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# Responsible design and assessment of a SARS-CoV virtual reality rehabilitation programme: guidance ethics in context

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**ABSTRACT**

In many digital health technologies, the design does not align with the needs and values of users within a specific healthcare context. This results in low uptake of these technologies. Health technology assessments should encourage successful technology adoption. Yet, its traditional focus on the cost-effectiveness of technology results in missing important qualitative insights. More recent initiatives to include qualitative outcomes in assessments generally remain too speculative to identify the actual effect of technology on individual needs and values. In this article, we adjust the 'guidance ethics' framework to study the lived value experiences of users while interacting with technology in context. We apply this novel framework in a case study of developing and evaluating a virtual reality rehabilitation service for long COVID patients. We end the article by evaluating the strengths and limitations of this novel framework as an addition to traditional health technology assessments.

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## Introduction

Digital health refers to technology and data informing and improving healthcare provision (The Lancet Digital 2019). Health Technology Assessments (HTAs) should guide the implementation of digital health. Inspired by evidence-based medicine, HTAs gather 'best available evidence' in a multidisciplinary process to evaluate and inform decision-making in order to promote an efficient and high-quality health system (O'Rourke, Oortwijn, and Schuller 2020).

However, a large part of digital health technologies does not achieve successful uptake (World Health Organization 2010). A major reason for this is the misalignment between the digital health solution and the needs and values of users within a specific healthcare context (Van Velsen, Wentzel, and Van Gemert-Pijnen 2013; Pagliari 2007; Birnbaum et al. 2015; Lupton 2013). HTAs commonly assess technology based on quantitative outcomes, in particular, costs, quality, and safety of healthcare technologies. In that, HTAs

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have been criticised for their overemphasis on cost-effectiveness (Banta 2003, 2009) and quantitative health outcomes only (Sarri et al. 2021). Qualitative outcomes, in particular user needs and values, are rarely part of an HTA, which results in missing important insights necessary to successfully implement the solution.

'Multi-criteria Decision Analysis' (MCDA) models are increasingly used to broaden the scope of HTAs. MCDA models provide various criteria, ranging from cost-effectiveness to patient experiences, as a basis for technology assessment (Belton and Stewart 2002). The INTEGRATE-HTA is a recent European MCDA initiative. It particularly stresses the importance of considering the context of technology as a part of the assessment (Wahlster, Brereton, and Burns 2017). In addition, numerous frameworks have been proposed focusing in particular on qualitative technology assessment. For example, Lehoux and Blume (2000) illustrate the importance of identifying the socio-political context of technologies by identifying actors, resources, the flow of knowledge, and power relations. Likewise, Reuzel et al. (2004) propose to assess the social context of technology from a 'social shaping' perspective of technology. More recent initiatives primarily call for inclusion of stakeholders in the assessment procedures. For example, Baltussen et al. (2017) propose an 'evidence-informed deliberative process' approach to HTA in which stakeholders are invited to take part in discussions on technology. Likewise, Van der Wilt, Reuzel, and Grin (2015) closely interview stakeholders to examine their opinions related to technology in their 'interactive technology assessment'. Furthermore, the method of 'guidance ethics' of Verbeek and Tijink (2020) considers workshops with stakeholders to identify opportunities for responsible technology design and evaluation.

We encourage HTA initiatives involving stakeholders in the assessment procedures to align technology to user needs and values. Yet, so far, most initiatives predominantly involve a few stakeholder representatives to partake in technology discussions. The quality of the HTA then depends on the ability of the few stakeholders to reflect on the potential value of a technology for the group they are representing. Such stakeholder involvement is limited and speculative. Instead of involving stakeholders through speculation, we argue for stakeholder involvement through empirical assessment of the interaction between technology and users.

The need to assess technologies in practice is stressed by the increasing complexity of technologies. Complex technologies are 'interventions that involve multiple components acting either independently or interdependently, and which aim to improve health outcomes by addressing stakeholder needs along the patient journey' (Sarri et al. 2021; Medical Research Council 2021). Technology, in particular digital health, should not be assessed on its own, but as a socio-technical system (Boenink 2012). The increasing complexity of such systems challenges the ability to speculate on its value. It rather demands the empirical study of the interaction between the user and the system.

Empirical research is also required to align technology to user values. Many HTA models assume that technology does not affect moral values and as such, do not reflect on the effect of technology on morality (Boenink and Kudina 2020). However, technology mediates values; values can change in the interplay between users and technologies (Smits et al. 2022). Such value mediation should be assessed as part of HTAs. However, it is commonly very difficult to speculate on the effect of technology on values as these are abstract concepts difficult to bring into words (Kujala and Nurkka 2009). Boenink and Kudina (2020), therefore, argue that researchers should study practice to comprehend the effect of technology on user values. Instead of speculation, values can only be understood while observed in the authentic context of use. In other words, values have to be lived.

We aim to set the next step in stakeholder involvement in HTA. Instead of stakeholders speculating on the potential value of technology, we aim to study stakeholders' lived experiences of a complex technology in its context of implementation. For this aim, we build on the work of Verbeek and Tijink (2020) on 'guidance ethics'. First, we illustrate the guidance ethics framework in more detail. Consequently, we adapt the framework to study stakeholders' lived experiences. Finally, we illustrate and evaluate the framework through a case study of developing a Virtual Reality (VR) rehabilitation service for long COVID patients.

## *Guidance ethics in context*

The guidance ethics approach is inspired by the 'theory of technological mediation'. This theory is typically described by two dimensions: the 'hermeneutic' and 'existential' dimensions (Verbeek 2010). Hermeneutic technological mediation describes how technologies influence human perception and experience. Existential mediation encompasses the influence of technology on human action. More recently, a novel dimension of mediation has been described: technological mediation of morality. This dimension refers to the effects of technology on moral action and decision-making. Even more, it includes how technology mediates our value frameworks by shaping how we define and experience moral values (Verbeek 2014). Guidance ethics provides the tools to assess the three dimensions of mediation of technology through workshops with stakeholders.

The approach consists of three stages: (1) *Case*, (2) *Dialogue*, and (3) *Options for action*. Within stage 1, the context of using the technology is identified and described. Stage 2 consists of a workshop in which relevant stakeholders speculate on technological mediation. This stage is split into *actors* (who will be affected by the technology), *effects* (how does technology mediate experiences and actions of the actors), and *values* (how does technology affect the values of the actors). Within stage 3, options are identified for a more responsible technology design, context of implementation, and user behaviour. Below, we slightly adjust the guidance ethics framework to enable 'guidance ethics in context'. Figure 1 visualises the approach (adjusted from Verbeek and Tijink 2020).

### *Case*

The first stage begins with clearly studying and describing the full socio-technical system that will be studied in stages 2 and 3: what type of technology is studied, what components are interacting with each other, and in which context will the solution be deployed? Also, all actors mediated by the technology are identified. These actors can be both direct and indirect actors. A direct actor closely interacts with novel technology. An indirect actor is not in interaction with the technology but is mediated by its presence. Where traditional guidance ethics ends with actor identification, an empirical approach requires identifying what actors will be studied empirically in context, and what actors will be left out of the study's scope. The case description results in one qualitative outcome: *values*.

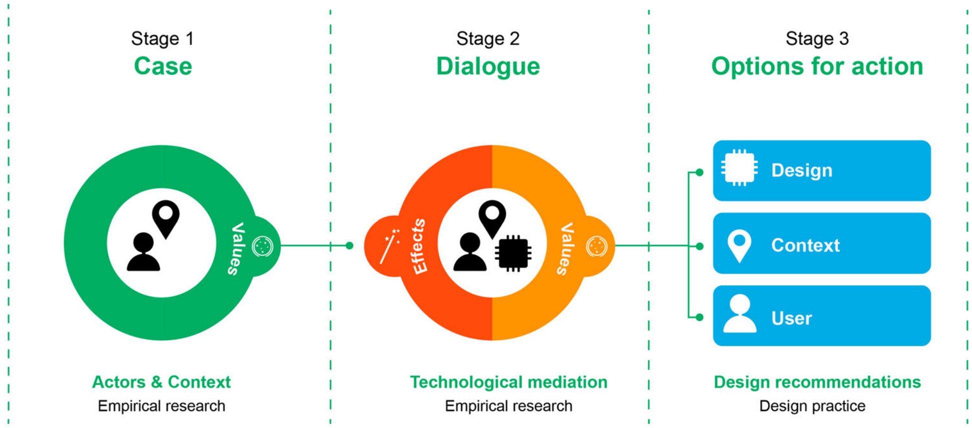

**Figure 1.** Guidance ethics in context: an adaptation of the guidance ethics approach (Verbeek and Tijink 2020) to study users' lived experiences. The approach differs from guidance ethics in considering empirical research of users' lived experiences in stages 1 and 2 and providing recommendations for responsible design and implementation that go beyond ethics only.

*Values.* Values include everything actors consider important in life (Friedman, Kahn, and Borning 2006). This first stage aims to create a baseline value framework which is the pre-measurement in the pre-post measurement that is executed. The baseline value framework consists of all values important for an actor in the defined context before technology implementation. A value framework can be constructed via a value-oriented semi-structured interview (Friedman and Hendry 2019). Such interview aims to identify important values for actors and their experiences of these values. It starts with constructing interview guidelines consisting of open questions referring to what people consider important in their context and including questions on specific values. The final set of questions can be constructed via a literature study. There is typically literature available describing what values matter for a specific patient population (for example, patients with chronic low-back pain), or a specific context (for example, hospital admissions), or a specific technology (for example, virtual reality). A literature search should enable the identification of a set of values that matter in the context of the study, which requires a normative evaluation of the researcher. The interview guidelines consequently only serve as loose guides. Throughout the interview, the interviewer should enable the interviewee to focus on important personal topics related to the defined context. After the interview, data are transcribed, analysed, and coded by the researcher into concrete values, which might differ from the initial set of values identified through literature. Values are subsequently divided into norms. Norms are all 'conditions needed to realise values in practice' (Van de Poel 2018; Smits et al. 2022). The result of this phase is a clear value framework for each actor in the identified context.

### *Dialogue*

In this stage, a complex technology is introduced to actors in the previously studied context. Whereas this phase traditionally takes place through a workshop, we propose to conduct empirical research to reduce the speculative character of workshops and understand actors' lived experiences. Actors are instructed to interact with the complex technology for a certain period. The interaction is observed and evaluated afterwards via semi-structured interviews. These interviews form the basis of the post-measurement in the pre-post measurement study design. Interview data are translated into *effects* and *values*. To prevent the study outcomes can be attributed to other causes apart from the technology, the research team should ensure that the technology is the only variable that differs compared to the initially studied context.

*Effects*. Effects include any hermeneutic and existential mediating outcome of technology on actors. Effects could be derived from observation and interviews and coded into experiences or needs, positive and negative effects, or facilitators and barriers.

*Values*. Albeit an instrumentalist view of technologies as neutral objects are standard in HTA, such view is also outdated (Boenink and Kudina 2020). Technologies co-shape the values in our moral frameworks, of which we should be vigilant. In this stage, the research team, therefore, observes the interaction between user and technology and conducts a second value-oriented semi-structured interview. All data are translated into a novel value framework.

## Options for action

Stage 2 provides empirical data on the technological mediation of actors' experiences and actions ('effects') and value framework ('values'). A comparison of the baseline value framework established in stage 1 with the value framework constructed after technology use in stage 2 supports the understanding of how technology changes values ('value mediation'). Technology could improve or threaten actor's experience of values from the baseline value framework. Technology can also transform values from the baseline framework. Value transformation can take on different forms, including the introduction of novel values or disappearance of old values, change in the (relative) importance of values, change in the definition of a value, and change in how values are specified into norms (Van de Poel 2018; Smits et al. 2022).

Insights into technological mediation of effects and value frameworks can be translated into options for action. The research and design team should identify all negative effects and value transformations. This requires normative work and maybe even an ethical framework for assessing what value experiences should be considered as 'negative' (Manders-Huits 2011). This normative assessment should be closely inspired by the lived experiences of the actors. When possible, we argue that all negative effects and negative value mediations should consequently be targeted by options for action. Guidance ethics identifies three options to better embed ethics in technology: ethics by design, ethics by context, and ethics by the user. To broaden the scope from ethics to responsible HTA, we translate these actions into normative *recommendations*. We particularly provide recommendations as these are guiding principles that practitioners can use to better align design with its context of implementation. We provide *recommendations for design*, *recommendations for context*, and *recommendations for user*. It should be noted that in particular cases certain recommendations for improved value mediation can conflict with other recommendations. In case of such value conflicts, the research team should make use of one of the various methodologies to weigh values and deal with the value tensions (van de Poel 2014).

*Recommendations for design*. Negative effects and value mediations, or opportunities for better effects and value mediations can oftentimes be considered by changing the design of the solution. Consider, for example, the design of an Artificial Intelligence (AI) platform that provides nurses with information on the health status of an admitted patient. When this platform results in the effect 'difficult to understand graphical interface', the design can be improved by applying better universal user interface design principles. Or, a negative effect of this solution on the value of 'privacy' can be countered by applying body masking principles in the design of the AI solution. A method for translating identified value mediations into design is provided by Van de Poel (2013), who recommends translating values into 'norms' and specifying these into 'design requirements'.

*Recommendations for context.* Successful adoption and implementation of technology might require restructuring the context studied in stage 1. To return to our example, successful implementation of AI to monitor the health of patients requires not only that AI works as it should (design) but also requires regulation on its use, support services for nurses, infrastructural adaptations, and possibly changes in financial structures.

*Recommendations for user.* User behaviour is an important facet in each user-technology interaction. The term multi-stability nicely represents this. Multi-stability refers to the widespread ways users might use a novel technology, including ways not foreseen by designers (Ihde 1990). Optimal adoption of technology might require behaviour change. To return to our example, the implementation of AI to monitor patients' health, requires the provision of education sessions to nurses to ensure that they know how to use the technology responsibly and efficiently.

## Case study: virtual reality rehabilitation long COVID

To evaluate the approach, it was applied to a case study of VR rehabilitation for long COVID patients. This research was part of the 'COVRehab study' (NCT04505761), for which the medical ethics committee (CMO Arnhem-Nijmegen) provided approval (study identification number: 2020-6770). The study was conducted between July 2020 and March 2021. Given the aim of this article to consider actors' lived experiences as input for a multi-criteria HTA, we only report on the qualitative data of the COVRehab study. Quantitative results will be reported separately.

Qualitative data were collected through semi-structured value-oriented interviews, diaries, and phone calls. We constructed interview guidelines based on open questions referring to patients' experiences of the situation (for example: 'How did you feel during the SARS-CoV infection?' and 'What are your experiences related to using VR?') and questions directly considering patients' values. The value questions were based on a study by Schreuder, Lebesque, and Bottenheft (2016) describing important values for recovering patients. Schreuder et al. identify the values of spatial comfort, safety and security, autonomy, sensory comfort, privacy, and social comfort. We followed their values in constructing the interview guidelines (for example: 'Did SARS-CoV affect your feelings of safety?' and 'Did VR affect your feelings of safety?'). We were also open to suggestions of patients when they considered topics important to mention during the interviews. All interviews were recorded and transcribed verbatim. Data of diaries and phone calls were saved in the data processing program CastorEDC (Amsterdam, The Netherlands). Two independent researchers with a background in industrial design and biomedicine first analysed all results separately, after which results were compared and a consensus was reached on a final set of codes, including effects, values, and norms, following the guidelines for thematic content analysis (Braun and Clarke 2006). Results are reported following the Standards for Reporting Qualitative Research (O'Brien et al. 2014). More information on the study's in- and exclusion criteria and interview guides can be found in Appendices 1 and 2

We identified patients and physical therapists as primary actors and studied the values of patients, and the effects of VR use on patients and physical therapists. For practical reasons, we left the values of physical therapists out of this article's scope. Stage 1 describes the baseline value framework of patients. Stage 2 describes the effects of VR on patients and physical therapists using a common set of themes that both groups shared. We also describe the mediation of values of VR on patients. Considering the analysis of stage 2, we provide recommendations for optimal design, context, and user in stage 3. Table 1 illustrates the aims and methods of the empirical research in stages 1 and 2. Table 2 summarises the results of stages 1, 2, and 3.

## Case

Long COVID encompasses an array of varying persistent symptoms after COVID-19 infection (The Lancet 2020). Much is still unknown about these symptoms and their treatment. Symptoms include, among others, mental and/or cognitive dysfunction, functional impairment, and fatigue (Van den Borst et al. 2020; Logue et al. 2021). Numerous patients seek the assistance of a physical therapist in their recovery process (Barker-Davies et al. 2020).

VR was identified as a tool for physical therapists to provide patients with rehabilitation therapy (Smits, Staal, and van Goor 2020). We expected that VR would benefit

**Table 1.** Characteristics empirical research in stages 1 and 2.

| | Case | Dialogue | |
|---|---|---|---|
| | *Patient* | *Patient* | *Physical therapist* |
| Empirical research tools | Semi-structured value-oriented interviews | Semi-structured value-oriented interviews, diary for reporting use and problems related to VR, weekly phone calls for support | Semi-structured interviews |
| Research goal | Establishing value framework | Identifying effects of the use of VR and establishing novel value framework | Identifying effects of the use of VR |
| Context | Patient receives physical therapy for long COVID treatment | Patient uses VR for long COVID treatment | Physical therapist supports patient in use of VR for long COVID treatment |
| Population | - 20 adult patients<br>- Average age of 51 (youngest 20, oldest 69)<br>- 12 females, 8 males<br>- 7 admitted to hospital of whom 5 to intensive care unit. 13 diseased at home | Similar as patient population in case | - 15 physical therapists (12 participated in study, 3 used VR for own rehabilitation purposes)<br>- Average age 36 (youngest 24, oldest 60)<br>- 13 females, 2 males<br>- Average support provided to 4 patients |
| Average length interviews | 18 min | 25 min | 28 min |

**Table 2.** Results guidance ethics in context of long COVID VR rehabilitation program.

| 1. Case | 2. Dialogue | | 3. Options for action | | |
|---|---|---|---|---|---|
| | | | Design | Context | User |
| **Effects of patients and physical therapists** | | | | | |
| | Attitude towards the use of VR | + VR is fun | Offer more content and competition | | |
| | | + VR is motivating to do rehabilitation exercises | | | |
| | Rehabilitation effects | + VR allows for physical rehabilitation | | | |
| | | + VR allows for cognitive rehabilitation | | | |
| | | + VR allows for relaxation and breathing exercises | | | |
| | Use of VR | – Adverse effects of VR | Design content focused on the prevention of adverse effects | Physical therapists should assess whether patients are eligible to use VR before VR is offered | |
| | | – Not offering VR to elderly patients | | Physical therapists should provide VR to any patient with rehabilitation needs regardless of age | |
| | Making VR part of daily practice | – Difficult to make VR part of daily routine | | | Physical therapists should support patients in use schedule |
| | | – Flaws in game design | Improve game design for optimal user experience | | |
| | | – No knowledge of VR or scientific evidence available | | | Physical therapists should obtain time to become acquainted with VR<br>VR should become part of the standard education of physical therapists |
| | | – No business model available | | A business model is required for VR rehabilitation | |
| | | – No resources to provide logistical support on VR use | | A VR support centre could aid in providing VR, education on VR, cleaning, and solving technical issues | |

| | Values of patients | | | | |
|---|---|---|---|---|---|
| | Baseline value framework SARS-CoV | Value framework mediated by VR | | | |
| Self-identity | + Experiencing increased positive appreciation of life | | | | |
| | + Taking better care of the body | + Taking better care of the body | | | |
| | – Not understanding rehabilitation needs of the body | + Understanding rehabilitation needs of the body | Provide patients with insight into their rehabilitation path | Provide physical therapists with insight into patient progress through a dashboard | |
| | – Having a negative body image | + Having a positive body image | Provide patients with insight into own progress<br>Use motivating and encouraging game design for a positive body image | | |
| Safety | – Feelings of fear and unsafety during infection | – Feelings of fear and unsafety in the virtual world | | Physical therapists should provide patients with instructions on the safe use of VR (sitting on a chair, safeguarding personal limits) | Physical therapists should obtain experience in using VR for rehabilitation purposes |
| | – Feelings of fear for society after infection | | Enlarge the VR toolkit with games focused on treating anxiety and post-traumatic stress disorder | | |
| | | + Reduction of fear to mobilise | | | |
| | | – Risking physical overload | Show time clock in VR | | |
| | | | Set time limit on games | Physical therapists should support patients in the use of VR through a use plan including the maximum use time of VR | |
| | | | Use a fitness tracker to prevent physical overload | Physical therapists could use a fitness tracker to obtain insight into the vital signs of patients while they are practising in the physical therapist's practice | |
| Autonomy | – Being dependent on the assistance of others | + Having control over rehabilitation | | Physical therapists should support patients in how to use VR as part of rehabilitation | |
| | | – Being dependent on difficult technology | | | |

(*Continued*)

**Table 2.** Continued.

| 1. Case | | 2. Dialogue | 3. Options for action | | |
|---|---|---|---|---|---|
| | | | Design | Context | User |
| | – Being dependent on the recovery process | | Use hardware and software allowing for easy navigation menus<br>Begin each game with an explanation of the game<br>Use same control buttons per game | | |
| Social Comfort | + Being grateful for others' (medical) assistance | | | | |
| | – Feeling alone and not understood | | | | Physical therapists and patients should together decide on how often live support is needed<br>VR could be utilised to empathise relatives with the rehabilitation needs of patients |

recovering long COVID patients as these patients suffer from physical, mental, and cognitive complaints. For each of these domains, VR has already been applied as a rehabilitation tool in the past (see, for example, for the physical domain Darekar et al. 2015, for the mental domain Pourmand et al. 2018, and for the cognitive domain Maggio et al., "Virtual Reality and Cognitive Rehabilitation," 2019). An initial VR-rehabilitation toolkit for long COVID was developed by our research team, consisting of researchers, medical doctors, physical therapists, designers, and VR developers. The toolkit could be prescribed by physical therapists treating long COVID patients for use at home in addition to traditional physical therapy exercises. The VR toolkit consisted of a VR headset, the Oculus Quest (Facebook, Inc.; Menlo Park, United States of America). The Oculus Quest was equipped with three-game packages consisting of games already used in healthcare focusing on the three long COVID-related rehabilitation domains: physical, mental, and cognitive rehabilitation. The first two packages, *FitterVandaag* and *SyncVR Medical* were developed by the company SyncVR Medical (Utrecht, The Netherlands) and consisted of several games for physical and mental rehabilitation. The third package, named *Koji's Quest* contained a range of games for cognitive rehabilitation developed by the company NeuroReality B.V. (Amsterdam, The Netherlands). Figure 2 provides a visualisation of several of the presented games.

## Values before use of VR

All interviewed patients were infected with Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV) in early 2020. At the time of the study, participants had postinfectious complaints such as physical impairment, fatigue, difficulties in breathing, difficulties processing environmental stimuli, and inability to focus and memorise. In addition, patients admitted to the intensive care unit also mentioned the loss of muscle strength and post-traumatic stress disorder (PTSD). All participants received physical therapy for these complaints. In addition, some also visited dieticians, occupational therapists, speech therapists, or psychologists. Below, we address how the SARS-CoV infection affected the value experiences of patients through the values of self-identity, safety, autonomy, and social comfort.

**Figure 2.** Several games offered as part of the long COVID VR toolkit. Image on the left: physical rehabilitation by means of an interactive soccer game. Image in the middle: breathing exercise in a relaxing environment. Image on the right: cognitive exercise focused on spatial perception.

*Self-identity.* The SARS-CoV infection affected the self-identify of the interviewed patients. An increase in appreciation of life was experienced by 5 out of 20 patients, especially as they experienced death so closely. The experienced vulnerability during infection and the lasting symptoms afterwards made nine participants value their health more, as described by patient 12 (male, 53 years old): 'I am thankful for COVID, we should see it as a present. It helped me to better take care of my body and mind'. This expressed itself in better listening to the body, healthier eating habits, and desire for increased physical activity. Simultaneously, numerous participants disliked not knowing what to expect from the rehabilitation process. Nineteen out of 20 participants experienced a negative body image. They were frustrated that their bodies did not allow for faster recovery and expressed a loss in self-confidence. Patient 21, for example, described (female, 48 years old): 'I had to lower the bar. I needed help with that. I was 47 years old at that time, but I had the body of someone aged 80. Everything you do is so different. I really had to adjust'.

*Safety.* An often-mentioned value in the interviews was safety. During infection, almost half of the participants expressed to have had severe fears. Five participants even expressed to have feared for their lives, as patient 4 (female, 36 years old) described: 'I never experienced such a fear to die. Really, an existential fear to die. I hoped every evening to wake up the next morning'. During recovery, five participants feared becoming infected again and, therefore, felt uncomfortable in public. Two feared a return to their jobs as a nurse. Five remained to have fears from the infection, resulting in low quality sleep, and for two, in PTSD.

*Autonomy.* All patients experienced a reduction of their autonomy during infection and rehabilitation. During infection, half of the participants accepted their need for support as they were too diseased to bother. Eight different participants disliked their dependence on the assistance of others during infection. During recovery, seven participants experienced dependence on their recovery process. They severely disliked their inability to execute activities of preference, as patient 13 (male, 64 years old) described: 'I was a do-er, I was always busy. But now I can't do anything anymore. Yes, it is so damn difficult'.

*Social comfort.* In general, participants are grateful for the aid they received from medical professionals and family members. During infection, six of the participants felt alone as they were unable to see others risking virus transmission. After infection, some participants disliked that others did not understand their needs for recovery as patient 7 (female, 38 years old) illustrated: 'I am the only one that had COVID-19 of my family and friends. They don't understand it. That is difficult'.

## Dialogue

Patients were individually instructed regarding the use of VR at the start of the dialogue period. In consultation with their physical therapist, decisions were made on the location, frequency and duration of use, and type of games played. Participants generally used VR for six consecutive weeks. Figure 3 shows a photo of a patient using VR in one of the participating physical therapist practices. We report below on the experienced effects of VR for patients and physical therapists and describe how VR mediated the values of patients.

**Figure 3.** Patient using VR rehabilitation for long COVID in the physical therapist’s practice.

### *Effects after use of VR*

The effects of the use of VR on patients and physical therapists were grouped into several themes in which facilitators and barriers for use were identified: attitude towards the use of VR, rehabilitation effects, use of VR, and making VR part of daily practice.

*Attitude towards the use of VR*. All but one patient were positive about the use of VR. Patient 14 (female, 53 years old) described this by the words: ‘I can only say, it is an awesome device! […] Yes, it is a great invention!’ One patient did not see the added value of VR rehabilitation and only finished the six weeks of VR use for study purposes. All physical therapists had positive experiences regarding the use of VR. Major facilitators were patients’ enjoyment and motivation to use VR. Physical therapist 1 (female, 55 years old) explained what most patients and other physical therapists acknowledged: ‘It is so much more fun to practice VR than doing traditional exercises on paper’. After six weeks of use, most patients expressed a desire for more content and more competition in the games.

*Rehabilitation effects*. Most patients believed VR to provide added benefits compared to regular physical therapy. Of 20 patients, 13 expressed to experience improvements in physical rehabilitation due to VR, 12 indicated to successfully use VR as a relaxation tool, 11 believed VR to have accelerated cognitive rehabilitation, and seven successfully used VR as a means to do breathing exercises. Physical therapists had similar experiences; all considered VR to provide added value, mostly with regard to physical and cognitive training.

*Use of VR*. Physical therapists indicated that not all patients were eligible to participate in the study. Frequent reasons to exclude patients were adverse effects related to VR use. The inability to handle all stimuli of VR resulting in dizziness and nausea was regularly reported. Other reasons for not offering VR included epilepsy, bacterial infection, visual impairment, anxiety, claustrophobia, and Attention Deficit Hyperactivity Disorder (ADHD). Patients acknowledged that adverse effects were a barrier to use. Half of them experienced either fatigue, disbalance, or headache resulting from VR. For one-third of physical therapists older age of patients was a reason for not offering VR. Contrary, none of the (older) patients considered themselves to be too old for the technology. Conversely, three physical therapists indicated that young people were not the ideal target group. This is illustrated by physical therapist 10 (female, 26 years old): ‘My experience so far is that patients aged 15–30 cannot be encouraged to use VR. They consider it boring. Especially young men, gamers'. The physical therapists concluded that the patient population aged 30–65 is the ideal age group for implementing VR.

*Making VR part of daily practice*. Most patients used the VR headset four to five days a week, 30 min a day. The majority used VR solely at home, five also practised VR at the physical therapist's practice. What games were played mostly, depended on the rehabilitation needs. Daily schedule and feelings greatly affected the patient's willingness and ability to practice VR and make it a daily routine. Ten of 15 physical therapists expressed a desire to continue using VR as part of their rehabilitation programmes, of which 5 already had purchased VR headsets. Physical therapist 3 (female, 35 years old) described that frequent VR usage would change her job: 'Patients will experience increased autonomy, so instead of caring, I will be more coaching'. Several barriers were identified that currently withhold physical therapists from upscaling VR usage. These included flaws in game design, lack of knowledge and evidence on how to implement VR integral to rehabilitation, no business model available, and lack of time to provide logistical support (for example, distributing and disinfecting headsets).

### Values after use of VR

Results of the interviews held with patients after using VR led to a novel value framework for patients in the context of VR use. We describe how the values of self-identity, safety, and autonomy get meaning in the context of VR use.

*Self-identity*. Four of 20 participants indicated that VR taught them to take better care of their health. These patients consciously took moments for relaxation (for example, through virtual meditation) and set boundaries to prevent physical overload. Doing the VR rehabilitation exercises provided five participants with a better understanding of their own rehabilitation needs. Experiencing progress in the games (being able to choose a higher game level every week) felt motivating and affirmed that the participants were progressing in their health. Patient 18 (female, 56 years old) described how this improved her body image: 'It provides me with some satisfaction. That you now notice that your brain is not so damaged. It creates trust. I now foresee that I will be able to recover and return to my old normal'. A desire was expressed to obtain better insight into game scores for even better health tracking.

*Safety*. Being immersed created feelings of unsafety for some participants. Four disliked the full immersion of VR. Half of the patients were scared to fall while experiencing disbalance during mobility exercises. The immersion and motivational elements in the games fully distracted two patients from their fear and tiredness to mobilise. They expressed astonishment that they were able to exercise beyond what they considered possible. Contrary, the same immersion resulted for some patients in training sessions that lasted longer than what may be right to prevent physical overload. Patient 6 (male, 69 years old) described this: 'I just continued. I shouldn't. It made me so, só tired! But when you're doing these games, you just don't notice that you feel so excessively tired'.

*Autonomy*. VR improved patients' experience of autonomy in rehabilitation. Ability to decide when and where to use VR was regularly praised. Also valued was the ability to choose an appropriate level of rehabilitation, choose games of preference, being able to successfully execute rehabilitation exercises guided by the visualisation of VR, and the ability to better take control over own health. Patient 18 (female, 56 years old) described: ‘Yes, I could control this. I lost control over my job, my house, everything. But this is something I can do; I can play’. Improvements in the value of autonomy through VR could be achieved even more when VR would have been easier to use. Numerous technical problems were mentioned, including malfunctioning controllers, failures to connect to wi-fi, updates, forgotten passwords, and malfunctioning games.

## Options for action

The 20 patients and 15 physical therapists provided rich insights into the optimal design and implementation of a VR rehabilitation solution. Recommendations are generated for overcoming identified negative effects and related barriers. Other recommendations are derived from the comparison between the baseline value framework of stage 1 with the value framework as mediated by VR in stage 2. Negative value mediation exerted by VR is translated into recommendations for better value mediation. Values that were not mediated by VR, but which were experienced negatively by patients in their baseline value framework, provided design inspiration. We discuss recommendations for design, context, and user.

### Recommendations for design

This set of recommendations refers to changing the design requirements of the VR toolkit.

*Effects*. The content and difficulty levels of the toolkit should be enlarged depending on the length of the use period. The experienced disbalance mostly occurred in the same set of games (in videos from a bird’s eye perspective). We recommend removing these games and focusing on game design for the reduction of adverse effects, for which recommendations already exist (Barrett 2004). For optimal user engagement and effectiveness, the games must be optimally designed. Flaws in design might reduce the willingness to use, which could negatively affect the efficacy results in studies (Blandford et al. 2018).

*Self-identity*. VR positively mediated self-identity, which corresponds with previous studies on VR usage for better self-identity (Pimentel and Kalyanaraman 2020; Irvine et al. 2020; Matamala-Gomez et al. 2019). We identified an opportunity for even better mediation. For example, more than half of all patients expressed the desire to perceive how much progress they had made during the six weeks of VR use. We recommend including insights into the rehabilitation process in the game design (for example, through an overview of scores and VR use over time) and using motivating and encouraging design techniques for achieving a positive body image.

*Safety*. As VR can be used at home, it reduces the need for patients to go out and thereby the fear of reinfection. At the same time, it did not treat this fear. VR has been used in recent years for anxiety and PTSD (Oing and Prescott 2018; Kothgassner et al. 2019). Our toolkit could be enlarged with games focusing on anxiety rehabilitation. With regard to the games offered, we identified a clear risk for physical overload when practising too long in the virtual world. This so-called ‘time compression’ is a common effect of VR (Mullen and Davidenko 2021) and could be prevented by showing the time in VR and setting a time limit on VR games. Subsequently, we recommend studying the use of fitness trackers in combination with VR to alarm when, for example, patient's heart or respiratory rate exceeds an upper threshold.

*Autonomy*. Ease-of-use of VR can be improved by employing user-friendly hardware and software that allows for simple navigation menus. A virtual explanation before the start of each game, and the use of similar control buttons per game, would as well improve ease of use and thereby autonomy for a large group of patients.

### Recommendations for context

In addition to changing the design requirements of the VR toolkit, also changes in the context of implementation facilitate the successful use of VR.

*Effects*. Considering the input of physical therapists, we recommend broadening the set of exclusion criteria for offering VR with claustrophobia and ADHD. Fatigue and inability to process stimuli are common symptoms of long COVID (Smith 2021), which result several times in the inability to use VR. Therefore, each physical therapist should assess patients' abilities before VR use to reduce side effects. This might also result in not offering VR to patients when it is considered too harmful. Further, whereas physical therapists deliberately excluded older patients from VR use, the efficacy of VR might actually be even higher in elderly (Lier et al. 2018). We, therefore, recommend not to exclude patients in advance due to older age. At the end of the study, patients and physical therapist practices had to buy headsets themselves when they desired to continue using VR. Costs were considered high. While one patient tried to get her headset reimbursed by her healthcare insurance company, her request was rejected as VR care was not part of insured care and was not considered an evidence-based practice. Ideally, VR rehabilitation would be covered by insurance companies to broaden accessibility for everyone in need of rehabilitation.

A final major barrier experienced by physical therapists referred to the lack of resources to provide logistical support for VR use. In the current study, supportive services were provided by researchers; VR headsets were cleaned and charged and provided for free to physical therapists and patients. Educational sessions were also provided by the research team. A 24/7 support line was available where researchers provided support to patients and physical therapists that experienced technical problems. In upscaling VR rehabilitation outside the study context, physical therapists indicated not to be able to provide this support themselves. A VR service and support centre could be established to take over this responsibility.

*Self-identity*. We recommend creating an infrastructure for physical therapists to obtain insight into the VR usage data of patients. All therapists indicated that this would support them in follow-up and shared decision-making on the rehabilitation programme. Most patients considered such service beneficial for their treatment. Two considered this as an intrusion of privacy.

*Safety*. To improve safety in use, physical therapists should observe patients before they offer them VR. The therapist should not only study the risk of dizziness but should also examine patient's balance and behaviour in the games. Consequently, the physical therapists should provide careful instructions to a patient on the ability to do the exercises sitting on a chair to reduce disbalance, the importance of safeguarding physical limits to prevent physical overload, and create a strict treatment plan on maximum use of VR depending on the physical needs and limits of the patient. Also, the use of a vital sign sensor in the physical therapist's practice during the first time that patients use VR would benefit the safety of patients.

*Autonomy*. Although VR allows for autonomous rehabilitation, patients expressed the desire to receive support for optimal use of VR as part of rehabilitation. They, for example, wondered how often to use VR, which games to play, and which play level best suited their needs. In the study, multiple patients considered the support obtained from physical therapists too little. Physical therapists would, ideally, closely coach and educate patients from a distance so that patients can autonomously and responsibly practise.

### *Recommendations for user*

Finally, the behaviour of patients and physical therapists can be addressed to responsibly and successfully implement VR.

*Effects*. Physical therapists mentioned the barrier of lacking awareness and scientific evidence for implementing VR as part of treatment. Yet, they acknowledged not to be aware of what scientific evidence is available (for example, VR has been used in other rehabilitation domains for physical training (Darekar et al. 2015), cognitive rehabilitation (Maggio et al., “Virtual Reality and Cognitive Rehabilitation,” 2019; Maggio et al., “Virtual Reality in Multiple Sclerosis Rehabilitation,” 2019), and relaxation (Riches et al. 2021)). An intern physical therapist expressed the desire to be educated on the use of VR in physical therapy. At the same time, physical therapist 5 (female, 50 years old) indicated that many of her colleagues did not consider education important: ‘We have a team of 25/26 physical therapists, but only 2 or 3 showed up during a VR demonstration’. To counter the barrier of lacking awareness of VR, physical therapists should be nudged to spend time on getting to know VR, for example, by providing them with paid time for education.

*Safety*. For both patients and physical therapists, the use of VR was a process of trial and error. For example, a physical therapist proposed a rollercoaster game to her patient (accessible in the VR headset but not part of our rehabilitation toolkit), who became nauseous immediately. She quickly learned that some content should not be offered to recovering patients. In line with this experience, several physical therapists discouraged patients to play certain games we offered as part of our toolkit as they experienced these would soon result in adverse effects. These insights show the importance of wisely using VR for better safety and stress how important it is for physical therapists to have tried VR themselves and be educated on the use of VR.

*Social comfort*. Social comfort was expressed as an important value during recovery after SARS-CoV but was rarely mentioned related to VR. To address this value, the patient and physical therapist should agree on an optimal frequency of personal contact to ensure that the patient feels supported. In addition, one physical therapist mentioned VR to facilitate relatives' understanding of patients' needs. Increasing empathy for patients through VR has been evaluated previously (Wijma et al. 2018). As patients expressed a dislike at the start of the study of not being understood, VR might also be deployed here to better empathise with the needs of patients.

## Discussion

Through the case study of VR rehabilitation for long COVID, we aimed to study how the lived experiences of users could responsibly guide the design and assessment of complex technologies. We observed how the interplay between complex technology, user, and context affected user needs and values and translated these insights into recommendations for an optimal technology, context of implementation, and user behaviour. Compared to traditional guidance ethics, our approach provided rich insights into how user experiences and values might change when a complex socio-technical system is introduced and how these experiences even differ per individual. We reflect here on the successes and limitations of the empirical approach to evaluate technological value mediation.

### From value to values

Traditionally, HTAs consider 'value' as the cost-effectiveness of a technology. Decision-making and reimbursement by insurance are commonly solely considering this cost-effectiveness. Consequently, technology does not necessarily need to align with user needs and values when implemented. Our approach focused on individual 'values' as a basis for 'value' creation in the design of technology. There have been previous initiatives aiming to improve values by technology design. Value Sensitive Design (VSD) is one of the most well-known approaches in the field (Friedman 1996). VSD aims to embed values in technology design through empirical research into users and similar technologies. Nonetheless, the approach does not consider that values might change after initial value embodiment, the so-called 'positivist problem' (Albrechtslund 2007). Values are also considered as 'stable entities' within the field of Responsible Research and Innovation (RRI) – in particular within the two primary approaches: RRI by Von Schomberg (2011) and the AIRR framework by Stilgoe, Owen, and Macnaghten (2013)-(Boenink and Kudina 2020). Our anticipatory assessment in practice supports us in studying how values emerge in the interaction between users, technology, and context, and to identifying recommendations for considering value mediation as part of the design. This will eventually result in better uptake of the technology.

Nonetheless, many challenges still exist in designing and assessing user values. First, it remains challenging to prevent bias in value identification. We identified values from coding interviews, including open-ended questions and questions referring to values that we earlier identified as important by studying literature. To improve reliability, interviews were coded twice, and codebooks were compared. Nonetheless, our way of posing questions in the interviews, and the coding process itself may have introduced bias (Aagaard 2017). An alternative to this process would be to let users identify values solely by themselves. It is, however, very challenging for most users to express their experiences in terms of abstract values (Kujala and Nurkka 2009). A form of researcher involvement remains necessary to translate user experiences into values. As long as no ideal methodology has been identified, transparent reporting on value identification is required.

Second, value identification through lived experiences is a very time-consuming process. To this end, we only studied the values of patients. Ideally, also values of physical therapists should be considered to examine if the design of a VR service aligns or conflicts with their value framework. Further, in an ideal situation also, non-users of technology should be studied (Kiran, Oudshoorn, and Verbeek 2015). Even when people cannot or do not want to use technology, they are often influenced by its implications. Studying non-users allows for opening 'the black box' of all (moral) implicit shaping of technology. A distinction should be made between non-users that cannot use technologies and users that do not want to use technologies. In particular, in healthcare, the first group has to be identified and addressed by inclusive, universal, and in some cases, even personalised design. A study of the second group is also of major importance, as reasons for conscious non-use should be addressed in the implementation of healthcare technologies, especially when technology should become part of standard healthcare provision. Extensive assessment, including non-users might not always be realistic given the limited resources. We advise research teams to consciously spend their resources by an initial assessment of whom to include in the study.

## *From a quantitative HTA to a multi-criteria HTA*

The ethical technology assessment (eTA) framework introduced by Palm and Hansson (2006) is a well-known (H)TA framework moving beyond cost-effectiveness only. eTA aims to assess technologies to prevent unintended ethical consequences via an ethical checklist. Albeit a consideration of ethics is valuable, the approach only considers ethics using a quantitative checklist. Without qualitative research, it cannot provide insight into the value mediation exerted by technology (Kiran, Oudshoorn, and Verbeek 2015). When we would have applied the ethical checklist of eTA to our case study, we might also have found safety risks of dizziness and physical overload that should be prevented through recommendations for design and context. Yet, we would not have found opportunities for VR to positively affect self-identity, nor would we have identified the benefits and possibilities of VR for autonomy. Even more, we would only have identified general outcomes and missed the nuances of individual experiences, which are gaining increasing attention in healthcare today (Vlaeyen et al. 2020). Our qualitative approach to studying technology in practice supports the identification of a wide range of outcomes that cannot be identified using a checklist. Also, it endorses not only the prevention of negative outcomes, but also supports a focus on positive value mediation. Finally, the approach facilitates personalisation of the socio-technical solution to individual needs and values.

A drawback of the empirical approach is the discrepancy between user experiences and important values that remain out of users' sight. For example, the value of privacy was never mentioned as an important value by patients and physical therapists. Nonetheless, this value returned several times as an important item of discussion in the research and design team and has often been described as a concern related to VR (see Madary and Metzinger (2016), O'Brolcháin et al. (2016), and Adams et al. (2018)). Concerns relate to in-depth data collection (for example through eye-tracking) of personal virtual habits by the companies developing VR hardware. These concerns have also been expressed related to the company developing the VR headset we made use of (Adams et al. 2018). Solely deriving insights from empirical research might result in missing such important insights. Therefore, we believe that traditional HTA checklists are still required in addition to empirical research. Future research should focus on how to weigh the empirical qualitative outcomes against the traditional quantitative outcomes.

### *From assessment to guidance*

Today, the mechanisms of design and assessment are linear. An assessment generally only begins after finalising the design process. This is remarkable because normative assessments might result in not even desiring a technology for solving a problem while resources are by then already spent on its design. Also, by its traditional focus on quantitative outcomes, an assessment typically focuses on different outcomes than those which were initially designed for (Blandford et al. 2018). This again might result in a waste of resources. Guidance ethics is a promising approach to merging digital health design and assessment by using the evaluation process as a basis for design requirement creation and vice versa. Such a process should typically only start after obtaining a positive normative evaluation of why the technology is necessary.

The approach to guidance ethics in the context we proposed here, is even more suitable for merging design with assessment. In healthcare, it is commonly challenging to involve the right users in the design process (Van Velsen, Wentzel, and Van Gemert-Pijnen 2013) and embedding technology design within current healthcare services and protocols (Shaw et al. 2018). A practice-based guidance ethics approach can support designers to optimally embed user needs and values in technology design.

Traditional HTA is the basis for decision-making, reimbursement, and health policy (Sarri et al. 2021). Combining design and assessment of technology challenges these existing structures. Research is required in the transition management of healthcare institutions to facilitate multidisciplinary collaborations for responsible technology design, assessment, and implementation.

## Conclusion

We argued for the need to add lived experiences of users to HTAs to evaluate the fit between technology and user needs and values. To this end, we adjusted the guidance ethics approach to assessing technological mediation in context. We studied in particular how value change can be assessed and considered in the design of complex technologies. Our approach might be a valuable addition to traditional HTAs to include a wide range of qualitative outcomes next to the traditional focus on cost-effectiveness. Our practice-based approach facilitates technology assessment to move from economic value to user values, to personalise the socio-technical solution to individuals, and to responsibly guide technology design, assessment, and implementation.

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## Data availability statement

Data are available on request from the authors.

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## Appendices

Appendix 1. In- and exclusion criteria COVRehab study

**Inclusion criteria**

(1) Patient has had (symptoms of) SARS-CoV.
(2) Patient has an indication for physical therapy in the context of rehabilitation after SARS-CoV.

(3) At the day of recruitment, the estimated length of the physical therapy is at least 3 weeks after inclusion.
(4) Patient is willing to comply to the study protocol and is able to speak the Dutch language.

**Exclusion criteria**

(1) Patient is participating in another study interfering with this study.
(2) Patient has difficulties to handle VR:
  a Patient suffers from delirium or acute confusional state.
  b Patient has (a history of) dementia, seizure, or epilepsy.
  c Patient has severe hearing/visual impairment not corrected.
  d The skin of the patient's head or face is not intact (for example, head wounds, psoriasis, eczema).
(3) Patient has a high risk of contamination with a therapy-resistant micro-organism, e.g. MRSA.
(4) Patients suffer from severe anxiety or depression (HADS≥16).
(5) Patient meets so-called red flags as drafted by the Royal Dutch Society for Physical Therapy (KNGF 2020).

## Appendix 2. Semi-structured value-oriented interview guidelines

### Interview guideline patients stage 1: case

1. Could you illustrate from begin to end the process of being infected with SARS-CoV?
2. How did you feel during the SARS-CoV infection?
3. What are your current rehabilitation needs?
4. What care do you currently receive for your rehabilitation needs?
5. Were some of your relatives also infected with SARS-CoV?
6. Did SARS-CoV affect how you consider yourself?
7. Did SARS-CoV affect how you consider your health?
8. Did SARS-CoV affect your feelings of safety?
9. Did you receive support of others during your SARS-CoV infection?
10. What do you expect from your rehabilitation?
11. Did you use a VR headset before?
12. What do you expect from using VR?

### Interview guideline patients stage 2: dialogue

1. Can you explain how you have used VR in the past six weeks?
2. What are your experiences related to using VR?
3. Did the VR experience provide you benefits for your rehabilitation?
4. Can you enlist three positive effects of VR for rehabilitation?
5. Can you enlist three negative effects of VR for rehabilitation?
6. Did VR affect your feelings of safety?
7. How did you experience the comfort of the VR headset?
8. Were you able to use the technology without problems?
9. How would you appreciate the design feature of caregivers having insight into your VR usage data?
10. How did you rate using VR at home compared to using VR in the physical therapist's practice?
11. When we would use VR in the future as a means to rehabilitate, how would it look?
12. Would you like to continue using VR in the next weeks?
13. Would you like using VR in the future for rehabilitation needs?
14. Would you recommend VR to others?
15. Whom is the ideal target group for VR rehabilitation?

16. Do you have any other comments?

**Interview guideline physical therapists stage 2: dialogue**

1. How many patients did you support in the use of VR for this study?
2. Did you also screen patients that did not want or could participate in the study?
3. How did patients experience the use of VR?
4. Do you think that VR provided patients with added benefit for their rehabilitation?
5. Does VR provide an added benefit compared to normal physical therapy?
6. What is the mechanism that makes VR work?
7. What modules (mental, physical, cognitive) work best for what type of patient?
8. Is there a specific patient group that seems to benefit less from VR?
9. Was this the first time you have used VR in your practice?
10. What is your opinion on using VR?
11. What did you think about the offered VR content?
12. How did you experience applying VR as part of your physical therapy?
13. How did you support patients in VR use?
14. What barriers did you encounter in using VR?
15. Does VR change your daily work?
16. Would you like to continue using VR as part of your daily practice?
17. Can you describe the ideal VR rehabilitation program?
18. How many support did patients need in using VR?
19. How should a future VR rehabilitation as part of physical therapy look?
20. Would you like to be able to monitor vital signs of patients (at practice and at home)?
21. Would you like to be able to obtain insight into VR usage data of patients via a dashboard?