entirely logical-positivism approach to evidence generation will not satisfy either due to eHealth complexity and the difficulty this represents to formulate and test predictions about the system's intended (and unintended) effects in the real world. In practice, professionals from both fields cope with these epistemological differences, but the literature does not explain *how* they perform this practice in eHealth development. Hence, this paper will investigate their evidence practices through an empirical study.

3   METHODOLOGY

This study aims to clarify how healthcare and design professionals cope with epistemological evidence differences in eHealth. Our study is grounded in the qualitative tradition, with a relativism ontology orientation and a constructionism epistemology view (Braun and Clarke, 2013). Our theoretical grounding allows us to explore and produce, rather than discover, the 'truths' of both fields–health and

design. Accordingly, we use an experiential approach via interviews since we want to understand the multiple accounts of evidence practice from healthcare and design professionals. Our research question is: *how do healthcare and design professionals conduct evidence practices in eHealth development?*

3.1 Sampling and data collection

We recruited healthcare and design professionals from previous eHealth projects via email and selected participants with at least four years of experience in eHealth development. Their expertise in eHealth development and implementation included diverse digital health apps, systems, devices to collect health data remotely, and strategic visions for digital hospitals. We conducted eight semi-structured online interviews with a cohort of four healthcare professionals (HP) and four design professionals (DP) between January and May 2021. DP had an academic background in design (e.g., strategic, product, interaction) and an MSc degree. While HP had a biomedical, medical, or human movement science background and had or were pursuing a PhD (see Table 1). All were based in the Netherlands.

Our interview procedure included two steps. First, we asked participants to introduce themselves, and then we briefly presented the evidence differences found in our literature review to explain the research context and to have a starting point for reflection on their practices. Second, we asked open-ended questions about how they managed the generation and use of evidence in recent eHealth projects and follow-up questions about activities or evidence they mentioned. The interviews lasted between 40 to 70 minutes and were audio-recorded for qualitative analysis with the participants' consent.

Table 1. Participants' background details.

Participant	Cohort	Job title (years of experience)	Institution affiliation
HP1	Healthcare professional	Assistant professor (5)	Technical university
HP2	Healthcare professional	Professor (21)	University hospital
HP3	Healthcare professional	PhD candidate (5)	University hospital
HP4	Healthcare professional	PhD candidate (4)	University hospital
DP1	Design professional	Strategic designer (7)	Design consultancy
DP2	Design professional	Data-design specialist (6)	Multinational company
DP3	Design professional	UX and Service designer (4)	Design consultancy
DP4	Design professional	Founder and CEO (4)	Start-up company

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

3.2 Data analysis

We transcribed all the interviews verbatim, de-identified names, and proceeded to analysis with Reflexive Thematic Analysis–RTA (Braun and Clarke, 2013) in Microsoft Excel. We adopted RTA to identify patterns of shared meaning in the practice accounts described by participants. Within RTA, we used an inductive data approach and interpreted the data with a latent strategy to explore meaning at the underlying level. Below, we describe our analytic process based on the six RTA steps.

The first step involved familiarising ourselves with all the transcriptions by reading them multiple times. In the second step, we coded the transcripts in relation to our research question to identify patterns and themes in the data. For instance, we coded the following sentence 'Running alignment workshops': *"where even from the kick-off for the alignment, we involve all the stakeholders, we run workshops, 1,2,3 workshops, making sure all the stakeholders are involved."* For the third step, we grouped our codes to generate initial sub-themes. For example, the codes 'Running alignment workshops', 'Bringing stakeholders together through co-creation', and 'Conducting ideation sessions with stakeholders' created the sub-theme 'Facilitating stakeholders' participation'. The fourth step consisted of reviewing and gathering sub-themes into themes. For instance, the sub-themes 'Find stakeholder's evidence needs', 'Navigate complex stakeholder spaces', 'Identifying who values what evidence', 'Facilitating stakeholders' participation', 'Fostering project ownership', and 'Creating tailored arguments' were gathered under the theme 'Stakeholder-driven evidence practice' due to their fixation with stakeholder influences. Then, in the fifth step, we continued the process by defining each theme and refining it. For example, we went back to the transcripts to observe how the sub-themes within 'Stakeholder-driven evidence practice' related or not to each other. This step helped us to identify challenges and strategies within themes. Finally, in the sixth step, we wrote the five final practice themes and related sub-themes.

4 RESULTS

As a result of our qualitative analysis, we identified five shared themes of evidence practices among healthcare and design professionals: stakeholder-driven, process-driven, problem-driven, effect-driven, and solution-driven (see Table 2). A different factor drives each practice (e.g., stakeholder, process) and highlights the perspective from which one can act with regard to 'evidence' throughout the development of eHealth systems. Within each practice, we identified the challenges that participants face and the strategies they use to overcome these. Below, we present each practice by introducing its description and evidence conceptualisation, the participants involved, and the challenges and strategies identified.

Table 2. Overview of shared evidence practice themes.

Evidence practice (participants)	Description	Challenge sub-themes	Strategy sub-themes
Stakeholder-driven (HP2, HP3, HP4, DP1, DP2, DP3, DP4)	Describes how stakeholders' evidence needs (e.g., evidence topic or type, study design) and a persuasive intention influence what evidence is and its generation.	- Find stakeholder's evidence needs - Navigate complex stakeholder spaces	- Identifying who values what evidence - Facilitating stakeholders' participation - Fostering project ownership - Creating tailored arguments
Process-driven (HP3, HP4, DP2, DP3, DP4)	Describes how the type of process (e.g., CE certification) and process phase influence the evidence requirements and its generation.	- Manage the process's evidence requirements - Address incoming people to the process	- Choosing methods based on process phase - Tracing decision-making during process - Mapping who is relevant based on process phase
Problem-driven (HP2, HP3, DP3)	Describes how the reasons giving rise to a problem (e.g., user needs and concerns) influence what evidence is and its rationale.	- Get the right problem-solution picture	- Establishing evidence rationale from people's needs - Finding people's real problems - Defining what success means with people
Effect-driven (HP1, HP2, HP3, HP4, DP1, DP2, DP4)	Describes how the desired effect (e.g., clinical outcome) influences what evidence is and its generation.	- Clarify effectiveness in eHealth - Manage effectiveness uncertainty	- Specifying upfront what evidence is - Managing effect assumptions early on - Scaling-up evidence generation
Solution-driven (HP2, HP4, DP1, DP3)	Describes how the aspects of the solution being developed (e.g., usability) influence what evidence is and its generation.	- Manage eHealth system's complexity - Handle multiple handover points in product development	- Splitting evidence generation into solution aspects - Building evidence as a documentation process

4.1 Stakeholder-driven evidence practice

Stakeholder-driven evidence practice describes how stakeholders' evidence needs (e.g., evidence topic or type, study design) and a persuasive intention influence what evidence is and its generation. Evidence is conceptualised as results from (scientific or user) research, evaluation, and participatory activities with stakeholders that support a statement about what is valuable to them–e.g., a sketch from an ideation session explaining the eHealth system's vision. This practice is shared by three healthcare professionals (HP2, HP3, HP4) and all design professionals (DP1, DP2, DP3, DP4). Participants expressed that during the development of eHealth systems, it is challenging to navigate complex stakeholder spaces where diverse stakeholders' needs must be managed to ensure the products' successful implementation.

Stakeholders have different evidence needs to judge for themselves if the solution is successful. They explained that these needs could be regarding specific topics such as costs or value for the user, but also about scientific evidence or other evidence types, as illustrated by DP4: *"The insurance companies, they need very heavy, heavy evidence, scientific evidence. So, what does the key opinion leaders need? the physicians need? Do the hospitals need to learn? So, everybody has a different kind of evidence need."*

In addition, participants described strategies such as facilitating stakeholders' involvement with participatory activities to understand who values and needs what evidence. For example, alignment workshops can help to bring an initial shared understanding. Then, inviting them to join research and evaluation activities can help to increase the project's transparency, and co-creation and ideation sessions can help to understand their concerns, needs, and past failures. This stakeholder knowledge could help to craft a compelling story by (1) capturing the significant evidence for each stakeholder per phase and (2) using storytelling to explain the overall argument of the eHealth system. However, participants mentioned that evidence and arguments sometimes are not enough, and to implement a product successfully, stakeholders need to believe in and own the project throughout the process. They mention that participatory activities such as co-creation could help to create a shared belief and reflect on the overall project rationale could help stakeholders advocate for the project. For instance, DP1 describes that although evidence is subjective at the early stages of development, creating a shared understanding and belief among stakeholders through participatory activities helps to make subjectivity more tangible and actionable: *"Well, I think in that process, evidence tends to be a bit of a fluffy thing right? Because it's mostly quite subjective what people think the future is going to look like. It really depends on, you know, their own needs, but also the concerns and worries that they have for the future. So, in that phase evidence for us meant, you know, gathering all these perspectives and make them as tangible as possible for people. Which means, which is not so much about evidence, but more about creating a shared vision. So, involving a lot of people, throughout the process."*

4.2 Process-driven evidence practice

Process-driven evidence practice describes how the type of process (e.g., CE certification) and its phases influence the evidence requirements and its generation. Evidence is conceptualised as documentation that supports a statement about the rationale behind the solution's development in terms of processes, results, and decisions–e.g., a report describing the development process of the eHealth system. This practice is shared by two healthcare professionals (HP3, HP4) and three design professionals (DP2, DP3, DP4). Participants shared that managing evidence requirements across the development process is challenging due to the various product certifications and corresponding requirements. They explained that the process dictates the different product phases, thereby indicating evidence needed, methods, and stakeholders to be addressed per phase. For example, HP3 explains that the process behind bringing a product to the market will influence its evaluation: *"If you talk about having validity and really putting it on the market, then I do think there's a lot of ask for having that more quantitative assessment."*

Additionally, participants expressed that strategies such as mapping stakeholders' relevance or the recommended methodologies for evidence generation per process phase can provide guidance and that decision-making about evidence generation should be traceable through the process. For example, DP3 explains how the CE certification process demands a chain of evidence starting at the early development stages, where problem and intentions are defined: *"Look into the CE certification process for healthcare products. And if you go through the process to build your product to market, and look at the kind of documentation you have to do, or the evidence you have to show, it starts linking back to your first phase of the design. It's where's this problem coming from? What research was done? What target group was addressed? What were the outcomes of that research? How did it build to the design, and then design research. So, your evidence-based design is really that process of backtracking and ensuring not just stakeholder wise, but also certification wise that at least what's coming out is what it was intended."*

4.3 Problem-driven evidence practice

Problem-driven evidence practice describes how the reasons giving rise to a problem (e.g., user needs and concerns) influence what evidence is and its rationale. Evidence is conceptualised as results from (scientific or user) research and participatory activities that support a statement about the link between the problem and the meaning of success–e.g., a quote from an interview explaining why a specific need is relevant for that user. This practice is shared by two healthcare professionals (HP2, HP3) and one design professional (DP3). Participants mentioned that finding the fundamental problems of people and a

solution is challenging, and not clarifying the need for this search upfront can be confusing for others unfamiliar with design practice where the problem space needs exploration. For example, HP3 shares the confusion of working with designers, as they did not understand why designers would not just start working on solutions to the given problem and instead had to search for the problem: *"I noticed that also with colleagues that they said, it's okay, but we have a clear problem, and you want a solution. So, designers go ahead. But then as a designer, you sort of, indeed you redefine that whole problem space."*

In addition, participants shared that evidence finds its meaning when it is connected to the problematic situation aimed to be solved–i.e., people's needs and pain points, and advised establishing an evidence rationale starting from people's needs as a first strategy. Also, they shared that another strategy when creating an eHealth system should be finding people's real problems and unambiguously describing them, as this could help identify future steps within the development and iteratively define the meaning of success with the people experiencing the problem. For example, HP2 shares that analysing the problem from multiple perspectives is essential to define the solution's success later: *"Such process needs to start from a very rigorous analysis of the problem to be solved. And for that, only that aspect alone, it will determine half of the success. Because if you have not really clearly and unequivocally described the problem, you will never know whether you have succeeded. Because what is the, you never know, it's a yes or a no, if it is that vague. It will help you focus on the true, on a true problem. And not something that resembles it or looks like it, no. And also, by doing so, you come to learn the, say the surroundings of the problem, the connotation, the context of the problem, both from your perspective, but as well, from the healthcare professional's perspective, or the patient's perspective, much better."*

4.4 Effect-driven evidence practice

Effect-driven evidence practice describes how the desired effect (e.g., clinical outcome) influences what evidence is and its generation. Evidence is conceptualised as results from (scientific or user) research and evaluation that support (or do not) a statement about the degree to which the effect is being achieved–e.g., data collected using an eHealth system that shows the time a user is physically active. This practice is shared by all healthcare professionals (HP1, HP2, HP3, HP4) and three design professionals (DP1, DP2, DP4). Participants described that evidence of eHealth effectiveness is contested. HP3 explains that one reason is the unclarity of the main eHealth objective guiding evidence generation: *"When do you call that evidence-based eHealth? And, that also has to do with the whole objective of eHealth. Is it indeed that you expect large improvement in quality of life? Or is it sufficient that somebody feels that he is able to self-manage his or her disease more effectively?"*

Another challenge explained by participants was the management of effectiveness uncertainty. They shared that a common request before any test with users in healthcare is high certainty that the product is effective, yet it is difficult to meet in the early development phases. One reason, as explained by DP2, is that design is a process based on assumptions and, thus, not 100% certain: *"You cannot, I think, completely hammer down upfront, which ideas are worth to take the leap of faith and you also cannot prove upfront which of these will be a success to the full extent. You can make it a better guess, but it will always be a guess. And that's also due to the part that design is a process based on assumptions."*

Participants expressed that a strategy to deal with effectiveness unclarity is to specify upfront 'why' evidence is needed and then define 'what' evidence could satisfy that need. Then, multidisciplinary teams could establish desired outcomes, endpoints, and suitable methods to generate this evidence, as establishing evidence upfront makes the process and outcomes more transparent to others. For instance, HP4 describes how they teamed up to look at risk management in app development, evaluated the need for evidence in relation to the effect, and then decided on suitable methods: *"An app, which has quite some risks, or which can really affect someone's health. There, it should contain solid evidence, which really builds on the clinical effectiveness in which supports hypotheses, and which shows that it's actually good and does not harm someone's health. But for apps just helping reaching 10,000 steps, for instance, well, you don't need this kind of heavy clinical evidence, you don't need a very heavy investigation. So, we help them establishing kind of risk classification. And then we think with them, what kind of mainly used methodologies can be used to establish evidence on this part."*

Another strategy shared by participants to deal with effectiveness uncertainty was using scientific literature to manage assumptions about effectiveness at early development stages. They highlighted that literature could be used to uncover assumptions that later could become hypotheses to be tested in conceptual development. For example, HP1 shares that establishing a working principle supported by scientific literature can guide decision-making: *"You can get a lot of your assumptions answered,*

based on previous literature based on previous models that we know that if you improve a specific part of well, your autonomy, for instance, or a specific part of your external motivation, then that can result into, well, a change in behaviour, for instance. And if you already use like these kind of models for your concept phase, for your design decisions, I think it makes it already a bit stronger."

The last strategy shared by participants to deal with uncertainty is to scale-up evidence generation by starting with a small-scale test of the assumption(s) related to effectiveness. By small scale, participants meant conducting a test with low-fidelity prototypes and a small group of people–not necessarily from the patient group but in the envisioned context of use. They explained that small iterative tests with different time frames could indicate which prototype aspects work for the intended purpose. In addition, participants shared that product requirements could establish a quality management system to evaluate the prototype before clinical testing. However, this iterative approach might not be familiar to healthcare professionals, and thus discussing its benefits might help to persuade them, as explained by DP1: *"Is me saying to doctors, so, if I would do it your way, which is probably you know, academically the best way to get the best evidence, the problem is, that is going to cost a lot of money and it's going to take me years […] So, the alternative is, or you wait two years for me to be finished, or we start doing it with the people we can get. And we learn along the way. And we keep making sure that in the end, you know, when you launch the thing, you will have enough evidence to be certain that you should launch it."*

4.5 Solution-driven evidence practice

Solution-driven evidence practice describes how the aspects of the solution being developed (e.g., technical functionality, usability) influence what evidence is and its generation. Evidence is conceptualised as results from (scientific or user) research and evaluation that support (or do not) a statement about the solution's requirements being fulfilled–e.g., results from a usability test showing the user's problems when using the eHealth system. This practice is shared by two healthcare professionals (HP2, HP4) and two design professionals (DP1, DP3). Participants described that managing the multiple eHealth aspects that need to be developed complicates evidence generation because they are interrelated. In addition, they shared that one needs to handle the multiple handover points between the development departments to avoid misunderstandings. As an example, HP4 shares that besides finding the aspects to generate evidence for, one should also find the best method and setup: *"What aspects should we look at? And can we do so in one study? Should we do that within clinical studies? Or can we also do this in simulation processes? or just by well, exploring, for instance, whether the eHealth tool uses the law, and it, well, works according to the law, for instance."*

Additionally, participants explained that one strategy to deal with complexity was splitting evidence generation per solution aspects to focus on different studies and facilitate analysis. They mentioned that these aspects could be studied using qualitative and quantitative methods. Also, they expressed that building this evidence starts with jointly generating ideas and then synthesising them into sketches, prototypes or other forms to allow for evaluation, process documentation, and dissemination. As an example, HP4 explains that one should divide evidence generation into multiple studies with focused research questions to facilitate analysis at later stages: *"We evaluated usability by interviews, and we asked general practitioners, what do you think of the system? Do you like it? Is it easy to use the kind of stuff. So, I think that's through usability. And we don't really look at clinical effectiveness yet in that study, because it was more of a feasibility study. But in within that study, we also looked at the technical and legal aspects. […] And you shouldn't make a study too large, but you should really define as small as possible research questions because otherwise it gets extremely difficult to analyse the results."*

5 DISCUSSION AND CONCLUSION

This study identified five shared evidence practices through interviews with healthcare and design professionals working in eHealth development in response to epistemological evidence differences between health sciences and design. These evidence practices relate to design and engineering literature concepts and eHealth development approaches that could support part of their implementation.

A stakeholder-driven practice brings a systems perspective by addressing all audiences' evidence needs in the development process, as it emphasises the rhetorical dimension of design (Buchanan, 1985). This practice could be supported by the CeHRes Framework (van Gemert-Pijnen et al., 2011), which proposes a participatory development process for eHealth. However, developers should add explicit discussions about evidence with stakeholders to the steps stated. A process-driven practice relates to the 'Design

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Methods Movement' and its attempts to support the designer's intuition and imagination with prescriptive and systematic processes to develop solutions (Buchanan, 2009). Also, this practice relates to the efforts in engineering to create processes that ensure quality and safety through product certifications. In addition to the methods suggested per certification, the E-Health Methodology Guide (Bonten et al., 2020) offers methods per eHealth development phase to support this practice.

A problem-driven practice relates to the theory of co-evolution of problem-solution (Dorst and Cross, 2001), where there is a constant development and refining of a problem and solution ideas. However, it does not have frameworks to facilitate its practice in eHealth. Nonetheless, participants highlighted the essential role of getting the right problem-solution picture to develop effective eHealth systems. Tightly connected to this practice is an effect-driven practice that relates to validation, where one confirms if the requirements for the intended use are fulfilled (ISO, 2015). An effort to support this practice is the NICE Evidence Standards Framework (Unsworth et al., 2021), which advises the evidence of effectiveness that should be generated concerning the eHealth system's intended use. Finally, a solution-driven practice relates to verification, where one confirms if the specified requirements are fulfilled (ISO, 2015). The Digital Health Scorecard (Mathews et al., 2019) proposes a requirements-driven approach that can help to split evidence generation and manage complexity.

The outcomes presented in this paper extend the current understanding of evidence practice in two ways. First, our outcomes show that although epistemological differences in evidence exist between both fields, their evidence practices overlap within five views to act upon evidence generation in eHealth development. This overlap means that both fields recognise the same factors as influence variables for evidence generation (e.g., stakeholders, problem, effect) regardless of the development and research practices from each field, but their implementation across the process might differ during development. Hence, development teams should use these shared evidence practices as starting points to discuss *what evidence* conceptualisation the team is referring to and *how to generate* this evidence accordingly to foster a shared understanding of evidence between fields during development.

Second, our outcomes show that healthcare and design professionals employ more than one evidence practice, suggesting that the practices complement each other. For instance, at the start of a project, a stakeholder-driven practice could identify stakeholders' evidence needs to be embedded in the process, while later, the focus might shift to validation and therefore follow an effect-driven practice. Hence, this outcome indicates that *evidence has a relational role* that brings together stakeholders, process, problem, effect, and solution. Evidence is constructed for a purpose—i.e., the desired effect of a solution in a problematic situation; it does not just exist, and different stakeholders interpret this evidence across the development process. Thus, development teams should reflect on how the multiple evidence practices influence their process and implement more than one during eHealth development.

Despite interviewing professionals with diverse expertise in eHealth development, our study's sample size and specific context in the Netherlands may hinder the generalizability of our results to other eHealth development contexts. Nevertheless, the five evidence practices offer a basis to create a shared understanding of evidence between health sciences and design. We hope the challenges and strategies per practice help professionals identify problematic situations and provide guidance to solve them. While we acknowledge the emergence of approaches to support individual practices, we urge the research community to explore ways to assist development teams in implementing multiple evidence practices in eHealth development and maintain the discourse about evidence and its relational role alive.

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