UiT The Arctic University of Norway

Faculty of Science and Technology, Department of Computer Science

Dia-Continua: An Information System for Type 1 Diabetes Consultation

Interoperability, Privacy, and Information Quality on a FHIR-Based Information System for Type 1 Diabetes Consultations based on Patient-Generated Health Data

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Abstract

Patient-generated health data (PGHD) is required to monitor chronic conditions like Type 1 Diabetes (T1D). This data includes information from medical devices like insulin pumps and continuous glucose monitors and lifestyle insights from commercial wearables devices such as smartwatches. To improve the quality of medical consultations, we need a unified information system that can integrate PGHD.

Designing such a system will pose several challenges. The system should be able to navigate through fragmented information and the complexities of various data formats, proprietary interfaces, and storage methods while ensuring robust security, privacy, and adherence to data ownership principles. It should also enable controlled data sharing with healthcare providers (HCPs) and external entities such as national registries and informal caregivers.

This dissertation details designing, developing, and testing an information system for individuals with T1D. The project involved integrative research in health informatics, collaboration with international projects, and collaboration with experienced users and HCPs to address three research questions. These questions focused on interoperability, the security and privacy of the information collected, and the quality of the information presented during consultations.

The result is Dia-Continua, a Fast Healthcare Interoperability Resources (FHIR)-based information system with a microservices architecture orchestrated through Kubernetes on an Infrastructure as a Service (IaaS) platform. The system integrates data from various diabetes management devices, questionnaires, and PGHD. Furthermore, using SMART on FHIR for authorization and authentication enables data sharing and reuse with national registries and informal caregivers.

Eleven interviews with HCPs evaluated Dia-Continua's new functionalities and information quality. Despite the limitations due to proprietary device systems, the system was assessed positively by HCPs, highlighting the need for a system like Dia-Continua that includes physical activity, sleep, and stress in medical consultations. Dia-Continua is a significant step for a patient-centred model for consultations in T1D. Future work should expand the system's model to other chronic diseases.

Preface

The dissertation is submitted to fulfil the requirements for the degree of Doctor of Philosophy at the Department of Computer Science in March 2023. This doctoral dissertation presents the results of research carried out during my doctoral studies at the Department of Computer Science, Health Informatics and - Technology (HIT) group. The research was supervised by Professor Eirik Årsand and Professor Gunnar Hartvigsen, and funding was provided by the University of Tromsø – The Arctic University of Norway.

Additionally, my role as a system developer and researcher (part-time 20%), mainly in two projects at the Personal E-health department of the Norwegian Centre for E-Health Research until 2023, has contributed to the results of my research. The first project was DiaDig (Diabetes Digital Guidelines), funded by the Northern Norway Regional Health Authority, Helse Nord (HNF1425-18). The other project was a Horizon 2020 HEIR (Healthcare Environment for Informatics Resilience) project (grant agreement n° 883275).

Over the course of the previous four years, I had the privilege of being hosted by various research institutions. My first host was the Innovation Department and Ethics team at Caritas Coimbra, where I spent June and July 2022, courtesy of the Horizon 2020 LIFEBOTS Exchange program (Grant agreement: 824047).

Subsequently, from September to November 2022, I was hosted by Professor Louise Pape-Haugaard and the Department of Health Science and Technology at the Faculty of Medicine, Aalborg University, as part of the Erasmus+ Staff Mobility for Training program.

Finally, from February to September 2023, I was hosted by the Centre for Digital Therapeutics at the University Health Network in Toronto, Canada. During my research stay, I had the pleasure of collaborating with Dr. Quynh Pham, the Scientific Director, Dr. Ian Connell, the Director of Engineering, and Dr. Joseph Cafazzo on my research.

Acknowledgement

From day 0 of my PhD journey, I decided to document every step of the process. I started filming a short video of myself every day, with the intention of creating a time-lapse video that would encapsulate the essence of my PhD journey. To spice things up, I had a post-it note with the number of days I had been enrolled in the PhD program and the number of days left until the end of my contract. Due to the pandemic, these numbers changed several times, and it was quite an experience to see the days remaining go from 1255 to just 5. Throughout this journey, I did my best and am grateful to many people for their support. My PhD experience was like a rollercoaster ride with its ups and downs. Still, it was also a fantastic opportunity for personal and professional growth. Below, you can see some of these post-it, but the video is still a work in progress.

Firstly, I would like to express my sincere gratitude to my supervisors, *Eirik* and *Gunnar*, whose dedication over the past 25 years has enabled me to have great research opportunities. Reflecting on my PhD journey, I am convinced I would not have had the same possibilities elsewhere. I would also like to extend my thanks to the numerous members of the past and present HIT group, such as *Ashenafi*, *Marc*, *Erlend*, and *Andre*, and some colleagues/friends of the Norwegian Centre for E-Health Research like *Paolo*, *Elia*, *Meghan*, *Elisa*, and *Alexandra*. I am particularly grateful to *Dillys* for proofreading the health section of my dissertation, *Rouven* for managing the HEIR project after Celia, and *Celia* for her priceless support with my start-up ideas. Of course, I must also thank the 'Kubernetes King' *Mirek*. I would like to thank *Michael* and Sensotrend for allowing me to reuse some of their components.

During my PhD program at UiT, I served as a board member of an organization called *Todos*, which is dedicated to promoting the welfare of PhD. I would like to express my sincere gratitude to my fellow board members, particularly *Laura*, *Nadine*, and *Steffi*, who shared this experience with me. Nevertheless, much more can and should be done to support and prevent burnout in PhD students.

I would also like to thank *Gigi* and *Enrico*, the two 'Biricchini'. They have been my closest Italian companions from my Erasmus to the PhD since August 2015. Watching them defend their PhDs was truly inspiring. *Tena* and *Bilal* also deserve a special mention. Over the last seven years,

together with the 'Biricchini', we have shared countless trips, dinners, parties, comedy shows and memes. They have created from the beginning a good reason to stay in Tromsø.

I want to give special thanks to *Helge* for giving me the best car ever, the *Mazda 6*, for proofreading my dissertation's technical parts, and for that fantastic summer trip to Portugal. Speaking of Portugal, I want to thank the amazing people at Caritas of Coimbra, especially *Bruna*.

As some of you know, I changed a 'few' houses, but I spent most of my time at Mackbratta and its *Garage*. I am grateful to the Mackbratta family (*Behrouz*, *Enrico*, *Aakash*, *Line*, plus *Helge* and *Susan* as special guests). I was fortunate to have their support, especially during the pandemic that hit Italy particularly hard. Thank you, *Behrouz*, for calming me down during the last weeks of writing my dissertation and welcoming me back to Mackbratta. *Aakash* and *Line* have now become part of the Fjordgård family. *Aakash* was my best *'Teams background'* and my *'Sun'* at the IFI department. *Line* was always ready to go house-hunting with me. If you appreciate the figures in this dissertation, it's because Line introduced me to the power of Figma.

Another group that holds a special place in my heart is my Greeks, *Daniela* and *Apo*, with whom I have shared great moments, from Åsgård to Villa Greca, all filled with *'good food, good people, good vibes'*. A special thanks to *Daniela* for making those moments unforgettable. The great company extends to *Nikos* and *George* for all their help during my *'krykkefar time'*. And, of course, *Marina*, the honorary non-Greek, for all the traditional 17th of May and Carnival celebrations and our friendship since the Åsgård days.

Although not mentioned first, two guys deserve a special mention: *Chris* and *Alex*. Their lovely company during our cabin trips, dinners, and Catan games, not to mention their wise advice and supportive friendship, have been invaluable. *Margherita*, who left us for Oslo, also deserves a mention, along with *Nina* and *Merete*, who are still in Tromsø. :)

I struggle with expressing my emotions through text, and I felt great pressure to properly thank the people who have supported me. If I have unintentionally missed someone, please accept my apologies in advance. To make up for it, you can choose your favourite dish, and I will cook it for you. Now, allow me to conclude these acknowledgements in Italian, the language of my heart.

Oggi, per me, la distanza è difficile e complessa, ma ciò che mi conforta è sapere che siamo il frutto di tutto ciò che ci ha circondato e dell'educazione che abbiamo ricevuto, le nostre origini insomma. Se oggi ho un fuoco dentro che mi spinge a vivere ogni esperienza con passione, è grazie ai miei genitori e a tutta la mia famiglia, sia sarda che calabrese. Un ringraziamento speciale a *Mamma Daniella* e *Papà Salvatore*, per non essere 'zumpati' e per il vostro incondizionato sostegno in questi anni. Un omaggio speciale va anche alla mia terapeuta *Luisa*, fondamentale in questo periodo storico difficile. E poi a *Sergio*, *Melina*, *Andrea*, *Erika* e *Grazia* per la loro amicizia sincera. Infine, un pensiero al *Separé* per le nostre chiacchierate da teneri romantici. Sono convinto che un giorno troveremo l'amore; non dobbiamo perdere la speranza, arriverà. Nel frattempo, io mi godo l'affetto di tutte le persone a me care.

Pietro, March 2024

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List of Papers

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Table 1.1: Included papers.

#	Refer to as	Title	REF
1	Review Paper (Journal)	**P. Randine**, A. Sharma, G. Hartvigsen, H. D. Johansen, and E. Arsand, "Information and Communication Technology-based Interventions for Chronic Diseases Consultation: Scoping Review," *International journal of medical informatics*, vol. 163, p. 104784, Jul 2022, DOI: 10.1016/j.ijmedinf.2022.104784.	[1]
2	Delphi Paper (Conference)	D. Larbi, **P. Randine**, E. Arsand, M. Bradway, K. Antypas, and E. Gabarron, "Criteria for Assessing and Recommending Digital Diabetes Tools: A Delphi Study," *Studies in health technology and informatics*, vol. 281, pp. 850-854, May 27 2021, DOI: 10.3233/SHTI210299.	[2]
3	Model Paper (Conference)	**P. Randine**, J. G. Cooper, G. Hartvigsen, and E. Årsand, "Towards a New Model for Chronic Disease Consultations," *in 18th Scandinavian Conference on Health Informatics*, Tromsø, Norway, 2022: Linköping University Electronic Press, Sweden, pp. 82-87, DOI: 10.3384/ecp187014.	[3]
4	Privacy Paper (Journal)	**P. Randine**, M. Pocs, J. G. Cooper, D. Tsolovos, M. Muzny, R. Besters, and E. Arsand, "Privacy Concerns Related to Data Sharing for European Diabetes Devices," *Journal of diabetes science and technology*, Nov 13 2023, DOI: 10.1177/19322968231210548.	[4]
5	Consent Paper (Conference)	**P. Randine**, E. Salant, M. Muzny, and L. Pape-Haugaard, "Consent Management System on Patient-Generated Health Data," *in 19th World Congress on Medical and Health Informatics (MedInfo)* 2023, 2024: IOS Press, pp. 204-208, DOI: 10.3233/SHTI230956.	[5]
6	Interoperability Paper (Journal)	**P. Randine**, M. K. Wolff, M. Pocs, I. Connell, J. A. Cafazzo, and E. Arsand, *"Obstacles in Accessing Real-Time Diabetes Data for Treatment and Research: Toward an Interoperability Model,"* 2024. (under-review)	[6]

List of Other Publications

Table 1.2 lists the published work during the PhD timeframe and not directly included as a contribution to this thesis:

Table 1.2: Other publications

Type	**Title**	**REF**
Journal Paper	D. Larbi, **P. Randine**, E. Arsand, K. Antypas, M. Bradway, and E. Gabarron, "Methods and Evaluation Criteria for Apps and Digital Interventions for Diabetes Self-Management: Systematic Review," *Journal of medical Internet research*, vol. 22, no. 7, p. e18480, Jul 6 2020, DOI: 10.2196/18480.	[7]
Journal Paper	M. Bradway, A. Giordanengo, R. Joakimsen, A. H. Hansen, A. Grottland, G. Hartvigsen, **P. Randine**, and E. Arsand, "Measuring the Effects of Sharing Mobile Health Data During Diabetes Consultations: Protocol for a Mixed Method Study," *JMIR research protocols*, vol. 9, no. 2, p. e16657, Feb 10 2020, DOI: 10.2196/16657.	[8]
Conference Paper	D. Larbi, M. Bradway, **P. Randine**, K. Antypas, E. Gabarron, and E. Årsand, "Do diabetes mHealth and online interventions evaluate what is important for users?," in *17th Scandinavian Conference on Health Informatics*, Oslo, Norway, 2019, Linköping Electronic Conference Proceedings: LiU: Linköping University Electronic Press.	[9]
Abstract	**P. Randine,** L. Pape-Haugaard, G. Hartvigsen, and E. Arsand, "Including Patient-Generated Health Data in Electronic Health Records - a Solution for CGM-Data," in *Diabetes Technology & Therapeutics*, Feb 2023, vol. 25, pp. A66-A66, DOI: 10.1089/dia.2023.2525.abstracts	[10]
Abstract	M. Bradway, D. Larbi, **P. Randine**, K. Antypas, E. Gabarron, and E. Arsand, "Intervention Studies Need to Adapt to Address Patient Needs for Diabetes Self-management," in *Diabetes Technology & Therapeutics*, 2020, vol. 22: MARY ANN LIEBERT, INC 140 HUGUENOT STREET, 3RD FL, NEW ROCHELLE, NY 10801 USA, pp. A149-A149.	[11]

List of Abbreviations

AGP	Ambulatory Glucose Profile
AKS	Azure Kubernetes Service
API	Application Programming Interface
CGM	Continuous Glucose Monitoring
CI/CD	Continuous Integration and Continuous Deployment
COVID-19	Coronavirus Disease
CSV	Comma-separated values
DiaDig	Diabetes Digital Guidelines
DIY	Do-It-Yourself
DPO	Data Protection Officer
DSR	Design Science Research
DSRM	Design Science Research Methodology
EEA	European Economic Area
EHR	Electronic Health Record
EU	European Union
FDA	Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
GDM	Gestational Diabetes
GDPR	General Data Protection Regulation
HCP	Healthcare Personnel or Healthcare Professional
HEIR	A Secure Healthcare Environment for Informatics Resilience
HL7	Health Level Seven International
IaaS	Infrastructure as a Service
iCoDE	Project Continuous Glucose Monitor Data Integration into the EHR
iCoDE2	Integration of Connected Diabetes Device Data into the EHR
ICT	Information and Communication Technology
ISO	International Organization for Standardization
IVDR	In Vitro Diagnostic Regulation
LOINC	Logical Observation Identifiers Names and Codes
MDR	Medical Device Regulation
NCD	Non-communicable disease
Noklus	Norwegian Diabetes Registry for Adults

OAuth	Open Authorization
OIDC	OpenID Connect
OpenAPS	Open Artificial Pancreas System
PAID	Problem Areas in Diabetes
PGHD	Patient-generated health data
PII	Personal Identifiable Information
PROMs	Patient Reported Outcome Measures
REST	Representational State Transfer
Sikt	Norwegian Agency for Shared Services in Education and Research
SNOMED CT	Systematized Nomenclature of Medicine—Clinical Terms
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes
U.S.	United states
WHO	World Health Organization

Part I: Synopsis

Your thesis is like your first love: it will be difficult to forget.
In the end, it will represent your first serious and rigorous academic work,
and this is no small thing.

Umberto Eco, *How to write a thesis*, MIT Press.

Chapter 1 Introduction

Nowadays, individuals with diabetes have a wide range of digital and health applications, such as mobile applications (apps) or more generic systems, to help them manage their diabetes. The combination of various software, hardware, and communication networks to collect data, especially disease-related ones, opens new approaches to exploring unexplored possibilities.

The core objective of the proposed information system, "Dia-Continua", is to develop a new model of medical consultation based on patient-generated health data. This model aims to introduce innovative functionalities designed to improve the consultation process between healthcare providers (e.g., doctors and nurses) and patients or their informal caregivers, thereby optimising treatment discussions and outcomes.

In this context, an information system for health is responsible for gathering data from the health sector and other relevant sectors. It then analyses this data while ensuring that it is of high quality, relevance, and timeliness. The system is designed to transform the data into actionable information to facilitate health-related decision-making. Additionally, it should provide support for monitoring and evaluation and have an alert and early-warning capability [12].

Although computer science may initially appear unrelated to chronic disease management, its significance has become increasingly evident. Specifically, technological advancements, such as Information and Communication Technology (ICT) encompassing eHealth (electronic health) [13], mHealth (mobile health) [14] and telemedicine [15], have assumed critical roles. The integration of smartphone applications, commercial wearable devices (e.g., smart watches or rings), and the Internet of Things (IoT) enables patients to monitor, record, and access their self-reported health data [16]. These ICTs highlight the potential to improve information exchange among patients, informal caregivers, healthcare personnel, and health authorities [17].

Explaining the context of the dissertation in this introductory chapter is crucial. It clarifies the circumstances and rationale for developing the Dia-Continua information system.

1.1 Background, Context and Challenges

Non-communicable diseases (NCDs), or chronic diseases, constitute a major global health challenge due to their long duration involving genetic, physiological, environmental, and behavioural factors. Unlike infectious diseases, NCDs are non-transmissible and largely preventable through effective long-term management strategies, including regular medical attention and lifestyle modifications [18].

The burden of chronic diseases extends beyond individual patients, significantly impacting healthcare systems and social structures through direct factors, such as increased healthcare expenses [19] and indirect costs, like decreased productivity [20].

To address these challenges, the management of chronic diseases requires an integrated approach that encompasses not only continuous medical care but also the support of informal caregivers (e.g., family and spouses) [21, 22]. Proper chronic disease management can lead to improved quality of life, reduced healthcare costs, and better health outcomes. On the contrary, ineffective management can worsen the condition, leading to decreased patient well-being and increased healthcare costs [18].

1.1.1 Chronic Diseases and a Healthy Lifestyle

The diagnosis of a chronic disease significantly changes individuals' lives, obliging them to adopt self-management strategies for effective daily management of their condition [23], which may involve tasks such as maintaining a consistent medication routine, engaging in physical or occupational therapy, following a specific diet, and exercising regularly [24]. Such elements, while essential for managing chronic diseases, also align with the practices of a healthy lifestyle that is beneficial for the general population.

A healthy lifestyle is characterised by three crucial pillars: a balanced diet, regular physical activity, and adequate sleep. These pillars are vital in preventing some chronic diseases, mitigating risk factors, and reducing complications associated with NCDs. **Figure 1.1** illustrates the hierarchical importance of these three pillars in promoting a healthy lifestyle.

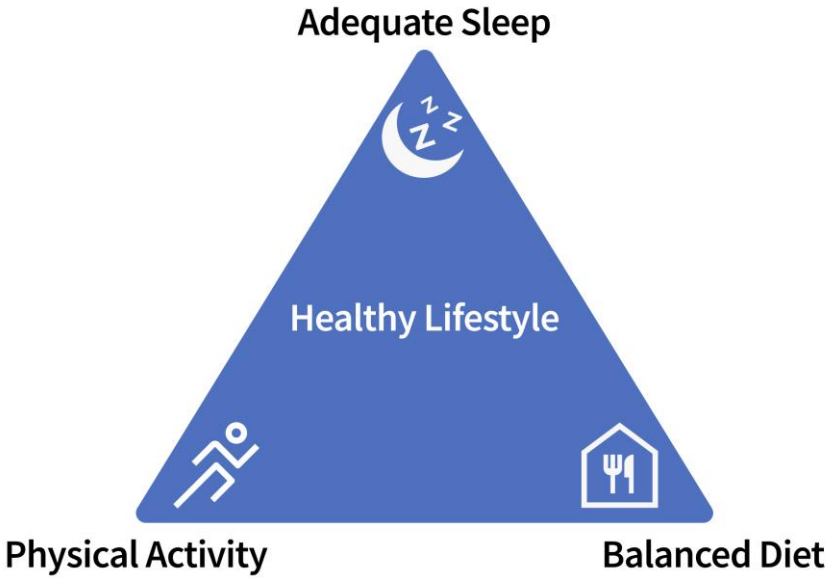

Figure 1.1: Three pillars for a healthy lifestyle.

Quality sleep is essential for boosting immune defences and reducing the risk of various diseases [25]. Insufficient sleep has been linked to an increased risk or worsening of chronic diseases [26, 27], and they are also associated with weight gain and obesity [28], both factors that elevate the risk of developing type 2 diabetes and some other chronic diseases [29]. The recommended sleep duration for adults between 18-64 years is 7 to 9 hours per night [30]. There are several commercial wearable devices available in various forms (e.g., rings, smartwatches) for measuring the different sleep phases

(e.g., deep sleep, light sleep) and factors [31] to provide feedback to improve an individual's sleep quality.

Regular physical activity is associated with a lower risk of chronic diseases and more than 40 chronic conditions, such as cardiovascular disease, diabetes, and cancer [32]. The World Health Organization (WHO) recommends 150–300 min moderate-intensity or 75–150 min vigorous-intensity physical activity per week for adults [33]. Furthermore, while wearable devices collecting only sleep data may be considered a niche market, physical activity trackers have gained an extensive market [34], emphasising their importance to improved health.

Lastly, a healthy diet plays a key role in preventing obesity, diabetes, and cardiovascular diseases [35, 36]. Physical activity and diet are interconnected elements that need to be in place for a healthy lifestyle and proper chronic disease management and prevention [35]. The following section will describe how these elements affect people with diabetes, the primary chronic condition addressed in this PhD project.

1.1.2 Type 1 Diabetes

This PhD project will focus on Type 1 Diabetes, a condition that is part of the broader category of diseases known as Diabetes Mellitus, which affects the endocrine system [37]. Diabetes Mellitus includes two primary conditions: Type 1 Diabetes (T1D) and Type 2 Diabetes (T2D). Additionally, Gestational Diabetes Mellitus (GDM) may develop in pregnant women, usually resolving after pregnancy. Another related condition is Prediabetes, where blood glucose levels are higher than normal but not high enough to be classified as diabetes, indicating an increased risk of developing T2D.

Managing diabetes involves various medical devices. These include blood glucose meters, continuous glucose monitoring (CGM) devices, insulin pumps, and hybrid closed-loop systems, some of which are integrated with mobile applications. The combination of medical devices and software has crucial roles in diabetes care [38-40], as detailed in Section 3.1, which will present the State-of-the-Art regarding these essential tools and their impact on patient management and consultation. In understanding diabetes management, it's also essential to grasp the basics of glucose metabolism. During food digestion, carbohydrates break down into glucose, which is carried by the bloodstream to various organs of the body. The mechanism that regulates the glucose level involves multiple hormones. The most effective regulators of glucose metabolism are α-cells (Glucagon) and β-cells (Insulin and Amylin), both produced by the pancreas. Furthermore, L-cells (e.g., Synthetic glucagon-like peptide-1) released by the intestine have an active role in this process (Glucose homeostasis) [41].

T1D or, more generally, people with Insulin-Dependent Diabetes Mellitus require insulin injection to supplement a deficiency caused by an autoimmune reaction that destroys the β-cells, leading to a high blood glucose level [42]. Therefore, individuals with the condition require daily insulin administration via injection to avoid high blood glucose levels and stay alive.

The previously described pillars of a healthy lifestyle (sleep, physical activity, and diet) also impact glucose metabolism. Insufficient sleep not only affects hormonal changes, particularly metabolic hormones like insulin and glucagon, which play a crucial role in regulating blood glucose levels [43], but it also disrupts both ends of the metabolic blood sugar equation, leading to fluctuations in glucose levels [43]. A study conducted using Fitbit smartwatches revealed that even in healthy individuals without diabetes, the lack of sleep impaired the body's ability to regulate blood sugar and absorb glucose [44]. This highlights the significant impact of sleep on glucose control. The reciprocal relationship between sleep and glucose regulation is well-established, with sleep disturbances contributing to impaired glycaemic control and disrupted sleep patterns. Meanwhile poor glycaemic control can disrupt normal sleep patterns [45].

Physical activities are crucial in promoting overall health and achieving optimal glycaemic control in individuals with diabetes. Specifically, for individuals with diabetes, it is recommended to engage in a minimum of 150 minutes of moderate-intensity exercise per week. Additionally, incorporating 2-3 days of strength training (e.g., weightlifting) into their routine can help reduce cardiovascular risk [33, 46].

Carbohydrates play a crucial role in the glucose mechanism. However, the estimation of carbohydrates is challenging to perform. There are multiple ways to record carbohydrate intake [47, 48]. Although various methods exist to log carbohydrate consumption, there is no fully mature machine learning algorithm or technological solution to estimate the carbohydrate content of foods [49]. Most carbohydrate intake by individuals with diabetes is based on the patients' estimations.

Understanding the intricate dynamics of glucose metabolism is fundamental to manage T1D effectively. Factors such as smoking, alcohol consumption, stress, and others significantly impact blood glucose levels, making diabetes management challenging [45]. Some of these factors are graphically summarised by the non-profit organisation diaTribe [50] in **Figure 1.2**.

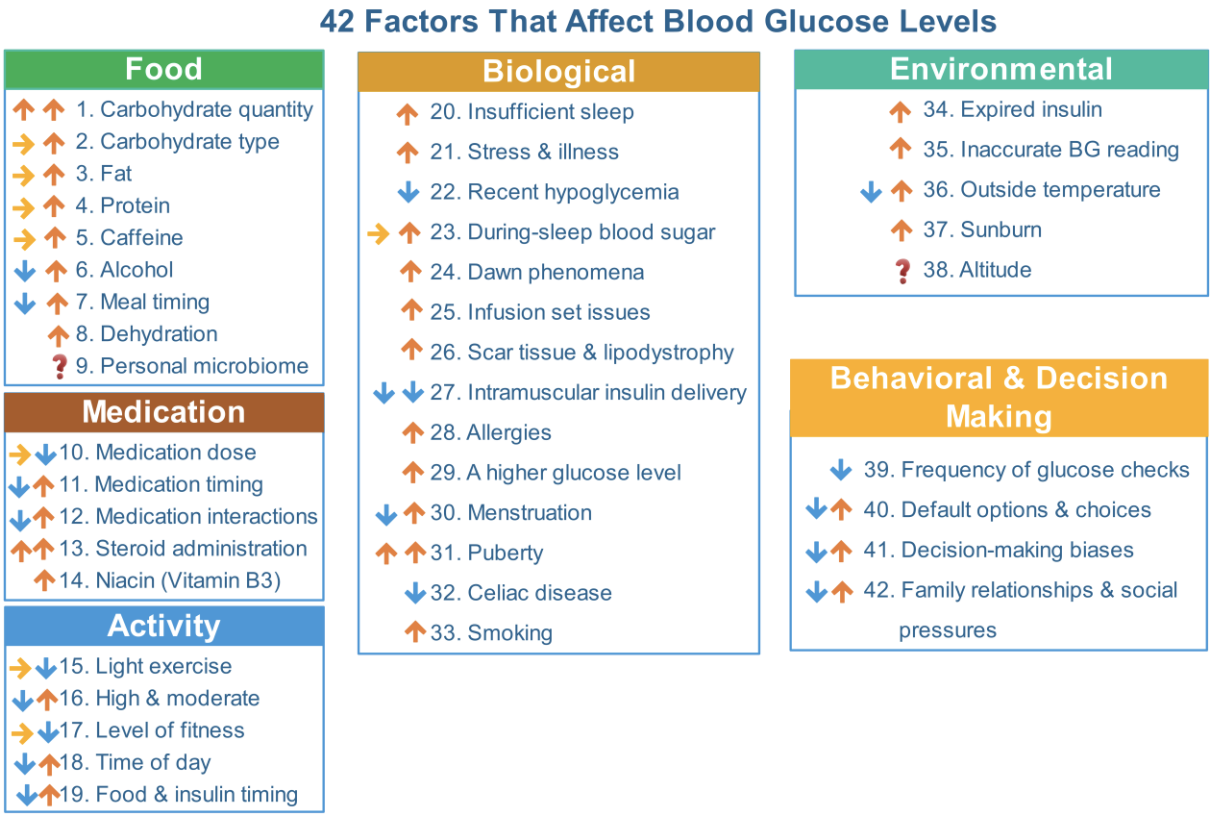

Figure 1.2: 42 factors that affect blood glucose levels. Modified from diaTribe reference [50].

1.1.3 The Need for a Unified Information System in Diabetes Consultation

To illustrate the challenges in the current consultation process, two fictional cases related to T1D, represented by the personas Rosa and Erik, are presented. These cases serve as a starting point to highlight the complexities and difficulties faced by individuals with diabetes and HCP during consultations. These consultations occur regularly [51] and serve as an important opportunity to help patients better comprehend the nature of the disease [52] and gain clarity or improve the different self-management activities they need to engage in [24].

The first scenario focuses on Rosa managing her diabetes with Abbott's FreeStyle Libre 2 system [53]. When Rosa visits her endocrinologist, the consultation begins with her registration in the Electronic Health Record (EHR) system. However, to access Rosa's diabetes data, the doctor needs to navigate through the Abbott system called LibreView in this example (see **Figure 1.3** part A). This process involves various steps, such as logging into the system, remembering usernames and passwords, and searching for the relevant information.

After accessing data in LibreView (see **Figure 1.3,** part A), a third-party system at the medical consultation site (e.g., hospital clinic), the endocrinologist may record Rosa's values on paper or use a digital approach by copying and pasting the information via the computer and switching between the different systems. Subsequently, the HCP updates Rosa's information in both the EHR system and, if applicable, the national diabetes registry system for national statistics [54] (see **Figure 1.3** part B).

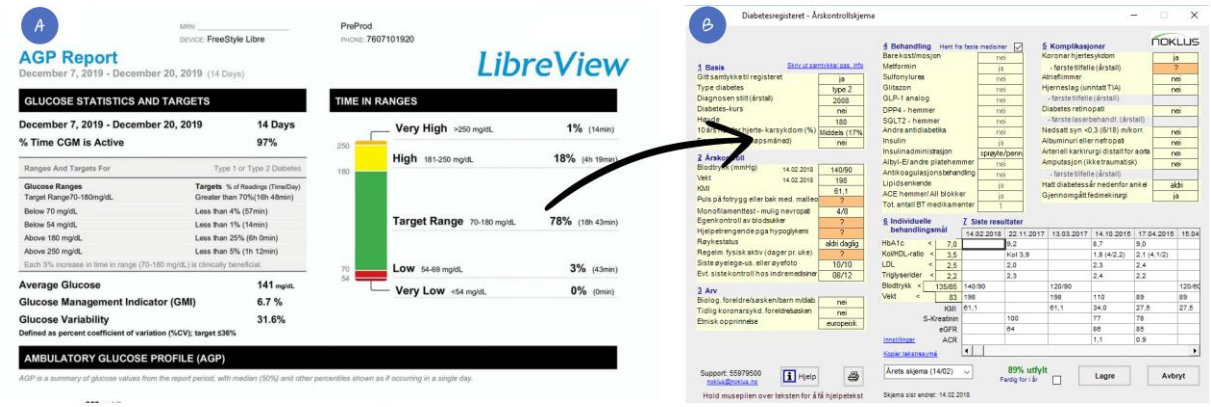

Figure 1.3: Challenges in transferring diabetes data between systems. Part (A) showcases the LibreView Third-Party System, a platform for healthcare professionals to access diabetes-related information, with modifications based on Figure 1 from the reference [55]. Part (B) displays the National Diabetes Registry for Adults (Noklus) interface used by endocrinologists to update and maintain comprehensive patient records within the national registry, reproduced from reference [54].

These semi-manual data entry methods can introduce errors or inconsistencies in the recorded information [56]. Moreover, the existing consultation practice may not adequately account for data from Rosa's wearable devices or physical activity information recorded by mobile applications or wearable devices. These additional sources of data, which could provide valuable insights into Rosa's health and well-being, are not fully integrated into the consultation process. As a result, important information related to Rosa's physical activity or lifestyle choices may not be considered during the consultation, potentially limiting the healthcare provider's understanding of her overall condition. This situation is valid for both T1D and T2D and for most other health conditions as well.

The second case involves Erik, who utilizes a Medtronic MiniMed 780G device [57] for managing his diabetes. During the consultation, the endocrinologist must access Erik's diabetes data, which is stored in the Medtronic System, another third-party system [57] (see **Figure 1.4**, part A). When Erik visits his endocrinologist, the consultation may also focus on addressing Erik's diabetes-related psychosocial issues or concerns. In this context, it is important to note that patients like Erik may track additional health parameters, such as sleep patterns, which can provide valuable insights into their overall well-being and help detect potential health issues [58] (see **Figure 1.4**, part B).

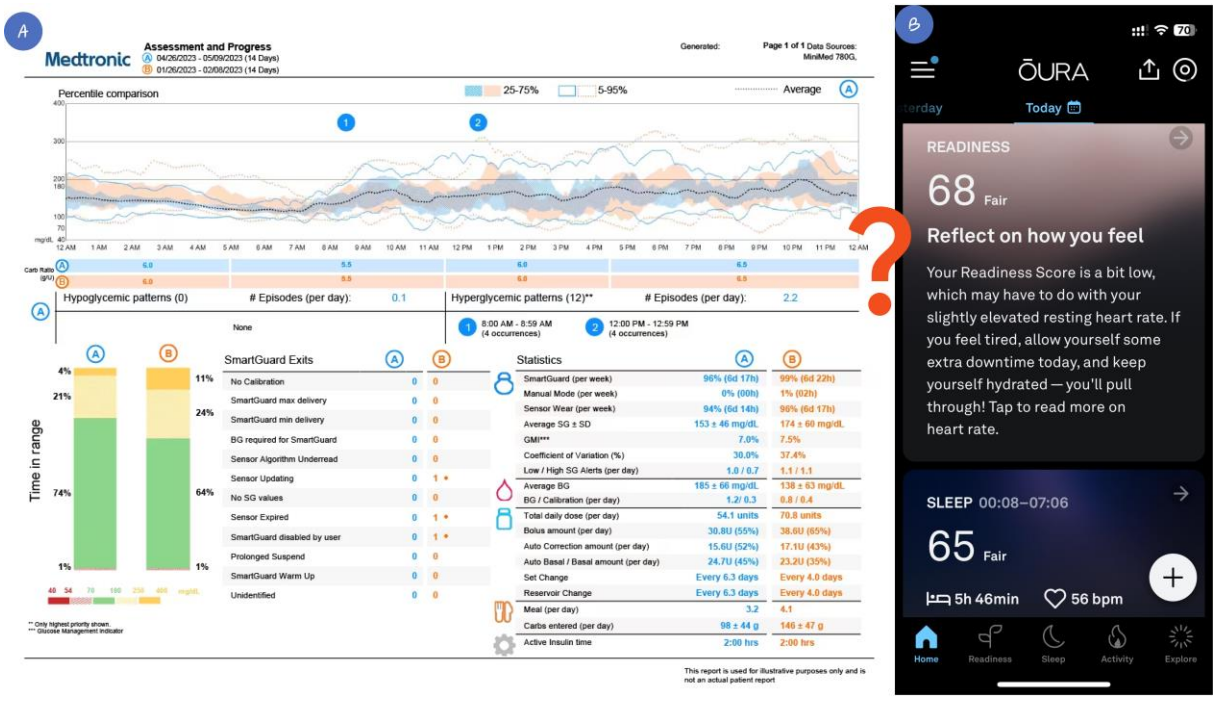

Figure 1.4: Bridging the gap: integrating diabetes and lifestyle data. This figure illustrates the missing connection between health-related diabetes data (A), exemplified by a third-party system like the Medtronic System, and lifestyle-related data (B), shown here as sleep patterns tracked by the Oura mobile application. Adapted from references [57] for diabetes data and [58] for lifestyle data.

Currently, in diabetes consultation, there is an opportunity to assess the patients' well-being and overall status through validated questionnaires, such as the PAID (Problem Areas in Diabetes) or other Patient Reported Outcome Measures (PROMs) [7]. By utilizing these questionnaires, healthcare professionals can gather additional information contributing to a more holistic assessment of the patient's overall health and well-being.

Like the previous case, Erik's medical consultation requires the health personnel to navigate a different system to retrieve the relevant information. Accessing data from a separate system adds complexity and may consume extra time during the consultation. The complexities are also relevant for patients and informal caregivers [59, 60]. During the consultation, the endocrinologist reviews Erik's data and records essential values on paper. Subsequently, the healthcare provider updates Erik's information in the EHR system and the national diabetes registry system. This manual data entry process adds another layer of complexity and increases the risk of errors and data discrepancies [61].

Regarding both Rosa and Erik's consultations, today's practice is that most of the discussions with the health personnel are conducted orally, and the information about lifestyle (e.g., physical activity, sleep) is not part of the medical vendors or EHR reports. Therefore, not all this information is reported and documented in the EHR or any other system. As a result, there is a risk that patients may forget important details about what was discussed and the agreed-upon plan of action until their next consultation.

Relying on oral communication alone can lead to misunderstandings or incomplete recollections of the information shared during the consultation. Patients may struggle to remember specific instructions, medication changes, lifestyle recommendations, or other essential aspects of their care plan [62]. This can affect their ability to manage their condition between consultations effectively and may impact the overall effectiveness of the treatment [61, 63]. Moreover, the process that health personnel must undergo to access and update patient data during a medical consultation is extensive, as shown in the examples of Rosa and Erik. This process has various steps, including patient registration in one system, retrieval of data from multiple third-party systems, and subsequent updating of the data in the primary EHR system. Evidently, this process could be inefficient and pose challenges in the effective utilization of the data and the efficacy of the consultation.

In summary, three crucial points can be discerned from these observations:

- **Multiple Systems:** Patient data is distributed in various proprietary systems, including the EHR system, medical vendors' third-party systems, national diabetes registry and third-party systems for non-medical information such as physical activity and sleep. This data distribution across multiple systems makes it challenging for healthcare providers to access and consolidate complete patient information during a consultation, leading to information fragmentation and less effective and efficient treatment for patients [64].
- **Multiple Devices:** In the given examples, Rosa uses an Abbott's FreeStyle Libre 2, while Erik uses a Medtronic MiniMed 780G device. These devices have different interfaces and collect diverse information [53, 57, 65]. As a result, healthcare providers must navigate systems to access the relevant patient data, further contributing to information fragmentation.
- **Multiple Formats:** Multiple systems and devices lead to multiple ways of storing with different format. Notably, a standardized method for representing insulin data is lacking [66, 67].

These points introduce the technological challenge that extends beyond information fragmentation, including security, privacy, and data ownership. It is important to emphasize that patients own their data. Additionally, challenges emerge when sharing this data with other entities, like external entities such as national registries, device vendors, and informal caregivers. Overcoming these technological challenges requires a comprehensive approach that considers various factors.

1.1.4 Collaboration with Research Projects

This doctoral dissertation presents the results of research carried out during the PhD candidate's doctoral studies in the Health Informatics and - Technology (HIT) group. The research group's previous experience within the last 25 years represents a heritage for this project.

As a brief background, the HIT group was established in 1994. It has a long tradition of collaborating with the University Hospital of North Norway (UNN), the main hospital in Tromsø, and its associated research centres. The collaboration is mainly with the Norwegian Centre for E-

health Research (NSE), formally known as the Norwegian Centre for Integrated Care and Telemedicine (NST), until 2016.

The coming subsections (1.1.4.1 and 1.1.4.2) present two relevant projects linked to this PhD project. They are all focusing on Diabetes from different perspectives.

1. **DiaDig** – Diabetes Digital Guidelines founded by Helse Nord (HNF1425-18).
2. **HEIR** – A secure Healthcare Environment for Informatics Resilience founded by the Horizon 2020 Research and Innovation program (grant agreement No 883275).

1.1.4.1 Diabetes Digital Guidelines (DiaDig) 2018-2020

The Diabetes Digital Guidelines project, in short DiaDig, was funded by the Northern Norway Regional Health Authority, Helse Nord (HNF1425-18). It aimed to design and validate instruments to assess the efficacy, effectiveness, and safety of digital and health applications targeting the Norwegian population with diabetes.

The research project produced multiple publications [2, 7, 9], significantly influencing the information system evaluation presented in this PhD dissertation. For further insights into the evaluation process, including specific details, refer to Chapter 2 Research Discipline and Methodology (Section 2.2.3).

Notably, one of the publications included in this dissertation [2] was made possible through the support of the DiaDig project funding. This funding enabled the recruitment of 15 healthcare professionals with specialized knowledge in diabetes who participated in a Delphi study. The Delphi study is an established technique used to reach a consensus and collect expert opinions [68], and the result [2] will be presented in Section 4.2.2.

1.1.4.2 HEIR – A secure Healthcare Environment for Informatics Resilience 2020 - 2023

A Secure Healthcare Environment for Informatics Resilience referred to as the HEIR project, was a Horizon 2020 research project funded by the European Community's Horizon 2020 Research and Innovation Programme under grant agreement no. 883275.

The HEIR project was dedicated to advancing science and technology in healthcare, with a strong focus on privacy and data security. It included four pilot studies, one of which was led by NSE in collaboration with the Norwegian Diabetes Registry for Adults, also known as Noklus [54]. This pilot aimed to showcase the secure exchange of patient diabetes data, especially CGM data, with Noklus.

Throughout the project, the author of this dissertation actively participated, working closely with a network of researchers and healthcare professionals at Noklus, as well as international lawyers and industries. This collaborative effort resulted in the publication of two papers [4, 5], which are included in this dissertation.

1.2 Project Goals

The PhD project focuses on new functionalities for diabetes consultations with a secure data exchange, storage, and interaction between patients, healthcare providers, and research institutions. This research project aims to enhance the quality of information, privacy and security in the healthcare system, specifically focusing on individuals with Type 1 Diabetes.

The project aims to improve the overall experience of medical consultations by conceptualizing them as a continuous process that extends beyond a single visit. This project aims to introduce a medical consultation approach involving three key phases: preparation, consultation, and follow-up. We exemplified this with the use case of T1D, where we propose the inclusion of three different phases before, during and after the consultation (see **Figure 1.5**).

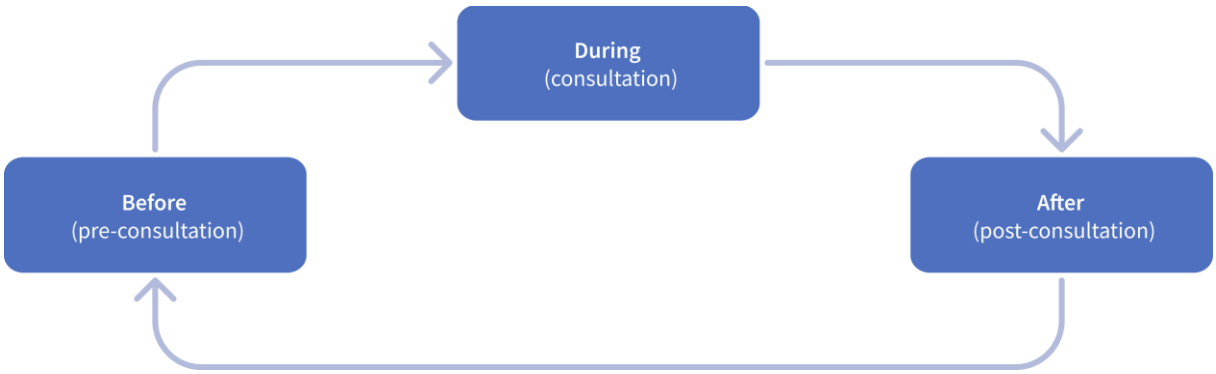

Figure 1.5: Three different phases before, during and after the consultation.

The novelty of this project extends beyond analysing patients' improved access to health-related information through various technologies, including monitoring devices, mobile apps, and other tools. It further explores and proposes new approaches to utilising this information for medical consultation with HCPs and sharing it with health institutions, such as national diabetes registries. These advancements may empower patients to engage in healthcare decisions, and healthcare organisations may actively use these data.

This project investigates the innovative opportunities that arise from the flow of information from patients to healthcare personnel [17]. It focuses on how this information exchange can streamline decision-making processes during consultations and contribute to the creation of new care plans for patients. The information sources for this research project focus on diverse technologies categorised under ICT within the scope of the PhD dissertation. ICT is an umbrella term encompassing multiple sources like medical devices (e.g., CGM, glucometer, insulin pump) currently used by most individuals with diabetes in high-income countries, and commercial wearable devices for people in general (e.g., physical activities tracker, smartwatches).

1.2.1 National Relevance

The project initiated in 2019 was in line with distance monitoring for chronic disease proposed by the Norwegian Directorate of Health in 2018 [69]. Within this PhD project, several elements are of

national significance in Norway, particularly related to medical distance monitoring in Norwegian: "medisinsk avstandsoppfølging".

The introduction of remote medical monitoring was expected to bring several advantages, including improved physical and mental health for patients, enhanced patient experience, and cost savings for the healthcare system. This is especially relevant in remote areas of Norway, where travelling can be expensive in terms of costs and time [69]. Regarding the early detection of symptoms, remote medical monitoring can prevent the progression of diseases and allow for remote or in-person consultations when needed. Moreover, it can also help avoid unnecessary travel and appointments in cases where the disease is well-managed. This should optimise healthcare resources and reduce the burden on the system. Incorporating remote medical monitoring into the Dia-continua system and integrating patient-generated health data into a single system may support optimising healthcare resources.

1.2.2 International Relevance

To better understand the project's international relevance and goals, it is necessary to take a step back and reflect on 2019, when the project started since it about one year after the General Data Protection Regulation (GDPR) became effective in Europe Union (EU), on May 25, 2018 [70].

The GDPR impacted companies' and governments' collection, storage, and sharing of personal information. It represented a critical turning point in data protection and privacy practices. The regulation covers various personal identifiable information (PII), including names, contact details, computer locations, and health data. The most significant change was that organisations needed to demonstrate a legal basis for retaining such data and, more importantly, establish measures to ensure its security [70].

Under GDPR, individuals gained the right to access their personal data. Additionally, the regulation introduced the Right to data portability [70], enabling individuals to reuse their personal data for their own purposes. Furthermore, GDPR grants individuals the right to request the deletion of their data, commonly referred to as the Right to be forgotten. These conditions significantly empower individuals to control and manage their personal information.

Furthermore, the impact of the GDPR extends beyond Europe, as companies operating in European countries and organisations outside of Europe that store data belonging to EU citizens must also comply with the regulations. Therefore, the GDPR has implications on a global scale and has led to a shift in how data is perceived worldwide [71]. The project must adhere to GDPR and protect PII to ensure data privacy and security.

1.2.2.1 EU communication on the Digital Transformation of Health and Care in the Digital Single Market (2018)

When considering health data, as in this PhD project, the initial focus was on the EU communication on the Digital Transformation of Health and Care in the Digital Single Market [72]. The EU communication, published in 2014 and updated in 2018, set out several key objectives, like

promoting citizen-centred care, integrating health and social care systems, supporting research and innovation in digital health, and facilitating cross-border access to healthcare services. The document highlighted the importance of interoperability, exchanging data, and securely and efficiently using health data across different countries. It emphasizes the potential of digital technologies like EHR through open exchange formats and data analytics in improving healthcare delivery and empowering patients [72].

Since its beginning, this EU communication of 2018 has influenced this project, aligning with the broader goals of digital transformation in healthcare. It recognizes the significance of interoperability, data exchange, and the secure use of health data, which are important considerations within the European Union and the global healthcare landscape. By incorporating these principles, the project contributes to advancing the digital transformation agenda and addressing key concerns in healthcare. On the other hand, it promotes patient empowerment and engagement in their healthcare since it aims to give individuals greater control over their health information, allowing them to make more informed decisions about their care and treatment.

Integrating these aspects (i.e., interoperability, data exchange, patient empowerment and engagement) in this PhD project is essential for developing a comprehensive solution that meets technological and regulatory standards and promotes the patient's engagement in their care.

1.2.2.2 Health European Data Space initiative (2022)

Starting from the Digital Transformation of Health and Care in the Digital Single Market [72], the project has been aligned with the evolving landscape of healthcare data management. Over the years, the establishment of the GDPR and the initiation of the Health European Data Space initiative in 2022 have further emphasized the importance of data protection and secure data exchange in the healthcare domain [73]. The GDPR has introduced stringent regulations for handling personal data, including health information, to safeguard individuals' rights and privacy [70]. Simultaneously, the Health European Data Space initiative aims to create a trusted and secure environment for exchanging health data across Europe [73].

The project goals are in line with the EU's proposal for the European Health Data Space, which aims to support individuals in taking control of their health data, promote the use of health data for better healthcare delivery, research, innovation, and policy making, and enable the EU to fully utilize the potential offered by a safe and secure exchange, use, and reuse of health data.

These objectives (i.e. individuals in taking control of their health data, reuse of health data) reinforce the project's commitment to contributing to the broader European agenda of advancing healthcare through digital transformation, fostering patient empowerment, and facilitating improved healthcare outcomes.

1.2.2.3 Sustainable Development Goals (2016-2025)

Many people will develop at least one chronic disease in later life. 65% of people over 65 have more than one disease, and this number rises to 85% for people over 85 [74]. With the global population getting older, there is an underlying need to strengthen information systems to address the expected increase in the occurrence of NCDs [74, 75].

According to the European Commission, it was estimated in 2016 that treating NCDs, like Diabetes, consumes 70 to 80% of healthcare budgets, totalling over 700 billion euros annually. Alarmingly, only 3% of these budgets are allocated to prevention, with the remaining 97% focused on treatment, chronic disease management, and healthcare administration. In response to this trend, the WHO developed an action plan to prevent and control NCDs in the European Region (2016–2025). One of the objectives outlined in this plan is strengthening health information systems to enhance prevention and control efforts related to NCDs [74].

Assisting patients in self-management plays a crucial role in alleviating the impact of chronic diseases [19]. NCDs disproportionately affect individuals in low- and middle-income countries, accounting for 70% of all deaths, with over three-quarters of global NCD deaths occurring in these regions [75]. In 2015, world leaders came together and established 17 Global Goals with a target deadline of 2030. Goal 3, represented in **Figure 1.6**, focuses on Good Health and Well-being and includes target 3.4, specifically addressing NCDs [76].

Figure 1.6: Advancing Target 3.4: promoting Good Health and Well-being. Source reference [76].

1.3 Problem Statement and Research Questions

To guide the research work within this project and to contribute to achieving the project goals (Section 1.2), it is possible to state the main research problem as follows:

Design a unified information system capable of integrating patient-generated health data to improve the quality of information during medical consultations. This system should navigate through fragmented information and the complexities of various data formats, proprietary interfaces, and storage methods while ensuring robust security, privacy, and adherence to data ownership principles. It should facilitate controlled data sharing with healthcare providers and external entities like national registries and informal caregivers.

The problem statement is divided into three research questions to answer such an extensive problem.

1.3.1 Research Question 1

RQ1. How can we integrate different health-related devices used daily by individuals with diabetes and patient-generated health data into a unified information system for patients and health personnel to use before, during, and after medical consultations?

Description RQ1: A health-related device represents a medical device used daily by individuals with diabetes and provided by health authorities (e.g., CGM, patch pump, hybrid closed loop system), and a commercially wearable device (e.g., smartwatch, smart ring) that provides patient-generated health data related to the user's health or lifestyle. As illustrated in Section 1.1.3, these devices are not integrated into a unified information system before, during or after the medical consultation (refer to **Figure 1.7**).

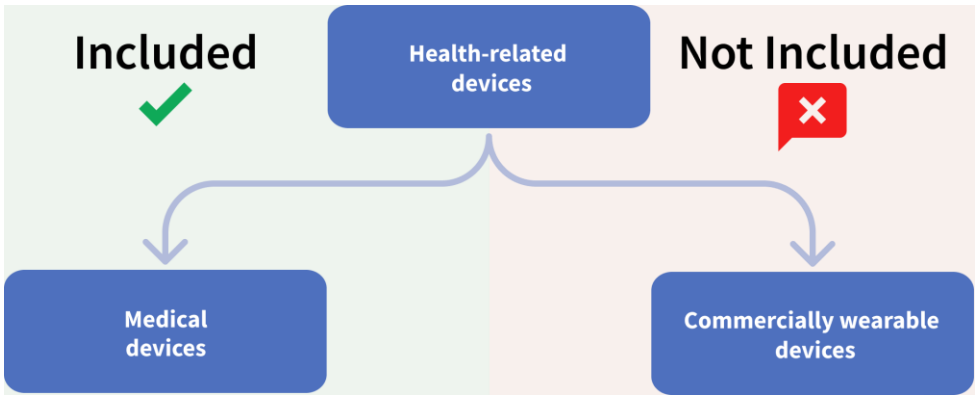

Figure 1.7: Devices included in the medical consultation.

These two classes of devices (see **Figure 1.7**) share the commonality of being the intellectual property of third-party companies. Consequently, patient-generated health data generated by these devices is often accessible only via proprietary systems with a specific format, affecting the integration and limiting the possibilities in information system design.

Section 1.1.3 presented several scenarios where HCPs must access multiple and diverse vendor systems to access patient data. The health personnel adapt to systems, not vice versa, leading them to use multiple third-party systems based on different patient equipment.

1.3.2 Research Question 2

RQ2. How can patient-generated health data be exchanged between clinicians, patients and informal caregivers before, during and after the consultation, with robust security and privacy measures?

Description RQ2: The integration of diverse patient-generated health data (PGHD) —sourced from applications, sensors, wearables, and automated, self-reported inputs into a single information system presents a significant challenge in contemporary healthcare. This challenge requires ensuring the secure and private exchange of data across various formats and volumes. A critical aspect of this process involves aligning with security and privacy principles that empower patients with control over their data in accordance with initiatives like the European Union's European Health Data Space [73] (Section 1.2.2.2). Addressing these concerns requires a focus on interoperability and the standardized exchange of data, utilizing frameworks such as Fast Healthcare Interoperability Resources (FHIR) and OpenEHR, to facilitate the effective reuse of information [77].

Moreover, deploying secure platforms or systems that conform to the latest standards and best practices for data security offers a solution for the future. Such systems need to implement robust security measures, including data encryption, stringent access controls, and comprehensive consent management. These measures safeguard the confidentiality and integrity of personal identifiable information (PII) and ensure its security throughout its lifecycle—from collection and processing to analysis and application in primary and secondary use.

1.3.3 Research Question 3

Once a single information system successfully collects PGHD (RQ1) and securely shares personally identifiable information for both primary and secondary use (RQ2), the next challenge is to use this data and evaluate its impact on the medical consultation process.

RQ3. How can individual-specific patient-generated health data improve the information quality during the medical consultation?

Description RQ3: Health informatics systems are expected to maintain the continuity of care, shared care, and the empowerment of patients in the management process [78]. In practice, it means that healthcare aims for patients' continuity of care, not viewing them as passive consumers of health services but as responsible for their treatment and decisions. This is especially relevant for patients with chronic conditions that rely often on self-management [22, 23].

This research question focuses on enhancing the quality of information in medical consultations through a patient-centred approach, encapsulated by the concept of *"P5 medicine"*. That calls for

preventive, predictive, personalised, participatory and psycho-cognitive medicine [79], as listed in **Table 1.1** with a brief explanation.

Table 1.1: P5 in eHealth.

P5 element	**Short explanation**
Preventive	Taking action to control a disease rather than just responding to it after it has happened.
Personalized	Tailoring interventions on people's needs, abilities, context and decision-making priorities.
Predictive	Having the effect of predicting an event or result.
Participatory	Allowing different stakeholders (e.g., patients, relatives, healthcare providers, policymakers) to take part in or become involved in an activity (e.g., design, testing, developing).
Psycho-cognitive	Emphasize the patients as a unique human being in their behavioural, psychological, and emotional aspects.

Source [79].

This project's challenge is using PGHD for the 3P described in **Table 1.1** (preventive, predictive, personalized) and the empowering patient as described by the last 2P (participatory and psycho-cognitive). Meanwhile, the evaluation measure (i.e., information quality) was selected based on collaboration with the DiaDig project presented in Section 1.1.4.1.

Diabetes presents a unique example of personalized medicine due to the presence of active communities on social media platforms, such as the #WEARENOTWAITING movement [80]. These communities consist of well-informed patients and engage relatives who have taken the initiative to formulate, develop, and distribute solutions to address their specific challenges. Their efforts have influenced vendors and researchers and advocated for improved treatment options [81].

1.4 Dissertation Structure

The remaining chapters are organized as follows:

Chapter 2 Research Discipline and Methodology, present the academic discipline of this PhD project (Section 2.1) and details the Design Science Research Methodology (DSRM) applied for the Dia-Continua information system's design, development, and evaluation (Section 2.2). It also discusses the project's strengths and limitations (Section 2.3).

Chapter 3 State-of-the-Art reviews current systems in diabetes management and medical consultations (Section 3.1), examines how health information is exchanged with a focus on interoperability (Section 3.2), and provides an snapshot of relevant standards and regulations (Section 3.3)

Chapter 4 Result presents both published and unpublished materials. It begins with an overview of the results (Section 4.1), the summary of the research papers included in this dissertation and their contributions to the research questions (Section 4.2). Unpublished material follows, detailing the technical implementation of the Dia-Continua information system (Section 4.3) and the outcomes of system testing and evaluation through semi-structured interviews with healthcare professionals (HCPs), focusing on real patient use cases and assessing information quality (Section 4.4).

Chapter 5 Discussion: engages in a comprehensive discussion organized around the three main research questions, addressing how the project's findings relate to each (Section 5.1 addresses RQ1, Section 5.2 addresses RQ2 and Section 5.3 addresses RQ3).

Chapter 6 Conclusion: concludes the dissertation by summarizing the findings in relation to the research questions (Section 6.1). It suggests potential directions for future research considering new regulatory challenges (Section 6.2) and concludes with the candidate's personal reflections on the project's journey (Section 6.3).

Chapter 2 Research Discipline and Methodology

Chapter 2 provides a comprehensive overview of the research methodology for this PhD project in Health Informatics (Section 2.1). It discusses the importance of integrative research in Health Informatics (Section 2.1.1), the process of creating new knowledge throughout the PhD project's journey (Section 2.1.2), and the significance of extending collaboration beyond the PhD to amplify its impact (Section 2.1.3). This chapter also explains the application of the Design Science Research Methodology (DSRM) Process Model (Section 2.2), in the design, development, and evaluation of the Dia-Continua Information System for Type 1 Diabetes. Section 2.2 covers the design and development (Section 2.2.1), demonstration (Section 2.2.2), evaluation (Section 2.2.3), and the communication of findings (Section 2.2.4). Lastly, the chapter assesses the strengths and limitations encountered throughout the project (Section 2.3).

2.1 Health Informatics

All the different sciences, such as natural sciences, social sciences, empirically based science, and analytical science, are problem-solving activities that acquire knowledge about phenomena. Before how the project aims to acquire new knowledge, later presented in Section 2.1.2, it is necessary to discuss the research discipline of this PhD.

This project is under the Faculty of Science and Technology at the Department of Computer Science and aims to produce new knowledge mainly in Health Informatics. Health informatics, it is the field of science and engineering that concerns the use of Information and Communication Technologies (ICTs) within healthcare [82]. Working with health informatics often implies different research fields (e.g., eHealth, mHealth, Telemedicine) and overlapping usage of ICTs [83], as shown in **Figure 2.1**.

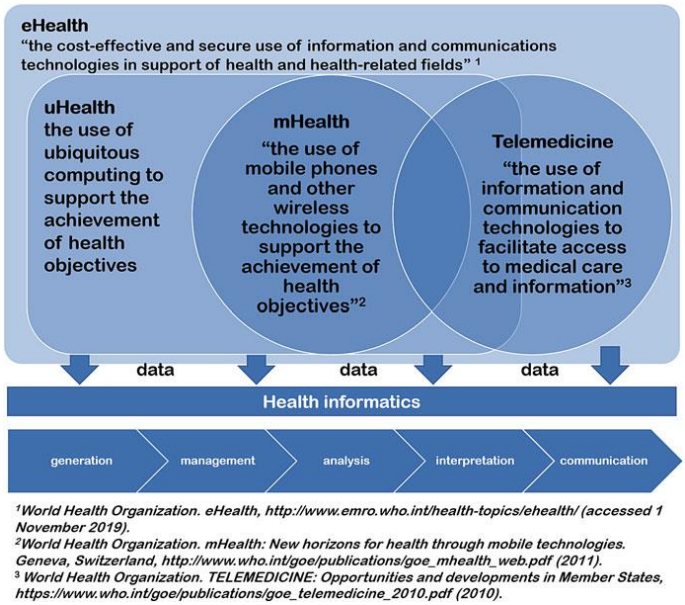

Figure 2.1: Concepts in the field of digital health. Figure reproduced from Figure 1.1 reference [83].

Although eHealth is often used interchangeably with Health Informatics, the two terms have different focuses. As shown in **Figure 2.1**, the former refers to the application of technology [83], while the latter is a field of science [82].

2.1.1 Integrative Research in Health Informatics

Today, in the academic world, interdisciplinarity is often the key to producing new knowledge. Interdisciplinary is defined as involving or drawing on two or more branches of knowledge [84]. Nevertheless, research in health informatics is not only concerned with the academic world. Addressing a real-world problem such as chronic disease consultations require "stepping out" from the academic world. A project like this PhD also requires integrating various points of view and requirements. Thus, this PhD project falls under the "integrative research" definition [85], as shown in **Figure 2.2**.

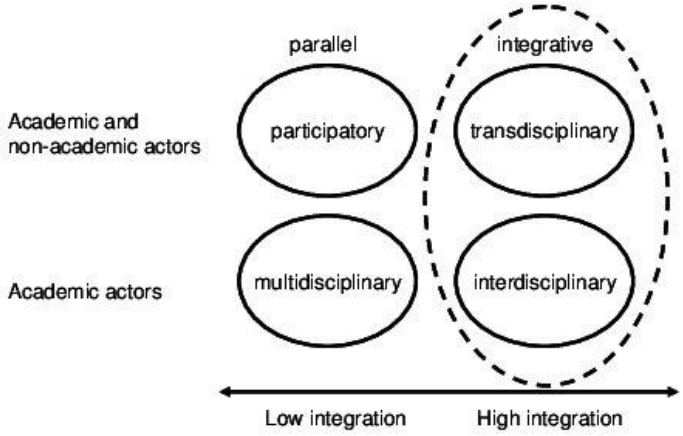

Figure 2.2: A model for integrative research. Reproduced from Figure 2: A model for integrative research [85].

Integrative research summarizes interdisciplinary and transdisciplinary research efforts [85]. In interdisciplinary research, unrelated academic disciplines (e.g., computer science, medicine, psychology) create new knowledge or theory or solve a common goal. On the other hand, transdisciplinary research also creates new knowledge or theory or solves a common goal by adding non-academic participants (e.g., policymakers, medical equipment vendors, and multinational conglomerates) [85].

The complexity of integrative research and its research discipline was reflected in this PhD project under multiple levels. In particular, the research paradigm and its complexity have imposed the need to seek and collaborate with actors outside the academic world, mainly patients, health personnel, medical vendors, lawyers, and policymaker. Although these actors' involvement and recruitment are essential, it leads to several limitations and require delimitations of the project, later discussed in Section 2.3.

2.1.2 Creating New Knowledge: A PhD Project's Journey

In the context of integrative research, both academic and non-academic stakeholders are involved in creating new knowledge [85]. This PhD project uses Design Science Research (DSR) to design and develop an information system, addressing complex challenges by connecting theoretical knowledge (e.g., information quality, interoperability, security, privacy) with a practical application [86] (e.g., T1D consultation).

DSR is particularly valuable in health informatics for its ability to produce practical solutions (e.g., software artifacts, models) and contribute new knowledge. **Figure 2.3** details the Design Knowledge components within a DSR framework [87].

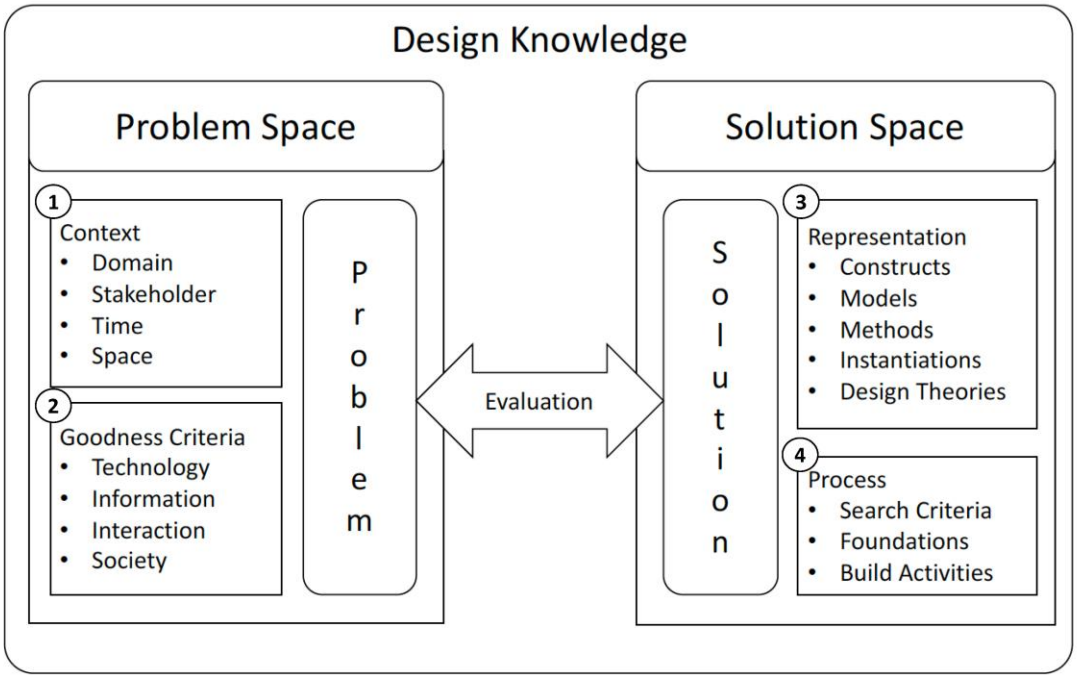

Figure 2.3: Components of Design Knowledge for a specific DSR project. Modified and reproduced from Figure 1 reference [87].

Figure 2.3 distinguish two fundamental constructs within the framework of DSR: Problem Space and Solution Space. Each space includes elements critical to the research process:

- The *Problem Space* is described by the application *Context* (**Figure 2.3**, box (1)), and the *Goodness Criteria* or criteria for solution acceptance (**Figure 2.3**, box (2)) discussed later in section 2.2.3.
- The *Solution Space* holds the knowledge produced on the specific problem. Knowledge in the Solution Space can refer to a *Representation* (**Figure 2.3**, box (3)). The representation has different forms, such as models, constructs, or artifacts. The Solution Space also includes the design *Processes* (**Figure 2.3**, box (4)), such as iterative build-evaluation cycles, later described in Section 2.2.1.

Although the *Problem Space* and *Solution Space* are conceptualized as independent entities, they interplay through the Evaluation mechanism. This interconnection underscores the fundamental

role of *Evaluation* in bridging theoretical and practical domains, constituting a critical component of the DSR project [88].

2.1.3 Collaboration and Impact: Extending Beyond the PhD

One of the risks associated with DSR and PhD projects is the tendency to create a single, stand-alone contribution. Such contributions with a monolithic structure often remain isolated and limit the potential for further research [87].

The collaborations with multiple projects via the DiaDig (Section 1.1.4.1) and HEIR (Section 1.1.4.2) was a strategic approach to diversify perspectives and enhance the research environment.

Participation in various projects was strategically aimed at gathering input from a broad spectrum of sources, thereby expanding insights and deepening understanding of the topic. This strategy not only expanded the research viewpoint but also enabled a more holistic interaction with the topic. Notably, these collaborations facilitated engagement with stakeholders who are often difficult to reach, such as health personnel, lawyers, and public health authorities who use or contribute to the national diabetes registry, thus adopting a comprehensive approach to the PhD project.

It is important to acknowledge that increased collaboration can bring its own set of challenges. The expanded PhD *Problem Space* requires careful management due to the many variables and potential complexities involved. Similarly, the *Solution Space* and *Evaluation* processes become more challenging when communicating with diverse stakeholders and collaborators who come from different backgrounds, have different levels of technological expertise, and have varying interests.

For example, in the HEIR project, technology and cybersecurity experts found it difficult to grasp the clinical implications and the importance of patient care. Similarly, healthcare professionals, despite their focus on quality patient care, might overlook the significance of interoperability and cybersecurity, finding less relevant data protection and privacy issues, as observed in the DiaDig project.

2.2 Design, Development, and Evaluation of an Information System through the Design Science Research Methodology Process Model

Design Science Research (DSR) is a methodology for guiding Information System research. It focuses on generating innovative solutions to complex issues through designing and evaluating artifacts, as presented in Section 2.1.2. The Design Science Research Methodology (DSRM) Process Model builds on this by turning DSR principles into a practical, step-by-step process [89]. This process encompasses six key steps: 1) problem identification and motivation; 2) definition of solution objectives; 3) design and development; 4) demonstration; 5) evaluation; and 6) communication, as illustrated in **Figure 2.4**.

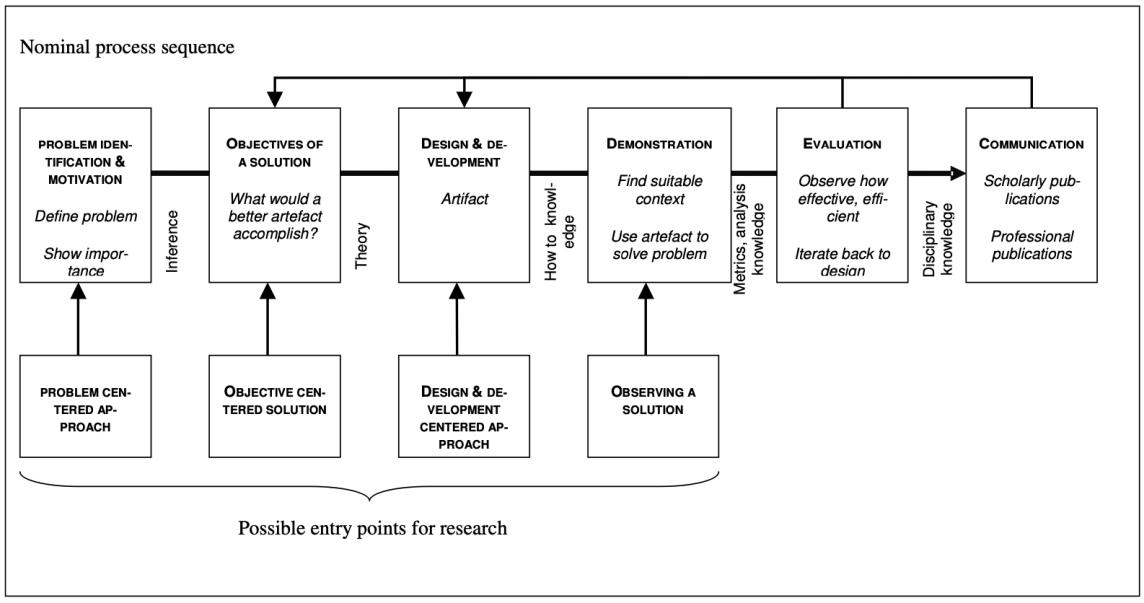

Figure 2.4: Design Science Research Methodology (DSRM) Process Model. Reproduced from Figure 1 reference [89].

While DSRM process model may be designed to follow a structured, sequential process, it is important to note that researchers are not necessarily bound to this order [89]. For example, at the end of the fifth step (*Evaluation*), the researchers can decide whether to iterate back to the fourth step (*Demonstration*) to improve the artifact's effectiveness or to continue and move forward to the sixth step (*Communication*) and leave further improvement to future projects. This PhD project, as detailed in the testing and evaluation in Section 4.4, acknowledges the potential of revising the developed information system, introducing new functionalities, and performing another evaluation. As illustrated in **Figure 2.4**, the process employs an 'agile methodology' for designing information systems. Traditionally, Information System Research has predominantly focused on business applications [89-91]. However, ICT and integrative research approach can make these models equally applicable to other research disciplines, such as health informatics [86, 92].

Chapter 1 of this PhD dissertation details the first two steps of the Design Science Research Methodology Process Model—Problem Identification and Motivation and Objectives of a Solution. The following subsections, from 2.2.1 until 2.2.4, explore the remaining steps of the Design Science Research Methodology Process Model [89]: Design and Development, Demonstration, Evaluation, and Communication.

2.2.1 Design and Development

During the design and development phase, researchers craft artifacts that align with the research objectives [89].

A central consideration for this PhD dissertation and for Information System design and development is the evolution of technology design, marked by the advent of various cloud service models. Notably, the introduction of Infrastructure as a Service (IaaS), exemplified by Amazon Web Services (AWS) in 2006, signified a significant shift. The emergence of containers, notably Docker in 2013, and the subsequent development of container orchestrations like Kubernetes in 2015, have revolutionized technology design [93]. Currently, applications are increasingly designed and developed as discrete and reusable services, known as Microservices [94]. This approach marks a change from the traditional Monolithic application architecture, as illustrated in **Figure 2.5**.

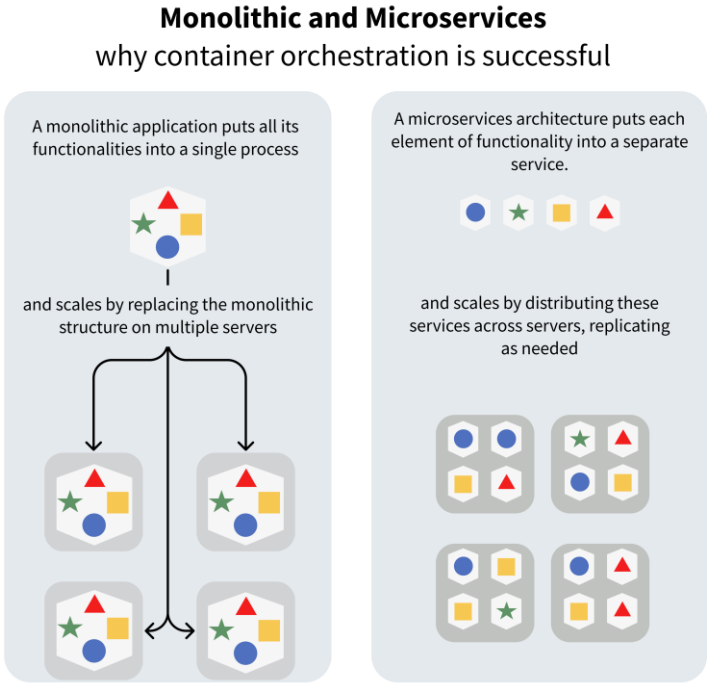

Figure 2.5: Monolithic vs Microservices.

This PhD project involves the design and development of an Information System utilizing microservices. The technical implementation will be detailed in Chapter 4. Microservices offer many advantages, such as code reusability, better support for continuous delivery, and reduced redundancy in development efforts "reinventing the wheel" [94].

The project follows a software engineering approach of continuous delivery to design the artifact, thus enabling software production in short cycles [95]. The development (and deployment) for this PhD project is based on Continuous Integration and Continuous Deployment (CI/CD). The CI/CD pipeline automates and continuously tests, builds, and releases code changes to the deployment environment. Consequently, when a developer (the PhD candidate, in this case) commits new code into the repository, the DevOps tool (e.g., GitLab, Azure DevOps) automatically executes the CI/CD pipeline [95]. These pipelines, configured within the project, release code changes to the end environment, such as the Azure Kubernetes Service (AKS), making them accessible to end users. This project's design and development approach is based on CI/CD methods and enhances Agile development by providing a framework and tools for automating the build, test, and deployment processes [95].

The development and deployment process in this PhD project can be summarised as follows:

1. **Azure DevOps** is utilized for initiating the code repository, as well as testing and debugging within a local AKS cluster.

2. **CI/CD pipelines** automate the build and deployment processes. This process is supported by IaaS (Azure, in this project), which, through the pipelines, creates container images.

3. **The Azure Container Registry** stores container images before deployment, including those built by CI/CD pipelines or existing ones, such as Helm charts for Kubernetes applications predefined by the open-source community or other projects (e.g., ingress controller for Kubernetes using NGINX [96], cert-manager for certificates [97]).

4. **The AKS production cluster** hosts the prototype for demonstration and evaluation, representing the final stage of the deployment.

Consequently, end users (e.g., patients, informal caregivers, and healthcare professionals) can access and utilise immediately the newly developed functionalities. **Figure 2.6** graphically summarize development and deployment process in this PhD project.

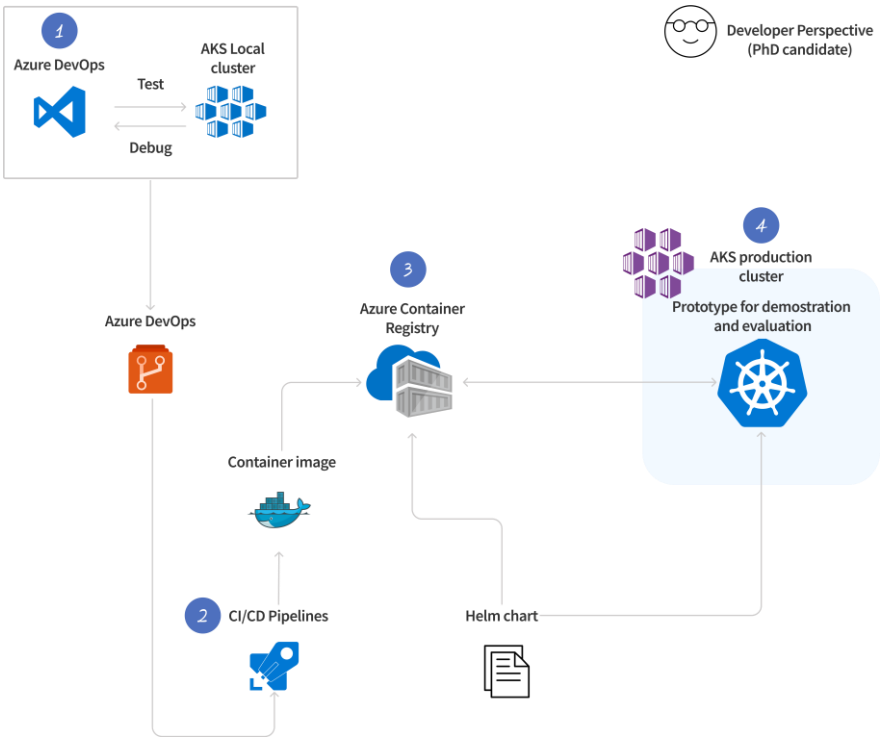

Figure 2.6: Overview of the development and deployment process for the PhD.

2.2.2 Demonstration

Design Science is the design and investigation of artifacts in context. This phase is crucial for demonstrating the artifact's ability to address the identified problem, which might include its application in experiments, simulations, case studies, proofs, or other suitable methods [89]. Value and effectiveness are realized only when tested in a real-life context. For instance, a machine-learning algorithm crafted for medical diagnoses must be evaluated within the setting of actual medical diagnostic processes to evaluate its practicality and impact.

Chapter 4 presents demonstration outcomes. When processing personal identifiable information (PII), it is essential to obtain ethical approval. This approval ensures that the research project adheres to ethical standards and safeguards the rights of the participants. It also ensures that any potential risks to the participants are minimized, and that informed consent is obtained.

Several steps were performed to obtain ethical approval for this project, including:

1. Consulting with the university's Data Protection Officer (DPO) to confirm appropriate data management and protection.

2. Conducting a Risk Analysis on the PhD project's technical implementation to mitigate potential participants risks.

3. Creating a detailed data management plan in compliance with the standards set by the Norwegian Agency for Shared Services in Education and Research (Sikt).

4. Applying to the Regional Committees for Medical and Health Research Ethics (REK) in response to a specific directive from Sikt.

All of these steps contributed to the ethical approval of the study is documented in Appendix 1: Assessment of Processing of Personal Data (Sikt project reference number 671274).

More details about the information system demonstration are provided in Appendix 2: Notification Form for Processing of Personal Data. This document contains all the relevant information about the study sample, which included individuals with diabetes, health personnel, and informal caregivers. It provides comprehensive demographic details, including age groups, to help better understand the participant base. The document also describes the legal basis for processing general personal data in compliance with the General Data Protection Regulation (GDPR). It outlines detailed procedures for withdrawing consent, ensuring adherence to ethical standards and GDPR requirements.

2.2.3 Evaluation

The selection of appropriate criteria and analysis techniques is essential [89]. The selection of how to evaluate the PhD project, began by determining the evaluation methods and criteria for artifacts through a systematic review [7] and the patients' reported needs identified in another study [9]. The Delphi study [2] indicates criteria for recommending ICTs to individuals with diabetes, and *"Information Quality"* and *"Usability"* emerged as the primary evaluation criteria.

The standardized questionnaire AIMQ [98] was initially employed to assess the various dimensions of information quality. This instrument evaluates a comprehensive list of attributes, including accessibility, appropriate amount, believability, completeness, concise and consistent representation, ease of operation, error minimization, interpretability, objectivity, relevancy, reputation, security, timeliness, and understandability.

Given the significant challenge of recruiting HCPs, primarily due to their constrained schedules, employing an extensive questionnaire, although standardized, proved impractical. Consequently, the evaluation of information quality among health professionals was conducted through semi-structured interviews. These interviews focused on a subset of the criteria derived from the AIMQ questionnaire [98] for information quality assessment. The focus was on verifying the appropriate amount, timeliness, believability, and interpretability of the information. The semi-structured interviews, lasting no more than 30 minutes, targeted health personnel who had not previously interacted with the system. Recruitment for the semi-structured interview was based on the research group's network, as no additional funds were allocated to recruit health personnel. The results of the semi-structured interview with HCPs will be extensively described in Section 4.4.

The semi-structure interview guideline is available as an Appendix 3: Semi-Structured Interview Guideline.

2.2.4 Communication

The last step of the selected model is communication. The academic results were disseminated via conferences and journals in computer science and medical/health informatics, listed **Table 2.1**.

Table 2.1: Communication via journal and conference.

Types	Name	Reference
Journals	International Journal of Medical Informatics	[1]
	Journal of Diabetes Science and Technology	[4]
	Journal of Medical Internet Research	[7]
Conferences	European Medical Informatics (MIE)	[2]
	Scandinavian Health Informatics (SHI)	[3, 9]
	World Congress on Medical and Health Informatics (Medinfo)	[5]
	Diabetes Technology Meeting, the yearly Advanced Technologies & Treatments for Diabetes	[10, 11]

Building a research community is another crucial aspect of integrative research. As presented in Section 2.1.3 collaborating beyond the PhD project is necessary to expand its relevance. As a result of this approach, the communication included several diabetes-specific conferences. This led to an invitation for the PhD candidate to the Project "*Integration of Connected Diabetes Device Data into the EHR*" (iCoDE2) in 2023 [99], initiated by the Diabetes Technology Society. This project builds on the Project "*Continuous Glucose Monitor Data Integration into the EHR*" (iCoDE) from 2022 [100]. The iCoDE2 project was crucial to understanding the various views of industry partners (e.g., Medtronic, Abbott, Tidepool), healthcare organizations (e.g., clinics in Europe and the U.S.), and policymakers from the U.S. (including the Food and Drug Administration), and also contributing towards the standardization, particularly within the FHIR and Diabetes communities.

2.3 Strengths and Limitations in the Project

Communicating and collaborating effectively with a wide range of participants in this PhD project was challenging. The project included academic participants from fields outside of computer science and non-academic stakeholders like patients, caregivers, and healthcare workers. The collaboration and communication were further complicated by the variability of terminologies in health informatics, depending on the context [101]. An exclusive focus on technology could potentially alienate these key stakeholders, given the complexity of technical jargon such as *"Interoperability"*, *"Information System"*, and *"Kubernetes"*. Collaboration with co-authors from various fields (health science, law, cybersecurity, psychology) brought further variability in terminology, with references to '*ICT*', *'digital diabetes tools*', *'patient-generated health data'*, or *'diabetes data'*, changing based on the context of publication (Section 2.2.4).

To overcome the communications challenges, engagement with projects like DiaDig and HEIR was crucial, providing insights that helped address challenges in evaluation methods, security, and privacy effectively. This integrative approach expanded the scope of the research, enhancing its relevance and potential impact. Furthermore, the invitation and participation in iCoDE2 [100] project towards the end of the PhD project was an important step toward recognising the relevance of the findings and research.

The PhD project faced limitations in accessing health-related information due to the proprietary nature of medical devices. Downloading data for individuals with diabetes is a known challenge [59, 60], and uploading patient data proved to be a complicated process, as it will be further detailed in the technical implementation (Section 4.3.3) and discussion (Section 5.2) of this dissertation. These limitations narrowed the opportunities for design and development, and as a result, patient recruitment was stopped after completing three different use cases.

Despite these limitations, the project had its strengths. One of the project's strengths was its adaptability, demonstrated through the modification of the AIMQ questionnaire [98] into a more accessible semi-structured interview format that facilitated participation from busy HCPs. This strategic adaptation led to the recruitment of 11 HCPs for system evaluation. This approach ensured that the PhD evaluation had a broad enough sample to uncover common themes without reaching saturation [102].

The ethical approval process took about eight months, from December 2022 to August 2023, which further delayed the project. Since access to real patient data was not feasible, simulated data from tools such as UVA/Padova [103] or Synthea [104] was used to demonstrate specific functionalities of the information system, as was done in Paper [5].

Overall, the flexibility of the Design Science Research Methodology was a key advantage. This methodology allowed for a non-linear progression through the various phases (e.g., design, demonstration, evaluation), providing the ability to revisit and adapt as necessary. This adaptability was especially beneficial in navigating tight schedules and unexpected situations, like

the Coronavirus Disease (COVID-19) pandemic, which significantly affected the ability to work directly with patients and HCPs during the design and development of the information system [105]. Furthermore, the use of CI/CD pipelines and hosting on an IaaS platform like Azure facilitated the development and integration of new features, highlighting the project's dynamic and responsive approach to information system design and development [94, 95] (Section 2.2.1).

Chapter 3 State-of-the-Art

A significant challenge with information systems in diabetes management is their heterogeneity and the rapid pace at which they evolve [4, 6]. These systems vary significantly in design and functionality, with manufacturers frequently updating them to introduce new features or modify existing ones. This dynamic nature poses a challenge in providing a current and comprehensive overview of these technologies.

This chapter focuses on the level of development achieved at the end of 2023 and the beginning of 2024 that reflects the common state-of-the-art existing at that time.

3.1 Consultation and Diabetes Management

Consultations for chronic diseases involve in-person or remote interactions between patients and healthcare professionals. These sessions serve as crucial opportunities to make patients better understand their medical conditions and offer guidance, tools, and advice for effectively managing their diseases and related challenges [52]. Research indicates that active patient involvement in these consultations and the decision-making process leads to better-informed choices regarding treatment options [106] and self-management strategies [63].

One of the principal challenges in healthcare is the limited time allocated for consultations. This constraint can limit the effective disease management for patients and increase the workload for healthcare providers [107]. A review of studies conducted in 67 countries found that the duration of consultations is typically brief, even though the health issue at hand may be significant [108]. Such brief interactions may negatively impact patient disease management, burdening HCPs [108] and heightening the risk of medical error [61].

The landscape of diabetes consultation is complex at a high level, involving advanced technology that integrates devices across various systems. This landscape requires the active participation of diverse individuals, as detailed in **Table 3.1**, and involves a range of organisations and domains, as outlined in **Table 3.2**.

Table 3.1: People potentially involved in diabetes consultation.

Category	Description
Patient / People with Diabetes	Individuals require medical devices as part of their health management due to diabetes.
Informal caregiver	Parents, spouses, legal guardians, or others involved in healthcare decision-making or providing patient care.
Healthcare Providers (HCPs)	Licensed healthcare professionals interacting with patient data during care, including physicians, trainees, nurses, nurse practitioners, physician assistants, registered dieticians, diabetes educators, pharmacists, etc..

Adapted from reference [109].

Table 3.2: Domain of the diabetes consultation.

Category	Description
Healthcare Organisation	Hospitals, clinics, health systems, national registries.
Diabetes Device Manufacturer	Companies producing devices for individuals with diabetes.
Data Aggregator	A Data aggregator is a third party that collects data from diverse diabetes device manufacturers (and often other devices) and makes it available to healthcare organisations via portals for patients and clinicians. Original definition [110].

Adapted from reference [109].

Furthermore, **Figure 3.1** offers an expanded overview of the diabetes consultation process, adapted from the research conducted by Espinoza, J., et al. [109]. This figure delineates the medical consultation process into four primary domains: Patients, Device Manufacturers, Data Aggregators, and Healthcare Organizations. Each domain's representation and connections provide a comprehensive view of the current state and potential integrations within the diabetes consultation process.

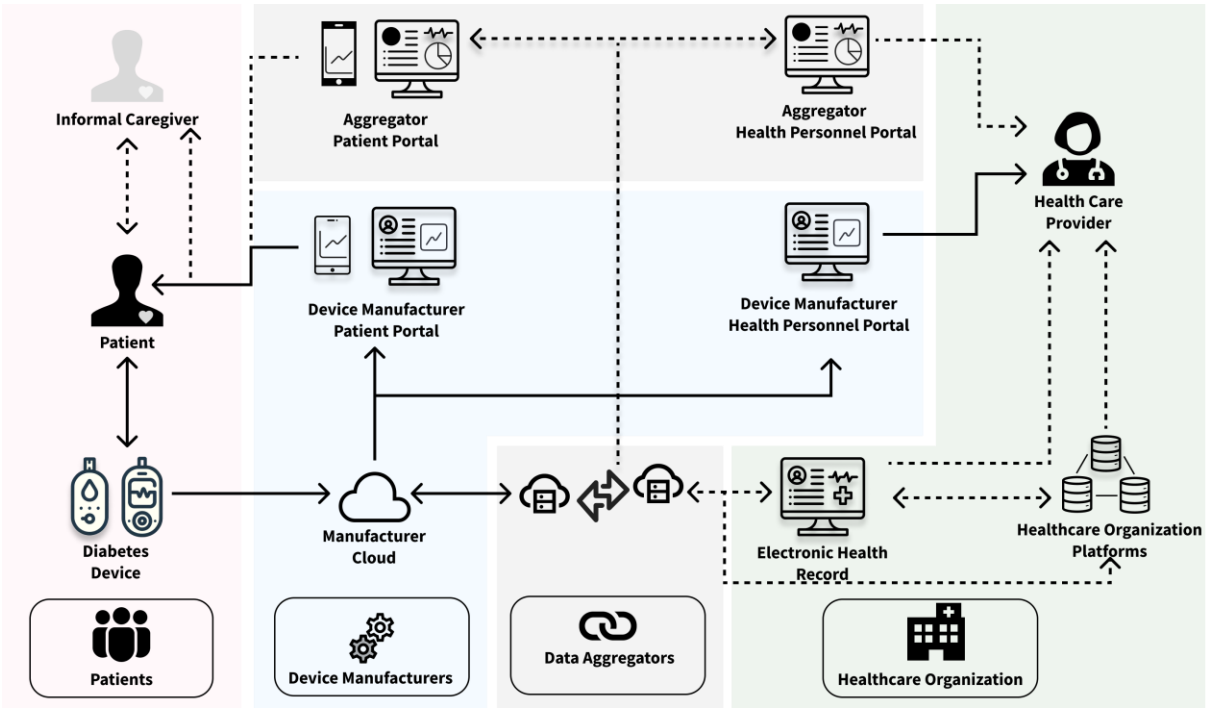

Figure 3.1: Medical consultation overview. Solid black lines indicate established connections that are commonly present in today's medical consultations. In contrast, dotted black lines signify optional or less frequent connections, including the integration with Electronic Health Records. For clarity, the domain of Aggregators has been considerably simplified. Figure based and modified Figure 1.3 reference [109].

3.1.1 Diabetes Medical Devices

Figure 3.2 offers an extensive overview of the complex landscape, as explored by prior researchers [111], of medical devices, drug delivery mechanisms, and wearable technology utilised in managing diabetes. These devices will represent the primary medical data sources for the information system described in this PhD project.

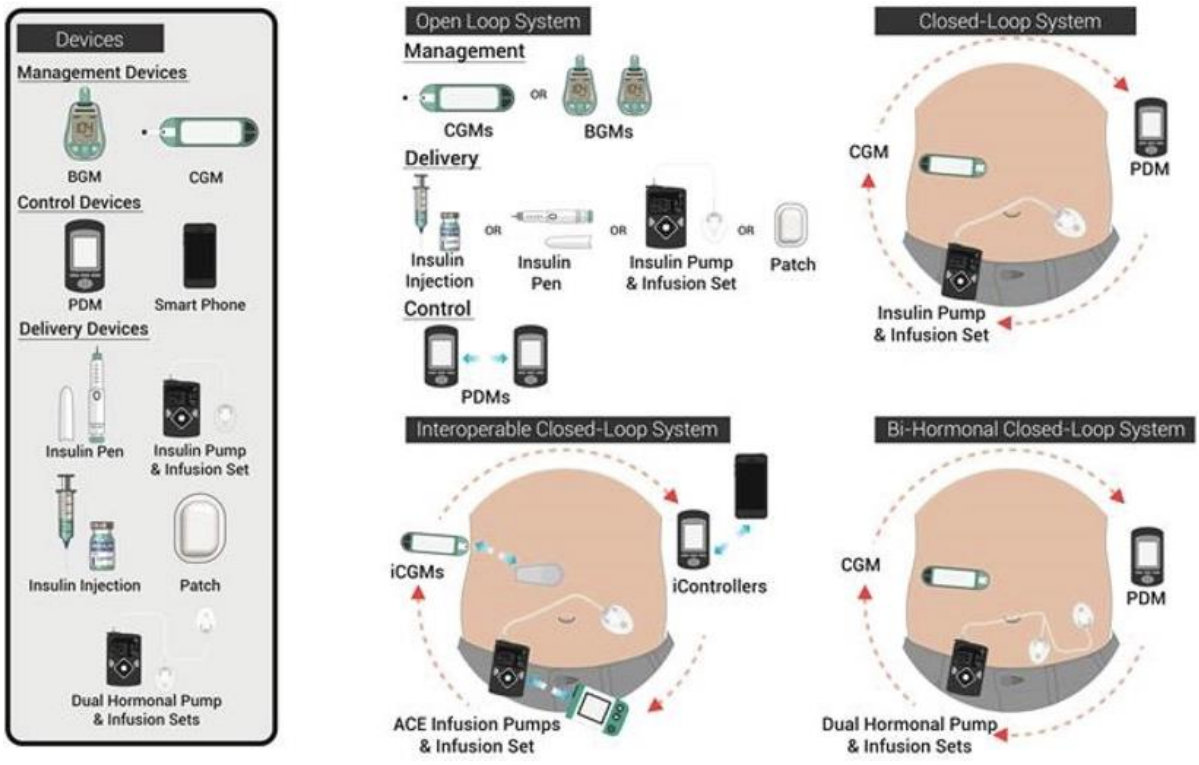

Figure 3.2: Main diabetes device overview. Reproduced from Figure 2 reference [111].

Since 2010, interest in closed-loop insulin delivery systems, including hybrid and fully automated models, has risen [112, 113]. Predominantly, hybrid closed-loop systems have become increasingly prominent in managing T1D [113, 114], with expanding research into their application for T2D patients [115, 116] and those requiring dialysis [117]. A fully automated closed-loop system combines a CGM, an insulin pump, and a control algorithm that continuously adjusts insulin delivery in real time. Additionally, Bi-Hormonal closed-loop system can also manage glucagon delivery [114, 118]. Unlike hybrid closed-loop system, which automates many aspects but still requires manual management of certain elements, such as meal-related insulin doses [119].

Despite the ongoing development towards a fully operational artificial pancreas, the collaboration among various stakeholders involved in integrative research, both academic and non-academic (as indicated in Section 2.1.1), has pushed the advancement of closed-loop systems, moving society closer to realizing such innovative solutions.

In the European Economic Area (EEA), some devices presented in **Figure 3.2**, are made available through customized national agreements to meet specific healthcare needs. Throughout this PhD project, an in-depth analysis of medical devices distributed in Norway was conducted, revealing insights into the assortment of devices accessible to diabetes patients via periodically updated national agreements. These findings are documented in Paper [4] and Paper [6], noting that national authorities frequently update these agreements, typically twice a year.

Table 3.3 provides a detailed summary of the evolution of diabetes-related medical equipment in Norway from 2022 to the beginning of 2024, highlighting the technological advancements and transitions in the available devices.

Table 3.3: Evolution of diabetes medical equipment in Norway (2022-2024).

Medical equipment (n=7)	**Type**	**2022**	**2023**	**2024**
MiniMed 780G + Guardian Connect G4	Insulin pump and CGM – Hybrid Closed Loop System	✓	✓	✓
MiniMed 640G + Guardian Connect G3	Insulin pump with Predictive Low-Glucose Suspend (PLGS)	✓		
Tandem t:slim X2 Insulin pump with Control-IQ + Dexcom G6 or Dexcom G7	Insulin pump and CGM – Hybrid Closed Loop System	✓	✓	✓
OmniPod Dash	Patch pump for insulin	✓	✓	✓
Accu Chek Solo	Patch pump for insulin	✓	✓	✓
Accu Chek Insight	Insulin pump	✓		
Freestyle Libre 2 / Freestyle Libre 3	Stand-alone CGM	✓	✓	✓
Guardian Connect G4	Stand-alone CGM (2022) / Part of MiniMed 780G (2023, 2024)	✓	✓	✓
Simplera	Stand-alone CGM			✓
Dexcom G6	Stand-alone CGM	✓	✓	
Dexcom G7	Stand-alone CGM			✓
Eversense E3	Stand-alone CGM	✓	✓	

Sources [4, 6, 120].

Table 3.3 highlights the prioritization of the MiniMed 780G and Tandem t:slim X2 with Control-IQ, which reflects a continued commitment with the same devices to hybrid closed-loop systems. Meanwhile the introduction of Simplera and Dexcom G7 in 2024 marks the expansion of CGM options available to patients.

3.1.2 Software in Diabetes Consultation

To categorize software utilized in diabetes consultations, distinct categories have been delineated, as outlined in **Table 3.4**. Each category may include smartphone apps, web and cloud portals.

Table 3.4: Software categories in diabetes

Software Categories	Description
Manufacturers Device Software	Developed by established medical device manufacturers, this software is regulated and often integrated with specific devices. Refer to Section 3.1.2.1 for more details.
Third-Party Software (Aggregator)	Crafted by entities other than the original device manufacturers, these may also be regulated. They are designed to interface with a variety of medical devices, including those from different manufacturers and further presented in Section 3.1.2.2.
Do-It-Yourself (DIY) Software*	Created by individuals or communities for off-label use. More information in Section 3.1.2.3

*DIY Software is not formally recognized as part of the standard diabetes consultation process. Source Paper [6].

3.1.2.1 Manufacturers Device Software

The presentation of information to HCPs during medical consultations varies, reflecting the distinct approaches by companies like Medtronic [57], Abbott [53], and Dexcom [65]. Research conducted by Espinoza, J., et al. [67], reveals and compares the unique styling of interfaces, demonstrating how each company present similar information in a way that sets them apart from competitors. In line with the challenges presented in Section 1.1.3.

The reports generated by these systems are typically comprehensive, spanning multiple pages and covering a broad spectrum of information. This underlines the diversity in presentation styles. **Figure 3.3** illustrates some of the primary dashboards from leading manufacturers such Abbott with the Ambulatory Glucose Profile (AGP) report [53], and Dexcom [65], as Medtronic [57], providing a visual comparison of their different approaches.

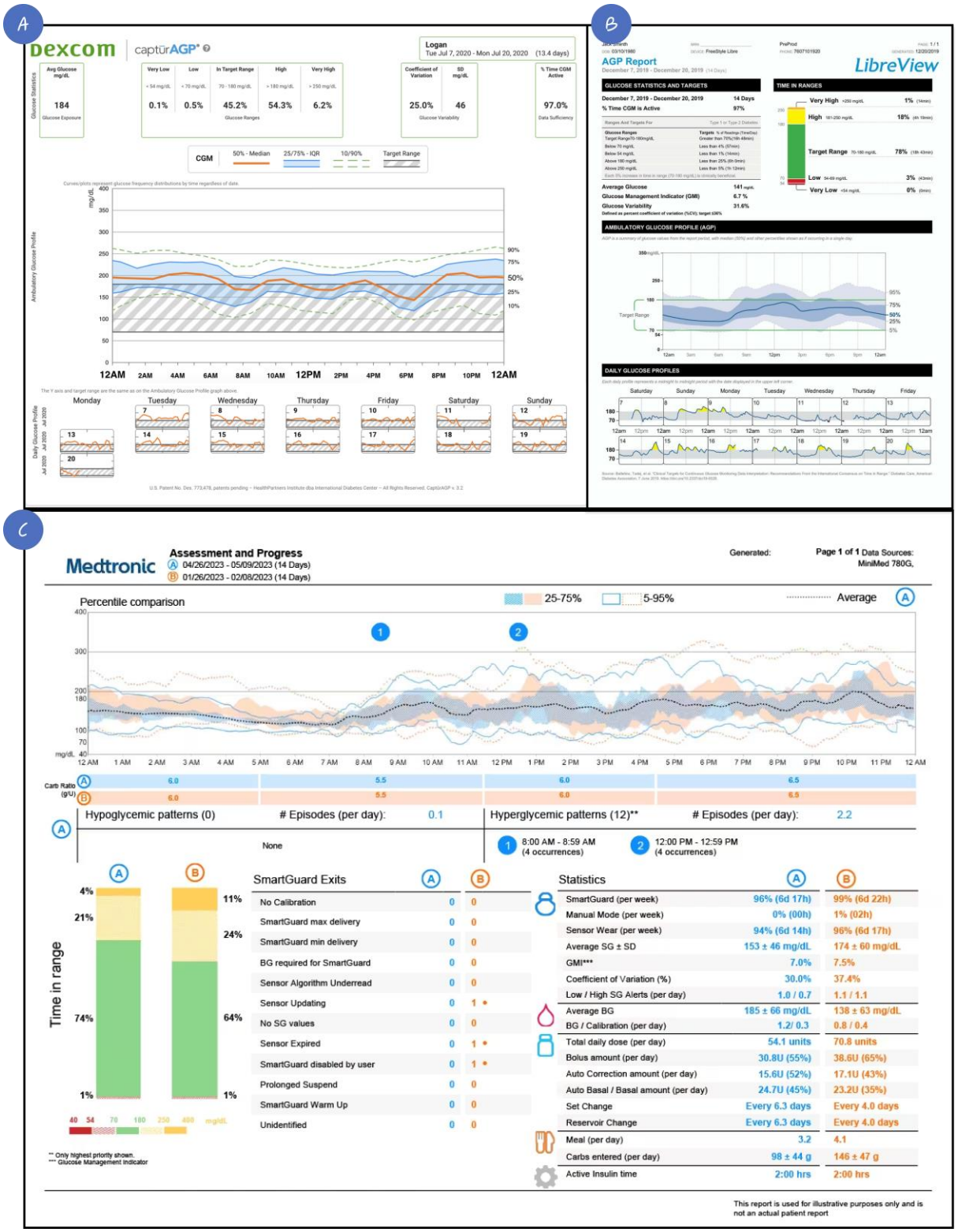

Figure 3.3: A comparison between different system interfaces. The System (A) is the Dexcom AGP report, source reference [65]. System (B) is the Libre View report reproduced from Figure 5 in reference [53]. System (C) is the Medtronic MiniMed 780G, source reference [57].

3.1.2.2 Data Aggregator, Third-Party Software and National Diabetes Registry

A data aggregator [110], as defined in **Table 3.2**, such as the Information System developed in this PhD dissertation, aims to collect data from multiple sources [110]. The market offers various

software solutions for this purpose. Glooko, utilized in Norway [4, 6] and other countries, provided data aggregation from various devices, including glucose meters, CGMs, and insulin pumps. Health personnel can access this data either through physical devices within healthcare organizations or through Glooko's web portals [121].

Another third-party software, originating from open-source initiatives, Tidepool, established in 2013 [122], has been compatible with numerous glucose meters, CGMs, insulin pumps and patch pumps. Tidepool has led the development of many data aggregators, including Stenopool, developed by the Steno Diabetes Center in Denmark [123], and Sensotrend in Finland [124]. Both projects adapted or reused Tidepool's open-source framework to facilitate data aggregation. Tidepool's collaborations with major medical device manufacturers have highlighted the capacity of open-source software to enhance data integration across devices [125].

However, diabetes device manufacturer support for such initiates has proven difficult to maintain. For instance, the collaboration between Tidepool and major manufacturers like Medtronic on the Tidepool Loop project, a component designed for closed-loop system integration, was discontinued in January 2023 [126], shortly after receiving Food and Drug Administration (FDA) clearance [127]. This setback left OmniPod as the only device compatible with Tidepool's hybrid closed-loop system, illustrating the difficulties in securing continuous support from device manufacturers [126].

Moreover, national diabetes registries, such as Noklus in Norway [54], represent a special category of data aggregator. These registries, crucial for collecting and analysing diabetes data, face their own set of challenges. A preliminary WHO report [12] indicates a diverse landscape of European diabetes registries. As of 2021, seven countries had established comprehensive registries, 21 focused on specific demographics or diabetes types, and 13 lacked a national registry. The heterogeneity in national diabetes registry implementation and data sources makes it difficult to compare the quality of care and diabetes outcomes across countries [128], limiting the need to strengthen health information systems to enhance prevention and control efforts [74].

3.1.2.3 DIY software and Off-Label Use

Tidepool exemplifies the innovations emerging from the open-source community focused on diabetes management. The DIY movement, particularly noted in the United States since 2013, has seen a global spread, advocating for enhanced device functionalities, and addressing gaps in technology distribution [80, 129]. Major DIY projects include Tidepool Loop [122], OpenAPS (Open Artificial Pancreas System) [130] Loop [131] and Nightscout [132] (CGM in the cloud).

This movement aims to enhance accessibility to glucose and insulin data and develop more effective hybrid closed-loop systems. By July 2016, individuals worldwide had collectively utilized open-source hybrid closed-loop systems for over 250,000 hours, demonstrating significant benefits [133]. Despite their initial commercial release in 2016 [134], these innovations took an additional three years to become available in Norway [135], with similar delays observed in other countries.

Individuals often choose quality of life over official approval, using devices off-label for more convenient insulin management via smartphones or smartwatches. Open-source solutions may provide remote control capabilities for parents to manage their children's diabetes remotely without extra equipment [136]. The community aspect is strong, with individuals sharing experiences and seeking support through social media platforms and groups focused on specific devices or systems [137, 138], thus bridging technological gaps and fostering a supportive network.

While DIY software is not formally recognized in medical consultations, its impact extends beyond healthcare settings, with patient groups on social media playing a central role. These groups offer a platform for discussing symptoms, treatment options, and self-management devices, supporting and complementing traditional consultations [139, 140]. However, the reliance on social media for medical information raises concerns about misinformation and the challenge of ensuring the quality and accuracy of shared knowledge [81, 141, 142].

3.1.3 Wearable Device Data and Data Aggregator

Recent studies have emphasized the more central role of the Internet of Things (IoT) in healthcare, also known as the Internet of Medical Things (IoMT) [143-149]. This domain includes deploying medical devices and patient monitoring systems categorized as ICT. A notable trend is the rising preference for wearable technologies, such as smartwatches, fitness rings, and smartphones, for monitoring daily routines, sleep patterns, and physical activities. Several studies affirm the benefits of affordable and user-friendly wearable devices in tracking health metrics across various NCDs [150, 151]. However, there is an identified need for enhanced precision in data capture, especially concerning sleep patterns [152, 153] and physical activity [143], highlighting the demand for more accurate wearable devices.

The expansion of wearable devices presents notable integration challenges within information systems. These challenges include addressing security and privacy concerns related to sensitive health data [145-148], ensuring interoperability among diverse devices and systems [154], and facilitating efficient data utilization via Application Programming Interface (APIs) [154].

Data aggregators have become essential data hubs for simplifying the process of gathering and combining information from various devices. Leading technology firms like Google and Apple have become predominant in this space, acting, as other researchers have explained, as gatekeepers of health data [155]. Platforms such as Apple Health, Google Fit, and Samsung Health exemplify central data aggregation hubs, which are crucial for gathering health data from multiple sources. However, extracting data from these platforms typically necessitates the development of a specialized mobile application acting as a mobile gateway [156]. Notably, Google Fit distinguishes itself by providing data access through a Representational State Transfer (REST) API, offering a comparative advantage regarding platform data accessibility [156], as shown in **Figure 3.4**.

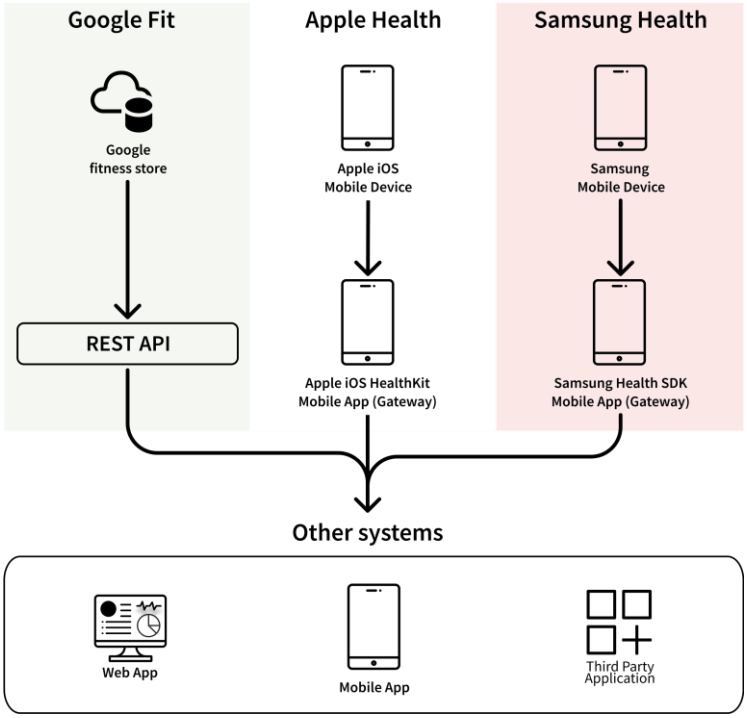

Figure 3.4: Wearable Aggregators Comparison: Google Fit, Apple Health, Samsung Health.

3.2 Exchanging Health Information

Interoperability is broadly defined as "the ability of two or more systems or components to exchange information and to use the information that has been exchanged." This definition is among 17 identified definitions of interoperability [157], emphasizing the multifaceted nature of this concept.

Interoperability comprehends several layers, as outlined by (Benson T, Grieve G)[157].

- **Technical Interoperability**: This layer involves the actual exchange of information between systems.
- **Semantic Interoperability**: This ensures that the information exchanged is meaningful and usable, allowing the recipient to interpret and use the data within clinical processes (e.g., medical consultation).
- **Process Interoperability**: This refers to integrating and applying exchanged information in operational and clinical workflows.

Policymakers may want to consider different levels of interoperability. The National Interoperability Framework Observatory (NIFO), which provided advice to the European Commission, introduced the concept of **Legal Interoperability** [158]. This layer of interoperability concerns to the legal, regulatory, and policy frameworks facilitating information sharing while safeguarding patient privacy and data security. Section 3.3 will cover more information on legal and regulatory considerations.

In the context of health data exchange, interoperability demands a holistic strategy [158]. This strategy must not only address the legal aspect and technical aspects (technical interoperability and legal interoperability) of transmitting healthcare data from sources, such as medical or wearable devices, to destinations, including healthcare providers or national registries but also ensure that this data is interpretable (semantic interoperability) and actionable within healthcare settings (process interoperability).

The importance of data storage and health exchange representation becomes evident, especially when considering the challenges of consistently representing simple data elements. In a simple example, such as patient gender across different systems, as demonstrated in **Figure 3.5,** without a standardized approach, all systems may not understand such information universally.

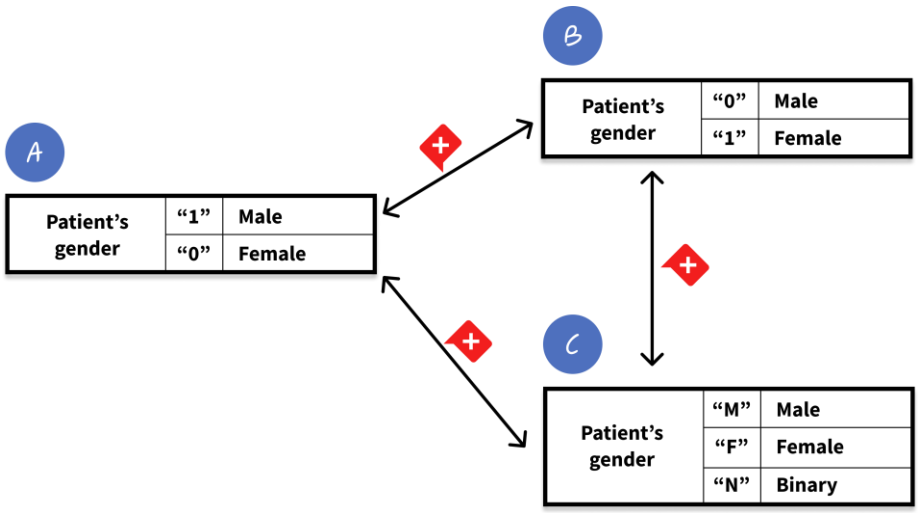

Figure 3.5: Why is interoperability needed? A simple example. System A codes gender using binary digits, with males as "1" and females as "0". In contrast, System B reverses this coding. System C introduces a different approach, utilizing "M" for male, "F" for female, and "B" for binary. However, when these three systems need to exchange gender data, none of them represent the data in the same way. Furthermore, System C introduces another gender concept, "B", which may be required for legal or process interoperability needs. Unfortunately, none of these systems can communicate with each other due to the differences in their gender coding schemes semantics.

3.2.1 Fast Healthcare Interoperability Resources Standard

The Fast Healthcare Interoperability Resources (FHIR) standard, conceived by Grahame Grieve in 2011, embodies a transformative approach to health information exchange. As a Health Level Seven (HL7) standard, FHIR outlines the structures for data formats and elements and an API to facilitate healthcare information exchange. The domain of FHIR encompasses clinical care, public health, clinical trials, and even administrative and financial dimensions, designed for universal applicability across many healthcare scenarios and systems [157].

The main FHIR components are Resources, and as illustrated in **Figure 3.6**, FHIR resources, encoded in various formats (e.g., JSON, XML), are widely supported across numerous programming environments, reinforcing their ease of use for data exchange.

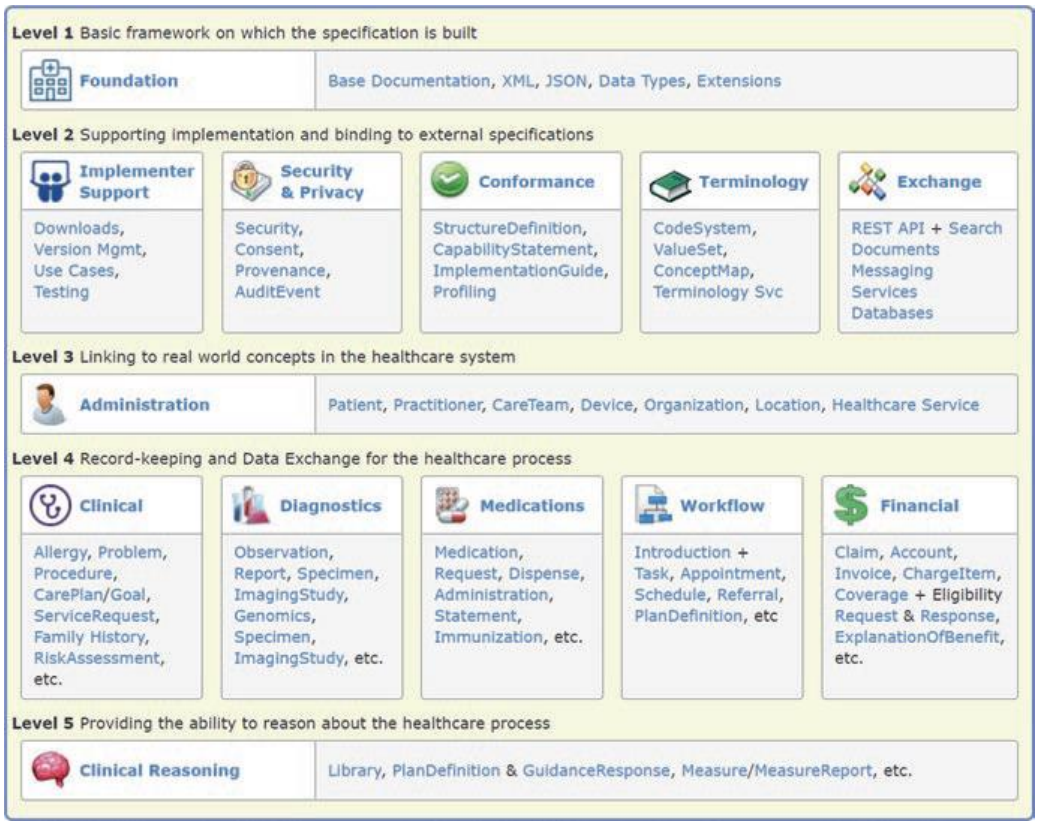

Figure 3.6: FHIR Resources levels. The FHIR specification follows a hierarchical model that represents its structure. This model consists of five levels, each covering different aspects of the specification. To ensure consistency, the model recommends the use of standardized medical coding (such as Terminology), methods of data exchange (such as REST API), and data exchange for healthcare systems (clinical, medications, and financial aspects like invoicing). Reproduced from Figure 9.1 reference [159].

It is essential to remember that **Figure 3.6** displays FHIR Resource levels, which should not be confused with the Maturity of FHIR Resources. These Maturity levels indicate the stability of FHIR Resources, with Level 0 indicating a "draft status" and Level 6 indicating a "normative status". Some resources in **Figure 3.6** may only be at Level 2, which means they are still being developed and may change in future versions. FHIR has extensive documentation [160] and literature [159], all publicly available and enhanced by a vibrant and enthusiastic community [161]. The REST API architecture of FHIR facilitates its use [159]. **Figure 3.7** shows the concept of REST API.

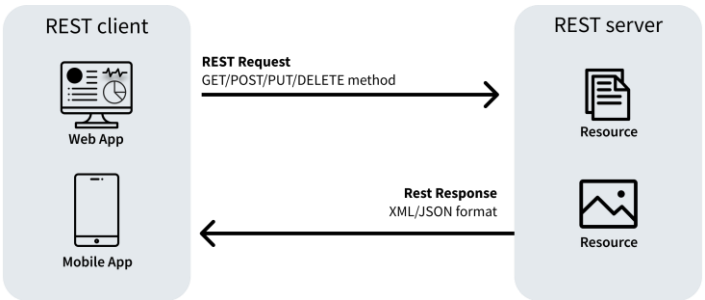

Figure 3.7: REST API in action. The REST client (a web app and a mobile app) communicates with the REST server on the right. The server provides access to resources like text documents and images and performs actions based on client requests. This is the foundation of many modern web services.

HL7 FHIR is tailored to support REST APIs, making it the predominant standard for data access discussed in this dissertation. While other standards like OpenEHR and ISO 13606 exist [77], FHIR is preferred due to its design focus on EHR exchange [77].

Most importantly, a FHIR API adoption is required in various regions, including the U.S. The Office of the National Coordinator for Health Information Technology (ONC) in the U.S. has stipulated that providers enforce a FHIR APIs by December 2022 [162], a directive that has some potential to be followed by in EEA and Europe as well [163].

In terms of FHIR adoption, a survey among 141 health companies in the U.S. [162] found that 73% reported using a standards-based EHR API, with varying degrees of FHIR or proprietary API implementation, as detailed in **Figure 3.8**.

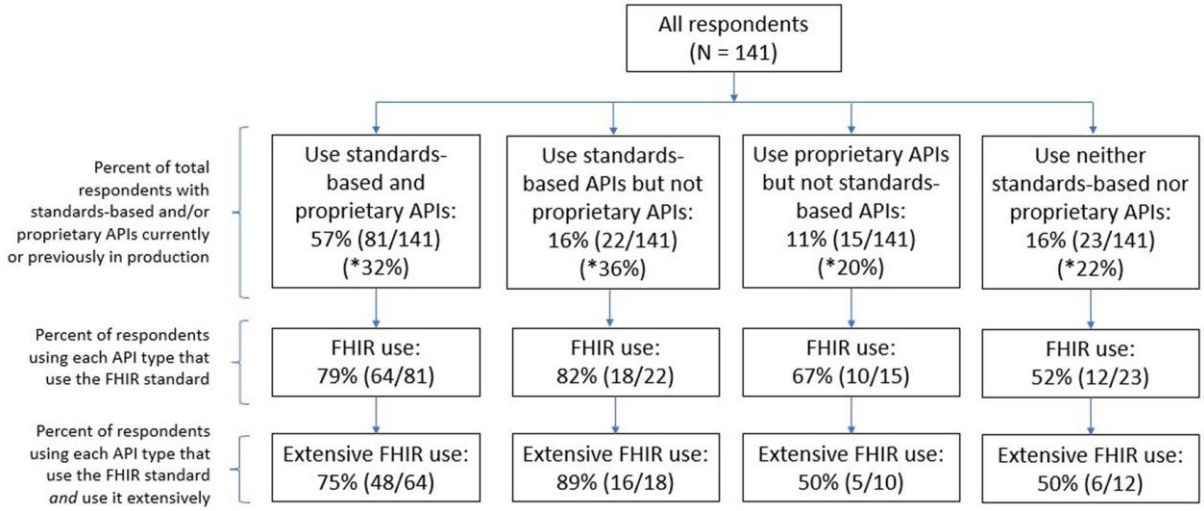

Figure 3.8: Survey on the distribution of EHR API usage. Reproduced from Figure 2 reference [162].

Furthermore, the FHIR has synergies with clinical interoperability standards, highlighted by the collaboration between Logical Observation Identifiers Names and Codes (LOINC) and FHIR. This partnership has led to the creation of the LOINC FHIR Terminology Server (as previously shown in **Figure 3.6**), which provides programmatic access to LOINC's extensive content through FHIR resources such as CodeSystem, ValueSet, and ConceptMap [157]. This integration is critical in reinforcing FHIR's position as a central standard for modern healthcare interoperability. Additionally, SNOMED International and LOINC are collaborating to address the overlaps between SNOMED Clinical Terms (SNOMED CT) and LOINC terminologies, enhancing the consistency and utility of these codes across healthcare systems [164].

3.2.2 SMART on FHIR - Authorization and Authentication

As we delve into the landscape of health data exchange, particularly with a lens on FHIR, SMART on FHIR emerges as a key protocol for securely connecting client applications to any information systems [165].

SMART on FHIR offers a standardized approach to ensuring that information systems comply with established standards such as FHIR, OAuth2, and OpenID Connect [165]. OAuth2 is critical in the authorization process [166], enabling patients and healthcare personnel to consciously authorize third-party applications to access specific data from service providers such as information systems and EHRs. This authorization mechanism maintains controlled and consensual data access, giving users autonomy over their health information. OIDC, building upon OAuth2, establishes a reliable method for user authentication. This protocol allows end users to sign into applications securely, using credentials authenticated by external identity providers [167].

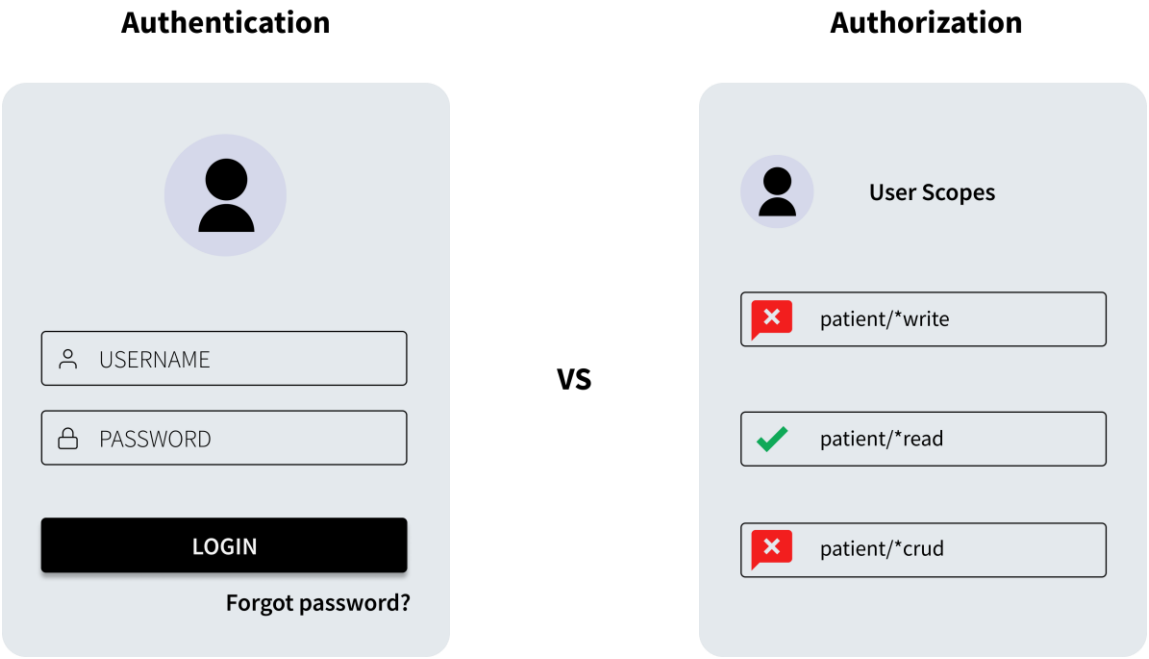

Figure 3.9: Authorization vs Authentication in SMART on FHIR. In authentication, the username and password are used to verify the identity of the user logging in. In authorization, specific scopes are defined to determine what actions a user can perform on specific FHIR resources. For example, a user may be granted permission to read only patient data ('patient/*read' scope) but may not have permission to perform all CRUD operations (Create, Read, Update, Delete) on other FHIR resources.

SMART on FHIR-based protocols are in line with a high level of security. For example, in the Norwegian context, the integration of BankID provides a high level of assurance for electronic identities [168] and operates on OIDC 1.0 and OAuth 2.0. Today, the state-of-the-art technology.

In surveying the current state of health data exchange with an emphasis on FHIR, it is possible to observe that leading cloud providers, EHR vendors, and the open-source community are moving towards FHIR, introducing their unique implementations of the FHIR and SMART on FHIR protocols. Examples that showcase the significance of these standards include Google's Cloud Healthcare API [169], Microsoft Azure Health Data Services [170], Amazon AWS HealthLake [171], and Apple's HealthKit [172], all of which support FHIR. In the U.S., the renowned EHR vendor Epic [173] and the influence of FHIR is also arriving in Norway, where services like OpenDips [174] are focusing the way for FHIR-based exchanges in the healthcare sector, or in the rest of Europe [158].

3.3 Standards and Regulations

Navigating the landscape of standards and regulations for information systems presents a formidable challenge due to international standards' global complexity and diversity. Organizations such as the International Organization for Standardization [175] (ISO) and the Institute of Electrical and Electronics Engineers (IEEE) are key in developing and disseminating standards across various fields.

These standards, alongside contributions from open-source communities (e.g., FHIR) and other entities, govern the intricacies of information systems. For example, The iCode report presented ten different ISO, IEEE or open standards applicable to CGM data schema and its integration with EHR [109].

The complexity of navigating standards and regulations is not confined to the international stage but extends to national contexts. In Norway, for instance, the "Helseplattformen project" underscores the regulatory landscape, detailing a list of 72 laws and regulations complemented by 20 standards and guidelines related to a new Norwegian EHR system [176]. **Figure 3.10** summarises the complexity of standards and regulations.

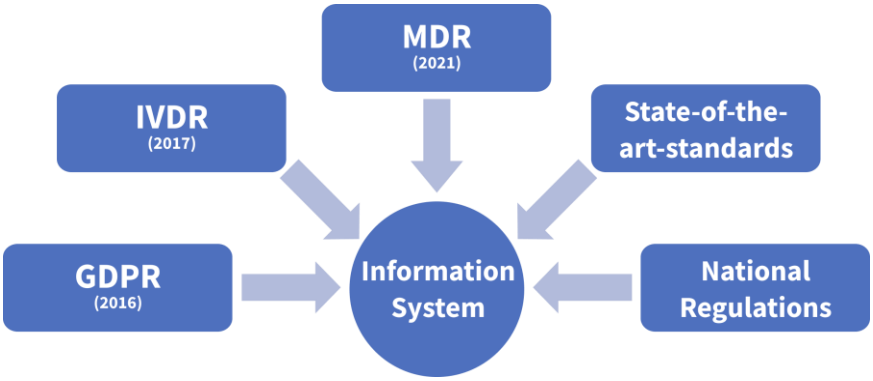

Figure 3.10: Regulations and standards affecting information systems in EEA. Adapted from Figure 1 Paper [4].

Users who wish to use diabetes management software (Section 3.1.2) are required to agree to the Terms of Service and Privacy Policies documents. These agreements usually refer to regulations and standards that are designed to protect users' rights under prevailing legal and regulatory frameworks, such as GDPR.

3.3.1 General Data Protection Regulation

In the intricate ecosystem of healthcare, policymakers emerge as crucial stakeholders, with legal interoperability becoming a fundamental necessity [158]. While privacy and security are universal concerns. Introduced in May 2018, after its initial proposal in January 2012, GDPR serves as a basis European regulation dedicated to data protection and privacy within the EEA. It is noteworthy that GDPR is recognized by various acronyms across member states, such as BDSG in Germany, and Tietosuojalaki in Finland, reflecting its widespread adoption with room for national legislative modifications, like additional restrictions [70]. Meanwhile in the U.S. Health Insurance

Portability and Accountability Act of 1996 (HIPAA) is a federal law that concerns patient health information [177].

The GDPR notably broadens the scope of what constitutes personal data and PII, impacting the classification and handling of numerous data types (e.g., IP address, biometric information) discussed within or outside the healthcare domain [70]. GDPR not only aims to safeguard data within the EEA but also scrutinizes the transfer of personal data to countries outside the EEA, ensuring a uniform level of data protection and privacy.

The legality of transferring personal data to non-EEA countries has been a subject of significant debate, especially highlighted by the Schrems II case, leading to the dissolution of the Privacy Shield on July 16, 2020 [71]. The Privacy Shield once facilitated data transfers between Europe and the U.S. by allowing U.S. companies to certify their compliance with EU data protection standards. In the aftermath of the Schrems II decision, the European Commission introduced Standard Contractual Clauses (SCCs) to regulate data transfers from the EU/EEA to third countries not governed by GDPR [4].

3.3.2 Software as Medical Device

Understanding the intricate landscape in which diabetes information systems operate requires the acknowledgement of a critical emerging topic: software as a medical device. This concept has gained prominence over the last five years and plays a pivotal role in the research domain of this PhD dissertation. Mobile health, or mHealth, is a significant field within health informatics, including mobile devices to extend patient care and enhance health outcomes [14, 178]. These technologies are increasingly integral to medical consultations, as highlighted in Section 3.1.2, reflecting their growing importance in Diabetes.

For mobile apps to genuinely benefit users and offer natural health advantages, they must undergo strict regulation and testing. Without such measures, there is a risk of safety concerns; unregulated apps might be unsafe and negatively impact health [155, 179]. Incorrect or unreliable app information could lead to wrong diagnoses, inappropriate treatments, or delays in getting the right medical care. Even apps that are accurate but limited in functionality could mistakenly guide users towards incorrect health decisions [179].

Regulating mobile apps is essential to protect users' privacy and security effectively. Without following strict standards, there is a risk of data breaches or hacking [147-149, 180]. The regulatory framework for mobile medical apps is complex and presents significant challenges for developers, manufacturers, and others in the healthcare sector [181].

The following subsection will examine how guidelines and regulatory frameworks in North America and Europe affect the software as medical device.

3.3.2.1 Software as Medical Device in Canada, U.S., and EU

Medical devices are categorized based on their application and interaction with the body, including Invasive, Non-invasive, and Active Devices and In Vitro Diagnostic Devices (IVDD) aimed at disease diagnosis and prevention [182].

In Canada, the legal framework governing medical devices (SOR/98-282) stipulates that any software included or utilized by a medical device must perform as intended by the manufacturer, with its performance validated through specific studies [183].

In the U.S. the FDA defines software functions that are considered device functions as "device software functions". This includes "Software as a Medical Device (SaMD)" and "Software in a Medical Device (SiMD)" [184].

In the EU, the Medical Device Regulation (MDR), effective from May 26, 2021 [185], broadens the definition of a medical device to include software among instruments, appliances, and other tools intended for various medical purposes such as diagnosis, prevention, treatment, or modification of physiological processes. The MDR introduces comprehensive criteria for software's inclusion in medical device categorization [185] in addition to existing In Vitro Diagnostic Regulation (IVDR) [186].

The risk associated with a medical device, including software-based applications, determines the level of regulatory oversight it receives. Devices are classified into classes ranging from I (lowest risk) to higher risk categories, with the regulatory scrutiny intensifying with the potential risk to users [187]. This classification system ensures that devices are subjected to an appropriate level of evaluation and validation, safeguarding patient safety.

Figure 3.11 provides a visual summary of these regulatory frameworks and risk classifications across Canada, the U.S., and the EU, offering a comparative perspective on the governance of medical devices, including software applications, within these regions.

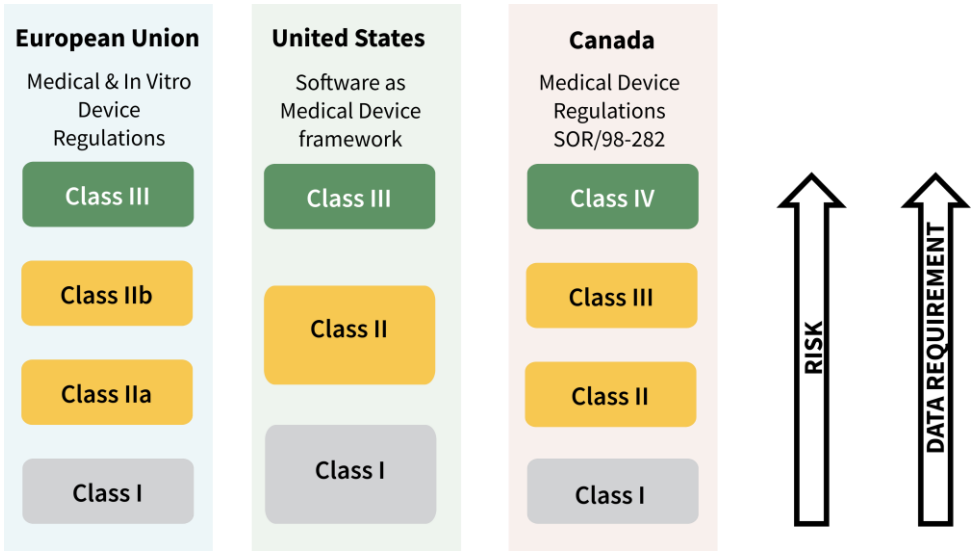

Figure 3.11: Overview of medical devices definitions. Based on a figure from reference [187].

Chapter 4 Result

This chapter combines four years of research findings, including six papers [1-5] and one under review [6]. All of them summarized in Section 4.2. The main focus of this PhD thesis is to present an information system designed for T1D consultations. The dissertation describes the technical implementation (Section 4.3) and testing and evaluation (Section 4.4) of the system, which has not yet been published.

To facilitate better understanding of the following sections, an overview of the research results, and how each paper, research question, and result section are interrelated, is presented.

4.1 Results Overview

The first step of the PhD project was to identify the problem space and the project's main problem. Paper [1] reviewed the use of Information and Communication Technologies (ICT) in interventions for Non-Communicable Diseases (NCDs) from 2015 to 2020, just before the outbreak of COVID-19. The scoping review found that these interventions had minimal integration with EHR systems, limited utilized interoperability standards such as FHIR and OpenEHR, and rarely focused on privacy. Moreover, the review exposed the extensive use of sensors for various NCDs. It also revealed a shortage in ICT interventions for continuous patient follow-up before, during, and after consultations.

Further refining the project's main problem, Paper [2] identified specific criteria for the Dia-Continua Information System that healthcare professionals (HCPs) would value and recommend for ICT in diabetes management. These criteria emerged from insights from earlier DiaDig project publications [7, 9]. HCPs prioritized "Information Quality" and "Usability" as primary criteria in the Delphi study [2].

These findings from the scoping review [1] and the Delphi study [2] were used to refine the research questions. Paper 1 refined the RQ1 and RQ2 in more technical terms, including interoperability, security, privacy, and automated data collection of patient-generated health data (PGHD). The Delphi study [2] influenced RQ3, emphasizing the information quality in diabetes consultation. It also redirected the focus towards privacy since HCPs expected other stakeholders to address privacy and security concerns, underlining the necessity for these elements to be inherently integrated within the information system (RQ2).

After refining the initial research questions, Paper [3] introduced a new model for T1D medical consultations. This model integrates medical data (such as blood glucose levels, insulin doses, and carbohydrate intake) and lifestyle data (including sleep patterns and physical activity) into a structured medical consultation process. It envisions a future where such data are collected and shared with EHRs, facilitating follow-up consultations.

The following PhD phase involved assessing the feasibility of the model proposed in Paper [3]. Paper [4] tackles the challenges of privacy and legal interoperability, drawing on prior findings that

indicated a general lack of detailed privacy measures [1] and a limited concern for security and privacy among HCPs [2] since the 'security and privacy' were ranked among the last criteria in order of importance. Paper [4] examines the regulatory practices of proprietary software regarding data access to determine if the model outlined in Paper [3] could be realistically implemented.

Paper [5] introduced a consent management system using FHIR since privacy, legal interoperability and informed consent emerged as critical considerations in Paper [4]. This system simplifies the consent process, empowering patients to make informed decisions about the use of their health data for various purposes (e.g., primary and secondary uses).

Lastly, Paper [6] focuses on the crucial aspects of real-time data access and secure data exchange via APIs, essential components of the consultation model proposed in Paper [3]. Paper [6] explored both technological and legal challenges, further informed by Paper [4] findings, which highlighted how restrictive Terms of Service may limit health personnel's data access abilities.

This dissertation also addresses the Research Questions outlined in the PhD project. Section 4.3 presents the technical implementation of the information system, which corresponds to RQ1. It details the capabilities of a unified information system designed to integrate PGHD, encompassing both medical and lifestyle information, thus addressing RQ1. The systems ensure robust security, privacy, and adherence to data ownership principles that address RQ2. Furthermore, the dissertation explores how the system facilitates controlled data sharing with HCPs and external entities such as national registries, informal caregivers, and researchers (RQ2). Section 4.4 presents the system's evaluation by healthcare personnel after real patient data testing, which aligns with RQ3. All the contributions to the research questions presented in the chapter are concisely summarized **Table 4.1**.

Table 4.1: Connecting research questions with papers and results.

Research Question	**Research Question Description**	**Papers/Chapter**
RQ1	How can we integrate different health-related devices used daily by individuals with diabetes and patient-generated health data into a unified information system for patients and health personnel to use before, during, and after medical consultations?	P1*, P3, P4, P6 Section 4.3
RQ2	How can patient-generated health data be exchanged between clinicians, patients and informal caregivers before, during and after the consultation, with robust security and privacy measures?	P1*, P2*, P4, P5, P6 Section 4.3
RQ3	How can individual-specific patient-generated health data improve the information quality during the medical consultation?	P2*, Section 4.4

* The paper refines the contribution rather than contribute directly.

4.2 Summary of the Included Papers

The subsequent subsections from 4.2.1 to 4.2.6 will discuss each of the papers. For each paper, key elements such as the authors' contributions, main findings, and their relation to the research questions are summarized. The published papers will be available in Part II: Research Papers, meanwhile **Table 4.2** lists the papers included in this PhD dissertation.

Table 4.2: Included papers overview.

#	Refer to as	Title	REF
1	Review Paper (Journal)	Information and communication technology-based interventions for chronic diseases consultation: Scoping review.	[1]
2	Delphi Paper (Conference)	Criteria for Assessing and Recommending Digital Diabetes Tools: A Delphi Study.	[2]
3	Model Paper (Conference)	Towards a New Model for Chronic Disease Consultations.	[3]
4	Privacy Paper (Journal)	Privacy Concerns Related to Data Sharing for European Diabetes Devices.	[4]
5	Consent Paper (Conference)	Consent Management System on Patient-Generated Health Data.	[5]
6	Interoperability Paper (Journal)	Obstacles in Accessing Real-Time Diabetes Data for Treatment and Research: Toward an Interoperability Model (under review)	[6]

4.2.1 Paper 1: Information and Communication Technology-based Interventions for Chronic Diseases Consultation: Scoping Review

Authors: Randine Pietro, Sharma Aakash, Hartvigsen Gunnar, Johansen Håvard, Årsand Eirik

Authors' contribution: Randine took the lead in writing the paper as the main author. Randine, in collaboration with Hartvigsen and Årsand, developed the research protocol [188]. The paper's 'Materials and Methods' section [1] provides more specifics on the scoping review process. Randine and Sharma conducted the main parts of the eligibility and data collection with the support of Årsand. Hartvigsen and Årsand supervised the research, with all authors contributing to the writing of the paper.

Main findings presented in the paper: The review identifies 24 studies that use ICTs across all phases of the consultation process (before, during, and after). Web-based portals and smartphone applications were identified as the predominant ICTs, frequently supported by cloud-based services and EHRs. Overall, the identified ICTs were used mainly by patients and healthcare personnel, predominantly physicians and nurses. Others, such as family members, were participants in only two studies. Additionally, sensors and wearable devices were emphasised for managing various chronic conditions. They were used in (23/24) studies showcasing the variety of data collected for different diseases. The review points to a shift towards automated data collection, acknowledging

certain limitations associated with manual data-gathering methods. It also highlights the limit in discussing privacy and security concerns within these studies.

Relation to the research questions: Paper [1] outlines the state of the ICT interventions in chronic disease management, refining RQ1 with a focus on interoperability and automated data collection. For RQ2, it emphasised the importance of ensuring security and privacy in these solutions.

4.2.2 Paper 2: Criteria for Assessing and Recommending Digital Diabetes Tools: A Delphi Study

Authors: Larbi Dillys, Randine Pietro, Årsand Eirik, Bradway Meghan, Antypas, Konstantinos, Gabarron Elia

Author contribution: Larbi led the paper writing and study, and Gabarron provided general supervision to the research. As the second author, Randine contributed to the manuscript writing and, together with all authors, refined the criteria definitions presented to HCPs. Moreover, the HCPs received compensation for their participation via the DiaDig funds.

Main findings presented in the paper: The study aims to determine criteria for evaluating and recommending ICTs for managing diabetes, involving a diverse group of 15 healthcare professionals in a Delphi study over three rounds. The expert panel identified "information quality" and "usability" as the main criteria for evaluating digital diabetes management tools (ICTs). Most healthcare professionals considered "security and privacy" less critical and assumed that these ICTs would comply with all necessary security and privacy regulations.

Relation to the research questions: This Paper establishes consensus on criteria for evaluating the information system, focusing specifically on "information quality". This directly shapes the RQ3. It stresses the importance of addressing security and privacy in the design and development objectives since they are assumed to be there and considered little relevant (RQ2).

4.2.3 Paper 3: Towards a New Model for Chronic Disease Consultations

Authors: Randine Pietro, Cooper John Graham, Hartvigsen Gunnar, Årsand Eirik

Author contribution: Randine took the lead in writing the paper as the main author and analysing regulatory, privacy, and interoperability challenges associated with the model. Cooper, as a healthcare professional working with Diabetes, provided feedback on the medical side of the model in order to identify existing gaps in current practice. Årsand and Hartvigsen provided general supervision of the research and the paper.

Main findings presented in the paper: This article introduces a model for managing chronic disease consultations focusing on T1D. The proposed model organises consultations into three phases—before, during, and after the consultation—utilising ICT. The proposed model seeks to improve medical consultations by incorporating more health data into clinical decision-making, facilitating

personalised care plans, and reusing health data. It emphasises the importance of interoperability and the necessity for data exchange standards (e.g., FHIR, OpenEHR) while also addressing regulatory and privacy challenges (e.g., MDR, GDPR) and technical difficulties in implementing such a model in clinical practice [3].

Relation to the research questions: This model is an artifact within the Design Science Research Methodology [81]. It contributes to RQ1 in proposing a structured approach and organisation for integrating various health-related devices into a unified information system, as shown in **Figure 4.1**.

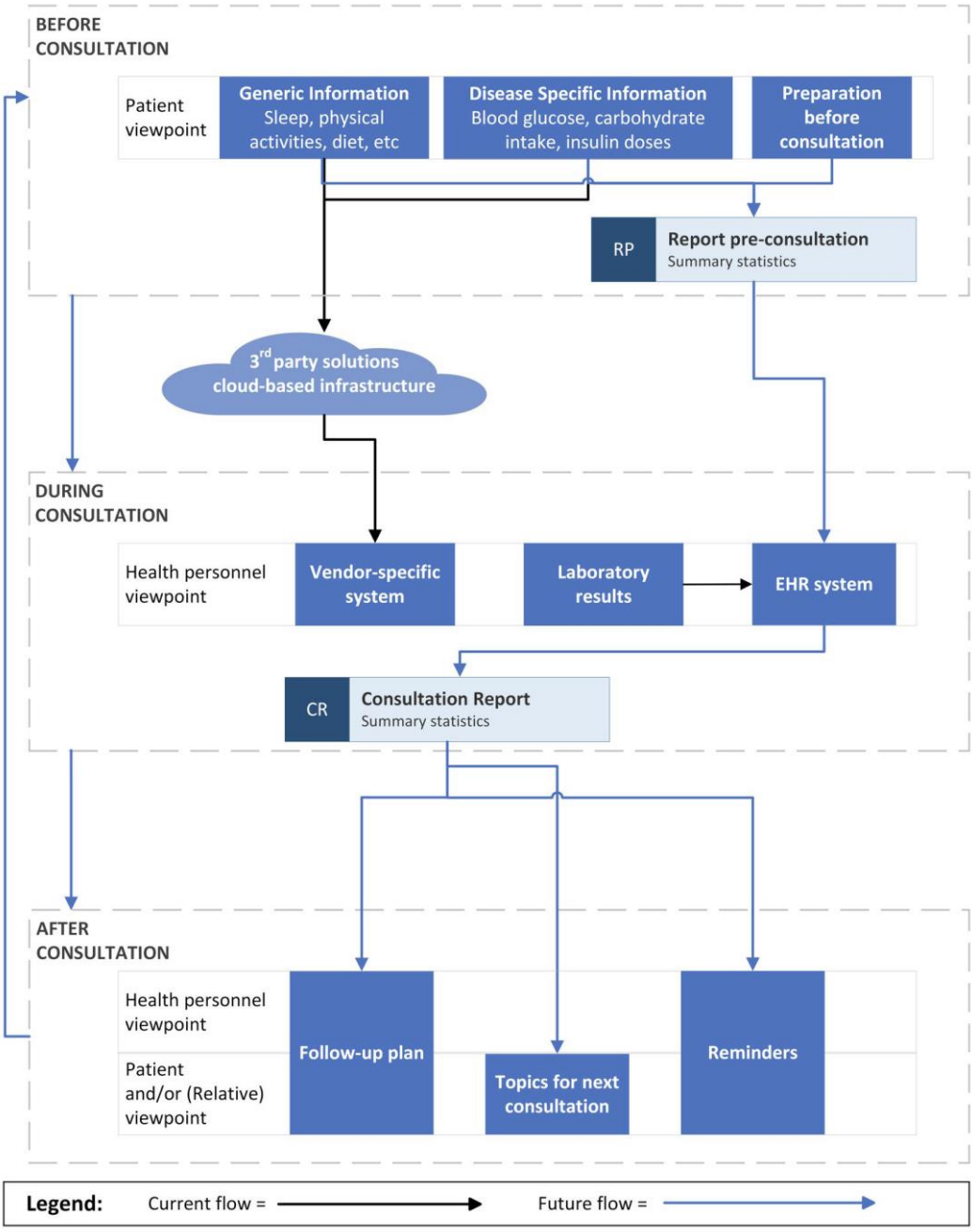

Figure 4.1: A new model for chronic disease consultation. Reproduced from Figure 1 from Paper [3].

4.2.4 Paper 4: Privacy Concerns Related to Data Sharing for European Diabetes Devices

Authors: Randine Pietro, Pocs Matthias, Cooper John Graham, Tsolovos Dimitrios, Muzny Miroslav Besters Rouven, Årsand Eirik

Author contribution: Randine took the lead in writing the paper as the main author. Randine, Cooper, Muzny and Årsand had the initiative to investigate the data sharing of diabetes devices in the HEIR project scope. Cooper, with his healthcare expertise, verified software and medical device usage. Besters contacted the medical vendors for validation of the Terms of Service and privacy policy documents identified. Pocs and Tsolovos, working in security technology law, collaborated to extract information from legal documents. Randine formulated and refined the legal discussion with Pocs. Årsand provided overall research supervision. All authors reviewed and revised the manuscript.

Main findings presented in the paper: As outlined by previous studies in this dissertation [1-3, 7], developing an information system that adheres to the current legal framework and standards (Legal Interoperability) is crucial. Non-adherence to existing legislation would render new models of medical consultation, such as the one presented in Paper [3], unfeasible. Verifying how manufacturers and third parties regulate the data flow from the patient's medical equipment is necessary to achieve a unified information system. The findings of this paper report 11 types of medical equipment diabetes patients use in Norway and identified 12 software associated with the medical equipment. Some software has a dual purpose, serving patients and health personnel (3/12), while others are exclusive to one group (patients 6/12 and health personnel 3/12). An analysis of GDPR security measures compliance revealed that most software (8/12) applications depend on an adequacy decision (is a recognition by the European Commission that a non-EU country or organization provides the same level of protection for personal data as the EU does [189]), with the rest (4/12) not indicating any. Additionally, the study assessed the registration status of medical equipment and software in the European Database on Medical Devices (EUDAMED database) to ensure alignment with new MDR and IVDR regulations [185, 186]. Only three medical equipment (3/11) were registered in the database, although none of their respective software applications were registered (0/12). This investigation reveals that some systems explicitly state in their Terms of Service that they are not an EHR system, and HCPs must print or download the data to provide treatment or advice to the patient.

Relation to the research questions: It addresses RQ1 by discovering that some medical vendors have explicit disclaimers regarding their non-EHR status, and that HCPs need to print or download data to give their patients treatment advice. It underscores the need for an information system with explicit functionalities to bridge this gap and avoid manual inputs. Additionally, analysing how manufacturers and third parties manage patient device data flow contributes to RQ2 by analysing the gap in current data processing.

4.2.5 Paper 5: Consent Management System on Patient-Generated Health Data

Authors: Randine Pietro, Salant Eliot, Muzny Miroslav, Pape-Haugaard, Louise

Author contribution: Randine took the lead in writing the paper as the main author and had the initiative in the HEIR project to utilize the FHIR consent resource to develop a more advanced consent management system with FHIR. Salant worked with Muzny and Randine to tailor the IBM-Fybrik framework [190] to the system's specific requirements. Pape-Haugaard contributed to FHIR standards expertise and supervised the manuscript writing. All authors reviewed and revised the manuscript.

Main findings presented in the paper: This paper addresses the complexity and challenges of consent management in healthcare, particularly highlighted in Paper [4], by proposing a consent management system built on HL7 FHIR. This system aims to clarify and facilitate the process by which individuals with diabetes, and people in general, can consent to HCPs and researchers using their health data for both primary purposes like treatment and secondary purposes like research. The system is based on FHIR Consent Resource and Data access policies to enable health data owners, like patients are when they are using their health tools, to share their information effectively. We generated and used synthetic data to demonstrate the system's capabilities. When data requesters, such as researchers or organizations like Noklus, seek health data access, they must submit an FHIR request. The consent management system then evaluates this request against defined policies, the identity of the requester, and a constraint, such as geo-locational limitations, ensuring compliance with initiatives like the European Health Data Space [73]. The consent management system architecture overview is presented in **Figure 4.2**.

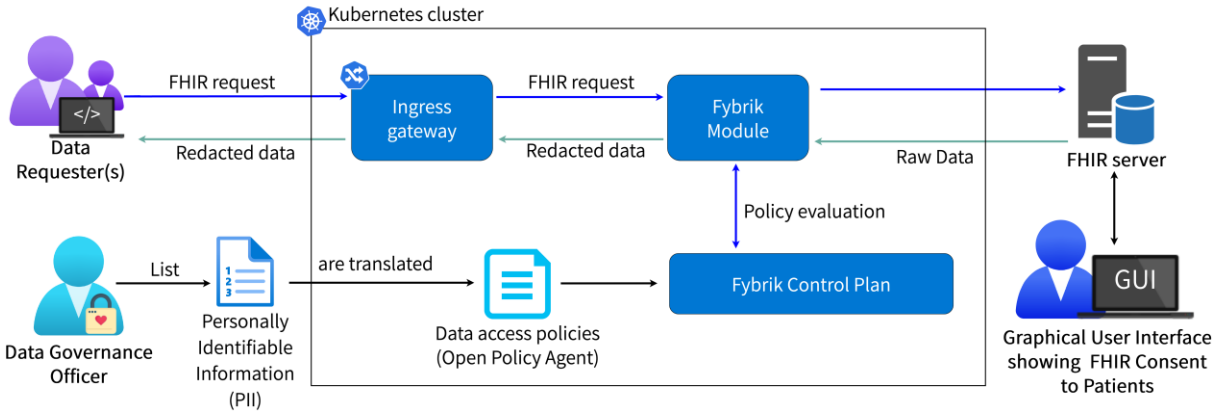

Figure 4.2: Consent management system architecture. Reproduced from Figure 1 from Paper[6].

Relation to the research questions: This paper introduces a consent management system that implements the HL7 FHIR standard for patient consent management. It contributes specifically to RQ2, and it demonstrate via synthetic data how a system based on FHIR, has the capability to manage consent for both primary usage such as treatment of people with T1D, and secondary usage such as research, ensuring compliance with legal standards (e.g., GDPR).

4.2.6 Paper 6: Obstacles in Accessing Real-Time Diabetes Data for Treatment and Research: Toward an Interoperability Model

Please note that this paper is under review.

Authors: Pietro Randine, Miriam Kopperstad Wolff, Matthias Pocs, Ian R. O. Connell, Joseph A. Cafazzo, Eirik Årsand

Author Contribution: Randine led the writing and was the main author, setting the study goals with Cafazzo and Connell, while Årsand oversaw the project. Randine also engaged with national authorities on cloud functionality and, along with Wolff, evaluated DIY community solutions. Together with Pocs, Randine examined Terms of Service documents. Pocs focused on German copyright law, and Randine on Norwegian copyright law. Randine proposed an interoperability model and revised it with Cafazzo and Årsand. All authors contributed to reviewing and revising the manuscript.

Main findings presented in the paper: The paper concludes with a proposed interoperability model and standards targeting policymakers, offering solutions to navigate data reuse challenges and compliance with GDPR. It also aligns with the European Union's initiatives towards the Health European Data Space [73]. This study revealed that none of the hybrid closed-loop systems provide real-time data access via a regulated API or through unofficial software in Norway. Only 2 out of 9 software solutions possess a publicly documented API. The absence of official real-time data access options prompted the exploration of seven DIY software alternatives. However, none were considered suitable for large-scale projects due to data accessibility, security, or legal constraints such as copyright violations. Regarding copyright, the study also investigated whether Directive 2009/24/EC exception to copyright in the EEA [191] could be used to utilise for DIY solutions on a large scale (e.g., research study). The study looked into the directive's implementation in Norway and Germany [192, 193] and its relation to the Term of Service of these manufacturing software. DIY software solutions were ineligible for the directive, focusing only on interoperability, not new functionalities. **Figure 4.3** illustrates the regulated and unregulated paths to access real-time diabetes data.

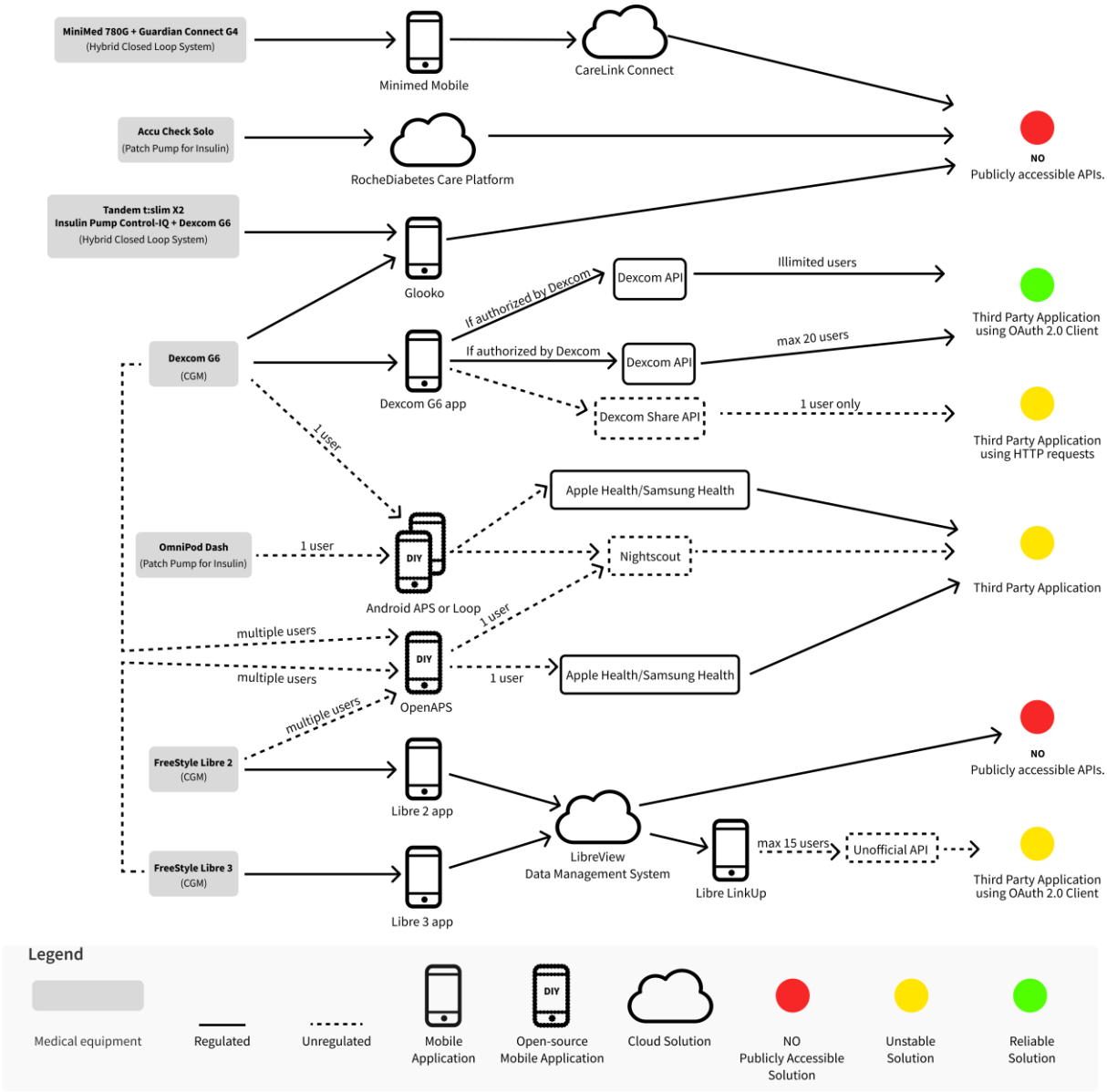

Figure 4.3: Limitation in data access in diabetes. This figure illustrates the various paths for using a data solution suitable for large-scale projects. The paths are colour-coded at the end, with circles representing their reliability and safety levels. The circles are coloured red (no publicly accessible API available), yellow (unreliable), and green (reliable). The red circle indicates that no publicly accessible API is defined, making it impossible to obtain data. The yellow path represents solutions with limitations, such as copyright infringement, security vulnerabilities, or limited user connectivity. Finally, the green path denotes fully reliable solutions that utilize official APIs and do not have the significant drawbacks of the red or yellow categories. Reproduced from Figure 1 of Paper [6].

Relation to the research questions: This paper proposes an interoperability model and a set of standards targeting the model proposed in Paper [3] in line with RQ1. It demonstrates the practical challenges when implementing systems like Dia-Continua in T1D consultations. This includes the specific issue of accessing real-time data from medical devices through both regulated and unregulated software. It addresses the RQ2 in terms of measures that need to be in place in order to use alternative solutions like the one by DIY, revealing that none of them are feasible. It also makes an evaluation via the software: "conversion-csv-FHIR" and "Libre-link-up-FHIR", developed as part of this study and made available in public repositories [194], [195]. Both software highlight

the challenges and emphasise the need for an interoperability model. The Interoperability model for policymakers is shown in **Figure 4.4**.

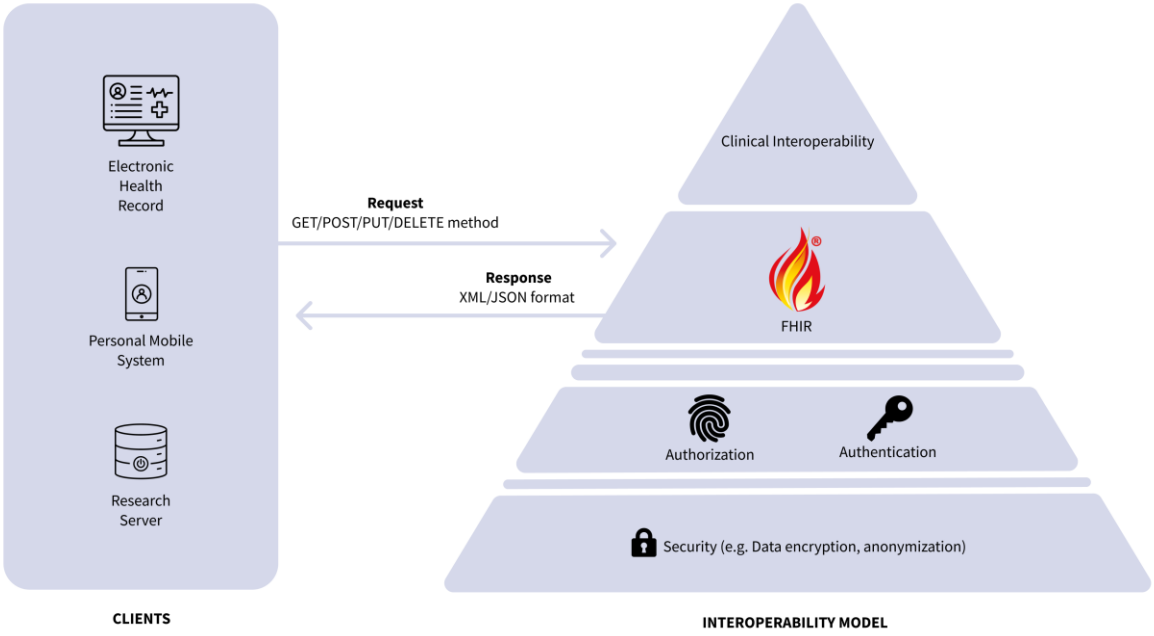

Figure 4.4: Proposal for an interoperability model. This figure illustrates an interoperability model that proposes a set of standards for diabetes data within healthcare information systems. The diagram shows various clients on the left, such as Electronic Health Records, Personal Mobile Systems, and Research Servers. These clients interact with the central interoperability model using standard methods like the REST API method (e.g., GET, POST, PUT, and DELETE). Responses are exchanged in formats like JSON. The core of this model is FHIR for health data exchange. The entire structure is based on layers of security, authorization, and authentication. Reproduced from Figure 2 of Paper [6].

4.3 Dia-Continua: Technical Implementation

The Dia-Continua information system is designed to interact with its environment, which includes various elements such as users (e.g., patients, informal caregivers, and healthcare professionals), medical devices like CGM, insulin pumps, and patch pumps, and wearable devices like Oura Ring or smartwatches such as Fitbit, along with their corresponding cloud platforms like Google Fit or Oura Ring cloud. **Figure 4.5** illustrates the Dia-Continua and its interaction with these elements.

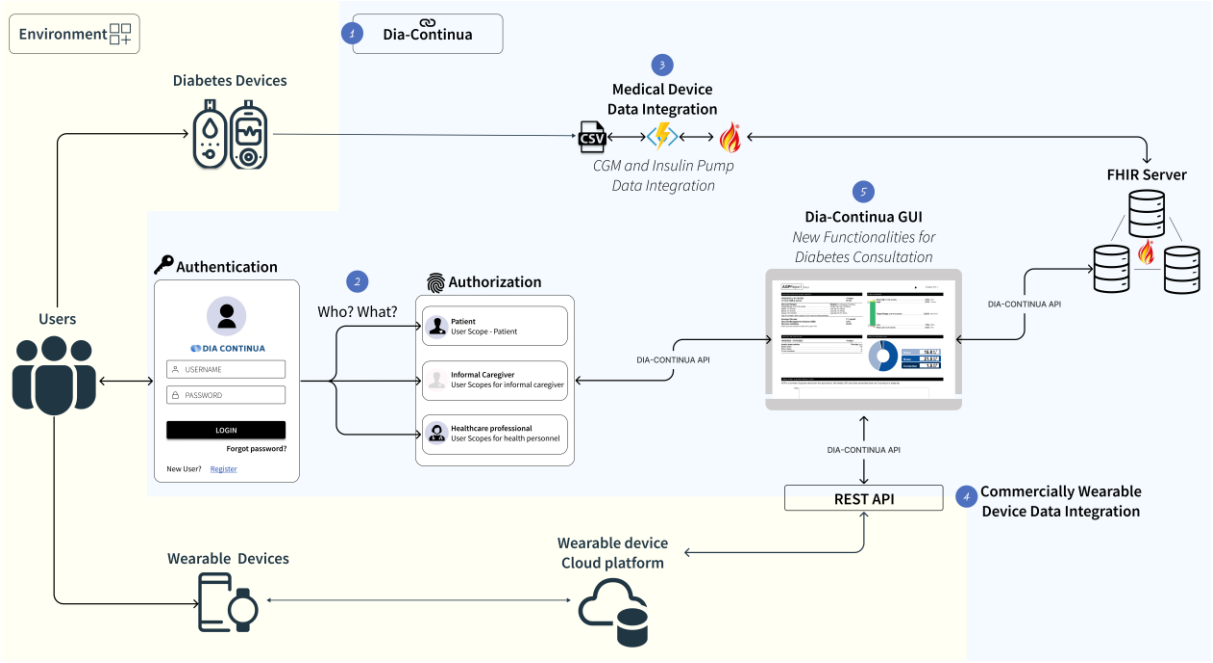

Figure 4.5: Dia-Continua: Artifact vs Environment.

All components of **Figure 4.5** will be further explored in subsections from 4.3.1 to 4.3.5. Below is a brief overview of each component, serving as an introduction to the detailed technical implementation that follows:

1. **Microservice Architecture of Dia-Continua** (Section 4.3.1): This section details the base of Dia-Continua specifically its network of independent microservices. This Microservice Architecture is the outcome of the design and development efforts presented in Section 2.2.1.

2. **Authentication / Authorization Protocols** (Section 4.3.2): This section describes the Dia-Continua implementation of the SMART on FHIR, presented in Section 3.2.2, to ensure the privacy and security of health data through robust authentication and authorization mechanisms.

3. **Integration of Medical Device Data** (Section 4.3.3): This section describes how the medical device data can be integrated using the device introduced in Section 3.1.1.

4. **Integration of Commercially Wearable Device Data** (Section 4.3.4): This section focuses on the integration of wellness and lifestyle data from commercially wearable devices via REST APIs, introduced in Section 3.1.3.

5. **New Functionalities for Diabetes Consultation in Dia-Continua** (Section 4.3.5): This section describes how Dia-Continua GUI integrates patient-generated health data from both medical devices and commercially available wearable devices to introduce new functionalities for the diabetes consultations.

4.3.1 Microservices Architecture Overview

The Dia-Continua information system is built on cloud infrastructure provided by Azure IaaS, with servers located in the EEA. Appendix 1: Assessment of Processing of Personal Data presents the ethical approval, which was necessary to test and demonstrate the technical solution in real-world scenarios. The Azure infrastructure includes various components, such as CI/CD pipelines, Azure Kubernetes Service (AKS), Azure Load Balancer, and Azure Container Registry.

In summary, **Figure 4.6** provides a visual overview of the Dia-Continua information system architecture, indicating how its various microservices in the AKS production cluster interact within the Azure IaaS. This architecture is the result of the deployment process shown in **Figure 2.6** in Section 2.2.1.

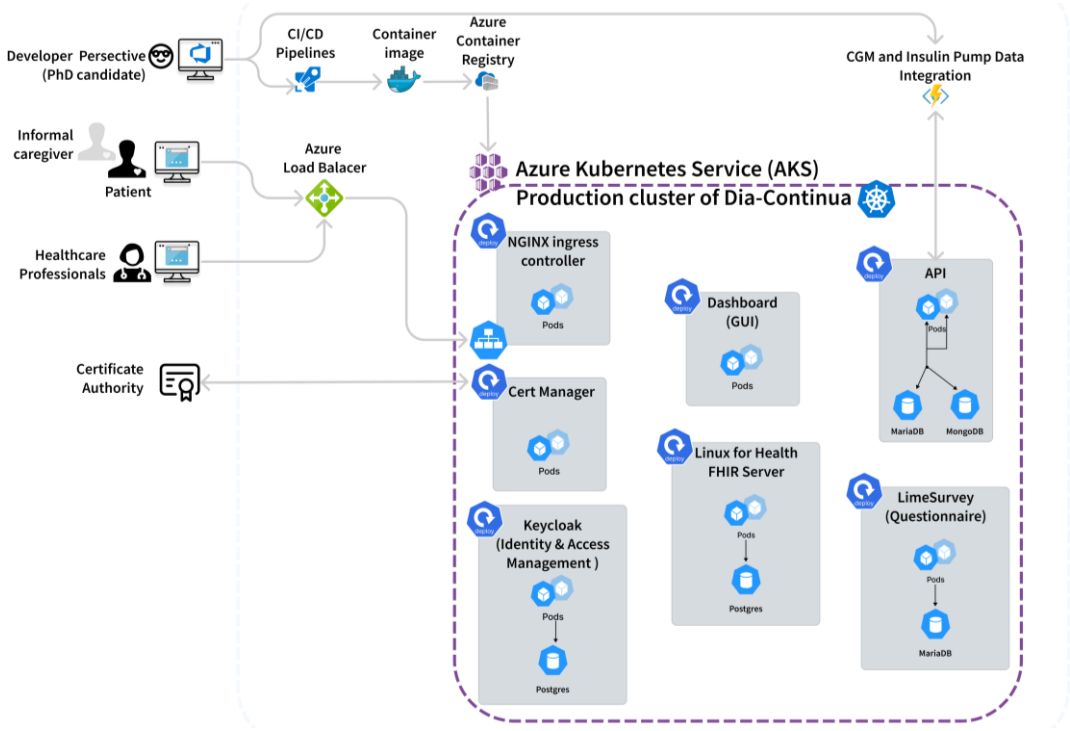

Figure 4.6: Dia-Continua architecture - simplified overview. Dia-Continua system's architecture utilizes a microservices framework orchestrated by Kubernetes, facilitating the communication between services. The CI/CD pipelines are integral for updates and deployment processes. Within the AKS production cluster, various pods operate with multiple virtual databases (e.g., Postgres, MariaDB) as PVCs (Persistent Volume Claims) in Kubernetes. Any updates by the developer (the PhD candidate in this case) or revisions to the microservices (e.g., API, GUI) initiate a CI/CD pipeline process that builds a new Docker image. This Docker image is then uploaded to the Azure Container Registry, followed by its deployment for user access, ensuring that the system is up-to-date and accessible for end-users.

AKS production cluster of Dia-Continua integrates multiple microservices, each fulfilling different functionalities as shown in **Figure 4.6**. The microservices architecture allows for splitting the application into smaller, independent services, which are described in detail in **Table 4.3**. This approach ensures that the services communicate with each other in a self-contained and isolated manner through API calls, both synchronous and asynchronous.

Table 4.3: System architecture: main microservices.

Microservice	**Description**
NGINX ingress-controller	Directs incoming traffic to the appropriate services within the Kubernetes cluster, enhancing both efficiency and security [96].
Cert-Manager	Handles the management, issues, and renewals of SSL/TLS certificates from certification authorities, ensuring secure communications [97].
Keycloak	Provides identity and access management solutions, offering secure user authentication and authorization [196]. More details about both mechanisms are presented in Section 4.3.2.
API	A Java servlet that orchestrates API calls, directing them towards system components like the Dashboard (GUI) or Keycloak for effective management.
Dashboard (GUI)	A React Component serving as the GUI, enabling system interaction, data visualization, and access to various functionalities. More details are in Section 4.3.5.
LimeSurvey	Open-source survey software used to create and manage online surveys, facilitating user feedback and research [197]. It also includes a Python component that translates questionnaires or PROMs stored in PostGRES into FHIR resources [10]. More details are in Section 4.3.5.1.
Linux for Health FHIR Server	Supports healthcare data management adhering to FHIR standards, facilitating efficient data storage, retrieval, and system interoperability and support SMART on FHIR configuration [198].

Appendix 2: Notification Form for Processing of Personal Data provides additional details on the security measures (such as encryption and data storage) and how PII is protected in the various databases shown in **Figure 4.6** or the microservice presented in **Table 4.3**.

4.3.2 Authorization and Authentication for Patients, Informal Caregivers and Health Personnel

The Dia-Continua information ensures security and appropriate health data access (e.g., blood glucose, insulin, and carbohydrate intake). The authentication process, integral to the system's functionalities, employs the principles of SMART on FHIR, earlier described in Section 3.2.2. This process is critical to managing the access rights of different users, including patients, healthcare personnel, and informal caregivers, within the system's architecture, as shown in **Figure 4.7**.

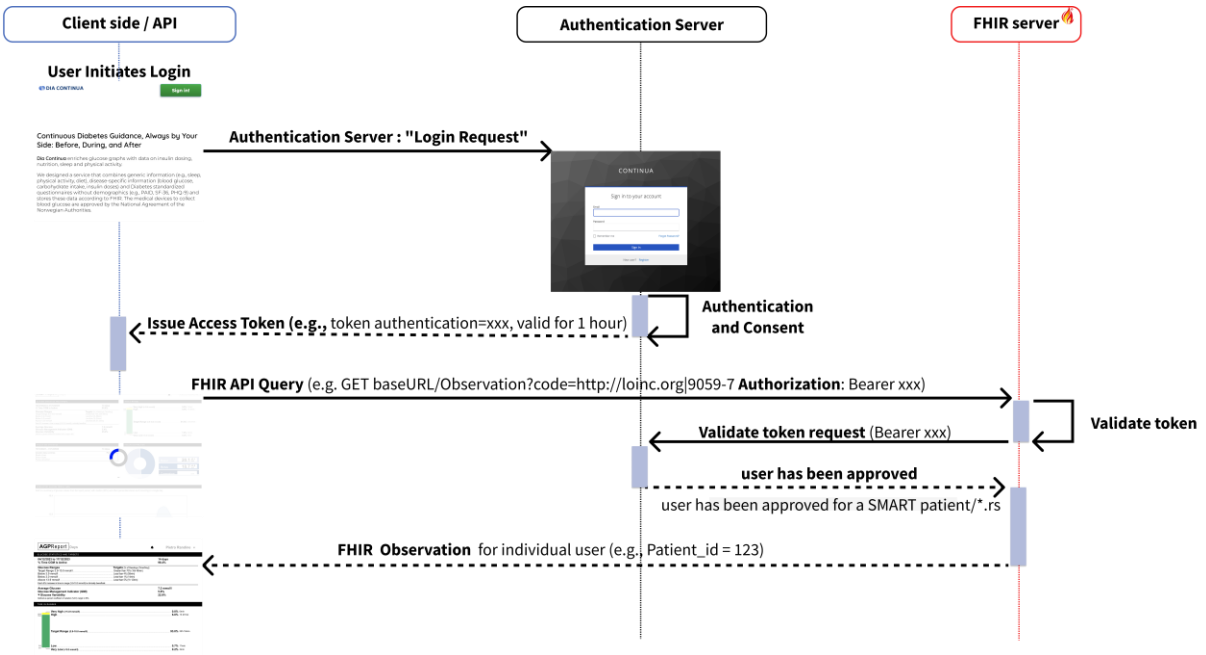

Figure 4.7: Authorization and authentication process. Users can start the authorization and authentication process by logging in via the browser (if they are already registered). Once the login process begins, it is redirected to the authentication server (such as Keycloak) and if the login is successful, an access token (e.g. xxx) is generated. The client side/API can use this access token to request specific FHIR resources (e.g. carbohydrates estimation with code=9059-7) within their scope (e.g. patient/*.rs). However, for a successful GET operation, the authentication server must validate the token request with the FHIR server. If the user and access token are valid and approved, the client side can now visualize the requested FHIR Resource via the Dashbord/GUI.

Configuring the FHIR [198] server to recognize a designated identity provider (i.e., Keycloak in this system) is part in the authentication process. This SMART-configuration, usually specified at *.well-known/smart-configuration*, confirms the server's ability to use secure and validated access tokens for user authentication, improving the integrity of the data exchange process.

The integration of SMART on FHIR provides a secure method for the client side (e.g., the Dashboard) to enable conditional access to the health data [165]. This conditional access is governed by OAuth2-based authorization protocols [166], which ensure that health data interactions are securely managed. The system assigns specific scopes to each user role, i.e., *patient/*.rs,* which means that the user can only read all data about a specific patient. The system's authentication and authorization mechanisms distinguish between users based on the various scopes associated with their accounts, as shown in **Figure 4.8**.

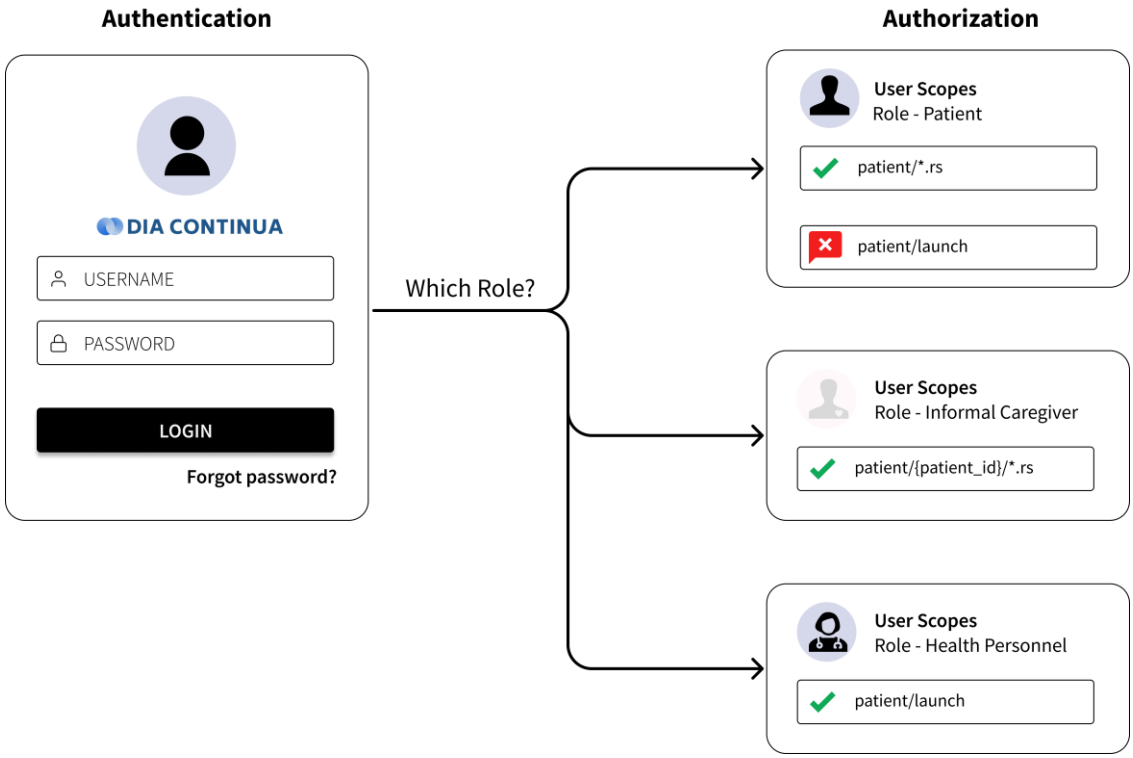

Figure 4.8: Authorization and authentication in Dia-Continua based on the role. The following figure illustrates the primary differences in scope associated with the FHIR server. The 'patient/*.rs' permission grants the ability to read all FHIR resources associated with the current patient. Conversely, 'launch/patient' requests the selection of a patient during application launch, making this scope reserved for healthcare personnel only. Additionally, for informal caregivers to define the patient with whom the user is associated, knowledge of the patient's FHIR 'patient_id' is necessary to successfully read the FHIR resources associated with that specific patient.

While the system is structured to support advanced two-factor authentication (2FA) methods, such as Bank ID [168], the demonstration and testing phases did not employ these methods. Instead, the system's current authentication structure utilizes widely accepted authenticator apps (e.g., Microsoft Authenticator and Google Authenticator), ensuring a balance between robust security and user convenience for those residing outside Norway [167].

Moreover, to register with Dia-Continua, patients must confirm their identity and get information about how their personal data will be handled. This follows the guidelines set by Sikt and GDPR regulations. More details about the project and informed consent can be found in Appendix 2: Notification Form for Processing of Personal Data. Meanwhile, the informal caregivers or HCPs must also register upon request. Based on the specific user, data access can be granted, for example, a doctor can visualize all his/her patients. The registration process is summarized in **Figure 4.9**.

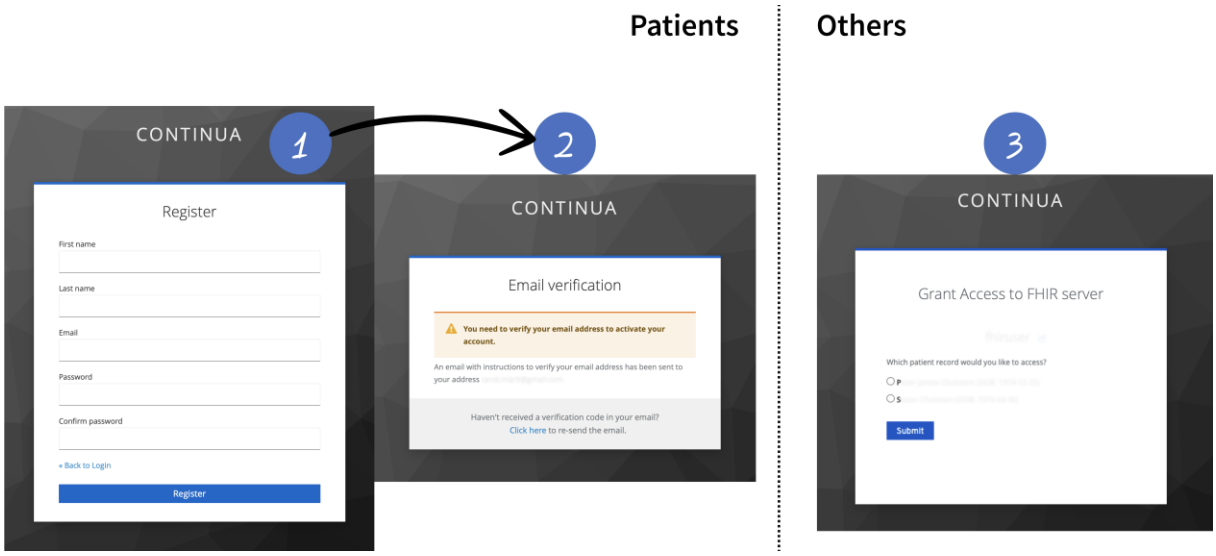

Figure 4.9: Registration process. To sign up for the platform, patients should go to the "Register" page and provide the required details. After submitting the information, they will receive a mail containing the informed consent. By clicking on the link in the email, they can confirm their consent and access the Dia-Continua. However, the registration process differs for healthcare professionals (HCPs) and informal caregivers. In this project, the PhD candidate creates an account for them, and they will receive a confirmation link via email, like for the patients (2). Once they log in, they will be prompted to select the patient they are representing from a list of possible patients. This step is shown in (3), where they can choose which patient's information they want to view.

4.3.3 Hybrid-Close Loop Data Integration

Hybrid closed-loop system generate extensive data, thousands of daily records, like glucose readings, insulin doses, carbohydrate estimations and metadata. This volume of information presents various challenges and opportunities, which are discussed in more detail in Section 5.1.

The main challenge is obtaining data from medical devices. Paper [6] proves the limits of regulated and unregulated software channels for incorporating data from the hybrid close loop system, which are not possible access with OIDC and OAuth2. Additionally, compatibility issues with newer medical devices identified from January 2023 [126] led to the deprecation of the Tidepool Uploader in Dia-Continua. Moreover, the cloud solution for the OmniPod Dash was also found to be unavailable in Norway, as confirmed by national authorities [6].

To collect data from the hybrid-closed loop system and enable patients or informal caregivers to upload it, an alternative Azure Function was created. This function simplifies uploading data through Comma-Separated Values (CSV) files, as illustrated in **Figure 4.10**.

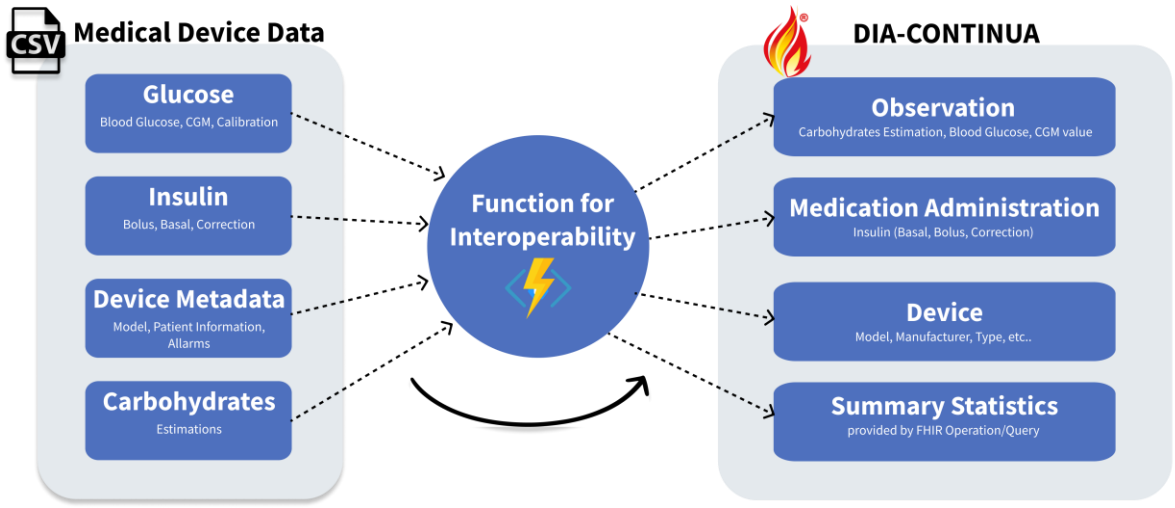

Figure 4.10: Hybrid-close loop data integration from CSV to FHIR Resources.

To process this large volume of data, the following steps need to be performed:

1. This anonymized data is organised into a weekly FHIR bundle, with an FHIR Conditional Create operation to avoid data duplication.

2. Each bundle is forwarded to the FHIR server and safeguarded through an authentication and authorisation mechanism, the Client Credentials Flow (part of the OAuth2, designed for applications without user interaction [166].

3. Data are available in an anonymised FHIR resource for queries, operations and information systems.

This function for interoperability, shown in **Figure 4.10**, is made publicly accessible through a GitHub repository maintained by the author of this dissertation [161]. This transparency serves the scientific community and aligns with the philosophy of open research and collaboration, although there are some limitations in software for interoperability, as discussed later in Section 5.2.1.

4.3.4 Commercially Wearable Device Data Integration

The Dia-Continua system integrates health data from Google Fit and Oura Ring via OAuth2 and OIDC. It redirects the user to external OAuth consent screens. Users explicitly control their health data-sharing preferences. This allows for tailored data sharing before, during, and after medical consultations. Consent interfaces notify users about the data being accessed, as shown in **Figure 4.11**.

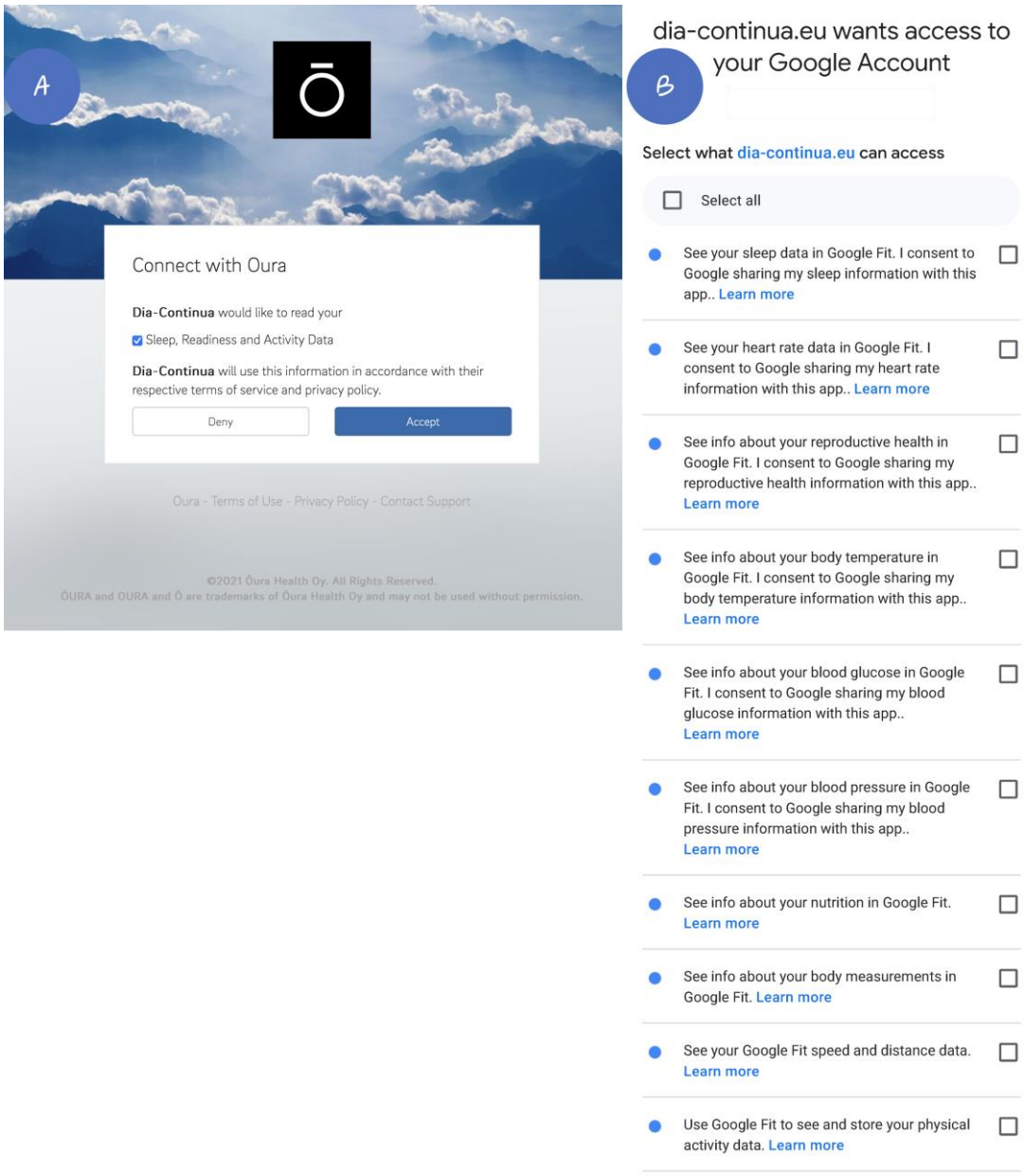

Figure 4.11: OAuth2 authentication: Oura Ring vs Google API. This figure compares the OAuth2 page authentication processes for Oura Ring (A) and Google API (B), illustrating the information that users receive before sharing data with the Dia-Continua.

Regarding the integration of wearable device data into the FHIR standard, the changing nature of FHIR resources led to a decision not to store this data directly, as will be further explained in Section 5.1.2. Instead, the approach chosen involves dynamically retrieving and displaying this data on the user dashboard.

4.3.5 New Functionalities Before, During After Diabetes Consultation

The collaboration with Sensotrend, a data aggregator based on Tidepool as described in Section 3.1.2.2, plays a strategic role due to their licensed use of the AGP (Ambulatory Glucose Profile) report within their Dashboard. This AGP report, recognized as a standard for representing CGM data [55], contrasts with the lack of standards for insulin data [67]. An example AGP report [53] was illustrated in **Figure 3.3** in Section 3.1.2.1.

The AGP report is the foundation of the information system, avoiding the need to "reinvent the wheel" for CGM data representation [55]. The innovative aspect of the system's GUI lies in its ability to integrate hybrid closed-loop system data (e.g., insulin data, insulin pump settings, insulin-to-carb ratio, CGM data) with lifestyle data, such as sleep and physical activity. To utilize all the new functionalities for diabetes consultation, users must connect their devices through the GUI, as shown in **Figure 4.12**.

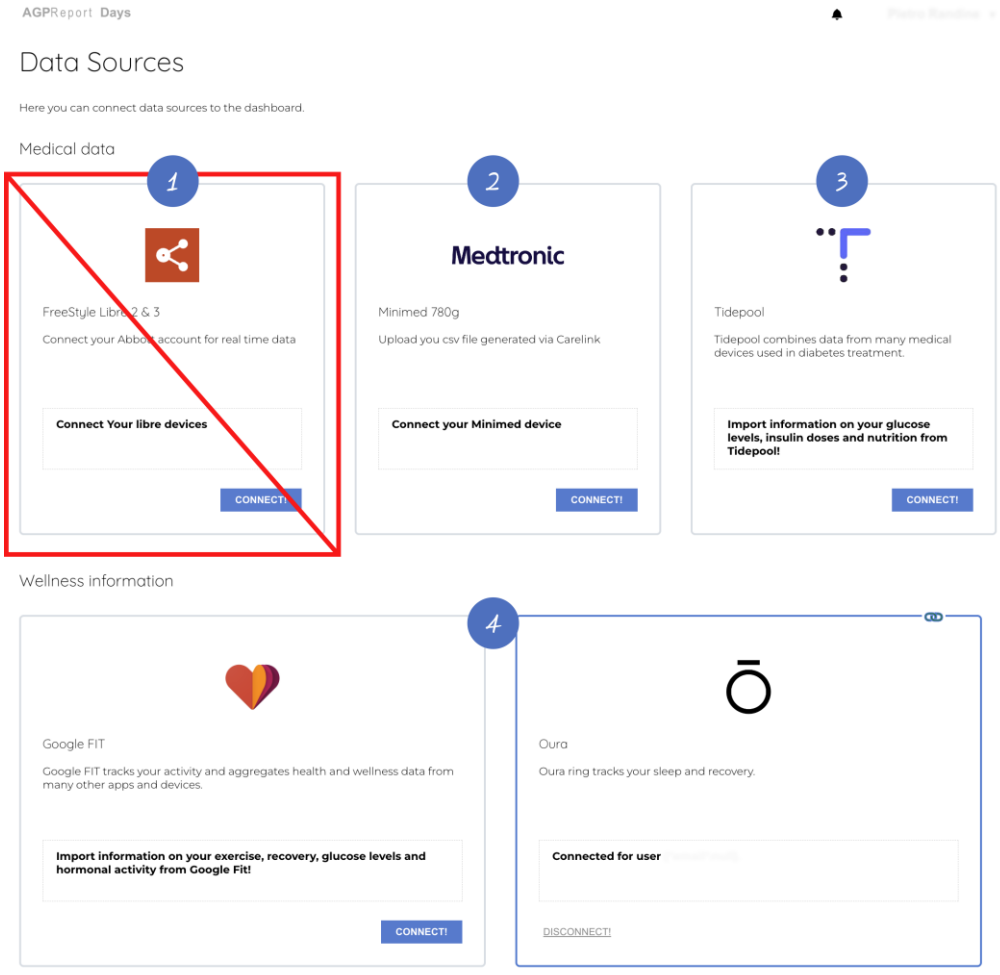

Figure 4.12: Data collection - how users can connect medical and wearable devices. When it comes to integrating medical data, there are two potential options available (2,3). Firstly, the freestyle Libre 2 & 3 integration (1) is no longer available as it violates the Terms of Service as found in Paper [6]. Secondly, users can upload a CSV file for Medtronic devices (2), as explained in section 4.3.3. Finally, there is the Tidepool uploader (3), which is only compatible with older devices and has only been tested by a user in Norway with OmniPod and Dexcom G6. As for wellness information, Google Fit and Oura are the two main options available, as documented in section 4.3.4.

Figure 4.12 illustrates the process of integrating the difference data sources. Once integrated, several new functionalities become available to users (patients, health personnel), enabling the selection of specific timeframes (e.g., 1 week, 14 days, 1 month) for data visualization. These features represent the primary modifications to the AGP reports. The functionalities can provide either a summary of statistics for the last 14 days or insights into specific days.

The evaluation and feedback from health personnel are detailed in Section 4.4, with a primary focus on the main functionalities designed to address **RQ3** (*How can individual-specific patient-generated health data improve the information quality during the medical consultation?*). Each new functionality will be detailed in Section 4.4. Meanwhile **Figure 4.13** presents the main page of the GUI developed.

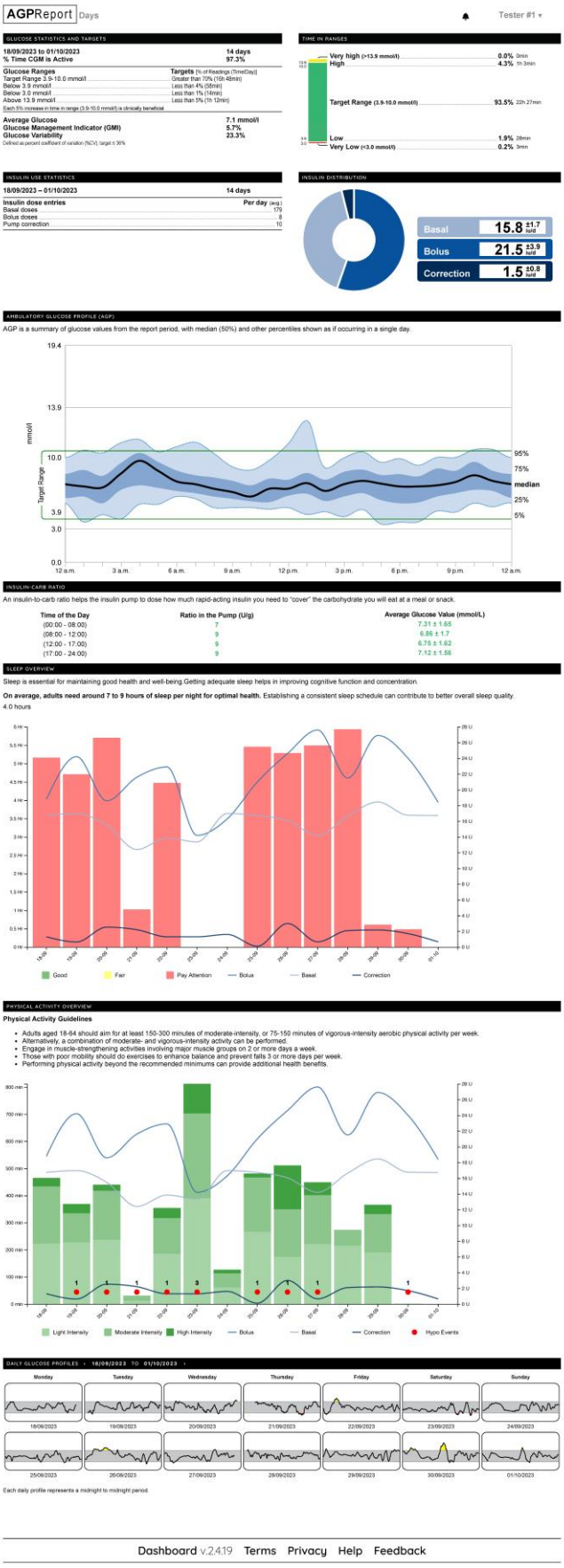

Figure 4.13: Dia-Continua main dashboard page.

The Dia-Continua information system showcases the potential of integrating additional information like insulin carbohydrate intake, sleep, and physical activity. Patients, informal caregivers, and HCPs could use these new functionalities before, during, and after the medical consultation.

1. **Insulin Overview** summarises insulin usage, showing daily insulin distribution and distinguishing between basal, bolus, and correction doses.

2. **Sleep Overview** highlights the interaction between sleep patterns and insulin distribution.

3. **Physical Activity Overview** demonstrates how varying levels of physical activity (light, moderate, and high intensity) affect diabetes management.

4. **Insulin-Carb Ratio** provides insights into the insulin-to-carb ratio, a key parameter for diabetes management.

5. **Daily View** offers a comprehensive daily overview, combining all relevant patient-generated health data. This functionality is present in the AGP report but was modified to include wellness information such as sleep and physical activity.

Two other functionalities were developed but not evaluated with HCPs. These functionalities include questionnaires for Patient Reported Outcome Measures (PROMs) and data sharing for primary and secondary use.

4.3.5.1 Questionnaires

This feature involved the possibility of patients answering specific standardized diabetes questionnaires. The suitable standardized questionnaires for diabetes were identified in another study [7]. The microservice used for administering questionnaires was LimeSurvey, an open-source implementation also used in previous studies [8]. The open-source community implementation [197] was integrated inside Dia-Continua, and **Figure 4.14** shows the editor of the LimeSurvey and an example of the PAID-5 (Problem Areas in Diabetes) questionnaire.

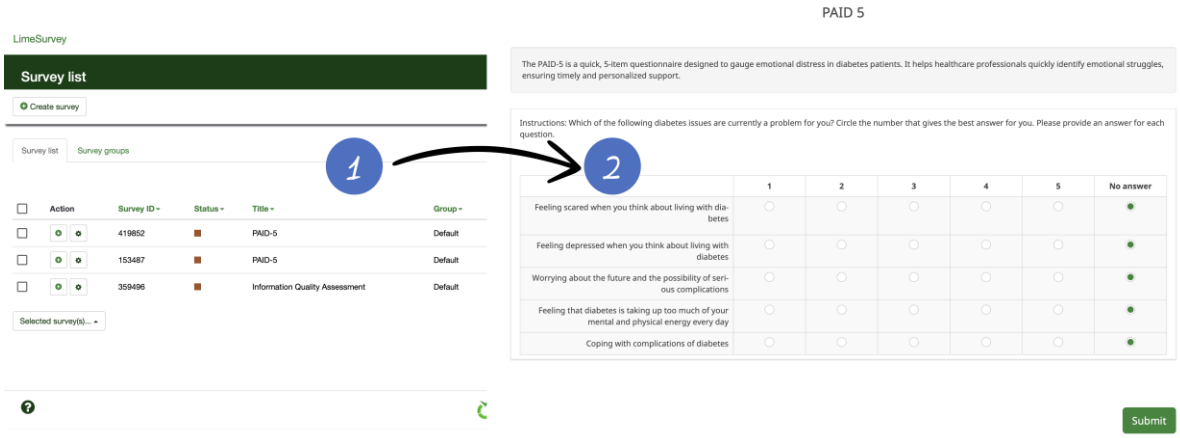

Figure 4.14: LimeSurvey questionnaires. This diagram illustrates two distinct features of the LimeSurvey platform. In Part 1, users such as healthcare professionals or researchers can create and modify surveys and view the collected results. Part 2 showcases the PAID-5 questionnaire, a self-reported survey that healthcare providers can use to assess their patients' emotional responses to diabetes management.

Compared to the previous usage [8], this new technical implementation involves connecting a Cronjob in Kubernetes (a regularly scheduled action) to the LimeSurvey Database. This Cronjob configuration automates the task of converting questionnaire answers and structured content into FHIR resources (Questionnaire and QuestionnaireResponse) via a Python script. The process is illustrated in **Figure 4.15**.

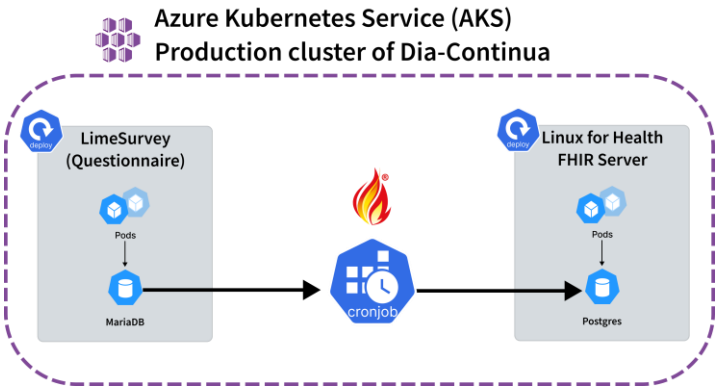

Figure 4.15: Questionnaire conversion from SQL tables to FHIR resources. This figure provides a closer look into the microarchitecture overview of **Figure 4.6**. It shows that two microservices (LimeSurvey and the Linux for Health FHIR Server) are connected using a Kubernetes cronjob. The cronjob reads data the tables from the MariaDB database and translates it using a Python script, and then uploads it to the specific FHIR server using a Client Credentials Flow.

4.3.5.2 Data Exchange and Data Reuse

The goal of a unique information system is to promote both the primary and secondary uses of health data in line with the project goals presented in the national strategies (referenced in section 1.2.1), and international strategy (detailed in section 1.2.2).

The information system based on an interoperability model like the one proposed in Paper [6] was tested on simulated data to facilitate data sharing through various mechanisms:

- **Consent management system [5]:** This implementation provides an alternative to what user type users typically agree to generic privacy policies and Terms of Service as document in Paper [4], since in this system, the patient directly decides with which institution they would like to share their data as discussed in Section 4.2.4.
- **Data Sharing with the National Diabetes Registry for Adults (Noklus):** Currently, data sharing with Noklus is restricted to CGM data. The integration with Noklus necessitates an additional software component, the DIPS Communicator, a requirement present during the HEIR project's process documentation [199].

The experience with the Noklus reveals constraints in data recording and the heterogeneity of information that can be documented, aligning with findings from previous studies for national registries [12, 128]. This situation complicates efforts to enhance diabetes prevention and control [74], as the Norwegian registry does not support the inclusion of insulin data. Specifically, the registry's inability to include insulin data represents a significant challenge for process interoperability, and this PhD project cannot resolve this limitation alone. If the national registry

eventually adds the capability to include insulin data, the Dia-Continua information system will be able to transmit this information.

A necessary remark is that Paper [5] was "ahead of its time", addressing the gaps in policy definition and consent management within FHIR standards by proposing a solution with the Fybrik framework. The FHIR community itself recognized the need for better consent management within FHIR. By early 2024, the FHIR Consent Management Implementation Guide Project was initiated with preliminary design outcomes, acknowledging the importance of advanced consent management and the lack of the FHIR standard in this regard [200].

4.4 Testing and Evaluation

The system testing and evaluation are based on data collected from three users diagnosed with T1D: two using the hybrid closed-loop system (MiniMed + Guardian G4) and one utilizing the Patch pump for insulin and CGM (OmniPod Dash + Dexcom G6).

These three users, actively involved in diabetes research, registered an account in the Dia-Continua system, uploaded their diabetes data and connected their wearable devices, following the methods outlined in Sections 4.3.3 and 4.3.4, respectively. Although ethical approval allowed for the recruitment of up to 100 participants, the initial testing phase specifically targeted users with experience in diabetes research. Despite being very knowledgeable users with diabetes and working in diabetes research, they faced difficulties downloading their diabetes data from the medical vendor systems, a problem later discussed in Session 5.2.1. Due to the research methodology's adaptability, which allows for multiple iterations and evaluations, the first round considered three sets of data provided by the three users, each with diverse demographics and sensor types, as sufficient for analysis. Previous studies [59, 60] have documented the challenges patients and informal caregivers face when attempting to download data from the medical vendor system. These difficulties were not limited to general users; even expert users in diabetes research encountered similar issues in the Dia-Continua evaluation. Given the problems across both user groups, it was determined that the current selection of users was sufficiently representative for testing and evaluation purposes.

Semi-structured interviews were carried out in the first quarter of 2024 with nine endocrinologists and two nurses based in Norway; among the 11 participants, one was associated with the Norwegian Childhood Diabetes Registry (NCDR) and one with Noklus. These interviews were carried out remotely via Teams and discussed five functionalities of the information system. The functionalities included overviews of insulin, sleep, physical activity, insulin-carb-ratio, and the day-to-day view. The participants had no prior exposure to these functionalities except for screenshots sent with the invitation email.

The interviews evaluated specific information quality measures described in Section 2.2.3. These measures included *'Timeliness'*, assessing whether health personnel would allocate time during consultations for specific system functionality. The *'Interpretability'* was to determine the ease of understanding the system's data presentation. Additionally, the interviews aimed to determine the *'Concise Representation'* and *'Appropriate Amount'* of information the system should provide for practical clinical use before, during and after the consultation.

The complete interview guideline is specified in the Appendix 3: Semi-Structured Interview Guideline. Meanwhile, the subsections from Section 4.4.1 to Section 4.4.6 focus on the interviews with the nine endocrinologists, and Section 4.4.7 presents the interview with the two nurses.

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4.4.1 Insulin Overview

The insulin overview was the first feature evaluated by the nine endocrinologists, as illustrated in **Figure 4.16**.

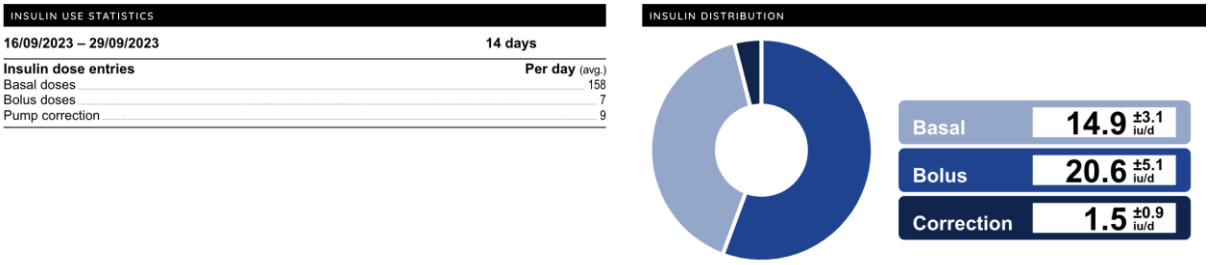

Figure 4.16: Insulin overview for hybrid-close loop system. The insulin overview is divided into two parts. The left part displays insulin dose entries based on a specific period (e.g., 14 days in this example). It calculates, on average, the number of insulin distributions performed (basal, bolus correction). For instance, the basal dose equals 158, as the MiniMed pump utilizes a mechanism called microbolus [201], which delivers small units (e.g., 0.2 U) every 5 minutes. The right part of the figure, the doughnut chart, aims to provide a graphical overview of how many units are distributed per day within the selected period.

Most of the informants (5/9) found the feature satisfactory, with comments such as, Informant #7: *"I quite like the doughnut chart"* and Informant #6: *"How this appears to me, it would be very easy to see both the relation between the basal and the bolus and how much correction, and I think that's a very nice start."* These responses indicate an appreciation for the feature's ability to display the insulin overview.

However, some informants (4/9) expressed conditional satisfaction, highlighting a desire for a more comprehensive overview. For instance, Informant #2 remarked: *"I would prefer also to have a summary of all insulin"*. This conditional satisfaction was also motivated by the challenge to adapt to a new system: *"It's a hard question because my brain is so accustomed to other ways of downloading the data. But as I said, this is a good start for me,"* (Informant #4) and concerns about the insulin correction aspect: "*I'm not totally sure how to use the correction part, but I guess it might be used to say something about whether the pump is aggressive enough or not."* (Informant #5). Moreover, Informant #3 highlighted a potential area of confusion for patients: *"The basal is 14.9, and the standard deviation is plus, minus 3.1. I think most of my patients do not grasp what that actually means"*.

An interesting observation emerged during the interviews regarding the variability in pump algorithms, highlighted by three out of nine informants (3/9). Informant #8 mentioned: *"In most of our system, the correction and the bolus are together"*. In line with this observation, the OmniPod patch pump user did not report any correction in the data, as shown in **Figure 4.17**. Furthermore, Informant #9 expressed a high appreciation for the consistency in visualising the insulin delivery mechanisms, exemplified by systems like MiniMed (**Figure 4.16**) and the OmniPod (**Figure 4.17**), emphasising the value of a unified approach to insulin distribution visualisation regardless of the system used.

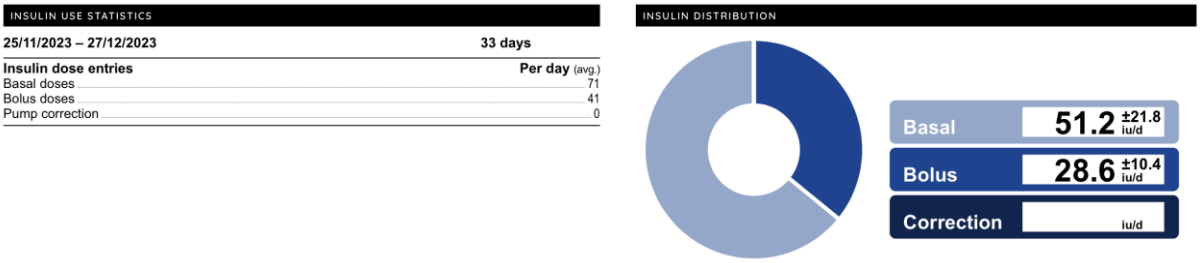

Figure 4.17: Insulin overview for patch pump user. Patch pump users, such as this user who uses the OmniPod Dash, do not collect any information about the pump's correction. This is evident from the GUI, which displays 0 in both sections of the figure: on the left side (Insulin use statistics) and on the right side (Insulin distribution).

4.4.2 Sleep Overview

The evaluation on incorporating sleep data into diabetes consultations revealed that all informants (9/9) acknowledged the theoretical importance of sleep in managing diabetes. Within this context, a subset of the endocrinologists (2/9) highlighted that discussions about sleep are already part of their consultations, especially for patient groups like non-pump users and those diagnosed with Gestational Diabetes Mellitus (GDM). One endocrinologist, Informant #8, provided insight into the relevance of sleep data by saying: *"[when asked why they need sleep information] that is because when we try to find the basal dose"* since the discussion of the consultation is about the in determining the appropriate basal insulin dose for the patient.

However, practical constraints in the daily practice of endocrinologists influenced attitudes toward the routine evaluation of sleep. A few informants (2/9) expressed no interest in routine sleep evaluation due to time constraints, with comments like *"I do not think there is any time to evaluate it"* (Informant #1) and limitations of existing systems like Noklus that do not allow sleep data reporting (Informant #5). The remaining participants (5/9) expressed uncertainty, pointing to the lack of detailed sleep analysis and the challenges it presents: *"The night is complex because it sums up what has happened the day before... Important but difficult"* (Informant #3) suggesting an acknowledgement of sleep's significance but a limitation of the information system visualization (see **Figure 4.18**).

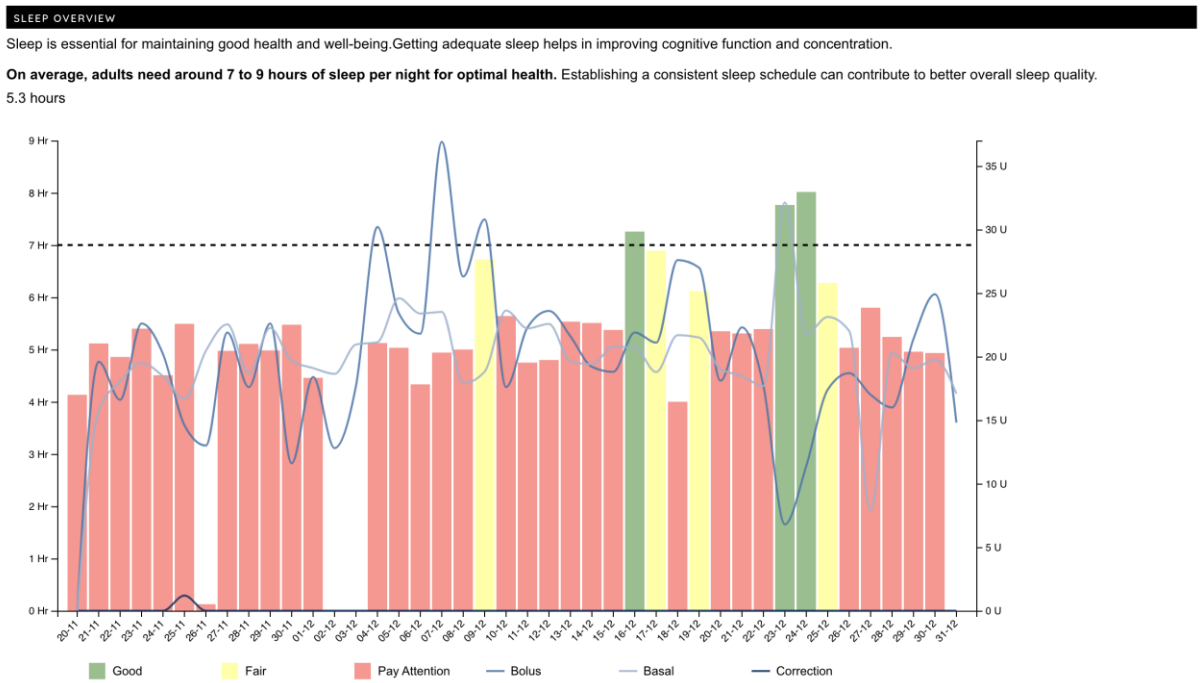

Figure 4.18: Sleep overview for 42 days. This feature categorizes sleep data collected by Oura Ring for a specific period selected from November 20 until December 31. It classifies sleep into three categories: "Good" (green) when the user sleeps above the selected threshold (7 hours for this user, based on their specified target); "Fair" (yellow) when sleep is less than 7 hours but more than 1 hour according to the target; and "Pay attention" (red) when the user sleeps less than the target of 7 hours. This functionality aims to illustrate the relationship between basal and bolus corrections to determine if a good or bad night of sleep influences insulin distribution during the day.

Concerning the interpretability of sleep data, the interviews emphasised the significance of stress and distress over direct sleep data. A significant concern among multiple informants (4/9) is the lack of information about the timing of sleep and the overall impact of stress on sleep patterns. For instance, one informant pointed out, *"Here you tell me how many hours the patient is sleeping, but you do not tell me what part of the day they are sleeping"* (Informant #6). Furthermore, the impact of lifestyle behaviours on sleep quality, such as the use of smartphones before bed, was identified as a critical factor: "*The stress, distress, is also a very important factor, for example, if a teenager uses a smartphone before going to bed ... [and received a bad message], it will affect the sleep and glucose in the night."* (Informant #9).

There was collective recognition of the potential value and importance of integrating sleep data into diabetes care (9/9). However, the current approach to the sleep overview feature may lack certain elements necessary for a comprehensive understanding of its impact on diabetes management (5/9) and the interplay between sleep, stress and distress. These factors are relevant and influence blood glucose levels [45]. The results of this interview present an opportunity for future evaluations.

4.4.3 Physical Activity Overview

All informants (9/9) agreed that physical activity is essential to managing diabetes, showing more interest in it than the sleep functionalities mentioned in Section 4.4.2.

The evaluation of physical activity began by looking at its current role in diabetes care, as described in Section 4.4.3.1, followed by assessing the information system visualization (Section 4.4.3.2), and finally, suggestions for improving the system functionality (Section 4.4.3.3).

4.4.3.1 Physical Activity in Today's Consultation

One informant explicitly mentioned the challenge of time constraints, highlighting the importance of physical activity while acknowledging practical limitations: *"Physical activity for me is a bit more important than sleep. But I wouldn't again, time would make it difficult to discuss this in detail."* (Informant #1).

A minority of informants (2/9) emphasized the need for personalized physical activity discussions, especially for patients with specific interests such as high-intensity training or those facing significant glucose control challenges: *"The patients, the only thing that is common is that they have diabetes and with certain patients, having the ability to discuss high-intensity training would be a very positive thing. But for most of the patients, I will not have the time."* (Informant #4).

Most informants (6/9) considered the discussion of physical activity to be very important, and the need to include family or informal caregivers in these discussions was acknowledged: *"Yes, we address it together with the families"* (Informant #9). Furthermore, they highlighted the challenges that patients face in accurately reporting their daily activity levels in the current system: *"So we try to motivate them all to be physically active and to ask them how often do you do exercises... it is very difficult to answer that in retrospect."* (Informant #2), as some patients often find it difficult to remember specific details about their physical activities.

4.4.3.2 Can we consider Dia-Continua an Improvement?

Most informants (6/9) endorsed integrating an "objective measure" of physical activity across different intensities, identifying it as a significant improvement over the current practice. **Figure 4.19** illustrates an overview of physical activity presented to the health personnel.

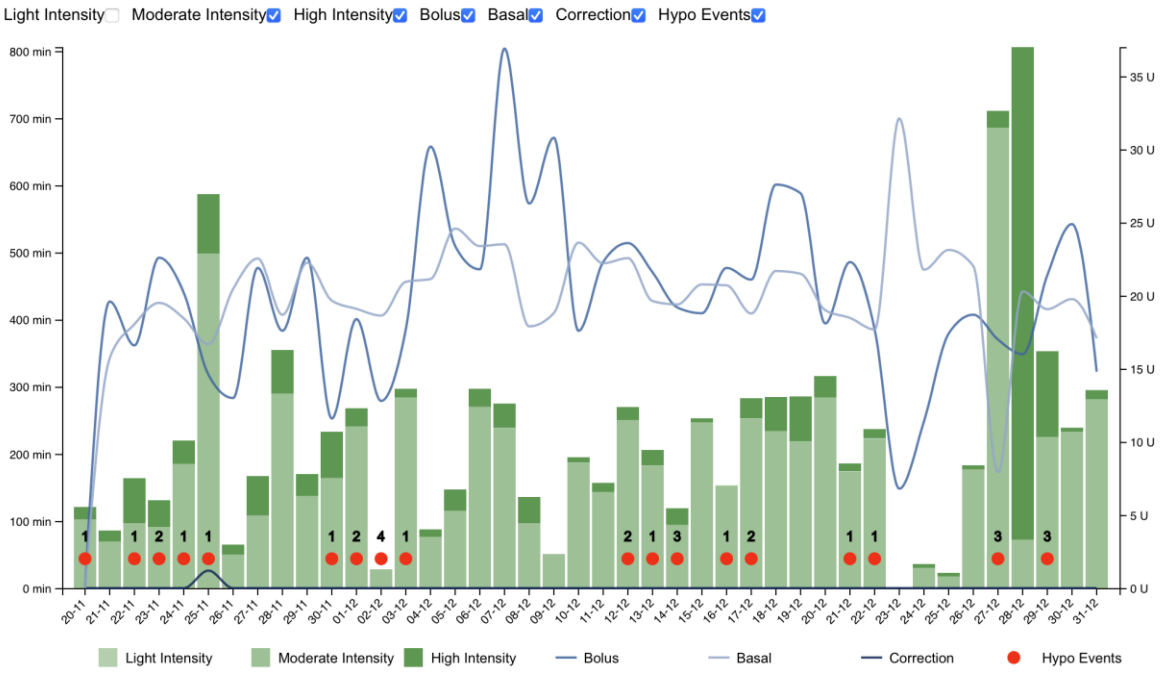

Figure 4.19: Physical activity overview for 42 days. This feature provides an overview, from November 20 to December 31, of the relationship between different types of physical activity and their intensity in minutes. Light-intensity activities are filtered out for this analysis, focusing solely on moderate and high-intensity activities categorized by wearable devices. Additionally, the feature presents insulin distribution for each specific day and hypoglycemic events, calculated as the number of times the user experienced hypoglycemia (below 3.9 mmol). This example was selected by one user who was curious why high-intensity activity on December 28 did not cause any hypoglycemic episodes, unlike the days before and after.

Among the informants who found the functionality valuable (6/9), Informant #6 saw the potential for such discussions to be "very instructive", indicating an opportunity to enhance patient understanding of how physical activity impacts their glucose control. Informant #8 commented on the accuracy benefits of this approach: *"So if these numbers are reliable, then it's definitely a much better and maybe faster way to get a feeling how much they actually [patient] are active."*. This statement reflects some informants' (5/9) belief that using objective measures from physical activity could significantly improve patient lifestyle assessment and consultation.

Despite acknowledging the current technological limitations, only two informants appreciated the opportunity to view insulin, glucose, and physical activity together. Informant #4 mentioned that some CGMs have difficulty tracking rapid glucose changes due to physical activity. While detailed daily analyses are preferred for their granularity, summarized data was seen as a potential starting point for discussions, *"I would prefer the day-to-day view, but it could start a discussion."*(Informant #7).

4.4.3.3 How can the Information System Improve?

Table 4.4 encapsulates the key improvements proposed by informants, categorized into four areas: 'Visualization Improvements', 'Objective Measures and Specific Metrics', 'AI and Data Analytics', and 'Considerations for Diverse Patient Groups'.

These categories reflect each informant's holistic view when addressing the complexities of diabetes management in the context of physical activity. Each entry outlines the specific improvement suggested, provides a brief description, and identifies the informant(s) who highlighted the area of focus.

Table 4.4: The main improvement to physical activity overview

Improvement Classification	**Description**
Visualization Improvements	**Marking Weekends and Holidays**: Proposing modifications to data visualization to mark weekends and holidays since the different routines compared to the weekdays could influence diabetes management (Informant #8).
Objective Measures and Specific Metrics	**Integrating "time in range" for each day** (Informant #2). **Hypoglycaemia Type**: differentiate glucose levels more finely between *"low glucose between 3 and 3.9 and below 3"* (Informant #9). **Difference between Cardio Activity and Strength Training**: *"There is a difference between cardio activity and strength training, which may not be captured by calling it moderate and high-intensity"* (Informant #7).
AI and Data Analytics	**AI** to identify day-to-day variations in physical activity to improve the system data analysis (Informant #3, #5). **Data-Driven Pump Optimization**: Data analytics to provide recommendations for adjusting insulin pump settings in response to physical activity (Informant #5).
Considerations for Different Patient Groups	**Overwhelming the Patient**: Cautioning against overwhelming certain patients with too much information. *"Some patients, I do not think they should have this much information because they can look at this and think, OK, I should train high-intensity training every day to avoid hypos."* (Informant #8). **Varied Needs and Capabilities of Patients**: Addressing the needs of patients who range from highly engaged and proficient in managing their condition to those who struggle with basic diabetes management concepts. *"It has to be simple... you have this different population or diabetes type ones using the same equipment."* (Informant #3).

4.4.4 The Impact of Missing Data on Clinical Decision-Making

The evaluation of sleep and physical activity data provided the opportunity to assess the impact of missing data from wearable devices on clinical decision-making. During the analysis, examples of sleep data with significant gaps or partial information are shown in **Figure 4.20**.

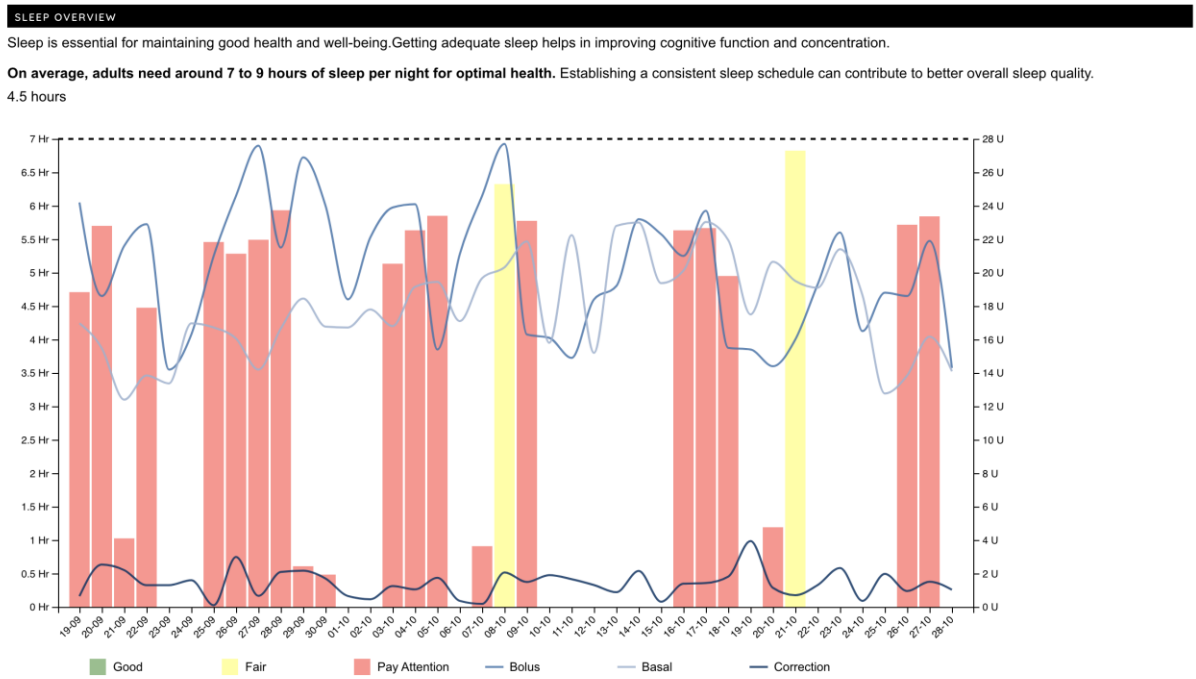

Figure 4.20: An example of missing data. From September 19 to October 28, one of the participants in the user testing had issues with the Oura Ring. As evident in this figure, there is a significant amount of missing data, particularly regarding hours of sleep or potentially incorrect data showing less than 1 hour of sleep.

The concern about missing data was shared by most informants (4/9), with Informant #9 succinctly stating, *"If they go below 50% of missing data, I don't really know what I'm looking at"*, highlighting the challenge of interpreting incomplete data.

Two informants (2/9) preferred having some data, even if incomplete, over having no data. Informant #3, reflecting on his/her experience with T2D patients, said: *"That is my clinical reality,"* suggesting a willingness to work with whatever information is available.

Additionally, two informants (2/9) emphasised the importance of discussing any uncertainties in the data with patients. Informant #5 mentioned the need for validation: *"I would have to validate it against what the patient tells me about it..."* indicating a collaborative approach to data interpretation. In certain situations, like a case mentioned by Informant #7, they ask patients to closely monitor specific parameters and return with more detailed data, aiming for a comprehensive assessment over a period, such as a week.

Lastly, Informant #4 also expressed a sentiment of uncertainty, saying, "*My scientific fantasy is not that good. So, I really do not know*". This statement highlights the varying levels of sensitivity, engagement, and curiosity toward technology among the different endocrinologists. While some

exhibit a high level of "fantasy" and confidence, others approach the topic with more caution and uncertainty.

4.4.5 Insulin-to-carbohydrate Ratio Overview

The insulin-to-carbohydrate ratio (or, shortly, insulin-to-carbs ratio) is a parameter that can be configured inside the insulin pumps (MiniMed and Tandem) in Norway (Section 3.1.1). The evaluation of this specific parameter also provided an opportunity to discuss how endocrinologists value the hybrid closed-loop system. The subsequent two sections initially discuss the role of the insulin pump and algorithm in today's medical consultations (Section 4.4.5.1). This will be followed by Section 4.4.5.2, which presents the evaluation of the system functionalities.

4.4.5.1 Insulin-Carb Ratio in Today's Consultation

Most informants (8/9) considered the discussion on adjustments to the insulin-to-carbohydrate ratio essential for pump users. Among these eight informants, each gives varying levels of attention to this parameter, recognised as the one and only aspect that can be modified during a medical consultation. As noted by two informants, *"There's not a lot of settings I can adjust to change how the insulin pump works"* (Informant #5), and *"with the Medtronic, the most used pump, we discuss that almost every time because it's one of the few things we can adjust"* (Informant #8). Another point is the trust in the pump's algorithm, as highlighted by some informants (#6, #3): *"I think that we try to teach the patient to have trust in the algorithm, especially in the Medtronic and the Tandem algorithm, which is a bit different"* (Informant #2). This parameter's importance is also noted under hormonal changes, especially during pregnancy, as highlighted by Informant #7.

However, only one informant focused on adolescents with T1D, emphasizing the prioritization of carbohydrate counting over the insulin-to-carbohydrate ratio: *"In paediatric diabetes, they are taught to count carbs from the first day in the hospital. More than 80% of children with Type 1 Diabetes are using carb counting for more than 50% of all their meals"* (Informant #9).

4.4.5.2 Insulin-Carb Ratio in Dia-Continua

The new functionality of the insulin-carb ratio and its interpretability, as shown in **Figure 4.21**, produced a mixed response from informants on its perceived added value during the consultations and follow-up.

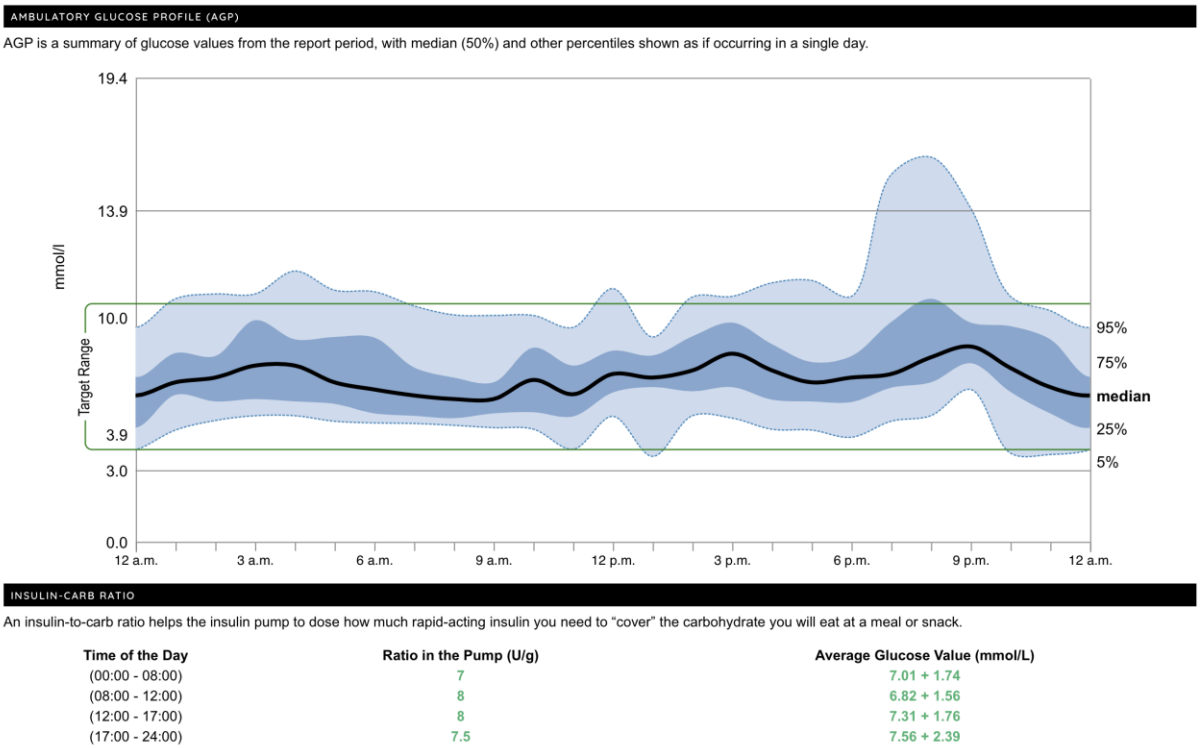

Figure 4.21: Insulin-to-carbohydrate Ratio. This functionality integrates the standard Ambulatory Glucose Profile with the insulin-carb ratio for a specific period selected (e.g., 14 days). Additionally, it incorporates the insulin-carb ratio reported by the insulin pump. (Please note: This functionality is exclusively for pump users, as patch pump users do not have an insulin-carb ratio.) This specific case was intended to initiate a conversation about adjusting the insulin-carb ratio during the evening, as there is high variability during this period.

Some informants (3/9) identified this feature as a clear improvement over current practice. One informant appreciated the direct correlation between insulin-to-carbohydrate ratios and glucose trends, saying, *"This is quite useful... It is quite useful to put it up like that"* (Informant #2), indicating the utility of this feature in facilitating informed adjustments. For example, Informant #9 would start a conversation around dinner time, noting a pattern where blood glucose levels rise in the evening: *"The real outliers are also in the evening. So, what is this? Is it because they are having more difficult meals to count? Is that a part? Or is the insulin-carbs ratio wrong? Then I would have to discuss with the patient"*.

However, other informants (3/9) expressed concerns or noted existing practices that might limit the new feature's utility. Informant #1 highlighted information overload. In contrast, Informant #8 mentioned, "*I think we already have this with the carb insulin carb ratio in this graph*", suggesting that the proposed feature might not offer new insights to those already familiar with the existing systems.

The remaining informants (3/9) would like to see something different, like mental stress: *"... because stress affects patients and the insulin need very much"* (Informant #3). Additionally, the importance of daily management was emphasized by those preferring to focus on day-to-day data rather than aggregated overviews, *"I prefer the daily view, but I would consider the carbs rather than the glucose in this feature"* (Informant #6).

4.4.6 Day-to-Day Feature Evaluation

When looking at the possibilities offered by the system, we examine specific days with an overview, as shown in **Figure 4.22**, which is the standard in the AGP Report [55], and it was an opportunity to discuss the role of the day-to-day discussion with patients during the medical consultation.

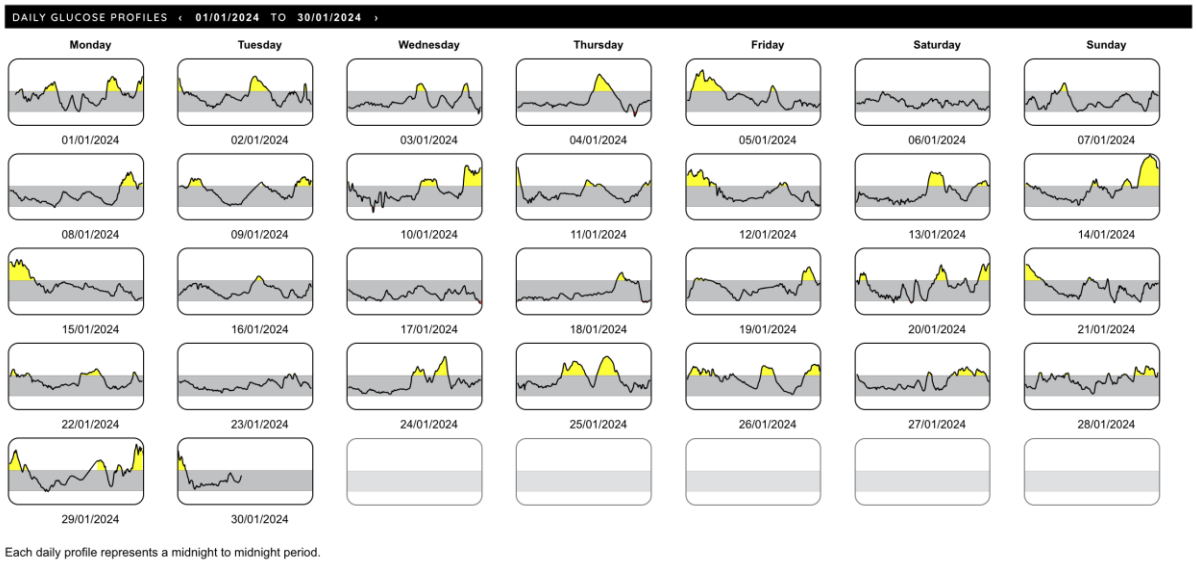

Figure 4.22: Daily glucose profiles from the AGP report. This view is based on the AGP report [55]. It provides a simplified overview of the diverse glucose values. It colour-codes glucose areas below or above the specified range: below 3.9 mmol/l or above 10 mmol/l.

All the informants (9/9) recognized the importance of focusing on specific days during consultations, particularly when patients clearly recall events; however, their strategies vary. Some health professionals, as mentioned by Informant #5, review data from the last 14 days: *"We usually download data from these pumps, and we get 14 days, and we also got the sort of the separate days."*.

The common challenge is that patients often struggle to remember specific events. As a result, some health personnel adapt their approach based on what the patient could remember: *"In my practice, if they had specific days they would like to discuss, we take it ... [otherwise] I always take yesterday and the day before yesterday because then those days are best remembered"* (Informant #2). Additionally, some informants exclude certain days that may not represent the patient's typical routine, as noted by Informant #7: *"We would maybe disregard those days with fever because they are not quite representative. Or maybe if the patient said I had the COVID vaccine."*.

In order to evaluate the information quality of the day-to-day functionalities, then we focus on specific day (see **Figure 4.23**).

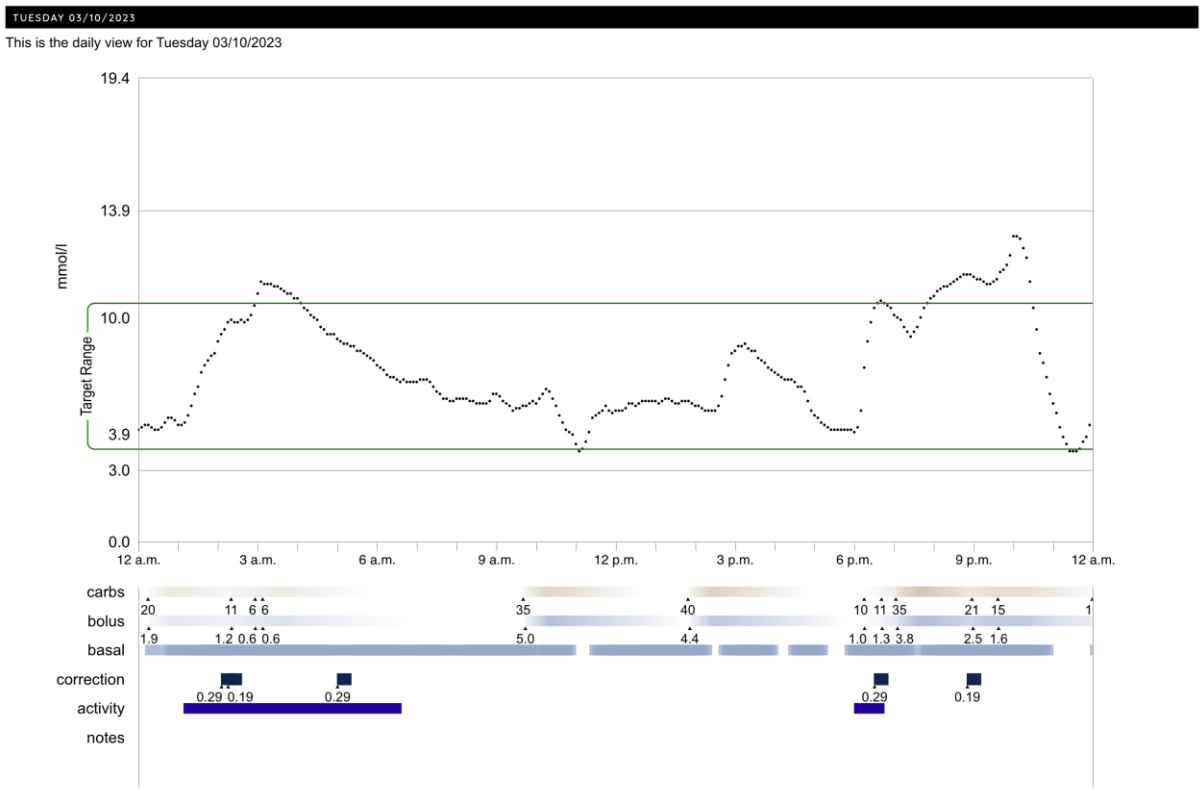

Figure 4.23: Specific day view. This functionality presents a specific day that one of the participants in the user testing would like to discuss during a medical consultation. It specifies, for a given day, the number of carbohydrate estimations made by the users in grams (orange line). Additionally, it displays the different types of insulin boluses: basal (or micro-boluses in the case of the MiniMed Pump), allowing verification of instances where the pump stops delivering insulin in the case of low glucose values. Lastly, there is correction insulin, extra insulin the pump dispenses to lower glucose values. Additionally, different activities are indicated; for instance, sleep is represented by a dark blue colour, while other activities, such as those shown in dark green (not present in this picture), denote physical activity.

Among the informants, there was a diversity of opinions regarding the features. Four out of nine informants (4/9) appreciated the functionality and believed it added value to the consultation. One emphasized the improvement over current systems: *"That is very good. That is much better than we have today ... I don't think any of our systems have that one [referring to the feature] because we need to scroll down, and then you get lost in days, and you miss them. You just end up looking at specific day, but you lose the big picture. So that one [referring to* **Figure 4.22***] was actually a very good feature. I think one was, yeah, very big improvements from what we have today."*(Informant #8). Others highlighted the benefit of being able to take notes, with one stating: *"As a clinician, I would ask the patients, at least in the notes, to say, well, did you have mental stress or and for women, where are you in your menstrual cycle?"* (Informant #3). However, one informant acknowledged the system's appeal but expressed confusion over specific elements like the carbohydrate line: *"I don't quite understand. I can understand that you have the basal, the bolus, and the carbs. There is a line, but what does it really represent the carbs line?".*

The remaining informants (3/9) perceived the provided information as incomplete, especially in terms of detailed pump information. This perceived gap is attributed to modifications in the proprietary data format received after January 2024. The implications of these changes, how they

influenced the day-to-day visualization and the consequences on the entire Information System will be further explored in the discussion chapter, Section 5.2.

4.4.7 Nurses Evaluation

A 30-minute interview was conducted with two nurses to evaluate the functionalities of the information system. Participating in the same Teams meeting, both nurses occasionally completed each other's sentences, providing a more collaborative evaluation of the system's features.

The nurses recommended the insulin overview, emphasizing the importance of displaying insulin percentages as they frequently use these metrics to assess insulin distribution. They mentioned, *"If we see that the basal has more than 50 or like 60, 70%, we say, 'This is a little too much,' because the whole measure [basal] is about 30 to 50%. If [it is above] 70%, it is something wrong... and we need to check."*.

Regarding the sleep functionality, they commented, *"The future is that the pumps do everything themselves, and we do not need to make the fine adjustment, but maybe for non-pump users."* They acknowledged sleep as a variable in the consultation but were unsure about using this feature for recommendations.

They value the need to monitor carbohydrate intake for the insulin-carbohydrates ratio function. They recalled using Carelink to determine *"how many carbs and how many units the patient has given themselves... how many carbs, what the blood sugar was, and how this doses,"* highlighting the need to verify with the daily view the carbohydrates count with patients.

This interview also discussed the daily view, where both nurses appreciated the ability to navigate between days, similar to some endocrinologists, *"Because it is very easy to see. So that is very nice."* They pointed out the absence of Time in Range percentages for each day and, like three endocrinologists, missed the auto-correction and micro boluses, *"We are used to having the micro boluses and the auto-corrections."* They also expressed confusion about the term "basal", questioning, *"What do you mean with basal? Do you mean micro bolus?"* referring to the MiniMed Pump, and highlighted the need to see basal adjustments automatically, which will be discussed in Section 5.2.

The last feature evaluated was the physical activity feature. Physical activity was identified as a challenging aspect to adjust in insulin pump therapy. Both nurses saw the physical activity overview as beneficial for discussions with patients, particularly young individuals and those with high activity levels. Despite some uncertainties about how to fully utilize this feature, they recognized its value in conversations about managing diabetes in the context of physical activity.

When asked about future improvements, they first stressed the challenges faced in managing various programs like Carelink, Glooko, and LibreView, indicating a preference for directly integrating Dia-Continua's physical activity data feature into Carelink. They concluded, *"We are used to looking at Carelink downloads and have adapted to it. So, it is kind of difficult to switch. I would prefer to*

have a link download activity [referring to physical activity] on top... Instead of learning a whole new system." They commended the Medtronic Carelink system for its ease of use and comprehensive information, considering it the best system they have ever used. The interview concluded with reflections on the ambition of the Information System and the PhD project, "*But you are trying to make this one system for everything. Yeah, that is a high goal [they both smiled]".*

Chapter 5 Discussion

This discussion is organized around three research questions, each aimed at exploring different faces of integrating and utilizing PGHD data within diabetes management. These questions, refer to **Table 5.1**, guided the investigation into creating a single information system that benefits patients, health personnel, and informal caregiver, and national registries before, during, and after medical consultations.

Table 5.1: Research questions and discussion.

Research Question	Research Question Description	Section
RQ1	How can we integrate different health-related devices used daily by individuals with diabetes and patient-generated health data into a unified information system for patients and health personnel to use before, during, and after medical consultations?	5.1
RQ2	How can patient-generated health data be exchanged between clinicians, patients and informal caregivers before, during and after the consultation, with robust security and privacy measures?	5.2
RQ3	How can individual-specific patient-generated health data improve the information quality during the medical consultation?	5.3

The first research question (RQ1) focuses on establishing a technical infrastructure. The result is an information system capable of facilitating the integration and exchange of data from various health-related devices used by individuals with diabetes. This infrastructure facilitates the availability and utility of health-related information for patients and health personnel across all phases of medical consultations.

The second research question (RQ2) transitions the focus towards enhancing security and privacy measures for the data exchanged within the system. The result showcases how patient-generated health data remains secure and private when shared among clinicians, patients, and their informal caregivers based on state-of-the-art technology protocols that ensure compliance with regulations and legislation.

Lastly, the third research question (RQ3) discusses how specific patient-generated health data can improve the quality of information used in medical consultations. The result is an evaluation based on the data of three experienced users with T1D and eleven healthcare professionals on the possibility of a new model that includes preventive, personalized, predictive, participatory, and psycho-cognitive elements. The section will also discuss the possibility of generalizing the system findings to other chronic diseases, its scalability to more users and the commercialization path of the Dia-Continua information system.

5.1 A FHIR-tale of Information System in Type 1 Diabetes

FHIR's importance as a standard for healthcare data exchange is recognized, particularly with its required use in the U.S. [162], and the relevance in the EEA as well [163]. However, achieving complete integration across different information systems requires more than what FHIR alone can offer; interoperability extends beyond purely the technical exchange of data [157, 158], as discussed in Chapter 3.

The final phase of this PhD project was aligned with the release of FHIR version 5.0 [160]. This version introduced new resources and improved data operation flexibility. These features could improve summary statistics generation, like Time in Range (TIR) and Time Below Range (TBR). They also allow for the integration of Clinical Decision Support (CDS) Hooks with SMART on FHIR. However, the adoption of CDS Hooks version 2.0 by leading EHR vendors has been limited [202]. This situation highlights the ongoing development of the standard. CDS Hooks were not utilized in the Dia-Continua project, presenting an opportunity for future work.

The Dia Continua information system utilises FHIR for data exchange but has not fully implemented the standard's latest updates and capabilities. This limitation originates from the Linux for Health FHIR server choice since it does not support these recent updates [198]. The project faced unique challenges in developing a T1D, particularly in managing large data volumes (5.1.1) and effectively representing data from medical and wearable devices (5.1.2). These issues are not only pertinent to T1D but also extend to other NCDs [1], highlighting the complexities of integrating health data within a unique information system.

5.1.1 Data Volume Implication for Primary and Secondary Use

A future information system like Dia-Continua that processes data generated by hybrid closed-loop systems, as presented in Section 4.3.3, necessitates a discussion of this data's volume and relevance for primary and secondary use. One key challenge is processing the extensive daily data generated by these devices, including CGM data, manual blood glucose readings, insulin dosages, and metadata. An analysis conducted over three months for a single user, as shown in **Figure 5.1**, showcases the considerable data volume produced, approximately 13000 records per month.

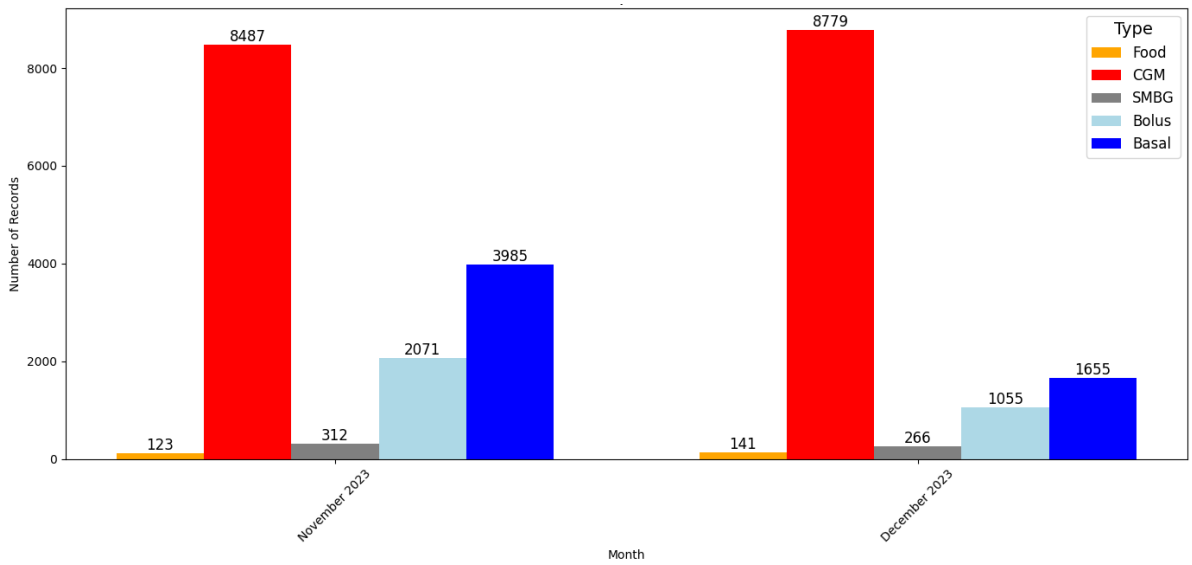

Figure 5.1: Data generated by a hybrid close loop system. Some clarification about the Type shown in this figure. Food is carbohydrates estimation, SMBG is instead the manual glucose measurement. The records source is OmniPod Dash + Dexcom G6.

This significant data volume raises questions about the efficacy of using FHIR for data exchange for primary secondary uses. The Evaluations with health personnel revealed that after a month or less—14 days in some instances—the clinical relevance of the data for patient discussions diminishes. However, the data retains value for national registries to compare the quality of care and diabetes outcomes across countries [12, 128].

The distinction between primary and secondary uses of data brings to light an essential question: How feasible is it to store the large amounts of data generated by health devices in a single information system or directly within the EHR? Integrating data into the EHR introduces challenges, including compliance with specific regulations [158]. GDPR in EEA mandates that data be stored for as short a period as necessary (minimal data retention) [70]. Nevertheless, this data can offer significant value for secondary uses.

The Information System serves as a Data Aggregator [110], particularly in processing health data according to FHIR specifications. Through FHIR's Operation $stats on Observation Resources, the system enables the creation of summary statistics. These functions allow the analysis of various health metrics (e.g., average, maximum, minimum, lower quartile, regression) tailored to specific subjects (patients) and observations (e.g., blood glucose levels and carbohydrate intake) over specific periods.

The system's ability to generate these summary statistics for periods like the last 14 days, the previous month, or comparison across several months, proved valuable for medical consultations (Section 4.4). These functionalities offer a more practical approach for EHR storage than preserving each data record over long periods. Storing and processing a single glucose reading of *3.4 mmol/l* for a patient for extended times lacks clinical value compared to summary statistics, where this *3.4 mmol/l* is included as part of the overall analysis, as shown in **Figure 5.2**.

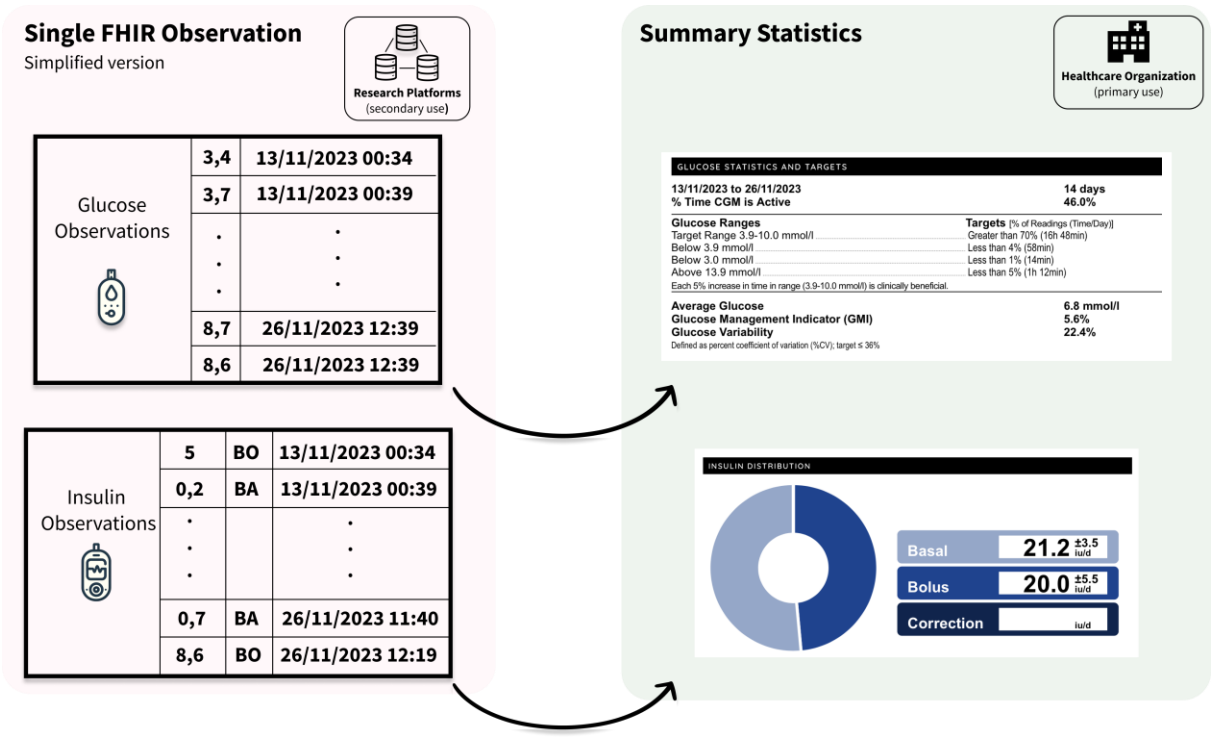

Figure 5.2: Singles FHIR observations (secondary use) vs summary statistics (primary use).

Furthermore, the system's aggregating capability may provide comprehensive datasets for registries or research purposes for secondary use. Components like the consent management system [5] highlight new opportunities for data reuse and exchange across multiple nations and align with initiatives like the Health European Data Space Europe [73] and efforts to prevent NCDs [75].

The RQ1 findings highlight the importance of process and legal interoperability in effectively managing health-related data since the technology is available to solve the data exchange problem.

5.1.2 Patient-Generated Health Data on FHIR

The FHIR standard, while not dedicated to patient-generated health data (PGHD) like physical activity or sleep data from commercial wearables, is a versatile standard for healthcare interoperability. It allows adding FHIR Extensions to cover specific use cases beyond its core Resource specifications [160]. However, the inventor of FHIR has cautioned against the overuse of extensions [157].

During this PhD project, the developed information system did not incorporate FHIR specifications for storing lifestyle activity, focusing instead on data types like glucose observations, insulin, and carbohydrate intake.

The challenge lies in integrating PGHD, requires consideration of two future strategies:

1. **Creating a New FHIR Resource**: This would involve developing a resource specifically for PGHD, necessitating community consensus—a feasible but challenging path.

2. **Utilizing Existing FHIR Resources**: This approach considers the current Resources to document PGHD.

In the author's view, the development of FHIR, especially with the advancements seen in versions 4 and 5 in March 2023 and CDS Hooks 2.0 [202], aims to make FHIR "the standard" for health data exchange. However, and this extremely important to remark, FHIR 4.0 does not ensure compatibility with future updates like the FHIR 5.0.

Designing information systems and applications with the flexibility to adapt to these updates is crucial. In the PhD project, the logical approach was to integrate insulin data from pumps into existing medical administration resources [194], which Roche's FHIR API also used later [203]. Nevertheless, these resources are at a maturity level of 2, indicating expected modifications [157, 159]. For instance, changes in insulin representation between FHIR versions 4.0 and 5.0 [160] led to compatibility issues in the Dia-Continua system. **Table 5.2** illustrates key differences between versions R4 and R4B in the MedicationAdministration resource.

Table 5.2: Changes in MedicationAdministration FHIR Resource between R4 and R4B.

MedicationAdministration Parameter	**Changes between R4 and R4B**
MedicationAdministration.medication	Renamed from medication[x] to medication
MedicationAdministration.occurence[x]	Added Mandatory Element
MedicationAdministration.effective[x]	Deleted

Source FHIR from reference [160].

These updates impacted insulin data management data processing, highlighting the challenges of adapting to FHIR version changes. Since the conversion from CSV file formats to FHIR specifications as detailed in Section 4.3.3 was not anymore functioning for FHIR 5.0.

This PhD project reveals the challenges of integrating data from diabetes medical devices into EHR systems and sharing this data between different EHRs. It's often difficult for EHR systems to quickly adapt to new standards or versions, as shown by the Norwegian Helseplattformen difficulties in retrieving the existing records, as 90% of doctors felt patient safety was compromised due to the new system [204]. Meanwhile, FHIR continues to evolve, already discussing version 6.0. This PhD use case focusing only on Diabetes suggests that using existing FHIR resources to represent medical device data is a viable approach within certain design limits (i.e., consider the maturity level of the Resource and limit the use of FHIR Extension).

Integrating non-medical device data, such as information from physical activity and sleep trackers, into information systems requires careful design. Within this project's scope, the Dia-Continua system also aims to integrate these data into the FHIR standard to store physical activity and sleep data in the FHIR specification. However, this was not technically developed, as elaborated in Section 4.3.4.

As of March 13, 2023, the FHIR U.S. community's recent advancements now offer conditions for lifestyle parameters like physical activity data, marking a significant step towards integrating

PGHD in the FHIR standard [205]. The evaluation of the information with health professionals highlighted the value of having such data in medical discussions, especially about physical activity, with all informants (11/11) agreeing on its usefulness (Section 4.3).

New LOINC codes also highlight the attention towards lifestyle parameters to capture physical activity metrics [206], detailed in **Table 5.3**.

Table 5.3: Semantic codes for physical activity.

LOINC CODE	Description
73985-4	Exercise activity (Bicycling, Running, Swimming)
41950-7	Number of steps in 24 hours
40443-4	Heath rate --resting

Source LOINC reference [206].

These updates indicate that physical activity and lifestyle data are likely to be integrated as a new FHIR resource or as part of FHIR's existing resources, indicating a high recognition by the standards. Meanwhile, **Table 5.3** shows a commitment to establish a standard case to achieve semantic interoperability.

5.2 Publicly Accessible API for Security, Privacy and Usability

This project uses FHIR and SMART on FHIR to develop a RESTful application that facilitates secure data exchange. The technical implementation uses SMART on FHIR, which explicitly requires users to consent to data access (refer to Section 4.3.2). It is crucial to understand that no system can be completely secure. A correct implementation of OAuth2 and OpenID Connect is necessary to avoid vulnerabilities, as highlighted by studies identified by other authors with incorrect implementation [207].

Exchanging data among patients, informal caregivers, and clinicians across all stages of the consultation process (before, during, and after) presented a substantial challenge. The "before" stage of the future model of medical consultation [3] was problematic because there was no standardized way to integrate hybrid closed-loop devices into the Dia-Continua information system [6].

The security measures employed by Medtronic, such as two-factor authentication (2FA), highlight the protocols endorsed by regulatory authorities like the European Commission [208] and the FDA [209]. Additionally, these regulatory bodies have warned against the unauthorized use of diabetes devices due to cyber-attack risks [210]. However, the unavailability of publicly accessible APIs led to reliance on CSV uploads for data collection before consultations, as described in Section 4.3.3. Furthermore, the OmniPod Dash's functionalities were inaccessible to testers in Norway, adding to the data collection challenges [6].

This limitation in device integration influenced the project's goals, especially since the system's usability was considered a critical factor in recommending the usage of the system [2]. Usability, in this context, refers to how effectively, efficiently, and satisfactorily a user can interact with the system [211]. The principal method for data collection—predominantly through CSV file uploads—fell short of these usability standards, being neither user-friendly nor intuitive for downloading data [59, 60]. Consequently, these usability concerns led to the decision to limit recruitment to three experienced users familiar with downloading and using hybrid closed-loop systems.

5.2.1 The Challenge of Undocumented Proprietary Format

The lack of clear and public document API and the data accessibility from newer devices presents a significant challenge compared to older models. This problem is not unique to Dia-Continua, as similar challenges have been encountered by other initiatives like Tidepool [126].

The use of proprietary formats, exemplified by devices like the MiniMed 780G, introduces significant obstacles. In January 2024, an update to the Carelink software altered how insulin data was categorized, affecting the data analysis and interpretation. While these formats comply with GDPR requirements for machine readability, the lack of detailed documentation on these formats [212] presents additional challenges. For instance, the discovery of undocumented constants in CSV files from Medtronic, as shown in **Table 5.4** further complicates understanding and utilizing the data effectively.

Table 5.4: Constant used by proprietary format undocumented (before and after)

Constant	**Before**	**After**
CLOSED_LOOP_AUTO_BASAL	X	
CLOSED_LOOP_AUTO_BOLUS	X	
CLOSED_LOOP_AUTO_INSULIN		X
CLOSED_LOOP_BG_CORRECTION_AND_FOOD_BOLUS	X	X
BOLUS_WIZARD	X	X

Despite these format challenges, the microservices architecture facilitated a rapid adaptation to changes in data format, allowing user testing to continue. Unfortunately, these format changes resulted in inconsistencies in categorising insulin data. To illustrate the extent of these changes by the software update, **Figure 5.3** shows the comparison of the same insulin data before and after the January 2024 update.

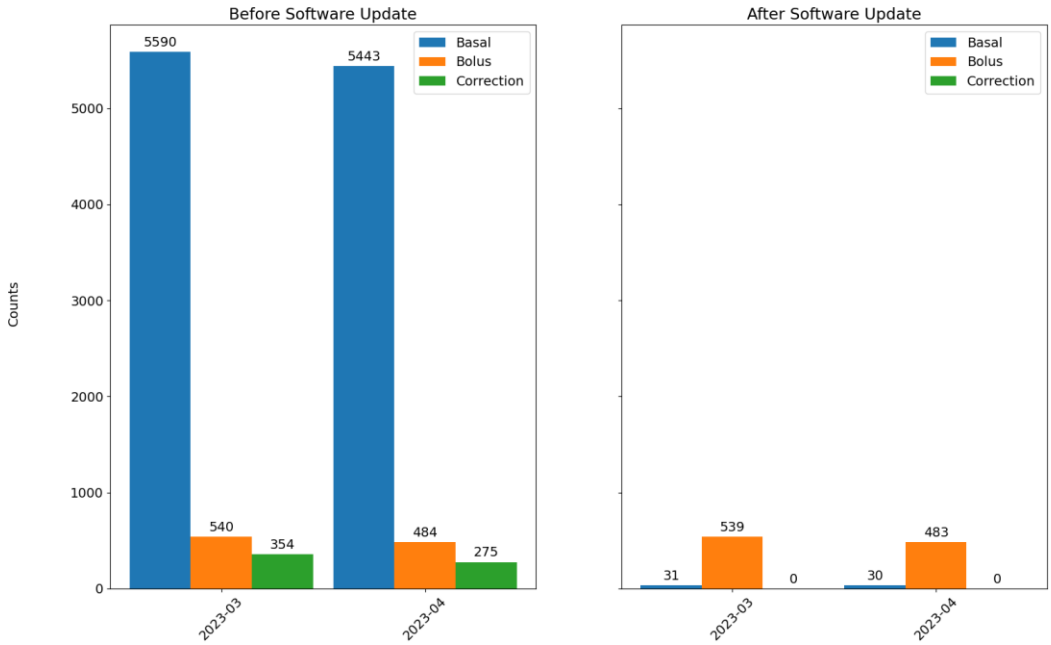

Figure 5.3: Comparison between before and after proprietary format update.

The software update introduced a significant changed in the classification of basal (or micro-boluses according to Medtronic System [201]) and correction insulins by aggregating multiple readings into a single daily measure of total basal insulin, thus reducing the granularity of data available for detailed analysis. Furthermore, the change in documenting correction doses complicated the situation further since the system discontinued the use of previous identifiers. This challenge is detailed in **Table 5.4**.

This change in format affected the clinical value and information quality. **Figure 5.4** illustrates the situation before the Carelink update, detailing how basal and correction insulin delivery was paused at specific times of the day due to the insulin pump's internal algorithm stopping insulin delivery.

Figure 5.4: Daily view - before proprietary format update. It is observable that insulin delivery (basal line in the figure) was halted when the tester's blood sugar level fell below 3.9 mmol/l around 11 a.m., also before the day ended.

The evaluation in Section 4.4.6 revealed that three of nine endocrinologists and both nurses found the information system's output incomplete. Some participants (5/11) noted what is shown in **Figure 5.5** with the day-to-day feature of the system, that the unique value per day for the "basal" insulin and the lack of correction, now incorporated in the "bolus" insulin.

Figure 5.5: Daily view - after proprietary format update. The figure demonstrates that the insulin delivery (basal line) has a unique value of 20.29 iu/h, making it problematic to determine when the pump stops distributing insulin.

The format changes impact the information system in two significant ways. Firstly, they limit the depth of patient consultations, as shown in the evaluation (Section 4.4.6). It also has a significant limitation for an overall model of medical consultation [3]. These poor data limit discussions about physical activity and how it influences insulin requirements and insulin-carbohydrate ratios, thus affecting the system's overall quality of information. Secondly, the poor quality of data provided via the proprietary format complicates the possibility of delivering recommendations through the system or developing AI algorithms for preventive and personalized predictive medicine in diabetes [79].

5.2.2 Overcoming Data Accessibility Barriers in Diabetes Device Integration

During the evaluation of the information system, feedback from three testers—all highly knowledgeable within the diabetes research sector—revealed significant obstacles. Mainly, users of the MiniMed system experienced practical difficulties with data export. One tester expressed frustration over new limitations imposed on data export, stating, *"I noticed I now cannot even export my entire CareLink history at once; there is a 90-day limit that now applies to CSV data as well. Frustrating. I do not think this was the case before."*. Another tester experienced an inconsistency in the data volume exported versus their selection, stating: *"I chose only April in the GUI, but CareLink exported much more."*.

These incidents not only spotlight the functional limitations in data export but also raise concerns over potential security issues from unintentional data oversharing. APIs are critical in addressing these challenges, facilitating technical data access [213], improve interoperability [214], create new opportunities for AI applications [215] and promotion integration across diverse healthcare and research platforms [216]. This situation underscores a broader issue: the inadequacy of a closed system approach. Notably, entities like Dexcom and Roche are adopting more open models, as detailed in Paper [6], and even insulin pen manufacturers like Novo Nordisk moved towards authorized API access through their developer portal [217], or wearable device data access like Oura [58]. Meanwhile, this is not the case for hybrid-close close-loop systems [6].

Lack of standardized APIs poses other "unnecessary" challenges, including difficulties in ensuring consistent patient identity across different organizations and systems, as highlighted in other studies [218]. This project successfully demonstrated the technical feasibility of accessing real-time data from Libre 2 and Libre 3 CGM devices [195]. However, doing so risked violating the Terms of Service established by the device manufacturers, as detailed in Paper [6]. Furthermore, even if data from the Libre devices had been obtained, matching this data to individual patient records in Dia Continua system would have faced significant problems without an official API, as shown in **Figure 5.6**.

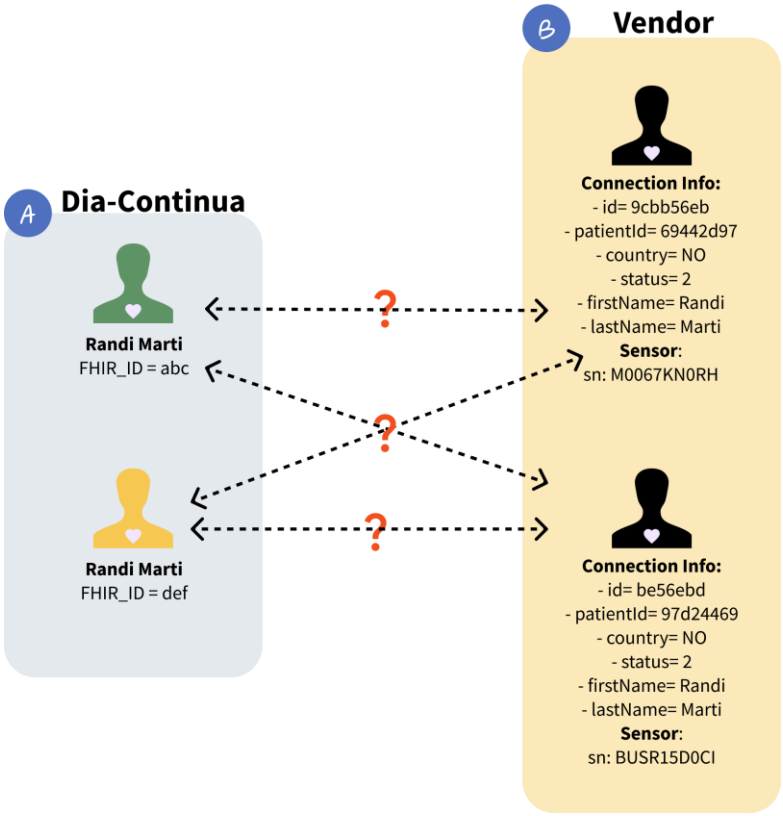

Figure 5.6: Patient identity issues across organizations without standard API. When there is no standard API, System (A) cannot identify which data comes from Medical Vendor (B) because they use different identifiers for users with the same name. A temporary technical solution might be to ask users to enter their sensor identification, labelled as 'sn' in System (B). However, this would have to be repeated every two weeks due to the sensor's limited lifespan. While technically feasible, this approach is less user-friendly than an OAuth2 page requiring users to link their accounts, regardless of the specific sensor.

The example shown in the previous Section 5.2.1, in conjunction with insights from Paper [6], spotlight the obstruction posed by some medical device vendors acting as data gatekeepers, or restrictive practices observed with tech leading technology firms like Google and Apple, discussed by other authors [155].

5.3 A Future Model for Medical Consultations

The system testing and evaluation involved data from three users diagnosed with T1D: two using the MiniMed + Guardian G4 hybrid closed-loop system and one using the OmniPod Dash + Dexcom G6 patch pump for insulin delivery and glucose monitoring. The Dia-Continua system functionalities were presented to nine endocrinologists and two nurses from Norway through remote semi-structured interviews conducted via Teams in early 2024. It was evident during these sessions that the system, based on the existing AGP report [55], made it easier for endocrinologists to understand the new functionalities compared to a new interface. Opting not to "reinvent the wheel" with a completely new GUI proved successful in this regard.

The HCPs evaluation of the system provided crucial feedback and suggested improvements for future versions. For example, improvements to the insulin overview function were made based on this feedback. Endocrinologists highlighted the need to display total insulin amounts, while nurses suggested including percentage values. A proposal update for the GUI update is illustrated in **Figure 5.7.**

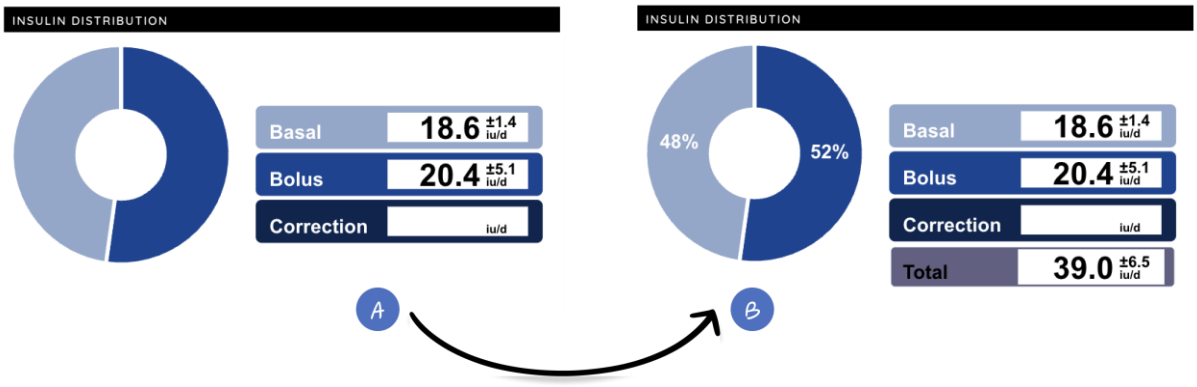

Figure 5.7: An example of how the evaluation can be used for future versions. The Insulin Distribution Overview was presented to HCPs (A), and the proposed update (B) which includes the total daily average insulin and its percentage distribution. Note: The correction insulin is not displayed in this example.

Moreover, including additional data types, like physical activity, was particularly appreciated by all 11 HCPs for its potential to improve the current daily practice. All HCPs also positively received the integration of sleep data into diabetes consultations. However, they noted the need for improvements in sleep data visualization, citing the complexity of nights because they reflect the previous day's activities. Stress and distress are other factors that should be considered for future integration into medical consultations (Section 4.4.2). Sensors like the Oura ring are also moving in this direction by introducing a daytime stress functionality update in the late 2023 version [58], which could be considered as a parameter to add to the existing system.

The P5 model [79], introduced when described RQ3 (Section 1.3.3), encapsulates five crucial aspects of modern medicine: preventive, personalized, predictive, participatory, and psycho-cognitive. These aspects should guide the development of health interventions and emphasize the importance of tailoring care to individual patient needs, including their behaviour, psychological state, and

emotional well-being [79]. This PhD project aimed to incorporate more elements to perform a comprehensive assessment of patients, and it succeeded. One limitation of the PhD project is that data provided by medical device vendors restricted the full realization of the P5 model, particularly in terms of its preventive and predictive aspects. Real-time data, crucial for these models, would require a direct collaboration with device manufacturers, but this PhD project was not able to establish such a collaboration. This obstacle is not unique to the PhD project; even well-resourced entities like Tidepool encountered difficulties in securing direct collaboration with manufacturers [126], as noted in Section 3.1.2.2. The DIY movement provides some alternatives for real-time data, but these are not suitable for larger-scale implementation due to legal and security concerns [6].

This project has demonstrated the potential of a new model for medical consultations that integrates both lifestyle and diabetes-specific data [3], marking a significant step forward from current practices. A notable achievement is the integration of physical activity data into the consultation process, as highlighted by HCPs in Section 4.3. Despite this progress, challenges remain, as outlined in Sections 5.1 and 5.2. These include the need for standardized APIs for diabetes data and transparent data formats to facilitate this integration [6].

As presented in Paper [5], it has been found that some medical vendor software are not designed for direct interaction with EHR systems. This highlights the need for a new medical consultation model, as described in Paper [3]. Dia-continua succeeded in integrating PGHD into EHRs even though it is not directly connected to existing EHR systems. However, this integration and the evaluation have a limitation: the lack of access to clinical data such as HbA1c levels or medication information, which suggests opportunities for improvement in future versions. Nevertheless, Dia-Continua's FHIR component, which is designed for data exchange with EHR systems, offers the possibility of incorporating such data in the future.

5.3.1 Generalizability of Information System Findings

The review paper [1] explains how ICT interventions use different sensors to manage chronic NCDs, each with its own requirements for prevention, treatment, or management, which necessitate specific information. It also emphasizes the significance of sensors in gathering data for medical consultations.

Dia-Continua's implementation, detailed in Section 4.3, contains general components applicable to various NCDs and specific components designed for T1D diabetes. The system's inclusion of FHIR and SMART on FHIR showcases the main functionalities supporting the secure exchange of PGHD with EHRs. This microservice architecture provides a flexible base that improves the system's applicability across different chronic disease contexts:

- **General Components (Reusable across NCDs)**: The system uses microservices designed for broad reusability, such as the NGINX ingress controller [96], Cert-Manager [97], and Keycloak [196]. These services are flexible and can be replaced with alternative technologies as needed. For example, LimeSurvey [197], used for questionnaire distribution and PROMs (Section 4.3.5.1), can also be substituted to meet specific requirements.

- **Specific Components for T1D**: The Dashboard and GUI (Section 4.3.5) are optimized to present T1D diabetes-related PGHD. However, the evaluation with HCPs indicates that these components can also be beneficial for consultation with T2D and GDM (Section 4.4). These diabetes-specific components must be adapted to meet each NCD's specificity, as various NCDs require distinct information [1].

Dia-Continua aligns with two emerging trends, highlighting the relevance of future works and the generalizability of the findings. Firstly, there is an increasing recognition of the importance of lifestyle data, with the field moving towards semantic interoperability [206] (Section 5.1.2). This evolution suggests that EHR systems may include lifestyle parameters such as steps and heart rate in the future. Secondly, adopting FHIR as a standard for data exchange is gaining momentum, supported by both the U.S. [162] and the EU [163]. Furthermore, major technology companies, including Google [169], Microsoft [170], Amazon [171], Apple [172] and EHR vendor Epic [173], are also adopting FHIR, indicating a broader industry interest.

In order to improve Dia-Continua or any future research project that investigates into PGHD in EHR systems, it would require direct collaboration EHR vendors. This will help to identify any practical barriers, such as financial, technical, or operational barriers [109]. Addressing these barriers will increase the generalizability of the findings. The collaboration with Dips, the primary EHR vendor in Norway, was limited only to the HEIR project [174]. This collaboration was required to install the Dips Communicator, a mandatory software in order to share CGM data with Noklus [199], as reported in Section 4.3.5.2. Cooperating with EHR vendors may lead to new research opportunities on emerging trends, such as the International Patient Summary (IPS) [77, 157, 159]. The IPS is an FHIR-based, summarized version of a patient's clinical data (i.e., medications and allergies), facilitating cross-border data exchange [160] and comorbidities analysis. Dia-Continua, an FHIR-based information system, could serve as the starting point for the IPS.

5.3.2 Scalability and Commercialization

The system's architecture is hosted on Azure and Infrastructure as a Service (IaaS), which offers a pay-as-you-go model that significantly reduces the need for upfront hardware investments (e.g., servers). **Figure 5.8** presents the analytical dashboard that details the costs of cloud services over six months, from August 2023 to January 2024. The total cost accumulated is $1,775, averaging approximately $300 per month. Most of the expenses are attributed to the use of virtual machines, which predominantly represent the Azure Kubernetes Service (AKS).

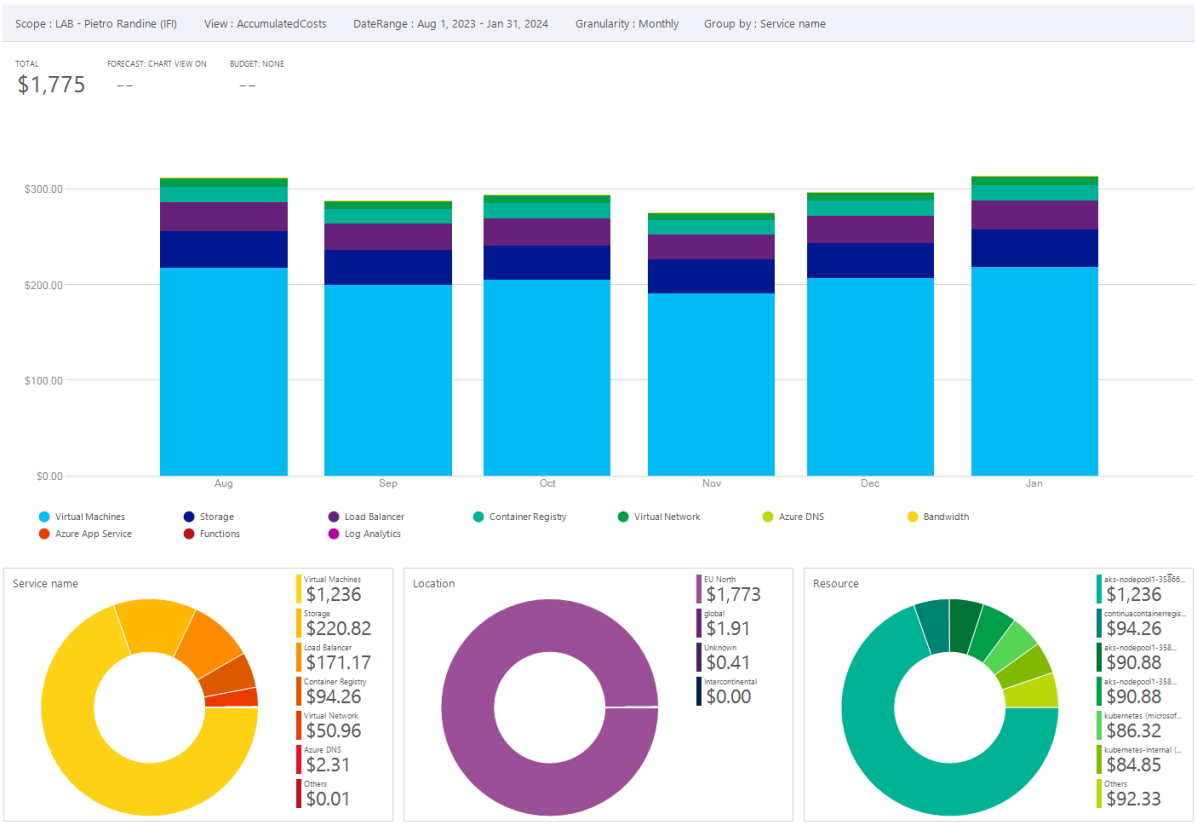

Figure 5.8: Dia-Continua: cost overview. Dia-Continua operates on a standard computing node with moderate processing power and memory, making it suitable for general tasks instead of intensive machine learning or AI processes (a single node equipped with 4 CPUs, 16GB of RAM, and 32GB of SSD temporary storage). The system's cost distribution is visually represented through a series of charts. A multi-coloured piled bar chart breaks down monthly expenses by various services such as Virtual Machines and Storage. The three pie charts provide a finer analysis: one illustrates the cost distribution across different services, with Virtual Machines (the node of the AKS) being the most significant contributor. The one in the centre shows the geographical source of costs, with the EU North region being the primary location, and the last chart categorizes expenses by resources, highlighting the AKS cluster as a major cost factor.

The cost evaluation presented in **Figure 5.8** was based on a small initial user group of only three participants, and it demonstrates the stability in costs. However, future testing with a larger user group may impact the resources required and potentially increase the overall cost. It is worth mentioning that the Dia-Continua system (Section 4.3), with its consultation model [3], can be easily transferred to other public cloud providers like Amazon Web Services (AWS) or used in different cloud configurations, such as private or hybrid, to meet specific legal requirements. This flexibility is particularly relevant when regulations require data processing in a private cloud environment, ensuring that cloud resources are exclusively allocated to a single organization such as a hospital or clinic. The Dia-Continua architecture's flexibility and scalability make it a solution for healthcare organizations seeking to optimize their cloud infrastructure while complying with regulatory requirements (e.g., GDPR).

The Dia-Continua system fills a gap in today's medical consultation. Six out of nine endocrinologists and both nurses recognized the inclusion of an "objective measure" of physical activity as a significant improvement. Such innovations and system scalability suggest a hypothetical scenario where Dia-Continua could emerge as a competitor to the systems used today in medical

consultations presented in Section 3.1.2. However, the path to commercialization for Dia-Continua is not without challenges. One of the major obstacles is the lack of a publicly documented API for diabetes data retrieval, as well as the usability limitations for patient data download. These technical limitations are currently posing significant barriers, as described in Paper [6] and Section 5.2. While it is possible to integrate insulin data from pens via APIs [217], it does not fully address the essential needs for supporting hybrid-closed loop data. Moreover, the potential development of a mobile app to access more health data, including from Samsung and Apple devices [156], does not mitigate the core challenge. Therefore, despite its benefits to the medical consultation, the commercialization of Dia-Continua remains complex and currently not feasible.

Chapter 6 Conclusion

This final chapter of the PhD dissertation provides a summary of the research journey, contributions to the research questions (Section 6.1), future works (Section 6.2), and personal reflections (Section 6.3).

During the evaluation, nurses commented on the Dia-Continua aspiration: *"You are trying to make this one system for everything. Yeah, that is a high goal. [They both smiled]"*.

The PhD project successfully designed, developed, and demonstrated an Information System within a relatively short period, using the Design Science Research process model [89]. Incorporating a microservices architecture that aligns with current software engineering best practices. The advantages, such as code reusability, enabling continuous delivery, and avoiding redundant development efforts, are well-recognized benefits of microservices and Continuous Integration/Continuous Deployment (CI/CD) practices [94, 95].

At the start of the project, significant advancements were being made in diabetes management technologies [111] including the introduction of hybrid closed-loop systems in Norway in 2019 [135]. As outlined in Chapter 2, Research Discipline and Methodology, designing an information system requires an interdisciplinary approach and collaboration with the industry, reflecting the essence of integrative research [85]. The collaboration with multiple stakeholders in healthcare with the PhD project opened many opportunities for further development, contributing to health informatics from diverse perspectives. It showcased a future model of medical consultation [3] where medical data and lifestyle data are integrated into a unified system (RQ1).

Despite its ambitions, the project faced multiple constraints due to a lack of direct collaboration with the medical vendors, facing issues with various data formats, proprietary interfaces, and storage methods. These challenges limited the system's ability to integrate health data (Section 5.1) and commercialization potential (Section 5.3.2). Nevertheless, the Dia-Continua system managed to successfully integrate patient-generated health data using the FHIR standard, although at the expense of usability, primarily because the only method to acquire hybrid closed-loop data was through CSV file [6] or USB and Bluetooth connection via the Tidepool Uploader for the previous devices.

The Dia-Continua system integrates health-related data, relying on SMART on FHIR and its standards for robust security and privacy measures (RQ2). OAuth2 for authorization [166] and OIDC for user authentication [167]. The existing systems have a scarcity of standardized APIs for data retrieval [6], complicating the data-gathering process, limiting interoperability [154], and exposing the patients to data oversharing (Section 5.2). As an alternative to today's practice, the project presents an FHIR-based consent management system for PGHD data sharing by patients and others like research institutions or hospitals [5].

The system was tested with experienced users with T1D who actively engaged in diabetes research. These users uploaded their diabetes data and connected their wearable devices themselves, which may not be feasible for an average user, especially when it comes to diabetes data. The initial testing focused on knowledgeable users with diabetes research experience who also encountered difficulties with data upload (Section 5.2). Eleven healthcare professionals across Norway evaluated the first version of the information system. The evaluation yielded positive results, particularly in regard to the inclusion of new features, such as incorporating physical activity and other lifestyle factors like stress and sleep, in future medical consultation (RQ3). Future works should build on this initial feedback, undertaking another cycle to design, develop, demonstrate, and evaluate the new version (Section 5.3). However, any future developments would benefit from direct collaboration with the industry to facilitate real-time data processing and simplifying data collection in general.

6.1 Main Contribution Related to the Research Questions

This project started with a main problem to solve, which was:

Design a unified information system capable of integrating patient-generated health data to improve the quality of information during medical consultations. This system should navigate through fragmented information and the complexities of various data formats, proprietary interfaces, and storage methods while ensuring robust security, privacy, and adherence to data ownership principles. It should facilitate controlled data sharing with healthcare providers and external entities like national registries and informal caregivers.

This section presents the main contributions to each research question, including published work and additional material in this dissertation.

RQ1: How can we integrate different health-related devices used daily by individuals with diabetes and patient-generated health data into a unified information system for patients and health personnel to use before, during, and after medical consultations?

The theoretical model for integrating various health-related devices and patient-generated health data into a unified information system is presented in Paper [3] titled: "*Towards a New Model for Chronic Disease Consultations*". This Paper proposes a new consultation model focusing on T1D as a use case. Paper [4] titled *"Privacy Concerns Related to Data Sharing for European Diabetes Devices"* found that medical vendors have explicit disclaimers regarding their non-EHR status, needing health personnel to print or download data to provide patient treatment advice.

Paper [6] titled: "*Unlocking Real-Time Data Access in Diabetes Management*", further builds on this model [3] by advocating a set of standards that will enable diabetes data sharing between end-users, equipment vendors, researchers, and healthcare services. Meanwhile, Section 4.3 (Dia-Continua: Technical Implementation) explores the technical implementation of the model presented

in Paper [3], detailing the practical application of FHIR standards for data aggregation. The specific challenges of integrating diabetes management devices are discussed in Section 4.3.3 (Hybrid-Close Loop Data Integration), while commercial wearable device data integration is discussed in Section 4.3.4 (Commercially Wearable Device Data Integration). Additionally, Section 5.1 (A FHIR-tale of Information System in Type 1 Diabetes) discusses the more comprehensive implications of using FHIR standards for patient-generated health data. This section highlights the challenges (e.g., volume and relevance of data) and potential solutions for primary and secondary use and reuse of health data.

RQ2: How can patient-generated health data be exchanged between clinicians, patients and informal caregivers before, during and after the consultation, with robust security and privacy measures?

Paper [4] titled *"Privacy Concerns Related to Data Sharing for European Diabetes Devices"* examines the current data-sharing practice and its regulatory landscape. To ensure secure data sharing and informed consent, Paper [5] titled: "Consent Management System on Patient-Generated Health Data" proposes a consent management system based on HL7 FHIR. Paper [6]: *"Obstacles in Accessing Real-Time Diabetes Data for Treatment and Research: Toward an Interoperability Model"* contributes to RQ2 by analysing the present API availability and the challenges relative to data exchange posed by unregulated and proprietary software. Section 4.3.2 (Authorization and Authentication) presents the SMART on FHIR implementation to robust security and privacy practice. Meanwhile, Section 5.2 (Publicly Accessible API for Security, Privacy) discusses the current lack of public accessibility of APIs needed to promote interoperability and security [159, 213, 214].

RQ3: How can individual-specific patient-generated health data improve the information quality during the medical consultation?

In order to understand how individual-specific health data can improve the quality of information in consultations, the result from Paper [2] titled *"Criteria for Assessing and Recommending Digital Diabetes Tools: A Delphi Study"* was used to identify criteria for evaluating digital diabetes tools, emphasizing the significance of information quality and usability. Section 4.4 (Testing and Evaluation) presents the findings from healthcare personnel evaluations and the system's impact. Section 5.3 (A Future Model for Medical Consultation) considers the applicability of the P5 model of medicine [79] to diabetes management, proposing a forward-looking approach to integrating the system into broader chronic disease management.

6.2 New Regulatory Challenges and Future Work

This dissertation places significant emphasis on data privacy, particularly emphasising the Terms of Service and privacy policies examined in Papers [4] and Paper [6]. It also discusses the evolution of new regulations, such as the Medical Device Regulation (MDR), which became effective on May 26, 2021, and will be fully implemented by 2026 [185]. It also highlights new cybersecurity requirements like the Cyber Resilience Act in the EU [208] and the FDA's cybersecurity recommendations in the U.S. [209]. It appears likely that the EU AI Act will be the first regulation on artificial intelligence [219]. The evaluation with endocrinologists has highlighted the potential benefits of being open to AI suggestions for interpreting data. However, the EU AI Act, alongside the MDR, may introduce additional challenges for upcoming research projects or medical software, particularly during the ethical approval process.

The dissertation also highlights significant technical challenges, especially in data collection, and discusses potential solutions in Paper [6] and Sections 5.2 and 5.3. In addition, future studies and researchers working specifically on GDPR should investigate the GDPR's Right to Data Portability [70], particularly the 'Right to Transmit Data to Another Controller'. The project's findings show that patients face difficulties downloading their data or when other entities, such as universities or research institutions, attempt to integrate medical data into different systems. The 'Right to Transmit Data to Another Controller' is made to enable personal data transfer between entities without 'hindrance'—a term explicitly mentioned in the GDPR [70]. Therefore, research should investigate the technical hindrance and consult national authorities such as Datatilsynet in Norway. Based on this situation, they may take appropriate action.

Not all regulations will pose new challenges for information systems like Dia-Continua. Some upcoming regulations, such as the European Commission's Data Act, set to effect in January 2024 [220], could introduce new opportunities. The Data Act emphasises the need to avoid vendor lock-in, *"which undermines competition and the development of new services"* [220]. The act highlights the importance of interoperability between data processing services as also documented in this PhD project.

The language used in all the regulations mentioned (e.g., GDPR, MDR, Cyber Resilience Act) is notably complex and potentially challenging even for experienced researchers to understand. This complexity parallels the current state of Terms of Service and Privacy Policies that patients and others like HCPs must understand (for informed consent) when using any software involved in diabetes consultation. Paper [4] questions whether patients actually read and understand the terms and privacy policies for diabetes devices or skip over them because they need the mobile application to visualise their data in any case. Future work should dive deeper into this issue, looking at why patients might accept these terms without fully understanding them, possibly because they feel they have no other choice.

6.3 Author's Reflection and Final Remarks

This project began with high ambitions to enhance medical consultations for those managing Type 1 diabetes, especially by addressing how physical activities, insulin, diet, sleep, and more influence blood glucose levels. My previous work in diabetes research prepared me for some challenges, especially in terms of data gathering from medical devices. I had high expectations between 2020 and 2021 that Tidepool would cover this gap. Unfortunately, this was not the case for the hybrid closed-loop systems. These systems have gained rapid trust among healthcare providers. Some have reported asking patients to trust both the pump and its algorithms. These devices have also dramatically improved the quality of life of individuals with diabetes.

Given the complexity of data access, this PhD journey has taken me further and enabled me to explore new challenges. I collaborated with diverse groups, from health and diabetes research to data protection officers and the FHIR community. Participating in EU projects and discussions about regulations deepened my understanding of cybersecurity and healthcare laws, broadening my perspective and the PhD problem space. As discussed in this dissertation, legal interoperability will be a critical challenge in the future, especially regarding data ownership and privacy. Unfortunately, the lack of documented APIs, as described in this dissertation, complicates the design and commercialisation of a system like Dia-Continua due to many constraints. This project has also observed how the FHIR standard can potentially become the "standard for health data exchange". However, the standard has gaps regarding lifestyle data, although the work in progress about semantic interoperability (e.g., new LOINC codes) indicates a positive future perspective. The FHIR community is a group of technology enthusiasts that is devoted to the development and implementation of new functionalities for healthcare data exchange standards. However, there is a potential risk that the frequent changes may affect its adoption. It is crucial to balance the need for innovation with the stability and consistency required for its successful adoption.

Health Informatics bridges several disciplines and sometimes presents challenges not typically found in Computer Science. Engaging with diverse communities and employing various methodologies, like interviews, was a success factor in the project. Adapting the evaluation method for better accessibility over standardised questionnaires facilitated a dialogue with health personnel. Unfortunately, the same was impossible for the main design phase of Dia-Continua due to the COVID-19 pandemic, which has significantly impacted the ability to work directly with patients and healthcare workers [105]. Meanwhile, the ethical approval process took eight months (four months for the University DPO and four months for Sikt), delaying the opportunity to demonstrate the system with real data. Despite these problems, one round of evaluation was performed. Future iterations of system evaluation could further enhance its functionalities, especially regarding stress management and system recommendations. Adhering to upcoming regulations like the EU AI Act will be crucial for analysing patterns in health data and potentially making the ethical approval process even longer. On the bright side, it may also enhance individuals' control over their personal data.

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Appendix 1: Assessment of Processing of Personal Data

Sikt

Assessment of processing of personal data

Reference number
671274

Assessment type
Standard

Date
26.06.2023

Title
Information System Before, During and After Clinical Visits for Diabetes Consultation

Institution responsible for the project
UiT Norges Arktiske Universitet / Fakultet for naturvitenskap og teknologi / Institutt for informatikk

Project leader
Eirik Årsand

Project period
17.04.2023 - 30.03.2024

Categories of personal data
General
Special

Legal basis
Consent (General Data Protection Regulation art. 6 nr. 1 a)
Explicit consent (General Data Protection Regulation art. 9 nr. 2 a)

The processing of personal data is lawful, so long as it is carried out as stated in the notification form. The legal basis is valid until 30.03.2024.

Notification Form

Comment
ABOUT OUR ASSESSMENT
Data Protection Services has an agreement with the institution where you are a student or a researcher. As part of this agreement, we provide guidance so that the processing of personal data in your project is lawful and complies with data protection legislation. We have now assessed that you have legal basis to process the personal data.

PRESENTED TO REC - NOT REQUIRED TO APPLY
You have presented the project to The Regional Committees for Medical and Health Research Ethic (REC). REC has stated that the project does not appear to be health research encompassed by the Health Research Act, and therefore does not need approval from REC.

TYPE OF DATA
The project will process special categories of personal data about health, in addition to general categories of personal data.
The project includes 3 samples.
Sample 1 consists of Patients with Diabetes (Main Study in EEA/EU Area), 18-80 years. The project will be processing special categories of personal data about health for this sample.
Sample 2 consists of Health Personnel
Sample 3 consists of informal caregivers, related to sample 1

LEGAL BASIS
For sample 1, the data subjects give their consent to the processing of their personal data. The legal basis for the processing is art. 6.1 a) of the GDPR. The data subjects give their explicit consent to the processing of special categories of personal data. Thus, the conditions in art. 9.2 a) are met and the prohibition against processing special categories of personal data does not apply.

This sample will be recruited through social media, but will not give their reply/consent publicly in social media. The project are taking measurements to avoid that any health data is shared before consent is given.

For sample 2, there will only be processed general categories of personal data.
The legal basis for processing personal data will be the data subject's consent, in accordance with Article 6(1)(a) of the General Data Protection Regulation.

For sample 3 there will only be processed general categories of personal data.
The legal basis for processing personal data will be the data subject's consent, in accordance with Article 6(1)(a) of the General Data Protection Regulation.

DUTY OF CONFIDENTIALITY
The data subjects in Sample 2 are bound by their duty of confidentiality and cannot share confidential data with the research project. Please note that it is not sufficient to avoid using names patients, but also be careful when using examples and background data such as age, sex and pinpointing exact time or place.

FOLLOW YOUR INSTITUTION'S GUIDELINES
The project has been provided by a Risk assessment approved by Leder Teknisk Kompetansegruppe (TK) on behalf of the Institutt for informatikk at UiT .

You should always store, send and secure the collected data in accordance with your institution's guidelines. This means that you must use data processors (and the like) that your institution has an agreement with (i.e. cloud storage, online survey, and video conferencing providers).

Our assessment presupposes that the project will meet the requirements of accuracy (art. 5.1 d), integrity and confidentiality (art. 5.1 f) and security (art. 32) when processing personal data.

DATA PROCESSOR
We presuppose that the processing meets the requirements of data processors under the General Data Protection Regulation, cf. Art. 28 and Art. 29.

NOTIFY CHANGES
If you intend to make changes to the processing of personal data in this project, it may be necessary to notify us. This is done by updating the information registered in the Notification Form. On our website we explain which changes must be notified. Wait until you receive an answer from us before you carry out the changes: https://sikt.no/en/notify-changes-notification-form

FOLLOW-UP OF THE PROJECT
We will follow up the progress of the project at the planned end date in order to determine whether the processing of personal data has been concluded.

Good luck with the project!

Appendix 2: Notification Form for Processing of Personal Data

Sikt

Notification Form

Reference number
671274

Which personal data will be processed?

- Name
- Online identifiers
- Health data

Project information

Title
Information System Before, During and After Clinical Visits for Diabetes Consultation

Summary
The PhD project focuses on new functionalities for Diabetes consultations with a secure data exchange, storage, and interaction between citizens, health personnel, and research institutions. This research study aims to enhance the quality of information in our healthcare system, specifically focusing on individuals with Type 1 Diabetes. Our goal is to improve the overall experience of medical consultations by conceptualizing them as a continuous process that extends beyond a single visit. In this study, we aim to introduce a new approach to medical consultations that involves three key phases: preparation, consultation, and follow-up. This is a PhD project, and the funding was provided by the University of Tromsø – The Arctic University of Norway. This project proposes a future-proof architecture for diabetes medical consultation using the Fast Healthcare Interoperability Resources (FHIR) specification. One of the most used healthcare standards for data exchange.

What is the purpose for processing personal data?
We designed a service that combines generic information (e.g., sleep, physical activity, diet), disease-specific information (blood glucose, carbohydrate intake, insulin doses) and Diabetes standardized questionnaires without demographics (e.g., PAID, SF-36, PHQ-9). The medical devices to collect blood glucose are approved by the National Agreement of the Norwegian Authorities (sykehusinnkjop). The patients use the same equipment provided by the health authorities to operate the data collection independently. Following GDPR definitions, we are gathering Personal Data (GDPR Article 4.1) and Data concerning Health (GDPR Article 4.15). All data are accessible will be accessible to the project application, and clinicians in the study will get limited access to data for a short time to evaluate the system functionalities.

If the personal data will be used for other purposes, please describe
Potentlially if the patients agrees via a consent management system (part of this research project), anonymized data can be shared with researchers.

Project description

Project Description.docx

External funding
- Other

Other source of funding
A grant from the fund of UiT - The Arctic University of Norway

Type of project
Research/PhD project

Data controller

Institution responsible for the project
UiT Norges Arktiske Universitet / Fakultet for naturvitenskap og teknologi / Institutt for informatikk

Project leader
Eirik Årsand, eirik.arsand@uit.no, tlf: 77644760

Do multiple institutions share responsibility (joint data controllers)?
No

Sample 1

Describe the sample
Patient with Diabetes (Main Study in EEA/EU Area)

Describe how you will identify or contact the sample
We aim to recruit patients in EEA/EU Area via posts on social media.

Age group
18 - 80

Are any of these groups included in the sample?
- Patients, disabled people, or sick people

Which data relating to sample {{i}} will be processed? 1
- Name
- Online identifiers
- Health data

How will data relating to sample 1 be collected?

Web-based experiment

Legal basis for processing general personal data
Consent (General Data Protection Regulation art. 6 nr. 1 a)

Legal basis for processing special personal data
Explicit consent (General Data Protection Regulation art. 9 nr. 2 a)

Justify the choice of legal basis for processing

Information for sample 1

Will the sample receive information about the processing of personal data?
Yes

How does the sample receive information about the processing?
Written (on paper or electronically)

Information letter

Information Letter for Patient.docx

Sample 2

Describe the sample
Health Personnel (Main Study in EEA/EU Area)

Describe how you will identify or contact the sample
We plan to find active Health Personnel el (e.g., endocrinologists, clinicians, and nurses) or retired clinicians willing to participate, via mail.

Age group
18 - 80

Which data relating to sample {{i}} will be processed? 2

- Online identifiers

How will data relating to sample 2 be collected?

Web-based experiment

Legal basis for processing general personal data
Consent (General Data Protection Regulation art. 6 nr. 1 a)

Information for sample 2

Will the sample receive information about the processing of personal data?
Yes

How does the sample receive information about the processing?
Written (on paper or electronically)

Information letter

Information Letter for Others.docx

Sample 3

Describe the sample
Informal caregiver

Describe how you will identify or contact the sample
Sample 1 (can request to share their data) to their informal caregiver

Age group
18 - 80

Which data relating to sample {{i}} will be processed? 3

- Online identifiers

How will data relating to sample 3 be collected?

Web-based experiment

Legal basis for processing general personal data
Consent (General Data Protection Regulation art. 6 nr. 1 a)

Information for sample 3

Will the sample receive information about the processing of personal data?
Yes

How does the sample receive information about the processing?
Written (on paper or electronically)

Information letter

Information Letter for Others.docx

Sample 4

Describe the sample
Health Personnel Semi-structured Interview

Describe how you will identify or contact the sample
We will recruit Health Personnel via our own network. We are expecting to recruit a maximum of 5 clinicians.

Age group
26 - 80

Are any of these groups included in the sample?
- Persons residing in countries outside the EU/EEA

Which data relating to sample {{i}} will be processed? 4

How will data relating to sample 4 be collected?

Group interview

Attachment

Semi-Structure Interview - Guideline - Pietro_2.docx

Legal basis for processing general personal data
Consent (General Data Protection Regulation art. 6 nr. 1 a)

Personal interview

Attachment

Semi-Structure Interview - Guideline - Pietro_3.docx

Legal basis for processing general personal data
Consent (General Data Protection Regulation art. 6 nr. 1 a)

Information for sample 4

Will the sample receive information about the processing of personal data?
Yes

How does the sample receive information about the processing?
Written (on paper or electronically)

Information letter

Letter for recruitment.docx

Third persons

Will the project collect information about third persons?
No

Documentation

How will consent be documented?
- Electronically (email, e-form, digital signature)

How can consent be withdrawn?
The user can withdraw consent through a simple process. The user has two options to withdraw consent: 1) Contacting the Designated Contact Person: The user can get the designated contact person whose contact details are provided in the privacy policy or any other relevant documentation. The user can express their intent to withdraw consent by contacting this person. The designated contact person will guide the user through the necessary withdrawal steps. 2)Deleting the Account: Alternatively, the user can delete their account directly through the platform. The user can initiate the account deletion process by selecting the "delete your account" option provided within the user's account settings. This action will automatically remove all the information associated with the account, including personal data collected during their use of the Dia-Continua platform. It's important to

emphasize that when consent is withdrawn, the platform will no longer process the user's data, and any existing information will be permanently deleted. By providing these two options for consent withdrawal, we aim to ensure a user-friendly and straightforward process for users to exercise their rights over their data.

How can data subjects get access to their personal data or have their personal data corrected or deleted?
1) User Account Access: Users can log in to the research platform using their credentials after creating an account. Once logged in, they can view and modify their personal information. This includes downloading their data and receiving a copy of your personal data (data portability) in a human-readable format. 2) Connection and Disconnection of Data Sources: Users can manage the sources from which their data is collected within their user account settings. They can connect new data sources or disconnect existing ones as per their preference. This allows users to have control over the specific data being processed. 3) Account Deletion: Users have the right to request the deletion of their accounts. Users can initiate the account deletion process by choosing the "delete your account" option or a similar functionality provided within their account settings. This action will result in the automatic and complete erasure of their data from our systems.

Total number of data subjects in the project
1-99

Approvals

Will any of the following approvals or permits be obtained?

- Other approval

Other approval
Risk assessment approved by Leder Teknisk Kompetansegruppe (TK) on behalf of the Instituttleder Institutt for informatikk - Anders Andersen at UiT The Arctic University of Norway | UiT

Approvals

Risk Analysis - PhD project Pietro Randine.pdf

Security measures

Will the personal data be stored separately from other data?
Yes

Which technical and practical measures will be used to secure the personal data?

- Encrypted transmission
- Encrypted storage
- Restricted access
- Continuous anonymisation
- Multi-factor authentication
- Other security measures

Indicate which measures
The system prototype is hosted in the UiT Office 365 (UniversitetetiTromso.onmicrosoft.com) subscription under Microsoft Azure. All the applications and data are deployed in a Kubernetes service. Encryption managed by the service provider protects access to the Kubernetes service and the Kubernetes clusters. This approach is commonly used in cloud computing environments. In containerized environments such as Kubernetes, the PhD prototype use Persistent Volume Claim (PVC) and stores data in Azure Disk storage located in North Europe. All the sensitive information, such as passwords for the storage, API keys, and TLS certificates, are stored inside Kubernetes secret. Kubernetes secrets are stored as API objects within the Kubernetes cluster and are encoded using base64 encoding for storage. Furthermore, the access to secrets and, more generally, the Kubernetes clusters are protected by Local accounts with Kubernetes RBAC (Role-Based Access Control). Only the PhD candidate has access to it with two-factor authentication enabled. The users (patients, health personnel and researchers) can access the prototype via an Azure Load Balancer that distributes incoming network traffic across multiple backend resources in the Kubernetes cluster. The interviews will held via the Teams, and the automatic data recorder will recover the data.

Where will the personal data be processed

- ?

Who has access to the personal data?

- Data processor
- Student (student project)

Which data processor will be processing/have access to the collected personal data?
A specific data processor will process and access the personal data collected. In this case, the system prototype is hosted under a subscription with Microsoft Azure owned by the Department of Computer Science, Faculty of Science and Technology ath UiT The Arctic University of Norway. Only the designated PhD student, who is authorized and responsible for managing the platform, will have access to connect to and interact with the collected personal data. More formally, the project's responsibility is the Department of Computer Science, Faculty of Science and Technology, UiT The Arctic University of Norway, via Prof. Eirik Årsand. The data subject may also contact Our Data Protection Officer at UiT, The Arctic University of Norway or Sikt.

Will personal data be transferred to a third country?
No

Closure

Project period
17.04.2023 - 30.03.2024

What happens to the data at the end of the project?
Personal data will be anonymised (deleting or rewriting identifiable data)

Which anonymisation measures will be taken?

- The identification key will be deleted

Will the data subjects be identifiable in publications?
No

Additional information

We are examining a scenario in which the system, aka prototype, will use to get a response about the concept devaluated and defined during the PhD project. We aim to get feedback from health personnel about an information system for patients with Diabetes. The goal is to demonstrate the prototype developed that proves the feasibility and practicality of the PhD project. We added in the attachment the risk assessment of the PhD project, and due to the nature of the PhD project. A low-risk project. Additionally, we applied to the Regionale komiteer for medisinsk og helsefaglig forskningsetikk (REK) for the assessment wherever the project was relevant to be considered a health research project, and the answer received is in the attachment. The system prototype is hosted in the UiT Office 365 (UniversitetetiTromso.onmicrosoft.com) subscription under Microsoft Azure. All the applications and data are deployed in a Kubernetes service. More details about security and privacy are available in this document, and it requires some knowledge about cloud computing.

Other attachments

Risk Analysis - PhD project Pietro Randine.pdf

Answer - Ikke fremleggingspliktig.pdf

Appendix 3: Semi-Structured Interview Guideline

Title of the Research Study: Evaluation of the Information Quality in Information Systems for Type 1 Diabetes Consultation

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Interviewer: Pietro Randine

Date and Location of the Interview: [Teams, TBD]

Data collection: Automatic Transcription

Interviewee Information: [Prior to the Intervirew]

Name: [Prior to the Intervirew]

Introduction [4 min]:

- Greet the interviewee and introduce myself and my affiliation. **[1 min]**
- Explain the purpose of the study, focusing on evaluating the information quality of the infomation system. **[1 min]**
- Before beginning the interview, obtain consent to record and ensure confidentiality. Notify interviewee of the option to leave or remove information at any point. **[1 min]**
- Confirm the interview duration and provide an overview of the process (discussion, system demo, and feedback). **[1 min]**

Interview Questions [24 min]

- Video for the Demo of the System functionalities [1 min]
- Feature Evaluation [23 min]

For each feature, we present a video and one or more screenshots, and we ask the informants multiple questions to evaluate specific measures.

Feature #1*: Insulin Overview*

Q#	Measure	Question
1	Appropriate Amount	Is the amount of information on Insulin provided by the system satisfactory for your needs?
2	Concise Representation	How would you rate the way the system displays Insulin-related information?

Feature #2*: Sleep Overview*

Q#	Measure	Question
3	Timeliness	Does the system provide the information up-to-date and relevant to your work?
4	Believability	Does the fact that the information doesn't come from a medical device impact its credibility for you?
5	Interpretability	What improvements would you recommend making the information more accessible to understand and apply in your daily practice?

Feature #3*: Physical Activity Overview*

Q#	Measure	Question
6	Timeliness	How much is a patient active, is it a measure you want and have time to discuss with the patient during the consultation?
7	Appropriate Amount	For those who find it interesting, could you explain if the information the system provides meets your needs or if it feels overwhelming?
8	Concise Representation	How do you feel about how the system formatted and presented the information? Is it easy to understand?

Feature #4*: Insulin Carb-Ratio*

Q#	Measure	Question
9	Timeliness	Is the insulin-carb ratio a measure you want to discuss with the patient during the consultation?
10	Interpretability	What improvements would you recommend making the information more understandable and user-friendly?

Feature #5 *Daily view for Specific Case (e.g., Sickness or Physical Activity)*

Q#	Measure	Question
11	Timeliness	Would you have time in your work routine to review information for a specific day?
12	Appropriate Amount	For those who find it interesting, could you explain if the amount of information the system provides meets your needs or if it feels overwhelming?

Conclusion [**3 min**]

- Thank the interviewee for their valuable insights. [1 min]
- Discuss any next steps, including how their feedback will be used. [1 min]
- Offer to share the findings of the study or any subsequent improvements to the system. [1 min]

Part II: Research Papers

Paper 1

Information and Communication Technology-based Interventions for Chronic Diseases Consultation: Scoping Review

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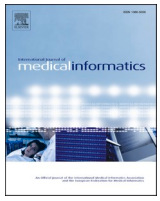

Review article

Information and communication technology-based interventions for chronic diseases consultation: Scoping review

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ABSTRACT

Background: Medical consultations are often critical meetings between patients and health personnel to provide treatment, health-management advice, and exchange of information, especially for people living with chronic diseases. The adoption of patient-operated Information and Communication Technologies (ICTs) allows the patients to actively participate in their consultation and treatment.
The consultation can be divided into three different phases: before, during, and after the meeting. The difference is identified by the activities in preparation (before), the meeting, conducted either physically or in other forms of non-face-to-face interaction (during), and the follow-up activities after the meeting (after).
Consultations can be supported by various ICT-based interventions, often referred to as eHealth, mHealth, telehealth, or telemedicine. Nevertheless, the use of ICTs in healthcare settings is often accompanied by security and privacy challenges due to the sensitive nature of health information and the regulatory requirements associated with storing and processing sensitive information.
Objective: This scoping review aims to map the existing knowledge and identify gaps in research about ICT-based interventions for chronic diseases consultations. The review objective is guided by three research questions: (1) which ICTs are used by people with chronic diseases, health personnel, and others before, during, and after consultations; (2) which type of information is managed by these ICTs; and (3) how are security and privacy issues addressed?
Methods: We performed a literature search in ACM, IEEE, PubMed, Scopus, and Web of Science and included primary studies published between January 2015 and June 2020 that used ICT before, during, and/or after a consultation for chronic diseases. This review presents and discusses the findings from the included publications structured around the three research questions.
Results: Twenty-four studies met the inclusion criteria. Only five studies reported the use of ICTs in all three phases: before, during, and after consultations. The main ICTs identified were smartphone applications, web-based portals, cloud-based infrastructures, and electronic health record systems.
Different devices like sensors and wearable devices were used in 23 studies to gather diverse information.
Regarding the type of information managed by these ICTs, we identified nine categories: physiological data, treatment information, medical history, consultation media like images or videos, laboratory results, reminders, lifestyle parameters, symptoms, and patient identification. Security issues were addressed in 20 studies, while only eight of the included studies addressed privacy issues.
Conclusions: This scoping review highlights the potential for a new model of consultation for patients with chronic diseases. Furthermore, it emphasizes the possibilities for consultations besides physical and remote meetings.

Abbreviations: COVID-19, coronavirus disease; EHR, electronic health record; FHIR, Fast Healthcare Interoperability Resources; GDPR, General Data Protection Regulation; HIPPA, Health Insurance Portability and Accountability Act; ICD-11, International Classification of Diseases version 11; ICT, information and communication technology; ICTs, information and communication technologies; IoT, Internet of Things; PHR, personal health record; PRISMA-ScR, PRISMA extension for Scoping review; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PROMs, patient-reported outcome measures; SMS, short messaging service; SSL, Secure Sockets Layer; WHO, World Health Organization.

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The scoping review also revealed a narrow focus on security and privacy. Security issues were more likely to be mentioned in the included publications, although with limited details. Future research should focus more on security and privacy due to the increasing amount of sensitive information gathered and used for consultations.

1. Introduction

1.1. Chronic diseases consultation

Chronic diseases include non-communicable diseases like diabetes, heart diseases, depression, and communicable diseases like AIDS and Tuberculosis. Long-term management, possibly lifelong, ongoing medical attention, and symptoms management characterize chronic diseases [1]. Being diagnosed with a chronic disease represents a life-long change in patients' lives, which and potentially affects others such as parents, spouses, and informal caregivers [2,3].

Patients with chronic diseases require self-management, namely coping with their conditions in their daily lives [4], including various activities such as medication routine, physical or occupational therapy, diet, and exercise [5]. Supporting patients to self-manage is essential to limit the burden of many chronic diseases [6], and therefore self-management of diseases is often discussed during medical consultations. A medical consultation is a two-way interaction between a patient and the health personnel, where better communication leads to better clinical outcomes [7]. These consultations are periodical [8] and an opportunity to clarify patients' understanding of the disease [9] and the different self-management activities to perform [5].

Chronic diseases are often complex, and consultations with health personnel based on missing, incomplete, or inaccurate information may result in a lower quality of care and a higher risk of medical errors [10]. For example, written information shared during or after the consultations is perceived as difficult to access by patients with impaired reading ability. Consequently, patients might not get the information and advice they need [11]. Furthermore, patients' lack of information and inadequate follow-up can lead to depression and unhealthy lifestyle changes [12].

1.2. Information and communication Technology-based interventions

Chronic disease consultations can be based on interventions supported by various Information and Communication Technologies (ICTs), like eHealth [13], mHealth [14], and telemedicine [15]. Smartphone applications, commercial wearable devices, or the Internet of Things (IoT) also offer patients the opportunity to track, register, and view their self-gathered/reported information [16]. Such tools highlight a potential information flow from patients to health personnel [17] that should be explored.

Including self-gathered data in the medical consultation is possible, however the information collected and processed from wearable sensors and IoT devices introduces additional security and privacy challenges [18–21]. Multiple security and privacy analyses highlighted smartphone applications' vulnerabilities due to lack of encryption, user profiling or poor standards of privacy policies [22–24]. The sensitive nature of health information requires health systems to guarantee secure storage, access, and processing of personal identifiable information [25] before potentially including them in the medical consultation. Furthermore, few studies do primarily focus on evaluating privacy and security [26].

Different legislations in different regions govern data collection and storage, such as the General Data Protection Regulation (GDPR) in the European Union and European Economic Area (EEA) [27], and the Health Insurance Portability and Accountability Act (HIPPA) in the United States of America (USA). These regulations have been introduced partly because smartphones and wearables are now collecting massive amounts of sensitive information. They provide organizations with guidelines on storing, accessing, and processing sensitive information such as health data. They are also interconnected because GDPR is European Union legislation that has consequences outside the EEA, including the USA.

1.3. Objective

This scoping review aims to map the existing knowledge and identify gaps in research about the use of ICT-based interventions for chronic diseases consultation.

We will operationalize the consultation into three different phases: before, during, and after. Before a consultation includes all the activities performed by ICT prior to the meeting. During a consultation comprises all the activities conducted in a physical meeting or in non-face-to-face interaction via ICT. After a consultation includes all the activities performed using ICT as a follow-up of the medical consultation.

The following research questions were formulated to guide the scoping review:

RQ1. Which ICTs are used by people with chronic diseases, health personnel, and others, before, during, and after consultations?
RQ2. Which type of information is managed by these ICTs?
RQ3. How are security and privacy issues addressed in these ICTs?

2. Materials and methods

2.1. Study design

We chose to perform a scoping review to summarize findings from the literature and identify knowledge gaps [28,29]. A scoping review enables us to discuss the publications regardless of their quality [29,30]. Consequently, the confidence in the evidence and risk of bias of the included articles were not performed.

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping review (PRISMA-ScR) guidelines [31] to verify the structure and content of this scoping review. The checklist for the reported items can be found in Appendix A, and the protocol for the scoping review is registered in Open Science Framework [32]. Considering the rapid evolution of technologies and the fact that GDPR was adopted in 2016 [27], we considered studies published in the last five years (2015–2020) and before the coronavirus disease (COVID-19) pandemic.

2.2. Data sources and search strategy

We identified relevant published literature by searching in ACM, IEEE, PubMed, Scopus, and Web of Science. We performed a single data search in June 2020 for studies in English published from January 2015. The search strategy utilized in the scoping review is available in Appendix B.

2.3. Inclusion and exclusion criteria

Peer-reviewed articles were included if a primary study used ICT before, during, and/or after a consultation for chronic diseases. Quantitative, qualitative, and mixed-method studies were included to cover all the different adoptions of ICT.

Articles were excluded if they did not include a chronic condition, consultation, and ICT. Additionally, articles were excluded if they used ICT but focused only on the COVID-19 pandemic or on an individual evaluation, for example, medical evaluation, qualitative evaluation, cost

analysis, or machine learning evaluation. Other exclusion criteria were articles published before 2015, not written in the English language, or not a primary study (e.g., reviews, essays).

2.4. Eligibility and data collection procedure

We proceeded by removing the identified duplicates from the identified publications. Afterward, two passes were done to assess the eligibility of the articles. For the first pass, all titles and abstracts were examined by two independent reviewers (PR and AS). Conflicts were resolved by a third reviewer (EÅ). For the second pass, full texts of the selected articles were extracted and analyzed to confirm their eligibility. Two reviewers (PR and AS) then independently extracted and recorded the data from these articles in an Excel spreadsheet standardized for this review. Incongruences in the extracted data were discussed among all authors.

2.5. Strategy for data synthesis

We synthesized the findings from the included publications, structured around the three research questions. Due to the heterogeneity of the included publications, a large variety of data emerged. We categorized and grouped each intervention by whether real patients used the ICT or not. We cataloged for each chronic condition (e.g., chronic headache, diabetes, hypertension, chronic skin complications) and the corresponding human system (e.g., nervous system, endocrine system, cardiovascular system, skin) based on WHO International Classification of Diseases version 11 (ICD-11) [33]. To address the first research question, information on the specific ICT or devices used, who used it, and when in the consultation it was used (before, during, after) were extracted. To address the second research question, we categorized the type of information managed by these ICTs, and the mode of recording information: automatic versus manual reporting.

Finally, to analyze security and privacy for the included publications, we categorized and grouped each intervention based on the global regions (i.e., Europe, Asia, Oceania, North America, South America, and Africa) and how security and privacy issues were addressed in these studies.

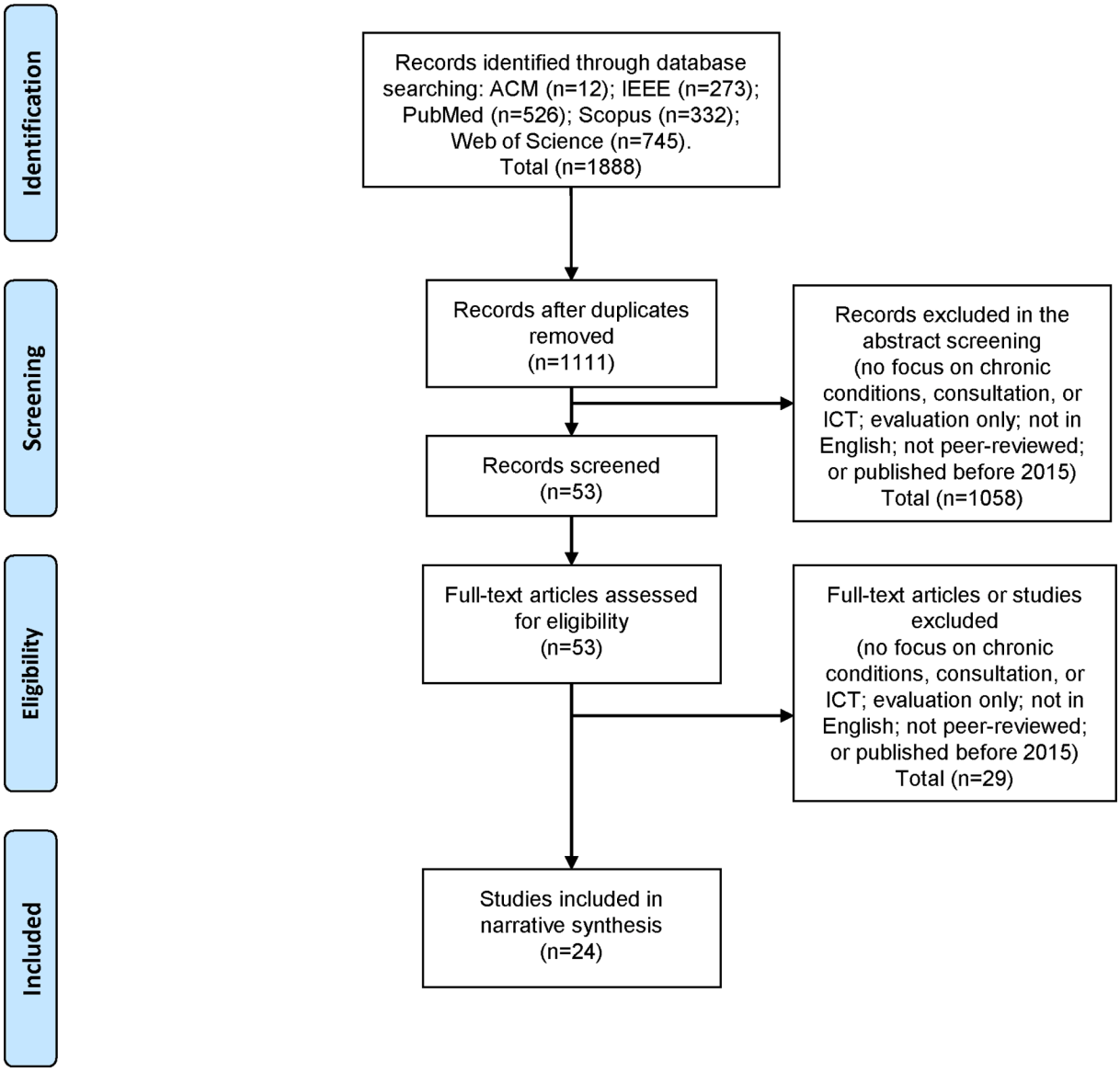

Fig. 1. PRISMA flow diagram of the performed scoping review.

3. Results

3.1. Identified and included studies

The search performed in the five databases resulted in 1888 articles in total. After removing duplicates, 1111 articles were included in the screening process. In the abstract screening, we excluded 1058 articles based on the inclusion and exclusion criteria. In total, 53 articles were eligible for full-text screening. Among these, 29 full-text articles were excluded. Finally, a total of 24 articles [34–57] were included in the scoping review and the PRISMA flow diagram in Fig. 1 summarizes the process.

3.2. Intervention and targeted chronic condition

The 24 included studies were conducted across the globe and distributed as follows: 12 in Europe [34,36–39,41,46,49,53–55,57], five in North America [35,42,45,48,50], two in South America [47,51], two in Asia [40,43], two in Oceania [44,56] and one in Africa [52].

Most of the studies (18/24) included real patients [35,36,38–44,48–51,53–57]. The remaining (6/24) only described the potential use of the developed technologies and how patients may be involved [34,37,45–47,52]. The chronic conditions and the corresponding human system based on ICD-11 for the 24 included studies are reported in Appendix C.

3.3. Icts identified (RQ1)

This section presents the ICTs identified, who was using them, and when they were used in the consultation (before, during, and/or after).

Each study typically used one or more ICTs in their interventions. The most used ICTs were smartphone applications (17/24) [34,36–38,40–42,44–46,49,50,52–56] and web-based portals (16/24) [34–37,39,40,42,44,45,47,48,51,53,54,56,57].

The smartphone applications were made for both Android and iOS in seven studies [36,38,40,41,44,49,56]. In two studies, the smartphone applications were supported by three mobile operating systems: Android, iOS, and Windows Phone [42,55]. The remaining applications targeted only one operating system, either Android (7/24) [34,37,45,46,52–54] or iOS(1/24) [50].

Furthermore, we identified (7/24) cloud-based infrastructures [42,44,46,48,52,54,55], which were: a Fitbit cloud server and a cloud-based communication platform to send and receive text messages [42], a cloud-based database server to host patient data [44], a cloud-based platform to host and process information coming from IoT devices [46], a commercial third-party cloud-based caregiver portal [48], an undefined cloud-based infrastructure to host and analyze patients' sensors data [52], a wearable sensor third-party cloud [54], and a commercial cloud platform to host patients' smartphone and sensors data [55].

The remaining identified ICTs were: Electronic Health Record (EHR) systems (6/24) [37,40,41,47,53,57], video conferencing tools [39,40], decision support systems [39,40], short message service (SMS) [40,52], one ICT-enabled Kiosk [43] and a personal health record (PHR) system (1/24) [47].

Lastly, the devices used for collecting information were smartphones in 17 of the studies [34,36–38,40–42,44–46,48,49,52–56] and tablets in four studies [39,50,51,57]. The devices used to record symptoms, lifestyle parameters, and physiological data include: blood pressure monitors [35,40,41,46,48], pulse oximeters [35,39,46,48], weight scales [35,40,41,48], glucometers [35,38,46], ECG monitors [40,41], and oxygen saturation sensors [40,53]. Other devices were: Wristbands [35,42], an accelerometer [53], an unspecified Bluetooth device [52], an ICT-kiosk embedded with both a blood pressure monitor and scales for height and weight [43] and an unspecific qualified medical Bluetooth device [37].

3.3.1. Use of ICT by patients, health personnel, and others

Both patients and health personnel were ICT users in all 24 studies. Physicians [34,36,40–42,44,47,50,51] and nurses [35,39,41,43,44,48,54] were the most involved health personnel, in nine and seven studies, respectively. Other individuals involved in using the ICTs were researchers [51,55] and family members [40,55]. In particular, there were functions allowing patients to invite their families to participate in self-management of chronic heart failure [40] and for notification regarding the activities of a patient with Parkinson's disease [55].

3.4. Information managed by identified ICTs (RQ2)

We identified nine categories of information that are gathered, stored, retrieved, processed, analyzed, or transmitted by ICTs. The information was grouped as follows: identification, medical history, laboratory results, treatment, reminders, consultation media, physiological data, lifestyle parameters, and symptoms. The relationship between the defined categories and each study is presented in Fig. 2.

In the subsequent paragraphs, we provide additional details of some of the identified categories.

Identification included demographic characteristics [51,57], patient profiles [34] or phone number [42]. Medical history included clinical diagnosis [40], medical records [52], EHR and PHR information [47], comorbidities [51,57], mental health history [56], clinical records [55], patient history [49] and health status [55,57].

Treatment referred to medications [40,44,51,57], therapy [46], treatment advice [45], care plans [52] and treatment without further explanation [36]. Consultation media included videos [39,40,50], images [45,47,49] or messages [46] shared during a consultation. The physiological data and lifestyle parameters were strongly related to the chronic condition and the devices used in the interventions. The former included a large variety of information, with blood pressure, weight, and oxygen saturation being the most recurring ones. The latter included daily activities such as exercise [56], nutrition [55], and physical activity tracking [37].

We excluded payment information from Fig. 2, which was registered in only one study [47].

3.4.1. Mode of recording information: automatic versus manual reporting

Except for one study [47], the 23 studies included devices for collecting information. We identified 15 studies with ICTs that required manual input to gather information [34,36,38–40,43–46,49,51,53,55–57]. Among these, smartphone applications were the most common ICTs [38,40,44,46,49,53,55]. Web-based portals were used to register information in two studies [36,57], while in three studies, smartphone applications were used together with web-based portals [34,45,56]. Other manual collection methods involved an Android tablet [51], a tablet with an unspecified operating system [39], and an ICT-kiosk [43].

We identified 14 studies [35,37–39,41–43,46,48,52–56] that used wearable devices or sensors to gather information automatically. We found two exceptions where the data collected from devices had to be manually transferred to the system. In one study [40], the patients manually recorded the psychological information (e.g., systolic pressure, pulse, weight) gathered from devices. In the other study [44], patients used personal devices to record their treatment parameters and medications and have to manually reported their values via a smartphone application.

3.5. Security and privacy in the identified ICTs (RQ3)

3.5.1. Security

Twenty studies of the included 24 [34–40,42,44–50,52,54–57] addressed at least one security issue. The remaining four studies did not mention security as an aspect of their system [41,43,51,53], even though they involved real patients. Two of these were based in Europe [41,53], one in South America [51], and one in Asia [43].

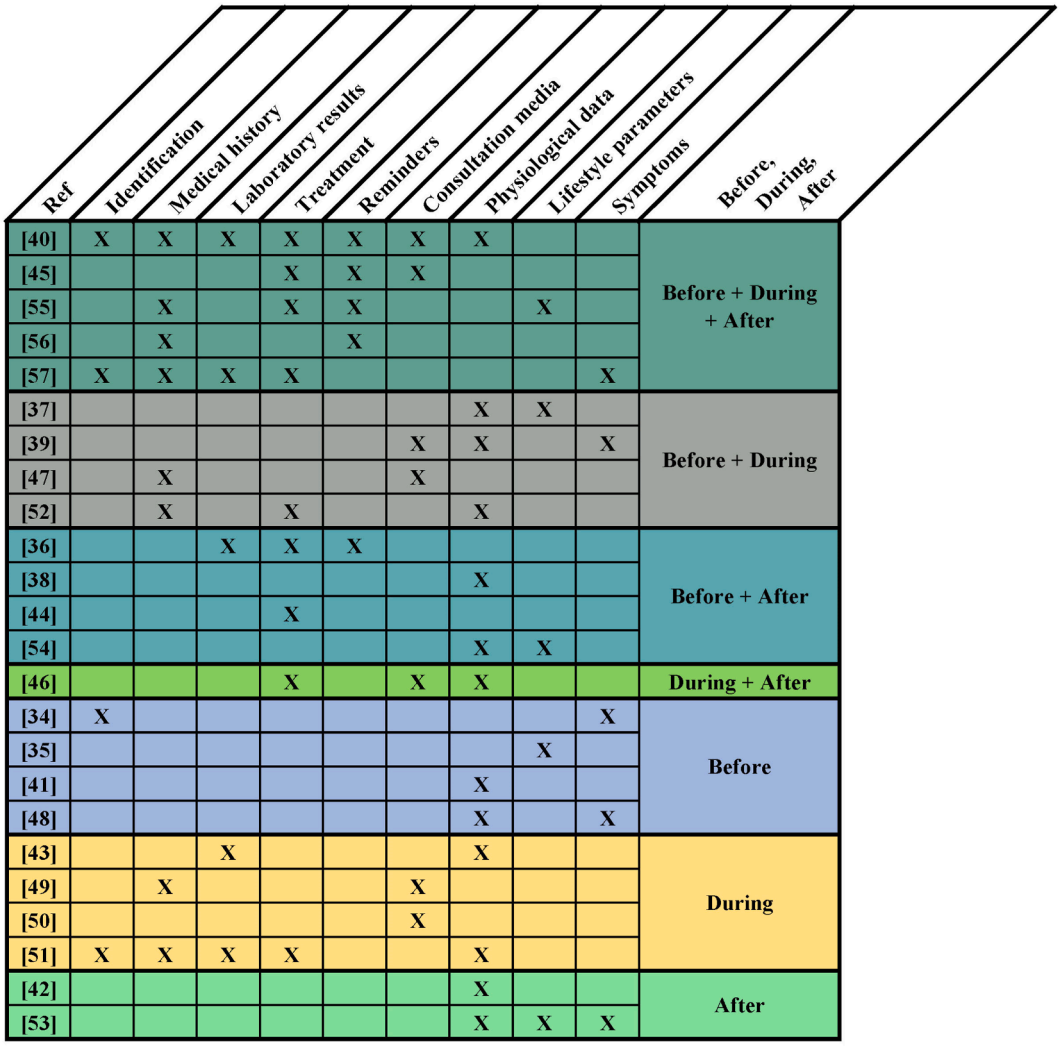

Fig. 2. Information categories identified in the 24 studies.

One study [52] mentioned the importance of security in mobile healthcare. Four studies [35,49,54,57] discussed compliance with regional regulations without providing any details. Two studies relied on a third party's assurance of security [34,50]. The former [34] relied on the guarantees of secure data hosting in a trusted data center. The latter [50] relied on Apple FaceTime's security guarantees.

Password-based authentication was used by seven studies [34,37,40,42,46,47,56] to avoid unauthorized access. Encryption for data transmission is recommended for sensitive data, and many of the reviewed studies mentioned the usage of Secure Sockets Layer (SSL) for security. We found eight studies [36–40,44,48,55] that used SSL to secure their system against unwanted access to the data during transmission. In terms of secure storage, only one study [36] mentioned using encrypted storage of data.

3.5.2. Privacy

Only eight studies [34–36,42,47,49,54,57] addressed privacy issues. Many of these stated their compliance with certain regulations such as HIPPA or GDPR without providing any details. Three of the eight studies [35,42,54] claimed to be compliant with HIPPA, one study [57] with GDPR, and one study [49] with privacy norms in Norway.

One study [47] mentioned validating their care model using an expert institutional team, which involved getting legal advice to evaluate possible privacy risks. However, they did not mention if there were any findings. Only two studies [34,36] mentioned design choices that mitigated the privacy risks associated with the patients' data. Both studies avoided storing any patient identifying information to ensure privacy.

4. Discussion

4.1. Principal findings

We identified 24 studies that used various ICTs to support consultations for chronic diseases. Only five studies [40,45,55–57] used ICTs to support all three phases: before, during, and after consultations. We found significant heterogeneity among the ICTs used and chronic diseases. However, smartphone applications and web-based portals were the most used ICTs regardless of the chronic disease. This finding is consistent with the high relevance of smartphone applications for eHealth research, reported by WHO [58]. Overall, the identified ICTs were used mainly by patients and health personnel, predominantly physicians and nurses. Others, such as family members, were participants in only two studies [40,55].

Further, we investigated the types of information managed by these ICTs, including the devices used and the manner of reporting the information. We identified nine categories of information, and physiological data were the most managed information. We found that the ICT-based interventions spanning across all three phases (before, during, and after) were the most complete in terms of information [40,45,55–57]

and allowed a continuous follow-up of patients via reminders and treatment information. Moreover, the devices for gathering information were widespread among patients and widely adopted in the included studies (23/24).

ICTs for chronic disease consultation have potential privacy risks associated with handling health information. They must guarantee that the sensitive information is handled carefully in terms of security and privacy. Many (20/24) of the studies mentioned at least one security issue. However, the focus on privacy issues was found to be limited. Only eight studies mentioned privacy issues.

4.2. ICTs and new information

The traditional ICT-based interventions were teleconsultations, which replaced physical meetings and diversified health personnel practice [59]. In this scoping review, the scope of these interventions was diverse and broad. Fig. 3 displays how the primary ICTs were distributed among the different interventions and consultation phases.

Even though most of the studies used smartphone applications, half supported only one mobile operating system (e.g., Android, iOS). The reason for this is likely due to the additional cost of developing and maintaining native applications for each mobile platform. From a technical perspective, hybrid smartphone application frameworks can be used in most cases to reduce the cost of cross-platform support [60], and we found this approach used in one study [36]. Additionally, studies have shown that the restriction to a unique mobile operating system may impose limitations on patient recruitment and difficulties in generalizing findings [61–63], which generally compromises the adoption of

Ref	Smartphone apps	Web-based portal	Cloud infrastructure	EHR	Before, During, After
[40]	X	X		X	Before + During + After
[45]	X	X			
[55]	X		X		
[56]	X	X			
[57]		X		X	
[37]	X	X		X	Before + During
[39]		X			
[47]		X		X	
[52]	X		X		
[36]	X	X			Before + After
[38]	X				
[44]	X	X	X		
[54]	X	X	X		
[46]	X		X		During + After
[34]	X	X			Before
[35]		X			
[41]	X			X	
[48]		X	X		
[43]					During
[49]	X				
[50]	X				
[51]		X			
[42]	X	X	X		After
[53]	X	X		X	

Fig. 3. Main ICTs used in the interventions.

these interventions in regular practice.

Regarding the use of these ICTs, we have expanded the search to other actors, those who could use them to support the patient's chronic disease management. There is evidence that patients find sharing information with their family or guardians to be positive [64–66], within certain limits. For example, some chronic conditions such as HIV [36] or mental illness [56] are often seen a stigma or very personal, in which case patients would like to keep their information confidential, as identified in previous reviews [58,67]. Excluding the mentioned studies [36,56], this scoping review found only two studies that involved family members [40,55]. This limited participation of others may represent a limitation in the current ICT-based interventions. Future studies should consider the possibility of including others in the use of ICT for chronic disease consultation, and address the technology-related challenges [68,69].

In considering the information managed by these ICTs, we found an information flow from sensors and wearables into the medical consultations. In this scoping review, we found a significant preference and use of automatically reported information via sensors. Automatically collecting information could alleviate the health personnel and patients' concerns about data entry errors. These errors can lead to wrong treatment and guidance, especially when an ICT uses treatment and screening algorithms [67]. However, the limited number of EHR systems identified in the review could be motivated by the challenges in integrating physiological data, lifestyle parameters, and/or symptoms recorded via different patient devices or wearables with EHR systems. Future studies should investigate this kind of integration, and the potential for use in medical consultation. There is little research validating wearable activities monitors [70,71]. Interoperability standards, such as Fast Healthcare Interoperability Resources (FHIR) [71], were mentioned in only one study [37], although the use of standardization when dealing with sensor data is found to be beneficial for reducing such risks [72].

4.3. Security and privacy challenges

ICTs have introduced new information and possibilities relevant for chronic diseases consultations. In multiple studies [73–75], researchers have argued that ICTs must identify and address security and privacy issues in the healthcare system. Lack of transparency in ICTs about security and privacy safeguards makes it difficult to ascertain to what extent a patient's data is stored and processed in a compliant manner. Moreover, failing to protect a patient's data can result in legal fines [76] and may lead to the non-adoption of new technologies [77].

This scoping review also highlights the need to address the existing privacy and security challenges for chronic disease consultation via new studies. Some ICT interventions relied on third-party systems such as secure cloud-based storage, secure hosting, and secure applications for security guarantees. Even if it is technically possible to rely on third-party systems, researchers must also consider the legal issues around using such solutions. Public cloud services may be restricted by laws that do not allow hosting sensitive medical data outside a country's physical boundaries. For example, only one out of the 12 included European studies described their systems compliance with the GDPR [57]. As shown by previous studies, these interventions often do not become regular clinical practice due to security and privacy issues [77,78].

4.4. Limitations

Due to the type of review, the publications were included and discussed regardless of their quality.

The search strategy included publications within a short period (2015–2020) because of the rapid development of technologies. The grey literature was not explored, and our search was limited to peer-reviewed research only in English. The search strategy also excluded articles related to the COVID-19 pandemic because we wanted to investigate the consultations outside the unexpected COVID-19 context.

Lastly, we encountered taxonomy problems since this review includes both quantitative and qualitative studies with heterogeneous information. We decided to first use the authors' definitions when extracting the data and then grouped the information under new or modified definitions. This process might limit the specificity of the presented results. However, it provides a snapshot of recent ICTs used in consultations.

5. Conclusions

This scoping review can serve as a starting point for researchers interested in exploring consultations that are not merely physical or remote meetings (during) but are expanded to include a preparation (before) and a follow-up (after) phase. We discovered a few examples of continuous consultation (before, during, after) and involvement of others such as family members or informal caregivers.

ICT currently supports this new way of doing consultations where patients can gather health information automatically via sensors or manually via mobile devices, before and/or after the consultations. However, the use of sensors and wearable devices produced by third-party companies makes it exceptionally relevant to design secure systems and protect individuals' privacy.

Our scoping review revealed a narrow focus on security and privacy. Security issues were more likely to be mentioned in the included publications than privacy issues, although, with limited details. Future research should emphasize security and privacy due to the increasing amount of sensitive information gathered outside health care settings to be potentially used in consultations.

Lastly, we have chosen to discard all the literature focusing on the COVID-19 pandemic. As we have seen during the pandemic, restricted access to primary and secondary care has forced health sector to seek alternatives, compared to a normal situation – which has increased the use of ICTs. In the coming years, future studies should verify if the COVID-19 pandemic has permanently affected the way of performing a consultation or not.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijmedinf.2022.104784.

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Paper 2

Criteria for Assessing and Recommending Digital Diabetes Tools: A Delphi Study

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Criteria for Assessing and Recommending Digital Diabetes Tools: A Delphi Study

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Abstract. Diabetes self-management, an integral part of diabetes care, can be improved with the help of digital self-management tools such as apps, sensors, websites, and social media. The study objective was to reach a consensus on the criteria required to assess and recommend digital diabetes self-management tools targeting those with diabetes in Norway. Healthcare professionals working with diabetes care from all health regions in Norway were recruited to participate in a three-round Delphi study. In all rounds, the panellists rated criteria identified in a systematic review and interviews on a scale from 0-10, with the option to provide comments. On a scale of 0:not important to 10:extremely important, the highest rated criteria for assessing and recommending digital diabetes self-management tools were "Usability" and "Information quality", respectively. For assessing apps, "Security and privacy" was one of the lowest rated criteria. Having access to a list of criteria for assessing and recommending digital self-management tools can help diabetes care stakeholders to make informed choices in recommending and choosing suitable apps, websites, and social media for self-management. Future work on quality assessment of digital health tools should place emphasis on security and privacy compliance, to enable diabetes care stakeholders focus on other relevant criteria to recommend or choose and use such tools.

Keywords. Diabetes; Mobile Applications; Internet-Based intervention; Social Media; Delphi Technique

1. Introduction

Diabetes self-management, often looked upon as a daunting task, is an integral part of diabetes care [1,2]. The use of digital self-management tools such as apps, sensors, websites, and social media has been associated with the effectiveness and improved health of individuals with diabetes [3,4]. However, some digital self-management tools could also be ineffective or detrimental to users' health. For example, the many in-

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accurate apps for calculating insulin doses could in the worst case, be life-threatening [5]. Therefore, criteria are needed to assist with evaluating and validating these tools.

However, there is little to no information about criteria for quality assessment of digital self-management tools. Individuals with diabetes and their healthcare providers should be given the opportunity to use a list of criteria to assess apps, sensors, websites, and social media before they choose to use and/or recommend them. A Delphi study is an appropriate method for obtaining academic and experience-based consensus on identified evaluation criteria, as it elicits individualized but group-generated information and allows for a wide geographical access to experts [6].

The study objective was to reach a consensus on the criteria required to assess and recommend digital diabetes self-management tools (apps, websites, and social media) targeting the Norwegian diabetes population.

2. Methods

Healthcare professionals working within diabetes care from the four health regions in Norway were recruited to participate as panellists in a three-round Delphi study over six weeks (May to June 2020).

From a previous systematic review [7], Usability, Clinical impact, Cognitive impact, Behavioral impact, Feasibility, Engagement, Acceptability and acceptance, and Security and privacy were identified as the 8 criteria categories [7]. In addition, the following criteria were identified from interviews [8] with stakeholder representatives (individuals with diabetes, healthcare professionals, informal caregivers, health authorities, health researchers and developers): Usability, Information quality, Data accessibility, Tailorability, Visual presentation, Remote monitoring, and Automated data recording.

In the first round, panellists rated these criteria on a scale from 0 - not important to 10 - extremely important, with the option to provide comments. Their ratings and comments were analysed and used for the second round. The criteria were then presented together with the average rating and each participant's previous value for each criterion. The third round provided the panellists with another opportunity to change their opinion.

The analysis of the participants' data was done using SPSS version 25. NVivo 12 Pro was used to organize and perform an inductive thematic analysis of the qualitative data. The treatment of personal information in this study was approved by the Data Protection Officer at the University Hospital of North Norway (ref. 2018/3325).

3. Results

Fifteen healthcare professionals with an average of 19 years' diabetes care experience were enrolled: 20% (3/15) were medical doctors, 67% (10/15) were diabetes nurses and the remaining two were a clinical dietitian and an occupational therapist. Females made up 73% (11/15) of the panellists. The average level of experience and observed use of digital diabetes tools, on a scale from 0 - very low to 10 - very high, in the panellists' daily practices were 6.8 and 6.5, respectively.

With regards to the criteria for recommending digital self-management tools: Information quality had the highest average rating for apps (9.7), websites (9.6), and social media (8.8). The second highest rated criteria, with an average rating of 8.9, were Usability and Automated data recording for apps. Clinical impact for both websites and

social media, with an average rating of 8.1 and 7.9, respectively. With an average rating of 7.2, Usability, Feasibility and Acceptability were the third highest rated criteria for social media, Usability (7.9) for websites and Clinical impact (8.8) for apps, see Figure 1.

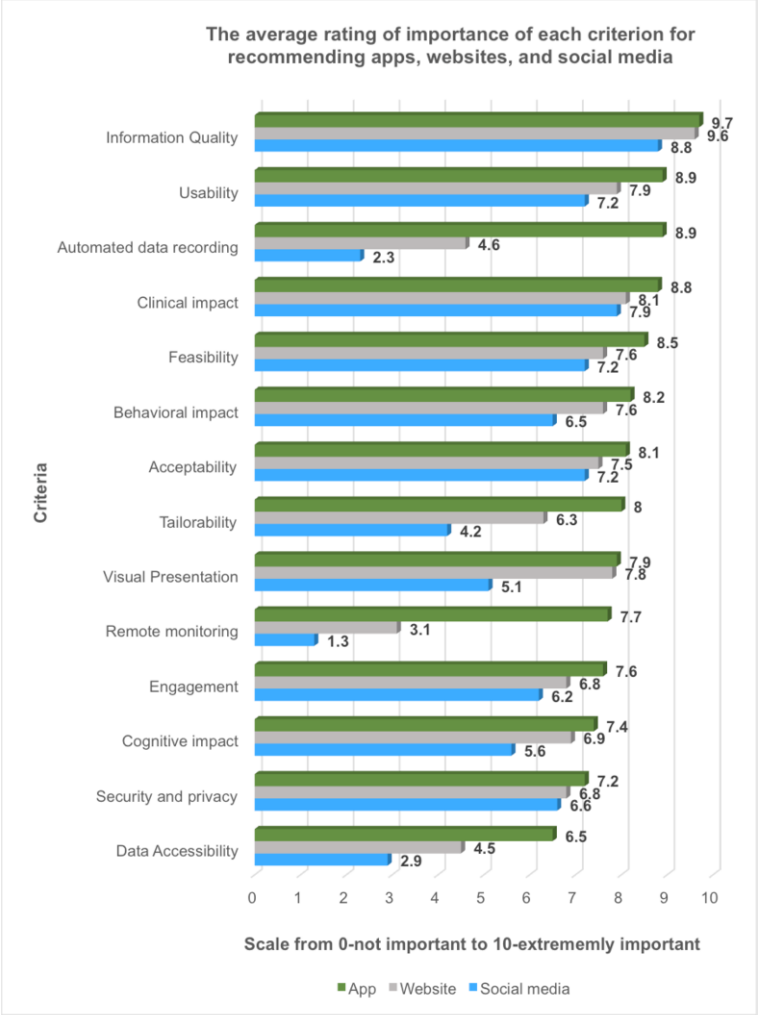

Figure 1. Average rating of importance of the criteria for recommending apps, websites, and social media, given by 15 healthcare professionals in a 3-round Delphi Study.

For assessing digital diabetes self-management tools, Usability was the highest rated criterion for apps, websites, and social media with an average rating of 9.6, 8.6 and 7.4, respectively. The second highest rated criterion was Feasibility with an average rating of 8.6, 7.3, and 7.0, respectively. The third highest rated criterion was Behavioral impact (8.1) for apps, Clinical impact (7.1) for websites, and Acceptability (6.8) for social media.

4. Discussion

With this Delphi study, we elicited the opinions of healthcare professionals on the criteria required to assess and recommend digital self-management tools to individuals with diabetes. The highest rated criteria were Usability and Information quality, respectively. For assessing apps, Security and privacy was one of the lowest rated criteria.

In our study, we found that the panellists consider the Usability of digital diabetes self-management tools essential to their adoption and use. Usability was amongst the three highest rated criteria for both assessing and recommending apps, websites, and social media. Our findings are supported by studies that consider Usability an important criterion in the evaluation and use of developed digital diabetes health tools [9-11]. For recommending diabetes apps, websites, and social media to patients, the panellists unanimously agreed that the quality of the self-management and diabetes-related information (Information quality) was highly important. This is supported by Fernandez-Llatas [12], who notes that diabetes-related information should be *precise and correct* to encourage successful self-management.

To be effective as digital self-management tools, apps, websites, and social media should positively impact the health and self-management behaviours of individuals with diabetes [13-15]. The panellists rated Clinical impact and Behavioral impact as equally important for assessing and recommending digital diabetes self-management tools. Feasibility and Acceptability are criteria to consider when assessing and recommending digital self-management tools, especially social media, as the use of this for self-management is still novel and unfamiliar [13] to many individuals with diabetes and their healthcare providers.

Similar to previous findings [7], Security and privacy received little attention as an evaluation criterion. Most of the healthcare professionals assumed that a commercially available app should have fulfilled all necessary security and privacy regulations.

Limitations: Though the panellists' in this study were healthcare professionals with diabetes care experience, they might not represent the perspectives of the average healthcare person supporting patients in the use of digital diabetes tools. Panellists were asked to refer to a specific list of criteria to assess digital diabetes self-management tools targeting the Norwegian population, therefore, the consensus may not apply to other countries or health conditions. Future research is required to explore the opinions of individuals with diabetes and their relatives on the importance of these and other criteria, for this rapidly growing field.

5. Conclusions

Digital diabetes tools like apps, sensors, websites, and social media are being increasingly used by patients and healthcare professionals. It is however, challenging for them to assess, choose or recommend the right self-management tools for optimum health benefits for each patient.

Having access to a list of criteria for assessing and recommending these digital diabetes tools could help both patients and healthcare professionals make informed choices in recommending and choosing suitable apps, websites, and social media for self-management. Future work on quality assessment of digital health tools should place emphasis on security and privacy compliance, to enable patients and healthcare professionals focus on other relevant criteria to recommend or choose such tools.

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Paper 3

Towards a New Model for Chronic Disease Consultations

Towards a New Model for Chronic Disease Consultations

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Abstract
Medical consultations for chronic diseases form an arena to provide information from health personnel to patients. This information is necessary for patients to understand how to deal with the possible lifelong symptoms and needed self-management activities. The amount of patient-generated health data is increasing. Today's patients gather an increasing amount of personalised health-related information. Meanwhile, the health personnel get more patients to care for and fewer resources. This paper summarises information and communication technologies possibilities for improved diabetes consultations. It aims to inform how the medical consultation for chronic diseases needs to change drastically to meet today and future's challenges.

Keywords
Health information system, Patient-generated health data, Chronic disease, Diabetes, Consultation

1 INTRODUCTION

Compared with the general population, those with chronic diseases (e.g., diabetes, cardiovascular diseases, and pulmonary diseases) require more frequent medical attention and symptom management [1]. Individuals from any age group, region and country can be affected by chronic diseases. Chronic diseases impose a significant economic burden on the global healthcare system [2], with predictions becoming more severe regarding the number of people affected and the costs to society.

Once an individual is diagnosed with a chronic disease, this often represents a life-long change in their life. First, the patient needs to understand their new condition and possibly define a health care plan together with the health personnel. This plan may include medication, exercise, therapy, and diet [3]. Then it should be explained and discussed during the medical consultations. After the first consultation, the following consultations often become periodic and are typically performed one to four times a year [4]. This scenario may be more complicated if the patient belongs to a vulnerable group such as children or the elderly. In this case, the medical consultation often involves others, such as parents, next of kin, and informal caregivers [5, 6], introducing additional challenges to the medical consultation.

1.1 Patient-generated health data

Especially in the last 5-10 years, patients have gained more access to health-related devices and information. It is now much easier to track, register and view physical activities, symptoms or treatments via smartphone applications (apps), commercial wearable devices [7], and Internet of Things (IoT) solutions.

This new information can be used in the decision-making process during consultations and help to define an individual health care plan for the patient. The information flow also expands outside healthcare settings via patient groups on social media [8] and the possibility of sharing patient-gathered health data through apps and cloud-based solutions. Nowadays, social media groups are also used as an alternative resource to prepare before a consultation about symptoms, treatment options, related illnesses, self-management devices, and other health-related issues [9]. Social media groups may complement the consultation with information support without bypassing the health personnel [10]. However, patients seeking missing information on social media can be exposed to misinformation [11] due to difficulty ensuring information quality and accuracy [12, 13].

2 OBJECTIVE

This paper discusses a new model of medical consultation for chronic diseases. As our example, we will focus on a specific chronic condition, type 1 diabetes. First, we describe the current practice for medical consultation. Then we present the proposed model and discuss its implications.

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3 WHAT DO WE KNOW ABOUT MEDICAL CONSULTATIONS TODAY?

Medical consultations for chronic diseases are physical or remote meetings between patients and health personnel. A medical consultation represents an opportunity to clarify the patient's understanding of their condition [14] and can provide procedures, tools and advice for managing their disease(s) and challenges. Studies have shown that if the patient is an active part of the consultation and the decision-making process, they become better informed about their treatment options [15] and self-management alternatives [16].

The success of a consultation is often determined by how well the patients and the health personnel communicate [17]. A systematic review, including studies from 67 countries, discovered that consultations usually last only a few minutes despite the importance of the health issue. Short consultations may adversely affect patients' disease management and health personnel's workload [18] and increase the risk of medical errors [19].

3.1 A Use case: type 1 diabetes consultations

Patients with type 1 diabetes may use devices from diverse vendors, such as continuous glucose monitors (CGMs), insulin pump systems, blood glucose meters or insulin pens, based on their needs and availability. These devices allow the patient to record and monitor glucose levels, medication (insulin) use, and daily food intake. The devices are connected to the vendors' technological solution, typically a smartphone app for the patient, a web interface for the health personnel, and a cloud-based infrastructure that synchronises the collected information and possibly shares it with others such as relatives, family members, and health personnel.

The goals of diabetes treatment are to prevent or delay short- and long-term complications and optimise quality of life. Treatment goals and management plans should be created together with patients based on their individual preferences, health status, and goals. People with diabetes should have at least one annual consultation. This consultation should be a comprehensive medical evaluation that includes an assessment for diabetes complications and potential comorbid conditions together with a review of previous treatment and risk factor control. Together with the patient, the health personnel should then assess the need to adjust the individual treatment targets. There may also be a need to address diabetes-related psychosocial problems. In clinical practice, the health care provider will often have to prioritise the components of the medical assessment due to limitations in available resources and time.

Modern diabetes devices can improve diabetes care and the patients' quality of life. A downside may be that data analysis from these devices can be very time-consuming and lead to "information overload" for both health personnel and the patient.

Additionally, the health personnel need to register summary statistics about these patient-gathered data inside the electronic health record (EHR) system, often manually using vendor-specific systems in addition to the EHR system. Although other relevant information such as physical activities, sleep duration, and stress may be discussed during the consultation, this information is usually neither registered nor followed up in the next patient consultation [20].

3.2 Community-based type 1 diabetes consultations

Some type 1 diabetes patients may participate in technical advanced Do It Yourself (DIY) projects. They are often well-educated patients, or engaged relatives, who have formulated, developed, and distributed solutions that answer specific problems to their needs in managing their disease [21].

The diabetes community's effort has also been reflected in patient-started companies like Tidepool, where their technological solution can be used instead of vendor-specific solutions [22]. Their system integrates a subset of CGM devices from different vendors inside the same platform and makes the information available to the patients and health personnel.

4 PROPOSED MODEL

We argue for a new way of defining the consultation, where we propose the inclusion of three different phases: before, during and after the consultation. The motivation behind including also "before" and "after" consultations is the increased possibilities of information and communication technology (ICT) for chronic disease management. Furthermore, the consultation should be conceptualised as a continuous process over time, with a preparation (before), a physical or remote meeting (during) and a follow-up phase (after) [23]. Consequently, the proposed model aims to use various ICTs, some diseases-specific (e.g., CGMs, insulin pumps), some commercial devices (e.g., physical activity trackers, IoT devices), and introduce new practices both for patients and health personnel, supporting the increased information gathering and exchange (see Figure 1).

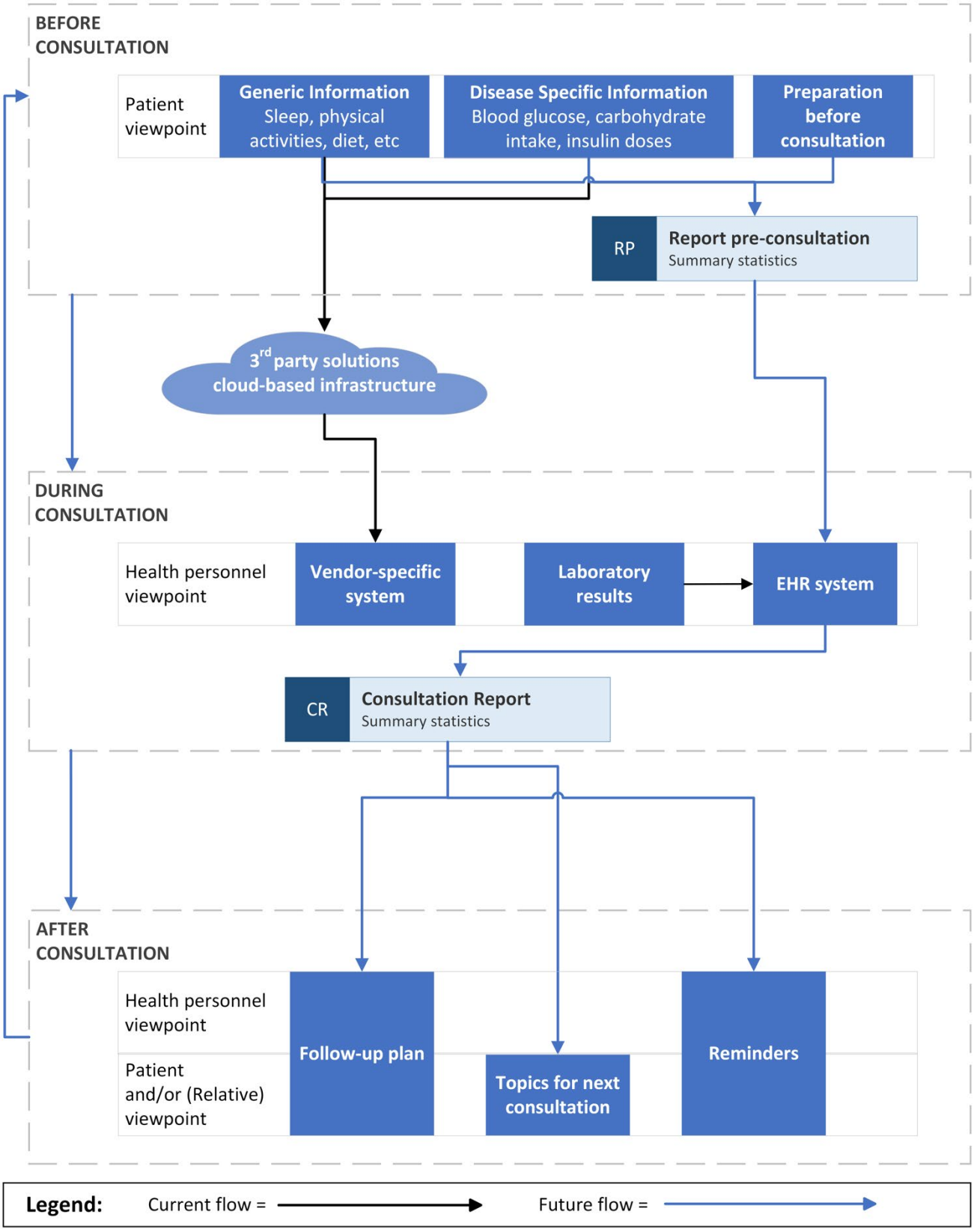

Figure 1 Proposed model, with current and future flow of information for type 1 diabetes consultation.

Before the consultation: patients could prepare themselves by looking at their self-gathered health data. Furthermore, make these available for the health personnel, e.g., physical activities, diet, and sleep, including disease-specific data, such as blood glucose values, insulin doses, carbohydrate intake, and comprehensive summary statistics.

During the consultation: The data collected before the consultation should be reviewed and registered, preferably automatically, into the EHR system during the consultation. Meanwhile, the necessary adjustments to treatment goals and management plans could also be discussed based on this data during the medical consultation.

After the consultation: What was discussed during the consultation should be made available after the consultation. This can include understandable summaries and follow-up plans for the patients and/or their relatives. Meanwhile, the health personnel could follow up with the patients via reminders before the upcoming visits and encourage them to follow their care plans discussed in the previous consultation. Additionally, the patients can make notes about the side effects of the treatment and note down topics to discuss during their next consultation.

Overall, the presented model includes various elements of remote monitoring and envisioning the medical consultation to be extended beyond than the physical meeting between health personnel and the patient. Therefore, it could provide both parties with more information and better support in difficult situations, e.g., when the patients are not reaching their medical aims or have difficulties in their everyday life caused by their disease.

5 DISCUSSION

The adoption of commercial and medical devices in this model demands the use of third-party companies' devices and software, often located outside the European Union and European Economic Area (EEA). Due to existing regulations, such as the General Data Protection Regulation (GDPR), and their compliance, such a model may raise different critical points and challenges [23], especially from a European perspective.

5.1 Medical devices

The GDPR is not the only regulation that may impact the successful adoption of all the technologies mentioned previously. The recent European Medical Device Regulation (MDR), established in May 2021, updated and extended the definition of medical devices.

The new MDR regulation now also covers health-related smartphone apps. Partially motivated by the fact that thousands of commercial apps are publicly available, and patients with chronic diseases are one of the most prominent target groups [24]. Digital health apps are used in both developed and developing countries [25], and if the intended function of the apps is compromised, it could harm the users (aka patients) [26].

The proposed model would require trust from patients, health personnel and authorities in commercial and medical devices to be considered as a source of information for the medical consultation. In a previous study [27], health personnel ranked the main criteria for recommending medical devices such as digital health apps to patients based on information quality and usability, which employ the openness of health personnel to use these medical devices as part of the medical consultation.

An open question still remains to be answered: Will this European regulation facilitate the integration of what today is not considered a medical device into the medical consultation? Or, on the other hand, will it slow down the integration?

5.2 Interoperability

Accepting the information gathered from commercial devices inside the medical consultation would require the information collected by the patients to be registered inside the EHR systems. Nowadays, there are technical and legal barriers to registering data generated from medical devices such as CGMs directly into EHRs.

Overall, one of the main challenges is to ensure interoperability and the possibility of data exchange using standards (e.g., FHIR, OpenEHR). Regarding the profiling of health sensor data, standardisation today is limited as well as the adoption of such standards for medical consultation for chronic diseases [23]

5.3 European health data space

The GDPR established in May 2018 has emphasised the potential value and challenges of managing e-health data, especially in terms of security and privacy issues.

Respecting patients' privacy and confidentiality are increasingly becoming more critical, and they represent two of the core values in health care [28]. A key to adopting such technologies is the security and privacy of data, considering the highly sensitive nature of medical data (confidentiality, availability, integrity).

The proposed model in Figure 1 describes an extensive data transmission with many security and privacy challenges. Using these ICTs give access to a vast amount of personally identifiable information and possible target of cyber-attacks. For the following reason, the proposed model will be further worked on in collaboration with the EU-funded HEIR project – a secured Healthcare Environment for Informatics Resilience (grant agreement No 883275).

In the coming years, new legislation, such as the Data Governance Act in 2023, may potentially impact access to more data within the EEA and open the possibility of a Health Data Space. The model presented in Figure 1 could align with such regulations and facilitate data exchange across EEA countries.

5.4 Strengths and limitations

The model presented reflects the findings from previous studies [23, 27, 29], where ICTs were used in intervention for chronic diseases [23] or specifically for diabetes self-management [29]. Many health-related ICTs of today have significant relevance for daily clinical practice, and this model empathises how ICT and interoperability standards may impact future clinical practice.

Therefore, caution should be exercised in evaluating the feasibility of such a model. The medical devices used daily by patients with diabetes are, in practice, the intellectual property of third-parties companies. Consequently, health-related information is often accessible only via proprietary systems, limiting the execution of such a model.

5.5 Future research

Since this study represents an early stage of a new model for medical consultations, future research is now required to interpret this model as a proof of concept to demonstrate

its feasibility. In addition, resource implications and limitations regarding medical device accessibility should be considered.

6 CONCLUSION

Chronic disease consultations are complex. Multiple and diverse stakeholders are often involved, such as health personnel, policymakers, vendors, relatives, and patients. Unclear definitions of the involved technologies [30] and the absence of a shared language in describing them make it harder to integrate apps and new services with health sector stakeholders [31].

This latest introduction of a vast number of medical devices, and commercial wearable devices that enable patients to collect health-related data themselves, calls for new routines and a revision of today's consultation model. Technological innovations are, to an increasing degree, being used by people with chronic conditions. However, consultations are still considered physical or remote meetings only and do not utilise all the potential that self-reported/gathered data can provide.

Regardless of the enthusiasm about these emerging technologies, we must address the adverse effects and risks these technologies can have on data security and privacy issues. Furthermore, we must facilitate the process and assume that patients will wear and adopt consumer technologies in everyday life and that health personnel will use them as part of the medical consultation.

In conclusion, such a model is technologically feasible, and its implementation in clinical practice will be dependent on the policymaking decision in the coming years.

7 SUMMARY

This paper has discussed a new model that views medical consultation as a continuous process in terms of preparation (before), a meeting (during), and a follow-up phase (after).

We are in a phase where patients have more access to health-related information such as physical activities, symptoms or treatments via diverse technologies or social media communities. This new information can be used in the decision-making process during consultations and be used in refining the individual health care plan for the patient.

Designing a system that can possibly be integrated with the clinical EHR systems used for patient treatment and follow-up is conceptually possible. Although, mainly security, privacy and interoperability issues slow down the integration of such innovation in the medical consultation and the healthcare systems.

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Paper 4

Privacy Concerns Related to Data Sharing for European Diabetes Devices

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Symposium/Special Issue

Privacy Concerns Related to Data Sharing for European Diabetes Devices

Journal of Diabetes Science and Technology
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Abstract

Background: Individuals with diabetes rely on medical equipment (eg, continuous glucose monitoring (CGM), hybrid closed-loop systems) and mobile applications to manage their condition, providing valuable data to health care providers. Data sharing from this equipment is regulated via Terms of Service (ToS) and Privacy Policy documents. The introduction of the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) in the European Union has established updated rules for medical devices, including software.

Objective: This study examines how data sharing is regulated by the ToS and Privacy Policy documents of approved diabetes medical equipment and associated software. It focuses on the equipment approved by the Norwegian Regional Health Authorities.

Methods: A document analysis was conducted on the ToS and Privacy Policy documents of diabetes medical equipment and software applications approved in Norway.

Results: The analysis identified 11 medical equipment and 12 software applications used for diabetes data transfer and analysis in Norway. Only 3 medical equipment (OmniPod Dash, Accu-Chek Insight, and Accu-Chek Solo) were registered in the European Database on Medical Devices (EUDAMED) database, whereas none of their respective software applications were registered. Compliance with General Data Protection Regulation (GDPR) security requirements varied, with some software relying on adequacy decisions (8/12), whereas others did not (4/12).

Conclusions: The study highlights the dominance of non-European Economic Area (EEA) companies in medical device technology development. It also identifies the lack of registration for medical equipment and software in the EUDAMED database, which is currently not mandatory. These findings underscore the need for further attention to ensure regulatory compliance and improve data-sharing practices in the context of diabetes management.

Keywords

security, privacy, software as medical device, GDPR, medical device

Introduction

People with type 1 and type 2 diabetes mellitus often have a wide range of devices and digital health applications (apps) available to help them manage their diabetes.[1] These can support lifestyle and pharmacological interventions, eg, devices such as blood glucose meters, continuous glucose monitoring (CGM) devices, insulin pumps, hybrid closed-loop systems, smart insulin pens, and associated apps.[2,3]

In Europe, medical equipment for chronic diseases like diabetes may be distributed to patients based on national agreements between health authorities and device producers.

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These agreements are valid for all citizens covered by national health insurance in most European Economic Area (EEA) countries. Data from diabetes devices and apps can provide crucial input to health care providers (HCPs) when they assess risk factors, review treatment plans, and assess patient well-being at periodic medical assessments.[4-6]

What is a Medical Device in Europe?

The definition of a medical device in the European market is outlined in the Medical Device Regulation (MDR), which became effective on May 26, 2021.[7] The MDR's definition of "device" includes standalone software that meets certain criteria, such as being designed to diagnose, prevent, monitor, predict, prognosis, treat, or alleviate disease. Another regulation related to medical devices is the In Vitro Diagnostic Regulation (IVDR), established in 2017,[8] which governs medical devices related explicitly to tests performed outside of a living organism.

European Commission, in conjunction with the new regulations (MDR and IVDR), has also established a database called the European Database on Medical Devices (EUDAMED), aiming to enhance traceability, cooperation, and transparency within the medical device sector.[9] Participation in this database is currently voluntary and will become mandatory in all its components in 2026.[10]

General Data Protection Regulation and Other Standards

The General Data Protection Regulation (GDPR) is the most prominent European regulation, established in 2016, that concerns data protection and privacy in EEA.[11] In addition to GDPR, individual countries may have their own national regulations for sensitive data, which are particularly relevant for the medical domain (GDPR—Article 9).

Thus, the global picture is exceptionally complex, with various international standards concerning technological aspects (see Figure 1). There are global standards on privacy and security management (ISO/IEC 27701, ISO 27799), privacy impact assessment (ISO/IEC 29134), pseudonymization and de-identification techniques (ISO 25237, ISO/IEC 20889), on secure health software development lifecycle (ISO/IEC 62304), or other standards such as data protection by design (prEN 17529) or more recent standards on the International Patient Summary and its implementation in Europe (EN ISO 27269 and CEN/TS 17288).

Controversies on Data Sharing Outside Europe: Schrems Cases

Although GDPR governs the data transfer between the EEA and external countries, significant doubt has arisen concerning the legitimacy of transferring personal data to countries outside the EEA area. One of the most known cases is the Schrems II case which highlighted some of these challenges and led to the invalidation of the Privacy Shield as a mechanism for transferring data from Europe to the United States on July 16, 2020.[12] The Privacy Shield was a self-sign certification in which US companies certify to the US Department of Commerce that they meet the data protection standards (eg, GDPR). In response to the court case, the European Commission has proposed the Standard Contractual Clauses to regulate data transfer from the EU/EEA (subject to the GDPR) to entities outside the EU/EEA that are not subject to the GDPR.

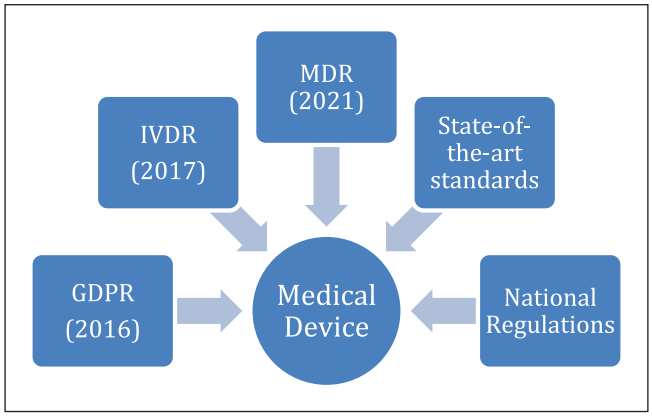

Figure 1. Regulations and standards affecting medical devices in EEA.
Abbreviations: EEA, European Economic Area; GDPR, General Data Protection Regulation; IVDR, In Vitro Diagnostic Medical Devices Regulation; MDR, Medical Devices Regulation.

The information about data transfer in Europe must be available to the users (eg, patients). This information is often available via the Terms of Service (ToS) and Privacy Policy documents made by the processor of the data (eg, manufacturer).

Objective

This study aims to analyze the mandatory ToS and Privacy Policy documents for medical equipment used by individuals with diabetes, to existing regulations regarding data sharing. To guide our analysis, we formulated 2 research questions:

Research Question 1: How do ToS and Privacy Policy regulate the data flow from the patients' medical equipment to the manufacturers, third parties, and countries outside EEA?
Research Question 2: How do HCPs access patient-gathered data?

Materials and Methods

We performed a Document Analysis[13] to summarize findings from the ToS and Privacy Policy documents.

Documents Sources and Search Strategy

We only considered the medical equipment devices available for individuals with diabetes in Norway that are listed in the purchasing agreement between the Norwegian Regional Health Authorities and the vendors from October 1, 2022 to September 30, 2023.[14] Based on the medical devices listed, we performed multiple data searches in October 2022 for the documents referencing the ToS and Privacy Policy. Then, we approached each medical supplier listed in the National Agreement for confirmation about the document identified.

Identification and Evaluation Key Elements

We investigated the documents provided by vendors/manufacturers (after searching contact via e-mails and phone calls) or those to which we were referred to online. Regrettably, some medical suppliers listed in the national agreement did not respond to our inquiries, and for those, we used the ones identified by online search. Afterwards, we identified and evaluated related software that regulates the data flow from all the eligible medical devices.

The authors (MP and DT) have extracted multiple items for the identified ToS and Privacy Policy documents. All the authors agreed upon the analysis of the elements reported in Figure 2 in line with the analysis objectives.

Results

Medical Equipment Identified

We identified 11 different medical equipment distributed by Norwegian Regional Health Authorities,[14] reported in Table 1.

Medical equipment registration in the European Database on Medical Devices database. Only 3 of the 11 diabetes devices studied have been registered in the EUDAMED database. The OmniPod Dash has been classified as a Class IIb risk under the MDR. In addition, both the Accu-Chek Insight and Accu-Chek Solo have been registered under Annex II List B of the IVDR.

Data Flow From Medical Equipment to Patients and Health Care Providers

Vendors of several medical devices require patients to use their smartphones to display measured health information. Patients who lack access to a smartphone or choose not to use one are referred to built-in monitoring systems, such as the FreeStyle Libre 2 and Dexcom G6 which have a dedicated data reading device.[14]

Table 2, which supplements Table 1, illustrates potential software additions for the identified medical equipments in Europe. Notably, several of these software applications may

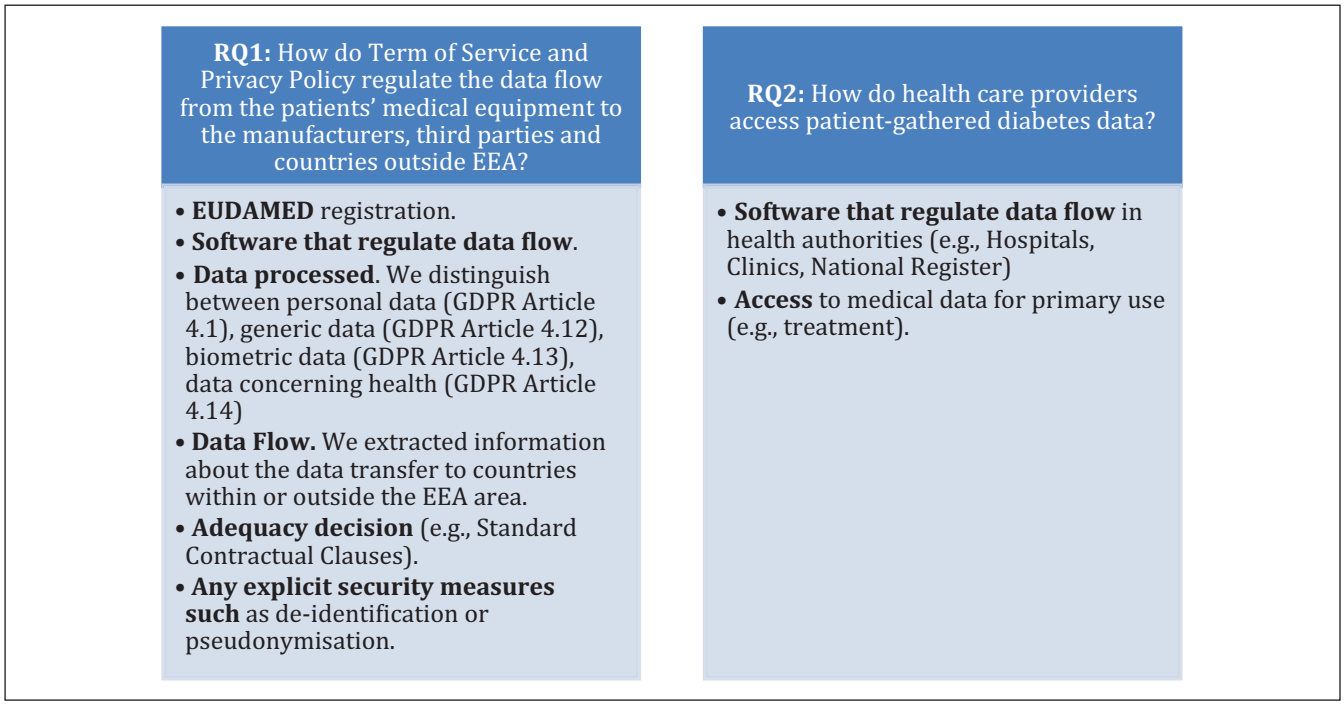

Figure 2. Document analysis key elements.
Abbreviations: EEA, European Economic Area; EUDAMED, European Database on Medical Devices; GDPR, General Data Protection Regulation.

Table 1. Insulin Pumps, CGMs, and Hybrid Closed-Loop Systems Available for Patients in Norway.

Medical equipment (n = 11)	Categories
MiniMed 780G + Guardian Connect G4	Insulin pump with hybrid closed-loop technology
MiniMed 640G[a] + Guardian Connect G3	Insulin pump with Predictive Low-Glucose Suspend (PLGS)
Tandem t:slim X2 Insulin pump Control-IQ technology + Dexcom G6	Insulin pump with hybrid closed-loop technology
OmniPod Dash	Insulin patch pump
Accu-Chek Solo	Insulin patch pump
Accu-Chek Insight[a]	Insulin pump
Guardian Connect G4	Stand-alone CGM
FreeStyle Libre 2	Stand-alone CGM
FreeStyle Libre 3	Stand-alone CGM
Dexcom G6	Stand-alone CGM
Eversense E3	Stand-alone CGM

Abbreviation: CGM, continuous glucose monitoring.
[a]Supported until April 2023.

Table 2. Software Applications for the Medical Equipment.

Medical equipment (n = 11)	Software that regulate the data flow (users) (n = 12)	References
MiniMed 780G MiniMed 640G Guardian Connect G4	CareLink Connect (HCP), MiniMed Mobile (P), Guardian Connect (P)	15-18
Tandem t:slim X2 Insulin pump Control-IQ technology	t:connect mobile (P, HCP), Glooko (P, HCP)	19-22
OmniPod Dash	Omnipod Display (P), Glooko (P, HCP)	21-24
Accu-Chek Solo Accu-Chek Insight	mySugr (P), RocheDiabetes Care Platform (HCP), Glooko (P, HCP)	21,22,25-28
FreeStyle Libre 2 FreeStyle Libre 3	LibreView Data Management System (HCP), FreeStyle App (P)	29-32
Dexcom G6	Dexcom Clarity (P, HCP), Glooko (P, HCP)	21,22,33,34
Eversense E3	Contour Diabetes (P)	35,36

Abbreviations: P, patient; HCP, health care provider.

be compatible with multiple devices, whereas the Privacy Policies and ToS documents may have joint applicability to more than one software application.

Software registration for health care providers and European Database on Medical Devices database. At present, patient-gathered data from medical equipment and apps cannot be directly downloaded into the electronic health record (EHR) systems used in Norwegian hospital clinics. As a result, HCPs need to access patient data through other software. In Table 2, we analyzed the software that can be used to access patient data and identified 6 options for the clinics: CareLink Connect, LibreView Data Management System, RocheDiabetes Care Platform, t:connect mobile, Dexcom Clarity, and the only data aggregator Glooko is compatible with multiple devices. Furthermore, when examining the related software, we found that none (0/12) of these software applications are registered as medical devices in the EUDAMED database.

Overview of Data Processed by Software

The software that regulate the data flow (n = 12), previously identified in Table 2, collect and process different data. In Table 3, we present an overview of the software processing health-related data (GDPR Article 4.14). All software applications collect personal data (GDPR Article 4.1), whereas only Glooko[12,13] and t: connect mobile[8,9] collect biometric data.

As follows, we provide an overview of the specific security measures identified. All software applications use third-party service providers to deliver their services, such as information technology and hosting services. Table 3 also presents the legal basis for data export to non-European jurisdictions under "Adequacy decisions."

Table 3. Data Processed From Various Software.

Software that regulate data flow (users)	Data concerning health	Specific security measures	Adequacy decisions[a]	Reference to documents (ToS, Privacy Policy)
Glooko (P, HCP)	X	GDPR-compliant anonymization, encryption	Standard contractual clauses, privacy shield, Binding Corporate Rules (BCRs)	21,22
MiniMed Mobile (P) Guardian Connect (P)	X	GDPR compliance	Standard contractual clauses	16,18
CareLink Connect (HCP)		GDPR compliance, possibly pseudonymization, anonymization, and encryption	Adequacy decision or else, standard contractual clauses	15,17
t:connect (P, HCP)	X	GDPR compliance, encryption, access control, event logging	None	19,20
OmniPod DISPLAY (P) OmniPod VIEW (HCP)	X	GDPR compliance	None	23,24
mySugr (P)	X	Specific security measures such as Data transfer via HTTPS (hypertext transfer protocol secure), user can operate via pseudonym, and anonymization	Standard contractual clauses	25,26
RocheDiabetes Care Platform (HCP)		GDPR compliance, access control	Standard contractual clauses	27,28
LibreView Data Management System (HCP)		GDPR compliance, access control, de-identifying, pseudonymizing, aggregating, and/or anonymizing the personal information	Compliance with laws of patient's jurisdiction	30,31
FreeStyle App (P)	X	De-identify, pseudonymize, aggregate and/or anonymize, encrypted Bluetooth connections for FreeStyle Libre sensors, 2-factor authentication for LibreView users	None	29,32
Dexcom Clarity (P, HCP)	X	GDPR compliance, transmission encrypted	Standard contractual clauses	33,34
Contour Diabetes (P)	X	GDPR compliance, encryption, anonymized, or de-identified/ pseudonymized information	Standard contractual clauses	35,36

Abbreviations: ToS, Terms of Service; P, patient; HCP, health care provider; GDPR, General Data Protection Regulation.
[a]An "adequacy decision" is a decision made by the European Commission (EU) that recognizes that a non-EU country or organization provides the same level of protection for personal data as the EU does.

Discussion

Main Findings

We identified 11 types of medical equipment used by diabetes patients in Norway (Table 1). To analyze how HCPs access patient diabetes data (RQ2), we identified software that regulates data flow (n = 12) (Table 2). Some software applications can be used by both patients and HCPs (3/12), whereas others are used exclusively by 1 group (6/12 by patients, 3/12 by HCPs).

We analyzed compliance with GDPR security measures (RQ1) and found that some software relies on adequacy decisions (8/12). The remaining 4 software applications did not specify any adequacy decisions (4/12).

We also investigated the registration status of medical equipment and software in the EUDAMED database to comply with the new MDR and IVDR regulations. Only 3 devices (OmniPod Dash, Accu-Chek Insight, and Accu-Chek Solo) were registered in EUDAMED, but none of their respective software applications (RQ1).

Perceived Necessity vs Policy Overload: A Dilemma for Medical Equipment Users

While a smartphone is not strictly necessary for managing diabetes, it can be helpful due to the ability of mobile apps and software to facilitate glucose monitoring and automatic data recording and data transfer. Medical equipment used for

diabetes management includes Bluetooth or Near-Field Communication (NFC) tags for wireless communication with smartphones.[37] Alternative devices can be provided for patients who choose not to use a mobile phone.

Patients who use vendor software applications are required to acknowledge and accept the ToS and Privacy policies.[15-36] In addition, patients must provide informed consent for the processing of their data.[38] However, the documents governing the use of these software applications can often be intricate and broad, presenting, creating a dilemma for users who may simply decide that the benefits outweigh the challenges of navigating these lengthy documents.

Future studies should investigate the different sensitivity of users toward data sharing, the perceived need for this technology, and the impact on the acceptance of these terms.

Data-Sharing Challenges for Primary and Secondary Use of Data

The medical equipment outlined in Table 1 play a crucial role in health care, and many software applications are widely used for planning the treatment of patient (primary use of data). However, none of these applications are directly integrated into the EHR system, which creates a challenge for HCPs who must use multiple systems with different login processes and platforms. This can take up valuable time during consultations, potentially affecting the quality of patient care.[5,39-41] Furthermore, it is important to note that these systems, in their current state, are not designed for integration with EHR. The systems do not intend to be an EHR, as exemplified by the LibreView data management system's declaration: "THE LIBREVIEW DATA MANAGEMENT SYSTEM IS NOT AN ELECTRONIC HEALTH RECORDS SYSTEM AND YOU MUST PRINT AND/OR DOWNLOAD PATIENT INFORMATION THAT YOU DEEM RELEVANT TO YOUR PROVISION OF MEDICAL CARE, TREATMENT OR ADVICE."[30,31] The manual process of transferring data from the data management systems into EHRs can increase the risk of errors and create inefficiencies in the data reporting process.[6]

When it comes to sharing data for secondary use, the GDPR grants patients the right to receive personal data in a machine-readable format (ART.20 Rights to data portability). However, patients and informal caregivers often face difficulties when attempting to download diabetes data.[42,43] These challenges bring into question the ownership of patient data, as it remains largely within the medical vendor ecosystem.

Thus, the diverse data structures used by medical equipment manufacturers make integrating or sharing data directly into EHR systems or for research studies challenging. To mitigate these issues, the adoption of a common data exchange standard like Fast Healthcare Interoperability Resources (FHIR) is essential.

The controversy about whether software applications should be considered as medical device. None of the software applications listed in Table 2 is registered as medical devices in the EUDAMED database. We have identified 2 different potential reasons. The first one could be due to the disclaimers presented to patients, such as "No medical advice: THE LIBREVIEW DATA MANAGEMENT SYSTEM IS NOT INTENDED FOR THE DIAGNOSIS OF OR SCREENING FOR DIABETES MELLITUS"[30] or "YOUR USE OF THE SERVICE IS SOLELY AT YOUR OWN RISK."[21]

While disclaimers might reduce the legal obligations of software providers, it is crucial to prioritize their intended use. Moreover, disparities in software registration as medical devices could give rise to issues. The absence of medical device registration might spark controversy, especially when these software applications are used or endorsed within hospital premises and can be perceived as medical devices.

Ultimately, the effectiveness of EUDAMED will need to be evaluated once it is fully implemented as it will become mandatory in 2026.[10] This database includes a module for reporting severe events related to devices and corrective safety measures. Besides the intended use of the software, including digital health applications in this module is challenging due to the constantly evolving nature of Information and Communications Technology (ICT) data security and managing multiple security risks.[44]

Technical Overview and How Data Are Shared

Although the legal documents provide details about the data processed by the software, they often lack specific and detailed security measures. The documents primarily offer recommendations for password handling and highlight the responsibility of professional users to protect their accounts.[30,31]

Data sharing between software applications can complicate the understanding of how patient health information is processed. Patient software applications may collect and process health information, which is then accessed by HCPs software through a cloud solution without further processing. We could assume that as the software exclusive for HCPs, as indicated in Table 3, do not collect any health data. Furthermore, there is a lack of comprehensive information regarding the specific categories of data processed, the manner in which data flows, how long it is stored, techniques employed for de-identification, encryption protocols, and data formats.

Finally, it is important to understand the ToS and Privacy Policies for any third-party applications before opting in and consenting to sharing data with them. For example, once data are shared with a third-party application, the provider, or the patient, no longer controls its use, access, or disclosure.[21,22] Abbott, for instance, uses cloud providers like Amazon Web Services and Microsoft Azure.

Limitations

The presented analysis has some limitations, such as restricting the devices to those available in Norway and that we did not receive adequate feedback from all the vendors. Nevertheless, the work is still relevant for the entire EEA/EU area because Norway is part of the EEA Board without a voting right for GDPR-related matters. General Data Protection Regulation and the security and privacy issues discussed are also highly relevant for those outside EEA/EU. It is important to note that the list of compatible apps (described in Table 2) may evolve over time, and this study only examines those available during the specified period.

Conclusions and Implications for the Future

The current state of medical device technology development is largely dominated by companies outside of the European Economic Area (EEA).

This study is the first to analyze the ToS and Privacy Policy documents for diabetes medical equipment that national authorities have approved. These documents are not easy to understand to end-users and require a high level of legal and digital literacy, as indicated by a previous study.[45] Due to complex or legalistic terminology, most users may consent without adequately understanding the terms and conditions presented online.[46,47] Future research should explore users' levels of sensitivity toward data sharing, their perceived necessity for this technology, and their acceptance of the related terms and conditions.

Future research should also investigate how to effectively educate and train health care professionals on data security and privacy to increase their awareness and understanding of these issues,[48] as HCPs prioritize functionalities over security and privacy concerns when recommending these tools to patients.[49] A standardized health care data-sharing approach (eg, FHIR) could integrate these tools into existing EHR systems. This would simplify the work of health care providers in their clinical practice as they would no longer need to interact with multiple systems and procedures to access and view patient data.

Abbreviations

AIMD, Active Implantable Medical Devices; Apps, mobile applications; CGM, continuous glucose monitoring; EEA, European Economic Area; EULA, end-user license agreement; GDPR, General Data Protection Regulation; HCPs, health care providers; IVDR, In Vitro Design Regulation; MDD, Medical Device Directive; NFC, Near-Field Communication; SCCs, standard contractual clauses; ToS, Term of Service.

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Paper 5

Consent Management System on Patient-Generated Health Data

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Consent Management System on Patient-Generated Health Data

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Abstract. We consent to many things in life, but sometimes we do not know what we consent to. When discussing data protection in Europe, consent has been associated with permission under the GDPR, and health data are highly sensitive. Patients cannot make an informed decision without being provided with the information they need upfront: no informed decision, no informed consent. This paper presents a consent management system for patient-generated health data stored with HL7 FHIR specification, tested on Type 1 diabetes synthetic data. This architecture, based on using FHIR as an unequivocal data exchange format, can lead to individuals (patients) taking control of their data, enabling potential data exchange and reuse of health data across countries and organisations, in line with the European Commission proposal of a European Health Data Space.

Keywords. Adoption and use of digital health standards, health information exchange, interoperability, privacy

1. Introduction

The sensitive nature of health data requires information systems to guarantee secure storage, access, and processing of Personal Identifiable Information (PII) [1]. To maximize the potential and value of health data, we need to improve access and compliance with relevant regulations, such as GDPR and then find ways to reuse or share the data. Thus, the patient's informed consent is an indispensable requirement.

This paper presents a consent management system using the HL7 Fast Healthcare Interoperability Resources (FHIR) with data obtained from a Diabetes continuous glucose monitor (CGM). Whilst FHIR defines health-related data exchange, unifying data access permissions, management, and usage across organizations remains a challenge due to the distributed nature of health data, which is often scattered across

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multiple entities such as healthcare systems, medical device producers, and third-party companies.

1.1. Objectives

We propose a system that unifies unify data access, governance and orchestration in order to facilitate informed data sharing by patients for primary and secondary use of their health data for specific purposes and periods of time.

Previous studies [2-5] have demonstrated how various software solutions can be applied to obtain patients' digital and paper-based informed consent when the FHIR standard for managing consent has been insufficient [3,5] or has been limited to the exporting of consent definitions previously defined [4].

2. Methods

2.1. Pilot and data simulation

The demonstration of this system requires at least two HL7 FHIR resources: Observation, which will store health data such as blood glucose level, and Consent, a resource that declares the "intent of use" in terms of action (e.g., collect, access) or scope (e.g., research, treatment) of the health data.

We generated synthetic data using a UVa/Padova simulator [6], which produced blood-related information and then profiled FHIR Observation resources to simulate data flow from patient devices. The FHIR Consent resources were designed in collaboration with a health domain expert from the Norwegian Diabetes Register for Adults to reflect a real-world scenario where patients are asked to provide time-limited consent for sharing their data to improve the quality of treatment for people with diabetes.

2.2. Developed solution

The system is built on top of open-source software, such as the Fybrik framework [7] and other open-source technologies, such as Kubernetes for container orchestration and Istio for service mesh implementation. Data access policies are defined via Open Policy Agent [8].

We have extended the Fybrik platform to allow for real-time decision-making about which data the requester can access based on policies and other contextual information provided by the FHIR resources. To configure this workflow, the patient defines their consent conditions through a Graphical User Interface (GUI). Organizational data policy is defined by an authority in the field, which typically would be the organization’s Data Policy Officer.

When a data requester (e.g., NOKLUS, Researchers) seeks data access through an FHIR request, the Fybrik platform assesses the request and applies data access policies based on the relevant FHIR resources (i.e., Observation, Consent) and requester identification. These data access policies can dictate redaction actions on specific FHIR resources or resource attributes, such as anonymization through statistical analyses or the redaction of PII (e.g., patient identifiers) from the data response while allowing other types of information to remain visible.

The high-level picture of the developed solution is presented in Figure 1.

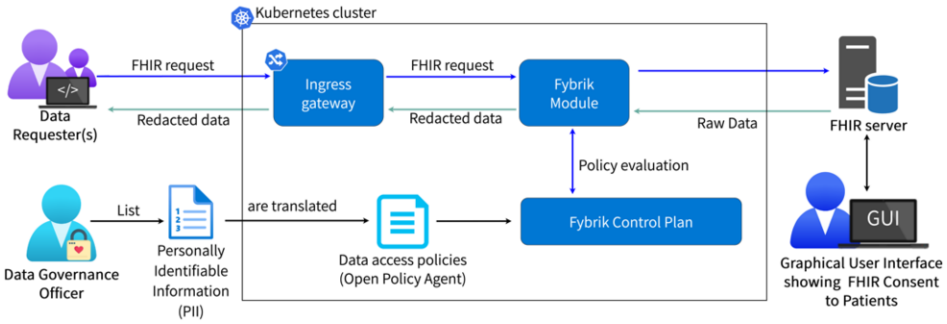

Figure 1. Consent management system - high-level architecture.

3. Results

3.1. Scenario and consent request

We simulated two weeks of Observations for each patient with diabetes, with a total of 4032 Observations and defined FHIR Consent for the different recipient(s) to perform one or more data redaction actions within a given data access policy.

Figure 2 displays how FHIR Consent resources are presented to patients.

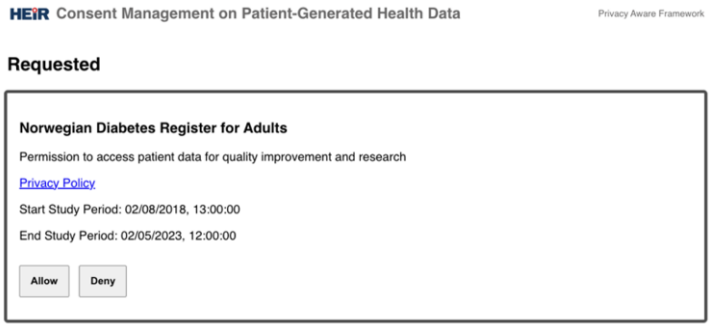

Figure 2. Consent request - patient perspective.

3.2. Observation returned according to the policy

As presented in Figure 1, a third-party entity may request data via a FHIR request. The Fybrik module passes the request to the backend server. It returns the Observation data according to the conditions enforced by the contextual information provided by the FHIR resources (i.e., Consent and Observation). Then it redacts the data by applying the policy.

The entire process is summarised in Figure 3.

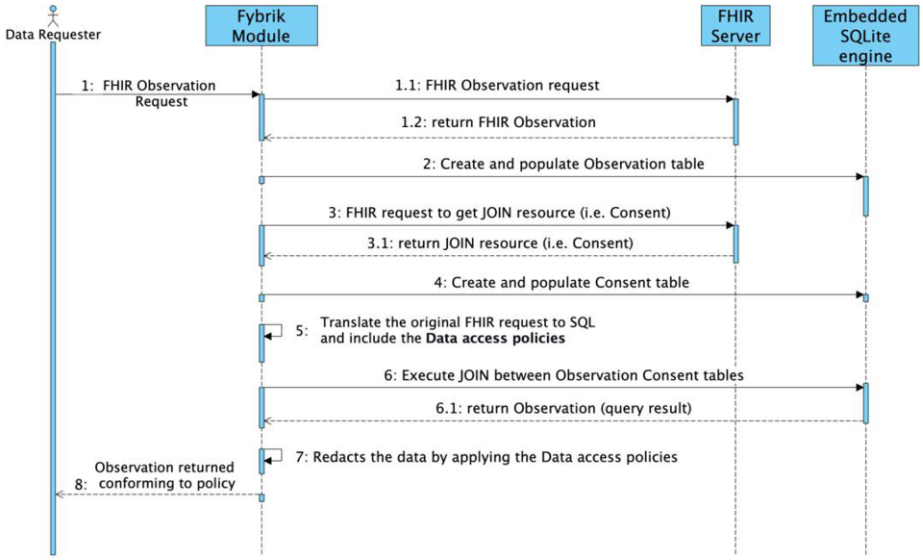

Figure 3. How FHIR Observation data are returned according to policies and FHIR Consent.

4. Discussion

4.1. Benefits of governance mechanisms for facilitating health data exchange

One of today's problems is the fragmented infrastructure where health-related data is stored in various formats, often owned by different entities, and not connected or interoperable. This fragmentation can result in challenges in health data reuse, leading to data access-, governance-, and orchestration challenges.

The proposed system unifies data access, governance, and orchestration. It ensures that data is available to the right individuals at the right time while maintaining appropriate security, privacy, and consent levels.

Adopting common data standards, such as FHIR, and establishing governance and orchestration mechanisms, like the consent management system presented, can facilitate the exchange and integration of health data, leading to better clinical decision-making, research, and patient outcomes. Additionally, the data access policies can contain more constraints [8] (e.g., geo-locational), allowing a cross-border exchange in line with the European Commission proposal of a European Health Data Space [9].

4.2. Limitations

A technical limitation is that all FHIR Observations are returned and then selected based on the constraints of the FHIR Consent. However, this approach could result in many Observations being returned, negatively impacting the system's memory usage.

Additionally, the idea behind this solution calls for the data owner (patients) to choose and evaluate with whom and why they share their data. It may require a high level of digital and health literacy. Thus, consent requests presented to patients should be reviewed by designated authorities.

5. Conclusions

The proposed system assumes the usage of HL7 FHIR. It allows data owners to share health data for the primary purpose (e.g., treatment) and secondary purposes (e.g., research) via the use of FHIR Consent and policy access rules designed by experts (e.g., Data Governance Officer). Furthermore, the system can be used for data access, governance, and orchestration. It can help ensure that health data is shared in a responsible and ethical manner, protecting the privacy and confidentiality of patients while enabling data reuse.

Future work will include exporting consent receipts and inspecting the use of consent to read data via an audit log, which is a record of all events. Additionally, the system presented will be evaluated using benchmarks and suitable evaluation criteria (i.e. usability, information quality) [10].

Acknowledgments

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Paper 6

Obstacles in Accessing Real-Time Diabetes Data for Treatment and Research: Toward an Interoperability Model

This article in under review

Obstacles in Accessing Real-Time Diabetes Data for Treatment and Research: Toward an Interoperability Model

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Abbreviations:

2FA: Two-factor authentication

APIs: Application Programming Interfaces

CGM: Continuous Glucose Monitoring

CSV: Comma-separated values

DIY: Do It Yourself

EEA: European Economic Area

EHR: Electronic Health Record

EU: European Union

FDA: Food and Drug Administration

FHIR: Fast Healthcare Interoperability Resources

GDPR: General Data Protection Regulation

HCPs: Health care providers

MDR: Medical Device Regulation

OpenAPS: Open Artificial Pancreas System

REST: Representational State Transfer

SNOMED CT: Systematized Medical Nomenclature for Medicine – Clinical Terminology

ToS: Terms of Service

U.S.: United States

Abstract

Aims: In today's data-driven era, 'Openness' promotes transparency and accessibility. This article discusses the importance of real-time data access in Diabetes for primary (treatment) and secondary (research) use in diabetes management through medical devices. It explores how Application Programming Interfaces (APIs) contribute to secure data retrieval and the impact of copyright law on patient-driven innovation within open-source communities.

Methods: We assessed diabetes medical devices and software solutions for real-time data access in Norway, API functionality, and legal frameworks relevant to open-source DIY communities.

Results: We found seven diabetes medical devices and nine regulated software solutions, but only one with a publicly accessible API. There is a significant need for real-time data access options. The analysis compares vendor-specific and open-source software, highlighting substantial limitations in data accessibility. DIY solutions, while innovative, present technical and legal challenges that limit their practical application.

Conclusions: We propose a model for diabetes management that requires regulatory decisions, including standardized, publicly accessible APIs. This aims to enhance transparency, accessibility, and patient-driven innovation. We advocate for regulatory frameworks that enable secure, standardised data access, potentially improving patient care and diabetes research outcomes.

Keywords: Diabetes, Interoperability, Policy, GDPR, and Security

1 Introduction

The concept of 'openness' in the context of health data, software, and research is increasingly recognised, especially within the European Union (EU) and European Economic Area (EEA)[1]. This movement, characterised by transparency, participatory engagement, and data sharing and exchange[2], is exemplified by initiatives like the European Health Data Space, which seeks to empower individuals and organisations through accessible and reusable health data[3]. Complementing this trend is the General Data Protection Regulation (GDPR), which advocates for the rights of European citizens in data processing[4]. Application Programming Interfaces (APIs) play a critical role in facilitating technical data access and promoting interoperability[5], aligning with the GDPR's core principles.

User-friendly APIs empower developers to meet their data needs and usage objectives, fostering data access and GDPR compliance. Consequently, APIs increase the possibilities for Big Data applications[6], making it easier for different healthcare and research systems to work together. The use of publicly accessible APIs for health data exchange is becoming increasingly relevant, as evidenced by the widespread adoption of Fast Healthcare Interoperability Resources (FHIR) APIs[7], particularly in the United States for Electronic Health Records (EHR)[8], and a with a similar interest in the EEA and Europe[9].

In the field of diabetes management, 'openness' presents unique challenges, especially concerning real-time data access[10], a topic we explore further in this article.

1.1 Diabetes Management Regulated Devices and Off-Label Use

Diabetes is a chronic disease that affects many people. The management of this condition employs a diverse range of technologies, including blood glucose meters, continuous glucose monitoring (CGM) devices, insulin pumps, and hybrid closed-loop systems. This technological ecosystem is further enriched by mobile apps that facilitate access and visualisation of pertinent health data[11].

Managing a long-term chronic condition like diabetes requires ongoing monitoring, personalised treatment, and regular healthcare consultations. Moreover, the active participation of informal caregivers (e.g., family members, next of kin) plays an important role, especially for children, highlighting the significance of data sharing[12]. Furthermore, they are crucial in contributing to innovation projects through research activities. In light of these considerations, data sharing in diabetes management has become even more relevant.

The need for improved functionalities and data sharing options (e.g., viewing children's glucose values remotely[13]) has given rise to a DIY movement known by different hashtags on social media, such as #WeAreNotWaiting. Since its beginning in the U.S. in 2013, this movement has globally advanced diabetes technologies with open-source hybrid closed-loop systems and improved CGM data access[14]. For instance, in 2016, the introduction of hybrid closed-loop systems faced regulatory approval delays in EEA counties, which affected their availability in Norway, where hybrid closed-loop systems arrived only in 2019[15]. As a result, some patients and informal caregivers choose alternative solutions, such as DIY options and off-label use of medical devices, to meet their needs.

These DIY solutions have cultivated a strong online community where users exchange information and seek support[16]. However, healthcare professionals (HCPs) should not endorse DIY solutions and warn patients against using off-label devices[13, 17]. Notable initiatives within the DIY movement in

diabetes include OpenAPS[18] (Open Artificial Pancreas System), Loop[19], Nightscout (CGM in the cloud) and Tidepool.

1.2 Terms of Services, Copyright and Cybersecurity

The use of diabetes medical devices in the EEA is governed by legal frameworks, including GDPR-compliant privacy policies and Terms of Service (ToS) documents – which often cover intellectual property rights and copyright.

In the context of open-source communities using medical devices off-label, conflicts with manufacturer ToS and copyright agreements can arise. However, exceptions exist under copyright laws. Directive 2009/24/EC in the EEA allows limited use of copyrighted material for specific purposes like achieving interoperability[20]. The implementation of this Directive varies among countries in the European Economic Area (EEA). For instance, Norway incorporates it through the Intellectual Property Act[21], while Germany does so through the Copyright Act[22]. Despite these different legislative approaches, both countries adhere to the same essential conditions for allowing decompilation of software to achieve interoperability, as follows:

1. The action is performed by a user who holds a valid license.
2. The necessary information for achieving interoperability has not been provided to the user.
3. Only the portions of the software that are essential for achieving interoperability can be manipulated.

Cybersecurity is another crucial aspect, with the EU proposing the European Cyber Resilience Act[23] and the U.S. FDA issuing medical device security recommendations[24]. Regulatory bodies are especially vigilant in diabetes, warning about using CGM devices in unauthorised diabetes management solutions[25] like DIY projects. In response, manufacturers are proactively enhancing data security and safeguarding patient information, as they are responsible for ensuring software security in the products they release to the public[23, 24].

2 Material and Methods

This study explores real-time data access from diabetes medical devices approved in Norway with a particular focus on their potential application in primary (treatment) and secondary (research) contexts. Central to our investigation is the role of APIs in facilitating secure and efficient data transfer. The data collection via the regulated software solution received ethical approval from the Norwegian Agency for Shared Services in Education and Research (Sikt N 671274).

We define 'real-time' data in the context of diabetes as the capability to access and process data instantly or with minimal delay (maximum 5 minutes after registration), ensuring a timely and accurate reflection of the device's status. The study concentrates on remote data access, excluding software solutions reliant on Bluetooth and Near Field Communication (NFC) technologies.

2.1 Objectives and Research Questions

To provide a clear and structured overview of our study, we have summarised the main objectives and associated research questions in Table 1.

Table 1. Objectives and Research Questions.

Objective	**Research Questions**
Identify available diabetes medical devices in Norway and assess their real-time data access capabilities.	**RQ1.** Can real-time data from diabetes medical devices be accessed using regulated software solutions via publicly accessible APIs? **RQ2.** Is there any working off-label alternative available for real-time data access?
Evaluate the potential application of the identified solutions in primary (treatment) and secondary (research) contexts	**RQ3.** What technologies are utilised for accessing real-time data from diabetes medical devices in third-party applications? **RQ4.** What are the key considerations within the terms of service governing the access to real-time data from diabetes medical devices in third-party applications?
Develop an interoperability model for data sharing and real-time access within third-party applications.	Based on insights from RQ1-RQ4.

2.2 Study Design

In this study, we followed a series of steps. We (PR, MKW) have identified relevant diabetes medical devices available in Norway through the national agreement[26]. Next, we explored how third-party applications can access real-time data for regulated software (**RQ1**) and searched for specific alternatives from open-source projects via a grey literature search (**RQ2**). Once we identified all possible solutions, we assessed the technology landscape (**RQ3**). We (PR, MC) conducted a document analysis[27] on Terms of Service documents, focusing specifically on the sections outlining 'Prohibited or Acceptable Uses' to address potential intellectual property violations associated with DIY solutions (**RQ4**). After combining the research questions findings, we designed an interoperability model for diabetes that included standards, protocols, and security measures to facilitate use and reuse.

3 Results

3.1 Medical Devices Available in Norway and Associated Regulated Software (RQ1)

Table 2 presents the available medical devices in Norway[26] and the regulated software solutions that can collect real-time data, giving an overview also for the European context. We have also identified cases where publicly accessible APIs are available to interact directly with the data collected by the medical devices or related software solutions.

Table 2. Comparison of Medical Equipment, Regulated Software and Publicly Accessible APIs

Medical equipment (n=7)	**Type**	**Regulated software that processes data (n=9)**	**Publicly accessible APIs.**
MiniMed 780G + Guardian Connect G4	Insulin pump and CGM – Hybrid Closed Loop System	CareLink Connect, MiniMed Mobile	No
Tandem t:slim X2™ Insulin pump Control-IQ + Dexcom G6	Insulin pump and CGM – Hybrid Closed Loop System	Glooko*	No
OmniPod Dash	Insulin patch pump	Not Available in Norway	No
Accu Check Solo	Insulin patch pump	RocheDiabetes Care Platform	No[28]
Freestyle Libre 2	Stand-alone CGM	LibreView Data Management System, Libre Link Up FreeStyle Apps for Libre 2 and Libre 3,	No
Freestyle Libre 3	Stand-alone CGM		
Dexcom G6	Stand-alone CGM	Dexcom G6 mmol/L, Glooko*	Yes[29]

*Wired connection required

Table 2 does not include the Eversense E3 sensor because it is scheduled for removal in 2024, as confirmed by national authorities. Additionally, the Omnipod cloud service, which includes cloud functionality for the Omnipod Dash, is unavailable in Norway. Therefore, data transfer with the Omnipod Dash system required a wired connection through Glooko and was excluded since it does not provide real-time data[30]. Although the Roche Diabetes Care Platform has a publicly documented API, it is not accessible to the general public[28].

3.2 DIY Software and Off-label Use (RQ2)

To access real-time data from diabetes medical devices, we searched for publicly available repositories and explored DIY alternatives. We identified mobile applications: Loop[19], AndroidAPS[31] and OpenAPS[18]. These systems can operate with either iPhone or Android devices, although they may require additional hardware to establish connections. It is crucial to emphasize that while these solutions enable real-time data access, they also control insulin delivery. It means they offer read-only data functionalities and allow direct input to the insulin pump, thereby providing control over the treatment process.

We also identified two repositories designed to interface specifically with Libre 2 and Libre 3 sensors[32], and Dexcom G6[33].

3.3 Technological Assessment of Regulated and DIY Software (RQ3)

The technological assessment for all the software solutions identified are illustrated in Figure 1. This assessment follows two distinct paths: the regulated and the unregulated path. We also consider cardinality, which indicates how many users can connect via third-party applications for real-time data access, serving primary (e.g., treatment) or secondary (e.g., research) purposes. Some of the identified solutions need supplemental software for data retrieval.

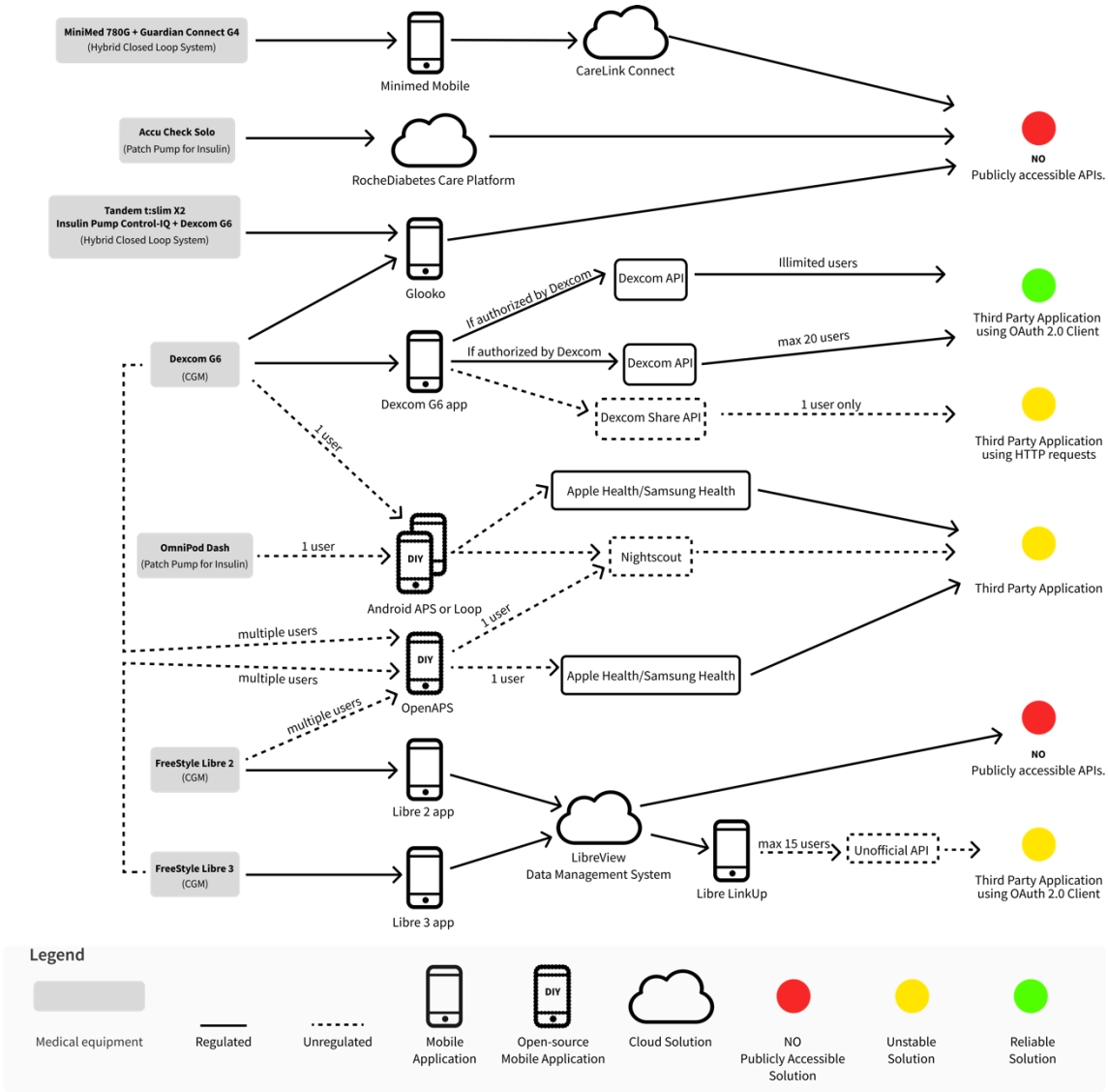

Figure 1. Technological Assessment Overview of Regulated and DIY Software.

Regarding medical equipment, the DIY software is designed to interface with the Libre 2 and Libre 3 sensors using the LibreLink Up app, or the Dexcom G6 mmol/L app[33]. The OmniPod Dash may connect with Loop and AndroidAPS systems, while newer Medtronic devices like MiniMed 780G are

unavailable for open-source software. Open-source software enables data sharing with other software like Apple Health, Samsung Galaxy, and Nightscout, facilitating real-time data collection. Table 3 lists the limitations of the seven identified DIY software solutions.

Table 3. Software solutions that enable real-time access to data sharing and their limitations.

Solution identified (software category)	**Limitation for a Third-Party application**	**Devices**
Open Aps (DIY Software)[18].	Additional software involved (Nightscout, Samsung Health, etc.). Taking control over the insulin delivery in the pump	Dexcom G6, Freestyle Libre 2 and 3
Android APS (DIY Software)[31]	1-1 user cardinality Additional software involved (Nightscout, Samsung Health, etc.). Taking control over the insulin delivery in the pump	OmniPod Dash, Dexcom G6, Freestyle Libre 2 and 3
Loop (DIY Software)[19]		
Dexcom Official (Manufacturers Device Software)[29]	None	Dexcom G6
Dexcom Authorized (Manufacturers Device Software)[29]	20 users with 30-min delay (Not real-time)	
Dexcom DIY solution[33] (DIY Software)	1-1 user cardinality requiring plain username and password credentials for access.	
Libre (DIY Software)[32]	Limit to 15 users with 1 Libre Link Up account. Non-functional if 2FA (2 Factor Authentication) is enabled.	Libre 2 and Libre 3

3.4 Terms of Service Analysis (RQ4)

The solutions identified in Table 3 and visualized in Figure 1 are either based on or require the use of copyrighted software. This is the case for Freestyle Libre 2 and Freestyle Libre 3, requiring the official

Libre Link Up app. In the ToS, among the statements of "Prohibited Uses", users agree not to: *'interfere with or disrupt the LibreView Data Management System (including accessing the LibreView Data Management System through any automated means, such as scripts or web crawlers)' and reverse engineer, decompile, disassemble, decode, create derivative works of, gain access to the source code, or modify the LibreView Data Management System except and then solely to the extent permitted under applicable law'*[34]. The term 'applicable law' is a generic term that covers all laws relevant to this agreement.

Similarly, Dexcom applies a similar restriction*: 'Reverse engineer or derive the source code for any DexCom Product, DexCom Service, or Software App not provided to you in source code form, except to the extent such restriction is expressly prohibited by applicable law'*[35]. The same principles apply to the OmniPod Dash[36].

One of the applicable laws for achieving interoperability is the Directive 2009/24/EC, which provides exceptions. However, even with these exceptions, it is not possible to directly use DIY software for large-scale use due to technical limitations. Even if it were legally possible, the existing technical constraints, as outlined in Table 3, the existing technical constraints would make it impractical for large-scale use, whether for treatment or research purposes. In most cases, its use would be limited to 15 users or restricted by limited security measures (e.g., no 2FA, plain passwords).

3.5 Interoperability Model for Diabetes Data

The findings highlight a significant gap in real-time data access for diabetes management, as evident in the regulated (Table 2) and DIY solutions (Table 3). While DIY solutions have made it easier for individual users to access data, they cannot be used on a large-scale basis for treatment and research.

Given the unavailability of real-time data from any hybrid closed-loop system, we investigated data generated by a hybrid closed loop system, using the MiniMed 780G as an illustrative example. This system offers an option to produce a proprietary CSV file, which generates historical data in 32 columns and additional metadata[37]. We also developed a code that analyses the patient-health generated data[38]. In this technical implementation[38], we observed and documented missing information about the proprietary format used by the medical vendors[37].

The data volume can also be significant, typically comprising thousands of CGM glucose readings, hundreds of manual glucose measurements and carbohydrate estimations, and approximately a thousand insulin injections per month—distributed across closed-loop auto-correction and patient input. These data with different granularity can be relevant to both primary and secondary use. Doctors may require only summary statistics, while researchers may need all data points, both granularity of data hold relevance.

3.5.1 A Set of Standards to Ease Diabetes Data Transfer

The proposal is based on several recommendations for exchanging electronic health records (EHR) in Europe[9, 39] and the existing implementation of the RocheDiabetes Care Platform[28]. It recommends using the REST API architecture to facilitate interoperability and the reuse of diabetes healthcare data. The proposal suggests using the FHIR[7] standard for data exchange, which ensures efficient communication across varied healthcare platforms[8]. The proposal recommends incorporating clinical terminology codes such as SNOMED CT and LOINC for clinical interoperability.

The proposal advocates for implementing OAuth 2.0 and OpenID Connect for authorization and authentication, respectively, to enhance security and control over data access[40]. Promoting the possibility of 2FA for patient data protection[41]. These protocols are integrated within the SMART on FHIR framework which creates an interoperability model based on FHIR that allows connection to various software clients such as personal mobile systems, research servers, and EHR. The proposal is visually summarized in Figure 2.

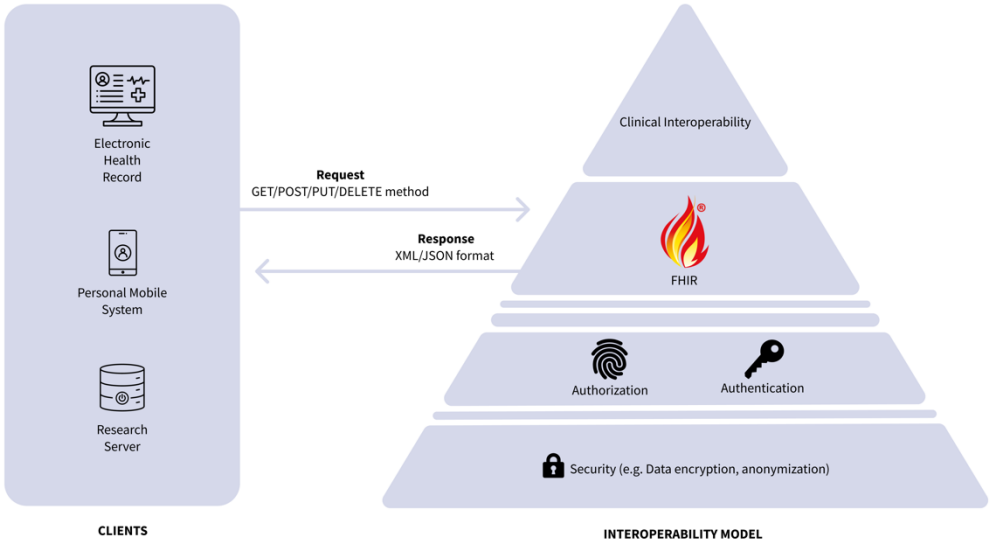

Figure 2. Proposal for a set of standards that will enable diabetes data sharing between end-users, equipment, vendors, researchers, and healthcare services.

It is necessary to clarify a key aspect of the proposed interoperability model: it focuses on data that is only available after it has been processed by medical device manufacturers' proprietary algorithms. This proposal excludes direct control over insulin delivery mechanisms in the pump.

Illustrating the practical application of this model, one technical implementation[42] demonstrates how FHIR can be used for real-time diabetes by adapting the DIY repository[32]. Furthermore, another technical implementation[38] provides a practical example of how the FHIR standard can be used for hybrid closed-loop data.

4 Discussion

The interoperability challenges and barriers in diabetes healthcare are widely recognized[43]. Our study, set in the Norwegian context, identified seven diabetes medical devices and nine regulated software solutions, with the Dexcom G6 CGM device being a notable exception in offering publicly accessible APIs (Table 2). Meanwhile, the RocheDiabetes Care Platform has a publicly FHIR-based documented API that is not directly accessible to the public[28]. The limited availability of official real-time data access solutions prompted us to explore seven DIY software alternatives (Table 3). These alternatives revealed technical and practical limitations (Table 3), underscoring the impracticality of regulated and off-label medical device use for real-time data access in diabetes, particularly in hybrid closed-loop systems.

The crucial insight from our research is the availability of the required technology for effective data access Nevertheless, the absence of coherent governance, policies, and security measures in the processing of diabetes data makes its utilization and reutilization challenging. To overcome these difficulties, we present an interoperability model for diabetes, as shown in Figure 2.

4.1 Why is a Model for Interoperability Needed?

The data fragmentation evident in diabetes management highlights the urgent need for a regulated interoperability model. While some APIs, such as Dexcom's, provide valuable solutions[29], they represent a rare exception in a landscape where the norm is limited real-time data access for crucial activities like treatment and research. This situation contrasts with other sectors where APIs promote interoperability and innovation[44].

Current software, primarily controlled by device manufacturers, often restricts data access. Typically, these software tools are designed not as comprehensive EHR systems but as analytical and reporting tools for HCPs, leading to a reliance on manual data entry into EHRs[45]. This manual process increases the workload of HCPs, introduces potential errors and inconsistencies in patient records[46] and elevates the risk of medical errors. Furthermore, given the time constraints faced by HCPs[47], the need for a standardized and accessible interoperability framework in diabetes care becomes imperative, allowing HCPs to prioritize patient treatment and consultation over the burden of data access.

4.2 Enhancing Diabetes Data Access for Citizen

Device manufacturers provide machine-readable Comma-Separated Values (CSV) files to comply with the GDPR, our study found that none of the hybrid closed-loop systems in Norway allow real-time data collection through public APIs or DIY solutions. The complexity and incomplete documentation of this data[37] may potentially conflict with the GDPR's Right to Data Portability[4], making it challenging for individuals without advanced technical skills to effectively reuse their data, as also observed in our testing[38]. In particular, this study showcase a challenge with the 'Right to Transmit Data to Another Controller'[4] since we were unable to produce any technical solution to obtain real-time data for the hybrid-closed loop system.

The lack of a standard format for exchanging data poses significant challenges in realizing the objectives of the European Health Data Space program[3] or European Commission's Data Act[48] Without an accepted model for interoperability, a scenario like vendor lock-in emerges, severely restricting patients' ability to transfer their data to a different data controller.

To address these challenges, we propose implementing a FHIR-based RESTful architecture with publicly accessible APIs (Figure 2) to facilitate easier data exchange among EHRs and research initiatives. Additionally, simplifying data representation would enhance patients' understanding of these data.

4.3 Navigating the Complex Landscape of DIY Diabetes Management Solutions

DIY users prioritise functionality over regulatory concerns, with limited technical skills and the need for technology maintenance being their primary apprehension[49]. Our study findings validate this concern due to identified technical complexities (see Table 3, Figure 1).

Legal frameworks like Directive 2009/24/EC, as implemented in Norway and Germany[21, 22], set conditions for software use, focusing on interoperability rather than new functionalities or research applications. The technical constraints of DIY solutions (Table 3) make them impractical for large-scale projects and healthcare institutions. Security concerns, such as the lack of 2FA and reliance on plain passwords, make this solution unsuitable for future use[23, 24].

Despite these challenges, patients and caregivers may still opt for DIY solutions due to their valued functionality and good community support. However, HCPs cannot formally recommend these unregulated solutions [13, 17] and users might risk legal liability under the Medical Devices Act and Product Liability Act[23]. Manufacturers are aware of these solutions, which are often publicly accessible and may expose software vulnerabilities, as we have also tested and observed in our testing[42].

4.4 Limitations

While our study addresses key research questions (RQ1-RQ4) and offers important insights, it is geographically limited to Norway. However, it is important to note that our findings are based on the Norwegian context and may only partially apply to other countries. Nonetheless, the insights we have gained can serve as a foundation for future comparative studies throughout EEA. It is also important to acknowledge that technology is constantly evolving, and the DIY software and devices we examined in this study may need to be updated.

5 Conclusion

In the EU, there is an ongoing discussion about mandatory interoperability requirements with EHR systems[9]. Our study, set within the context of diabetes management in the EU, underscores the delicate balance between data privacy, manufacturer transparency, and individual empowerment. The challenge lies in reusing health data and accessing real-time information in a complex landscape. While real-time data access is currently unregulated with limited publicly documented APIs, it can potentially enhance diabetes treatment and research if necessary policies are developed and implemented.

DIY alternatives may not align with ToS agreements, raising questions about market regulation, especially in contrast to governmental regulations. The EU has recently implemented the Medical Device Regulation (MDR)[50], which covers devices used for medical purposes. Given that the diabetes devices discussed in this article fall under the MDR, one approach for promoting data access in healthcare is mandating publicly documented APIs and an interoperability model as proposed within the new medical device regulation.

Our call to action is for regulatory frameworks to facilitate secure and standardised health data access. The necessary technology is available; the challenge lies in interoperability and data accessibility, as outlined in our study.

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7 Research data for this article.

7.1 Medtronic-csv-FHIR

The underlying code for this study will be available on a public repository[38].

7.2 Libre-link-up-FHIR

The underlying code for this study will be available on a public repository[42].

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