to screen, diagnose, and monitor a patient's illness. Screening is the routine examination of individuals for indications of illness or of high risk for illness [10]. Diagnosis is the inferred state that an illness is present in a person [10]. Mobile patient monitoring uses "technology to manage, monitor, and treat a patient's illness from a distance" [11] once an illness has been attributed to an individual.

A number of studies have developed mobile app solutions for particular illnesses, including diabetes [12, 13], asthma [14], and depression [15], and have reported lessons learnt. Goyal et al. [13] take a user-centered design approach, ensuring that the features of a mobile app are informed by the needs of patients with type 2 diabetes. The resulting application allows patients to self-monitor their physical activities, diets, and weights, to identify glycemic control patterns in relation to their lifestyles, and to guide them towards remedial decision-making. Årsand et al. [12] illustrate that their mobile app can motivate type 2 diabetes patients to think about how they can improve their health. The authors conclude that their system has the potential to support the collaboration between patients and clinicians. In another study, Oresko et al. [16] integrate a Holter monitor with mobile technology and develop smartphone-based cardiovascular disease detection. Another study presents a remote monitoring system for elderly patients with multiple chronic conditions [17] that allows users to see current medical reports on their smartphones based on sensor data, to perform new measurements, and to communicate with caregivers via the mobile app. Schnall et al.'s study evaluates existing mobile apps for patients living with HIV and concludes that the design of such mobile apps requires a thoughtful, patient-centered, and evidence-based approach [18].

From a medical perspective, recent healthcare research has revealed that a large number of mobile apps available in public app stores are not based on empirical evidence [19]. These shortcomings can have serious consequences. For instance, Wolf et al. [20] measure the performance of four mobile apps that evaluate photographs of skin lesions. When such a picture is evaluated, the mobile app gives the user feedback about the likelihood of malignancy. The sensitivity of the investigated mobile apps ranged from 6.8% to 98.1%. Hamilton and Brady [4] link the weak performance of some existing mobile apps to low professional medical involvement in the design of mobile apps. Based on the analysis of 111 mobile apps that focus on pain management, one study found that the content of mobile apps contain misleading claims and a lack of academic references [7].

Software technology-oriented communities suggest mobile health frameworks that target developers of mobile apps [21, 22]. One study provides an ontology-based context model and a related application framework that focuses on alarm notification in chronic patient care [22]. Broens et al. [21] suggest a framework to facilitate the use of contextual information (i.e. context acquisition, context provisioning, and context reasoning) for user-tailored mobile apps. While mobile health frameworks are valuable to ensure software component re-usability or functional decomposition, they target the project's implementation phase rather than the design and conceptualization of a mobile medical app. Other studies suggest specific architectural approaches for mobile health app usage [23]. For instance, Kumar et al. [24] performed a comprehensive survey on the use of ubiquitous computing for remote cardiac patient

monitoring. They discuss the architecture and quality of service characteristics of the underlying platform for mobile cardiac monitoring systems.

We identified two research opportunities in the scientific literature. First, current studies on mobile medical apps mainly report on the design of illness-specific tools without abstracting higher-level concepts or design principles from their specific solutions. This makes it difficult to apply the learnings from one illness-specific study to the design of a mobile medical app in another context. Second, the rapid advances in mobile technology outpace the rigorous and critical evaluation of the impacts of mobile apps. This leads to a situation in which mobile medical apps continue to proliferate, with little evidence of their effectiveness and little support for understanding how best to design these tools [2]. We build on these gaps in the research and seek to answer the following research question: *What are suitable principles in mobile medical app design?*

3 Research Method

Considering our research goal, we opted for the design science research paradigm, which emphasizes a construction-oriented view of information systems (IS), i.e. research centered around designing and building innovative information technology (IT) artifacts to solve the identified business needs [25]. The research we present here derives rigor from the effective use of the medical and the IS knowledge bases. Our research process followed the ADR approach proposed by Sein et al. [9], a research method for "generating prescriptive design knowledge through building and evaluating ensemble IT artifacts in an organizational setting" (see Figure 1). The ADR project we present here was an engaged research collaboration between academics (two medical and two IS researchers) and practitioners (two senior physicians, a graphic designer, and a software developer). Our ADR study seeks to build and evaluate an innovative IT artifact (i.e. a mobile medical app) and uses heuristic theorizing to synthesize information about artifact solution [26]. The ADR project started in November 2013 with the problem formulation and continued with two building, intervention, and evaluation cycles. The project reached its first complete state in May 2016, when we formalized our learnings from constructing the IT artifact into a set of design principles.

Problem formulation: Our research was driven by the practical need to design a mobile medical app that provides a way for patients to participate in the identification of age-related macular degeneration and the monitoring of this illness. Our case is particularly interesting from both a medical and an IS perspective. From a medical perspective, global projections of any age-related macular degeneration cases are 196 million by 2020, rising to 288 million in 2040 [27]. Current treatment regimens in age-related macular degeneration are suboptimal, owing to 1) the late identification of treatable age-related macular degeneration, 2) non-individualized treatment leading to under-treatment in about 30% of patients, and 3) the challenge to identify the best time for re-treatment after successful treatment and/or treatment suspension. From an IS design perspective, the patients are elderly people who are usually not familiar

with touch-based mobile devices; also, owing to their limited vision, it becomes particularly challenging to design an easy-to-use mobile app. Our research effort can be classified as IT-dominant [9], since it emphasizes creating an innovative technological design as its outcome. Our review of extant literature about mobile medical apps revealed that existing studies often report on the design of illness-specific tools, which makes it difficult to transfer their findings when constructing an artifact in another context.

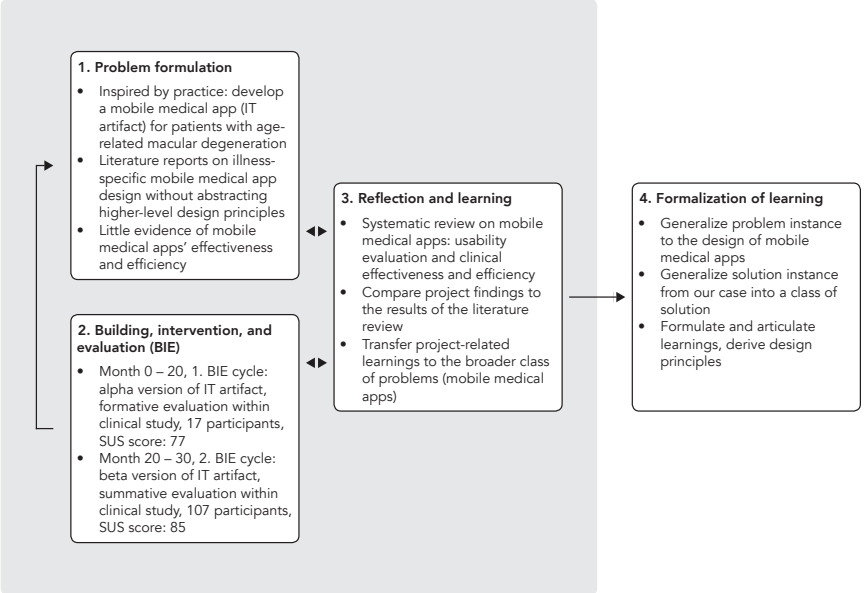

Figure 1. Action Design Research Process (following Sein et al. [9])

Building, intervention, and evaluation (BIE): We built the IT artifact in an agile software development approach with short iterations. During the building phases, we conducted regular meetings (approx. every second week) to evaluate current prototypes in the project team. Each meeting led to new requirements and guided the development of the next prototype version, which we then distributed to members of the ADR team. Overall, we created more than 50 prototypes. Collected data (e.g. field notes from meetings, emails, and visualizations of graphic user interfaces) informed the design of the next prototype version. We also used the prototypes for research purposes, since the data provided us with a history of errors and learnings from the building phases. During the first BIE cycle, we built and evaluated an alpha version of the mobile medical app that included all the functionalities with a strong focus on the measurement task. At that stage, we did not prioritize the presentation and interpretation of the test results in way that is easy to understand by patients. After a project duration of 18 months, we engaged in a naturalistic formative evaluation to determine areas for improvement and refinement of our alpha version. The clinical study took place at the Department of Ophthalmology of the Cantonal Hospital of

Lucerne – Switzerland's largest public eye clinic. This study, in which 17 patients took part, was approved by the Ethics Committee and allowed us to get first-hand feedback from potential end-users. Each patient provided written informed consent. All patients who had had an ophthalmological consultation at the hospital's eye clinic between June and October 2014 were evaluated for inclusion. Patients were excluded if they were unable to use the mobile medical app, i.e. owing to cognitive or visual problems. Patients had a mean age of 78.1 years, and the proportion of women was 53%. Of the participants, 13% used a smartphone daily, while 60% had never used one. During the clinical study, the measurement task had to be executed three times per week, between two routine clinical visits (approx. one month). After data cleaning, we had 240 measurement results.

In the second BIE cycle, we implemented the learnings from the first BIE cycle to build a beta version of the mobile app. The beta version's aim was to be self-explanatory to patients, which required a complete re-design of the user interface and easy-to-understand communication of the measurement results. After several iterations and new prototype versions, we performed a second clinical study as a naturalistic summative evaluation of the IT artifact. We enrolled 107 patients in this study. All patients who had had an ophthalmological consultation at the hospital's eye clinic were evaluated for inclusion. Participants provided written informed consent, and the study was approved by the Ethics Committee. This time, the patients had a mean age of 72.8 years, and the proportion of women was 47%. Of these participants, 40% used a smartphone daily and 53% had never used a smartphone. Compared to the first clinical study, we did not only provide iPod touch devices with the mobile app pre-installed; patients could also use their own smartphone and could download the mobile app via the Apple app store. Of the patients, 29 used their own device. The participants performed repeated self-monitoring measurements between monthly ophthalmological examinations. We collected more than 4,500 measurement results over this clinical study.

In both clinical studies, patients provided oral feedback on the mobile app's user-friendliness, answered pre-defined questions of interest, and filled out the System Usability Scale (SUS). Originally developed by Brooke [28], the SUS is a valid and reliable tool for measuring usability [29]. The SUS has received much attention in the scientific community and, after 30 years from its initial presentation, "has certainly stood the test of time" [29]. In view of the fact that the study participants were elderly patients with substantial visual impairment, and sometimes also impaired cognitive functions, we opted for the short, straightforward SUS as an evaluation instrument. Based on the 500 tools investigated as reference, a SUS score higher than 68 is considered to be above-average [30]. Since the participants in our clinical study were native German speakers, we relied on a German translation of the SUS that was made available via a crowdsourcing project [31].

Reflection and learning: We conducted reflection and learning cycles in parallel to the two BIE cycles. To get an overview of the current state of mobile medical apps, and to learn about their clinical effectiveness and efficiency, we collaborated with medical researchers to perform a comprehensive literature review that integrated the medical and the IS perspectives. We continuously consulted the collected data from

the ADR project, i.e. the history of prototypes, presentation material, emails, questionnaire results, opinions from study participants, and measurement results. This allowed us to compare our findings to the literature review results and to apply our situated learning to findings that apply to a broader class of problems. The outcome of the reflection and learning stage was a preliminary set of design principles.

Formalization of learning: Following Sein et al. [9], we distinguish between three levels for this conceptual move. First, we generalized the problem instance to the design of mobile apps that support the monitoring and screening of specific illnesses. Second, we generalized the solutions instance into a class of solution, abstracting highly specific solutions concepts from our own ADR project to make the concepts applicable to the entire class of problems. Third, we captured the knowledge gained in developing an illness-related mobile medical app. Building on the design principles we identified and refined in the previous stage, we fully formulated and articulated our learnings. In the derivation of the design principles, we followed the heuristic theorizing framework suggested by Gregory and Muntermann [26].

4 A Mobile Medical App for Age-related Macular Degeneration

In an engaged academic-practitioner relationship, we built and evaluated Alleye – a mobile app that seeks to provide a way for patients to participate in screening and monitoring age-related macular degeneration. We created this mobile app for Apple's iPhone and the iPod touch, targeting iOS 8.0 and later. It builds on HTML5 technologies and is wrapped inside a web view that provides access to native platform features such as a camera and secure storage. The mobile app has four components: instructions, setup, measurement, and feedback (see Figure 2). For the instructions, Alleye includes a help-center with visual graphics explaining all the functionalities. These graphics were also used by the research assistant to explain the mobile app's use during clinical studies, and patients received a printed booklet with large visual graphics and brief explanations. During initial setup, the patient must insert a unique identification code, so as to match measurement results with his or her electronic health records at the eye clinic. Patients choose to perform the measurement task in training mode or in test mode. The measurement task implemented in Alleye is based on a computerized version of a Vernier hyperacuity alignment task. Hyperacuity is a property of our visual system that allows us to see straight lines as straight. The term derives from the fact that it detects misalignments of borders with a precision that is up to 10 times better than visual acuity. In Alleye, we implemented an alignment task that examines the extent to which the visual system is capable to see straight lines as straight. The performance of an individual completing the measurement task empirically measures the hyperacuity level. Owing to the fact that a drop in hyperacuity precedes a drop in visual acuity, Alleye is capable to detect a decrease of visual acuity before a person sees less. Since this task is monocular (i.e. only the treated eye is open), the patients must select an eye (left or right) before they begin to measure. At the end of each measurement, the patient confirms that the measurement is valid (e.g. that there have been no disturbances). Feedback is provided right after

the patient successfully completes a measurement task. The feedback indicates a score and a color scheme inspired by traffic lights, comparing the score to previous test results.

The alpha version of Alleye's user interface followed generic practical guidelines for mobile development. During evaluation in a real-life medical setting, 17 patients reported an average SUS score of 77. From a medical perspective, the first clinical study revealed that the measurement task (i.e. the assessment of the hyperacuity level) is a promising instrument for screening and monitoring patients with age-related macular degeneration. However, we encountered some issues with the mobile app design. For instance, patients could hardly read written text, had difficulties with insufficient color contrast, and the navigation (based on a standard icon-based menu) was unclear to them. To re-design the user interface during the build phase of the second BIE cycle, we simulated the look of the user interface for patients with limited vision and a shadowlike void in the center of their visual field by holding a filter over the mobile device. This provided important insights into the use of colors, minimum font size, or the number of words that should appear on one screen. Further, we implemented a very structured navigation (i.e. minimizing variability via limited navigation options) with buttons occupying the entire screen width in order to guide patients along the mobile app's four components (instruction, setup, measurement, and feedback). The complete redesign of the user interface during the build phase of the second BIE cycle did not impact the measurement task, and captured clinical data could still be compared between the two clinical studies.

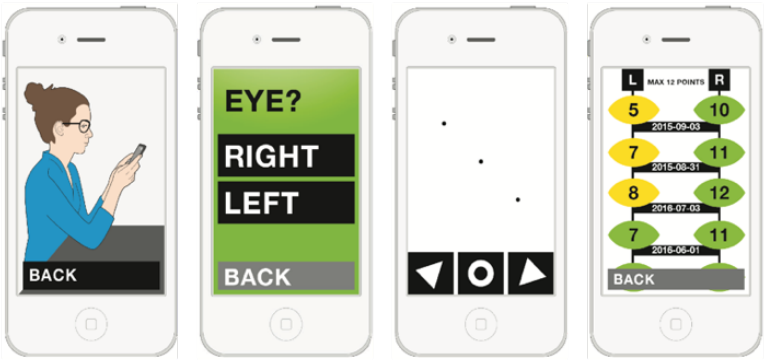

Figure 2. Screenshots of Alleye: Instructions, Setup, Measurement, and Feedback

The second clinical study sought to test the mobile app' use over several months in a real-world medical setting. This would help us to gather data for a longitudinal clinical study and to learn whether or not patients were willing to adopt Alleye and its re-designed user interface. Of 107 patients, 83 provided oral feedback on user-friendliness and filled out the SUS. Compared to the first BIE cycle, the SUS score increased from 77 to 85. We corrected for age and frequent smartphone use in the SUS analysis. In the unadjusted analysis, the estimated mean increase in the SUS score was 8.2 (95% CI: 1.3 to 15.1), while in the adjusted analysis the estimated mean

increase in the SUS score only dropped slightly (average SUS score increase 7.5, 95% CI: 0.5 to 14.4, p = 0.036). Thus, the user interface optimized for patients with age-related macular degeneration created a higher SUS score. This score was confirmed by oral feedback from patients and a decrease in the help needed by the research assistant to explain the mobile app's usage.

5 Principles in Designing Mobile Medical Apps

Based on the insights gained from the BIE cycles and reviews of other studies on mobile medical apps, we derived four design principles. The design principles' purpose and scope are to provide guidance on how to design mobile medical apps. They capture the knowledge gained about the development of Alleye, and formalize this knowledge to guide the design of other instances of the same class. Justificatory knowledge represents insights from the literature that inform, explain, and validate our design decisions. Table 1 summarizes the design principles, exemplary instantiation based on our research project, and justificatory knowledge.

Table 1. Design Principles and Exemplary Instantiation

Design principles	*Instantiation in Alleye*	*Justificatory knowledge*
DP1: Mobile medical apps should consist of four functional components that guide a patient: instruction, setup, clinical measurement, and analysis and feedback.	• Instruction: help center in mobile app • Setup: identification, select eye for testing • Measurement: alignment task • Analysis and feedback: score and color scheme	[23]
DP2: The user interface should be adapted to cope with patients' physical and cognitive restrictions.	• Limited vision: high color contrast, large font sizes, and buttons that occupy screen width • Cognitive restrictions: limited navigation options, simplify medical information	[32, 33]
DP3: A mobile medical app should build on a robust medical knowledge base, ensuring an evidence-based approach to mobile app design.	• Measurement: hyperacuity level informs diagnosis of age-related macular degeneration • User interface and the use of sensor technology remain independent of the medical knowledge base	[4, 7, 20]
DP4: Mobile medical apps should facilitate both patients' and physicians' routines.	• Instructions trigger conversation between the patient and the physician • Patient feedback should be aligned with actions that the physician can manage and is integrated into his or her routines	[34, 35]

Design principle 1 (DP1): Mobile medical apps should consist of four functional components that guide a patient: instruction, setup, clinical measurement, and analysis and feedback. From our experiences with Alleye, we found that mobile medical apps have four stable functional components that are specific for patient screening and monitoring. Given the logical order of these components, primary navigation elements of mobile medical apps should be structured along these four building blocks in order to provide a patient with guidance. Estrin and Sim [23] present similar components in their seminal paper on an open mobile health architecture, but focus more on technical aspects and leave out the instruction component. The latter is important because it assists the patient through the mobile app's usage and provides explanations on the setup, the clinical measurement task, and the provided feedback. Instructions might be communicated via graphics, audio, and/or videos that support patients who have difficulties reading text. The setup component is crucial to prepare the measurement and to provide context-specific information relevant to perform and analyze the measurement task. For instance, personal data such as weight, age, clinical data, or configuration options might modify the measurement task, are important factors to interpret measurement results, or have diagnostic value (i.e. modify the probability of the presence of the illness). The illness-related measurement is key to the mobile medical app. The analysis and feedback component provides the patient with information about his or her measurement results and might suggest context-specific actions such as the advice to contact a physician. At the same time, feedback should motivate the patient to continue performing clinical measurements. For instance, Marin et al. [36] suggest serious games as a means to keep patients engaged.

Design principle 2 (DP2): The user interface should be adapted to cope with patients' physical and cognitive restrictions. In the development of Alleye, we experienced the limitations of general human interface guidelines provided by mobile platform providers to design mobile apps that target their operating systems. These guidelines provide various user interface patterns, which are helpful to design mobile apps that target a broad audience. However, as we have seen with Alleye, the same human interface guidelines do not consider the very specific limitations of patient groups such as impaired vision, cognitive impairment, or limited motor functions. Designers of mobile medical app should bear in mind end-users' physical and cognitive restrictions [32, 33]. For instance, patients with Parkinson's disease might have difficulties entering data via a smartphone's tiny keyboard. Thus, Parkinson's patients could be provided with structured forms and large buttons to enter data. On the other hand, patients with poor vision can be provided with audio guides and speech recognition instead of written guidance and text fields to enter data. For building the user interface, it is helpful to simulate end-user limitations, so that the designer feels how the mobile app's form and functions works in the hands of future users. In our project, the physicians guided the implementation of this simulation to ensure that designers work with scenarios that are realistic to real-life occurrences. In the case of Alleye, studies on user interface design for elderly people informed the mobile app's development. However, usability studies have certain limitations, since they focus on a user's physical limitations rather than on cognitive restrictions. With

Alleye, we have seen that presenting correct, unbiased information that is hardly understandable by patients not only renders this information useless, but can also cause misunderstandings in patient-physician communication. An evaluation with potential users was required to ensure that patients have the cognitive capabilities to understand the information communicated via the mobile medical app.

Design principle 3 (DP3): A mobile medical app should build on a robust medical knowledge base, ensuring an evidence-based approach to mobile app design. A robust medical knowledge base builds trust among physicians [4, 7], laying the ground for an implementation of mobile medical apps in clinical practice. In Alleye, the assessment of the hyperacuity level informs the diagnosis of age-related macular degeneration. Our mobile app builds on this principle, which is robust. In the course of the use of Alleye, the medical knowledge base might inform us that the changes in hyperacuity are not the same in the various retinal conditions. It might also inform us that, besides hyperacuity, other easily accessible parameters can be measured. While the availability of new sensors embedded in mobile devices might facilitate or even enable the measurement of additional signs and symptoms, they do not necessarily impact the biological model. Advances in mobile technology that impact the mobile app's underlying medical knowledge base would require the mobile app to be clinically reassessed, ensuring that the approach to mobile app design remains evidence-based. While it is very likely that mobile medical apps' forms and functions require adaption and optimization over time owing to technological advances, the underlying biological models and particularly the manifestations (signs and symptoms) of an underlying illness remain fairly stable over time. This is crucial from a medical perspective. Only the stable measurement of clinical parameters allows medical researchers to perform longitudinal clinical studies, and physicians in the hospital can compare a patient's test results over a certain timeframe.

Design principle 4 (DP4): Mobile medical apps should facilitate both patients' and physicians' routines. Patients potentially have a long-term relationship with their physicians. In our project, instructions within Alleye were designed with a specific purpose: They should allow a physician to explain to the patient the mobile app's usage within a few minutes. After basic instructions, the mobile app's use should be self-explanatory. With Alleye, we also learnt that feedback provided after the measurement tasks should be aligned with actions that can be handled by a medical practice. For instance, if the mobile app asks a patient to contact his or her physician because his or her measurement task scores are decreasing, the physician in the medical practice must be aware of the meaning of this call to action. Mobile medical apps offer unique opportunities to improve the quality of the patient-physician relationship [34], since they allow for a continued exchange of clinically useful information that might have remained unrevealed during a routine consultation; such exchanges are of great importance for chronic illnesses in particular. Thus, the design of a mobile medical app for patients is not something that can be done in isolation. Any design of patient routines is linked to the design of the physician's clinical routines. To be fully implemented in routine patient care, it is crucial that a mobile medical app considers requirements from clinical practice. This impacts especially two functional components: instruction (trigger of a patient's routine) and feedback

(call to action at the end of a patient's routine). On the one hand, physicians need to explain to the patient the mobile app's use (instructions). This new task should be implemented in existing clinical routines. On the other hand, data collected via a mobile app should become part of the physician's decision-making process. Thus, the mobile app might ask a patient to contact their physician for consultation if their measurement results worsen. The integration of mobile medical apps into clinical routines faces several hurdles, including a lack of knowledge or training on mobile medical apps or incompatibility with current healthcare practices and technology platforms [34]. It is only when physicians adapt their clinical routines to a patient's use of mobile medical apps that the technology's potential can be fully explored.

While DP1 identifies the functional components that guide a patient in using a mobile medical app, DP2 to DP4 provide specific insights on a mobile medical app's architectural design. The identified design principles foster a patient-physician relationship, ensuring that both the patient's and the physician's requirements are addressed when designing a mobile medical app.

6 Conclusion

Mobile medical apps continue to proliferate, with little evidence of their clinical effectiveness and efficiency. From a bottom-up perspective, a number of studies have focused on illness-specific cases of mobile medical apps (e.g. [13–15]). While these studies have revealed important illness-specific insights on building mobile apps in their specific domain, their findings were hardly generalizable to other illnesses. From a top-down perspective, more software technology-oriented approaches provided abstract mobile health frameworks (e.g. [21, 22]) that can be implemented in a broad range of mobile medical apps. This paper links these two research streams by generalizing the solution instance (i.e. a mobile app that targets patients with age-related macular degeneration) into a class of solution. Thus, we abstracted highly specific solution concepts from our project to make the concepts applicable to the entire class of problems (i.e. a mobile medical app that targets patients with a specific illness). Therefore, our study is among the very first to provide principled design knowledge for mobile medical apps. The suggested design principles form a theoretical contribution [26], since they extend the body of knowledge on the creation of mobile app solutions in the healthcare sector. The design principles also assist practitioners in solving current and anticipated problems in the design of mobile medical apps. The abstraction of our learnings allows practitioners to build on the suggested design principles and to apply them in the development of a mobile medical app that targets a different illness than age-related macular degeneration.

Further, our project revealed the importance of involving people from multiple disciplines in a mobile medical app project. In line with our argument, Nilsen et al. [37] criticize current mobile health tools that arise from siloed fields with little reference to previous research. Doing research in an interdisciplinary team involves additional effort, since the team must create and share a vocabulary. However, such an interdisciplinary collaboration enables solutions that could hardly emerge within a

single discipline. The application of each of the four suggested design principles in future studies calls for an interdisciplinary collaboration, since they all require inputs from both the medical and the software technology's side.

While our research is grounded in a successful 30-month research project, it has limitations. Although we integrated our insights with findings from the literature to inform, explain, and validate our design decisions, we cannot guarantee that our findings are exhaustive or fully independent of our specific research project. The research we presented here has opened up possibilities for new and exciting future research. Our design principles can serve as a basis to develop a design theory, as suggested by Gregor and Jones [38]. While a design theory provides prescriptions for the design of an artifact, future research should also study de facto implementation and how mobile medical apps change interactions between patients and physicians. What affordances and constraints do mobile medical apps bring to daily clinical practice? And how does the physician's corresponding clinical information system interact with a patient's mobile medical app? These are important issues to address the current gap between mobile technology advances and critical evaluation of the impacts of mobile medical apps in healthcare.

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