Human-centered design strategies for device selection in mHealth programs: A review of evidence and novel framework

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Abstract

Despite growing use of remote measurement technologies (RMT) such as wearables or biosensors in healthcare programs, challenges associated with selecting and implementing technologies in these programs persist. Many healthcare programs that use RMT rely on commercially available, 'off-the-shelf' devices to collect patient data. However, validation of these devices is sparse, the landscape is constantly changing, and relative benefits between different device options are often unclear. Further, research on patient and healthcare provider preferences is often lacking. To address these and other common challenges with device selection, we aimed to identify and synthesize existing methods or best practices. A review of published literature and industry guidance confirmed that few relevant best practices exist. Therefore, we proposed a novel device selection framework extrapolated from human-centric design principles commonly used in de-novo digital health product design. The framework describes a three-stage approach to device selection based on stakeholder engagement, iterative design, and rapid learning. We then used the framework to successfully identify, test, select, and implement off-the-shelf devices for RADAR-CNS (Remote Assessment of Disease and Relapse – Central Nervous System), a collaborative research program using RMT to study central nervous system disease progression. The RADAR Device Selection Framework provides a structured yet flexible approach to device selection for healthcare programs and can be used to systematically approach complex decisions that require teams to consider patient experiences alongside scientific priorities and logistical, technical or regulatory constraints.

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Abstract

Despite growing use of remote measurement technologies (RMT) such as wearables or biosensors in healthcare programs, challenges associated with selecting and implementing technologies in these programs persist. Many healthcare programs that use RMT rely on commercially available, 'off-the-shelf' devices to collect patient data. However, validation of these devices is sparse, the landscape is constantly changing, and relative benefits between different device options are often unclear. Further, research on patient and healthcare provider preferences is often lacking. To address these and other common challenges with device selection, we aimed to identify and synthesize existing methods or best practices. A review of published literature and industry guidance confirmed that few relevant best practices exist. Therefore, we proposed a novel device selection framework extrapolated from human-centric design principles commonly used in de-novo digital health product design. The framework describes a three-stage approach to device selection based on stakeholder engagement, iterative design, and rapid learning. We then used the framework to successfully identify, test, select, and implement off-the-shelf devices for RADAR-CNS (Remote Assessment of Disease and Relapse – Central Nervous System), a collaborative research program using RMT to study central nervous system disease progression. The RADAR Device Selection Framework provides a structured yet flexible approach to device selection for healthcare programs and can be used to systematically approach complex decisions that require teams to consider patient experiences alongside scientific priorities and logistical, technical or regulatory constraints.

Keywords

human-centric design, design thinking, patient centricity, device selection, technology selection, remote patient monitoring, remote measurement technologies, wearables

Introduction

When used as part of healthcare programs, remote measurement technologies (RMT) such as wearables or biosensors have the potential to affect clinical decision-making, provide novel health insights, and improve the standard of care in a variety of disease areas [1–4]. RMT is a subset of mobile health (mHealth) technologies which includes "any technology that enables monitoring of a person's health status through a remote interface, which can then be transmitted to a healthcare provider" for review or as a means of education for the user themselves [5]. Though use of RMT in healthcare programs has grown in recent years [1,2,6,7], its impact on health outcomes does not always live up to its supposed potential [1,7,8].

Successful utilization of RMT depends on careful consideration of the program's scientific, technical and usability requirements. However, many programs employ commercially available, "off-the-shelf" devices which cannot be customized according to these requirements. In such cases, program designers are challenged to select devices from hundreds of options [9] in a marketplace where validation is sparse [1,7,8], product turnover is high [10], and relative benefits between device options are often unclear. Comparative studies show either limited accuracy or low to moderate agreement between similar, widely-used devices for common measurements such as activity levels [11–14], sleep [14–16], heart rate [12,17,18], and energy expenditure [14,16,19]. Few industry-wide data standards are established [6,9,20], so different devices may define and report measurements in ways that are not directly comparable [13]. Additionally, the experiences of potential users – including patients, caregivers, and healthcare professionals – affect the usage of RMT heavily [21–23], but these insights are often not collected or transformed into technology requirements [24]. Unfortunately, RMT that does not cater to user needs can increase patient, caregiver, and healthcare provider burden in otherwise promising healthcare programs [6,7,49] and may negatively impact

enrollment and retention [25].

Those designing healthcare programs often struggle to navigate device selection due to the technology landscape's complexity and potential tensions between device selection criteria [4,20,26]. To date, few best practices exist to guide those selecting of off-the-shelf devices. This is problematic, as device-related factors have the potential to limit the success, reproducibility, or scalability of otherwise promising healthcare programs. Here, we review the limited landscape of published methods and recommendations for device selection. We then propose a framework that uses human-centered design principles to guide device selection. Finally, we demonstrate the use of this framework in a research program using RMT to identify relapse in Multiple Sclerosis (MS).

Existing Methods & Frameworks

We reviewed existing literature to identify published device selection methods and best practices using combinations of search terms such as 'mHealth,' 'digital health,' 'remote patient monitoring,' 'device selection,' 'design,' 'method,' and 'framework' in PubMed and EMBASE. Guidance for industry by relevant bodies such as regulatory agencies, the Clinical Trial Transformation Initiative (CTTI) [27], TransCelerate [28], Critical Path [29], and others were also reviewed. This search yielded two types of frameworks: those that addressed device selection specifically and those that described methods for overall healthcare solution design. Because few published frameworks were identified, we also reviewed individual studies for reported device selection methods by identifying publications referenced in recent systematic reviews. At the time of our search, two reviews provided an up-to-date list of high-quality studies that met our desired search criteria (a systematic review by Vegesna et al. (2017) [7] and meta-analysis by Noah et al. (2018) [1]), though they did not assess the studies' device selection methods. Therefore, we built on their previous work with an assessment of device selection methods.

Device Selection Methods & Frameworks

Only two frameworks designed to guide device selection were identified. The "Framework of Specifications to Consider During Mobile Technology Selection" developed by the Clinical Trial Transformation Initiative consisted of a list of factors to consider when selecting RMT, including technical performance, data management, safety, human factors, and others [30]. However, it did not provide a method by which to apply or prioritize these factors. The Digital Health Selection Framework by the Institute for Healthcare Improvement [31] described a computational method for assessing the technology landscape based on high-level selection criteria. However, this framework aimed to support the development of healthcare policy, and methods did not support the identification and ranking of sufficiently detailed requirements for use in individual program design. Further, it described a rigid, linear process without critical evaluation of device selection criteria or stakeholder engagement, rather relying on previously published evidence, which is often limited.

Additional publications provided high-level commentary on device selection and suggested that designers should consider technical requirements, user experience, data quality, safety, privacy, regulations, validation, complexity, adaptability, compatibility with existing systems and practices, and cost when choosing technologies. [26,30–32] Such publications also discussed the need to set detailed objectives [26,30,33] and gather requirements from a diverse set of stakeholders. [24,30,33] However, no publication described actionable methods for systematically gathering, prioritizing, and weighing device selection criteria within the context of the program's users, environment, and goals.

Methods reported in Individual Studies

Similarly, few individual studies reported device selection methods or considerations. Recent systematic reviews by Vegesna et al. (2017) [7] and Noah et al. (2018) [1] identified 54 unique clinical validation studies of healthcare programs that used RMT. Of the 46 programs for which full-

text manuscripts were accessible, 44 used at least one commercially-available device including blood pressure monitors, ambulatory electrocardiograms, physical activity trackers, and others. Of these, only one study provided commentary on the considerations that led to the selection of their device over others [34,35], and seven studies did not report which commercial device was used [36–42]. None provided detailed device selection criteria or methods that could be applied to other research programs. This analysis and a full list of references is described in greater detail in Multimedia Appendix 1.

Human-Centered Design Frameworks

Though not directly related to device selection, seven additional frameworks applied human-centered design (HCD) methods to novel program or product design and validation [4,10,43–48]. HCD is a series of methods through which designers study a product's users' needs and environment and then design accordingly [49,50]. Designers engage or 'empathize' with potential users then generate ideas, develop prototypes, and test those prototypes with the people for whom they are designing [49,50]. Designers alternate between divergent and convergent thinking, first looking broadly to understand context and possible solutions, and then converging onto a final problem statement, approach, or solution [49,51]. Many methods also employ Agile or Lean principles which use rapid prototyping, feedback loops, and learning cycles to drive an iterative design and implementation process [49,52]. These methods allow designers to develop a deep understanding of the contextual factors that affect design, making them well-suited to support product design in complex, ambiguous, and rapidly-changing environments. The merits of HCD in healthcare program design have been discussed at length elsewhere [24,44], though such methods are largely applied to de-novo design, rather than technology selection.

Identified frameworks focused on a variety of topics, including behavioral intervention design [43], implementation of patient-facing technology in interventional clinical trials [33], mHealth solution development and validation [10,44,45,53], stakeholder engagement [47], and requirements development [54]. Though these frameworks were inconsistent in their language, they employed a set of common steps and recommendations to inform design of digital solutions within the context of the healthcare system which may be applicable to device design (Table 1).

All frameworks applied HCD methods to address design challenges like those that complicate device selection, such as understanding complicated contextual factors [33,43,45,53,54], engaging multi-functional stakeholders [47], and addressing diverse stakeholder needs [54]. However, each did so within the context of novel product design and none explicitly described methods for selecting the off-the-shelf devices that digital healthcare interventions often require. Though no framework was directly applicable to device selection, the described methods were grounded in relevant design theory [49,51,52,55] and had the potential to address device common selection challenges.

Table 1: Human-Centered Design principles recommended in mHealth solution design

Human-Centered Design Technique or Strategy	Technique Referenced By
Assemble a multidisciplinary team	[33,43,44,54]
Iterate throughout the design process	[10,33,43–45,47,53,54]
Begin by conducting stakeholder engagement activities to understand user needs and context of use.	[33,43–45,47,53,54]
Conduct ideation sessions in which a variety of approaches and potential solutions are explored	[10,33,43,45,53]
Enable a variety of stakeholders, including patients, healthcare professionals, technical experts, and others, to participate in the design process	[33,43–45,47,53]
Prioritize identified requirements and resolve conflicting requirements through further engagement with team members and stakeholders	[54]
Prototype and test with end users prior to scaled implementation	[10,33,43–45,53,54]
Consider the implementation strategy early and refine it during the design process	[33,43,44]
Measure the solution's impact and/or efficacy	[10,33,43,44,54]
Share both positive and negative lessons learned with relevant stakeholders to improve current and future designs	[33,43]

RADAR Device Selection Framework

Considering the limited guidance in published literature, we now share the device selection method used in the RADAR-CNS (Remote Assessment of Disease and Relapse – Central Nervous System) project, a collaborative research program using RMT to study central nervous system disease progression. This framework is based primarily on HCD techniques and was developed based on the authors' previous experience with HCD in medical technology design. We hypothesized that HCD methods could help design teams manage the complexity inherent to device selection. Therefore, the three-stage RADAR-CNS Device Selection Framework (Figure 1) uses HCD techniques to explore the technology landscape, refine device requirements, develop an implementation strategy, and make informed decisions in parallel with program design and implementation.

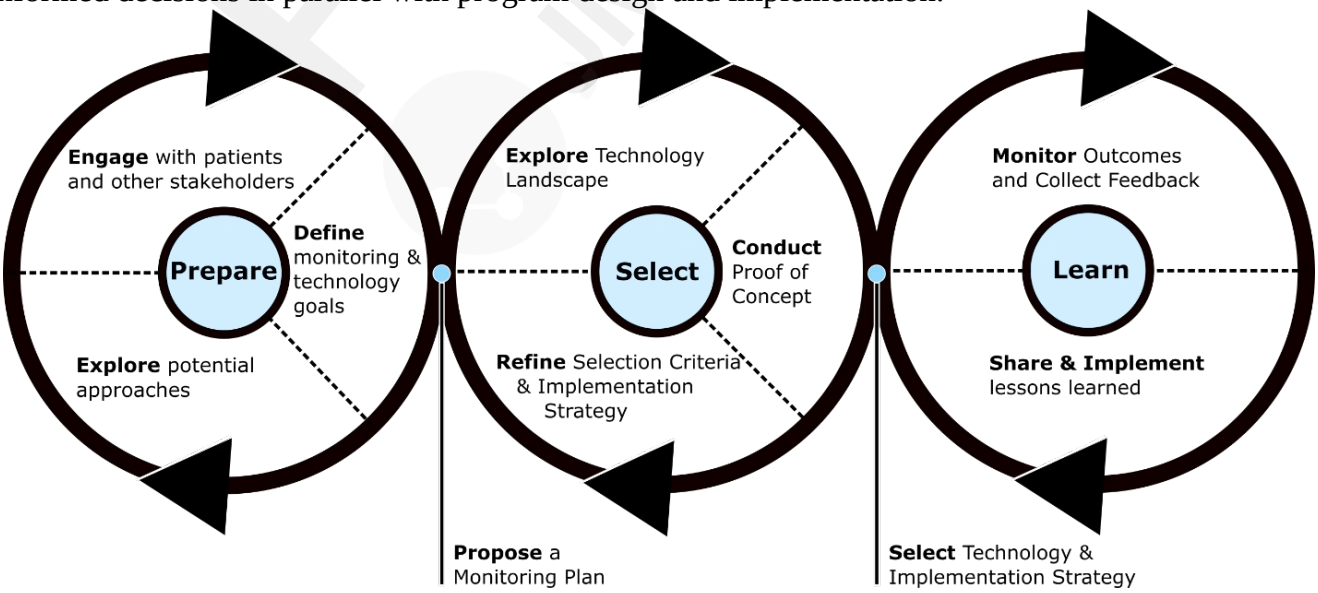

Figure 1 – RADAR Device Selection Framework

Stage 1: Prepare

In this stage, the team studies contextual and user-related factors that may affect device use and implementation. The goals of the program, motivations and experiences of patients, involvement of caregivers, and symptoms or sensitivities related to the target disease area will define how user-friendly, discreet, configurable, or multi-functional a device must be. These activities are analogous to the empathize, define, and ideate steps of the Design Thinking process [56], and similar steps have been proposed in other frameworks [43,57]. Here, we highlight relevant device-related insights that can be collected through HCD methods early in the program planning process.

Engage with patients and other stakeholders

Simblett et al. (2018) described five categories of facilitators and barriers that influence patient engagement with RMT: health status, usability, convenience and accessibility, perceived utility, and motivation [22]. During the preparation stage, the device selection team engages with patients and other stakeholders to explore these factors, identify user needs, and draft technology requirements. These activities can be conducted alongside other engagement activities designed to inform program goals or design. Methods for engaging with these and other relevant stakeholders have been proposed, including co-design sessions, focus groups, interviews, workshops, and surveys [56,58–61]. Integrated patient advisory boards can also guide discussions and decisions throughout the device selection process.

Though published literature on research priorities and usability requirements may provide general insights into patient perspectives in a variety of disease areas [22,24,62], primary research with the program's target population is critical [4,24]. RMT can increase the burden associated with giving and receiving care [4,9,63], which must be minimized to enable sustained program adoption. Direct engagement with potential users provides the nuanced insights that are necessary to minimize burden and increase the chances of program success. While patients may be the primary users of the technology, caregivers and healthcare professionals and others should also be engaged, as they affect patients' willingness and motivation to engage with RMT [22].

Explore Potential Approaches

The team then explores different approaches for measuring health status. Options should reflect scientific and clinical goals as well as patients' priorities. The team should propose potential 'measurement schemes' which list relevant variables or outcomes, surrogate measurements, data streams, required sensors, and desired frequency of measurements. In this stage, it is helpful to use good brainstorming technique such as that described in IDEO's Design Thinking Bootleg [56] to generate a variety of options and encourage creativity by limiting discussion of potential constraints. The team should define potential program goals, endpoints, and measurement schemes before exploring technology options and implementation strategies [20,26,33]. Delaying discussion of specific technology options forces the team to frame device selection around program and user needs, thereby preventing the design of a program around a familiar but ill-suited technology.

Define Measurement & Technology Goals

Based on the outcomes of the engagement and brainstorming activities, the team should converge on one or more promising measurement schemes and clearly define goals for the RMT. Only once these are defined should the team draft selection criteria. The team should clearly state what compromises they are and are not willing to make, as these choices will drive final device selection. Examples of relevant device selection criteria have been published elsewhere [26,30,31].

Milestone 1: Propose a Monitoring Plan

By the end of this stage, the team should have developed 1) a robust understanding of stakeholder needs and priorities, 2) a well-defined program goal, 3) one or more potential measurement schemes, and 4) a preliminary understanding of the technology landscape and technology selection criteria. The activities that led to this preliminary plan will provide necessary context to support device selection decisions, especially when no device meets all criteria and concessions must be made. To achieve this level of clarity, the team may need to conduct multiple iterations of the 'Prepare' stage. For example, the team may need to re-engage stakeholders to confirm the acceptability of a measurement scheme and then adjust the scheme in subsequent brainstorming activities.

Stage 2: Select

In this stage, the team progresses iteratively through a series of activities to identify a suitable device and refine an implementation strategy. With each iteration, the team should identify and answer outstanding questions, refine their thinking, and add detail to their proposed implementation plan. The team should first think broadly before refining the measurement scheme and implementation plan to reflect the program's constraints. This approach allows the team to explore multiple approaches efficiently and to pursue creative options for getting as close to an 'ideal' solution as possible.

Explore Technology Landscape

First, the team performs an initial technology landscape assessment and compiles a list of potentially suitable technologies. Devices should then be systematically excluded from this list based on user feedback and updates to the selection criteria or measurement scheme. When appropriate, additional options should be added to reflect updates to the selection criteria and implementation strategy. A 'short list' of candidates should be defined based on the team's selection criteria.

Refine Selection Criteria & Implementation Strategy

Based on identified technology options and insights from user engagement, the team should begin to define how the technology will be implemented. Necessary connections to IT systems, device provisioning, training, frequency of device usage, compliance monitoring, and data syncing methods, etc., should be considered. While this strategy may change over time, considering these factors early in the selection process will help the team understand potential infrastructure or logistical constraints which could impact device selection. Lack of such strategic planning has been shown to hinder successful implementation of RMT [32].

Off-the-shelf devices may not fit the initial measurement scheme and selection criteria perfectly. Iterative refinement of the selection criteria, measurement scheme, implementation strategy and technology landscape will help the team explore creative alternatives, make minor concessions, and identify a small group of candidate technologies that meet most criteria.

Conduct Proof of Concept

Throughout this process, additional questions about candidate devices' characteristics and relative advantages are likely to emerge. In the Proof of Concept (PoC) phase, the team should conduct targeted tests to answer these questions. PoCs are targeted device assessments that can be conducted quickly prior to implementation in a clinical study which enable rapid learning and decision-making during the technology selection process [4,33]. PoCs can test technical characteristics (e.g., bench testing for data quality, connectivity, durability), assess user experience in the target population (e.g., usability studies), compare candidate devices, or test aspects of a technology's implementation strategy (e.g., 'dry runs' to test training protocols and technology support systems) [33]. The results of any PoC should be actionable, either in a technology selection decision or to influence refinement of the implementation strategy.

Milestone 2: Select Technology & Implementation Strategy

By the end of this stage, the team should have narrowed the landscape to a few well-defined technology options, though each is likely to require compromise. To weigh these options, the team should use a systematic method to compare candidate devices and their required compromises. The team should facilitate multi-functional conversations to develop understanding of the required compromises and consensus on a final decision. The team should also finalize an implementation strategy, validating it through proof of concept testing and additional user feedback as necessary.

Stage 3: Learn

Monitor Outcomes & Collect feedback

The team should devise mechanisms to collect feedback, experiential data, opportunities for improvement, and learning opportunities from active programs, and these mechanisms should be included in research protocols if appropriate. Validated questionnaires such as the Post-Study System Usability Questionnaire (PSSUQ) [64] or the Technology Assessment Model (TAM) [65] are widely used, and additional quantitative metrics such as device usage or help desk engagement rates may also provide insights. Qualitative interviews with patients and healthcare professionals can identify specific opportunities to improve the implementation strategy, training materials and methods, technology, or technology support systems.

Share & Implement Lessons Learned

The design and learning processes should not stop when the program is launched [32]. Quantitative, qualitative, and experiential data collected during all three stages of the framework should be used to continually refine the implementation strategy to ensure efficacy, efficiency, user engagement, ease of use, and clinical utility. In the case of a clinical study where continuous adjustments to the implementation strategy may jeopardize a program's scientific aims, feasibility studies or clinical process evaluations may be used to test and refine the implementation strategy [4,20,66]. Sometimes, devices or technologies selected for an investigational system may not be practical for use in scaled clinical practice. In this case, appropriate technologies should be selected or designed to fit the system requirements that were collected during investigational implementation. Both positive and negative findings should be shared to inform technology selection decisions in future programs.

Case Study: RADAR-CNS

RADAR-CNS is a public-private research program leveraging RMT to develop new ways of assessing disease progression in depression, epilepsy, and MS [67]. While the RADAR Device Selection framework was used to select devices for several RADAR-CNS studies, only its use in a study of MS disease progression is described here. In this two-year study, wearable devices and a custom application collect longitudinal health-related data from people with relapsing-remitting MS. The aim is to develop algorithms that can predict relapse and improve patient care. Details of the study's full protocol are outside the scope of this publication, and only device selection procedures are described here.

RADAR-CNS: Prepare

A cross-functional team of clinicians, researchers, and technical experts was established, and RADAR-CNS' patient advisory board [68] was also regularly consulted. First, we worked with people living with MS to understand their perspectives on research priorities, usability requirements, desired device features, and factors influencing sustained engagement with RMT. We conducted a

systematic literature review to identify relevant discussion topics [22] and initiated a series of surveys and semi-structured focus groups with people living with MS to identify factors affecting engagement with RMT [69]. Participants provided feedback on preferred device features and engagement schemes as well as perspectives on value and privacy. Much of this work has been published previously [69–71]. Participants emphasized the importance accommodating MS symptoms, making the system easily usable, and enabling users to exert control within the RPM system [69].

We then explored areas of scientific research priority, including cognition, mood, physical activity, sleep, social interactions, speech, and stress. We identified variables that aligned with patient and scientific research priorities, discussed potential measurement schemes, and began to research technological options (e.g., data streams, sensors, active tasks, analytical methods, etc.). We also began to discuss a variety of technical, user experience, regulatory, and other considerations relevant to the research program. These are described in Multimedia Appendix 2.

Milestone 1: Propose a Monitoring Plan

We prioritized the identified variables based on clinical utility, technological feasibility, alignment with patient priorities, and ethical considerations to select a final measurement scheme for the biosensors (Table 2). Additional clinical, traditional, and mobile data collection methods were also selected, but are outside the scope of this case study. Based on this scheme and patient insights, we defined a preliminary list of required and desired device selection criteria, their relative priorities, and opportunities for compromise. Briefly, criteria described desired technical capabilities, data quality, user experience, regulatory status, privacy, required investment, and vendor characteristics. Opportunities for compromise included conditions under which multiple devices could be used, acceptable concessions described by patients, and acceptable trade-offs to meet study budget (e.g., willingness to develop bespoke software if device costs are reduced). A summary of these criteria is available in Multimedia Appendix 2.

Table 2 –Device-based remote measurement scheme for the RADAR-CNS MS Study

Factor	Measurement	Measurement Frequency
Gait	Measured via accelerometer and gyroscope during a 2 Minute Walk Test, Tandem Walk Test, and normal daily activities	Clinical Tests: Once every 3 months Home Tests: Once every 3 months Free Living: One week every 3 months
Balance	Measured via accelerometer placed on the chest during Romberg's Test and normal daily activities	
Fatigue	Measured via heart rate variability and accelerometer during a 2 Minute Walk Test and normal daily activities	
Heart Rate & Heart Rate Variability	Measured via one-lead electrocardiogram placed on chest during tests and normal daily activities	
	Measured via photoplethysmography	Daily over the course of the study
Sleep	Total sleep time and sleep patterns monitored via actigraphy or other mechanism	
Daily Activity	Measured via actigraphy	

RADAR-CNS: Select

We then identified relevant commercially-available consumer and research-grade devices. As no published database contained up-to-date information on available RMT, we conducted an online

search and a literature search to identify devices that contained some or all of the sensors in the desired measurement scheme. This search yielded over 100 devices of various embodiments. Devices were systematically excluded through an iterative review process with clinical, analytical, and technical experts, during which potential technologies, priorities, and protocol adjustments were discussed. Though no single technology fulfilled all selection criteria, several devices that fulfilled *most* criteria were selected for further consideration either as stand-alone devices or for use in conjunction with other devices. These included the Fitbit Charge 2 (Fitbit, Inc., San Francisco, CA, United States), the Withings Steel HR (Withings, Issy-les-Moulineaux, France), the Actigraph Link (ActiGraph LLC, Pensacola, FL, United States), the Suunto Movesense sensor (Suunto Oy, Vantaa, Finland), the eMotion Faros 180 (Biomation, Ottawa, Canada), and the MetaMotion R (MBIENTLAB Inc, San Francisco, CA, United States).

Proof of Concept Testing

Questions regarding usability, data quality, and technical characteristics of the devices arose, prompting appropriate PoC testing of usability, technical features, and training procedures. Here, we describe two examples of these PoC tests and their impacts on technology selection.

Example - User Experience PoC

Because participants could be enrolled for up to two years, sustained patient engagement with the devices was critical to the study's success. The patient advisory board participated in a workshop to provide feedback on candidate devices. Board members, including two members living with MS (authors JW and PB), interacted with each device and provided feedback on user-friendliness, technology preferences, potential impacts of MS symptoms on use, and suggestions for the implementation strategy. This feedback provided us with important context for prioritizing desired device characteristics. The board preferred adhesive patches over chest straps to affix chest-based devices and wrist-based wearables with a subtle or mainstream appearance. They also noted that any goals or feedback shown by the devices (e.g., daily activity counts) should be customizable. They voiced concern that displaying unrealistic goals could negatively impact participants' motivation to engage with RMT or participate in the study, as people living with MS will almost certainly observe a decline in function over time.

Example - Technical PoC

Following a brainstorming session, the team decided to explore the option of sourcing sensors from an original equipment manufacturer. These devices would be less expensive and more customizable but required additional validation and configuration compared to other options. For commercial reasons, the identities of these devices are not shared. Data were collected from two devices to understand data structure, battery life, reliability of the Bluetooth connection, potential for data loss, data transfer requirements (time, file size, memory availability), and device durability. While the devices' published specifications met requirements, testing demonstrated that neither device met study requirements. The first device's data files were too large to sync more than a few hours of data over a Bluetooth connection, though the study required devices to sync data over Bluetooth outside the clinic. The second device did not meet battery life or data quality requirements in the desired configuration. Similarly, we tested other candidate devices to address the risks identified by the advisory board and the study teams.

In response to this PoC, we adjusted our technology landscape to include more expensive devices since the tested devices were the only two to meet original budget requirements. To accommodate this change, we also adjusted the implementation strategy to include logistics associated with device returns and re-provisioning, thereby reducing the number of required devices and reducing per-patient device cost. While this PoC did not yield positive results, it allowed the team to make data-informed decisions on device candidates without compromising timelines or posing risk to the study.

Milestone 2: Select Technology & Implementation Strategy

Ultimately, we selected two devices to conduct all desired measurements. The eMotion Faros 180 was selected to monitor cardiac activity, gait, and balance during home-based active tasks and normal daily activities. The Fitbit Charge 2 was selected to monitor daily activity and sleep based on its superior user experience, battery life, and precedence of Fitbit devices in MS programs [72–74], despite its inability to provide raw accelerometer data. Since no device containing an electrocardiogram, accelerometer, and gyroscope met the necessary criteria, data from the gyroscope sensor in participants' cell phones was collected to identify turns during the 2 Minute Walk Test. A discussion guide used by the team to facilitate the final selection of the wrist-based device is included in Multimedia Appendix 3.

RADAR-CNS: Learn

The RADAR-CNS study is ongoing at the time of this publication. Surveys and interviews with participants are being conducted periodically throughout the study and device usage rates will be monitored as the study progresses. Feedback will also be collected from investigators who conducted the studies. Insights gained through these interactions will be published at the end of the study and will be used to identify improvements to the measurement scheme, device selection, and implementation strategy before the system is available for use in clinical practice.

Discussion

The RADAR-CNS Device Selection Framework provides methods to assess, prioritize, and adapt device selection criteria for healthcare programs according to stakeholder needs. While the framework is presented linearly, it is intended to be flexible so teams can move forward, backward, or repeat steps as needed to support device selection. In the RADAR-CNS study, we conducted several iterations of the Prepare and Select stages as our thinking evolved during study design. These iterations enabled dialogue between the technical and clinical subject matter experts on the project, allowing us to establish common ground between stakeholders and ensure consensus on the final decision. We found that our success depended on engagement of a multi-functional team during each stage of the framework, including investigators, IT specialists, data analysts, patients, healthcare professionals, and others. Each brought unique perspectives and needs to the process, and each ultimately made compromises to align on a single technology and implementation strategy. To ensure alignment and mutual understanding between these stakeholders, it was important that members of the device selection team were skilled in 'translating' clinical and technical requirements and their context for team members of diverse backgrounds.

Navigating complex stakeholder needs is one of the strengths of HCD, especially when program success is dependent on the willingness of people to continually engage with a technology. As its name suggests, HCD starts by asking designers to understand the people who will be using the technology [49,51,56]. It then enables designers to simultaneously explore program context and constraints, identifying connections and priorities between human and non-human factors [49–51,56]. In a systematic review of systematic reviews, Ross et al. (2016) found that early engagement with relevant stakeholders such as patients, clinicians, and others was important for successful mHealth implementation [32], and most frameworks for digital healthcare solution design echo that sentiment [44]. However, Altman et al. (2018) found that user engagement activities were frequently not conducted in such programs [24]. Limited stakeholder centricity during program design and technology selection may ultimately threaten the program's success. Poor user experiences caused by increased burden [4,25], technical issues [22], lack of accommodation for health status [22], impersonal experiences [25], slowness [22,25], and poor or unclear interface design [22] may cause patients to stop using the technology, or worse, drop out of the program. Altman et al. suggested that,

by addressing user needs, HCD methods such as design thinking could increase uptake, adherence, and impact of healthcare programs that use RMT [24]

Here, we use HCD methods not to create new designs, but to identify which existing designs are best suited to a particular program. In the RADAR-CNS program, we used HCD methods to identify and prioritize a vast number of often conflicting needs and constraints, not only from patients but also from other 'users' of the program: the clinicians caring for patients, the researchers studying disease, and the technologists developing new monitoring tools. Many common HCD strategies, such as empathizing with users, brainstorming and iterative design, are present in this framework, making it compatible with other HCD approaches to program design or validation.

Limitations

Though the RADAR Device Selection framework was implemented successfully in an observational research program, its validity in other settings, such as clinical trials of investigational therapies or interventional mHealth program design, must be established in future work. While examples of successful implementation of human-centric methods in healthcare and academic environments exist, their use is not yet routine. Such methods require a mindset shift, new skills, and adoption of additional study planning activities, with more time spent initially on stakeholder engagement [24]. To achieve the benefits HCD offers, demonstrations of these methods must continue to be shared.

Conclusions

Though selecting off-the-shelf devices for healthcare programs is often difficult, few best practices exist to guide program designers. To address this gap, we developed and successfully implemented the RADAR Device Selection Framework, which incorporates human centric design strategies into a three-stage approach for systematically identifying selection criteria, testing and selecting devices, and monitoring device-related outcomes. To improve RMT implementation in future programs, the methods used and lessons learned during device selection should be more routinely shared.

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Conflicts of Interest

None declared.

Abbreviations

EFPIA: European Federation of Pharmaceutical Industries and Associations
HCD: Human-centered design
MS: Multiple Sclerosis
PoC: Proof of concept
RADAR-CNS: Remote Assessment of Disease and Relapse – Central Nervous System
RMT: Remote measurement technology

Multimedia Appendices

Multimedia Appendix 1: Review of Device Selection Methods
Multimedia Appendix 2: RADAR-CNS device selection considerations and selection criteria
Multimedia Appendix 3: RADAR-CNS Multiple Sclerosis Study Device Selection Discussion Guide

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