Shaping Workflows in Digital and Remote Diabetes Care During the COVID-19 Pandemic: A Service Design Approach.

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Table of Contents

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Abstract

Background: The COVID-19 pandemic poses new challenges to healthcare providers to deliver continuous care. Although diabetes technology is increasingly established today, data rarely gets assessed, and telemedicine has not been sufficiently integrated into clinical workflows.

Objective: This project sought to remotely support children with type 1 diabetes and their caregivers to enhance clinical outcomes and quality-of-life, engage multiple stakeholders through a participatory approach, evaluate the feasibility of using an interoperable open-source platform in a university hospital setting, and analyze success factors and barriers in transitioning from conventional to digital care.

Methods: Service design methods were used to adapt clinical workflows. Remote consultations were performed monthly and on-demand. Device data were uploaded from patients' homes to an open-source platform. Clinical and patient-reported outcomes were assessed before, during and after the lockdown period in Germany due to COVID-19.

Results: A total of 28 children with type 1 diabetes and their caregivers enrolled and completed 6 months of remote visits. Of them, 16 participants opted to perform at least one of their regular visits online. After 3 months, Time-in-Range and Time-in-Hyperglycemia significantly improved whilst Time-in-Hypoglycemia did not increase. These improvements were maintained during the COVID-19 related lockdown between month 3 and 6 of the study. Psychosocial health improved after 6 months.

Conclusions: Remote consultations and data access can improve clinical outcomes and quality-of-life in children with type 1 diabetes even during challenging circumstances. Service design helped to deliver a comprehensive and holistic solution taking multiple stakeholders into consideration. These findings can inform further integration and use of digital tools into clinical care during the pandemic and beyond. Clinical Trial: Clinical Trial registration number: DRKS00016170, IRB: Charite? ethics approval number: EA2/125/18

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Abstract

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Trial Registration: Clinical Trial registration number: DRKS00016170, IRB: Charité ethics approval number: EA2/125/18

Keywords: *Telemedicine; Telehealth; Remote Care; Digital Care; Type 1 Diabetes; Pediatric Diabetes; Open-Source; Service Design; Digital Health.*

Introduction

The interest in digital and remote care continues to increase globally. Although previous research has demonstrated the effectiveness and increasing acceptance of telemedicine [1], knowledge of how to implement digital care in healthcare settings and workflows remains limited.

The COVID-19 pandemic forced many healthcare teams to look for alternative approaches to deliver care to patients with chronic conditions. The demand for acute and emergency care dramatically increased, whilst other areas of healthcare have been significantly compromised [2]. This is particularly concerning as people living with chronic conditions often represent high-risk groups with respect to COVID-19, and are recommended to avoid any potential exposure. New legal frameworks have been introduced that encourage healthcare teams to perform remote online consultations and prescribe medical software or apps [3].

Diabetes represents a highly relevant field for telemedicine [4,5]. Intensive diabetes management has been proven beneficial in delaying the onset and reducing the severity of long-term complications [6]. Therapeutic guidelines have recommended HbA1c targets <7.0% (<53 mmol/mol) for people living with type 1 diabetes [7,8], though the majority does not meet these recommendations with the current standard of care [9]. Modern treatment options such as insulin pumps and continuous glucose monitoring (CGM) sensors are available and widely used by people with diabetes (PwD) in most industrialized countries today. The uptake of insulin pumps and CGMs is the highest in Western European countries [10-12] and the United States [9]. However, although less than a half of the population of people with type 1 diabetes is using insulin pumps, the uptake is much higher in children and adolescents. In Germany, Switzerland, Luxembourg and Austria, the uptake of technology is one of the highest worldwide, with 92% of preschoolers using pumps in 2017. The uptake, however, decreases with age. Although CGM was used by less than half, and more often by the youngest PwD, the uptake had increased over time [11,12]. However, to fully benefit from these relatively modern treatment options, a high level of self-management is required on the patients' side, as well as expertise and training of diabetes teams, and the availability of appropriate digital infrastructure in healthcare settings..

Value-based and integrated care are promising strategies to manage chronic conditions, with special emphasis on shared-decision making and organization of care. These are to a large extent information-driven processes. Technological tools for collecting and exchanging information are considered essential to make integrated care work for all stakeholders involved [13,14]. From a patient's perspective, integrated care aims to meet their health and social needs by taking these as a starting point for redesigning their healthcare experience.

With the increasing interest in the transition to digital care, that has been significantly accelerated by the circumstances of the pandemic, evidence on experiences of healthcare professionals (HCPs), patients, and caregivers in transitioning from traditional to digital care is currently emerging from various fields of medicine [15-28]. A variety of healthcare providers show increasing interest in the possibilities of digital health, although it remains unclear how they can be integrated into existing structures and workflows.

Therefore, the *Digital Diabetes Clinic* (DDC) project sought to i) remotely support children living with type 1 diabetes and their caregivers in managing diabetes, increase time spent in their optimum glucose range (Time-in-Range), and quality-of-life (QoL), ii) engage multiple stakeholders through a participatory project design involving patients, caregivers, and care teams, iii) evaluate the feasibility of using an interoperable open-source platform to upload, store, and review diabetes device data in a university hospital setting, and iv) analyze success factors and barriers in the transition from conventional to digital care.

Methods

Setting

The DDC study was conducted in a tertiary, multidisciplinary pediatric diabetes care center of a university hospital. All participating HCPs were actively seeing children and adolescents with diabetes, and all participating families were previously receiving diabetes care at the department. An overview of the methods used in this study, including design thinking methods and the clinical trial design, is shown in **Figure 1**.

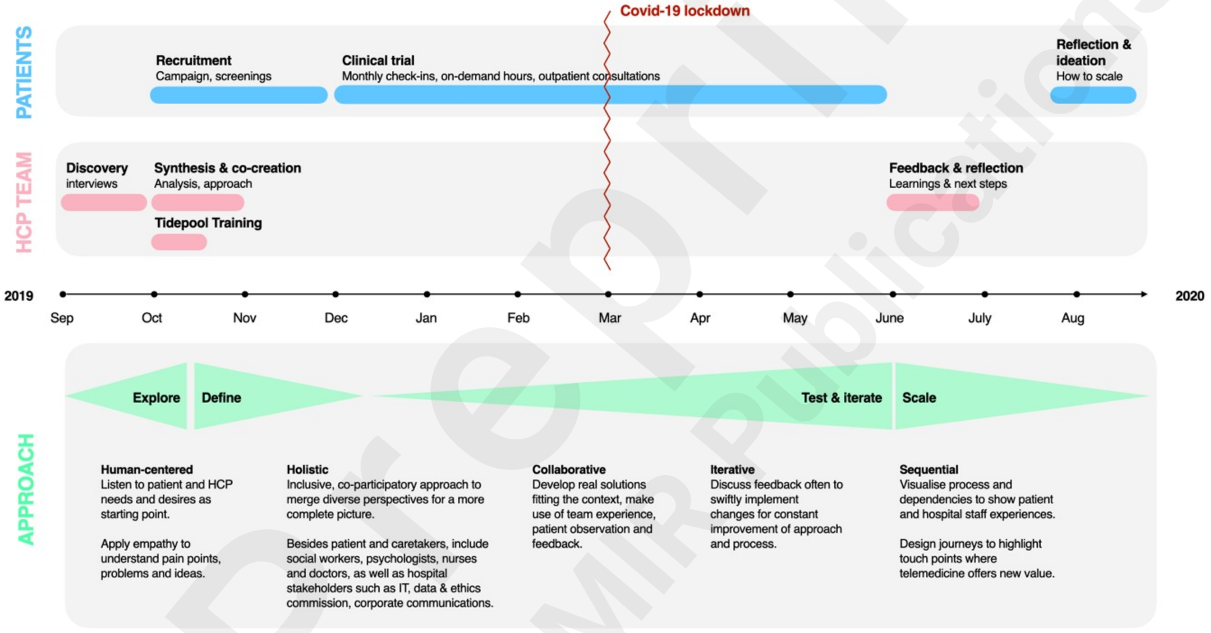

Figure 1: Overview of the methods used in this study, including interventions with the HCP team, the patients and caregivers, as well as the design thinking approach across the project timeline.

Service Design: A New Approach in Healthcare

Service design is a strategic approach typically used in business environments and public sectors to create new or improve existing processes, with the aim to deliver desirable, consistent, and seamless experiences to the users [29-31], such as staff, patients, and caregivers in healthcare settings. By applying design thinking methods, service design looks at how different people, groups, organizations, resources, technologies, processes, and communication paths interrelate to deliver value to users. Physical and digital touchpoints and resources are being identified and evaluated by looking at data capturing, storing, and usage, examining multiple communication channels including apps, email, phone, and written documentation.

Workflow Analysis and Patient Journey

We followed the design thinking process starting with qualitative interviews to explore the current status of the user experience ("journey") of pediatric diabetes care in a university hospital setting and identify problem areas ("pain points"), such as moments of frustration, challenges or gaps in the current process.

Semi-structured interviews following an exploratory approach were conducted with the healthcare team, including physicians, diabetes educators, nurses, social workers, and psychologists, to learn about current workflows, group-specific wishes, and needs. The interviews were conducted on-site in the hospital, in-person, and in small groups, with 2 researchers and two to four interviewees each. Documentation with voice recordings, notes, and photographs of the hospital workspace allowed us to better understand and portray the context and current technology. Post-its and sketches were used by interviewees and interviewers to visualize the process steps patients and caregivers experience during hospital visits, starting at scheduling appointments and time spent waiting to receiving consultations, running laboratory tests, and receiving prescriptions. This information was used to map a comprehensive patient journey and the team's workflow around it (**Figures 2-4**), including the different viewpoints of all stakeholders.

Based on these findings, an optimized journey was co-created, taking the needs of target users, organizational or technical limitations, possibilities, and goals into consideration. Next, we developed a strategic concept with a clear "value proposition", which was delivered in a "service blueprint", showing how different stakeholders can better coordinate their activities to enable users to access new or improved services [32,33].

Once the concept was defined, we progressed to the implementation phase during which the care team transitioned to its new capabilities, adopted new technologies, and changed its routines and ways of communication. This included upskilling certain actors and transparent communication of changes to patients, caregivers, care team, the wider organization, or the public at large.

Stakeholder Workshops

A series of interactive workshops were held in preparation of and throughout the project, first as in-person meetings, later as online meetings later due to the circumstances of the COVID-19 pandemic. A participatory approach was followed to facilitate a process to create team trust, clear communication, alignment, commitment, and shared goals. Relevant information about the project proposal was shared and discussed in order to identify concerns and expectations. Attendees were able to give feedback and contribute to the design and organization of the study. The following questions were discussed: i) *"What do the terms 'telemedicine' and 'digital care' mean to us?"*; ii) *"What are the pros and cons of a healthcare service that is carried out remotely?"*; iii) *"How can healthcare settings, like a university hospital, adopt digital tools, new processes and communication patterns into their current workflows?"*; iv) *"Which processes have to be adapted or re-designed?"*; v) *"What roles and responsibilities exist amongst the stakeholders?"*; vi) *"What technical and organizational support is needed?"*.

After successful completion of 6 months of remote visits, a group of caregivers participated in an online workshop to share learnings, reflections, and feedback. Similar to previous workshops, the intention was to facilitate a participatory, co-creative session during which caregivers could safely and comfortably voice opinions to improve the user experience of remote care. The study team formulated the following research questions: i) *"What was the study's greatest benefit for you and* *your child?"*, ii) *"If you could, what would be the one thing you would change?"*, iii) *"What are the advantages or disadvantages of the DDC? What elements should be adopted by existing healthcare services?"*, iv) *"What challenges or benefits did you experience?"*, v) *"How did the experience impact the children? Did they give any feedback on the new process?"*.

Clinical Trial Design

A prospective, longitudinal open-label feasibility trial was conducted in a single clinical center from December 2019 to June 2020. Children aged 3-12 years with type 1 diabetes were enrolled. The child had to live with a caregiver performing the data uploads and remote visits. The treatment at the time of the initiation visit had to include an insulin pump for at least 6 months and the use of CGM for at least 1 month. Children were asked for their consent to continue CGM use during the study. The ability of caregivers to use pump and CGM were verified, including inserting, changing, and calibrating sensors, and reading and interpretation of data.

Participation was not possible if the caregiver operating with the study tools was diagnosed with a physical or mental health condition considered to severely interfere with the ability to complete the study protocol, if the family had no access to a computer, or if there were known problems regarding their cellular/WiFi connectivity at home, considered to interfere with the ability to perform data uploads and video consultations.

Recruitment

Families were made aware of the study through posters in the hospital's waiting area, by informational material mailed to all families with children that fulfilled the inclusion criteria, and by direct approach of their pediatric endocrinologist. Additionally, a website was launched to communicate the project's overall goals and activities, technicalities, and recruitment process. Eligible participants were invited to workshops in small groups, where they were made familiar with the study design and tools, gave their informed consent, and enrolled in the study.

Hardware

Webcams with integrated microphones and speakers were provided to all participants. Caregivers could also use their own computer, tablet, or smartphone camera. Access to a PC or Mac with an internet connection was required to upload data.

Data Platform

A personalized version of the open-source platform *Tidepool* (Palo Alto, CA, USA) was used [34]. Caregivers uploaded CGM and pump data to a secure and encrypted server hosted by Charité - Universitätsmedizin Berlin and accessed their data via a web-based platform. As *Tidepool* is an open-source project run by a non-for-profit group of parents of children with diabetes, its license permits use, multiplication, and alteration by third parties. Therefore, we were able to create a version adapted to the hospital's IT infrastructure and local data protection requirements [35-38]. This decision was based on the platform's compatibility to multiple devices and manufacturers, the ability to visualize CGM and pump data at a single platform in an integrated, device-agnostic fashion, the easy upload process, equal data access for care team and caregivers at all times, a user interface that was simple to understand, and the availability of ambulatory glucose profiles with all important clinical outcome parameters.

Caregivers signed up for an account, installed the uploader on their computer, and provided data access to the care team. All participants received training on how to upload and review data. Other software, such as Dexcom Clarity® and Abbott FreeStyle Libre View®, were additionally used by some participants.

Remote Visits

A secure web-based video chat application (Patientus, Berlin, Germany) was used. As previously agreed on in the stakeholder workshops, remote visits with a certified diabetes educator were scheduled monthly to ensure frequent follow-ups but keep the additional burden to the participating families to a minimum. In addition, optional daily on-demand consultations hours were offered. Participants could furthermore opt to perform their two- to three-monthly routine appointment with their pediatric endocrinologist remotely, which would otherwise have been an in-person visit as part of their standard care.

Outcome Measures

The primary outcome parameter was Time-in-Range (% of sensor glucose levels 70-180 mg/dL/3.9-10.0 mmol/L).

Secondary endpoints included:

1) Time-in-Hypoglycemia: % of sensor glucose <54 mg/dL/3.0 mmol/L and 54-70 mg/dL/3.0-3.9 mmol/L,
2) Time-in-Hyperglycemia: % of sensor glucose >250 mg/dL/13.9 mmol/L and 180-250 mg/dL/10.0-13.9 mmol/L,
3) Incidence of severe hypoglycemia with the need for assistance by others and/or unconsciousness,
4) Incidence and suspected cause of diabetic ketoacidosis (DKA),
5) Diabetes-related hospitalizations,
6) HbA1c (if available) and/or estimated HbA1c (eA1c),
7) QoL, parent-reported via an online survey, using the PedsQL questionnaire,
8) Feasibility of the care model based on the proportion of participants who successfully complete 6 months of remote visits and on caregiver feedback provided by an online survey and interactive workshops (optional).

Caregiver Feedback

By the end of the study, caregivers were invited to provide feedback in an online survey, if they desired, sharing the pros and cons of their experiences with remote care and their expectations and needs for diabetes care in the future.

Data Collection and Analysis

A de-identified dataset including demographic data, outcome measures, and consultations were documented and analyzed using REDCap, a secure electronic data capture tool hosted locally at Charité - Universitätsmedizin Berlin [39]. Furthermore, remote and in-person consultations were documented in the hospital's information system. Quantitative analyses were conducted using the R programming framework (v4.0.2) and the ggplot2 package was used to generate figures.. Change of primary and secondary outcome parameters was assessed with Wilcoxon signed-rank test (p-value threshold 0.05, for paired data, one-tailed test with alternative hypothesis: "less"). For HbA1c descriptive statistics and associated statistical tests, missing HbA1c values were substituted by the eA1c when available.

Ethical Conduct of the Study and Informed Consent

The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines and with the Data Privacy Law of Berlin (Berliner Datenschutzgesetz; BlnDSG), was approved by the Charité ethics committee (EA2/125/18) and registered under the clinical trial registration number DRKS00016170. Informed consent was obtained from each child's caregiver prior to inclusion. A child-friendly version of the information sheet was provided to children aged 8-12, and they were asked for their assent to participate.

Results

This study presents results from a six-month feasibility trial and portraits its conceptual development and lessons learned throughout the process.

Patient Journey and Workflow Analysis

The design thinking activities involved 5 pediatric endocrinologists, 3 diabetes educators, 3 nurses, 3 psychologists and social workers, 1 resident physician, and 4 families that previously participated in the telemedicine intervention.

Figure 2 illustrates the patient journey and current workflow of a conventional visit to the hospital. Multiple pain points were identified, such as long waiting hours, lack of digitally available data from devices, limited insight of patients/caregivers into their own data, and time-consuming tasks for the care team, such as documentation and logistics of paper files. In the proposed workflow for scheduled remote consultations (**Figure 3**) and on-demand remote consultations (**Figure 4**), the identified problem areas were being addressed: HCPs and patients/caregivers were provided equal data access, and collaboratively agreed on individual therapy goals and ways on how to achieve them. The documentation process was simplified.

Figures 2-4: Patient journey and workflow analysis of conventional **(Figure 2)**, remote **(Figure 3)** and on-demand **(Figure 4)** consultations.

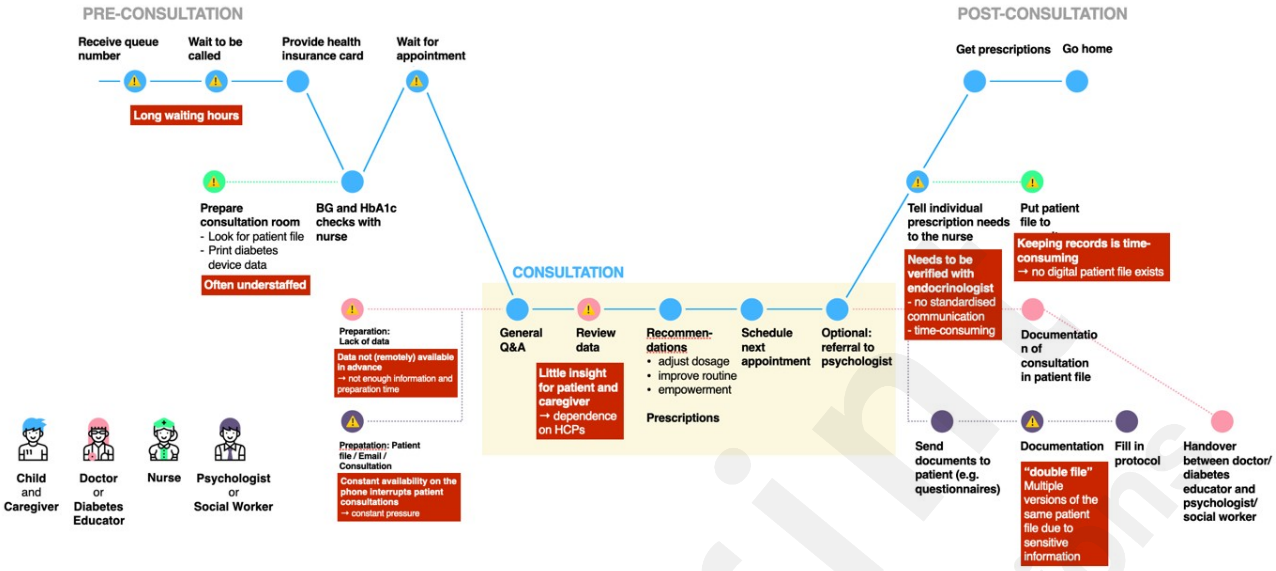

Figure 2: Patient journey and workflow of a conventional clinic visit with current problem areas to improve.

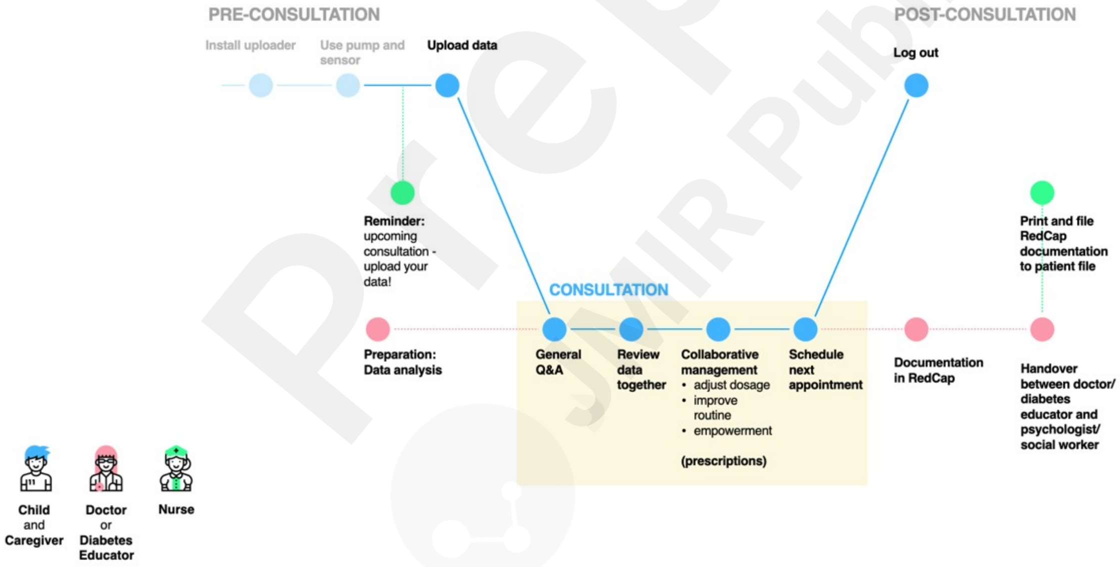

Figure 3: New patient journey experience and workflow of the remote monthly check-ins.

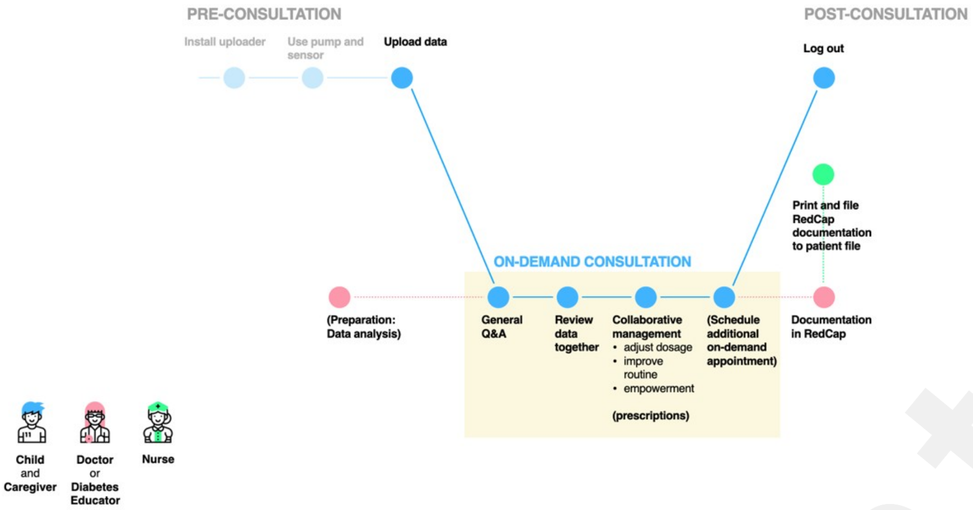

Figure 4: Patient experience and workflow of a remote consultation on-demand (between monthly check-ins).

Stakeholder Workshops

The stakeholders agreed that the project’s value proposition was to improve the patients’ wellbeing by complementing existing ambulatory services with remote consultations instead of replacing them completely, and by improved data access and analysis. Much time was spent to structure a remote service that caters to better interaction and higher flexibility and reduces stress on both ends. Clear advantages of telemedicine were identified, such as saved time and effort and the possibility to deliver healthcare to families based in rural areas. Digital care was perceived as less bureaucratic and hence less time-consuming in documentation, which could save costs for healthcare providers. The care team expressed to be generally open to adopting new technology and saw clear benefits for patients. Limited staff availability due to the increasing economization of the healthcare sector, organizational and structural challenges were perceived to be the main barriers toward the adoption of new tools and care pathways. Furthermore, safety concerns were being addressed and a triage system for emergency scenarios was created (**Figure 5**).

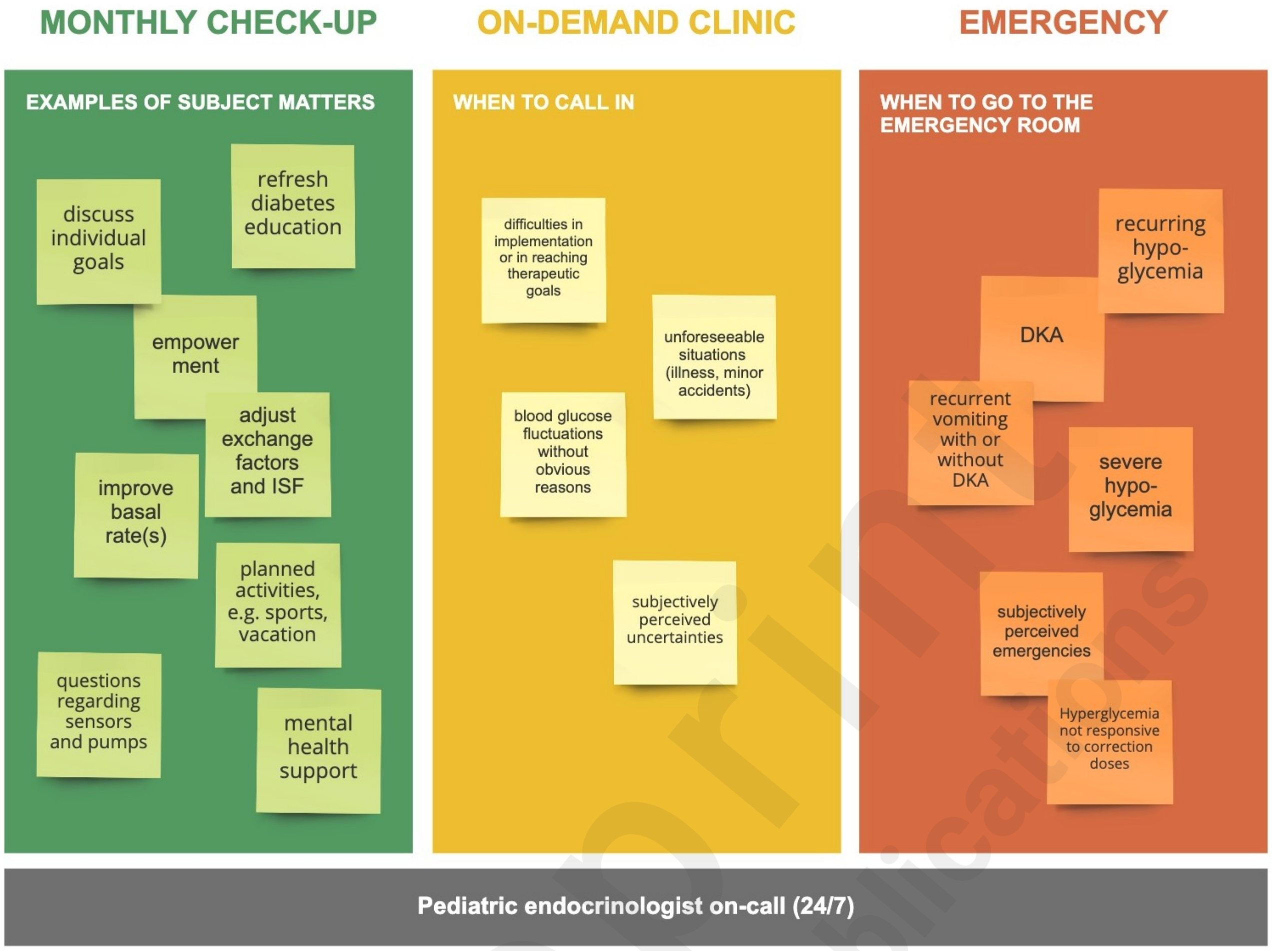

Figure 5: Triage system for use of the on-demand consultations, risk assessment and emergency management in case of severe hypoglycemia, diabetic ketoacidosis (DKA) or other emergencies subjectively perceived as serious.

Perceived challenges during the study were mainly of technical nature, such as compatibility of some sensors and pumps with the uploader, and server errors on the hospital's side that were time-consuming and complex to resolve.

Study Cohort

A total of 28 patients with a median age of 8 ±2.6 years and a median diabetes duration of 4 ±2.2 years were enrolled. Three more families were interested in participating but could not be included due to hardware incompatibility of their diabetes technology in use (N=1), lack of access to a computer (N=1), and technical issues with their available personal computer at home (N=1). One family participated with two children with diabetes, there were two single-parent households and two families where the parents lived separately. Of the 27 families, 26% (N=7) had a migration background, with at least one parent being born in a country other than their country of residence. All 28 children used insulin pumps and CGM, either as sensor-augmented pump therapy or as a hybrid closed-loop system by one participant. With a median annual household net income of 60,000 ±34,078 EUR, and 45% (N=28) of the caregivers holding a university degree, both income and education levels of the cohort were above national average. For all children, CGM and pump supplies were fully covered by health insurance, with 85% (N=23) families being on a public and 15% (N=4) families on a private healthcare plan. Further characteristics are visualized in **Table 1**.

Table 1: Sociodemographic characteristics of the study cohort.

Gender [n (%)]	Female Male Other	18 (64.2) 10 (35.7) 0 (0)
Comorbidities [n (%)]	Coeliac's disease Hashimoto thyreoiditis other	3 (10.7) 1 (3.6) 2 (7.1)
Type of insulin pump [n (%)]	Medtronic 670G Medtronic 640G Medtronic Veo	1 (3.6) 23 (82.1) 4 (14.3)
Type of CGM sensor [n (%)]	Medtronic Guardian Dexcom G6 Dexcom G5 FreeStyle Libre 2	13 (46.4) 5 (17.9) 1 (3.6) 9 (32.1)
Caregiver's employment status, mother [n (%)]	Full-time Part-time Unemployed Student N/A	10 (35.7) 13 (46.4) 4 (14.3) 1 (3.6) 0 (0)
Caregiver's highest education level completed, mother [n (%)]	No/some high school High school University degree or diploma Doctorate Other N/A	1 (3.6) 4 (14.3) 12 (42.9) 2 (7.1) 9 (32.1) 0 (0)
Caregiver's professional background, mother [n (%)]	Healthcare/science Education and childcare IT Service Other None N/A	8 (28.6) 3 (10.7) 1 (3.6) 3 (10.7) 9 (32.1) 1 (3.6) 0 (0)
Caregiver's employment status, father [n (%)]	Full-time Part-time Unemployed Student N/A	22 (78.6) 2 (7.1) 2 (7.1) 1 (3.6) 1 (3.6)

Caregiver's highest education level completed, father [n (%)]	No/some high school High school University degree or diploma Doctorate Other N/A	4 (14.3) 3 (10.7) 13 (46.4) 1 (3.6) 6 (21.4) 1 (3.6)
Caregiver's professional background, father [n (%)]	Healthcare/science Education and childcare IT Service Other None N/A	2 (7.1) 1 (3.6) 4 (14.3) 2 (7.1) 14 (50.0) 2 (7.1) 1 (3.6)

Feasibility

All enrolled participants completed 6 months of monthly remote visits. In addition, 57% (N=16) of the participants opted to perform at least one of their two- to three-monthly regular clinic visits with their pediatric endocrinologist remotely. The on-demand clinic was used by 29% (N=8) of the families, of which 7 made use of the service once, and one family multiple times throughout the study. Subject matters discussed are summed up in **Table 2**. In 96.4% of the consultations, participants felt confident in how to upload, access, and review their data remotely. Whilst technical aspects of the data and video chat platforms were mostly discussed during the first virtual visit, follow-up visits largely focussed on diabetes- and otherwise health-related topics. At the monthly check-ups, individual therapy goals have been fully achieved in 90.4%, and partially achieved in 6.1% of the cases. There were no study dropouts. No severe hypoglycemia, DKA, or other urgencies that required the study personnel to consult the endocrinologist on-call did occur. A handover to psychologists and social workers was necessary 6 times.

Table 2: Activities and subject matters discussed in remote care visits.

Activities and subject matters	**Monthly check-in [n (%)]**	**On-Demand Clinic [n (%)]**
Reviewed data together	96 (85.7)	6 (60.0)
Basal rate adjustments	59 (52.7)	4 (40.0)
Carb exchange factor adjustments	52 (46.4)	3 (30.0)
Technical aspects of the data platform	34 (30.4)	1 (10.0)
General organizational matters	32 (28.6)	1 (10.0)

Refreshed diabetes education and training	25 (22.3)	2 (20.0)
Technical aspects of the video chat platform	18 (16.1)	2 (20.0)
Mental health concerns	13 (11.6)	1 (10.0)
Technical aspects of CGM	9 (8.0)	1 (10.0)
Technical aspects of insulin pumps	8 (7.1)	1 (10.0)
Therapy adjustments for physical activity	7 (6.3)	0 (0)
Insulin sensitivity factor adjustment	5 (4.5)	1 (10.0)
Acute illness	2 (1.8)	1 (10.0)
Other topics	30 (26.8)	3 (30.0)

Clinical and Patient-Reported Outcomes

After completing 3 months of remote consultations, Time-in-Range and Time-in-Hyperglycemia had significantly improved (**Figure 6**). This improvement could be maintained over the lockdown between month 3 and 6, with daycare, playgrounds, schools, universities, non-essential businesses, and international borders being closed during the first wave of COVID-19 cases in Germany from March to May 2020. Time-in-Hypoglycemia did not increase. No changes in HbA1c were observed. Psychosocial health was significantly improved. All detailed outcome parameters are shown in **Table 3**.

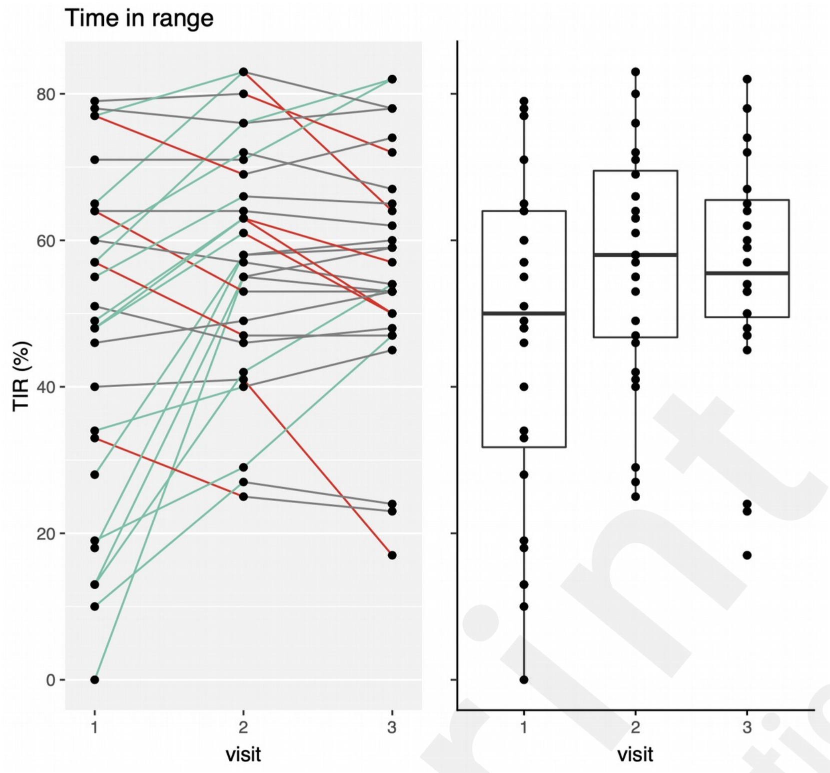

Figure 6: Individual changes and overall distribution of Time-in-Range of sensor glucose [%] before (visit 1), after 3 months (visit 2) and 6 months (visit 3) of remote consultations. Green: Individual change in TIR was > 5% (considered as higher). Red: Individual change in TIR was < 5% (considered as lower) Grey: Individual change of TIR was within +/- 5% (considered as stable).

Table 3: Clinical and patient-reported outcomes before, during and after 6 months of remote consultations. All significance levels of results from visit 2 and 3 are calculated in comparison with visit 1 (see Methods).

	Visit 1 (at enrollment)	**Visit 2** (with 3 months of remote consultations completed)	**Visit 3** (with 6 months of remote consultations completed)
Time in Range [%]	**46.9 ±22.9**	**57.5 ±16.3** p=0.001	**56.3 ±16.5** p=0.016
Time in Hypoglycemia [%]	**5.1 ±12.1**	**4.7 ±6.9** p=0.209	**3.7 ±4.3** p=0.080
54-70 mg/dL/3.0-3.9 mmol/L	3.1 ±5.4	3.5 ±5.0 p=0.165	2.7 ±3.0 p=0.107
<54 mg/dL/3.0 mmol/L	2.0 ±6.9	1.2 ±2.1 p=0.388	1.1 ±1.4 p=0.117
Time in Hyperglycemia [%]	**48.0 ±26.2**	**37.9 ±18.8** p=0.004	**40.0 ±18.7** p=0.015
180-250 mg/dL/10.0-13.9 mmol/L	26.7 ±14.4	25.9 ±13.2 p=0.348	26.1 ±10.0 p=0.469
>250 mg/dL/13.9 mmol/L	21.3 ±20.2	12.0 ±12.8 p=0.004	13.9 ±14.7 p=0.013
HbA1c [% (mmol/mol)]	**7.5 ±0.9** (58.2 ±9.0)	**7.7 ±0.9*** (58.1 ±9.3) p=0.434	**7.6 ±1.1** (59.1 ±13.0) p=0.420
Quality of Life [PedsQL Score]			

Psychosocial health summary	72.5 ±14.0	-	78.0 ±14.4 p=0.038
Physical health summary	81.0 ±17.9	-	82.7 ±16.0 p=0.136
Diabetes-related	70.3 ±10.7	-	73.6 ±9.0 p=0.063

** Not available for patients who opted to perform their month 3-visit remotely. Instead, estimated HbA1c values (eA1c) were calculated based on sensor data.*

Caregiver Feedback

Caregivers expressed that remote care was beneficial to them and their child and advantages exist compared to in-person meetings. The reduction in time and stress associated with hospital visits, flexibility around times of the day, and the ability to be in a safe, comfortable and familiar setting allowed for more engaged and dedicated interaction with the health service providers, who were perceived as less stressed, more dedicated and focussed. Reviewing data together generated new and valuable insights for most, and enabled caregivers to take over the initiative and perform therapy adjustments. The families were satisfied with the received care and expressed their desire to continue digital care after their participation in the study, and suggested to fully integrate them into routine care. Furthermore, remote consultations with psychologists and social workers were desired. Intervals between visits were more frequent, which was perceived as beneficial to discuss arising questions, and the late afternoon and evening hours were preferred times of the day. Technical problems with the internet connection, video chat and data platform did occasionally occur.

Finally, the service was perceived to be “more at the pulse of time”, with a perceived general improvement of the children’s well-being, improved glycemic outcomes, and newly gained insights. Further feedback is shown in the **Multimedia Appendix, Suppl. Table 1**.

Discussion

This study describes the transition to, and feasibility of, remote care and the use of an interoperable health data platform in an ambulatory pediatric diabetes care setting. Digital care could be delivered successfully and to the participants' satisfaction. Remote and continuous data access has been significantly improved for patients, caregivers and the healthcare team, and was perceived as helpful for therapeutic decision-making. Despite the COVID-19 pandemic having numerous potential implications on physical and mental health [40,41], as well as social and family life, better clinical outcomes were achieved before and maintained during the intervention period, and psychosocial health was significantly improved.

Our findings are in line with previous studies and opinions from before [4,5,42-44] and during [45-51] the COVID-19 pandemic, where benefits of remote care were reported from various regions and settings. This study is the first to report the impact of remote care during the COVID-19 pandemic on clinical outcomes, the first to report on remote care during the COVID-19 pandemic in pediatric diabetes care, and the first to describe how service design methods were used for stakeholder engagement and to improve workflows in clinical care.

Conventional hospital visits and admissions put patients in artificial time windows that rarely represent their actual daily challenges and individual needs. Young PwD and caregivers often perceived a lack of communication regarding their/their child's treatment amongst healthcare providers and felt that their care teams did not sufficiently understand their daily problems, and did not have a lot of involvement in therapeutic decision making [52]. Previous research has shown that only a minority of PwD and caregivers regularly download and review their own data [53,54] and how self-assessment and specialists' referrals to the data can improve diabetes management [55].

The findings from this study allowed us to validate the necessary technical instruments and organizational processes around the transition to digital care and into new workflows. Both, the "as-is" journey and "desired" journeys were key artifacts to create shared understanding and alignment amongst stakeholders. As the recent modalities have led to an overall change in working culture and socializing, with the majority of professional meetings, social gatherings, university, and school classes held online, there is a strong need for the healthcare sector to adopt new ways of communication. The implementation of remote data assessment and virtual communication can therefore improve access to specialty care not only during but also beyond the pandemic, but a paradigm shift is required in how healthcare services are delivered, managed, and funded.

The use of an open-source data platform was evaluated positively for a number of reasons: 1) interoperability between devices from different manufacturers, 2) immediate access to data for both parties, 3) positive user experience. However, technical issues occurred occasionally throughout the intervention period, which were sometimes challenging to solve, as the product was not a plug-and-play service provided by a third party. Therefore, follow-up projects should include structured management plans clarifying roles and responsibilities for technical support.

In the transition towards technological innovation, the "digital divide" might leave some user groups behind. Hence, while PwD generally report positive experiences with diabetes technology, the complexity of accessing and maintaining them remains challenging for some. In this regard, it is notable that younger adults, who are generally considered to be more 'tech savvy', are in fact less likely to embrace the use of diabetes technology and showed the highest diabetes distress compared to older cohorts [56].

In this study, interactions were primarily done with caregivers. Further research is needed on how to involve children and adolescents more actively in telemedicine consultations, and how the intervention could be adapted to cater to the needs of other age groups and of PwD other than type 1, and of those using SMBG and/or MDI (e.g. by uploading data from glucometers and electronic pens or integration of diabetes diary apps). Based on the stakeholder feedback we conclude that it is crucial to integrate new, digital tools with routine care instead of conducting separate care pathways. Therefore, further service design research should address how healthcare teams in other healthcare settings, e.g. high volume clinics in adult diabetes care, and staff with limited technical skills can be trained in confidently providing digital care.

The ability to effectively provide telemedicine increases if a clinic has experience in diabetes technology provision (insulin pumps, CGM, electronic health records, diabetes-management software etc.), and the required infrastructure (software, computers, internet connection). It is worth to acknowledge, however, that although the use of diabetes technology is clearly associated with the countries' local reimbursement strategies or health insurance [59], uptake is heterogeneous in the countries offering full reimbursement also. Individual aspects such as personal attitude or interest (of a PwD, but more importantly HCP), awareness, structure and capacity are among other than insurance determinants of access to diabetes technology [60]. Thus, we are aware that the proposed model may not be suitable for all pediatric diabetes clinics.

The beliefs and attitudes of HCPs may be among the barriers to impacting universal access to advanced diabetes technologies [56-58]. New care models may initially cause feelings of uncertainty and might seem overwhelming to some, who have usually delivered in-person care for the past decades [61]. Organizational and structural changes can lead to frustration and consequently have a negative impact on the motivation to adopt new care pathways. To make sure that healthcare teams do not shy away from new technology and additional work requirements, it is therefore important to engage all relevant stakeholders in the transition process as early as possible. The business environment has learned the value of service design as a way to innovate in addressing people's needs - and the healthcare ecosystem could benefit greatly from doing the same [31]. As an applied research and innovation framework, service design prioritizes empathy for users of a service or product, embraces interdisciplinarity and collaboration within project teams, and encourages an action-oriented rapid prototyping of user-derived insights rather than top-down hypotheses. It has shown to be beneficial to encourage them to contribute their ideas to the process design, acknowledge their concerns, and build supportive practices [61].

Our study adds to the ongoing discussion on the importance of Time-in-Range as a measure comparable to or even more important than HbA1c. The choice of Time-in-Range as the primary and HbA1c as a secondary outcome parameter being a possible strength, compared to most other studies reporting clinical outcomes of people with diabetes. Although Time-in-Range and quality-of-life had significantly improved for our study cohort, there were no observed changes in HbA1c levels. Although HbA1c is still widely used as a primary outcome parameter in many CGM studies [62-66], Time-in-Range has been acknowledged to be a representative outcome measure for glycemic control [67,68]. Previous research has shown only moderate correlation between Time-in-Range and associated HbA1c levels, with a considerable spread of change in HbA1c levels for a given change in Time-in-Range, and vice versa [69]. Our findings strengthen the need for using CGM-derived outcome measures in clinical care as well as clinical research, as well as for new surrogate markers for developing diabetes-related long-term complications [67-69], as CGM data can be assessed remotely and with no additional invasive procedures for the PwD, and clinical outcome improvements may remain unobserved with the focus of evaluation being limited to HbA1c.

It is acknowledged that several strengths and limitations apply to our study. Firstly, this study provides a practical example for other diabetes care teams on how to use the opportunities given by the necessity of remote care. Secondly, it supports the use of technology in the delivery of diabetes care and patient involvement in the co-creation of services. Thirdly, it is based on real-world data and presents different perspectives of health-services providers and users. The limitations of this study should also be acknowledged. This study was a single-armed, non-randomized feasibility trial based on data from a small cohort of patients. Due to its observational nature, and the lack of a control group comparison, it limits our ability to assess the effectiveness of remote vs. routine care for all PwD universally. Although our participants were widely distributed through various education and income levels and professional backgrounds, the majority of the participants were from middle to high income and education families, and all participants were using insulin pumps and CGMs, which may cause socioeconomic status' related bias. Furthermore, those with language barriers or low levels of tech literacy might have felt less confident to participate, which might indicate another selection bias. Access to the internet and a computer was required, which was available to most, but not to all eligible families. As CGM, insulin pumps, and supplies are fully covered for children with diabetes by public and private health insurance plans in Germany, this project may not be applicable to all diabetes care settings. Limited access to diabetes technologies, as it is evident in many regions outside Western Europe, could limit the applicability of this approach. Although advances in technologically mediated treatments are promising, there remain concerns with respect to social inequality and the challenge of ensuring that they are widely diffused across the population. More research is needed to understand these potential obstacles and provide appropriate education and support.

Conclusions

This study sought to identify and solve multiple problems currently existing in diabetes care: limited access to diabetes device data, poor interoperability of data from different devices, and restricted access to specialists, especially during the circumstances of a global pandemic. The study design allowed the care team, patients, and caregivers to actively contribute to the process and enabled shared decision making. The results generated by this project will help to better inform and improve ways for implementing remote and digital care for diabetes and in the wider healthcare sector - during the pandemic and beyond.

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Author contributions

KBr performed the literature search. KBr, KBo and KR designed the study. KBr, KBo, JSH, LS and BP collected the data. KBr, AT, LS and BP analyzed and interpreted the data. KBr wrote the initial draft. All authors have critically reviewed and revised the draft and read and approved the final version of the article. KBr is the guarantor of the study.

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Conflicts of Interest

All authors have completed the Unified Competing Interest form and declare:

KBr received research grants from the BIH Junior Clinician Scientist program for the conduction of the study. She has further received research grants from the BIH Digital Clinician Scientist program, the European Commission’s Horizon 2020 Research and Innovation program, Wellcome Trust, Stiftung Charité, and the German Diabetes Association (DDG); outside the submitted work. She has served as a speaker and advisory board member for Medtronic Diabetes, and received fees for medical consulting and public speaking from Roche Diabetes Care, Dexcom, Medtronic Diabetes, Diabeloop and Bertelsmann Stiftung; outside the submitted work.

JSH is employed as a diabetes coach by mySugr on a part-time basis.

KR reports grants from the European Commission's Horizon 2020 Research and Innovation Program under the grant agreement number 823902, is an advisory board member of Lilly Diabetes Care and Abbott Diabetes Care; outside the submitted work.

All other co-authors have no conflict of interest to declare.

Abbreviations

CGM: continuous glucose monitoring

DKA: diabetic ketoacidosis

eA1c: estimated HbA1c

PwD: people with diabetes

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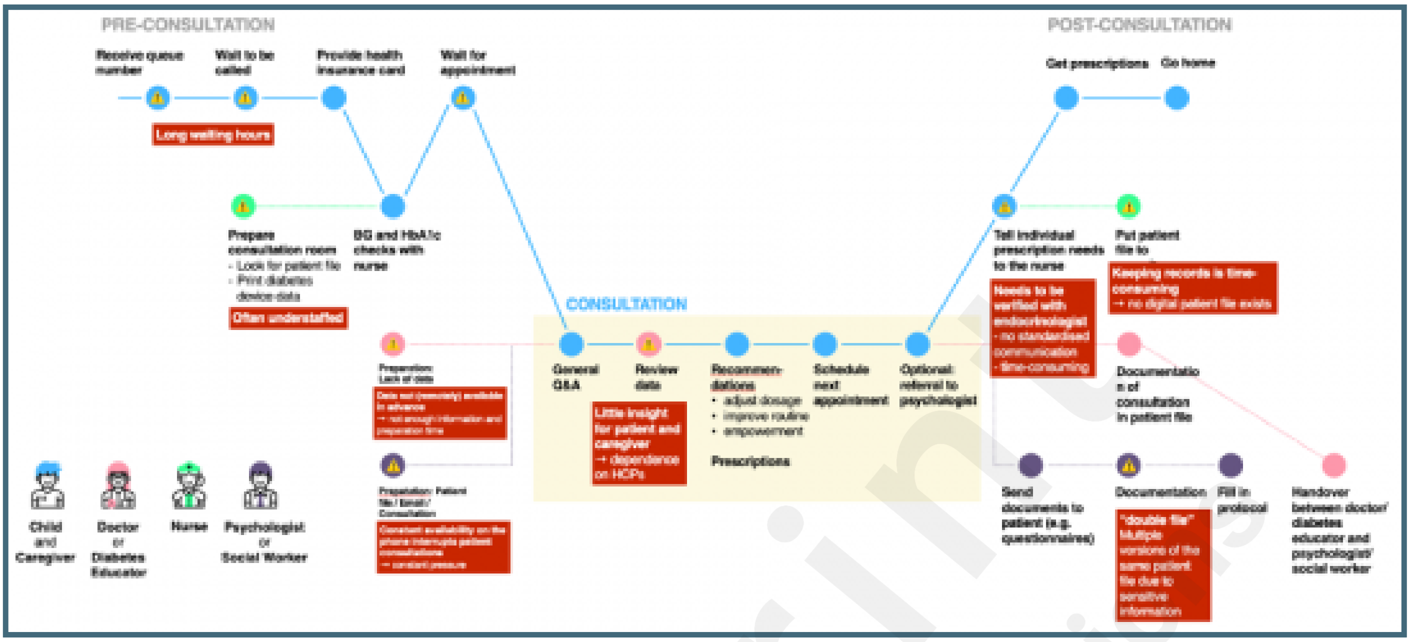
Supplementary Files

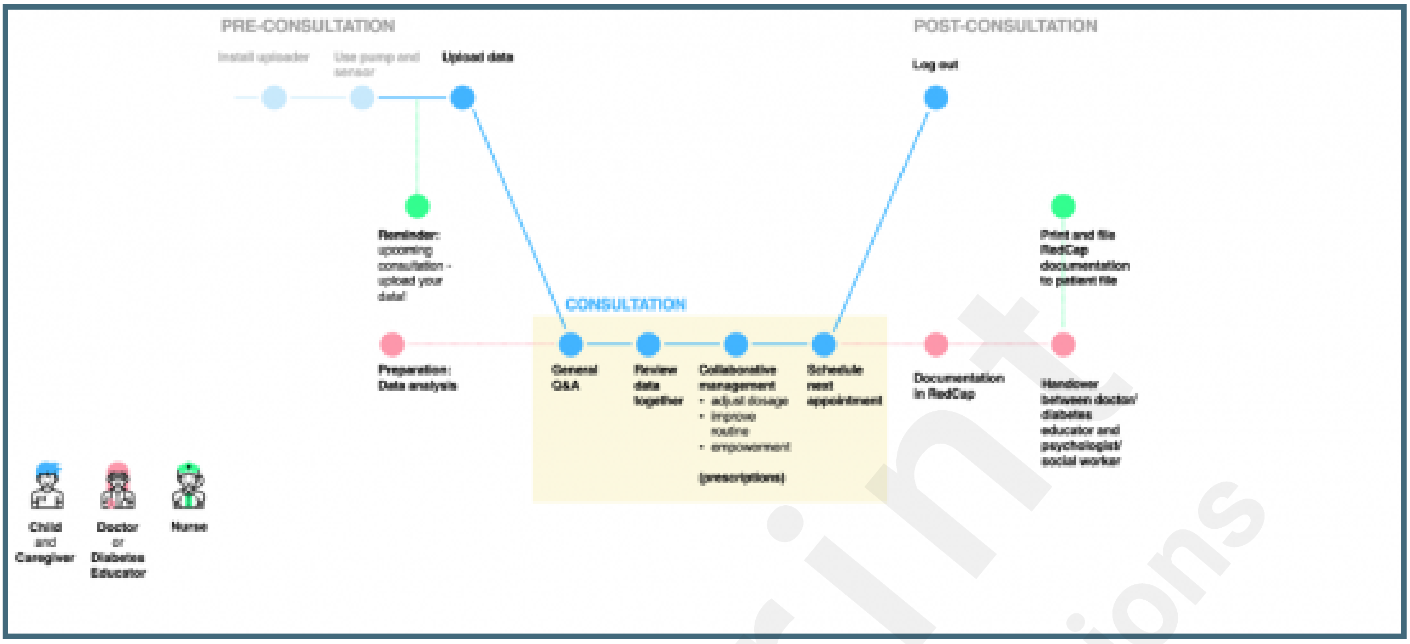
Untitled.
URL: https://asset.jmir.pub/assets/48cd209a2fd7ecb27b521b0658cdf17d.docx

Figures

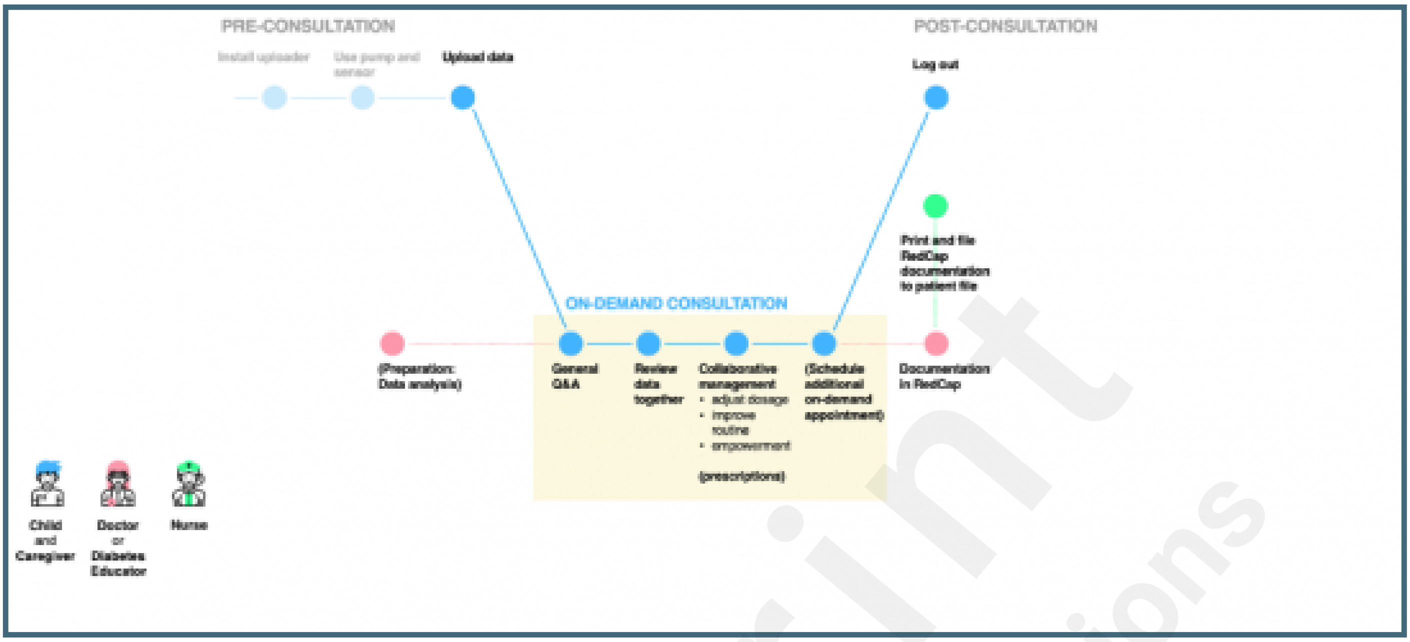
Patient journey and workflow of a conventional clinic visit with current problem areas to improve.



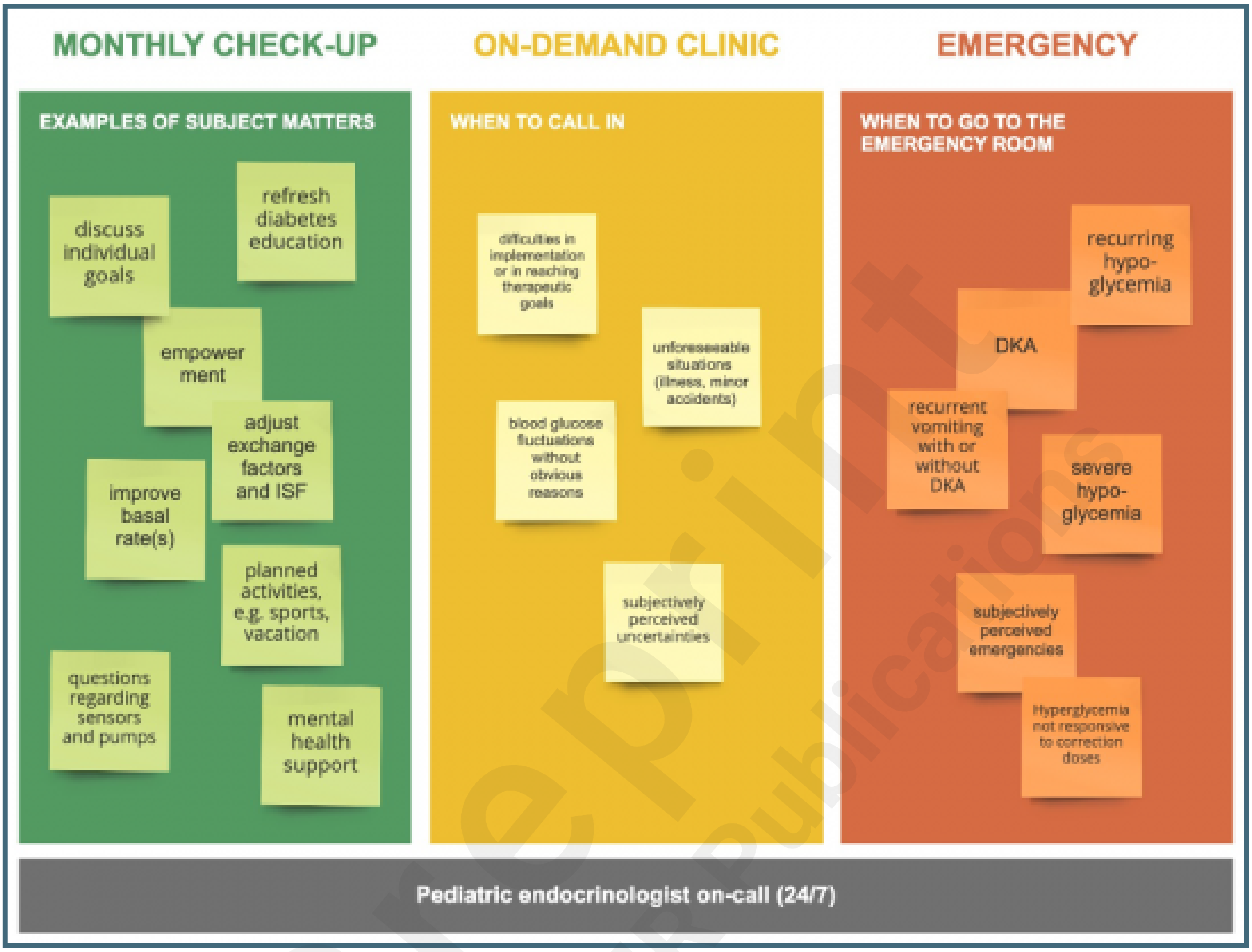
New patient journey experience and workflow of the remote monthly check-ins.



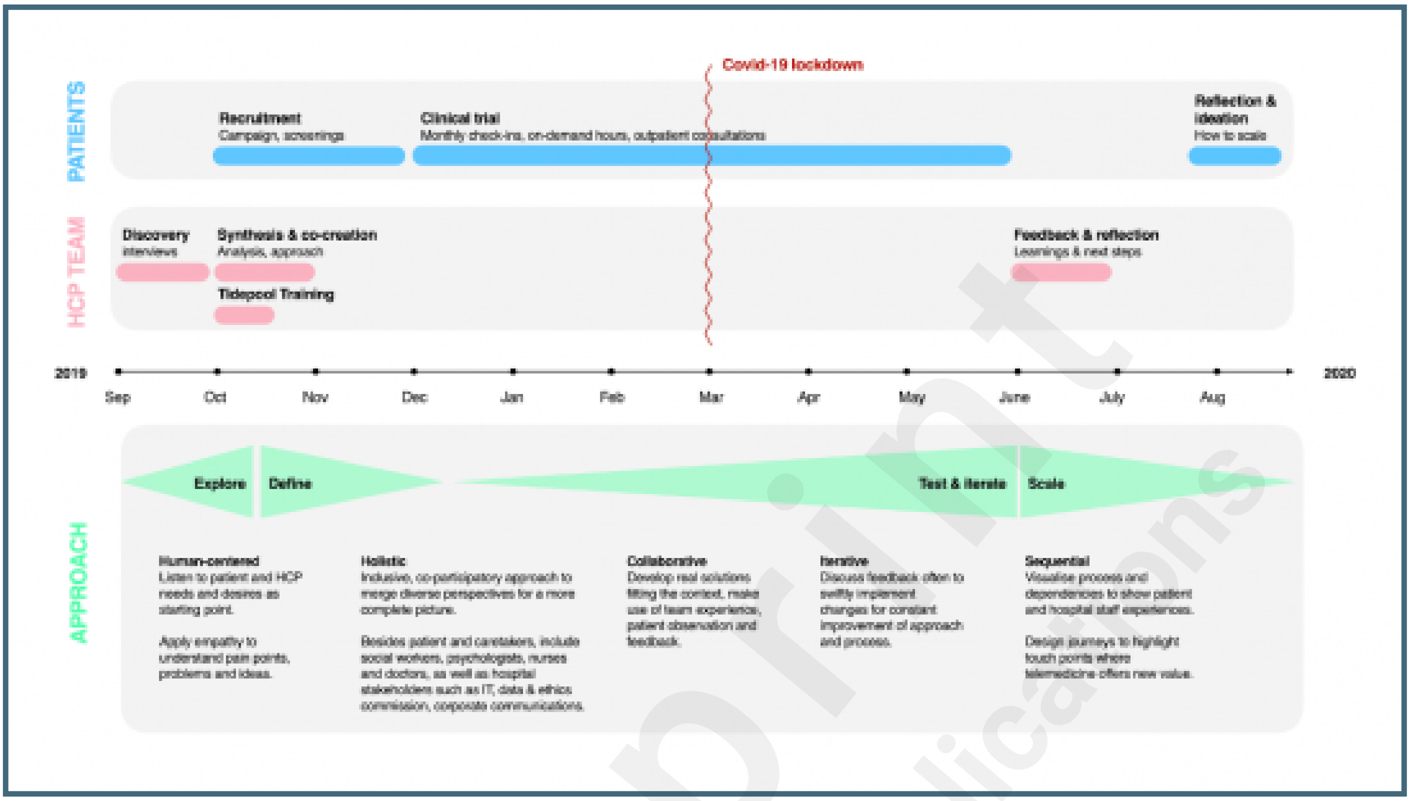
Patient experience and workflow of a remote consultation on-demand (between monthly check-ins).



Triage system for use of the on-demand consultations, risk assessment and emergency management.



Overview of the methods used in this study, including interventions with the HCP team, the patients and caregivers, as well as the design thinking approach across the project timeline.



Human-centered
Listen to patient and HCP needs and desires as starting point.

Apply empathy to understand pain points, problems and ideas.

Holistic
Inclusive, co-participatory approach to merge diverse perspectives for a more complete picture.

Besides patient and caretakers, include social workers, psychologists, nurses and doctors, as well as hospital stakeholders such as IT, data & ethics commission, corporate communications.

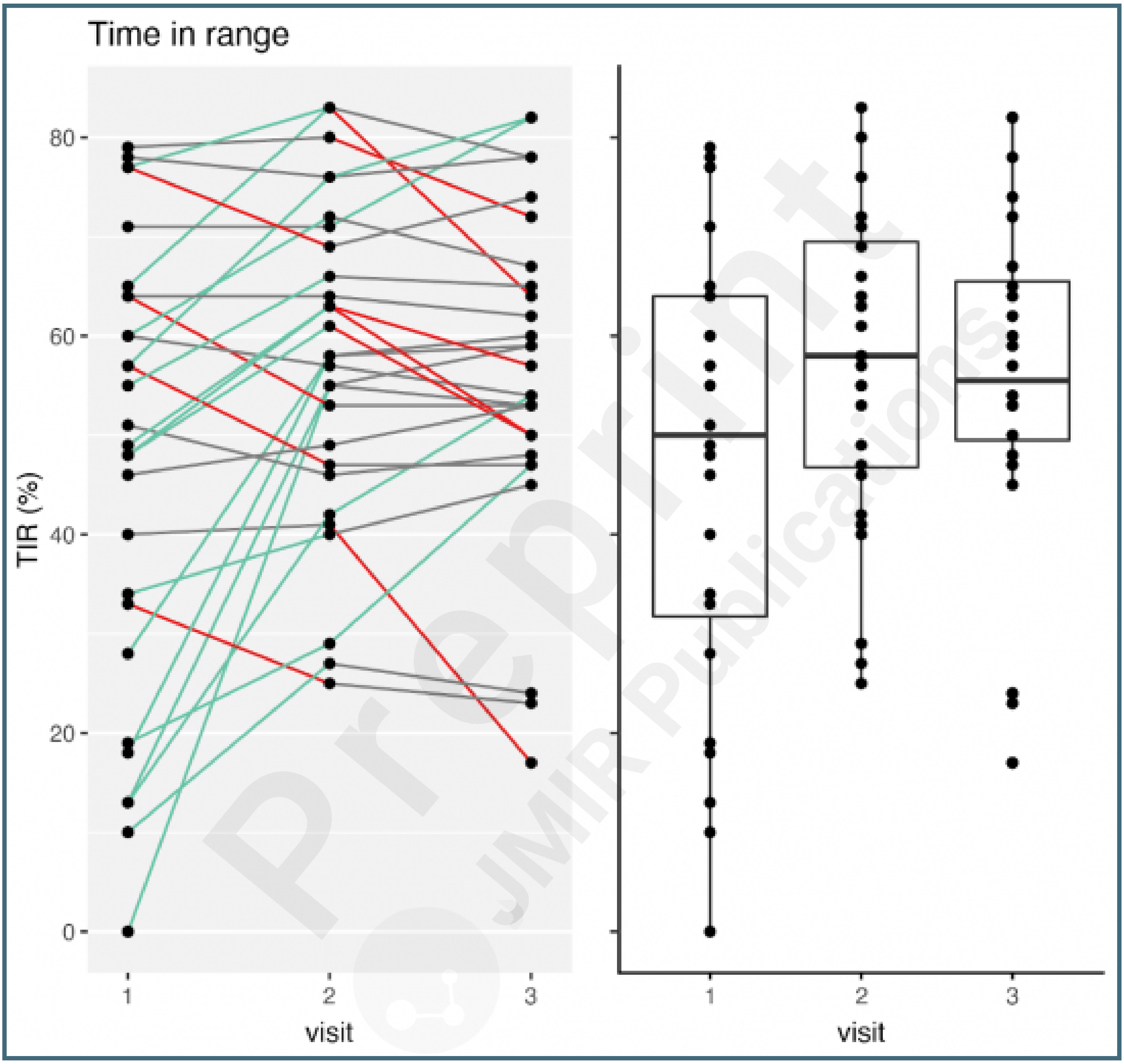
Collaborative
Develop real solutions fitting the context, make use of team experience, patient observation and feedback.

Iterative
Discuss feedback often to swiftly implement changes for constant improvement of approach and process.

Sequential
Visualise process and dependencies to show patient and hospital staff experiences.

Design journeys to highlight touch points where telemedicine offers new value.

Individual changes and overall distribution of Time-in-Range of sensor glucose [%] before (visit 1), after 3 months (visit 2) and 6 months (visit 3) of remote consultations. Green: Individual change in TIR was > 5% (considered as higher). Red: Individual change in TIR was < 5% (considered as lower) Grey: Individual change of TIR was within +/- 5% (considered as stable).



Multimedia Appendixes

Suppl. Table 1: Caregiver feedback regarding their experience with remote consultations.
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TOC/Feature image for homepages

Digital Diabetes Clinic.