The Personal Health Technology Design Space

Currently, the design of personal health technologies is based on widely different approaches and assumptions. The proposed design space aims to address this, enabling informed, well-articulated design decisions based on key design dimensions.

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In recent years, there has been an increase in scientific and commercial interest in using mobile platforms to foster improved health and well-being. Research has targeted health-related issues such as tracking physical activity,[1,2] managing chronic illness such as diabetes,[3] managing mental illnesses such as depression[4,5] and bipolar disorder,[6,7] monitoring sleep patterns,[8] and creating general-purpose wellness apps to increase people's awareness about their own well-being.[9,10] This category of pervasive computing systems has many names; here, we refer to them as personal health technologies (PHTs).

We consider PHTs to be high impact technologies; the health and well-being of users and patients are not to be taken lightly. Yet, many design decision are difficult to make. A lack of systematic consideration in designing these technologies could prevent widespread and successful adoption in the long run. In design, there are no "right" or "wrong" decisions—all of the systems just mentioned are typically designed in close cooperation with both patients and clinicians. However, a need exists to consider options in a more systematic way when designing PHTs.

To help these designers make informed and well-articulated decisions, we propose a design space for constructing PHTs. This design space consists of 10 dimensions related to the design of a treatment model, data sampling strategies, feedback approaches, and regulatory constraints.

Personal Health Technology

PHT is a generic class of pervasive computing technologies that uses personal mobile devices and back-end servers for health- and behavior-related data sampling, processing, visualization, and feedback. Figure 1 shows a generic PHT architecture consisting of two main hardware nodes:

- a mobile device with sensors—typically a smartphone with embedded sensors or a smartphone communicating with body-worn or environmental sensors; and
- an infrastructure—typically a scalable, cloud-based server infrastructure accessible over open Internet protocols.

A personal health technology application typically implements a set of core components (shown in yellow in Figure 1): data sampling, self-reporting, data processing, feedback, and a Web portal.

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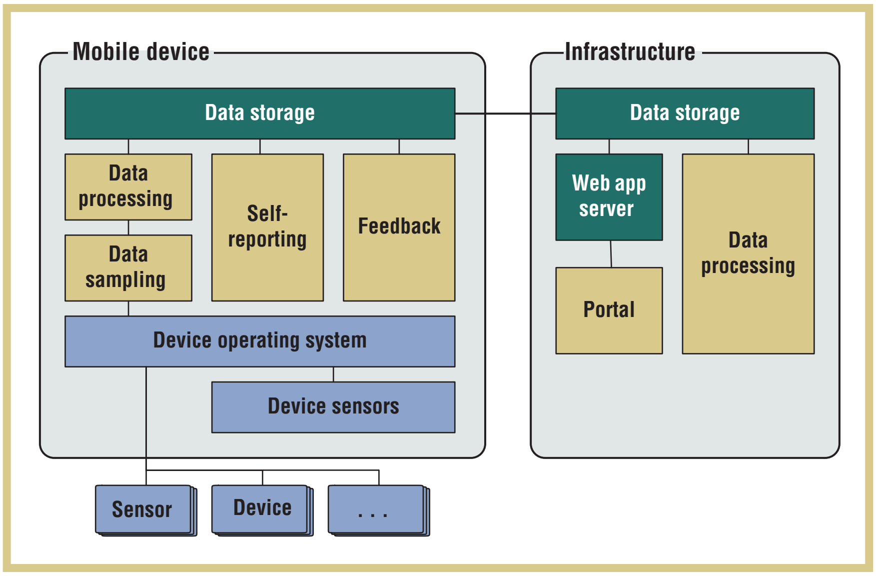

Figure 1. A generic personal health technology architecture. The architecture consists of three types of components: the blue components are device-specific operating system and sensor systems; the green components are generic components for mobile data management and synchronization; and the yellow components are special-purpose components designed for the specific personal health technology application.

Core Components

The *data sampling* component automatically collects behavioral data, mainly from three sources. The first is sensors built into the mobile device, such as the accelerometer, GPS, and microphone, while the second is external sensors, such as a scale, a blood pressure monitor, or a glucose meter. The final source of data is device usage monitoring, such as sampling the number of phone calls and text messages or analyzing application use.

The *self-reporting* component collects data from the user via questionnaires or a diary on the device. Examples of self-reported data include daily reporting of moods, stress, sleep duration and quality, exercise type and duration, and medication adherence. Self-reported data questionnaires are typically tailored to a specific application area.

The *data processing* component on the mobile device handles data preprocessing—such as cleaning and aggregation—on the mobile device before transmitting the data to a remote server. More advanced data processing, such as feature extraction and classification, typically takes place in the infrastructure, which has more processing power as well as access to historical data. Examples of local data processing include activity recognition for typical everyday activities, such as walking, stair climbing, and running. Examples of more advanced server-side data processing include correlation analysis of historical mood data in mental health systems.

The *feedback* component is responsible for providing motivational, educational, and data visualization feedback to users of the mobile device. Examples of visualization include historical overviews of sampled and processed data; abstract metaphors and graphical images; correlations between behavior and health; advice and guidelines based on specific data patterns (such as advice on how to lose weight); and warnings based on decision support rules (such as contacting a doctor if blood pressure readings are above a certain level).

The *Web portal* component provides browser-based system access to users and other relevant people (such as caregivers and relatives). A Web portal might show the same functionality as the mobile device, or it might be designed to provide much more functionality for different users. For example, users might use the portal to provide more extensive data entry—such as in a diary—via a PC keyboard; caregivers might use the portal to update medication information for patients; and relatives might be granted access to see all or parts of the patient's data to better provide support and care.

Developing the Design Space

Figure 2 illustrates the PHT design space, which seeks to illustrate important tradeoffs in the overall design of PHT features. We used two main sources in developing the design space. First was the three-year process of designing the Monarca system for treating bipolar disorders,[6,7] which involved evaluating many design considerations and systems features. Second, we refined the design space based on a review of 21 existing personal health systems as reported in the academic literature (specifically, in pervasive computing, HCI, and health technology journals and conference proceedings).

Inclusion criteria were that the system should fall within our definition of a PHT system definition (described earlier), thereby excluding many simpler mHealth apps, such as self-assessment apps or those that deliver advice using SMS messaging. Table 1 provides an overview of nine of the 21 systems, which span the design space and represent different types of health interventions. In this way, the design space incorporates both specific experience from the design of the Monarca system, as well as features from related PHTs.

The PHT design framework focuses on the design of technical features in a system and thus doesn't focus on establishing evidence of a health

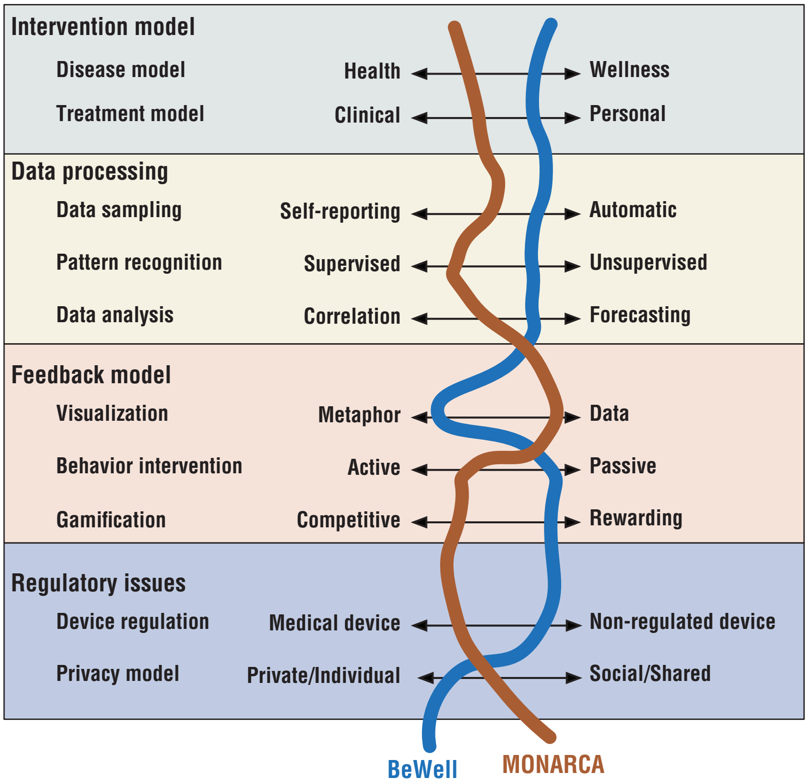

Figure 2. The personal health technology (PHT) design space. The space consists of 10 design dimensions organized into four feature categories: intervention, data processing, feedback, and regulatory issues. A PHT system can be designed along these dimensions, as illustrated here with the Monarca[7] (orange) and the BeWell[9] (blue) systems.

outcome per se. The design space is to be used when designing a PHT, which happens during the *preclinical phase* of the overall process of establishing evidence for a new health intervention.[11] As such, evidence and reviews of appropriate clinical results should be incorporated if the PHT is designed with a health outcome in mind. For example, if the focus is on behavioral change, such as smoking cessation or increased physical activity, then existing clinical evidence must be considered (see Caroline Free and her colleagues' work in this area[12]), and more generally, a design framework, such as the behavioral intervention technology (BIT) model,[13] can be applied.

Finally, methods for running a user-centered design process should supplement use of the PHT design framework during the design process. For example, in the Monarca project, we applied the patient clinician designer (PCD) framework,[14] which involves considering different—and sometimes conflicting—concerns from the perspective of each group and mediating codesign activities to find appropriate solutions.

The PHT Design Space

The PHT design space is organized around four main feature categories: intervention, data processing, feedback, and regulatory issues. Although these categories aren't completely independent, each covers major features to be addressed in the design of PHTs. The *intervention model* category contains design considerations related to the overall purpose and intervention approach, such as whether the system will be part of a clinical treatment. The *data processing* category deals with design questions related to how data is collected, stored, and processed, such as whether the system will rely on self-reporting from the patient. The *feedback* category investigates different feedback mechanisms, such as whether a visualization metaphor can be applied. The final category on *regulatory* issues has not been discussed much in research so far. However, addressing questions related to, for example, device classification and FDA approval should be addressed upfront in the design process.

Figure 2 shows the "design path" of two different types of PHTs: the Monarca system[7] (orange) and the BeWell system[9] (blue). Table 1 offers details on the classification of the other systems according to the PHT design space.

Intervention Model

The first and most fundamental PHT design decision is to determine the system's *disease model*. In general, a personal health system can be targeted at a specific health problem or designed to be a system for fostering everyday wellness. So this design dimension heavily influences decisions regarding which features to include and which users to involve in the design process. For example, the Monarca system focuses on supporting bipolar disorder patients; it's not designed as a tool for mental wellness in general. The BeWell system, on the other hand, is designed to support general physical wellness rather than targeted at any specific health condition.

If a system's design is targeted at health, it's important to consider clinical evidence in terms of the effectiveness, efficiency, and efficacy of the proposed solution. Unfortunately, clinical evidence from controlled trials of the effectiveness of mobile health technologies in relation to health behavior change or disease management have shown little clinical effect so far.[12] Moreover, due to the longitudinal nature of clinical trials, the technology features applied in the interventions are quite old (most of them use SMS to contact patients) and thus don't represent the kind of PHTs discussed here. Still, the design of new systems should consider features of previous systems that have proven effective.

The second dimension—the *treatment model*—relates to the degree to which a system will be used as part of a clinical setup or as a personal tool. If the system will be used in a clinical setting, this design dimension is tied to the system's claims on effect, because the effect will come from the clinical treatment. For example, the Monarca system was deliberately designed to be a tool in a psychoeducational treatment of bipolar disorder patients and was associated with a clinic for affective disorder. Because the clinical effect of this treatment has already been established, the design goal of the Monarca system was to improve adherence to the treatment program as well as to improve the quality of the data collected—not to show clinical effect on its own. Other PHTs, such as UbiFit Garden and BeWell, embed a personal treatment model; the user isn't in contact with a clinic, and the system isn't designed for clinical use.

Basic questions to consider when establishing the treatment model include: Is the system to be used as part of a clinical treatment? Should medical professionals have access to data? Should the system be controlled from a clinic? Who will do the system configuration and setup? Will there be clinical support during use? Who owns the data produced? Can the system be used independent of clinical treatment? Who pays for the system (the clinic or patients)?

Data Processing

Support for body-worn or phone-based sensors for data sampling and analysis is a defining feature of PHTs. In this feature category, the design space differentiates between how to collect data (data sampling), how to make sense of data (pattern recognition), and what to use data for (data analysis).

Overall, *data sampling* can happen either automatically through sensors or can be reported by the user. Some systems—such as BeWell and Bant—rely entirely on automatic data sampling, whereas system such as MobileMoodDiary and ShutEye rely completely on self-reporting. The Monarca system applies both approaches by relying on self-reporting of, for example, mood and stress, while using the phone to automatically collect data on physical activity (sampling accelerometer data) and social activity (sampling phone calls and messaging).

An increasing number of sensors to automatically capture data are becoming available. For the design of PHTs, three broad categories of sensors are relevant:

- *Environmental sensors* capture aspects of the user's environment, such as location, temperature, and nearby objects.
- *Behavioral sensors* capture aspects of the user's behavior, including movement, steps, activity, social interaction, and phone usage.
- *Physiological sensors* capture data related to the user's bodily state, including glucose level, blood pressure, weight, and electrocardiogram (EKG).

Overall, the system design must consider which data can be automatically sensed and at what level of quality. Basic behavioral, biological, and environmental data can be automatically collected via sensors, whereas subjective assessments—on, for example, mood, stress, and coping—can't. The benefit of relying on automatically sensed data is its "objective" nature; sensor data reports what is sensed and is independent of human involvement, interpretation, and "tampering." The drawbacks of sensor-based data collection are mainly tied to its dependency on proper usage—such as correct placement of body-worn sensors—and to resource demands, such as battery consumption.

A core feature of many recent PHTs is their support for *pattern recognition*. For example, the mobile sensing platform in the UbiFit Garden system applied a set of classifiers that could infer walking, running, cycling, and use of elliptical trainers and stair machines. Similarly, the BeWell system can classify physical activity, sleep, and social interaction based on models trained on 10 people. Once these models are trained, the intent is to allow for nonpersonalized and unsupervised classification. Besides machine-learning algorithms, rule-based pattern recognition can be applied, such as in the Bant system, where a simple rule detects if blood sugar is outside the target range for three days. Other systems apply a supervised, personal pattern-recognition approach. For example, the Monarca system applies supervised classification and prediction of mood scores based on a personal supervised machine-learning algorithm. The benefit of this supervised approach is that it achieves a personalized pattern recognition. The benefit of the unsupervised model is that it can be embedded into the technology and used without training or modification.

In terms of *data analysis*, systems generally fall into two categories. Some systems do correlation analysis of data to help users identify patterns between behavior and health outcome, such as correlations between physical activity and weight. For example, the Mobile Health Mashups system[10] applies advanced correlation analysis to identify significant connections between weight, sleep, step count, calendar data, location, weather, pain, food intake, and mood. Data analysis can also be applied to

TABLE 1
Positioning of personal health technology systems in the PHT design space.

System	Intervention		Data processing		
	Disease/treatment model		Data sampling	Pattern recognition	Analysis
BeWell (wellness, exercise, social activity, sleep)	Wellness/personal		Automatic	Unsupervised classification	
Mobilyze! (depression)	Health/personal		Automatic self-reporting	Supervised	Forecasting/ prediction
UbiFit Garden (encourage physical activity)	Wellness	Personal	Automatic self-reporting	Unsupervised classification	
Bant (diabetes)	Health	Personal	Automatic	Rule-based classification	
Fish'n Steps (obesity)	Wellness	Personal	Automatic (simulated)		
MobileMoodDiary (mental health/mood charting)	Health	Clinical	Self-reporting		
ShutEye (sleep)	Wellness	Personal	Self-reporting		
Mobile Health Mashups (well-being, insight)	Wellness	Personal	Automatic		Correlation
Monarca (bipolar disorder)	Health	Clinical	Self-reporting/automatic	Supervised correlation	Forecasting/ prediction

forecast and predict health-related issues. For example, in the Mobilize! system, the mobile phone application sends unlabeled sensor values to a server that uses these sensor readings to predict and infer the user's state.

In general, identifying correlations is very useful for both users and their caregivers. Correlations can provide insight into long-term relationships that might otherwise be difficult to identify during, for example, outpatient treatment. Forecasting should, on the other hand, be used with caution. Forecasting inherently entails an error margin that can be significant and that might not be easy for users to understand. In the Monarca project, designers discussed whether the mood forecast should be available to patients, but this idea was rejected by the psychiatrists. They argued that mood prediction could be a self-fulfilling prophecy; for example, if a patient were predicted to become depressed, this forecast in itself would be a depressing factor.

Feedback Model

Feedback to the user is a core feature of PHTs, and many feedback approaches have been suggested. The design space identifies three important issues to consider: data visualization techniques, behavior intervention approaches, and the degree of gamification.

In most PHTs, two distinct approaches to *data visualization* are applied. Some systems, such as Monarca, present data directly to users. This approach was chosen because patients are already familiar with it from their use of paper-based self-assessment forms. The data-centric format is used in many other systems, including the MobileMoodDiary, Bant, and Mobilyze! systems. A radically different approach is to use a metaphor for data visualization, as is done in several systems. The earliest example is the UbiFit Garden system, which—as its name reflects—uses a garden as a metaphor: the more active the user is, the more his or her virtual garden flourishes. Similarly, the Fish'n Step system uses a fish's age to reflect the number of steps the user takes—a metaphor similar to the BeWell system's aquarium. In such metaphorical design approaches, it's argued that data visualizations should be abstract, non-intrusive, public, and aesthetic. That is, data should be presented in an abstract manner (rather than as raw data) without interrupting the user and in a manner that can be viewed in a public place; the technology's physical and virtual aspects should also be comfortable and compatible with the user's personal style.

Good data visualization is key to PHTs and hence must be designed with great care. Some types of applications—typically, those that are clinical- and healthcare-oriented—seem to apply a data-centric approach, whereas the personal wellness applications seem to pursue a more abstract approach based on metaphors. Our experience from the Monarca project indicates, however, that there's not necessarily a one-size-fits-all approach; some users like to get feedback in terms of an overall metaphor, whereas others prefer

Feedback model			Regulatory model	
Visualization	**Intervention**	**Gamification**	**Device regulation**	**Privacy**
Metaphor (aquarium)	Passive		N/A	Individual
Data	Active		N/A	Individual (shared)
Metaphor (garden)	Passive		N/A	Individual
Data	Passive	Rewarding	N/A	Social (shared)
Metaphor (fish bowl)	Passive	Rewarding/competing	N/A	Individual/social
Data (online)	Passive		N/A	Individual
Data	Passive		N/A	Individual
Data	Passive		N/A	Individual
Data	Active		N/A	Shared/individual

direct visualization of data. Hence, a design approach that allows for personal configuration in terms of visualization preferences might be ideal.

Behavior intervention is core to many PHTs because they are often designed to motivate people to adopt healthy behavior patterns, such as to cease smoking, increase physical activity, reduce weight, eat healthy, sleep healthy, or reduce stress. In the design space, we differentiate between two types of behavior intervention: active and passive. With active feedback, the system notifies or communicates information to the user, whereas passive feedback occurs when users look up information on their own.

Using data visualization—both in terms of showing data and applying more abstract metaphors—can be part of a passive feedback strategy. For example, in the BeWell, UbiFit Garden, Bant, and Fish'n Steps systems, users looks up information on the phone's wallpaper or in different data graphs. This passive behavior intervention strategy is based on medical evidence suggesting that insight into your own long-term behavioral patterns might motivate more healthy behavior.

In contrast, as the BIT Model summarizes,[13] a set of more active behavior change strategies exists, including

- education, in which the system provides educational material to the patient (such as in-situ advice for smoking cessation);
- goal setting, in which the system tracks whether the user achieves objective or self-declared goals (such as walking 10,000 steps each day);
- feedback, in which the system actively prompts the user on potential problems (such as insufficient sleep); and
- motivation enhancements, in which the system provides positive reinforcements in terms of rewards or social support (such as via Facebook or other social media).

An example of an active feedback mechanism is applied by the Monarca system, which automatically detects unhealthy behavior patterns (such as too little sleep) and actively pushes these to the phone's notification system.

Some PHTs have been incorporating *gaming elements* into their design as a way to motivate usage, adherence, or healthy behavior. Although this might be considered part of the behavior intervention dimension as a motivation enhancement, we separate gamification into its own dimension in the PHT design space because it's a distinctive feature. In general, two different approaches to gamification can be applied: a rewarding approach, in which users are rewarded individually for desired behavior, or a competitive approach, in which users compete against each others individually or in teams.

For example, in the Bant system, users are rewarded for regular glucose measurements with points that can be converted to ITunes gift cards. The Fish'n Steps system implements both a rewarding and a competitive setup. In the first case, the user is rewarded with a growing fish, whereas in the latter case, teams of four users compete against each other to maintain a healthy fish bowl. A controlled study comparing the two gamification strategies did not show any significant difference between the two approaches, and there is as yet no evidence that gamification has an effect on healthy behavior.[1] Thus, it's still an open research question regarding the degree to which gamification can play a positive role in the design of PHTs.

Regulatory Issues

When designing PHTs, designers must closely consider the degree to which the system will be considered a "medical device" and thus whether it needs approval and certification from the authorities. In July 2011, the US Food and Drug Administration (FDA) released a draft guidance document containing recommendations for regulating "mobile medical applications" and has since updated it twice (in 2013 and in February 2015).[15] According to these guidelines, the FDA will regulate mobile apps that transform a mobile platform into a "regulated medical device." This includes apps that extend one or more medical devices by controlling or connecting to them, and apps that provide patient-specific analysis, diagnosis, or treatment recommendations. Examples mentioned in that document are apps that control and read data from a blood pressure cuff, an insulin pump, or EKG electrodes; apps that use the built-in accelerometer on a mobile platform to collect motion information for monitoring sleep apnea; and apps that calculate dosage for a specific medication or radiation treatment, or provide recommendations that aid a clinician in making a diagnosis or selecting a specific treatment for a patient.

Given the FDA's view on medical apps, it's surprising that none of the PHTs report on regulatory issues; neither Monarca, BeWell, UbiFit Garden, nor any of the other systems we reviewed discuss whether they are regulated as a medical device. And yet, this design decision is of utmost importance if the technology is to be used in clinical practice. For example, the Monarca system provides clinicians with a five-day mood forecast. According to the FDA guidance, it might thus be considered to "provide recommendations that aid a clinician in making a diagnosis or selecting a specific treatment for a patient."[15]

The guide also describes a set of mobile medical apps for which FDA intends to exercise "enforcement discretion"—that is, the FDA doesn't intend to enforce requirements under the Federal Food, Drug, and Cosmetic (FD&C) Act, but it will monitor these types of systems. The guide states that apps in this category include those that help patients self-manage their disease or conditions without providing specific treatment or treatment suggestions; provide patients with tools to organize and track their health information; provide access to information related to patients' health conditions or treatments; and help patients document, show, or communicate potential medical conditions to caregivers. As such, most PHTs fall within this category.

Regarding the *privacy model* of personal health systems, there are similar regulatory issues to consider. The European Union (EU) Data Protection Directive[16] regulates the protection of individuals with regard to the processing of personal data and the free movement of such data within the EU. This directive basically states that personal data should not be processed at all, except when certain conditions are met. These conditions fall into three categories: transparency, legitimate purpose, and proportionality. In this context, transparency implies that the user has given consent and has the right to demand the rectification, deletion, or blocking of data that is incomplete, inaccurate, or isn't being processed in compliance with the data protection rules. Moreover, extra restrictions apply when sensitive personal data, including health data, is being processed. It's beyond the scope of this paper to go into details on regulatory issues on patient data protection, but the main point is that it's a fundamental design consideration in the design of PHTs.

Many of the proposed systems suggest a private/individual approach to the design of these systems, giving only the patient access to the data. Examples include the BeWell, ShutEye, and the UbiFit Garden systems. In theses cases, the main regulatory issues are to comply with the data protection acts in the countries in which the system is used. However, some PHTs apply a social approach to data processing, allowing data to be shared with peers, relatives, or caregivers. For example, a core design decision in the Monarca system was to support sharing of data between the patient, relatives, and caregivers. Similarly, the Bant system allows for microblogging with other users and integrates directly with an electronic medical record at the hospital. In these cases, in which data is shared, special care for maintaining privacy should be considered. In the Monarca project, for example, we found that the feature that let users share health data with relatives was not used at all—mainly because users had no detailed control over exactly which data they could share and how; sharing was "all or nothing" and many patients found this infeasible from a privacy viewpoint.

Using the Design Space

The PHT design space is intended for use in a systematic PHT design process. As a "design space," its categories and dimensions can be explored with users and relevant stakeholders in a user-centered design process. Table 1 offers an overview of the systems discussed in this article and how they fit in the design space. As such, the PHT design space provides a good overview—and hence starting point—for designers of novel PHTs.

For a specific application, some dimensions might not be relevant, however. For example, some applications—such as in the Fish'n Steps system—do not use data analysis or pattern recognition. And few systems apply gamification strategies. Furthermore, a design doesn't necessarily need to position itself in one end of a dimension; in most of the design dimensions, it's possible to design a system that supports both ends. For example, the Monarca system focuses primarily on a clinical treatment model, but can be—and has been—applied for personal mental health. Similarly, even though the main focus of the UbiFit Garden was the visualization using a metaphor, users did have access to view the raw data on their phones.

The dimensions are, in principle, independent and can be explored one at a time. However, in practice, we often see some sort of clustering in the design of different PHTs. As such, we can identify PHT "families"—that is, systems that that share similar traits.

In the *clinical treatment technologies* family, the intervention is targeted at a specific health problem and is used in clinical treatment by professional clinicians. Such systems are typically used for the collection of self-reported data but might include automatically sensed data as well. More advanced data processing and analysis are rarely applied, because data is interpreted and used by clinicians. In these systems, the feedback model is often based on showing the data combined with active behavior intervention from clinicians or simple rules. Gamification is rarely used. Such clinical treatment apps lend themselves to regulatory control to some degree and work entirely according to a sharing model between patients and clinicians. Users of clinical treatment apps are typically diagnosed patients associated with an outpatient clinical treatment. Examples of clinical treatment apps include Monarca and MobileMoodDiary.

The *personal wellness technologies* family embeds an intervention model focusing on personal wellness. Data sampling can apply self-assessment as well as automatic sampling; however, because no clinical interpretation is done, emphasis is often on advanced data processing, including pattern recognition, correlation analysis, and forecasting. Personal wellness systems are not prescribed as part of a medical treatment and should thus include intrinsic motivation for people to use them. Therefore, they typically have a more aesthetically appealing look and feel, including the use of graphical metaphors, dynamic and interactive feedback, and gamification elements. Personal wellness systems are typically designed for nonregulated devices, while complying with any local data protection acts. Users of personal wellness apps are typically people with a general interest in their own well-being rather than diagnosed patients. Prototypical personal wellness apps include the UbiFit Garden, BeWell, and Fish'n Steps systems.

PHTs are emerging as a common type of system both in academia and commercially. The PHT design space we present here highlights the need to address core design constraints and decisions for these applications, including which disease model to support; how to capture, process, and analyze data; which behavior intervention strategies to apply; and how to identify any relevant regulatory issues. This PHT design space will be applied and extended in our continued research and design of PHTs at the Copenhagen Center for Health Technology. We hope that designers of future PHTs can use this design space in a systematic design process and thereby invent more innovative and exciting systems to benefit users and patients worldwide.

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