Heinrich Heine Universität Düsseldorf

DIGITAL PHARMACIST: PILOTING AND ASSESSING DIGITAL HEALTH TOOLS FOR THE PROVISION OF PHARMACEUTICAL CARE SERVICES IN GERMANY

INAUGRAL - DISSERTATION

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I. Erklärung zur Dissertation

Hiermit versichere ich an Eides statt, dass die vorgelegte Dissertation mit dem Titel:

"Digital Pharmacist: Piloting and Assessing Digital Health Tools for the Provision of Pharmaceutical Care Services in Germany"

von mir selbststandig und ohne unzulassige fremde Hilfe unter Beachtung der Grundsatze zur Sicherung guter wissenschaftlicher Praxis an der Heinrich-Heine-Universitat Dusseldorf erstellt worden ist. Die Dissertation wurde in der vorgelegten oder in ahnlicher Form noch bei keiner anderen Institution eingereicht. Ich habe bisher keinen erfolglosen Promotionsversuch unternommen.

Düsseldorf, den 07.08.2024

Bushra Ali Sherazi

II. Acknowledgements

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III. Summary

Digital health (DH) has grown enormously over the last few years. Technology-enabled healthcare services have impacted all stakeholders in the healthcare sector, including healthcare professionals (HCPs), policymakers, payers, and patients. Various DH interventions namely mobile health (mHealth), electronic health (e-health), and telehealth connected patients and providers without any restrictions during the global coronavirus disease 2019 (COVID-19). The implementation of DH solutions continues to successfully optimize healthcare processes in post-pandemic situations. In addition, patient satisfaction and acceptance have further enhanced this success, however, their adoption by the pharmacy profession has been slow. Among other barriers, a lack of awareness, education, and training in digital health makes it challenging for the pharmacy workforce to adapt to technological advancements. To keep pace with these advances, there is a need to explore DH prospects for practicing pharmacists and to integrate experiential learning and education for future pharmacists.

The overall aim of this thesis is to explore the possibility of integrating DH interventions into German pharmacy practice and pharmacy education. To achieve this aim, the three research areas examined were: 1) the development of pharmaceutical care criteria and evaluation of selected disease-specific (e.g. diabetes) mobile health applications (mHealth apps) based on developed criteria; 2) the usability of and satisfaction with mHealth apps among patients and HCPs; 3) the integration and assessment of DH tools in pharmacy education. These objectives were addressed by four independent studies. The focus was on chronic disease management and the provision of clinical pharmacy services through DH tools. For this purpose, digital diabetes apps and telepharmacy-based inhaler technique training service were included.

First, evaluation criteria were developed, and ten popular diabetes apps were evaluated based on these criteria. Evaluation criteria were divided into three main categories: Pharmaceutical care criteria, general app characteristics, and patient preferences. The ten popular diabetes apps were identified based on a literature review, their availability, and status in Germany. Sixteen developed criteria related to pharmaceutical care were met by the apps such as Diabetes:M and mySugr (11

criteria); Contour™Diabetes, Dario Health, and OneTouch Reveal® (ten); and DiabetesConnect and ESYSTA (nine); followed by Glucose Buddy (eight), meala (seven), and lumind (three). The most prevalent functions were related to promoting adherence and non-pharmacological management, but most criteria relevant to medication management were lacking. Five apps allowed within-app communication between patients and healthcare professionals (HCPs); however, no app included communication with pharmacists.

Second, a cross-sectional survey study of type 1 diabetes mellitus (T1DM) pediatric patients, their parents, and HCPs in the context of remote and rural areas was conducted to explore the usability of and satisfaction with a diabetes digital app after using the app for 12 weeks. A total of 50 pediatric patients (children/parents and adolescents), and 09 HCPs participated in the study and subsequent survey. The app was reported usable in the domains of ease-of-use and satisfaction by T1DM children/parents (5.82/7.0), T1DM adolescents/young adults (5.68/7.0), and HCPs (5.22/7.0). The usefulness of various app features, as well as the overall app experience, were rated positively by the participants.

Thirdly an elective course on diabetes apps was conducted with final-year pharmacy students to introduce mHealth apps into clinical pharmacy education. Students evaluated four digital diabetes apps (Esysta, Diabetes: M, mySugr, and One-Touch Reveal) and their useful features relevant to pharmaceutical care services (e.g., adherence, insulin dose calculation, visualization of blood glucose regulation). The final-semester pharmacy students could quickly learn and comprehend the features of the various diabetes apps, and use the information provided to promptly identify drug-related problems (e.g., hyperglycemia, hypoglycemia, glucose level variability, etc.) and use clinical and patient-centered problem-solving skills. The elective “m-Health and Diabetes” course provided new digital skills to final-year pharmacy students, equipping them with the new competencies needed in the growing digital healthcare environment in diabetes.

Lastly, a randomized cross-over assessment was conducted among 39 final-year pharmacy students to evaluate the non-inferiority of the telepharmacy approach to the traditional face-to-face consultations in providing the inhaler technique training service. Outcomes were measured by comparing Objective Structured Clinical

Examination (OSCE) scores of participants' performance between two modes of communication. Moreover, the participants also completed self-assessment and perception questionnaires. The telepharmacy approach was non-inferior to the face-to-face approach for demonstrating and practicing the correct inhaler technique based on OSCE scores and a predefined non-inferiority margin of -10%. The results also revealed no significant differences in student self-confidence between the two modes of communication. Moreover, participants had a largely positive perception of telepharmacy and its use in providing inhaler technique training service.

The findings of these studies highlight the opportunities to integrate DH interventions into pharmacy practice. We also assessed the patient and provider's ease of use and satisfaction with DH tools and demonstrated the viability of such solutions for delivering pharmaceutical care services. Integrating DH into pharmacy education might help to solve knowledge and training gaps and prepare the future pharmacy workforce for professional practice. Besides implementation and investments, the future of greater uptake of DH tools in pharmacy practice depends on awareness, experiential learning, and education of future pharmacists.

Keywords

Digital health, electronic health, mobile health, telehealth, telepharmacy, telemedicine, chronic disease management, pharmaceutical care

IV. Zusammenfassung

Die digitale Gesundheit (DH) hat in den letzten Jahren enorm zugenommen. Technologiegestützte Gesundheitsdienste haben sich auf alle Beteiligten im Gesundheitswesen ausgewirkt, einschließlich der Angehörigen der Gesundheitsberufe, der politischen Entscheidungsträger, der Kostenträger und der Patienten. Verschiedene DH-Maßnahmen, nämlich mobile Gesundheit (mHealth), elektronische Gesundheit (E-Health) und Telemedizin, haben Patienten und Anbieter während der weltweiten Coronavirus-Krankheit 2019 (COVID-19) ohne Einschränkungen miteinander verbunden. Die Implementierung von DH-Lösungen optimiert weiterhin erfolgreich die Gesundheitsprozesse in Situationen nach einer Pandemie. Die Zufriedenheit und Akzeptanz der Patienten haben diesen Erfolg noch verstärkt, doch die Akzeptanz durch die Apothekerschaft ist nur langsam. Neben anderen Hindernissen macht es ein Mangel an Bewusstsein, Ausbildung und Schulung im Bereich der digitalen Gesundheit für die Apothekenmitarbeiter schwierig, sich an die technologischen Neuerungen anzupassen. Um mit diesen Fortschritten Schritt zu halten, ist es notwendig, DH-Perspektiven für praktizierende Apotheker zu erforschen und Erfahrungslernen und Ausbildung für zukünftige Apotheker zu integrieren.

Das übergeordnete Ziel dieser Arbeit ist es, die Möglichkeit der Integration von DH-Interventionen in die deutsche Apothekenpraxis und Apothekenausbildung zu untersuchen.Um dieses Ziel zu erreichen, wurden die folgenden drei Forschungsbereiche untersucht:1) die Entwicklung von Kriterien für die pharmazeutische Versorgung und die Bewertung ausgewählter krankheitsspezifischer (z.B. Diabetes) Mobile-Health-Anwendungen (mHealth-Apps) anhand der entwickelten Kriterien; 2) die Nutzbarkeit von und die Zufriedenheit mit mHealth-Apps bei Patienten und Gesundheitsdienstleister (HCPs); 3) die Integration und Bewertung von DH-Tools in der Apothekenausbildung. Diese Ziele wurden in vier unabhängigen Studien untersucht. Der Schwerpunkt lag auf dem Management chronischer Krankheiten und der Bereitstellung klinischer Apothekendienste durch DH-Tools. Zu diesem Zweck wurden digitale Diabetes-Apps und ein telepharmaziegestützter Dienst zur Schulung der Inhalationstechnik einbezogen.

Zunächst wurden Bewertungskriterien entwickelt und zehn beliebte Diabetes-Apps anhand dieser Kriterien bewertet. Die Bewertungskriterien wurden in drei Hauptkategorien unterteilt: Pharmazeutische Versorgungskriterien, allgemeine App-Eigenschaften und Patientenpräferenzen. Die zehn populären Diabetes-Apps wurden auf der Grundlage einer Literaturrecherche, ihrer Verfügbarkeit und ihres Status in Deutschland ermittelt. Sechzehn der entwickelten Kriterien in Bezug auf die pharmazeutische Versorgung wurden von den Apps erfüllt, darunter Diabetes:M und mySugr (11 Kriterien); Contour™Diabetes, Dario Health und OneTouch Reveal® (zehn); und DiabetesConnect und ESYSTA (neun); gefolgt von Glucose Buddy (acht), meala (sieben) und lumind (drei). Die häufigsten Funktionen bezogen sich auf die Förderung der Therapietreue und das nicht-pharmakologische Management, aber die meisten Kriterien für das Medikationsmanagement fehlten. Fünf Apps ermöglichten die Kommunikation zwischen Patienten und Angehörigen der Gesundheitsberufe innerhalb der App; keine App bot jedoch die Kommunikation mit Apothekern an.

Zweitens wurde eine Querschnittsstudie mit pädiatrischen Patienten mit Typ-1-Diabetes mellitus (T1DM), ihren Eltern und medizinischen Fachkräften in abgelegenen und ländlichen Gebieten durchgeführt, um die Benutzerfreundlichkeit und Zufriedenheit mit einer digitalen Diabetes-App zu untersuchen, nachdem die App 12 Wochen lang genutzt wurde. Insgesamt nahmen 50 pädiatrische Patienten (Kinder/Eltern und Jugendliche) und 9 Vertreter des Gesundheitswesens an der Studie und der anschließenden Befragung teil. Die App wurde von T1DM-Kindern/Eltern (5,82/7,0), T1DM-Jugendlichen / jungen Erwachsenen (5,68/7,0) und Vertretern des Gesundheitswesens (5,22/7,0) in den Bereichen Benutzerfreundlichkeit und Zufriedenheit als brauchbar bewertet. Die Nützlichkeit der verschiedenen App-Funktionen sowie das Gesamterlebnis der App wurden von den Teilnehmern positiv bewertet.

Drittens wurde ein Wahlkurs über Diabetes-Apps mit Pharmaziestudenten im letzten Studienjahr durchgeführt, um mHealth-Apps in die klinische Pharmazieausbildung einzuführen. Die Studenten bewerteten vier digitale Diabetes-Apps (Esysta, Diabetes: M, mySugr und One-Touch Reveal) und ihre nützlichen Funktionen, die für die pharmazeutische Versorgung relevant sind (z. B. Adhärenz, Berechnung der Insulindosis, Visualisierung der Blutzuckerregulation).

Die Pharmaziestudent en des letzten Semesters konnten die Funktionen der verschiedenen Diabetes-Apps schnell erlernen und verstehen und die bereitgestellten Informationen nutzen, um arzneimittelbezogene Probleme (z. B. Hyperglykämie, Hypoglykämie, Schwankungen des Blutzuckerspiegels usw.) sofort zu erkennen und klinische und patientenzentrierte Problemlösungskompetenzen anzuwenden. Der Wahlkurs „m-Health und Diabetes“ vermittelte den Pharmaziestudenten im letzten Studienjahr neue digitale Fertigkeiten und stattete sie mit den neuen Kompetenzen aus, die sie im wachsenden digitalen Umfeld der Gesundheitsversorgung im Bereich Diabetes benötigen.

Schließlich wurde eine randomisierte Cross-over-Studie mit 39 Pharmaziestudierenden im letzten Studienjahr durchgeführt, um die Nichtunterlegenheit des Telepharmazie-Ansatzes gegenüber der traditionellen persönlichen Beratung bei der Bereitstellung des Inhalationstechnik-Trainings zu bewerten. Die Ergebnisse wurden durch den Vergleich der OSCE-Ergebnisse (Objective Structured Clinical Examination) der Teilnehmer zwischen den beiden Kommunikationsarten gemessen. Darüber hinaus füllten die Teilnehmer auch Fragebögen zur Selbsteinschätzung und zur Wahrnehmung aus. Der Telepharmazie-Ansatz war dem Face-to-Face-Ansatz bei der Demonstration und dem Üben der korrekten Inhalationstechnik nicht unterlegen, basierend auf den OSCE-Ergebnissen und einer vordefinierten Nicht-Unterlegenheitsmarge von -10 %. Die Ergebnisse zeigten auch keine signifikanten Unterschiede im Selbstvertrauen der Studierenden zwischen den beiden Kommunikationsformen. Darüber hinaus nahmen die Teilnehmer die Telepharmazie und ihren Einsatz bei der Schulung von Inhalationstechniken weitgehend positiv wahr.

Die Ergebnisse dieser Studien unterstreichen die Möglichkeiten, DH-Interventionen in die Apothekenpraxis zu integrieren. Wir bewerteten auch die Benutzerfreundlichkeit und Zufriedenheit von Patienten und Leistungserbringern mit DH-Instrumenten und zeigten die Machbarkeit solcher Lösungen für die Erbringung pharmazeutischer Versorgungsleistungen. Die Integration von DH in die Pharmazieausbildung könnte dazu beitragen, Wissens- und Ausbildungslücken zu schließen und die künftigen Apothekenmitarbeiter auf die berufliche Praxis vorzubereiten. Neben der Umsetzung und den Investitionen hängt die künftige

stärkere Verbreitung von DH-Tools in der Apothekenpraxis von der Sensibilisierung, dem Erfahrungslernen und der Ausbildung künftiger Apotheker ab.

Schlüsselwörter

Digitale Gesundheit, elektronische Gesundheit, mobile Gesundheit, Telemedizin, Telepharmazie, Management chronischer Krankheiten, pharmazeutische Versorgung

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VIII. List of Abbreviations

ABDA	Federal Union of German Associations of Pharmacists (*Bundesvereinigung Deutscher Apothekerverbände e. V.)*
AI	Artificial Intelligence
Apps	Applications
ApBetrO	Ordinance on the operations of pharmacies *(Apothekenbetriebsordnung*)
CI	Confidence Interval
COVID 19	Coronavirus disease 2019
DH	Digital Health
DiGA	Digital Health apps (*Digitale Gesundheitsanwendungen*)
DTx	Digital Therapeutics
DVG	Digital care Act (*Digitale Versorgung Gesetz*)
DVPMG	The Digital Care Modernization Act *(Digitale Versorgung und Pflege Modernisierungs Gesetz)*
EHR	Electronic Health Record
eHealth	Electronic Health
EU	European Union
GIDH	Global Initiative on Digital Health
HIT	Health Information Technology
ICT	Information and Communications Technology
IoT	Internet of Things
IQR	Interquartile Range
IST	Information Society Technology
KHZG	The Hospital Future Act *(Krankenhauszukunftsgesetz*)
MAU	Mobile App Usability Questionnaire
mHealth	Mobile Health
ML	Machine Learning
OSCE	Objective Structured Clinical Examination
PCNE	Pharmaceutical Care Network Europe
pDL	Clinical Pharmacy Services (Pharmazeutische Dienstleistungen)
p-Health	Personalized Health

SaMD	Software as a Medical Device
SDGs	Sustainable Development Goals
UN	United Nations
VOASG	The Local Pharmacy Strengthening Act (*Vor-Ort Apothekenstärkungsgesetz*)
WHO	World Health Organization

IX. Research outputs

Peer reviewed publications

1. **Ali Sherazi B**, Läer S, Krutisch S, Dabidian A, Schlottau S, Obarcanin E. Functions of mHealth Diabetes Apps That Enable the Provision of Pharmaceutical Care: Criteria Development and Evaluation of Popular Apps. *Int J Environ Res Public Health*. 2022 Dec 21;20(1):64. doi: 10.3390/ijerph20010064
2. **Ali Sherazi B**, Läer S, Hasanbegovic S, Obarcanin E. Evaluating usability of and satisfaction with mHealth app in rural and remote areas-Germany GIZ collaboration in Bosnia-Herzegovina to optimize type 1 diabetes care. *Front Digit Health.* 2024 Jun 17;6:1338857. doi: 10.3389/fdgth.2024.1338857
3. **Ali Sherazi B**, Sayyed SA, Möllenhoff K, Läer S. Telepharmacy versus Face-to-Face Approach in Providing Inhaler Technique Training Service: A Non-Inferiority Assessment Among German Pharmacy Students. *Integr Pharm Res Pract.* 2024 Sep 20;13:165-180. doi: 10.2147/IPRP.S468881
4. Obarcanin, E., **Ali Sherazi B**., Dabidian, A., Schlottau, S., Deters, M. A., & Läer, S. Introducing m-Health and Digital Diabetes Apps in Clinical Pharmacy Education in Germany. *Journal of Diabetes and Clinical Research*. 2022 July *4*(1), 17-19.
5. Sharkas AR, **Ali Sherazi B**, Sayyed SA, Kinny F, Steichert M, Schwender H, Laeer S. Development and Evaluation of Interprofessional High-Fidelity Simulation Course on Medication Therapy Consultation for German Pharmacy and Medical Students-A Randomized Controlled Study. *Pharmacy (Basel).* 2024 Aug 21;12(4):128. doi: 10.3390/pharmacy12040128
6. Kinny F, **Ali Sherazi B**, Dabidian A, Laeer S, Obarcanin E. Development of a Theoretical Continuous Glucose Monitoring Module for Pharmacy Students: Preparing Pharmacists for the Future. *Pharmacy*. October 2024; 12(5):154. doi: 10.3390/pharmacy12050154
7. Sayyed SA, Sharkas AR, **Ali Sherazi B**, Dabidian A, Schwender H, Läer S. Development and Assessment of Innovative High-Fidelity Simulation Vaccination Course Integrating Emergency Cases for Pharmacy

Undergraduates-A Randomized Controlled Study. *Vaccines (Basel).* 2023 Jan 31;11(2):324. doi: 10.3390/vaccines11020324

8. Dabidian A, Obarcanin E, **Ali Sherazi B**, Schlottau S, Schwender H, Läer S. Impact of a Digital Tool on Pharmacy Students' Ability to Perform Medication Reviews: A Randomized Controlled Trial. *Healthcare (Basel).* 2023 Jul 7;11(13):1968. doi: 10.3390/healthcare11131968
9. Kinny F, Schlottau S, **Ali Sherazi B**, Obarcanin E, Läer S. Digital health in pharmacy education: Elective practical course integrating wearable devices and their generated health data. *Explor Res Clin Soc Pharm.* 2024 Jun 11;15:100465. doi: 10.1016/j.rcsop.2024.100465

Conference abstracts and presentations

1. Sayyed, S., Sharkas, A. R., **Ali Sherazi, B**., Dabidian, A., Schwender, H., & Läer, S. Innovative high-fidelity simulation for vaccination training of pharmacist including emergency cases-a randomized controlled study. European Society for Developmental Perinatal and Paediatric Pharmacology Congress, 27-30 June 2022, Liverpool, United Kingdom.
2. Dabidian, A., **Ali Sherazi, B.,** Schlottau, S., Obarcanin, E., & Läer, S. mHealth Diabetes Apps for the delivery of Pharmaceutical Care and Inter-professional point of care communication in Adolescent Type 1 Diabetes Mellitus patients. European Society for Developmental Perinatal and Paediatric Pharmacology Congress, 27-30 June 2022, Liverpool, United Kingdom.
3. Obarcanin Emina, Hasanbegovi Snijezana, Rustempasic Elma, **Ali-Sherazi Bushra**, Kinny Florian, Laeer Stephanie. m-Health Clinic Partnership Project between HHU Düsseldorf and Bosnia-Herzegovina: Creation of a digital network of Diabetes Type 1 children and adolescents in rural and remote areas in Bosnia and Herzegovina. European Society for Developmental Perinatal and Paediatric Pharmacology Congress, 28-30 June 2023, Prague, Czech Republic.
4. Obarcanin Emina, **Ali-Sherazi Bushra**, Hasanbegovi Snijezana, Rustempasic Elma, Sibila Tabakovic, Kinny Florian, Laeer Stephanie. Clinic partnership project, GIZ and Heinrich-Heine University Duesseldorf: mHealth

usability, effectiveness, and satisfaction survey among children, adolescents, and care providers in rural and remote municipalities of Bosnia-Herzegovina. 49th Annual Conference of International Society for Paediatric and Adolescent Diabetes, 18-21 October 2023, Rotterdam, The Netherlands.

Other trainings and workshops attended during the PhD

1. Good Scientific Practices	19-20 May 2022
2. Writing Paper and Thesis in Life Sciences	19-20 August 2022
3. Presenting in science	21-22 September 2023
4. Get into teaching	30 Nov/1Dec 2023
5. Continuing Medical Education (CME) 20.5 credits	18-20 October 2023
6. Night Science - A workshop on the creative side of the scientific process	20 September 2024

And that man shall have nothing but what he strives for

Al - Quran 53:39

1

Chapter 1: General Introduction

1.1 DIGITAL HEALTH

Over the past decade, the transformative role of digital technologies has been seen in every field of life including healthcare [1]. Digital health (DH) has become a widespread term, especially in the wake of the coronavirus disease 2019 (COVID-19) [2], when numerous implemented DH solutions demonstrated enormous potential [3, 4]. DH refers to the "use of information and communications technologies in medicine and other health professions to manage illnesses and health risks and to promote wellness" [2]. The broad scope of DH covers "wearable devices, mobile health (mHealth), health information technology (HIT), telehealth and telemedicine, and personalized medicine [5]. "DH expands the electronic health (eHealth) concept to include digital consumers, with a wide range of smart and connected devices. It also encompasses other uses of digital technologies for health such as the Internet of Things (IoT), advanced computing, big data analytics, artificial intelligence (AI) including machine learning, genomics, and robotics" [4, 6, 7]. Within DH different terms are used interchangeably and overlap without clear borders around and between them. The definitions of DH umbrella terms and their interrelationship are detailed in Table 1 and Figure 1 respectively.

DH tools can potentially make healthcare processes more efficient, precise, and less error-prone than those in traditional healthcare and promote patient engagement and empowerment [4]. The evidence of the effectiveness, acceptability, feasibility, cost-effectiveness, and successful implementation of DH interventions has been reported in many studies worldwide [8-12]. A DH intervention is "the application of digital, mobile, and wireless technologies for a defined purpose, in order to address specific health system challenges" [13]. Some examples of positive health outcomes and efficient healthcare delivery following DH interventions are improved: adherence to medications [14], self-management and care [15], health behaviors [16], patient-provider communication and relationship [17-19], chronic disease management [12], preventive care [20], diagnosis and decision-making [21], health care access and equity [22, 23], wellbeing and quality of life [24], and safety within health systems [25].

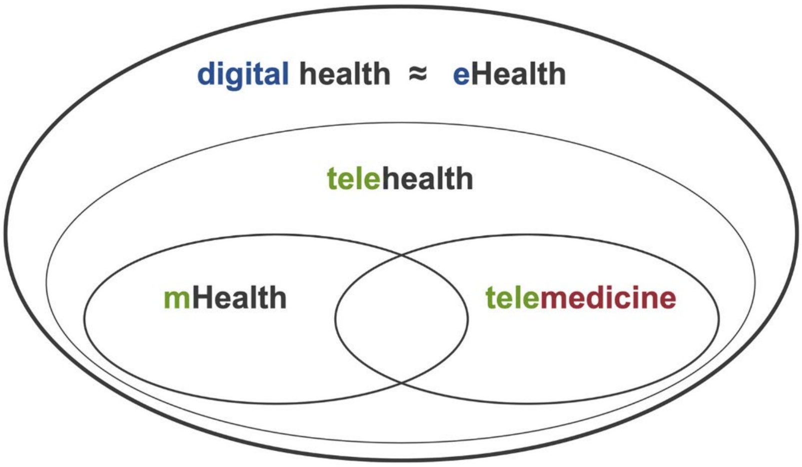

Figure 1. Conceptual framework for digital health umbrella terms. [Burrell A, Zrubka Z, Champion A, et al; ISPOR Digital Health Special Interest Group Key Project. How Useful Are Digital Health Terms for Outcomes Research? An ISPOR Special Interest Group Report. Value Health. 2022 Sep;25(9):1469-1479]. eHealth, electronic health; mHealth, mobile health; blue text, information technology; green text, communications technology; black/purple text, application (health or medicine)

The use of DH technologies has been supported by regulatory and ethical considerations in several countries worldwide and also advocated by the World Health Organization (WHO) [4]. In the seventy-third World Health Assembly 2020, WHO acknowledged the importance of DH by forming the Global Strategy on DH [26]. This strategy aims to achieve the vision of health for all, bolstering health systems by deploying DH technologies for healthcare professionals, clients, and industry [26]. DH contributes towards attaining universal health coverage [27], a central component of the United Nations (UN) Sustainable Development Goals (SDGs) [28]. Recently, in October 2023, WHO launched the Global Initiative on

Digital Health (GIDH) network to support full-scale DH transformation in countries worldwide and contribute toward sustainable health system digitalization [29].

Table 1. Glossary of digital health terms as per the World Health Organization (WHO) [30,31]

Term	WHO Definition
Digital Health	"An overarching term that comprises eHealth (which includes mHealth), and emerging areas, such as the use of computing sciences in the fields of artificial intelligence, big data, and genomics"
eHealth	"The use of information and communications technology (ICT) in support of health and health-related fields, including health care services, health surveillance, health literature, and health education, knowledge, and research".
mHealth	"The use of mobile wireless technologies to support health objectives".
Telehealth	"The delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities".

Patients generally accept DH interventions and tend to have favorable attitudes toward them [32-34]. Similarly, HCPs see digital healthcare services as positive [34] leading to increased acceptance and implementation [35]. DH services on the one hand improve patient access to care and support HCPs on the other hand by optimizing their performance [36, 37]. However, certain facilitators and barriers exist to implementing and adopting these modalities [35] emphasizing the involvement of the users of these services in DH tool development and design [38]. WHO defines users of DH services as "the individuals who directly utilize the technology using their digital devices, either to deliver health services (e.g. community health workers, district managers, clinicians) or to receive services (i.e. clients, patients)" [13]. Figure 2. illustrates the WHO classification of DH services based on the main users of services.

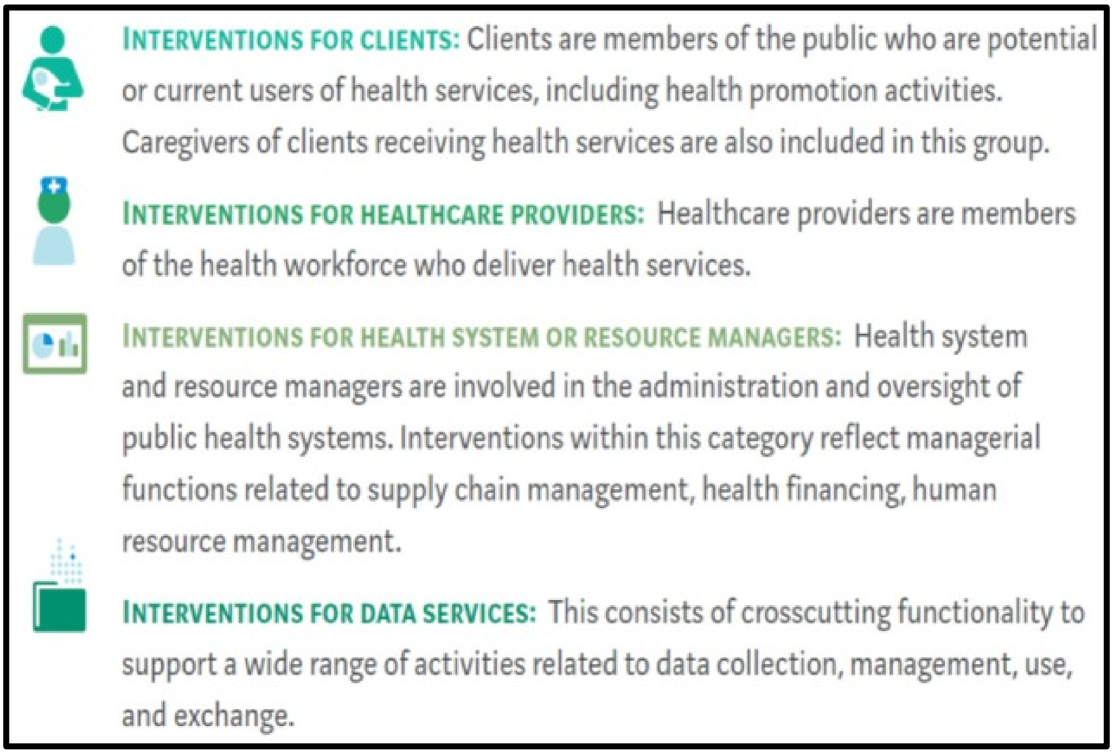

Figure 2. WHO classification of digital health services by the users.[Ricciardi W, Pita Barros P, Bourek A, Brouwer W, Kelsey T, Lehtonen L; Expert Panel on Effective Ways of Investing in Health (EXPH). How to govern the digital transformation of health services. Eur J Public Health. 2019 Oct 1;29(Supplement_3):7-12. doi: 10.1093/eurpub/ckz165]

1.1.1 Electronic health (eHealth)

Providing health services by electronic means is known as electronic health (eHealth), one of the most rapidly growing areas in healthcare [39]. eHealth enables data storage, retrieval, and transmission, and supports clinical decision-making and remote care [40]. HCPs have used eHealth for administration, health records maintenance and access, communication and consulting, information gathering, and medical education [41]. The different domains of eHealth include mHealth (mobile apps and personalized health / P-Health in the form of wearables or sensors), telemedicine, clinical information systems (i.e. Electronic Health Records / EHR), big data, and integrated networks such as electronic prescribing / E - prescribing [42]. Among all the domains above, the three major disruptive are telemedicine, mobile apps, and wearable sensors [42]. Figure 3. illustrates different domains of eHealth.

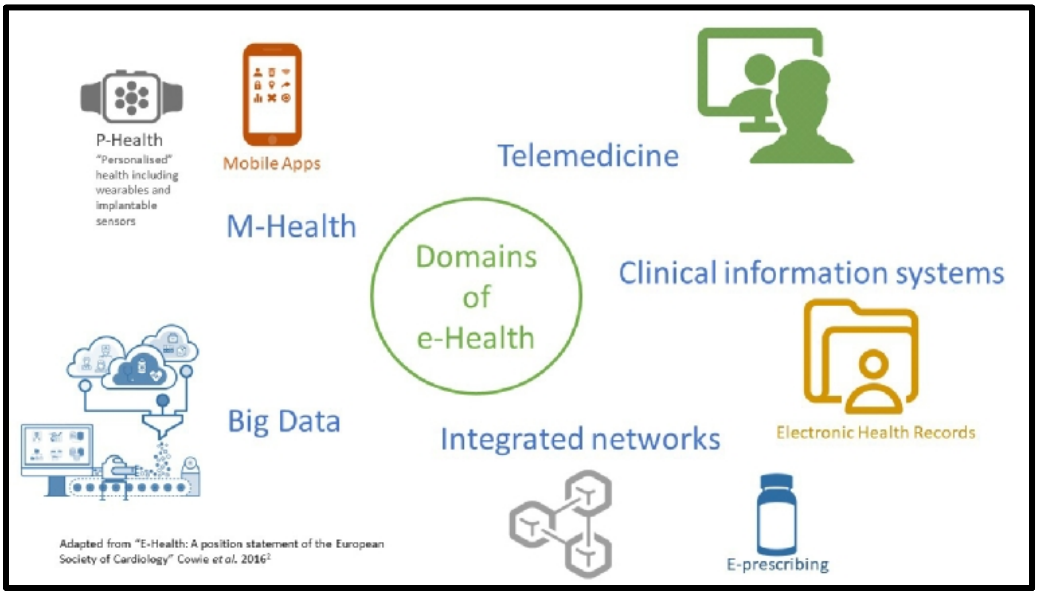

Figure 3. Domains of eHealth.[Arvind Singhal., Martin R. Cowie. The European society of cardiology (ESC). What is eHealth? Available from: https://www.escardio.org/Journals/E-Journal-of-Cardiology-Practice/Volume-18/what-is-e-health. Accessed 1st April 2024]

1.1.2 Mobile health (mHealth)

Mobile health or mHealth, a field of eHealth is defined as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices" [43]. The percentage of the global population that owns a feature phone and a smartphone reaches 92% and 86% respectively [12]. This increased availability of smartphones and other portable electronic communication devices equipped with computing functions resulted in increased access to healthcare in the form of mHealth [44]. These devices have a range of functions from Short Message Service (SMS), Multimedia Messaging Service (MMS), telephone and internet access, to multimedia playback and software application support [45]. Of these functions, smartphone apps and SMS have been widely used and proven effective in many studies to carry out mHealth interventions [46-48].

A health app is defined as “a computer program or software application (designed to run on a mobile device) intended to be used specifically for managing, maintaining, or improving the health of individual persons or delivery of care” [49]. In 2021 there were approximately 350,000 health-related mobile applications (mHealth apps) worldwide with 90,000 apps added in 2020 alone, reflecting an average of 250 apps added to app stores daily [50]. mHealth apps include two categories of apps i.e. medical, and health and wellness [51]. Medical apps meet the definition of a regulated medical device or more specifically “Software as a Medical Device (SaMD)” as they treat, diagnose, cure, mitigate, or prevent a disease or condition [52]. These apps are used as an accessory to a regulated medical device, or for transforming a mobile platform into a regulated medical device [52]. Whereas the health and wellness apps are generic and a large majority of them are not intended for medical use falling under the unregulated category [53]. Health and wellness apps promote or encourage healthy eating, physical activity, weight loss, and other activities for a healthy lifestyle and wellness [51, 52].

Half of the widely used mHealth apps are medical apps [54] designed for chronic disease management including diabetes, mental health, cardiovascular diseases, etc., and specific clinical practice areas [55]. These apps contain features to encourage a healthy lifestyle, improve treatment adherence, and promote prevention by targeting behavior change and self-management [56]. Moreover, there are professional as well as patient-facing apps [49]. Falling into the definition of medical devices implies that HCPs must be involved in the mHealth app development and usage process. Among others, pharmacists are very relevant in this growing landscape of mHealth apps. As the most accessible primary health care providers, pharmacists must be familiar with the app features and other technical aspects to guide patients as with other medical devices—the objectives of study 1 in this thesis.

Moreover, the success of mHealth interventions for delivering healthcare services is largely dependent on their adoption by HCPs [45]. Among other factors usability including ease of use, satisfaction, usefulness, and overall experience of users with mHealth apps must be considered as this remains very critical for their uptake and sustained use [57, 58]—the objectives of study 2 in this thesis.

1.1.3 Telehealth/Telemedicine/Telepharmacy

Telehealth is a subclass of eHealth [59] which includes “the use of telecommunications and virtual technology to deliver healthcare outside of traditional healthcare facilities” [43]. Telehealth connects individuals with their HCPs resulting in improved; access, cost efficiencies, quality of healthcare services, and consumer demand [60]. Both synchronous (e.g. teleconferencing) and asynchronous (e.g. patient portals) services are included in telehealth [61]. Although telehealth service delivery is not a new concept as its usage was reported decades ago [62] the COVID-19 health crisis provided an opportunity for and marked the turning point in its adoption [61, 63] that remains high beyond the pandemic [64]. Evidence-based models exist for acute and chronic care telehealth services and show non-inferiority to those provided in traditional clinical settings [65]. Previous literature includes many examples of positive telehealth impact on chronic disease management such as cardiovascular diseases [66, 67], diabetes [68], asthma [69], chronic obstructive pulmonary disease (COPD) [70], and rheumatoid arthritis [71]. Similarly, telemedicine-based care deemed potential and demonstrated non-inferiority over face-to-face delivered care in acute presentations [72]. Telehealth interventions are also recommended in clinical practice guidelines and this recommendation is based on scientific evidence from randomized controlled trials [73, 37].

Telemedicine and telehealth are interchangeable [43], sometimes distinguished by the healthcare providers involved, telemedicine includes clinical services that are exclusively related to physicians whereas telehealth involves all other HCPs [60]. Moreover, telehealth is broader than telemedicine in that it includes clinical services and other health-related activities such as administration, continuing medical education, and or provider training [64]. Similarly, telepharmacy is the provision of such services by pharmacists. Pharmacy services are one of the most remarkably influenced areas undertaking advanced utilization of telehealth or telemedicine [74].

“Telepharmacy specifically refers to the delivery of pharmacy services including remote dispensing, medication therapy management, and remote consultation” [75]. Pharmacists have used telehealth technologies effectively to provide public health and other pharmaceutical care services [76,77]. Substantial evidence shows that telepharmacy interventions are as effective as usual care (i.e. in most cases face-to-face consultations) in improving patient outcomes and satisfaction [78-80]. Despite some barriers, telepharmacy technology provides pharmacists with a unique opportunity to practice without geographical boundaries. Studies indicate that practicing pharmacists and pharmacy students are willing to deliver telepharmacy services but lack the necessary education, awareness, and training [81]. Especially when it comes to medical device training through telepharmacy, pharmacists and pharmacy students perceive that telepharmacy is not appropriate for this purpose [82, 83]. This self-perception and self-assessment along with actual performance need to be further investigated - the objectives of study four in this thesis.

1.1.4 Other Core Technologies and Terminologies in DH

Wearable devices: “devices that can be worn or mated with human skin to continuously and closely monitor an individual’s activities without interrupting or limiting the user’s motions” [84].

Cloud computing: is **“**the delivery of computing services (including servers storage, databases, networking, software, analytics, intelligence, etc.) over the internet rather than a local server to offer faster innovation, flexible resources, and economies of scale” [85].

Artificial intelligence (AI): is the “technology that uses algorithms and software to approximate human cognition in the analysis of complex data. Machines can perform tasks in ways that are “intelligent” and can adapt to different situations; examples include visual perception, speech recognition and decision making” [85].

Machine learning (ML): is “a branch of AI based on the idea that machines can be built to process large amounts of data and learn on their own using algorithms and statistical models relying on patterns and inference” [85].

Robotics: “a field of technology that deals with the design and construction, operation and application of robots. There are many uses in healthcare such as providing physical assistance and fostering patient engagement through socially assistive robotics" [85].

Digital therapeutics (DTx): "regulated, evidence-based software intervention that can be independent or complementary to other therapies" [86]

Digital Biomarkers: "hardware-software based measurement of physiological data in real-time for prognostic or diagnostic measurements" [86].

The Internet of Things (IoT): the concept of IoT is defined as "the network of physical devices and other items, embedded with electronics, software, sensors, and network connectivity, which enables these objects to collect and exchange data" [87].

Blockchain: "A blockchain is a continuously growing list of records, called blocks that are linked and secured through the use of cryptography. A blockchain can serve as an open distributed ledger or shared record book that can record transactions between multiple parties efficiently and in a verifiable and permanent way" [88]

Big data: "big data can be defined as digital data that are generated in high volume and high variety and that can accumulate at high velocity, resulting in datasets too large for traditional data processing systems. Large quantities of patient information are regularly collected and shared between providers and pharmacy staff to ensure that patients receive the care that they need" [88].

Electronic health record (EHR): "An EHR is a digital version of a patient's paper chart. EHRs are real-time patient-centered records that make information available instantly and securely to authorized users" [88].

e-prescribing and e-dispensing: "e-prescribing is a prescriber's ability to electronically send an accurate, error-free, and understandable prescription directly to a pharmacy from the point of care. It is an important element in improving the quality of patient care. E-dispensing is defined as the act of electronically retrieving a prescription and giving out the medicine to the patient as indicated in the corresponding e-prescription" [88].

1.1.5 Digital transformation of the German healthcare system

In recent years healthcare systems have undergone a major disruptive transformation through digital technologies worldwide [22]. Digital transformation is "a process that aims to improve an entity by triggering significant changes to its properties through combinations of information, computing, communication, and connectivity technologies" [23]. The percentage of countries with a DH strategy and scaled DH programs reaches 70%, nevertheless, many countries still face challenges and obstacles to implementing their DH strategies. [29]. Despite years of efforts, adopting DH tools in Europe remained slow and challenging before the COVID-19 pandemic [89]. However, their use gained momentum during the pandemic and was furthered by legislative reforms, reimbursements, investments in technical infrastructure, and HCP training [89]. Regional DH action plan for the WHO European Region 2023-2030 supports member states in the WHO European region for scaling up and leveraging digital transformation to achieve better health in Europe [3]. In addition, the European Union (EU) considers the digitalization of health a top priority and established programs such as EU4Health 2021-2027 and DIGITAL underlining the importance of DH policies in member states [90].

Germany is one of the world's largest healthcare markets [91] with a network of around 1893 hospitals, 18068 pharmacies, and 150,000 office-based physicians

[92-94]. Health insurance is mandatory consisting of private and statutory health insurance (SHI), and the SHI system covers 88% of the population [92]. The German healthcare system has undergone a significant digital transformation after being at one of the lowest levels of digitalization among developed countries [91]. The approval and adoption of several acts such as the 2016 eHealth Act, the 2019 Digital Care Act (Digitale Versorgung Gesetz-DVG), the 2020 Hospital Future Act (Krankenhauszukunftsgesetz-KHZG), and the 2021 Digital Care Modernization Act (Digitale Versorgung und Pflege Modernisierungs Gesetz-DVPMG) further facilitated digital transformation [95-98]. Apps on prescription (Digitale Gesundheitsanwendungen- DiGA), online video consultations, and access to a secure healthcare data network are some notable achievements of DVG [99]. Early implementation of telemedicine and mHealth apps in the healthcare sector since 2018 has shown short-term benefits during the COVID-19 pandemic [100]. Moreover, the Federal Ministry of Health established a department for digitalization [92] and took initiatives such as the Health Innovation Hub (HIH) to drive the digital transformation of the healthcare system [101] and set international digitalization as a top priority for the new initiative [102]. The HIH is a source of ideas for DH solutions that aim to improve patient care through digitalization [101]. Recently in 2023 two new laws, the Digital Act (Digital-Gesetzt, DigiG) and the Health Data Use Act (Gesundheitsdatennutzungsgesetzt, GDNG) passed by the German parliament (Bundestag) further advanced digitalization of the healthcare sector. [103] Germany is among the seven European countries that introduced reimbursement mechanisms of different extents owing to the importance of pricing and reimbursement for DH adoption [104]. All the reforms made in legal and regulatory frameworks, infrastructure, and reimbursement domains ultimately led to a

tremendous increase in the use of HIT products and services, particularly AI, telemedicine, cyber security, remote patient monitoring, medical apps, and digitalization solutions for hospitals or other healthcare institutions [103,105-107]. For instance, there have been around 374,000 prescriptions of DiGA, and more than half of the general practitioners in Germany have already prescribed these apps [103]. This most likely continues as the German DH market is projected to be valued at US$5.77 billion in 2024, reaching US$7.53 billion by 2028 with an annual growth rate of 6.88% [107]. The growth trajectory is consistent with the Global digital healthcare market which is expected to rise from US$175 billion in 2019 to US$660 billion by 2025 [108]. In addition to the legislative advancements, the other drivers of digital transformation are an increasingly aging population, a high internet penetration rate, a strong healthcare system, growing demand from patients, rising healthcare costs, and a digitally matured population [109-111].

1.2 DIGITAL PHARMACEUTICAL CARE

The gradual shift in the role of pharmacists and pharmacies led to patient-centered clinical pharmacy services incorporating new skills and new societal demands and challenges in the 21st century [112], especially in the last four decades, where these roles have become well recognized [113]. The current post-pharmaceutical care era (from 2010 to onwards) includes services such as medication therapy management, vaccinations, health screenings, and other public health campaigns aiming to promote healthy lifestyles and behavioral changes, and now moving towards the service-based patient-centered care era [112,114]. Figure 4. illustrates the historical evolution of the roles, responsibilities, and duties of the pharmacist.

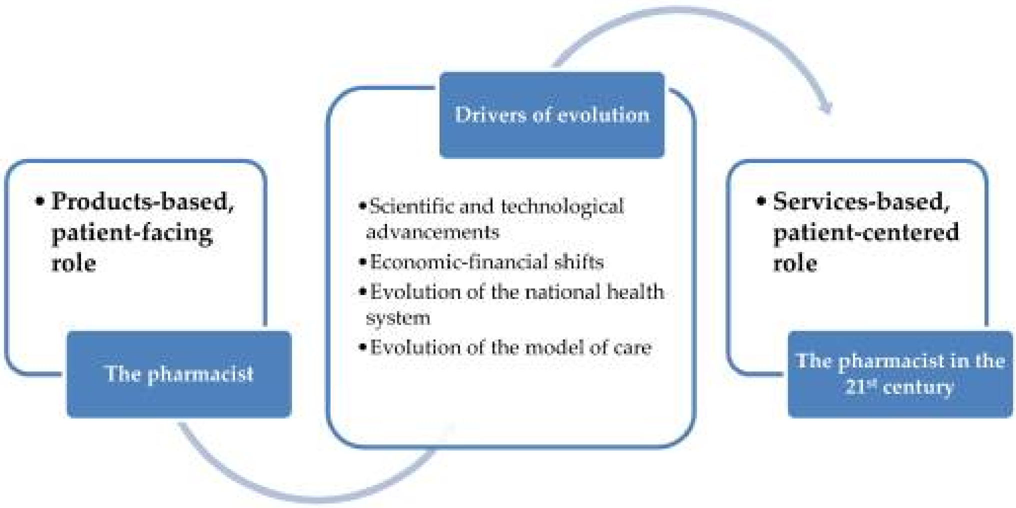

Figure 4. The historical evolution of the roles, responsibilities, and duties of the pharmacist. [Bragazzi NL, Mansour M, Bonsignore A, Ciliberti R. The Role of Hospital and Community Pharmacists in the Management of COVID-19: Towards an Expanded Definition of the Roles, Responsibilities, and Duties of the Pharmacist. Pharmacy (Basel). 2020 Aug 7;8(3):140. doi: 10.3390/pharmacy8030140]

The scope of practice has expanded from pharmacy management to additional clinical services to broader public health functions [115] and involves any pharmacist providing patient care regardless of practice setting [116]. The Pharmaceutical Care Network Europe (PCNE) specifies pharmaceutical care as a service and defines it as “the pharmacist’s contribution to the care of individuals to optimize medicines use and improve health outcomes” [117]. In several countries such as Australia, Canada, and the United Kingdom (UK) an advanced expansion of pharmaceutical care services in the form of independent and supplementary prescribing for pharmacists has been introduced [118].

The recent pharmaceutical care definitions now add the role of new technologies in providing such services [119] and consider technological advancements to be among the drivers of evolution in pharmacy practice [112]. Baines, D. et al defined pharmaceutical care technologies as “technologies that enable pharmacists to optimize medication use and to enhance patient health and outcomes” [120]. Previously pharmacy services focussed on in-person consultations and paper-based procedures, however during the global shift towards digital healthcare, the pharmacy profession also embraced digital transformation [121]. Research indicates the successful implementation of digitally enhanced pharmaceutical care services and programs worldwide [78,122-128]. Although new technologies support and facilitate pharmaceutical care processes, however, adaptation to new technologies requires gradual replacement of the current manual practices [129]. It is also important to consider that new technologies and tools augment instead of replacing personal interventions [85]. Therefore, Baines D. et al suggested an interesting term “blended pharmacy practice” for the mixture of manual and technological processes in current professional practices [129]. Figure 5 illustrates the concept of blended pharmacy practice.

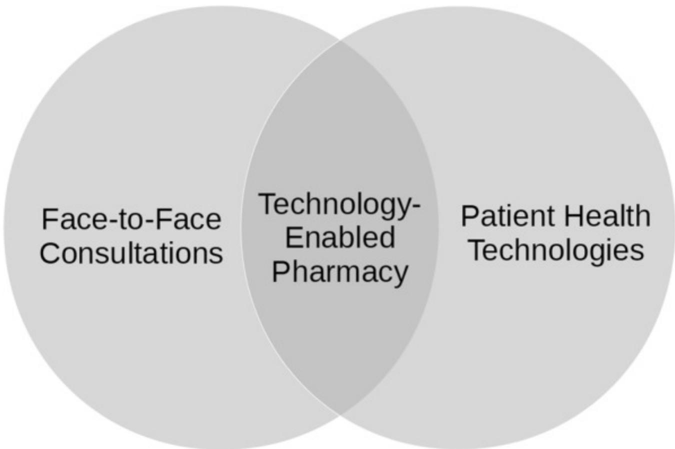

Figure 5. Blended pharmacy practice. [Baines D, Bates I, Bader L, Hale C, Schneider P. Conceptualising production, productivity and technology in pharmacy practice: a novel framework for policy, education and research. Hum Resour Health. 2018 Oct 3;16(1):51. doi: 10.1186/s12960-018-0317-5]

1.2.1 Current Evidence Worldwide

Although pharmacists in community and hospital pharmacy settings have been using DH technologies to various extents [76,130,131], the global pandemic further drives the integration of DH tools into routine pharmacy practice [132,133]. DH focus areas for pharmacists include wearables, telepharmacy, digital biomarkers, DTx, personalized healthcare, mobile health, cybersecurity, AI, and home diagnostics [134]. For example, pharmacists use AI-powered apps and tools to provide clinical pharmacy services such as medication order review, health product dispensing, pharmaceutical interviews, therapeutic education, etc. [135].

A systematic review of nineteen studies on clinical pharmacists' use of DH interventions reported the use of mobile apps, telephone calls, and web-based tools [130]. The systematic review demonstrated these interventions to be at least as effective as usual care in lowering health service use (e.g. reduced hospitalizations) and improving drug-related outcomes (e.g. reduced adverse events) [130]. Similarly, most of the studies reviewed in another systematic review of thirteen studies showed positive impacts of using telehealth and digital tools on participants' outcomes in community pharmacy settings [76]. The digitally integrated community pharmacy services included public health topics such as smoking cessation, vaccination uptake, hypertension management, and medication adherence and counseling [76].

Telepharmaceutical care services included e-prescriptions, e-dispensing, EHR, virtual consultations, home delivery of medicines, and remote patient monitoring [108]. Telepharmacy-based ambulatory care anticoagulation management services appeared as effective as face-to-face services in a systematic review and meta-analysis of 11 studies involving 8395 patients, thereby supporting the utilization of telepharmacy for such services [78]. Additionally, the economic value of pharmacist-led DH interventions has been established by Park T et al in a systematic review of fourteen studies [136]. They recommended their synthesized evidence to be a basis for DH adoption, reimbursement decisions, and a better understanding of the benefits of extensive DH investments [136].

1.2.2 Examples from German pharmacy practice

The provision of pharmaceutical care services by Community pharmacists has evolved across Europe facilitated by remuneration [137]. Additionally, the COVID-19 outbreak and resulting policy and regulatory changes afforded new opportunities for pharmacists [138]. In Germany, the importance of pharmacies in providing healthcare services is underscored by the various challenges confronting the healthcare system such as demographic changes, a shortage of HCPs, and financial constraints on resources [94]. Therefore, community pharmacies have been integrated into primary healthcare as an important component, and the roles of community pharmacists have evolved with an important recognition as medication management experts in healthcare teams [92]. As of late 2022, there were 18068 pharmacies, having one billion patient interactions per year and serving three million patients per day [94]. The pharmacy services are well rated by the German citizens, as 83% of them trust their pharmacist, 92% are satisfied or very satisfied with local pharmacies, and 83% of adults describe the quality of healthcare services provided at pharmacies as good to excellent [94]. The Local Pharmacy Strengthening Act (VOASG 2020) entitles patients to five new pharmaceutical services [139]. From June 2022 pharmacies are allowed to offer these services at the expense of SHI. These services include standardized risk identification for high blood pressure, extended instruction on the correct administration of medicines using inhaler devices, extended medication advice in case of polymedication, pharmaceutical care for organ transplant recipients, and in case of oral antitumor therapy [94]. Additionally, COVID-19 and influenza vaccination administration has been permitted at specially qualified and equipped pharmacies [140], and as of March 2023, 1600, such pharmacies carried out 342,000 COVID-19 vaccines [94].

The additional, low-threshold vaccination program is to be extended to other vaccinations in order to improve vaccination rates among the adult population [141]. To provide better patient care processes and services are also being digitalized at German community pharmacies such as the introduction of electronic prescriptions (e-Rezept), medication plans (eMP), and patient records (ePA) [94]. The community pharmacies have been integrated into telematics infrastructure as 100% have institution cards (SMC-B) with owners and managers having an electronic HCP card (HBA) [94]. As of December 2022, 99% of pharmacies were connected to the telematics infrastructure (TI) healthcare network via “eHealth connectors, 34% integrated eMP, and 21% incorporated ePA into their software programs [94]. Moreover, as of April 2023, 75% of pharmacies were equipped for e-prescriptions whereas 54% redeemed e-prescriptions [94]. A small number of pharmacies have already obtained access to an email service within the TI (Kommunikation im Medizinwesen, KIM) through which they can digitally communicate with other players in the Healthcare system [94]. The online pharmacy market in Germany is projected to be US$ 2.48 billion in 2024 and with an annual growth rate of 8.29% will reach US$ 3.41 billion by 2028 [109]. The pharmacies complete 300,000 courier deliveries per day and the consultation about the medications is usually given beforehand at the pharmacy, over the phone, or by pharmacy staff upon delivery [94].

There are also examples of successful implementation of DH solutions providing pharmaceutical care services for inpatients. For instance, telepharmacy services at German intensive care units (ICUs) improved medication safety, particularly in liver and renal failure patients [142]. Telepharmaceutical consultations focussed on drug-drug interactions and dosage adjustments [142]. Similarly, drug-related problems

(DRPs) were detected during telepharmacy consultations at a German state-wide telemedicine network of adult patients in rural ICUs of ten general care hospitals with 514 patients and 1056 consultations [143]. In another study, the structured closed-loop medication management system (CLMM) at a university hospital in Germany has shown efficient medication management of inpatients. This system starts with an e-prescription by a physician, as a second step the e-prescription is checked by a clinical pharmacist and released for unit dose dispensing at a hospital pharmacy followed by administration and electronic documentation by the nurse. With this system, clinical pharmacists were able to perform a high number of medication reviews as well as detect and resolve medication errors before they could have caused harm to the patients [144].

The increasing digital transformation of the German healthcare system and the above examples of effective integration of digital solutions into German community and hospital pharmacy settings will require pharmacists to be digitally competent. These examples also show that the methods and processes used in providing products and services to patients are changing and these opportunities in digital health are not free of challenges for pharmacists. Therefore, there is an urgent need to introduce didactic content, practical experiential education, and awareness about new technologies for future pharmacists before they enter their professional careers. Moreover, their attitudes and perceptions towards DH solutions need to be investigated for wider acceptance - the objectives of studies 3 and 4 in this thesis.

1.3 DIGITAL HEALTH IN PHARMACY EDUCATION

Given the considerable attention that DH is garnering globally, it becomes imperative to integrate it into pharmacy practice and education to define the future of the pharmacy profession. WHO considers DH literacy as a key to overcoming the barriers to the use and uptake of new technologies by HCPs [145]. The high-quality evidence in a recent WHO study corroborates that appropriate training and educational programs, HCPs' willingness to use, and perceptions about the effectiveness of DH tools are among the facilitators of DH adoption [146]. The Digital Health Action Plan for WHO European Region 2023-2030 strongly emphasizes strengthening digital literacy skills and capacity building for the general population and specifically for the healthcare workforce [146].

Digital competence is defined as "the confident and critical use of Information Society Technology (IST) for work, leisure, and communication" [147]. Digital competence, eHealth literacy, and digital literacy have been used interchangeably in the scientific literature and healthcare profession [148-150] meaning "the skills and characteristics required to navigate the professional digital world" [151]. The UN SDG4 (quality education) promotes changes in education and learning systems to match the rapidly changing world with technological shifts [88].

Many studies have pointed out the lack of DH education and DH literacy among Health professional students [152, 153] and identified this shortcoming as a barrier to implementing and adopting DH [34]. Also, HCPs reported limited DH experience and insufficient awareness about DH solutions [6]. The need to integrate DH content into the curricula of pharmacy schools and formal DH training in the form of continuing education programs for practicing pharmacists is strongly endorsed by expert academicians and professionals [85]. The 2017 FIP technical report on Pharmacy and Pharmaceutical Sciences Education addressed the timely developments in curriculum keeping in mind the changes in profession, technology, and society [129]. Later the 2021 FIP report specifically took up the topic of digital health in pharmacy education in response to the DH revolution that transformed the healthcare systems, the delivery of pharmaceutical care, and the roles of pharmacists [88]. The FIP global survey indicated that very few pharmacy programs integrated digital health into their curriculum [154]. Moreover, a scoping review of 57 studies provides the current state of digital literacy education in undergraduate pharmacy programs worldwide [7]. These studies focussed on various digital health education aspects such as digital literacy competency and skills, EHR skills, pharmacy informatics, telepharmacy, mHealth, and prescription drug insurance tools [7]. Recently health informatics courses are being increasingly introduced as mandatory courses, highlighting the importance of such topics for the professional development of pharmacists [155]. Furthermore, HCPs' knowledge of utilizing DH solutions in patient care has been enhanced by the growing number of DH-related conferences and webinars as well as other educational events offered by professional associations [85]. In such an effort Aungst and Patel envisioned the options for DH training in their study as illustrated in Figure 6 [86].

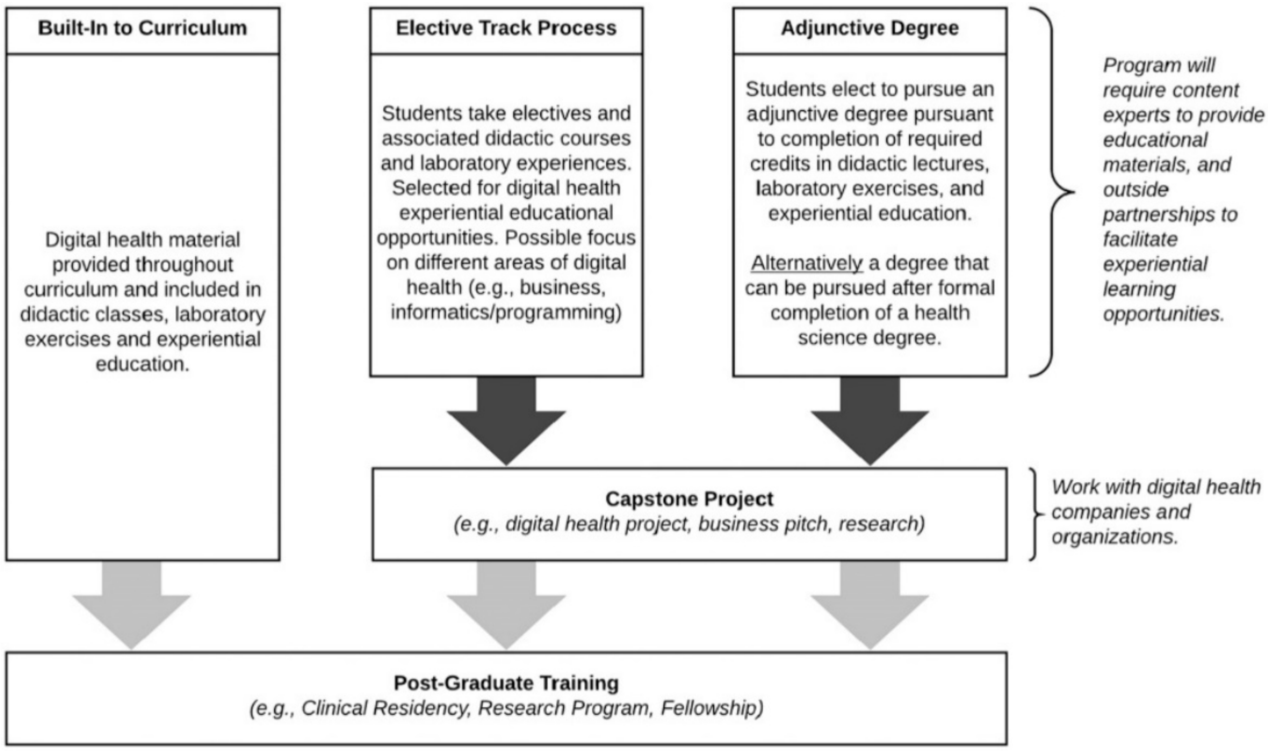

Figure 6. Digital health training options. [Aungst, T. D., & Patel, R. (2020). Integrating Digital Health into the Curriculum—Considerations on the Current Landscape and Future Developments. Journal of Medical Education and Curricular Development, 7. https://doi.org/10.1177/2382120519901275]

The German Council for Science and Humanities recommended integrating digitalization as a central topic in medical education [153]. Therefore, Digital competence has already been introduced as elective and compulsory courses of varying scope and design in medical education including skills such as dealing with datasets, telemedicine, ethics, law, AI, robotics, and apps [153]. However, these courses are still in the developing stage [153]. While some efforts have also been made at individual university levels in Germany to introduce elective practical courses in DH for pharmacy students [156], a built-into curriculum approach is still lacking.

1.4 AIM OF THE THESIS

The overall aim of this thesis was to explore the possibility of integrating DH interventions into German pharmacy practice and pharmacy education. To achieve this, the four independent studies comprising this thesis aimed to develop the pharmaceutical care criteria in evaluating diabetes mHealth apps, investigate the usability of and satisfaction with mHealth apps among end users i.e. diabetes patients and HCPs, and assess the non-inferiority of telepharmacy consultations over face-to-face patient consultations for medical device training. The overall focus was on chronic disease management and the provision of clinical pharmacy services through DH tools.

1.5 RESEARCH QUESTIONS

Four independent studies addressed the following eleven research questions to achieve the aim.

Study 1: Functions of mHealth Diabetes Apps That Enable the Provision of Pharmaceutical Care: Criteria Development and Evaluation of Popular Apps.

1. What functions of diabetes apps support the provision of pharmaceutical care?
2. Which currently available diabetes apps fulfill criteria relevant to pharmaceutical care?
3. What additional app functions should pharmacists consider satisfying the technological needs and preferences of diabetes patients?

Study 2: Evaluating the usability of and satisfaction with mHealth app in rural and remote areas—Germany GIZ collaboration in Bosnia-Herzegovina to optimize type 1 diabetes care.

1. How usable are diabetes apps from the perspective of end users i.e. T1DM pediatric patients, their parents, and HCPs?
2. How satisfied the end users are with these modalities? and
3. What are their experiences regarding app efficiency in managing T1DM?

Study 3: Introducing m-Health and Digital Diabetes Apps in Clinical Pharmacy Education in Germany

1. What criteria are important to learn for future pharmacists to realize the full benefits of app-based chronic disease management such as diabetes?
2. What are the technical aspects of patient data obtained through diabetes apps?

Study 4: Telepharmacy vs. face-to-face consultations for inhaler technique training: A non-inferiority assessment among final year pharmacy students

1. Is telepharmacy non-inferior to face-to-face consultations in the context of student performance for inhaler technique training service?
2. How do the pharmacy students self-assess themselves between the two modes of communication?
3. What are student perceptions about telepharmacy and telepharmacy-based inhaler technique training?

1.6 OUTLINE OF THE THESIS

The first chapter includes an overview of the DH concepts, terminologies, and the overall landscape of DH transformation in healthcare systems, pharmacy practice, and pharmacy education worldwide, as well as in Germany. **Chapter 2** reports study 1, which is about pharmaceutical care through mHealth apps and includes diabetes app evaluation based on pharmaceutical care criteria, general app characteristics, and patient preferences. **Chapter 3** reports study 2, which explored the usability of and satisfaction with the diabetes mHealth app among end users (i.e. pediatric T1DM patients, their parents, and HCPs) in the context of rural and remote areas. **Chapter 4** is further divided into two parts. **Chapter 4.1** reports study 3, introducing mHealth apps into clinical pharmacy education. **Chapter 4.2** reports study 4, evaluating the non-inferiority of telepharmacy over face-to-face patient consultations for medical device training among pharmacy students. **Chapter 5** is about the final discussion and conclusion. This chapter combines the findings of all individual studies and presents an overall discussion about digital health in pharmacy practice and education. Recommendations for future implications and research are also provided in this chapter. Figure 7 describes the outline of the thesis with an overview of the chapters.

The manuscripts of studies 1, 2, 3, and 4 are published and have been reproduced in compliance with the CC BY 4.0 license for open-access publications. These publications are reformatted to be consistent with the rest of the thesis.

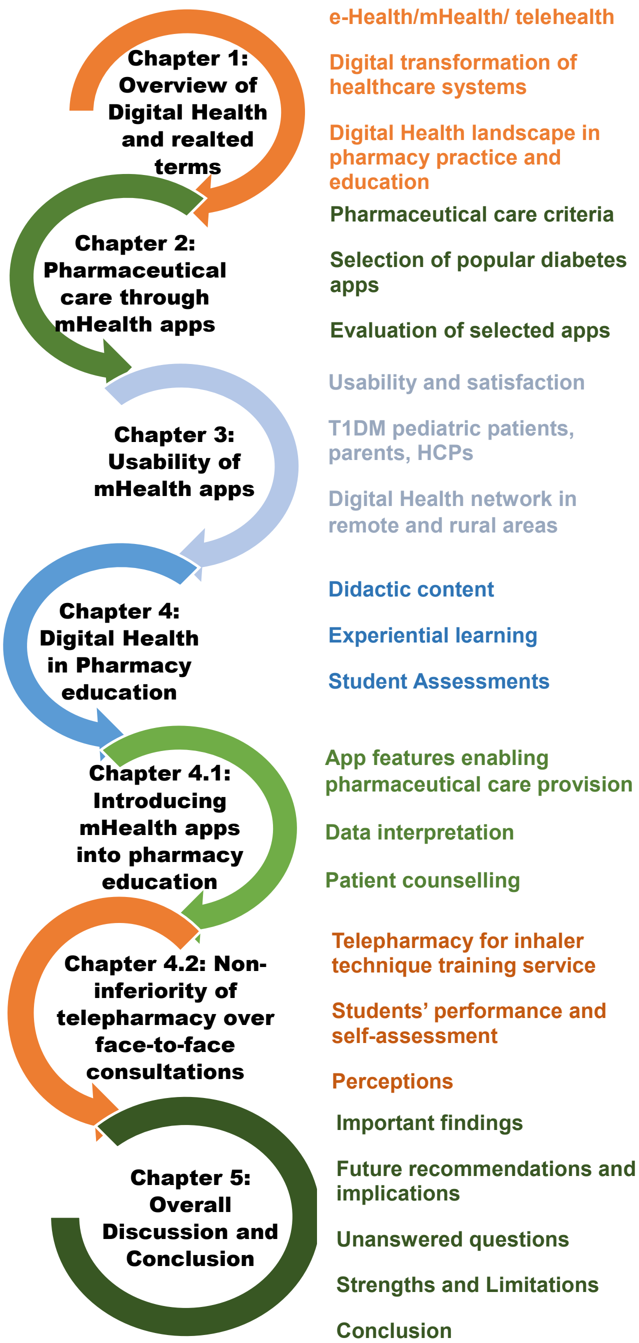

Figure 7. Outline of the thesis with an overview of chapters.

2

Chapter 2: Pharmaceutical Care Through mHealth Apps

Functions of mHealth Diabetes Apps That Enable the Provision of Pharmaceutical Care: Criteria Development and Evaluation of Popular Apps

Ali Sherazi, B., Laeer, S., Krutisch, S., Dabidian, A., Schlottau, S., & Obarcanin, E. *International Journal of Environmental Research and Public Health*. 2023; 20(1):64. https://doi.org/10.3390/ijerph20010064

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PREAMBLE

In the previous chapter (chapter 1) the concepts and terminologies that will be used in this thesis, the current evidence of digital pharmaceutical care services worldwide and some examples from Germany, the digital transformation of healthcare systems, and the digital health in pharmacy education have been established. Moreover, the aim and outline of the thesis have been described with research questions.

In this chapter (chapter 2) we will answer the first three research questions through Study 1. This chapter was published under the title " Functions of mHealth Diabetes Apps that Enable the Provision of Pharmaceutical Care: Criteria Development and Evaluation of Popular Apps" in the Journal *International Journal of Environmental Research and Public Health* (*Int J Environ Res Public Health)* in December 2022.

The author of this dissertation had a lead role in and substantially contributed to the methodology, formal analysis, investigation, visualization, writing - original drafts, and writing - review and editing.

Work arising from this chapter has also been presented at the 19th European Society for Developmental Perinatal and Paediatric Pharmacology (ESDPPP) Congress, 27-30 June 2022, held in Liverpool, United Kingdom.

2.1 ABSTRACT

Background: Personal digital health apps for managing diabetes should include functions that enable the provision of pharmaceutical care services and allow within-app communication with pharmacists and other healthcare providers, thereby improving patient outcomes.

Objectives: The primary aim of this study was to assess the functions of diabetes apps that were relevant to providing pharmaceutical care services (i.e., medication management, adherence, non-pharmacological management, interoperability, and communication).

Methods: Sixteen criteria related to pharmaceutical care were developed and then used to assess ten popular diabetes apps.

Results: The highest numbers of pharmaceutical care criteria were met by the apps Diabetes:M and mySugr (11 criteria); Contour™Diabetes, Dario Health, and OneTouch Reveal® (ten); and DiabetesConnect and ESYSTA (nine); followed by Glucose Buddy (eight), meala (seven), and lumind (three). The most prevalent functions were related to promoting adherence and non-pharmacological management, but most criteria relevant to medication management were lacking. Five apps allowed within-app communication between patients and healthcare professionals (HCPs); however, no app included communication with pharmacists.

2.2 INTRODUCTION

Digital health solutions, particularly mobile health applications (mHealth apps), are increasingly being used to monitor patients remotely and deliver healthcare services outside conventional healthcare settings. The recent COVID-19 pandemic further intensified the need for digital health services [50].

It is necessary to choose carefully among the widely available mHealth apps, including disease-specific apps, as concerns exist regarding their reliability, data privacy and security, suitability of use, and clinical benefits [50,157,158]. Regulatory assessments and approvals are still not available for the majority of available mHealth apps in most countries [159]. In 2019, Germany became the first country worldwide to introduce statutorily reimbursable “apps on prescription” (Digitale Gesundheit Anwendungen, DiGA) under the Digital Healthcare Act (Digitale Versorgung Gestzt—DVG) and the Digital Health Applications Ordinance (Digitale Gesundheitsanwendungen Verordnung—DiGAV) [160]. mHealth apps undergo a strict evaluation process to qualify for inclusion in the official DiGA directory [160]. The General Federal Institute for Drugs and Medical Devices (Bundesamt für Arzneimittel und Medizinprodukte—BfArM) approved the first DiGA in October 2020, and as of 21 November 2022, it has approved a total of 33 DiGAs for different indications [161, 162]. Since the approval of the first DiGA, 50,100 DiGAs have been prescribed or approved directly by health insurers in Germany [163].

The integration of mHealth apps into clinical practice, however, requires much greater support by healthcare professionals (HCPs) in order to optimize the effectiveness of these apps [164, 165]. Pharmacists, as the most accessible HCPs, are in an ideal position to promote awareness and the effective use of digitally assisted health support in the form of mHealth apps [166, 167]. In addition, interactive mHealth interventions have the potential to improve pharmaceutical care outcomes by supporting contact between pharmacists and patients [168, 169]. mHealth apps in the DiGA directory can only be prescribed by physicians and psychotherapists or approved directly by health insurers at the patient's request; however, two surveys of German physicians have reported very low rates of prescribing of mHealth apps [170, 171]. Adherence to mHealth apps has also been reported to be suboptimal, with only 78% of approved or prescribed DiGAs having been activated by patients [163]. Hence, pharmacists could play an important role in recommending mHealth apps to patients and increasing adherence to their use. Data from England suggested that 56% of respondent pharmacists were aware of mHealth apps, and 60% of those recommended apps to patients [167].

Recently, a boom has been occurring in the global market of digital apps for diabetes patients [172], with diabetes apps accounting for 15% of the total number of disease-specific apps in 2021 [50]. This high interest has been reflected in the increased usage of these apps by patients with diabetes [173]. An increasing body of evidence corroborates the effectiveness of mHealth apps in diabetes management [165, 174, 175]. A systematic review and meta-analysis of 13 interventional studies reported an improvement in glycated hemoglobin (HbA1C) values and diabetes self-management through the use of diabetes apps [176].

When pharmacists and other HCPs are considering which diabetes app to recommend, it is important that they consider the various capabilities of the apps. Studies have used a number of different terms to describe the wide range of app capabilities, such as app functionalities/functions, app characteristics, and app features [177]. A study by Smahel et al. used the term 'functions' as an overreaching term to describe the various app features that enable their users to select among a range of capabilities such as monitoring, setting goals, planning, providing feedback on performance, and communicating with other users [178]. Accordingly, 'function' is used in this evaluation to describe such features. To our knowledge, subcategories of app functions, especially those that are clinically relevant (i.e., pharmaceutical care criteria) have not been defined in the literature.

Selecting the appropriate mHealth diabetes app with adequate clinical functions for pharmaceutical care and to satisfy the technological needs of both HCPs and patients is critical. Currently, there is large variability in the key functions of diabetes apps, making it difficult to select the app that is most appropriate for an individual [179]. Salari et al. identified a minimum set of functions for diabetes mobile apps, which include the tracking of blood glucose, insulin and medication, physical activity, weight and body mass index, blood pressure, and diet; the provision of food databases, educational materials, and features that promote healthy coping, risk reduction, and problem-solving; the ability to message, color code, customize themes, set alerts, reminders, and target ranges and view trend charts, logbooks, and numerical indicators; and the inclusion of preset and custom notes [180].

Current diabetes apps focus on blood glucose monitoring, self-management, motivation for medication adherence, and lifestyle modifications [181-183]. Many of these functions including unique functionality to store and display data, to indicate trends and patterns in blood glucose and HbA1C values, and to track medication, diet and physical activity, allowing pharmacists to monitor patient therapy and intervene remotely when necessary. However, diabetes apps may lack some important functions, such as within-app interactions with HCPs and/or pharmacists, that could enhance the provision of pharmaceutical care. The inclusion of pharmaceutical care functions in diabetes apps is important, as they could enhance the development of individualized pharmaceutical care plans, thereby improving patient outcomes, as has been shown with the implementation of other pharmacist interventions in diabetes care [184 -187]. The general technological functions of diabetes apps are also important, as are the functions that pertain to the preferences of the individual patient.

Although the functions of diabetes apps have been previously reviewed [181, 188-190], to our knowledge, no study has evaluated the functions of currently available diabetes apps from a pharmaceutical care perspective. Therefore, in the present study, we aimed primarily to provide information about the functions of popular diabetes apps relevant to providing pharmaceutical care services to patients with diabetes. The first major question— 'What functions of diabetes apps support the provision of pharmaceutical care?'—was answered by developing evaluation criteria based on the literature.

These criteria were then used to evaluate the functions of selected diabetes apps, thereby answering the second question— 'Which currently available diabetes apps fulfill the criteria relevant to pharmaceutical care?'. By answering the first two questions, this study addresses whether diabetes apps can be used as tools in pharmaceutical care and, if this is the case, provides a resource that pharmacists and other HCPs can use to better select apps based on their pharmaceutical care functions.

To give a more complete overview of the functions of diabetes apps, the final question addressed in this study was 'What additional app functions should pharmacists consider satisfying the technological needs and preferences of diabetes patients?’. This was answered by developing relevant evaluation criteria, which were used to evaluate the selected diabetes apps.

2.3 METHODS

2.3.1. Developing the App Evaluation Criteria

2.3.1.1. Criteria Relevant to Pharmaceutical Care

To answer the three study questions, diabetes app evaluation criteria first needed to be developed. Thus, EO, SL, BAS, AD, and SS (pharmacy faculty members of Heinrich-Heine-University Düsseldorf; HHU) defined app evaluation criteria using the three major study objectives: app criteria relevant to pharmaceutical care; general aspects of diabetes apps; and special app functions and patient preferences.

To the best of our knowledge, diabetes app functions have not previously been defined and explored from a pharmaceutical care perspective. Therefore, the authors (EO, BAS, AD, SS) performed an extensive literature search using the PubMed database. The literature search was conducted for papers published until January 2022, using the search terms “Pharmacy”, “digital apps”, “Mobile apps”, “mHealth”, “Pharmaceutical care”, and “adherence”. We compiled a list of essential criteria based on the important pharmaceutical care interventions for diabetes management and included three major categories: Medication Management, Adherence/non-pharmacological management,and Interoperability/Communication [167,168,191-196]. After initially defining the app criteria, the authors (EO, SL, BAS, AD, SS) tested the criteria in a practical elective course in February 2022 with the final year pharmacy students to evaluate the usefulness of various digital diabetes apps in the pharmaceutical care process, as previously reported [197]. The initial

25-item criteria were then discussed and re-evaluated by the authors (EO, BAS, SL, AD, and SS) and the list was refined to include the 16 most relevant criteria.

2.3.1.2. General Characteristic Criteria

The criteria for the general characteristics of diabetes apps were extracted from the available literature [28,198-200], and by consulting a diabetes patient who was also an app developer (SK) to avoid bias. General characteristics ranged from very basic technical criteria (e.g., operating system, category, etc.) to more precise criteria, such as regulatory aspects (e.g., data protection, privacy policy, Conformitè Europëenne (CE) mark, etc.), financial options (e.g., cost, reimbursement), and the presence of scientific studies on selected apps.

2.3.1.3. Patient Preference Criteria

Criteria for patient preferences related to active engagement with diabetes apps were also extracted from the available literature [28,43-45] and by consulting the diabetes patient/app developer (SK) and a pharmacist evaluator (EO) to ensure that the patient perspective was included. Patient preference criteria that were already covered by the pharmaceutical care criteria (e.g., reminder, food, activity functions) were excluded to avoid duplication.

2.3.2. Selecting the Diabetes Apps to Be Evaluated

All the authors selected ten widely used diabetes digital apps for evaluation based on a study by Kebede and Pischke, “Popular Diabetes Apps and the Impact of Diabetes App Use on Self-Care Behaviour” [201]; the DiGA directory [161]; and their availability and status in Germany [202].

2.3.3. Procedure for Evaluating the Apps Using the Criteria

The authors (EO, BAS, AD, SS) downloaded and installed all the apps on their smartphones (Android/iOS) and used the predefined evaluation criteria. Before evaluating the apps, the authors discussed the criteria (pharmaceutical-care-related criteria and general characteristics criteria) to ensure an understanding of all items listed for evaluation. All of the apps were assessed in their basic and premium versions, and their corresponding apps and app store websites were consulted to obtain information about certain functions. All the authors independently performed the app evaluation process.

The evaluation results were double-checked, compared, and discussed during six online meetings among evaluators. In total, there were five disagreements in the individual assessors' evaluations of the apps, which are presented as follows:

- Pharmaceutical care criteria: drug information item. Some apps allow logging and tracking of medications but do not contain drug information, such as dosage, warnings, indications, and other aspects. As some of the criteria were not quite clear in regard to all evaluators, an additional literature review was performed in some cases so that a consensus could be reached.
- Pharmaceutical care criteria: drug selection item. The DiabetesConnect app allows the selection of a drug from a standard list of medications and not according to the latest guidelines. After double-checking, all assessors agreed that this was an important function and gave it a score of one for at least having the list of medications.
- Pharmaceutical care criteria: insulin bolus calculator item. The Dario Health bolus calculator was not found within the app. However, a discrepancy was

noted as the app's website stated that the app contained a bolus calculator. This was rechecked by the evaluators, who confirmed that this feature was not available in the app downloaded from the German app store. It was therefore given a score of zero.

- Pharmaceutical care criteria: communication item. Some apps (e.g., One Touch Reveal®) offered the possibility of exchanging information through SMS, but this was not considered within-app communication. Therefore, a score of zero was given to all apps with SMS capability.
- General characteristic: scientific studies on apps. Initially, no scientific studies were found for the Diabetes:M app. However, after double-checking the proceedings of a conference, a study on Diabetes:M was found. Therefore, it was given a 'Yes'.

After a consensus was reached, the results were collated and summarized.

2.3.3.1. Criteria Relevant to Pharmaceutical Care

The authors assessed the essential functions of apps related to the provision of pharmaceutical care by reusing anonymized data from real diabetes patients. The authors thoroughly assessed the defined criteria within the apps and searched on app store websites and on homepages of individual app developers in cases of discrepancies. The criteria were considered absent if they were not found in any of the above-mentioned sources.

The criteria relevant to digital diabetes pharmaceutical care were scored based on an objective assessment as 'Yes' (1) and 'No '(0) depending on the presence or absence of specific functions, respectively. The higher the total score, the more potentially helpful the app was in supporting pharmacists to provide pharmaceutical care to diabetes patients.

2.3.3.2. General Characteristic Criteria

The authors (EO, BAS, AD, SK, and SS) also analyzed the apps for their general characteristics and made additional descriptive notes in cases of unique functionalities. To determine whether clinical studies supporting the use of the selected app had been published, EO, BAS, AD, and SS conducted additional PubMed and Google Scholar searches using the name of each selected app.

2.3.3.3. Patient Preference Criteria

The diabetes patient/app developer (SK) evaluated the patient preference criteria for their presence or absence in the selected apps. These criteria were further re-checked by pharmacist evaluators (EO, BAS, AD, SS) to eliminate any discrepancies.

2.4 RESULTS

2.4.1. App Evaluation Criteria

The 16 pharmaceutical-care-related criteria (Table 2) included: four criteria related to medication management (e.g., insulin dose and bolus calculation, drug information and selection, interaction checks); five related to adherence and non-pharmacological management (reminder/alert functions, warning functions, food and sport/activity functions, and personal notes), and seven related to interoperability and interaction/communication (e.g., communication and data exchange between patients and HCPs, interoperability with other devices/software, data storage and display, and the involvement of pharmacists).

These functions, necessary to support the pharmaceutical care process, have been evaluated in all ten selected apps (Table 3). It is important to note that these criteria were neither exhaustive, nor were they used to evaluate the overall quality of the selected diabetes apps. Thirteen criteria were included in the list of general characteristics to be evaluated for diabetes apps (Table 4) and ten were included in the list of patient preferences for active engagement with diabetes apps (Table 5).

2.4.2. Selected Diabetes Apps

Of the ten diabetes apps selected for evaluation, six (mySugr, Diabetes:M, Contour™ Diabetes, OneTouch Reveal®, Dario Health, and DiabetesConnect) were selected based on a survey of the use of popular diabetes apps in Germany by Kebede and Pischke [201] (continuous glucose monitoring apps were excluded). The ESYSTA app was also included, as it was DiGA-approved for diabetes management at the time of evaluation [161]. The lumind app was selected based on its DiaDigital app quality certificate in Germany [202] and meala was chosen as a newer app developed by the same company. Glucose Buddy was selected as one of the most downloaded apps in February 2022. However, the authors of this paper are aware that there are also other potentially helpful and popular diabetes apps in addition to those chosen for this study.

2.4.3 Functions of the Apps Relevant to Pharmaceutical Care

The functions of diabetes digital apps supporting pharmacists in the pharmaceutical care process were evaluated for all ten selected apps (Table 3). Concerning the 16 criteria relevant to pharmaceutical care, Diabetes:M and mySugr met the most criteria, with each meeting a total of 11 criteria; Contour™ Diabetes, Dario Health, and OneTouch Reveal® each met ten criteria; DiabetesConnect and ESYSTA both met nine criteria; Glucose Buddy and meala met eight and seven criteria, respectively, and lumind met only three criteria.

Table 2. Description of criteria relevant to digital pharmaceutical care for patients with diabetes

Criteria	Description of the ability of the app
Medication management	
1. Drug information	Able to provide information about drugs, such as indication, dosage, warnings, and other aspects
2. Drug selection	Able to help select drugs according to the latest guidelines
3. Insulin bolus calculation	Able to calculate insulin bolus doses
4. Interaction check (type 2)	Able to check drug interactions
Adherence/Non-pharmacological management	
5. Reminder/alert	Able to remind or alert users on insulin administration, blood glucose measurements, doctor appointments, etc.
6. Warning function	Able to notify or warn users about hypo-or hyperglycemic events in real-time
7. Food feature	Able to enter additional different foods manually, by bar code scanning, selecting from databases, taking pictures, etc.
8. Sports/activity feature	Able to log sports or other physical activities
9. Personal notes	Able to add personal notes when desired
Interoperability and interaction/communication	
10. Communication (between patient and HCPs)	Able to communicate with HCPs (within the app)
11. Possible to exchange data with HCPs	Able to retrieve and share data with healthcare professional
12. Possible to connect to devices	Able to connect to other devices, such as blood glucose measuring devices, insulin pens, pumps, etc.
13. Smartwatch compatibility	Compatible with smart watch and smartwatch apps
14. Synchronization option	Able to synchronize between different apps and operating systems
15. Data storage and display	Able to store and display graphical and statistical data
16. Pharmacist involvement	Able to allow pharmacists to intervene with a pharmacist-specific dashboard

2.4.3.1. Medication Management

The Diabetes:M, mySugr, and OneTouch Reveal® apps include insulin bolus calculators to modify insulin doses according to individual needs (Table 3). The Insulin Mentor bolus calculator in the OneTouch Reveal® app assists in calculating insulin bolus doses by considering multiple factors such as active insulin, blood glucose values, and carbohydrate intake. Similarly, the mySugr bolus calculator tool uses automatic algorithms and has been tested in clinical studies [203, 204]. The Diabetes:M app bolus calculator provides extended bolus calculations by considering protein and fat intake in addition to carbohydrates. Overall, nearly all the evaluated apps lacked criteria relevant to medication management. None of the evaluated apps included drug information, drug interaction checking, or drug selection according to the latest guidelines (Table 3). Only DiabetesConnect allowed for drug selection from a list of standard medications rather than from the latest guidelines.

2.4.3.2. Adherence and Non-Pharmacological Management

Overall, criteria that can support pharmacists in motivating patients for medication adherence and non-pharmacological management were met in most of the ten evaluated apps. All of the apps (except ESYSTA) included a reminder or alert function (Table 3) which reminded users about administering insulin, measuring blood glucose levels, doctor appointments, taking medications, or other essential tasks as set by the users. The reminders were in the form of text notifications or alarms or both. In addition, 80% of the apps could warn and alert users about hypo- or hyperglycemic events with either a color scheme (color codes indicating low, normal, and high blood glucose levels) or light (lumind). Most of the evaluated apps also included a food function (90%), a sports/activity function (80%), and/or the ability to add personal notes (90%).

Table 3. Evaluation scores for mobile health apps for diabetes patients based on criteria relevant to digital pharmaceutical care for diabetes patients

Criteria relevant to digital diabetic pharmaceutical care[a]	Diabetes mobile health apps									
	ESYSTA	mySugr	Diabtes: M	Contour™ Diabetes	Dario Health	Diabetes Connect	Glucose Buddy	lumind	meala	OneTouch Reveal®
Medication management										
1. Drug information	0	0	0	0	0	0	0	0	0	0
2. Drug selection	0	0	0	0	0	1[b]	0	0	0	0
3. Insulin bolus calculation	0	1	1	0	0	0	0	0	0	1
4. Interaction check (type 2)	0	0	0	0	0	0	0	0	0	0
Adherence/non-pharmacological management										
5. Reminder/alert	0	1	1	1	1	1	1	1	1	1
6. Warning function	1	1	1	1	1	1	0	1	0	1
7. Food feature	1	1	1	1	1	1	1	0	1	1
8.Sports/activity feature	1	1	1	1	1	1	1	0	0	1
9. Personal notes	1	1	1	1	1	1	1	0	1	1
Interoperability and interaction/communication										
10. Communication (between patients and HCPs)	1	1	0	1	1	0	0	0	1	0
11. Possible to exchange data with HCPs	1	1	1	1	1	1	1	0	1	1
12. Possible to connect to Devices	1	1	1	1	1[c]	0	1	1	1	1[c]
13. Smartwatch compatibility	0	0	1	0	0	0	0	0	0	0
14. Synchronization option	1	1	1	1	1	1	1	0	0	1
15. Data storage and display	1	1	1	1	1	1	1	0	1	1
16. Pharmacist involvement	0	0	0	0	0	0	0	0	0	0
Total score (maximum 16)	**9**	**11**	**11**	**10**	**10**	**9**	**8**	**3**	**7**	**10**

HCP, healthcare professional; 1 indicates that the individual features/function was found within the app, app store websites, or homepages of individual app developers; 0 indicates that the individual features/function was not found.
[a] See Table 1 for a description of the criteria.
[b] Drug selection according to a standard list instead of the latest guidelines.
[c] only their own devices

2.4.3.3. Interoperability and Interaction/Communication

Half of the ten evaluated apps, namely, ESYSTA, mySugr, Contour™ Diabetes, meala, and Dario Health possessed the ability to allow communication between patients and HCPs within the app (Table 3). The majority of apps (except lumind) allowed patient data to be exported to and shared with HCPs in various formats (PDF, CSV, etc.), and through various online platforms (e.g., email, WhatsApp). The OneTouch Reveal® app allowed the exchange of information through the short message service (SMS) option.

Ninety percent of the evaluated apps (all but DiabetesConnect) provided the option to connect to other devices, such as blood glucose measuring devices, insulin pens, pumps, etc. (Table 3). However, the Dario Health and OneTouch Reveal® apps only allowed connections with their related devices. Diabetes:M was the only app that included a smart watch compatibility. Most (80%) apps provided the option of synchronization with other apps or operating systems, and 90% could store and display all patient data graphically and statistically. Some apps (ESYSTA, Diabetes:M, DiabetesConnect, and Glucose Buddy) also allowed automatic data synchronization with an online web portal. Although the functions promoting interoperability and exchange with HCPs were present in most apps, no app provided direct communication between patients and pharmacists (Table 3) or explicitly mentioned pharmacists as diabetes care providers.

2.4.4. General Characteristics of the Apps

The general characteristics of the evaluated diabetes apps are presented in Table 3. All the apps were developed for both Android and iOS platforms. Most (80%) of the apps fell into the medical category, with only lumind and meala falling into the health and fitness category. Important aspects of data protection and privacy policy were included in all the apps. Most of the apps (60%) contained the CE mark, which gives market authorization to the product throughout Europe. Four of the evaluated apps (Contour™ Diabetes, lumind, meala, and OneTouch Reveal®) were cost-free. The remaining apps offered a trial version or free-of-cost access in the form of a basic version, with premium versions being associated with a variety of prices. As of March 2022, only the ESYSTA and mySugr apps could be reimbursed by the statutory health insurance in the German healthcare system. Advertising was not present in premium (paid) versions of any of the apps.

Studies providing evidence on app effectiveness and other patient-reported outcomes were found for mySugr [205, 206], Glucose Buddy [206, 207], Diabetes:M [208], OneTouch Reveal® [209], ESYSTA [210], Dario Health [211], and Contour™ Diabetes [212]. All the apps, except meala, could be accessed offline. Registration or login was required for accessing most of the apps; Diabetes:M could be used without logging in but with limited functionality, whereas lumind and meala could be used with their full functionality without the need to log in. Only Glucose Buddy could be logged into with an existing account (e.g., Facebook, Google, etc.)

Table 4. General characteristic criteria of mobile health apps for diabetes patients

General Characteristics	Diabetes mobile health apps									
	ESYSTA	mySugr	Diabetes: M	Contour™ Diabetes	Dario Health	Diabetes Connect	Glucose Buddy	lumind	meala	OneTouch Reveal®
Category	Medical	Medical	Medical	Medical	Medical	Medical	Medical	Health & fittness	Health & fittness	Medical
Android/iOS operating system	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Data protection	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Privacy policy	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Medical device classification	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes
Cost	Yes	Yes[a]	Yes	Free	Yes	Yes	Yes	Free	Free	Free
Trial version/test version	Yes	Yes	Yes	NA	Yes	Yes	Yes	NA	NA	NA
Reimbursement	Yes	Yes	No	NA	No	No	No	NA	NA	NA
Advertising	No	No	No[b]	No	No	No	No	No	No	No
Studies conducted with apps	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes
Offline availability	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Usable without login/registration	No	No	Yes[c]	No	No	No	No	Yes	Yes	No
Login possible with an existing account	No	No	No	No	No	No	Yes	No	No	No

NA,not applicable, as app is cost-free.
[a] Free when used with Accu-Chek® devices.
[b] Only the basic version includes advertisements.
[c] Can be used without login but with limited functionality

2.4.5. Patients' Preferences and Other Special Functions

The availability of patients' preferences for active engagement with the ten selected diabetes apps were also evaluated (Table 5). These criteria included peer support (20% of evaluated apps), swarm knowledge (10%), training and educational material (50%), analysis of blood glucose values and therapy recommendations (80%), usability and appealing design (70%), app accessibility in the case of visual and hearing impairments (10%), the ability to set individual target ranges (70%) or carbohydrate units (50%), multiple-profile management (10%), and the ability to share data with followers (10%).

The evaluated apps also included some unique functions of interest, including motivation through gamification and challenges (mySugr), emergency contact functions (Contour™ Diabetes and Dario Health), estimated HbA1C function (ESYSTA, mySugr, and Dario Health), food databases (Diabetes:M and Glucose Buddy), personal diabetes coaching (Dario Health, mySugr, and Glucose Buddy), and a smart assistant function (Diabetes:M). Blood pressure, weight management, and other laboratory data could also be stored in some apps in addition to diabetes-related data (Dario Health, Diabetes:M, and DiabetesConnect), hence offering an option for the management of multiple chronic diseases.

The two apps belonging to the health and fitness category (i.e., meala and lumind) offered additional unique functions. In particular, the meala app had functions to recognize meals and avoid mistakes when estimating carbohydrates, and the lumind Habitat app retrieved data on blood glucose levels from compatible meters and converted them into sounds, light, and colors, which is especially useful for patients with hearing aids and visual impairment.

Table 5. Patients' preferences for active engagement with diabetes apps

Patient preferences (description)	Diabetes mobile health app									
	ESYSTA	mySugr	Diabetes:M	Contour™ Diabetes	Dario Health	Diabetes-Connect	Glucose Buddy	lumind	meala	One Touch Reveal®
Peer support/exchange with other patients										
Is there a way to exchange ideas with other patients? (e.g., forums)			✓						✓	
Swarm knowledge/insight into others' experiences										
Is it possible to view the experiences of other patients and learn from them? (e.g., CGM values)									✓	
Training and information materials										
Are information/training materials available to improve one's knowledge and, if necessary, health care?		✓	✓		✓		✓		✓	
Analysis of blood glucose values										
Are the blood glucose values entered automatically analyzed and therapy recommendations given for optimization?	✓	✓	✓	✓	✓	✓	✓			✓
UI/UX design										
Is the app easy to understand and is the UI/UX design appealing?		✓		✓	✓		✓	✓	✓	✓
Accessibility										
Is the app accessible to people with visual or hearing impairment?								✓		
Individual target area										
Can the target range be set manually?	✓	✓	✓	✓	✓	✓	✓			
Individual carbohydrate units (e.g., bread units, carbohydrate units/g)										
Can the unit of carbohydrates be individually adjusted?	✓	✓	✓	✓		✓				
Management of multiple profiles with one account										
Can one account manage multiple blood glucose profiles?			✓							
Follower function										
Can data be shared with family and friends as "followers"?								✓		

CGM continuous glucose monitoring; UI user interface; UX user experience

2.5. DISCUSSION

Pharmacists have successfully initiated various pharmaceutical care programs for patients with diabetes by implementing pharmacological and non-pharmacological interventions [184, 213]. Their success has become even more critical in the post-pandemic era in relation to lowering the risks of diabetes-related acute complications and subsequent hospitalizations [214]. As the use of diabetes apps may help pharmacists improve pharmaceutical care and outcomes in diabetes patients, it is important that pharmacists are aware of the functions of such apps when recommending their use.

The aim of this study was to provide information about the functions of diabetes apps related to providing pharmaceutical care services to diabetes patients. To accomplish this, in this study we evaluated the functions of selected diabetes apps based on criteria relevant to pharmaceutical care, as well as criteria relevant to technological needs and the preferences of patients. We also addressed the shortcomings of the apps to unfold the full potential for patients' interaction with HCPs, such as direct communication with HCPs (i.e., pharmacists) and the lack of medication management functions, which is particularly important for polypharmacy in patients with type 2 diabetes.

The first major question to be answered in this study was 'What functions of diabetes apps support the provision of pharmaceutical care?' In order to answer this, the criteria to evaluate such functions first needed to be developed. Based on the literature, a list of essential criteria based on the important pharmaceutical care interventions for diabetes management was compiled. These criteria were then tested and refined to include the 16 most relevant criteria from a pharmaceutical care perspective. Criteria for evaluating the general characteristics and patient preferences for diabetes apps were also developed based on the available literature and consultation with appropriate individuals. These novel evaluation criteria were then used to evaluate the selected diabetes apps, and could be used in future evaluations of diabetes apps and refined to evaluate the functions of digital apps for other health conditions.

The second major question to be answered was ‘Which currently available diabetes apps fulfil the criteria relevant to pharmaceutical care?’ The results of this study revealed that most of the evaluated digital apps for diabetes patients could help provide pharmaceutical care, as eight of the ten apps integrated >50% of the criteria related to pharmaceutical care. The total scores ranged from 3 to 11 out of a maximum score of 16; 80% of the apps had a score of ≥8, and only 20% of apps had a score of <8. The pharmaceutical care functions that were lacking in these apps may be due to the current lack of involvement of pharmacists (unlike other members of the multidisciplinary diabetes care team) in the initial design of diabetes apps.

The pharmaceutical care criteria comprised three major categories, the first of which was ‘medication management’. Medication logging and tracking functions were available in some of the apps. However, medication management functions, particularly for patients with type 2 diabetes, such as drug information, drug selection according to guidelines, and checking for drug interactions, were not provided by any app. A 2019 study also reported a general lack of medication management functions in diabetes apps [215]. Four of the ten evaluated diabetes apps were integrated with a bolus insulin calculator, simplifying the complex task of insulin dose calculation, a very useful function for patients prescribed with insulin. However, they need to be carefully and cautiously employed, as mistakes resulting from user errors and/or software errors can lead to serious consequences [216]. Moreover, the lack of important functions to validate insulin dose calculations could result in harmful dose recommendations [181] and adverse events [172]. Pharmacists can have an important role in minimizing these potential errors by carefully considering all the user- and app-related factors. ‘Adherence/non-pharmacological management’ was the second major category of pharmaceutical care criteria. These were the most prevalent functions of the selected diabetes apps. Of the ten evaluated digital apps, 60% met all five criteria in this category. Ninety percent of the apps included a reminder/alert function, personal notes, and/or food function. In addition, 80% of the apps had a warning function and a physical activity logging function. Evidence suggests that app-based adherence interventions for patients with diabetes have resulted in decreasing HbA1C levels by improving adherence behaviors to medications, diet, and exercise [217].

The final major category of pharmaceutical care criteria was ‘interoperability/communication’. Communication between patients and HCPs through mHealth apps serves as an alternative to in-person clinical visits and face-to-face contact. Diabetes care can benefit greatly from patient–provider contact facilitated by apps and web portals [218]. Clinical outcomes and medication adherence among diabetes patients have been reported to be improved by pharmacist-led follow-up interventions that involved the simplest methods of telecommunication, such as telephone calls and text messages [185-187]. Although half of the evaluated apps (ESYSTA, mySugr, Contour™ Diabetes, meala, and Dario Health) allowed for communication with HCPs inside the app to ensure real-time support and feedback for diabetic patients, none of the apps allowed for communication specifically with pharmacists. Within-app communication is also important as regular follow-up of patients by HCPs has been shown to help prevent long-term complications of diabetes [219]. High-frequency HCP feedback through diabetes apps resulted in a mean HbA1C reduction of 1.12% compared with less frequent feedback (0.33%) and no feedback (0.24%) in a systematic review and meta-analysis of 21 randomized trials that evaluated the effect of diabetes apps [165]. Similar findings have been reported by other studies focusing on the effect of real-time HCP support and communication through mobile app interventions in diabetes management [218, 220].

The third and final question to be answered in this study was ‘‘What additional app functions should pharmacists consider to satisfy the technological and health-related needs, and preferences of diabetes patients?’ The general technological characteristics of the evaluated diabetes apps were assessed descriptively to ensure an understanding of their usability, regulatory requisites, cost, reimbursement, and outcomes as published in studies in the scientific literature. It is also important for pharmacists to review these aspects before recommending apps to their patients. Most of the apps belonged to the medical category and contained a CE mark, which means that they met the standards set by the Medical Device Regulation policy standards [182]. However, the presence of a CE mark does not mean that the app has been tested for accuracy and clinical outcomes [221]. Disclosures of privacy policies and data protection policies were present in all apps. Only four of the apps were free to use; however, nearly all other apps offered a test or trial version. Reimbursement through statutory health insurance was only possible for the ESYSTA and mySugr apps at the time of evaluation.

Studies in the scientific literature were found for 70% of the apps, with a range of beneficial study outcomes. Two broader categories of study outcomes were clinical outcomes (e.g., impact on HbA1C, glycemic variability, etc.) and self-reported outcomes (e.g., self-care, quality of life, patient empowerment, satisfaction, engagement, etc.). A study by Drincic et al. reported similar findings regarding safety and efficacy outcomes for diabetes apps based on the published literature [222].

Patients' preferences for certain functions are very important in order to foster their long-term and consistent engagement with diabetes apps [199] and, in turn, guide HCPs to recommend suitable apps [183]. We believed it was important to evaluate diabetes apps according to patients' perspectives, since the insufficient assessment of end-users' expectations has been related to a low level of app adoption and use [199]. In addition to the most used and preferred functions of blood glucose tracking, carbohydrate/calorie counting, and physical activity tracking [200, 223], the present study also included more sophisticated functions. Training and educational material, analysis of blood glucose values and therapy recommendations, usability and appealing design, individual target range settings, and individual carbohydrate unit functions were available in most of the assessed apps. However, the ability to share data with followers, access to peer support and swarm knowledge, multiple profile management, and app accessibility in the case of visual and hearing impairments were found in very few diabetes apps.

In the context of "apps on prescription" (DiGA), pharmacists in Germany are often confronted by patients with questions about mHealth apps and their effectiveness. Therefore, this review of app functionality could help practicing pharmacists to become familiar with the essential aspects of apps and to become aware of the need to educate and counsel their patients about practical app usage during patient encounters. Although the focus of this study was diabetes apps, the findings from this study can be applied to evaluate the pharmaceutical-care-related functions of other disease-specific apps.

The study has several limitations. The general characteristics of the diabetes apps were evaluated only on a descriptive level, as a more detailed assessment was outside the scope of this study. Once each assessor had independently evaluated the various app criteria, the assessors met to double-check, compare, and discuss their results and resolve any discrepancies in their evaluations via a consensus. The inter-rater variability among all four authors was not determined and therefore the lack of statistical analyses of the inter-rater reliability of the assessors is a potential limitation of the study. In addition, some of the personal preference criteria were vague and subjective, i.e., the criteria ‘Is the app easy to understand and is the UI/UX design appealing?’, and the results may have been influenced by the experience and knowledge of the diabetes patient who was also an app developer and assessor. It may have been more appropriate to have this criterion evaluated by other diabetes patients rather than by individuals who were familiar with such apps. Furthermore, this review is limited by the selection of only ten diabetes apps for evaluation, which could limit the generalizability of our findings. Moreover, only one diabetes patient was involved in the evaluation process; however, this individual had profound knowledge and experience in designing and developing apps. Finally, app functions are continuously updated, and there is a possibility that many of the apps will have been upgraded with new functions by the time the results of this study are available.

2.6. CONCLUSION

Our evaluation showed that diabetes apps were equipped with the necessary functions to support pharmacists and other HCPs in providing pharmaceutical care services to patients with diabetes. Nonetheless, improvement in their functions is needed as they often lacked medication management functions. Furthermore, the careful supervision of diabetes self-management through apps is necessary in order to amplify app effectiveness, increase app adherence, and mitigate the risks associated with improper use. On the other hand, the provision of app-integrated pharmaceutical care could provide an unprecedented opportunity for pharmacists to develop active interactions with their patients through remote monitoring and intervention, which is currently not possible. The evaluation of digital diabetes apps shows that apps can be powerful tools for pharmaceutical care; however, they are still broadly underutilized by pharmacists. Hence, diabetes app providers should recognize pharmacists' expertise and specifically include them alongside other clinicians in customized versions of diabetes apps. In addition, a direct exchange through the app between patients and pharmacists (i.e., a chat function) would further enhance the pharmaceutical care process and help improve diabetes outcomes

3

Chapter 3: Usability of and Satisfaction with mHealth Apps

Evaluating usability of and satisfaction with mHealth app in rural and remote areas—Germany GIZ collaboration in Bosnia-Herzegovina to optimize type 1 diabetes care

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PREAMBLE

The previous chapter (chapter 2) found that diabetes apps are equipped with the necessary functions to support pharmacists and other HCPs in providing pharmaceutical care services to patients with diabetes. On the other hand, this finding explored an unprecedented opportunity for pharmacists to augment their patient care services through such apps.

This chapter (chapter 3) will explore other important factors for app acceptance and adoption by patients and Healthcare professionals. These factors namely usability (i.e. of use and satisfaction), user experience, and usefulness of app features have been investigated. This chapter was published under the title “Evaluating usability of and satisfaction with mHealth app in rural and remote areas—Germany GIZ collaboration in Bosnia-Herzegovina to optimize type 1 diabetes care” in the Journal *Frontiers in Digital Health (Front. Digit. Health*) in June 2024.

The author of this dissertation had a lead role in and substantially contributed to the conceptualization, methodology, formal analysis, investigation, resources, software, visualization, writing - original drafts, and writing - review and editing.

Work arising from this chapter has also been presented at the 20th European Society for Developmental Perinatal and Paediatric Pharmacology (ESDPPP) Congress, 28-30 June 2023, held in Prague, Czech Republic, and at the 49th Annual Conference of International Society for Paediatric and Adolescent Diabetes (ISPAD), 18-21 October 2023, held in Rotterdam, The Netherlands.

3.1 ABSTRACT

Background: Type 1 diabetes mellitus (T1DM) management in children and adolescents requires intensive supervision and monitoring to prevent acute and late diabetes complications and to improve quality of life. Digital health interventions, in particular diabetes mobile health apps (mHealth apps) can facilitate specialized T1DM care in this population. This study evaluated the initial usability of and satisfaction with the m-Health intervention Diabetes: M app, and the ease of use of various app features in supporting T1DM care in rural and remote areas of Bosnia-Herzegovina with limited access to specialized diabetes care.

Methods: This cross-sectional study, performed in February–March 2023, evaluated T1DM pediatric patients who used the Diabetes: M app in a 3-month mHealth-based T1DM management program, along with their parents and healthcare providers (HCPs). All participants completed selfadministered online questionnaires at the end of the 3-month period. Data were analyzed by descriptive statistics.

Results: The study population included 50 T1DM patients (children/parents and adolescents) and nine HCPs. The mean ± SD age of the T1DM patients was 14 ± 4.54 years, with 26 (52%) being female. The mean ± SD age of the HCPs was 43.4 ± 7.76 years; all (100%) were women, with a mean ± SD professional experience of 17.8 ± 8.81 years. The app was reported usable in the domains of ease-of-use and satisfaction by the T1DM children/parents (5.82/7.0), T1DM adolescents/young adults (5.68/7.0), and HCPs (5.22/7.0). Various app features, as well as the overall app experience, were rated positively by the participants.

Conclusion: The results strongly support the usability of mHealth-based interventions in T1DM care, especially in overcoming care shortage and improving

diabetes management and communications between HCPs and patients. Further studies are needed to compare the effectiveness of apps used to support T1DM management with routine care.

KEYWORDS

children and adolescents, mobile health applications, type 1 diabetes mellitus, rural and remote areas, specialized diabetes care

3.2 INTRODUCTION

Type 1 diabetes mellitus (T1DM), a common chronic condition in children and adolescents, requires lifelong insulin therapy, regular blood glucose monitoring, diabetes education, and collaborative care to achieve favorable treatment outcomes [224, 225]. Personalized holistic care with frequent monitoring and adjustments of insulin doses has been recommended [226], with optimal adherence to the devised treatment plan, along with adequate self-management activities, being the cornerstone of effective T1DM management [227]. Suboptimal adherence to insulin regimens, as well as to food and exercise recommendations, is common in pediatric patients with T1DM, resulting in poor glycemic control [228-231] increased morbidity, and premature mortality [232]. Suboptimal diabetes control during childhood can lead to the development of late diabetes complications when these patients reach adulthood [228, 233]. The costs of diabetes complications are significant and represent a substantial economic burden on healthcare systems worldwide [234-237].

Although the incidence of T1DM in children and adolescents is highly variable, this incidence and the global burden of T1DM is increasing worldwide [224, 238, 239]. In 2022, a total of 8.75 million people were living with T1DM worldwide, with 1.9 million living in low- and lower-middle-income countries, including 1.52 million aged <20 years, accounting for 182,000 deaths in 2022 [240]. According to the International Diabetes Federation (IDF), the highest number of patients with T1DM in 2022 lived in Europe, followed by North America and the Caribbean regions [240]. The highest incidence of T1DM in upper-middle-income countries were in Europe and Brazil [224]. The World Health Organization (WHO) has reported that the prevalence of diabetes in Bosnia-Herzegovina (BiH) was 9.3%, being one of the highest rates in Europe [240]. The annual incidence of T1DM per 100,000 inhabitants under age 18 years was 7.5 in the peripheral parts of BiH from 1998 to 2010 and 6.5 in the central region of BiH from 1999 to 2004 [241]. Unofficial data estimate that the number of newly diagnosed patients has doubled in the last 10 years. The unreported numbers are likely much higher, as BiH does not yet have a nationwide registry for T1DM.

The everyday management of T1DM significantly burdens the affected patients and their families in BiH [242]. Healthcare resources are insufficient to cope with the growing demand, with resources in BiH remaining below the regional average for universal health coverage owing to many factors, including the limited-service capacity and poor access among the most disadvantaged members of the population [243]. There are only five diabetes reference centers nationwide, with only six specialist pediatric diabetologists, who practice in the major urban areas, Sarajevo, Tuzla, Zenica, Mostar, and Banja Luka [244]. BiH, however, remains one of the most rural countries in Europe, with around 60% of the population living in rural areas [245]. In rural and remote areas of BiH, children with T1DM are diagnosed and provided with insulin therapy by healthcare centers and ambulances [245]. A structured diabetes training provided by an interdisciplinary diabetes team, which is highly essential for controlling the disease according to International Society for Pediatric and Adolescent Diabetes (ISPAD) guidelines [225], is often unavailable. Children with diabetes-related complications are transferred to the closest diabetes reference centers, which are often at full capacity and cannot take on additional patients. The COVID-19 pandemic worsened the situation for these patients. One study from BiH reported that treatment of diabetes complications had a major share in overall diabetes management costs [241].

The American Diabetes Association (ADA) has recommended regular follow-up, ongoing nutrition and diabetes self-management education (DSME) and support (DSMS), and access to specialized healthcare as necessary for effective T1DM management [246]. Technology-based interventions can be helpful in patients who miss appointments and/or have poor accessibility to specialized T1DM care [233, 247], as these interventions enable remote monitoring and increase access to evidence-based practices outside conventional clinical settings [248, 249]. The use of diabetes technology has increased markedly among children and adolescents with T1DM worldwide [250], with guidelines recommending that it be integrated into pediatric diabetes care [225, 251]. The ADA has classified diabetes technology into three categories: hardware, devices, and software, which help patients manage their diabetes [252]. mHealth interventions have been recommended for improving diabetes management among young people [253, 254]. One such example is the increasing use of diabetes mobile apps to support disease management, prevent diabetes-related complications, and improve overall quality of life [50, 173]. Diabetes apps have been reported effective in improving clinical outcomes and diabetes self-management [165, 174-176, 254]. The functions of diabetes apps developed to date have been found to vary, as various apps have focused on blood glucose monitoring, self-management, motivation for medication adherence, and lifestyle modifications [255, 256]. Tailored education, timely feedback [249], remote monitoring, and follow-up [256] can enable diabetes apps to reduce the risks of increased HbA1c levels, psychosocial problems, and the development of complications associated with disrupted clinic visits [253]. Moreover, diabetes apps have great potential for T1DM management in children and adolescents owing to the widespread, viability, and acceptance of the use of technology among young persons [247, 257, 258].

The development of diabetes apps and evidence supporting their efficacy and effectiveness in T1DM management [207, 247, 257, 259-261] suggest that the use of these apps can effectively extend patient-centered care to remote and rural areas of BiH with limited access to specialized diabetes care, as well as providing frequent points of contact with specialist pediatric diabetologists. Evaluations of mHealth interventions in different contexts can influence their implementation, such as the settings in which they are used, the HCPs, and the entire implementation process [35]. Accordingly, the current study was designed to assess the initial usability of a mHealth intervention among children and adolescents with T1DM, as well as their parents and HCPs, after using the Diabetes: M app for three months. User satisfaction, experience, and the perceived usefulness of various mHealth app features were investigated using a questionnaire. Findings of this study may provide reference points for the usability of the mHealth app in T1DM management from the perspectives of pediatric patients, their parents, and HCPs in underserved and remote areas.

3.3 MATERIAL AND METHODS

3.3.1 Study design and data collection

This cross-sectional survey conducted in February–March 2023 collected data related to user satisfaction, experience, and the usefulness of different features of the Diabetes: M app in managing T1DM. Pediatric patients with T1DM, along with their parents and HCPs, who had been enrolled in the 3-month mHealth-based T1DM management program, trained and connected through a digital health network, were invited to participate in the present survey. This T1DM management program established a digital network that included all children, adolescents, and young adults with T1DM across Middle Bosnia Canton in Bosnia-Herzegovina (Figure 8).

Figure 8. Digital health network.

All participants were approached and recruited through their respective diabetes type 1 patient organizations in Bugojno and Vitez. The network utilized a mobile health app and remote digital monitoring to bridge the gap between the main pediatric diabetology clinic in Sarajevo and the remote regions of Middle Bosnia Canton. The network also included local pediatricians and doctors from the hospital in Bugojno, Middle Bosnia Canton, Additionally, an online Viber peer support chat group was integrated into the network, facilitating daily communication and exchange among patients and healthcare providers. The establishment and complete structure of the digital health network has been described elsewhere [262].

Patients with T1DM were divided into two age groups, children aged ≤12 years, along with their parents, and adolescents/young adults aged >12 years. This division was based on the rationale that parents of children aged ≤12 years are generally responsible for managing T1DM in their children, whereas adolescents/young adults during the period of transition of care generally require less support from their parents and start managing their disease on their own [257, 259]. Three online versions of the survey (i.e., for children/parents, adolescents/young adults, and HCPs) were created using Qualtrics XM®. The links, which were generated separately, were distributed through email and WhatsApp groups to the enrolled T1DM pediatric patients/parents and HCPs. Data were collected within 3 months after the end of the mHealth-based T1DM management program to minimize recall bias. The questionnaires were kept short to reduce respondent fatigue.

3.3.2 mHealth app intervention

The Diabetes: M app platform consists of a mobile app (Figure 9) and a clinician monitoring system (Figures 10 and 11) developed by Sirma Medical Systems. This app has been shown useful in improving diabetes control in T1DM patients [208] and is used in managing and monitoring all types of patients with diabetes and pre-diabetes. Table 6 shows a detailed description of its key features.

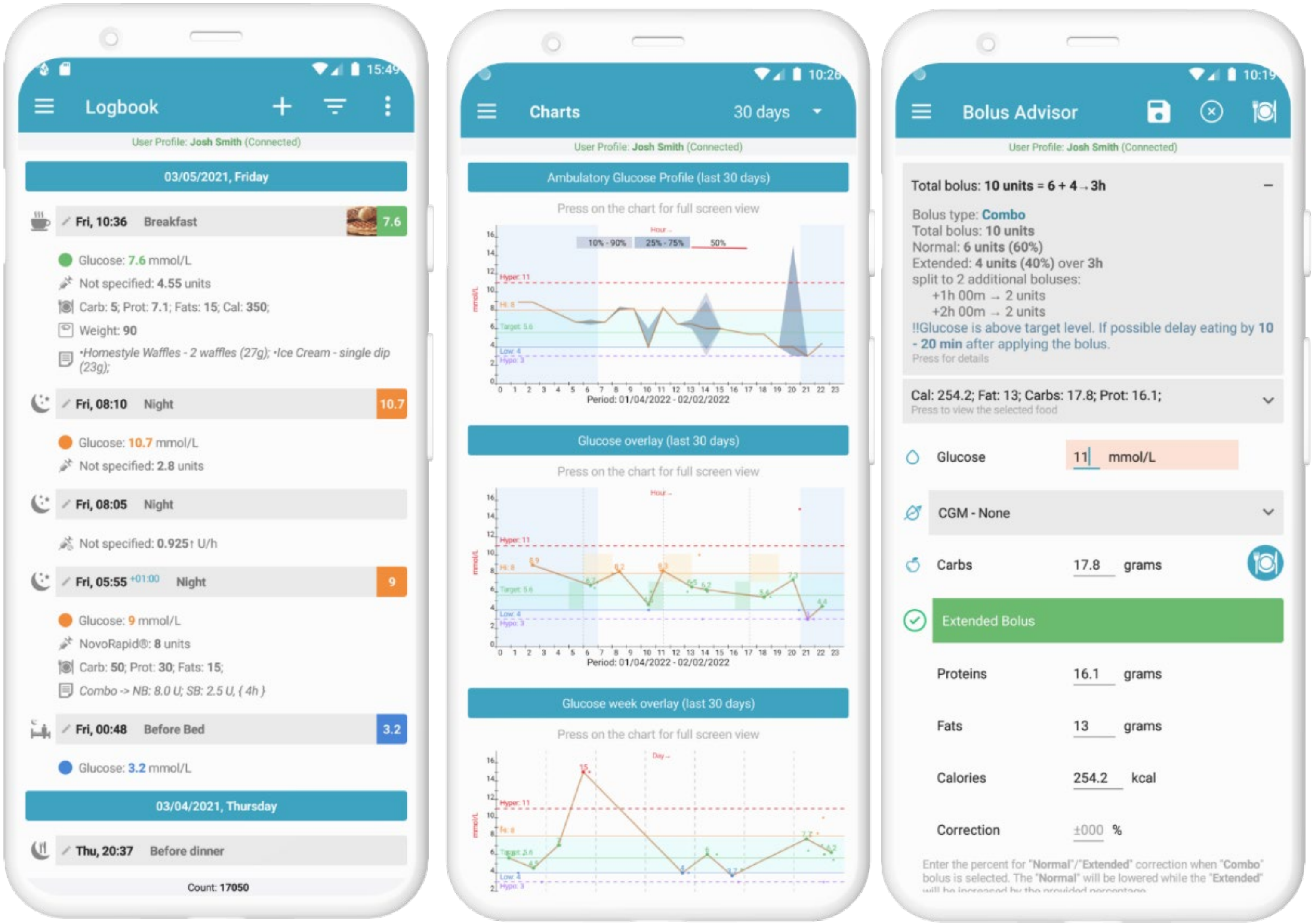


Figure 9. Screenshots of Diabetes: M app key features. Photo Credit (https://diabetes-m.com/features/)

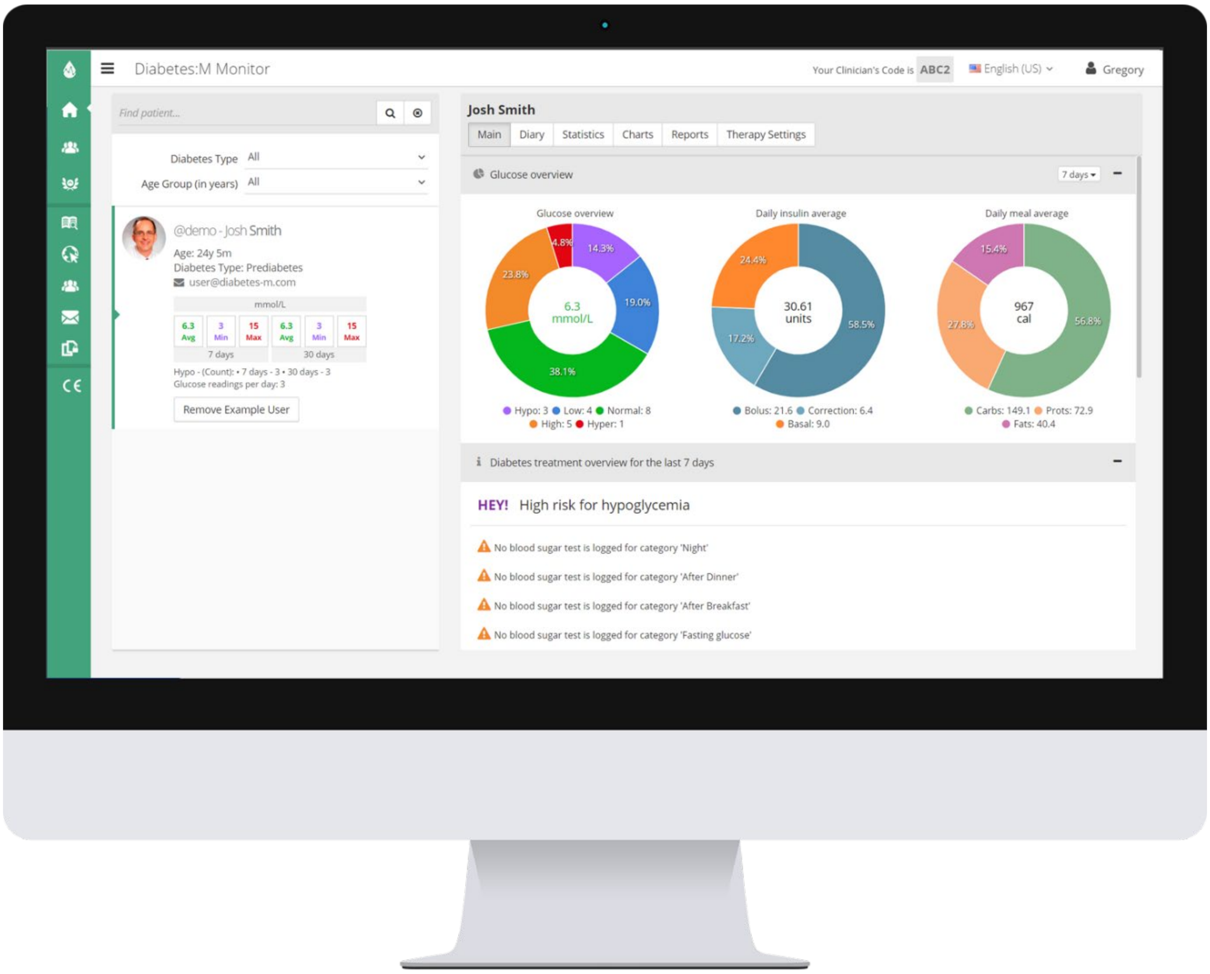


Figure 10. Diabetes: M online monitor tool for professionals. Photo credit (https://diabetes-m.com/monitor/)

Name: Age: , T1DM
Diabetes:M report - 25/08/2022

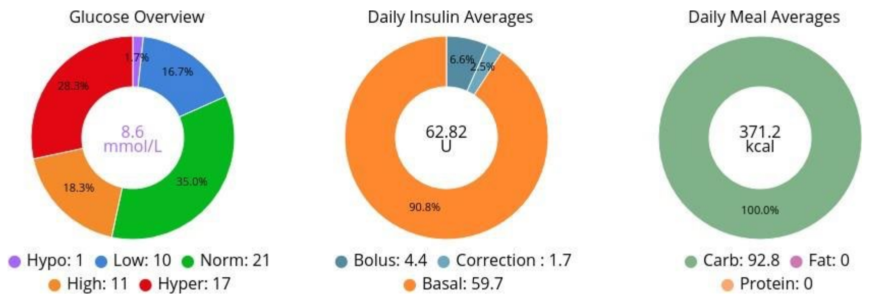
Diabetes:M Analytics
https://www.diabetes-m.com

Diabetes:M report - 25/08/2022

Personal

Name:	
Birthday:	Age
Weight:	
Body Mass Index (BMI):	
Daily calorie needs:	
Total insulin (TDD):	20.9 U Novorapid
Total basal insulin (TBD):	8.4 U Lantus

Distribution by days



Statistics

Total records:	162
Glucose readings per day:	3
Estimated HbA1c:	7%

Period	Count	Hypo	Low	Norm	High	Hyper
7 days	11	-	1	2	4	4
14 days	28	-	3	9	9	7
30 days	60	1	10	21	11	17
90 days	161	6	31	54	30	40

	Glucose (mmol/L)		
Period	Average	Lowest	Highest
7 days	10.1	4.1	20
14 days	9	3.5	20
30 days	8.6	2.9	20
90 days	8.5	1.9	27

Period	Daily Bolus	Daily Correction	Daily Basal	Bolus% / Basal%
7 days	5.8 U	2.6 U	56.9 U	9.3%/90.7%
14 days	4.6 U	1.9 U	66.8 U	6.4%/93.6%
30 days	4.4 U	1.7 U	59.7 U	6.8%/93.2%
90 days	6.5 U	1.8 U	59.6 U	9.9%/90.1%

1/5 25/08/2022 06:22

Figure 11. Anonymous 14-year-old T1DM patient's Diabetes: M report. (1st page only)

Table 6. . Key features of the Diabetes: M app, an interactive mHealth app consisting of a smartphone application for patients and a remote monitor software platform for HCPs

Functions	Description
Food database	The food database provides a categorized list of the most common foods and products. It also integrates with external food databases and allows customized entries of products and portions.
Logbook	The logbook function allows the entry of glucose concentrations, insulin injections, and carbohydrate amounts. Additional values, including ketones, cholesterol, HbA1c levels, weight, blood pressure, pulse, and physical activities, can also be added.
Bolus calculator	The bolus calculator calculates insulin units based on carbohydrate, protein, and fat intake or on measured glucose concentrations and notifies about the need for additional carbohydrates or to delay meals due to high blood glucose concentrations.
Reminders	The reminder function reminds user of various tasks, such as taking medications and scheduling doctor appointments.
Charts and graphs	Entries including blood sugar concentrations, medications, and physical activities can be viewed as graphs over time (daily, weekly, monthly, and yearly). This application also includes analytical charts with more detailed and various types of data.
Pattern analysis	The pattern recognition function allows analyses of data over the previous 14 days and helps recognize issues associated with behavior and adherence to treatment. This app also promotes increased understanding of insulin dosing, correction effects, and glycemic variability.
Reports	The report function can generate very detailed reports in various formats (i.e., pdf, XLS, and HTML) and can share them with HCPs.
Online monitoring and follow-up by HCPs*	The remote monitoring tool provides HCPs with real-time patient information. This tool promotes monitoring, coaching, and education of patients in close connection with their HCPs.

*HCPs = Healthcare professionals

3.3.3 Outcome measures

The three questionnaires, for T1DM children/parents, adolescents/young adults, and HCPs, were each divided into four main parts: participant characteristics, satisfaction and ease of use, the usefulness of different app features, and user experience with the app in managing T1DM. The questionnaires were developed in English, then translated into Bosnian by forward and back translation methods and adapted for cultural considerations. The two experts in pediatric diabetology checked these questionnaires for face and content validity. Based on their feedback, each questionnaire was revised to its final form. Participant information sheets were also evaluated for comprehensibility and appropriateness.

3.3.3.1 Participant characteristics

The first part of the questionnaires included questions about the sociodemographic characteristics of the participants, including age, gender, previous experience with mHealth apps, professional experience, and healthcare specialty (in the HCP questionnaire only)

3.3.3.2. Satisfaction and ease of use

The primary objective of the usability element was to assess patient and provider satisfaction and ease of use of the app. This objective was measured using the 8-item subscale of the Mobile Health App Usability Questionnaire (MAUQ) [263], a reliable and validated questionnaire with four different versions depending on the type of app (interactive or standalone) and the target user of the app (patient or provider). The MAUQ Interactive app, provider, and patient versions were selected for this study. Satisfaction and ease of use were measured using a seven-point

Likert-type scale, ranging from 1 (strongly disagree) to 7 (strongly agree). A higher score indicated greater satisfaction with and ease of use of the app.

3.3.3.3 Usefulness of different app features

Assessments of the app usability included evaluations of the usefulness of different app features, namely logbook, food database, reminders, bolus calculator, charts and graphs, reports, pattern analysis, and online monitoring by HCPs (8 items). Each item was graded on a five-point Likert-type scale, ranging from 1 (not at all useful) to 5 (extremely useful). A higher score indicated greater perceived usefulness of the app feature. Participants were also provided with the option "I have not used this feature."

3.3.3.4 User experience with the app

The fourth part of the questionnaires consisted of questions examining participants' experiences with the app in the management of T1DM. These questions, based on previous studies [247, 263, 264], were adjusted depending on the populations being assessed i.e., pediatric patients, parents, and providers. All of these questions were dichotomous, although participants could also state that they were uncertain.

3.3.4 Data analysis

Data were extracted from QualtricsXM® and descriptive statistics were analyzed using Microsoft Excel (2019). Categorical variables were reported as frequencies and percentages, whereas continuous variables were reported as means, standard deviations (SD), and ranges.

3.3.5 Ethical considerations

The current study is part of the project "Improving Diabetes Type 1 Care in Children and Adolescents in Bosnia and Herzegovina" [265] and was approved by the Ethics

Committee of the Medical Association of the Central Bosnian Canton (Ethical Approval number 839/22). Subjects were provided with a detailed participant information sheet and informed consent/assent documents, with all participants providing written informed consent/assent using the checkbox option before starting the online survey. The individual questions were not linked and could be skipped to continue the questionnaire. The anonymity of the participants was ensured at all times, and the study was conducted in accordance with the Declaration of Helsinki [266].

3.4 RESULTS

3.4.1 Outcome measures

3.4.1.1 Participant characteristics

From August to September 2022, 50 children,adolescents, and young adults diagnosed with T1DM were screened and enrolled in a 3-month mHealth-based T1DM management program. In addition, nine HCPs were trained in the use of the mHealth app in diabetes management as part of the digital health network [262]. All 50 T1DM patients (children, adolescents, and young adults) and all nine HCPs completed the program and responded to the online survey, leading to response rates of 100%. The mean ±SD age of T1DM patients was 14 ± 4.54 years (Table 2). Thirty-five (70%) were aged >12 years, 26 (52%) were female, and 37 (74%) reported previous experience with mHealth apps. The mean ±SD age of the HCPs was 43.4 ± 7.76 years; all nine (100%) were women and had a mean ±SD professional experience of 17.8 ± 8.81 years. Five (56%) of the nine HCPs had no previous experience using mHealth apps professionally. The nine HCPs included seven physicians, one pharmacist, and one other healthcare professional. Table 7 includes details of particpants’ charcterictics.

Table 7. Demographic characteristics of the participants included in this cross-sectional study.

Characteristics	Values
Characteristics of T1DM children/adolescents (N = 50) *	
Age (years, mean ± SD)	14 ± 4.54
Age categories, n (%)	
≤12 years	15 (30)
>12 years	35 (70)
Gender, n (%)	
Male	24 (48)
Female	26 (52)
Previous experience with mHealth apps, n (%)	
Yes	37 (74)
No	13 (26)
Characteristics of healthcare professionals (N = 9)	
Age (years, mean ± SD)	43.4 ± 7.76
Gender, n (%)	
Male	0 (0)
Female	9 (100)
Professional experience (years, mean ± SD)	17.8 ± 8.81
Previous professional experience with mHealth apps, n (%)	
Yes	4 (44.4)
No	5 (55.6)
Health care specialty, n (%)	
Physician	7 (77.8)
Pharmacist	1 (11.1)
Nurse	0 (0)
Others	1 (11.1)

* Parents filled out the questionnaires for children aged ≤12 years

3.4.1.2 Satisfaction and ease of use

Satisfaction with the mHealth app intervention was determined by measuring eight items on the MAUQ subscale for satisfaction and ease of use. The app was reported usable in the domains of ease-of-use and satisfaction by the T1DM children/parents (5.82/7.0), T1DM adolescents/young adults (5.68/7.0), and HCPs (5.22/7.0), indicating that all participants rated the Diabetes: M app as satisfactory (Table 8). The agreement among T1DM pediatric patients/parents for satisfaction and ease of use was >80% (Figures 12A and 12B), whereas the agreement among HCPs was 74.5% (Figure 12C).

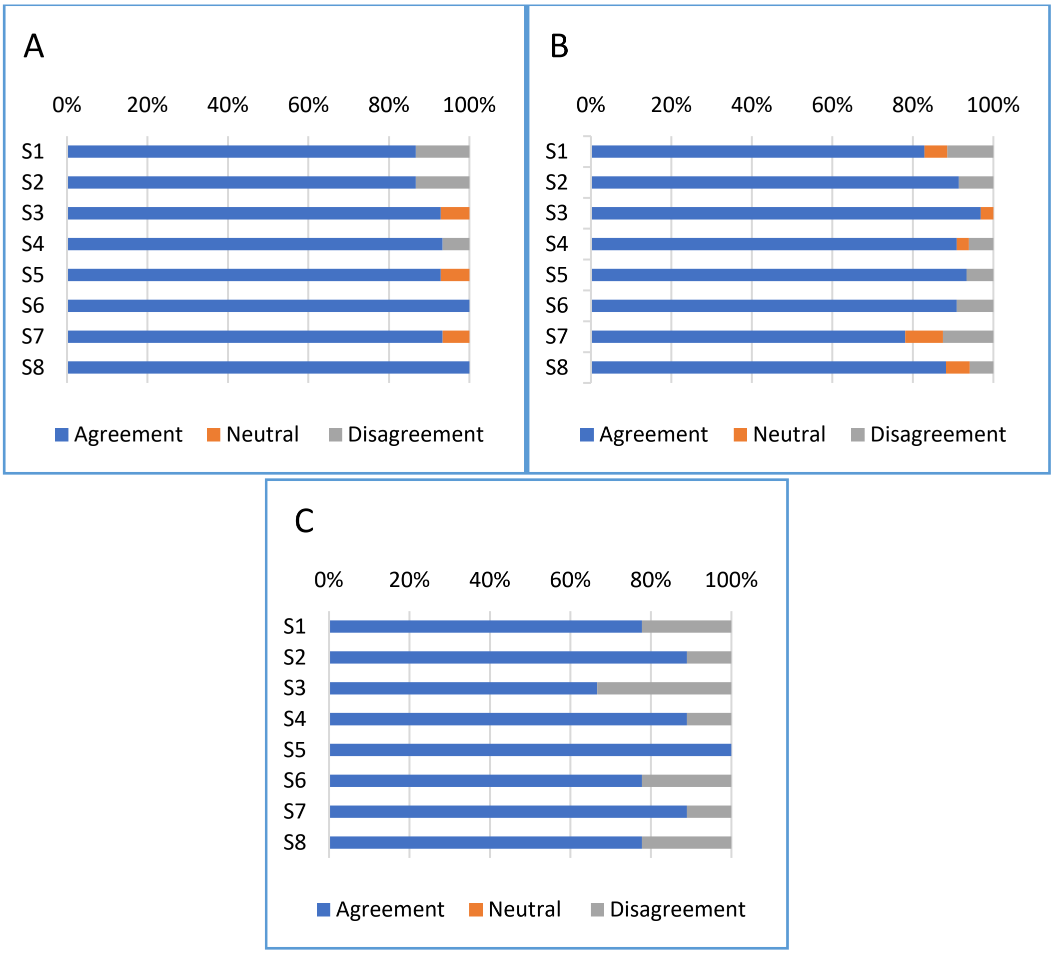


Figure 12. Responses of (A) T1DM children/parents, (B) T1DM adolescents/young adults, and (C) HCPs to eight items on the satisfaction and ease of use subscale of the MAUQ. Results reported as the percentages of participants who achieved scores on a 7-point Likert scale (Strongly agree, agree, and somewhat agree defined as agreement; strongly disagree, disagree, and somewhat disagree defined as disagreement)

Table 8. Satisfaction of the participants with the Diabetes: M app, measured using the mHealth App Usability Questionnaire (MAUQ) sub-scale for satisfaction and ease of use

Variables (scored on a scale of 1-7) *	T1DM Children /parents		T1DM Adolescents/young adults		Healthcare professionals	
	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range
S1- The app was easy to use.	5.33 (1.84)	1-7	5.63 (1.42)	1-7	4.88 (2.32)	1-7
S2- It was easy for me to learn to use the app.	5.67 (1.63)	1-7	5.60 (1.56)	1-7	5.56 (1.81)	1-7
S3- I like the interface of the app.	5.93 (0.83)	4-7	6.06 (0.76)	4-7	4.44 (2.60)	1-7
S4- The information in the app was well organized, so I could easily find the information I needed.	5.80 (0.86)	3-7	5.52 (1.18)	1-7	5.44 (1.81)	1-7
S5- I feel comfortable using this app in social settings.	5.79 (0.80)	4-7	5.87 (1.36)	1-7	6.13 (0.4)	6-7
S6- The amount of time involved in using this app has been fitting for me.	5.93 (0.59)	5-7	5.64 (1.29)	2-7	5.11 (1.9)	1-7
S7- I would use this app again.	5.93 (0.80)	4-7	5.41 (1.60)	1-7	5.44 (1.81)	1-7
S8- Overall, I am satisfied with this app.	6.20 (0.56)	5-7	5.71 (1.38)	1-7	5.11 (1.9)	1-7
All satisfaction items	5.82 (0.25)	1-7	5.68 (0.21)	1-7	5.22 (0.38)	1-7

* Response categories: 1 = strongly disagree, 2 = disagree, 3 = somewhat disagree, 4 = neither agree nor disagree, 5 = somewhat agree, 6 = agree, 7 = strongly agree.

3.4.1.3 Usefulness of app features

The mean usefulness score was more than 3 for all 8 features in both patient age groups. The top three key app features rated by T1DM children/parents who used these features during the 3-month trial of the T1DM management program were the reports (3.93/5), bolus calculator (3.91/5), and online monitoring and follow-up by HCPs (3.90/5) (Figure 13). Similarly, T1DM adolescents and young adults found online monitoring and follow-up by HCPs (3.87/5), bolus calculator (3.79/5), and charts and graphs (3.65/5) to be more useful (Figure 14). The HCPs rated bolus calculator (4.42/5), pattern analysis (4.3/5), and reports (4.3/5) to be the top three "extremely useful/very useful" app features for T1DM management with a mean usefulness score of more than 4 for all 8 features (Figure 15).

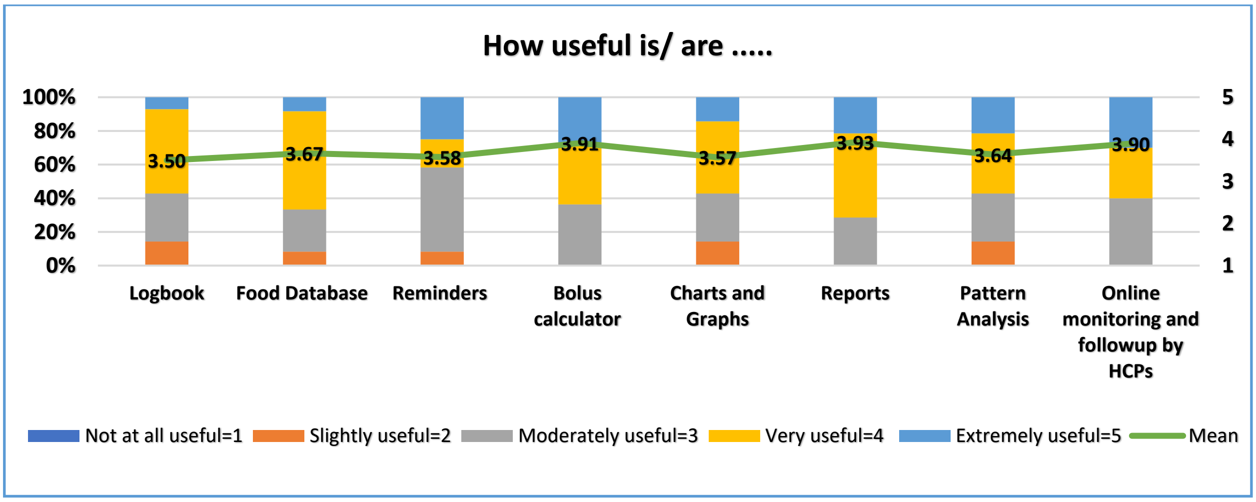


Figure 13. Diabetes: M app features rated by children/parents (n=15). Mean values are shown in the bars.

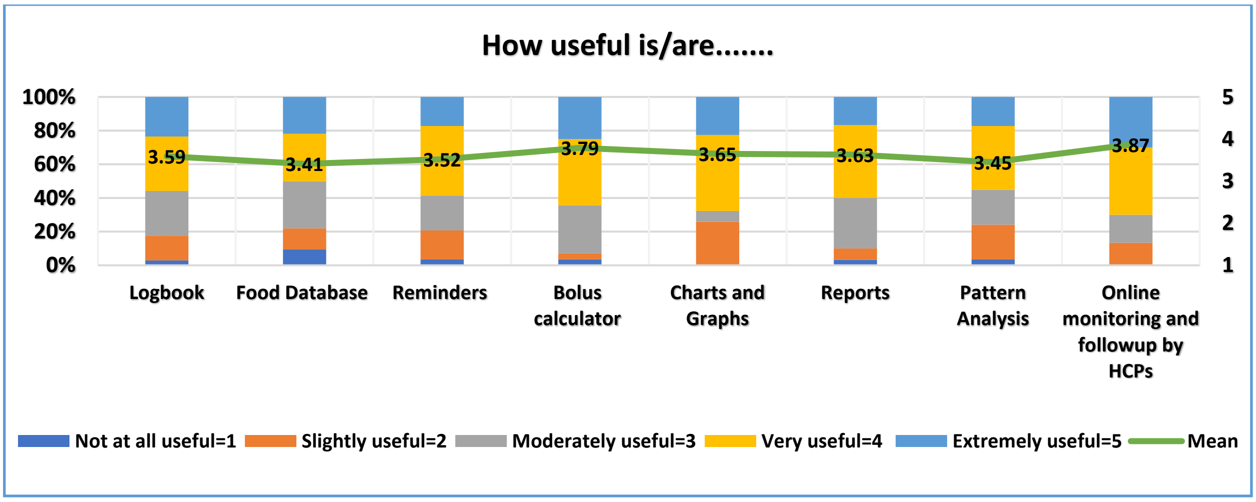


Figure 14. Diabetes: M app features rated by adolescents/young adults (n=35). Mean values are shown in the bars.

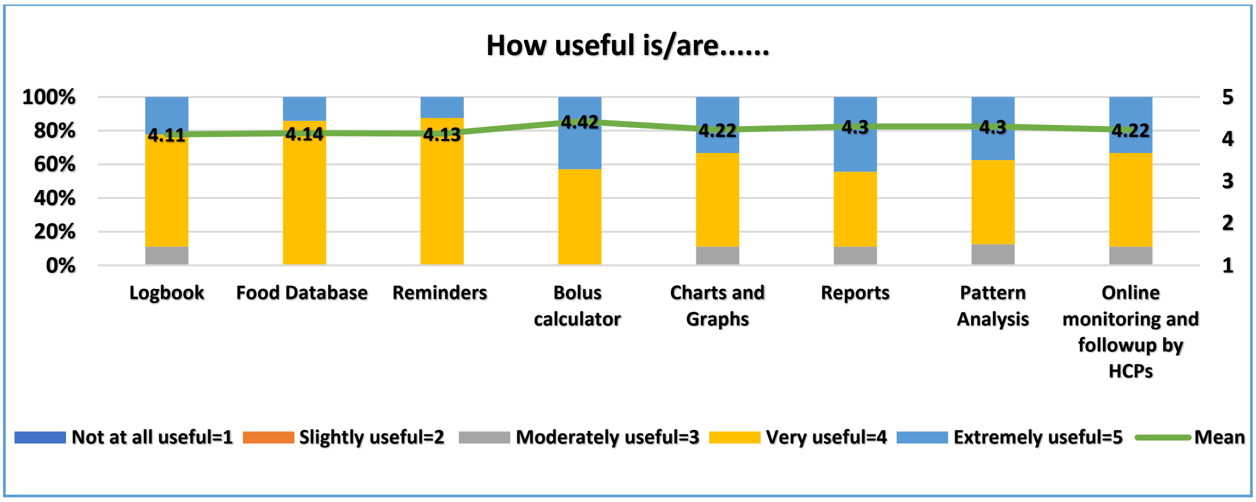


Figure 15. Diabetes: M app features rated by HCPs (n=09). Mean values are shown in the bars.

3.4.1.4 User experience with the app

The nine HCPs rated their experiences with the Diabetes: M app in managing and supporting T1DM care of their pediatric patients as highly favorable. Only two of the nine HCPs encountered technical issues, with six reporting improvements in managing their patients with diabetes. Eight of the HCPs reported that use of the app improved their communications with patients, their understanding of patients' diabetes management, and their sharing of information and other educational material (Table 9).

Table 9. HCPs' experiences with the app (N = 9)

Statement	Yes %
Have you noticed an improvement in your patient's diabetes management while using the app?	67
Were there any technical issues or bugs you encountered while using the app?	22
Did the app promote communication with your patients and their parents?	89
Did the app help you better understand your patient's type 1 diabetes management?	89
Were you able to send information and other educational materials to your patients and their parents through the app?	89

Of the 15 parents evaluated, seven (47%) noticed improvements in their child's T1DM management while using the app. Only four (27%) noticed changes in their child's daily activities, with two (13%) encountering technical problems while using the app. Eight (54%) parents agreed that the app helped them communicate with HCPs, and ten (67%) found that use of the app provided better understanding of their child's T1DM management (Table 10).

Table 10. Parents' experience with the app (N = 15)

Statement	Yes %
Have you noticed any improvements in your child's diabetes management since using the app?	47
Did you find any changes in your child's daily activities?	27
Were there any technical issues or bugs you encountered while using the app?	13
Did the app help you communicate with your child's healthcare provider?	53
Did the app help you better understand your child's type 1 diabetes management?	67

Of the 35 adolescents/young adults, 15 (43%) noticed improvements in their diabetes management, whereas only six (17%) encountered technical issues while using the app. Sixteen (46%) of the 35 adolescents/young adults agreed that the app helped them communicate better with their HCPs. Nineteen (54%) adolescents/young adults found that the app enabled better management of their T1DM while traveling or during unexpected events, with Twenty-two (63%) being better able to understand their diabetes management. (Table 11).

Table 11. T1DM Adolescents'/young adults' experience with the app (N = 35)

Statement	Yes %
Have you noticed any improvements in your diabetes management since using the app?	43
Were there any technical issues or bugs you encountered while using the app?	17
Did the app help you communicate with your healthcare provider?	46
Did the app help you manage your diabetes while traveling or during unexpected events?	54
Did the app help you better understand managing type 1 diabetes?	63

3.5. DISCUSSION

This study provides insights into the initial usability of the mHealth app intervention among T1DM pediatric patients/parents and their HCPs. Our findings provide clues to the management of T1DM pediatric patients with limited access to healthcare facilities, especially to patients living in rural and remote areas. The survey items focused on the subjective evaluations by T1DM patients and their parents and by HCPs of satisfaction, ease of use, usefulness, and experience with the mHealth app intervention following the completion of a 3-month mHealth-based T1DM management program. At the end of the 3-month trial, the participants expressed satisfaction with the Diabetes: M app, with children/parents having an overall mean ± SD satisfaction score of 5.82 ± 0.25, adolescents/young adults with an overall mean ± SD satisfaction score of 5.68 ± 0.21, and HCPs having an overall mean ± SD satisfaction score of 5.22 ± 0.38, each on a 7-point Likert-type scale. Moreover, HCPs had a largely positive view of the usefulness of different app features and rated the app as more efficient than T1DM pediatric patients and their parents.

Patient satisfaction, defined as outcomes meeting patient expectations [267], has been associated with greater compliance to devised treatment plans and more improved outcomes [268]. Satisfaction with patient-centered mHealth technologies is usually assessed using descriptive and quantitative measurements [267]. The high mean overall satisfaction scores among T1DM pediatric patients and their parents in the present study indicate high satisfaction and ease of use in engaging with the mHealth app. This is in line with previous studies showing high levels of satisfaction with mHealth apps among children and adolescents with T1DM, as well as their parents [247, 259, 260, 269-272].

As revealed by different items on the MAUQ multi-item sub-scale [263], T1DM pediatric patients and their parents reported that the app was easy to use and easy to learn to use. These participants liked the app interface and found that the information component of the app was well-organized and easily accessible. They felt comfortable using the app in social settings, similar to findings showing that adolescents found that mHealth apps were an acceptable method of communicating with their parents, particularly in social settings [259]. Participants' satisfaction in the present study was also shown by their intention to use the app again, similar to previous results showing that 96% of study subjects indicated intent to use the app if available outside the trial [260]. “The amount of time involved in using this app has been fitting for me" was also rated positively by the respondents as was the overall satisfaction with the app . These high scores for satisfaction and ease of use may have been due to the ease of use of the simple platform and the familiarity of younger patients with mHealth apps, as 74% reported previous use of mHealth apps. High patient satisfaction in our study may also be due to the prompt responses of HCPs to their patients via an online platform created specifically for this purpose. Moreover, the nine HCPs who took part in the study also rated the app as satisfactory. In other studies, HCPs have also reported high satisfaction with mHealth-based systems for chronic disease management in children and adolescents [247, 273].

Participants were also asked to rate the usefulness of different app features in assisting with daily T1DM self-management. Overall, pediatric patients and their parents found various app features to be "moderately useful to very useful," whereas HCPs rated these app features to be "very useful to extremely useful." Online monitoring and follow-up by HCPs, bolus calculator, and reports were the top three rated features by the T1DM children/ parents. Similarly, adolescents and young adults found online monitoring and follow-up by HCPs, bolus calculator, and charts and graphs to be more useful. This contrasts with previous studies conducted in New Zealand and Canada where the logbook feature was among the most favored and used features [274, 275]. We found clues for this finding in the local context of Bosnia and Herzegovina where the Diabetes: M app could not be integrated with continuous glucose monitoring (CGM) systems and the patients had to enter their blood glucose levels manually every time. This may have led to possible patient fatigue and less interest in blood glucose tracking feature and consequent usability. However, similar to our study a Scottish survey reported the blood glucose data feature was felt useful by a minority of patients and the bolus calculator was the most desired feature by T1DM patients [276]. Connected through the digital health network, the patients were regularly monitored by the HCPs which is depicted by the favorable rating of online monitoring and follow-up feature by the patients and their parents. During the 3 - month T1DM management program, the HCPs responded to immediate patient needs. Nevertheless, the frequency of remote monitoring and communication consistency can be decided mutually among HCPs and patients/parents that fit their daily activities. Moreover, scaling up such mHealth interventions requires an adequate number of dedicated well-trained HCPs, an appropriate workload, task shifting, and other encouragement approaches such as monetary incentives and opportunities for training [277-280]. In our study , HCPs rated the bolus calculator, reports , and pattern analysis as the most highly useful features. Graphically and statistically generated reports and pattern analysis were rated as helpful by HCPs in another study of children and adolescents with T1DM [247].

Although HCPs were very positive about their experience with the Diabetes: M app in managing T1DM, pediatric patients and their parents rated their experience as moderate. For further implementation, it is therefore important to highlight all stakeholders' lived initial user experiences and insights. These findings about the optimal functional experience are also important for the long-term engagement of users and sustained use of apps beyond the initial adoption stage owing to the problem of high dropout rates and less user retention [281]. Although the results of the present study correspond with those of earlier studies, the present findings indicate that the mHealth solutions might fill the care gaps and compensate for a lack of functional health infrastructure in remote and rural areas with limited to almost no facilities. Patients in rural areas with limited healthcare access can get an advantage from digitally assisted remote care options, however, existing care should be supplemented gradually instead of substitution, keeping in mind the local context and individual patient characteristics [282]. The favorable attitude of HCPs and T1DM pediatric patients/parents towards the mHealth app underlines their great interest and has led to increased adoption of mHealth care services by these populations [283, 284]. Increased satisfaction with diabetes apps provides evidence for the increased implementation of mHealth interventions for the management of chronic diseases. Launching the diabetes program in BiH was not easy due to complexities in the political and economic situation in BiH and large regional disparities in diabetes care of children and adolescents. Unless they live in larger cities with pediatric diabetology clinics, these children do not have regular access to pediatric diabetes clinics or pediatric diabetologists. Children and their families often have to self-manage this complex and life-long disease, with late complications becoming inevitable. One of the key successes of this initiative was the active participation of patients and providers, with response rates of 100%. Moreover, this initiative included active parent involvement, improving T1DM management among children [285, 286], particularly through the mHealth apps [287]. After enrollment into the digital health network, participants received formal training on how to use the mHealth app based on the significance of adequate training for using and implementing mHealth interventions [35, 288]. This digital network can serve as an example for other remote or rural regions and it can accommodate other chronic disease management apps.

The present study had several limitations, including its use of self-reported measures, with these data subject to recall bias, possibly skewing the results.

Another limitation was the small sample size, however, we had a minimal proportion of missing data. A third limitation was the short period of mHealth app usage of only 3 months. Finally, The current study may contain a response bias as all the HCPs, and T1DM patients/ their parents voluntarily participated in the T1DM management program and subsequent survey, and might therefore be more enthusiastic and positive about the mHealth app or more motivated to use the app. Studies that include a larger number of patients and a longer period of mHealth-based T1DM management are needed to provide more robust conclusions.

3.6. CONCLUSION

A mobile app intervention, involving communications between pediatric patients with T1DM living in remote and rural areas of BiH and large specialized pediatric diabetology clinics in the capital city or other cities can facilitate diabetes care for the former. This app and other mHealth apps can be useful in overcoming the limitations of diabetes care in rural areas and improving diabetes management and HCP-patient communications. The positive experiences and satisfaction with the app reported by patients, their parents, and HCPs may be useful for other HCPs and policymakers in BiH and other countries with similar circumstances, suggesting that mHealth apps can facilitate the delivery of healthcare services. Randomized controlled trials with objective clinical outcomes, such as HbA1c and other glucose biomarkers, are needed to determine the efficacy and sustainability of mHealth interventions in pediatric patients with T1DM.

4

Chapter 4: Digital Health in Pharmacy Education

4.1 Introducing m-Health and Digital Diabetes Apps in Clinical Pharmacy Education in Germany

Obarcanin, E., **Ali Sherazi, B**., Dabidian, A., Schlottau, S., Deters, M. A., & Läer, S. *Journal of Diabetes and Clinical Research*. 2022., *4*(1), 17-19.

4.2 Telepharmacy vs. face-to-face inhaler technique training. A non-inferiority assessment among German pharmacy students

Ali Sherazi B, Sayyed SA, Möllenhoff K, Läer S. *Integr Pharm Res Pract.* 2024 Sep 20;13:165-180. doi: 10.2147/IPRP.S468881

PREAMBLE

The previous chapter (chapter 3) demonstrated high usability and satisfaction with a diabetes app among pediatric T1DM patients, their parents, and healthcare professionals. The usefulness of different app features and overall app experience were also rated positively by the users.

This chapter (chapter 4) explores different opportunities for piloting and assessing the integration of digital health tools into pharmacy education. The first part of this chapter (4.1) reports the integration of diabetes digital apps into clinical pharmacy education to prepare pharmacy students for their future professional practice. The chapter was published under the title "Introducing m-Health and Digital Diabetes Apps in Clinical Pharmacy Education in Germany" in the *Journal of Diabetes and Clinical Research (J Diabetes Clin Res)* in July 2022.

The second part of this chapter (4.2) investigates the non-inferiority of telepharmacy over face-to-face consultations in providing inhaler technique training service among final-year pharmacy students. The chapter was published under the title "Telepharmacy vs. face-to-face inhaler technique training. A non-inferiority assessment among German pharmacy students" in the Journal *Integrated Pharmacy Research and Practice (Integr Pharm Res Pract)* in September 2024.

The author of this thesis had a lead role in and substantially contributed to the conceptualization, methodology, formal analysis, investigation, resources, project administration, visualization, writing - original drafts, as well as writing - review and editing.

4.1 Introducing m-Health and Digital Diabetes Apps in Clinical Pharmacy Education in Germany

4.1.1 ABSTRACT

Germany was the first country worldwide to introduce prescription and reimbursement of digital health apps. To keep pace with recent digital healthcare developments and to prepare our pharmacy students for the digital pharmaceutical care services, the Institute of Clinical Pharmacy and Pharmacotherapy Heinrich Heine University (HHU) Düsseldorf introduced a one-of-a-kind elective practical course in m-Health and diabetes.

Keywords
m-Health, Digital diabetes apps, Diabetes mellitus, Pharmaceutical care, Education

4.1.2 INTRODUCTION

Germany was the first country worldwide to implement German Digital Healthcare Act in 2019 to allow prescription and reimbursement of digital health applications (Digitale Gesundheitsanwendungen, DiGA) [289, 290]. The German Federal Government has prioritized increased usage of mobile-Health (m-Health: use of mobile devices and digital technology in health care), recommending that physicians, other healthcare professionals, and patients work together to utilize the potential benefits of such technology [291]. Digital healthcare evolved quickly in the everyday delivery of pharmaceutical care in hospitals and community pharmacies [88].

To keep pace with the rapidly changing landscape in digital health in Germany, the Institute of Clinical Pharmacy and Pharmacotherapy at the Heinrich Heine

University Düsseldorf developed and introduced an elective practical course in m-Health and diabetes in October 2019.

4.1.3 AIMS AND METHODS OF PHARMACY COURSE ON M-HEALTH DIGITAL DIABETES APPS

By developing this elective practical pharmacy course on digital diabetes apps, the HHU Institute of Clinical Pharmacy and Pharmacotherapy is striving to train the next generation of pharmacists to be able to:

- use modern digital health technologies in pharmaceutical care delivery
- make digital technology accessible for the profession of pharmacy
- participate in interprofessional care teams involved in digital development.

To achieve these aims, the course focuses on improving the pharmaceutical care of diabetes patients via the use of m-Health diabetes apps. By learning how to use digital diabetes apps, final-year pharmacy students have the option of acquiring m-Health skills to solve clinical problems (Figure 16).

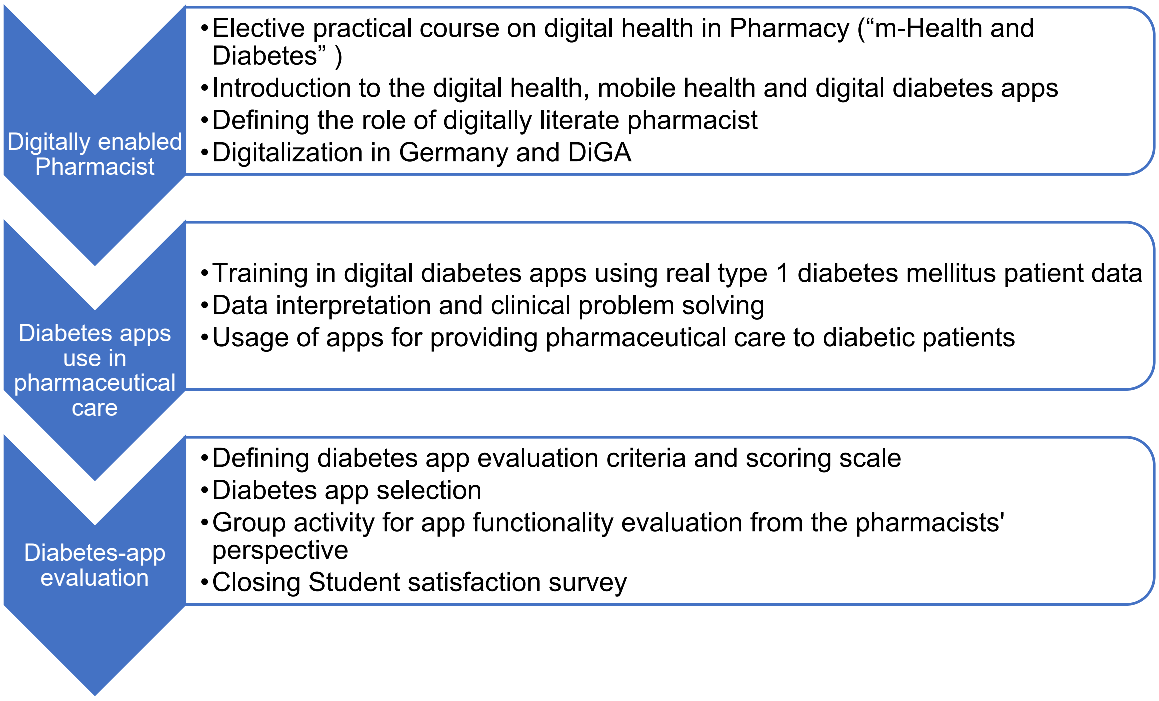


Figure 16. The elective "m-Health and Diabetes" course: Aims and Design

During the course, students were trained to use the different diabetes apps available on the German market, such as mySugr, One Drop Diabetes Management, Esysta, Diabetes Connect, Diabetes:M, One Touch Reveal, Lumind, and Si Diary. They became familiar with apps by entering real patient data, such as blood glucose levels, insulin dose, and carbohydrate intake. Furthermore, students learned how to interpret the patients' blood glucose records using diabetes apps' graphs and charts and apply clinical problem-solving to improve patient outcomes. In addition, students evaluated the usefulness of diabetes apps in providing pharmaceutical care to patients with diabetes.

4.1.4 OUTCOMES OF THE ELECTIVE COURSE

The elective "m-Health and Diabetes" course provided new digital skills to our pharmacy students, equipping them with the new competencies needed in the growing digital healthcare environment in diabetes. The final-semester pharmacy students could quickly learn and comprehend the features of the various diabetes apps, and use the information provided to promptly identify drug-related problems (e.g., hyperglycemia, hypoglycemia, glucose level variability, etc.) and use clinical and patient-centered problem-solving skills. Students evaluated the usefulness of various digital diabetes apps, indicating that these apps have many useful features relevant to pharmaceutical care services (e.g., adherence, insulin dose calculation, visualization of blood glucose regulation). In the recent elective practical course in February 2022, students evaluated four digital diabetes apps (Esysta, Diabetes:M, mySugr, and One-Touch Reveal). Course facilitators reevaluated the apps using four sets of anonymized data from real patients with type 1 diabetes. The app evaluation employed 25 predefined evaluation criteria, which included: 12 criteria related to pharmaceutical care (e.g., insulin dose and bolus calculation, adherence to medication, alarm functions); 8 criteria related to interoperability (e.g., interoperability with other devices/ software, communication between patients and pharmacists) and 5 criteria related to “other aspects” such as cost and data protection. All four assessed apps fulfilled at least 19 of the 25 evaluation criteria. Concerning the 12 criteria relevant to pharmaceutical care, mySugr, OneTouch Reveal, and Diabetes M met 11 criteria, and Esysta met 8 criteria. Of the eight criteria regarding interoperability with other devices or software, Esysta and Diabetes: M met 6 criteria, and mySugr and OneTouch Reveal 5 out of 8 criteria. However, no app provided direct communication between patients and pharmacists (criteria: interoperability), nor were pharmacists explicitly mentioned as healthcare providers by any app.

After completing this elective practical course, pharmacy students expressed high satisfaction with the course, felt enabled to care for their patients using diabetes apps, and expressed their interest in expanding the use of digital tools to other disease areas.

4.1.5 DISCUSSION AND CONCLUSION

Our elective practical “m-Health in Diabetes” course shows that final-semester pharmacy students are able to use diabetes apps, then incorporate the findings into the pharmaceutical care process. Educating our students to deliver pharmaceutical care using digital diabetes apps prepares them for digital healthcare provision now and in the future. However, to be able to fully utilize the benefits of pharmaceutical care using diabetes apps, app providers should provide a customized version that also includes pharmacists as part of an integrated healthcare team.

4.2 Telepharmacy vs. face-to-face inhaler technique training. A non-inferiority assessment among final year pharmacy students

4.2.1 ABSTRACT

Background: The use of telepharmacy in delivering pharmaceutical care services has grown in the past few years, however, there are perceptions of its inappropriateness for providing device training among pharmacy students and practicing pharmacists.

Objectives: The primary objective of this study was to determine if the telepharmacy approach for providing inhaler technique training service was non-inferior to the face-to-face approach regarding pharmacy students' performance in simulated patient encounters. Secondary objectives were to determine students' self-assessment of their ability to demonstrate and practice inhaler technique between the two modes of communication and their perceptions of telepharmacy.

Methods: A randomized crossover non-inferiority trial was conducted among undergraduate pharmacy students. Outcomes were measured by comparing Objective Structured Clinical Examination (OSCE) scores of participants' performance between two modes of communication while providing inhaler technique training service. Moreover, the participants also completed self-assessment and perception questionnaires.

Results: The telepharmacy approach was non-inferior to the face-to-face approach for demonstrating and practicing the correct inhaler technique based on OSCE scores and a predefined non-inferiority margin of -10%. The results also revealed no significant differences in student self-confidence between the two modes of communication. Moreover, participants had a largely positive perception of telepharmacy and its use in providing inhaler technique training service.

Conclusion: Considering our findings, telepharmacy is a viable alternative to traditional face-to-face consultations for providing inhaler technique training service. However, to address perceived difficulties and differences between virtual and face-to-face consultations, the pharmacy curriculum should include more telepharmacy-related didactic content with experiential learning and simulations.

Keywords: Pharmacy Education, Digital Health, eHealth, Videoconferencing, Clinical Pharmacy Services, Inhaler technique

4.2.2 INTRODUCTION

Healthcare professionals (HCPs) are utilizing digital health (DH) technologies increasingly to deliver healthcare services [292], which has led to increased investments in telehealth and digitalization [293]. Telehealth refers to using electronic information and telecommunication tools to enhance a patient's health, including the telephone, videoconferencing, text messaging, email, internet, health applications, social media, or fax [294, 295]. Telehealth enables providing healthcare services to those in remote areas and has been more widely implemented and embraced over time, sometimes exceeding in-person visits [296, 297]. The global coronavirus disease 2019 (COVID-19) pandemic changed how healthcare was delivered, moving from in-person to telehealth, and continues to change in post-pandemic situations [298]. These new digital healthcare activities and services add novel opportunities for healthcare systems and providers worldwide [296].

Like others, the Pharmacy profession has also embraced telehealth technologies often referred to as telepharmacy [299, 300]. Telepharmacy is a method used in pharmacy practice in which a pharmacist utilizes telecommunications technology to oversee aspects of pharmacy operations or to provide patient care services [299]. Many examples of telepharmaceutical care and services worldwide include chronic disease management, medication review, prescription verification, dispensing, drug information, patient counseling, education, and remote monitoring [77, 301-312]. The telepharmacy approach has proven successful in various settings such as inpatient, ambulatory, nursing facility, and resident care [122, 124, 302, 306, 313, 314]. Moreover, patient acceptance and satisfaction with telepharmacy services have also been reported in many studies [307, 310, 315, 316].

The Federal Union of German Associations of Pharmacists (ABDA) prioritized DH as one of the first-level priority development goals for 2021 [317]. In recent years, many efforts have been made to digitalize the German healthcare system [99]. For instance, the electronic patient record (ePA), prescribable DH applications (DiGAs), and video consultations for HCPs are some of the notable examples [318]. Telepharmacy services have also been implemented in Germany to improve patient outcomes and medication safety [142, 143]. Furthermore, Changes in regulatory policies such as the inclusion of telepharmacy consultations through amendments to the rules governing the operation of pharmacies (Apothekenbetriebsordnung, ApBetrO), and reimbursement for clinical pharmacy services through the On-site Pharmacy Strengthening Act (Vor-Ort-Apotheken-Stärkungsgesetz, VOASG) have created new opportunities for German pharmacists [139, 319]. It implies the importance of DH education and training for pharmacy students to advance their professional development and prepare them for future pharmacy practice [317]. The International Pharmaceutical Federation (FIP) reported in its global survey that pharmacy students, practitioners, and academics are interested in learning and teaching about DH tools [320]. On the other hand, pharmacy professionals' lack of interest, low comfort level, and slow adoption of DH technologies have been attributed to inadequate information and limited awareness of or training in these modalities [320-322].

DH education and training for pharmacy students require the inclusion of more DH-related content into the curriculum that can be taught theoretically as well as through educational activities and simulations [197, 321, 322]. In such an effort the Institute of Clinical Pharmacy and Pharmacotherapy Heinrich Heine University, Duesseldorf has introduced DH education for pharmacy undergraduates by incorporating DH solutions such as mobile health applications (mHealth apps), high-fidelity simulators, and digital medication review tools [197, 323, 324]. Students are regularly trained in basic foundational skills required for providing clinical pharmacy services in a traditional face-to-face format [325-327]. One such service is the inhaler technique training service (In German: Erweiterte Einweisung in die korrekte Arzneimittelanwendung mit Üben der Inhalationstechnik) for patients from six years of age to practice their inhalation technique with a pharmacy professional according to a standardized procedure [139] when a new device is prescribed, when an existing device is changed, or when patients have not practiced their inhalation technique at a doctor's office or community pharmacy in the previous 12 months and have not participated in a disease management program for chronic obstructive pulmonary diseases (COPD) or asthma [328]. This service is being reimbursed and provided in-person or through telepharmacy at German community pharmacies [329]. In this instance, synchronous videoconferencing is required to demonstrate the inhaler technique and assess patient comprehension [300]. It includes a real-time face-to-face encounter with a patient using a two-way interactive audio-video technology [330]. Inhalation technique demonstration and practice require a three-dimensional view from the patient and provider [319] and a unique set of verbal and nonverbal communication skills [331, 332].

Telepharmacy consultations involving pharmacist-led video telehealth and telephone calls have facilitated inhaler technique training leading to improved inhaler use and positive patient feedback [333-335], however, there are still questions raised on the practicality of this approach [319]. Despite of high willingness, readiness, and positive attitudes towards telepharmacy [82, 83, 295, 336-339], there is also a strong perception among pharmacy students and professionals regarding the inability to provide device training (such as inhalers, insulin pumps, etc.) via telepharmacy [82, 83]. Moreover, the literature investigating the suitability of the telepharmacy approach in providing inhaler technique training in terms of the provider's ability is scant. Therefore, to address these concerns, the primary objective of this study was to ascertain whether the telepharmacy approach is non-inferior to the traditional face-to-face format in terms of pharmacy students' performance when providing inhaler technique training service. Secondary objectives included student self-assessment of their inhaler technique demonstration and practice skills between two modes of communication and their perceptions of telepharmacy.

4.2.3 MATERIAL AND METHODS

4.2.3.1 Study Design and Participants

The investigation was conducted as a randomized cross-over non-inferiority trial. The participants were undergraduate pharmacy students in their final semester of pharmacy studies at Heinrich Heine University, Duesseldorf, Germany. We evaluated the effect of different communication mediums on student performance, and self-assessment of their abilities to carry out the inhaler technique demonstration and practice with Standardized Patients (SP). Following the informed consent procedure, participants were randomized to two sequences of simulation i.e., Group A and Group B by using a random number generator in Microsoft Excel 2019 [340]. In a cross-over design Group A was first evaluated in a face-to-face simulation followed by telepharmacy whereas Group B was first evaluated in a telepharmacy simulation followed by a face-to-face simulated patient encounter. The complete study design is illustrated in Figure 17.

4.2.3.2 Study Procedure

The investigation was carried out from May - June 2023 as a part of the Clinical Pharmacy course in the summer semester of 2023. The study was conducted in two stages over four days (Figure 17). Stage 1 included student recruitment during which students were informed about the study and invited to participate followed by randomization to two sequences of simulation. An introductory lecture on Inhalation therapy, hands-on training with placebo inhalation devices, and a pre-simulation self-assessment survey were conducted at this stage. The second stage, the simulation encounters, consisted of telepharmacy and face-to-face consultations about the correct use of inhalers between a pharmacy student as the community pharmacist and an SP in a crossover manner. The telepharmacy simulation was conducted using the secured WebEx videoconferencing platform (Cisco Webex, Version 44.1.0.28423). To control for the possible learning effect students were switched to the second encounter instantaneously without any feedback. For every student, both simulation encounters were identical regarding the examiner, and inhalation device, and differences were the communication medium and SP. During both encounters, the pharmacy students conducted the clinical pharmacy service according to the standard procedure described by the ABDA [328] where they first demonstrated the inhaler technique to the SP and then asked the SP to redemonstrate whereby, they identified and corrected the errors made by the SP. According to the Association of Standardized Patients Educators (ASPE) Standards of Best Practice [341], the SPs were trained to act consistently and provided with written instructions to deliberately make one critical error while redemonstrating the inhaler technique.

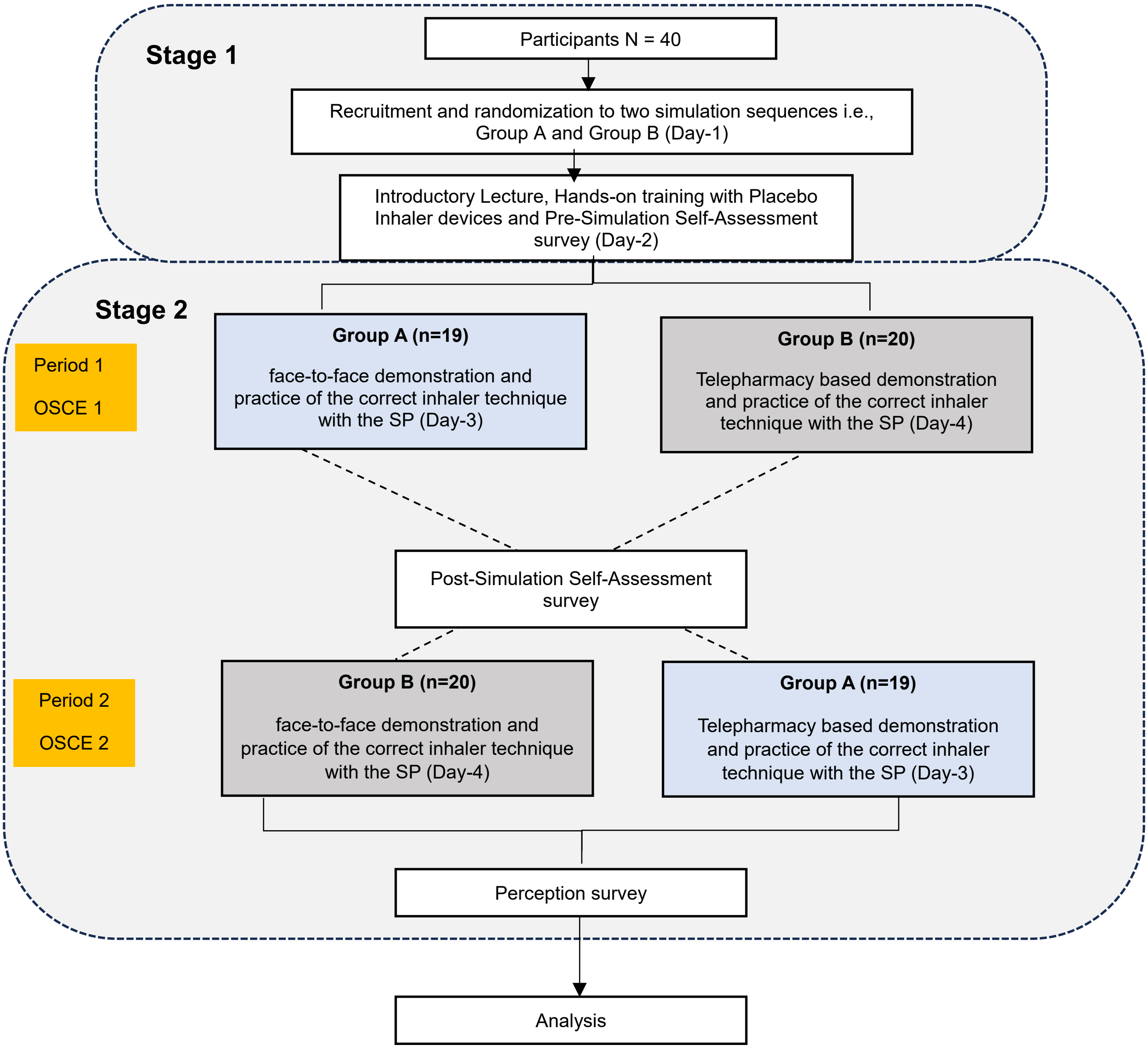


Figure 17. Overview of the study design. OSCE, objective structured clinical examination.

The pre-specified critical inhaler technique errors were included according to each inhaler type [331]. Moreover, six different types of inhalers and their critical errors were also randomized to students. Student performance was evaluated during both simulation encounters through Objective Structured Clinical Examinations 1 and 2 (OSCE1 and OSCE2). A post-simulation survey of self-assessment was distributed after period 1 (OSCE 1) and a student perception survey after period 2 (OSCE2) of crossover design.

4.2.3.3 Objective Structured Clinical Examination (OSCE)

Participants were assessed individually during OSCE1 and OSCE2 in a crossover manner to measure any differences in performance between the two means of communication i.e. face-to-face and telepharmacy. Participants were provided with individual time slots and received a brief description of the whole simulation process after registration. An OSCE lasted a maximum of 12 minutes. The SPs were played by faculty members and final-semester pharmacy students who took part in the pilot study conducted in the scope of their elective course in the winter semester of 2022/23. In total four faculty members served as observers who were replaced after every five students. The same observer assessed each participant during both OSCE encounters however SPs were replaced after each encounter.

4.2.3.4 Inhaler technique training

After recruitment, all the participants received a lecture on inhalation therapy. The content included background information about inhalation therapy, its history, indications, advantages/disadvantages, different types and principles of inhalation devices, critical errors in inhaler technique, an overview of the inhaler technique training service, and the role of community pharmacists in this regard. Afterward, participants were trained with different types of placebo inhaler devices including the metered dose and dry powder inhalers.

4.3.3.5 Instruments used in the study

Analytical Checklists for OSCE

The analytical checklist was created by faculty members based on previous literature [342, 343] and by incorporating the necessary steps described by the ABDA in the standard procedure for the inhaler technique training service [327]. The analytical checklist was adjusted to every inhaler device type, resulting in six different analytical checklists (Appendix 1). The analytical checklists consisted of three stations with different total scores. Station 1 was related to the initiation of the encounter including the general preparation and introduction with a total of five points. Station 2 comprised the necessary steps of demonstration and practice of the correct inhaler technique with 12-14 points depending on the type of inhaler. Finally, Station 3 was related to communication skills, documentation, and the participant's ability to recognize critical inhaler technique errors made by SP with a total of eight points. Regarding items performed correctly, one point was awarded, if not zero points were given. Total scores varied among the checklists for every inhaler device, therefore the assessment was based on percentage points. Before the study, the analytical Checklists were pilot-tested and discussed among faculty members for comprehensibility and clarity, and necessary revisions were made as needed.

Pulmobox training material

Pulmobox was used as the training material for inhaler technique training. The Pulmobox contains around 17 different placebo inhaler devices for demonstration purposes, a manual on counseling aids for inhalation therapy, and information sheets for patient counseling and inhaler technique [331, 343].

Self-assessment Questionnaire

To ascertain the impact of different modes of communication on the participant's self-assessment of their competency in demonstrating and practicing the correct inhaler technique a pre- and post-simulation self-assessment questionnaire was developed. The pre-survey was conducted before OSCE1, and the post-survey was conducted after OSCE1 where every participant passed through only one format of simulation either face-to-face or telepharmacy therefore they were asked to rate the statements by keeping in mind the communication medium they have recently used for the OSCE1 encounter. The questionnaire consisted of 8 items rated by a six-point Likert-type scale from "strongly disagree" to "strongly agree". The participant demographic characteristics such as age, gender, additional education as a pharmaceutical technician assistant, current or former work in a community pharmacy, and previous provision of the inhaler technique training service were also included in the self-assessment questionnaire.

Perception Questionnaire

A perception survey was conducted at the end of the study consisting of 10 items rated on a six-point Likert-type scale ranging from "strongly disagree" to "strongly agree". These items were related to students' perceptions of; telepharmacy in general, the difference between telepharmacy and face-to-face encounters, and the provision of inhaler technique service through telepharmacy. Additionally, one item was included where the participants were required to rate their experience of telepharmacy simulation. The items were worded based on previous studies of student perceptions regarding telepharmacy [322, 344].

4.2.3.6 Statistical Analysis

All the data were collected in pseudonymous form and were anonymized after data analysis. Descriptive statistical analyses were conducted for quantitative survey and analytical checklist data. The Mann-Whitney U test was used to evaluate student performance and self-assessment regarding inhaler technique demonstration and practice between different mediums of communication. The non-inferiority of the telepharmacy medium compared to the face-to-face medium between groups and per group in terms of the OSCE checklist scores was examined. We defined a non-inferiority margin of -10% based on a previous study [345]. To rule out any learning effect from period 1 to period 2 we applied a linear mixed model (LMM) incorporating the intra-individual variation for the non-inferiority analysis, given by

$$\textbf{Response (\% of achieved Scores)} = ß_0 + ß_1 * I_{Tele} + S_0 + e$$

where S_0 corresponds to the random intercept of the participants, $ß_0$ (intercept) and $ß_1$ (slope) denote the fixed effects, I_{Tele} equals 1 if the participant was assigned to telepharmacy and is 0 otherwise, and e is the residual error of the model. The non-inferiority test was performed as a one-sided t-test based on $ß_1$, i.e. non-inferiority was concluded at a significance level of alpha=0.05 if the lower bound of the two-sided 90% confidence interval for $ß_1$ was larger than the non-inferiority margin of -10%. A corresponding p-value was deduced from the one-sided t-test. The model mentioned above was applied in total four times: for the total scores and for each of the three individual stations of OSCEs. Microsoft Excel 2019 [340] was used for data entry whereas, Origin Pro 2021 [346], and R statistical software [347] were used for statistical analysis. To account for multiple testing, Bonferroni-Holm correction was applied. For all statistical analyses, p-values below 0.05 were considered significant.

4.2.3.7 Ethical Approval

Approval for this study was granted by the responsible Ethics Commission of the Faculty of Medicine, Heinrich Heine University, Duesseldorf (Number: 2023-2401). The participation was voluntary, and all participants provided signed informed consent before the start of the study.

4.2.4 RESULTS

4.2.4.1 Participant Characteristics

Of 44 students in the last semester of their pharmacy studies, 40 provided informed consent and participated in the study excluding those four students who took part in the pilot study and served as SPs. A total of 40 participants were randomized to the two sequences (Group A and Group B) of simulation resulting in 20 participants per group, however, one participant from Group A remained absent on the day of OSCE evaluation resulting in a total of 19 participants in Group A. All 39 students participated in the self-assessment and perception surveys. Table 12. provides further details regarding participant characteristics.

Table 12. Participant Characteristics (N=39)

Characteristics	Group A (Face to Face --- Telepharmacy) (n=19)	Group B (Telepharmacy --- Face to Face) (n= 20)
Age in years		
Mean (SD)	24.47 (2.9)	24.63(3.18)
Median (IQR)	24 (4.5)	24 (3.5)
Range	21-30	22-32
Gender		
Male, n (%)	06 (31.58)	05 (25)
Female, n (%)	13 (68.42)	15 (75)
Training as a pharmaceutical technical assistant		
Yes, n (%)	03 (15.79)	01 (05)
No, n (%)	16 (84.21)	19 (95)
Currently or formerly worked in a Community Pharmacy		
Yes, n (%)	09 (47.37)	05 (25)
No, n (%)	10 (52.63)	15 (75)
Previous provision of inhaler technique service		
Yes, n (%)	03 (15.79)	04 (20)
No, n (%)	16 (84.21)	16 (80)

SD, standard deviation; IQR, interquartile range.

4.2.4.2 OSCE Scores

The total OSCE scores did not differ significantly between the two groups for OSCE1 (p = 0.79) and OSCE2 (p = 0.65). Similarly, the total OSCE scores at two OSCE encounters did not differ significantly within group A (p = 0.23) and group B (p = 0.13). The detailed results for the OSCE scores are depicted in Table 13 and Figure 18. Regarding the LMM and non-inferiority analysis in terms of the student performance between different communication mediums, all tests are significant and, consequently, non-inferiority of telepharmacy format in terms of student performance can be concluded at all OSCE stations and for the total OSCE scores, also after adjusting for multiple comparisons. Table 14 summarizes the estimated coefficients, the confidence intervals for $ß_1$, and the p-values of the corresponding non-inferiority tests (unadjusted and adjusted).

Table 13. Achieved OSCE Scores

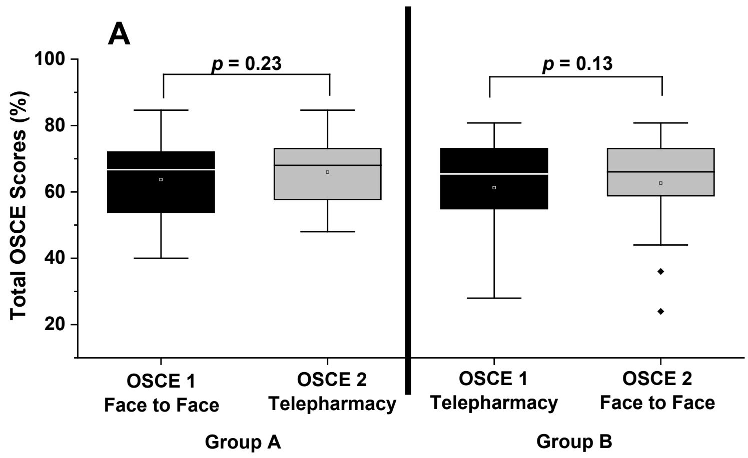
OSCEs	Group A Scores Mean (SD) %	Group B Scores Mean (SD) %	***P_2-value*** **
Station 1: General Preparation & Introduction			
OSCE 1	40.00 (16.33)	27.00 (17.50)	0.02
OSCE 2	35.79 (20.63)	29.00 (17.74)	0.26
*P_1-value**	0.52	0.67	
Station 2: Inhaler technique demonstration and practice			
OSCE 1	66.45 (13.68)	68.83 (18.23)	0.33
OSCE 2	68.76 (15.77)	67.77 (16.39)	0.92
P_1-value	0.37	0.93	
Station 3: Communication skills, critical error identification & documentation			
OSCE 1	74.34 (15.29)	70.63 (20.78)	0.89
OSCE 2	80.26 (10.47)	75.63 (20.47)	0.98
P_1-value	0.21	0.05	
Total			
OSCE 1	63.69 (10.82)	61.25 (14.97)	0.79
OSCE 2	65.94 (10.52)	62.63 (14.25)	0.65
P_1-value	0.23	0.13	

All *p*-values were calculated by the Mann-Whitney U test per group (*paired tests, *p_1*-value) and between groups (***p_2*-value); p-values below 0.05 were considered significant. OSCE, objective structured clinical examination; SD, standard deviation.

Table 14. Coefficients of the linear mixed model and corresponding non-inferiority analysis

	Total Scores	**Station 1**	**Station 2**	**Station 3**
$ß_0$	63.15	34.36	67.13	75
$ß_1$	0.39	-3.08	1.67	0.321
90% CI for $ß_1$	(-1.48, 2.26)	(-8.71, 2.56)	(-0.725, 4.06)	(-3.73, 4.37)
95% CI for $ß_1$	(-1.85, 2.63)	(-9.84, 3.69)	(-1.2, 4.54)	(-4.54, 5.18)
p-value (NI)	<0.0001	0.0247	<0.0001	<0.0001
Adjusted p-value*	<0.0001	0.0247	<0.0001	0.0001

*Calculated by applying Bonferroni-Holm correction for all four analyses; p-values below 0.05 were considered significant. NI, non-inferiority analysis.



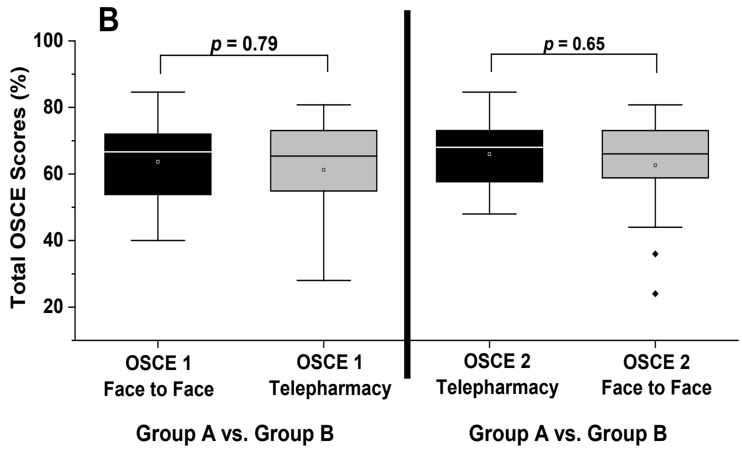


Figure 18. Box plots of total OSCE scores. OSCE scores (%) of Group A and Group B during two periods of assessment OSCE1 and OSCE2 showing per group ***(A)*** *and between-groups* ***(B)*** *comparisons; The p-values were obtained by Mann-Whitney U tests per group (paired tests) and between groups; p-values below 0.05 were considered significant; Black diamonds = outliers. OSCE, objective structured clinical examination.*

4.2.4.3 Self-assessment score

The self-assessment scores did not differ significantly between groups at baseline (*p*= 0.75) and after the first simulation activity (*p*= 0.42). Similarly, there were no significant differences in self-assessment scores from pre- to post-simulation within the telepharmacy group (*p* = 0.21) and the face-to-face group (*p* = 1). The detailed results of the self-assessment scores are depicted in Table 15. Regarding individual statements of the post-simulation self-assessment questionnaire, only the statement that concerns the participant's ability to identify the inhaler technique errors made by patients showed a statistically significant difference (p=0.03) between telepharmacy and face-to-face formats (Figures 19 & 20).

Table 15. Achieved scores by Group A and Group B in pre- and post-simulation self-assessment survey

Groups	Pre-Simulation Mean (CI)	Post-Simulation Mean (CI)	*p*-Value (Intragroup)
Group A (face-to-face)	34.95 (2.98)	34.79 (2.19)	1
Group B (telepharmacy)	34.40 (2.84)	36.35 (2.58)	0.21
***p*-Value (Intergroup)**	0.75	0.42	

All *p*-values were calculated by the Mann-Whitney U test per group (paired tests) and between groups; *p*-values below 0.05 were considered significant. CI, confidence interval

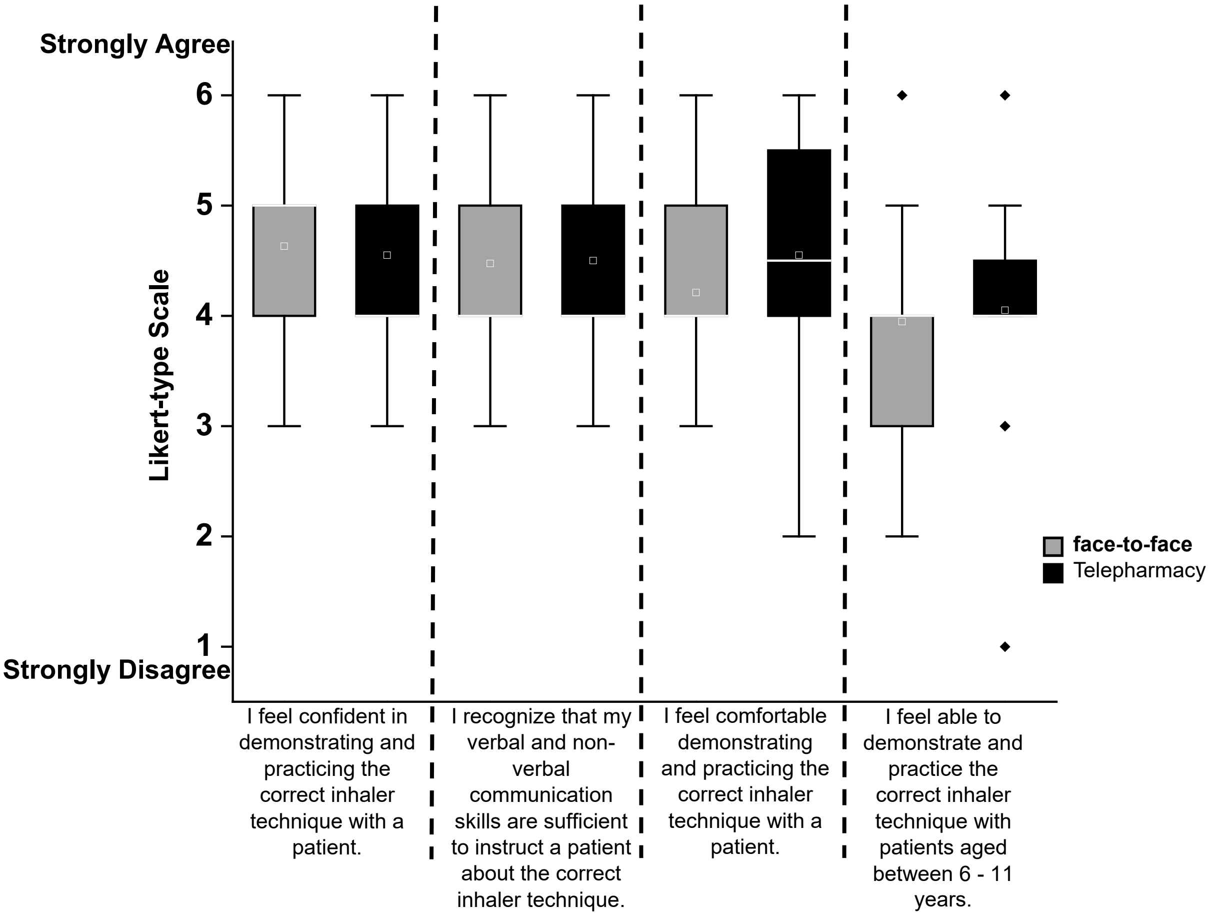


Figure 19. Box plots of post-self-assessment scores (statements 1-4). post self-assessment scores of Group A (face-to-face) and Group B (telepharmacy) showing between-group comparisons; Responses were rated on a six-point Likert scale where 1 = strongly disagree and 6 = strongly agree; Black diamonds = outliers; All p-values were obtained from Mann-Whitney U tests; p-values below 0.05 were considered significant.

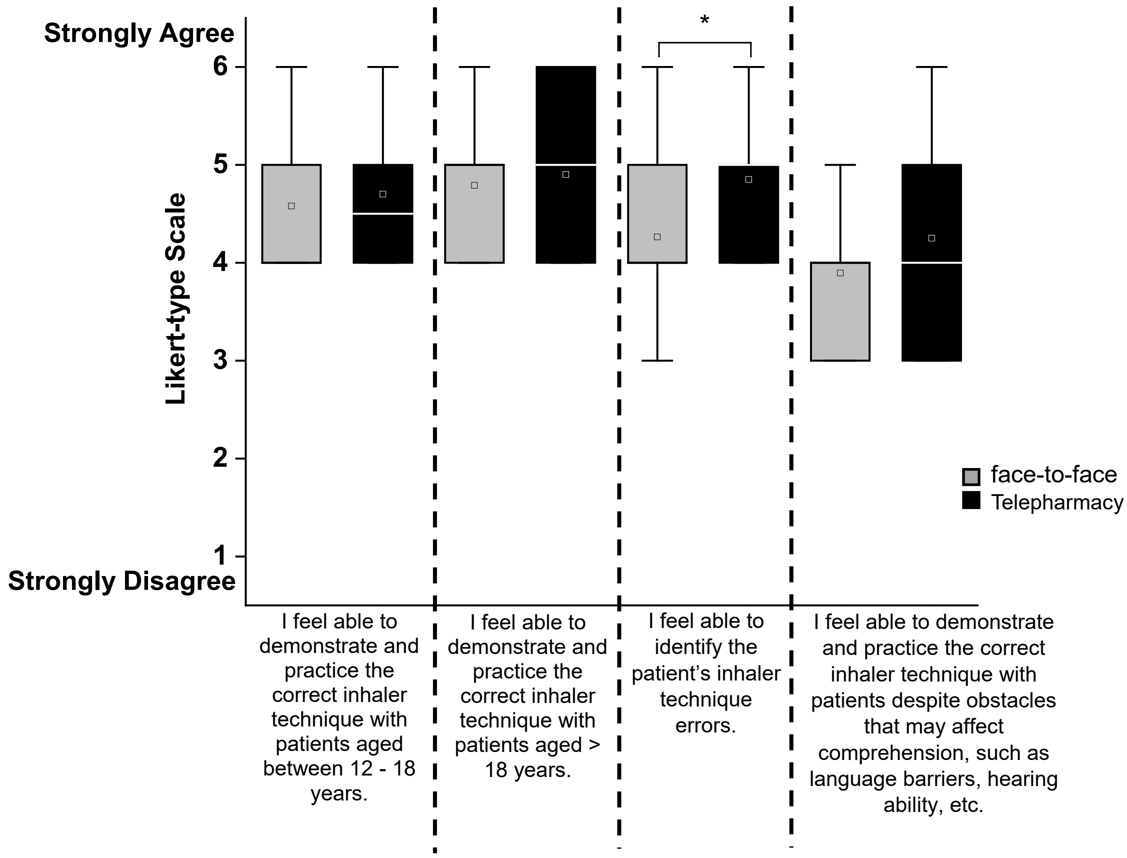


*Figure 20. Box plots of post-self-assessment scores (statements 5-8). post self-assessment scores of Group A (face-to-face) and Group B (telepharmacy) showing between-group comparisons; Responses were rated on a six-point Likert scale where 1 = strongly disagree and 6 = strongly agree; Black diamonds = outliers; * p value= 0.03; All p-values were obtained from Mann-Whitney U tests; p-values below 0.05 were considered significant.*

4.2.4.4 Perception Survey

The participants reported an overall positive perception of telepharmacy and its use for the provision of inhaler technique training service (Figure 21). All the participants (100%) perceived telepharmacy as another option for patient consultations in the future.

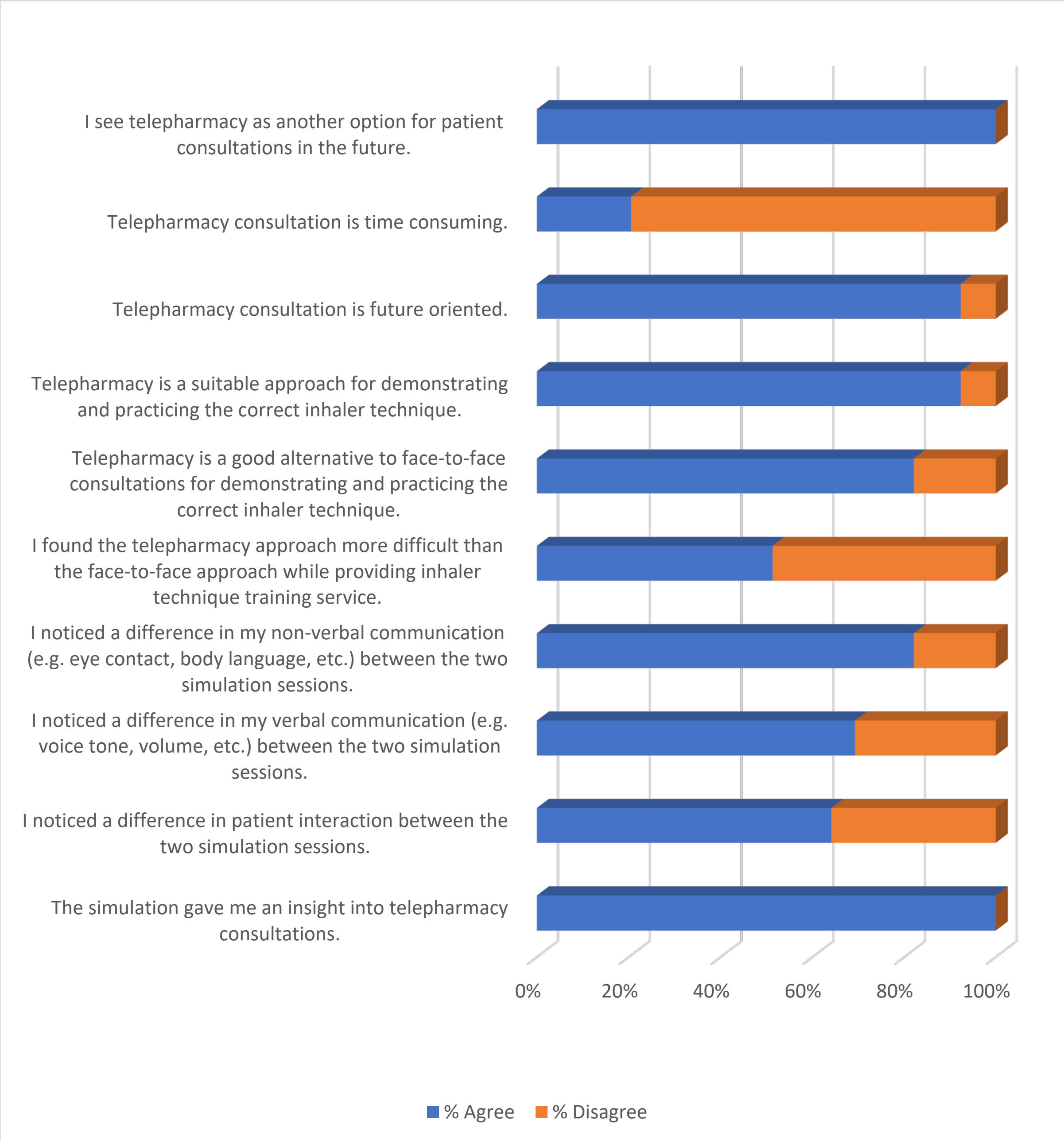


Figure 21. Responses to the perception survey (N=39). Responses were rated on a six-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = rather disagree, 4 = rather agree, 5 = agree, 6 = strongly agree); strongly disagree, disagree and rather disagree= disagreement; rather agree, agree, and strongly agree= Agreement.

A large majority agreed that telepharmacy is future-oriented (92.3%), a suitable approach (92.3%), and a good alternative to face-to-face consultations for providing inhaler technique training service (82.1%). On the other hand, 51.2% of participants found telepharmacy more difficult than face-to-face consultation and found a difference in their verbal (69.2%), and non-verbal (82.1%) communication and their interaction with the patients (64.1%) between the two formats. Most of the participants (79.5%) tend to disagree with the statement that telepharmacy is time-consuming, and all of them (100%) found the educational activity helpful in getting an insight into telepharmacy consultations. The detailed results of the perception survey are also presented in the Appendix Table 16.

4.2.5 DISCUSSION

The randomized cross-over study demonstrates that, based on OSCE scores and a non-inferiority margin of -10%, the telepharmacy approach was non-inferior to the traditional face-to-face approach for demonstrating and practicing the correct inhaler technique. Referring to “equally good consultation, whether face-to-face or via telepharmacy for patients living in remote localities or unable to visit the community pharmacy for various reasons”. The results also revealed that there are no significant differences in student self-confidence and perceived competence between the two modes of communication. Moreover, participants had a largely positive perception of telepharmacy and its use in providing inhaler technique training service.

We evaluated the student performance between different mediums of communication (face-to-face and telepharmacy). Students performed equally well regardless of the communication medium during both simulation encounters, the additional practice and previous evaluation during OSCE 1 did not influence their performance in OSCE2 for both groups and allocation to group A or group B did not advantage or disadvantage them. Students' ability to conduct telepharmacy consultations without prior practice could be explained by their extensive experience with videoconferencing both during and after COVID-19, a period of digital transformation in education [348, 349]. Moreover, demographic characteristics showed that the participants of this study belong to Generation Z (persons born between 1997-2012) or digital natives who are quite comfortable and expert in using Information and communication technology (ICT) [150, 350]. The present study builds on previous research, which demonstrated that pharmacy students successfully provided consultations via telepharmacy without prior practice, but they were more successful during face-to-face consultations [322]. However, that study did not include device training and was conducted before the pandemic with minimal exposure to online teaching formats.

Students demonstrated the stepwise standard procedure of the inhaler technique training service equally well using both mediums of communication as shown by the scores at station 2 of relevant OSCEs. Studies have reported the effectiveness of pharmacist-led home video telehealth inhaler training programs in improving inhaler technique, and other patient outcomes [333, 334]. However, no study evaluated the provider's abilities in using video telehealth technology to provide inhaler technique training. OSCE scores were also comparable at station 3 which was related to verbal and non-verbal communication skills as well as identification of critical inhaler technique errors made by patients during the encounter. Concerning communication skills Skoy et al. found no significant differences in pharmacy students' verbal communication during face-to-face and telepharmacy consultations, however, there were inappropriate nonverbal cues for the telepharmacy format [322]. Another study cited student comments about differences in body language and in developing a relationship with the patient between both formats of consultation [83].

The secondary objective of this study was to enhance our understanding of participants' self-assessments and perceptions of telepharmacy. The simulation activity minimally impacted students' self-assessment of their abilities to carry out the inhaler technique training service for both mediums of communication. In the post self-assessment survey students rated their self-confidence after the first simulation activity where each group had an experience of only one mode of communication i.e. either face-to-face or telepharmacy. The self-assessment survey results demonstrate that the telepharmacy format is a viable alternative to the face-to-face format for the provision of inhaler technique training service as participants in both groups rated their competence equally in all aspects of their self-confidence. However, there was a statistically significant difference in participants' self-assessments of their ability to recognize critical inhaler technique errors made by patients. These findings are interesting as the participants in the telepharmacy group felt more confident in recognizing the critical errors than in the face-to-face group (mean scores 4.85 vs. 4.26). Similarly, Porter et al demonstrated that all the pharmacy students who participated in their study were able to identify errors during telepharmacy-based prescription verification activities [344].

In our study, participants had an overall positive perception of telepharmacy. Many studies have pointed out the positive perceptions and well acceptance of telepharmacy among pharmacy students and practicing pharmacists [81-83, 336-339]. Despite their equivalent performance most of the participants perceived differences between telepharmacy and face-to-face SP encounters and found telepharmacy as more difficult than the face-to-face approach. In previous studies, pharmacy students have reported perceived differences in their abilities to counsel patients using telepharmacy vs. in-person [322, 339, 344]. In our study, this perception could also be attributed to the first formal telepharmacy consultation experience of students during their pharmacy studies. Students agreed to the suitability of telepharmacy for providing inhaler technique training service and found it an alternative to face-to-face format whereas a previous study conducted with 390 pharmacy students in two pharmacy programs reported perceived difficulties in providing device training through telepharmacy, however, the authors of that study suggested that these perceptions could be addressed with extra practice and training in telepharmacy [83].

We believe that the simulated telepharmacy encounter with SPs also provided the students with an opportunity to practice their foundational consultation skills in new ways of pharmacy practice as students agreed to the statement that the simulation gave them an insight into telepharmacy consultations. It has also previously been reported that simulated telehealth encounters improved communication skills and enhanced learning among medical and nursing students [351, 352]. This experience is also shared by pharmacy students, who felt that telepharmacy simulations improved their comfort and confidence in utilizing this technology in the future [344]. Videoconferencing is becoming popular for patient consultations and previously videoconferencing systems have been used to train online consultation skills among healthcare professional students [353]. In the future, this research could lead to more adoption of the telepharmacy approach for providing inhaler technique training service and other pharmaceutical care services at community pharmacies in Germany. It could also help in taking academic initiatives aimed at incorporating more telepharmacy practice models into the professional development of the future pharmacy workforce.

Our study is subjected to certain limitations. Firstly, the present study was conducted at a single university limiting the generalizability of results. Secondly, there may be a learning effect from OSCE1 to OSCE2 however to minimize it, students were immediately switched from one format to the other without any feedback in between and further the statistical analysis ruled out this effect during data analysis. Thirdly, we did not collect data about students' previous experience with telepharmacy during their internships or other experiential education that may have affected the results. Finally, the SP encounters did not represent all patient populations (different age groups, language barriers, digital literacy, etc) and consultation scenarios students could face while providing inhaler technique training service through videoconferencing such as technical issues, low-video quality, etc. Further research could be conducted with real patients and practicing pharmacists in real-world scenarios to determine the non-inferiority of the telepharmacy format over the face-to-face medium of communication and to further explore the acceptance of telepharmacy in this regard.

4.2.6 CONCLUSION

The results from the study suggest that telepharmacy is as effective as traditional face-to-face consultation for providing inhaler technique training service. The anticipated comparable OSCE scores, self-confidence, and positive perceptions about telepharmacy supported the idea that implementation may occur and be delivered as routine clinical pharmacy services. However, to address the special verbal and non-verbal communication skills and etiquette when performing telepharmacy services, the pharmacy curriculum should include more telepharmacy-related didactic content with experiential learning and simulations.

5

Chapter 5: Overall Discussion and Conclusion

PREAMBLE

This chapter summarises the findings of all four studies (chapters 2-4) within the broader scope of digital health in pharmacy practice and pharmacy education. It also concludes the research findings for future implications, makes recommendations and highlights unanswered questions for future research.

5.1 DISCUSSION OF THE MAIN FINDINGS

The overall aim of this thesis was to explore the opportunities for integrating digital health tools into pharmacy education and practice. This aim was achieved by conducting four independent studies: evaluating popular diabetes digital apps after developing evaluation criteria mainly pharmaceutical care criteria, general characteristics criteria, and patient preferences (Chapter 2, Study 1); exploring the users' experience with a diabetes app by including usability, satisfaction, app efficiency, and usefulness of different app features (Chapter 3, Study 2); integrating the use of digital health tools in pharmacy education (Chapter 4, Studies 3 and 4) by piloting digital diabetes apps for student training and by assessing the non-inferiority of telepharmacy over traditional face to face patient consultations i.e. for inhaler technique training.

This thesis provides insights into the ever-increasing use of DH technologies in healthcare delivery with a focus on pharmaceutical care services and emphasizes the importance of digital competence for future pharmacists. In this era, pharmacy professionals must explore opportunities and obtain the necessary skills to augment their traditional ways of providing services by keeping pace with the constantly evolving DH landscape. Several factors at the level of HCPs have been identified as influencing their adoption of DH tools and their decision to recommend them to patients [354]. These factors include digital skills, knowledge of the availability of effective DH tools, perceptions of the quality of DH tools, and the availability of training and informal support to use DH tools [354]. While much progress has been made through policies and legislation at the government and organization levels, challenges remain to incorporating DH tools into existing systems and practices [354]. It is also imperative that other stakeholders in the healthcare system acknowledge the possibility of augmenting pharmacists' competence through the use of DH solutions [85].

Pharmaceutical care through mHealth apps

Pharmacists are the most accessible healthcare providers and the first line of contact for patients to get advice on their medications and medical devices without any appointments and waiting times. In Chapter 2 (study 1) we highlighted the opportunity that pharmacists are in the best position to answer and guide patients regarding their "software as medical devices" i.e. mHealth apps. Furthermore, one of this study's main objectives was to identify the functions of diabetes apps enabling medication management, adherence/non-pharmacological management, interoperability, and communication (Table 2) to facilitate the pharmaceutical care process. Our evaluation demonstrated that most of the evaluated apps lack medication management features, however, features related to promoting adherence, non-pharmacological management, interoperability, and communication with HCPs were present in the majority of the selected apps (Table 3).

In a few years since reimbursement approvals, the 374,000 prescriptions of DiGA in Germany indicate a tremendous trend toward their use [103]. As of July 2024, 56 DiGA have been listed in the DiGA directory out of which six are related to diabetes [355]. Moreover, from 2025 the five Clinical pharmacy services at German community pharmacies will be expanded to also include intensive diabetes counseling [356]. We anticipate the integration of SHI-covered DH tools such as diabetes apps and wearable sensors along with their patient-generated health data to be part of routine consultations at community pharmacies in Germany.

The resulting insights also guide better tailoring the content and features of diabetes apps to pharmacists' expertise, and to avail this expertise for app-based diabetes management and positive patient outcomes.

Usability of and satisfaction with mHealth apps

Individuals' mHealth app adoption is determined by several determinants including the perceived ease of use and usefulness as postulated by the Technology Acceptance Model (TAM) [357]. We explored these determinants for a diabetes app intervention among T1DM pediatric patients, their parents, and HCPs and reported in Chapter 3 (study 2) of this thesis. An initial feasibility study was required to consider the acceptability of the mHealth app in the context of remote and rural areas with limited specialized diabetes care for T1DM pediatric patients. Moreover, diabetes apps with insulin and carbohydrate calculators improved clinical outcomes in T1DM young patients [358] therefore we were interested to know whether such an app is supported by the evidence of usability and satisfaction among end users.

Ultimately we were able to use one of the most highly rated apps (i.e. Diabetes: M) for pharmaceutical care criteria (11/16) and patient preferences criteria (6/10) evaluated during the conduct of study 1 of this thesis, in our study 2. The Diabetes: M app was used for 3 months by the T1DM pediatric patients, their parents, and HCPs all connected through a digital health network (Figure 8). Our findings of high satisfaction with and ease of use of the app (Figure 12 and Table 8) among T1DM pediatric patients, parents, and HCPs resonate with the previous literature [247, 259, 260, 269-272]. In addition, our results regarding user experience of app efficiency and the usefulness of different app features provided clues that app-based intervention in this population may provide additional support for T1DM management and prevention of long-term complications, a major problem in children and adolescents.

Digital health in pharmacy education

The deficiency of pharmacy programs in DH content and training has been identified all over the world [88]. On the other hand use of DH tools is increasing in pharmacy practice and research [7, 121]. Therefore the need to educate and train future pharmacy workforce is expanding day by day. Pharmacy students' urge for DH education and their attitudes toward DH solutions in healthcare were reported to be very positive [359]. However, they felt inadequately prepared to use these tools in their future practice [359].

We selected two DH solutions i.e. mHealth apps and telepharmacy to be integrated into pharmacy education for student training and further investigated student performance, self-assessment, and perceptions of these tools. Study 3 (Chapter 4.1) reports the introduction of diabetes apps into clinical pharmacy education in the form of an elective course. The course aimed to improve the mHealth skills of final-year pharmacy students and their understanding of providing pharmaceutical care to diabetes patients through apps (Figure 16). Pharmacy students evaluated four diabetes apps according to a list of 25 predefined criteria. They learned how to interpret the patients' blood glucose records using diabetes apps' graphs and charts and apply clinical problem-solving to improve patient outcomes. Students' informal feedback at the end of the course demonstrated high satisfaction with the course, they felt enabled to care for their patients using diabetes apps and expressed their interest in expanding the use of digital tools to other disease areas.

The study 4 (Chapter 4.2) in this thesis aimed to answer the question raised by pharmacists and pharmacy students of the appropriateness of a telepharmacy approach for medical device training i.e. inhaler devices [82, 83]. The randomized cross-over study assessed the non-inferiority of telepharmacy-based inhaler technique training service over the traditional face-to-face approach. The OSCE scores of student performance and (Table 13) their self-assessment scores (Table 15) showed no significant differences between the two modes of communication. Moreover, students' perceptions of telapharmacy-based services were positive (Figure 21). The recent Draft law for the reform of pharmacy fees and pharmacy structures “the Pharmacy Reform Act” (Apotheken-Reformgesetz – ApoRG) in Germany provides the possibility of opening community pharmacies with the presence of experienced pharmaceutical-technical assistants, provided that a telepharmacy connection to pharmacists in the branch network is ensured and the pharmacy management is personally present for at least 8 hours per week [141]. These reforms point toward the increasing role of telepharmacy at community pharmacies in the near future.

5.2 STRENGTHS AND LIMITATIONS

A detailed description of the strengths and limitations of each study is discussed in relevant chapters. The key strengths of this thesis lie in its pioneering exploration of opportunities for pharmaceutical care delivery through mHealth apps and telepharmacy and their integration into pharmacy education. It contributes evidence of the usability and satisfaction with diabetes apps among T1DM patients and HCPs in the context of remote areas with limited access to specialized diabetes care. We were able to collect data from real-world app users in a more reliable way that goes beyond user ratings and reviews in app stores. Moreover, the non-inferiority of telepharmacy for device training has been established through pharmacy students' performance and self-assessment in a randomized cross-over study. All four studies are published in peer-reviewed open-access journals. A particular limitation is the lack of evidence of DH adoption and application in real-world pharmacy practice settings and the perspectives of practicing pharmacists in this regard.

5.3 RECOMMENDATIONS AND FUTURE IMPLICATIONS

Based on the studies conducted for this thesis, we made the following five recommendations.

1. During app evaluation (conducted in Study 1) we realized that pharmacists are not being explicitly mentioned as HCPs in any of the selected apps. To get full use of pharmacists' expertise, app developers and manufacturers should recognize the important role of pharmacists in chronic disease management through apps. The future app designs should be customized to include pharmacists as members of the multi-professional healthcare teams working for positive patient outcomes.

2. Secondly, this role recognition is also required on the part of policymakers. For instance, in Germany, the process of app prescription and use should also include pharmacists to realize the maximum benefits of prescribable apps (DiGA).

3. In the context of study 2, we recommend the establishment of app-based digital health networks for chronic diseases other than diabetes. Such interventions are accepted by patients and could decrease the disparities in healthcare access in resource-limited settings.

4. Integration of DH didactic content and experiential learning in pharmacy education needs urgent attention. Elective and compulsory courses should be

developed to increase the digital competence of pharmacy students thereby securing the future of the profession.

5. Keeping in mind the increasing role of telepharmacy through recent draft legislative reforms and the future integration of more advanced forms of DH technologies such as wearable devices, AI, machine learning, and blockchain into routine practice necessitates the development of an adequately trained and fully aware pharmacy workforce to deliver technology-enabled pharmaceutical services.

5.4 UNANSWERED QUESTIONS FOR FUTURE RESEARCH

1. How robust is the evidence on Pharmacists' use of digital health tools in particular mHealth apps to improve health-related clinical outcomes for patients?

This thesis explored the role of pharmacists in providing pharmaceutical care through apps. However, there is a lack of robust evidence in pharmacy practice literature about the pharmacists' use of mHealth apps to improve patient outcomes. For instance, Crilly P et al conducted a systemic review of randomized controlled trials (RCTs) of DH technology use by community pharmacists to improve public health. This review highlighted pharmacists' limited use of novel technology (i.e., mHealth apps, social media, and videoconferencing). In their analysis, thirteen studies were included out of which only one study reported the use of the mHealth app [73]. A more recent systematic review of nineteen studies conducted by Park T et al also found only two studies with mHealth app-based interventions by clinical pharmacists [130]. More studies are required to address this gap in the literature and to establish the rationale for pharmacists' use of mHealth apps in improving patient outcomes.

2. What are the factors other than usability and satisfaction that affect the sustained use of and long-term engagement with apps?

The evidence generated in this thesis, informed by the TAM has provided quantifiable insights into the app usability and satisfaction among end users and identified some descriptive intuitions about the user experience of app efficiency and usefulness in the context of rural and remote areas. However, the low attrition rate is another serious issue with chronic disease management apps limiting their use and uptake [360]. The attrition rate represents the sustained use of and long-term engagement with mHealth apps [360]. Therefore the question arises of how long a patient is expected to use the app? Future studies are required to answer this question and to understand the extent to which other factors might facilitate long-term app adherence and prevent dropout rates in this population. Moreover, Longitudinal assessments over a long period are critical to contextualizing the usability and satisfaction data.

3. Is it cost-effective to use app-based chronic disease management in terms of infrastructure, staffing, and equipment?

The remote monitoring through mHealth apps seems feasible and has received acceptance from patients and providers however such remote monitoring systems face challenges such as 1). Frequency of monitoring and communication between HCPs and patients 2). Adequate staffing, infrastructure, and equipment when more patients are required to be monitored 3). The cost-effectiveness of such interventions in remote and rural areas particularly in developing countries, with limited healthcare infrastructure. All these aspects need to be further investigated.

5.5 CONCLUSION

The expansion of the pharmacists' roles and responsibilities as well as the digital transformation of the German healthcare system, present both opportunities and challenges for pharmacists. In this thesis, we explored the prospect of integrating DH technologies into pharmacy practice and education by piloting and assessing such technologies for the provision of pharmaceutical care services. With the potential of DH for better service delivery and positive patient outcomes, we urged that pharmacists be able to develop their digital competencies and be recognized by other stakeholders in the healthcare system.

The future of DH tool use in German pharmacy practice appears to be likely influenced by supportive legislations, policies, incentivization of services, addressing ambivalences, and necessary DH education and training for the pharmacy workforce. On the other hand, it will also be of paramount importance to address the relevant attitudes and perceptions of pharmacists for wider adoption and uptake of DH technologies.

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8. APPENDIX

Appendix 1: Checklists OSCE evaluation, Telepharmamcy vs. Face to Face consultations study.

Appendix 2: Results of perception survey, Telepharmamcy vs. Face to Face consultations study.

Appendix 1: Checklists OSCE evaluation, Telepharmamcy vs. Face to Face consultations study.

Participant code: ____________ Date:_______ Examiner______________________

OSCE-Nr. ___ Communication medium: Face-2-Face □ Telepharmacy □

OSCE Checklist (Aerosol)			
Steps to be carried out and checked	Fulfilled	Not fulfilled	Remarks
Station 1: General Preparation and Introduction (5 P.)			
1.1 The examinee greets and identifies the patient.			
1.2 The examinee checks whether the patient is eligible for the clinical pharmacy service (Inhaler technique training). • *Newly prescribed* • *Device change* • *Last training ≥ 1 year ago and no participation in the Disease-Management-Programm (DMP)*			
1.3 The examinee obtains the patient's consent.			
1.4 The examinee explains the stepwise procedure.			
1.5 The examinee explains the importance of the correct inhaler technique.			
Station 2: Inhaler technique demonstration and practice (13 P.)			
The examinee instructs the patient by demonstrating how to……	Fulfilled	Not fulfilled	Remarks
2.1 … verify the condition of the inhaler (Functionality, completeness, cleanliness).			
2.2 … shake the inhaler.			
2.3 … remove the cap of the inhaler.			
2.4 …hold the device and maintain body posture in the correct position (standing or sitting straight).			
2.5 … exhale completely sideways.			
2.6 … Put the mouthpiece between teeth, close the lips to form a good seal, and keep the head upright.			
2.7 … press the canister and inhale at the same time.			
2.8 … inhale slowly and deeply.			
2.9 … hold breath for 5-10 seconds after inhalation.			
2.10 … slowly exhale from the mouth or nose and away from the mouthpiece.			
2.11 … close the device with the cap.			
2.12 The examinee provides additional information (rinsing mouth, brushing teeth, drinking water, repeating all the steps in case of an additional dose, and storage of the device).			
2.13 The examinee asks the patient to demonstrate all the steps.			
Station 3: Communication skills, critical error identification & documentation (8 P.)			

	Fulfilled	Not fulfilled	Remarks
3.1 The examinee maintains sufficient eye contact during the counseling session.			
3.2 The examinee pays attention to appropriate non-verbal communication (gestures, facial expressions, etc.).			
3.3 The examinee pays attention to comprehensible expression.			
3.4 The examinee ensures the patient's understanding.			
3.5 The examinee remains attentive during the inhaler technique demonstration by the patient.			
3.6 The examinee responds to critical inhaler technique errors made by the patient. • *Not shaking the inhaler.* • *Not holding breath.*			
3.7 The examinee responds to the patient's questions.			
3.8 The examinee completes the necessary documentation.			

Participant code: ____________ Date: _______ Examiner:__________________

OSCE-Nr. ___ Communication medium: Face-2-Face □ Telepharmacy □

OSCE Checklist (Autohaler)			
Steps to be carried out and checked	Fulfilled	Not fulfilled	Remarks
Station 1: General Preparation and Introduction (5 P.)			
1.1 The examinee greets and identifies the patient.			
1.2 The examinee checks whether the patient is eligible for the clinical pharmacy service (Inhaler technique training). • *Newly prescribed* • *Device change* • *Last training ≥ 1 year ago and no participation in the Disease-Management-Programm (DMP)*			
1.3 The examinee obtains the patient's consent.			
1.4 The examinee explains the stepwise procedure.			
1.5 The examinee explains the importance of the correct inhaler technique.			
Station 2: Inhaler technique demonstration and practice (14 P.)			
The examinee instructs the patient by demonstrating how to……	Fulfilled	Not fulfilled	Remarks
2.1 … verify the condition of the inhaler (Functionality, completeness, cleanliness).			
2.2 … shake the inhaler.			
2.3 … remove the cap of the inhaler.			
2.4 … set the inhaler ready for use (push lever up).			

2.5 …hold the device and maintain body posture in the correct position (standing or sitting straight).			
2.6 … exhale completely sideways.			
2.7 … Put the mouthpiece between teeth, close the lips to form a good seal, and keep the head upright.			
2.8 … activate the spray by inhalation and keep breathing in after the click is heard			
2.9 … Inhale slowly, deeply, and for a long time.			
2.10 … hold breath for 5-10 seconds after inhalation.			
2.11 … slowly exhale from the mouth or nose and away from the mouthpiece.			
2.12 … push the lever down and close the device with the cap.			
2.13 The examinee provides additional information (rinsing mouth, brushing teeth, drinking water, repeating all steps in case of an additional dose, and storage of the device).			
2.14 The examinee asks the patient to demonstrate all the steps.			
Station 3: Communication skills, critical error identification & documentation (8 P.)			
	Fulfilled	Not fulfilled	Remarks
3.1 The examinee maintains sufficient eye contact during the counseling session.			
3.2 The examinee pays attention to appropriate non-verbal communication (gestures, facial expressions, etc.).			
3.3 The examinee pays attention to comprehensible expression.			
3.4 The examinee ensures the patient's understanding.			
3.5 The examinee remains attentive during the inhaler technique demonstration by the patient.			
3.6 The examinee responds to critical inhaler technique errors made by the patient. • *Not shaking the Autohaler.* • *Not holding breath.*			
3.7 The examinee responds to the patient's questions.			
3.8 The examinee completes the necessary documentation.			

Participant code: _____________ Date: _______ Examiner: _________________________

OSCE-Nr. ___ Communication medium: Face-2-Face □ Telepharmacy □

OSCE Checklist (Breezhaler)			
Steps to be carried out and checked	Fulfilled	Not fulfilled	Remarks
Station 1: General Preparation and Introduction (5 P.)			
1.1 The examinee greets and identifies the patient.			

1.2 The examinee checks whether the patient is eligible for the clinical pharmacy service (Inhaler technique training). • *Newly prescribed* • *Device change* • *Last training ≥ 1 year ago and no participation in the Disease-Management-Programm (DMP)*			
1.3 The examinee obtains the patient's consent.			
1.4 The examinee explains the stepwise procedure.			
1.5 The examinee explains the importance of the correct inhaler technique.			
Station 2: Inhaler technique demonstration and practice (13 P.)			
The examinee instructs the patient by demonstrating how to……	Fulfilled	Not fulfilled	Remarks
2.1 … verify the condition of the inhaler (Functionality, completeness, cleanliness).			
2.2 … remove the cap of the inhaler.			
2.3 … set the device ready for use (insert capsule).			
2.4…Prepare the dose by piercing the capsule.			
2.5 …hold the device and maintain body posture in the correct position (standing or sitting straight).			
2.6 … exhale completely sideways.			
2.7 … Put the mouthpiece between the teeth, close the lips to form a good seal, and keep the head upright.			
2.8 … Inhale deeply and rapidly			
2.9 … hold breath for 5-10 seconds after inhalation.			
2.10 … slowly exhale from the mouth or nose and away from the mouthpiece.			
2.11 … Remove the capsule and close the device.			
2.12 The examinee provides additional information (rinsing mouth, brushing teeth, drinking water, repeating all the steps in case of an additional dose, and storage of the device).			
2.13 The examinee asks the patient to demonstrate all the steps.			
Station 3: Communication skills, critical error identification & documentation (8 P.)			
	Fulfilled	Not fulfilled	Remarks
3.1 The examinee maintains sufficient eye contact during the counseling session.			
3.2 The examinee pays attention to appropriate non-verbal communication (gestures, facial expressions, etc.).			
3.3 The examinee pays attention to comprehensible expression.			
3.4 The examinee ensures the patient's understanding.			
3.5 The examinee remains attentive during the inhaler technique demonstration by the patient.			

3.6 The examinee responds to critical inhaler technique errors made by the patient. • Not "filling" the Breezhaler with the medication capsule or pressing the side buttons. • Exhalation into the device.			
3.7 The examinee responds to the patient's questions.			
3.8 The examinee completes the necessary documentation.			

Participant code: ____________ Date: _______ Examiner: ______________________

OSCE-Nr. ___ Communication medium: Face-2-Face □ Telepharmacy □

OSCE Checklist (Diskus)			
Steps to be carried out and checked	Fulfilled	Not fulfilled	Remarks
Station 1: General Preparation and Introduction (5 P.)			
1.1 The examinee greets and identifies the patient.			
1.2 The examinee checks whether the patient is eligible for the clinical pharmacy service (Inhaler technique training). • *Newly prescribed* • *Device change* • *Last training ≥ 1 year ago and no participation in the Disease-Management-Programm (DMP)*			
1.3 The examinee obtains the patient's consent.			
1.4 The examinee explains the stepwise procedure.			
1.5 The examinee explains the importance of the correct inhaler technique.			
Station 2: Inhaler technique demonstration and practice (12 P.)			
The examinee instructs the patient by demonstrating how to……	Fulfilled	Not fulfilled	Remarks
2.1 … verify the condition of the inhaler (Functionality, completeness, cleanliness).			
2.2 … remove the cap of the inhaler.			
2.3 … set the device ready for use (loading by pressing the lever).			
2.4 …hold the device and maintain body posture in the correct position (standing or sitting straight).			
2.5 … exhale completely sideways.			
2.6 … Put the mouthpiece between the teeth, close the lips to form a good seal, and keep the head upright.			
2.7 … Inhale deeply and rapidly			
2.8 … hold breath for 5-10 seconds after inhalation.			
2.9 … slowly exhale from the mouth or nose and away from the mouthpiece.			

2.10 … close the device.			
2.11 The examinee provides additional information (rinsing mouth, brushing teeth, drinking water, repeating all the steps in case of an additional dose, and storage of the device).			
2.12 The examinee asks the patient to demonstrate all the steps.			
Station 3: Communication skills, critical error identification & documentation (8 P.)			
	Fulfilled	Not fulfilled	Remarks
3.1 The examinee maintains sufficient eye contact during the counseling session.			
3.2 The examinee pays attention to appropriate non-verbal communication (gestures, facial expressions, etc.).			
3.3 The examinee pays attention to comprehensible expression.			
3.4 The examinee ensures the patient's understanding.			
3.5 The examinee remains attentive during the inhaler technique demonstration by the patient.			
3.6 The examinee responds to critical inhaler technique errors made by the patient. • No "loading" of the diskus. • Exhale into the device.			
3.7 The examinee responds to the patient's questions.			
3.8 The examinee completes the necessary documentation.			

Participant code: ____________ Date: _______ Examiner: _______________________

OSCE-Nr. ___ Communication medium: Face-2-Face □ Telepharmacy □

OSCE Checklist (Elpenhaler)			
Steps to be carried out and checked	Fulfilled	Not fulfilled	Remarks
Station 1: General Preparation and Introduction (5 P.)			
1.1 The examinee greets and identifies the patient.			
1.2 The examinee checks whether the patient is eligible for the clinical pharmacy service (Inhaler technique training). • *Newly prescribed* • *Device change* • *Last training ≥ 1 year ago and no participation in the Disease-Management-Programm (DMP)*			
1.3 The examinee obtains the patient's consent.			
1.4 The examinee explains the stepwise procedure.			
1.5 The examinee explains the importance of the correct inhaler technique.			
Station 2: Inhaler technique demonstration and practice (13 P.)			

The examinee instructs the patient by demonstrating how to……	Fulfilled	Not fulfilled	Remarks
2.1 … verify the condition of the inhaler (Functionality, completeness, cleanliness).			
2.2 … remove the cap of the inhaler.			
2.3 … set the device ready for use (Take out the blister from the package and insert it correctly into the device).			
2.4…Prepare the dose by pulling off the overhanging end.			
2.5 …hold the device and maintain body posture in the correct position (standing or sitting straight).			
2.6 … exhale completely sideways.			
2.7 … Put the mouthpiece between the teeth, close the lips to form a good seal, and keep the head upright.			
2.8 … Inhale deeply and rapidly			
2.9 … hold breath for 5-10 seconds after inhalation.			
2.10 … slowly exhale from the mouth or nose and away from the mouthpiece.			
2.11 … remove the empty blister and close the device.			
2.12 The examinee provides additional information (rinsing mouth, brushing teeth, drinking water, repeating all the steps in case of an additional dose, and storage of the device).			
2.13 The examinee asks the patient to demonstrate all the steps.			
Station 3: Communication skills, critical error identification & documentation (8 P.)			
	Fulfilled	Not fulfilled	Remarks
3.1 The examinee maintains sufficient eye contact during the counseling session.			
3.2 The examinee pays attention to appropriate non-verbal communication (gestures, facial expressions, etc.).			
3.3 The examinee pays attention to comprehensible expression.			
3.4 The examinee ensures the patient's understanding.			
3.5 The examinee remains attentive during the inhaler technique demonstration by the patient.			
3.6 The examinee responds to critical inhaler technique errors made by the patient. • Exhaling into the device. • Not holding breath.			
3.7 The examinee responds to the patient's questions.			
3.8 The examinee completes the necessary documentation.			

Participant code: ____________ Date: _______ Examiner: _______________________

OSCE-Nr. ___ Communication medium: Face-2-Face □ Telepharmacy □

OSCE Checklist (Novolizer)			
Steps to be carried out and checked	Fulfilled	Not fulfilled	Remarks
Station 1: General Preparation and Introduction (5 P.)			
1.1 The examinee greets and identifies the patient.			
1.2 The examinee checks whether the patient is eligible for the clinical pharmacy service (Inhaler technique training). • *Newly prescribed* • *Device change* • *Last training ≥ 1 year ago and no participation in the Disease-Management-Programm (DMP)*			
1.3 The examinee obtains the patient's consent.			
1.4 The examinee explains the stepwise procedure.			
1.5 The examinee explains the importance of the correct inhaler technique.			
Station 2: Inhaler technique demonstration and practice (12 P.)			
The examinee instructs the patient by demonstrating how to……	Fulfilled	Not fulfilled	Remarks
2.1 … verify the condition of the inhaler (Functionality, completeness, cleanliness).			
2.2 … remove the cap of the inhaler.			
2.3 … set the device ready for use (press the lever down until it clicks).			
2.4 …hold the device and maintain body posture in the correct position (standing or sitting straight).			
2.5 … exhale completely sideways.			
2.6 … Put the mouthpiece between the teeth, close the lips to form a good seal, and keep the head upright.			
2.7 … Inhale deeply and rapidly, and for a long time			
2.8 … hold breath for 5-10 seconds after inhalation.			
2.9 … slowly exhale from the mouth or nose and away from the mouthpiece.			
2.10 … close the device.			
2.11 The examinee provides additional information (rinsing mouth, brushing teeth, drinking water, repeating all the steps in case of an additional dose, and storage of the device).			
2.12 The examinee asks the patient to demonstrate all the steps.			
Station 3: Communication skills, critical error identification & documentation (8 P.)			
	Fulfilled	Not fulfilled	Remarks
3.1 The examinee maintains sufficient eye contact during the counseling session.			

3.2 The examinee pays attention to appropriate non-verbal communication (gestures, facial expressions, etc.).			
3.3 The examinee pays attention to comprehensible expression.			
3.4 The examinee ensures the patient's understanding.			
3.5 The examinee remains attentive during the inhaler technique demonstration by the patient.			
3.6 The examinee responds to critical inhaler technique errors made by the patient. • Shaking the Novolizer. • Not "loading" the Novolizer.			
3.7 The examinee responds to the patient's questions.			
3.8 The examinee completes the necessary documentation.			

Appendix 2: Results of perception survey, Telepharmamcy vs. Face to Face consultations study.

Table 16. Responses to the perception survey

Statements	% Agreement	% Disagreement	Mean (SD)	Median
I see Telepharmacy as another option for patient consultations in the future.	100	0	5.25 (0.75)	5
Telepharmacy consultation is time-consuming.	20.5	79.5	2.72 (0.91)	3
Telepharmacy consultation is future-oriented.	92.3	7.7	4.74 (0.96)	5
Telepharmacy is a suitable approach for demonstrating and practicing the correct inhaler technique.	92.3	7.7	4.56 (0.88)	4
Telepharmacy is a good alternative to face-to-face consultations for demonstrating and practicing the correct inhaler technique.	82.1	17.9	4.38 (1.06)	4
I found the Telepharmacy approach more difficult than the face-to-face approach while providing inhaler technique training service.	51.3	48.7	3.64 (1.24)	4
I noticed a difference in my verbal communication (e.g. voice tone, volume, etc.) between the two simulation sessions.	82.1	17.9	4.28 (1.29)	5
I noticed a difference in my non-verbal communication (e.g. eye contact, body language, etc.) between the two simulation sessions.	69.2	30.8	4.53 (1.07)	5
I noticed a difference in patient interaction between the two simulation sessions.	64.1	35.9	4.10 (1.33)	4
The simulation gave me an insight into telepharmacy consultations.	100	0	5.20 (0.65)	5

Responses were rated on a six-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = rather disagree, 4 = rather agree, 5 = agree, 6 = strongly agree); strongly disagree, disagree and rather disagree= disagreement; rather agree, agree, and strongly agree= Agreement.