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## Stepwise Design and Evaluation of a Values-Oriented Ambient Intelligence Healthcare Monitoring Platform



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## ABSTRACT

*Objectives*: The majority of all developed digital health technologies do not reach successful implementation. A discrepancy among technology design, the context of use, and user needs and values is identified as the main reason for this failure. Value-sensitive design (VSD) is a design method enabling to align design with user values by embedding values in technology, yet the method is lacking clear heuristics for practical application. To improve the successful design and implementation of digital health, we propose and evaluate a stepwise approach to VSD.

*Methods:* The approach consists of the phases: experiment, demonstrate, and validate. Experiment takes place in an office to create makeshift solutions. Demonstrate takes place in a mock-up environment and aims to optimize design requirements through user feedback. The validate phase takes place in an authentic care situation and studies how the novel technology affects current workflows.

*Results:* We applied the stepwise VSD approach to the design of a hospital-based ambient intelligence solution for remotely and continuously monitoring quality and safety of patient care. We particularly focused on embodiment of the values of safety, privacy, and inclusiveness in the design. Design activities of the experiment and demonstrate phase are discussed.

*Conclusions:* A stepwise approach to VSD enables a design to optimally meet the values of all users involved, while aligning the design process with the practical limitations of healthcare institutions. We discuss some benefits and challenges related to VSD and the potential for transfer of this approach to other digital health solutions.

Keywords: ambient intelligence, digital health, value-sensitive design.

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## Introduction

The application of digital health is expected to rise in the upcoming years.<sup>1</sup> The term "digital health" refers to "proper use of technology for improving the health and wellbeing of people at individual and population levels, as well as enhancing the care of patients through intelligent processing of clinical and genetic data."<sup>2</sup> The benefits of digital health are promising: it might improve efficiency and quality of care provision and reduce the workload of healthcare professionals.<sup>3</sup>

With these benefits, it is remarkable that more than half of all digital health technologies do not reach successful implementation.<sup>4</sup> The discrepancy among technology design, the context of use, and user needs and values is identified as the main reason for this failure.<sup>5</sup> Considering a values-based design approach to digital health would improve the fit between technology and user values. A well-known approach to design for values is value-sensitive design (VSD).<sup>6</sup> VSD defines values as everything that people consider important in life. The methodology consists of 3 phases of investigation: conceptual, empirical, and technical. User values are identified through literature search and stakeholder deliberation in the conceptual investigation. These values are evaluated and translated into design requirements through empirical research in the empirical investigation. Similar technologies are studied to comprehend how the identified values can be embodied in the novel technology in the technical investigation.<sup>7</sup>

Although VSD provides an interesting perspective to technology design, no clarity exists on how to apply VSD into practice<sup>8</sup> and especially not into the practice of healthcare. For example, VSD does not guide the desired order of phases. In addition, the involvement of users in identifying and evaluating values remains unclear. Further, the process of translating values into an actual digital health design is subject to several questions.<sup>9,10</sup> In this article, we aim to understand and facilitate the practical use of VSD in digital health, for which we will apply and evaluate VSD via the design of an ambient intelligence hospital solution.

Ambient intelligence refers to the use of contactless sensors in an environment for analyzing this environment using artificial intelligence (AI).<sup>11</sup> Ambient intelligence is increasingly applied in healthcare to inform decision-making. Application domains

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ltem	Experiment	Demonstrate	Validate
Who	Multidisciplinary development team, involve main users	Involve healthy volunteers	Involve patients and healthcare providers
What	Stakeholder and value identification and specification	Value experiences	Value validation
Where	Office/laboratory	Simulated care environment	Authentic care situation
Technology	Makeshift solutions	Prototype for demonstration	Functional technology

#### Table 1. Stepwise values-based design approach to digital health.

include, among others, mobility monitoring to prevent intensive care acquired weaknesses,<sup>12</sup> hand hygiene compliance to reduce infections,<sup>13</sup> and monitoring of surgery to assess and improve the technical skills of surgeons.<sup>14</sup> In this article, we will design ambient intelligence for remotely and continuously monitoring the quality of care and safety of patients in the patient room in the context of an acute care facility. To facilitate the implementation of VSD to this technology, we propose a stepwise framework to VSD. We based this framework on our experiences as healthcare designers and the practical needs and limitations of the healthcare context.

#### Stepwise Approach to VSD

We propose here a stepwise VSD approach to digital health to have hands-on guidance in designing for healthcare. The approach considers the practical needs and limitations of healthcare institutions. First, there is a need for research and evidence on the efficacy of a technology but, at the same time, this research requires substantial funding, time, and research capacity, which are all sparse. Second, the involvement of actors in the process is demanding; recovering patients frequently do not have the energy to participate, and healthcare providers often do not have the time.<sup>15</sup> Therefore, the stepwise approach to VSD that we propose provides practical guidance on designing for values in healthcare considering the need for evidence while reducing the research burden and workload for participating actors. The approach is summarized in Table 1 and consists of 3 steps in which the 3 phases of VSD are embedded: experiment, demonstrate, and validate.

## Experiment

Within experiment, all 3 phases of VSD are conducted. Literature research in the conceptual phase enables definition of the context of the technology, identification of important actors, and exploration of what values should be considered. In addition, the empirical investigation is conducted to provide first insights into the design requirements derived from the main actors. In addition, the technical investigation of VSD is executed to explore which values are embodied in the design of similar technologies and how. This information serves as a basis to design makeshift solutions that can be tested in office settings by the team.

#### **Demonstrate**

Here, the empirical investigation of VSD is conducted with an initial prototype to understand how actors experience the embodied values in the prototype. This enables to refine the list of values important in the design and specify how these values should be translated into design requirements. The phase takes place in a mock-up environment with the exact layout of the authentic care environment. A demonstration of the initial prototype is provided to different actors, for example, caregivers and healthy volunteers mimicking the real patient population, who provide values-based feedback during enacted care scenarios. The technical investigation is repeated to translate empirical research into practical design requirements for creating a functional prototype.

#### Validate

The functional version of the technology is ready for testing with admitted patients and their caregivers in an authentic care context. Researchers study how the technology mediates the previously embodied values through empirical inquiry. Namely, the context of use and the user-technology interaction might affect how the values are expressed, which does not necessarily correspond to the initial value embodiment, the so-called positivist problem.<sup>16</sup> Insights can be translated into design recommendations for better value mediation and an adapted version of the technology.

## Methods

With a team of (clinical) researchers based in a university medical center (Radboud University Medical Center, Nijmegen, The Netherlands), and a team of engineers of the company Ouva (San Francisco, CA), we applied the stepwise approach to VSD to develop an ambient intelligence solution for remote, continuous monitoring of patients. We focused on patients recovering at the surgery ward after they underwent major abdominal surgery. Overall, these patients are older adults; some have multimorbidities with polypharmacy, and part of them is vulnerable to infections, thrombosis, and delirium.<sup>17-19</sup> The solution would have to secure the safety of these patients by providing nurses with real-time data on the status of the patient and their rooms. The solution should be able to identify potential events leading to decreased patient safety and automatically take action (eg, alerting staff or using bedside screens to inform patients). The local ethical committee approved the process (study identification: 2020-6908).

## Technology

Ambient intelligence is a form of AI where several sensors are embedded in the everyday environment to make it sensitive to the occupants' needs. Our solution was a video-based AI platform that comprised multiple machine learning models that generate various predictions and classifications. These models process images from color, infrared, thermal, and depth sensors in real time. For example, separate models locate people in the room, classify them based on their role, and predict their activity and posture. These models all learn to make such predictions using a large data set of sample scenes from the patient room. A central server translates all the data points and predictions into practical insights. It displays them on a dashboard visible at the nursing ward to provide insight into the status of a patient and the care operation. In our case, we started the development of the AI model by fine-tuning publicly available open-source machine learning models. Researchers have trained these models using large, public data sets. We closely screened the base models to understand what had to be added to the data set feeding the models to detect events in the patient room. Based on this screening, we started adding novel video data to the models to recognize healthcarerelated activities. This is what we call "training". This training occurs through the 3 research phases.

## Study Design

### Phase 1: experiment

In this first phase, our multidisciplinary team identified the main goal of the project, the main actors, and important values. For that, we interviewed 9 nurses. Interviews were transcribed through thematic content analysis.<sup>20</sup> Data were categorized into values and these were specified in norms. Norms are "all kinds of prescriptions for, and restrictions on, action."<sup>21</sup> Norms were translated into design requirements via the "values hierarchy" methodology.<sup>21</sup> Design requirements are more specific guidelines for design. In addition to the definition of the context of the design, this phase is focused at creating an initial prototype of the solution by training the models in office settings.

We aimed to design for patients and nurses and their values of safety, privacy, and inclusiveness. Safety was studied because the goal of the project was to increase patient safety. Safety is "a state in which or a place where you are safe and not in danger or at risk."<sup>22</sup> Privacy was studied because this value was directly mentioned as a concern related to ambient intelligence. Privacy has been defined in literature as "the right to be let alone."<sup>23</sup> Three types of privacy are commonly distinguished. Relational privacy refers to a right to be let alone without observation or interference from other people. Informational privacy includes control over personal data. Finally, privacy as a freedom from surveillance refers to "the right to not be tracked, followed, or watched."<sup>24</sup>

Value 3, inclusiveness, was considered as a wide variety of patients and caregivers will be making use of the technology and should be able to use it without bias. Computer technology is biased when it "systematically and unfairly discriminate[s] against certain individuals or groups of individuals in favor of others."25 Prevention of bias in AI through inclusive design is an important topic today. There are ample examples of algorithmic bias, also in healthcare alone.<sup>26</sup> Obermeyer et al,<sup>27</sup> for example, showed how health models in the United States contained racial bias, to such an extent that black patients were identified as needing less care than white patients in the same situation. AI models work by detecting and responding to specific events identified in large data sets based on what these models have observed in the past. Initial data sets used to train the models often contain hidden biases. An AI model can embody biases in initial data sets and even amplify them. In the whole process, we aimed at preventing algorithmic bias by carefully considering what initial data sets are used as input for the models and safeguarding the variety of the data used to train the models.

## Phase 2: demonstrate

This second phase is aimed at improving the accuracy of the solution for the values of safety and inclusiveness by training the models in a mock-up patient room via enacted simulated care scenarios. In addition, this phase is aimed at understanding actors' experiences as mediated by the solution regarding the values of safety and privacy. We report here on one systematic study of 8 healthy volunteers mimicking the real patient population reducing burden on real patients. The volunteers were admitted to

a hospital mock-up room equipped with the monitoring solution for a 2.5-hour stay. To ensure that the healthy volunteers provided useful information similar to how patients would experience it, we admitted the volunteers to a simulated care protocol by, among others, attaching a fake infusion pump to their arms and simulating care via a research nurse that entered the room regularly. The use of the solution was demonstrated via photos or videos as a basis for the semistructured value-oriented interviews.<sup>28,29</sup> Interviews were processed in the same way as the interviews with nurses.

#### Phase 3: validate

This phase will not be reported in this article as it still needs to be conducted. We will study the use of the solution in an authentic care situation and collect experiences and evidence on safety, privacy, and inclusiveness to generate design recommendations for improving the solution. An initial study design of this validate phase is presented in Appendix Table A in Supplemental Materials found at https://doi.org/10.1016/j.jval.2021.11.1372.

## Results

This section reports results for the first 2 design phases separately. An overall summary of the design process is presented in Table 2.

#### Experiment

The design process began in January 2018 with the experiment phase. Here, we started by clearly defining each value through literature research and conversations with various actors as a basis for creating initial design requirements that the solution should fulfill. In addition, we started training the initial models for recognizing safety-related events in the patient room.

#### Safety

Nine nurses provided their input on how to increase safety by the solution. First, nurses expressed the need for alerts on unsafe situations in the patient room. Nurses desired early warning alerts for fall prevention in vulnerable patients and early warnings for wandering patients. In addition, mobility and sleep monitoring were listed as facilitators for the improvement of patient safety. Providing nurses and physiotherapists with insight into sleep and mobility data through a dashboard allows them to engage patients in increased mobility to prevent pressure ulcers and speed up recovery. Based on the requirements for increasing safety through AI, the design team created the dashboard as shown in Figure 1 and Appendix Figures A,B in Supplemental Materials found at https://doi.org/10.1016/j.jval.2021.11.1372.

## **Privacy**

This value is central to the design of computer technology. In relation to the solution, the interviewed nurses mostly defined privacy as freedom from surveillance. The nurses particularly feared that the solution would be used against them to keep them responsible for mistakes that they could make during their shifts. Therefore, all nurses desired not to be recognized when they entered the patient room. Based on this desire, we studied the several computational methods available to deidentify persons for privacy preservation and explored a method called "body mask-ing," which consists of adding a layer over the identifiable person to prevent this person from being recognized (see Fig. 2). We added this option to the list of design requirements even though this option requires additional computational power.

Item	Experiment	Demonstrate	Validate		
Who	Team with engineers, medical doctors, nurses, designers, and researchers, nurses from surgery ward	Healthy volunteers mimicking real patient population and nurses from surgery ward			
What	Stakeholders Patients recovering from surgery, nurses working at surgery ward Value identification Safety, privacy, inclusiveness Value specification Safety: wellbeing monitoring and safety alerts Privacy: anonymous data processing, body masking Inclusiveness: set of variables identified to consider in training the solution	Value experiences Safety: feeling safe by monitoring solution Privacy: no "big brother is watching you" Inclusiveness: being accurately recognized by the solution	Value validation Safety: reduction of falls and infections, improved sleep and mobility, experiences of patients and nurses when using technology in authentic care Privacy: compliance to GDPR guidelines, experiences of patients and nurses when using technology in authentic care situation Inclusiveness: technology works in every situation for every individual		
Where	Office	Mock-up room simulating real patient room	Ten patient rooms at surgery ward		
Technology	Sensor installed in office; initial solution is able to roughly detect a variety of events and people		Sensor installed in 10 patient rooms; solution works for every event and individual, collecting and analyzing patient safety and quality data displayed at a provider dashboard		
GDPR indicates general data protection regulation.					

Table 2. Stepwise values-based design of hospital-based ambient intelligence for remotely and continuously monitoring care safety and quality of patients

## Inclusivity

Inclusive design refers to design that works for and addresses the needs of as many users as possible. In the context of ambient intelligence, this includes the absence of bias in software. An ambient intelligence model should be able to monitor each person to the same extent regardless of body size, skin color, sex, or clothes. To prevent bias in our system, our team generated a set of scenarios that critically included a variety of events, lighting conditions, people, attributes, and clothing as input for training the models.

Based on the values identification and definition, we initiated the design of the first prototype of the AI solution. We built on baseline models that we closely screened to understand possible biases in these models and understand what had to be added to train the models for recognizing safety-related events in the patient room. Training started in office settings. We drew the walls of a patient room on the floor of the office. Care scenarios were enacted in this imaginary patient room and recorded by 3 video cameras located at the opposite corners of a sensor. In addition, the video feed from the contactless sensor was processed in real time by the initial models running on a local workstation. Data generated by the models were then manually compared with video data, after which the models were trained. In Appendix Table B in Supplemental Materials found at https://doi.org/10.1 016/j.jval.2021.11.1372, we show what training sessions were done to develop the solution.

## Demonstrate

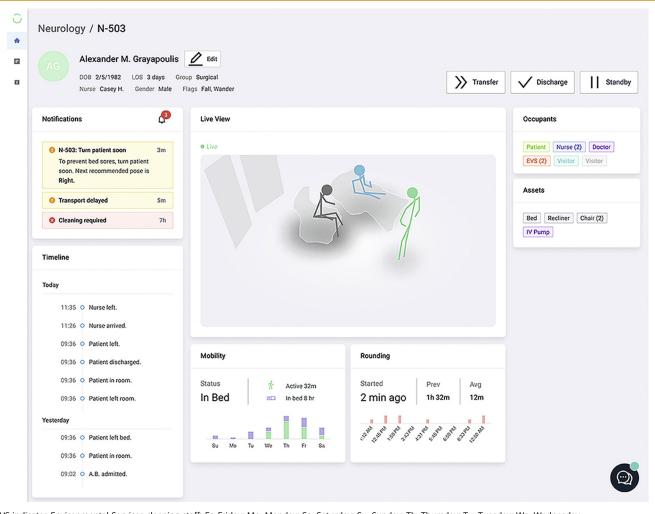
The experiment phase resulted in a clear context of use, 2 main actors, 3 defined values providing the basis of the solution's design requirements, and a first working prototype of an ambient intelligence solution trained by 1408 video clips recorded in the office and added to the baseline models. This solution can detect events in the patient room with an accuracy of 77% and recognizing patients with an accuracy of 91% compared with video footage. In the demonstration phase, we located a sensor with the running solution at the ceiling of a mock-up patient room. There, it was used to obtain empirical feedback on experiences regarding the values of safety and privacy and increase the accuracy of the solution by training it for the values of safety and inclusiveness. Results of one systematic analysis of semistructured interviews with 8 healthy volunteers on the values of safety and privacy are described here. More information can be found in Appendix Table C in Supplemental Materials found at https://doi.org/10.1 016/j.jval.2021.11.1372.

## Safety

The solution was trained with volunteers and care providers to increase its accuracy in detecting safety-related events. The interviews with healthy volunteers aimed to provide an understanding of how patients would experience their safety mediated by the technology. Four types of definitions were provided by volunteers when they explained what safety in a hospital meant for them, of which the first 3 would be mediated by the model: provision of high-quality care; the absence of adverse effects, including falls, infections, and food poisoning; and absence of harm and violence. The final one, not mediated, was the unsafety of medical equipment or the absence of safety precautions. Six of the volunteers agreed that they would experience increased safety when monitored by an ambient intelligence sensor. Two volunteers indicated they would not experience their safety differently. Only one volunteer mentioned a concern related to safety. This volunteer expressed the concern that the data of the sensor might be hacked.

#### Privacy

The healthy volunteers provided their definitions of privacy in a hospital, which accorded with the 3 types of privacy mentioned before. Relational privacy was most often referred to. It included the importance of a single-patient room, personnel knocking on **Figure 1.** Dashboard for displaying information of the ambient intelligence solution. The ambient intelligence solution collects data for increased patient safety. Risk of falling and wandering, mobility, and sleep quality of a patient is monitored and displayed on a dashboard providing nurses and physiotherapists with valuable insights for care provision. Based on the interviews with several nurses, an initial version of the dashboard is designed.



EVS indicates Environmental Services-cleaning staff; Fr, Friday; Mo, Monday; Sa, Saturday; Su, Sunday; Th, Thursday; Tu, Tuesday; We, Wednesday.

the door before entering, and having a curtain or door to close the room. Informational privacy was also mentioned several times. Being able to hear personal conversations from the hallway, for example, decreased informational privacy. Freedom from surveillance was mentioned by half of the participants as part of privacy. Three volunteers continued that a hospital admission inevitably decreased feelings of privacy. The volunteers were divided in their opinion on how the sensor mediated privacy. Half believed the sensor would not affect their privacy or considered this effect acceptable. The other half considered the sensor to be a privacy infringement. Remarkably, most volunteers that considered the sensor no harm to their privacy had experienced a hospital admission in the past, whereas the volunteers that did consider the sensor harmful had no past hospital experience.

Different design choices for optimal privacy mediation were discussed. Volunteers clearly expressed improvement of privacy when using the body-masking option. Providing consent on using the sensor before admission and the ability to turn off the sensor during admission were also discussed with volunteers. Most of the volunteers indicated that they did not want to be involved in deciding on whether to use the technology, because that would reduce its effectiveness. Some volunteers suggested not to inform patients about the sensor at all to prevent them from asking questions about it. Finally, several volunteers expressed that they would want to obtain insight into their data to comprehend what is being monitored for greater feelings of privacy. Not all suggestions are realistic in the context of care, but they aided the design team in finalizing the design requirements. The list of design requirements with the values and norms they were derived from is presented in Table 3.

## Inclusivity

To train the solution for higher inclusivity, care scenarios were played out in the mock-up room (see Fig. 3). Scenarios varied in attributes, events, clothes, lighting conditions, and persons. A total of 442 videos were collected during this phase and added to the database. This increased the accuracy of the models for event recognition by 10% (from 77% to 87%) and recognition of individuals by 4% (from 91% to 95%) compared with phase 1.

**Figure 2.** Body masking to protect user privacy. Privacy is an important value in the design of ambient intelligence models. Computational methods are available to deidentify personal information to increase user privacy. Nevertheless, these methods require additional computational resources.<sup>11</sup> Technology acceptance among nurses greatly improved using computational methods for anonymized data processing.



## Discussion

This article studied how VSD can benefit the design process of a hospital-based ambient intelligence platform aiming to improve the value of safety of all patients (value of inclusiveness) while respecting the value of privacy of patients and nurses. We proposed a stepwise approach to VSD to enable using the method in practice by considering the need for design and clinical research while keeping the workload of users to a minimum. We will reflect below on (1) the use of the stepwise approach to VSD and (2) the general use of VSD in digital health.

## A Stepwise Approach to VSD

Because VSD provides no practical guidance on how to apply the method, we followed a stepwise approach to VSD. This stepwise approach saves costs, time, and research burden on authentic care, while involving actors and collecting evidence on efficacy for making design adoption decisions. When using this stepwise approach to VSD in the future, several considerations are required regarding the *location of research* and the *involvement of actors*.

First, the *location of research* depends on the type of digital health solution. Our process spread over 3 locations: an office, a mock-up room, and an authentic care context. Starting in office settings allowed us to develop an initial prototype without the need for intensive stakeholder involvement in developing the model. The next phase took place in a mock-up patient room close to the general wards, allowing for demonstrations of the technology when that suited healthcare personnel and volunteers. In addition, because phase 3 will be executed at the nursing ward,

Design requirement Absence of adverse effects The solution should identify vulnerable patients. Safety The solution should detect risks of falling. The solution should detect risks of wandering. The solution should detect and display mobility of patients. High-quality care The solution should detect and display sleep patterns of patients. Absence of violence and harm Strictly meeting all GDPR guidelines in the design of the solution. Communicating to patients how the GDPR guidelines are met in the design of the solution. Providing patients with insight into personal data collected by the solution. Privacv Informational privacy Providing patients information on the use of the solution before admission. Freedom from surveillance The solution uses body masking to deidentify personal information. The solution is only used in vulnerable patients. The sensor with the running solution is placed out of sight. Ability to "be yourself" Inclusivity Solution can adequately monitor each The solution is able to recognize any person irrespective of skin and hair color, individual to the same extent disability, used medical equipment, and clothes. GDPR indicates general data protection regulation.

Table 3. Values hierarchy with values, norms and design requirements of the ambient intelligence hospital-based monitoring platform

**Figure 3.** Training session ambient intelligence solution. The ambient intelligence solution is trained by enacting care scenarios, recording these, and manually labeling the video images. Care scenarios varied in events, attributes, lighting conditions, people, and clothes to obtain optimal accuracy of the solution in detecting safety-related events for any patient. A total of 1850 videos were collected by our team to train the solution.



the use of the technology will become part of daily care under close support. This increases the involvement of care professionals. Although we experienced benefits from this approach, the use of a mock-up patient room and validating technology at the general ward is environment specific. Applying remote ambient intelligence technology at home, for example, to monitor the aging population or patients with chronic diseases needs another mock-up environment.<sup>11</sup> In such cases, the demonstrate phase could take place in other easily accessible locations, for example, the local general practice, or a community center. Another possibility is to set up community laboratories simulating the home environment nearby the target groups. The validate phase should then take place at the patient's home and requires additional work in support of using the technology and installing the technology.

Second, involvement of actors requires reflection before the design process begins. In our case, we identified and involved where possible the main users of the technology, without burdening them too much. To facilitate this, we commonly involved healthy volunteers with past patient experiences instead of actual patients. The involvement of healthy volunteers over patients reduces study load for patients and allows for speeding up the process. Although they provided valuable insights, they might have different value experiences than patients.<sup>30</sup> Here, we observed that privacy mattered more for healthy volunteers than for actual patients. We took this difference into account by valuing safety over privacy while working on the design requirements. Knowledge of differences between healthy volunteers and patients is required before healthy volunteers are involved. In addition, it is not always possible to involve healthy volunteers with past patient experiences, for example, when actors are patients with long-term care needs or with congenital disorders. Even more, involvement of mentally disabled patients, or people with dementia, requires different participatory design principles (see, eg, designing for down syndrome<sup>31</sup> or designing for dementia<sup>32</sup>). In these cases, it is often needed to involve

spokespersons for the patient group. Thus, a clear investigation on the how and whom of stakeholder involvement before the design process starts is required in any digital health technology.

## VSD of Digital Health

Current digital health development and assessment is mostly concerned with quantitative evidence on efficacy, so-called "hard impacts".<sup>33</sup> A values-based approach to technology design allows for considering the "soft impacts" (qualitative impacts on experiences and values) of technology, because these provide insight into aligning technology to its context of use and user needs and values for increased chances of success. Although VSD is a promising approach, we faced several practical challenges evoked by the unclarity of the concept of "values" and its practical use in design. These challenges refer to designing for *what values*, understanding different *types of values*, dealing with *conflicting values*, and the role of *empirical research on values*.

VSD prescribes to study what values are embodied by similar technologies. Values often included in the design of information technologies are, among others, privacy, security, and justice.<sup>34</sup> Values designed for in healthcare relate to other values, including dignity, autonomy, and social comfort.35,36 Considering other technologies leads to a myriad of values. Therefore, we defined our values with actors. To demarcate the scope, we consciously decided to only focus on 3 values and 2 main actors. In addition, the number of actors involved could have been enlarged, including medical doctors, visitors of patients, and other healthcare personnel entering the patient rooms. VSD was critiqued for its inability to provide tools to identify all values and actors involved in VSD.<sup>9</sup> We agree upon the need for guidance on value and stakeholder identification but believe that there is an even larger need for studies to identify which values and actors are pivotal and which could be left out in the design process. A systematic empirical study on a wide range of values of each stakeholder involved is unrealistic considering the large time and

money investment necessary for such a study. We recommend digital health development teams to begin each project with a clear demarcation of the study's scope with respect to actors and values.

Likewise, when we began the design project, we encountered problems in dealing with different *types of values*. We particularly aimed to focus on moral values in the design. Although nonmoral values can include anything that people consider important, moral values are more fundamental and include an accepted, rationally shared set of "right" and "wrongs,"<sup>37</sup> yet this demarcation remains questionable. The value of inclusiveness, for example, could be seen as a moral value when it refers to justice and equal treatment, yet considered from a usability perspective in inclusive design, it would be regarded as a nonmoral design value. In addition, we encountered differences in procedural and contextual values. Procedural values result from the design process. Contextual values result from actors' experiences. Inclusiveness was mostly defined as a procedural value, because it requires a certain process of technology development for preventing bias. At the same time, inclusiveness would become contextual when it refers to usability. Privacy and safety were mostly considered contextual values, yet safety also includes functional safety, which is an inherent feature of the design and could be seen as procedural. Moreover, the values can be separated based on designer values (what designers consider important) and user values (what actors consider important).<sup>38</sup> The multiple "faces" of values complicate designing for them. Values-based digital health designers would benefit from an early and clear definition of each value that is considered. We encourage reporting on values-based design processes, because digital health designers can learn from previous experiences. A value as inclusiveness, for example, matters in any type of ambient intelligence model irrespective of its use in a hospital or home setting. Ideally, future research should allow for identifying universal values related to digital health, and factors affecting how such universal values should be considered in design, such as user factors, for example, acute versus long-term care needs, and context-dependent factors, for example, use in hospital or at home.

The third issue we encountered was related to dealing with conflicting values. In the example, experiences of safety and privacy conflicted; increased feelings of safety required reduction of privacy. In the past, many solutions have been proposed on how to deal with these so-called value conflicts or value tensions.<sup>39,40</sup> We based our decision of valuing safety over privacy on the great need to increase safety in hospitals. This choice was justified by a study by Schreuder et al<sup>36</sup> showing that patients, among other values, consider safety as most important whereas privacy is least important to them during admission. We argue that there is no optimal framework for solving value conflicts. The solution will greatly depend on the type of values, the actors, and the context of use. For example, changing the context of developing an ambient intelligence monitoring platform from hospital to remote home monitoring or changing the actors from acute care to long-term care patients might result in increased importance for privacy. This could result in different design decisions. For digital health designers, it is important to be aware of value conflicts and find the right solution depending on the specific technology, values, actors, and context of use.

The role of empirical research in VSD is subject to debate. Dantec et al<sup>28</sup> critiqued VSD's focus on known values over value discovery and plea for empirical research on users' lived experiences through photo elicitation techniques. Although we endorse the need to study values in context through lived experiences, such an empirical approach to values raises questions. In our values hierarchy, values were derived from a mixture between

empirical research, literature reviews, and research and engineering knowledge. We noticed how difficult it is for actors to speak in terms of values. For example, one of the healthy volunteers considered her privacy to be intruded on by AI but she could not illustrate what privacy meant. Therefore, insights were translated by the research team into data useful for the design. Norms were based on empirical input solely. Design requirements were created by the design team inspired by empirical research. We could have created a long list of design requirements solely derived from actors' opinions, yet actors' lack of understanding in technology development, need for evidence-based design, rules and regulations, and the context of use would result in suboptimal and sometimes even unrealistic solutions. This happened, for example, when a volunteer suggested leaving patients ignorant about the use of the monitoring solution to prevent privacyrelated stress. Such a solution is not only unethical but also illegal. Our experiences exactly relate to the critique posed by Manders-Huits<sup>9</sup> on the use of empirical research in VSD. Continuous involvement of one stakeholder representative that comprehends the context of technology development could solve some issues, but reduces the richness of opinions gathered through semistructured interviewing. As long as no optimal solution is provided, we suggest being transparent in how empirical research is applied to inform design to enable critical reflection for better design.

#### Strengths and Limitations

Our article contributes to the practical application of values in technology design and in particular of values in digital health. We show the benefits and challenges of embedding values in technology and contribute to the vocabulary on designing for values. Our study is also subject to limitations. First, the development of an AI model is time consuming. In the time frame available, we were not able to conduct the validate phase, as initially proposed. In future research, we will research the use of values in digital health validation studies. In addition, to optimally test the application of VSD to digital health and its ability to improve the fit between technology and user values, more design teams and case studies are required. Experiences of using VSD will vary per design team. Future research should ideally follow multiple design teams in their needs related to embedding values in technology. In addition, our case study of AI is a very particular technology. Again, future research in other digital health technologies should provide insight into the generalizability of our findings.

## Conclusions

Given that digital health is expanding in healthcare, consideration should be given to the design, evaluation, and implementation of these technologies. We recommend each healthcare institution and digital health developer to join forces, form a multidisciplinary team, and follow a stepwise and values-based approach to digital health development. Such an approach involves actors while reducing costs, time, and research load. In addition, it systematically generates evidence on technology's effects. By studying the values of all actors involved, the process allows for aligning the digital health solution with the context of use and user needs and values to ensure successful technology adoption. Several challenges with regard to the use of values were encountered. In addition, strengths and limitations to implementing and generalizing such an approach to other digital health solutions were identified. We believe there is not one way to design digital health solutions for improving actors' values, given that each actor and each care context might require different practical tools. Reporting on values-based design processes, raising questions on its use, and improving the vocabulary on values through heuristics improve awareness of the importance of designing for values and show designers the need to consider users and context of use to create value through values.

## **Supplemental Materials**

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.jval.2021.11.1372.

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