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Closing the Loop for Patients with Chronic Diseases - from Problems to a Solution Architecture

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Abstract—**There is growing evidence that mobile health (mHealth) applications can assist patients with chronic conditions. However, most mHealth apps are isolated from healthcare professional (HCP) workflows and IT infrastructure. The resulting fragmentation of digital support in healthcare calls for integrating architectures. They would benefit patients, HCPs, product managers, and software developers. Our analysis of existing architectures has revealed valuable architectural elements, but none of the analyzed architectures provided sufficient integration for the chronically ill. Therefore, we propose an architecture for integrated mHealth solutions. We followed a design science research approach and performed all activities of the DSRM Process Model. By forming a closed control loop and engaging HCPs, the architecture is designed to improve patient adherence to treatment, health literacy, and recall of recommendations and information. The resulting Closing-the-Loop Architecture (LoopArt) deploys three software agents: a Health Literacy Agent, an Adherence Agent, and a Conversational Agent. For demonstration purposes, the Health Literacy Agent was implemented for obese patients as an integrated system consisting of a mHealth app and a collaboration tool as part of the electronic medical record (EMR).**

Keywords—mHealth, Electronic Medical Records, Chronic Care Management, Software Architecture, Software Agents

I. INTRODUCTION

Chronic diseases account for 71% of all deaths worldwide and pose an enormous economic burden on society [1]. A substantial share of the more than 300,000 existing mHealth apps address this problem and aim to assist patients with chronic conditions [2]. Given this large number of apps, several mHealth architectures have been developed to inform the design of mHealth interventions. Moreover, there are patient portals as extensions of the physician's electronic medical records (EMRs), personal health records to be maintained by patients themselves, and public information on the Internet. In addition, mHealth apps have recently become more sophisticated due to advances in AI, sensor input and conversational output.

However, this digital support is fragmented and not integrated into physician workflows and EMRs. Fragmentation leads to suboptimal healthcare for patients and wasted time for physicians. Because of time constraints, physicians cannot know dozens of isolated mHealth apps and interpret data of unknown quality presented in various forms and formats. In the worst case, this leads to mHealth apps contradicting and working against healthcare professional (HCP) recommendations. This poses a challenge for providers who want to offer solutions that effectively support patients without compromising the efficiency of physicians.

As a remedy, we propose to close the loop from one physician-patient consultation to the next with the help of the novel Closing-the-*Loop Ar*chi*t*ecture (LoopArt) for integrated mHealth solutions. It builds on the current understanding of medical care and uses recent advances in information technology to promote the development of solutions that better support both patients and physicians. LoopArt guides software vendors to open their systems and integrate suitable mHealth apps into a comprehensive modern EMR system.

This architectural work is part of a larger design science research project addressing chronic care in collaboration with a major Swiss health software vendor and HCPs. The HCPs validated the identified problems and medical solution approaches; the software vendor provided input and validated the architecture. Two architectural components were implemented individually and evaluated regarding their value by HCPs and their patients. Finally, a fully functional prototype was implemented using LoopArt to prove it's applicability and feasibility.

In what follows, we overview prior work on architectures and our methodology. The subsequent sections follow the DSRM Process Model [3]. These are sect. IV: Problem identification, sect. V: Solution objectives, sect. VI: Design and development, sect. VII: Demonstration, and sect. VIII: Evaluation. We conclude with a discussion and conclusions.

II. RELATED WORK

In a prior study [4], we identified the following core concepts for a functional architecture specifying systems that integrates EMRs with mHealth applications: (1) Patient-centeredness, (2) support of physician-patient relationship and collaboration, (3) adaptive interventions, and (4) integration of mHealth apps into medical workflows and EMRs. We use these concepts to assess existing architectures [5, 6].

The "mHealth Architecture for Diabetes Self-Management System" is a functional component architecture [7]. At the heart of the architecture is a cloud-based decision support system that provides feedback and alerts to patients and their registered clinicians. Input data for the system is collected from sensors and patients using a mHealth app. However, the architecture leaves open how the activities are divided between the decision support system and the clinician and how the clinician is supposed to work with the data collected, processed, and stored in the system.

"Health Apps by Design" [8] (HAbD) is an architecture not limited to diabetes. As opposed to many mHealth apps, this architecture acknowledges and incorporates the importance of the patient-provider relationship. This is reflected in the high interoperability of the mHealth app and EMR. HAbD models the interactions between the mHealth app and EMR as well as between EMR and the health system. However, no further functional decomposition of the system shows how the objectives claimed are achieved.

A different approach was chosen for the "Reusable Framework for Health Counseling Dialogue" [9]. It encodes the "conceptualization of the domain of theory-driven, conversational agent-based behavior change interventions" into an ontology. Based on the ontology, autonomous dialog systems can then be implemented to provide behavior change interventions using natural language. The main idea of the concept is to stay as close as possible to the "face-to-face interaction with an expert human counselor" that is still considered the gold standard. However, the framework is limited to patient-reported experiences and ignores objective measurements, such as from sensors.

Finally, "The Behavioral Intervention Technology (BIT) Model" offers guidance for "the translation of treatment and intervention aims into an implementable treatment model" [10]. It meticulously separates and defines BIT components such as aims, behavior change strategies, elements, characteristics, and workflow. It furthermore considers the context in which the mHealth app is used, although it leaves open exactly how the context is detected. It also emphasizes the potential of personalizing the characteristics or content of a BIT for individual patients. It explicitly introduces dynamics through its three paradigms, "Reactive," "Deliberative," and "Hybrid". Described in terms of a finite state machine, these paradigms link sensing, planning, and acting primitives. Regarding an outlook, the BIT model contemplates adaptive BITs based on artificial intelligence but without elaborating on them. The BIT model ignores the physician-patient relationship and collaboration by its very purpose. This reduces BIT to a basis for developing prescribable interventions or digital therapeutics, similar to pills or exercise. While this allows for scalability, it removes the physician as a powerful resource in the treatment and healing process [11] from the equation.

The idea of adaptive mHealth interventions is embraced and pursued by Collins [12] and Hekler, Rivera et al. [13]. Collins looks at adaptive interventions from the evaluation end and argues that before such interventions are evaluated with randomized controlled trials (RCTs), they should be optimized in a white-box approach. For the development of interventions, they propose engineering approaches, similar as in design science research. Taking a different perspective, Hekler, Rivera et al. focus on the control of adaptive interventions and suggest the use of control systems engineering. The reason for relying on control systems engineering is its ability to master systems that change over time and are affected by many variables. The ideas of Collins and Hekler, Rivera et al. do not amount to an architecture in a strict sense. Yet, we see them as essential components of modern mHealth architectures to support patients with chronic diseases.

In summary, we recognize valuable architectural elements in all of them. A commonality is the support for evidence-based interventions. All the other building blocks in TABLE I. were part of the approaches described and they contribute to the must-have core concepts. However, none of the existing approaches integrates all building blocks, and therefore none provides a comprehensive patient experience.

Consequently, it remains unclear how to design an architecture supporting the development of mHealth apps that combine patient self-management and patient-HCP collaboration, that incorporate evidence-based interventions and provide a comprehensive patient experience.

TABLE I. BUILDING BLOCKS

Nr.	Building Block
1	Provision of evidence-based interventions
2	Integration of patient-HCP relationship and collaboration
3	Interoperability of mHealth app and EMR
4	Incorporation of feedback based on sensor and patient-entered data
5	Dialogue with patient in natural language
6	Personalization of interventions based on patient characteristics and context
7	Control systems engineering for tailoring adaptive interventions

III. METHODS

To derive and design LoopArt, we followed a design science research approach [3, 14]. We performed the activities of the DSRM Process Model [3], including problem identification and motivation, defining a solution's objectives, design and development, demonstration, and evaluation. The approaches for each activity are described in detail below.

The *problem identification and motivation* activity is based on related work and two studies conducted by us [4, 15]. Both studies are based on in-depth interviews [16]. The interviews of the first study were inductively coded [17], which resulted in a codebook that was used to deductively code [17] the interviews of the second study. The coding allowed for generalizing the findings from the interviews and reflecting on them against the literature. This resulted in validated classes of problems justifying the value of their solution, and ultimately ensuring relevance [14].

To define *the objectives for a solution*, we inferred the objectives based on the problem classes from the previous activity. We ensured that the resulting objectives or requirements were consistent, feasible, comprehensible, and able to be validated [18]. To increase creativity and reduce the subjectivity of the objectives, we conducted this activity with a group of IS researchers rather than working individually.

In the *design and development* activity, the resulting artifact is LoopArt. In creating the artifact [14], we explored ways to implement the objectives while drawing on a body of theoretical knowledge. As in the previous activity, we also conducted this activity with a group of IS researchers.

For *demonstration* purposes, we implemented two architectural components individually before implementing a fully functional prototype. One component can translate diagnoses and therapies specified by physicians in professional language to lay language. Another component is a mobile application for patients, which provides interactive access to the contents of a consultation such as diagnoses and therapies. The fully functional prototype contains more mature implementations of these two components together with the means to input information during consultations.

As an *evaluation* of LoopArt, we conducted two proof-of-value [19] studies of the translating and interactive access components. Those were conducted in real-world environments involving five HCPs and 17 patients. Furthermore, a proof-of concept [19] study of a fully functional prototype was conducted with software engineers and test users including an HCP with two patients. The overall architecture was evaluated in interviews with four HCPs and a EMR vendor.

IV. PROBLEM IDENTIFICATION

Ultimately, the purpose of LoopArt is to contribute to solving current problems in medical healthcare. These problems were analyzed in two prior studies. The first was based on interviews with seven patients, eight physicians, and three other HCPs [15]. The second included interviews with 25 patients with various diseases and 22 physicians from different medical disciplines [4].

We summarize the findings of these two studies in three main categories: Problems and findings in consultations, problems and findings in the preparation and follow-up of consultations, and the fragmentation of digital support.

A. Problems and findings in the consultation

The physician-patient relationship is very important for both patients and physicians. It is the basis for productive collaboration and successful treatment.

Shared decision-making has become state of the art for developing a treatment plan. The physician and the patient consider the physician’s expertise and the patient’s preferences to agree on an appropriate treatment plan. However, it has become apparent that not all patients are willing or able participate in shared decision-making. Some like to leave the decision entirely to the physicians, and only few want to decide on their own.

Information exchange (or patient education) is central to shared decision-making and supports patient health literacy: patients and physicians like drawings, visualizations, and 3D models to develop good treatment options collaboratively. A challenge is to capture the results, store them, and make them accessible to both physicians and patients.

Patients and physicians perceived *time pressure* as disruptive and a hindrance to good conversations.

Personalization is implemented by most physicians by tailoring language to the medical knowledge or educational background of their patients. However, to stimulate successful behavior change, many other personal characteristics and contexts of patients must be considered.

The *physician’s computer use during the consultation* can disrupt the conversation with the patient. But if patients are assured of the physician’s attention, they have no problem with it. They do, though, expect their physicians to have sufficient skills in operating the computer.

Low *recall of recommendations and information* requires frequent repetition of what was discussed. In addition, it can also lead to inaccurate or even dangerous therapy behavior.

The situation is similar for *adherence to treatment.* Despite a wide variety of information available in the form of brochures, TV programs, and the Internet, adherence to treatment averages only 50%. While adherence to treatment is primarily patients' responsibility, systematic adherence measurement would be the responsibility of physicians. However, only a smaller proportion of physicians reported that they systematically measure adherence to treatment.

B. Problems and findings in the preparation and follow-up

Information gathering or (self-taught) patient education is practiced by many patients. Dr. Google plays an important role in this. In many cases, however, physicians must guide patients from self-diagnosis back to symptoms. So better-informed or misinformed patients may cost more consultation time than less well-informed ones.

Patients often receive *recommendations* from physicians through generic paper brochures or printouts. Both patients and physicians would prefer personalized recommendations. Challenges are that physicians lack the necessary time and do not have the technical means required to compose personalized recommendations.

Monitoring patient behavior or patient-reported outcomes is important in many treatment plans. Paper-based diaries or questionnaires are frequently used for this purpose. Some patients are open to the use of digital monitoring tools. Problems are that (1) physicians lack the time and willingness to become accustomed to different application interfaces and data formats, (2) physicians lack the time to process all data available and to react to monitoring alerts, and (3) patient behavior could be negatively affected by being monitored.

Physician-patient *interaction* between consultations could help reassure patients and help them better adhere to treatment. However, being aware of physicians’ time constraints, patients are reluctant to contact physicians. Physicians see the benefit of such interaction but worry about frequent interruptions. Finally, health insurers do not reimburse communication by e-mail or telephone.

C. Fragmentation of digital support

From a mHealth architecture perspective, the overarching problem is the fragmentation of available digital support. There is a disconnect between what happens during a consultation and what happens in between. Processes, tools, and data used in the consultation are neither connected nor aligned with those used between consultations.

V. SOLUTION OBJECTIVES

The objectives of the solution are derived from related work, the identified problems, and relevant medical theories and best practices. Next, we separately identify fundamental objectives, one central paradigm and three main objectives.

A. Fundamental objectives

In the scope of our work, the improvement of health outcomes for patients with chronic conditions was set as the main medical objective of integrated mHealth solutions. As health literacy and adherence to treatment are important intermediate outcomes, we focus on supporting them. The main idea is to support literacy and adherence with adaptive interventions [10, 12]. These adaptive interventions should be implemented in a patient-centered approach that overcomes the current fragmentation by closing the loop from one physician-patient consultation to the next and integrating mHealth apps into the physician workflows and EMRs.

Patient-centeredness has become an imperative in medical care [20]. It is particularly important in consultation [21–23] and communication [11, 24]. In accordance with the four components of the Patient-Centered Clinical Method [20], effective mHealth solutions ideally assist in (1) exploring health, disease and the illness experience, (2) understanding the patient as a whole person, (3) finding common ground, and (4) enhancing the patient-physician relationship.

This implies that such systems must support *physician-patient collaboration* and be able to *personalize patient care*. Physician-patient collaboration needs to include *shared decision-making* [25–27]. Support for shared decision-making goes beyond the implementation of purely technical aspects such as with checklists, and is expected to support humanistic communication [28]. Consequently, an integrated mHealth app must be designed as an extension of the physician and accompany the patient between consultations. Furthermore, it needs to be empathetic, supportive, and motivating.

B. *Central Paradigm: Closing the Loop*

Closing the Loop bridges the gap between the processes, tools, and data used in consultation and those used in between. It also connects the functional components of the architecture. Finally, it serves to control adaptive interventions. Closing the Loop stipulates the implementation of a closed control loop, as known from engineering sciences. The concept found its way into quality management with the Plan-Do-Study-Act (PDSA) cycle [29] and also in the healthcare domain [30].

In our solution, the PDSA cycle is implemented as follows (Fig. 1): In the Plan phase, the physician and patient agree on a therapy plan for the patient. In the Do phase, patients implement the therapy plan by taking medication, exercising, or changing their lifestyle. In the Study phase, first patients alone and later patients and physicians together assess the patient's adherence to therapy and health outcomes. In the Act phase, patients and physicians agree on necessary adjustments to the therapy plan. Then, the cycle starts anew.

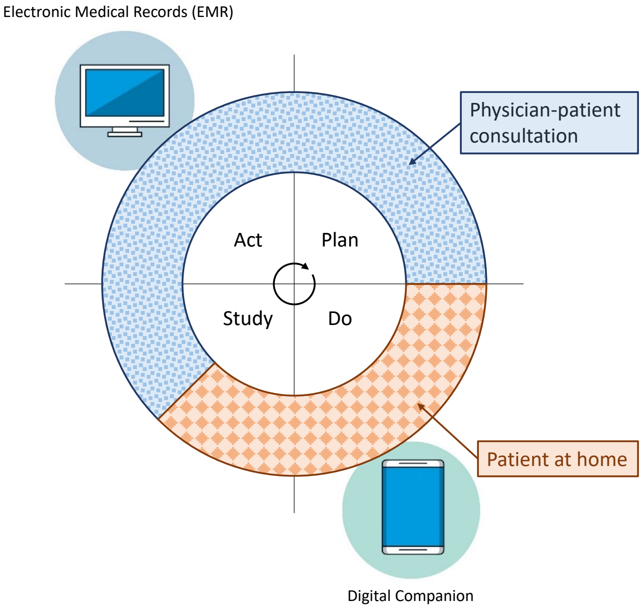


Fig. 1. Closing the Loop

Closing the Loop aims to improve patient literacy and adherence with adaptive interventions controlled by a closed-loop system in which HCPs, patients, and technology are part of the controller. Closed control loops are suitable for controlling output variables that depend on input variables [13, 31, 32].

From a technical perspective, the loop is closed by integrating an EMR used during consultations with an mHealth app that accompanies the patient between consultations. In Fig. 1 as well as in the following text, we refer to such an mHealth app as the "Digital Companion". As a result, the LoopArt architecture enables to build systems that support health literacy (first design goal), support adherence to treatment (second design goal), and integrate consultations (third design goal).

C. *Support health literacy*

According to the WHO, "Health literacy represents the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health." [33]. The Digital Companion must therefore promote health literacy by providing personalized information on individual diagnoses and therapies. The information needs to be presented in lay language, enriched with multimedia content (audio, images, video) where appropriate, and supplemented with additional resources selected during the consultation. Overall, health literacy support must be theoretically grounded, such as based on the Health Literacy Skills Framework [34].

D. *Support adherence to treatment*

Treatment adherence needs to be supported by the Digital Companion that provides the patient with consistent feedback on treatment adherence and suggests appropriate actions to improve it. Measures are appropriate if they recognize the patients' contexts and individual behaviors, and if they provide them with personalized advice that considers these contexts. The advice must cover both, encouraging healthy behavior as well as warning against undesirable behavior. Effective adherence support can be drawn from behavior theories [e.g. 35–37] and pathway models [e.g. 11, 38].

E. *Integrate consultations*

The Loop starts and ends with a consultation. Diagnosis and therapy information must be available to patients when they leave the physician's office. Furthermore, patients should receive new information such as lab results as soon as they are available and thus in between consultations. At the same time, additional work for the physicians must be avoided.

Therefore, the input of the information related to diagnoses and treatment plans must be integrated with an existing EMR where the user interface is optimized for fast and efficient data entry during the consultations. As will be shown in sect. VII, this additionally promotes physician-patient communication and collaboration, while physicians no longer need to write patient reports after consultations.

As part of subsequent consultations, the patient's behavior between the consultations often needs to be studied. Physicians and patients typically interactively assess the execution of the therapy plan and collaborate in refining it. The Digital Companion thus must be able to collect patient behavior data between consultations. This data should be aggregated and visualized for efficient and intuitive handling.

VI. DESIGN AND DEVELOPMENT

In this section, we introduce LoopArt by showing how its main components and functionality contribute to achieving the solution objectives presented in the previous section. LoopArt is depicted in Fig. 2. The white box at the top represents a system context consisting of HCPs, and their existing data repositories, tools, and processes involved in patient treatments during consultation. The architecture contains three main components: a health literacy agent, an adherence agent, and a conversational agent.

An agent-based architecture was chosen to accommodate the fact that the solution objectives highlight different aspects of adaptive interventions with separable goals. Furthermore, patient support needs to be initiated proactively, devised autonomously and flexibly, and delivered timely, all of which lie within the scope of common notions of an agent [e.g. 39].

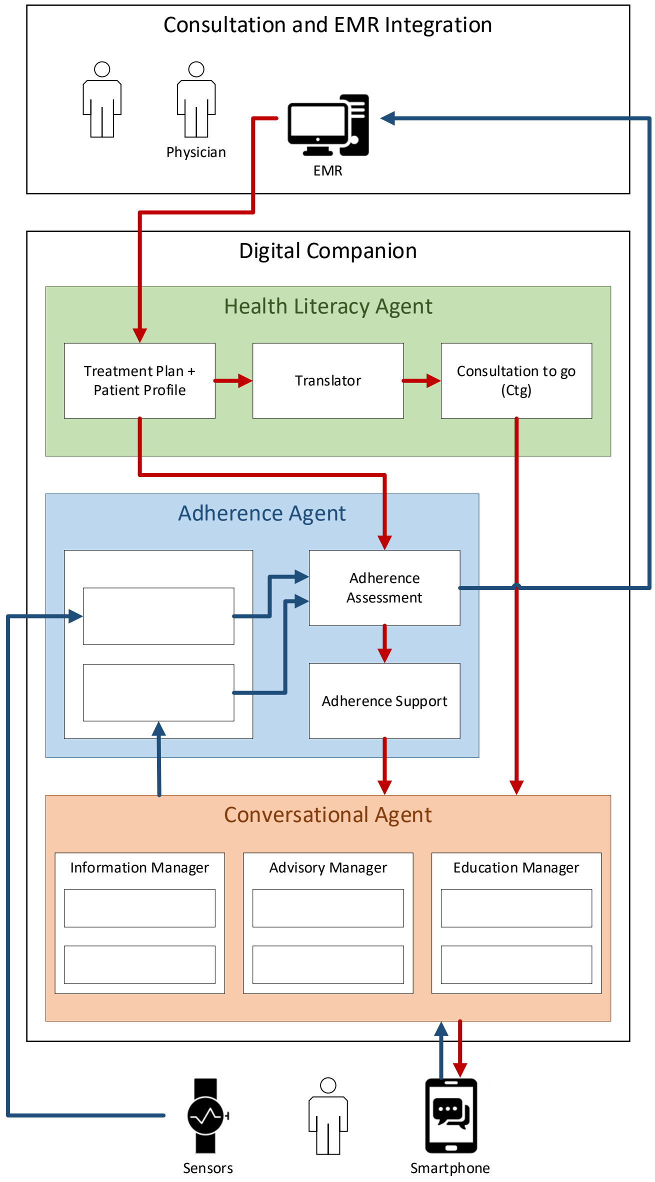


Fig. 2. Closing-the *Loop Ar*chi*t*ecture (LoopArt)

A. Health Literacy Agent

The process begins with physicians determining treatment plans and patient profiles through their EMR application. This information is then handed over to the Health Literacy Agent. The Health Literacy Agent then deploys a Translator to translate physician jargon into lay language. Next, the Consultation-to-go component compiles a patient-specific and interactive report on diagnosis and therapy plan on the Digital Companion app. Depending on the patient profile, this report is enriched with multimedia content such as audio, images, and video. While a therapy plan defines the content of the report, the patient profile determines its appearance. Finally, the report is made available to the patient.

Consultation-to-go's content consists of behavior goals, such as specific levels of physical activity, glucose level, and body weight, and explanatory material. These are translated from the therapy plan. The goals presented to the patient depend on their condition, therapy, and profile.

B. Adherence Agent

The treatment plan and patient profile are also passed on to the Adherence Agent as the basis for patient adherence assessments. Such assessments consist of actual-target comparisons based on the therapy plan and all data collected by sensors and extracted from conversations. An adherence measurement component pre-processes all data collected to enable these comparisons.

Depending on the therapy plan, the pre-processing of sensor data consists of simple readings from medical-grade sensors and data transformations, movement data classifications such as for activity detection [40], or time-series analyses [41] for monitoring and change detections. If meaningful for adherence assessment, this component may also process smartphone usage data [42], including screen times, mobile application usage patterns, product purchases, and even tap into push notifications.

As with the pre-processing of sensor data, all patient interactions with the Conversational Agent can be examined regarding the occurrence, changes, or patterns of relevant aspects such as moods, attitudes, interests, and intentions [43].

The results of the adherence assessment are used in two ways. First, adherence support is triggered, presented visually, or provided by the conversational agent. Second, the results are used to inform physicians. For this purpose, the results are continuously fed back into the EMR. They are thus made available to support decisions regarding treatment adjustments that are the subject of subsequent consultations.

C. Conversational Agent

The Conversational Agent at the bottom of Fig. 2 is triggered by the Adherence Agent when support is to be provided. The Conversational Agent consists of three managers, one dedicated to conversation-based elicitation (Information Manager), another one to stimulating good behavior (Advisory Manager), and a third one to answering questions and providing patient education (Education Manager).

The *Information Manager* uses structured dialogs to capture specific information such as scale-typed indications of well-being or pain, subjective appraisals related to behavioral goals, or results from measurements, such as of body weight or glucose level, conducted by the patients. Furthermore, conversation analysis using natural language processing, enables a more holistic assessment of the patient's condition and therapy progress [44].

The *Advisory Manager* subsumes the interventions affecting patient behavior [45], such as goal setting, increasing self-determination, or motivational interviewing.

The *Education Manager's* task is to contribute to patient health literacy. The Education Manager can answer patient questions and provide explanations [44]. In addition, it may provide health guidance, such as the suggestion to contact the physician at the end of the conversation shown in Fig. 2. To increase the relevance of responses and guidance, all answers must be generated based on the treatment plan, patient profile, medical records, and general medical knowledge.

VII. DEMONSTRATION

To demonstrate the use of LoopArt, we present the implementations of two fundamental components of the architecture as well as a fully functional prototype of the Health Literacy Agent. First, a Translator component was implemented. It enables physicians to enter the key points of diagnoses and therapies in a professional language. A translation mechanism then generates a PDF document of up to five pages for the patient. This document contains the diagnosis and therapy information that is relevant to the patient, described in lay language and enriched with images. Moreover, the information entered allows for initial drafts of patient reports to be generated. Second, a clickable prototype of a Consultation-to-go component was implemented for the treatment of atherosclerosis. It demonstrated the functionality of a mobile application for patients, where diagnosis and therapy information is made available in an interactive manner. For example, patients can see their current and past vital parameters, review their individual risk factors, and consult explanations in lay language.

We then implemented a fully functional full-stack prototype of the Health Literacy Agent based on the findings of the evaluations of the first two component implementations. The prototype consists of a Digital Companion app for the patient and a collaboration tool integrated with the EMR that physicians and patients use during the consultation. The loop from one consultation to the subsequent consultation was closed by feeding all data gathered with the Consultation-to-go back into the EMR as indicated with the blue arrow in Fig. 3. While we make no assumptions about native integration vs. external implementations, we assume the availability of APIs (either proprietary of EHRs/EMRs or standardized such as HL7/FHIR).

As the condition for which the prototype was to be configured, we chose obesity for the following reasons. (1) Economic relevance: Obesity is a risk factor for many non-communicable diseases, with a global prevalence of 13% in 2016. [1]. This equates to 650 million obese adults aged 18 years and over [1]. (2) Rich therapeutic and behavior change options: Since LoopArt is designed for supporting health literacy and adherence to treatment, a convincing demonstration requires a condition for which health literacy and adherence to treatment are challenges. (3) Importance of the therapeutic alliance between patient and HCP: HCPs play an essential role in LoopArt. In medical and humanistic terms, they establish a relationship with the patient and facilitate shared decision-making. In technical terms, they are part of the controller in the closed loop by which the interventions are adapted.

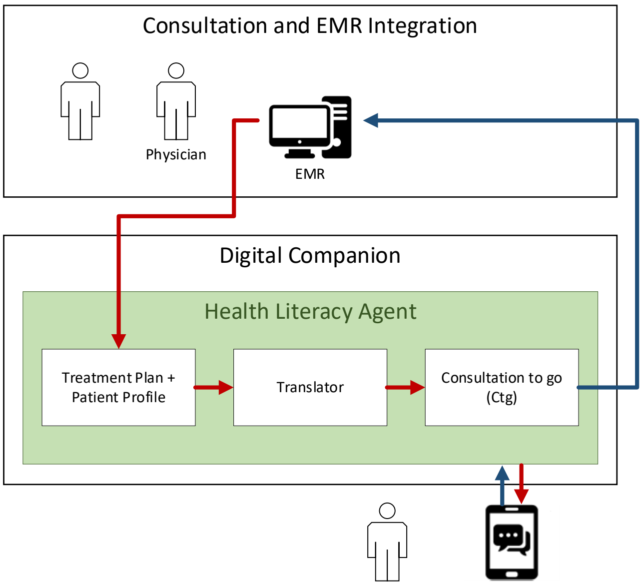
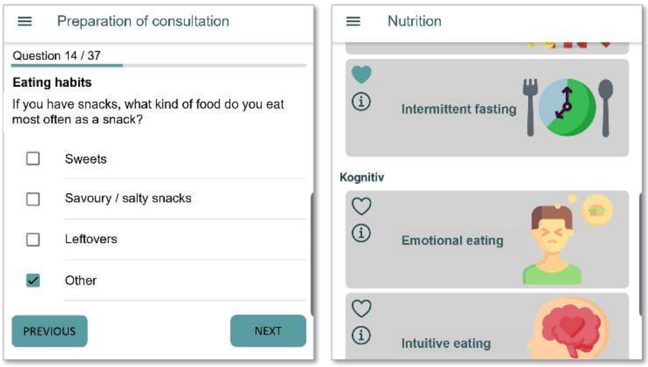


Fig. 3. LoopArt implementation

The following scenario illustrates the interplay of the different Health Literacy Agent components and the EMR and also shows how the solution objectives in sect. V. are met. The scenario demonstrates how obese Michael Quinn is treated by Dr. Rachel Wilcox using the Digital Companion app and the collaboration tool as part of the EMR. The prototypic treatment cycle includes four phases: (1) preparation by patients and HCPs, (2) initial consultation, (3) treatment, and (4) follow-up consultation. The terms in curly brackets show the corresponding solution objectives.

A. Preparation by patients and HCPs

Prior to the first consultation, Michael is asked to complete a questionnaire (Fig. 4, left), keep a diary, and indicate preferences related to treatment options (Fig. 4, right).



Question 14 / 37

Eating habits

If you have snacks, what kind of food do you eat most often as a snack?

- ☐ Sweets
- ☐ Savoury / salty snacks
- ☐ Leftovers
- ☑ Other

Intermittent fasting

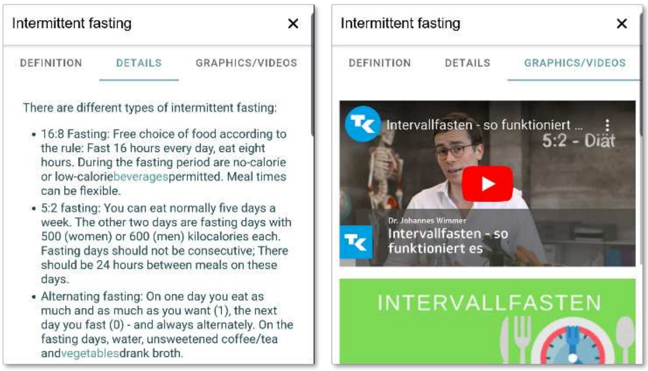
Emotional eating

Intuitive eating

Fig. 4. Questionnaire (left) and preferred treatment options (right)

As a first diary entry, Michael takes a picture of a meal at his favorite fast-food restaurant and connects it with the reference to a rather negative emotion. He makes a note stating that, despite knowing about the unhealthy effects of fast food, he could not resist it. Feeling much better the next day, he takes a picture of his walk with the neighbor's dog.

In the evening, Michael checks out possible treatment options for diet and exercise. He did hear about intermittent fasting from work colleagues but doesn't know how it works. That's why Michael consults the explanations (Fig. 5, left) *{support health literacy}*. Since he does not like to read much, he prefers to watch the provided video instead (Fig. 5, right) *{personalization}*. Pleased with what he learned, he marks intermittent fasting as his favorite diet option. Similarly, he chooses walking and swimming as preferred workout options. Finally, he fills out the requested questionnaire.



There are different types of intermittent fasting:

- 16:8 Fasting: Free choice of food according to the rule: Fast 16 hours every day, eat eight hours. During the fasting period are no-calorie or low-caloriebeveragespermitted. Meal times can be flexible.
- 5:2 fasting: You can eat normally five days a week. The other two days are fasting days with 500 (women) or 600 (men) kilocalories each. Fasting days should not be consecutive; There should be 24 hours between meals on these days.
- Alternating fasting: On one day you eat as much and as much as you want (1), the next day you fast (0) - and always alternately. On the fasting days, water, unsweetened coffee/tea andvegetablesdrank broth.

Fig. 5. Treatment options – definition, further details, multimedia content

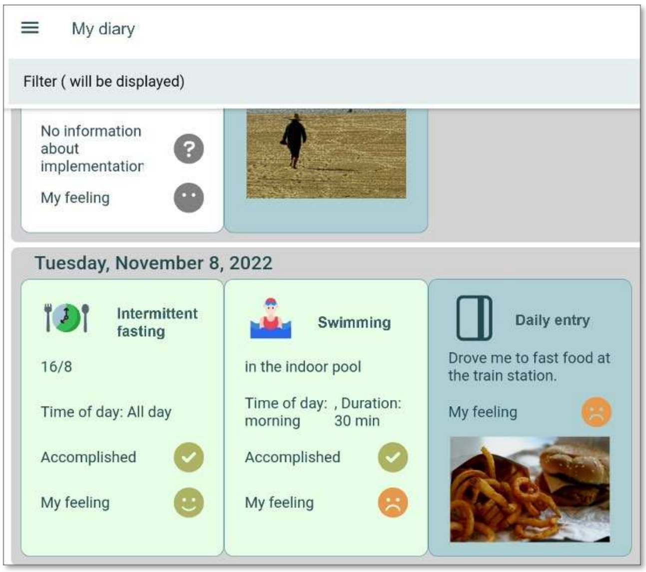
On the morning of Michael's appointment, Dr. Wilcox scrolls through his diary entries, preferences, and questionnaire made available in her EMR by Michael.

B. Initial consultation

Dr. Wilcox welcomes Michael to her medical office. After a few introductory words, she places her tablet computer between them (Fig. 6). Visible for both, she delves into some of Michael's answers from the questionnaire and discusses Michael's diary entries. Michael greatly appreciates Dr. Wilcox's empathetic assessment *{patient-centeredness}*. Next, Dr. Wilcox and Michael negotiate the intended weekly weight loss. Using the sliders on the screen (Fig. 7), Michael can play with variations until he finds a treatment duration and weekly weight loss that he is comfortable with *{physician-patient collaboration, shared decision-making}*. The last part of the consultation is spent on defining suitable treatment options. Michael's pre-selection (Fig. 4, right) helps Dr. Wilcox save time and better meet his preferences *{patient-centeredness, personalization}*. Discussing the pros and cons, Michael and Dr. Wilcox agree on intermittent fasting on a 16:8 regimen, swimming 30 minutes twice a week at the local indoor pool and replacing walking with Nordic walking *{physician-patient collaboration, shared decision-making}*. All necessary entries in the EMR are made directly on the tablet's touch display during the conversation. This way, Michael remains involved and can intervene if he reconsiders what has been agreed. Finally, Dr. Wilcox wishes Michael success with his diet and exercise program and bids him farewell. Michael leaves the medical office. Outside, his wife Catherine picks him up in her car. Catherine asks Michael how it went with Dr. Wilcox. Michael shows her his new goal and treatment plan on the Digital Companion app (Fig. 8).

C. Treatment

The day after his visit with Dr. Wilcox, Michael prepares for his first Nordic walking workout. He watches the video on the Digital Companion app to better memorize the walking technique (Fig. 5) *{support health literacy}*. On his way, Michael takes a picture of the beautiful sunset he is seeing. Back home, he tells Catherine about his new experience and uploads the sunset picture to his Digital Companion app. The other day, when Michael checks his treatment plan in the Digital Companion app (Fig. 8), he realizes that he completely forgot to start intermittent fasting the day before *{support adherence to treatment}*. With mixed feelings, he reports this in his app and goes through the explanations. Catherine lifts his spirits by joking that she no longer must prepare dinner because of Michael's fasting intentions.



Tuesday, November 8, 2022

16/8

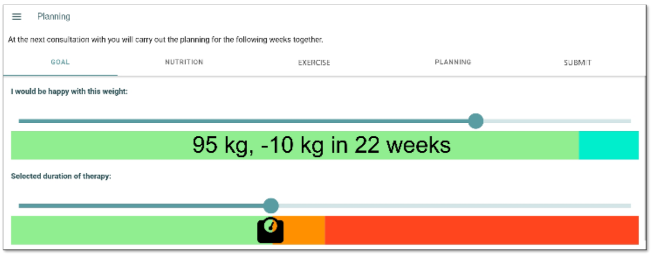
Time of day: All day

in the indoor pool

Time of day: , Duration: morning 30 min

Drove me to fast food at the train station.

Fig. 6. Diary



At the next consultation with you will carry out the planning for the following weeks together.

I would be happy with this weight:

95 kg, -10 kg in 22 weeks

Selected duration of therapy:

Fig. 7. Weight loss goal definition

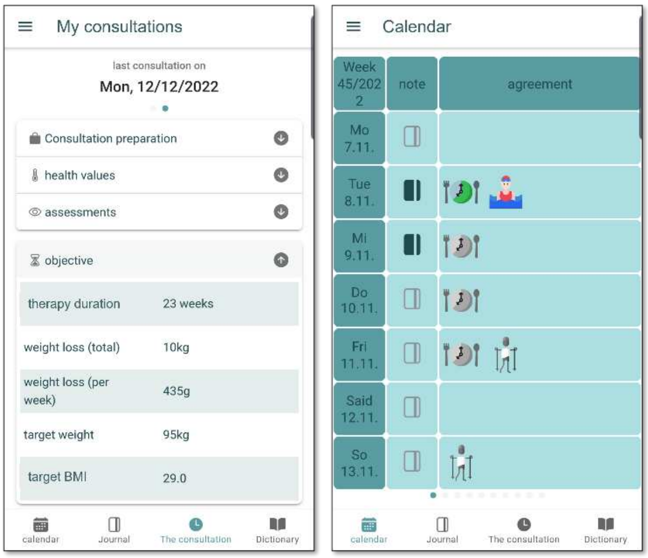
D. Follow-up consultation

Two months later, Michael has his next appointment with Dr. Wilcox. As they did last time, they go through Michael's diary together *{patient-centeredness}*. It becomes clear that swimming didn't work out as planned. After a brief discussion, they decide to do aqua aerobics instead for the next treatment cycle (Fig. 1) *{shared decision-making, closing the loop}*. The information in the Digital Companion is updated accordingly.

VIII. EVALUATION

LoopArt was evaluated as part of two proof-of-value [19] and one proof-of-concept [19] study. In the first proof-of-value study, the Translator component was evaluated by three physicians. The main finding was that a comprehensive and valid report in lay language and enriched with images could be generated based on the input they made during the consultations. Another finding was that the physicians were able to input all required information in less than three minutes. In the second proof-of-value study, the clickable prototype of the Consultation-to-go was evaluated by two physicians and 17 of their patients. The results led to valuable design guidelines for the next iteration in the form of a fully functional prototype.

The fully functional Health Literacy Agent prototype was designed and implemented as part of a proof-of-concept study. It's implementation proves the feasibility of using LoopArt to develop applications. Since the prototype demonstrably provides the support stipulated by the solution objectives, it is evident that the use of LoopArt effectively supports the development of applications meeting these objectives.



last consultation on
Mon, 12/12/2022

therapy duration	23 weeks
weight loss (total)	10kg
weight loss (per week)	435g
target weight	95kg
target BMI	29.0

Week 45/2022	note	agreement
Mo 7.11.		
Tue 8.11.		
Mi 9.11.		
Do 10.11.		
Fri 11.11.		
Said 12.11.		
So 13.11.		

Fig. 8. Consultation-to-go

The overall architecture was further evaluated by four HCPs and an EMR vendor. In the scope of interviews, all of them have indicated, that they consider Closing the Loop as helpful to improve patient adherence and health literacy. One physician emphasizes the potential of Closing the Loop and adaptive interventions for individualizing procedures and tailoring them to patient preferences. He believes this will improve health outcomes compared to standard interventions. The EMR vendor credits the Digital Companion with the ability to promote behavior change among patients toward better adherence to treatment and among HCPs toward better adherence to guidelines. Both have been shown to lead to better health outcomes and lower economic costs, not least due to fewer unnecessary procedures and thus fewer unnecessary side effects.

All the interview participants stated that they consider LoopArt suitable to overcome fragmentation through its integrated approach. One physician acknowledged the integration of data collected using the Digital Companion app with the EMR by emphasizing the need for such data to be integrated with the instruments with which HCPs are working. The EMR vendor anticipates the Digital Companion to be a highly integrated extension of the existing EMR that provides seamless and sophisticated support to the medical workflow.

IX. DISCUSSION & CONCLUSION

LoopArt was inspired by attentive and curious listening to patients and physicians. A physician who complained about having to start repeatedly with explanations of diagnosis and therapy triggered the idea of Closing the Loop. The insight into how different patients respond to physician recommendations led to personalized and adaptive interventions. And recognizing the impact of the physician-patient relationship and collaboration on the health outcomes convinced us to find solutions to overcome fragmentation and strive for integration with physician workflow and EMR.

We developed LoopArt, an architecture that combines and evolves all the identified building blocks (TABLE I.) from the existing architectures we studied.

We draw on the functional decomposition of the "mHealth Architecture for Diabetes Self-Management System" [7] while more explicitly defining both the interaction of functional components and the role of physicians as part of the overall system. We maintained a purely functional view and avoided technical prescriptions or constraints. This gives developers enough room to choose among technical alternatives. The chosen level of detail enabled proof-of-value implementations and a prototype reflecting the solution goals while providing flexibility for creative variety.

From "Health Apps by Design" we incorporate physician-patient collaboration, mHealth app, EMR integration, and process and outcome measurement [8]. We extend their architecture by providing a more thorough functional decomposition and explaining how the functional components contribute to the objectives in more detail. Based on this, we developed the first prototype for a collaboration tool. The seamless integration of the Digital Companion App into the EMR and the identical look and feel was well received by HCPs and patients. We could observe patients that actively engaged in the conversation and did not hesitate to interact directly with the collaboration tool. A broader evaluation should reveal whether this type of collaboration takes up more counseling time than a traditional setting. If that were the case, ways should be identified to save time elsewhere.

We rely on the "Reusable Framework for Health Counseling Dialogue" [9] to design LoopArt's Conversational Agent. We complement the approach by combining patient-reported experiences with sensor-based objective measures of behavior and vital signs. Feedback from HCPs helped us realize that the reliability of information can be increased by combining patient statements with vital signs. For example, it can make a difference whether patients report an emergency with a heart rate in the 70s or in the 120s.

Closing the Loop, as the processual paradigm of our architecture, extends the concept of adaptive interventions [10, 12, 13] by including HCPs as part of the system. In our view, this has several advantages: First, since HCPs perform at least part of controlling adaptive interventions with human intelligence, dynamic models as part of the controller for adaptive interventions can be kept more straightforward. Second, HCPs play an active role and take responsibility by tailoring or even being part of adaptive interventions. This creates space for patient-HCP communication, which is essential in improving health outcomes [11]. Third, patients' awareness that their treatment progress is being reviewed by HCPs could lead to lower dropout rates (compared to isolated mHealth apps). Although feedback from HCPs and patients on our approach and prototypes has been encouraging, our hypotheses have yet to be substantiated by clinical trials.

By having the *Health Literacy Agent* provide patient education in a highly personalized way, our architecture contributes to *patient-centeredness* and *shared decision-making*. Our interviews suggest that personalized information and the confidence that entered information will be read by HCPs motivate patients to engage with information and keep diaries. Observations and feedback from patients on our prototype confirm these suggestions. However, it became very clear that we underestimated the complexity of personalizing information. The challenges are at the conceptual rather than the technical level. Further research may reveal whether it is useful to define a set of complete personas for patients or whether personalization needs to be done at a lower level of granularity such as at the level of individual personality traits.

It can be considered a limitation that we based LoopArt only on architectures described in the scientific literature. Therefore, it is possible that individual elements of LoopArt are already part of existing EMRs. Our primary intent was to develop a comprehensive, integrated architecture connecting EMRs with mHealth apps. This does not imply that all architectural elements have to be new.

While traversing the DSRM process [3] in a first pass, LoopArt emerged as a theoretically and empirically grounded functional architecture for integrating mHealth apps for chronically ill patients and physician EMRs. LoopArt shows how (1) to overcome the fragmentation of digital support while building on the current state of the art, (2) to increase automation and integration of patient support with EMR, (3) patient health literacy and adherence could be increased with the generation of patient-specific, interactive mHealth apps, (4) to increase the reach of HCPs into patient lives, and (5) to increase the data basis available to HCPs, all the while not requiring additional effort/time. Based on LoopArt and as a demonstration, the Health Literacy Agent was successfully implemented and tested in a real-world setting with positive feedback from HCPs, their patients, and the EMR vendor. To tackle the health economic challenges and support patient adherence, the EMR vendor will now implement a market-ready Consultation-to-go. In parallel, a first prototype for the Adherence and Conversational Agents will be developed.

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